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Using Administrative Healthcare Records to Identify Determinants of Amputee Residuum Outcomes

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This is to certify that the doctoral dissertation by

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Abstract

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by

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Dissertation Submitted in Partial Fulfillment

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Abstract

In the United States, the number of major limb amputees is predicted to exceed several million in the coming decades. For those amputees using a prosthesis, their quality of life (QoL) is often modulated by residuum limb problems resultant from its use. Multiple factors preclude quality evidence-based medicine (EBM) research in the field of prosthetics, leading to greater health risk from prosthetic prescription ambiguity. Positive social change is integral to good QoL; studies support administrative healthcare (AHc) as useful to support such, especially in the absence of EBM. This study utilized Veterans Healthcare Administration (VHA) AHc data to discriminate determinants of residual limb skin problem severity (RLSPS), relative to the artificial limb configuration (ALC) used through a retrospective, longitudinal study of a cohort of U.S.Veteran dysvascular amputees. The dataset was derived from multiple archival VHA AHc databases from which 279 Cohort members were identified who underwent amputation surgery during the fiscal year (FY) 2007 were dispensed a prosthesis, and had clinical records through FY 2011. ICD-9-CM and HCPCS codes were used to identify categories of RLSPS and ALC, respectively, with generalized estimating equations modeling to identify likelihood associations of parameters. Derivation of the study cohort dataset was encumbered by data integrity issues and coding system limitations; significant associations were detected for RLSPS with chronic obstructive pulmonary disease, substance use disorder, and major depressive disorder, regardless of the ALC dispensed. The findings support the utility of an amputee-prosthesis AHc database to drive product, policy, and medical decisions toward an improved QoL for this vulnerable population.

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Dedication

This dissertation is dedicated in memory of my father, Dr. Harold Smith Kolmer, who fostered my interest in medicine and mentored me in research, who I will always love and cherish; and my sister Patricia Kolmer-Stanley, whose active mind, creativity, passion and intelligence inspired me to embrace challenges, rather than avoid them.

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Of particular note and importance, I wish to thank and acknowledge my Committee Chair, Dr. Vibha Kumar for her extraordinary patience with me and overall perseverance; , former Committee Member, Dr. Cassius Lockett for study direction; and Committee Member Dr. Naoyo Mori for stepping up in a time of need and providing sound advice. Acknowledgement and thanks is also deserved by all the Walden University faculty and staff that taught, guided, and supported me throughout this endeavor.

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Additionally, this study would not have been at all possible were it not for the policies and support of the South Texas Veterans Health Care System - Audi Murphy Division Physical Medicine and Rehabilitation Service and the Research and Development Service. The leadership of these entities not only provided access to necessary data, but also allowed some time to pursue this endeavor.

Finally, I wish to acknowledge the VHA that provides health care for nearly nine million Veterans. I have learned much about the organization over the years and have come to appreciate its complexities, and have also met and worked with providers and staff that truly care about the Veterans we serve. I am proud to be an employee of the VHA.

Table of Contents

List of Tables

List of Figures

Chapter 1: Introduction to the Study

Background

Etiology and Epidemiology of Acquired Limb Loss

Relevant literature and health statistics suggest a continuing, increasing prevalence of individuals in the United States with lower extremity acquired limb loss (Ziegler-Graham, MacKenzie, Ephraim, Travison, & Brookmeyer, 2008). Collectively, sources indicate three primary reasons account for this rise: (a) a rising incidence and subsequent prevalence of diabetes mellitus with associated foot complications, (b) an aging population with a high risk of peripheral arterial disease (PAD), which includes critical limb ischemia, and (c) injuries due to vehicular accidents, occupational/recreational incidents, and military events and practices (Dillingham, Pezzin, & MacKenzie, 2002; Limb Loss Resource Center, 2012.)

Although acquired limb loss incidence has decreased significantly since 1996 (185,000 amputations annually), in 2005, more than 71,000 major limb amputations were performed annually, with approximately 70% involving the lower extremities and approximately 30% involving the upper limbs (Limb Loss Resource center, 2012). Of the lower extremity amputations, the majority (65%) were due to diabetic complications and other dysvascular diseases; the remainder were a consequence of trauma or cancer (Limb Loss Resource Center, 2012)

Over the next 45 years, the number of persons living with the loss of a limb is expected to rise from 1.6 million in 2005, to an estimated 2 million in 2007, to 3.6

million in 2050 (Ziegler-Graham et al., 2008). Most such amputations will likely be due to dysvascular conditions (diabetes and PAD), with population totals increasing from less than 1 million in 2005 to 2.3 million in 2050 (Ziegler-Graham et al., 2008).

Living with Limb Loss

Acquired limb loss is indiscriminant of gender, ethnicity, or socio-economic status, although it is frequently related to a disease or condition that is associated with any of these factors. The loss of a limb exacts on-going lifestyle and quality of life outcomes, regardless of etiology or demographics. (Christensen, Ipsen, Doherty, & Langberg, 2016; Dillingham, Pezzin, & MacKenzie, 2002).

Whereas the younger person, who more typically experiences a trauma-acquired limb loss, may be able to return to an active lifestyle and pursue their former recreational and occupational activities, the older individual with dysvascular acquired limb loss may be less fortunate. These individuals are given a 30-day post-operative mortality rate ranging from 15 % to 30%, depending on the level of amputation (Dillingham, Pezzin, & Shore, 2005; Ephraim, Dillingham, Sector, Pezzin, & Mackenzie, 2003; Feinglass et al., 2001; Mayfield et al., 2001). In general, within 5 years of the index amputation, second amputation and mortality rates increase with age, more proximal amputation, and poorer health status, especially for those with comorbid cardiovascular disease (CVD), renal failure, pulmonary disease, and systemic infection or sepsis (Aulivola et al., 2004; Dillingham et al., 2005; Feinglass et al., 2001; Mayfield et al., 2001).

Many persons living with limb loss are faced with restricted use of their artificial limb due to surgical consequences, residual limb complications, disease comorbidities, and/or additional injuries. Overall, it is estimated that nearly 25% of lower limb amputees will forego their artificial limb in lieu of a wheelchair, most often due to chronic pain (musculoskeletal and phantom limb), hypersensitivity, poor skin resiliency of the residual limb, poor prosthetic socket fit or artificial limb prescription, costs, and the psychological and physical exertion required to ambulate with an artificial limb (DePalma et al., 2002; Desmond, Gallagher, Henderson-Slater, & Chatfield, 2008; Desmond & MacLachlan, 2002; Dudek, Marks, Marshall, & Chardon, 2005; Legro et al., 1999). Emotionally, not only must the amputee contend with the depression and grieving process associated with losing a major limb, but in concert with such, they are faced with adapting to a new body image (with and without an artificial limb) as well as a potentially new way of life (Coffey, Gallagher, Horgan, Desmond, & MacLachlan, 2009). They may need to consider changes in their choice or status of employment, level of independence, and an increased awareness or monitoring of their overall health (Boutoille, Feraille, Maulaz, & Krempf, 2008; Desmond & MacLachlan, 2002; Gallagher, 2004; Uustal, 2009). Further, the individual’s coping strategies (such as avoidance behavior, denial, problem-solving skills) seem to be at the heart of their ability to adapt to the loss of a limb and acceptance of an artificial limb (Desmond & MacLachlan, 2006b). Maladaptive coping behaviors (such as drug/alcohol consumption), greater disability, poorer social functioning, and loss of functional independence may exacerbate artificial limb use as result of difficulties in psychological adjustment (Callaghan, Condie, & Johnston, 2008; Desmond & MacLachlan, 2006a; Desmond & MacLachlan, 2006b; Livneh, Antonak, & Gerhardt, 1999).

The Artificial Limb

The artificial limb prescription is based on multiple factors and significantly impacts the potential user's future, to include, beyond mere mobility: employment, self-image, socialization, health care costs, subsequent numerous treatment visits, and the expenses associated with the provision, maintenance, repair, or replacement of an artificial limb (Dillingham et al., 2005; Zidarov, Swaine, & Gauthier-Gagnon, 2009). Subsequently, multiple competing factors drive the prescription of an artificial limb and hinge on a meaningful evaluation of the prospective user (DePalma et al., 2002). Consideration must be given to the amputee's needs, goals, functional abilities (both cognitive and motor), learning capacity, health status and accommodations upon discharge, health care accessibility, and social/emotional support (DePalma et al., 2002; Kerkovich, 2004; Nelson et al., 2006; Zidarov et al., 2009). These concerns reflect not only the potential needs of the artificial limb user, but also offer insights for the physician and prosthetist as to the most appropriate artificial limb configuration to be prescribed and provided. In most cases, it is the patient's surgeon or physiatrist who prescribes the artificial limb, to include the type of foot, suspension system, and socket material; it is the prosthetist who crafts the socket, recommends specific components, assembles and aligns the artificial limb, and trains the user on use and care of the limb (DePalma et al., 2002;

DeLisa & Kerrigan, 1998).

Typically, when the site of surgery has healed sufficiently, the patient begins physical therapy with a temporary artificial limb—a limb that is designed to accommodate their immediate needs, not their ultimate goals (DePalma et al., 2002; DeLisa & Kerrigan, 1998). For the next 6 to 12 months, the residual limb may go through significant changes in size and shape as it continues to heal and as the patient trains with their temporary artificial limb, gradually increasing their mobility and endurance (DePalma et al., 2002; G. W. Bosker, CPO, personal communication, January 2011). At the point of residual limb stabilization, a definitive artificial limb is configured, one that is designed to accommodate the patient's near and ultimate goals (DePalma et al., 2002; DeLisa & Kerrigan, 1998).

The modern artificial limb is comprised of multiple prescribed components that in combination describe the function and performance of the entire unit. The basic transtibial artificial limb is composed of (from the bottom up): a prosthetic foot, a multi- or single-axis ankle, pylon, a handcrafted socket, and a suspension system that works to keep the leg on and in place over the residual limb (DePalma et al., 2002; G. W. Bosker, CPO, personal communication, January 2011). Commercially, there is a significant prosthetics–orthotics device industry with a vast array of component makes and models having varying marketed functions and capabilities (DePalma et al., 2002; G. W. Bosker, CPO, personal communication, January 2011). For example, the transtibial artificial limb may include a prosthetic foot structured of materials that give it specific mechanical qualities and/or contain sensors that help mediate its use; the suspension system may be as simple as Velcro belts and wraps or as sophisticated as a Vacuum Assisted Suspension System (VASS) (DePalma et al., 2002; Mak, Liu, & Lee, 1994). All such products are considered Class II medical devices by the U.S. Food and Drug Administration (FDA) and thus are exempt from FDA approval beyond premarketing notification. Clinical trials are not required, although manufacturers are asked to report serious adverse events that they learn about (2012).

Of the components used to configure an artificial limb, a well-fitted, well-crafted prosthetic socket is essential, as it is this part of the artificial limb that forms the interface between the mechanical aspects of the prosthesis with the human residual limb (Ferguson & Smith, 1999; Mak, Zhang, & Boone, 2001). The socket is typically handcrafted, although computer aided design–computer aided manufacture (CAD-CAM) techniques, which are used to improve fit, standardize materials and methods, and ultimately reduce cost and production time are being increasingly explored (Rogers et al., 2007; Collins, Karmarkar, Relich, Pasquina, & Cooper, 2006; Mak et al, 2001; Sewell, Noroozi, Vinney, & Andrews, 2000)

Regardless, the socket is the one component of the entire artificial limb that, because of its customized fit to an individual's residual limb, cannot be mass produced (Ferguson & Smith, 1999). Thus the fit and comfort of the socket is primarily dependent on the skill and expertise of the prosthetist, but may be complicated by the shape and length of the residual limb (DePalma et al., 2002). Beyond the skill of the prosthetist, it is generally accepted (although not systematically investigated) that a poorly prescribed or configured artificial limb will exacerbate the human/mechanical interface supplied by the socket, resulting in excessive discomfort, a compromised residual limb, and user frustration (DePalma et al., 2002; Legro et al., 1999; Mac et al., 1994).

Research Trends in the Field of Artificial Limb Function, User Outcomes

To date, based on literature review, most research conducted regarding persons living with limb loss and the use of an artificial limb has been focused on gait and balance biomechanics, functional capacity, energy cost, and patient satisfaction as measured by varying questionnaires and survey tools. While there is an abundance of case reports on residual limb complications, given the nature of scientific publication practices, most are about an unusual condition or circumstance (Meulenbelt, Geertzen, Dijkstra, & Jonkman, 2007). Little attention has been given to the incidence or prevalence of common residual limb complications in relation to artificial limb configurations or components, despite implications thereof and significant rates of re-amputation and patient dissatisfaction (Dudek et al., 2005; Meulenbelt, Dijkstra, Jonkman, & Geertzen, 2006). Additionally, there is a dearth of literature on long-term effects of artificial limb use (after more than 1 year), to include the associated psychosocial conditions, barriers, and implications of living with limb loss (Desmond & MacLachlan, 2002; Gallagher, 2004).

Most studies addressing issues of artificial limb use, outcomes, or design are of moderate methodological design and have small case numbers, unique populations, and short follow-up periods (less than 6 months) (Iezzoni, 2004). Very few randomized control trials have been conducted, in part due to the nature of the study population, but also due to the fact there are few (if any) standardized measures or outcomes that are universally accepted or easily quantified (Meulenbelt et al, 2006).

Subsequently, population-based, comprehensive, and objective information that facilitates the development of universal prescription guidelines, identification of adverse patterns of patient outcomes, geographic or ethnic influences, and the monitoring of artificial limb costs, usage, availability and/or marketing influences, is seriously encumbered (Iezzoni, 2004). As such, there is a need to exploit alternative means of facilitating the analysis and dissemination of objective, outcomes-based (patient/artificial limb) results that may fill informational gaps associated with anecdotal evidence and the experiential knowledge of the practitioner. In short, there is a need to promote, facilitate, and disseminate evidence-based clinical information regarding the person living with limb loss and the use of an artificial limb, as a means to improve relative health care practices.

Alternative Artificial Limb-Outcomes Research Resources

In those cases where conducting a clinical trial may be unfeasible or unethical, many disciplines have turned to the development of a high-quality clinical database (HQCD) as a means for consolidating evidence-based medicine in a systematic, consolidated manner (Arlet et al., 2008). An HQCD is typically a relational database that focuses on an intervention and the related patient outcome. It allows for the generation of large samples that improve statistics, promote generalizability of analyses, and allow for subgroup identification to include the aggregation of rare cases and/or interventions for study (Black, 1997). In the United States, a database of this sort does not exist for the field of prosthetics/limb loss.

In the absence of an appropriate HQCD (or to facilitate the development of such), a healthcare administrative database may serve as a viable alternative. Though broad in scope and without direct clinical information beyond diagnosis and procedural codes, a healthcare administrative database is a proven and effective tool for calculating population disease incidence/prevalence and/or health service practices (Boyko, Koepsell, Gaziano, Horner, & Feussner, 2000; Hlatky, 1991; Nordio, Antonucci, Feriani, Inio, & Marchini, 2009). Further, when a healthcare administrative database is linked to a systematic patient follow-up with outcomes directly related to medical coding, what emerges is a tool not dissimilar to an HQCD. Though such a tool would likely prove highly valuable for the clinical decision-maker for identifying those factors that strongly predict good or poor outcome, the concept is as yet untested (Iezzoni, 2004). It is projected that this is due in part to the lack of an amputee/prosthetics surveillance or monitoring system, the lack of a universally accepted and obtainable outcome measure, and to a highly prolific and profitable prosthetics industry.

To this end, the Veterans Health Administration (VHA), with its rich history in information technology, may provide a viable source for such patient/artificial limb outcomes analysis. The VHA has maintained a National Patient Care Database (NPCD) since 1976 that contains patient care information in the form of ICD-9 codes, procedure codes, V-codes, and HCPCS codes, as well as certain demographic information (Murphy, Cowper, Seppala, Stroupe, & Hynes, 2002). The database is derived from regional applications supported by the Veterans Health Information Systems and Technology Architecture (VISTA), an integrated, interactive information technology set of applications and tools that support healthcare system-wide security, device access, data-sharing, and communications (Brown, Lincoln, Groen, & Kolodner, 2003). A key application supported by VISTA is the Computerized Patient Record System (CPRS), which provides much of the medical coding (for example, ICD-9-CM and CPT codes) associated with each patient's facility inpatient stay or outpatient visit (Boyko et al., 2000; Brown et al., 2003; Murphy et al, 2002). Currently, the NPCD represents the medical care of over 8 million veterans in the United States, and this number is growing (Department of Veteran Affairs, 2010).

Additionally, since 2000, the VA's Prosthetics and Sensory Aids Service (PSAS) has maintained a unique database: the National Prosthetic Patient Database (NPPD), of which data is transmitted via the Orthotic WorkLoad (OWL) or the Prosthetics Software Package (PSP) applications, also integrated with VISTA (Werner, 2010). With a developmental intent to provide a means to monitor the VA's Prosthetic Service, as well as to be a source of artificial limb prescription practice information for clinicians, the NPPD is a compilation of prosthetic and orthotic provision records acquired from VA facilities across the nation—a roll-up of all prosthetic, orthotic, and sensory aids transactions performed per patient visit per fiscal year (Downs, 2000; Pape, Maciejewski, & Reiber, 2001). Further, as of 2005, the NPPD has been significantly improved, evaluated, and made more easily integrated with other VA administrative databases, including the NPCD (Smith, Su, & Phibbs, 2010). Therefore, the longitudinal tracing of factors and patient outcomes associated with artificial limb component provision has been significantly facilitated and is encouraged by VHA leadership.

To this end, recent strides have been made by investigative leaders in the field of amputee care to develop a National Amputee Registry within the VHA system (G. Reiber, personal communication, August 2012). It is believed that this level of surveillance will, at the least, simplify the identification of patterns of outcomes and will facilitate the development of prescription guidelines and reduction of prescription ambiguity for the practitioner, as well as provide manufacturers with greater insight/evidence for improved design and marketing information, ultimately benefiting the artificial limb user (Downs, 2000).

Problem Statement

For the individual living with limb loss and an artificial limb, their success and quality of life is often modulated by residual limb problems resultant from artificial limb use. Normal and excessive biomechanical forces (e.g., pressure, friction, shearing, and torques) are generated at the interface of the artificial limb socket and the users residual limb, setting up conditions adverse for normal tissue growth and healing. Excessive heat and sweat facilitate bacterial and fungal growth, undue pressures can lead to soft tissue damage or calluses, friction and shearing is often related to blistering, and all such effects have a deleterious effect on the integrity of the skin, thereby increasing the risk for infection and non-use of the artificial limb (Bui, Raugi, Nguyen, & Reiber, 2009; DeLisa & Kerrigan, 1998; Dudek et al., 2005; Meulenbelt et al., 2006; Meulenbelt et al., 2007).

Further, it is not uncommon for persons having difficulty making adjustments following amputation to report bouts of depression, feelings of hopelessness, grief, low self-esteem, fatigue, anxiety, and sometimes suicidal ideation (Singh et al., 2009; Williams et al., 2011). For those who also suffer from peripheral vascular disease or diabetes, such emotions and their associated behaviors may confound the artificial limb use because their condition is associated with compromised circulation and poor healing capacity in the residual limb. Depending on the severity of such complications, artificial limb use may be restricted, minimized, or terminated. Re-amputation of the same limb may be required, or death may ensue due to sepsis originating from residual limb tissue infection (Centers for Disease Control and Prevention [CDC], 2004). With the current and projected continued rise in the numbers of individuals with diabetes, peripheral arterial disease, and co-morbidities associated with aging, the present and pending population of persons living with acquired dysvascular below-knee amputations will correspondingly increase (Ziegler-Graham, et al., 2008).

While it is generally accepted among amputee care practitioners that artificial limb components and characteristics (such as prosthetic feet, sockets, and socket suspension systems) can and do impact residual limb skin integrity/condition, there is little to no evidence-based clinical research that directly assesses such a relationship, with or without the consideration of influence of mental health disorders as a complicating factor (Desmond & Maclachlan, 2002, Dudek et al, 2005; Meulenbelt et al., 2006; Meulenbelt et al., 2007).

Without evidence-based outcomes research, this population will remain especially vulnerable for poor quality of life, in conjunction with excessive medical care and costs, due to inappropriate artificial limb prescriptions that are based on biased industry marketing and/or anecdotal information, rather than on objective clinical data.

An extensive literature search on evidence-based medical research in the field of prosthetics, revealed three key factors hindering the practice: (a) currently, no amputee–artificial limb surveillance or monitoring is established or practiced among the general public in the United States, and thus comprehensive data collection on the matter is seriously encumbered and limited to specific sites (hospitals) or centers; (b) large clinical trials of artificial limb components are not required or truly feasible; and (c) suitable prospective studies are hindered by rapidly changing and expensive artificial limb technology. However, the VHA, with its rich history in national patient care databases, offers a viable alternative solution. Although untested to date, a dataset derived from the integration of VHA healthcare administrative database subsets, and relevant to patients with acquired limb loss and a dispensed artificial limb, may provide meaningful evidence-based information useful toward lessening artificial limb prescription ambiguity, while promoting positive healthcare and patient outcomes. Further, analysis of such a dataset may prove highly resourceful by identifying those variables most relevant for future surveillance.

Nature of the Study

Purpose

The purpose of this study was to address the utility of VHA administrative healthcare records to discriminate determinants of residual limb skin outcomes relative to the artificial lower limb configuration prescribed, as a source of information toward the potential development of a suitable amputee-artificial limb database and future surveillance system.

Utilizing subsets from two health care administrative databases maintained by the VHA (the National Patient Care Database and the National Prosthetics Patient Database), this study derived an integrated dataset representative of a cohort of veterans having undergone a transtibial amputation for dysvascular complications during fiscal year (FY) 2007 (October 1, 2006 through September 30, 2007), subsequently provided with an artificial limb prior to the end of FY 2007, and then followed through FY 2010, or a maximum of 3 years. A more thorough description of the cohort, derivation of the integrated dataset, and definitions of the outcome variable, residual limb skin problem severity (RLSPS), covariate conditions, and independent variable artificial limb configuration (ALC) is provided in Chapter 3.

Objectives

As detailed more completely in Chapter 3, a significant component of the study was dedicated to the compilation and derivation of the study dataset that linked patient care data with their dispensed artificial limb configuration, to include categorization of the ALCs and definition of the outcome variable. This dataset then formed the foundation and source for the study's primary objective. However, while not an Objective per se, the development of this dataset is key not only to the epidemiological questions at hand, but also in addressing the potential for a similarly derived database as an informatics tool in the development of an amputee-care surveillance system. Thus, aspects of the dataset itself warrants discussion based on the study's findings.

Primary Objectives

Statistical analysis of the refined dataset and identification of the patterns and trends of the cohort with regard to artificial limb provision and subsequent RLSPS (categorical) outcomes.

Research Questions and Hypotheses

The research questions that follow were derived from a literature review of artificial limb prescription trends and recommendations, residual limb complications of artificial limb use, and healthcare informatics.

As elucidated in Chapter 2, multiple factors contribute to residual limb skin problems in conjunction with the use of an artificial limb. This study addressed aspects of two categories of those factors: mechanical and behavioral, although the two categories are not mutually exclusive, as both involve exacerbation of the existing residual limb/artificial limb interface. Mechanical factors are those in which skin problems are the consequence of continued biomechanical forces (for example, friction, pressure, and shearing) acting on traumatized skin tissue, and thus pertain primarily to the ALC utilized. Behavioral factors are those in which a similar exacerbation exists, but is driven by the actions of the user (for example, poor self-care or disease management, activity/ambulation level, treatment non-compliance). Therefore, the following research questions focused on both mechanical and behavioral factors as main effects or covariates.

Finally, because the study dataset was comprised of a selected subset of extant data that was uncertain in quality (the NPPD), containing the independent variable that is characterized but yet to be indexed or categorized; because the subsequent dataset was rich in clinical information (the NPCD); and because such a systematic and long-term assessment of amputee outcomes relative to specific artificial limb configurations and components has not yet been reported, a veritable new knowledge base was established. As such, the research questions and hypotheses reflect the exploratory nature of this retrospective observational study, and the dataset and cohort warrants current and future characterization (for example, cohort age ranges, mortality rates, rates of artificial limb components and configurations dispensed, frequencies of specific residual limb skin conditions; an accounting of nonsensical data or invalid values, and case matching/linking complications).

RQ1. Do categories of RLSPS differ with ALC/component? (Mechanical main effect)

Null Hypothesis ($H_0$1). RLSPS categories (frequency and type) will not differ significantly on the basis of the ALC or component dispensed.

Alternative Hypothesis (H_a1). *More* severe RLSPS (such as ulcers) will be significantly more frequent among ALC Categories of higher function or technical sophistication and will be least for low function, low technically sophisticated configurations (H_a1a); over 50% of all the cohort members will have at least one less severe RLSPS category treated during the 3 year follow-up period, regardless of the ALC dispensed to them (H_a1b).

RQ2. Using the Region of Veterans Integrated Service Network (VISN) where the artificial limb was dispensed as a proxy for the prosthetist responsible for crafting the socket and configuring the artificial limb, do categories of RLSPS (frequency and type) differ with ALC and the responsible prosthetist? (Mechanical as covariate)

Null Hypothesis ($H_0$2). RLSPS categories (frequency and type) will not differ between Regions, regardless of ALC dispensed.

Alternative Hypothesis (H_a2). Significantly more “severe” category RLSPS will be noted among cohort members with higher function or more technically sophisticated ALC, regardless of the responsible prosthetist.

RQ3. Do categories of RLSPS (frequency and type) differ relative to a comorbid condition diagnosis to include major depressive disorder (MDD), post-traumatic stress disorder (PTSD), or substance use disorder (SUD) during the three-year follow-up period? (Behavioral main effect)

Null Hypothesis ($H_0$3). Cohort members with a diagnosis of MMD, PTSD, or SUD will not differ in RLSPS categories (frequency or type) than members of the cohort with no such diagnosis.

Alternative Hypothesis (H_a3). Cohort members with a diagnosis of MMD will have fewer severe residual limb skin problems and fewer residual limb skin problems treated overall, as compared to those members with no such depression diagnosis (HA3a); cohort members with a diagnosis of PTSD or SUD will have significantly more (in frequency) RLSPS (such as ulcers) than those members without PTSD or SUD, but no significant difference in frequency of less severe RLSPS compared to those cohort members with no such diagnosis (H_A3b).

RQ4. Do categories of RLSPS (frequency and type) differ significantly with ALC and a diagnosis of a comorbid condition to include MDD, PTSD, or SUD? (Interaction effect, mechanical by behavioral factors)

Null Hypothesis ($H_0$4). RLSPS categories relative to ALC will not differ for cohort members with a diagnosis of MDD, PTSD, or SUD, compared to cohort members with similar ALC artificial limbs and no such diagnoses.

Alternative Hypothesis (H_a4). Cohort members with a diagnosis of PTSD or SUD and an artificial limb of high function or technical sophistication will have significantly more "severe" residual limb skin problems (such as ulcers) than all other cohort members

(Ha4a); cohort members with a diagnosis of MDD and a lower function or less technically sophisticated artificial limb configuration will have significantly fewer “severe” residual limb problems than all other cohort members (Ha4b).

Theoretical Basis

The goal of most epidemiological studies is to infer causation, specifically to reveal unbiased relationships between exposures and outcomes (morbidity/mortality). Most outcomes are consequent of multiple factors—a web of interactions that define a cause or condition. Causal relationships can be considered as necessary, sufficient, or probabilistic conditions. If a necessary condition can be identified and controlled, the harmful outcome can be avoided (Phillips & Goodman, 2004).

To this end, the informatics model and the evidence-based medicine model are the means toward unbiased, objective information; the biopsychosocial model offers the necessary, sufficient, or probabilistic condition; and the practice-based evidence model provides a framework with which to explore causal relationships.

The informatics model. The informatics model is a simplistic way to conceptualize such a potentially complex process. It consists of three essential parts: “data, information, and knowledge, arranged hierarchically, with data at the base of the model providing the basis for establishing information and leading, in turn, to the potential generation of knowledge.” (Georgiou, 2002). Within this model, data take on the character of facts or observations, which have little or no meaning. The data are placed in context and managed accordingly, becoming useful information, which can then be further synthesized with social, economic, and even political contributing influences, to be ultimately disseminated as knowledge (Georgiou, 2002). The significance and fundamentals of the informatics model are demonstrated in the section "Surveillance, Informatics, and the Amputee" in Chapter 2. Further, it is this informatics model that forms the basic concepts underlying evidence-based medicine, converging with its principles, aims, and tasks, particularly in regard to transforming data and information into evidence-based knowledge.

Evidence-based medicine. Evidence-based medicine (EBM) became a feature of medical and health care planning in the 1990s, being partly driven by significant advances and accessibility in information technology to include health informatics (Charles, Gafni, & Freeman, 2011). It may be defined as a process of using the best evidence to make decisions on care for patients—a process of decision-making that incorporates best practice medicine; external, related scientific evidence; and social, economic, and cultural factors that influence a patient's quality of life, morbidity and mortality (Borg & Sunnerhagen, 2008; Sackett, Rosenberg, Gray, Haynes, & Richardson, 2007). The paradigm incorporates clinician expertise as "evidence" derived through patient interactions, field specialty, and education; related external scientific evidence ranging from the basic sciences of medicine, to mechanical/electrical engineering, to the computational and communication sciences (IT); as well as patient input, communication, and education (Borg & Sunnerhagen, 2008; Georgiou, 2002; Sackett et al., 2007).

Perhaps the most important component of evidence-based medicine however is patient-centered clinical research that utilizes randomized control trials, especially those that challenge the accuracy, power, safety, and efficacy of diagnostic tests, prognostic tools, and therapeutic, rehabilitative, and preventive regimens (Sackett et al., 2007). Because the randomized control trial—especially the systematic review of several randomized control trials or the meta-analyses thereof—typically promotes greater validity and reliability but less bias, it has become the gold standard for judging whether a treatment does more good than harm (Sackett et al., 2007). Examples of the significance of evidence-based medicine, specifically through the use of clinical or health care administrative databases, are presented in the section “To Build a Better Database or Not” in Chapter 2.

The practice-based evidence model. To meet the requirements of the evidence-based medicine paradigm, there has been a trend toward using newer methodological and statistical design techniques to better accommodate the unique practice and patient population characteristics of rehabilitation medicine and similar specialties (Iezzoni, 2004; Groah et al., 2009; Charles et al., 2011).

For example, a variant of the prospective observational cohort design (a gold standard for many epidemiologic health studies) is the practice-based evidence (PBE) model. The PBE model basically seeks to systematically categorize patient interventions to determine which interventions are most strongly associated with outcomes, taking into account a large number of patient characteristics that may also be influential (Groah et al., 2009). The label *practice-based evidence* is rather self-explanatory as the model/design is focused on actual medical practice. It utilizes hypotheses and inclusion criteria that are general (with more specific hypotheses being developed and tested as associations are warranted), selection criteria are broad and designed to maximize generalizability and external validity, and data collected includes an array of patient characteristics that may account for the outcomes observed: demographic and socioeconomic profiles, comorbid conditions, and functional status (Groah et al., 2009). These characteristics are then controlled for through the use of multivariate statistical analyses (Groah et al., 2009; Iezzoni, 2004). “PBE aims to place greater emphasis on real-world practice and behavior to determine which patient characteristics and interventions are associated with better outcomes” (Groah, et al., 2009, 945).

In many cases, the clinical epidemiologist, grounded in the informatics model and under the umbrella of evidence-based medicine, will turn to alternative data sources when a randomized control trial is inappropriate or not feasible, a prospective cohort study too costly or complex to manage, or pre-existing data is to be synthesized into useful information and evidence (for example, literature systematic reviews or meta-analyses) (Georgiou, 2002; Groah et al., 2009; Sackett et al., 2007). The study presented in this dissertation is an example of such a situation and therefore, in keeping with the evidence-based medicine paradigm, the informatics model, and the practice-based evidence cohort framework, this study is based on a retrospective cohort design utilizing VHA national databases containing patient demographics and extensive clinical histories in the form of medical, clinical, and billing codes. While the ultimate goal (as per the informatics model and evidence-based medicine paradigm) may be to produce evidential knowledge, such is outside the scope of the study. Instead, the intent is to merely collect data and manipulate it with multivariate statistics in the context of prosthetics intervention, culminating in useful information that may prove as evidence in future studies. As such, these theoretical models, in combination, drive the purpose and exploratory nature of the study and support all 4 research questions and hypotheses.

The biopsychosocial model. When psychiatry was challenged as a legitimate branch of medicine in the 1970s, the field was criticized for failing to follow the medical model that posited a purely molecular explanation of all disease processes (Wilson, 1993; Freedman, 1995). In 1992, G. L. Engel defended the need to include psychological and social factors in considering the diagnosis and treatment of both physiologic and psychiatric disease, using the examples of diabetes and schizophrenia to illustrate the importance of “a biopsychosocial model which includes the patient as well as the illness” (Engel, 1977, 133). This model has been further embraced in multiple other medical care models, including those specific to chronic disease and self-management, especially diabetes (Rakovec-Felser, 2011; Zinszer, Mulhern, & Kareem, 2011).

More recently, Fischer and colleagues (2005) posit a “Resources and Support Self-management” model that is based on two key premises: that an individual’s behavior (and subsequent decision-making) is strongly influenced by their physical and social environment, and that their perspective regarding their circumstance and resource availability is central to disease control and quality of life, basically coming full-circle to

Engle's initial theory (Fisher et al., 2005; Goodman, Yoo, & Jack, 2006).

Therefore, as exemplified in the section "Living with Limb Loss" in Chapter 2 and under the mantel of these models and theories, it is believed that patient psychological status (as indicated by a diagnosis of MDD or PTSD), and behavioral factors such as SUDs, with direct and indirect influence from socio-demographic factors (age, gender, marital status, being subject to medical care co-payments), will cause variations in their maintenance of disease self-management, to include care of their residual and artificial limbs (Hypotheses 3 and 4).

Definition of Terms

CPRS: Computerized Patient Record System. The VHA's electronic medical record system, a component of VISTA (Brown et al., 2003).

Current Procedural Terminology (CPT) codes: CPT codes are numbers assigned to every task and service a medical practitioner may provide to a patient, including medical, surgical, and diagnostic services, primarily for billing purposes (American Medical Association [AMA], 2013). They are developed, maintained, and copyrighted by the American Medical Association. CPT coding is similar to ICD coding, except that it identifies the services rendered rather than the diagnosis. There are 3 types of CPT codes: Type I has six categories: (a) Evaluation and Management, (b) Anesthesia, (c) Surgery, (d) Radiology, (e) Pathology and Laboratory, and (f) Medicine (AMA, 2013). Type II codes have to do with "performance measurement" and are distinguished by being alphanumeric rather than strictly numeric (as Type I codes are) (AMA, 2013). Type III codes have to do with emerging technologies and all end with the letter “T” (AMA, 2013). A further discussion of CPT codes is provided in Chapter 2.

D*ysvascular:* Dysfunction or failure of the vascular circulatory system, to include peripheral arterial disease (PAD), diabetes mellitus, and peripheral vascular disease (PVD) (Dillingham et al, 2005)

General Estimating Equations: General Estimating Equations (GEE) are amultivariate statistical modeling method considered more robust than General Linear modeling for it accommodates non-continuous dependent variables, a Poisson distribution, and the dependent variable need not be linearly linked to the independent/predictor variable (Garson, 2008, 2011a).

HCPCS codes: Healthcare Common Procedure Coding System—A standard code developed by the Centers for Medicare & Medicaid Services (CMS) for reimbursement purposes. The U.S. Food and Drug Administration (FDA) forwards information on durable medical equipment (DME) applications to the CMS. CMS then assigns the item an HCPCS code. These are frequently referred to as “L-codes” or “billing codes” (Centers for Medicare & Medicaid Services [CMMS], 2012).

ICD-9-CM codes: The International Classification of Diseases, 9th Revision, Clinical Modifications. ICD-9-CM is a standardized classification of disease, injuries, and causes of death, by etiology and anatomic location. The combined information is assigned a unique, searchable, six-digit number, allowing various national and international stakeholders to exchange information. ICD codes are maintained by the World Health Organization (Centers for Disease Control and Prevention [CDC], 2012).

Intact limb: In the case of the unilateral lower limb amputee, that limb which has not undergone any amputation, although it may lack peripheral sensation (as in diabetic peripheral neuropathy), or be arthritic, or have other musculoskeletal problems that may compromise its use. Frequently this limb is also referred to as the sound limb.

Major Depressive Disorder (MDD): Major depressive disorder, diagnosed by structured psychiatric interviews and specific diagnostic criteria, is present in 5-13% of Veterans seen by primary care physicians. Depression is a major cause of impaired quality of life, reduced productivity, and increased mortality. Social difficulties are common (for example, social stigma, loss of employment, marital break-up). Depressive symptoms include depressed mood, loss of interest in most activities (anhedonia), significant change in weight or appetite, insomnia or hypersomnia, decreased concentration, decreased energy, inappropriate guilt or feelings of worthlessness, psychomotor agitation or retardation, and suicidal ideation. Symptoms must persist for at least two weeks (The Management of MDD Working Group, 2009). The ICD-9-CM codes used are listed in Appendix B, Table B15.

Medical SAS Dataset: The VHA Medical Statistical Analysis System (SAS) Datasets are national administrative data for VHA-provided health care. The datasets include provided health care information primarily for Veterans, but also for non-Veterans such as employees and research participants. The datasets are provided in SAS format by fiscal year (October 1 - September 30), and are extracted from the National Patient Care Database (NPCD). They include: VA inpatient care (four datasets); VA outpatient care (two datasets); VHA extended care (four datasets); VA inpatient short stay (less than 24 hours) observation care (four datasets); and health care provided for Veterans outside the VA with VA funding (four datasets) (VA Information Resource Center (VIReC), 2012b). In all of the Medical SAS Datasets, each patient has a unique identifier referred to as the scrambled SSN, which is a formula-based encryption of the individual's Social Security Number. The identifier is consistent for a given patient across datasets and fiscal years.

NPCD: National Patient Care Database. This is maintained by the U.S. Veterans Administration. The NPCD is an Oracle database maintained at the Austin Information Technology Center (AITC) on a Unix platform (VA Information Resource Center (VIReC), 2012b). It is the VHA's centralized data warehouse that receives patient visit and encounter data from VHA clinical information systems across the VA system. It is updated daily and contains such information as: patient demographics, facility type and location, visit dates, ICD-9-CM codes, procedure and/or surgery codes, provider codes, and so forth. Since 1980, data from this database has been made available as annual medical SAS datasets (VIReC, 2012b).

NPPD: National Prosthetic Patient Database. Maintained by the U.S. Veterans Administration Prosthetic and Sensory Aids Service Strategic Health Care Group (PSAS). It is an Access relational administrative database comprising orthotic, prosthetic and sensory devices dispensed to Veterans nationwide (Downs, 2000). Data fields include visit dates, prosthetics provision, repair or replacement information, product identification (cost, type, and so forth), and contractor (VA Information Resource Center (VIReC), 2012a).

OPCF: Outpatient Care File: a subset of the VA's NPCD. Each outpatient data record represents one date of service for one outpatient, either as a visit or an event. Visits on a single day to multiple clinics, laboratories, and treatment programs are captured. Outpatient care is reported in terms of diagnoses (ICD-9-CM codes) and procedures (CPT codes) (VIReC, 2012b).

Peripheral Arterial Disease (PAD): See "dysvascular" definition. Basically a collapse of artery blood vessels.

Peripheral Vascular Disease (PVD): See "dysvascular" definition. Similar to PAD but not limited to arterial blood vessels; PVD may include breakdown of venous vessels.

Post Traumatic Stress Disorder (PTSD): Chronic post traumatic stress disorder (symptoms lasting more than three months after exposure to trauma) can appear alone (presenting with common symptoms of PTSD) or other co-occurring conditions (persistent difficulties in interpersonal relations, mood, chronic pain, sleep disturbances, somatization, and profound identity problems) or psychiatric disorders (meeting DSM criteria for another disorder, such as substance abuse, depression, and anxiety disorder). It is typically characterized by low energy, memory problems, an inability to focus on work or daily activities, indecision, , irritability, agitation, anger, or resentfulness; emotional numbness, withdrawal, disconnection from others, spontaneous crying, despair, or hopelessness; extreme protectiveness or fear for loved ones; inability to face certain aspects of the trauma, avoidance of activities, places, or persons associated with the traumatic event (The Management of Post-Traumatic Stress Working Group, 2010). The ICD-9-CM codes used are listed in Appendix B, Table B16.

Prosthetic foot: An artificial, mechanical foot component. These are typically categorized into five groups as defined by their functional design: SACH (solid ankle cushioned heel), multiaxis, dynamic response, dynamic response–multiaxis, and hybrid/microprocessor (DePalma et al., 2002.

P*rosthesis:* Another word for an artificial limb.

Region: Regions represent four virtual divisions and the distribution of the VISNs as determined and established by the Office of Information Technology (OIT) VHA

Central Offices, 2013. They may be loosely described in geographical terms: Region 1 - Northwest and Western U.S, Region 2 - North- and South-Central U.S. (includes Texas), Region - Eastern Mid-West and Southern U.S. (includes Ohio), and Region 4 - Mid-Atlantic and Northeast U.S. (includes Washington DC/Maryland). It should be noted that a single VISN may cover areas in multiple states.

Residual Limb: That part of an extremity that remains intact after amputation.

Socket: Refers to that prosthetic component that fits over the residual amputated limb and serves as the interface between the mechanical components of the artificial limb and the human tissue. It is typically hand-crafted and customized to the patient's residual limb (DePalma et al., 2002).

Substance Use Disorder (SUD): Substance use disorder includes conditions and disorders of unhealthy alcohol use ranging from risky use, problem drinking, harmful use and alcohol abuse, to alcoholism and alcohol dependence. It is defined as the maladaptive use of substances (drugs or alcohol) leading to clinically significant impairment or distress, typically manifested by at least three of the following behaviors within a 12 month period: persistent desire or inability to control use of the substance, significant time spent obtaining, using, or recovering from the substance; social, occupational, or recreational activities are sacrificed in lieu of use of the substance; and substance use persists despite knowledge and evidence of its harmful effects (The Management of SUD

Working Group, 2009). The ICD-9-CM codes used are listed in Appendix B, Table B17.

Suspension system: A component of the artificial limb and of various types, the sole purpose of which is to facilitate the fit and hold of the socket and artificial limb over the residual amputated limb (DePalma et al., 2002).

Transfemoral amputation: a lower extremity amputation below the hip and above the knee. It transects the femur and also is frequently referred to as an “above-knee amputation”.

Transtibial amputation: an amputation of the lower extremity, below the knee but above the ankle that transects the tibia /fibula. It also is frequently referred to as a “below-knee amputation.”

V-codes: Visit codes identify occurrences of medical encounters related to circumstances other than a disease or injury and are also used to report problems or factors that may influence present or future care. The V-code is a supplemental classification of ICD-9-CM and includes categories V01–V89 (CDC, 2012).

VISN: Veterans Integrated Systems Network. Regional offices of the Veterans Administration that oversee the budgets and employment of over 163 VHA facilities (Boyko et al., 2000).

VISTA: Veterans Health Information Systems and Technology Architecture, the core of the VHA’s information technology system (Brown et al., 2003).

Assumptions and Limitations

There were two primary assumptions maintained throughout this study analysis: (a) that the data provided and used for analysis was reliable and valid, and (b) that the prosthetic socket provided to the Veteran amputee was of good quality and design.

Data reliability and validity. Health care coding used in most administrative databases (for example, ICD-9-CM, CPT, HCPCS codes) are prone to random and systematic error resultant of physician judgment, communication failures, and/or coding procedures. Therefore, they may not reflect precisely an individual's disease condition or appropriate treatment procedure (van Walraven & Austin, 2012). The VHA, through its dependence on the VISTA and electronic medical record system (CPRS), has taken significant steps to reduce this potential for error. Data that comprise both the NPCD and NPPD are derived from roll-up applications from all VISNs, of which there are 23 across the nation. Each VISN receives data from various facilities under its direction, and each facility is responsible for compiling and maintaining its own administrative electronic records (Boyko, et al., 2000).

The primary source of data for the NPCD is CPRS, the electronic medical record system utilized by the VHA. It has features specific to each VISN, but the data features and dictionary are standardized across all VISNs (Brown, et al., 2003). At the time of the patient "encounter" or visit, the physician is responsible for selecting the appropriate treatment (CPT) or diagnosis (ICD-9-CM) code from selection boxes as part of their signed progress note or consult. However, the selection of these codes is prone to multiple sources of error to include: poor communication between the patient and clinician leading to inaccurate decisions; the clinician's depth (or lack thereof) of knowledge and training regarding ICD9-CM and CPT codes or field of medicine, leading to the use of more generic codes over a more precise definition; and pressures of patient workload leading to fatigue and case confusion or inaccuracy (O'Malley et al., 2005). Ultimately these codes reach professional medical coders who, based on a review of all the pertinent medical information, assign a "principal diagnosis" (as defined by the Uniform Hospital Discharge Data Set—UHDDS), as well as a principal treatment code and, in the VHA, up to 14 additional diagnostic codes and 7 procedure codes in a patient's day, for those cases that required multiple evaluations, therapeutic interventions, extended care or monitoring, and diagnostic procedures such as laboratory and imaging (O'Malley et al., 2005). The degree of accuracy of the selection of these codes, which are eventually rolled-up from the various facilities and VISNs into the VHA's national administrative database, is dependent on the skill, training, and experience of the coders who are, in turn, dependent on the clinician's code selections for accurate information regarding a patient's condition and care.

Similarly, the NPPD is a roll-up of fields from the Prosthetics Software Package (PSP) which has recently (as of FY 2010) been upgraded and includes the Orthotics Workload (OWL) application (G. W. Bosker CPO, personal communication, January 2013). The PSP is integrated with six other Vista applications including: PSAS (the Prosthetics and Sensory Aids Service—Central office); IFCAP (Purchasing/Supply services); Consult Tracking (prosthetic purchases are resultant of consultation requests from other services); CPRS, Patient Care Encounters (for purposes of patient and clinician workload tracking); DSS (Decision Support Service, which is responsible for vendor contracts); and billing (Werner, 2010). They are integrated through an exchange of data via Vista which allows for the direct transference of data rather than merely copies of files, thereby limiting another source of systematic error. Similar to CPRS notations, for every patient encounter with the Prosthetics–Orthotics Service, there is an accounting of that visit via various menus and associated electronic forms, including one for purchasing prosthetic devices (Werner, 2010). The software application provides lists of items (device model and make), as well as edit fields to provide additional information for the vendor, including a specific model or type (Werner, 2010). To complete the transaction, the practitioner selects the status of the device (initial, repair, replacement, or spare) as well as the corresponding HCPCS code that is provided based on the item selection (Werner, 2010).

With such controls to minimize communication and systematic error, one can only assume that, for both CPRS and PSP, the selection made by the practitioner was correct and appropriate. The NPCD has been and is regularly evaluated for validity and reliability, and found to attain levels of over 90% validity (Murphy et al., 2002). However, the NPPD, being a fairly new database, has not yet undergone similar reliability and validity testing, although it has been utilized for multiple published works— to include a comparison of artificial limb distribution frequencies across VISNs and between VA and commercial providers (Downs, 2000), an estimation of total prosthetics spending across a selection of VISNs in FY 1999 (Render, Taylor, Plunkett, & Nugent, 2003), some wheelchair type distribution and costs comparisons during FY 2000-2001 (Hubbard et al., 2007), and a determination of clinical characteristics associated with artificial limb prescription for the elderly amputee (Kurichi et al., 2007). M. L. Smith and colleagues conducted and published an evaluation of the NPPD in 2010 in which they compared an accounting of outpatient and inpatient visits (as recorded in the NPCD) related to the Prosthetics–Orthotics Service with an accounting of device delivery dates as specified in the NPPD. They determined that while the number of devices delivered (as determined by Type II CPT codes) was significantly greater than the corresponding number of related visits, this could be explained by the fact that a single clinical outpatient or inpatient visit (as per the NPCD) could amount to multiple devices delivered (as per the NPPD) (Smith et al, 2010). Additionally, as per an accounting of visits and visit dates, the authors determined that there was a 40–60% discrepancy between clinic visit dates and the VA mandated delivery date of 14 days post request; however, again, this discrepancy may be due to the availability of devices, types of devices dispensed (for example, artificial limbs must be custom fabricated), and manpower issues (Smith et al., 2010). For the proposed study, this discrepancy is fairly irrelevant as the intent is to merely note and account association frequencies between artificial limb configurations and components with the presence or absence of categorized residual limb problems.

Finally, in this study, CPT codes and/or ICD-9-CM codes were used to define residual limb status, based on the procedure (or diagnosis) required to treat a residual limb related problem. The intent of such coding is to provide uniform information. As the focus of the study is on patient outcome and not on healthcare service, an assumption was maintained that different residual limb problems require different treatment procedures, and thus different CPT codes or combinations thereof, and that the CPT codes for service were reflective of actual patient outcomes.

A further discussion of the NPCD and NPPD database structures is provided in Chapters 2 and 3; further definitions of CPT, ICD-9-CM, and HCPCS codes are found in Chapter 2, as well as a listing of codes of interest in Chapter 3 and Table 3.

Prosthetic socket craftsmanship. As stated in the Background section of this chapter and further described in Chapter 2, the fit of the prosthetic socket has direct bearing on the residual limb's condition. A poorly crafted socket may cause not only pain and discomfort for the amputee, but may also exacerbate forces and frictions exerted on the residual limb, leading to residual limb breakdown of skin and soft tissue (Ferguson & Smith, 1999). While not all prosthetists associated with the VHA may be licensed in their particular state of residence, all are certified by the American Board of Certification and thus are trained in the fit and manufacture of prosthetic sockets. (G. W. Bosker CPO, personal communication, January 2011). Therefore, this study assumes that all prosthetic sockets provided are fitted and crafted to the best of the ability of the prosthetist, but that the craftsmanship may vary between prosthetists on the basis of experience and/or skill;

that any ensuing residual limb problems are due to artificial limb configurations concurrent with medical comorbidities, and/or the patient's living conditions (independent or assisted, single or married), but not due specifically to poor craftsmanship of the socket.

Each VISN station represents multiple VHA facilities and/or prosthetists (the VHA also frequently contracts with prosthetists in the local economy) (G. W. Bosker CPO, personal communication, January 2011). The study tracked patients over a three-year period, during which time the patient may have moved, or the prosthetist supervising their artificial limb provision may have changed, even within a VISN. For the purposes of this study, it was assumed that the patients being followed and remaining within a particular VISN was treated by the same prosthetist and skill level.

A unique population. While the VHA national databases provide significant case numbers to support statistical power, characteristics of its patient population are unique and thus not necessarily generalizable to the non-military or general public

More specifically, the Veteran population seeking health care from the VHA is over 90% male, predominately of low socio-economic status, and of a racial mix that is not representative of the current United States population rates (Mayfield et al., 2000; Department of Veteran Affairs, 2010). For example, the 2010 U.S. Census reported the following statistics: 69.1% of the population reported being White, 12.1% reported being Black, 3.96% as Asian, 12.5% reported being Hispanic, 0.7% reported being American Indian/Alaskan Native, and 0.2% reported as being "other" (http://www.census.gov/popfinder/2010)/. In contrast, the Veterans Administration reported for 2009 a population that was 79.3% White, 11.3% Black, 1.3% Asian, 5.8% Hispanic, 0.8% American Indian/Alaskan Native, and 1.3%"other (Department of Veteran Affairs, 2010). Further, especially for the service-connected Veteran amputee, health care costs are significantly lower than those in the private sector, likely influencing the number of visits and/or severity of condition, as well as the configuration of the artificial limb provided. In fact, for individuals with service-connected medical conditions, there is a VHA directive that they receive "best practice" and "state-of-the-art" artificial limbs and prosthetic devices (DePalma et al., 2002, The Rehabilitation of Lower Limb Amputation Working Group, 2007). Such devices would likely be cost prohibitive for similar individuals in the non-military, general public.

The dysvascular amputee. As discussed in Chapter 2, acquired limb loss consequent of dysvascular complications is frequently characterized by issues not shared by limb loss from other etiologies. Most significant of these is a high one-year mortality rate and re-amputation of the same or contralateral limb. It is primarily for these two reasons that a decision was made that the cohort under study have undergone transtibial amputation during the same fiscal year. Relative to this decision however, one might argue that limitations of the study include: (a) all the artificial limb users will be inexperienced and thus more prone to complications (or not); (b) findings will not be necessarily generalizable to the proven successful long-term artificial limb users; and (c) the study population (dysvascular amputees) does not lend itself to activity levels that truly challenge the efficacy of some artificial limb configurations and thus may bias the results (for example, fewer residual limb problems because of less activity, not because of the artificial limb configuration).

A novel dataset. Another limitation of the study is related to the uncertain validity and reliability of the NPPD. A study that investigates the actual configuration of an artificial limb has yet to be reported or published, although a study of wheelchair type (lightweight, motorized, or standard) has, and suggests study feasibility (Hubbard et al., 2007). Nonetheless, a limitation of this study is its retrospective database study design as opposed to a prospective observational study. Given this methodology, it is not feasible to confirm artificial limb configurations, fully appreciate a cohort member's residual limb outcome, or measure the extent to which they actually utilized their artificial limb. As noted under "Assumptions," the medical codes being utilized are reflective only of a cohort member's actual condition. A CPT code describes the treatment, but not the actual problem; some skin wounds may not warrant an ICD-9-CM code, or a physician's selection of either code may be imprecise. None of the patient codes were validated with a chart review or abstraction, and were thus limited to database accuracy. Further, there is no standardized or universally agreed-upon patient outcome to associate with artificial limb use (a matter discussed further in Chapter 2), and thus the use of medical coding may be considered to be a limitation of the study because its value as an outcome measure of artificial limb usage is untested and speculative.

The scope of the study. This study was a descriptive analysis of a cohort of Veterans identified in the NPCD as having undergone a transtibial amputation between October 1, 2006 and September 30, 2007 (FY 2007). Utilizing this same database, the cohort was followed for three sequential years: FY 2007, FY 2008, FY 2009, and FY 2010. Given the seriousness of the comorbid dysvascular etiology underlying their amputations, some cohort members did not survive the observation period. Only mortality rates as ascertained from this database were calculated and thus did not include deaths outside VHA facilities, nor from other databases such as the Beneficiary Identification and Records Locator System (BIRLS) utilized to confirm a cohort member's death (Dominitz, Maynard, & Boyko, 2001)

Some cohort members may have been "lost" due to unaccounted death, before or after receiving their definitive artificial limb; or because further health care was sought outside the VHA system; or because use of the artificial limb was abandoned. This study did not address the lost cohort member beyond an accounting of relevant episodes such as residual limb problems (to include surgical revision), changes in artificial limb configurations, or discharge due to death during the three-year observation period.

The cohort was also tracked over the same time period through the NPPD in order to identify dates of artificial limb provision and component replacement. Although several other artificial limb components are necessary or may improve performance (for example, pylons and rotators), for the purposes of this study, the identification of prosthetic artificial limb components was limited to categories of prosthetic feet and socket suspension systems. For example, as discussed in Chapters 2 and 3, a single make and model of prosthetic foot may require several HCPCS codes but be representative of a particular category of prosthetic foot (such as a multiaxis foot or a dynamic response foot) (G. W. Bosker CPO, personal communication, January 2011)

The categories of prosthetic feet are relatively arbitrary and typically based on function, but also generally accepted by the prosthetics community. To simplify data analysis, this study endeavored to categorize artificial limb components into such accepted categories rather than examine individual makes and models of components, as to do so is beyond the scope of the study. Later studies may focus on other artificial limb components, or specific component makes and models. Additionally, it is beyond the scope of this study to ascertain whether or not a dispensed artificial limb is abandoned by the cohort member.

Finally, the follow-up period of three years was determined on the basis of data availability. As noted under “limitations,” the NPPD is a relatively new and not-yet validated database. In 2005 significant software upgrades were made to improve its reliability. A FY 2007 cohort was selected to allow for these database improvements, but subsequently limited the follow-up period. Nonetheless, literature suggests that the average durability for a transtibial artificial limb is 5 years, but the typical user’s accommodation period is six months to one year (Datta, Vaidya, & Alsindi, 1999; DePalma et al., 2002; TheRehabilitationofLowerLimbAmputationWorkingGroup, 2007).

It is not clear if a longer follow-up period would reveal more meaningful information, but this may be considered for future studies.

While a major thrust of this study was to develop a framework for a useable and meaningful amputee-artificial limb database derived from administrative health care records with standardized coding systems, the value of the epidemiological analysis used to “test” the derived database is not to be discounted. As revealed by multiple reports, few studies have used a systematic approach to assess artificial limb use outcomes, and even fewer have applied such an approach to residual limb skin problems (Bui et al., 2009; Collins et al., 2006; Meulenbelt, et al., 2006). As discussed previously, multiple factors have led to such a dearth of research, not the least of which has to do with the sheer complexity of artificial limb use, both in terms of mechanics of the artificial limb itself and the user’s state of health (mental and physical). Given such complexity and the dynamic interrelationships therein (especially in light of the biopsychosocial model), it was felt that an analysis of the user’s demographics, outcomes, and artificial limb used would not suffice or add any truly useful information to the existing body of knowledge. However, and by the same token, (that is, the complexity of the subject matter), a simple but robust analysis would provide more useable information than a more structurally complex approach (such as regression analysis), given the vagrancies and limitations of the data sources.

For these reasons, the epidemiological analysis of this study employed multivariate analysis modeling (via General Estimating Equations – GEE), was limited to only two components of an artificial limb (the prosthetic foot and the socket suspension system) in relation to a single binomial outcome (a medically coded residual limb skin condition categorized as “severe” or “less severe”) and potentially modulated by the behavior of the user as suggested by medically coded and diagnosed comorbid conditions to include depression, PTSD, or SUD. Despite these scope limitations, the findings from the epidemiological analysis successfully addressed some major issues to include: (a) information as to the viability of medical coding relative to artificial limb devices and patient conditions as a tool for future studies, (b) identify trends in artificial limb component dispensed to Veterans across VISNs that may prove useful for future VHA leadership Quality Assurance/Quality Improvement evaluations, and (c) perhaps more importantly, offer insight and add to the body of knowledge regarding the significance of comorbid conditions and mental health status toward the long-term successful use of a lower extremity artificial limb, especially in light of the artificial limb components used.

In conclusion, this study was intended only to lay the methodological and descriptive analysis foundation for future studies that may seek predictive relationships regarding artificial limb configuration and patient outcome. Such studies should, logically, lead to improved prescription and/or design and clinical guidelines, as well as provide support for the establishment of an amputee care surveillance system or registry.

Significance of the Study

While the purpose and methodology of this study is fairly simplistic, the driving factors behind the investigation are not.

Today's society of capitalism and marketing has influences that reach deep into the medical and health care industries. The field of prosthetics is not immune to these influences and is further not open to governmental control such as by the FDA Subsequently, marketing information is a prime source (if not the only source) for many practitioners and prosthetists, because objective, evidence-based outcomes are not easily accessible.

Marketing information provided for artificial limb components and prosthetic devices is typically not based on generalizable, objective, or long-term evidence-based measures of user outcomes, but rather on manufacturer design and selected study results. Further, manufacturers of such devices are faced with the high cost of development, materials, and production, coupled with a rather small niche market, and thus, they have minimal incentive/resources to conduct large scale, randomized, control trials, which are typically a source for objective, evidence-based information.

Unfortunately, unlike a pair of shoes, it is not a simple matter to exchange one artificial limb for another, nor does the typical artificial limb user have any prior experience, so most are dependent on the decisions and recommendations of their practitioner. Many times, those decisions and recommendations are based on ambiguous, if not biased, evidence, and the results thereof are borne by the patient in the form of further complications, health risks, and costs. Consequently, given an artificial limb, 25% of the intended users will ultimately choose to abandon it and, in the case of the lower extremity amputee, this means a significant loss of mobility, independence, and socialization, although many resort to using a wheelchair with its own set of barriers and issues (van der Linde et al., 2004). Clearly, in the field of prosthetic devices and components, evidence-based practice recommendations are needed that go beyond personal experience and anecdotal evidence.

Without objective outcome measures of artificial limb acceptance and usability, it is very difficult for practitioners to make the best possible decisions and recommendations for their patients. For example, an artificial limb design that will function well for a young active individual will likely be totally inappropriate for an older less active user, and vice versa. Marketing practices may not make such a differentiation, claiming instead that technological advances have led to the development of a more “life-like” limb, without the benefit of objective evidence to support its properties, limitations, or conditional considerations. A practitioner, then, may rightly or wrongly prescribe such an artificial limb on the basis of significantly biased information, patient persuasion, and the presumption that more advanced technology must be better, which is a logically seductive concept. Such a decision may put the patient at undue risk, and also may ultimately be considered fraudulent in regard to medical care costs and insurance coverage. In fact, more and more, insurance companies, including Medicare and Medicaid, are requiring objective evidence to support billing and payment practices (G. W. Bosker CPO, personal communication, January 2011). It is therefore hoped that the findings of the study will help the practitioner/prosthetist to overcome marketing influences and capitalistic tendencies in the prescription of prosthetic devices, by providing objective evidence of artificial limb component impact on residual limb outcomes for the lower extremity amputee.

This small step away from marketing and commercialism is one step toward social justice for a very vulnerable population, the amputee, and any move towards social justice is a move towards positive social change. Albeit small and incremental, this move toward social justice is relative to many, not just in regard to racial or gender disparity, but more towards that which governs disabled persons. Regardless of an individual’s so-called disability, it should be the goal of the healthcare and medical system to not merely diagnose and treat the individual, but to selflessly facilitate their community integration, good health, and any necessary lifestyle change—the same care that is expected by any able-bodied individual. Countering or supporting relative marketing information, through the acquisition, evaluation and/or dissemination of objective evidence-based outcomes—the basis of translational and comparative effectiveness research—is key to such facilitation.

More specifically and relative to lower extremity amputees, this move towards social justice will help to ensure that any individual receiving a prosthetic device that does not require FDA approval can be assured that the device will cause minimal subsequent harm, that any ensuing costs are minimal, that the device is appropriate for their condition, and that there is unbiased evidence to support such claims. To this end, it is hoped that this study will begin to lay the foundation for the development of a patient prosthetic high-quality clinical database through demonstration of its potential value.

While an administrative healthcare database (such as those to be used in this study) may be an imperfect tool for assessing patient outcome, it nonetheless is an eloquent tool for describing trends and patterns relative to patient care and diagnosis. Areas of more defined research may be identified, leading to more focused and efficacious human research or, as in the case of this study, better device design and manufacture. It is further hoped that the results from this study will inspire prosthetic manufacturers, prescribing practitioners, patients, and their prosthetists, to more carefully consider the appropriateness of an artificial limb component, rather than just considering its state-of-the-art status or its high-tech qualities

Summary

It is well understood that the primary purpose of an artificial limb is to restore function, but function should not be at the cost of pain and/or residual limb complications (DeLisa & Kerrigan, 1998). It is also understood that rarely is any one artificial limb component solely responsible for such complications, but rather it is one of several factors, to include the individual's demographics, their health status (physical and mental), socket fit/craftsmanship, and influences from other components (DePalma et al., 2002; Desmond & MacLachlan, 2002)

Nonetheless, this study is believed to be one of the first of its kind as it takes advantage of large case numbers in national databases maintained by the VHA (2,321 unique new major lower limb amputations in FY 2009; personal communication: L. Copeland, PhD February20, 2010) to examine patient outcomes relative to artificial limb devices, as well as focusing on long-term residual limb outcomes rather than more immediate artificial limb functionality, or subject/patient measures.

The ensuing chapters further articulate the need for such a study, characterize the cohort/population, and provide detail regarding the compilation of the integrated dataset and subsequent descriptive statistical analysis plan.

Chapter 2: Literature Review

Outline of the Chapter

This chapter will highlight the literature by providing background information about the key components of the research study: the amputee population, their artificial limbs, outcomes, and methods of research relative to the field of prosthetics and the amputees. As such, emphasis is placed on the epidemiology of the dysvascular lower limb amputee, artificial limb components suitable for a transtibial amputation, factors driving and contributing to the prescription thereof, and outcomes, both physical and psychosocial, faced by an individual utilizing a lower extremity artificial limb. Additionally, a brief discussion of the practices of evidence-based medicine (EBM) and its limitations in the realm of rehabilitation medicine (specifically prosthetics) is presented, leading to a discussion of alternative methodologies such as practice-based evidence (PBE) and healthcare database analysis specific to the VHA. In conclusion, the long term goals and objectives of this research study are presented as a means to define the relevance and importance of this research study, both medically/clinically and socially.

Review Strategy

Given the breadth and novelty of the study, literature searches were conducted topically, but with overlapping terms. An initial keyword search utilizing the Ovid search engine was conducted with the terms *artificial limb* or *prosthesis*, *prescription* or *guidelines*, *amputee* or *amputation*, limited to human studies, English text, and as of 1996 (to find the most relevant literature and current prosthetics), in an effort to ascertain what literature was available pertaining to artificial limb prescription guidelines. No articles were found in Medline and/or EBM Cochrane Reviews, so the search terms were modified to explore literature available on amputee outcomes, prosthetics research, and amputee databases, registries, or repositories. Of note, using the above designated limits, only one article was found for the keywords *amputee* and *outcomes*, and two (though not sufficiently relevant) for the terms *amputee* and *database* (none for *amputee* plus the term *registry* or *repository*). Further, on the matter of amputation epidemiology, the search terms *amputee*, *amputation*, *acquired limb loss*, *epidemiology*, and *statistics* were used in various combinations using both the Ovid and PubMed search engines and were limited to those articles with abstracts, English text, and published as of 1991. For topics related to psychological and/or social issues, databases were expanded to include PsychInfo, Social work abstracts, and Ovid HealthStar. Finally, references of relevant review articles, and original papers were also examined for additional titles of interest. Citations of articles published before 2005 were also searched for, in an effort to identify updated findings of relevant topics.

This strategy was repeated for the main topics of the proposal: the epidemiology of lower extremity amputation, dysvascular amputation (complications of PAD, PVD, and diabetes), artificial limbs for the transtibial amputee, risk factors and barriers following amputation, psychosocial issues for the amputee, evidence-based medicine practices and methods, healthcare administrative records in research, and VHA healthcare national databases. While many original papers and journal articles were reviewed or read for context and general background, only those original articles of particular topical relevance and specific to the United States population and health care system were selected as reference material for this study. Most articles were retrieved as full text from online sources.

Certain websites were accessed that provided direct information or served as portals to publications of interest. Websites of particular note include: Amputee Coalition of America–National Limb Loss Resource Center (http://www.amputee-coalition.org/nllic_about.html),VA Information Resource Center (http://www.virec.research.va.gov), National Center for Veterans Analysis and Statistics (http://www.va.gov/VETDATA/index.asp), Centers for Disease Control and Prevention (CDC)—Diabetes (http://www.cdc.gov/diabetes/statistics/complications_national.html), and National Institute of Diabetes and Digestive and Kidney Diseases (http://www2.niddk.nih.gov/).

The Etiology and Epidemiology of Dysvascular Limb Loss

Overview

Limb loss is indiscriminant of gender, age, race or socio-economic status, but it is frequently closely associated with lifestyle and disease patterns among disparate population groups (Dillingham et al., 2002). There are four primary etiologies of limb loss, of which cancer, traumatic accident, and dysvascular disease are the most common and are responsible for cases of "acquired limb loss" or true amputation (Limb Loss Resource Center, 2012). Such afflicted individuals describe the predominance of artificial limb users, particularly for the lower extremities. Limb loss due to congenital causes and birth defects are the least common and typically do not require amputation, but such persons are frequently practiced and uncomplicated users of artificial limbs (Limb Loss Resource Center, 2012).

Cancer is the third most frequent etiology for acquired lower limb loss, with a 2005 estimated prevalence of “13,000 persons or approximately 72% of all cancer-related amputations” (Ziegler-Graham et al., 2008). Of the various cancers, osteosarcoma is the most frequent cause for amputation. Whenever possible, the affected limb is salvaged such that only the cancerous bone and marginal tissue are removed, and may involve the replacement of a limb joint rather than limb amputation. Depending on the location of the tumor and level of amputation, use of an artificial limb is quite practical and successful (Bacci et al., 2003).

Limb loss due to trauma is the second most frequently occurring etiology and accounts for the predominance of upper extremity amputations (Limb Loss Resource Center, 2012). The 2005 prevalence estimate for major lower limb traumatic amputations was 106,000 or 15% of all trauma-related amputations estimated for that year (Ziegler-Graham et al., 2008). Traumatic amputations usually result directly from occupational hazards and motor vehicle or recreational accidents. Natural disasters, war, and terrorist attacks can also cause traumatic amputations and explain sudden increases or decreases in worldwide incident rates (DePalma et al., 2002). However, a “traumatic amputation” is not limited to the individual who suffers a severed limb consequent of the causes mentioned. Serious burns (chemical, radiation, fire, and so forth) are a contributing factor, as such patients are susceptible to compartment syndrome in which there is a significant interstitial tissue fluid imbalance. In such cases, the fluid imbalance leads to muscle necrosis that, when uncontrolled and substantial, may necessitate amputation over limb salvage (DePalma et al., 2002; Li, Liang, & Liu, 2002; Sandnes, Sobel, & Flum, 2004).

In the United States and most developed nations, amputation due to dysvascular diseases is the most common. More specifically, as derived from the National Health Interview Survey between 1988 and 1996, approximately 82% of all nonfederal hospital discharges for amputations annually were due to dysvascular disease complications, for example: critical limb ischemia due to peripheral arterial disease (PAD), peripheral vascular disease (PVD), complications of foot ulcers among persons with diabetes and PAD, and joint or bone infection (Centers for Disease Control and Prevention [CDC], 2006). In 2005, Ziegler-Graham et al., estimated that 504,000 persons were living with the loss of a major lower limb due to dysvascular disease complications (nearly five times that for traumatically acquired limb loss), accounting for nearly 60% of all lower limb amputations (Ziegler-Graham et al., 2008).

Generally speaking, incident rates for lower extremity amputations are nearly four times more common than upper extremity amputations, and diabetic/dysvascular amputations are at least twice as common as traumatic amputations (CDC, 2006;

Dillingham et al., 2002). Persons in the 65–74 year age group represent the largest group of new amputees (although individuals over the age of 75 are twice as likely to undergo amputation) and, across all age groups, men are 15% more likely to undergo an amputation than women (Dillingham et al., 2002a; Ephraim et al., 2003). While the predominance of persons living with limb loss may be White, the risk of amputation is three times greater among Black, and approximately 1.5 times more likely among Hispanics. Age, diabetes and heart disease, smoking, lack of exercise, and lack of proper nutrition are, as well as barriers to preventive and primary health care, postulated to be contributing risk factors for the loss of a limb and observed disparities (Dillingham, Pezzin, & Mackenzie, 2002b; Ephraim, Dillingham, Sector, Pezzin, & MacKenzie, 2003; Resnik & Borgia, 2004).

Acquired Limb Loss Due to Dysvascular Diseases

Amputation subsequent to peripheral vascular diseases (PVD) is a common occurrence among the more developed nations as well as being age-related and primarily of the lower extremities. While individuals with PVD or peripheral arterial disease (PAD) may also experience loss of foot sensation, more often the complaint is of limb pain and weakness (Steffen, Duprez, Boucher, Ershow, & Hirsch, 2008). Medication, vascular bypass surgery, and angioplasty/stents are the first line of treatment, but ultimately amputation is required to remove potentially gangrenous and painful extremities (Osterman, 1992; Steffen, et al.,2008). The primary explanation for high PVD rates revolves around a growing elderly population and the concordant rise in both diabetes and PAD. In fact, in 1996 there were an estimated 10 million persons living in the United States with a diagnosis of PAD (diabetes-related or otherwise), of which about 129,000 required in some level of amputation, equating to about one out of every 2,000 persons being an amputee (Criqui, 2001).

Of the dysvascular conditions, diabetes and diabetic complications account for the largest proportion of below-knee amputations, typically subsequent to foot ulceration and infection (Adler, Boyko, Ahroni, & Smith, 1999; Davis, Norman, Bruce, & Davis, 2006; Ephraim et al., 2003; Mayfield, Reiber, Maynard, Czerniecki, & Sangeorzan, 2004; Rayman, Krishnan, Baker, Wareham, & Rayman, 2004; Reiber, Lipsky, & Gibbons, 1998). In fact, by 2005 estimates, approximately 70% of persons with dysvascular-related acquired limb loss were also recorded as having comorbid diabetes, with this percentage reducing to approximately 60% by 2010 (CDC, 2014). Further, it is likely that nearly 85% of the estimated 359,000 major limb amputations among this population were preceded by a foot ulcer (CDC, 2011a; Ziegler-Graham, et al., 2008).

One of the complications of diabetes is neuropathy and, when in the presence of poor microvascularization, an individual is particularly prone to foot ulceration (CDC, 2011a; Reiber & Raugi, 2005). Individuals with this condition cannot feel pressure points or “hot spots” on their feet, and thus do not adjust their gait and foot fall patterns accordingly to protect the injured tissue. Without regular visual inspection of their feet, these pressure sores go undetected, tissue breaks down and ulcers form, providing an entrance for infection (Reiber & Raugi, 2005). The big toe, first and second metatarsal heads, fourth and fifth metatarsal heads, and heel (in order of frequency) are those regions of the foot most prone to ulceration (Adler et al., 1999; Izumi, Satterfield, Lee, & Harkless, 2006; Reiber et al., 1998). Typically, symptoms of peripheral neuropathy will manifest themselves within 10 to 20 years of diabetes onset—and even sooner, with uncontrolled glucose levels (CDC, 2011a; CDC, 2014). It is also estimated that approximately 25% of individuals with limb loss due to diabetes will undergo re-amputation, typically due to complications of the residual limb, or ulceration and infection of the intact, contralateral foot (CDC, 2011a; Davis, et al., 2006; Dillingham, et al., 2005; Izumi, et al., 2006).

For Blacks, the risk of dysvascular lower limb acquired limb loss is estimated to be 1.5 to 3.5 times that of non-Hispanic Whites, while for Hispanic Americans the risk is estimated to be 1.5 times greater than their White counterparts (CDC, 2011a). These variations in rates among racial and ethnic groups may be attributed, in part, to differences in the prevalence of underlying disease (for example, the prevalence of diabetes among Blacks is 1.8 times greater than that of Whites), but regardless, the incidence of diabetes-related amputation in men is two to three times greater than that in women, irrespective of age, race, ethnic origin, or nationality (CDC, 2011a; Dillingham, et al., 2002b).As such, the difference in limb loss rates between men and women is likely more a reflection of society behavior norms and expectations for men versus that of women, particularly in the realm of health and healthcare self-management (Ephraim et al., 2003; Jack, 2004; Tudiver & Talbot, 1999).

Limb Loss Current Trends and the Future

Typically, incidence and prevalence rates offered regarding limb loss or amputation are derived from multiple sources, the most commonly used being hospital discharge records, results of the National Health Interview Survey (NHIS), or the Health Care Utilization Project National Inpatient Sample (HCUP-NIS). However, as of 1996, national estimates of persons living with limb loss (acquired or otherwise) became increasingly difficult to acquire due to the discontinuation of “triggering” and relevant questions in the NHIS (Ziegler-Graham et al., 2008). Given no other national monitoring or surveillance system for limb loss, and in an effort to provide more current relevant statistics, Ziegler and colleagues (2009) calculated limb loss estimates for 2005 with projections for 2050 (Ziegler-Graham et al., 2008).

Rate estimates were based on historical patterns of age-specific and sex-specific limb loss incidence rates, mortality, and relative risk rates by race and ethnicity, as well as incidence patterns of underlying disease etiologies of limb loss (for example: PAD, cancer, diabetes and diabetes complications, and so forth). Utilizing census data, non-federal hospital discharge records, and established algorithms, the authors constructed estimates of limb loss prevalence by age, race, gender, and limb loss, anatomical level, and etiology (see Table 1 for examples of their findings). However, the derived estimates do not include VHA amputation records, reported to account for nearly 10% of all amputation-related discharges in a given year, nor do they include amputations resulting from armed conflicts or any other cause for which military personnel were treated in a military hospital (Dillingham et al., 2002b; Ziegler-Graham et al., 2008).

Despite an obvious under-counting of cases, the 2005 estimated prevalence for acquired limb loss amounted to 1.6 million persons, an increase of 10% from the 1996 estimate of 1.3 million (Ziegler-Graham et al., 2008). These estimates represent all levels and most causes of acquired limb loss from fingers and toes to upper and lower major limb amputations, due to cancer, dysvascular disease, diabetic complications, and non-combat trauma. Further, for 2005, Ziegler-Graham estimated that 33% were amputations of the major lower limbs, 42% were over the age of 65 years, 65% were men, and 42% were non-White. Given present and projected population trends, the authors further estimated that by 2050, the prevalence rate would double to over 3.6 million persons, be proportionally more Hispanic, and would be driven by an aging population, extended life expectancies, and associated age and ethnic dysvascular disease/diabetic patterns.

Given such projections, policies are obviously needed that provide for effective access to artificial limbs, assistive devices, and appropriate health and prosthetic services.

Table 1

Past and Predicted Prevalence Rates of Persons Living with Limb Loss

Etiology	1996	2005	2020	2050
All etiologies	1,286,000	1,568,000	2,213,000	3,627,000
Traumatic	Unavailable	704,000[a]	906,000	1,326,000
Cancer	Unavailable	18,000[a]	22,000	29,000
Dysvascular (PAD & diabetes)	Unavailable	846,000[a]	1,285,000	2,272,000
Dysvascular (diabetes only)	Unavailable	592,000[a]	899,000	1,667,000

Note. From "Estimating the prevalence of limb loss in the United States: 2005 to 2050," by Ziegler-Graham, K., MacKenzie, E. J., Ephraim, P. L., Travison, T. G., & Brookmeyer, R, 2008, Archives of Physical Medicine and Rehabilitation, 89(3), p. 425. Copyright © 2008 American Congress of Rehabilitation Medicine and the American Academy of Physical Medicine and Rehabilitation Published by Elsevier Inc. Reprinted with permission.
2005 prevalence estimates of persons living with the loss of a lower limb [by etiology: dysvascular (PAD & diabetes)—504,000; dysvascular (diabetes only—359,000; trauma—106,000; cancer—13,000.]

Living with Limb Loss

Limb loss for any individual is not a simple matter. It is physically and mentally and even socially challenging, regardless of one's age, gender or ethnicity. The loss of even a single toe may affect one's balance; the loss of a finger may be socially unsettling. The loss of a major limb has profound effects including one's ability to work or to maintain a job, to care for oneself or another, to pursue recreational interests, and to maintain a good quality of life (Coffey, Gallagher, Horgan, Desmond, & MacLachlan, 2009; Gallagher, 2004). The loss of a major lower limb inhibits one's mobility and is often characterized with long-term pain from phantom limb sensations, osteoarthritis of overused or stressed joints, chronic low back pain, and the risk of re-amputation

(Desmond et al., 2008; Dudek et al., 2005; Ephraim, MacKenzie, Wegener, Dillingham, & Pezzin, 2006; Flood et al., 2006; Gallagher, 2004; Legro et al., 1999).

While an artificial limb provides the promise of a return to a previous lifestyle, it is nothing like a “real” leg or arm. All artificial limbs are biomechanically inefficient compared to one’s own natural limb, to the point that many amputees, frustrated with these inefficiencies and complications, will choose to forgo its use. It is estimated that nearly 25% of major lower limb amputees will forgo their artificial limb in lieu of crutches or a wheelchair (Legro et al., 1999). In fact, even the competitive athlete, especially the above-knee amputee, will compete with an artificial limb, but often will use a wheelchair otherwise (Karmarkar et al., 2009). The common explanations for such behavior are: physical demands required to ambulate, environmental barriers, overall comfort, and even social acceptance Karmarkar et al., 2009). It has been suggested that since the passage of the Americans with Disabilities Act, wheelchairs have gained significant social acceptance, perhaps more so than artificial limbs (Hubbard et al., 2007).

It could be argued, however, that the continuing physical and social barriers faced by many individuals with acquired limb loss, are not due to a lack of interest or effort on the part of the artificial limb component manufacturers, but that the cost of such components is in itself a barrier. In fact, in the United Kingdom, a study revealed such to be the case, although the UK does not use a system of classification like that of Medicare in the US (Sansam, O'Connor, Neumann, & Bhakta, 2014). Nonetheless, based on Medicare billing codes and reimbursements, an artificial limb is surprisingly expensive, ranging from approximately $600 for the simplest and least sophisticated below-knee artificial limb, to nearly $10,000 for the most technically sophisticated version configured with state-of-the-art components (G. W. Bosker CPO, personal communication, January 2011). Further, over the past decade, significant advances in artificial limb technology and materials have led to a vast array of components and some fairly profitable manufacturers and marketers (for example, Otto Bock Health Care USA, one of the more prominent prosthetics manufacturers) (http://www.ottobock.com/cps/rde/xchg/ob_us_en/hs.xsl/12952.html).

Some of this growth is driven by the increase in numbers of traumatic amputees consequent of the Middle East—United States war tactics, and the Department of Defense efforts to return such Wounded Warriors to their pre—injury status with the option of remaining on active duty (Bilmes, 2007). Given, in part, such a demand for heightened and accelerated artificial limb engineering, current state-of-the-art prosthetic technology is approximately six times more expensive than prosthetic technology used in 2000 (Bilmes, 2007; Kerkovich, 2004).

While it seems that “providing the best for our war Veterans” has been a driving force behind new artificial limb technology and even, perhaps, greater social acceptance, there is, in addition, a rising prevalence of limb loss due to dysvascular complications (Downs, 2000; Ziegler-Graham et al., 2008; CDC, 2011a).

Ethically, every individual who loses a major limb should have at least the option of a “state-of-the-art” artificial limb. However, not only is this cost prohibitive, but also there are no prescription guidelines based on evidence-based medicine to help practitioners and patients ascertain which device will serve that individual best. Instead, marketing information, anecdotal evidence, insurance company directives, and expert or experiential knowledge provide the basis for these decisions and, by their nature, the decisions are biased, if not unfounded. Nonetheless, considerable research is ongoing regarding the benefits of these latest devices, the associated biomechanics, and even patient satisfaction. Typically, though, such research does not lend itself to the standards of evidence-based medicine, due to the small sample size and moderate design, nor is there a measureable, reliable and consensual outcome measure in the field. However, one outcome remains constant: if the artificial limb causes pain and/or is uncomfortable or difficult to use, the amputee will not use it. And, if the residual limb that interfaces with the artificial limb is compromised, the amputee will likely not be able to utilize the artificial limb temporarily or even permanently. Particularly in the case of the dysvascular amputee, a compromised residual limb may even be life threatening.

The Dysvascular Lower Limb Amputee

Surgery—limb salvage or amputation? Peripheral arterial disease (PAD) is the primary etiology for dysvascular limb loss and is a significant characteristic of diabetes. While not every individual diagnosed with PAD will also have diabetes, with or without a comorbid diagnosis of diabetes, PAD is initially treated with diet, exercise and medication (Steffen et al., 2008). As lipid deposits build and blockage of the peripheral vascular system continues, neuropathy may set in, as well as poor healing of tissue. Foot ulcers may develop providing a portal for infection, or the blockage of main vessels may engender tissue necrosis or gangrene (Jude, Oyibo, Chalmers, & Boulton, 2001; Steffenet al, 2008).

Typically, prior to such grave conditions, the vascular surgeons may perform angioplasty, vessel by-pass surgeries, or even place stents in the major arteries of the lower limb to improve circulation and prevent necrosis or gangrene. It is not uncommon for individuals with severe PAD to undergo multiple by-pass or stent surgery in an effort to maintain and control critical limb ischemia (Steffen et al, 2008). However, at some point, the resting pain may become so intense or the threat of sepsis or gangrene so great as to necessitate amputation (Steffen et al., 2008). Upon making such a decision, the surgeon will perform the amputation at a point just above the evidence of good healthy tissue and blood flow, at the same time attempting to maintain as long a residual limb as possible (DePalma et al., 2002). The simple consideration as to whether or not the patient has potential as an artificial limb user will also dictate the course of a surgery: how best to secure muscle flaps, the shape of the residual limb so as to best fit an artificial limb, how much fat padding to leave at the distal end of the residual limb—considerations that influence the fit and comfort of an artificial limb (Butler et al., 2014; DePalma et al., 2002; Hakimi, 2009; Pinzur, Gottschalk, Pinto, & Smith, 2008; Randon, Deroose, & Vermassen, 2003).

Surgery outcome is varied given the complexity of the underlying disease for the dysvascular patient. Amputation as a consequence of diabetes is typically indicative of prolonged disease and/or poor glycemic control (CDC, 2011a; CDC, 2014b). PAD is of course closely associated with other vascular problems such as heart disease, hypertension and renal failure (Criqui, 2001). Both are complicated by poor circulation and wound healing such that recovery from surgery and inpatient stays may be anywhere from weeks to months (Jude et al., 2001. Given the fragility of many such patients, mortality rates are high and, for many, discharge is due to death (Criqui, 2001; Jude et al., 2001; DePalma et al., 2002).

Mortality. Mortality due to amputation is very rare, but rather indicative of the severity of an underlying disease, especially diabetes. Further, mortality rates among such populations are typically presented as 30-day or one-year mortality rates, and reports vary due to a lack of national measures regarding limb loss. Hence many rates reflect single hospital sites and small samples that may be biased by surgeon preference or even hospital care accessibility.

In any case, persons who undergo amputation due to diabetic complications tend to be younger, and subsequently die younger, than their non-traumatic dysvascular counterparts (Dillingham et al., 2002a). For the dysvascular amputee, survival outcomes tend to worsen with advancing age, proximal amputation level, renal disease, and cardiovascular, cerebrovascular, and peripheral vascular disease (Aulivola et al., 2004; Mayfield et al., 2004; Roberts et al., 2006). Among the non-traumatic dysvascular amputees, 30-day mortality rates for the transtibial amputee range from 5.6% for patients in a tertiary hospital and academic medical center (Aulivola et al., 2004), to 7.0% among a cohort of Veterans as of 1998 (Mayfield et al., 2000), to as high as just over 12% in a study conducted by Cruz and colleagues (2003) among a population of Veterans with below-knee amputation of unspecified etiology (Cruz, Eidt, Capps, Kirtley, & Moursi, 2003). Heart problems, wound infection, and pneumonia were the most frequent complications associated with 30-day mortality rates, whereas one-year and five-year survival rates were significantly influenced by the presence of diabetes and/or end-stage renal disease, reducing survival rates by 20% to 50% at five years post-surgery (Aulivola et al., 2004; Feinglass et al., 2001; Mayfield et al., 2001).

Rehabilitation—from the temporary to the definitive artificial limb. If the patient's overall health condition will allow, the goal is to get the patient up and standing with a temporary artificial limb as soon as possible. To do so speeds up the process of "shaping" the residual limb to best accommodate an artificial limb, to build the patient's balance confidence, and to begin accepting and accommodating to the pressure from the artificial limb (Payne & Marks, 2003). For example, a psychologist may work with the patient prior to surgery to deal with present and future depression. Physical therapy even before receiving a temporary artificial limb will work to strengthen the intact limb and to encourage stretching of hip muscles and knee joints to prevent contractures (Rehabilitation of Lower Limb Amputation Working Group, 2007). Compression hose are placed on the residual limb to prevent excessive swelling and again to help "shape" it (Nawijn, van der Linde, Emmelot, & Hofstad, 2005; Smith, McFarland, Sangeorzan, Reiber, & Czerniecki, 2003; The Rehabilitation of Lower Limb Amputation Working

Group, 2007). As soon as healing of the wound permits, the patient destined to receive an artificial limb is fitted with a “temporary” artificial limb. The components of the temporary limb may be the same as what will configure the definitive limb, or it may be comprised of components equal to the patient’s current stage of rehabilitation (The Rehabilitation of Lower Limb Amputation Working Group, 2007).

During this period of adaptation, the residual limb undergoes considerable and notable changes: swelling, then shrinking in size, as the wound continues to heal and mature; some muscles atrophy as others develop; and tissues shift internally in response to external pressures. All this creates a shape to the residual limb that will ultimately dictate the design and fit of the definitive artificial limb socket (Butler et al., 2014; DePalma et al., 2002; Smith, et al., 2003). Typically, a patient is transitioned from the temporary to definitive artificial limb when the wound is mature, and these changes in the residual limb have stabilized, a process that may take anywhere from three months to a year (DePalma et al., 2002). For some, the definitive artificial limb may be only for cosmetic purposes, may serve only to assist in transitions (that is, from sitting to standing, but not really for walking), may be suitable and safe only for maneuvering in the household, or may be an artificial limb that can accommodate varied terrains and impact forces such as those generated during sport activities. These outcomes, however, depend on multiple factors, to include the health status of the individual, level of insurance coverage, their physician’s and prosthetist’s perceived capabilities, and, of course, the patient’s personal goals and beliefs (Abrahamson, Skinner, Effeney, & Wilson, 1985; DePalma et al., 2002; Sansam, O'Connor, Neumann, & Bhakt, 2014; aUustal, 2009).

Patient and practitioner goals. Key to the successful artificial limb prescription is the evaluation of the amputee: the amputee’s needs, goals, functional ability (both cognitive and motor), health status, and living conditions upon discharge (DePalma et al., 2002; Desmond & MacLachlan, 2002; Nelson et al., 2006; Sansom et al., 2014). In most cases such an evaluation is accomplished with a team approach, the team being comprised of a physiatrist, the surgeon, a social worker, psychologist, physical therapist, and the prosthetist (DePalma, et al., 2002; The Rehabilitation of Lower Limb Amputation Working Group, 2007; Sansom et al., 2014). Further, the psychological component of the amputee’s recovery is complex. It involves changes in body-image, self-esteem, cultural and religious belief systems, grief, fear, and the prospect of both minor and major lifestyle change (Desmond & MacLachlan, 2002; Flood et al., 2006). In the end, the best the patient’s team can hope to accomplish is to prepare and set up the patient for success rather than failure. This is one of the key reasons why “prescription guidelines” are so important, for while it is true that each patient is an individual case and requires a level of customization, artificial limb prescription guidelines would go far to focus the field and help practitioners distinguish what is a realistic from an unrealistic goal, without ignoring or denying the patient’s input (Sansom et al., 2014).

Functional levels and other concerns. The perceived and measured functional level of the amputee is key to artificial limb prescription. Their functional level at the time of amputation helps determine their course of rehabilitation with and without an artificial limb (Cumming, Barr, & Howe, 2006; DePalma et al, 2002; The Rehabilitation of Lower Limb Amputation Working Group, 2007). It also provides a measureable guideline for artificial limb configuration prescription (Nelson, et al, 2006; The Rehabilitation of Lower Limb Amputation Working Group, 2007; van der Linde et al., 2004).

In general, functional levels are dependent upon several factors, among them the overall physical condition of the amputee. The functionality the amputee will have following surgery is dependent on the level of amputation; other orthopedic, cardiovascular, respiratory conditions; and vascular problems (particularly PVD); as well as any sensory loss or neurological issues (DePalma et al., 2002; Nelson, et al, 2006; Cruz al., 2003). Moreover, an amputee's functional level or potential thereof is not limited to their physical condition. Also involved are aspects of their emotional and cognitive abilities (an understanding of their situation), as well as their activity level, degree of motivation, vocation, age, and the presence, or lack thereof, of a support system made up of family and friends (Cumming et al., 2006; DePalma et al., 2002; Desmond & MacLachlan, 2002; Livneh et al., 1999).

There are five functional levels (K0–K4) that are used to establish a functional level for the amputee:

> K0–The amputee does not have the ability or potential to ambulate or transfer safely without assistance, and an artificial limb does not enhance their quality of life or mobility;
>
> K1–The amputee does not have the potential for ambulation, but may benefit from an artificial limb to assist in transitions and transfers with minimal to no assistance;
>
> K2–The amputee has the ability or potential to be an independent household ambulator, able to walk short distances over level terrain and in limited community environments;
>
> K3–The amputee has the ability or potential to be an independent ambulator, able to walk longer distances over un-level terrain (curbs, outdoor terrains, hills, and so forth) and at more than one cadence;
>
> K4–The amputee has the ability or potential for ambulation with an artificial limb that exceeds the basic ambulation skills, exhibiting high impact, stressor energy levels, typical of the demands of active adults, or athletes (DePalma et al., 2002).

Many private insurance companies base their determinations of what artificial limb component they will provide coverage for on the patient's assessed functional level (Cigna Health Care, 2010). Typically, the functional level of the patient is determined by their physician, physical therapist, or kinesiotherapist, and the prosthetist (DePalma, 2002; The Rehabilitation of Lower Limb Amputation Working Group, 2007; Uustal, 2009).

Artificial Limb Prescription

As indicated previously, each member of the patient's medical team may contribute to the patient's artificial limb prescription, particularly in terms of whether or not the patient is a good candidate for such a device, and in determining the patient's previous, present, and potential functional level. For the dysvascular major lower limb amputee, a surprising number will not benefit from an artificial limb, at least not at the K3–K4 level. Nearly 60% of such individuals will not progress beyond the K2 level and a fairly rudimentary artificial limb, primarily because of the complications associated with their underlying disease (Smith et al., 2003; Uustal, 2009). Ambulation with an artificial limb takes considerable stamina, strength, and motivation. An individual whose PAD has progressed to the point of limb amputation is typically aged, with cardiovascular problems that will not support physical exertion (Criqui, 2001; Uustal, 2009). For the individual with diabetes, many are dealing with similar problems as well as renal complications and vision loss (diabetic retinopathy) (CDC, 2004). However, for the remaining 40%, especially those of a younger age and reasonable glycemic control, an artificial limb may prove truly beneficial by helping them to maintain an exercise level necessary for the continued control of diabetes (Chitragari, Mahler, Sumpio, Blume, & Sumpio, 2014).

For the dysvascular transtibial amputee, while the tissue at the point of amputation may be healthy, the natural progression of the disease will ultimately compromise the vascular health of the residual limb. Thus, a key aspect of the artificial limb prescription should perhaps revolve around not only comfort and mobility for the amputee, but also protection of the residual limb.

The importance of a good socket fit. A well-fitted, well-crafted prosthetic socket is essential as it is this part of the artificial limb that forms the interface between the mechanical aspects of the artificial limb with the human residual limb (Fergason & Smith, 1999). In this capacity, the socket fit is responsible for minimizing undue biomechanical forces, providing necessary support and protection of the residual limb, as well as providing a means to connect the artificial limb's mechanical parts to the living residual limb (Butler et al., 2014; (Chitragari et al., 2014; Ferguson & Smith, 1999; Rogers et al., 2007). A poorly-fitted socket, no matter how good the remaining artificial limb components may be, will likely lead to patient discomfort, skin irritation of the residual limb from friction, undue swelling from circulation constriction, and additional physical effort to maintain balance or to ambulate (Butler et al., 2014; Fergason & Smith, 1999; Sewell et al., 2000).

The socket is typically handcrafted by the prosthetist, and is the one component of the entire artificial limb that, because of its customized fit to an individual's residual limb, cannot be mass produced. Even though computer aided design/computer aided manufacture (CAD-CAM) techniques are used as a means to improve fit, standardize materials and methods, and ultimately reduce cost and production time, this manner of socket manufacture has only very recently been embraced by the field with the advent of 3D printers, and the resultant socket is still dependent on the expertise and skill of the prosthetist (Fergason & Smith, 1999; Sewell et al., 2000; Rogers et al., 2007; G. W. Bosker CPO, personal communication, March 2016).

The socket is typically made of a hard carbon fiber or plastic material with a smooth exterior and internal topography to accommodate bony structures of the residual limb, particularly the knee (Chitragari et al., 2014; Ferguson & Smith, 1999; Sewell et al., 2000; G. W. Bosker CPO, personal communication, January 2011). There are three primary designs: the patella tendon bearing socket (with or without a liner); the patellar tendon bearing supracondylar; and the total surface bearing socket (Chitragari et al., 2014; DePalma et al., 2002; Ferguson & Smith, 1999). The decision regarding which socket type to employ is typically dependent on the shape and condition of the residual limb, the potential functionality of the artificial limb (for transfers only or for high impact activity), the cost and insurance coverage, and the suspension system to be utilized (DePalma et al., 2002; Fergason & Smith, 1999; Sewell et al., 2000).

The socket suspension system. There are three main types of socket suspension systems: differential pressure system (suction/vacuum assist systems), anatomical suspension system, and cuff suspension (DePalma et al., 2002). The suction and vacuum assist systems tend to be preferred by the more active amputee as they fit closely to the residual limb and hence provide the best control of the artificial limb (Chitragari et al., 2014; G. W. Bosker CPO, personal communication, January 2011).

Differential pressure suspension systems are quite popular. For example, in those cases where the residual limb is prone to swell and shrink during the day or where additional padding is needed for comfort, the amputee may use a pellite, silicon, urethane, or mineral gel liner over their residual limb. The liner has a small pin-locking mechanism near its base that fits into the socket. The locking mechanism serves to ensure a connection with the socket during periods when the fit is not quite as air-tight (Chitragari et al., 2014; DePalma et al., 2002). It should be noted that a residual limb for the transtibial amputee may change in girth up to 15% throughout the day, depending on the level of activity (Nawijn et al., 2005). Also, scars or bumps on the residual limb may prevent perfect airtightness within the socket, which is a primary reason to use a liner that will shape itself to fill the gaps between the residual limb and socket wall, while providing cushioning over bony areas (Chitragari et al., 2014; G. W. Bosker CPO, personal communication, January 2011).

Another popular differential pressure suspension system is the vacuum assisted suspension system or VASS. The VASS incorporates a small pump in the pylon of the artificial limb that assists in maintaining the temporary vacuum, actually creating a negative pressure that more or less pulls the residual limb into the socket (Klute et al., 2011).

While these “differential pressure” suspension systems are very popular, they are also the most expensive types and are not suitable for all amputees. They require a certain level of understanding of their operation so as to detect when they are not working properly. Also, if not properly donned, they can cause significant harm to an already compromised residual limb of the dysvascular amputee (Chitragari et al., 2014; DePalma et al., 2002; Laferrier & Gailey, 2010; Meulenbelt et al., 2007).

The anatomical suspension systems are achieved through the contouring of the inside of the socket wall to fit over bony protuberances (femoral epicondyles) of the amputee’s residual limb. It is especially effective for those persons with short residual limbs and those that require a little more medial-lateral stability of the knee (transtibial amputations only) (DePalma et al., 2002). Another variation includes shaping of the inside socket wall over the patella. In either case, the socket veritably hangs in position and provides a modicum of increased stability, but at the cost of greater flexibility. Nonetheless, this system is less expensive than the differential pressure system and is suitable for the K2-K3 ambulator (DePalma et al., 2002; Laferrier & Gailey, 2010).

The third form of socket suspension is basically a cuff or strap that can be wrapped around the limb above the socket and then attached to a waist belt. It is the most inexpensive system and the least complicated, and able to accommodate significant volume changes of the residual limb (DePalma et al., 2002). Unfortunately, it is also associated with pistoning of the residual limb within the socket, which can lead to skin irritation and blistering. However, because of its simplistic design, it is often prescribed for the household ambulator (functional level K2) or when an artificial limb is used primarily for transitions from sit to stand and stand to sit (DePalma et al., 2002; van der Linde et al., 2004). Because such individuals do not typically walk for long periods, pistoning is kept to a minimum and the harmful potentials of this type suspension system are kept in check.

The prosthetic foot. There are five main types of prosthetic feet: solid ankle cushion heel (SACH), single axis, multi-axis, dynamic response, and hybrid dynamic response/multi-axis feet (DePalma et al., 2002; Versluys et al., 2009). The purpose of the various designs and types of prosthetic foot are to perform human-like functions with inanimate materials. When the foot does not act properly or animatedly enough, the rest of the body must compensate to remain balanced. It is this compensation that creates the undue biomechanical forces to act on the residual limb through the limb-socket interface (Chitragari et al., 2014; DeLisa & Kerrigan, 1998; Soares, Yamaguti, Mochizuki, Amadio, & Serrao, 2009; Versluys et al., 2009).

SACH feet were developed in the 1950s and remain the simplest design, the least expensive, relatively lightweight, and the most reliable feet that are clinically accepted. There are no moving parts, which makes the foot very durable and suitable for the individual limited to walking. It is comprised of a cushioned heel to absorb forces at heel strike, a webbed keel for stability during stance, and a molded sole for “roll over,” as the person’s weight shifts from the heel to the toe in preparation for swinging the leg forward (Chitragari et al., 2014; Versluys et al., 2009).

Single axis prosthetic feet are those that allow for rapid foot flat at heel strike (unlike the SACH foot) and thus provide greater stability, especially for the individual who has an unstable artificial limb such as those using cuff and belt suspension (DePalma et al., 2002; Versluys et al., 2009). They also allow the foot to accommodate uneven terrain, but only in one direction (anterior/posterior). Unfortunately, the foot is relatively heavy, less durable, noisy (because of moving parts), and also more costly than the SACH foot (DePalma et al., 2002).

The multi-axial foot adds an additional axis of motion (inversion/eversion) and thus makes it more suitable for varied terrain than the single-axis foot. This particular type of foot may have the multi-axis feature built in or an actual multi-axis ankle built onto the foot, such as a SACH foot (a SACH foot with a multi-axis ankle then becomes, and is billed as, a multi-axial foot) (Hofstad, Linde, Limbeck, & Postema, 2004). The multi-axial foot is typically prescribed for the K2 or above ambulator, but is more costly, heavier, and requires accommodation and training for safe use (Chitragari et al., 2014; DePalma et al., 2002).

Dynamic response/energy storing feet have a plastic spring keel that provides a “dynamic responsiveness,” giving a more life-like feel during stance and push-off (Versluys et al., 2009). There are numerous dynamic response feet, all having a variation on the material, placement, and responsiveness of the keel (Hafner, Sanders, Czerniecki, & Fergason, 2002). More responsiveness usually equates to more potential energy release, making it easier to move the foot and artificial limb. These types of feet are suitable for the more aggressive ambulator (K3–K4), including runners, but are typically expensive, and require an accommodation (getting accustomed to it) for the user (DePalma et al., 2002).

The hybrid multi-axis-dynamic response foot combines the best features of both types and is considered, as of 2009, to be state of the art. They come the closest in function to replacing the anatomical foot and often incorporate materials and designs, to include microprocessors, to mediate their functional capacity (Chitragari et al., 2014; Versluys et al., 2009). As such, they are most suitable for the high-functioning amputee, but even so, require an accommodation period. They are also typically the most expensive of prosthetic feet and require the most maintenance (DePalma et al., 2002).

Putting the parts together. While the surgeon and physiatrist may devise the artificial limb prescription, it is the Prosthetist who actually builds the artificial limb and consequently is frequently relied upon to assist in, if not define the specifics of that prescription (G. W. Bosker CPO, personal communication, January 2011). An artificial limb is not something that is ordered from a catalogue the way a pair of shoes are. Rather, components are assembled that, in combination, will most effectively meet the needs of the user.

A typical lower limb prosthesis is comprised (from the bottom up) of a prosthetic foot (with or without multi-axis functions), the pylon, prosthetic socket, suspension system, and cosmetic features. Given a well-constructed socket, the remainder of the artificial limb components are bolted together and attached to the base of the socket. The amputee then dons the artificial limb, stands, and takes a few steps to test the alignment and the position of the foot relative to the socket. While the manufacturer will suggest starting alignment positions, it is through the trained eye of the prosthetist and feedback from the amputee that a good alignment is achieved (G. W. Bosker CPO, personal communication, January 2011). A good alignment is essential to promote the most efficient gait possible for the amputee, and to minimize undue biomechanical forces on the residual limb (Butler, et al., 2014; DePalma et al., 2002; Soares et al., 2009).

All these components, except for the socket, are produced by competitive prosthetic manufacturers such as Ohio Willowood, Hanger, and Otto Bock, who subsequently provide extensive marketing influences on the prosthetists, physicians, and amputees (G. W. Bosker CPO, personal communication, January 2011). As stated on the FDA website “Medical Device Exemptions 510(k) and Good Manufacturing Practices (GMP) Requirements,” “Part 890 – Physical Medicine Devices”.

External limb prosthetic component; external limb orthotic component; and external assembled lower limb prosthesis are exempt from FDA approval and GMP requirements, including premarket approval. Only general recordkeeping and compliance files are required. (U.S. Food and Drug Administration [FDA], 2012).

Subsequently, components are typically “bench-tested” by the manufacturer but no randomized clinical trials are conducted, although biased trials occur as companies “test” their products on core volunteers (G. W. Bosker CPO, personal communication, January 2011).

Life with a Transtibial Artificial Limb

Typically, it takes six months to a year for an amputee to feel fully confident while using their artificial limb (G. W. Bosker CPO, personal communication, January 2011). "Balance confidence" is a driving factor and lack of it can impede success, even if the amputee has never fallen (Miller, Deathe, Speechley, & Koval, 2001). One of the unspoken aspects of normal gait is its "automaticity:" the sense that it just happens, with minimal thought or concentration. In a study by Gauthier-Gagnon, Grise, & Potvin (1999) where a five-year follow-up survey using the Prosthetic Profile of the Amputee was used for a study of nearly 400 transtibial and transfemoral amputees, the loss of automaticity of gait was a significant factor contributing to their use or disuse of their artificial limb (Gauthier-Gagnon, Grise, & Potvin, 1999). Unfortunately, balance confidence and automaticity of gait are not always achieved, even after years of ambulation with an artificial limb and, as previously mentioned, are often a consequence of poor artificial limb alignment or prescription (Butler et al, 2014; van der Linde et al., 2004).

Many barriers, both social and physical, exist for even the successful amputee with an artificial limb. Physically, the use of a lower extremity artificial limb demands considerable additional energy as well as coordination. The inefficiencies of the artificial limb require gait and balance compensations that frequently put unnatural forces and torques on other body segments, the negotiation of ramps and stairs become more complicated and fatiguing, and even walking over uneven terrain will significantly challenge an already compromised balance system (Soares et al., 2009).

Psychosocial factors and their implications. Many factors contribute to the successful use of an artificial limb, not the least of which is the emotional/psychological status of the user, a matter that is closely interwoven with the physical adaptations required. A component of rehabilitation for the new amputee involves not just the attainment of independence in activity, but also socialization, because that is key to overall health and well-being. In fact, prior to and immediately following surgery, the patient undergoes psychological evaluation and treatment for depression (Singh et al., 2009). Also, during the rehabilitation process and training in the use of an artificial limb, occupational, physical and social work therapies are incorporated into the program (The Rehabilitation of Lower Limb Amputation Working Group, 2007; Zidarov et al., 2009b).

Emotionally, not only must the amputee contend with the depression and grieving process associated with losing a major limb but, in concert with such, they are also faced with adapting to a new body image (with and without an artificial limb) as well as a potentially new way of life. They may need to consider changes in their choice or status of employment, level of independence, and an increased awareness or monitoring of their overall health (Boutoille et al., 2008; Desmond & MacLachlan, 2002; Gallagher, 2004; Uustal, 2009). Further, attitudes about living with an artificial limb will vary from person to person. Given the same conditions and artificial limb, one individual may view having an artificial limb as an asset, a means to perform certain physical tasks and social roles, while another may consider the artificial limb inhibitory, an inability to perform certain physical functions and social roles (Desmond & MacLachlan, 2002). It is not uncommon for persons having difficulty making such adjustments to report bouts of depression, feelings of hopelessness, grief, low self-esteem, fatigue, anxiety, and sometimes suicidal ideation (Williams et al., 2011; Roberts et al., 2006). Further, the individual's coping strategies (such as avoidance behavior, denial, problem-solving skills) seem to be at the heart of their ability to adapt to the loss of a limb and acceptance of an artificial limb (Coffey et al., 2009). Maladaptive coping behaviors (such as drug/alcohol consumption), greater disability, poorer social functioning, and loss of functional independence may exacerbate artificial limb use as result of difficulties in psychological adjustment (Callaghan et al., 2008; Desmond & MacLachlan, 2006a; Livneh et al., 1999).

Unfortunately, compared to the amount of research literature available regarding artificial limb biomechanics or physical rehabilitation of amputations, little is available on psychosocial, demographic, and other factors impacting living with a disability (Desmond & MacLachlan, 2002). Nonetheless, Darnall and colleagues (2005) published an article containing a current literature review and results of a survey regarding psychosocial issues faced by a lower extremity amputee. From their literature review, the authors noted that for the inpatient dysvascular lower limb amputee, significant depression prevalence ranged from 29% to 54%, while outpatient lower limb amputees' prevalence of significant depression ranged from 21% to 35%, amounts not very different from those found for spinal cord injury patients, chronic pain patients, and persons with diabetes (Darnall et al., 2005). Further, it has been reported that adults who experienced social discomfort, limited social interaction, or unsatisfactory social support related to their amputation were at greater risk for depressive symptoms (Desmond & MacLachlan, 2006a; Gallagher, 2004; Remes et al., 2010; Singh et al., 2009). Considering that amputation-specific pain is associated with functional limitations and decreased activity, for the lower limb amputee this means greater difficulty attaining satisfactory social interaction and thus greater risk for depression (Boutoille et al., 2008; Desmond et al., 2008; Gambassi, 2009).

The actual study conducted by Darnall and colleagues confirmed many of these reports. They derived their study population from a survey database maintained by the Amputee Coalition of America from 1998 to 2000. Stratifying their population by limb loss etiology (dysvascular, trauma, and cancer), 914 persons were identified as eligible (meeting- inclusion/exclusion criteria), and consented to participate in a computer-assisted telephone interview (Darnall et al., 2005). The population was fairly evenly distributed across etiologies and included both upper and lower limb, as well as bilateral, amputees. The phone interview conducted by trained personnel included the Center for Epidemiologic Study Depression Scale (CES-D 10-item) which asks subjects to rate the frequency of symptoms over the previous week for pain incidence (of the residual limb, back or phantom limb), as well as including questions regarding characteristics of the amputation, socio-demographics, and mental health status (Darnall et al., 2005).

Ultimately, the study population was predominately White, male, with a high school education, mean age of 55 years with at least two comorbid conditions, not poor, and mostly lower limb amputees that were, on average, 4.5 years post-surgery (Darnall et al., 2005). It should be noted that the original database was derived from a web-based survey on the ACA website, which may explain the “middle-America” profile of the population. These were persons who had easy access to a computer, unlike many in the poverty or below-poverty range. Analysis of the survey data revealed the prevalence of significant depressive symptoms to be 28.7%, not unlike that reported for amputee outpatients (see above). Following logistic analyses, the risk factors for depression among the population included being between 18 and 54 years of age, being divorced or separated, living at the near-poverty level, having comorbid conditions, being somewhat bothered or extremely bothered by back pain and phantom limb pain, and having residual limb pain (Darnall et al., 2005). Of the sample reporting significant depressive symptoms, over 67% reported not needing mental health services, suggesting some level of maladaptive coping such as denial or selective social separation (Darnall et al., 2005; Desmond & MacLachlan, 2006; Livneh et al., 1999).

Further evidence of the link between depression and limb loss is reported by Williams and colleagues (2011) in a study conducted to ascertain the relationship between a diagnosis and treatment for depression, diabetes, and incidence of major (transtibial, transfemoral) and minor (toes, partial foot) amputations among a cohort of U.S. Veterans. A retrospective analysis of over 530,000 Veterans was conducted that examined the amputation rates between those diagnosed with diabetes and being treated for depression, versus those diabetics not requiring or receiving treatment for depression. (Williams et al., 2011). The mean follow-up period was 4 years, during which time there was a 33% increase in major limb amputation for those being treated for depression compared to those not diagnosed or treated for depression (Williams et al., 2011). A similar relationship did not exist for minor amputations. What is somewhat surprising is that this increase occurred despite treatment (as per anti-depressant prescription records), leading one to question treatment effectiveness or perhaps patient compliance. It is possible that the difference in minor and major limb amputations relative to depression is as reflective of disease (diabetes) progression, as it may be to the level of depression. Additionally, coping mechanisms and stressors associated with the amputation and subsequent residual limb management may influence an amputee's willingness to re-expose themselves to the stressors during clinic visits, whether visits are to the prosthetist, the psychologist, or the physical therapist, and thus influence their clinic attendance (Desmond & MacLachlan, 2006). Also, many people will be reluctant to seek mental health help simply on the basis of the stigma associated with such (although this trend has been shifting over the past decade) (Golberstein, Eisenberg, & Gollust, 2008). All in all, this study clearly demonstrates that depression due to amputation is not limited to the inpatient, but is a real factor for many amputees, surely impacting their quality of life beyond the limb loss itself, and potentially throughout their lifetimes.

Finally, in a prospective study specific to lower limb dysvascular amputees and conducted by Coffey and colleagues (2009), 38 participants with diabetes-related lower limb amputations, recruited from two limb-fitting centers in the United Kingdom, completed three psychological self-report assessments: the Trinity Amputation and Prosthesis Experience Scales; the Hospital Anxiety and Depression Scale; and the Amputation Body Image Scale—Revised. Although the study sample was fairly small, the homogeneity of the population affords the results sufficient power. As such, the most noteworthy finding was the relationship between body image and depression. While the authors noted that over 18% of the study population scored above the normal range for depression and anxiety, even nearly four years post amputation, it is also known that a strong association between depression and diabetes exists, regardless of any limb loss due to diabetic complications (Coffey et al, 2009; Singh et al., 2008). Some even suspect that this association is hormonal in basis (Lustman & Clouse, 2007). Nonetheless, among this study population, body image disturbance was strongly correlated with both depression and anxiety and, although causality cannot be inferred, it is quite suggestive that the level of depression detected is not solely a consequence of the underlying disease—that the loss of one's limb may have a profound effect on the psychological well-being of the amputee. Further, it is not surprising that there should be an increase in anxiety levels, for not only must one be concerned with controlling their disease, but now, as an amputee, they are faced with environmental and social barriers, as well as the constant vigilance required taking care of their residual and artificial limbs.

For any amputee, but especially for the dysvascular amputee, care of the residual limb and artificial limb requires self-discipline, diligence, and considerable self-care to remain ambulatory and healthy- not totally inconsistent with the “chronic care model” (Zinszer et al., 2011). It is up to the user of the artificial limb to care for their residual limb with proper hygiene practices, and to recognize problems such as undue soreness or redness, and to adjust their artificial limb wearing schedule accordingly, basically to prevent residual limb breakdown (G. W. Bosker CPO, personal communication, January 2011). It is also typically up to the person living with limb loss and utilizing an artificial limb to note when the artificial limb is not working properly. For example, the amputee would need to note when the suspension system is failing, or when an additional pair of stump socks are needed to improve the socket fit due to temporary changes in the residual limb fluid retention. When sent home with a lower extremity artificial limb, the amputee is instructed on how to maintain it and what signs of failure to look for, and what to do (DePalma et al., 2002; The Rehabilitation of Lower Limb Amputation Working Group, 2007). In fact, in a study by Larner, van Ross, & Hale (2003), the authors determined that success with an artificial limb was fairly “site specific” (that is, the more proximal the amputation, the less successful the artificial limb user), and that learning and memory capacity was more important than emotional stability, as well as being the most significant predictor of success. Memory and learning capacity becomes particularly relevant in regard to the ability to retain instruction such as that which would be necessary to don and doff an artificial limb, in particular the more sophisticated socket suspension systems, such as the VASS described previously in this chapter. The study also indicated that someone with a mild case of dementia might still be able to use an artificial limb, albeit of simple design and function (Larner et al., 2003).

The consequences of poor disease/limb self-management and care. Whereas primary prevention for diabetes revolves around healthy eating, moderate exercise, and diabetes awareness, the preferred method of diabetes treatment is the incorporation of self-management, where the individual is responsible for daily monitoring of blood glucose levels, medication compliance, foot inspection, weight control, and regular clinical visits (Funnell et al., 2011). In most cases, "self-management" is clinician driven and, although effective, may be fraught with numerous environmental barriers for the amputee (such as treatment costs, medical care access, and a lack of effective diabetes education) (Ephraim et al., 2006; Gallagher, O'Donovan, Doyle, & Desmond, 2011).

The point is, the dysvascular amputee with comorbid diabetes—even PAD—must contend with matters of daily self-management and care. For the amputee, the same barriers, including both economic and individual motivational, may preclude participation in diabetes education, foot care management programs, and regular clinical visits necessary to maintain the function of their artificial limb or health of their residual limb (Ephraim et al., 2006; Gallagher et al., 2011). Failure to do so may lead to serious consequences, not the least of which is chronic residual limb pain, infection, and the inability to use the artificial limb or, ultimately, re-amputation.

The risks of reamputation. Re-amputation, most often within five years of the index amputation, is not uncommon and is typically a factor of health complications, especially PVD and diabetes (Dillingham et al., 2005; Izumi et al., 2006). Most often, undue biomechanical forces and/or poor fitting artificial limbs cause the residual limb's integrity to break down, or poor vascularization (especially in combination with poor sanitation) engenders gangrenous tissue (Bui, Raugi, Nguyen, & Reiber, 2009; Meulenbelt et al., 2007). Additionally, there is a significant risk of amputation of the contralateral limb, due either to the bilateral nature of PAD and critical limb ischemia, or tissue breakdown, foot ulceration, and infection subsequent to a greater dependency on the intact limb with associated biomechanical changes (Izumi et al., 2006; DeLisa & Kerrigan, 1998).

In a study by Izumi, Satterfield, Lee, & Harkless (2006) the likelihood of re-amputation among a population of diabetic dysvascular amputees was determined to increase with time, reaching estimates of over 60% five years post index (initial) amputation. While the actual period before re-amputation was dependent on the level of amputation, the highest incidence occurred within six months of the operation (Izumi et al., 2006). In their 10-year observational study, the authors also determined that re-amputation of the same (ipsilateral) limb occurs in 14% of those individuals with a transtibial or transfemoral index amputation (Izumi et al., 2006). Additionally, for those persons with a unilateral transtibial or transfemoral amputation, it was estimated that within five years there was a 50% likelihood they would undergo some level of amputation of the contralateral (non-amputated) limb (Izumi et al., 2006).

To contrast, Dillingham, Pezzin, and Shore (2005) conducted an analysis of approximately 71,300 Medicare beneficiaries, of which 3,565 lower limb amputees secondary to dysvascular disease were identified. In this study, 74% of the study sample had comorbid diabetes. Of these, 26% underwent a re-amputation (of either the ipsilateral or contralateral limb) within the one-year study period, suggesting a much higher re-amputation rate than that presented by Izumi and colleagues (Dillingham et al., 2005; Izumi et al., 2006). Further, about 16% of all Medicare beneficiaries with a dysvascular amputation secondary to diabetes died before age 65, a rate 2.5 times that of non-diabetic dysvascular amputees, and costs associated with caring for beneficiaries with a dysvascular amputation exceeded $4.3 billion yearly (Dillingham et al., 2005). Table 2 provides additional comparisons between the non-diabetic dysvascular and diabetic dysvascular amputees.

In summary, the two studies suggest that (a) the diabetic amputee tends to be younger at the time of their index amputation and first re-amputation, and die at a younger age than the non-diabetic dysvascular amputee, (b) the prevalence of single or multiple re-amputations was significantly greater among the diabetic dysvascular amputees, suggesting greater medical care costs, and (c) while the diabetic dysvascular amputee may have died at a younger age, they survived for a longer period of time following their index amputation, again suggesting a higher burden of medical care costs.

However, neither of these studies gives any real suggestion as to why re-amputation rates are higher among the diabetic dysvascular amputees other than to suggest greater comorbid diagnoses (Dillingham et al., 2005). Perhaps the younger age of the diabetic amputee is also indicative of a more active individual, one more likely to remain mobile with an artificial limb, and thus put their residual limb more at risk for complications, and causing their contralateral limb to bear more biomechanical forces.

Table 2

Reamputation Rates among Dysvascular Amputees

Group	Index transtibial with revision	Progress to transfemoral	Progressed to bilateral	At least one reamputation	1 year mortality rate
All dysvascular	81.3%	9.4%	9.4%	77%	35.5%
With comorbid diabetes	80.0%	9.3%	10.5%	75.4%	34.0%
Non-diabetic	85.4%	9.6%	5.0%	83.3%	41.5%

Note. From “Reamputation, mortality, and health care costs among persons with dysvascular lower-limb amputations,” by Dillingham, T. R., Pezzin, L. E., & Shore, A. D., 2005, Archives of Physical Medicine and Rehabilitation, 86(3), p. 484

Skin problems associated with the residual limb. For the dysvascular amputee, the residual limb is particularly vulnerable to skin problems, primarily due to its inherent poor healing capacity resultant of poor circulation. Poor circulation leads to poor oxygenation of tissue, poor inflammatory responses, and poor tissue growth stimulation such that the skin is unable to recover sufficiently from insults (Guo & Dipietro, 2010).

These so-called insults may be biologically or mechanically induced, such as from friction, pressure, shear forces, heat, moisture, or foreign bodies present at the residual limb/artificial limb socket interface (Butler et al., 2014; DeLisa & Kerrigan, 1998; Roberts et al., 2006). For example, the residual limb within the socket may experience undue friction from pistoning of the residual limb within an ill-fitting socket and suspension system. Excessive sweating consequent of the materials comprising the socket can lead to blistering, and infection from non-hygienic conditions (Bui et al., 2009; Butler et al., 2014; Meulenbelt et al., 2007). Also, allergic reaction to the materials that are used to make the socket, suspension systems, liners, sleeves, and socks are not uncommon (Meulenbelt et al., 2006). Many times, these problems are resolved with the application of a topical ointment or powder and with restricted use of the artificial limb. However, when such problems persist or consistently reoccur, consideration is given to the fit, alignment, or appropriateness of the artificial limb, as well as to the health status, disease progression, and self-management practices of the patient (G. W. Bosker CPO, personal communication, January 2011).

Regardless of the skin condition or its cause, the danger lies in the residual limb's inability to heal rapidly and the formation of ulcers, which then serve as portals to infection (Mayfield et al., 2004; Meulenbelt et al., 2006; Salawu, Middleton, Gilbertson, Kodavali, & Neumann, 2006). The infection (osteomyelitis or sepsis) is the primary reason for limb surgical revision and re-amputation. It is also one of the four primary causes of death for the dysvascular amputee, along with heart failure, renal failure, and pneumonia/pulmonary failure, all of which, it should be noted, are also closely associated with diabetes and PAD, and not necessarily with amputation (Feinglass et al., 2001; Mayfield et al., 2001).

In a six-year retrospective chart review of outpatient lower extremity amputees, Dudek, Marks, Marshall and Chardon (2005) determined that 26.7% of the residual limbs examined were noted to have had at least one ulcer treated. Overall, 47% of the cases were treated for some skin problem: irritation 17.6%, inclusion cysts 15.0%, callus 11.4%, verrucous hyperplasia 8.9%, blister 6.6%, fungal infection 4.9%, cellulitis 2.1%, and “other” 6.8% (Dudek et al., 2005). The population examined was predominately male (77%) with a mean age of 58 years; 66% were transtibial amputations and 19% transfemoral, with the majority of the amputations being due to PVD. In their analysis, the authors found that being a younger amputee, having any amputation level other than transfemoral, being employed, being a community ambulator, and not using any other gait aid beyond a single point cane were traits of the amputees most likely to incur a skin problem (Dudek et al., 2005). Interestingly, the authors also noted that having a comorbid diagnosis of PVD decreased the likelihood of developing a skin problem. They went on to attribute this finding to a reduced activity level among such persons (as compared to those without PVD), ultimately concluding that more active amputees have an increased risk of skin problems (Dudek et al., 2005). This, then, suggests that at the crux of most residual limb skin problems is excessive biomechanical forces acting on the residual limb at the residual limb–artificial limb interface, although the authors found that neither the type of socket nor suspension system for the transfemoral or transtibial amputee significantly increased or decreased the likelihood of developing a skin problem (Dudek et al., 2005).

Of note, most, if not all, of the amputees in the study received their artificial limbs and care from the same group of prosthetists associated with the outpatient clinic where the study was conducted (Dudek et al., 2005). The most commonly provided socket suspension system for the transtibial amputees was the anatomical type of suspension (supera-condylear) with a patellar tendon bearing socket; approximately 11% utilized a vacuum (pin-lock) suspension with a patellar tendon bearing socket (a brief description of these suspension systems is provided in this chapter) (Dudek et al., 2005). The authors provided no further analysis to associate the incidence of ulcers or skin problems relative to the presence or absence of PVD and a particular socket suspension type, nor did they take into consideration the type of prosthetic foot utilized. Given that the population likely received similar practitioner care, it is fairly safe to assume that poor alignment of the artificial limb was not a significant contributing factor to the etiology of the skin problems, but a question remains as to whether or not certain artificial limb configurations are more prone to incur skin problems than others, regardless of the activity level of the user. Such an analysis would go far to define prescription guidelines for the person living with limb loss.

Residual limb conditions other than ulcers may be less life-threatening but are equally responsible for preventing the use of an artificial limb. For example, neuromas or aggravated nerve bundles at the site of the residual limb may become so painful as to prevent wearing a socket; osteoarthritis of the knee, hip or back can be so painful as to prevent ambulation; loss of bone density is also not uncommon but typically is associated with the long term traumatic amputee (DePalma et al., 2002). However, an individual who loses a limb to trauma, “recovers,” and then develops PAD or diabetes, suffers the same problems as any similarly diagnosed individual who loses their limb to complications thereof (DePalma et al., 2005; G. W. Bosker CPO, personal communication, January, 2011).

Clearly the residual limb is highly vulnerable and at the crux of many issues faced by the person living with limb loss. In fact, from a survey conducted by Legro, et al. (1999), it was determined that among a diverse population of 92 lower limb amputees, artificial limb fit, ability to walk with the artificial limb, avoidance of blisters or sores on the residual limb, and avoidance of rashes on the residual limb were the most important factors they associated with the use of an artificial limb. Since residual limb health (for example, skin problems, swelling, pain, sweating) affects the fit of the artificial limb, it is not surprising that residual limb health is of high priority for the person living with limb loss. The authors suggest that improved education as to the care of the residual limb, as well as more regular and “finely tuned” visits with a practitioner may be a means to resolve the issue (Legro et al., 1999). Unfortunately, for many, medical care access is a barrier, and the additional visits add to health care costs (Ephraim et al., 2006; Legro et al., 1999). Perhaps an alternative is to further explore residual limb outcomes relative to specific artificial limb configurations and components, in an effort to determine those that act best to ameliorate harmful biomechanical forces acting on the residual limb. Given such evidence, practitioners may be in a better position to prescribe an artificial limb configuration that is least likely to promote skin problems, and most likely to promote physical activity.

Artificial limb failure and repair. As noted above, a key factor or concern for residual limb breakdown is the fit and alignment of the artificial limb. Results can be pistoning of the residual limb within the socket and the potential for blistering from friction, occlusion of blood flow from a socket that is too tight, an allergic skin reaction to socket or suspension system materials, or inefficient ambulation (Butler et al., 2014; Fergason & Smith, 1999). In other words, an artificial limb that is not well maintained sets up the amputee for failure, such as poor, inefficient gait; joint pain; residual limb compromise; and an overall reduced quality of life (Chitragari et al., 2014; DeLisa & Kerrigan, 1998).

In a study by Datta, Vaidya, & Alsindi (1999), the authors conducted a detailed retrospective review of a cohort of 104 transtibial and transfemoral amputees. The purpose was to identify patterns of “prosthetic episodes:” how often and what sort of repair or maintenance was required of an individual’s artificial limb over a 10-year period. The patients on average needed 5.54 visits per year when all age groups were considered together, 6.42 visits per year for the 15-60 year age group, and 4.8 visits per year for the 60+ age group (Datta et al., 1999). Overall, the amputees in the study on average needed about one new prosthesis and one new socket every two years, one major repair every five years, and about two same-day repairs per year (Datta et al, 1999). However, the authors concluded that the actual frequency of repairs or artificial limb replacements was truly unique to the individual and dependent on multiple factors, to include different levels of amputation, degree of artificial limb use (activity level), type of componentry used, and availability of services (Datta et al., 1999).

Conclusion and Future Prospects

The naïve observer watching a lower limb amputee walk through a parking lot or through a grocery store may not appreciate all that that person has gone through or continues to go through. For the dysvascular amputee, the goal to live a full and productive life is challenged given a five-year mortality rate of 50%, and psychological and physical issues that press even the strongest body and soul (Dillingham et al., 2005; Coffey et al., 2009; The Rehabilitation of Lower Limb Amputation Working Group, 2007). Despite human ingenuity, we have yet to cure diabetes or PVD. The disease's progression can be controlled or slowed with diligence and discipline, but it cannot be cured and, as long as there are dysvascular diseases, there will be limb loss. As long as there is limb loss, there will be matters of psychological and physical adjustment.

Human ingenuity also has yet to build a better artificial limb. Engineers and scientists have come closer with microprocessor components, special designs, and special materials, but in regard to the socket-residual limb interface—to create seamlessness between mechanical parts and the human body—this goal has yet to be achieved (Mak et al., 1994; Sewell et al., 2000). Osteointegration of a socket to a residual limb, the in vitro or in vivo regeneration of limbs, as well as limb transplants are techniques being researched to improve functionality for the amputee, but all are plagued with problems of chronic infection, medication issues, or rejection (Mak et al., 1994; Brandacher et al., 2009).

Whether due to purely mechanical influences (for example, poor socket fit, artificial limb alignment, or component design) or behaviorally induced (for example, poor hygiene, issues of self-management, or emotional status), the residual limb for the lower extremity amputee is vulnerable and at risk, for it is being required to perform in a manner for which it was not designed (Boutin, Pathria, & Resnick, 1998). Given known limitations, the question becomes how best to overcome certain barriers, while at the same time pressing the boundaries of our skills and knowledge.

Surveillance, Informatics, and the Amputee

The Current Monitoring System

Surveillance is a key component of public health for it serves as a means to monitor the progress of a disease, program, or population. It includes the "systematic collection, analysis and interpretation of health data for purposes of improving health and safety" (http://www.cdc.gov/niosh/topics/surveillance/). Data derived from a surveillance system is powerful for it transcends opinion and politics, being objective in nature, and thus highly useful for the dissemination of health information. However, when performed selectively, or within a narrow framework, it can prove to be biased or skewed, and thus become more a case of health care marketing than public health surveillance. Nonetheless, when conducted on the basis of individual activities, public health surveillance takes on the function of patient screening or monitoring. On this level, the goal of such surveillance is early detection of disease or dysfunction, followed by appropriate interventions to prevent further exacerbation of the condition (Boyko et al., 2000; O'Carroll et al., 2003). At this point, surveillance likely becomes increasingly relevant to the clinician or practitioner for it tends to focus on more specific characteristics of the population and condition in question.

An extensive search of the available literature and Internet resources has revealed that no coordinated surveillance or monitoring program exists for limb loss in the United States, except for that conducted by state health departments for Emergency Medical Services (EMS), or from limited research studies of hospital discharge records or health insurance beneficiaries. Such is understandable given the relatively low incidence of major limb loss (relative to incidence rates for major life-threatening conditions such as diabetes, cancer, and infectious disease), the complexity and variation of the condition, and the likely high cost–benefits ratio a concerted surveillance effort would require (Groah et al., 2009). However, as suggested previously, with a prevalence rate of 1.6 million persons living with limb loss in 2005 and a potential rate of 3.6 million in 2050, perhaps surveillance specific to the limb loss condition should be developed (Ziegler-Graham et al., 2008). Such a system would potentially provide information useful in the development of artificial limb prescription guidelines, patient therapy standards, and cost-effective rehabilitation practices, as well as providing stakeholders' (including manufacturers') insights into the real needs (instead of perceived needs) of the individual living with limb loss.

The CDC diabetes model. In the case of limb loss, the benefits of surveillance are demonstrated by the monitoring of the incidence and prevalence of diabetes, with the subsequent accounting of acquired limb loss due to diabetic complications (a subset of CDC's National Diabetes surveillance). As of 2005, the Centers for Disease Control and Prevention estimated there were 20.6 million adults living with diabetes (approximately 9.6% of the total U.S. population over the age of 20 years), but by 2010, this number had increased to 25.7 million or approximately 11.3% of the U.S. population (CDC, 2011b). By 2012, while the actual number of adults with diabetes continued to increase to 29.1 million people, the percentage of such persons in the U.S. population decreased to 9.3%

(CDC, 2014). The latest available statistics derived from hospital discharge records indicate approximately 82,000 lower limb dysvascular amputations in 2002, 71,000 in 2004, about 65,700 in 2006, and approximately 44,000 in 2010the decline being attributed to improved diabetic foot care and management, improved glucose control methods, and a heightened awareness from extensive diabetes education programs—a blending of clinical care and self-management improvements (CDC, 2011a; CDC, 2014; Dillingham, 2002; Reiber & Raugi, 2005; Ziegler-Graham, 2008;). However, for 2010, 44,000 amputations indicates those directly related to diabetes, while a larger number of 73,000 lower limb amputations were performed in persons diagnosed with diabetes , likely a reflection of a growing, aging population (CDC, 2014). Of note, the data reported in these estimates are derived from self-reported responses to national surveys such as the 2005-2008 National Health And Nutrition Examination Survey, United States Census Statistics, 2007–2009 National Health Interview Survey, Indian Health Service, National Patient Information Reporting System, state or local level Behavioral Risk Factor Surveillance System, and various study groups and research groups (CDC, 2011). Obviously, there is no accessible specific database from which to derive information to explore the actual limb loss condition.

The British model. While such a system does not yet exist in the United States, some countries that practice forms of socialized medicine, such as Great Britain, Australia, and The Netherlands, maintain national databases that benefit both the artificial limb user and the health care provider. For example, in the British Society of

Rehabilitation Medicine (BSRM) Working Party Report on Amputee and Prosthetic Rehabilitation Standards and Guidelines (2003), patient care steps—pre-surgical, surgical, post-surgical, wound healing, physical therapies, physician requirements, therapy access, artificial limb prescription, and accessibility to health care facilities—are all outlined and categorized as *required/must*, *recommended/should* or *suggested*. The overall objective of the work is to establish a basis for the *provision of a service of excellence to the amputee population with equity of access throughout the UK*. (British Society of Rehabilitation Medicine [BSRM], 2003). The targeted population includes not only the person with limb loss, but also the clinicians, practitioners, therapists, and even artificial limb manufacturers. The various recommendations, standards, and guidelines were and are based on evidence derived from previous BSRM Working Party Reports, research literature and reviews, as well as on the consultation and consensus of experts in the field of amputation and artificial limb rehabilitation (BSRM, 2003). Of note, clearly stated in the standards and guidelines and as its own surveillance measure, the various Prosthetic and Amputee Rehabilitation Centers (PARCs) of the British Health System are strongly recommended ("should") to collect, maintain, and provide statistical data relative to amputee rehabilitation and prosthetics to the National Amputee Statistical Database (NASDAB) (BSRM, 2003). To be included in this data is that specifically related to trends in artificial limb prescription and patient functional outcomes.

A stated goal of the BSRM's standards and guidelines for data collection and analysis (surveillance) is to serve as a means to audit the service practices and outcomes of the PARCs as well as to provide future and present evidence of patient outcomes (BSRM, 2003). It is this sort of surveillance that is lacking in the United States and potentially contributes to the high healthcare costs and questionable quality of life for the amputee.

However, in a study by Sansam, O'Connor, Neumann, & Bhakta (2014), 23 clinicians were interviewed from 4 different amputee rehabilitation centers. Those interviewed included physicians, prosthetists, physical therapist, and specialty nurses.

In the UK, not unlike the US) the process whereby an individual’s artificial limb prescription is determined, is generally influenced by the clinical observations, training and experience of the treating team, the difference being that in the US, that decision is also often driven by health insurance coverage and classifications. In the UK, there are several national and international guidelines on amputee rehabilitation and, while they all include “the need for a patient centered, multidisciplinary assessment to establish each individual’s needs and goals”, they do not specify how the decision of whether to provide a prosthesis or what components to choose should be made (Sansom et al., 2014). Analysis of the interviews identified four thematic factors when considering an artificial limb prescription: the patient’s estimated outcome (ability to learn how to use an artificial limb and their predicted activity level), the complexity of the case (patient attributes, success with early walking aids, and social support), the patient’s choice (mediated by family influence, clinician management of patient expectations, and patient goals), and barriers to prescribing (budget limitations, component availability, and risk of the patient's ultimate aversion to the artificial limb (Sansom et al., 2014). As indicated previously in this chapter, these same themes are present for the team prescribing an artificial limb in the US, the primary difference being the influence of insurance coverage (if any). Of particular note, of the four rehabilitative center clinicians interviewed, only one center and team actually used any form of prescription guidelines, and the guidelines were ones they derived themselves (Sansom et al., 2014). This same center claimed greater confidence and success in their artificial limb prescription process although any assessment of such was beyond the scope of the study (Sansom et al., 2014). Nonetheless, in conclusion, the authors stressed the importance of including all four factors in any clinical artificial limb prescription algorithm or guideline, noting the paucity of research on patient motivation and the implications of psychosocial factors (Sansom et al., 2014). However, this study presents another issue, that the problem as to the best artificial limb to provide a patient, resides not only with patient compliance, cost, and expert knowledge and practice,, but also with the provision and acceptance of evidence- based material by the practitioner as guidelines were available but not used and/or recreated to meet the knowledge base of the clinicians using the guidelines (Cicerone, 2005; Groah et al., 2009; Sansom et al., 2014). Perhaps with the availability of a system of surveillance, monitoring, and standards and guidelines in place, the person living with limb loss can be set up for success, as those various stakeholders involved have greater access to less biased information, greater accountability, and greater insight for future research and development.

Meaningful Evidence

One of the primary benefits of a database specific to people living with limb loss (such as the British National Amputee Statistical Database [NASDAB]) is the ability to utilize objective data in large case numbers and identify patterns and trends of the data therein. This practice becomes particularly valuable when the data includes not only cross-sectional data useful for the calculation of incidence and prevalence rates, but also an outcome measure indicative of some interventional measure. The best outcome measures are those that can be applied with universal acceptance, can be easily standardized or quantified, and are sufficiently relative to bear meaning (Arlet et al., 2008; Black, 1997; Borg & Sunnerhagen, 2008; Deathe et al., 2009). Such an approach is particularly important for the clinical decision-maker that may be looking to an analysis of the database to identify factors that strongly predict good or poor patient outcome.

To date, most lower extremity prosthetic outcome measures have been related to gait and balance biomechanics, functional capacity, energy cost, and patient satisfaction (as measured by varying questionnaires and survey tools) (Meulenbelt, et al., 2006). While useful for describing the functional capacity of the artificial limb user, the mechanics of the artificial limb itself, or overall user performance, these outcome measures are not universal (not easily obtained, especially in large case numbers), not well standardized, and, though relative to the condition, are limited in scope and meaning for the patient or clinical decision-maker. Interestingly, the impact of various artificial limb components on the integrity of the residual limb has not been extensively researched, specifically such outcomes as skin irritation, ulceration, infection, and/or surgical revision; these are conditions that are classified by standardized, universally accepted CPT and ICD-9-CM codes, and that have direct impact on the amputee and their use of an artificial limb (Bui et al., 2009; Dudek et al., 2005). Instead, the relevant literature tends to focus on case studies that report rare or unusual conditions rather than focusing on more common conditions, and few relate such conditions to the artificial limb configuration in use (Meulenbelt, Dijkstra, Jonkman, & Geertzen, 2006; Meulenbelt et al., 2007). Nonetheless, a few studies have reported the findings of extensive literature searches specific to skin disorders of the residual limb and offer various models of categorization based on morphology or presumed etiology, for example: mechanical forces, foreign bodies, concurrent disease, or occlusion (Bui et al., 2009; Butler et al., 2014; Meulenbelt et al., 2006).

Recognizing the need to better understand the relationship between artificial limb use and residual limb skin problems, Meulenbelt, Geertzen, Jonkman, & Dijkstra (2009) surveyed over 2,000 lower limb amputees, representing 75% of the amputee population in the Netherlands. The purpose of the study was to identify determinants of residual limb skin problems, as determined by a self-designed questionnaire that consisted of a series of open questions and multiple choice questions intended to assess the “domains:” demographics, characteristics of the amputation and prosthesis, activity level of the amputee, residual limb and prosthesis hygiene, and skin problems (Meulenbelt, Geertzen, Jonkman, & Dijkstra, 2009). Since the researchers did not actually examine the participants' residual limbs, they defined their outcome variables as "suspicious", such as, suspicion for eczema, suspicion for mechanically-induced skin problems, suspicion for skin problems caused by occlusion, and suspicion for skin problems caused by PAD (Meulenbelt et al., 2009). Stepwise backward logistic regression was then utilized to identify the determinants of skin problems.

Forty percent of the individuals to whom surveys had been mailed subsequently responded with completed questionnaires (respondents were significantly younger than those who did not complete or return the questionnaire) (Meulenbelt et al., 2009). Most respondents were men (62%), nearly half were transtibial amputees, another third were transfemoral amputees, and 42% had acquired limb loss due to trauma, with only 28% due to dysvascular complications (although the authors stated that nearly 94% of all amputations in the Netherlands were due to PVD complications) (Meulenbelt et al., 2009). Most of the respondents were unemployed and relatively inactive (walked less than 500 meters/day), half used a liner with their socket suspension system, and yet 82% of the respondents reported skin problems and 63% reported more than one. Most were pressure ulcers (57%), infection accounted for another 35%, and 57% stated they could not wear the artificial limb temporarily because of the skin problems (Meulenbelt et al., 2009). Such findings tend to lead one to question the premise that activity level, and therefore mechanical forces acting on the residual limb, is the primary cause behind residual limb skin problems.

From their regression analysis, the authors identified two levels of skin problem determinants, those that were protective in nature, and those that were considered "provocative" (Meulenbelt et al., 2009). The protective determinants most closely associated with respondents who were older, male, and had a dysvascular amputation—a finding that correlates well with the results of the Dudek study discussed previously and suggestive that inactivity among older persons with dysvascular amputations tended to result in fewer skin problems (Dudek et al., 2005). On the other hand, Meulenbelt also noted that the provocative determinants were use of antibacterial soap, smoking, and washing the residual limb four times a week or more often, challenging the premise that mechanical forces in association with activity level are the primary reason for residual limb skin problems. Additionally, the researchers noted that: (a) suspicion for eczema or skin problems due to occlusion significantly correlated with the use of walking aids; and (b) suspicion for mechanically induced skin problems, occlusions or subsequent of PVD were significantly correlated with washing the residual limb more than four times a week (Meulenbelt et al., 2009). While such correlations do not necessarily infer causation, it is interesting to consider that a significant correlation with "walking aids" suggests poor gait, perhaps due to weakness or a comorbid condition (possibly such as older age), and frequent washing suggests good hygiene in response to accumulated sweat and/or possible infection.

Several aspects of the authors' findings are somewhat counter-intuitive, especially in regard to hygiene and the use of antimicrobial soap. Frequent, or at least, regular washing of a body part is generally accepted as good health practice. Given the moist environment in which the residual limb is typically trapped (due to sweating and impervious materials such as liners and the artificial limb socket), frequent washing with an antimicrobial soap would seem a protective determinant against certain skin problems, specifically fungal or bacterial infections. The fact that it was considered a “provocative” determinant instead and that infection was one of the most frequent skin problems reported by the respondents, leads one to (a) question the accuracy of the respondents’ perception of the skin problem, (b) question their interpretation of the survey question, or (c) question if there is some sort of skin chemical sensitivity to the soap. While the methodology employed by the authors was a viable means to reach a larger and broader sample, such self-designed and delivered surveys are fraught with validity issues and sample bias such as the results demonstrated— the sample was not representative of the older dysvascular amputee that they reported accounted for nearly 94% of the entire Netherlands amputee population; and without the guidance of a trained interviewer, standardized and validated survey questions, or a practitioner’s skilled eye at identifying specific skin problems, it is difficult to quantify and measure outcomes. Thus the findings of this study further support the concept that not only are skin problems of the residual limb a consistent and problematic issue for the lower limb amputee that need further investigation beyond mere case reports, but that some other means besides subjective survey should be employed to assess such, for example: standardized medical coding such as ICD-9-CM, HCPCS, or CPT codes universally accepted and utilized extensively by most healthcare facilities and providers.

An Alternative Source of Evidence

The high quality clinical database. In those cases where the conduction of a clinical trial may be unfeasible or unethical, many disciplines have turned to the development of high-quality clinical databases (HQCD) as a means for consolidating evidence-based medicine in a systematic manner (Arlet et al., 2008). An HQCD is typically a relational database that focuses on an intervention and the related patient outcome. It allows for the generation of large samples that improve statistics, promote generalizability of analyses, and allow for subgroup identification to include the aggregation of rare cases and/or interventions for study (Black, 1997; Hlatky, 1991; Sacristan & Galende, 1999).

While databases such as the Thoracic Surgery database may exemplify the gold standard for an HQCD, most such databases are limited in scope or site (hospital specific) and take considerable time, forethought, and expertise to develop (Arlet et al., 2008). Nonetheless, it is exactly this specificity and direct clinical application that makes an HQCD so powerful, whereas other databases such as the Cancer Registries may offer important population-based data that is disease specific and can be used to identify trends and patterns of associations, but they do not necessarily link an intervention outcome with the disease or support long-term follow-up of specific cases or cohorts of interest that could lead to policy change (Black & Tan, 2013; CDC, 2013).

Healthcare administrative databases. In the absence of an appropriate HQCD (or to facilitate the development of such), a healthcare administrative database may serve as a viable alternative. Despite being broad in scope, and even though a healthcare administrative database typically does not contain direct clinical information beyond diagnosis and procedural codes, such a database is nonetheless useful for clinical research when used for calculating population disease incidence/prevalence and/or health service practices (Boyko et al., 2000). Further, when the administrative database is linked to a systematic patient follow-up, and/or outcomes are directly related to medical coding, what emerges is a framework with which to study patient outcomes and disease or intervention prognosis (Boyko et al., 2000; Hlatky, 1991; Miller & Pogach, 2008; Rosato et al., 2008). An example of such is presented by Rosato, D'Errigo, Badoni, Fusco, Perucci, & Seccareccia (2008) in which they compared data from the Coronary Artery Bypass Graft (CABG) project clinical database with that obtained from administrative hospital discharge records of individuals identified in both data sources. They then applied a risk model to the CABG data, the hospital discharge data, and the hospital discharge data supplemented with a few key variables from the CABG database. Analysis and comparison of the three data sources for the assessment of hospital/surgical performance revealed that the clinical CABG and administrative hospital discharge records were quite similar in outcome (Rosato et al., 2008). However, when the administrative dataset was supplemented with clinical data, the assessment improved and became more accurate (Rosato et al., 2008).

Other studies demonstrate a similar value of administrative databases for assessing disease treatment protocols such as foot care management for diabetic patients (Moreland et al., 2004); yet others have demonstrated their value as effective tools that facilitate quality assurance among professionals, actually improving communication between such persons (de Bont, Stoevelaar, & Bal, 2007). Perhaps a key reason for the continued value of healthcare administrative databases is their dependence on standardized, easily accessible, well-defined and accepted medical coding systems—a feature that has been developed over many years, and has been refined and expanded and utilized internationally.

Medical Coding Systems

Coding for disease and diagnoses. The International Classification of Diseases, 9th Revision, Clinical Modifications (ICD-9-CM) is a standardized classification of disease, injuries, and causes of death, by etiology and anatomic location. The combined information is assigned a unique, searchable six-digit number, allowing for the easy exchange of information and organization of detail (CDC, 2012). Historically, the International Classification of Diseases evolved from the need to track mortality and morbidity rates, primarily for the declaration of property rights and insurance payments (Moriyama, Loy, & Robb-Smith 2011). In 1948, the World Health Organization published the initial International Classification of Disease, a listing of the known diseases at the time, to be used as a means to statistically track morbidity and mortality (Moriyama et al., 2011). The ninth revision of this listing (ICD-9) was published in 1977, and having attained considerable international acceptance, the U.S. National Center for Health Statistics decided to modify the disease listing so as to accommodate the statistical analysis of clinical and morbidity information (Moriyama et al., 2011). This resulted in the publication of the ICD-9-CM, which contains information sufficient to precisely delineate the clinical picture of each patient, beyond that needed merely for disease groupings and the statistical analysis of healthcare trends. Subsequently, in 1989, the United States Congress passed a mandate that required the use of ICD-9-CM codes on each Part-B Medicare claim submitted by physicians (Moriyama et al., 2011).

To date, these codes have become a standard for both public and private company insurance claims and health records, warranting the need for trained, professional coders, because failure to use or to improperly use ICD-9-CM codes can lead to serious repercussions (Moriyama, et al., 2011). In fact, the Centers for Medicare and Medicaid Services provides specific guidelines to aid in standardizing coding practices across the United States and these are summarized in Table 3 (Centers for Medicare & Medicaid Services [CMMS], 2012b). These rules are useful for helping one understand the organization and implications of the codes as they appear in healthcare administrative records.

Table 3

Basic Standardized ICD-9-CM Coding Practices as Extracted from The Centers for Medicare and Medicaid Services (CMMS) Guidelines (CMMS, 2012b)

Rule	Additional explanation
Identify each service, procedure, or supply with an ICD.9 code from 001.0 through V82.9.	To describe the diagnosis, symptom, complaint, condition, or problem.
Identify services or visits for circumstances other than disease or injury, with V codes.	Example: follow-up care after chemotherapy.
Code the primary diagnosis first, followed by the secondary, tertiary, and so on.	Code any coexisting conditions that affect the treatment of the patient for that visit or procedure as supplement information. Do not code a diagnosis that is no longer applicable.
Code to the highest degree of specificity.	Carry the numerical code to the 4th or 5th digit when necessary. There are only approximately 100 valid three-digit codes; all other ICD.9 codes require additional digits.
Code a chronic diagnosis as often as it is applicable to the patient's treatment.	
When only ancillary services are provided, list the appropriate V code first and the problem second.	For example, if the patient is receiving physical therapy, list the V code first, then the diagnosis code.
For surgical procedures, code the diagnosis applicable to the procedure.	If the postoperative diagnosis is different than the preoperative diagnosis, use the postoperative diagnosis.

Coding for treatment and services. While ICD-9-CM codes describe an individual's condition, they provide little to no indication of what treatment or service was provided, a necessary component for billing and accounting services. Current Procedural Terminology (CPT) is a listing of descriptive terms and identifying codes for reporting medical services and procedures (American Medical Association [AMA], 2013). The codes "provide a uniform language that accurately describes medical, surgical, and diagnostic services…" (Footnote AMA website at http://www.ama-assn.org/med-sci/cpt/template.htm). First published in 1966, Current Procedural Terminology (CPT) is trademarked by the American Medical Association (AMA), and used for reporting in both public and private health insurance systems, primarily for reimbursement and claims processing purposes (AMA, 2013). Such a coding system also allows for the monitoring of services provided relative to a diagnosis (as indicated by ICD-9-CM codes) and thus, ultimately, cost control and health care management (AMA, 2013). In fact, the Health Care Financing Administration (HCFA) has adopted CPT as part of its Healthcare Common Procedure Coding System (HCPCS) for use in reporting medical services in Medicare and Medicaid, as well as the VHA (CMMS 2012). An important and notable difference between CPT and HCPCS codes is that CPT codes are only for services provided, while HCPCS codes may include durable medical equipment (DME) provided as part of that service (CMMS, 2012). Therefore, HCPCS codes rather than CPT codes are particularly useful to represent services rendered in hospitals and skilled nursing facilities, outpatient clinics, and rehabilitation centers to include physical and occupational therapy services as such services frequently include the administration of such items as canes, walkers, braces and other orthopedic DME (CMMS, 2012a).

Clearly a key strength of the above-mentioned coding systems (ICD-9-CM, CPT, and HCPCS) is their uniformity of language and universal acceptance within the healthcare and medical industry. However, the codes and definitions are often obtuse and complex, such that it may be difficult to assign a patient's condition and service with a single code, nor does the typical patient have a single condition. The accuracy of the codes is only as good as the person doing the coding, be that person a professional coder, an office manager, or the physician. Also, whereas the ICD-9-CM code is specific per diagnosis, the CPT/HCPCS codes are considerably more general, as a single "procedure" may actually be appropriate for multiple diagnoses or conditions; that is, CPT codes indicate the treatment procedure to treat a particular condition and thus, it seems then, are considerably more non-specific as a research outcome variable, and more appropriate as confirmation or validation of the condition being accounted.

The Veterans Health Administration System of Care

A Public health system at work. The Department of Veteran Affairs attained cabinet-level status under President George H. Bush in 1989 (Brown, et al., 2003). The VHA is a section thereof and accounts for nearly half the budget (in Fiscal Year 2010, estimated Congressional appropriation for the VA was $127.0 billion, of which the VHA's portion was $48.1 billion). As of 2010, the VHA was serving over 8.6 million Veterans, nearly twice the number served in 2001 (Department of Veteran Affairs, 2010a). During times of war, the VHA provides health care for active duty military personnel, as well as for the general civilian public during national disasters. Subsequently, nearly 4% (285,103) of the Veterans served were rated 100% disabled, and as of FY 2009, 981 were Operation Iraqi Freedom/Operation Enduring Freedom war amputees (DVA, 2010).

Table 4

Sample Veteran Population Demographics as of 2009 (National Center for Veterans Analysis and Statistics, 2010)

Characteristic	Percentage
Gender	8% Female, 92% male
Over 65 years old	39.9%
Race	White 79.3%
	Black 11.3%
	Asian/Pacific Islander 1.5%
	Hispanic 5.8%
	American Indian/Alaska Natives 0.8%

The Veterans Healthcare Administration of the United States is one of the largest centralized health systems in the world with 153 hospitals, more than 800 community-based and facility-based clinics, 135 nursing homes, 43 domiciliaries, 206 readjustment counseling centers, and various other facilities, and employing approximately 180,000 healthcare professionals (DVA, 2010). Further, as part of VHA policy, VHA hospitals are aligned and affiliated with medical and dental schools throughout the United States such that, as of FY 2009, approximately 114,685 healthcare professionals (residents and students) rotated through VHA facilities (DVA, 2010). In fact, more than half of the United States practicing physicians have received training in VA hospitals (Boyko et al., 2000). In part, due to this close association with graduate education institutions, the VHA is a major contributor to medical and scientific research and is second to the National Institutes of Health in funding biomedical research in the U.S (DVA, 2010; Boyko et al., 2000). As is apparent from this accounting of VHA facilities, there is considerable variability in scope and complexity within the VHA system. For example, a small facility (such as a community outreach center) may provide only routine primary care and a subset of specialties, whereas moderate-sized facilities, such as hospital satellite centers, may provide outpatient clinics to facilitate medical care access for large geographical regions (Boyko et al., 2000). Typically, larger centers are affiliated with educational medical centers and universities for collaborative clinical support (students and faculty provide necessary manpower; clinical patients are an educational resource (Boyko, et al., 2000). Such centers frequently provide expanded services to include inpatient and highly specialized medical care units, for example, spinal cord injury, organ transplant, traumatic brain injury, and polytrauma units (Boyko et al., 2000).

One of the key factors contributing to the VHA's success and growing status as a health care system is its early recognition and innovation in medical informatics. Currently, medical documentation and ordering are computerized at every facility, with national registries and databases being maintained since 1976; administrative and patient information from all VA facilities is directed to a repository maintained at the VA Office of Information, Austin Information Technology Center (Boyko et al., 2000; Murphy et al., 2002). At the core of this information system is the Veterans Health Information Systems and Technology Architecture (VISTA).

The Veterans information systems technology and architecture program. VISTA has its beginnings in the late 1970s, a time during which the VHA medical centers began acquiring their own computing systems, largely for research purposes, and from which emerged the Decentralized Hospital Computer Program (DHCP) (Brown et al, 2003). The DHCP turned out to be a prototype for medical information systems being based on a common data dictionary, common database, and sharing common tools and needs such as scheduling, laboratory reporting, administrative records, pharmacy, mental health applications, and radiology (Brown et al., 2003). By 1989, DHCP had expanded to nationwide implementation and had expanded in scope to include dietetics, fiscal/supply, medical center management, medical records tracking, nursing, and surgery (Brown et al., 2003). Following a move toward “three-tiered architecture,” in 1996 DHCP was renamed VISTA (Brown et al., 2003). By 2000, VISTA contained over 99 computer software applications and, presently, most VHA medical centers run the program on Compaq Alpha clusters ranging from 1 to 12 or more processors (Brown et al., 2003). Given that the various applications supported by VISTA share a common infrastructure (common database, common data dictionary, and so forth), this allows for (a) sharing of common data, not replication thereof; (b) consistency of software application for the user and developer; (c) simplified maintenance since the core code is centrally updated and then distributed; and (d) stability between the operating system and applications—failure protection (Brown et al., 2003). Data sharing continues to improve. The Computerized Patient Record System allows for near real-time, nationwide patient medical record access, and similar access to the Department of Defense health care records for the Veteran (while on previous active military duty) is now more easily available and congruent (Brown et al., 2003).

The computerized patient record system. In the 1990s, the VHA launched their Computerized Patient Record System (CPRS), shifting an emphasis from departmental-centered clinical records to a more patient-centered clinical recordkeeping system, as well as a departure from traditional paper charting to electronic charting (Boyko et al., 2000; Brown et al., 2003; Murphy et al., 2002). CPRS is more than an electronic medical record system; it is an umbrella program that organizes various clinical tools and applications in a tabular and clinically relevant manner (Murphy et al., 2002). Virtually all clinical documents are entered and accessed using CPRS, including all forms of clinical notes, physician orders, consultations, procedure reports, and radiology and pathology examinations - legacy paper medical records are no longer maintained on wards or clinics, as virtually all necessary information is maintained and directly input through CPRS (Brown, et al., 2003; Murphy et al., 2002). In fact, per VHA policy, clinicians and practitioners are required to enter progress notes, orders, and reports directly into CPRS at the time of the patient visit or as soon as possible thereafter. Upon completion of such, and as part of the procedure to digitally sign the document, the signor must assign an appropriate ICD-9-CM and/or CPT code, facilitated by a searchable lexicon available within the required data field (Murphy, et al., 2002). Additionally, other background applications provide order checking, allergy checking, a notifications engine, patient demographics and eligibility status, and clinical reminders (Brown et al., 2003; Murphy et al., 2002). Of note: Although the clinician/provider is required to enter diagnosis and treatment codes, professional coders are employed to review ICD-9-CM codes for their appropriateness prior to weekly and monthly database roll-ups. CPT/HCPCS codes are under the review of service chiefs and Medical Administration Service staff (Murphy et al., 2002). It is through CPRS, facilitated by VISTA, that the various VHA national clinical databases and registries obtain most (but not all) ICD-9-CM and CPT codes (Murphy, et al., 2002). Additional clinical data may be acquired from pharmacy, laboratory, admissions (demographic data), and scheduling applications as part of the numerous administrative data files managed by VISTA and summarized in CPRS (Brown et al., 2003; Murphy et al., 2002).

The national patient care database. Supported by VISTA, the National Patient Care Database (NPCD) is a centralized relational Oracle database (Murphy, et al 2002). It receives patient visit information from CPRS from all VHA facilities across the nation, but is not directly accessible by interested parties or researchers. Instead, upon request and approval, data is provided in the form of annual (per fiscal year) SAS datasets that may represent inpatient, outpatient, extended care, inpatient short stay/observation care, and health care provided for veterans outside the VA with VA funding (VIReC, 2012b). Basically, all patients having a health care episode at a VA medical center, hospital, or clinic in a given fiscal year will have their demographic information, location, date, time, and type of health service provided (that is, surgical or CPT code). The type of provider and the purpose of the visit or reason for admission (diagnostic ICD-9-CM codes) are recorded in the database (Murphy et al., 2002; VIReC, 2012b). The information is organized as either inpatient or outpatient (ambulatory care) data files, from which more specific SAS datasets may be extracted (VIReC, 2012b). Common to both data files is demographic information to include age; sex; race; birth date; marital status; city, county, and state of residence; period of military service; and selected special characteristics such as spinal cord injury status, Agent Orange exposure, and service connected disability status (Murphy et al., 2002; VIReC 2012b). Inpatient data includes the patient's admission date, specialty, provider, and facility; their primary diagnosis, patient care data (as indicated by ICD-9-CM codes and diagnosis related groups, CPT codes); and discharge date and type (for example, death or relocation) (Murphy, 2002; VIReC, 2012b). As such, the service provided is indicated by the date, provider/specialty, and associated clinic, while the actual patient care is indicated by ICD-9-CM and CPT codes (Murphy et al., 2002).

Data from the NPCD has been used extensively in VHA medical/clinical research. Examples include a study to determine if race/ethnicity was an independent predictor for dysvascular amputation versus lower limb vascular by-pass procedures (Collins, Johnson, Henderson, Khuri, & Daley, 2002), the clinical utilization patterns of Traumatic Brain Injury patients (Homaifar, Harwood, Wagner, & Brenner, 2009), and psychiatric comorbidities among Veterans diagnosed with epilepsy (Pugh, Zeber, Copeland, Tabares, & Cramer, 2008). Relative to limb loss, Mayfield et al., (2001) published their findings following a solid epidemiological analysis of Veteran patients, to identify factors associated with survival following amputation. The authors identified amputee patients from FY 1992 from the VA Patient Treatment File, a subset of the NPCD. The outcome measure was death with information derived from the Beneficiary Identification and Records Locator System (BIRLS), maintained by the Department of Veteran Affairs (not a VHA data file) (Mayfield et al., 2001). All lower-limb amputations were evaluated—toe (ICD-9-CM 84.11), transmetatarsal (ICD-9-CM 84.12), transtibial (ICD-9-CM 84.13-84.17), and transfemoral (ICD-9-CM 84.18-84.19) (Mayfield, et al., 2001). Comorbid conditions were identified from the ICD-9-CM codes associated with the hospitalization for the amputation and included diabetes, renal disease, and PVD, as well as the presence or absence of congestive heart failure (CHF) (Mayfield et al., 2001). The analysis included descriptive statistics, cross tabulations, frequencies, and the Kaplan-Meier Survival Curve analysis. From these analyses the authors determined that nearly half of all amputations were performed on persons over the age of 65 years, most (60%) were White, nearly all (99%) were male, and most had diabetes (62%) (Mayfield et al., 2001). The primary diagnoses at the time of amputations were cardiovascular disease (23%), CHF (11%), renal failure (9%), cerebrovascular disease (10%), and PVD (56%) (Mayfield et al., 2001). Almost 20% of the persons undergoing transtibial amputation died before discharge, and the three-year mortality rate for all amputations was calculated to be 41.5%, and the five-year mortality rate was 55.5% (Mayfield et al., 2001). Kaplan-Meier curves demonstrated worse survival outcomes with advancing age, proximal amputation level, renal disease, and cardiovascular, cerebral vascular, and PVD (Mayfield et al., 2001).

As can be concluded from the extensive results the authors were able to compile, the NPCD contains a wealth of information suitable for epidemiologic studies to describe and account for amputation. However, as the study utilized data strictly from the NPCD, there was no way to ascertain if patients received an artificial limb following amputation surgery, and, if they did, what type of artificial limb configuration they got, or if that artificial limb contributed to their survival or death.

From the PSP to the national prosthetics patient database. The Prosthetics Software Package/Prosthetics Suspense Program (PSP) (recently upgraded and renamed the OWLS—Orthotic WorkLoad Software) is the Prosthetics and Sensory Aids Service's product accounting and information software packet that runs separately from CPRS. It is supported by VISTA and serves as the interface between the user and administration of prosthetic devices (Werner, 2010; G. W. Bosker CPO, personal communication, January 2011). The Prosthetics Software Package performs all aspects of prosthetics provision, from ordering, to purchasing, to accounting, to reconciliation; allowing for the review of past current and pending provisions (Werner, 2010). It is a necessary tool for, unlike the process in the private sector wherein the patient selects a vendor to supply the assistive devices, which are then billed to Medicare/insurance, the VHA provides the patient with assistive devices, purchasing or renting them using a competitive bid process (G. W. Bosker CPO, personal communication, January 2011). The prosthetics–orthotics service practitioner is responsible for entering product name, type, reason for purchase, and the appropriate HCPCS (billing code, selected from an on-line lexicon) of the device prescribed, allowing for limited interface with the National Prosthetics Patient Database (NPPD), with a collection of tools to facilitate such (Werner, 2010).

NPPD is maintained by the U.S. Veterans Administration Prosthetic and Sensory Aids Service Strategic Healthcare Group (PSAS). Originally developed to oversee and monitor the VA Prosthetic Service, as well as to provide clinicians with information regarding prosthetic prescription practices, the NPPD is a roll-up of all dispensed prosthetic, orthotic, and durable medical equipment data extracted from the local VISTA Prosthetics Suspense Package (PSP) for each VHA facility in the United States (Pape et al., 2001). The database groups' items/devices provided on the basis of HCPCS codes, with subsequent groups being: wheelchairs and accessories, artificial limbs, braces and orthotics, neurosensory aids, oxygen and respiratory, durable medical equipment, and surgical implants (Pape, et al., 2001). There are a total of 25 data fields including visit dates, device provided, reason for visit (provision, repair or replacement), product identification (cost, type, and so forth), and contractor or vendor providing the device (device usage or abandonment is not recorded) (Pape et al, 2001; VIReC, 2012a). The database is maintained at the Austin Information Technology Center, and requested data is transferred as a flat text file or Excel spreadsheet with one record per device purchased and dispensed (VIReC, 2012a).

The NPPD is a relatively new database, having been made available to researchers only since 2001 (Pape et al., 2001). Unfortunately, the quality of the data entry and data extraction process has not been evaluated fully, although significant improvements and greater compatibility were put in place as of 2005 (VIReC, 2012a). The key limitation of this database is its potential lack of reliability and validity in terms of visit dates that should correspond with outpatient encounter dates as indicated by the NPCD. In the study by Mark W. Smith (2010) it was determined that only about 40% to 60% of visit dates in the NPPD could be matched to corresponding outpatient care visits, and only about 10% of related inpatient dates as per Patient Treatment Files from the NPCD. Such discrepancies between the two databases would clearly impact research having to do with the timing of patient response relative to receipt of a device, or when tracking health care delivery practices, but would probably be accurate in regard to an accounting of devices or components dispensed. However, in part due to problems with data validity and reliability, the NPPD has not been exploited to the extent the NPCD data files have, and thus few studies utilize the NPPD database.

Nonetheless, the NPPD has been shown to be valuable when attempting to assess the national distribution of devices, or as a means to understand prescription practices. For example, Hubbard, Fitzgerald, Vogel, Reker, Cooper, & Boninger (2007) used data from the NPPD as an initial step toward devising prescription guidelines for wheelchairs and scooters, hypothesizing that “enhanced prescription guidelines would facilitate more equitable cost distributions of wheelchairs,” while leading to enhanced clinician expertise and more personalized prescriptions (p582). The authors endeavored to determine patterns of wheelchair and scooter provision across the 23 Veteran Integrated Systems Networks (VISN regional offices) to include what primary diagnoses were associated with wheelchairs versus scooters, estimate mean number of devices per Veteran, and the cost per VISN for the provision of devices (Hubbard et al., 2007). Data for fiscal years 2000 and 2001 were extracted from the NPPD, amounting to over 120,000 observations (Hubbard et al., 2007). Although the data were found to have numerous errors suggestive of data entry problems (for example, HCPCS code for manual wheelchair linked with a cost more suitable for a powered wheelchair), the authors were nonetheless able to determine that the most commonly prescribed wheelchair was the standard manual wheelchair (53%) followed by the light rehabilitative manual wheelchair (17%), and then the scooter (13%) (Hubbard et al., 2007). No patterns of relation to age or diagnosis were discerned beyond geographical (by VISN) differences suggesting either over or under prescription between regions (Hubbard et al., 2007). However, without additional clinical information, it is difficult to clearly understand the trends noted. For instance, many times a power wheelchair is prescribed for persons who have developed chronic shoulder pain due to prolonged manual wheelchair use; scooters are frequently prescribed due to patient preference and/or for patients dealing with complications of obesity (D. Barber MD, personal communication, October 2013). Without the addition of ICD-9-CM codes to establish comorbid conditions, it is difficult to ascertain why the prescription patterns noted by the authors actually exist. Finally, while cost was not assumed to be a driving factor behind prescription, but rather was assumed to be an outcome or mere unit of analysis, it would have been interesting to note or look for manufacturer or supplier patterns among VISNs in relation to actual geographical regions (for example, Northwest United States vs. New England; Southwest vs. Midwest United States). The author's conclusion that the differences in prescription trends may have been geographically based begs the question of the impact of regional marketing/sales influence. Regardless, the findings from this study highlight the advantages of linking NPPD data with NPCD patient care data in order to draw more defined inferences, while also demonstrating both the limitations and strengths of using administrative data to research health issues.

In a study that actually linked patient care data from the NPCD with the provision of an artificial limb as indicated by the NPPD data, Kurichi et al., (2007) attempted to identify factors related to lower limb artificial limb provision (transtibial, transfemoral, and hip disarticulation among elderly veterans—specifically what factors seem to drive clinical decisions as to who receives an artificial limb (the artificial limb configuration was not considered. The authors utilized a grouping of patient-related factors available from administrative records into clinically meaningful domains to predict patient outcomes and patterns of artificial limb provision. Specifically, they used the PAQ (Post Amputation Quality-of-life) framework, comprised of 6 domains (socioeconomic status [SES], amputation etiologies, amputation level, co-morbidities, medical acuity, and functional performance outcome status) to explore patient factors, while a simple binomial (yes/no) variable was used to indicate if the patient was provided an artificial limb, as discerned from the NPPD (Kurichi et al., 2007). Utilizing data from FY 2002-2003, the authors combined inpatient and outpatient files from the NPCD to describe the patient's condition, amputation etiology and outcome (discharge or death), ultimately identifying 2,375 Veterans with index amputations (Kurichi et al., 2007). Following multivariate and logistic regression analysis, the authors determined that clinical factors of CHF, neurological disorders, metastasis cancer, PVD, and renal failure are factors most contributory to a patient not being provided an artificial limb (Kurichi et al., 2007). They also ascertained that grouping of variables into relative domains of SES, etiology, co- morbidity, functional, amputation level, and medical acuity (as per the PAQ framework) are all predictive of artificial limb provision (Kurichi et al., 2007).

While this study was very comprehensive in its definition of the patient (in terms of co-morbid conditions) and potential factors driving a clinician's decision to prescribe an artificial limb or not, there are other issues to be considered. Provision does not mean the artificial limb was used, nor does it ensure a well-fitting, properly prescribed artificial limb. The configuration of the artificial limb is not addressed nor the patient's outcome following provision, thereby limiting the ability to ascertain the effectiveness of the clinician's prescription decision.

To Build a Better Database or Not

As has been stated and inferred throughout this review, at the time of this writing there is (a) no systematic means for tracking or monitoring the incidence, prevalence, or health of persons living with limb loss, (b) little literature and/or research on the longitudinal impact of living with limb loss, (c) a low number of systematic studies that directly assess the residual limb's health, and (d) little incentive to conduct clinical trials on artificial limb components, let alone configurations. While the development of a high quality clinical database is one way to address or resolve many of these issues, the development of such would be a very complicated and most likely expensive endeavor, fraught with complications such as universal and standardized outcome measures, decisions as to what constitutes a meaningful measure, and a means to collect unbiased information/data (let alone disseminate it). Given the growing incidence and prevalence of persons living with limb loss, which is expected to reach nearly four million people by 2050, some means of surveillance or monitoring of their condition seems imperative (Ziegler-Graham et al., 2008).

The abundance of administrative healthcare records that are generated regularly by healthcare institutions to include Medicare, private insurance, and state public health programs seems a potential source with which to "build a better database" focused on persons living with limb loss. Obvious advantages of such a database include large numbers of observations, standard measures (that is, ICD-9-CM, CPT, and HCPCS codes), pre-existent data systems, and data unbiased by recall or study design. The VHA comes close to having such a database at hand. By linking patient data from the NPCD (ICD-9-CM, CPT codes and demographics) with artificial limb provision data (HCPCS codes) from the NPPD, what emerges is a framework from which to build a database that addresses many of these issues mentioned as currently lacking—a database from which to derive evidence-based clinical guidelines.

Where's the evidence? Evidence-based medicine became a feature of medical and health care planning in the 1990s, being partly driven by significant advances and accessibility in information technology, to include health informatics (Georgiou et al., 2002). It may be defined as a process using the best evidence to make decisions on care for patients, a process of decision-making that incorporates best practice medicine, external, related scientific evidence, and social, economic, and cultural factors that influence a patient's quality of life, morbidity and mortality (Borg & Sunnerhagen, 2008; Sackett et al., 2007). Within this paradigm, there is an emphasis on the randomized control trial, especially the systematic review of several of such studies or the meta-analyses thereof, due to the belief that a randomized control trial is most likely to promote greater validity and reliability but less bias (Charles et al., 2011; Giacomini, 2009). As such, this methodology has become the gold standard for judging whether a treatment does more good than harm (Sackett et al., 2007). Unfortunately, in the medical practice of prosthetics, and for various reasons, this aspect of evidence-based medicine is lacking.

In a clinical review by Groah, Libin, Lauderdale, Kroll, DeJong, & Hsieh (2009), the authors presented an explanation and review of the dimensions of evidence-based medicine through Knowledge Translation (KT) and into “best practices,” focusing these paradigms on rehabilitation medicine practice and research. They argued that for research in this field, required to embrace a wide variety of outcomes and diverse populations, the exploitation of multiple data sources and study designs is preferable to randomized control trials whose design may not be suitable for a specific question, is frequently applicable only to a specific population and circumstance, and often has limited external generalizability (Groah et al., 2009). Unfortunately, because of the paucity of randomized control trials in rehabilitation medicine, the perception is that rehabilitation research suffers from a lack of methodological rigor and hence, evidence (Groah et al., 2009). The authors explain that the reasons for the lack of "high-quality" randomized control trials in rehabilitation research are multifactorial, but can be aligned with two fundamental issues. First of all, the practice is multidisciplinary such that an intervention is commonly comprised of concurrent numerous treatments (for example, physical and occupational therapy treatments and modalities, pharmacology, procedural interventions, nursing and behavioral interventions, prosthetics, sensory, and mobility aids), making it difficult to design and manage a high-quality randomized control trial (Groah et al., 2009). Secondly, informative randomized control trials are typically most feasible in highly prevalent conditions that allow for large, homogeneous study populations so as to maximize both internal validity and the probability of demonstrating an effect that might otherwise be obscured by broader selection criteria (Groah et al., 2009; Sacket, et al., 2007). In rehabilitation medicine (inclusive of prosthetics), such conditions and patient populations are fairly limited to those with musculoskeletal disorders (for example, fractures and dislocations), chronic pain, joint replacement, and stroke recovery, but the practice also serves low-incidence, heterogeneous populations, such as those with spinal cord injuries, burns, amputation, and many of the neuromuscular conditions such as multiple sclerosis and amyotrophic lateral sclerosis (Groah et al., 2009; Iezzoni, 2004).

Therefore, in order to meet the requirements of the evidence-based medicine and best practices paradigm, Groah, as well as others, suggests a shift toward using newer methodological and statistical design techniques to better accommodate the unique practice and patient population characteristics of rehabilitation medicine and similar specialties (Borg & Sunnerhagen, 2008; Groah et al., 2009; Iezzoni, 2004). More specifically, Groah and colleagues suggest a variant of the prospective observational cohort design (a gold-standard for many epidemiologic health studies) referred to as the practice-based evidence (PBE) model (Groah et al., 2009). The practice-based evidence model basically seeks to systematically categorize patient interventions to determine which interventions are most strongly associated with outcomes, while taking into account a large number of patient characteristics that may be influential (Groah, et al., 2009). The label practice-based evidence is rather self-explanatory as the model/design is focused on actual medical practice. Specifically, hypotheses and inclusion criteria are rather general (with more specific hypotheses being tested as warranted); selection criteria are broad so as to promote generalizability and external validity; and data collected includes patient demographic and socioeconomic variables, co-morbid conditions, and functional status measures that may account for the outcomes observed, and statistically controlled for through multivariate analyses (Groah et al., 2009).

A "proof of concept." The study proposed in this dissertation is clearly aligned with the practice-based evidence model by relying heavily on clinical data such as CPT, ICD-9-CM, and HCPCS codes as independent and dependent variables in a multivariate analysis. Admittedly, a significant difference between the practice-based evidence model and the methodology being proposed in this study is the use of retrospective data acquired from national healthcare databases, as opposed to conducting a prospective observational study with the advantage of direct clinical data, with perhaps greater detail. While it is true that direct information is always better than second-hand or indirect data, for the purposes of identifying trends and patterns for further study, perhaps indirect data that is unbiased in its acquisition is nearly as powerful. However, in the field of prosthetics, and at the crux of this study, such has not been addressed beyond the use of diagnostic and procedural codes to describe patient conditions, and the absence or presence of a prosthetic device (Kurichi et al., 2007) or wheelchair/scooter (Hubbard et al., 2007). Nonetheless, perhaps a more significant hurdle of this proposed study is the reliability of the NPPD. It is a relatively recent national database that has not been fully tested, evaluated, or proven, certainly not to the same extent as the NPCD (VIReC, 2012a; Smith et al., 2010). Therefore, there is a definite possibility that the information to be drawn from the NPPD is insufficient to draw any conclusions or inferences relative to the research questions.

The fact remains, however, that no other database of its nature (artificial limb provision on a national level) exists at present and if any sort of surveillance or monitoring of persons living with limb loss is to be advanced or advocated, it would be highly beneficial to know (a) if such indirect data to represent patient care and residual limb condition is sufficiently meaningful, (b) if residual limb condition is a suitable outcome measure, and (c) if the concept of developing an amputee–artificial limb database is feasible or worthwhile. In other words, the study conducted here was designed as a proof of concept—a concept to be tested and challenged before investing further time, resources, and stakeholders.

The development of the study database/dataset with residual limb condition as a longitudinal outcome measure, and subsequent patterns of artificial limb provision relative to such, served as a challenge to the proof of concept in regard to the actual structure or design of a future database. However, a key component of the concept was its viability as a tool to detect changes in outcome, given conditional input as factors potentially contributing to outcome results.

For this particular study and subsequent dataset, the population (dysvascular amputees) was actually fairly homogenous. All had a transtibial amputation due to dysvascular complications; most were over the age of 50; given the etiology of the amputation, their comorbid conditions (COPD, renal failure, diabetes, congestive heart failure, and so forth) had direct bearing on blood circulation and thus the outcome measure; all were U. S. Veterans enrolled with the VHA and enjoyed the advantages of socialized medicine, to include access to preventive care and the provision of artificial limbs at no or minimal cost. As such, perhaps the more interesting test to the sensitivity of the outcome measure and its relationship to artificial limb configuration was the inclusion of variables more directly associated with a patient's inferred ability to maintain their artificial limb and healthy residual limb.

In keeping with the dataset design and data sources, the factor would need to be one identifiable by diagnosis and/or procedural codes, and not as common among the population as to overwhelm the sensitivity of the outcome measure. Further, it is always beneficial to introduce a factor that will add to the body of knowledge, rather than merely to duplicate or repeat what is already known. For these reasons, the test factor(s)/variable(s) selected represented the mental health status of the amputee, especially because of the dearth of research and literature currently available and its implications toward the long-term success of the amputee utilizing an artificial limb.

Therefore, the following chapter on methodology will provide the details of data acquisition, data manipulations, and plans for analysis, given a study dataset that represented a cohort of Veterans having undergone a transtibial amputation for dysvascular complications. In an effort to assess long-term residual limb outcomes, the cohort was followed for three years following amputation and the comorbid condition of several mental health conditions included in the analysis to assess the influence, if any, on the patient's care of their residual limb (as indicated by outcome).

Chapter 3: Methodology

Background

The purpose of this study was to address the utility of VHA administrative healthcare records to discriminate determinants of residual limb skin outcomes relative to the artificial lower limb configuration prescribed, as a source of information toward the potential development of a suitable amputee-artificial limb database and future surveillance system. The goal and purpose of the study was derived from the fact that the number of persons living with limb loss (specifically that due to dysvascular complications) is estimated to continue to rise over the next decades, reaching an estimated three million individuals by 2050 (Ziegler-Graham et al., 2008). As presented in Chapter 2, the lives of such persons are frequently modulated by factors related to their amputation, ranging from mild discomfort (psychosocial and physical), to impaired or restricted mobility, to significant residual limb complications that lead to reamputation and even death. Some, though not all, of these factors may be attributable to poor or inappropriate artificial limb prescriptions—prescriptions that are not sufficiently tailored to the individual's mental status, physical condition, or realistic capacity (Kurichi et al., 2007; Nelson et al., 2006; van der Linde et al., 2004).

Further, and as also indicated in Chapter 2, prescription of an artificial limb is not a simple matter and is hampered by a lack of quality evidence-based medicine (EBM) literature, clinical trial results, or even surveillance/monitoring system reports, from which to draw conclusions and facilitate decisions (Van der Linde et al., 2004). This lack of substantiated information is, in part, a consequence of the complex nature of the patient/artificial limb interface, relative specificity of the population (compared to more common conditions such as hypertension), and the resources required to conduct research that meets EBM standards (Groah et al., 2009). It is a combination of these factors that led to the second half of the stated study purpose: “exploring the utility of an integrated amputee–artificial limb dataset as a means to fill informational gaps regarding artificial limb prescription and amputee outcome,” and supports the underlying study goal of exploring the feasibility of healthcare administrative data as a source and basis of EBM in the field of prosthetics research.

This chapter describes the research plan, measures, and analyses that were relevant to the goals presented above in a strategy that combined two phases: one grounded in informatics principles, the other in epidemiology. The first phase, “Developing an informatics tool,” focused on the compilation of a cohort study dataset derived from multiple VHA national patient care databases. Given the uniqueness of such a dataset, not only was its quality, validity, or reliability unknown, but so also was its potential value as an informatics tool for the development of artificial limb prescription guidelines or to provide evidence for policy makers. No matter how well or poorly constructed the tool, its potential value, limitations, and weaknesses remain truly unknown until challenged with thoughtful analyses. Such analyses may ascertain its potential value for continued development and refinement, or to determine its demise, before expending limited resources. This strategy, specific to the compiled dataset and epidemiological in structure, formed the basis of the second phase of the study.

At the time of this project, there were no known studies that utilize medical coding to examine the relationships between artificial limb configuration, residual limb conditions, and mental health. Therefore, this seemed worthy of a thoughtful analysis.

The second phase of the study, “An epidemiological study of a cohort of U.S. Veterans with transtibial amputations,” utilized the derived cohort study dataset that included two novel fields: artificial limb configuration (ALC), as the independent variable, and Residual Limb Skin Problem Severity (RLSPS), as the repeated measures dependent variable. These were examined in a series of statistical analyses in a study designed to test the viability of the outcome/dependent variable that was based on medical coding, while addressing significant factors relevant to success with an artificial limb, namely certain mental health conditions and artificial limb configurations. Details of the variables contributing to the epidemiological analysis are presented in the Instrumentation and Materials section of this chapter.

The section entitled Research Design and Approach outlines each phase of the study and presents the primary objective with associated tasks and explanatory background information, thereby representing the logical flow of the overall methodology. Phase 1 focused on the derivation, construction, and description of a dataset as an example of a prosthetics practice-based informatics tool. Phase 2 focused on an epidemiological analysis of the previously defined cohort of U.S. veteran dysvascular transtibial amputees, based on a retrospective observational cohort study design.

While the study methods utilized are not necessarily novel, the derived database is, as is the epidemiological analysis, given its data source and selection of independent-dependent variable focus. For this reason, a level of detail is presented regarding VHA software applications that serve to interface the clinician with the VHA's core information system, VISTA (and ultimately the national databases from which the study dataset was extracted), in order to more clearly explain data and study assumptions and limitations. A fair amount of attention has also been given to matters of data acquisition requirements and data security measures, as such factors are highly relevant to the confidentiality of protected health information of our military veterans.

Ultimately, it is felt that in combination, the two study phases, objective, tasks, analyses, and data quality serve to provide insight into the value of the study model for future investigations, as well as provide an initial evaluation of practice-based evidence relevant to the dysvascular lower limb amputee and their artificial limb prescription.

Research Design and Approach

Overview

Health planners have predicted that over the next 40 years the number of persons living with the loss of a limb will rise from an estimated 2 million in 2007 and increase dramatically to 3.6 million in 2050 (Ziegler-Graham, et al., 2008). Much of this increase in amputations will likely be due to dysvascular conditions, most significantly diabetes and PVD, with a patient population increasing from just under 1 million in 2005 to 2.3 million in 2050 (Ziegler-Graham et al., 2008). For such persons with lower limb amputations and an artificial limb, their success and quality of life is often modulated by residual limb complications; however, little evidence-based research has been conducted to explore this relationship. Without evidence-based outcomes research, this population will and has remained especially vulnerable and at risk of poor quality of life, in conjunction with excessive medical care and costs, subsequent of misguided artificial limb prescription and resultant residual limb breakdown (Collins et al., 2006; Hermodsson & Persson, 1998; Legro et al., 1998; Meulenbelt et al., 2006; Ziegler-Graham et al., 2008).

Achieving the goal of establishing evidence based practices and outcomes based care protocols for this growing patient population requires a thorough assessment of the informatics tools and methods currently available for research. At the time of this writing, there was no reported practiced-based evidence research to support residual limb complications relative to artificial limb components—a status that may be, in part, due to a lack of active surveillance/monitoring of amputees with artificial limbs. Such a practice would facilitate the development of registries or high quality clinical databases (HQCD) and provide direct clinical implications from which to derive prescription guidelines for various populations of amputees (Groah et al., 2009; Black, 1999). Further, the complexity of the patient condition and treatment (the provision of an artificial limb being only one component thereof) renders evidence-based medicine difficult to pursue—

prospective cohort studies are complex and costly, meaningful outcome measures arguable, and randomized control trials veritably infeasible(Borg & Sunnerhagen, 2008; Groah et al., 2009; Iezzoni, 2004). However, in the absence of prospective studies or clinically specific databases, other medical specialties (for example, surgery, endocrinology, and nephrology) have demonstrated the value of healthcare administrative databases that record patient resource utilization, in the form of CPT codes and HCPCS/billing codes, as reliable alternative resources(Boyko et al., 2000; Murphy et al., 2002; Render et al., 2003). Thus, this study explored the value of a compiled and integrated dataset derived from multiple national VHA health care datasets as a means to provide observed practice-based evidence for the ascertainment of relationships specifically relative to the lower limb amputee. What follows is an outline of that process.

Developing an Informatics Tool

The goal of this phase of the study was to derive a viable dataset composed of healthcare administrative data from which to conduct an epidemiological analysis. A compiled dataset was derived from the integration of subsets of the VHA’s NPCD (from which were drawn pertinent patient health status information) with the NPPD (which contained artificial limb components dispensed). Both databases maintain information on the patient level that can be linked by a common variable, ”ScSSN,” the patient’s encrypted Social Security Number, that is consistent throughout most VHA national databases (VIReC, 2012b). The study dataset ultimately represented a cohort of United States veterans having undergone a dysvascular transtibial amputation during FY 2007, selected clinical and demographic variables of interests from that time through FY 2010 (or death or loss) and included the artificial limb configuration (socket suspension system and prosthetic foot combination) they were dispensed. From such a dataset, it was possible to identify patterns of artificial limb prescription/disbursement relative to patient clinical conditions and, in particular, RLSPS following disbursement and concurrent with certain psychosocial conditions (the second phase of the study).

Aim 1. Integration of the multiple subsets. The first aim of this study was to compile and integrate multiple subsets of the VHA's NPCD and NPPD, that would represent a cohort of veterans' health statuses from the time of their amputation surgery in FY 2007, to the date they were dispensed a definitive artificial limb (to include identification of artificial limb components and configuration), and up to 3 years thereafter. To accomplish this, the following tasks were performed:

- Task 1.1 Data acquisition—The NPCD is the VHA's centralized relational database that receives patient encounter data from the VHA's, CPRS. It is an Oracle database that has been maintained at the Austin Information Technology Center (AITC) on a UNIX platform (VIReC, 2012b). Therefore, data is not accessible directly from the mainframe, but rather, upon approval and the establishment of an account, is provided as medical SAS datasets per fiscal year and preferred data file extract (see section entitled Setting and Sample). Approval requires an approved IRB protocol, VA Research and Development Service Subcommittee approval, Office of Information Security approval, and application through the on-line Data Access Request Tracker (VIReC, 2012b). Inpatient and outpatient medical SAS datasheets for fiscal years 2007 through 2010 were retrieved from the AITC and stored on a South Texas Veterans Health Care System (STVHCS) secure server for further manipulation. NPPD data are under the stewardship of the VHA's Office of Patient Care Services (PCS). Data are available for use in IRB-approved research studies and are provided as an Excel worksheet or flat text file extract (VIReC, 2012a). Data requests require submission of the PCS Data Transfer Agreement Request Form and associated documentation to include proof of IRB and VA Research and Development Subcommittee approval, certification of VA data security training, and employment status (VIReC, 2012a). Flat text files extracts for FY 2007 through 2010 were stored on a STVHCS secure server for further manipulation.

- Task 1.2 Compile/construct dataset (identify the cohort)—In-patient FY 2007 medical SAS datasets were examined and all cases with ICD-9, CPT and/or surgical codes for transtibial amputation and a diagnosis code for diabetes mellitus, PAD, or PVD were extracted to include available demographic data. The extracted data formed the initial study dataset/cohort. Text file extracts from the NPPD were then searched for cases having the same ScSSn as those identified above, with HCPCS codes indicative of a dispensed definitive artificial lower limb, as well as the date the limb was dispensed. The identified information was then extracted and linked to the initial study dataset by ScSSn. Finally, representing the follow-up period, data from the NPCD outpatient encounter and event datasets, per matched ScSSN and subsequent of the definitive artificial limb provision date, procedural codes (V-codes and CPT codes), diagnosis codes (ICD-9-CM codes) and associated visit dates were extracted from datasets representing FY 2007 through 2010. Diagnosis codes representative of skin conditions such as rashes, ulcering, blistering, allergic responses, or cysts/tumors, coexistent with V-codes or CPT codes indicative of residual limb treatment, were linked to the cohort study dataset under development, and used to define the outcome variable RLSPS. Similarly, dates and diagnosis codes for MDD, PTSD and SUD, were identified and used as psychosocial covariates, while dates and diagnosis codes for cerebral vascular disease (CVD), chronic obstructive pulmonary disease (COPD), obesity, renal failure, and congestive heart failure (CHF), were also identified and served as explanatory variables in the epidemiological analysis of the dataset (phase II). Further, dates and diagnosis and procedural codes representative of residual limb revision and/or lower extremity amputation, as well as discharge status (specifically death), were extracted from the NPCD Inpatient Surgical and Main medical SAS datasets (FY 2007–FY 2010) and served to calculate cohort mortality rates and serious outcomes. The specific codes for which a search was conducted are listed in Table B27 in Appendix B – Data dictionary.

- Task 1.3 Assess, describe and “clean” the study cohort dataset—Per fiscal year, the study dataset was searched for nonsensical, superfluous, or missing data, which was corrected or deleted depending on circumstances and best judgment. Rules for data cleaning were devised accordingly and applied to subsequent fiscal year extracts prior to compilation of the entire cohort dataset. A data dictionary of the dataset was devised providing variable names, definitions, and characteristics such as data types (date fields, categorical, binomial, continuous), data format restrictions (that is, 1 = “yes”, 0 = “no”; date = mmddyy, and so forth), rules used to extract necessary data, and any variable labels to facilitate data manipulations and statistical analyses. Included in this data dictionary were new variables to represent ALC categories (based on groupings of HCPCS codes) and RLSPS categories (based on CPT, ICD-9-CM and DRG codes), as well as the rules or algorithms used to define the variables. Figure 1 provides a schematic of the derivation of the study cohort dataset.

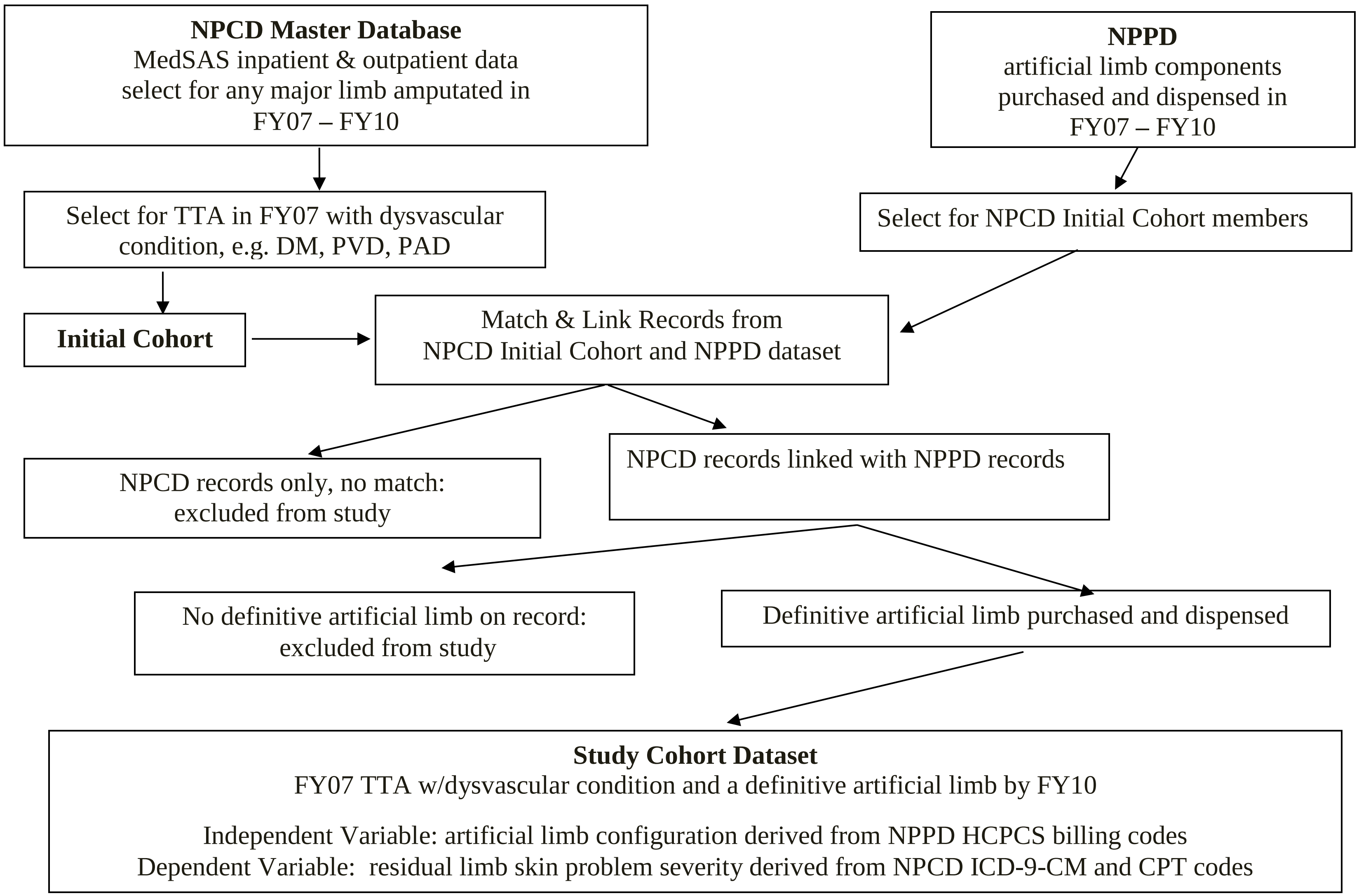

Figure 1. Derivation of study cohort dataset from NPCD and NPPD databases

Aim 2. Independent and dependent variables. The second aim of this study was to categorize the independent variable ALC and define the dependent variable RLSPS. These are described as two separate tasks:

- Task 2.1 from the cohort dataset, a categorical variable was derived to represent ALC. As described above, the NPPD was the source for ALD descriptions in the form of HCPCS codes, item descriptions and costs. Device transactions were categorized as a first time issue, a repair, or a replacement. Additionally, there was a specific HCPCS code for the definitive artificial limb (HCPCS L5301 definitive endoskeletal prosthesis) which, when present, defined the ALC to be used for the study. In some cases, the so-called "temporary prosthesis" that is prescribed and dispensed for an individual, may actually be their "definitive" prosthetic limb configuration and only the socket will be modified as the residual limb matures. In such cases, the L5301 code may be used in conjunction with an HCPCS code for a new or modified socket and it was the date corresponding with the dispensing of such a socket that was used to begin the "follow-up" assessment of the patient. Initially, frequencies per fiscal year were run on the study dataset for the various HCPCS codes associated with the known types of suspension systems and prosthetic feet, separately and in combination, to ascertain the most common components and potential configurations dispensed. From this initial pass, an algorithm for categorizing the ALC was determined, an example of which is described under the section Instrumentation and Materials. The rules defining the algorithm and categorization of the ALC were entered into the data dictionary (Appendix B).

- Task 2.2 Define the dependent (outcome) variable: RLSPS—Similar to the independent variable, the actual algorithm to be used to define the dependent variable was determined following an initial assessment of the study dataset per FY 2007 through 2010. The focus of the assessment was on the frequency or numbers of residual limb ulcerations and infections identified for the cohort relative to the frequency of other skin conditions such as rashes, blisters, calluses and cysts; and as identified by their corresponding diagnosis, procedural codes or combinations thereof. Severe and less severe residual limb skin problems were further categorized on the basis of an etiological classification suggested by Bui et al., (2009). Ulcers and infection are a tipping point for the individual utilizing an artificial limb—ulceration is typically associated with significant stress at the interface of the socket and residual limb and frequently requires that the individual not utilize the artificial limb until the ulcer has healed—a major impact on quality of life (G. W. Bosker CPO, personal communication, January 2011). Further, when the ulcer is compounded by infection, the risk of surgical revision and/or sepsis may be increased (Salawu, Middleton, Gilbertson, Kodavali, et al., 2006; DePalma et al., 2006). Rashes, blisters, calluses, and cysts are frequently treated with topical agents, may be mildly uncomfortable, but rarely are life or limb threatening; and although artificial limb use may be restricted, typically not for more than a day or two (ulcers may result in restricted usage for weeks and even months) (G. W. Bosker CPO, personal communication, January 2011). An example of a potential algorithm for this variable is presented in the section Instrumentation and Materials. The rules and algorithm ultimately used were entered into the data dictionary for the study dataset (Appendix B).

Epidemiological Analysis

Recommendations for improving the analytical usefulness of informatics methods and tools are key, but require initial evaluations to identify potential weaknesses and limitations. Therefore, the study included a retrospective observational cohort study design and subsequent analysis of the compiled dataset, utilizing patient demographics and extensive clinical histories in the form of medical, clinical, and billing codes, contained therein. The focus of this phase of the study was limited to the ascertainment of the relationships between artificial limb configurations dispensed, diagnosed psychosocial conditions (for example, depression, alcohol/substance abuse, PTSD), and the severity of long-term (up to three years) residual limb complications, for the cohort of Veteran amputees. Subsequently, this study attempted to address aspects of residual limb outcomes, subsequent of the artificial limb (mechanical)–human (behavioral/psychosocial) interaction at the socket-residual limb interface. Mechanical factors were those in which skin problems were considered the consequence of continued biomechanical forces (for example, friction, pressure, and torque) acting on traumatized skin tissue, and thus pertained primarily to the artificial limb configuration utilized

(DeLisa & Kerrigan, 1998; DePalma et al., 2002). Behavioral factors were those in which a similar exacerbation existed, but was driven by the actions of the user (for example, poor self-care or disease management, activity/ambulation level, treatment non-compliance) theorized to be consequent of the biopsychosocial paradigm and demonstrated by outcomes in association with diagnoses of MDD, PTSD, and SUD (Engel, 1977; Hanley et al., 2004; The Management of MDD Working Group, 2009; The Management of Post-Traumatic Stress Working Group, 2010; The Management of SUD Work Group, 2009; Zinszer et al., 2011)

Primary Objective. Statistical analysis of the dataset and multivariate model development. The primary objective of the study (Phase II) was the statistical analysis of the refined study dataset and identification of the patterns and trends of the cohort in regard to artificial limb provision and subsequent residual limb skin problems. Two specific tasks for this objective were endeavored, one focused on defining the parameters of the cohort data, and the other on determining relationships between ALC categories dispensed, subsequent residual limb skin problem outcome severity, and the implications of psychosocial, mechanical, and certain demographic factors on such outcomes. The aims and tasks are as follows:

- Aim 3.1 Descriptive analysis of the study dataset—In an effort to define the dataset's parameters, frequencies and percentages were calculated to include proportion of the initial population study sample (new transtibial dysvascular amputations in FY 2007) that did not receive an artificial limb, cohort mortality rates at 1 and 3 years post-amputation, frequencies of residual limb problems, and percentages of types of socket suspension systems, prosthetic feet and artificial limb configurations dispensed. Additionally the distribution of cohort members nationally as per Veterans Integrated Service Network (VISN) were determined, along with the types of artificial limb configurations and components dispensed. Finally, the demographic characteristics of the cohort were defined—for example, race, marital status, mean age, Veteran's priority status, and so forth.

- Aim 3.2 Development of multivariate models—To evaluate the interactions between the independent variable ALC, dependent variable RLSPS, and psychosocial covariates, General Estimating Equations (GEE) multivariate modeling was used to address most of the research questions. Two main reasons drove the preference for GEE over General Linear Modeling (GLM): (a) the dependent variable was non-continuous with a Poisson distribution, and (b) it was not necessarily linearly linked to the independent/predictor variable, in part due to covariate confounding (Garson, 2008, 2011a). Poisson distribution of the dependent variable was expected because the dependent variable is actually a count of diagnosis or procedure codes per the given number of time units (3 year follow-up in 6 month intervals), and because the "non-occurrence" of such codes cannot be counted because a code is not removed when no longer applicable, but typically remains until a new diagnosis is made or procedure performed (Garson, 2011b). Also it was expected to be censored data during the follow-up period, given the relatively high 3 year mortality rate associated with dysvascular amputations (Dillingham & Pezzin, 2008;Dillingham et al., 2005; Mayfield et al., 2001).

Specific research questions and hypotheses (discussed herein) addressed mechanical and behavioral main effects as well as their interactions relative to RLSPS medical coding as an outcome, and investigation of the implications of mental health status on those outcomes. As such, the primary statistic of interest was statistical significance of likelihood rather than odds ratios, and tested the sensitivity of the dependent variable relative to different ALC while under the influence of mental health disorders and physiological co-morbid conditions. Mental health disorders (or diagnoses) were considered suggestive of behavioral influences such as non-compliance and poor disease self-management, and physiological co-morbid conditions as suggestive of decreased activity levels. Thus, at the completion of the study, two key and interrelated goals were accomplished: (a) insights into the potential of the methodology as a tool to be used as an alternative to the conduction of randomized control trials or prospective observational cohort studies in the field of prosthetics evidence-based research, and (b) an initial, objective, practice-based ascertainment of the implications of conditions of mental health and artificial limb prescriptions, on residual limb outcomes.

Setting and Sample

Data Sources

The dates selected for the cohort and analysis were selected on the basis of several factors. Firstly, in 2005 the NPPD underwent significant upgrades to include structural changes, consequent of data quality checks and limited data validation studies (VIReC, 2012a; Smith et al., 2012). It was felt prudent to acquire data from this database at least one year post the upgrades to avoid problems with unstable data and acquisition time constraints. Secondly, near the end of FY2011 (September 30, 2011), the VHA initiated an archive data transfer from Oracle/Unix based platforms utilized at the Austin Information & Technology Center (AITC) to a national Corporate Data Warehouse system VIReC, 2012a. To avoid issues of timely and accurate data acquisition and potential data destabilization, it was felt prudent to acquire data prior to the national transfer. Thirdly, within these two time constraints, two other factors were given consideration: (a) following surgery, it may take a given patient between 6 and 12 months for full rehabilitation potential to be achieved and the fitting of a definitive prosthesis. Many of the factors driving this outcome were discussed in Chapter 2 and include age, co morbid conditions, surgical outcomes, and stabilization of the residual limb (DePalma et al., 2002; Kurichi et al., 2007). (b) Also as presented in Chapter 2, an amputee with a definitive artificial limb will require a new prosthetic socket or artificial limb approximately every 3 to 5 years, again depending on factors such as health status and activity levels (Nair et al., 2008). Thus, based on these criteria and constraints, in order to contiguously follow a cohort of veterans who undergo a major limb amputation one year, require as much as one year before being dispensed a definitive artificial limb, and then followed for approximately 3 years thereafter, preferably using the same artificial limb, it was determined that data should be collected beginning at the start of FY 2007 (October 1, 2006) through the end of FY 2010 (September 30, 2010)

Further, it was an overarching goal of the study to address the utility of VHA AHc records to discriminate determinants of residual limb skin outcomes relative to the artificial lower limb configuration prescribed, as well as the suitability of such data toward the potential development of a viable amputee-artificial limb database and future surveillance system (refer to Chapter 1, Nature of the Study.). Therefore, both in preparation of this study and future analyses, a request to acquire the describe datasets was initiated following the University of Texas Health Science Center at San Antonio (UTHSCSA) IRB and STVHCS – Audie Murphy Research Subcommittee approval of a protocol entitled "Practice based evidence on major limb amputation and artificial limb prescription in a cohort of U.S. Veterans", protocol number HSC20120047H, approved on November 14, 2011. Following this approval, the acquisition process for the NPC was initiated in Mid December 2011, access approved in March 2012, and data acquired in May 2012. The process for retrieving data from the NPPD was initiated in mid – December 2011, the application packet submitted Jan 19, 2012, approval received May 10, 2012, and the data received on November 20, 2012. In combination, these datasets formed a master dataset and the data/cohort being analyzed for this study were a subgroup (dysvascular below-knee amputees) thereof. It is anticipated that the methodology described within this proposal will be used to drive future studies and analyses of similar cohorts within the master dataset (for example, a cohort of upper limb amputees, above knee traumatic amputees, or above knee dysvascular amputees). The master data set was stored on a South Texas Veterans health Care System Research Service secure server under the oversight of the Veterans Evidence-based Research Dissemination and implementation Center (VERDICT) research group.

The National Patient Care Database (NPCD). The NPCD is a centralized relational database. It receives patient visit information from the VHA's electronic medical record system, CPRS, from all VHA facilities across the nation (Murphy et al., 2002; Boyko et al., 2000). Requested data is provided in the form of annual (per fiscal year) SAS datasets and those available include: inpatient, outpatient, extended care, inpatient short stay/observation care, and health care provided for Veterans outside the VA with VA funding (VIReC, 2012b). For this study, SAS datasets specific to inpatient and outpatient care were utilized. The inpatient and outpatient care datasets are patient-specific, and thus lend themselves to be searchable by any variable (VIReC, 2012b).

The inpatient care dataset is further divided into four files: Inpatient Main, Surgical, Bed Section, and Procedure (VIReC, 2012b). Only the Bed section file was not explored as the primary reason for examining inpatient data was to identify the cohort as of FY 2007. Inpatient variables of interest included: age, gender, race, marital status, Veteran priority status (a proxy for Socioeconomic status; described further under the section Instrumentation and Materials); admission date with primary diagnosis (ICD-9-CM code); type of discharge (for example, regular or death); date and surgical procedure (as designated by ICD-9-CM and/or Diagnosis-Related Group (DRG code); and relevant procedures (CPT codes) provided during an inpatient stay (VA Information Resource Center [VAReC], 2011b)

The outpatient care dataset is further divided into two files: outpatient visits and event files. Outpatient visit files represent “One day's occasions of service for an outpatient,” while event files represent “One ambulatory encounter by a patient” (VIReC, 2012b). A third data file was extracted—inpatient encounter files—that represent an inpatient’s clinical visits for outpatient procedures and diagnostics while designated as in acute care, extended care, observation care, or non-VA care status (VIReC, 2012b). It was anticipated that some amputees, particularly those in extended or observational care not directly related to their amputation, would still require wound care or attend clinics where residual limb skin problems were diagnosed and treated. Therefore, all three data files were extracted from the NPCD, and outpatient data searches were focused on procedures related to residual limb conditions/care, skin problem diagnosis codes, and mental health diagnosis codes. The actual codes searched for are presented in Tables S4-B17 in Appendix B - Data Dictionary, and event outpatient files were the primary source of such information, as they include date and time of visit, associated CPT and ICD-9-CM codes, as well as the type of clinic location where care was provided (VA

Information Resource Center [VAReC], 2011a). The actual data fields where these codes were found are presented in Table B27 in Appendix B - Data Dictionary.

The National Prosthetic Patient Database (NPPD). Maintained by the U.S. Veterans Administration Prosthetic and Sensory Aids Service Strategic Health Care Group, the NPPD is written in MS Access with one record per device transaction. It is a roll-up of all prosthetic data extracted from the local VISTA Prosthetics Suspense Package (PSP) for each VHA facility in the United States (VIReC, 2012a). The database group items/devices provided on the basis of HCPCS codes. The subsequent groups include: wheelchairs and accessories; artificial limbs; braces and orthotics; neurosensory aids; oxygen and respiratory; durable medical equipment; and surgical implants (VIReC, 2012a). There are a total of 41 data fields (14 are for Service internal use only and are unavailable to researchers) and are presented in Table B28, Appendix B – Data Dictionary. Data is transferred either as a flat text file or Excel spreadsheet, and permission from the Prosthetics and Sensory Aids Service (Patient Care Service) must be acquired prior to transfer to a secure VA server (VIReC, 2012a).

The NPPD is a relatively new database having been made available to researchers only since 2000. Unfortunately, the quality of the data entry and data extraction process has not been evaluated fully, although significant improvements and greater compatibility were put in place as of 2005 (VIReC, 2012a; smith et al., 2010). The key limitation of this database is its reliability and validity in terms of visit dates that should correspond with outpatient encounter dates as indicated by the NPCD. In a study by Mark W. Smith

(2010) it was determined that only about 40% to 60% of visit dates in the NPPD could be matched to corresponding outpatient care visits and only about 10% of related inpatient dates, within a 14-day window (M. W. Smith et al., 2010). However, given the nature of this study, such incongruences were not considered critical as the purposes of the NPPD were to (a) identify those individual's dispensed an artificial limb and (b) identify what components comprised that artificial limb. There was no need or real purpose to match dates the artificial limb was dispensed with outpatient clinic dates – it was only after the artificial limb was dispensed that a patient's residual limb status became noteworthy. Further, it was highly unlikely that an artificial limb would be dispensed if the patient had any evidence of a residual limb skin problem beyond scarring (G. W. Bosker CPO, personal communication, January 2011). Other aspects as to the reliability and validity of HCPCS coding, costs, and item descriptions have not been evaluated or at least not reported.

Sample Population (Cohort Criteria) and Sample Size

From the FY 2007 NPCD Inpatient Surgical and Procedure datasets, Patients having undergone a transtibial amputation for dysvascular reasons were extracted to include their Subject identification number (encrypted social security number), date of admission, date of discharge and discharge status. Dysvascular transtibial amputees were identified as those with an ICD-9-CM code for diabetes mellitus (250-250.99), PAD (443-443.9) or atherosclerosis of the extremities (440.20-440.29, 440.9); in conjunction with the CPT code for amputate lower leg at knee (27598). On the basis of the encrypted

Social Security Number, these same patients were extracted from the NPCD Inpatient main dataset to retrieve pertinent demographic data including age, gender, marital status, Means Test score, and race at time of admission. This then formed the initial cohort.

On the basis of matching encrypted Social Security Numbers, from the FY 2007, 2008, 2009, 2010 NPPD, any members of the cohort having been provided a definitive artificial limb were identified, as well as the associated HCPCS codes specific to the limb's socket suspension system and prosthetic foot, date dispensed, and facility/VISN that delivered the artificial limb. While the various components that comprise the total artificial limb may have multiple HCPCS (billing codes), a definitive/permanent lower limb prosthesis has a single specific and identifiable code: L5301 (G. W. Bosker CPO, personal communication, January 2011).

Table B26 in Appendix B – Data Dictionary, presents HCPCS codes of interest. Only those cohort members that received a definitive artificial limb (the independent variable) were followed through FY 2010, the remaining accounted for through discharge status (that is, death or transfer to hospice) as of FY 2010 and recorded in the NPCD main file. For a diagrammatic summary of the derivation of the study cohort dataset, refer to Figure 1.

Despite being a fixed dataset, the actual number of cases and variables were unknown, being dependent on the number of individuals meeting the cohort inclusion criteria, being dispensed an artificial limb, and having follow-up residual limb care visits. Nonetheless, in a search of the FY 2009 NPCD inpatient records, over 2,321 above-knee and below-knee new amputations were identified (report by L. Copeland, PhD; (see Appendix A). It was therefore anticipated, given the comparative incidence of transtibial dysvascular amputations relative to transfemoral and traumatic transtibial amputations (ratio of transtibial to transfemoral is 2:1; 75% due to dysvascular complications (Mayfield et al., 2000), the initial cohort identified in FY 2007 would number approximately 1,161 cases. Of these, based on a 30-day mortality rate of 7% and an estimated 20% of cases dying before discharge, it was anticipated that about 929 cohort members would be identified that met initial inclusion criteria (new transtibial amputation, dysvascular comorbidity, eligible for artificial limb use). However, the number of cohort members that would be dispensed a definitive artificial limb was unknown. The literature suggested that approximately 50% of older dysvascular amputees actually use an artificial limb for walking, suggesting that an estimated 464 members of the initial cohort would be dispensed an artificial limb and available for long-term follow-up (Dillingham & Pezzin, 2008; Fletcher et al., 2002). However, for dysvascular transtibial amputees, Dillingham and colleagues reported a 3 year mortality rate of 33% in 1996, suggesting that an estimated 311 cohort members would be available for the duration of the follow-up period (Dillingham et al., 2005). Alternatively, as the mortality rate reported was not specific to those amputees healthy enough to be prescribed an artificial limb, and medical (specifically diabetes control and management) and surgical advances have likely improved the survival rates over the past decade, a 3 year mortality/attrition rate of 20% may be more appropriate (suggesting 371 cohort members). Thus, it was conservatively estimated that the actual sample size for follow-up would range between 300 and 400 cohort members.

Power Analysis

For most researchers, the challenge is being able to detect a true significant effect, while balancing type I and type II errors in the face of limited resources, ethical considerations, and optimal effects. Too small a sample expose research findings to type II errors due to insufficient power. Too large a sample incurs unnecessary expense for the research project and may reveal trivial significant differences that may cloud data interpretation (Garson, 2011b). Whereas in most a priori power analyses the intent is to estimate the sample size required to attain a given power (for example 80% at an alpha of 0.05) and thereby maximize the effective use of resources, in the case of a fixed dataset, the purpose is more to ascertain what power can be attained given the sample size available—the smaller the effect size (difference) from the null hypothesis value of the dependent variable, the more likely the type II error, and thus the lower the power for a given sample size (Garson, 2011b).

As described under “Research Approach,” this study was exploratory in nature with a dual intent (that is, to develop a novel database and test its viability with an epidemiological analysis), and utilized a retrospective observational cohort study design. Thus the limitations associated with a fixed sample size applied to this study’s potential power and statistical significance or relevance. As such, as presented in Chapter 2, there is little to no literature that actually quantifies residual limb skin problems among a population (the repeated measure dependent variable), and thus no source from which to estimate variance or an anticipated effect size. At best, a study by Dudek and colleagues (2005) indicated that nearly 50% of the study population demonstrated at least one residual limb skin problem, of which 27% were ulcers, and the remaining 73% were comprised of various “less severe” conditions, but the actual variance in the frequency of these conditions were not reported (Dudek et al., 2005). Similarly, there were no identified studies that report the incidence of residual limb skin problems relative to artificial limb components, although the aforementioned study by Dudeck and colleagues did report no significant difference in the incidence of at least one skin problem among the socket types and suspension systems used (Dudek et al., 2005). Further, there were no identified studies that accounted for the frequency of residual skin problems over time to suggest normal distribution thereof such that a Poisson distribution of the outcome measure was projected and, given the unknown magnitude of effect size, example response rate ratios of 15%, 20%, 25%, and 30% were used a priori to estimate power (actual effect sizes were calculated post hoc on the basis of parameter confidence intervals) (Garson, 2011b).

Additionally, research questions 1 through 4 utilized one or more factors, both singularly and interactively, that ranged in levels from five (the anticipated number of artificial limb configurations that could actually range between 3 and 12 configuration types) to three (conditions of mental health), with outcomes potentially not influenced by covariates. Thus, because of the complexity of the analysis required to address the overall goal and purpose of this study having multiple research questions and hypotheses that utilize the same fixed sample/cohort, a power analysis was performed based on a Mixed Model analysis and a single factor with five levels (likely the maximum number of factor levels for an independent variable used for any of the sub-analyses).

Table 5 presents sample size and power calculations using the parameters described above. The software power analysis and sample size system (PASS) (NCSS, Kaysville, Utah) was used to perform the calculations and derive the values as presented, based on the following equation:

$$N = \emptyset \frac{(Z_{1-\alpha/2}\sqrt{V(b_1|\beta_1 = 0)}+Z_{1-\beta}\sqrt{V(b_1|\beta_1 = B1)})^2}{\mu_r e^{\beta_0} B1^2}$$

where α is type I error, β is type II error, B1 when X_1 is the only covariate of interest, N is sample size, ∅ is a measure of over-dispersion, μ_r is the mean exposure time and Z is the standard normal deviate.

In summary, it can be stated that a Poisson distribution of the repeated measure, catergorical dependent variable (RLSPS) from a three-year observational study of an initial cohort of dysvascular below-knee amputees dispensed an ALC category (the independent variable having five levels), a total sample size of 384 subjects (assuming a 20% attrition rate) would be required to achieve 80% power at a significant level of 0.05 and detect a response rate ratio of at least 20% for a two-sided test.

Table 5

Power Analysis Results

Response rate ratio	Unadjusted sample size (N)	Adjusted (20% attrition) sample size	Adjusted sample size per factor level
15%	526	658	132
20%	370	384	77
25%	204	255	51
30%	147	184	37

Data Assumptions

Two primary assumptions were maintained throughout this study analysis: (a) that the data provided and used for analysis was reliable and valid, and (b) that the prosthetic socket provided to the Veteran amputee was of good quality.

Coding assumptions. Health care coding used in most administrative databases (for example, ICD-9-CM, CPT, HCPCS codes) are prone to random and systematic error resultant of physician judgment, communication failures, and/or coding procedures (O'Malley et al., 2005). Therefore, they may not reflect precisely a disease condition or appropriate treatment procedure. However, the VHA, through its dependence on the VISTA and electronic medical record system (CPRS), has taken significant steps to reduce this potential for error. Data that comprise both the NPCD and NPPD are derived from roll-up applications from all VISNs, of which there are 23 across the nation. Each VISN receives data from various facilities under its direction, and each facility is responsible for compiling and maintaining its own administrative records (Murphy, et al., 2002). In particular, CPRS, the electronic medical record system utilized by the VHA, has features specific to each VISN, although the data features and dictionary are standardized across VISNs (Murphy, et al., 2002; Brown, et al., 2003).

At the time of the patient "encounter" or visit, the physician is responsible for selecting the appropriate CPT code(s) from selection boxes. This information goes directly into the facility's administrative database and is not edited but rather reviewed by coders (Szeto, Coleman, Gholami, Hoffman, & Goldstein, 2002). Ultimately, diagnostic codes or many ICD-9-CM codes are edited by professional coders, although the physician selected the code from another selection box as part of their clinical/medical note. In both cases, procedural or diagnostic codes may have been poorly selected, although the code values accurate because they are derived from selection boxes and thus, have inherent data controls applied.

Similarly, the NPPD is a roll-up of fields from the Prosthetics Software Package (PSP). They are integrated through an exchange of data. For every patient encounter with the Prosthetics–Orthotics service, there is an accounting of that visit via various menus and associated electronic forms, including one for purchasing prosthetic devices (Werner, 2010). The software application provides lists of “items” (device model and make), as well as edit fields to provide additional information for the vendor, including a specific model or type. To record a transaction, the practitioner selects the status of the device (initial, repair, replacement, or spare) as well as the corresponding HCPCS code that is provided based on the item selection (Werner, 2010). Most entries have lists from which to select a response and thus there is inherent data control and accuracy. With such controls to minimize communication and systematic error, one can only assume that, for both CPRS and PSP, the selection made by the practitioner was correct and appropriate. As this study used de-identified data, it was not possible to ascertain the correctness of coding selection (ICD-9-CM, CPT, OR HCPCS codes) against patient chart records and thus accuracy could only be assumed.

Socket craftsmanship. The skill of the prosthetist is in their choice of socket design, hand-crafting of the socket or mastery of Computer Aided Design/Computer Aided Manufacture (CAD/CAM) socket software and hardware; fitting the socket to the patient's residual limb; configuring the artificial limb; and aligning the components (G. W. Bosker CPO, personal communication, January 2011). Within the VHA system, prosthetists must be certified (thus it is assumed that they are properly trained and knowledgeable), but as discussed in Chapter 2, their level of experience and skill may vary. Nonetheless, a key assumption regarding the artificial limb configurations being analyzed in this study was that the socket was fitted properly to the patient's residual limb, and it is the configuration and design of the artificial limb, not merely the fit of the socket, that was responsible for the "mechanical effects."

Data Limitations

The outcome variable, RLSPS, was based on the presence or absence of certain ICD-9 codes recorded during a cohort member's visit to a VHA facility and treatment by a clinician. Therefore, those conditions or incidents that are treated and managed by the patient outside the VHA clinic were not captured. Typically, as part of their artificial limb training and rehab, patients are taught how to recognize and treat certain minor conditions, to include rashes and blisters, without clinical intervention (G. W. Bosker, CPO, personal communication, January 2011; The Rehabilitation of Lower Limb Amputation Working Group, 2007). Therefore, the measure of residual limb skin problems in this study may be skewed toward the more severe conditions and/or not register the true incidence of “less severe” conditions that any one cohort member may have experienced.

Finally, as discussed in Chapter 2, the gold standard for evidence based medicine (EBM) is a randomized controlled trial, a format not easily adhered to in the field of rehabilitation medicine, and a key reason for the observational practice-based evidence /cohort design of the study (Groah et al., 2009).

Instrumentation and Materials

Data Files and Variables

Given that the data for this study was derived from VHA repository data, no specific instrumentation or tools were required to collect the data other than administrative permissions and PCL (Program Control Language) coding necessary to transmit specified data from the VHA’s repository site (the Austin Information Technology Center (AITC) to a local secure server for further data manipulation and analysis. For this study, a master dataset containing the required cohort data was previously transferred to reside on a South Texas Veterans Health Care System Research Service secure server behind the VA firewall, accessible only with an appropriate user name and password directly via VISN17 VISTA network, or by an approved VPN from outside the VA network. Data was stored on the server as Excel workbook or SAS datasheets. The UTHSCSA IRB provided the necessary approval letter to acquire the data. Most data management and manipulations, to include statistical analyses, was performed using SAS software (Scientific Analysis Systems, SAS Institute, North Carolina, USA) also situated behind the VA firewall on a secure server, or on a personal computer with data access available only through an approved VPN and PC configuration.

Residual limb skin problem severity. The primary dependent variable for the epidemiological phase of the study was categorical representing three primary groups of residual limb skin problems that a cohort member may develop after being dispensed their definitive artificial limb: severe (skin ulcers and infections), less severe (calluses, blisters, rashes) and no treatment. It was felt that such a division was warranted on the basis of several factors: (a) an individual with a dysvascular condition such as Diabetes Mellitus not only suffers from a compromised immune system, but also struggles with poor healing capacity, making skin ulcers and skin infection particularly problematic and even life-threatening; (b) under most conditions, an ulcer of the residual limb requires that the individual not use, or minimize the use of, their artificial limb for the duration of the healing process which, for many, may take weeks and even months, (c) most of the “less severe” problems are treated with a topical agent and require only reduced use of their artificial limb, and typically are not life-threatening. However, ulcers and infection frequently do not occur in isolation—blisters may evolve into ulcers or serious infection, an ulcer may be present on one area of the residual limb and a rash may be present on another, or a rash may be sign of deeper infection (Osteomyelitis). Therefore, in those cases where an ulcer or infection was present, as well as a so-called “less severe” condition, such was classified as severe. The presence of a residual limb ulcer and/or infection of the residual limb places the artificial limb user at significantly higher risk of surgical revision, reamputation, or death more so than do the other skin problems, although the frequency of the less severe problems pose significant problems as well (DeLisa & Kerrigan, 1998; G. W. Bosker, CPO, personal communication, January 2011).While both conditions impact the amputee’s quality of life, ascertaining which condition more profoundly does so was beyond the scope of this study.

For those cohort members dispensed an artificial limb, the study dataset was searched for relevant codes at 6 month intervals during the follow-up period, amounting to six repeated measures for analysis. Representative codes for the RLSPS categories - less severe residual limb skin problems and severe residual limb skin problems, are presented in Tables B18 – B20 in Appendix B – Data Dictionary. Further, in order to insure that the skin conditions were associated with the residual limb, it was intended that only those detected while in the presence of the additional ICD-9-CM codes 997.60-.62, 997.69, V49.70, or V49.75 would be counted as problems definitely associated with the residual limb. However, such defining codes were not found in the study dataset and an alternative method was used as described in Chapter 4. Other relevant less severe and severe residual limb skin problem codes detected in the presence of certain CPT code modifiers (for example , YG –“ Lower extremity ulcer risk assessment”) were searched for but not found. For more definitions of codes, refer to Appendix B.

Studies have reported that 40-80% of individuals observed do develop some level of skin problem when actively using an artificial limb (Bui et al., 2009; Dudek et al., 2005; Meulenbelt et al., 2006; Meulenbelt et al., 2007). It should also be noted, though, that many patients, especially later in the follow-up period, may no longer seek medical care for skin problems as they become more competent and confident in treating problems themselves. Therefore, while there may be individuals dispensed an artificial limb who develop no skin problems, or those who self-treat and do not seek clinical care/treatment (and thus are not captured by hospital care records), a third category, “no treatment” was used to account for such situations.

Finally, the categories severe and Less severe were further sub-divided into four categories relative to their etiology as suggested by Bui and colleagues (2009), the categories were: surgical complications, repetitive trauma, occlusion: infectious, and occlusion: non-infectious. These sub-categories were used to describe the study cohort, however, as a goal of this study was to differentiate between those residual limb conditions that are especially debilitating with the greatest impact on quality of life (such as ulcers, osteomyelitis, or reamputation) versus those that are less so impactful, the three primary categories (severe, less severe, and no treatment) were used for statistical modeling, rather than just on etiology.

Artificial limb configuration. As the primary independent variable of interest, ALC represented the combinations of two key components of a lower limb artificial limb—the socket suspension system and prosthetic foot, both of which were also examined independently. The algorithm to be used to categorize ALC was determined upon receipt and manipulation of the data, in order to ascertain exactly what models and types of suspension systems and prosthetic feet were dispensed. Their identification was based on the matching of subject ID numbers from the NPCD (identified as new dysvascular transtibial amputees), with those in the NPPD, their corresponding HCPCS codes, model type, and "new cost," as well as date of dispensing, as per the HCPCS billing codes. The various components searched for and used, along with their corresponding HCPCS billing code, are presented in Table B1, Appendix B – Data Dictionary. The HCPCS codes were the most reliable within the dataset and thus the preferred means for identifying and categorizing artificial limb components. Whenever possible, the codes were checked against model types, vendors, and item descriptions. ALC were then categorized on the basis of combinations of the identified components. For example, category A=socket suspension system 3 (out of 4 possible) + Prosthetic Foot 8 (out of a possible 12). Further, given that the cost of these artificial limbs varied, depending on the components prescribed and purchased, the NPPD variable "new cost" was included in the algorithm as a summed value of the socket suspension system and the prosthetic foot. A possible algorithm would be to identify combinations of suspension system and prosthetic foot components, and then group them on the basis of their summed component cost. In almost all cases, as the cost/value of the component increases, so does its sophistication and number of moving parts. For example, DePalma and colleagues (2002), in their description of the categories of prosthetic feet available, point out that the hybrid foot is significantly more expensive than the SACH foot, or even the dynamic response foot (DePalma, et al., 2002).

Psychosocial covariates. From the main inpatient files, as well as outpatient data files, per fiscal year (2007-2010), diagnosis /DRG ICD-9 codes representative of the key covariates depression (309.81, V79.0, 296.2x, 296.3x, 311), PTSD (309.81), and alcoholism/substance abuse (291, 292, 303, 304, 305 excluding 305.1) were searched for within the cohort so as to capture psychosocial behaviors (or "proxies" thereof) that could impact the type of skin problems associated with an ALC category and user.

The joint VA-DoD Clinical Practice Guidelines for Mental Health (available for MDD, PTSD, bipolar disorder, and SUD online at http://www.healthquality.va.gov/) describe pharmacological and psychotherapy recommendations for the disorders, each with its own documentation. For each disorder, diagnosis paradigms are also provided:

- MDD - the patient presents with depressed mood or loss of interest or pleasure, along with at least 4 additional MDD diagnosis criteria symptoms (as per the DSM-IV-TR) for a duration of at least 2 weeks (The Management of MDD Working Group, 2009);

- PTSD - patients test positive on a screening survey tool (presented to all VHA Veteran patients) and then assessed by a mental health professional (The Management of Post-Traumatic Stress Working Group, 2010); and
- SUD - patients test positive on a screening tool (administered to all Veteran patients)and present with contraindications as determined through interview with a mental health professional or primary doctor (The Management of SUD Working Group, 2009). For more complete definitions of these mental health conditions, please refer to the section Definitions and Terms in Chapter 1 of this document.

The guidelines also describe frequency of psychotherapeutic encounters in terms of monitoring response to treatment and symptom improvement or exacerbation as well as potentially weekly meetings, but at least the need to "evaluate periodically" and to continue to follow up until the patient is symptom-free for at least two months.

Based on these definitions and criteria, it is recommended by clinicians in the field that the diagnosis of MDD appear in a patient record at least twice successively (at least two visits) and similarly, with PTSD and SUD, to account for false positives from the screening tools (L. Copeland, Ph.D., personal communication, March, 2013).

Therefore, for this study, the presence of a code for a particular condition was detected at least twice on different outpatient visit dates within a fiscal year to be counted as a comorbid condition for any cohort member during the follow-up period.

The covariates depression, PTSD, and SUD were explored in support of the biopsychosocial theoretical model that the health of the mind is connected to the health of the body—in this case, the residual limb. For example, a person suffering from any one of the three conditions may lack the impetus to seek medical care and treatment of a residual limb problem in a timely manner such that ulcers are more likely to evolve from a lack of preventive measures, and once evolved become infected for similar reasons. On the other hand, a significantly depressed individual may engage in less physical activity, thereby incurring fewer biomechanical forces on the residual limb–artificial limb interface, and thus may simply not develop skin problems that require treatment and therefore no evidence of skin problems will appear in the clinical record. Similarly, the person with PTSD and/or SUD may be more active and thus potentially more likely to incur "mechanical effect" residual limb skin problems, but as these conditions are frequently associated with community withdrawal (social isolation), as well as poor healthcare and disease management, by the time treatment is sought, a "less severe" skin problem may have evolved into a "severe" problem.

Socio-demographic covariates. Additionally, available from the NPCD inpatient and outpatient files, demographic factors to include age (by age group), gender, race, marital status, and VA Priority status (as an indicator of economic status) were explored as a means to describe the cohort and potentially identify those characteristics that associate with particular ALC categories prescribed and dispensed, and/or associated with residual limb skin problems. The values and categories associated with each of these variables are presented in Appendix B - Data dictionary, Table B27 under the Variable names : AG8R for age group, "SEX" for gender, "RACE", "MS" for marital Status, and "MEANS" for a patient's Means Test score / VA Priority status.

For example, as reported in a study by Kurichi (2007), more elderly cohort members (over the age of 74 years) may have a higher one year mortality rate , not prescribed an artificial limb, or be prescribed an artificial limb for transitions only (for example from bed to chair or toilet) (Fletcher et al., 2001; Kurichi et al., 2007). Further, the older dysvascular amputee is typically less active due to reduced energy levels, advanced complications, and less balance confidence; thus the artificial limb prescribed and dispensed will likely be one more suitable for a household ambulator rather than for a community ambulator (if an artificial limb is prescribed at all) (Kurichi et al., 2007; Miller & Deathe, 2004; Remes, et al., 2009).

VA priority status was used as an indicator of socioeconomic status. It is a measure incorporating economic need and disability status, and has been examined among VA patients and subsequently validated in VA administrative data in numerous studies (Kazis et al., 1998). VA priority status ranges from a ranking of "priority 1," in which the Veteran is not asked to make any payments for health care or pharmacy, to "priority 8," in which co-payments are required. It was anticipated that an individual with priority 1 status suffers from greater disability and thus the artificial limb configuration would reflect such; or a Veteran with a Priority 8 status will have the capacity to care for their health sufficiently that residual limb skin problems would be less frequent and/or less severe, despite a lifestyle that may incur more activity and thus a residual limb more at risk for mechanically induced problems (Meulenbelt et al., 2009).

Marital status (MS) was a variable available from the Inpatient files that was used primarily to characterize the cohort. For example, those marital status values suggestive of an individual living alone (such as single, never married, or divorced)would be indicative of less oversight as to the management of their disease and care of their residual limb and thus, demonstrate a pattern of more ulcers over the follow-up period. In contrast, a married individual would likely have some level of oversight as to the management of their health and care of their residual limb and demonstrate a pattern of less severe residual limb skin problems (Remes et al., 2009).

Comorbid conditions, such as chronic obstructive pulmonary disease (COPD), obesity, congestive heart failure (CHF), cerebrovascular disease (CVD), and renal failure ICD-9-CM codes) were used primarily to characterize the cohort. Additionally, these conditions were used as covariates (either present or absent) to help explain differences in RLSPS levels between and among ALC categories.

In the study by Kurichi and colleagues (2007) and mentioned above, the authors conducted a retrospective cohort analysis of lower limb amputees discharged for amputation surgery during FY 2003, to ascertain those clinical factors relative to artificial limb prescription (whether they were prescribed an artificial limb or not). The authors concluded that medical conditions (such as renal failure and dysvascular disease) and functional limitations (such as COPD, stroke, and obesity) adversely affect an individual's level of energy, ability to move independently, or ability to exercise judgment, and thusly reduces the likelihood of artificial limb prescription (Kurichi et al., 2007). Thus it was relative to determine the frequencies of cohort members having such comorbid conditions and actually dispensed an artificial limb, the ALC categories dispensed (anticipated to be low cost, low technical sophistication) and patterns of residual limb skin outcomes (severe/less severe) that developed over the course of the follow-up period. For example, a cohort member with a comorbid diagnosis of COPD may not be prescribed/dispensed an artificial limb due to the exertions required to ambulate with such; an obese individual may be more difficult to fit, be less physically active, and be more likely to struggle with proper hygiene (if without assistive care) and thus prone to mechanical skin problems compounded by infection; a cohort member that suffers a debilitating stroke may simply stop using their artificial limb or their prescription may need to be reconsidered, and a cohort member with advanced dysvascular disease (as indicated by CHF and renal failure) may have significantly compromised skin healing capacity as demonstrated by chronic ulcer treatment or surgical revision during the follow-up period.

Data Analysis

Overview

Data analysis for this observational study was primarily descriptive, as a novel knowledge base was explored, specifically the NPPD (which at the time was yet not fully validated), and long-term patient outcomes relative to ALC category dispensed.

Frequencies, means and standard deviations, ranges, and adjusted models were employed to describe the parameters of the integrated dataset. Chi square analyses and multivariate analysis models of variance and covariance, specifically general estimating equations (GEE), were used to examine the influence of comorbid conditions on amputee and artificial limb outcomes. More specifically, multivariate modeling was specific to the research questions with an emphasis on differences between ALC categories and the subsequent incidence of severe and less severe residual limb skin problems reported/treated in a clinical setting.

Defining the Integrated Study Dataset and Cohort

Upon compilation of the integrated study dataset that reflected the clinical history of U.S. Veterans having undergone a transtibial amputation for dysvascular complications during FY 2007 and followed through FY 2010, efforts were made to identify erroneous data, duplications, and nonsensical codes. Data across fiscal years and data files were linked by ScSSN (scrambled/encrypted Social Security Number) and aggregated to the patient level.

The initial statistical analyses of the dataset were descriptive and included: frequencies, rates, means, and standard deviations of the cohort's demographics (age, gender, marital status, race, VA priority status, comorbid conditions, and geographical /VISN distribution); one year and three year mortality rates during the follow-up period; percentage and frequency of different codes indicative of dysvascular complications associated with the amputation (those ICD-9-CM codes used to identify the initial cohort of new transtibial dysvascular amputations in FY2007); and frequencies, percentages, and geographical/VISN distribution of residual limb skin problem codes and categories (severe/less severe) during the follow-up period, as well as the various artificial limb components dispensed. Additionally, univariate and bivariate analyses of the various co-morbid conditions relative to the dependent variable (RLSPS levels) were conducted to identify those conditions (or combinations thereof) demonstrating an alpha of 0.25 or less, and therefore warranting their use in the multivariate modeling analyses.

In regard to artificial limb configurations dispensed, it was expected that while the potential combinations of socket suspension systems and prosthetic feet that constitute an artificial limb configuration could be as many as 60 (based on 5 different HCPCS billing codes for socket suspension systems and 12 for prosthetic feet), the actual number of different combinations/configurations dispensed would be relatively few (less than 10) and predominately those of low function and moderate technical sophistication. The primary factor driving such an expectation was the overall poor health status of the dysvascular amputee.

A common characteristic of most dysvascular conditions, that is, type 2 diabetes mellitus and PAD that lead to amputation is their relatively late onset—both diseases are typically associated with the older adult (65 years and above) (CDC, 2011a; Criqui, 2001). Additionally, the complications that ultimately resolve into the need for amputation may occur over a relatively long period of time such that prior to amputation, the patient likely becomes progressively less active due to chronic pain from neuropathy of the lower limb, foot ulcers, and limb revascularization surgeries (Boutoille et al., 2008; Sprengers et al., 2007). For example, the individual with PAD will likely undergo multiple stent and bypass surgeries of the lower limb vascular system prior to the onset of critical limb ischemia and the need for amputation; the diabetic with peripheral neuropathy may contend with multiple foot ulcers and toe or partial foot amputations prior to transtibial amputation (Mayfield, et al., 2004; Boutoille, et al., 2008). Such individuals are not likely to benefit from hi-tech, complicated, and costly artificial limb configurations that are more designed for the highly active, athletic individual. Two exceptions to this concept are the Vacuum Assisted Suspension System (VASS) (L5781, L5782), which is marketed to actually improve blood flow in the residual limb, and the Proprio-Foot (L5973), which is designed to reduce the amount of energy needed to ambulate and is actually recommended for the household and limited community ambulator (Chitragari et al., 2014; Hoskins, Sutton, Kinor, Schaeffer, & Fatone, 2014).

To specifically address this conjecture, descriptive statistics were used to describe patterns of artificial limb provision, to include frequencies and rates of artificial limb configurations, socket suspension systems, and prosthetic feet codes and categories dispensed. Low rates of VASS socket suspension systems (L5781, L5782), multiaxis-dynamic response Flex Foot or Flex Walk systems prosthetic feet (L5979, L5980, or L5981, respectively), or configurations comprised of the VASS with the multiaxis-dynamic response, Flex-foot, or Flex walk system would support the expectation that most of the artificial limb configurations or components dispensed were of low function and technical sophistication.

The Epidemiological Analysis

Utilizing the parameterized dataset and cohort, several further research questions were addressed that focused on the relationship between artificial limb use and the development of residual limb problems. As stated in Chapter 2, two key factors tend to drive most (if not all) residual limb problems experienced by the lower limb artificial limb user: mechanical effects and behavioral effects, and the interaction thereof.

Mechanical main effects. Research Question 1 addresses the issue of the artificial limb configuration as the main effect influencing the variability in residual limb skin problems. So-called “mechanical” effects as described previously are those in which undue biomechanical forces act on the residual limb-artificial limb interface (at the contact point of the socket and skin of the residual limb). Such undue forces may be consequent of poor socket fit, poor artificial limb alignment, an artificial limb configuration not suitable or congruent with the user’s activity level, or simply excessive forces generated given the user’s body type, residual limb shape, and activity level and type—the more active the user, the more potential for skin problems (DePalma et al., 2002; DeLisa & Kerrigan, 1998). Given the predicted demographics of the study population (that is, older, less active with significant comorbid conditions), coupled with the poor healing capacity of individuals with dysvascular disease, it was expected that the predominance of the cohort dispensed artificial limbs would be for limited household and minimal community ambulation (functional levels high K1 to low K3, as defined in Chapter 2) with artificial limbs dispensed that reflect such, for example, a SACH foot (L5970) with cuff suspension (L 5666) or suction suspension (L5647)—all considered low to moderate technical sophistication. Further, because of the cohort member's predicted low activity level, and predominately unvaried terrain (in house, few unlevel surfaces such as grass or unpaved paths), "mechanical" effects, as indicated by rates of RLSPS, would not vary significantly among artificial limb configurations, regardless of sophistication, simply because the skin at the socket-residual limb interface would not be overly stressed by undue or excessive biomechanical forces associated with high repetitive impact. Nonetheless, due to the relatively poor vascular system this population is characterized with, the risk of skin problems is heightened due to poor healing capacity. When such is coupled with skin fragility consequent of the normal aging process, the residual limb becomes especially vulnerable to abrasion, bruising, cellulitis, and blisters that can very quickly become slow healing ulcers. Therefore, despite the predicted low activity level of this population, the likelihood of skin breakdown is greater and, when combined with certain demographics (that is, socioeconomic status, age, comorbid conditions, and marital status), the chances for more severe skin problems are increased to not uncommon. In fact, in the chart review study by Dudek, Marks, Marshall, and Chardon (2005) among a population attending a Canadian outpatient rehab center, over 40% of the population were found to have at least one skin problem treated, of which 27% were ulcers. Therefore, it was hypothesized (Hypothesis 1) that severe residual limb skin problems would be significantly more frequent among artificial limb configurations/components of higher function or technical sophistication because of inappropriate prescription, and least for low function, low technically sophisticated configurations. It was also hypothesized that over 50% of all the cohort members would have at least one “less severe” residual limb skin problem treated during the three-year follow-up period, regardless of the ALC category they were dispensed.

To address this research question and hypothesis, the key variables of interest were: ALC and RLSPS (as described in the section entitled Instrumentation and Materials). Subsequent study research questions included: (a) what was the frequency of dispensation for each of the categories /levels of ALC, the independent categorical variable? This would be needed to better understand patterns of variance; (b) for each category of ALC, what was the summed count of severe as well as less severe residual limb skin problem per 6 month interval over the follow-up period? This would be needed to ascertain when variability of the dependent variable was greatest; and (c) following the dispense of a definitive Artificial limb to cohort members, over a 3 year period, was there a statistically significant (p-value < 0.05)difference in RLSPS levels (the dependent/outcome variable)given the factor “Artificial limb” (independent category variable) and the demographic constants age group, marital status, gender, and VA Priority status, and if so, how do the factor levels compare? Descriptive statistics defined the percentage of types of artificial limb configurations dispensed, as well as the frequency and type of skin problems treated per year and over the course of the follow-up period. Additionally multivariate modeling (general estimating equations—GEE) was performed with ALC as the categorical independent variable/ factor and the dependent variable RLSPS (severe/less severe; repeated measure), age group, VA priority status (categorical: 1-8), marital status (never married, married, divorced, widowed) and gender (as covariate constants). Pairwise contrast tests analysis of the independent /factor (ALC) was used to help determine which of the configurations were associated with significantly more or less frequency in residual limb skin problems. Mean values helped determine which configuration or component was associated with more severe residual limb skin problems. A p-value of less than 0.05 for the category deemed most sophisticated, for example, VASS suspension system (L5781, L5782), with multiaxis-dynamic response foot (L5979) would support the hypothesis that more sophisticated artificial limb configurations were associated with more residual limb skin problems.(HA1a)

Mechanical effects as a covariate. Research question 2 attempted to address a larger issue, namely the need for universal prescription guidelines.

As stated previously in this chapter and further described in Chapter 2, the fit of the prosthetic socket has direct bearing on the residual limb's condition. A poorly crafted or poorly fitted socket may cause not only pain and discomfort for the amputee, but also may exacerbate forces and frictions exerted on the residual limb, leading to residual limb breakdown of skin and soft tissue (De Palma et al., 2002). Further, the prosthetist is frequently not only responsible for crafting the artificial limb socket, but also for configuring, building, and aligning the finished product. A well-crafted and fitted socket may still be associated with residual limb problems if the configuration of the artificial limb is ill-suited to the activity level, mental capacity, or various socio-demographic characteristics of the user (as discussed in Chapter 2). While not all prosthetists associated with the VHA may be licensed in their particular state of residence, all are certified by the American Board of Certification and thus are trained in the fit and manufacture of prosthetic sockets. Therefore, it is fairly safe to assume that all prosthetic sockets provided are fitted and crafted to the best of the ability of the prosthetist, but the craftsmanship and knowledge base of artificial limb components may vary between prosthetists. If there was no significant difference in residual limb skin outcomes between prosthetists regardless of artificial limb configuration (H02), then it could be argued there is no real need for prescription guidelines. If, on the other hand, there were significant variability in the outcome measurement among prosthetists, the argument could be made that the knowledge base is unequally distributed, and that universal prescription guidelines (or at least updated ones) were needed to standardize care. The corresponding hypothesis (Hypothesis 2) was stated to reflect this concept within the bounds of the dataset (that is, the actual identification of the dispensing prosthetist is not available and thus the VISN served as a proxy thereof).

It could then be argued, given characteristics of the cohort and the hypothesized greater incidence of severe residual limb problems associated with higher function technically sophisticated artificial limb configurations (Hypothesis 1), that should such conditions exist regardless of the prosthetist/VISN ($_{Ha2}$), then perhaps those prescription guidelines that exist have not kept up with rapidly advancing technology (concurrent with certain VHA policies), or perhaps guidelines were simply not adhered to. On the other hand, if associations between artificial limb configurations and residual limb outcomes differ with VISNs, then the need for universal prescription guidelines or, at least, improved sharing of information among VISN prosthetists, would be of consideration.

The specific reason or cause why VISN outcomes may or may not vary is beyond the scope of this study. The intent was merely to identify such. Subsequent research questions included: (a) Per VISN, how many cohort members were there; (b) when VISNs were grouped geographically, what were the representative cohort numbers and how did the regions rank; (c) per region, what was the frequency of each ALC category dispensed and how did the regions compare/rank; (d) to assess the overall effect of who/where an artificial limb was crafted , was there a statistically significant difference (*p*-value <0.05) in RLSPS with the factor "Artificial Limb" the categorical independent variable ALC), the demographic variables age group, marital status, gender, and VA Priority status as constants, and VISN region as a covariate; and (5)to assess how the VISN regions compare, was there a significant difference (*p*-value <0.05) in RLSPS with "region" as one factor (each geographical region as a level) and "artificial limb" as a second factor (representing the categorical independent variable ALC), and the demographic variables age group, marital status, gender, and VA Priority status as constants, in order to explore factor interactions. To address these questions and hypotheses, descriptive statistics were used to determine the distribution of the categories of ALC among the VISNs (as there are 23 VISNs, they were eventually grouped into larger geographical regions to improve cell sizes). Multivariate modeling (GEE) was conducted with ALC as the independent variable/factor, RLSPS as the dependent repeated measure variable, and VISN/Region where the artificial limb was dispensed as a covariate as a means to ascertain the overall influence of VISN/prosthetist on RLSPS categories (as determined by the model's z-score). Pairwise contrast tests analysis of VISN/Region was used to help determine which of the VISN/Regions were associated with significantly more or less frequency in RLSPS categories; comparisons of significance (p-value ≤ 0.05) were supportive of the hypothesis that not only does the type of artificial limb configuration influence residual limb outcome (mechanical main effect), but the outcome is also influenced by (by proxy) the skill and expertise of the prosthetist (mechanical covariate).

Behavioral main effects. Research question 3 addressed the issue of the impact certain mental health and behavioral (coping strategies) disorders may or may not have on the types of residual limb problems that are associated with the use of an artificial limb for the dysvascular transtibial amputee. Specifically, diagnosis codes for the conditions MDD, PTSD, or SUD detected during the three-year follow-up period were of interest, not just the presence of such a diagnosis at the time of the amputation surgery or immediately postoperatively. Studies have shown that psychosocial factors impact the health and welfare of the artificial limb user and their success with an artificial limb. For example, Williams and colleagues (2011) showed that depression was associated with a

33% higher risk of major lower limb amputation among diabetic Veterans; Darnell and colleagues determined that just over 28% of persons in the general public living with limb loss suffered from depression, with associated risk factors being marital status (divorced or separated), living at the poverty level or lower, comorbid conditions, and discomfort with the artificial limb; Livnech, Antonak, and Gerhard (1999), as well as Desmond and MacLachlan (2006), showed that an individual's coping strategies significantly impacted their ability to adjust to major limb amputation and ultimate success with an artificial limb.

The conditions in question (depression, PTSD, and SUD) are prevalent among U.S. Veterans and have long lasting effects, particularly in their ability to manage chronic disease such as diabetes, hypertension, and vascular problems. For the dysvascular amputee, there is the additional complexity of managing the care of their residual limb as well as care of the artificial limb. Based on the biopsychosocial theoretical model, a person's mental state has direct (and indirect) bearing on one's physiology as well as their ability to manage their disease (Bradley et al., 2002; Engel, 1977). Given the apparent relationship between depression and incident amputation among diabetics, this suggests an apathy toward foot care that ultimately ends in amputation due to infection. This same apathy may lead to poor residual limb care and/or a low activity level, the combination of which may result in frequent skin problems but of less severity than those experienced by a more active individual. Behaviors associated with PTSD can range from significant depression and withdrawal to violent outburst; from forgetfulness to paranoia

(The Management of Post-Traumatic Stress Working Group, 2010). Any of these behaviors can have a direct impact on one's ability to manage physiological problems including seeking treatment appropriately or following through with treatment protocols (van der Kolk, 1994). Similarly, an individual diagnosed with SUD, frequently an outcome of poor coping strategies, will have difficulty making decisions, following through with health/disease management, and the substance being abused (for example, alcohol) may compound an existing disease condition such as diabetes (Haase, 2009). While potentially unable to maintain good health/disease management, the individual with PTSD or SUD may remain relatively active seeking emotional solace, but not necessarily seeking medical care. The activity increases biomechanical forces at the artificial limb–residual limb interface, increasing the likelihood of minor skin problems that go undiagnosed or untreated, and ultimately become severe skin problems.

Therefore, it was hypothesized (Alternative Hypothesis 3) that cohort members with a diagnosis of MDD would have fewer severe residual limb skin problems and fewer residual limb skin problems treated overall (primarily due to a low activity level) as compared to those members with no such depression diagnosis($_{Ha3a}$); cohort members with a diagnosis of PTSD or SUD would have significantly more severe residual limb skin problems (due to higher activity levels and/or poorer self-management) than those members without PTSD or SUD, but not significantly more less severe residual limb skin problems (H_a3b). The subsequent research questions included the following: (a) what was the frequency of diagnoses for each of the "Mental Health" factors (PTSD, MDD and

SUD) among the cohort members dispensed an artificial limb; (b) What percentage of the cohort had a single diagnosis for any of the three mental health conditions; and (c) for the period after being dispensed an artificial limb, was there a statistically significant difference (p-value<0.05) for RLSPS (dependent/outcome variable) given the factor mental health status (with three levels - PTSD, MDD, and SUD), and the demographic constants age group, marital status, gender, and VA Priority status, regardless of the artificial limb configuration dispensed?

The analysis plan for this research question and hypothesis included descriptive statistics to determine the frequencies and rates of ICD-9-CM codes for MDD, PTSD, and SUD among the cohort dispensed artificial limbs per the follow-up period (ICD-9-CM codes used to identify each condition can be found in Appendix B). Additionally, multivariate modeling (GEE) was conducted with mental health status as a factor, the co-morbid conditions COPD, CHF, CVD and renal failure as covariates, ,RLSPS levels as the dependent repeated measure, and demographic as covariate constants, to estimate differences in outcome relative to a diagnosis of MDD, PTSD, or SUD. A significant difference (p-value < 0.05) for a mental health disorder would support the hypothesis that the frequency of a residual limb skin problem outcome is influenced by a behavioral effect. A p-value less than 0.05 for depression (MDD) would support the hypothesis that outcome patterns for depression differ from that for PTSD or SUD. Adjusted odds ratios for the demographic variables will help explain the differences.

Interaction effect, mechanical by behavioral factors. Continuing to work off the premise that certain mental health conditions are characterized by behaviors expressed by activity levels and that activity level is one of the driving forces behind severe skin problems, this Research Question 4 and subsequent analysis attempted to address this interaction. As presented in Hypothesis 2, it is anticipated that the depressed individual will be more apathetic and less physically active, while the patients struggling with PTSD or SUD will have a fairly normal activity level but will be confounded by poor disease management and unwillingness to seek timely medical care. All will have skin problems regardless of the ALC category (given their dysvascular condition) and those prescribed a more sophisticated artificial limb configuration could have more problems than those with a less sophisticated limb (Hypothesis 1), but perhaps for different reasons and to different extents. A significantly depressed individual using a highly sophisticated artificial limb would likely not use it as extensively as others, but when they did, they could be less cognizant of mechanical factors. Subsequently, they would more likely incur mechanically induced skin problems, but because of their low activity level, most problems would not become severe ($_{Ha4a}$). On the other hand, the individual with PTSD or SUD would utilize a sophisticated artificial limb more extensively, but when problems occur, they would likely be reluctant to seek help while continuing to use the limb such that less severe problems would become severe ($_{Ha4b}$). Further, in the case of the individual with SUD, particularly alcoholism, the continued consumption of alcohol would compound their pre-existing vascular disorder, causing their residual limb to be more at risk for skin breakdown ($_{Ha4b}$). For all three mental health conditions, their particular sociodemographics will help determine their outcome. For instance, a younger individual would likely be more active and more likely dispensed a mechanically sophisticated artificial limb; an individual living in near poverty and not married, more prone to skin problems simply because of less capacity to seek help and/or maintain a mechanically sophisticated artificial limb properly.

The corresponding research questions included: (a) as determined previously, what percentage of the cohort presented with a single mental health condition (PTSD, MDD, or SUD), what was the most frequently and least frequently dispensed ALC category, and what percentage of the cohort had at least one comorbid condition(CHF, CVD, COPD, renal failure or obesity); (b) was there a significant difference (p-value < .05) in RLSPS for MDD, PTSD, or SUD given a specific ALC category and the demographic variables age group, marital status, gender, and VA Priority status as constants; (c) given a significant difference, what main effect (that is, artificial limb configuration or mental health) drove the difference; and (d) were there any other significant interactive or differences (p-value < .05) associated with any one of the co-morbid conditions? The analysis plan to address these interactions included descriptive statistics calculated to reveal frequencies of PTSD, MDD, and SUD diagnoses from the date the artificial limb was dispensed through the follow-up period. Additionally, because activity levels are closely associated with mechanical effects related to using an artificial limb, the presence/absence of the comorbid conditions CHF, CVD, COPD, renal failure, and obesity, were accounted for in the cohort, regardless of whether the comorbid condition ICD-9-CM code was registered before or after artificial limb dispensation. Multivariate modeling (GEE) was conducted in which ALC category, mental health, and activity (as suggested by comorbid conditions) served as factors, RLSPS as the dependent repeated measures variable, and demographic constants as covariates. Significant main effects for mental health status as a diagnosis code for MDD, PTSD, or SUD, support the hypothesis of behavioral effects on RLSPS. Significant interactions between categories of ALC and mental health status should indicate the relationship between more sophisticated artificial limb configurations and patients with depression, PTSD, or SUD relative to RLSPS levels.

Confidentiality

Cohort Member Confidentiality

For both national databases, each patient has a unique identifier that is an encryption of the patient's Social Security Number, and thus allows for patient identification across fiscal years and datasets without jeopardizing or compromising patient confidentiality. The requested and extracted data was matched and linked by these encrypted social security numbers, the code to which was not required nor requested. Further, because the encrypted social security number was considered a unique identifier by the VHA, as per VHA regulations, all protected health information (PHI), including dates, was protected by (a) maintaining up-to-date training for all persons having access to the data, (b) monitoring implementation of good data security practices by all such persons on an ongoing basis, (c) storing data behind the VA firewall on protected, limited-access research servers at all times, (d) using secure data transfer methods to obtain PHI, such as limited access password-protected and user-specific direct data transfer behind the VA firewall, (e) limiting PHI requested/obtained to the minimum needed to meet study objectives, and (f) reporting only aggregate results, with no ages greater than 90 years.

Data Security

The source data that comprised the master dataset and from which data were extracted to form the study cohort dataset, was available due to a protocol approved by the UTHSCSA (which serves as the oversite IRB for the South Texas Veterans Health Care System Research Service) and STVHCS Research Service Subcommittee approval. After obtaining the necessary permissions, a simple code was prepared, using SAS programming language that established data selection criteria. This code was then transmitted to the Austin Information Technology Center (AITC) housing the archived data and where the investigator established a temporary account. The requested SAS dataset was then prepared and results of any manipulations transmitted to the STVHCS Research Service secured server. All electronic data were stored in accordance with the VHA’s information security policy and encryption standards to include that any subsequent data results reported be fully de-identified as summary (statistical) or aggregate data.

IRB approval from the UTHSCSA, as well as the STVHCS – Audie Murphy Research Service Subcommittee, to acquire the master dataset was obtained in November 2011; the data requested and received as of November 2012. Prior to initiation of this dissertation study, Walden University Institutional Review Board approval was obtained (approval number: 08-11-14-0047713) on August 11, 2014. The extracted data used to develop the study dataset was stored and manipulated on a secure server behind the STVHCS firewall)

Summary

As presented in Chapter 2, the process of determining what artificial limb configuration is to be prescribed for anyone living with limb loss is highly individualized, being dependent on multiple and integrated factors. Despite the advances in materials and engineering associated with the development of new artificial limb components, the artificial limb remains imperfect relative to the intact human limb. This imperfection is particularly notable at the interface of the mechanical artificial limb and the human residual limb, and is expressed as residual limb skin problems. These residual limb skin problems jeopardize the integrity of the residual limb, compromising the individual's mobility and quality of life, and range from the "less severe" (calluses, blisters, rashes, and irritations) to the "severe" (ulcers, infection, limb breakdown). Ultimately two key factors drive the likelihood of residual limb skin problems—mechanical effects in which the design or configuration of the artificial limb creates forces and friction on the residual limb resulting in "microtrauma" to tissue; and behavioral effects in which the actions of the user, particularly activity level and health self-management, incur or exacerbate residual limb skin problems.

The methodology presented in this chapter was intended to address residual limb skin problems resultant of mechanical and behavioral effects in the process of exploring the viability of a novel dataset derived from AHc data. Specifically the study was designed to explore the value of medical coding (to include ICD-9-CM diagnosis codes, CPT procedural codes, and HCPCS billing codes) as a means to objectively describe the clinical picture and outcomes, relative to the category of artificial limb dispensed, for a cohort of U.S. Veterans with new transtibial amputations for dysvascular complications. The research plan included the compilation of the cohort clinical and artificial limb history over a period of three years, as derived from two VHA repository databases—the NPCD and the NPPD. The compiled, integrated study dataset was used to calculate descriptive and multivariate analyses in an effort to (a) describe the cohort in terms of co-morbid conditions, artificial limbs dispensed, and demographic characteristics; (b) assess the effects (main and interaction) of mechanical factors (ALC category, prosthetist skill/knowledge base); (c) assess the effects (main and interactions) of assumed behavioral factors associated with MDD, PTSD, and SUD; and (d) determine the value and usefulness of residual limb skin problem diagnosis codes (ICD-9-CM codes) as outcome measures. As with any research study involving humans, considerable effort was made to ensure the confidentiality and protection of health information of all the study cohort members. All source data was applied for and approved by VHA entities, all data retained behind the VHA firewall, source data only identifiable by an encrypted, scrambled patient social security number that was not decoded, and a unique subject ID per cohort member utilized in the derived dataset.

Given the relative novelty and questionable validity (see Data Limitations herein) of both the source data from the NPPD and, subsequently, the study dataset, the study is intended only to lay the methodological and descriptive analysis foundation for future studies. For this reason, data analysis was primarily limited to descriptive and multivariable analysis of the likelihood of differences as calculated by general estimating equation procedures. In other words, the research plan and analysis was designed as a “proof of concept”—that such a dataset of AHc medical coding of an individual’s clinical history and artificial limb prescription (with a focus on implications of mental health conditions) would provide sufficiently informative and valuable information for future studies. Such studies may include those that derive different algorithms to categorize artificial limb configurations, expand the clinical history of the cohort to include the prescription of mobility aids and/or medications, apply the methodology to cohorts of different amputation levels, or seek predictive relationships regarding ALC categories and patient outcome, specifically in regard to medically coded indicators. Such studies should, logically, lead to improved clinical prescription guidelines and/or artificial limb component design, as well as offer support for the development of an amputee care surveillance system or registry.

The ensuing chapters present the data analyses as described and discuss the findings in a manner that not only present the strengths and weaknesses of the study dataset, but also lay the foundation for further analyses and application of the dataset concept to other levels and causes of amputation.

Chapter 4: Results

Introduction

The purpose of this study was to address the utility of VHA AHc records as a source of information toward the potential development of a suitable amputee-artificial limb database and future surveillance system. To accomplish this, there were two main goals to be achieved: (a) derivation of a suitable dataset, referred to in the previous chapter as Phase 1 – Developing an informatics tool, and (b) utilization of that dataset in a meaningful epidemiological analysis, referred to as Phase 2 in the previous chapter and based on a retrospective observational cohort study design. While the study methods used were not necessarily novel, the derived database was, as was the epidemiological analysis, given its data source and selection of independent and dependent variables.

Phase 1 focused on the extraction and integration of administrative data from the VHA's NPCD from which clinical histories of the cohort were ascertained on the basis of diagnosis, surgical and procedure codes (ICD9-CM and CPT codes, respectively), and the NPPD from which the cohort's history of artificial limb components delivered and procedures performed were recorded as HCPCS (billing) codes. On the bases of these codes, the categorical variable ALC (representative of mechanical factors influencing outcomes) was developed, certain comorbid conditions (representative of behavioral factors influencing outcomes) were identified, and the outcome variable RLSPS was constructed. Ultimately, the derived dataset represented a cohort of veterans having undergone a transtibial amputation for dysvascular complications during FY 2007

(October 1, 2006 through September 30, 2007), subsequently provided an artificial limb, and followed through FY 2010. It was this dataset that was used for the epidemiological analysis in Phase 2 of the study, and served to address the potential for a similarly derived database as a prosthetics practiced-based informatics tool in the development of an amputee-care surveillance system.

Exploring the feasibility of healthcare administrative data as a source and basis of EBM in the field of prosthetics research is a necessary step and includes an initial description of the steps and rules used to derive the study dataset. The section entitled Phase1 – Developing the Informatics Tool, under the Data Preparation heading, includes a list of those steps and rules and includes a data dictionary of variable definitions pertinent to those rules, construction of the categorical variables ALC and RLSPS, and characterization of the study dataset in terms of frequencies, ranges, and invalid/unusable cases.

Statistical analysis of the refined dataset and identification of the patterns and trends of the cohort with regard to artificial limb provision and subsequent RLSPS outcomes follows in the section Phase 2 under the Results heading. The statistical analyses used to address each research question reflect both the complexity of the case histories of the cohort, as well as limitations of using unvalidated, archival data. Further, the research questions focused on both mechanical and behavioral factors as main effects or covariates and, as such, are reflected in the statistical model design and subsequent data manipulations. Details of such manipulations are described as needed

Data Preparation

Phase 1 – Developing the Informatics Tool

Overview. From a master database located on a STVHCS secure server, 2240 observations were extracted representing the inpatient clinical histories of 1487 veterans during FY 2007, all with an ICD9-CM or CPT code for below knee amputation and concurrent with ICD9-CM codes for dysvascular conditions such as diabetes, PAD or PVD. This was the initial cohort and served as the basis for the final study cohort.

Observations from the same master database containing extracts from the NPPD was then searched for encrypted Social Security Numbers (variable name – ScrSNN) that matched those identified in the initial cohort, extracted, cleaned, and prepared prior to merging with follow-up clinical data. The NPPD has not yet been fully validated or examined and thus presented with various data incongruencies, apparent missing data, and unknown reliability, requiring extensive data cleaning and preparation.

Ultimately, outcomes from data preparation defined the study dataset were those cases who in FY 2007 presented with a combination of ICD9-CM OR CPT codes indicative of a dysvascular transtibial amputation or revision surgery, dispensed an identifiable definitive artificial limb at some point during FY 2007 through FY 2011, and after which (the date the artificial limb was dispensed) the patient's clinical history would be followed through to the end of FY 2011 (September 30, 2011). (Note: it was decided to expand the follow-up period to FY 2011 from FY 2010 as the data were available and the extension would allow for more data points.) Specific rules defining the data preparation and identification of the study cohort are presented in Appendix C: Data Dictionary, and are summarized below.

Extraction of clinical data. NPCD data provides clinical (diagnosis and procedure) codes at the patient level for all veterans visiting a VHA facility. The master database housed at the STVHCS – Audie Murphy Hospital contains such data for inpatient and outpatient visits during fiscal years 2007 through 2011. It was from this database that all clinical data for the study was extracted to include identification of cohort members, their comorbid conditions, demographics, and all follow-up residual limb skin problems.

Identification of cohort members. The inclusion criteria and coding used to identify persons having undergone a below knee amputation was expanded from the CPT code 27598 to include the ICD9-CM codes 897.0, 897.1, 897.4, and 897.5 (definitions of these codes are presented in Appendix B: Data Dictionary, Table B25). This expansion of the cohort inclusion criteria was performed in an effort to maximize the number of cases for analysis. Further, because of the complex disease conditions of many veterans, especially those with dysvascular conditions, the ICD9-CM and CPT codes were searched for throughout the FY 2007 NPCD inpatient datasets, rather than being limited to a search in the dataset variable DXPRIME, the primary code and reason for hospital admission. The other dataset variables/fields from the NPCD datasets included: DXB2-DXB5, DXF2-DXF13, DXLSB, and DXLSF, all of which indicate the primary and secondary ICD-9-CM diagnostic codes that apply to the inpatient files (bed section or full stay) for the patient (see Appendix B, Table B27 for a full list of dataset fields/variables). In so doing, cases were not limited to those veterans undergoing an index transtibial amputation in FY 2007, but included veterans with existing below-knee amputations undergoing a revision surgery of the residual limb, a reamputation of the same limb (for example, from Syme's to transtibial; from transtibial to transfemoral), or a veteran with a pre-existing unilateral lower limb amputation undergoing a below-knee amputation of their intact limb. Ultimately, a total of 1487 unique cases were identified and formed the initial cohort.

Extraction of artificial limb data. NPPD patient level data were the source for artificial limb data and provided all patient prescribed equipment and device transactions conducted nationally at VHA facilities, including artificial limb components. The master database housed at the STVHCS-Audie Murphy Hospital contains all such data for fiscal years 2007 through 2011. It should be noted that, unlike the NPCD data which is composed of multiple MedSAS data files for inpatient and outpatient clinical data per fiscal year, the NPPD dataset was a single Excel worksheet containing all requested data for fiscal years 2007-2011. The dataset was structured as one row per patient transaction and amounted to 319,119 records with 34 variables, representing 6,590 unique cases. Transactions included those for any durable medical equipment (such as hospital beds or grab bars), wheelchairs, sensory aids (such as eyeglasses and hearing aids),oxygen tanks and portable ventilation systems, surgical implants (such as hip and knee joints), orthotics (such as shoe inserts and diabetic shoes), and prosthetic devices and components.

From this master database of NPPD data, a first pass for data extraction was made based on the presence of HCPCS codes indicative of an artificial limb to include the code L5301(used to indicate permanent/definitive artificial limb from temporary or immediate post-operative artificial limb), the codes for prosthetic feet (L5970, l5974, L5972, L5975, L5978, l5973, L5976, L5979, L5980, L5981, and L5987) and the codes for socket suspension systems (L5680, L5682, L5684, L5688, l5690, L5666, L5685, L5670, L5671, l5673, L5647, L5781, and L5782). Appendix B provides a full definition for each of these codes in Table B26. This first pass was performed to eliminate those potential cohort members who may have received wheelchairs or other durable medical equipment (DME) but no artificial limb components, and resulted in the identification of 3,394 unique cases and 18,526 records.

The scrambled SSNs of the 1487 unique cases identified from the clinical data were then compared with the scrambled SSNs of these NPPD cases, and matching cases with associated observations extracted for further analysis. The matching accounted for 597 cases and 3327 associated observations from the NPPD data file. The following inclusion/exclusion criteria were then applied to the 597 cases (artificial limb data only):

1. Inclusion criteria - The presence of HCPCS code L5301, expanded to include L5700, L5100, and L5629 (code labels are presented in Appendix B, Table B26). The expansion was made in order to include Veterans with pre-existing below-knee amputations, reamputations, and revision surgeries (as described above). Also required were HCPCS codes for

prosthetic feet and socket suspension systems as indicated above; delivery date, quantity, description, and VISN for each HCPCS code; and calculated cost for each L5301 code. A cohort member dispensed a below-knee preparatory socket (HCPCS codesL5510, L5520, L5530, L5540) but no definitive socket/limb code l5301 noted, was included only if the code l5700 ("replace socket below knee"), was dispensed at least one year post surgery. This modification to the inclusion/exclusion criteria was made in order to capture for analysis those cases where a definitive artificial limb was dispensed but possibly improperly coded as a replacement socket.

2. Exclusion criteria – The presence of HCPCS codes indicative of a Syme's amputation (an amputation through the ankle rather than transtibial) to include L5632, L5634, and L5636; those HCPCS codes indicative of an above-knee amputation to include L5321, L5560, L5580, L5585, and L5590 (Labels for each of these codes can be found in Appendix B, Table B26). It is not uncommon for a unilateral above-knee dysvascular amputee to undergo a below-knee amputation of the intact limb, subsequent of continued poor vascularization, foot ulceration, and infection (Dillingham, et al., 2005; Izumi et al., 2006). Exclusion of such individuals despite the below-knee amputation, was required because ICD9-CM codes for residual limb skin problems do not differentiate

between left and right (above knee and below-knee amputation) limb and therefore, residual limb outcomes could not be tracked accurately. This same factor was relevant to persons who became bilateral below-knee amputees following amputation surgery in FY 2007.

3. Additional exclusions - Cases that presented with no Delivery Date for the artificial limb of interest were excluded as it was impossible to determine if the date were merely missing, not recorded , or the component not delivered. Cases that included the l5301 code but missing codes for either a prosthetic foot or socket suspension system were excluded from the cohort as it was impossible to assign a category for the independent variable ALC.

The data extracts from the NPPD master database were then inspected for data quality and useability on a case by case basis, whereupon a temporary variable, DataStatus, was created to encode cases as to their useability: a value of 1 to indicate useable data (met all inclusion/exclusion criteria), a value of 88 to indicate a bilateral amputee (either above-knee/below-knee or bilateral below-knee), a value of 92 to indicate a case with missing relevant delivery dates or otherwise incongruent data (such as the HCPCS code l5301 used to denote repair or modification to a pre-existing definitive artificial limb), the value 93 for a case presenting with an HCPCS code for above-knee artificial limb (preparatory, definitive, or replacement), the value 94 when a case presented with a missing HCPCS code for prosthetic foot or suspension system in association with a definitive artificial limb (HCPCS code l5301, l5100, or L5700), and the value 95 for delivery of a Syme's artificial limb.

Assessment of the data revealed three coding strategies for the HCPCS code L5301. One strategy was to use the code to indicate a definitive (versus a preparatory or replacement socket and limb) and typically included a monetary amount in the NPPD variable CalCost reflective of multiple components (greater than $3,000) and a delivery date the same as that for an associated prosthetic foot and suspension system. A second apparent strategy was to use the L5301 code to indicate that some repair was made to the patient's pre-existing definitive artificial limb, and apparently used in lieu or ignorance of the codes L7510 or L7520 (code labels can be found in Appendix B, Table B26). Such cases were identified on the basis of monetary values for the NPPD variable CalCost being less than $2,500 (the new cost of a below-knee socket), the value $0 for this same variable, or a particular component was identified in the NPPD variable field ConsultDesc or Item, but instead of using the HCPCS code appropriate for that part, the l5301 code was used along with a unit cost reflective of the part described. For example:

Table 6

Sample Data from NPPD to Illustrate Coding Strategies.

Study _ID	Calc Cost	HCPC SPSAS	New Cost	Qty	HCPCSDesc	Delivery Date	Item	ConsultDesc
142	50	L5301	0	1	BELOW KNEE, MOLDED SOCK	04/28/2010 00:00:00	PROSTHESIS BELOW KNEE	RIGHT BK REPAIRS
167	103.68	L5301	103.68	1	BELOW KNEE, MOLDED SOCK	07/24/2007 00:00:00	1	REPAIR TO BK PROSTHETIC
925	68	L5301	68	1	BELOW KNEE, MOLDED SOCK		PROSTHESIS, BK	STUMP SOCK

As indicated previously, 1487 dysvascular below-knee amputees were identified in the FY 2007 inpatient data files, of which 597 (39%) cases had scrambled social security numbers that matched those extracted from the NPPD artificial limb data. The 890 unmatched cases (59.9% of the initial cohort) were not used any further in the study and can be supposed to be persons who died within the fiscal year or were simply not recommended or prescribed an artificial limb. In fact, of these 890 unmatched amputees, 245 (16.5%) died during the fiscal year, suggesting that the remaining 645 (43.4%) were not prescribed an artificial limb. This number/ percentage is not without merit as it has been estimated that nearly 60% of lower limb dysvascular amputees will not progress beyond use of a rudimentary or k2-level artificial limb (Smith et al., 2003; Uustal, 2009).

Of the 597 Veteran below-knee amputees identified and matched with artificial limb data, only 279 cases (47%) met all inclusion /exclusion criteria and could be used for epidemiological analysis. The remaining 318 cases (53%) could not be used, of which 39 cases were coded as 88(7%), 55 coded as 92 (9%), 121 coded as 93 (21%), 76 coded as 94 (13%), and 21 coded as 95 (4%). Definitions for each of these codes are presented above and can also be found in Appendix B Data Dictionary, Table B3.

Development of the Independent Variable – Artificial Limb Configuration

In an effort to detect an inherent categorizing strategy, frequencies were run on the extracted artificial limb data (from the master database) comprised of 597 cases and 1752 observations, in order to determine the most commonly prescribed socket suspension systems and prosthetic feet (frequency tables can be found in Appendix D, Tables D8 and D9. While this first pass at the data was not exclusive to the study cohort to be used in the epidemiological analysis, the study cohort was inclusive and the larger *N*, despite missing dates or bilateral amputations, was reflective of prescription patterns across the VA system.

Results revealed the following: The most frequently prescribed suspension systems were the L5671and L5685, each with 422 and 420 prescribed respectively and accounting for nearly 77% of all suspension systems prescribed for below-knee amputees. Suction sockets (L5647; *N* = 111), supracondylar (L5670 *N* = 54), cuff suspension (L5666; *N* = 45), straps and belts (L5680, L5682, L5684, L5688, L5690; *N* = 34) and vacuum assisted systems (VASS; L5781, L5782; *N*=8) accounted for the remaining 23%. The most frequently prescribed prosthetic feet were the Flex walk system (L5981; *N*=262) followed by the Flex-foot System (L5980; *N* = 192) accounting for 23% and 18% respectively.

Table 7 below presents the top ten combinations of prosthetic feet and suspension systems prescribed and, based on the prosthetic foot types, suggests that the re-dominance of the Veterans were considered community ambulators or better (K3-K3-4).

Table 7

Top Ten Most Frequently Prescribed Prosthetic Foot and Suspension System Combinations

Combination	Frequency	Percent
L5981 Flex Walk System L5674 suspension sleeve with locking mechanism	106	9.67%
L5980 FlexFoot System L5685 Below knee suspension sleeve	101	9.22%
L5980 Flex foot system L5685 Below knee suspension sleeve	78	7.12%
L5976 Energy Storing Foot L5674 suspension sleeve with locking mechanism	70	6.39%
L5976 Energy Storing Foot L5685 Below knee suspension sleeve	67	6.11%
L5980 Flex foot system L5674 suspension sleeve with locking mechanism	65	5.93%
L5987 shank foot system with vertical loading pylon L5674 suspension sleeve with locking mechanism	48	4.38%
L5987 shank foot system with vertical loading pylon L5685 Below knee suspension sleeve	47	4.29%
L5972 Flexible keel foot L5674 suspension sleeve with locking mechanism	41	3.74%
L5974 single axis ankle/foot L5674 suspension sleeve with locking mechanism	39	3.56%

Because a plausible categorization of the artificial limb configurations that would include all the combinations prescribed was not made evident by this first pass, two alternative algorithms were considered, one based primarily on the total cost of the artificial limb using the NPPD dataset variable CalCost, and the other more aligned with the category of prosthetic foot (for example, K1, K2, K3).

Algorithm one for development of the ALC variable. CalCost is a variable/field provided by the NPPD and part of the dataset extracted from the master database as described above. It is a currency type field and represented the total cost associated with the HCPCS code L5301 and includes cost beyond that of the socket suspension system and prosthetic foot. As a rule of thumb, the more high-tech, more complex an artificial limb, the more expensive (DePalma, et al., 2002). However, also as described above, the CalCost frequently did not represent the total cost of the artificial limb, but rather some part or component not otherwise identified except in the Item and/or ConsultDesc variables/fields which are truncated free text fields and inherently unreliable. An alternative may have been to simply sum the NewCost (another NPPD variable/field) for the suspension system and prosthetic foot, but this summing does not include the cost of the socket, additional fittings (such as rotators), or the use of special materials**)** (DePalma, et al., 2002; Cigna Health Care, 2010). Regardless, in most cases, the higher the k-level, the more complex and high-tech the prosthetic foot (DePalma et al., 2002). The exception to this is the Proprio Foot (HCPCS l5973) which is a microprocessor controlled ankle/foot system recommended for the K2 level amputee (G. W. Bosker CPO, personal communication, January 2015). HCPCS codes associated with prosthetic foot functional levels used to fill the temporary variable ALC foot in this study include: k1 functional level (HCPCS codes L5970, L5974); K2 (HCPCS codes L5972, L5978); K3 (HCPCS codes L5976, L5979), and, in order to indicate the more complex, technically sophisticated feet within the K3 level, K3-4 (HCPCS L5979, L5980, L5981, and L5987. Descriptions of each of these codes are presented in Appendix B Data Dictionary, Table B26.

Unlike that for prosthetic feet, there is no particular categorization of socket suspension systems discussed in the literature that is based on the amputee's functional level. Rather, as described by DePalma and colleagues (2002) suspension systems are typically organized in to differential pressure, anatomical, and simple. The differential pressure systems are the most popular and range in sophistication from a pin lock gel liner to a Vacuum Assisted Suspension System (VASS); the most popular anatomical suspension system is the supracondylar; and among the simple suspension systems, cuff suspension system is the most popular (DePalma et al., 2002). As may be expected, cost ranges from the VASS as the most expensive (being the most sophisticated) through the pin-lock liners which, though not mechanically complicated, utilize specialized materials such as urethane and silicon to construct the liners; to the simple suspension systems which other than the cuff suspension, amount to straps and belts that wrap around the socket and attach to a waist belt (G. W. Bosker CPO, personal communication, January 2011). Table 25 in Appendix B provides the description and costs (as determined by the Centers for Medicare-Medicaid Services) for each of the prosthetic feet and suspension systems.

To facilitate the development of a viable ALC variable, another temporary study dataset variable was created, ALCss, and suspension system HCPCS codes were categorized on the basis of mechanical complexity. Simple suspension systems (L5680, L5682, L5684, L5688, l5690, L5666) were grouped as low-tech (L); suspension sleeves and anatomical systems (L5685, L5670) were grouped together as mid-tech (M) with a subset , LOCK, dedicated to suspension sleeves with pin-lock mechanism(L5671, l5673) as these were so popular. Finally, the differential pressure suspension systems, which include the below-knee suction socket (L5647) and the VASS (L5781, L5782) were categorized as high-tech (H) based on their sophistication and cost. Because of the exceptional cost and reports of healing properties associated with the VASS, these components were SUB-categorized as Hv for descriptive statistics only.

Codes from ALCfoot and ALCss were then combined to form the independent variable ALC per unique case and amounted to a total of 18 combinations/values. Table D1 in Appendix D presents these combinations and frequencies. However, as can be noted, many of the cells had very low frequencies that would not lend themselves to accurate statistical analysis, and thus the various artificial limb configuration combinations were further categorized into 7 groups as presented in the same table. The frequencies and percentages reported represent the 279 cases with viable data only and include the categories transfers (*N* =12, *frequency* = 4%); household-high tech suspension system (*N* = 10, *frequency* = 3%); household-mid to low tech suspension system (*N* = 16, *frequency* = 5%); household-locking suspension system (*N* = 25, *frequency* = 8%); community-high tech suspension system (*N* = 49, *frequency* = 16%); community-mid to low tech suspension system (*N* = 53, *frequency* = 17%); and community-locking suspension system (*N* =150, *frequency* = 48%). A complete description of the coding system used for the independent variable is described in Appendix B Data Dictionary, Table B2.

Development of the Dependent Variable, Residual Limb Skin Problem Severity (RLSPS)

The variable RLSPS was comprised of three categories: severe (Severex), less severe (Lseverex), and No Treatment. The categories severe and less severe were further subdivided into four subcategories each, representative of those suggested by Bui et al (2009). Because the subcategories were based on the potential causes or etiologies of the skin problem, both severe and less severe skin problems could be categorized into the same sub category or etiology. The exception to this rule was for those skin problems felt to be caused or related to skin occlusions, in which those that were infectious were placed in the severe category and those that were not, placed in the less severe category. Thus the subcategories included: residual limb skin problems in reaction to a foreign body (Foreignbx, less severe; Foreignb2x, severe); residual limb skin problems in response to non-infectious occlusions (Occlusionx, less severe only); residual limb skin reaction to repetitive injury or microtrauma (Repetitivetx, less severe; Repetitivet2x, severe); residual limb complication directly consequent of limb surgery (Surgicalx, less severe; Surgical2x, severe); residual limb complication not otherwise categorized (Otherlsx, less severe; ,Otherls2x, severe); and residual limb skin problems in response to an infectious occlusion (Occlusion2x, severe only). The ICD-9-CM codes that comprised each of these subcategories are presented in tables B18 (Less severe category) and B19 (severe category) of Appendix B, Data Dictionary. Table 8 below presents an accounting of the RLSPS category and subcategory outcomes.

Because ICD-9-CM codes do not necessarily discriminate between body parts or locations, it was not always possible to be assured that the skin problem was actually on the residual limb, strictly on the basis of code. In an attempt to correct for this problem, it was initially planned to count only those RLSPS ICD-9-CM codes that were detected within the same encounter record as the ICD-9-CM codes 997.6 (Late amputation stump complication), 997.60 (Unspecified complication), 997.62 (Infection of stump, chronic), 997.69 (Other complication of stump), or V49.75 (Lower limb amputation status, below knee). However, a review of the cohort dataset revealed no cases in which any of these codes were present and thus could not be used to assure residual limb involvement. Therefore, RLSPS category ICD9-CM codes with descriptions that included mention of head, neck, torso, arms, hands, genitals, pelvis or feet were not included; those with specific mention of lower limb, thigh or shank were; and those that were non-specific to a body part were also included as long as they reasonably fit into one of the five subcategories described above or indicated by Bui et al. (2009).

Additionally, because it is common for a skin problem to be labeled as a less severe problem (according to the ICD-9-CM code) but be severe in nature, an attempt was made to utilize CPT codes indicative of treatments used to distinguish as a severe or less severe RLSPS category. The CPT codes used included those representative of wound drainage, wound debridement, and lesion removal (table B21, Appendix B – Data Dictionary presents the actual codes) but were not used in the categorization because of complications of associating procedural codes with the appropriate ICD-9-CM code.

Nonetheless, among the cohort 5 (2%) cases were noted to have undergone wound drainage, 95 (34% cases for wound debridement, and 9 (14%) for lesion removal.

Table 8

Frequencies for Residual Limb Skin Problem Severity Variables with Subcategories

Variable & Subcategories	Frequency (percent)	Comments
Residual Limb skin problem severity (RLSPS)	------	The dependent/outcome variable; categorical (severe/less severe/no treatment); repeated measure.
Less severe (total)	**131 (46.5)**	Skin problems considered non-life threatening with minimal restrictions on artificial limb use; includes callouses, non-infectious rashes or blisters, cysts, disorders of sebaceous or sweat glands and dermatoses.
Surgical	2 (0.7)	
Foreign Body	12 (4.3)	
Repetitive	56 (19.9)	
Occlusion (non-infectious)	84 (29.8)	
Other Less severe	38 (13.5)	
Severe (total)	**141 (50.0)**	Severe Residual Limb Skin Problems that are life/limb threatening or infectious, and may require extensive restrictions on artificial limb use. Includes skin ulcers, infectious rashes, or lesions, neuromas, osteomyelitis, cellulitis, malignant neoplasms.
Surgical	26 (9.2)	
Foreign Body	0 (0.0)	
Repetitive	56 (19.9)	
Occlusion (infectious)	96 (34.0)	
Other severe	42 (14.9)	
No Treatment (total)	**10 (3.5)**	Represents those cases in which neither a less severe nor a severe skin code was recorded.

The Mental Health Status Variables and Codes

As discussed in Chapter 3, many skin problems associated with the residual limb and use of an artificial limb are related to the amputee’s activity level (mechanical effects) or disease/condition self-management and care compliance (behavioral effect). Also, as discussed, these two effects are not necessarily independent of each other. For example, an individual with major depression not only may be inactive, but they may also lack the impetus for required personal hygiene or self-care of their residual limb; an amputee with anxiety issues associated with PTSD may exhibit normal activity but be reluctant to seek medical care of a skin problem in a timely manner; an amputee dealing with SUD may exhibit non-normal activity levels and poor self-care, but also be exacerbating their dysvascular condition with alcohol and drugs.

The three mental health conditions being included in this study all have specific ICD-9-CM codes associated with them as per guidelines supplied by the VHA and Department of Defense working groups specific to each condition and are presented in tables B14 MDD, B15 PTSD, and C16 SUD in Appendix B, Data Dictionary. Consideration was given to include diagnosable conditions not listed in these guidelines but clearly associated given their ICD-9-CM code descriptive label, especially in the case of MDD (such as depressive states of bipolar disease) and PTSD as an adjustment disorder. Subsequently, secondary variables labeled Otherdepx (in association with MDD) and Otheradjdisx (for PTSD) were created and are also described in tables B14 and B15 of Appendix B, respectively. Given the ICD-9-CM codes for Otherdepx, only five cases were identified, of which two cases also were diagnosed with MDD, increasing the number of cohort members with depressive symptoms from 38 (13%) to 41 (15%). Similarly, based on ICD-9-CM codes descriptive of behavior adjustment disorders in the variable Otheradjdisx, 22 cases were identified of which 12 were also diagnosed with PTSD, increasing the total number of cases with some behavioral adjustment disorder from 53 (19% - Ptsdx only) to 67 (24% - Ptsdx and otheraddax combined). Nonetheless, since the selected ICD-9-CM codes for Otherdepx and Otheradjx were based on their label rather than definition or guidelines, only the variables Majordepx for MDD and Ptsdx for PTSD (along with Sudx for SUD), were used for statistical modeling in order to preserve accuracy. Table 9 presents these outcomes as part of a characterization of the cohort.

Variables Representative of Physical Comorbid Conditions

As per study cohort inclusion criteria, all 279 members (transtibial amputees) had a diagnosis of concurrent dysvascular disease. More specifically, 188 (67%) had a diagnosis of diabetes, 123 (44%) diagnosed with PVD, and 49 (18%) were diagnosed with PAD.

ICD-9-CM codes used for the comorbid condition variables congestive heart failure (Chfx), renal failure (renalfailx), cerebral vascular disease (Cvdx), and chronic obstructive pulmonary disease (Copdx) were those identified by Kurichi et al., (2007) as being significantly related to a patient’s clinical outcome post lower limb amputation. Actual codes were searched for on the website http://www.eicd.com/EICDMain.htm using key terms such as heart failure, renal failure, respiratory disease and cerebral vascular disease.

COPD is described by groups of ICD-9-CM codes indicative of specific disorders that are associated with obstruction or difficulty with lung and respiratory function. The intent of the inclusion of the condition is because of the extra effort required to utilize an artificial limb and thus, the need for good exchange of gases as a consequence of metabolic increases (The Management of Chronic Obstructive Pulmonary Disease Working Group, 2011; Winter & Sienko, 1988). A secondary variable, Otherrespx, was created to include those respiratory conditions that were not necessarily obstructive in structure or function, but could, nonetheless, significantly impair oxygen/carbon dioxide gas exchange. Within the cohort, 64 (23%) of the members had a diagnosis of COPD, 13 (5%) had a significant pulmonary disease other than COPD, for a total of72 (26%) suffering from a pulmonary disease likely to impact their energy levels and gas exchange.

The comorbidity variables for CHF, renal failure (Renalfailx) and malnutrition (Malnutritx) were identified with ICD-9-CM codes because of their indication of overall poor health; CVD and obesity (Obesitx) were included because of their potential mechanical effects due to hemiparesis and weight bearing gait abnormalities. The codes used to describe each of the comorbid conditions selected are presented in Tables B4 for CHFX, B5 for COPDx and Otherespx, B6 for CVD, C6 for Renalfailx), and B8 for Malnutritx and Obesitx in Appendix B, Data dictionary. Given the chronic and life-threatening nature of these conditions, only inpatient files from FY 2007 through FY 2011 were reviewed. As binomial variables, the presence of at least one ICD-9-CM code for a condition in a cohort member's record was sufficient to be counted. Table 9 presents the outcome of this accounting in detail and indicates that CHF was diagnosed in 129 (46%) of the cohort members, CVD in 17 (6%) of the members, renal failure in 52 (18%), obesity in 7 (2%, and malnutrition in 1 (0.4%).

Demographic Variables Used in the Study

Demographic variables Gender, Age, Marital Status, Race, and VA Priority are all found in the Main section of NPCD inpatient files. The primary intent of these variables is to characterize the cohort and secondarily to help explain residual limb outcomes in the multivariable analysis. To help improve cell sizes, the variable marital status was condensed from 5 categories (not married, married, widowed, divorced, and unknown) to 2 categories - married of which there were 143 (53%) cohort members and other with 128 (47%) members. The variable VA priority (socioeco) was also condensed from 7 categories (VA Priority Status group 1 through 5, Group 7, and Group 8; no VA priority Group 6 cases were found within the cohort) to 3 new categories – Unemployable (frequency = 228 or 84%); Employable (frequency = 32 or 12%); and Co-pay Eligible (frequency = 13 or 5%).

Reduction of the original variable values to fewer values was based primarily on the projected influence or importance of the demographic on residual limb outcome. For example, in regard to the variable socioeco, the decision to categorize the VA Priority Groups into employable, unemployable, and co-pay eligible was based on the assumption that an employed individual was likely to be more active and healthier, a co-pay eligible individual of sufficient income and socioeconomic status to afford such (a co-payment) and thus of potential moderate health and activity, and unemployable individuals potentially less healthy and less active. Marital status was used as a proxy for the presence of a caregiver or personal help for the amputee; and the variable Age was a numeric type variable and used only to describe the cohort, in part because such a significant proportion of the cases were grouped within one age range (55 years to 75 years), and because there was 30% missing data (87 cases) for the variable Age from the NPCD Inpatient MedSAS FY 2007 data extracts. Attempts were made to use the variable AGE8 from the same data set and was found to have no missing data, and when age groups/values were combined to reduce the number of categories from 8 to 3 (54 years or less, 55-74 years, and 75 years or greater), data integrity was preserved. Ultimately it was determined that within the cohort 49 (18%) cohort members were 55 years or younger, 173 (62%) were between 55 and 74 years old, and 60 (22%) were 75 years or older.

Details regarding the formation of each of these demographic variables are presented in Table B9 through Table B14 of Appendix B, and a detailed accounting of each variable in Table 9 below.

Table 9

Variable Frequencies and Cohort Characteristics

Variable	*N**	Frequency (percent)	Comments
Gender:			
Male	282	280 (99.29)	Reflective of VA population (refer to Table 4, Chapter 2, p.117)
Female		2(0.72)	
Age:			
<25 years old		1 (0.35)	
25 - 34 years old		6 (2.13)	
35 - 44 years old		9 (2.13)	
45 – 54 years old	282	33 (11.7)	Mean Age = 62.4 ± 9.8; median = 60; minimum = 24, maximum = 98; mean age 1st quartile = 56years, 3rd quartile = 73 years.
55 – 64 years old		110 (39.01)	
65 – 74 years old		63 (22.34)	
75 – 84 years old		42 (14.89)	
>84 years old		18 (6.38)	
Race:			
White		181 (69.1)	
Black	282	72 (27.5)	
Asian		9 (3.4)	
Missing Data		20 (7.1)	
Marital status:			
Divorced		73 (26.94)	Variable condensed to Married = 143 (52.77%), Not-married = 128 (47.23%).
Married		143 (52.77)	
Never married	271	39 (14.39)	
Unknown		2 (0.74)	
Widowed		14 (5.17)	
Missing data		8 (2.83)	

(*table continues*)

Variable	*N**	Frequency (percent)	Comments
Socioeconomic (VA Priority group):			VA Priority groups are designated on the basis of degree of service-connected or incident disability, adjusted income (means test), and age/retirement status. For a more detailed description of Priority Groups, refer to Appendix B – Data Dictionary.
Unemployable (1,4,5)	279	195 (75.3)	
Employable, disabled (2, 3, 6)		34 (13.1)	
Copay eligible (7,8)		30 (11.6)	
		20 (7.2)	
Missing data:			
Major depressive disorder (MDD)	282	38 (13.48)	Total number of cohort members with a depressive condition represents those with either an ICD-9-cm CODE for MDD or another depressive disorder; those with both are counted only once. Frequencies indicate that only 2 (0.71%) had a depressive disorder other than MDD.
Other depressive disorders		5 (1.77)	
Total with depressive conditions		41 (14.54)	
Cases with no matching codes		241 (84.56	
Post traumatic stress disorder (PTSD)	282	53 (18.79)	The total number of cohort members with an adjustment disorder may have both andICD-9-CM code for PTSD and another adjustment disorder, but they are counted only once. Frequencies indicate that 14 (4.97%) had both categories of codes; 8 (2.83%) had an adjustment disorder other than PTSD.
Other adjustment disorders		22 (7.8)	
Cases with adjustment disorders		67 (23.76)	
cases with no matching codes		215 (76.24)	
Substance use disorder (SUD)	282	42 (14.89)	Includes both drug and alcohol abuse.
Cases with no matching codes		240 (85.11)	
Chronic obstructive pulmonary disease (COPD)	282	64 (22.7)	Frequencies indicate that only 5 (1.77%) of the cohort suffered from a chronic respiratory/pulmonary disorder other than COPD
Other chronic respiratory disorders		13 (4.61)	
Total with respiratory/pulmonary disorders		72 (25.53)	
Cases with no matching codes		210 (74.47)	

(*table continues*)

Variable	*N**	Frequency (percent)	Comments
Congestive heart failure (CHF) Cases with no matching codes	282	129 (45.74) 153 (54.26)	This large number is to be expected given the concurrent diagnoses of diabetes, peripheral vascular disease and peripheral arterial disease.
Cerebral vascular disease (CVD) Cases with no matching codes	282	17 (6.03) 265 (93.97)	Includes strokes and cerebral bleeds.
Renal failure Cases with no matching codes	282	52 (18.44) 230 (81.56)	Renal failure is a comorbid condition for both diabetes and congestive heart failure.
Nutrition: Obesity Malnutrition Cases with no matching codes	282	 7 (2.48) 1 (0.35) 274 (97.16)	Given that all the cohort members had diagnosis code for diabetes, peripheral vascular disease or peripheral arterial disease, the low frequency of a diagnosis code for obesity is unexpected.
Death: Year 2008 Year 2009 Year 2010 Cases with no matching codes	279**	2 (0.71) 2 (0.71) 2 (0.71) 273 (97.8)	Of the initial cohort, 41% died in 2007 (or were not accounted for); of the surviving 358, 279 (80%) were captured as members of the study cohort. Of the study cohort, a total of 6 (2.1%) died during their follow-up period

*: data extracted from inpatient/outpatient clinical files, except for socioeco/VA Priority which was extracted from NPPD data.

**: N = 279 represents cohort members with sufficient clinical and artificial limb data.

The variable VISN was identified from the NPPD extracts and served as an indication of where the amputee received their artificial limb and, by proxy, who decided on the configuration of components and crafted the socket. To improve cell sizes, the 22 VISNs across the nation were condensed into 4 Regions as described by the Veterans Administration Central Office, Office of Information Technology, Washington DC. Based on the locale of the VISNs, the regions fairly well divide the United States into four geographic areas: Region 1 – northwest and western U.S; Region 2 - north- and south-central U.S. (includes Texas); Region 3 - eastern mid-west and southern U.S. (includes Ohio); and Region 4 - mid-atlantic and northeast U.S. (includes Washington DC/Maryland) (http://www.va.gov/directory/guide/division.asp?dnum=1#main-content). Table D2, Appendix D presents the distribution of cohort members across the VISNs and subsequent regions, as well as the distribution of ALC categories delivered to cohort members per region. The total number of artificial limbs dispensed exceeds the total number of cohort members because some were dispensed more than one type of ALC during the follow-up period. The frequency per ALC category dispensed reflects not so much the total number of limbs dispensed for the cohort, but rather the different categories dispensed per cohort member. For example, a cohort member may have been dispensed a K3LOCK limb in FY 2008 and another in FY 2009 and be counted only once, whereas another may have been dispensed a K3m in FY 2007 and a K3LOCK in FY 2009 and thus be counted twice.

In summary, Region 3 was represented by 112 (40%) cohort members, followed by Region 2 with 62 (22%) cohort members, Region 4 with 57 (20%) members, and Region 1 with 48 (17%) members. The community-locking suspension system was the most frequently dispensed ALC category with 65 dispensed in Region 3 (53% of all ALCs dispensed within the region), followed by Region 1 with 30 (56% of all ALCs dispensed within the region), Region 2 also with 30 (42% of all ALCs dispensed within the region) and 25 in Region 4 (38% of all ALCs dispensed within the region). The ALC categories Transfers and Household-high-tech suspension system were the least frequently dispensed with a total of 12 and 10, respectively, across all four regions.

One of the underlying questions in this study has to do with the need for or enforcement of standardized prescription guidelines - that the Prosthetist's would practice the same prescription patterns across the nation. However, the distribution of ALC categories across the four regions was not homogeneous - in the case of ALC category household-locking mechanism suspension system, two of the regions dispensed only 1 such artificial limb and the other 2 nearly 10 times that amount. Similarly, regions one, two, and four dispensed 25-30 community-locking mechanism artificial limbs, whereas Region 3 dispensed twice that amount. Certainly, these findings may suggest some preference for certain types of artificial limb componentry per region; however, it is purely speculation without further analysis to include cohort member demographics and comorbid conditions that may influence a Prosthetists decision.

Data Quality Assessment and Selection of Variables for the Multivariate Analysis

Frequency tables and chi square analyses were run on the variables described above to check for missing data and significance of the variable relative to the dependent variable category severe (Severex) or less severe (lseverex) skin problems (RLSPS). Table D3 Appendix D presents the results of these calculations and reveals that the variables ALC, MDD, PTSD, SUD, marital status, region, age, CHF, COPD, and renal failure all met criteria (Chi-square *p*-value of 0.25 or less for at least one of the dependent variable categories) and thus , were to be included in the epidemiologic analysis statistical models. The variables for obesity and malnutrition were not included in the univariate analysis given their very low frequencies. Based on the univariate analyses, the variables socioeco, race, gender, and cerebral vascular disease (CVDx) could be removed from the multivariate analysis, given Chi-square p-values of greater than 0.25. However, only gender was removed because socioeco/VA priority as well as race, were constant covariates as demographic variables, and CVD particularly interesting because of its potential significance as a mechanical effect covariate.

Further, frequency tables and a univariate analysis were conducted using the variables Region (being used as a proxy for the Prosthetist that configured and dispensed the cohort member's artificial limb) and ALC to ascertain if there was a significant difference in artificial limbs dispensed across the regions. The findings indicated that, while the calculated *p*-value for the Chi-Square analysis is not significant at an alpha of

0.05, Region was included because of its relevance in addressing research question 2, as well as an indicator of national prescription guidelines.

Similarly, the variables severe (Severex) and Less severe (Lseverex) (categories of the dependent outcome variable RLSPS) were tested against the primary independent variable, ALC, to detect if any significant relationships existed without the influence of covariates. The findings indicated that severe skin problems were significantly associated with the type/category of artificial limbs used (Chi-square N = 315, p-value = 0.0428, while Less severe skin problems were less so (Chi-square N = 315, p-value = 0.26).

More specifically, Table 10, presents the frequencies for severe and less severe categories of RLSPS per ALC category, and reveals that, overall, the frequency of severe RLSPS was only about 3% more than that for less severe RLSPS. Additionally, problem frequencies were greatest for the Community-Locking Suspension System ALC category (severe RLSPS: frequency = 84 [27%]; less severe: frequency = 69 [22%]), but this was also the most frequently dispensed ALC category; the transfers and Household-High Tech Suspension System ALC categories demonstrated the least frequencies of severe and less severe RLSPS (transfers: severe frequency = 2 [0.6%], less severe – frequency = 6 [2%]; household-high tech suspension system: severe – frequency = 5 [2%], less severe – frequency = 2 [1%]), but were also the least frequently dispensed ALC categories. Finally, in regard to the ratio of severe RLSPS to less severe RLSPS, the ALC categories household-high tech suspension system and Household-mid to low tech suspension systems each had a rate of 2.5, while the ALC category transfers had a rate of 0.33 and ALC Category Community-mid to low-tech suspension system a rate of 0.7.

Table 10

Frequencies per ALC Category per Dependent Variable (RLSPS) Categories Severe and Less Severe

ALC Category	Severe Skin Problems Freq (%)*	Less Severe Skin Problems Freq (%)*	Comments
Transfer	2 (1.28)	6 (4.14)	Total of 12 ALC units distributed across all four regions; ratio of severe to less severe problems cases = 0.33
Household-high-tech suspension system	5 (3.21)	2 (1.38)	Total of 10 ALC units distributed across all four regions; ratio of severe to less severe problems cases = 2.5
Household-mid to low-tech suspension system	10 (6.41)	4 (2.76)	Total of 16 ALC units distributed across all four regions; ratio of severe to less severe skin problem cases = 2.5
Household-locking suspension system	14 (8.97)	13 (8.97)	Total of 25 units distributed across all four regions; ratio of severe to less severe problems cases = 1.1
Community-high tech suspension system	21 (13.46)	23 (15.86)	Total of 49 units distributed across all four regions; ratio of severe to less severe problems cases = 0.9
Community-mid to low-tech suspension system	20 (12.82)	29 20.0)	Total of 53 units distributed across all four regions; ratio of severe to less severe problems cases = 0.69
Community-locking suspension system	84 (53.85)	68 (46.9)	Total of 150 units distributed across all four regions; ratio of severe to less severe problems cases = 1.2
Totals	**156 (49.52)**	**145 (46.03)**	****Total of 315 units distributed across all four regions; ratio of severe to less severe problem cases = 1.07**

* *Frequency* = number of the RLSPS category codes counted (not the number of cases); a single case may have had none, one, or more RLSPS codes during their follow-up period. *Percent* = number of RLSPS codes counted per ALC category.
** Cohort N = 282; a single case may have been distributed more than one ALC category during their follow-up period.

The Epidemiological Analysis

Overview. The purpose of this phase of the study was to explore the value of a compiled and integrated dataset derived from multiple national VHA health care datasets as a means to provide observed practice-based evidence for the ascertainment of relationships specifically relative to the lower limb amputee. More specifically, the goal was to identify patterns of artificial limb prescription/dispensing relative to patient clinical conditions and, in particular, residual limb skin problem severity following dispensing and concurrent with certain psychosocial conditions, namely MDD, PTSD, and SUD.

For each research question, relevant frequency tables were created (as every variable was categorical and not conducive to other simple descriptive statistics), and as described above, unadjusted univariate analyses conducted to guide model development. However, demographic variables (such as married, race, age, and socioeco/VA priority) were included regardless of their unadjusted significance because of their explanatory value and basic importance. The remaining relevant variables (based on Chi-Square, Univariate Analyses Statistical Significance) were then used to develop a multivariate model using generalized estimating equations (GEE), logistic regression function (LOGIT), an independent correlation structure, and assuming a binomial distribution. The structure of the model included that the subject effect be the cohort member's study ID per repeated measure interval (6 month observation) and the cluster size not exceed one nor be less than one such that the number of clusters equaled the number of observations.

GEE was used rather than generalized linear modeling (GLM) because of the dependent (response) variable being a categorical repeated measure with discrete values (frequency counts of no treatment/severe/less severe RLSPS at six month intervals); because many of the covariates contained small cell sizes and there were significant missing data (considered inappropriate for GLM), and because the intent of the analysis was to estimate variability/differences, not risk ratios.

Using the described GEE model structure, estimates of covariance were calculated, but instead of attempting to model the within-subject covariance structure (as in GLM), errors were treated as a nuisance and the mean response modeled instead (Garson, 2008; Garson, 2011a). Ultimately, the *p*-value represents the statistical significance of the odds that the characteristic/covariate is present in an observation (Garson, 2008; Garson, 2011a).). This model type and structure was used for all four research questions, with only the covariates of interest used relevant to each research question. Of note, in an effort to simplify interpretation by establishing only binomial outcomes, for those variables having more than one category (other than the ALC independent variable) a category therein was identified as the reference category. For the demographic variable Socioeco, there were 3 categories – employable, unemployable, and copayment eligible, wherein the category unemployable was the reference category; Age Group (Agex) categories were those less than 55 years of age, those aged 55 to 74 years, and those older than 74 years, with the reference category being the youngest group; and for the variable Race categorized as White, Black and Asian, White was selected as the reference category. For the covariate Regionx, there are four regions encompassing all 21 VISN, Region 1, Region 2, Region 3, and Region 4. Region 2 was selected as the reference category as it is at a VISN within the Region that this study was conducted and findings could prove to be particularly relevant. Finally, in an attempt to track changes in residual limb skin problem frequencies over time, the three year follow-up period was divided into six month intervals/windows, with the reference interval being the first 6 months.

Research question 1 - mechanical main effects. Research Question 1 addressed the issue of the ALC as the main effect influencing the variability in residual limb skin problems. So-called "mechanical" effects as described previously are those in which undue biomechanical forces act on the residual limb-artificial limb interface (at the contact point of the socket and skin of the residual limb).

Initial analysis. Frequency tables were created wherein the number of cohort members having a severe or less severe RLSPS was accounted per ALC category as well as 6 month observation interval and is presented in Table 11 below. The values for percentage represents the percentage of cohort members identified per category among all the artificial limbs dispensed (315 artificial limbs) per time point. The values under the Total column represent the number of cohort members evaluated per ALC category, and total values per column represent the total number of residual limb skin problem condition/category per six month interval.

Table 11

Frequency Tables for Research Question One

ALC category	Statistic*	6 Month Follow-Up			12 Month Follow-Up			18 Month Follow-Up			Total**
		No Tx	Less Severe	Severe	No Tx	Less Severe	Severe	No Tx	Less Severe	Severe	
Transfer	Freq	10	1	0	10	1	0	9	1	1	…
	percent	3.58	0.36	0	3.58	0.36	0	3.23	0.36	0.36	…
Household-high tech suspension system	Freq	6	0	2	6	0	2	8	0	0	…
	percent	2.15	0	0.72	2.15	0	0.72	2.87	0	0	…
Household-mid to low tech suspension system	Freq	10	0	3	12	1	0	11	2	0	…
	percent	3.58	0	1.08	4.3	0.36	0	3.94	0.72	0	…
Household-locking suspension system	Freq	16	1	6	16	5	2	18	3	2	…
	percent	5.73	0.36	2.15	5.73	1.79	0.72	6.45	1.08	0.72	…
Community-high tech suspension system	Freq	31	4	7	34	4	4	33	4	5	…
	percent	11.11	1.43	2.51	12.19	1.43	1.43	11.83	1.43	1.79	…
Community-mid to low tech suspension system	Freq	38	5	5	37	5	6	36	6	6	…
	percent	13.62	1.79	1.79	13.26	1.79	2.15	12.9	2.15	2.15	…
Community-locking suspension system	Freq	110	11	13	110	7	17	116	9	9	…
	percent	39.43	3.94	4.66	39.43	2.51	6.09	41.58	3.23	3.23	…
Total	**Freq**	**221**	**22**	**36**	**225**	**23**	**31**	**231**	**25**	**23**	…
	percent	**79.21**	**7.89**	**12.9**	**80.65**	**8.24**	**11.11**	**82.8**	**8.96**	**8.24**	…

(*table continues*)

ALC category	Statistic*	6 Month Follow-Up			12 Month Follow-Up			18 Month Follow-Up			Total**
		No Tx	Less Severe	Severe	No Tx	Less Severe	Severe	No Tx	Less Severe	Severe	
		24 Month Follow-Up			**30 Month Follow-Up**			**36 Month Follow-Up**			**Total**
		No Tx	Less severe	severe	No Tx	Less severe	severe	No Tx	Less severe	severe	
Transfer	Freq	9	1	1	10	0	1	11	0	0	**11**
	percent	3.23	0.36	0.36	3.58	0	0.36	3.94	0	0	**3.94**
Household-high tech suspension system	Freq	8	0	0	8	0	0	8	0	0	**8**
	percent	2.87	0	0	2.87	0	0	2.87	0	0	**2.87**
Household-mid to lowtech suspension system	Freq	13	0	0	12	0	1	13	0	0	**13**
	percent	4.66	0	0	4.3	0	0.36	4.66	0	0	**4.66**
Household-locking suspension system	Freq	21	1	1	19	1	3	22	1	0	**23**
	percent	7.53	0.36	0.36	6.81	0.36	1.08	7.89	0.36	0	**8.24**
Community-high tech suspension system	Freq	35	3	4	38	1	3	39	2	1	**42**
	percent	12.54	1.08	1.43	13.62	0.36	1.08	13.98	0.72	0.36	**15.05**
Community-mid to low	Freq	40	2	6	44	1	3	43	3	2	**48**
	percent	14.34	0.72	2.15	15.77	0.36	1.08	15.41	1.08	0.72	**17.2**
Community-locking SS	Freq	115	8	11	123	4	7	126	4	4	**134**
	percent	41.22	2.87	3.94	44.09	1.43	2.51	45.16	1.43	1.43	**48.03**
Total	**Freq**	**241**	**15**	**23**	**254**	**7**	**18**	**262**	**10**	**7**	**279**
	percent	**86.38**	**5.38**	**8.24**	**91.04**	**2.51**	**6.45**	**93.91**	**3.58**	**2.51**	**100**

**Frequency* = number of cases per RLSPS category per ALC category; *percent* = number of cases per cohort N of 279.

In general, based on the total frequency of all the ALC categories, less severe RLSPS peaked at the 18 month interval with a frequency of 25 (9%) that diminished fairly rapidly to a frequency of 10 (4%) by the 36 month interval, the lowest frequency being 7 (3%) during the 30 month interval. severe RLSPS followed a similar trend but peaked during the six month interval with a frequency of 36 (13%) that more gradually diminished to a frequency of 7 (3%) during the 36 month interval. As a significant proportion of the cohort utilized the community-locking suspension system ALC category, the greater frequency and percentage of skin problems were associated with this artificial limb configuration.

The unadjusted analysis utilized Fisher's Exact Test instead of Chi-Square test as there were several cells with frequencies below 5, and was used to determine if there was a significant relationship between the type of ALC dispensed and the presence or absence of a less severe RLSPS and separately, the presence or absence of a severe RLSPS; frequency was based on the identification (or not) of cases with at least one residual limb skin problem ICD-9-CM code during their follow-up period. It did not compare the frequency of less severe problems to severe problems, and individuals may have been counted in both categories (lseverex, and Severex) as they were treated as separate dependent variables. Table D3, Appendix D presents the results of this unadjusted analysis,, indicating that the frequency of severe residual limb RLSPS differed significantly between the seven categories of artificial limbs ($p = 0.042$), but for less severe RLSPS there was no such significant finding ($p = 0.2636$).

GEE model analysis. Using the GEE model structure as described above, in order to most directly address the issue of mechanical main effects in relation to the outcome/response variable, the following covariates were included in the model: demographic (explanatory) variables married, race, socioeco/VA Priority, and age group. Three of the ALC categories – Transfers, household-mid to low suspension system, and household-high tech suspension system – as their dispensing rate and outcome frequencies were so low (compared to the other ALC categories) as to add little to the model outcome if included individually, were instead, combined to form a single ALC category, 'others'. This category represented 38 (12%) of the 315 artificial limb configurations dispense, and effectively preserved the sample size of 279 cases per model. In this and ensuing GEE analyses wherein the ALC variable was a contributing factor, each of the remaining 4 ALC categories were treated as binary and compared to the 'others' category (for example, community-locking suspension system versus others; household –locking suspension system versus others, and so forth). Table D2, Appendix D, presents the distribution of ALC categories.

The model also included the dependent variable, RLSPS as a repeated measure at 6 month intervals following the dispensing of a cohort member's definitive artificial limb, and represented three categories/conditions: no treatment, less severe, and severe.

Table 12 presents the results of the GEE model analysis and reveals that only the community-mid to low suspension system ALC category significantly contributed to the likelihood of a cohort member developing a less severe RLSPS at some point during the

3 year follow-up period (*Estimate* = 1.89, p = .02), but that this same ALC category plus the community-high tech suspension system and community-locking suspension system ALC categories also contributed significantly to the likelihood of a cohort member developing a severe RLSPS during the entire follow-up period (*Estimate* = 1.91, $p < .001$; *Estimate* = 1.17, p = .04; and *Estimate* = 1.05, p = .045, respectively). Of note, though not statistically significant, a potential association was evident for cohort members using a Household-locking suspension system ALC category who were likely to have a less severe residual limb RLSPS during the follow-up period (*Estimate* = 1.59, p = .06), as were those cohort members using a community-locking suspension system ALC category (*Estimate* = 1.26, p= .10).

Review of the demographic parameters/variables revealed that cohort members between the ages of 55 and 74 were less likely (compared to cohort members less than 55 years of age) to develop a less severe RLSPS during the follow-up period (*Estimate* = -0.93, p = .01), as well as in regard to a severe RLSPS (*Estimate* = -.73, p = .01), with the addition that cohort members older than 74 were also less likely than members aged less than 55 to develop a severe RLSPS (*Estimate* = -1.29, p = .002). Because of the structure of the model, it is not possible to declare what age group and ALC category was more likely to develop a less severe or severe RLSPS, only that the two conditions significantly influenced the outcome. Additionally, race as a main effect was only relevant in the case of severe RLSPS developed over the 36 month follow-up period, wherein Blacks were significantly less likely to develop a severe RLSPS compared to Whites (*Estimate* = -.63, *p* = .02). A potential association was evident for socioeco/VA priority and, though not statistically significant, , suggested that cohort members able to make a co-payment were less likely to have a less severe RLSPS during the follow-up period than were cohort members that were classified as unemployable (*Estimate* = -1.11, *p* = .08); and similarly, marital status was potentially associated with severe RLSPS, and indicated that married cohort members were less likely than other cohort members to have a severe RLSPS during the follow-up period (*Estimate* = -.37, *p* = .09).

Finally, only during the thirty-month follow-up window and the thirty-six month follow-up window was there a main effect evident for less severe RLSPS, the number of cases diminishing significantly during both windows as compared to the reference six month window (*Estimate* =-1.46, *p* = .01; *Estimate* = -.95, *p* = .04, respectively).

These findings indicate:

1. That the null hypothesis (H01) - RLSPS categories (frequency and type) will not vary significantly on the basis of the ALC category dispensed, was rejected. Unadjusted Chi-square analyses revealed that there was a significant association between type of ALC category and the number of cases with a severe RLSPS (*p* = 0.0428), but a similar association did not exist relative to less severe RLSPS; and results of the GEE analysis confirmed this finding by demonstrating that not every ALC category was significantly related to a RLSPS, especially in the case of the less severe category.

2. The alternative hypothesis H_a1a - more severe RLSPS (such as ulcers) will be significantly more frequent among ALC categories of higher function or technical sophistication and will be least for low function, low technically sophisticated configurations, is true in so far as the ALC categories analyzed; the ALC category household-locking suspension system did not attain statistical significance relative to the likelihood of having a severe RLSPS during the follow-up period, and assuming that the functional sophistication of an ALC category is based primarily on the complexity of the prosthetic foot. The household ALC categories utilize K1 or K2 functional level prosthetic feet (the remaining ALC categories utilize K3 and K3-4 functional level prosthetic feet, all of which did attain statistical significance).

3. The alternative hypothesis H_a1b - over 50% of all the cohort members will have at least one RLSPS treated during the three-year follow-up period, regardless of the ALC category dispensed to them, is unclear; frequency tables indicate that of the 279 cohort members analyzed, there were 102 cases of less severe RLSPS during a six month observation interval, and 138 cases of severe RLSPS for a total of 240 cases of residual limb skin problems within the cohort. The structure of the model prohibits determining how many of the skin problems were unique to a cohort member; a single cohort member may have been counted once for a less

severe problem, and again for a severe RLSPS during a different time interval. Furthermore, while a secondary analysis would have been to track the number of multiple residual limb skin problems per cohort member, such an analysis is confounded by a diagnosis code being entered every time a wound is treated, even if it is the same wound. Table 3, Chapter 2 presents ICD-9-CM coding practices as defined by the Centers for Medicare Medicaid Services, and states “Code a chronic diagnosis as often as it is applicable to the patient’s treatment” (CMMS, 2012b).

Table 12

General Estimating Equations Model Output for Research Question One – Mechanical (ALC category) as the Main Effect.

Less Severe Residual Limb Skin Problems – Analysis of GEE Parameters							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		-2.9184	0.7569	-4.4019	-1.4350	-3.86	0.0001
Window	12 month	0.0826	0.3979	-0.6973	0.8624	0.21	0.8356
	18 month	0.1226	0.3862	-0.6344	0.8796	0.32	0.7509
	24 month	-0.2662	0.4162	-1.0820	0.5495	-0.64	0.5224
	30 month	**-1.4616**	**0.5794**	**-2.5971**	**-0.3260**	**-2.52**	**0.0116**
	36 month	**-0.9511**	**0.4731**	**-1.8784**	**-0.0239**	**-2.01**	**0.0444**
(reference)	6 month	0.0000	0.0000	0.0000	0.0000		
*Household-locking suspension system	1:yes	1.5941	0.8463	-0.0646	3.2529	1.88	0.0596
	0:no	0.0000	0.0000	0.0000	0.0000		.
Community-high tech suspension system	1:yes	1.1701	0.8171	-0.4314	2.7717	1.43	0.1521
	0:no	0.0000	0.0000	0.0000	0.0000		

(table continues)

Less Severe Residual Limb Skin Problems – Analysis of GEE Parameters							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Community-mid to low tech Suspension system	**1:yes**	**1.8902**	**0.7901**	**0.3418**	**3.4387**	**2.39**	**0.0167**
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
*Community-locking suspension system	1:yes	1.2591	0.7638	-0.2378	2.7561	1.65	0.0992
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Marital status	married	-0.0053	0.2633	-0.5214	0.5107	-0.02	0.9838
	Others	0.0000	0.0000	0.0000	0.0000		
Age group	**55-74**	**-0.9297**	**0.3539**	**-1.6232**	**-0.2361**	**-2.63**	**0.0086**
	74 older	-0.0986	0.3743	-0.8322	0.6350	-0.26	0.7922
(reference)	55 younger	0.0000	0.0000	0.0000	0.0000	.	.
*Socioeco / VA Priority	*co-pay eligible	-1.1052	0.6338	-2.3473	0.1370	-1.74	0.0812
	Employable	0.2660	0.3696	-0.4583	0.9903	0.72	0.4717
(reference)	unemployable	0.0000	0.0000	0.0000	0.0000 .		

(table continues)

Less Severe Residual Limb Skin Problems – Analysis of GEE Parameters							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Race	Asian	0.1288	0.6663	-1.1771	1.4347	0.19	0.8467
	Black	0.2152	0.2735	-0.3208	0.7512	0.79	0.4313
Severe Residual Limb Skin Problems – Analysis of GEE parameters							
Intercept		-1.6022	0.6271	-2.8313	-0.3731	-2.55	0.0106
Window	12 month	0.0585	0.3310	-0.5903	0.7072	0.18	0.8598
	18 month	-0.2562	0.3511	-0.9444	0.4319	-0.73	0.4655
	24 month	-0.3257	0.3494	-1.0105	0.3591	-0.93	0.3512
	30 month	-0.5976	0.3714	-1.3256	0.1303	-1.61	0.1076
	36 month	**-1.5702**	**0.4722**	**-2.4958**	**-0.6447**	**-3.33**	**0.0009**
(reference)	6 month	0.0000	0.0000	0.0000	0.0000	.	.
Household-locking suspension system	1:yes	0.6328	0.6635	-0.6677	1.9333	0.95	0.3402
	0:no	0.0000	0.0000	0.0000	0.0000		

(*table continues*)

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Less Severe Residual Limb Skin Problems – Analysis of GEE Parameters							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Community-high tech suspension system	**1:yes**	**1.1717**	**0.5606**	**0.0730**	**2.2705**	**2.09**	**0.0366**
	0:no	0.0000	0.0000	0.0000	0.0000		
Community-mid to low tech suspension system	**1:yes**	**1.9093**	**0.5460**	**0.8392**	**2.9794**	**3.50**	**0.0005**
	0:no	0.0000	0.0000	0.0000	0.0000		.
Community-locking suspension system	**1:yes**	**1.0468**	**0.5232**	**0.0214**	**2.0723**	**2.00**	**0.0454**
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
*Marital status	married	-0.3720	0.2175	-0.7983	0.0544	-1.71	0.0873
	others	0.0000	0.0000	0.0000	0.0000		
Age group	**55-74**	**-0.7282**	**0.2872**	**-1.2911**	**-0.1652**	**-2.53**	**0.0112**
	74 older	-1.2948	0.4102	-2.0988	-0.4909	-3.16	0.0016
(reference)	55 younger	0.0000	0.0000	0.0000	0.0000		

(*table continues*)

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Less Severe Residual Limb Skin Problems – Analysis of GEE Parameters							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Socioeco /VA Priority	**co-pay eligible**	**-1.0491**	**0.4795**	**-1.9888**	**-0.1093**	**-2.19**	**0.0287**
	Employable	-0.6726	0.4212	-1.4982	0.1530	-1.60	0.1103
(reference)	unemployable	0.0000	0.0000	0.0000	0.0000		
Race	Asian	-0.5958	0.8412	-2.2445	1.0529	-0.71	0.4788
	Black	-0.6318	0.2632	-1.1477	-0.1159	-2.40	0.0164
(reference)	White	0.0000	0.0000	0.0000	0.0000	.	.

Estimate indicates direction of correlation; bolded text indicates statistical significance of 95% probability, alpha of 0.05; * indicates statistical significance at 90% probability, alpha of 0.10.

Research question 2 – mechanical effects as a covariate. The craftsmanship and knowledge base of artificial limb components may vary between Prosthetists. The extent to which this variability in skill and knowledge effects a patient's outcome is the basis for research question 2.

The actual identification of the dispensing Prosthetist was not available and thus the Veterans Integrated Service Network served as a proxy thereof, but because of small cell sizes and missing data, the broader variable, Regionx, was used wherein four categories (Region 1, region 2, region 3, and region 4) represent groupings of VISNs. Table D2, Appendix D, indicates VISN groupings per region and the number of cohort members per VISN.

Initial analysis. Frequency tables and unadjusted Chi-square analyses were conducted to detect statistically significant differences in the number of ALC categories dispensed per region. Region 1 accounted for 54 (17%) of all the ALC categories dispensed, Region 2 72 (23%) artificial limbs, Region 3 123 (39%), and Region 4 66 (21%); Chi-square analysis was not significant given an alpha of 0.05 with a *p*-value of 0.17. The least frequently dispensed ALC category across all four regions was the household-hi tech suspension system with only 10 (3%) delivered followed by (in order) transfers with 12 (4%) delivered, household-mid to low tech suspension system artificial limb configurations with 16 (5%) delivered, household-locking suspension system with 25 (8%), community-high tech suspension system with 49 (16%) limbs delivered, community-mid to low suspension system with 53 (17%) limbs delivered, and community-locking suspension system with a total of 150 (48%) limbs delivered.

Additionally, frequency tables and unadjusted Chi-Square analyses were conducted to determine if there was a statistically significant difference in the frequency of less severe and severe residual limb skin problems across the four regions. In regard to less severe RLSPS, of the 145 cases detected among the 279 cohort members, in order of frequency, Region 1 had 27 (9%) cases, Region 2 had 29 (9%) less severe residual limb skin problem cases, Region 4 had 33 (10%) cases, and Region 3 had 56 (18%); chi-square analysis was not statistically significant at an alpha of 0.05 with a *p*-value of 0.63, suggesting that Region was not a driving factor behind less severe RLSPS. For severe RLSPS, of the 156 cases detected among the 279 cohort members, in order of frequency, Region 1 had 29 (9%) severe residual limb skin problem cases, Region 2 had 30 (10%) such cases, Region 4 had 32 (10%) cases, and Region 3 had 65 (21%) cases; Chi-Square analysis was not statistically significant at an alpha of 0.05 with a *p*-value of 0.44, suggesting that Region was also not a driving factor behind the frequency of severe RLSPS within the cohort. However, as these analyses did not include demographic variables, nor did they treat the dependent variable as a repeated measure, to better address the research question, GEE modeling was employed using the same structure as described above.

GEE model analysis. For this analysis, the sample size was 279 and ALC category was not a parameter of the model. The variables included in the model were: the dependent variable RLSPS; Region (Table D2, Appendix D, provides the geographical description of the regions); and the demographic parameters/variables Marital Status, Race, Age Group, and Socioeco/VA priority.

Table 13 below provides the results of this analysis. In summary, as with the unadjusted analysis, for the less severe residual limb skin problem condition, Region did not attain statistical significance, suggesting that no one region was likely to be responsible for more less severe RLSPS than another. However, the analysis revealed that cohort members between the ages of 55 and 74 were less likely to develop a less severe RLSPS during their follow-up period than their younger counter parts (*Estimate* = -.90, p = .01) regardless of the region from which their artificial limb configuration was dispensed; and, socioeco/VA priority attained near significance indicative of a possible trend that cohort members able to make a co-payment were less likely to have a less severe RLSPS than their unemployable cohort members (*Estimate* = -1.20, p = .07). Finally, during the 30 month observation interval, as well as the 36 month observation interval, cohort members were less likely to have a less severe RLSPS as compared to their six month interval, and regardless of the region that delivered their ALC category (*Estimate* = -1.46, p = .01; *Estimate* = -.95, p = .04, respectively). However, for the severe RLSPS condition, region did have a significant effect. Cohort members having their ALC categories dispensed from Region 4 were significantly more likely to develop a severe RLSPS during their follow-up period, than cohort members delivered ALC categories from Region 2 (*Estimate* = .93, p = .009). Further, cohort members between the ages of 55 and 74 years, as well as those over 74 years, were significantly less likely to develop a severe RLSPS during their follow-up period (regardless of the Region delivering their ALC category) than those cohort members younger than 55 years (*Estimate* = -.64, p = .02; *Estimate* = -1.34, p = .001, respectively). Additionally, cohort members that were of a socioeconomic and VA priority status as to be required to make co-payments for treatment (co-pay eligible) were significantly less likely to have a severe RLSPS (regardless of the Region delivering their artificial limb) than those cohort members categorized as unemployable (*Estimate* = -1.07, p = .02); and cohort members who were Black were less likely to have a severe RLSPS during their follow-up period than their White cohort members (*Estimate* = -.59, p = .02), regardless of the Region where their artificial limb was configured and dispensed.

These findings suggest:

1. The null hypothesis (H_o2) – residual limb skin problems categories (frequency and type) will not vary between VISNs, regardless of ALC category dispensed – is rejected, assuming that Region is a suitable proxy for VISN Prosthetists; the GEE analysis identified a statistically significant relationship between the frequency of severe RLSPS the cohort experienced in that cases associated with Region 4 were significantly more likely to have a skin problem than cohort members from Region 2. This

same association did not exist for less severe RLSPS in which case, the Region from whence an artificial limb was configured and dispensed, had no real effect on outcome. However, given the lack of granularity in the variable Region, it is difficult to associate the skills of any prosthetists with the outcomes and rather, the variable may be a better proxy for climate and geography (discussed further in Chapter 5).

2. The alternative Hypothesis (H_a2) - Significantly more severe RLSPS will be noted among cohort members with higher function or more technically sophisticated artificial limb configurations, regardless of the responsible Prosthetist, although overall variability will be greater among Prosthetists than within a single Prosthetist – is unclear on the basis of the same lack of granularity within the variable Region. As can be noted in Table D2, Appendix D, each region accounted for up to 5 VISNs, within which the number of actual practicing prosthetists was unavailable for this study, but based on personal experience is at least 2 certified practitioners. Additionally, it is not uncommon for a veteran to have their artificial limb actually built by a prosthetist within the veteran's local community rather than at a VHA facility. However, what is clear is (a) severe RLSPS did vary significantly among the Regions with Region 4 demonstrating significantly more such conditions; (b) findings from research question 1 (mechanical main effects) determined that the community-high tech

suspension system was significantly associated with a likelihood of such cohort member users to have a severe RLSPS during their follow-up period, and (c) according to Table D2, Appendix D, Region 4 represented 20% of the cohort population (57 members) and 15 (23%) of the community-high tech suspension system ALC categories dispensed, For Region 4, this amount to a ratio of approximately 1 such artificial limb per 4 regional cohort members, as compared to Region 1 (1 limb per 8 regional cohort members), Region 2 (approximately 1 limb per 6 regional cohort members), and Region 3 (approximately 1 limb per 7 regional cohort members), suggesting a greater frequency of severe RLSPS relative to Region 4 and dispensed community-high tech suspension system ALC category. A secondary analysis in which ALC was included in the model with Regions as a covariate was not run, as if was felt that such an analysis would do little to address the question of the association between ALC type and the prosthetist, given the gross granularity of the variable Region and the unbalanced distribution of ALC categories across the regions (as discussed above).

Table 13

General Estimating Equations Model Output for Research Question Two – Mechanical Effect by Region.

Less Severe Residual Limb Skin Problem – Analysis of GEE Parameters							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		-1.5726	0.4770	-2.5075	-0.6376	-3.30	0.0010
Window	12 month	0.0767	0.4008	-0.7089	0.8624	0.19	0.8482
	18 month	0.1259	0.3877	-0.6339	0.8857	0.32	0.7454
	24 month	-0.2862	0.4131	-1.0959	0.5234	-0.69	0.4884
	30 month	**-1.4571**	**0.5812**	**-2.5962**	**-0.3180**	**-2.51**	**0.0122**
	36 month	-0.9545	0.4751	-1.8857	-0.0233	-2.01	0.0445
(reference)	6 month	0.0000	0.0000	0.0000	0.0000	.	.
Region	1 – region 1	-0.2030	0.4077	-1.0021	0.5960	-0.50	0.6184
	2 – region 3	-0.3967	0.3543	-1.0911	0.2977	-1.12	0.2628
	3 – region 4	0.2671	0.4185	-0.5531	1.0874	0.64	0.5233
(reference)	0 – region 2	0.0000	0.0000	0.0000	0.0000	.	.
Marital status	Married	0.0696	0.2596	-0.4393	0.5785	0.27	0.7886
	Others	0.0000	0.0000	0.0000	0.0000	.	.
Age group	**55-74**	**-0.8963**	**0.3487**	**-1.5797**	**-0.2128**	**-2.57**	**0.0102**
	74 older	0.0076	0.3635	-0.7047	0.7200	0.02	0.9832
(reference)	55 younger	0.0000	0.0000	0.0000	0.0000	.	.
* Socioeco / VA Priority	*co-pay eligible	-1.1953	0.6590	-2.4870	0.0964	-1.81	0.0697
	Employable	0.2518	0.4024	-0.5369	1.0406	0.63	0.5315
(reference	Unemployable	0.0000	0.0000	0.0000	0.0000	.	.
Race	Asian	0.4546	0.7151	-0.9469	1.8561	0.64	0.5249
	Black	0.3389	0.2783	-0.2066	0.8844	1.22	0.2234
(reference)	White	0.0000	0.0000	0.0000	0.0000	.	
Intercept		-0.7731	0.4373	-1.6302	0.0840	-1.77	0.0771

(table continues)

Less Severe Residual Limb Skin Problem – Analysis of GEE Parameters							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Window	12 month	0.0679	0.3280	-0.5749	0.7107	0.21	0.8359
	18 month	-0.2371	0.3466	-0.9163	0.4422	-0.68	0.4940
	24 month	-0.3026	0.3496	-0.9878	0.3827	-0.87	0.3868
	30 month	-0.5752	0.3652	-1.2909	0.1405	-1.58	0.1152
	36 month	**-1.5694**	**0.4789**	**-2.5080**	**-0.6308**	**-3.28**	**0.0010**
(reference)	6 month	0.0000	0.0000	0.0000	0.0000	.	.
Region	1 – region 1	0.3836	0.3377	-0.2783	1.0454	1.14	0.2560
	2 – region 3	-0.1231	0.3133	-0.7372	0.4910	-0.39	0.6944
	3 – region 4	**0.9320**	**0.3551**	**0.2360**	**1.6280**	**2.62**	**0.0087**
(reference)	0 – region 2	0.0000	0.0000	0.0000	0.0000	.	.
Marital status	married	-0.3417	0.2210	-0.7749	0.0914	-1.55	0.1220
	others	0.0000	0.0000	0.0000	0.0000	.	.
Age group	**55-74**	**-0.6441**	**0.2816**	**-1.1960**	**-0.0922**	**-2.29**	**0.0222**
	74 older	**-1.3385**	**0.3936**	**-2.1098**	**-0.5671**	**-3.40**	**0.0007**
(reference)	55 younger	0.0000	0.0000	0.0000	0.0000	.	.
Socioeco / VA Priority	**co-pay eligible**	**-1.0685**	**0.4639**	**-1.9777**	**-0.1593**	**-2.30**	**0.0213**
	*Employable	-0.7330	0.4409	-1.5972	0.1311	-1.66	0.0964
(reference)	unemployable	0.0000	0.0000	0.0000	0.0000	.	.
Race	Asian	-0.2712	0.7832	-1.8063	1.2638	-0.35	0.7291
	Black	**-0.5905**	**0.2579**	**-1.0959**	**-0.0851**	**-2.29**	**0.0220**
(reference)	White	0.0000	0.0000	0.0000	0.0000	.	.

Estimate indicates direction of correlation; bolded text indicates statistical significance at 95% probability, alpha of 0.05; * indicates statistical significance of 90% probability, alpha of 0.10.

Research question three-behavioral effect. Research question 3 addresses the issue of the impact certain mental health and behavioral (coping strategies) conditions may or may not have on the types of residual limb problems that are associated with the use of an artificial limb for the dysvascular transtibial amputee. Specifically, diagnosis codes for the conditions MDD, PTSD, and SUD, detected during the three-year follow-up period were of interest.

Initial analysis. Frequency tables and unadjusted chi-square analyses were conducted for the three mental health conditions MDD, PTSD, and SUD, as well as physiologic conditions that influence activity levels – chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), , cerebral vascular disease (CVD, and Renal failure. Table D3, Appendix D, displays the results wherein it can be seen that all the above mentioned conditions, except CVD, achieved a p-value of less than 0.25 and thus were included in the multivariable analysis. Because of the significant biomechanical impact a stroke and subsequent paresis can have on gait, CVD was included. However, as mentioned previously, these analyses did not include demographic variables, nor did they treat the dependent variable as a repeated measure and thus, to better address the research question, GEE modeling was employed using the same structure as described above under the section Overview.

GEE model analysis. For this analysis, the sample size was 279 as the ALC category was not a parameter/factor. The parameters/variables included in the model were: the dependent variable, RLSPS , demographic variables Marital status, Socioeco/VA priority, Age group, and Race; the mental health conditions MDD , PTSD, SUD; comorbid conditions COPD, CHF, CVD, and Renal Failure. The variables ALC and Region were not included as the intent of the question was to ascertain if behavioral conditions (psychological and physiological – especially in regard to affecting energy, endurance, and activity levels), were directly related to the outcome measure, RLSPS, regardless of mechanical effects as suggested in the two previous research questions and analyses.

Table 14 below provides the results of the analysis. The GEE analysis revealed that cohort members with diagnoses of SUD, COPD, CHF, or CVD were all likely to have less severe RLSPS at some point during their follow-up period (*Estimate* = 0.89, $p < 0.05$; *Estimate* = 0.59, $p < 0.05$; *Estimate* = 0.52, $p = 0.04$; and *Estimate* = 0.82, $p = 0.02$, respectively). Cohort members with diagnoses of MDD, SUD, and COPD were likely to have a severe RLSPS at some point during their follow-up period (*Estimate* = 0.86, $p < 0.001$; *Estimate* = 0.76, $p < 0.05$; and *Estimate* = 0.45, $p = 0.02$, respectively). Furthermore, cohort members with either a less severe or severe RLSPS were less likely to have such problems during their 30 and 36 month follow-ups (less severe – *Estimate* = -1.31, $p < 0.05$; *Estimate* = -0.98, $p = 0.02$), thirty and 36 months respectively; severe – *Estimate* = -0.84, $p < 0.05$; *Estimate* = -1.83, $p < .0001$), thirty and 36 months respectively).

The findings suggest:

1. The null hypothesis (H_o3) - Cohort members with a diagnosis of MDD, PTSD, or SUD will have no greater or less variability in RLSPS (frequency or type) than members of the cohort with no such diagnosis – is rejected. Cohort members with a diagnosis of SUD were significantly likely to develop a less severe or severe RLSPS, and cohort members with a diagnosis of MDD were significantly likely to have a severe RLSPS;
2. The alternative hypothesis (H_a3a) - Cohort members with a diagnosis of MDD will have fewer severe RLSPS and fewer RLSPS treated overall, as compared to those members with no such depression diagnosis) – is rejected. As indicated in Table 14 below, as part of the GEE analysis model, cohort members with no MDD diagnosis code were used as a reference to compare outcomes with those cohort members with a diagnosis of MDD (as was similarly true for all the parameters). In the case of severe RLSPS outcomes, cohort members with an MDD diagnosis were significantly more likely to develop such a problem (as indicated by a positive *Estimate* value and a p-value less than 0.05), but were not significantly likely to develop more less severe RLSPS outcomes (as indicated by a negative *Estimate* valued and a *p*-value greater than 0.05).
3. The alternative hypothesis (H_a3b) - cohort members with a diagnosis of PTSD or SUD will have significantly more severe RLSPS (such as ulcers)

than those members without PTSD or SUD, but no significant difference in frequency of less severe RLSPS compared to those cohort members with no such diagnosis. This alternative hypothesis is unclear. As seen in Table D3, Appendix D cases with PTSD accounted for approximately one-third of all cases with a less severe RLSPS and attained statistical significance in the Chi-square analysis, but not in the GEE model, suggesting other factors influenced the significance of the model outcome. Similarly, approximately one-third of all cases with a severe RLSPS were also diagnosed with PTSD, but did not attain statistical significance ($p < 0.05$) in the Chi-square analysis, nor in the GEE model analysis. Further, in the case of cohort members with a diagnosis of SUD, approximately one-quarter of all cases with a less severe or severe RLSPS were also diagnosed with SUD, but in neither condition was statistical significance attained using a Chi-square analysis, but for both conditions(less severe and severe RLSPS) statistical significance was attained using the GEE model analysis (less severe - *Estimate* = 0.89, $p = .006$; severe - *Estimate* = 0.76, $p = .004$). These findings suggest that behavioral factors such as PTSD and SUD are clearly not the only reason a cohort member developed a residual limb skin problem, and that cohort members with SUD were more likely to develop some sort of residual limb skin problem than a cohort member with a diagnosis of PTSD.

Table 14

General Estimating Equations Model Output for Research Question Three – Behavioral (Mental Health and Comorbid Conditions) as the Main Effect.

Less Severe Outcomes - Analysis Of GEE Parameter Estimates

Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		-3.0942	0.2907	-3.6640	-2.5244	-10.64	<.0001
Window	12 month	0.0188	0.3216	-0.6116	0.6492	0.06	0.9535
	18 month	0.0872	0.3151	-0.5305	0.7048	0.28	0.7821
	24 month	-0.4791	0.3542	-1.1733	0.2152	-1.35	0.1762
	30 month	**-1.3066**	**0.4489**	**-2.1864**	**-0.4268**	**-2.91**	**0.0036**
	36 month	**-0.9820**	**0.4038**	**-1.7733**	**-0.1906**	**-2.43**	**0.0150**
(reference)	6 month	0.0000	0.0000	0.0000	0.0000	.	.
Major depressive disorder	1:yes	-0.4909	0.3777	-1.2312	0.2494	-1.30	0.1937
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Post-traumatic stress disorder	1:yes	0.4369	0.2810	-0.1139	0.9876	1.55	0.1200
	0:no	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

Less Severe Outcomes - Analysis Of GEE Parameter Estimates

Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Substance use disorder	**1:yes**	**0.8946**	**0.3235**	**0.2606**	**1.5286**	**2.77**	**0.0057**
	0:no	0.0000	0.0000	0.0000	0.0000		
Chronic obstructive pulmonary disorder	**1:yes**	**0.5946**	**0.2226**	**0.1584**	**1.0308**	**2.67**	**0.0076**
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Congestive heart failure	**1:yes**	**0.5160**	**0.2543**	**0.0175**	**1.0145**	**2.03**	**0.0425**
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Cerebral vascular disease	**1:yes**	**0.8184**	**0.3414**	**0.1491**	**1.4876**	**2.40**	**0.0165**
	0:no	0.0000	0.0000	0.0000	0.0000	.	
Renal failure	1:yes	0.4350	0.2558	-0.0664	0.9364	1.70	0.0890
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Intercept		-2.3325	0.2317	-2.7867	-1.8783	-10.07	<.0001
Window	12 month	-0.1457	0.2682	-0.6714	0.3800	-0.54	0.5869
	*18 month	-0.4726	0.2881	-1.0372	0.0921	-1.64	0.1009
	*24 month	-0.5269	0.2900	-1.0953	0.0415	-1.82	0.0692

(*table continues*)

Less Severe Outcomes - Analysis Of GEE Parameter Estimates

Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
	30 month	-0.8405	0.3070	-1.4423	-0.2387	-2.74	0.0062
	36 month	-1.8294	0.4308	-2.6738	-0.9850	-4.25	<.0001
(reference)	6 month	0.0000	0.0000	0.0000	0.0000	.	.
Major depressive disorder	**1:yes**	**0.8578**	**0.2347**	**0.3978**	**1.3178**	**3.66**	**0.0003**
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Post-traumatic stress disorder	1:yes	-0.1386	0.2511	-0.6308	0.3535	-0.55	0.5809
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Substance use disorder	**1:yes**	**0.7582**	**0.2654**	**0.2380**	**1.2783**	**2.86**	**0.0043**
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Chronic obstructive pulmonary disease	**1:yes**	**0.4505**	**0.1942**	**0.0699**	**0.8312**	**2.32**	**0.0204**
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Congestive heart failure	1:yes	0.2671	0.2109	-0.1463	0.6806	1.27	0.2054
	0:no	0.0000	0.0000	0.0000	0.0000	.	.

(*table continues*)

Less Severe Outcomes - Analysis Of GEE Parameter Estimates							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Cerebral vascular disease	1:yes	-0.0208	0.3866	-0.7785	0.7369	-0.05	0.9571
	0:no	0.0000	0.0000	0.0000	0.0000		
Renal failure	1:yes	-0.0003	0.2433	-0.4772	0.4766	-0.00	0.9990
	0:no	0.0000	0.0000	0.0000	0.0000	.	.

Estimate indicates direction of correlation; bolded text indicates statistical significance at 95% probability, alpha of 0.05; * indicate statistical significance at 90% probability, alpha of 0.10.

Research question 4 – the interaction of mechanical with behavioral effects. Continuing to work off the premise that certain mental health conditions are characterized by behaviors expressed by activity levels and that activity level is one of the driving forces behind severe skin problems, this research question 4 and subsequent analysis attempts to address this interaction, in relation to the type ALC category dispensed.

More specifically, this analysis, using general estimating equations (GEE), Logit function, and an independent correlation structure as described above in the section Overview, identified those covariates that interacted sufficiently to significantly impact the cohort's response (in terms of RLSPS outcome), and specific to each ALC category.

Initial analysis. Frequency tables and unadjusted Chi-Square analyses were conducted on key variables and are presented in Table D3, Appendix D. Those variables with a Chi-Square probability less than 0.20 (80%) were automatically included in the model as long as statistical significance was attained under the less severe or severe RLSPS condition/category. These variables included: MDD, PTSD, SUD, COPD, CHF, CVD, Renal Failure; the demographic variables Marital Status, Age group, Socioeco/VA Priority, and Race (regardless of their Chi-Square significance as they were constants held throughout the analyses), and ALC categories household-high tech suspension system, community-high tech suspension system, community-mid to low tech suspension system, and community-locking suspension system, as these four categories were used for research question 1 and identified as mechanical main effects. Additionally, the parameter/variable region was included because of its significance as a mechanical covariate, as was CVD (although the variables Chi-Square probability did not attain significance) because of the profound influence hemiparesis frequently associated with stroke could have on gait biomechanics and hence the mechanical effects of the artificial limb. As with the previous models and analyses, the dependent variable, RLSPS, was comprised of three categories (no treatment, less severe, and severe) and was treated as a repeated measure at six month interval for a total of a 36 month follow-up period. Also, as described previously, each ALC category was treated as a binary variable with the category 'others' as the reference category, as the intent was to seek associations between ALC categories and RLSPS outcomes rather than compare ALC categories.

GEE model analysis. Table 15 (less severe RLSPS category) and Table 16 (severe RLSPS category) below summarize the findings of these Gee model analyses; the full statistical analysis outcome can be found in Appendix D, tables D4, D5, D6, and D7. To summarize, none of the four ALC categories analyzed achieved statistical significance as covariates likely to be associated with cohort member's development of less severe or severe RLSPS. Neither was there any obvious pattern in the Estimates indicating a positive or negative correlation other than the household-locking suspension system ALC category was negative for both less severe and severe RLSPS conditions, indicating a tendency toward being a less likely effect; the community-mid to low tech suspension system ALC category Estimates were positive for both less severe and severe RLSPS conditions and thus tending toward being a likely effect, while the community-high tech suspension system ALC category tended toward being a less likely effect for the less severe RLSPS and a likely effect for the severe condition; and the community-locking suspension system ALC category tended toward a likely effect (positive) for less severe RLSPS and a less likely effect for severe RLSPS.

Household-locking suspension system. When the household-locking suspension system ALC category was included in the model, cohort members with a diagnosis of SUD were likely to have a less severe RLSPS (*Estimate* = 0.87, $p = .05$) but not so for the severe condition, and similarly, cohort members with a diagnosis of CVD were likely to have a less severe RLSPS (*Estimate* = 1.51, $p < .001$) but there was no significant effect on the severe condition. COPD had a significant and likely effect on both the less severe and severe RLSPS (*Estimate* = 0.70, $p = .03$; *Estimate* = 0.59, $p = .02$ respectively), but no other disease or mental health condition had a significant effect on either RLSPS condition. Demographic factors, however, did have significant effects: Cohort members in the age group 55 to 74 years were less likely to have a less severe RLSPS than their younger members (*Estimate* = - 0.95, $p = .02$), and cohort members older than 74 years were less likely to have a severe RLSPS than those less than 55 years of age (*Estimate* = -1.15, $p = .005$); for both the less severe and severe RLSPS, cohort members required to make co-payments (due to their VA Priority classification) were significantly less likely to have RLSPSs than those cohort members classified as unemployable (*Estimate* = -1.56, $p = .03$; *Estimate* = -1.20, $p = .01$ respectively); and Black cohort members were significantly less likely to have a less severe RLSPS than White cohort members

(*Estimate* = -0.61, $p = 0.03$) but race had no significant effect on the likelihood of having a severe RLSPS.

Finally, cohort members were less likely to have a less severe RLSPS during both the 30 month and 36 month follow-up interval than during the six month interval (*Estimate* = -1.76, $p = 0.009$; *Estimate* = -1.11, $p = 0.03$ respectively), while for the severe RLSPS condition, only during the 36 month interval were they significantly less likely to have any such RLSPS as during the six month interval (*Estimate* = -1.62, $p < 0.001$).

Table 15

GEE Model Analysis – the Interaction of Mechanical and Behavioral Effects on Less severe Residual Limb Skin Problems.

Less Severe Residual Limb Skin Problems				
Parameter	Household-locking suspension system	Community-high tech suspension system	Community mid to low suspension system	Community-locking suspension system
	p (*Estimate* = +/-)	*p* (*Estimate* = +/-)	*p* (*Estimate* = +/-)	*p* (*Estimate* = +/-) sub-category
Less severe residual limb skin problems	0.58 (-)	0.24 (-)	0.74 (+)	0.30 (+)
Age group				
55-74 years	**0.02 (-)**	**0.01 (-)**	**0.03 (-)**	**0.02 (-)**
> 74 years	(0.44 (-)	0.31 (-)	0.46 (-)	0.44 (-)
<55 years (reference)	0.00	0.00	0.00	0.00
Region				
Region 1	0.79 (-)	0.64 (-)	0.62 (-)	0.75 (-)
Region 3	0.42 (-)	0.32 (-)	0.55 (-)	0.42 (-)
Region 4	0.70 (+)	0.76 (+)	0.70 (+)	0.73 (-)
Region 2 (reference)	0.00	0.000	0.00	0.00
Socioeco/VA Priority				
Co-pay				
eligible	**0.03 (-)**	**0.03 (-)**	**0.04 (-)**	**0.03 (-)**
employable	0.50 (+)	0.57 (+)	0.59 (+)	0.50 (+)
unemployable (reference)	0.00	0.00	0.00	0.00
Marital status	0.67 (+)	0.58 (+)	0.55 (+)	0.60 (+)
Race				
Asian	0.64 (+)	0.69 (+)	0.78 (+)	0.66 (+)
Black	0.45 (+)	0.45 (+)	0.45 (+)	0.41(+)
White (reference)	0.00	0.00	0.00	0.00
MDD- Major depressive disorder	0.29 (-)	0.31 (-)	0.32 (-)	0.41 (-)
PTSD – Post traumatic stress disorder	0.41 (+)	0.43 (+)	0.35 (+)	0.45 (+)
Substance Use Disorder	**0.05 (+)**	* 0.053 (+)	*0.057 (+)	**0.05 (+)**

(table continues)

Less Severe Residual Limb Skin Problems				
Parameter	Household-locking suspension system	Community-high tech suspension system	Community mid to low suspension system	Community-locking suspension system
	p (*Estimate* = +/-)	*p* (*Estimate* = +/-)	*p* (*Estimate* = +/-)	*p* (*Estimate* = +/-) sub-category
COPD – Chronic obstructive pulmonary disease	**0.03 (+)**	**0.03 (+)**	***0.054 (+)**	**0.02 (+)**
CHF – Congestive heart failure	0.62 (+)	0.70 (+)	0.70 (+)	0.61 (+)
CVD – Cerebral vascular disease	**0.0002 (+)**	**<.0001 (+)**	**0.0002 (+)**	**0.0001 (+)**
Renal failure	0.36 (+)	0.42 (+)	0.38 (+)	0.35 (+)

* indicates near significance where p < 0.06>.05;
Estimate =+indicates positive correlation, Estimate =- indicates negative correlation. bolded text indicates statistical significance at 95% probability, alpha of 0.05

Community-high tech suspension system. When the community-high tech suspension system ALC category was included as a covariate, none of the mental health conditions (MDD, PTSD, or SUD) attained statistical significance as an effect on cohort members likelihood to have a less severe RLSPS, although near significance was attained for cohort members with a diagnosis of SUD to likely have a less severe RLSPS (*Estimate* = 0.83, p = 0.06). In regard to other diseases, cohort members with a diagnosis of COPD were significantly likely to have a less severe RLSPS (*Estimate* = 0.68, p = 0.03) or a severe RLSPS (*Estimate* = 0.61, p = 0.02), and cohort members with a diagnosis of CVD were likely to have a less severe RLSPS (*Estimate* = 1.63, $p < 0.0001$), but for the severe RLSPS condition, a diagnosis of CVD had no significant effect. As with the household-locking suspension system ALC category, demographic parameters co-varied significantly with the outcome: Cohort members aged 55 to 74 years were significantly less likely to have a less severe RLSPS as compared to those less than 55 years of age (*Estimate* = -0.10, *p* = 0.01), while cohort members over the age of 74 were significantly less likely to have a severe RLSPS compared to cohort members less than 55 years of age (*Estimate* = -1.18, *p* = 0.005); cohort members whose VA Priority classification required them to make co-payments for health care were significantly less likely to have a less severe RLSPS (*Estimate* = -1.57, *p* = 0.03) compared to cohort members with a VA Priority classification as unemployable, and similarly, the likelihood of having a severe RLSPS (*Estimate* = -1.20, *p* = 0.014) was less likely for co-payment cohort members than those classified as unemployable; and Black cohort members were significantly less likely to have a severe RLSPS than White cohort members (*Estimate* = -0.60, *p* = 0.03) whereas race had no apparent effect on the less severe condition. Of note, Region was not a significant effect for the less severe RLSPS, but demonstrated near significance and possible trending such that , cohort members treated at or living in Region four were likely to have a severe RLSPS as compared to those treated or living in Region 2 (*Estimate* = 0.71, *p* = 0.0). Finally, during their 30 month interval follow-up, as well as their 36 month interval, cohort members were less likely to have a less severe RLSPS as compared to the six month interval (*Estimate* = -1.54, *p* = 0.019; *Estimate* = -1.03, *p* = 0.04 respectively) whereas for the severe RLSPS condition, only the thirty six month interval was significantly less likely (*Estimate* = -1.52, *p* = 0.005). None of the other variables included in the model and analysis attained statistical significance.

Community-mid to low tech suspension system. Results of adding the ALC category community-mid to low tech suspension system to the GEE model as a covariate included the finding that the mechanical effect represented by the artificial limb did not attain statistical significance for the less severe nor the severe RLSPS conditions (*Estimate* = -0.43, $p = 0.24$; *Estimate* = 0.27, $p = 0.66$ respectively). Further, none of the behavioral effects as represented by the mental health conditions attained statistical significance under either RLSPS condition, although SUD attain near significance to indicate that cohort members with such a condition were likely to have a less severe RLSPS during the follow-up period (*Estimate* = 0.83, $p = 0.06$), but a similar statistical significance was not attained for this variable under the severe RLSPS condition. Similarly, MDD attained near significance under the severe RLSPS condition (*Estimate* = 0.51, $p = 0.06$) indicating that cohort members with such a diagnosis were likely to have a severe RLSPS during their follow-up period, a finding that was not mirrored for the less severe RLSPS condition. Further, cohort members with a diagnosis of CVD were likely to have a less severe RLSPS (*Estimate* = 1.53, $p = 0.0002$), but no similar statistical significance was attained for the severe RLSPS condition; cohort members with a diagnosis of COPD were likely to have a less severe RLSPS during their follow-up period (*Estimate* = 0.60, $p = 0.05$), but a similar relationship was not evident under the severe RLSPS condition; none of the other disease diagnoses attained statistical significance for either less severe or severe RLSPS.

In regard to the demographic variables, cohort members between the age of 55 and 74 years of age were less likely to have a less severe RLSPS (*Estimate* = -0.89, $p = 0.03$) compared to cohort members less than 55 years of age, whereas cohort members of the same age bracket (55-74 years), as well as those over the age of 74 years, were also less likely to have a severe RLSPS compared to cohort members less than 55 years of age (*Estimate* = -0.61, $p = 0.03$; *Estimate* = -1.25, $p = 0.003$ respectively). Marital status was not a contributing element to either less severe or severe RLSPS outcomes, but race did contribute in that Black cohort members were significantly less likely to have a severe RLSPS than White cohort members (*Estimate* = -0.60, $p = 0.03$), while race had no significant effect on less severe RLSPS. Socioeconomic status(as indicated by VA Priority classification, was a contributing element for both the less severe RLSPS outcome as well as the severe ; cohort members categorized as co-pay eligible were significantly less likely to have a RLSPS (less severe or severe) than those categorized as unemployable (*Estimate* = -1.48, $p = 0.04$; *Estimate* = -1.15, $p = 0.02$ respectively) and demonstrating a trend toward significance, cohort members categorized as employable were also less likely to have a severe RLSPS than cohort members categorized as unemployable (*Estimate* = -0.82, $p = 0.07$). Of note, Region became a contributing element when in the presence of this ALC category in that severe RLSPS were more likely to be associated with cohort members treated or living in region four as compared to those treated/living in region two (*Estimate* = 0.80, $p = 0.03$), but was of no significance toward less severe RLSPS outcomes.

Finally, as with the other analyses, cohort members were less likely to have less severe RLSPS during the 30 month and 36 month follow-up interval/window than during the six month interval (*Estimate* = -1.56, $p = 0.02$; *Estimate* = -1.13, $p = 0.04$), and for severe RLSPS, cohort members were less likely to have RLSPS during the 36 month interval/window than during the six month interval (*Estimate* = -1.87, $p = 0.001$). None of the other variables/parameters included in the model achieved statistical significance as a covariate and included PTSD, CHF, renal failure, and intervals/windows twelve, eighteen and twenty-four months.

Table 16

GEE Model Analysis – the Interaction of Mechanical and Behavioral Effects on Severe Residual Limb Skin Problems.

Parameter	Household-locking suspension system	Community-high tech suspension system	Community-mid to low tech suspension system	Community-locking suspension system
	P (*Estimate* = +/-)	*P* (*Estimate* = +/-)	*P* (*Estimate* = +/-)	*P* (*Estimate* = +/-)
Severe residual limb skin problems	0.47 (-)	0.66 (+)	0.65 (+)	0.37 (-)
Age group				
55-74 years	0.08 (-)	0.07(-)	0.03 (-)	0.07 (-)
74 older	**0.005 (-)**	**0.005 (-)**	**0.003 (-)**	**0.003 (-)**
55 younger (reference)	0.00	0.00	0.00	0.00
Region:				
Region 1	0.66 (+)	0.60 (+)	0.76 (+)	0.55 (+)
Region 3	0.48 (-)	0.47 (-)	0.50 (-)	0.55 (-)
Region 4	*0.06 (+)	*0.053 (+)	0.03 (+)	0.04 (+)
Region 2 (reference)	0.00	0.000	0.00	0.00
Socioeco/VA Priority				
Co-pay eligible	**0.01 (-)**	**0.01 (-)**	**0.02 (-)**	*0.02 (-)*
Employable	0.14 -)	0.13 (-)	0.07 (-)	0.13 (-)
Unemployable (reference)	0.00	0.00	0.00	0.00
Marital status	0.31 (-)	0.26 (-)	0.24 (-)	0.26 (-)
Race				
Asian	0.85 (-)	0.89 (-)	0.74 (-)	0.89 (-)
Black	**0.03 (-)**	**0.04 (-)**	**0.03 (-)**	**0.03 (-)**
White (reference)	0.00	0.00	0.00	0.00
MDD- Major depressive disorder	0.10 (+)	0.10 (+)	*0.06 (+)	0.1 (+)

(table continues)

Parameter	Household-locking suspension system	Community-high tech suspension system	Community-mid to low tech suspension system	Community-locking suspension system
	P (*Estimate* = +/-)	*P* (*Estimate* = +/-)	*P* (*Estimate* = +/-)	*P* (*Estimate* = +/-)
PTSD – Post traumatic stress disorder	0.71 (-)	0.77 (-)	0.96 (+)	0.80 (-)
SUD – Substance Use Disorder	0.10 (+)	0.10 (+)	0.16 (+)	0.10 (+)
COPD – Chronic obstructive pulmonary disease	**0.02 (+)**	**0.02 (+)**	**0.11 (+)**	**0.02 (+)**
CHF – Congestive heart failure	0.62 (-)	0.61 (-)	0.57 (-)	0.60 (-)
CVD – Cerebral vascular disease	0.57 (-)	0.56(-)	0.60 (-)	0.60 (-)
Renal failure	0.98 (+)	0.99 (-)	0.87 (+)	0.99 (+)

* indicates near significance where *p* < 0.06>.05;
Estimate =+ indicates positive correlation, Estimate =- indicates negative correlation. Bolded text indicates statistical significance at 95% probability, alpha of 0.05.

Community-locking suspension system. When the ALC category community-locking suspension system was included as a parameter of the model ,of the behavioral effects (mental health conditions), SUD attained statistical significance to indicate that cohort members with such a diagnosis were likely to have a less severe RLSPS during the follow-up period (*Estimate* = 0.86, *p* = 0.05), but this same parameter/covariate only attained near significance for the severe RLSPS category, indicating that cohort members with a diagnosis of SUD were likely to have a severe RLSPS during the follow-up period (*Estimate* = 0.51, *p* = 0.10). Neither MDD nor PTSD attained statistical significance for either the less severe or severe RLSPS outcomes. Of the disease covariates, COPD attained statistical significance for both less severe and severe RLSPS outcomes , and indicated that cohort members with such a diagnosis were likely to have a less severe or severe RLSPS at some point during the follow-up period (*Estimate* = 0.7039, p = 0.02; Estimate = 0.5967, p = 0.02 respectively); CVD was also significant relative to the less severe RLSPS indicating that cohort members with this diagnosis were likely to have a less severe RLSPS during the follow-up period (*Estimate* = 1.53, p = 0.0001) but significance at the 95% probability levels were not attained relative to severe RLSPS outcomes.

Several demographic parameters contributed to the model outcomes. Cohort members between the age of 55 and 74 were less likely to have a less severe RLSPS than cohort members less than 55 years of age (*Estimate* = -0.95, p = 0.02), and further, cohort members over the age of 74 years were less likely than cohort members under the age of 55 to have a severe RLSPS (*Estimate* = 1.18, p = 0.003). The age group 55 to 74 years only attained near significance relative to severe RLSPS outcomes (*Estimate* = -0.51, p = 0.07). Additionally, Black cohort members were significantly less likely to have a severe RLSPS than White cohort members (*Estimate* = -0.60, p = 0.03), but no such relationship was evident for less severe RLSPS; and cohort members with a VA Priority level categorizing them as co-payment eligible were less likely to have either a less severe or severe RLSPS than those categorized as unemployable (*Estimate* = -1.58, p = 0.03; *Estimate* = -1.20, p = 0.02 respectively).

The mechanical effect covariate, region, only attained statistical significance for the severe RLSPS outcome, indicating that cohort members treated or living in region four were more likely to have a severe RLSPS than those treated/living in region two (*Estimate* = 0.73, p = 0.04). And finally, cohort members were less likely to have a severe RLSPS during the 36 month interval/window than during the six month window

(*Estimate* = -1.84, $p < 0.05$), although the same could not be said regarding less severe RLSPS nor any other interval/window. The parameters/variables marital status, PTSD, CHF and renal failure did not attain statistical significance as a RLSPS contributing element, for either less severe or severe RLSPS outcomes.

Findings. The above findings suggest:

1. The null hypothesis (H_o4) - residual limb skin problem (RLSPS) categories relative to artificial limb configuration will not increase or decrease for cohort members with a diagnosis of MDD, PTSD, or SUD,, compared to cohort members with similar artificial limb configurations and no such diagnoses – is actually unclear as it was not directly tested. The model and analysis used did not estimate variance so much as it estimated correlation - how likely a parameter was associated with the dependent variable in the presence of other parameters. Further, the limits of the dataset (missing data and small cell sizes) prevented comparison of the various ALC categories, at least with the model used to address this particular research question. However, in support of the alternative hypothesis, what is known is that although these mental health conditions definitely did not consistently play a major or singular role in the likelihood of a cohort member having a less severe or severe RLSPS, for each ALC category , at least MDD or SUD, attained significance at the 95% probability level or nearly so, suggesting that a cohort member with such a mental health condition is more likely to have a residual limb skin problem (less severe and severe RLSPS outcomes were each compared to

cohort members that had no skin problem codes).Table 10 above presents the frequencies of severe and Less severe RLSPS categories per ALC category and reveals that The greatest frequency for both RLSPS categories was associated with the Community-Locking Suspension System (21.6% - Less severe; 26.7% - severe). Frequencies decreased considerably (in order) for the Community-Mid to Low Tech Suspension System, Community-High tech suspension System, Household-Locking Suspension System, Household-Mid to Low Tech Suspension System, Household-High Tech Suspension System, to the Transfers category – all regardless of demographics, mental health or disease diagnoses.

2. The alternative hypothesis (H_a4a) - cohort members with a diagnosis of PTSD or SUD and an artificial limb of high function or technical sophistication will have significantly more severe residual limb skin problems (such as ulcers) than all other cohort members - could not be accepted. The analysis revealed that regardless of the artificial limb configurations sophistication or level of technology, having the diagnosis of PTSD was not a significant contributing element, and a diagnosis of SUD was only a contributing element for less severe RLSPS, not severe RLSPS. More specifically, for the community-high tech suspension system ALC category, the diagnosis for SUD trended toward a significant association with the likelihood of having a less severe RLSPS (*Estimate* = 0.83, $p = 0.05$). The only comorbid condition associated with a severe RLSPS and the community-high tech suspension system ALC category

was COPD, in which cohort members were more likely to have a severe RLSPS than those without such a diagnosis (*Estimate* = 0.61, p = 0.02)

3. The alternative hypothesis (H_a4b) - cohort members with a diagnosis of MDD and a lower function or less technically sophisticated artificial limb configuration will have significantly fewer severe residual limb problems than all other cohort members – can only be partially accepted, in part because the three lowest technically significant ALC categories were not included in the analysis and, as with the previous alternative hypothesis, the structure of the model is not amenable. Nonetheless, relative to this model, MDD was not a significant contributing element for less severe or severe RLSPS for users of the household-locking suspension system or community-mid to low suspension system ALC categories. Further, as described above, and in support of H_a4b, frequency tables clearly indicate that the least technically sophisticated artificial limb configurations (transfers, household-mid to low tech suspension system, and household-locking suspension system) had the lowest percentage of users with any skin problem (less severe – 1.9%, 1.3%, 4.1%; severe – 0.6%, 3.2%, 4.4% respectively) compared to more technically sophisticated artificial limb configurations.

Summary

The purpose of this study was multilayered: (a) to test the utility of healthcare administrative data (such as ICD-9CM and HCPCS codes) in the development of an infomatics tool in the field of prosthetics, (b) to identify determinants of severe and less severe residual limb skin problems relative to the artificial limb used, and (c) ascertain whether or not diagnoses of MDD, PTSD, or SUD were significant factors toward such outcomes.

To accomplish such, Phase I of this study was directed at developing the dataset derived from the merging of multiple VHA healthcare administrative database subsets, and then extracting the study cohort on the basis of specified inclusion/exclusion criteria, many of which were contrived post hoc, in order to preserve accuracy and a maximal number of cohort members. A subsequent data dictionary was created (Appendix B) and frequency tables prepared to define and characterize the study cohort. Subsequently, this phase of the study and results not only established the study cohort, but in so doing, identified various limitations of using AHc datasets, especially in regard to the NPPD and the use of HCPCS codes to identify ALC categories; as well as the use of ICD-9-CM codes to define RLSPS outcomes. These two issues address the useability of AHc data as a tool in prosthetics practice-based medical research and as an infomatics tool, and will be further discussed in the next chapter.

Phase 2 of the study was dedicated to an epidemiological analysis of the cohort with the aim of ascertaining the significance of mechanical effects (the ALC category and region where the configuration was made and dispensed) addressed by research question 1 and 2; behavioral effects (MDD, PTSD, SUD, and relevant comorbid conditions) addressed by research question 3; and the interaction of these two effects, as addressed by research question 4. Aspects of the final study dataset (low cell frequencies, subsequent binomial catergorization) required that the original intent of an analysis of variance with interactive factors, be shifted to one of covariance and correlation, accomplished through GEE modeling. GEE allows for the analysis and identification of patterns of relationships within the cohort without the specificity of linear regression that the dataset could not support.

Despite the limitations presented by the dataset (and ultimately, the analysis) several of the above issues were clearly addressed. For example, mechanical factors, specifically the ALC category, was not a statistically significant factor toward the development of a severe or less severe RLSPS, suggesting that something other than the type of artificial limb was at play. The parameter Region, originally intended to be a proxy for the prosthetist responsible for the configuration of the artificial limb, was too broad for such a definition, but still did influence the likelihood of cohort members associated with Region 4 (primarily Northeastern United States) to be significantly more likely to develop severe RLSPS. Further, behavioral effects MDD and SUD were associated with the likelihood of developing a residual limb skin problem, regardless of mechanical effects, although a diagnosis of PTSD had no similar influence; and the medical comorbid conditions, COPD was associated with a significant likelihood of developing severe and less severe RLSPS (in conjunction with the dysvascular conditions of diabetes, PVD or PAD that also described a cohort member). While the demographic factors age, race and socioeconomic status may not have been driving factors toward the likelihood of the development of a residual limb skin problem, all three parameters statistically significantly contributed to the explanation thereof, either potentially as an indicator of activity level, disease disparities, or social influences. These identified patterns and findings will thusly be discussed in the next chapter.

In conclusion, the discussion will turn to suggested changes to the source database (particularly the NPPD) to improve data quality and useability, overall implications of the study in regard to practice-based medicine in the field of prosthetics, shortcomings in the study itself, and potential future research endeavors to further refine a prosthetics informatics tool.

Chapter 5: Discussion

Introduction

The overarching purpose of this study was to explore the utility of an amputee-artificial limb database as a surveillance tool and as a means to improve prescription guidelines, support policy, facilitate evidential research, and inform the user. To address this purpose, this study attempted to achieve two goals: (a) to explore the viability of medical coding from health care administrative records as an outcome measure for artificial limb use in the field of prosthetics (an informatics perspective); and (b) to ascertain what, if any, relative comorbid condition, especially depression, PTSD, or SUD, has on those outcomes, (the epidemiologic perspective). These two goals are interdependent of one another, as the informatics perspective is necessary to address the epidemiological; the epidemiological perspective tests the informatics tool. In combination, I believe that these two goals lead toward a third goal and the stated purpose of the study: to address the utility of VHA AHc records to discriminate determinants of residual limb skin outcomes relative to the artificial lower limb configuration prescribed.

Prescription and configuration of an artificial limb is no simple matter, as multiple factors must be considered. Persons living with limb loss, specifically lower limb transtibial (below-knee) amputation, have multiple factors to overcome or contend with to enjoy a quality of life that approaches that of a healthy able-bodied counterpart. (Desmond et al., 2002; Desmond et al., 2008; Ephraim et al., 2006; Gallagher et al., 2011). For many, these factors are confounded by varying degrees of mental illness and becomes a matter of concern for the artificial limb provider, as it may influence a patient's activity level, their capacity to heal, and their health care self-management compliance including maintenance of their artificial limb.

Among the veteran population, MDD, PTSD and SUD are among the most common mental health diagnoses. More specifically, the prevalence of MDD in the veteran population is about 5 % to 13% and is frequently a comorbid condition with PTSD (The Management of MDD Working Group, 2009; Veterans and PTSD, 2015). PTSD is the third most prevalent psychiatric diagnosis among veterans utilizing VHA hospitals, and 50% of the veterans suffering from PTSD do not seek treatment (Veterans and PTSD, 2015). Vietnam veterans, who are likely represented by those cohort members over the age of 65, report lifetime rates of PTSD ranging from 10% to 31% (Veterans and PTSD, 2015). The rate of SUD among veterans, also frequently associated with PTSD, range from 3.7% among pre-Vietnam-era veterans, to 4.7% for those who served during the Vietnam conflict (1964 to 1975) to 7.7% for those who served between 1975 and 1990, to 12.7% among those who served in the military since September 2001 (Spotlight, 2015).

To complicate matters, an individual undergoing their first or index amputation has limited resources for information beyond that provided by their provider or prosthetist. Unfortunately, these same providers and prosthetists are hindered by a lack of scientific/medical evidence regarding outcomes related to certain artificial limb components and configurations, relying instead on manufacturer marketing and anecdotal evidence (Meulenbelt, et al., 2006; van der Linde et al., 2004; G. W. Bosker CPO, personal communication March 2014).

In order for an amputee-artificial limb surveillance system and informatics tool to be successful, all of these factors should be represented in one way or another. Therefore, a key component to all three goals identified above is a standardized description of each (as much as possible) in the form of a universally accepted code. In the case of the artificial limb the amputee uses, this was accomplished with Healthcare Common Procedure Coding System (HCPCS) codes, otherwise referred to as "billing codes". The Centers for Medicare Medicaid Services (CMMS) maintains such codes and updates them regularly to accommodate new technologies and innovation. Devices are categorized by common features of functionality and structure, but new devices may not be differentiated except by make and model (CMMS 2012). For example, the code L5976 is described as "All lower extremity prostheses, energy storing foot (Seattle Carbon Copy II or equal) " and includes the S.A.F.E. foot by American Prosthetic, the "K Series" K2A Assisted ADL foot, Quantum Truestep™ by Hosmer, the Steplite, the Impulse™ by Ohio Willowood , the Seattle Carbon Lightfoot by Trulife, and many others (Prosthetic Foot Reference Guide- Pel Supply: //www.pelsupply.com/related_files/978/315.pdf).

As will be discussed later, results of the study identified several similar limitations and issues relative to the "informatics perspective" primarily driven by shortcomings associated with the use of HCPCS codes (as described above) and ICD9-CM diagnosis codes, especially to define and ALC category or identify and categorize a RLSPS. Unfortunately, these shortcomings affected the results of the epidemiological perspective by reducing quality data availability, forcing the use of broader or more generalized variables that then could only offer limited interpretation. Regardless, adjustments were made to the study design, specifically a shift from an analysis of variance with multiple factor levels to generalized estimating equations with a logit function, to make best use of viable data, detect patterns of outcomes, and test the feasibility and usefulness of a potential amputee-artificial limb informatics tool.

Preparing the Dataset

Development of the final study dataset required the merging of extracts from two different databases, the link between the two being the patient's scrambled social security number. The VHA considers these scrambled social security numbers as identifiers and thus, all data manipulations were performed behind the VHA's firewall, even after the scrambled SSNs were stripped and replaced with unique study ID numbers. While in theory this merging seemed simple, in actuality it was cumbersome. This was due, in part, to the number of records that were reviewed (over 1.6 million) and because of differing cell formats between and within the extracted datasets, as well as differing source database structures.

The inpatient and outpatient clinical datasets were from the same national archive database (the NPCD) and shared the same platform and format, specifically MedSAS files that were completely compatible with Statistical Analysis Software (SAS), used for data cleaning and the study's analysis. Complete and updated data dictionaries were available online. On the other hand, the artificial limb component codes were registered in the NPPD and used a different format and platform (Microsoft Excel Worksheet comprised of 34 variables/columns and over 319,000 rows) that, though compatible with the clinical data, was not immediately so. A fair amount of data manipulation (such as cell reformatting) was required to render the extracted data sheets compatible with SAS and linked to the clinical data. There was no real data dictionary and only limited information about variables and fields to facilitate manipulations.

Final preparation of the study cohort dataset was further challenged by a lack of data integrity found in the NPPD extract. The source database and extracts frequently contained variable values that were inconsistent with other variables in the same row, truncated text fields that relayed little to no or contradictory information, missing values, nonsensical data, and unexplained duplications. The NPPD is a fairly new database, having only been established in 2000, and is not yet fully validated or evaluated (Downs, 2000; Pape et al., 2001; Smith et al., 2010). Data for the database is drawn from multiple sources via the VA's foundation software, VISTA originally called the Decentralized Hospital Computer Program (DHCP). VISTA consists of nearly 180 applications for clinical, financial, administrative, and infrastructure needs in VA integrated into a single, common database, permitting all VA applications to share one single, authoritative data source (Brown et al., 2003). Therefore, it is difficult to know the source of the missing or inaccurate data, if from a secondary application, human input error, or glitches in the associated input application.

Regardless of the source of data problems, best data interpretations were made on a case-by-case basis and, subsequently, of an initial cohort with 597 matching study IDs between clinical data from the NPCD and artificial limb component data from the NPPD, 315 could not be used because they did not meet inclusion/exclusion criteria (such as incomplete component and data fields, bilateral amputations, or reamputations of the ipsilateral limb). This significant reduction in the sample size led to smaller than expected cell sizes and required the compression of several variable categories to include the independent variable, which was the ALC category.

Manipulation of the NPCD extracts (clinical data) also proved cumbersome, primarily due to their size and necessary SAS programming strategies to insure accurate accounting of numerous ICD-9-CM codes. RLSPS codes and categories (the dependent variable) were complicated by the fact that few descriptions defined a particular anatomical region. Efforts to insure that skin problems were definitely associated with the residual limb of any case was thwarted when the code specific to stump complications was not found in any of the records and thus could not be used in conjunction with any RLSPS ICD-9-CM code. The alternative strategy for identifying RLSPS codes and categories based strictly on the code label may have identified more skin problems than may have been detected otherwise; however, it was felt that given the exploratory nature of the study, over identification was better than under identification of residual limb skin problems. Further, an objective of the study was to characterize the cohort to include health conditions and, while some skin problems may have been detected that had nothing overtly to do with the mechanical impact of the artificial limb on the residual limb, they may have impacted the overall behavior and activity level of the amputee and thus RLSPS outcomes.

Ultimately a study cohort of 282 cases was constructed containing copies of the inpatient data extract of fiscal year 2007, outpatient data extracts from fiscal years 2008, 2009, and 2010; and the extract from the NPPD for fiscal years 2007, 2008, 2009, and 2010; all linked by common identification codes. To preserve data integrity, all the extracts from the source data were left intact, and only copies thereof manipulated. These copies too were left intact, although as part of the coding process required to identify categories of ALC (the independent variable), subsets of the extracts were used and then reintegrated with the copied extract.

Key Findings

Phase 1 - the informatics perspective. The focus of the informatics perspective (Phase 1) was to develop the study dataset, derived from multiple VHA archival national database subsets, merged and linked together on the basis of common encrypted Social Security numbers of a cohort of patients/cases. The derived study cohort dataset was then used to address the epidemiological perspective and analysis.

Key findings associated with the development of this dataset include:

- HCPCS codes proved to be a viable means of identifying and categorizing an artificial limb configuration, but only in broad terms (that is, without specification of make and model), and to insure accuracy, care should be taken to note the date the component code was issued relative to the HCPCS codes available at that time (further discussion of this matter will follow later in this chapter).
- The use of ICD9-CM codes to create categories of RLSPS outcomes was technically feasible but only moderately meaningful due to limitations of the coding system – a matter likely resolved with the conversion to ICD10 codes that will include anatomical laterality and metrics of condition severity.
- The NPPD for the timeframe utilized for this study was weak in terms of data quality and integrity, primarily due to inconsistent cell formats and matters of data input to include timely updates to HCPCS codes, as well as human error at the interfacing application software level.

Phase 2 - the epidemiological perspective. Phase 2 of this study focused on an epidemiological analysis of the study dataset representing a cohort of dysvascular below-knee amputees dispensed a definitive artificial limb. Because of the novelty of the dataset, an objective of the epidemiological perspective was to characterize or describe the cohort in terms of their demographic and medical status, as well as the categories of ALC dispensed, and frequencies of RLSPS categories.

Characterization of the cohort. Descriptive statistics revealed the following:

- Diabetes was the most frequent dysvascular diagnosed disease and accounted for 67% of the cohort.
- Within the study cohort, the most frequently dispensed suspension system was the L5671, a differential pressure suspension system with pin locking mechanism, and dispensed to nearly 58% of the cohort; the most frequently dispensed prosthetic foot among the study cohort was the l5980 Flex Foot, a prosthetic foot suitable for the K3 level community ambulators and dispensed to nearly 46% of the cohort. In combination, this suggests that the majority of the veterans were considered community ambulators or better (K3, K3-4) and in fact, a total of 80% of the artificial limbs dispensed were configured with K3 level (community ambulatory) prosthetic feet.
- Forty percent of the cohort members received their artificial limbs and care from Region 3 (eastern Mid-West and Southern United States), with the remaining 60% fairly equally distributed across the remaining three regions. This same region was responsible for dispensing twice as many community-locking suspension system artificial limb configurations as any of the other regions.

- The frequency of cases with less severe residual skin problems only (47% of the cohort) was only slightly less than the frequency of cohort members that developed severe residual limb skin problems (50% of the cohort).
- The most common less severe RLSPS were noninfectious occlusion type (such as dermatitis or diseases of hair and hair follicles) and accounted for 30% of all less severe RLSPS; similarly, infectious occlusions (such as gas gangrene, carbuncles, and cellulitis) were the most common severe RLSPS, accounting for over 34% of the severe skin problems.
- ALC category of transfers not only represented the least number of cases with skin problems, but also the lowest ratio of severe to less severe RLSPS. The ALC categories household-high tech, household-mid to low tech, and household – locking suspension system all were associated with higher ratios of severe to less severe RLSPS, compared to the other ALC categories.
- PTSD was the most common mental health disorder of the cohort members (24%), followed by SUD and MDD (both at 15%).
- Sixty-four percent of the cohort was aged between 55 and 74 years of age with a median age of 60 years.
- Compared to 2009 veteran statistics, the cohort was represented by a lower percentage of women and nearly twice the percentage of Black individuals, although White and Asian percentages were similar
- Over half (52%) of the cohort were married, suggesting the presence of a caregiver.

- Eighty-four percent of the cohort were classified as disabled and considered unemployable (VA Priority status 1,4, and 5)
- Debilitating comorbid conditions were common with nearly a quarter of the cohort suffering with a respiratory disorder (COPD), 45% had CHF, and 8% were diagnosed with some stage of renal failure. CHF, renal failure and amputation are all indicators of advanced diabetes.

The epidemiological analysis. The design of the analysis was intended to test the usefulness of both the outcome variable (categories of residual limb skin problems) and the independent variable (ALC categories) in detecting meaningful patterns of association between them. Two elements of artificial limb use were of particular interest because of their potential separate or combined influences on the development and frequency of residual limb skin problems: mechanical affects in which a particular type of ALC category was associated with more residual limb skin problems than other categories (research questions 1 and 2); behavioral affects in which certain comorbid conditions (including MDD, PTSD, and SUD) were associated with more frequent residual limb skin problems than others (research question 3); and, given the combination of both affects (which are not totally independent of one another) what associations persisted or evolved (research question 4).

Further, in an effort to identify any temporal relationships regarding the development of a less severe or severe RLSPS over the three year follow-up period, frequencies of such were counted within the cohort at six month intervals/windows and each window compared to the frequency of the first window (six months) to determine if any change was significant.

Mechanical effects. In regard to mechanical effects (research questions 1 and 2), it was found that (a) not every ALC category was significantly related to a RLSPS category, especially in the case of less severe RLSPS; (B) severe RLSPS (such as ulcers) were significantly more frequent for cohort members dispensed ALC categories of higher function or technical sophistication and least for low function, low technically sophisticated configurations (in so far as the ALC categories analyzed); (c) Region was not a main effect in the development of less severe RLSPS, but was in regard to severe RLSPS with only Region 4 having significantly more severe residual limb skin problems relative to Region 2. In Summary then, mechanical effects tended to be more profound for cohort members using a K3 functional level prosthetic foot and, potentially, prescription practices, especially in Region 4, may have been a contributing factor.

Behavioral effects. Behavioral effects included the mental health conditions MDD, PTSD, and SUD; as well as several comorbid conditions that because of their debilitating health effects were likely to affect a cohort member’s activity level or capacity to heal. Similarly, mental health conditions are also posited to affect activity levels (for example, inactivity due to depression) and healing capacity due to poor nutrition or toxins (such as drugs and alcohol associated with SUD), as well as difficulties with health self-management associated with anxiety, coping mechanisms, and adjustment disorders (such as PTSD) (Desmond & MacLachlan, 2002; Desmond & MacLachlan, 2006; Desmond et al., 2008; Hanley et al., 2004; The Management of MDD

Working Group, 2009; The Management of Post-Traumatic Stress Working Group, 2010; The Management of SUD Working Group, 2009; Zinszer et al., 2011). Based on these behavioral effects and not including any mechanical parameters (research question 3), it was found that: (a)cohort members with a diagnosis of SUD were significantly likely to develop a less severe or severe RLSPS, (b) cohort members with a diagnosis of MDD were significantly likely to have a severe RLSPS; (c) PTSD accounted for approximately 24% of the cohort but was not significantly associated with either less severe or severe RLSPS; (d) COPD and CHF were both associated with the likelihood of a diagnosed case developing a less severe RLSPS, but only COPD was associated with the likelihood of severe RLSPS; and (e) CVD which frequently results in limb paresis and thus change gait biomechanics as well as reduce activity, was found to be significantly associated with the likelihood of developing a less severe skin problem, but not a severe one (the actual number of cases with a diagnosis of CVD was 17). In summary, it was noteworthy that only SUD and COPD were significantly associated with the likelihood of both severe and less severe RLSPS, and that the other mental health conditions had relatively little impact.

The interaction of mechanical and behavioral effects. Finally, as stated previously, mechanical and behavioral effects are not independent of each other and thus, one cannot simply sum the findings. Rather, it is the interaction of mechanical, behavioral, and demographic effects that should be used to predict a residual limb outcome, although in this study, prediction was not the goal, but instead a pattern of relationship. Given these parameters, key findings included (research question 4): (a) none of the four ALC categories analyzed achieved statistical significance as parameters likely to be associated with cohort members development of less severe or severe RLSPS; (b) cohort members between 55 and 74 years of age were less likely to develop a less severe RLSPS than younger cohort members, but older cohort members (aged 75 years or more) were less likely to develop a severe RLSPS compared to the same group; (c) region was only a significant contributing factor in the case of cohort members dispensed an artificial limb from Region 4 who had a greater likelihood of developing a severe RLSPS than cohort members associated with Region 2; (d) cohort members eligible to make co-payments for their health care were significantly less likely to develop less severe or severe RLSPS than cohort members classified as disabled; (e) Black cohort members were significantly less likely to develop a severe RLSPS than White cohort members, but in regard to less severe RLSPS, race was not a significant contributing factor; and (f) of the mental health disorders only SUD contributed to a cohort member's likelihood of developing a less severe RLSPS while, of the comorbid conditions, COPD was significantly associated with both less severe and severe RLSPS, regardless of the ALC category used. In summary then, the likelihood of a cohort member having a less severe RLSPS was more closely aligned with behavioral effects (namely a diagnosis of SUD or COPD), and not mechanical effects (the type of artificial limb configuration used or the region responsible for dispensing it), while the likelihood of a cohort member having a severe RLSPS was significantly associated with what region was responsible for the artificial limb (mechanical covariate), and/or a diagnosis of COPD (behavioral effect). Demographic parameters had limited impact on the likelihood of a cohort member having a residual limb skin problem, except that those cohort members assumed to be of a higher SES (copay eligible) were significantly less likely to have skin problems. Age also was associated with RLSPS and may have been more a behavioral effect than a physiologic relationship as the age range of those less likely to have a residual limb skin problem shifted from 55 to 74 years for less severe RLSPS, to over 75 years and the less likelihood of a severe RLSPS.

Temporal effects. For all research questions, only during the 30 month and 36 month windows were there a significant likelihood of fewer less severe RLSPS, the exception being the mechanical by behavioral interaction for the community-locking suspension system in which there was no significant comparisons. In regard to severe RLSPS, all the research questions/conditions indicated a significantly less likelihood of developing a problem by the 36 month window, the exception being for behavioral effects analysis in which the 30 month window was similarly significant.

Interpretation of the Findings

Phase 1 - Derivation of the Study Dataset and Coding Systems

A key component of this study was the derivation of the study dataset and the implementation of standardized health care coding systems to describe the artificial limb configuration, the residual limb status, and potentially contributing comorbid conditions including mental health disorders. While the two primary coding systems used (HCPCS billing codes to identify and describe the ALC category, and ICD-9-CM codes to identify residual limb skin problems and patient comorbidities) were fundamentally successful in achieving their purpose as standardized measures with which to infer an amputee's history with a particular artificial limb, they were not without important weaknesses and complication.

HCPCS codes were highly useful to identify functional components of an artificial limb, but said little about the overall limb whose more discrete functions can only be determined on the basis of the makes and models of components used and the skill of the prosthetist, especially in regard to socket craftsmanship, component prescription, and fitting and alignment of the limb (DePalma et al., 2002, The Rehabilitation of Lower Limb Amputation Working Group, 2007). Clinical expertise remains a crucial component in prescribing an artificial limb configuration and is dependent on the prosthetist's (clinician's) knowledge of the components available (van der Linde et al., 2004). To this end, the use of HCPCS codes will describe an artificial limb in fairly broad terms which, as part of an amputee-artificial limb surveillance system, may prove useful to a policy-maker or review board, insurance company, physician, or epidemiologist/researcher but will be less informative for the prosthetists, component manufacturers, marketers, or the amputee user.

Further, in the derivation of the dataset, difficulties arose differentiating between a definitive artificial limb and repair to one, based solely on HCPCS codes. This was a reflection of the time period of the retrospective data (October 2006 through September 2010) in that the Centers for Medicare Medicaid Services did not approve and update HCPCS codes that specifically indicated repair or modification to a component (such as the codes L7520 - Repair prosthetic device, labor component, per 15 minutes or L7510 - Repair of prosthetic device, repair or replace minor parts) until 2010. Had the source database used to acquire HCPCS codes for the study (namely the NPPD) been fully validated and the data therein deemed more reliable; had there been more data integrity, an algorithm may have been derived based on multiple fields to include costs associated with the HCPCS code, to clearly differentiate between the index definitive limb, a repair to a component thereof, or a modification of the limb or limb component. Instead, many times the cost associated with the L5301 HCPCS code was indicative of a definitive artificial limb, but a field in the database indicated that the type of service was a repair, not a new limb, and conversely, the cost was frequently significantly less than that typical for a definitive limb, but the type of service field was empty, giving no indication of why the cost was lower than that typically associated with a definitive artificial limb. These conditions demonstrate that, if using HCPCS billing codes as part of an amputee-artificial limb surveillance database, it would be imperative that updates to the coding system be noted regularly and in a timely manner (CMMS maintains such codes, and updates them regularly to accommodate new technologies and innovation [CMMS, 2012]).

Additionally, it would be useful if a data field were included to indicate the purpose of the artificial limb such as new, modified, secondary, or back-up. Many times an amputee may be prescribed and dispensed multiple artificial limbs – a primary limb, a back-up limb to use while the primary is repaired, and a specialized limb for a particular activity such as swimming, running or showering (G. W. Bosker CPO, personal communication, January 2011). All these types of artificial limbs may use the same L5301 code as they are all definitive and not temporary limbs, and thus it is difficult to know which component code (such as one for the prosthetic foot or suspension system) goes for which purpose and/or artificial limb – information that would be valuable for prosthetists, users, and vendors/marketers.

Determining the status of the artificial limb was further confounded by limitations of ICD-9-CM surgical codes that did not differentiate between a total amputation, a reamputation, and a revision of the residual limb. A total amputation or a reamputation would have required a new definitive limb (eventually) as described by a new socket, appropriate suspension system, pylon, prosthetic foot and any other facilitating components (DePalma et al., 2002; G. W. Bosker CPO, personal communication, January 2011). On the other hand, a revision most typically requires a modification to an existing definitive limb (a new socket or suspension system), and therefore would have been helpful toward the validation of seeming discrepancies in L5301 codes, costs, and repair versus new limbs.

Further issues arose with the use of ICD-9-CM codes in the identification of skin problems associated with the residual limb, but many of these problems may be resolved with the implementation of ICD-10-CM codes. Few dermatological diagnoses codes are defined by the part of the body and none are restricted to a residual limb. This fact posed a problem in the identification of codes for categorization as well as a weakness in the usefulness of diagnostic codes and RLSPS as an outcome measure. The original intent was to use those dermatological ICD-9-CM codes that were concurrent with the ICD-9-CM code 997.69 -Other amputation stump complication (a sub-division of the code 997 – Complications effecting other specified body systems, not elsewhere classified) , but this strategy was abandoned when no such code was detected in any cohort member's clinical history. The three most likely explanations for this matter may have been: (a) this investigator misinterpreted the meaning of the code label and the code was simply not used; (b) the archival NPCD, the source for all clinical histories in this study, only allows for 15 ICD-9-CM codes per patient event (outpatient day visit) and the code may have been truncated, or (c) a clinician's choice or error to not select the code from a procedural codes list in the electronic medical record system, a practice required for outpatient clinic visits only. Consequently, the strategy used for identifying residual limb skin problems dictated that any relevant code that included in its label a defined body part was excluded unless that body part was lower leg, the code was one of those identified by Bui et al. (2009) as a dermatological problem frequently associated with residual limbs and artificial limb use, or a possible systemic problem that could appear anywhere on the body but also fit into one of the categories of skin problem etiologies modified from the Bui et al recommendations (refer to Appendix B, Tables B19 and B20 for a listing of codes and categories).

Given this strategy, there is a definite likelihood of over-identification of residual limb skin problems. This may have been confounded by the use of outpatient administrative records in which it has been shown, specifically regarding the VHA electronic medical record system, that administrative data may be more sensitive than a chart review, but the chart review more specific (Szeto et al., 2002). In other words, the administrative files may have contained more diagnostic codes than a chart review may have revealed, however, based on the numbers of cases (cohort members) with residual limb skin problems and compared to results from other studies, over identification may not have been excessive. For example, Dudek and colleagues (2005), based on a six year retrospective chart review, reported that nearly 41% of their study population had at least one skin problem. In the study being reported here, nearly 47% of the cohort was identified as having at least one less severe RLSPS and 50% a severe RLSPS, of which many (if not most) of the cohort members may have experienced both categories of skin problems. While the data necessary to make such an accounting was available within the dataset, at the time of the analysis, to do so seemed beyond the scope of an this initial exploratory assessment and thus, the percentage of cohort members that experienced both less severe and severe RLSPS was not calculated. Nonetheless, two main factors explain the difference in RLSPS category frequencies between this study and the study by Dudek and colleagues: (a) study design – the Dudek study counted only the first skin problem in a patient’s record whereas this study was a longitudinal design such that an individual with a less severe RLSPS early on in the follow-up period, may have ultimately developed a severe RLSPS later and effectively have been counted twice; (b) this study included conditions such as chronic or acute osteomyelitis and systemic infections because of their significant impact on quality of life and life-threatening potential, conditions not included in the Dudek study.

Regardless, the use of ICD-10-CM codes will improve accuracy in the identification of residual limb skin problems and thus, this method of using diagnostic codes to identify residual limb outcomes in a surveillance system is not without merit. In fact, the Centers for Disease Control and Prevention have specifically stated that ICD-10-CM codes will improve public health surveillance systems with the codes increased granularity allowing for indication of complications/severity and anatomical locations, factors that are definitely relevant to a potential amputee-artificial limb database (http://www.cdc.gov/nchs/icd/icd10cm_pcs_impact.htm). Further, the inclusion of laterality and anatomical location will simplify the differentiation between an index amputation, a reamputation (from transtibial to transfemoral or amputation of the contralateral lower limb), or revision of the residual limb, and thus help insure proper association between an artificial limb configuration and the limb status of the amputee.

Characterization of the Cohort

In a study by Dillingham and colleagues (2002) that analyzed data from the Health Care Cost and Utilization Project of 1988 to 1996, it was determined that 82% of all limb loss hospital discharges were due to dysvascular complications, and that the elderly and minorities were most at risk, especially with nearly 60% being major lower limb amputations (Dillingham et al., 2002; Ziegler-Graham et al., 2008). In the United States, of the dysvascular conditions, diabetes and diabetic complications account for the largest proportion of below-knee amputations, typically subsequent to foot ulceration and infection (Adler et al., 1999; Davis et al., 2006; Ephraim et al., 2003; Mayfield et al., 2004; Rayman et al., 2004; Reiber et al., 1998). In fact, the CDC reported that in 2007, the rate of below knee amputation per 1000 diabetic population was 1.1, and that nearly 25% of the U. S. population aged 60 years and older was diabetic (CDC 2010). It is exactly because of these estimates that this study focused on a cohort of dysvascular transtibial amputees, and the cohort followed in this study represented all of the above statistics: predominately male and Caucasian, mean age of 64 years with 64% of the cohort being between the ages of 55 and 70 years, and 67% of the cohort having a diagnoses of diabetes. Further, while the cohort was represented by nearly twice the number of Black individuals compared to 2009 VA statistics, this can be understood given the report by the Centers for Disease Control and Prevention that, as of 2009, for Black Americans, the risk of dysvascular lower limb acquired limb loss was estimated to be 1.5 to 3.5 times that of non-Hispanic Whites (CDC, 2011a). Additionally, in a study by Collins and colleagues (2002) it was found that within the VHA, Blacks suffering with peripheral arterial disease were at a greater risk for limb amputation (as opposed to limb salvage) as compared to all non-Hispanic Whites.

Based on the cohort's characteristics frequencies, the typical dysvascular transtibial amputee veteran would be around 60 years of age, White, diabetic, married, unemployed (VA Priority Status group 1, 4, or 5), possibly have a diagnosis of CHF, no significant mental health disorders, and be a K3 functional level (community) ambulators using a Flex Foot prosthetic foot with a pin-locking mechanism suspension system. Relatively few members of the cohort were incapacitated to the point of only using an artificial limb for transfers. The reason for this incapacity can only be speculated as due to late age frailty or comorbid condition such as stroke and/or CHF. The low level of activity for such persons would help to explain why someone in such a morbid condition as to be prescribed and dispensed an artificial limb configuration suitable only for transfers, would also have fewer less severe RLSPS that become severe ones.

This concept of activity level as a key factor toward the development of residual limb skin problems becomes increasingly relevant as part of the epidemiological analysis, but in terms of a descriptive analysis of the cohort, is further supported by the finding that cohort members dispensed and artificial limb configuration suitable for a household ambulation (for short walks on level surfaces such as in one's home) were found to have a higher ratio of severe to less severe RLSPS, relative to the K1 functional level (transfers only) amputee. If the provider prescribed a K2 level prosthetic foot, it is likely that the expectation was that the user would be sufficiently frail as to not progress to community ambulation. Such a level of ill-health suggests equally frail residual limb skin and a greater propensity for skin breakdown or infection subsequent of increased pressures and friction consequent of walking with an artificial limb (Mak et al., 2010).

Further evidence of the relationship between activity level and residual limb skin problems is presented in the study by Dudek and colleagues (2005) mentioned above, in which the authors reviewed over 700 lower extremity amputees using an artificial limb. The investigators determined that nearly 41% of the residual limbs examined had at least one skin problem (if a patient had more than one skin problem during the study period of six years ,only the first problem was recorded), and that the majority of the amputations were due to PVD of which 60% were subsequent of diabetes. (Dudek et al., 2005). Further analysis of the data revealed that a primary risk factor for a residual limb skin problem was activity level, however a comorbid condition of diabetes or coronary artery disease did not contribute to the likelihood of a skin problem (Dudek et al, 2005).

While such findings support a relationship between activity levels and skin problems but no similar relationship with a dysvascular condition, such may be a consequence of the study design as it offered no real categorization of the patient's overall health status relative to their activity level. More specifically, socket types and suspension systems were noted but not included in the analysis, nor was the functional level of the patient at the time of recording, and thus no association with personal capacity as an indicator of health status could be made. Because the study being reported here categorized the artificial limb used by functional level of the prosthetic foot, cohort members were by default similarly categorized. Although their categorization may not have been perfect, it did allow for some rudimentary groupings that could be used as indicators of a cohort member's overall capacity, most likely dependent on the cohort member's health and living status. In fact, in a study by Kurichi and colleagues (2007) that reviewed the medical records of over 900 U.S. Veterans one year after a lower limb amputation, it was reported that "Medical and functional conditions that adversely affect level of energy, ability to move independently, or ability to exercise judgment" influenced not only the type of artificial limb prescribed, but the likelihood of being prescribed an artificial limb in the first place (Kurichi et al., 2007, p 904).

To further characterize the cohort, less severe and severe RLSPS were divided into sub-categories representative of those suggested by Bui and colleagues (2009) as potential etiologies of common residual limb skin problems. Among the cohort members being reported here, the most common severe RLSPS was infectious occlusions to include cellulitis and carbuncles, with the occlusions being thought to be a consequence of the residual limb/socket suspension system interface environment. This environment is typically warm and humid, under levels of physical pressure not typical for the anatomy of a lower limb, exposed to unnatural elements and materials (such as plastic, nylon, silicon and so forth), and frequently not very hygienic (DePalma et al., 2002; Mak et al, 2010). Further, the circulatory system of the residual limb is compromised in part due to surgical outcomes, but also because of disease (diabetes, PAD or PVD) progression. At the time of amputation, only "healthy" tissue remains, but over time the residual limb of a dysvascular amputee can become increasingly fragile, especially under conditions of poor glycemic control and advancing age (Brown, Crone, & Attinger,2012; Chitragari et al., 2014)

. The opportunity for occlusion of a sweat gland, hair follicle, capillaries, or lymph vessels are regular if not frequent – a problem compounded by the fact that diabetes is associated with a higher incidence and/or severity of infection due to a hyperglycemic environment (Casqueiro and Alves, 2012). Hyperglycemia associated with poorly controlled diabetes favors immune dysfunction to include reduced response of T cells, neutrophil function, and disorders of humoral immunity (Casqueiro and Alves, 2012). Some skin and soft tissue infections (such as the less severe residual limb skin problems folliculitis, furunculosis/boils, and subcutaneous abscesses) may break out during the course of the disease or may be the first sign of diabetes presentation (Casqueiro and Alves, 2012). It is also not uncommon for these less severe problems to develop into severe problems if not properly cared for, such as blisters becoming ulcers and abscesses becoming infectious and gangrenous. Such infections become life-threatening given that they may trigger further diabetic complications such as hypoglycemia, ketoacidosis, the possibility of sepsis, and diabetic coma (Casqueiro and Alves, 2012). Furthermore, significant infection of the residual limb frequently results in reamputation. It is not uncommon for a dysvascular amputee to undergo reamputation (from transtibial to transfemoral or amputation of the contralateral limb) within a three year time frame (Dillingham et al., 2005; Izumi et al., 2009). Izumi et al., (2009) reported cumulative amputation rates per person as 48% at three years, a rate of 12% for the ipsilateral limb, and 44% for the contralateral limb. Such grave outcomes subsequent of residual limb skin problems makes it difficult to accept the Dudek study conclusion that there was no real relationship between activity level, a dysvascular condition and the presence of a residual limb skin problem.

Unfortunately, the design of this study dataset did not lend itself to a full characterization of the cohort to include frequencies and percentages of cohort members with two or more comorbid conditions, other serious comorbid conditions (other than those associated with dysvascular conditions), service connected or combat related injuries that may compound health issues (such as agent orange exposure), cancers, joint osteoarthritis and so forth, nor is there a direct measurement of activity level (such as distance walked or steps taken) but instead the level of activity must be inferred. However, in an effort to address the interplay between a mechanical artificial limb and the health status of the user, research questions were designed to address the influence of mechanical factors (such as the ALC category used and the region responsible), behavioral factors (such as mental health conditions that impact activity and/or self-care and disease management), and the factors resulting from the interaction of mechanical and behavioral factors. What follows is a discussion thereof.

Phase 2 – the Epidemiological Analysis

The relevance of mechanical and behavioral factors. In the same study by Dudek and colleagues as mentioned above, the investigators determined that activity level was a contributing factor toward the development of a residual limb skin problem, but that the type of socket or suspension system was not (or at least was not considered) (Dudek et al., 2005). Nonetheless, in the Dudeck study, most of the transtibial amputees used a supracondylar suspension system and nearly 12% used a pin locking mechanism (with a silicon liner) suspension system. In contrast, 58% of the study cohort used for analysis in this study used a pin-lock mechanism suspension system and less than 10% used a supracondylar suspension system. The reason for this difference is unknown but may be a reflection of prosthetist preference as the Dudek study was limited to a single outpatient rehabilitation center, whereas the results of this study were national and reflected the preference of many prosthetists.

Further, nearly 80% of the cohort were dispensed a K3 (community ambulator) level prosthetic foot - the type prosthetic foot used was not reported in the Dudek study. As such, this describes by definition a cohort of below-knee amputees able to walk longer distances through a community landscape (to include steps and curbs, ramps, and variable surfaces) and able to walk at variable speeds; in other words, an individual of relatively normal activity level and, on the surface, supports the relationship of more activity – more residual limb skin problems, but without consideration of artificial limb componentry.

It is the mechanics and functionality of the prosthetic foot that is most likely to influence the stresses and forces on the residual limb, while the purpose of the suspension system is not so much to protect the residual limb from these forces, but rather to connect the residual limb to the artificial limb (DePalma et al., 2002; Versluys et al., 2009). As discussed and eluded to throughout this document, not only is the type of components used to configure the artificial limb important, but equally so is the prosthetist.

Research questions 1 and 2 address these “mechanical” factors in which it was hypothesized that cohort members dispensed and using a more technically sophisticated artificial limb combination, such as one with a k3 prosthetic foot and a differential pressure suspension system, would be more likely to develop severe RLSPS than users of a less technically sophisticated configuration. The primary premise behind this hypothesis was that such technically sophisticated apparatus would require attention as, having more moving parts, be more prone to mechanical breakdown, and failure of the device would inflict more harm than not on the residual limb (in other words, lead to a higher incidence of severe residual limb skin problems) (DePalma, et al., 2002; G. W. Bosker CPO, personal communication, January 2011). Thus, such an artificial limb configuration would be best suited for the capable user – someone of sufficient health and mental status to recognize problems and take appropriate action, be that to seek medical care, stop wearing the artificial limb, and/or take it in for repair or adjustment. In fact, it has been reported that cognitive ability is a significant patient factor to be considered as part of the prescription decision process in part due to the complexity of newer artificial limb components (to include those that are computer aided such as the ProprioFoot) as well as an individual's ability to learn how to use a prosthesis and maintain their independence (Coffey, O'Keeffe, Gallagher, Desmond, & Lombard-Vance, 2012). This suggests that activity level is more a reflection of behavior and not a function of the artificial limb configuration itself. In other words, an individual of physical status only capable of household ambulation, would not benefit from a K3 level artificial limb configuration (it would not make them walk more or better) and, given a potentially more fragile residual limb (due to poorer health) might be more prone to breakdown from biomechanical forces generated by a more technically sophisticated artificial limb (Mak et al., 2010). A better approach is to adapt the artificial limb configuration to the ability of the user, with some exceptions such as the Vacuum Assisted Suspension System (VASS), a technically sophisticated artificial limb component that has been demonstrated to actually facilitate the healing of ulcers and improve the overall healing capacity of a dysvascular residual limb (Traballesi et al., 2012; van der Linde et al., 2004).

While the premise and alternative hypothesis for research question 1 was borne out (the community level artificial limb configurations were associated with a greater likelihood of development of a severe RLSPS) the reason for the association is beyond the scope of this study. It can be speculated, however, that based on the findings by Dudek et al., (2005) and Meulenbelt et al., (2011), both of which determined activity level to be a significant contributing factor toward residual limb skin problems, that the greater likelihood of the community level ALC categories to associate with severe RLSPS, is due to the greater activity level of such persons as compared to the K1 and K2 level ambulators.

A secondary premise was that, the more technically sophisticated ALC category would require greater skill in fitting and aligning, such that there would be greater variability in the quality of fit as performed by the various prosthetists across the nation and would be manifest as greater incidence of severe RLSPS in one Region and fewer in another, relative to the ALC category dispensed. This particular issue was addressed in research question 2 in which it was asked if the frequency and type of residual limb skin problems associated with an ALC category would vary significantly between prosthetists in which Region was used as a proxy thereof. The null hypothesis, that there would be no such significant variability, would then suggest that across the VA system, prosthetists were of similar skill, followed similar guidelines, or, while they may have practiced their preferences, did so successfully with no more residual limb skin problems than another prosthetist. The alternative hypothesis was that there would be significant variability, suggesting that the quality of service was not consistent across the VHA system and that perhaps there needed to be greater adherence to prescription guidelines, additional training for prosthetists, or that geographical aspects such as terrain, population demographics and even climate affected a cohort member's likelihood of developing a residual limb skin problem.

A similar issue was addressed by Connally, Airey, and Chell, (2001) regarding the question of variability in rates of lower limb amputation across and within countries despite similar needs, hypothesizing that differences in clinical decision making might explain the variability. Six cases were each examined by 10 different vascular surgeons as to the decision to amputate or salvage the limb, whereupon only moderate agreement was attained among the surgeons. The authors ultimately concluded that the variations in limb amputation rates could be explained, at least in part, by differences in clinical decision making rather than just geographical differences (Connally et al., 2001). One caveat to this conclusion is that it would be expected that the clinician, especially in the case of prescribing an artificial limb, would necessarily take into consideration geographical factors such as terrain, rural versus urban, wet versus dry climes, and so forth, that is the environment the patient lives in. In fact, in a study of secondary data from National Physical and Sensory Disabilities Database of Ireland, it was determined that climate was a significant barrier for the lower limb amputee (Gallagher et al., 2011). It is likely that wet climates, either in the form of rain, snow or ice, would be especially treacherous for a lower limb amputee as the biomechanics of their gait and their prosthetic limb are less adaptable to sudden changes as that required to prevent a slip from becoming a fall (Winter, 1988; G. W. Bosker, CPO, personal communication, January 2011).

The findings of the GEE analysis used to address research question 2, revealed that cohort members who received their artificial limb configuration from Region 4 (the Mid-Atlantic to northeastern section of the United States), were in fact more likely to develop a severe RLSPS than the remaining 3 Regions, but Region 4 was only represented by 20% of the cohort, compared to 40% from Region 3, 22% from Region 2, and 17% from Region 1. Further, of the artificial limbs dispensed, for Region 4 19% were of the K3/community level , compared to 35% for Region 3, 19% for Region 2, and 16% for Region 1. If one assumes that the primary cause for severe residual limb skin problems is related to activity level, then it would be expected that Region 3 with the greatest number of cohort members and K3/community level ALC categories would have significantly more severe RLSPS compared to the other regions. However, the GEE analysis revealed that cohort members from Region 4 were significantly more likely to develop a severe RLSPS than Region 2 which had the same percentage of K3/community ALC categories dispensed. This suggests that something about Region 4 other than activity level of the cohort members was driving the likelihood of developing a severe residual limb problem and, while Region 4 was used as a proxy for the Prosthetists preparing the artificial limb dispensed, given the lack of specificity of the Region variable, it is not within the scope of the analysis to explain the phenomena. The variable Region was used instead of VISN because of small cell sizes and thus the loss of granularity, making it difficult to proclaim a problem with prosthetist expertise, the need for universal prescription guidelines, or the influence of geographical factors, although Region 4 and Region 2 do have distinctly different terrain and climates. More granular information (such as the zip code of the organization prescribing or dispensing the artificial limb)would likely be found valuable for policy makers or oversight agencies potentially using an amputee-artificial limb database for reasons of registering fraud or modifying policy.

Despite the above findings for research questions 1 and 2, it remains unclear if residual limb skin problems are subsequent of prosthetist decisions or skill, a function of a particular model or make of artificial limb component or some other aspect such as patient residual limb health, usage patterns and care practices. As presented throughout, mechanical factors or parameters are only one part of the equation that describes the relationship between an amputee and their artificial limb. A significant component of a provider's artificial limb prescription is based on the amputee's present and predicted health status, as well as their (the amputee's) goals and needs.

Studies by Desmond and colleagues (2002, 2005, 2006, and 2008), Callaghan, Condie, and Johnston (2008); as well as Coffey and colleagues (2009, 2012, and 2013) all reported findings that supported the importance of psychological and emotional well-being in the success of an amputee using an artificial limb, success being measured by use of the limb and activity level (but not residual limb skin problems). In the late 1970s, Engels posited the biosphychosocial model in which the health and quality of life for an individual was dependent on the interaction between their physiologic status, psychological condition and social barriers which, when applied to the transtibial dysvascular amputee includes disease control through self-care and management, psychological adjustments to changes in body image, independence, and mobility, as well as care and maintenance of both their artificial and residual limb (Engels, 1977). Thus, based on this model, it is not likely that activity level is solely responsible for a lower limb amputee to develop a residual limb skin problem, but rather a combination of factors that define their activity level and their ability to self-manage care (Engels, 1977; Jack et al., 2004; Hanley et al., 2004). To address this issue, research question 3 was intended to ascertain the association between certain comorbid physiological diseases frequently related to or in-line with dysvascular conditions (such as renal failure and CHF) with the development of a residual limb skin problem, regardless of any so-called mechanical factors. Other diseases of interest included those that would affect energy level such as COPD and CVD, as well as the mental health conditions PTSD (because of its association with anxiety and adjustment disorders- coping mechanisms), MDD (because of associated decrease in initiative and impetus), and SUD (because of its association with poor health care and maintenance).

The subsequent GEE model analysis revealed that SUD was associated with a significant likelihood of developing, either a less severe or severe RLSPS, and MDD with the likelihood of developing a severe RLSPS only. In both conditions, a lack of impetus regarding personal health care may be a factor leading to poorer overall health and a more fragile residual limb prone to breakdown when an artificial limb is in use – regardless of the configuration.

Substance use disorder is defined as having a continuum of spectra – from regular use to abuse to dependence (The Management of SUD Working Group, 2009). In the case of alcohol consumption dependence may be otherwise categorized as alcoholism, with which comes the increased possibility of cirrhosis of the liver, cancer, and other chronic conditions (The Management of SUD Working Group, 2009). A key characteristic of substance abuse, regardless of the substance or level of use, is a disregard for potentially harmful effects (The Management of SUD Working Group, 2009). In the case of substance dependence, a great deal of time is spent by the individual in activities necessary to procure the substance, use it, and recover from its effects. Social, occupational, or recreational activities are foregone in lieu of use of the substance and, despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance; usage continues (The Management of SUD Working Group, 2009). For example, a cocaine user will continue despite knowledge and experience of cocaine-induced depression; alcoholics will continue drinking despite acknowledgement that to do so exacerbates an existing ulcer (The Management of SUD Working Group, 2009). Thus, in the case of SUD, depending on the degree of usage, both activity level and personal health neglect could explain its significant association with the likelihood of developing both less severe and severe RLSPS.

However, in regard to MDD, the most likely explanation is personal health care neglect or a lack of impetus. Current trends in diabetes control require the dogged engagement of the patient to self-medicate (insulin or glucose control medications), self-care (exercise and eat properly) and self-manage their disease (CDC, 2011b; Jack, 2004). However, in a study of over 700 surveyed U.S. Veterans, it was found that while well-educated by their clinicians regarding the need for monitoring, exercise, and proper diet, The mean self-efficacy score for diabetes self-care was low and only half of the sample reported readiness to change their diet or level of exercise, whereas those with a high self-efficacy (confident and motivated) were successful in adjusting their lifestyle and self-managing their disease (Nelson, McFarland, & Reiber, 2007).

Any chronic disease, including diabetes, PAD, or PVD, is associated with some order of mood disorders and depression. In the case of the diabetic, the prevalence of depression may be three times greater than that of the non-diabetic population (Harris, 2003). Moreover, individuals suffering from depression and diabetes frequently present with poor glycemic control and a higher incidence of microvascular and macrovascular complications, ostensibly setting them up for poor healing capacity and skin breakdown (Harris, 2003; Williams et al., 2011). In fact, among a cohort of diabetic U.S. Veterans it was found that those with a comorbid diagnosis of depression also had a 33% higher incidence of major limb amputation (Williams et al., 2011).

Given that an individual diagnosed with diabetes is likely to suffer some level of depression that is then compounded by amputation, (which itself is associated with depression [Darnall et al., 2005]), it is not surprising that dysvascular amputees especially struggle with glucose control and self-management of their disease, as well as maintenance and usage of their artificial limb. In a prospective multisite study, Nelson and colleagues (2007) determined that U.S. Veterans one year post a dysvascular major limb amputation and fitted with an artificial limb, demonstrated poorer function given a comorbid diagnosis of MDD. A diagnosis of MDD is based on the presence of depressed mood or loss of interest or pleasure, with additional symptoms to include significant change in weight or appetite, insomnia or hypersomnia, decreased concentration, decreased energy, inappropriate guilt or feelings of worthlessness, psychomotor agitation or retardation, and suicidal ideation (The Management of MDD Working Group, 2009).

Given such states, interest in self-management of a chronic disease or the function of an artificial limb is likely wane, and when combined with poor hygiene of the residual limb or psychomotor agitation, the residual limb of a dysvascular amputee is prone to break down, especially, perhaps, as an infectious occlusion, given the potential for poor hygiene and personal neglect.

That PTSD was not associated with either a less severe or severe RLSPS may be reflective of both its symptoms and the age of the predominance of the cohort. 82% of the cohort was 55 years of age or older and the mean age was 64 years. Veterans of this age were likely soldiers in the Viet Nam war of which it has been estimated that approximately 9% still suffer from post-traumatic stress disorder, although the intensity and duration has likely diminished (The Management of Post-Traumatic Stress Working Group, 2010). Symptoms of the chronic version of the disorder include low energy, memory problems, unfocused during daily activities; inability to make decisions, feelings of irritability, agitation, resentfulness or anger; depression/despair, spontaneous crying; emotionally numb, withdrawn, or isolated; overly protective of or fearful for safety of loved ones; unable to face any reminders of the trauma (The Management of Post-Traumatic Stress Working Group, 2010). Many times, PTSD is concurrent with diagnoses for adjustment and mood disorders, pain, and sleep disturbances, as well as psychological conditions such as MDD or SUD (The Management of Post-Traumatic Stress Working Group, 2010). While this litany of symptoms seem to support the concept of an amputee with and increased likelihood of developing a residual limb skin problem, as mentioned above, most of the cohort members were middle - to older age, likely having dealt with such symptoms for decades, rendering the symptomology to a highly manageable state through treatment and time. However, while age is potentially an explanation for PTSD's lack of significant association with a RLSPS category, another explanation may be that a diagnosis of PTSD with no concurrent psychological disorder (such as mentioned above) does not present itself with symptoms and characteristics that would impact activity level or health self-care and management sufficiently to attain a significant likelihood of a residual limb skin problem. Future studies that address the outcomes associated with concurrent, multiples of mental health diagnoses may provide considerable more insight useful for artificial limb prescription guidelines.

Finally, The GEE analysis of so-called "behavioral factors" also revealed a significant association between COPD and the likelihood of developing a less severe or severe RLSPS. COPD was selected as a comorbid condition of interest because of its potential for low activity levels, as well as poorly oxygenated blood to inhibit rapid healing (The Management of Chronic Obstructive Pulmonary Disease Working Group, 2011; Gea, Agusti, & Roca, 2013). Medically, COPD comprises a combination of chronic and slowly progressive respiratory disorders including emphysema and chronic bronchitis with symptoms such as shortness of breath, coughing, and an irreversible worsening course (The Management of Chronic Obstructive Pulmonary Disease Working Group, 2011). While COPD is primarily a respiratory condition, it is associated with systemic inflammation and manifestations (especially impaired gases exchange and hyperventilation) that can then exacerbate other conditions (The Management of Chronic Obstructive Pulmonary Disease Working Group, 2011; Gea, Agusti, & Roca, 2013). Veterans are at higher risk of COPD than those in the general US population, and it has been shown that "within the VA population, patients with COPD have significantly higher all-cause and respiratory-related health care utilization than patients without COPD." (The Management of Chronic Obstructive Pulmonary Disease Working Group, 2011, p. 17). COPD was a diagnosis for approximately 25% of the cohort, whereas CHF was a diagnosis for 46%. Why COPD and not CHF was significantly associated with the likelihood of a RLSPS is unclear. Both conditions would likely be characterized by low activity/low energy, as well as poor tissue oxygenation leading to poor healing capacity (CHF due to poor blood circulation; COPD due to poor blood oxygenation), such that it can only be suggested that COPD may be more treatable or have a longer progression until incapacity than CHF or renal failure, both end-stage diseases. In concurrence with these findings, in his multisite prospective study, Webster reported that dysvascular amputees utilizing a prosthesis one year post amputation and with a concurrent diagnosis for COPD, reported "greater functional restriction" than those with no such diagnosis, and those with a diagnosis for renal failure demonstrated fewer hours of walking with an artificial limb (Webster et al., 2012). Furthermore, as with the psychological disorders, many of the cohort members may have had concurrent diagnoses of these physical conditions (as well as others) and it may have been the combination of comorbid conditions (COPD plus CHF) that was associated with residual limb skin problems – a factor beyond the scope of this study.

As with most human conditions, rarely can they be explained by a single cause, but rather more accurately by the interaction of systems. In the case of the dysvascular transtibial amputee, for example, it is clear that the artificial limb configuration and the prosthetist that dispensed it play a role, but also the overall health and behavior of the user. Research questions 1 through 3 were intended to determine if any one factor (mechanical or behavioral) was more responsible or associated with a RLSPS category more than the other, about which it can only be stated that proper fit of the artificial limb and the corresponding activity level of the user is key, and less clearly but equally important, the impetus of the user to self-manage their underlying (dysvascular) disease. Research question 4 addressed this more realistic condition by addressing the outcome when the interaction of mechanical and behavioral factors are at play in the face of some demographic conditions. A sort of assessment of the biopsychosocial model and the likelihood of developing a residual limb skin problem that could further impact quality of life for the artificial limb user. As with research question 3, the behavioral aspects of the analysis were focused on the psychological comorbidities with the physical comorbidities serving as proxies for activity level potential and overall health status. The four most popular of the seven ALC categories were included in the analysis, as were the demographic variables Marital Status (as an indicator of the presence of a care giver), Age (categorized by three age groups), Race (to detect any disparities), and VA Priority status (as a proxy for socioeconomic status).

The subsequent GEE analyses revealed that mechanical factors, in terms of the ALC category, had little to do with the development of a residual limb skin problem. This suggests that manufacturers are doing a good job of developing artificial limb components that are safe and appropriately categorized within the ambulatory functional levels (k1 through K3) (The Rehabilitation of Lower Limb Amputation Working Group, 2007). However, as revealed in the analysis for research question 2, who and where the artificial limb was dispensed played a significant role in the likelihood of a cohort member developing a severe RLSPS. Much of the information the prosthetist or provider gather and incorporate in their practice is acquired from vendor representatives, anecdotal evidence, experience, and select journal articles (G. W. Bosker, CPO; personal communication, January 2011; Iezzoni, 2004). This is one of the key reasons for exploring the development of an amputee-artificial limb database and surveillance system, to provide the prosthetists with a source of evidence based data rather than that from marketers or hearsay. Nonetheless, as mentioned previously, the variable Region is such a broad proxy for the prosthetist dispensing the artificial limb, the best that can be construed from its statistical significance in the model is that something was different about Region 4 compared to the other regions. Further analysis may have revealed that the demographics of the Region differed significantly, perhaps the predominance of Black cohort members resided in Region 4 (Blacks have a higher incidence of diabetic complications, especially amputation, and may therefore suffer from a poorer health status and propensity for severe residual limb skin problems); or, perhaps, a greater proportion of cohort members with COPD received care in Region 4 relative to the other regions and thus, an increased likelihood of developing a residual limb skin problem (Dillingham et al., 2002b); Webster et al., 2012). Both of these potential explanations are beyond the scope of this study but give credence to the value of an amputee-artificial limb database derived from a surveillance system utilizing ICD-10 codes, basic demographic parameters, and some indicator of where the artificial limb configuration was dispensed. The zip code or license of the individual actually responsible for building the artificial limb would add another level of granularity to the database and be useful for insurance companies and oversight agencies as a means to identify and protect against insurance fraud, while providing researchers with a geographical marker.

In regard to demographic parameters, only socioeconomic status (as defined by VA priority) and age appeared to be associated with the development of a residual limb skin problem. As indicated in Table B14 of Appendix B, VA priority categorizes veterans on the basis of the degree of their disability, whether it is connected to the duration or time of their military service or not, and their average adjusted income (means test score) or capacity for employment. This categorization is necessary because funding for the veterans is appropriated by Congress and thus is a finite amount (for all intents and purposes); to insure that those veterans most in need receive the care required, they are prioritized into eight categories (VIReC, 2011b; VIReC 2012b). Because of small cell sizes, for this analysis, the eight categories were collapsed into three, based on the likelihood that a particular priority group would or could be employed. Furthermore, categorization by employment level was used as it was assumed that an employed Veteran was likely to be of a reasonable health status (able to work, fewer comorbid conditions, relatively active), and a veteran able to make co-payments, if not employed, was of financial status sufficient to afford such as well as likely to be of a reasonable state of health. Supporting this assumption and definitions, several studies have reported significant associations between limb amputation and socioeconomic status - that living in poverty presents more barriers to success with using a prosthetic, that comorbidity is a common characteristic (especially in regard to U.S. Veterans and adults older than 65 years), and that rates of limb amputation are greater for those living in poverty than not

(Ephraim et al., 2006; Wachtel, 2005; Selim et al., 2007; Ferguson, Nightingale, Pathak, and Jayatung, 2010).

Given such definitions, 75% of the cohort was categorized as unemployable, 13% as employable, and approximately 12% as co-pay eligible. The GEE analysis for this research question 4 indicated that co-pay eligible cohort members were significantly less likely to develop a residual limb skin problem compared to those cohort members categorized as unemployable. It seems fairly safe to assume that a Veteran deemed unemployable because of their disability/health status, is more likely to develop a residual limb skin problem due to comorbid conditions than due to activity level, as compared to the veteran who is employed (in which activity level would likely be of greater relevance) or someone of the financial means (required to make co-payments). However, this assumption does not fully address differences in activity levels between employment categories as some jobs are more sedentary than others (lesser activity level), certain behavioral disorders are associated with physical activity but not employment (such as PTSD or SUD), and financial means may be related to retirement and less activity. Therefore, for this study and variable (Socioeco/VA Priority) perhaps it is more indicative of a cohort member's health status than their actual socioeconomic status, and seems to suggest that activity level for an albeit dysvascular amputee, is not necessarily the driving factor as is suggested by Dudek et al., (2005) and Meulenbelt et al, (2008). That being said, it should be remembered that the Veteran population is not generalizable to the general public, that the data in this study represents national conditions, and that both the Dudek and Meulenbelt studies were drawn from the records of a single outpatient clinic or survey of an amputee support group (Dudek et al., 2005; Meulenbelt et al, 2008; Selim et al., 2007).

Age may actually have a dual representation – one as an indicator of demographics and another as a proxy for health or activity level. For this research question, age was a significant parameter given its association with the likelihood of developing a residual limb skin problem. As with several of the other variables utilized in this study, the original eight age groups were compressed into three age groups in order to adjust for otherwise small cell sizes. The three groups were: (a) cohort members under the age of 55 and representing 17% of the cohort, (b) cohort members between the age of 55 and 74 representing approximately 64% of the cohort, and (c) cohort members over the age of 74 years representing approximately 20% of the cohort. As part of the analysis, outcomes for the 55 to 74 year age group and the over 74 age group were compared to the under 55 group. The selection of the younger group for comparison was based on the assumption that such individuals would likely be of better health status and subsequent fewer residual limb skin problems. At the time, the consideration of potentially greater activity was not considered. The results revealed, however, that the over 74 age group was significantly less likely to develop a less severe or severe RLSPS than the youngest age group, suggesting that older age group was either healthier or less active (based on the results from the previous research questions). Given the significance of COPD and its tendency to worsen with age, as well as the cumulative/progressive effects of dysvascular disorders over time, it is likely that the less likely development of RLSPS among the older group is a function of less activity to exacerbate poor residual limb health and fragility.

Summarization of the epidemiological analysis. A key finding resulting from the analyses of this study is the confirmation that activity level alone, does not explain the incidence or prevalence of residual limb skin problems in this cohort of transtibial amputees. Rather, activity level is closely associated with the health and well-being of the artificial limb user and, factors less tangible than the mechanical superiority of an artificial limb, contribute as much if not more to an amputees success with an artificial limb and the likelihood of residual limb skin problems. The findings further indicate that MDD, SUD, and COPD are such key factors that also interact with age and energy and activity levels. Further, while the expertise and knowledge base of the prosthetist and provider are paramount, the analyses in this study and the variable Region did not sufficiently address the matter, leaving it unclear why the outcomes for one region would be significantly different than the others.

Temporal effects. The premise or hypothesis underlying the influence of temporal effects on the development of residual limb skin problems was that early on in the follow-up period (for example between 6 months and 12 months) cohort members would have predominantly less severe RLSPS as they began using their artificial limb and minor adjustments were made to its alignment or configuration. As time progressed (months 12 to month 24) the number of severe RLSPS would increase as less severe problems failed to heal or activity levels increased; and as the end of the follow-up period ensued (month 30 to month 36), the predominance of residual limb skin problems would be severe as active users learned to self-treat, not coming in for clinic appointments until the problem had become severe.

The results of the GEE analyses revealed that there was little significant association between time and developing a less severe RLSPS throughout the follow-up period, except during the last 6 months of follow-up (months 30 and 36) in which cohort members were significantly less likely to develop a less severe RLSPS. However, in regard to severe RLSPS, only during the 36 month window was there less likelihood of developing such a skin problem. The exception to these findings was in regard to behavioral effects only in which both less severe and severe RLSPS were associated with less likelihood of development during the 30 and 36 month windows, and in regard to the interaction of behavioral and mechanical effects for the artificial limb category community-locking suspension system in which at no time was there a significant association for less severe RLSPS and only a significantly less likelihood of a severe problem.

In truth, though fairly consistent between conditions and analyses, these findings are inconclusive in terms of the proposed premise, but do support the suggestion that, at the very least, toward the end of the 36 month follow-up, cohort members were less likely to seek and receive treatment (no need for clinic visits an thus not registered on hospital records), for residual limb skin problems, although the need for treatment of severe residual limb skin problems lingered beyond that of less severe problems.

This analysis actually demonstrates a significant shortcoming of a database review as opposed to surveys or even a chart review as residual limb skin problems are only registered if the patient comes for treatment and then only as a single code thereof. As discussed by van Walraven and Demers (2001) a chart review might include a history of problems as reported by the patient to the physician that were self-treated, and as suggested by Meulenbelt et al., (2009) a survey may give a clearer indication of problems but, being self-diagnosed, be in correct or less specific than that presented by an ICD-9-CM (or ICD-10) code. Clearly further analysis is required to ascertain (1) the likelihood of the progression of a less severe residual limb skin problem to a severe problem, (2) what skin problems are most likely to progress, and (3) if the frequency of less severe skin problems actually diminish over time or, as suggested from this study, they are simply not recorded in a healthcare record system.

Limitations of the Study

Limitations Imposed by the Coding Systems

The use of HCPCS billing codes to identify ALC categories. The Centers for Medicare Medicaid Services (CMMS) maintains HCPCS codes, and updates them regularly and, new products are categorized by common features of functionality and structure. A device is then placed under an existing code or, after careful consideration, research and petition, a new code may be derived (CMMS, 2012).

A limitation of this approach is that innovative designs or new materials that improve performance but. not function, are not differentiated from others of the same category other than by model and Manufacturer name – data fields that were available in the NPPD dataset extract but not always containing appropriate data (for example, the vendor's name rather than the manufacturers). This created problems in validating the components used to configure the artificial limb (internal validity)and may also impact future studies in that the use of HCPCS codes will provide only limited information about the prosthetic device, and more subtle differences between products that may or may not impact the user will not be detectable. Additionally, there is anecdotal evidence that the user interface application used by the VHA Prosthetics and Sensory Aids Service to select/record the HCPCS code per device is not updated as frequently and thus, unless the provider/user inputs the code directly rather than depending on the drop-down list provided, codes used may inaccurately reflect the device delivered (G. W. Bosker CPO, personal communication, March 2015). In other words, the accuracy of the codes are only as good as the coder. The end result of depending on HCPCS codes to categorize artificial limbs is a lack of specificity. Not only is it impossible to distinguish between makes and models of components, or determine the purpose of the component (that is, whether for backup limb or a sports limb) but, in some cases, it is not a single HCPCS code that defines the functional capacity of the limb (or even the prosthetic foot) but rather a combination of codes. The lack of specificity made it veritably impossible to explain differences in residual limb outcomes within an ALC category (such as due to a particular model or manufacturer). Additionally, the fairly broad categorization of the ALC variable may explain the lack of significant association between ALC categories and residual limb outcomes. In general, the reliability of the dataset used in this study is questionable, primarily due to data integrity problems evident in the data acquired from the NPPD (from which the independent variable was derived).

Suitability of ICD-9-CM codes as an outcome measure for artificial limb use. This study's use of RLSPS as indicated by categories of ICD-9-CM codes was based on the premise that residual limb skin problems directly impact an amputee's use of their artificial limb – the more severe the problem, the less likely they will use the limb; the less they use the artificial limb, the greater toll on their mobility, independence, and quality of life. A distinct limitation of using ICD-9-CM codes as an outcome measure of this sort, is that the code alone gives no indication of the cause or extent of the disorder, only that the disorder was detected. Without a chart review (review of progress notes) or patient interview, it is impossible to know the extent of a problem (such as how much of the residual limb was covered with a rash, how large or deep an ulcer was, or how much discomfort the problem caused the patient). As to the cause of the disorder, for some, the etiology may be easily inferred or implied by the disorder itself (for example, calluses [ICD-9-CM code 700 - corns and callosities] as a consequence of repetitive microtrauma related to artificial limb fit), whereas others may be less easily inferred (such as Folliculitis [ICD-9-CM code: 704.8 - Other specified diseases of hair and hair follicles]).

To this end, Bui et al. (2009) recognizing the need for standard categorization of residual limb problems frequently associated with the use of an artificial limb, devised a categorization of residual limb skin problems either on the basis of etiology or morphology that could be used in conjunction with ICD-9-CM codes. However, the skin problems Bui and colleagues referenced did not include their associated International Codes for Diseases (ICD) and only included those conditions most commonly associated with artificial limb use (Bui et al., 2009). For this dissertation, the Bui categories were modified to account for additional conditions related to artificial limb use such as osteomyelitis and gas gangrene because of their debilitating effect on the user. However, without any indication of the extent of a problem, it is difficult to properly assign a ICD-9-CM code to a particular category. For example, a rash (categorized as a less severe problem) that covers most of the residual limb may better be categorized as severe; an ulcer (categorized as a severe problem) that is small in size and heals rapidly may better be categorized as a less severe problem.

This limitation of ICD-9-CM codes is further confounded as the codes themselves do not indicate where the disorder or condition is located. The actual location of the skin problem was inferred from the ICD-9-CM code label only. For example code labels that indicated body parts such as head, face, neck, trunk, foot, ankle, etcetera, were not used; those that indicated lower leg, shank, or below knee, were included, as were those conditions that were non-specific such as irritant dermatitis (ICD-9-CM: 692.9). Subsequently, residual limb skin problems may have been inappropriately assigned to a category. The relatively arbitrary categorization of RLSPS, though based on educated and informed decisions, likely diminished the reliability of the associations and both internal and external validity of the study.

The VHA will be transitioning to ICD-10-CM codes during Fiscal Year 2016; this upgraded coding system will include laterality (that is, left or right limb) as well as more detailed information about the condition. For example, in the case of pressure ulcers, ICD-9-CM codes include: 707.0 - Decubitus ulcer; 707.1 - Ulcer of lower limbs, except decubitus; 707.8 - Chronic ulcer of other specified sites; 707.9 - Chronic ulcer of unspecified site. ICD-10-CM codes will include the extent (depth) of the sore/ulcer, as well as its location. Examples include: L89.131 – Pressure ulcer of right lower back, stage 1; L89.134 – Pressure ulcer of right lower back, stage 4; L89.141 – Pressure ulcer of left lower back, stage 1; L89.144 – Pressure ulcer of left lower back, stage 4 (CDC, 2016).

The Categorization of the Independent Variable, Artificial Limb Configuration

As discussed in previous chapters 3 and 4, the artificial limb that a patient ultimately uses is comprised of multiple parts configured to meet the anticipated or expected needs of the patient. This study focused only on two parts of the total configuration, the socket suspension system and the prosthetic foot which, in combination, may not reflect the complexity or true functional level of the artificial limb. For example, a patient may use an artificial limb comprised of a SACH foot, a multiaxis ankle, a rotator, and a pin-lock suspension system with a patella-bearing socket; and be categorized as a K1LOCK user as the SACH foot (L5970) is classified as suitable for K1 functional level users. The K1 functional level implies an individual that uses their artificial limb for minimal walking and/or transfers only. However, with the addition of the multiaxis ankle (a separate component that sits on top of the SACH foot) effectively creates a system more suitable for a K2 functional level user (household ambulatory), and the addition of the rotator (a device that sits on top of the pylon and just below the socket to allow for a degree of twist of the shank portion of the limb and greater ease of turning during walking) effectively makes the artificial limb configuration suitable for a K3 functional level user (community ambulator) (DePalma et al., 2002; G. W. Bosker CPO, personal communication, January 2011). Therefore the categorization of the artificial limbs in this study may be inaccurate as to the actual functional level/capacity of the cohort member amputee and thereby threatens the internal validity of the results. However, the intent of the study was explorative, the use of GEE modeling robust, and insofar as the categorization was based on the component types and not the functional capacity of the cohort member, internal validity is fundamentally preserved as all causal relationships were considered estimates.

In regard to the categorization of the independent variable, another shortcoming of the study is the decision to combine the three ALC categories Transfers, Household-High Tech Suspension system, and Household- Mid to Low Tech suspension system, and have the combined categories serve as a single reference category for comparison with the remaining four. The decision was made on the basis of low cell sizes and a subsequent unbalanced model, but to have retained the categories in the model may have improved external validity by representing an important cohort of dysvascular amputees – those of lesser activity (walking) levels. Such an analysis may also have offered insight as to outcomes associated with activity or no activity.

Generalizability of the Cohort Dataset and Veteran Population

Several factors inhibit generalizability of the study findings to include demographics of the U.S. Veteran population, their access to health care, and aspects of the study design and its scope.

The U.S. Veteran population is unique , especially when Comparing 2009 U.S. Veteran statistics with 2010 U.S. census statistics: the Veteran population was comprised of 92%males and 8% female while U.S. census reported 49.8% male and 50.8% female; Among Veterans,39% were over the age of 65 years, whereas the Census reported 13% of the population as being over the age of 65 years; and in regard to race, the Veteran population was comprised of 7% more Whites, 1% fewer Blacks, 3%fewer Asian, 9% fewer Hispanic, but about the same percentage of American Indian .(DVA, 2010a; U.S. Census Bureau, 2016). Furthermore, in a cross-sectional survey of 887,775 veterans conducted by Selim and colleagues in 2004, using a valid and reliable survey, it was determined that elderly veterans were of poorer health quality than similar demographic older persons enrolled with Medicare, ranging from 0.5 to 1 standard deviations worse.

Another factor rendering studies with the US. Veteran population non-generalizable to the overall U.S. population is the veterans access to healthcare, especially during the time period of this retrospective study that utilized data from 2007 through 2010 – prior to the Patient Protection and Affordable Care Act of 2010 (O'Bama Care). The VHA is often noted as the largest public health system in the world, and where disabled veterans (representing 75% of the cohort) receive all health care, including their artificial limb, at no cost. Only 12% of the cohort were required to make co-payments. It is likely that the similar non-veteran, non-military, on-institutionalized individual living in the U.S. during that same period of time would not have had the same access, even with the support of Social Security Disability Insurance, Medicare, or Medicaid. While not all Veterans take advantage of the VHA (for whatever reason) those that do receive medical and surgical care, durable medical equipment, housing modifications (if required) and clothing allowances at no charge or a minimum co-payment (Department of Veteran Affairs, 2010b). Such elements of the U.S. Veteran population typically makes disease risk ratios and the like less relative to the general public, but for studies that are less concerned with predicting disease rate and more oriented in testing a hypothesis regarding an informatics tool (such as an amputee-artificial limb database), demographic issues as described above become less of a limitation.

This study was intended to test the feasibility and usefulness of an amputee-artificial limb database utilizing HCPCS codes (to define the artificial limb) and ICD-9-CM codes to defined comorbid conditions and the outcome variable – residual limb skin problem. The informatics phase basically tested the feasibility of designing such a database, and the epidemiological phase tested the usefulness of the data. The source data was the NPCD (clinical histories) with a long history and reports of data validity and reliability, and the NPPD (artificial limb component data) with a short history, very few reports of data validity and reliability and few reports of utilization in research (Smith et al., 2010; VIReC, 2012b). Unfortunately, no other similar database is maintained within the United States, and even thus, is only accessible to VHA personnel and researchers. Because of the relatively unknown quality of the NPPD data, the study design was structured to limit the scope of the study to only estimations of likelihood rather than risk ratios. Missing data, and data incongruencies resulted in a smaller sample size than predicted, and several variables had to be compressed into fewer categories because of small cell sizes leading to variables of low specificity and less meaning. The reason for such data quality is unknown at this point , as the data that fills the various fields within the NPPD are drawn from multiple other sources within the VHA (such as the purchasing and contracts service, clinical records, and decision support systems) via the VIST-A software (Pape & Reiber, 2001). If data from any of these other applications/systems is corrupted or poor, than so shall be the NPPD data.

The end result is that the informatics phase of the study has limitations subsequent of data type, regardless of the study population, and the epidemiological phase has limitations because of the data. Extrapulating or generalizing results from the epidemiological phase to the general public is not recommended as the U. S. veteran population has both unique health problems and benefits that separate them from the general public.

Summary

The Utility of Administrative Healthcare Data. The fundamental concept of utilizing standardized coding such as Health Common Procedural Coding System (HCPCS) billing codes and International Classification of Diseases codes, to identify relationships between artificial limb use and comorbid conditions, is clearly not only feasible but valuable. Many studies and case reports describe skin problems of the residual limb, but very few describe such problems relative to the artificial limb in use (Meulenbelt et al., 2007). At the same time, providers are being directed toward artificial limb prescription guidelines or standards as put forth by various institutions to include the Veterans Healthcare Administration, the Military Health system, the Centers for Medicare Medicaid Services, and private insurance companies (DePalma et al, 2002; The Rehabilitation of Lower Limb Amputation Working Group, 2007; Centers for Medicare Medicaid Services, 2015; Cigna Health Care, 2010).

As an example of a prosthetics surveillance database in action, in Great Britain surveillance measures by the various Prosthetic and Amputee Rehabilitation Centers (PARCs) of the British Health System are strongly encouraged to collect, maintain, and provide statistical data relative to amputee rehabilitation and prosthetics to the National Amputee Statistical Database (NASDAB) (British Society of Rehabilitation Medicine, 2003). A stated goal of the BSRM's standards and guidelines for data collection and analysis (surveillance) is to serve as a means to audit the service practices and outcomes of the PARCs as well as to provide future and present evidence of patient outcomes (British Society of Rehabilitation Medicine, 2003). It is this sort of surveillance that is lacking in the United States and likely contributes to the high healthcare costs and questionable quality of life for the amputee. Without artificial limb prescription guidelines, without a means to monitor patient outcomes, and without easy access to such information, the individual living with limb loss is, by necessity, at the mercy of their own resources.

This study was able to demonstrate the value of an amputee-artificial limb database as derived via a surveillance system based on healthcare administrative records. Two main aspects thereof are particularly relevant: (1) the study cohort dataset successfully served as a means for evaluating prescription practices and outcomes through the use of standardized coding systems and a clinical database, as opposed to localized chart reviews, and (2) the significance of comorbid conditions relative to an amputee’s use of an artificial limb versus purely mechanical influences.

While it is evident that database structure and format problems still exist for the NPPD, this study could not have been conducted without it as no similar database exists within the United States. It is believed that modifications toward improvement of the database are fairly straightforward and could be accomplished through thoughtful upgrades of the primary input applications (namely the Prosthetics Software Package [PSP]), as well as focused validation and reliability studies similar to that conducted by Smith et al., (2010). Basically, the more studies that exploit features of the NPPD, the more weaknesses or limitations can be identified and potentially rectified, increasing its value and usefulness. Some feature improvements might include a variable/field that indicates the manufacturer of a component (such as Otto Bok or Ohio Willowwood) and not just the local vendor; the model number of the component dispensed (not just ordered); a variable/field that indicates the purpose of the component (for example, primary limb, back-up limb, or sports limb); and regular updates with date notation of HCPCS codes. To this end, despite various problems and limitations of the VHA's NPPD and despite the fact that the U.S. veteran population's health condition and care system is not entirely generalizable to the general public, the NPPD deserves further development and improvement as a sole source of national prosthetics information.

In respect to the use of residual limb skin problem categories of ICD-9-CM codes as an outcome measure, primarily due to limitations with ICD-9-CM codes, there existed the potential for over or poor identification of problems. However, indications are, compared to a chart review study by Dudek and colleagues (2005), the overall frequency of skin problems may not be significantly more or less. With the implementation of ICD-10 codes, more accurate accounting of skin problems restricted to the residual limb are likely, given the greater granularity/specificity of the codes. Hence, more meaningful categories thereof (such as that suggested by Bui et al., (2009) may be implemented as standards, improving the robustness of a surveillance system and lead to more meaningful causal inferences between and within subcategories of outcomes and associated artificial limbs.

Determinants of Residual Limb Skin Problems. The results of the epidemiological analysis were as revealing as the development of the study cohort dataset. A common expectation and regularly identified determinant of residual limb skin problems is the activity level of the user (Dudek et al., 2006; Meulenbelt et al., 2009).

Conversely, in an observational study by Salawu and colleagues (2006), it was reported that continued use of an artificial limb despite the presence of an ulcer on the residual limb, resulted in only 2% of the population demonstrating deterioration of the ulcer over a six week period. However, the actual activity level of the population was not measured, comorbid conditions not recorded or reported and, as with the studies by Dudek and Meulenbelt, the type of artificial limb used not recorded or not included in the analysis (Dudek et al., 2005; Meulenbelt et al., 2009; Salawu et al., 2007). Perhaps one of the greatest advantages of the study cohort dataset used for analysis in this study was the ability to test for associations between multiple factors, especially the ALC categories and patient comorbid conditions (otherwise referred to as mechanical and behavioral factors, respectively). While the study design did not truly lend itself to causal inferences, it did reveal a fairly interesting outcome – that residual limb skin problems may be more closely associated with the user's comorbid conditions than with their actual activity level, as there was no significant mechanical effect but multiple behavioral effects related to their comorbid conditions. The finding of no significant associations between ALC categories and residual limb skin problems is promising as it helps to demonstrate that manufacturers and prosthetists are designing artificial limbs that are both functional and safe for the user, however, the remaining results suggest that perhaps more attention needs to be given to the psychosocial influences that drive a user's compliance in the care and maintenance of both their artificial limb and comorbid condition. In other words, that behavior (which drives activity) related to a disease is an equally important consideration when prescribing an artificial limb configuration as the actual components used. The significant association between COPD (frequently associated with smoking habits and resulting in poor oxygenation of tissue) and substance use disorder (including alcohol use, dependency, and abuse; associated with hyperglycemia among diabetics), were both significantly associated with the likelihood of developing a severe residual limb problem, regardless of the ALC category used, giving credence to this concept. Further, the association between MDD and severe residual limb skin problems, plus cited associations between MDD, COPD, and diabetes (let alone with amputation) strongly supports the need for providers to recognize and acknowledge the import of such parameters when estimating the best artificial limb for an individual. The so-called determinants MDD, SUD, and COPD support Engel’s theory of the biopsychosocial model - that the mind-body connection exists and plays a significant role in an amputee’s success with an artificial limb, not only in terms of self-management and medical compliance, but on activity/energy levels. The demographic variables Age Group, Socioeconomic/VA priority, and Race, all co-contributed to the outcomes of the final model, but less clearly so. The youngest age group (less than 55 years of age) were consistently more likely to have residual limb skin problems relative to the other age groups, the primary assumption and explanation being more activity; Cohort members of a higher socioeconomic status (required to make co-payments) were less likely to develop residual limb skin problems; and Blacks more likely than Whites to develop residual limb skin problems, assumed to be related to their greater susceptibility to complications of the underlying dysvascular condition (Dillingham et al, 2002b). Unfortunately, the use of a database such as the one developed for this study, is not conducive to more declarative statements regarding demographics in part due to the nature of the study (healthcare records instead of survey tools) and the fact that all Veterans are eligible for healthcare with at most, a co-payment

For these reasons and to further validate the usefulness of an amputee-artificial limb surveillance system and database, further manipulations of the existing dataset is warranted. Such manipulations may include the analysis of different amputee subpopulations, different or clusters of comorbid conditions, or a different statistical model. Of course, given sufficient resources, a prospective study of a cohort of amputees is preferred and the gold standard for practice-based evidence medicine, but because of the complexity of the functional amputee with an artificial limb and their relative scarcity compared to other chronic conditions, the concept(s) put forth by this study becomes more and more relevant, especially with the current trends toward population and public health practices.

Recommendations

Recommended Improvements and Modifications to the NPPD

As stated previously, a key component of this study was creating the study dataset using extracts from the NPPD, a repository of prosthetics transactions maintained by the VHA's Prosthetics and Sensory Aids Service. This database has only been in development since 2000, with a major adjustment made in 2005 and modifications to the primary input application in 2012 (G. W. Bosker CPO, personal communication, March 2015). Of course, validity and reliability studies involving the NPPD are recommended and will be accomplished with the continued use of the database. However, to facilitate its use, based on the experiences of this study, a few modifications could go far to improve its usability:

- Replace text fields (such as Item) with formatted fields that will reduce ambiguity and improve data integrity. This modification may be more a matter of improving the input application to include checkboxes or selection boxes. An example would be a checkbox to indicate if the component is for the amputee's left or right limb and for what level of amputation (for example, left above knee, right symes, or bilateral transtibial), which could then be validated against the ICD-10 surgical codes from the NPCD clinical histories. This modification would not only improve validity, but resolve conditions encountered with the present database of 2007-2010 wherein the Item NPPD variable would indicate "AKA" (above knee amputation) associated with the HCPCS code for a distinctly transtibial artificial limb component; or a prosthetic foot that could be used by either an above-knee or below knee amputee. Such clarifications become relevant when attempting to associate a particular component with a physical outcome as was addressed in this study.
- Another selection box (with each HCPCS code) that indicates the purpose of the limb the code is a part of such as primary, back-up, or other. Many times there were multiple related components (as indicated by HCPCS codes) for a single individual, dispensed within less than three months of each other, making it unclear if the patient had one or two artificial limbs (possibly suggesting a bilateral amputee), if the components were being replaced, or if there was a duplication in the records (sometimes the dispense date was missing). On occasion but infrequently, the NPPD field Item or Notes would indicate that one set of components was for a back-up/secondary artificial limb, or for a particular

purpose such as swimming or running. Again, this information becomes relevant when associating an artificial limb configuration or component to a specific outcome, especially as this study supported the import of activity level on the likelihood of developing a residual limb skin problem – knowing if the artificial limb was being used for a particular sport or for everyday use thereby becomes relevant.

- To improve data usefulness and meaning to the clinician, it would be helpful if the manufacturer of the component were included in the database. Presently, the vendor is indicated which is likely input from the purchasing and contract service but bears little meaning to a clinician or researcher from another VISN or region. As indicated in the section Limitations of the Study above, a single HCPCS code refers to a functional capacity or type of a component and may have multiple manufacturers thereof. Given that many clinicians receive almost strictly marketing information regarding a component, and that a purpose of an amputee-artificial limb informatics tool is to improve evidence-based medicine, identifying the manufacture (such as Otto Bock, Ohio Willowood, or Endo-lite) becomes especially relevant.

It is planned that the above information, as well as other problems encountered with the NPPD and a summary of the results of the study will be prepared as a White Paper and presented to the South Texas Veterans Health Care System Chief of Prosthetics and Orthotics Service, with the request that the paper be reviewed. If so desired, the contents will then be edited as deemed necessary and (hopefully) forwarded to the VISN 17 Prosthetic and Orthotics Service Chief for further consideration. Additionally, as a courtesy to the NPPD Data Steward that approved access to the data, a similar White Paper will be prepared and sent to that office.

Future Studies and Analyses

Based on the findings of this study and the apparent support from peer-reviewed literature, it seems apparent that the study dataset derived and utilized has merit: a chart review of residual limb skin problems had similar frequencies and types of problems (Dudek et al., 2005); the same comorbid conditions found to be significant in the likelihood of developing a severe residual limb skin problem (namely MDD, SUD, and COPD) were also found to significantly impact an amputee's functional ability at least one year post amputation (Webster et al., 2012); and that activity level alone does not explain the type and frequency of a residual limb skin problem among dysvascular U. S. Veteran amputees (Williams et al., 2011; Hanley et al, 2004). It therefore seems important to further assess the usability of the derived dataset by addressing subpopulations of the initial cohort such as transtibial amputees without a dysvascular comorbid condition (traumatic amputees). This would prove valuable not only medically by potentially identifying differences in comorbid conditions, particularly MDD, PTSD and SUD, their impact on a U. S. Veterans likelihood of developing a residual limb skin problem and, potentially, their quality of life, but also help to discern the sensitivity and specificity of the informatics tool by comparing results to that of the dysvascular amputee (this dissertation). Using the same methodology as described in this study, other sub-populations to consider might be the above-knee amputee or the upper limb amputee. The upper limb amputee is especially relevant in that one aspect of a clinical database (such as the one derived for this study) is its potential for assessing populations that would otherwise be difficult and expensive to research because of their scarcity (Black, 1997; Hlatky, 1991; Sacristan & Galende, 1999; Iezzoni, 2004). Upper limb amputees account for only approximately four percent of all amputees, but the source data used in this study was national in scope, with over three thousand unique amputees in 2007, a similar study of approximately 120 cases is feasible (Limb Loss Resource Center, 2012). Significant improvements in upper limb prosthetics that incorporate computerized control with myographic input makes an epidemiological analysis of upper limb amputees intriguing.

Reanalysis of the Study Cohort

One of the questions that consistently arose in this dissertation but was beyond its scope was the matter of the combined impact of comorbid conditions. This multivariable analysis considered each of the selected comorbid conditions and their association with the likelihood of an artificial limb user developing a residual limb skin problem. However, as reported by Selim and colleagues (2004) older adult U. S. veterans suffer from multiple comorbid conditions and all must act on an individual's capacity to heal and function in concert with each other rather than singly. The study by Webster et al., (2012) indicated that MDD and COPD were responsible for less functioning with an artificial limb, and this doctoral study eluded to combinations of comorbid conditions such as CHF and COPD, or PTSD or SUD as having a greater impact in combination than as separate conditions. In fact, in the case of PTSD the conditions SUD and MDD frequently go hand-in-hand (The Management of Post-Traumatic Stress Working Group, 2010). It is felt that combinations or 'clusters' of diseases will have a greater impact on the severity of a potential residual limb skin problem and thus could go far in helping clinicians determine the best prescription and prognosis for an individual.

Another approach to the data might be to reanalyze the data used in this study first to determine exactly which ICD-9-CM codes for residual limb skin problems were most frequently identified, and secondly look for significant correlations between those codes and a comorbid condition, regardless of the artificial limb used (especially as it was determined that mechanical effects were minimal and non-significant). This would help refine the list of dermatological ICD-9-CM codes and, as with the Bui study, provide a more specific list of residual limb skin problems to use in future studies.

Finally, I identified Region 4 as having significantly more severe residual limb skin problems than Region 2, while the other two Regions had no similar significance. It was also demonstrated that the ALC category had no significant relationship with residual limb skin problems, leading one to question what is so different about Region 4. The first step might be to compare Region 4 to Regions 1 and 3 (same approach as that used to address research question 2) by changing the reference category from Region 2 to Region 4; if no other Region outcomes differ significantly from Region 4, it would then be safe to state that there is something distinctly different between Regions 2 and 4. A next step, then, might be to assess the variability in frequency of residual limb skin problems among VISNs within the two regions using descriptive statistics – perhaps only a couple VISNs within Region 4 are skewing the results and their respective rates of comorbid conditions and demographic variables may be examined to help isolate the difference as being driven by geographical location and subsequent conditions, patient health status, or prosthetist’s practices. If no particular VISNs stand out as having results grossly different from the other VISNs within Region 4 then additional data is required, which was not available in the dataset.

Toward A Surveillance System

To date, no national amputee registry exists within the United States, although several entities recognize and are promoting the development of such to include the Amputee Coalition of America (ACA), the Military Health System, and Veterans Health System. As of 2014, a business plan was put forth to establish a VHA Amputee Registry and efforts made to initiate its progression , but to date, no such unique Registry has been made available (G. Reiber PhD, personal communication, May 2013). Additionally, the Amputee Coalition of America has included the formation and implementation of a National Limb Loss Registry as part of their five to ten-year strategic plan (Amputee Coalition of America, 2015).

Conclusion.

For the growing amputee population, the utilization of AHc records comprised of ICD-9-CM and HCPCS billing codes, is a viable means for identifying patterns of association between the type of artificial limb used, psychosocial factors, comorbid conditions, and the skin problems of the residual limb. However, at this stage and while feasible and viable, limitations associated with each coding system and the databases from which they are drawn, preclude a level of sensitivity and specificity to offer more than pattern recognition and support of general prescription guidelines. Nonetheless the significant associations identified demonstrated the key role of amputee behavior and comorbid health conditions play in the likelihood of an artificial limb user to develop residual limb skin problems that affect energy and activity levels of the amputee – further evidence of the strength of the biopsychosocial model and how difficult it is to separate the mind from the body, especially in terms of health care (Engels, 1977).

Of particular note as the finding that the combination of the prosthetic foot and suspension system had little to no effect on the likelihood of development of a residual limb skin problem and suggests that external forces placed on a residual limb are well contained by the artificial limb itself, but may be modulated by geographic conditions faced by the user. Further, it was indicated that healing capacity of the residual limb compromised by pre-existing dysvascular conditions of diabetes, PVD and PAD, was particularly prone to residual limb skin problems in the presence of the comorbid condition COPD (associated with poor blood oxygenation); and that behaviors associated with MDD and SUD increased the likelihood of a dysvascular amputee to develop residual limb skin problems, possibly consequent of poor disease self-management. Despite these associations that elude to the import of activity level relative to the development of residual limb skin problems, it was not possible to parameterize such given the use of coding systems as well as the close relationship between psychological status and the type and amount of activity. In other words, mechanical and behavioral factors are truly integrated and difficult to separate, at least given this cohort of amputees, and may continue to be a weakness of this type of evidence-based medicine technique. Ultimately, this study demonstrated the value of healthcare administrative data, manipulated to form a clinical database, as an effective tool in the field of prosthetics to more comprehensively associate health parameters (both physical and mental) with debilitating outcomes for the artificial limb user. Such determinants may have varying implications within an amputee cohort, depending on the homogeneity or heterogeneity of the cohort, but provides focus for future research as well as the import thereof. While an artificial limb need be customized to its user, that customization cannot be based on biomechanics alone, but needs to incorporate the psychosocial conditions of the user as well, in order to facilitate good quality of life.

Implications for Positive Social Change.

For those amputees using an artificial limb, their quality of life is often modulated by residual limb problems resultant from the use of the device. It is not always clear if the problems are due to the mechanics of the device or practices of the user. Unfortunately, unlike a pair of shoes, it is not a simple matter to exchange one artificial limb for another, nor does the typical artificial limb user have any prior experience, causing most to be dependent on the decisions and recommendations of their practitioner.

However, multiple factors preclude quality EBM research in the field of prosthetics and rehabilitative medicine, leading to prosthesis prescription ambiguity and associated greater health risk (Borg & Sunnerhagen, 2008; Groah et al., 2009; Iezzoni, 2004). Further, the field of prosthetics is not open to governmental control (such as by the FDA) beyond the requirements of Good Manufacturing Practices and subsequently, marketing information is a prime source for many practitioners and prosthetists (FDA, 2012).

Countering or supporting relative marketing information, through the acquisition, evaluation and/or dissemination of objective evidence-based outcomes, promotes the likelihood of a vulnerable population to receive unbiased educated medical care and decision. To this end, various studies support utilization of AHc derived clinical databases as a means to support improved quality of life, especially in the absence of randomized control trials – the foundation for most (EBM) research and information

(Guller, 2006; Nordio et al., 2009; Tseng et al., 2005; van Walraven et al., 2009) . The findings of this study support such and give credence to development of a national surveillance system, a proven means to drive product, policy, and medical decisions toward an improved quality of life for the target, involved population (CDC, 2012a). More specifically, especially given the current emphasis on patient-centered care, stakeholders of an amputee-artificial limb national database and surveillance system, could benefit from an unbiased resource (similar to the dataset used for this study) from which to ascertain the combined influences of psychosocial and comorbid conditions with artificial limb technology (a more holistic approach) and prescription guidelines more applicable to individual cases. Furthermore, an artificial limb for the below-knee amputee alone ranges in cost from $500 to over $10,000 (G. W. Bosker CPO, personal communication, January 2011), making less ambiguous prescription guidelines a veritable necessity in order to provide the most efficacious artificial limb for an individual, regardless of marketing pressures.

This small step away from marketing and commercialism is one step toward social justice for a vulnerable population (amputees), and any move towards social justice is a move towards positive social change. Albeit small and incremental, this move toward social justice is relative to many, not just in regard to racial or gender disparity, but more towards that which governs disabled persons who struggle to assimilate with the able-bodied public. The amputee population includes persons with mental health disorders, persons of all races, and persons of varying lifestyles, all of whom can be found on the fringes of society regardless of any limb loss, and whose quality of life should not be further compromised by the use of an artificial limb.

Therefore perhaps the most significant implication for positive social change that this study supports, is the feasibility of using easily accessible, standardized, evidence-based population data that can be transformed into meaningful information to improve the quality of life for a growing population of amputees, without sacrificing device innovation or technology, but rather by directing it toward the actual needs of an amputee, other than what may be perceived without unbiased evidence.

References

Abrahamson, M. A., Skinner, H. B., Effeney, D. J., & Wilson, L. A. (1985). Prescription options for the below knee amputee. A review. *Orthopedics*, *8*(2), 210-220.

Adler, A. I., Boyko, E. J., Ahroni, J. H., & Smith, D. G. (1999). Lower-extremity amputation in diabetes. The independent effects of peripheral vascular disease, sensory neuropathy, and foot ulcers. *Diabetes Care*, *22*(7), 1029-1035. doi: 10.2337/diacare.22.7.1029

Amputee Coalition of American. (2015), 2015-2017 Strategic goals. Retrieved from: http://www.amputee-coalition.org/wp-content/uploads/2014/08/2015-2017-strategic-plan.pdf

American Medical Association. (2013). Information on the definition of CPT codes and how they are processed. *About CPT*. Retrieved from http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/about-cpt.page?

Arlet, V., Shilt, J., Bersusky, E., Abel, M., Ouellet, J. A., Evans, D., & Reddi, V. (2008). Experience with an online prospective database on adolescent idiopathic scoliosis: Development and implementation. *European Spine Journal*, *17*(11), 1497-1506. doi:10.1007/s00586-008-0779-6

Aulivola, B., Hile, C. N., Hamdan, A. D., Sheahan, M. G., Veraldi, J. R., Skillman, J. J., & . Pomposelli, F. B., Jr. (2004). Major lower extremity amputation: outcome of a modern series. *Archives of Surgery, 139*(4), 395-399. doi: 10.1001/archsurg.139.4.395

Bacci, G., Burdach, S., Cotterill, S. J., Craft, A. W., Grimer, R., Jurgens, H., &. Spooner, D. (2003). Osteosarcoma FAQ. *Cancer Index*. Retrieved from http://www.cancerindex.org/ccw/faq/osteo.htm

Bilmes, L. (2007, January 5). The Economic Costs of the 50,000 Wounded Iraq War Soldiers. *Economist's View*, http://economistsview.typepad.com/ economistsview/2007/01/the _economic_co.html

Black, N. (1997). Developing high quality clinical databases. *British Medical Journal*, 315(7105), 381-382. Retrieved from http://www.bmj.com/

Black, N., & Tan, S. (2013). Use of national clinical databases for informing and for evaluating health care policies. *Health Policy*, *109*(2), 131-136. doi: 10.1016/j.healthpol.2012.10.007

Borg, K., & Sunnerhagen, K. S. (2008). Evidence-based medicine in physical and rehabilitation medicine: Is this evidence-based rehabilitation? *Journal of Rehabilitation Medicine*, *40*(9), 689-690. Retrieved from http://www.medicaljournals.se/jrm/

Boutin, R. D., Pathria, M. N., & Resnick, D. (1998). Disorders in the stumps of amputee patients: MR imaging. *American Journal of Roentgenology, 171*(2), 497-501. Retrieved from http://www.ajronline.org/

Boutoille, D., Feraille, A., Maulaz, D., & Krempf, M. (2008). Quality of life with diabetes-associated foot complications: Comparison between lower-limb amputation and chronic foot ulceration. *Foot and Ankle International*, *29*(11), 1074-1078. doi:10.3113/FAI.2008.1074

Boyko, E. J., Koepsell, T. D., Gaziano, J. M., Horner, R. D., & Feussner, J. R. (2000). U.S. Department of Veterans Affairs medical care system as a resource to epidemiologists. *American Journal of Epidemiology*, *151*(3), 307-314. Retrieved from http://aje.oxfordjournals.org/

Brandacher, G., Ninkovic, M., Piza-Katzer, H., Gabl, M., Hussl, H., Rieger, M., & Schneeberger, S. (2009). The Innsbruck hand transplant program: Update at 8 years after the first transplant. *Transplant Proceedings*, 41(2), 491-194. doi: 10:1016/j.transproceed.2009.01.013

British Society of Rehabilitation Medicine. (2003). Amputee and Prosthetic Rehabilitation—Standards and Guidelines. In A Report of the Working Party (Chair: Hanspal, Rajiv, Second ed.). London, UK: British Society of Rehabilitation Medicine.

Brown, B. J., Crone, C. G., & Attinger, C. E. (2012). Amputation in the diabetic to maximize function. Seminars in Vascular Surgery, 25(2), 115-121. doi:10.1053/j.semvascsurg.2012.04.003

Brown, S. H., Lincoln, M. J., Groen, P. J., & Kolodner, R. M. (2003). Vista—U.S. Department of Veterans Affairs national-scale HIS. *International Journal of Medical Informatics*, 69(2-3), 135-156. Retrieved from http://www.journals.elsevier.com/international-journal-of-medical-informatics/

Bui, K., Raugi, G. J., Nguyen, V. Q., & Reiber, G. E. (2009). Skin problems in individuals with lower-limb loss: Literature review and proposed classification system. *Journal of Rehabilitation Research D*evelopment, 46(9), 1085-1090. Retrieved from http://www.rehab.research.va.gov/jrrd/index.html

Butler, K., Bowen, C., Hughes, A. M., Torah, R., Ayala, I., Tudor, J., & Metcalf, C. D. (2014). A systematic review of the key factors affecting tissue viability and rehabilitation outcomes of the residual limb in lower extremity traumatic amputees. Journal of Tissue Viability, 23(3), 81-93. doi: 10.1016/j.jtv.2014.08.002

Callaghan, B., Condie, E., & Johnston, M. (2008). Using the common sense self-regulation model to determine psychological predictors of prosthetic use and activity limitations in lower limb amputees. *Prosthetics Orthotics International,* 32(3), 324-336. doi:10.1080/03093640802242326

Casqueiro, J., Casqueiro, J., & Alves, C. (2012). Infections in patients with diabetes mellitus: A review of pathogenesis. *Indian Journal of Endocrinology and Metabolism*, 16(Suppl1), S27–S36. doi:10.4103/2230-8210.94253

Centers for Disease Control and Prevention. (2004). Diabetes Data and Trends - Complications of Diabetes. Retrieved from http://www.cdc.gov/diabetes/statistics/complications_national.htm

Centers for Disease Control and Prevention. (2006). National Health Interview Survey, Vital Statistics Report on Disability. Retrieved from: http://www.cdc.gov/nchs/nhis.htm

Centers for Disease Control and Prevention. (2011a). Complications of Diabetes. Diabetes Data and Trends. Retrieved from http://www.cdc.gov/diabetes/statistics/complications_national.htm

Centers for Disease Control and Prevention. (2011b). National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the

United States, 2011. Diabetes Data and Trends. Retrieved from http://apps.nccd.cdc.gov/DDTSTRS/FactSheet.aspx

Centers for Disease Control and Prevention. (2012). ICD - Classification of Diseases, Functioning, and Disability. Retrieved from http://www.cdc.gov/nchs/icd.htm#content-main

Centers for Disease Control and Prevention, (2013). How Cancer Registries Work. Cancer Registries' Value for You. Retrieved from http://www.cdc.gov/cancer/npcr/value/registries.htm

Centers for Disease Control and Prevention. (2014). *National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014.* Retrieved from: http://www.cdc.gov/diabetes/data/statistics/2014statisticsreport.html

Centers for Disease Control and Prevention. (2016). ICD – ICD-10-CM – International Classification of Diseases. Tenth Revision. Clinical Modification. Retrieved from http://www.cdc.gov/nchs/icd/icd10cm.htm

Centers for Medicare & Medicaid Services. (2012). HCPCS - General Information. Retrieved from https://www.cms.gov/medhcpcsgeninfo/

Centers for Medicare & Medicaid Services. (2012b). ICD9-CM. Retrieved from http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/ICD9ProviderDiagnosticCodes/#main_content

Centers for Medicare Medicaid Services (2015) DMEPOS Quality Standards – ICN905709. Retrieved from: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/DMEPOS Qual Stand Booklet ICN905709.pdf

Charles, C., Gafni, A., & Freeman, E. (2011). The evidence-based medicine model of clinical practice: scientific teaching or belief-based preaching? *Journal of Evaluation Clinical Practice*, 17(4), 597-605. doi:10.1111/j.1365-2753.2010.01562.x

Charlson, M. E., Pompei, P., Ales, K. L., & MacKenzie, C. R. (1987). A new method of classifying prognostic comorbidity in longitudinal studies: Development and validation. *Journal of Chronic Disease*, 40(5), 373-383. Retrieved from http://www.sciencedirect.com/science/article/pii/0021968187901718

Chitragari, G., Mahler, D. B., Sumpio, B. J., Blume, P. A., & Sumpio, B. E. (2014). Prosthetic options available for the diabetic lower limb amputee. Clinical Podiatric Medicine and Surgery, 31(1), 173-185. doi:10.1016/j.cpm.2013.09.008

Christensen, J., Ipsen, T., Doherty, P., & Langberg, H. (2016) Physical and social factors determining quality of life for veterans with lower-limb amputation(s): a systematic review. Disability and Rehabilitation, 38(24), 2345-2353. Doi: 10.3109/09638288.2015.1129446

Cicerone, K. D. (2005). Evidence-based practice and the limits of rational rehabilitation. *Archives of Physical Medicine and Rehabilitation*, 86(6), 1073-1074. Retrieved from http://www.archives-pmr.org/

Cigna Health Care. (2010). Cigna Medical Coverage Policy Subject *Lower Limb Prosthetic Devices (Including Vacuum-Assisted Socket System and Microprocessor/Computer-Controlled Lower Limb Prostheses*): CIGNA Health Care, Inc.

Coffey, L., Gallagher, P., Horgan, O., Desmond, D., & MacLachlan, M. (2009). Psychosocial adjustment to diabetes-related lower limb amputation. *Diabetes Medicine*, 26(10), 1063-1067. doi:10:1111/j.1464-5491.2009.02802.x

Coffey, L., O'Keeffe, F., Gallagher, P., Desmond, D., & Lombard-Vance, R. (2012). Cognitive functioning in persons with lower limb amputations: a review. *Disability and Rehabilitation*, 34(23), 1950-1964. http://www.tandfonline.com/loi/idre20#.Vx-7RWz2bxk

Collins, D. M., Karmarkar, A., Relich, R., Pasquina, P. F., & Cooper, R. A. (2006). Review of research on prosthetic devices for lower extremity amputation. *Critical Reviews™ in Biomedical Engineering*, 34(5), 379-438. doi: 10.1615/CritRevBiomedEng.v34.i5.20

Collins, T. C., Johnson, M., Henderson, W., Khuri, S. F., & Daley, J. (2002). Lower extremity nontraumatic amputation among veterans with peripheral arterial disease: is race an independent factor? *Medical Care*, 40(1 Suppl), I106-116. Retrieved from http://journals.lww.com/lww-medicalcare/pages/default.aspx

Connelly, J., Airey, M., & Chell, S. (2001). Variation in clinical decision making is a partial explanation for geographical variation in lower extremity amputation rates. *British Journal of Surgery*, 88(4), 529-535. doi:10.1046/j.1365-2168.2001.01738.x

Criqui, M. H. (2001). Peripheral arterial disease—epidemiological aspects. *Vascular Medicine,* 6(3 Suppl), 3-7. Retrieved from http://vmj.sagepub.com/

Cruz, C. P., Eidt, J. F., Capps, C., Kirtley, L., & Moursi, M. M. (2003). Major lower extremity amputations at a Veterans Affairs hospital. *American Journal of*

Surgery, 186(5), 449-454. Retrieved from http://www.americanjournalofsurgery.com/

Cumming, J. C., Barr, S., & Howe, T. E. (2006). Prosthetic rehabilitation for older dysvascular people following a unilateral transfemoral amputation. *Cochrane Database Systems* Review (4), CD005260. doi: 10.1002/14651858.CD005260.pub3

Darnall, B. D., Ephraim, P., Wegener, S. T., Dillingham, T., Pezzin, L., Rossbach, P., & MacKenzie, E. J. (2005). Depressive symptoms and mental health service utilization among persons with limb loss: Results of a national survey. *Archives of Physical Medicine and Rehabilitation*, 86(4), 650-658. doi: 10.1016/j.apmr.2004.10.028

Datta, D., Vaidya, S. P., & Alsindi, Z. (1999). Analyses of prosthetic episodes in transtibial amputees. *Prosthetics and Orthotics International*, 23(1), 9-12. Retrieved from http://poi.sagepub.com/

Davis, W. A., Norman, P. E., Bruce, D. G., & Davis, T. M. (2006). Predictors, consequences and costs of diabetes-related lower extremity amputation complicating type 2 diabetes: The Fremantle Diabetes Study. *Diabetologia*, 49(11), 2634-2641. Retrieved from http://www.diabetologia-journal.org/

de Bont, A., Stoevelaar, H., & Bal, R. (2007). Databases as policy instruments. About extending networks as evidence-based policy. *BMC Health Services Research*, 7, 200. doi:10.1186/1472-6963-7-200

Deathe, A. B., Wolfe, D. L., Devlin, M., Hebert, J. S., Miller, W. C., & Pallaveshi, L. (2009). Selection of outcome measures in lower extremity amputation rehabilitation: ICF activities. *Disability and Rehabilitation*, 31(18), 1455-1473. doi:10.1080/09638280802639491.

DeLisa, J. A., & Kerrigan, C. K. (1998). *Gait analysis in the science of rehabilitation* (First ed.): Diane Publishing Co.

DePalma, R., Dougherty, P. J. Downs, F., Flood, K. M., Haven, E., Hebert, P., & Whatley, J. C. (2002, May, 2005). Department of Veterans Affairs Health Veterans Initiative, Traumatic Amputation and Prosthetics: Independent Study Course. Retrieved June 15, 2010 from http://www.publichealth.va.gov/docs/ vhi/traumatic amputation.pdf

Department of Veteran Affairs (2010). VA Benefits & Health Care Utilization VA statistics *20094X6_spring10_sharepoint [1].pdf*: National Center for Veterans Analysis and Statistics (008A3).

Department of Veteran Affairs (2010b). Veterans Administration Directive 1173-7-2-08 – Prosthetics and Sensory Aids Service. Retrieved from: http://www.index.va.gov/search/va/va_search.jsp?NQ=URL%3Ahttp%3A%2F%2Fwww.va.gov%2Fvhapublications%2Fpublications.cfm&QT=Veterans++Administration++Directive+1173-7-2-08&submit.x=0&submit.y=0#main-content

Desmond, D., Gallagher, P., Henderson-Slater, D., & Chatfield, R. (2008). Pain and psychosocial adjustment to lower limb amputation amongst prosthesis users. *Prosthetics and Orthotics International*, 32(2), 244-252. doi:10.1080/03093640802067046

Desmond, D., & MacLachlan, M. (2002). Psychological issues in prosthetic and orthotic practice: a 25 year review of psychology in Prosthetics and Orthotics

International. *Prosthetics and Orthotics International*, 26(3), 182-188. doi: 10.1080/03093640208726646

Desmond, D. M., & MacLachlan, M. (2006a). Affective distress and amputation-related pain among older men with long-term, traumatic limb amputations. *Journal of Pain Symptom Management*, 31(4), 362-368. doi:10.1016/j.jpainsymman.2005.08.014

Desmond, D. M., & MacLachlan, M. (2006b). Coping strategies as predictors of psychosocial adaptation in a sample of elderly veterans with acquired lower limb amputations. *Society of Science and Medicine*, 62(1), 208-216. doi: 10.1016/j.socscimed.2005.05.011

Dillingham, T. R., & Pezzin, L. E. (2008). Rehabilitation setting and associated mortality and medical stability among persons with amputations. *Archives of Physical Medicine and Rehabilitation*, 89(6), 1038-1045. doi:10.1016/j.apmr.2007.11.034

Dillingham, T. R., Pezzin, L. E., & MacKenzie, E. J. (2002a). Limb amputation and limb deficiency: Epidemiology and recent trends in the United States. *Southern Medicine Journal*, 95(8), 875-883. doi:10.1097/00007611-200208000-00018

Dillingham, T. R., Pezzin, L. E., & MacKenzie, E. J. (2002b). Racial differences in the incidence of limb loss secondary to peripheral vascular disease: A population-based study. *Archives of Physical Medicine and Rehabilitation*, 83(9), 1252-1257. doi:10.1053/apmr.2002.34805

Dillingham, T. R., Pezzin, L. E., & Shore, A. D. (2005). Reamputation, mortality, and health care costs among persons with dysvascular lower-limb amputations.

Archives of Physical Medicine and Rehabilitation, 86(3), 480-486. doi: 10.1016/j.apmr.2004.06.072

Dominitz, J. A., Maynard, C., & Boyko, E. J. (2001). Assessment of vital status in Department of Veterans Affairs national databases. Comparison with state death certificates. *Annuals of Epidemiology*, 11(5), 286-291. Retrieved from http://www.annalsofepidemiology.org/

Downs, F., Jr. (2000). The National Prosthetic Patient Database: A national information resource for prosthetic prescriptions written in the VA. *Journal of Rehabilitation Research and Development*, 37(3), vii-xi. Retrieved from http://www.rehab.research.va.gov/jrrd/index.html

Dudek, N. L., Marks, M. B., Marshall, S. C., & Chardon, J. P. (2005). Dermatologic conditions associated with use of a lower-extremity prosthesis. *Archives of Physical Medicine and Rehabilitation*, 86(4), 659-663. Retrieved from http://www.archives-pmr.org/

Engel, G. L. (1977). The need for a new medical model: a challenge for biomedicine. Science, 196(4286), 129-136. Doi: 10.1126/science.847460

Ephraim, P. L., Dillingham, T. R., Sector, M., Pezzin, L. E., & Mackenzie, E. J. (2003). Epidemiology of limb loss and congenital limb deficiency: A review of the literature. *Archives of Physical Medicine and Rehabilitation*, 84(5), 747-761. Retrieved from http://www.archives-pmr.org/

Ephraim, P. L., MacKenzie, E. J., Wegener, S. T., Dillingham, T. R., & Pezzin, L. E. (2006). Environmental barriers experienced by amputees: The Craig Hospital

Inventory of Environmental Factors–Short Form. *Archives of Physical Medicine and Rehabilitation*, 87(3), 328-333. Retrieved from http://www.archives-pmr.org/

Feinglass, J., Pearce, W. H., Martin, G. J., Gibbs, J., Cowper, D. Sorensen, M. &. Khuri, S. (2001). Postoperative and late survival outcomes after major amputation: Findings from the Department of Veterans Affairs National Surgical Quality Improvement Program. *Surgery*, 130(1), 21-29. doi:10.1067/msy.2001.115359

Ferguson, H. J., Nightingale, P., Pathak, R., & Jayatunga, A. P (2010). The influence of socio-economic deprivation on rates of major lower limb amputation secondary to peripheral arterial disease. Journal of Vascular Surgery, 52(1), 256-260. Doi: 10.1016/j.jvs.2010.05.059

Ferguson, J., & Smith, D. G. (1999). Socket considerations for the patient with a transtibial amputation. *Clinical Orthopedics Related Research* (361), 76-84. Retrieved from http://clinorthop.org/index.html

Fisher, E. B., Brownson, C. A., O'Toole, M. L., Shetty, G., Anwuri, V. V., & Glasgow, R. E. (2005). Ecological approaches to self-management: The case of diabetes. *American Journal of Public Health*, 95(9), 1523-1535. Retrieved from http://ajph.aphapublications.org/

Fletcher, D. D., Andrews, K. L., Butters, M. A., Jacobsen, S. J., Rowland, C. M., & Hallett, J. W., Jr. (2001). Rehabilitation of the geriatric vascular amputee patient: a population-based study. *Archives of Physical Medicine and Rehabilitation*, 82(6), 776-779. doi:10.1053/apmr.2001.21856

Fletcher, D. D., Andrews, K. L., Hallett, J. W., Jr., Butters, M. A., Rowland, C. M., & Jacobsen, S. J. (2002). Trends in rehabilitation after amputation for geriatric patients with vascular disease: implications for future health resource allocation. *Archives of Physical Medicine and Rehabilitation*, 83(10), 1389-1393. doi: 10.1053/apmr.2002.34605

Flood, K. M., Huang, M. E., Roberts, T. L., Pasquina, P. F., Nelson, V. S., & Bryant, P. R. (2006). Limb deficiency and prosthetic management. 2. Aging with limb loss. *Archives of Physical Medicine and Rehabilitation*, 87(3 Suppl 1), S10-14. Retrieved from http://www.archives-pmr.org/

Freedman, A. M. (1995). The biopsychosocial paradigm and the future of psychiatry. *Comprehensive Psychiatry*, 36(6), 397-406. doi:10.1016/S0010-440X(95)90246-5

Fry, D. E., Pine, M., Jordan, H. S., Elixhauser, A., Hoaglin, D. C., Jones, B., & Meimban, R. (2007). Combining administrative and clinical data to stratify surgical risk. *Annals of Surgery*, 246(5), 875-885. doi:10.1097/SLA.0b013e3180cc2e7a

Funnell, M. M., Brown, T. L., Childs, B. P., Haas, L. B., Hosey, G. M., Jensen, B., . & Weiss, M. A. (2009). National standards for diabetes self-management education. *Diabetes Care*, 32 Suppl 1, S87-94. doi:10.2337/dc09-S087

Gallagher, P. (2004). Introduction to the special issue on psychosocial perspectives on amputation and prosthetics. *Disability and Rehabilitation*, 26(14-15), 827-830.

Gallagher, P., O'Donovan, M. A., Doyle, A., & Desmond, D. (2011). Environmental barriers, activity limitations and participation restrictions experienced by people with major limb amputation. *Prosthetics and Orthotics International*, 35(3), 278-284. doi:10.1177/0309364611407108

Gambassi, G. (2009). Pain and depression: The egg and the chicken story revisited. *Archives of Gerontology and Geriatrics*, 49 Suppl 1, 103-112. doi:10.1016/j.archger.2009.09.018

Garson, G. (2008). GLM Repeated Measures. *Statnotes: Topics in Multivariate Analysis*. Retrieved from http://faculty.chass.ncsu.edu/ garson/pa765/statnote.htm

Garson, G. (2011a). Generalized Linear Models/Generalized Estimating Equations. *Statnotes: Topics in Multivariate Analysis*. Retrieved from http://faculty.chess.ncsu.edu/garson/pa765/statnote.htm

Garson, G. (2011b). Longitudinal Analysis. *Statnotes: Topics in Multivariate Analysis.* Retrieved from http://faculty.chass.ncsu.edu/ garson/pa765/statnote.htm

Gauthier-Gagnon, C., Grise, M. C., & Potvin, D. (1999). Enabling factors related to prosthetic use by people with transtibial and transfemoral amputation. *Archives of Physical Medicine and Rehabilitation*, 80(6), 706-713. doi:10.1016/S0003-9993(99)90177-6

Gea, J., Agusti, A., & Roca, J. (2013). Pathophysiology of muscle dysfunction in COPD. Journal of Applied Physiology, 114(9), 1222-1234. doi:10.1152/japplphysiol.00981.2012.

Georgiou, A. (2002). Data information and knowledge: The health informatics model and its role in evidence-based medicine. *Journal of Evaluation in Clinical Practice,* 8(2), 127-130. doi:10.1046/j.1365-2753.2002.00345.x

Giacomini, M. (2009). Theory-based medicine and the role of evidence: why the emperor needs new clothes, again. *Perspectives on Biology and Medicine*, 52(2), 234-251.

Retrieved from http://www.press.jhu.edu/journals/perspectives_in_biology_and_medicine/

Golberstein, E., Eisenberg, D., & Gollust, S. E. (2008). Perceived stigma and mental health care seeking. *Psychiatric Services*, 59(4), 392-399. doi:10.1176/appi.ps.59.4.392

Goodman, R. M., Yoo, S., & Jack, L., Jr. (2006). Applying comprehensive community-based approaches in diabetes prevention: Rationale, principles, and models. *Journal of Public Health Management and Practice,* 12(6), 545-555. Retrieved from http://journals.lww.com/jphmp/pages/default.aspx

Groah, S. L., Libin, A., Lauderdale, M., Kroll, T., DeJong, G., & Hsich, J. (2009). Beyond the evidence-based practice paradigm to achieve best practice in rehabilitation medicine: A clinical review. *Physical Medicine and Rehabilitation Journal*, 1(10), 941-950. doi:10.1016/j.pmrj.2009.06.001. Epub 2009 Oct 1.

Guller, U. (2006). Surgical outcomes research based on administrative data: inferior or complementary to prospective randomized clinical trials? World Journal of Surgery 30(3), 255-266. Doi: 10.1007/s00268-005-0156-0

Guo, S., & Dipietro, L. A. (2010). Factors affecting wound healing. *Journal of Dental Research*, 89(3), 219-229. doi:10.1177/0022034509359125

Haase, J. M. (2009). Co-occuring antisocial personality disorder and substance use disorder: Treatment interventions. *Graduate Journal of Counseling Psychology,* 1(2). Retrieved from http://epublications.marquette.edu/gicp/vol1/iss2/6

Hafner, B. J., Sanders, J. E., Czerniecki, J. M., & Fergason, J. (2002). Transtibial energy-storage-and-return prosthetic devices: A review of energy concepts and a proposed nomenclature. *Journal of Rehabilitation Research and Development*, 39(1), 1-11. Retrieved from http://www.rehab.research.va.gov/jrrd/index.html

Hadimi, K. N. (2009). Pre-operative rehabilitation evaluation of the dysvascular patient prior to amputation. *Physical Medicine and Rehabilitation Clinics of North America*, 20(4), 677-688. Retrieved from http://www.pmr.theclinics.com/

Hanley, M. A., Jensen, M. P., Ehde, D. M., Hoffman, A. J., Patterson, D. R., & Robinson, L. R. (2004). Psychosocial predictors of long-term adjustment to lower-limb amputation and phantom limb pain. *Disability and Rehabilitation*, 26(14-15), 882-893. Retrieved from http://www.tandfonline.com/toc/idre20/current

Harris, M. D. (2003). Psychosocial aspects of diabetes with an emphasis on depression. *Current Diabetes Reviews*, 3(1), 49-55. Retrieved from http://benthamscience.com/journal/index.ph

Hlatky, M. A. (1991). Using databases to evaluate therapy. *Statistics in Medicine*, 10(4), 647-652. Retrieved from http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1097-0258

Hofstad, C., Linde, H., Limbeek, J., & Postema, K. (2004). Prescription of prosthetic ankle–foot mechanisms after lower limb amputation. *Cochrane Database Systematic Reviews* (1), CD003978. Retrieved from http://community-archive.cochrane.org/editorial-and-publishing-policy-resource/cochrane-database-systematic-reviews-cdsr

Homaifar, B. Y., Harwood, J. E., Wagner, T. H., & Brenner, L. A. (2009). Description of outpatient utilization and costs in group of veterans with traumatic brain injury.

Journal of Rehabilitation Research and Development, 46(8), 1003-1010. doi: 10.1682/JRRD.2008.12.0166

Hubbard, S. L., Fitzgerald, S. G., Vogel, B., Reker, D. M., Cooper, R. A., & Boninger, M. L. (2007). Distribution and cost of wheelchairs and scooters provided by Veterans Health Administration. *Journal of Rehabilitation Research and Development*, 44(4), 581-592. Retrieved from http://www.rehab.research.va.gov/jrrd/index.html

Iezzoni, L. I. (2004). Risk adjusting rehabilitation outcomes: an overview of methodologic issues. *American Journal of Physical Medicine and Rehabilitation*, 83(4), 316-326. doi:10.1097/01.PHM.0000118041.17739.BB

Izumi, Y., Satterfield, K., Lee, S., & Harkless, L. B. (2006). Risk of reamputation in diabetic patients stratified by limb and level of amputation: A 10-year observation. *Diabetes Care*, 29(3), 566-570. doi:10.2337/diacare.29.03.06.dc05-1992

Jack, L. (2004). Diabetes and men’s health issues (Preface). *Diabetes Spectrum*, 17(4), 206-209. Retrieved from http://spectrum.diabetesjournals.org/

Jude, E. B., Oyibo, S. O., Chalmers, N., & Boulton, A. J. (2001). Peripheral arterial disease in diabetic and nondiabetic patients: a comparison of severity and outcome. *Diabetes Care*, 24(8), 1433-1437. Retrieved from http://care.diabetesjournals.org/

Karmarkar, A. M., Collins, D. M., Wichman, T., Franklin, A., Fitzgerald, S. G., Dicianno, B. E., &. Cooper, R. A. (2009). Prosthesis and wheelchair use in veterans with lower-limb amputation. *Journal of Rehabilitation Research and Development*, 46(5), 567-576. doi:10.2337/diacare.29.03.06.dc05-1992

Kazis, L. E., Miller, D. R., Clark, J., Skinner, K., Lee, A., Rogers, W., &. Linzer, M. (1998). Health-related quality of life in patients served by the Department of Veterans Affairs: Results from the Veterans Health Study. *Archives of Internal Medicine*, 158(6), 626-632. Retrieved from http://archinte.jamanetwork.com/article.aspx?articleid=191609

Kerkovich, D. M. (2004). A report on the amputee healthcare and prosthetics workshop sponsored by Walter Reed Army Medical Center and the Department of Veterans Affairs (VA) November 17-18, 2003. *Journal of Rehabilitation Research and Development*, 41(3B), xiii-xvi. Retrieved from http://www.rehab.research.va.gov/jrrd/index.html

Klute, G. K., Berge, J. S., Biggs, W., Pongnumkul, S., Popovic, Z., & Curless, B. (2011). Vacuum-assisted socket suspension compared with pin suspension for lower extremity amputees: effect on fit, activity, and limb volume. *Archives of Physical Medicine and Rehabilitation*, 92(10), 1570-1575. doi:10.1016/j.apmr.2011.05.019

Klute, G. K., Bere, J. S., Orendurff, M. S., Williams, R. M., & Czerniecki, J. M. (2006). Prosthetic intervention effects on activity of lower-extremity amputees. *Archives of Physical Medicine and Rehabilitation*, 87(5), 717-722. Retrieved from http://www.archives-pmr.org/

Kurichi, J. E., Kwong, P. L., Reker, D. M., Bates, B. E., Marshall, C. R., & Stineman, M. G. (2007). Clinical factors associated with prescription of a prosthetic limb in elderly veterans. *Journal of American Geriatrics Society*, 55(6), 900-906. Retrieved from http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1532-5415

Laferrier, J. Z., & Gailey, R. (2010). Advances in lower-limb prosthetic technology. [Review]. *Phys Med Rehabil Clin N Am*, 21(1), 87-110. doi:10.1016/j.pmr.2009.08.003

Larner, S., van Ross, E., & Hale, C. (2003). Do psychological measures predict the ability of lower limb amputees to learn to use a prosthesis? *Clinical Rehabilitation*, 17(5), 493-498. Retrieved from http://cre.sagepub.com/

Legro, M. W., Reiber, G., del Aguila, M., Ajax, M. J., Boone, D. A., Larsen, J. A., & Sangeorzan, B. (1999). Issues of importance reported by persons with lower limb amputations and prostheses. *Journal of Rehabilitation Research and Development*, 36(3), 155-163. Retrieved from http://www.rehab.research.va.gov/jrrd/index.html

Li, X., Liang, D., & Liu, X. (2002). Compartment syndrome in burn patients. A report of five cases. *Burns*, 28(8), 787-789. Retrieved from http://www.sciencedirect.com/

Livneh, H., Antonak, R. F., & Gerhardt, J. (1999). Psychosocial adaptation to amputation: The role of sociodemographic variables, disability-related factors and coping strategies. *International Journal of Rehabilitation Research*, 22(1), 21-31. doi:10.1097/00004356-199903000-00003

Lustman, P. J., & Clouse, R. E. (2007). Depression in diabetes: The chicken or the egg? *Psychosomatic Medicine*, 69(4), 297-299. doi:10.1097/PSY.0b013e318060cc2d

Mak, A. F., Liu, G. H., & Lee, S. Y. (1994). Biomechanical assessment of below-knee residual limb tissue. *Journal of Rehabilitation Research and Development*, 31(3), 188-198. Retrieved from http://www.rehab.research.va.gov/jrrd/index.html

Mak, A. F., Zhang, M., & Boone, D. A. (2001). State-of-the-art research in lower-limb prosthetic biomechanics-socket interface: a review. Journal of Rehabilitation Research and Development, 38(2), 161-174. Retrieved from http://www.rehab.research.va.gov/jrrd/index.html

Mayfield, J. A., Reiber, G. E., Maynard, C., Czerniecki, J., & Sangeorzan, B. (2004). The epidemiology of lower-extremity disease in veterans with diabetes. *Diabetes Care*, 27 Suppl 2, B39-44. doi:10.2337/diacare.27.suppl_2.B39

Mayfield, J. A., Reiber, G. E., Maynard, C., Czerniecki, J. M., Caps, M. T., & Sangeorzan, B. J. (2000). Trends in lower limb amputation in the Veterans Health Administration, 198-1998. *Journal of Rehabilitation Research and Development*, 37(1), 23-30. Retrieved from http://www.rehab.research.va.gov/jrrd/index.html

Mayfield, J. A., Reiber, G. E., Maynard, C., Czerniecki, J. M., Caps, M. T., & Sangeorzan, B. J. (2001). Survival following lower-limb amputation in a veteran population. *Journal of Rehabilitation Research and Development*, 38(3), 341-345. Retrieved from http://www.rehab.research.va.gov/jrrd/index.html

Meulenbelt, H. E., Dijkstra, P. U., Jonkman, M. F., & Geertzen, J. H. (2006). Skin problems in lower limb amputees: A systematic review. *Disability and Rehabilitation*, 28(10), 603-608. DOI: 10.1080/09638280500277032

Meulenbelt, H. E., Geertzen, J. H., Dijkstra, P. U., & Jonkman, M. F. (2007). Skin problems in lower limb amputees: An overview by case reports. *Journal of*

European Academy of Dermatology and Venereology, 21(2), 147-155. doi: 10.1111/j.1468-3083.2006.01936.x

Meulenbelt, H. E., Geertzen, J. H., Jonkman, M. F., & Dijkstra, P. U. (2009). Determinants of skin problems of the stump in lower-limb amputees. *Archives of Physical Medicine and Rehabilitation*, 90(1), 74-81. doi:10.1016/j.apmr.2008.07.015.

Miller, W. C., Deathe, A. B., Speechley, M., & Koval, J. (2001). The influence of falling, fear of falling, and balance confidence on prosthetic mobility and social activity among individuals with a lower extremity amputation. *Archives of Physical Medicine and Rehabilitation*, 82(9), 1238-1244. doi:10.1053/apmr.2001.25079

Miller, D. R., & Pogach, L. (2008). Longitudinal approaches to evaluate health care quality and outcomes: The Veterans Health Administration diabetes epidemiology charts. *Journal of Diabetes Science and Technology*, 2(1), 24-32. Retrieved from http://dst.sagepub.com/

Mirabello, L., Troisi, R. J., & Savage, S. A. (2009). Osteosarcoma incidence and survival rates from 1973 to 2004: Data from the Surveillance, Epidemiology, and End Results Program. *Cancer*, 115(7), 1531-1543. doi:10.1002/cncr.24121

Moreland, M. E., Kilbourne, A. M., Engelhardt, J. G., Jain, R., Gao, J., Macpherson, D. S. & Xing, G. (2004). Diabetes preventive care and non-traumatic lower extremity amputation rates. *Journal of Healthcare Quality*, 26(5), 12-17

Moriyama, I. M., Loy, R. M., & Robb-Smith, A. H. T. (2011, June 2011). History of the statistical classification of diseases and causes of death. *ICD–Classification of*

Diseases, Functioning, and Disability. Retrieved March, 2011, from http://www.cdc.gov/nchs/icd.htm

Murphy, P. A., Cowper, D. C., Seppala, G., Stroupe, K. T., & Hynes, D. M. (2002). Veterans Health Administration inpatient and outpatient care data: An overview. *Effective Clinical Practice*, 5(3 Suppl), E4. Retrieved from http://ecp.acponline.org/mayjun02/murphy.htm

Nair, A., Hanspal, R. S., Zahedi, M. S., Saif, M., & Fisher, K. (2008). Analyses of prosthetic episodes in lower limb amputees. *Prosthetics and Orthotics International*, 32(1), 42-49. Retrieved from http://poi.sagepub.com/

Nawijn, S. E., van der Linde, H., Emmelot, C. H., & Hofstad, C. J. (2005). Stump management after trans-tibial amputation: A systematic review. *Prosthetics and Orthotics International*, 29(1), 13-26. Retrieved from http://poi.sagepub.com/

Nelson, K. M., McFarland, L., & Reiber, G. (2007). Factors influencing disease self-management among veterans with diabetes and poor glycemic control. *Journal of General Internal Medicine*, 22(4), 442-447. Retrieved from http://www.springer.com/medicine/internal/journal/11606?token=prtst0416p

Nelson, V. S., Flood, K. M., Bryant, P. R., Huang, M. E., Pasquina, P. F., & Roberts, T. L. (2006). Limb deficiency and prosthetic management. 1. Decision making in prosthetic prescription and management. *Archives of Physical Medicine and Rehabilitation*, 87(3 Suppl 1), S3-9. Retrieved from http://www.archives-pmr.org/

Nordio, M., Antonucci, F., Feriani, M., Inio, A., & Marchini, P. (2009). [Reliability of administrative databases in epidemiological research: The example of end-stage renal disease requiring renal replacement therapy in patients with diabetes].

Giornale Italiano di Nefrologia, 26 Suppl 45, S7-11. Retrieved from http://www.academia.edu/23381009/_Reliability_of_administrative_databases_in_epidemiological_research_the_example_of_end-stage_renal_disease_requiring_renal_replacement_therapy_in_patients_with_diabetes.

O'Carroll, P. W., Yasnoff, W. A., Ward, M. E., Ripp, L. H., Martin, E.L. (2003). Public health informatics and information systems. New York, NY: Springer

O’Malley, K. J., Cook, K. F., Price, M. D., Wildes, K. R., Hurdle, J. F., & Ashton, C.M. (2005). Measuring diagnoses: ICD code accuracy. *Health Services Research*, 40(5 Pt 2), 1620-1639. doi:10.1111/j.1475-6773.2005.00444.x

Osterman, F. A., Jr. (1992). The use of angioplasty, bypass surgery, and amputation in the management of peripheral vascular disease. *New England Journal of Medicine*, 326(6), 414; author reply 415-416. Retrieved from http://www.nejm.org/

Pape, T. M. M., and Reiber, G. (2001). The National Prosthetics Patient Database (NPPD). A Primary Resource for Nationwide VA Durable Medical Equipment Data. Hines, IL: VA Information Resource Center. *VIReC Insights*, 2(3), 1-9. Retrieved from http://www.virec.research.va.gov/Resources/Publications

Payne, M. W., & Marks, M. B. (2003). Transtibial amputation management. *Journal of Rehabilitation Research and Development*, 40(6), ivi-xvii; author reply xvii. Retrieved from http://www.rehab.research.va.gov/jrrd/index.html

Perry, J., & Burnfield, J. M. (2010). *Gait analysis: Normal and pathological function* (second Ed.) Los Angeles, CA: SLACK Incorporated.

Phillips, C. V., & Goodman, K. J. (2004). The missed lessons of Sir Austin Bradford Hill. *Epidemiology Perspectives and Innovation*, 1(1), 3. Retrieved from http://epi-perspectives.biomedcentral.com/

Pinzur, M. S., Gottschalk, F., Pinto, M. A., & Smith, D. G. (2008). Controversies in lower extremity amputation. *Instructional Course Lectures*, 57, 663-672. Retrieved from http://jbjs.org/content/81/4/572

Pugh, M. J., Zeber, J. E., Copeland, L. A., Tabares, J. V., & Cramer, J. A. (2008). Psychiatric disease burden profiles among veterans with epilepsy: The association with health services utilization. *Psychiatric Services*, 59(8), 925-928. doi:10.1176/appi.ps.59.8.925

Randon, C., Deroose, J., & Vermassen, F. (2003). How to perform a below-knee amputation. *Acta chirurgica Belgica Société belge de chirurgie*, 103(2), 238-240. Retrieved from http://www.pubfacts.com/detail/12768873/How-to-perform-a-below-knee-amputation

Rakovec-Felser, Z. (2011). The biopsychosocial model of treatment the patients with inflammatory chronic bowel disease. *Collegium Antropologicum School of Biological Anthropology*, 35(2), 453-461. Retrieved from http://connection.ebscohost.com/c/articles/66586771/biopsychosocial-model-treatment-patients-inflammatory-chronic-bowel-disease

Rayman, G., Krisnan, S. T., Baker, N. R., Wareham, A. M., & Rayman, A. (2004). Are we underestimating diabetes-related lower-extremity amputation rates? Results and benefits of the first prospective study. *Diabetes Care*, 27(8), 1892-1896. doi: 10.2337/diacare.27.8.1892

Reiber, G. E., Lipsky, B. A., & Gibbons, G. W. (1998). The burden of diabetic foot ulcers. *American Journal of Surgery*, 176(2A Suppl), 5S-10S. Retrieved from http://www.americanjournalofsurgery.com/

Reiber, G. E., & Raugi, G. J. (2005). Preventing foot ulcers and amputations in diabetes. *Lancet*, 366(9498), 1676-1677. doi:10.1016/S0140-6736(05)67674-x

Reiser, M. F. (1980). Implications of a biopsychosocial model for research in psychiatry. *Psychosomatic Medicine*, 42(1 Suppl), 141-151. Retrieved from http://journals.lww.com/psychosomaticmedicine/pages/default.aspx

Remes, L., Isoaho, R., Vahlberg, T., Viitanen, M., Koskenvuo, M., & Rautava, P. (2010). Quality of life three years after major lower extremity amputation due to peripheral arterial disease. *Aging Clinical and Experimental* Research, 22(5-6), 395-405. doi:10.3275/6712

Render, M. L., Taylor, P., Plumkett, J., & Nugent, G. N. (2003). Methods to estimate and compare VA expenditures for assistive devices to Medicare payments. *Medical Care*, 41(6 Suppl), 1170-79. Retrieved from http://journals.lww.com/lww-medicalcare/pages/default.aspx

Resnik, L., & Borgia, M. (2015). Predicting prosthetic prescription after major lower-limb amputation. Journal of Rehabilitation Research and Development, 52(6), 641-652. doi:10.1682/JRRD.2014.09.021

Roberts, T. L., Pasquina, P. F., Nelson, V. S., Flood, K. M., Bryant, P. R., & Huang, M. E. (2006). Limb deficiency and prosthetic management. 4. Comorbidities associated with limb loss. *Archives of Physical Medicine and Rehabilitation*, 87(3 Suppl 1), S21-27. doi:10.1016/j.ampr.2005.11.025

Rogers, B., Bosker, G. W., Crawford, R. H., Faustini, M. C., Neptune, R. R., Walden, G., & Gitter, A. J. (2007). Advanced trans-tibial socket fabrication using selective laser sintering. *Prosthetics and Orthotics International*, 31(1), 88-100. doi:10.1080/03093640600983923

Rosato, S., D'Errigo, P., Badoni, G., Fusco, D., Perucci, C. A., & Seccareccia, F. (2008). [Comparison between administrative and clinical databases in the evaluation of cardiac surgery performance]. *Giornale Italiano di Cardiologia (Rome)*, 9(8), 569-578. Retrieved from https://www.researchgate.net/publication/23246328_Comparison_between_administrative_and_clinical _database_in_the_evaluation_of_cardiac_surgery_performance

Sackett, D. L., Rosenberg, W. M., Gray, J. A., Haynes, R. B., & Richardson, W. S. (1996). Evidence based medicine: what it is and what it isn't. *British Medical Journal*, 312(7023), 71-72. Retrieved from http://www.bmj.com/

Sacristan, J. A., & Galende, I. (1999). Clinical Trials. Randomised database studies could serve as new strategy. *British Medical Journal*, 318(7191), 1138. Retrieved from http://www.bmj.com/

Salawu, A., Middleton, C., Gilbertson, A., Kodavali, K., & Neumann, V. (2006). Stump ulcers and continued prosthetic limb use. *Prosthetics and Orthotics International*, 30(3), 279-285. doi:10.1080/03093640600836139

Salem-Schatz, S., Moore, G., Rucker, M., & Pearson, S. D. (1994). The case for case-mix adjustment in practice profiling. When good apples look bad. *Journal of the American Medical Association*, 272(11), 871-874. doi:10.1001/jama.272.11.871

Sandnes, D. K., Sobel, M., & Flum, D. R. (2004). Survival after lower-extremity amputation. *Journal of the American College of Surgeons*, 199(3), 394-402. Retrieved from http://www.journalacs.org/

Sansam, K., O'Connor, R. J., Neumann, V., & Bhakta, B. (2014). Clinicians' perspectives on decision making in lower limb amputee rehabilitation. Journal of Rehabilitative Medicine, 46(5), 447-453. doi:ED10.2340/16501977-1791

Selim, A. J., Fincke, G., Ren, X. S., Lee, A., Rogers, W. H., Miller, D. R., & Kazis, L. E. (2004). Comorbidity assessments based on patient report: Results from the Veterans Health Study. *Journal of Ambulatory Care Management*, 27(3), 281-295. Retrieved from http://journals.lww.com/ambulatorycaremanagement/pages/default.aspx

Sewell, P., Noroozi, S., Vinney, J., & Andrews, S. (2000). Developments in the transtibial prosthetic socket fitting process: A review of past and present research. *Prosthetics and Orthotics International*, 24(2), 97-107. Retrieved from http://poi.sagepub.com/

Singh, R., Ripley, D., Pentland, B., Todd, I., Hunter, J., Hutton, L., & Philip, A. (2009). Depression and anxiety symptoms after lower limb amputation: The rise and fall. *Clinical citation* 23(3), 281-286. doi:10.1177/0269215508094710

Smith, D. G., McFarland, L. V., Sangeorzan, B. J., Reiber, G. E., & Czerniecki, J. M. (2003). Postoperative dressing and management strategies for transtibial amputations: A critical review. *Journal of Rehabilitation Research and Development*, 40(3), 213-224. Retrieved from http://www.rehab.research.va.gov/jrrd/index.html

Smith, M. W., Su, P., & Phibbs, C. S. (2010). Matching prosthetics order records in VA National Prosthetics Patient Database to healthcare utilization databases. *Journal of Rehabilitation Research and Development*, 47(8), 725-737. Retrieved from http://www.rehab.research.va.gov/jrrd/index.html

Soares, A. S., Yamaguti, E. Y., Mochizuki, L., Amadio, A. C., & Serrao, J. C. (2009). Biomechanical parameters of gait among transtibial amputees: a review. *Sao Paulo Medical Journal*, 127(5), 302-309. Retrieved from http://www.scielo.br/scielo.php?script=sci_serial&pid=1516-3180&lng=en&nrm=iso

Spotlight. (2015). 1 in 15 Veterans Had a Substance Use Disorder in the Past Year. Retrieved January 30, 2016, from http://www.samhsa.gov/data/sites/default/files/report_1969/Spotlight-1969.html

Steffen, L. M., Duprez, D. A., Boucher, J. L., Ershow, A. G., & Hirsch, A. T. (2008). Management of Peripheral Arterial Disease. *Diabetes Spectrum*, 21, 171-177. Retrieved from http://spectrum.diabetesjournals.org/

Szeto, H. C., Coleman, R. K., Gholami, P., Hoffman, B. B., & Goldstein, M. K. (2002). Accuracy of computerized outpatient diagnoses in a Veterans Affairs general medicine clinic. *American Journal of Managed Care*, 8(1), 37-43. Retrieved from http://www.ajmc.com/

The Management of COPD Working Group. (2014). VA/DoD Clinical Practice Guideline for Management of Chronic Obstructive Pulmonary Disease (COPD), VA/DoD Evidence Based Practice, Document VADoDCOPDCPG.pdf (Chair: Render, Rice, Sharafkhaneh, Sherner, Third Ed.). Washington DC: Veterans

Health Administration, Department of Veterans Affairs, and Health Affairs, Department of Defense. Retrieved from: http://www.healthquality.va.gov/guidelines/cd/copd/ctice_Guideline.asp

The Management of MDD Working Group. (2009). VA/DoD Clinical Practice Guideline for Management of Major Depressive Disorder (MDD), VA/DoD Evidence Based Practice, Document #053013 (Chair: Engel, Williams, Second Ed.). Washington DC: Veterans Health Administration, Department of Veterans Affairs, and Health Affairs, Department of Defense. Retrieved from: http://www.healthquality.va.gov/Major_Depressive_Disorder_MDD_Clinical_Practice_Guideline.asp

The Management of Post-Traumatic Stress Working Group. (2010). VA/DoD clinical practice guideline for management of post-traumatic stress. In VA/DoD Evidence Based Practice, Document 11612 (Chair: Friedman, Ruzek, Second Ed.). Washington DC: Veterans Health Administration, Department of Veterans Affairs, and Health Affairs, Department of Defense. Retrieved from: http://www.healthquality.va.gov/Post_Traumatic_Stress_Disorder_PTSD.asp

The Management of SUD Working Group. (2009). *VA/DoD Clinical Practice Guideline for Management of Substance Use Disorders. In VA/DoD Evidence Based Practice Document* #601F (Chair: Haning, Kivlahan, Second Ed.). Washington DC: Veterans Health Administration, Department of Veterans Affairs, and Health Affairs, Department of Defense. Retrieved from: http://www.healthquality.va.gov/Substance_Use_Disorder_SUD.asp

The Rehabilitation of Lower Limb Amputation Working Group. (2007). *VA/DoD Clinical Practice Guideline for Rehabilitation of Lower Limb Amputation*. Washington, DC: Office of Quality and Performance, VA, & Quality Management Directorate, United States Army MEDCOM. Retrieved from http://www.healthquality.va.gov/amputation/amp_v652.pdf

Tudiver, F., & Talbot, Y. (1999). Why don't men seek help? Family physicians' perspectives on help-seeking behavior in men. *Journal of Family Practice*, 48(1), 47-52. Retrieved from http://www.jfponline.com/

U.S. Census Bureau (2016). 2010 Census Data - 2010 Census. Retrieved from: http://www.census.gov/2010census/data/

U.S. Food and Drug Administration. (2012). Part 890 – Physical Medicine Devices. *Medical Device Exemptions 510(k) and GMP Requirements*. Retrieved Jan. 31, 2011, from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm?GMPPart=890#main

Uustal, H. (2009). Prosthetic rehabilitation issues in the diabetic and dysvascular amputee. *Physical Medicine and Rehabilitation Clinics of North America*, 20(4), 689-703. doi:10.1016/j.pmr.2009.06.014

VA Information Resource Center (VIReC). (2011a). VHA Medical SAS® Outpatient Datasets and Inpatient Encounters Dataset FY2009: VIReC Research User Guide. Hines, IL: U.S. Dept. of Veterans Affairs, Health Services Research and Development Service, VA Information Resource Center. . Available at http://www.virec.research.va.gov/DataSourcesName/Medical-SAS-Datasets/MedSAS-Outpt-RUG/MedSAS-RUG-Outpt.htm

VA Information Resource Center (VIReC). (2011b). Medical SAS® Inpatient Dataset FY2009: VIReC Research User Guide. Hines, IL: U.S. Dept. of Veterans Affairs, Health Services Research and Development Service, VA Information Resource Center. Available at: http://www.virec.research.va.gov/DataSourcesName/Medical-SAS-Datasets/MedSAS-Inpt-RUG/MedSAS-RUG-Inpt.htm

VA Information Resource Center (VIReC). (2012a). National Prosthetics Patient Database (NPPD) *Data Sources*. Retrieved from http://www.virec.research.va.gov/NPPD/Overview.htm#content-wrapper

VA Information Resource Center (VIReC). (2012b). VHA National Patient Care Database (NPCD). *Data Sources*. Retrieved from http://www.virec.research.va.gov/NPCD/Overview.htm#content-wrapper

van der Kolk, B. A. (1994). The body keeps the score: memory and the evolving psychobiology of post-traumatic stress. *Traumatic Information Pages*. Retrieved from Trauma Information Pages, Articles: website: http://www.trauma-pages.com/vanderk4.htm

van der Linde, H., Hofstad, C. J., Ceurts, A. C., Postema, K., Geertzen, J. H., & van Limbeek, J. (2004). A systematic literature review of the effect of different prosthetic components on human functioning with a lower-limb prosthesis. *Journal of Rehabilitation Research and Development*, 41(4), 555-570. Retrieved from http://www.rehab.research.va.gov/jrrd/index.html van Walraven, C., & Austin, P. (2012). Administrative database research has unique characteristics that can risk biased results. *Journal of Clinical Epidemiology*, 65(2), 126-131. doi:10.1016/j.jclinepi.2011.08.002

Versluys, R., Beyl, P., Van Damme, M., Desomer, A., Van Ham, R., & Lefeber, D. (2009). Prosthetic feet: State-of-the-art review and the importance of mimicking human ankle–foot biomechanics. *Disability and Rehabilitation Assistant Technology*, 4(2), 65-75. doi:10.1080/17483100802715092

Veterans and PTSD. (2015). Veterans statistics: PTSD, Depression, TBI, and Suicide. Retrieved January 30, 2016, from http://www.veteransandptsd.com/PTSD-statistics.html.

Wachtel, M. S. (2005). Family poverty accounts for differences in lower-extremity amputation rates of minorities 50 years old or more with diabetes. Journal of the National Medical Association, 97(3), 334-338. Retrieved from: http://www.sciencedirect.com/science/journal/00279684

Webster, J. B., Hakimi, K. N., Williams, R. M., Turner, A. P., Norvell, D. C., & Czerniecki, J. M. (2012). Prosthetic fitting, use, and satisfaction following lower-limb amputation: a prospective study. Journal of Rehabilitation Research and Development, 49(10), 1493-1504. Doi: 10.1682/JRRD.2012.01.0001

Werner, G. (2010). Prosthetics Basics User Manual. In A. Scott (Ed.), (Version 3.1): Department of Veterans Affairs, VISTA System Design and Development.

Williams, L. H., Miller, D. R., Fincke, G., Lafrance, J. P., Etzioni, R., Maynard, C., Reiber, G. E. (2011). Depression and incident lower limb amputations in veterans with diabetes. *Journal of Diabetes Complications*, 25(3), 175-182. doi:10:1016/j.jdiacomp.2010.07.002

Wilson, M. (1993). DSM-III and the transformation of American psychiatry: a history. American Journal of Psychiatry, 150(3), 399-410. Retrieved from: http://ajp.psychiatryonline.org/loi/ajp

Winter, D. A., & Sienko, S. E. (1988). Biomechanics of below-knee amputee gait. Journal of Biomechanics, 21(5), 361-367.

Zidarov, D., Swaine, B., & Gauthier-Gagnon, C. (2009a). Life habits and prosthetic profile of persons with lower-limb amputation during rehabilitation and at 3-month follow-up. *Archives of Physical Medicine and Rehabilitation*, 90(11), 1953-1959. doi:10.1016/j.apmr.2009.06.011

Zidarov, D., Swaine, B., & Gauthier-Gagnon, C. (2009b). Quality of life of persons with lower-limb amputation during rehabilitation and at 3-month follow-up. *Archives of Physical Medicine and Rehabilitation*, 90(4), 634-645. doi 10.1016/j.apmr.2008.11.003

Zinszer, K. M., Mulhern, J. L., & Kareem, A. A. (2011). The implementation of the chronic care model with respect to dealing with the biopsychosocial aspects of the chronic disease of diabetes. *Advances in Skin Wound Care*, 24(10), 475-484. doi:10.1097/01.ASW.0000406474.13306.31

Ziegler-Graham, K., MacKenzie, E. J., Ephraim, P. L., Travision, T. G., & Brookmeyer, R. (2008). Estimating the prevalence of limb loss in the United States: 2005 to 2050. *Archives of Physical Medicine and Rehabilitation*, 89(3), 422-429. doi:10.1016/j.apmr.2007.11.005.

Appendix A: Pilot Study Results from Laurel Copeland, Ph.D.

From:
Sent: Saturday, February 20, 2010 8:27 AM
To: Walden, Judith G
Subject: fy09 leg amputations

Dear Gail,

I asked …, one of our data analysts (DA's), to determine the number of unique patients who met any of the following criteria in FY09 nationwide. We found 2,321 persons who appear to be new AKA/BKA amputees in FY09. I asked the DA to use 3 files, the inpatient discharge file (contains diagnosis; netted 3 cases), the inpatient surgery file (contains diagnosis and ICD9A codes; netted 1951 cases), and the inpatient encounter file (contains diagnosis and CPT codes; netted 1338 cases). The DA then merged them to get 2321 unique persons.

Here are the criteria I used (having any of these codes causes the person to be included in the count of AKA/BKA):

ICD9A:

'8414' = '8414 AMPUTATION OF ANKLE THROUGH MALLEOLI OF '

'8415' = '8415 OTHER AMPUTATION BELOW KNEE '

'8417' = '8417 AMPUTATION ABOVE KNEE '

CPT:

'27590' = '27590 AMPUTATE LEG AT THIGH'

'27591' = '27591 AMPUTATE LEG AT THIGH'

'27592' = '27592 AMPUTATE LEG AT THIGH'

'27598' = '27598 AMPUTATE LOWER LEG AT KNEE'

Amputation ICD9 Dx Codes

896 Traumatic amputation of foot (complete) (partial)

897 Traumatic amputation of leg(s) (complete) (partial)

Interesting, huh?!

Center for Applied Health Research, Health Outcomes Core, Central Texas Veterans Health System, Temple, Texas.

Appendix B: Study Cohort Database Data Dictionary
Artificial Limb Component HCPCS Codes

Table B1

Component	HCPCS billing code(s)
Socket suspension systems:	
Straps and belts	L5680, L5682, L5684, L5688, l5690
Cuff suspension	L5666
Suspension sleeve	L5685
Vacuum assisted	L5781, l5782
Suction suspension	L5647
Sleeve, pin-lock mechanism	L5671
Supercondyle	L5670
Prosthetic Feet:	
SACH foot	L5970
SAFE foot (flexible keel)	L5972
Single axis ankle/foot	L5974
Flexible Keel	L5972
Multiaxial ankle/foot	L5978
Energy-storing (dynamic response	L5976
Dynamic response/multiaxis	L5979
Flex foot	L5980
Flex-walk system	L5981
Shank system with vertical loading pylon	L5987
Microprocessor-controlled ankle foot prosthesis (for example, Proprio Foot®)	L5973
Multiaxis, flexible keel	L5975

Table B2.

Artificial Limb Configuration (ALC)

ALC	Artificial Limb Configuration
Source	National Patient Prosthetics Database (NPPD) file extracts
Type	Categorical
Values	1.transfer, 2.household high-tech ss, 3.household mid to low, 4.household locking ss, 5.community high-tech ss, 6.community mid to low, 7.community locking ss
Comments	Each value/category is a combination of a prosthetic foot and socket suspension system whose codes are presented below. The categories were derived to reflect the K-level of the prosthetic feet and the technical sophistication of the socket suspension system. "technically sophisticated" can be defined as a device having multiple moving parts or advance materials; as the k-level of prosthetic feet increases, so does the complexity of the design and materials; straps, belts, and cuff suspensions are classified as low, suspension sleeves and molded supracondylar suspension as moderate, and suction or vacuum assisted suspension systems as high in their level of technical sophistication. HCPCS codes were identified from the Durable Medical Equipment, Prosthetics/Orthotics, and Supplies Fee Schedule on the Centers for Medicare Medicaid Services website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html
Category definition:	
1.transfers	K1 level prosthetic feet (artificial limb used primarily for transfers such as from bed to chair), combined with any type of socket suspension system.
Sub-category	HCPCS Code Combinations
K1H	L5970+L5647, L5781, or L5782 l5974+L5647, L5781, or L5782
K1lm	L5970+L5671 or l5673 l5974+ L5671 or l5673
K1m	L5970+L5685 or L5670 l5974+L5685 or L5670
K1l	L5970+L5680, L5682, L5684, L5688, l5690 or , L5666 l5974+L5680, L5682, L5684, L5688, l5690 or , L5666
2.household high-tech ss	K2level prosthetic foot with a technically sophisticated socket suspension system
K2H	L5972+L5647, L5781, or L5782 L5975+L5647, L5781, or L5782 L5978+L5647, L5781, or L5782 l5973+L5647, L5781, or L5782
3.household mid to low	K2 level prosthetic foot with a low to moderate technically sophisticated socket suspension system

(*table continues*)

ALC	Artificial Limb Configuration
K2L	L5972+L5680, L5682, L5684, L5688, l5690, or L5666
	L5975+L5680, L5682, L5684, L5688, l5690, or L5666
	L5978+L5680, L5682, L5684, L5688, l5690, or L5666
	l5973+L5680, L5682, L5684, L5688, l5690, or L5666
K2m	L5972+ L5685 or L5670,
	L5975+ L5685 or L5670,
	L5978+ L5685 or L5670
	l5973+L5685 or L5670
4.household locking ss	K2 level prosthetic foot with a locking mechanism socket suspension system
K2lm	L5972+L5671 or l5673
	L5975+L5671 or l5673
	L5978+L5671 or l5673
	l5973+L5671 or l5673
5.community high-tech ss	K3 level prosthetic foot with a technically sophisticated socket suspension system
K3H	L5976+L5647, L5781, or L5782
	L5979+L5647, L5781, or L5782
	L5980+L5647, L5781, or L5782
	L5981+L5647, L5781, or L5782
6.community mid to low	K3 prosthetic foot with a low to moderate technically sophisticated socket suspension system
K3l	L5976+L5680, L5682, L5684, L5688, l5690, or L5666
	L5979+L5680, L5682, L5684, L5688, l5690, or L5666
	L5980+L5680, L5682, L5684, L5688, l5690, or L5666
	L5981+ L5680, L5682, L5684, L5688, l5690, or L5666
	L5987+L5680, L5682, L5684, L5688, l5690, or L5666
K3m	L5976+L5685 or L5670
	L5979+L5685 or L5670
	L5980+L5685 or L5670
	L5981+L5685 or L5670
	L5987+L5685 or L5670
7.community locking ss	K3 prosthetic foot with a locking mechanism socket suspension system
K3lm	L5976+L5671 or l5673
	L5979+L5671 or l5673
	L5980+L5671 or l5673
	L5981+L5671 or l5673
	L5987+L5671 or l5673

Table 3

Data Status

Data Status	Code assigned to study cohort members on the basis of NPPD inclusion/exclusion criteria
Source:	NPPD datafile extracts
Type:	Numeric
Values:	1, 88, 92, 93, 94, 95
Comments:	Values represent the useability of artificial limb data for analysis and are described below
Code	Definition
1	Useable data; cohort member and delivered artificial limb meet all inclusion criteria: (1) presence of both suspension system and prosthetic HCPCS codes with delivery dates (2) presence of HCPCS codes for definitive socket types L5301, l5100, or l5700, (3) otherwise congruent data field values
88	bilateral amputee (BK/BK or BK/AK)
92	Delivery date for suspension system and/or prosthetic foot missing or outside study parameters (before FY 2007 or after FY 2010).
93	Conversion to Above-knee amputee as indicated by associated text fields and/or socket type HCPCS code
94	Missing HCPCS code for prosthetic foot, suspension system, or socket type
95	Syme's amputation as indicated by HCPCS socket type and/or text fields.

Co-Morbid Conditions

Table B4

Congestive Heart Failure (CHF)

Chfx	Diagnosis codes for congestive heart failure
Source:	NPCD Inpatient and Outpatient data file extracts
Type:	Binomial
Values:	1 = one or more codes present; 0 = no codes present
Comments:	Codes in parentheses indicate that only select ICD9-CM codes were selected for this topic of diagnosis code. Codes were searched for using the terms "heart failure", "congestive heart failure", and "chronic heart failure" within the disease category DISEASES OF THE CIRCULATORY SYSTEM (390-459 found on the eICD website at http://www.eicd.com/EICDMain.htm).
ICD9-CM codes:	
398.91	Rheumatic heart failure (congestive)
(402)	Hypertensive heart disease
402.01	Malignant with congestive heart failure
402.11	Benign with congestive heart failure

(table continues)

Chfx	Diagnosis codes for congestive heart failure
02.91	Unspecified with congestive heart failure
404.01	With congestive heart failure (malignant Hypertensive heart and renal disease)
404.03	With congestive heart failure and renal failure
404.11	With congestive heart failure (benign heart and renal disease)
404.13	With congestive heart failure and renal failure
404.91	With congestive heart failure (Unspecified Heart and Renal Disease)
404.93	With congestive heart failure and renal failure
428.0	Congestive heart failure, unspecified
429.2	Cardiovascular disease, unspecified
(414)	Other forms of chronic ischaemic heart disease
414.0	Coronary atherosclerosis
414.00	Of unspecified vessel
414.01	Of native coronary artery
414.02	Of autologous biological bypass graft
414.03	Of nonautologous biological bypass graft
414.1	Aneurysm of heart
414.10	Of heart (wall)
414.11	Of coronary vessels
414.19	Other
414.8	Other specified forms of chronic ischaemic heart disease
414.9	Chronic ischaemic heart disease, unspecified

Table B5

Chronic Obstructive Pulmonary Disease (COPD)

Copdrespx	Diagnosis codes for Chronic obstructive pulmonary disease and allied respiratory conditions
Source:	NPCD Inpatient and Outpatient data file extracts
Type:	Binomial
Values:	1 = one or more codes present; 0 = no codes present
Comments:	Comprised of a combination of two categories of respiratory conditions: Copdx and otherrespx
Copdx	Chronic obstructive pulmonary disease and allied conditions
Source:	NPCD Inpatient and Outpatient datafile extracts
Type:	Numeric
Values:	ICD9-CM codes
Comments:	Codes in parentheses indicate that only select ICD9-CM codes were selected for this topic of diagnosis code. Codes were searched for using the terms “lung disease”, “obstructive pulmonary”, and “pulmonary disease” as well as within the category DISEASES on the eICD website at http://www.eicd.com/EICDMain.htm).
ICD9-CM codes:	
(491)	Chronic bronchitis
491.0	Simple chronic bronchitis
491.1	Mucopurulent chronic bronchitis
491.2	Obstructive chronic bronchitis

(*table continues*)

Copdrespx	Diagnosis codes for Chronic obstructive pulmonary disease and allied respiratory conditions
491.20	Without mention of acute exacerbation
491.21	With acute exacerbation
491.8	Other chronic bronchitis
491.9	Unspecified chronic bronchitis
(492)	Emphysema
492.0	Emphysematous bleb
492.8	Other emphysema
(493)	Asthma
493.0	Extrinsic asthma
493.00	Without mention of status asthmaticus
493.01	With status asthmaticus
493.1	Intrinsic asthma
493.10	Without mention of status asthmaticus
493.11	With status asthmaticus
493.2	Chronic obstructive asthma
493.20	Without mention of status asthmaticus
493.21	With status asthmaticus
493.9	Asthma, unspecified
493.90	Without mention of status asthmaticus
493.91	With status asthmaticus
494	Bronchiectasis
(495)	Extrinsic allergic alveolitis
495.9	Unspecified allergic alveolitis and pneumonitis
496	Chronic airways obstruction, not elsewhere classified
Otherrespx	**Other respiratory disorders not otherwise specified in COPDx**
Source:	NPCD Inpatient and Outpatient data file extracts
Type:	Numeric
Values:	ICD9-CM codes
Comments:	Codes in parentheses indicate only select ICD9-CM codes were selected for this topic of diagnosis code. Codes were searched for using the terms “pulmonary ” , “respiratory “, and “lung disease” on the website: http://www.eicd.com/EICDMain.htm
ICD9-CM codes:	
501	Asbestosis
(506)	Respiratory conditions due to chemical fumes and vapours
506.0	Bronchitis and pneumonitis due to fumes and vapours
506.4	Chronic respiratory conditions due to fumes and vapours
506.9	Unspecified respiratory conditions due to fumes and vapours
(507)	Pneumonitis due to solids and liquids
507.0	Due to inhalation of food or vomitus
507.1	Due to inhalation of oils and essences
507.8	Due to other solids and liquids
(508)	Respiratory conditions due to other and unspecified external agents
508.1	Chronic and other pulmonary manifestations due to radiation
508.8	Respiratory conditions due to other specified external agents
508.9	Unspecified

(*table continues*)

Copdrespx	Diagnosis codes for Chronic obstructive pulmonary disease and allied respiratory conditions
(511)	Pleurisy
511.0	Without mention of effusion or current tuberculosis
511.1	With effusion, with mention of a bacterial cause other than tuberculosis
511.8	Other specified forms of effusion, except tuberculous
511.9	Unspecified pleural effusion
513.0	Abscess of lung
513.1	Abscess of mediastinum
514	Pulmonary congestion and hypostasis
516	Other alveolar and parietoalveolar pneumopathy

Table B6

Cerebral Vascular Disease (CVD)

Cvdx	Diagnosis codes for cerebral vascular disease
Source:	NPCD Inpatient and Outpatient data file extracts; ICD9-CM codes
Type:	Binomial
Values:	1 = one or more codes present in patient record; 0= no codes present
Comments:	Codes in parentheses indicate that only select ICD9-CM codes were selected for this topic of diagnosis code. Codes were searched for and retrieved using the terms: cerebral", "stroke", and "cerebral vascular disease" as well as within DISEASES OF THE NERVOUS SYSTEM AND SENSE ORGANS (320-389) on the eICD website at http://www.eicd.com/EICDMain.htm.
ICD9-CM codes:	
430	Subarachnoid haemorrhage
431	Intracerebral haemorrhage
(432)	Other and unspecified intracranial haemorrhage
432.1	Subdural haemorrhage
432.9	Unspecified intracranial haemorrhage
(433)	Occlusion and stenosis of precerebral arteries
433.0	Basilar artery
433.00	without mention of cerebral infarction
433.01	with cerebral infarction
433.1	Carotid artery
433.11	with cerebral infarction
433.2	Vertebral artery
433.21	with cerebral infarction
433.3	Multiple and bilateral
433.31	with cerebral infarction
433.8	Other specified precerebral artery
433.81	with cerebral infarction
433.9	Unspecified precerebral artery
433.91	with cerebral infarction
(434)	Occlusion of cerebral arteries
434.0	Cerebral thrombosis

(*table continues*)

Cvdx	Diagnosis codes for cerebral vascular disease
434.01	with cerebral infarction
434.1	Cerebral embolism
434.11	with cerebral infarction
434.9	Cerebral artery occlusion, unspecified
434.91	with cerebral infarction
(435)	Transient cerebral ischaemia
435.0	Basilar artery syndrome
435.1	Vertebral artery syndrome
435.2	ubclavian steal syndrome
435.8	Other specified transient cerebral ischaemias
435.9	Unspecified transient cerebral ischaemia
(437)	Other and ill-defined cerebrovascular disease
437.0	Cerebral atherosclerosis
437.1	Other generalised ischaemic cerebrovascular disease
437.2	Hypertensive encephalopathy
437.4	Cerebral arteritis
437.5	Moyamoya disease
437.6	Nonpyogenic thrombosis of intracranial venous sinus
437.	Transient global amnesia
437.8	Other
437.9	Unspecified
438	Late effects of cerebrovascular disease

Table B7

Renal Failure

Renalfailx	Diagnosis codes for renal failure
Source:	NPCD Inpatient and Outpatient data file extracts; ICD9-CM codes
Type:	Binomial
Values:	1 = one or more codes present in patient records; 0 = no codes present
Comments:	Codes in parentheses indicate that only select ICD9-CM codes were selected for this topic of diagnosis code. Codes were searched for and retrieved using the terms: “renal failure”, “kidney disease”, and “renal disease”, as well as within DISEASES OF THE GENITOURINARY SYSTEM (580-629) on the eICD website at http://www.eicd.com/EICDMain.htm.
ICD9-CM codes:	
(403)	Hypertensive renal disease
403.01	Malignant with renal failure
403.11	Benign with renal failure
403.91	Unspecified with renal failure
404.02	Malignant Hypertensive heart and renal disease with renal failure
404.03	With congestive heart failure and renal failure
404.12	Benign Hypertensive heart and renal disease with renal failure
404.13	With congestive heart failure and renal failure
404.92	Unspecified Hypertensive Heart and renal disease with renal failure
404.93	With congestive heart failure and renal failure
(584)	Acute renal failure

(*table continues*)

Renalfailx	Diagnosis codes for renal failure
584.5	With lesion of tubular necrosis
584.6	With lesion of renal cortical necrosis
584.7	With lesion of renal medullary [papillary] necrosis
584.8	With other specified pathological lesion in kidney
584.9	Acute renal failure, unspecified
585	Chronic renal failure
586	Renal failure, unspecified
587	Renal sclerosis, unspecified

Table B8

Nutrition

Nutrition	Diagnosis codes for obesity and malnutrition.
Source:	NPCD Inpatient and Outpatient data file extracts; ICD9-CM codes
Type:	Binomial
Values:	1 = one or more codes present in patient records; 0 = no codes present
Comments:	Codes in parentheses indicate that only select ICD9-CM codes were selected for this topic of diagnosis code. Codes were searched for and retrieved using the terms: “obesity”, “nutrition”, and “malnutrition”, as well as within ENDOCRINE, NUTRITIONAL AND METABOLIC DISEASES, AND IMMUNITY DISORDERS (240-279) on the eICD website at http://www.eicd.com/EICDMain.htm.
Obesitx ICD9-CM codes:	
V77.8	Obesity
(278)	Obesity and other hyperalimentation
278.0	Obesity
278.1	Localized adiposity
278.2	Hypercarotinaemia
Malnutritx ICD-9-CM codes	
V77.2	Malnutrition
260	Kwashiorkor
261	Nutritional marasmus
262	Other severe protein-calorie malnutrition
(263)	Other and unspecified protein-calorie malnutrition
263.0	Malnutrition of moderate degree
263.1	Malnutrition of mild degree
263.8	Other protein-calorie malnutrition
263.9	Unspecified protein-calorie malnutrition
(264)	Vitamin A deficiency
264.8	Other manifestations of vitamin A deficiency
264.9	Unspecified vitamin A deficiency
(266)	Deficiency of B-complex components
266.0	Ariboflavinosis
266.1	Vitamin B6 deficiency
266.2	Other B-complex deficiencies
266.9	Unspecified vitamin B deficiency

(*table continues*)

Nutrition	Diagnosis codes for obesity and malnutrition.
(268)	Vitamin D deficiency
268.0	Rickets, active
268.1	Rickets, late effect268.2
268.2	Osteomalacia, unspecified
268.9	Unspecified vitamin D deficiency

Demographics

Table B9

Age

AgeXVariable:	Age at amputation
Source:	National Patient Care Database (NPCD)inpatient file
Type	Numeric
Values	18 through 89
Comments	A review of the data revealed that over73% of the cohort was between 45 and 74 years old with a mean age of 64 years, median of 62, minimum age of 22 and maximum age of 98. This variable was used only to describe the cohort and not as part of the statistical model.

Table B10

Gender

Gender	
Source:	NPCD outpatient file extracts
Type:	Categorical
Values:	M – Male; F – Female; O – Other.
Comments:	Within the cohort, only two females were identified, demonstrating VA trends of over 98% male population; this variable was not used in the analysis, only for description of the cohort

Table B11

Marital Status

Marital Status	
Source:	NPCD inpatient file extracts
Type:	Binomial
Values:	1-married; 0-not married
Comments:	Over 50% of the cohort was categorized as married, the remaining as divorced, widowed or never married (in order of highest to lowest frequency) with only 2 as unknown. To simplify the analysis, data was regrouped into only two categories, married and not-married, as the intent of the variable was to indicate the likelihood of the cohort member living alone. The 2 unknown status cohort members were categorized as “not-married”. This variable was used as part of the statistical model having a Chi square p-value of M0.25

Table B12

Race

Race	
Source	NPCD inpatient file extracts
Type	Categorical
Values	1 - White, 2 - Black, and 3 - Asian.
Comments	Only 4 groups were identified: White, Black, Asian, and Hispanic. However, since most Hispanics were also categorized as White, the Hispanic group was merged with the White group to form 3 final race groups and values. This variable was then further condense into two values: white and non-White and will be used in the statistical model having a Chi Square p-value of <0..25

Table B13

Region

Region	Groupings of Veteran Integrated Service Networks (VISNs)
Source:	NPPD datafile extracts
Type:	1. Categorical
Values:	1(VISN 18, 19, 20, 21, 22); 2 (VISN 12, 15, 16, 17, 23), 3 (VISN 6, 7, 8, 9, 10, 11); 4(VISN 1, 2, 3, 4, 5)
Comments:	The distribution of the VISNs among the four Regions was determined and established by the Office of Information Technology (OIT) VHA Central Offices, 2013. They may be loosely described in geographical terms as referenced below. It should be noted that a single VISN may cover areas in multiple states.
Region	Geographical description Veterans Integrated Service Network (VISN)

(table continues)

Region	Groupings of Veteran Integrated Service Networks (VISNs)	
Region 1	Northwest and Western U.S.	18.VA Southwest Healthcare Network; 19.Rocky Mountain Network; 20.Northwest Network; 21.Sierra Pacific Network; 22.Desert Pacific Healthcare Network
Region 2	North- and South-Central U.S. (includes Texas)	12.The Great Lakes Health Care System; 15.VA Heartland Network; 16.South Central VA Health Care Network; 17.VA Heart of Texas Health Care Network; 23.VA Midwest Health Care Network
Region 3	Eastern Mid-West and Southern U.S. Includes Ohio)	6.VA Mid-Atlantic Network; 7.The Atlantic Network; 8.VA Sunshine Healthcare Network; 9.Mid-South Veterans Healthcare Network; 10.VA Healthcare System of Ohio; 11.Veterans In Partnership
Region 4	Mid-Atlantic and Northeast U.S. (includes Washington DC/Maryland)	1.VA New England Healthcare System; 2.VA Healthcare Network Upstate New York; 3.VA NY / NJ Veterans Healthcare Network; 4.VA Stars & Stripes Healthcare Network; 5.VA Capitol Health Care Network
Comments:	VISNs 13 & 14 were combined to form VISN 23 in 2002. A VISN oversees the VA hospitals and associated satellite centers and programs within its domain.	

Table B14

Socioeconomic Status (VA Priority)

Socioeco	Socioeconomic status as suggested by VA Priority status
Source:	NPCD data file extracts
Type:	Categorical
Values:	1.unemployable, 2.employable, 3.co-pay eligible
Comments:	The intent of the inclusion of this variable was to identify those cohort members' socioeconomic status and/or employment capacity on the basis of their VA Priority status group derived from a patient's Means Test (adjusted income). None of the cohort met Priority 6 criteria. Veterans in Priority 7 and 8 can be considered employable or non-disabled, Priority 1 through 4 disabled or minimally to unemployable, and Priority 5 living at the poverty level, receiving VA pension benefits, but likely unemployable due to age.

Category Definitions

1.unemployable	Priority Status groups 1, 4, and 5
2.employable	Priority status groups 2 and 3
3.copay eligible	Priority status groups 7 and 8

VA Priority Status Group Definitions

"The number of Veterans who can be enrolled in the health care program is determined by the amount of money Congress gives VA each year. Since funds are limited, VA set up Priority Groups to make sure that certain groups of Veterans are able to be enrolled before others."

(table continues)

Socioeco	Socioeconomic status as suggested by VA Priority status
Group 1	50% or more service connected disability and/or determined unemployable; guaranteed enrollment and full health benefits).
Group 2	30-40% service connected disability
Group 3	former POWs, Purple Heart or Medal of Honor awardees, 10-20% service connected disability
Group 4	catastrophically disabled or receiving VA and attendance or housebound benefits
Group 5	non-service connected or non-disabled service connected veterans with annual incomes below regional adjusted levels, receiving VA pension benefits, eligible for Medicare
Group 6	for service connected 0% compensable disability Veterans who served under specified conditions
Group 7	Veterans with gross household income below the geographically-adjusted income limits (GMT) for their resident location and who agree to pay copays
Group 8	Veterans with gross household income above the VA and the geographically-adjusted income limits for their resident location and who agree to pay copays.

(http://www.va.gov/healthbenefits/resources/priority_groups.asp).

Mental Health Conditions

Table B15

Depression (MDD and Other)

Depression	Cohort member having a diagnosis code for Major Depressive Disorder (MDD) or other depressive condition during follow-up period
Source:	**NPCD Inpatient and Outpatient data file extracts**
Type	Binomial
Values:	1 = yes (one or more codes present); 0 = no (no codes present)
Comments:	Comprised of a combination of two categories of depressive disorders: major depressive disorder (Majordepx and clinical depression diagnosed as a condition of other disorders such as bipolar disease (Otherdepx) This variable was used to describe the cohort only.
Majordepx	Major Depressive Disorder (MDD)
Source:	NPCD Inpatient and Outpatient files data extracts; ICD9-CM codes
Type	Numeric
Values:	**ICD9-CM codes**
Comments:	ICD-9-CM codes as defined in The joint VA-DoD Clinical Practice Guidelines for Mental Health, The Management of MDD Working Group, 2009). This variable was used in the study’s statistical models.
ICD9-CM codes:	
296.2	Major depressive disorder, single episode
296.20	Unspecified
296.21	Mild
296.22	Moderate

(table continues)

Depression	Cohort member having a diagnosis code for Major Depressive Disorder (MDD) or other depressive condition during follow-up period
296.23	severe, without mention of psychotic behaviour
296.24	severe, specified as with psychotic behaviour
296.3	Major depressive disorder, recurrent episode
296.30	Unspecified
296.31	Mild
296.32	Moderate
296.33	severe, without mention of psychotic behaviour
296.34	severe, specified as with psychotic behaviour
Otherdepx	other depressive conditions not otherwise noted in the variable majordepx
Source:	NPCD Inpatient and Outpatient data file extracts
Type:	Numeric
Values:	ICD9-CM codes
Comments:	Includes depressive states of bipolar conditions. Codes were searched for and retrieved using the terms "depressive", "depression", and "depressive disorder", as well as within MENTAL DISORDERS (290-319) on the eICD website at http://www.eicd.com/EICDMain.htm. This variable was used only to describe the cohort.
ICD9-CM codes:	
296.5	Bipolar affective disorder, depressed
296.50	Unspecified
296.51	Mild
296.52	Moderate
296.53	severe, without mention of psychotic behaviour
296.54	severe, specified as with psychotic behavior
296.82	Atypical depressive disorder
298.0	Depressive type psychosis
301.12	Chronic depressive personality disorder
309.1	Prolonged depressive reaction
290.13	Presenile dementia with depressive features
290.2	Senile dementia with delusional or depressive features
290.21	Senile dementia with depressive features
290.43	Arteriosclerotic dementia with depressive features

Table B16

PTSD and Other Adjustment Disorders

Ptsdadjx	Post-traumatic stress disorder and other adjustment disorders
Source:	NPCD Inpatient and Outpatient data files extracts
Type:	Binomial
Values:	**1 = one or more codes present; 0 = no codes present**
Comments:	Comprised of a combination of two categories of adjustment disorders: post-traumatic stress disorder (Ptsdx) and those identified as relevant behavioral adjustment disorders such as social anxiety (Otheradjdisx)
Ptsdx	Post-traumatic stress disorder
Source:	NPCD Inpatient and Outpatient data file extracts

(*table continues*)

Ptsdadjx	Post-traumatic stress disorder and other adjustment disorders
Type:	Numeric
Values:	ICD9-CM codes
Comments:	Diagnoses codes were selected as defined by the joint VA-DoD Clinical Practice Guidelines for Mental Health, The Management of Post-Traumatic Stress Working Group, 2010. This variable was used in the study's statistical model.
ICD9-CM codes:	
309.81	Prolonged posttraumatic stress disorder
Otheradjdisx	Behavior adjustment disorder diagnosis codes
Source:	NPCD Inpatient and Outpatient data file extracts
Type:	Numeric
Values:	ICD9-CM codes
Comments	Codes in parentheses indicate that only select ICD9-CM codes were selected for this topic of diagnosis code. Codes were searched for using the terms: "adjustment disorder", "anxiety", "anxious", and "behavior disorder", as well as within MENTAL DISORDERS (290-319) on the eICD website at http://www.eicd.com/EICDMain.htm. This variable was used only to describe the cohort.
ICD9-CM codes:	
(308)	Acute reaction to stress
308.0	Predominant disturbance of emotions
308.2	Predominant psychomotor disturbance
308.3	Other acute reactions to stress
308.4	Mixed disorders as reaction to stress
308.9	Unspecified acute reaction to stress
(309)	Adjustment reaction
309.2	With predominant disturbance of other emotions
309.21	Separation anxiety disorder
309.24	Adjustment reaction with anxious mood
309.28	Adjustment reaction with mixed emotional features
309.3	With predominant disturbance of conduct
309.4	With mixed disturbance of emotions and conduct
309.8	Other specified adjustment reactions
309.82	Adjustment reaction with physical symptoms
309.83	Adjustment reaction with withdrawal
309.89	Other
309.9	Unspecified adjustment reaction
312	Disturbance of conduct not elsewhere classified
312.0	Undersocialised conduct disorder, aggressive type
312.00	Unspecified
312.01	Mild
312.02	Moderate
312.03	severe
312.1	Undersocialised conduct disorder, unaggressive type
312.10	Unspecified
312.11	Mild
312.12	Moderate

(table continues)

Ptsdadjx	Post-traumatic stress disorder and other adjustment disorders
312.13	severe
312.2	Socialised conduct disorder
312.20	Unspecified
312.21	Mild
312.22	Moderate
312.23	severe
312.3	Disorders of impulse control, not elsewhere classified
312.30	Impulse control disorder, unspecified
312.8	Other specified disturbances of conduct, not elsewhere classified

Table B17

Substance Use Disorder (SUD)

Sudx	Substance use disorder
Source:	**NPCD Inpatient and Outpatient data file extracts**
Type:	Binomial
Values	1 = one or more codes present; 0 = no codes present
Comments:	The codes selected were those as defined by The joint VA-DoD Clinical Practice Guidelines for Mental Health, The Management of SUD Working Group, 2009; codes in parentheses indicate only select ICD9-CM codes were selected for this topic of diagnosis code. This variable was used as part of the study's statistical models.
ICD9-CM codes:	
(291)	Alcoholic psychoses
291.0	Alcohol withdrawal delirium
291.1	Alcohol amnestic syndrome
291.9	Unspecified alcoholic psychosis
291.2	Other alcoholic dementia
(292)	Drug psychoses
292.1	Paranoid and/or hallucinatory states induced by drugs
292.11	Drug-induced organic delusional syndrome
292.12	Drug-induced hallucinosis
292.2	Pathological drug intoxication
292.8	Other specified drug-induced mental disorders
292.81	Drug-induced delirium
292.82	Drug-induced dementia
292.83	Drug-induced amnestic syndrome
292.9	Unspecified drug-induced mental disorder
(303)	Alcohol dependence syndrome
303.0	Acute alcoholic intoxication
303.00	Unspecified
303.01	Continuous
303.02	Episodic
303.9	Other and unspecified alcohol dependence

(*table continues*)

Sudx	Substance use disorder
303.90	Unspecified
303.91	Continuous
303.92	Epzisodic
304	Drug dependence
304.0	Opioid type dependence
304.00	Unspecified
304.01	Continuous
304.02	Episodic
304.1	Barbiturate and similarly acting sedative or hypnotic dependence
304.10	Unspecified
304.11	Continuous
304.12	Episodic
304.2	Cocaine dependence
304.20	Unspecified
304.21	Continuous
304.22	Episodic
304.3	Cannabis dependence
304.30	Unspecified
304.31	Continuous
304.32	Episodic
304.4	Amphetamine and other psychostimulant dependence
304.40	Unspecified
304.41	Continuous
304.42	Episodic
304.5	Hallucinogen dependence
304.50	Unspecified
304.51	Continuous
304.52	Episodic
304.6	Other specified drug dependence
304.60	Unspecified
304.61	Continuous
304.62	Episodic
304.7	Combinations of opioid type drug with any other
304.70	Unspecified
304.71	Continuous
304.72	Episodic
304.8	Combinations of drug dependence excluding opioid type drug
304.80	Unspecified
304.81	Continuous
304.82	Episodic
304.9	Unspecified drug dependence
304.90	Unspecified
304.91	Continuous
304.92	Episodic
(305)	Nondependent abuse of drugs
305.0	Alcohol abuse
305.00	Unspecified

(*table continues*)

Sudx	Substance use disorder
305.01	Continuous
305.02	Episodic
305.2	Cannabis abuse
305.20	Unspecified
305.21	Continuous
305.22	Episodic
305.3	Hallucinogen abuse
305.30	Unspecified
305.31	Continuous
305.32	Episodic
305.4	Barbiturate and similarly acting sedative or hypnotic abuse
305.40	Unspecified
305.41	Continuous
305.42	Episodic
305.5	Opioid abuse
305.50	Unspecified
305.51	Continuous
305.52	Episodic
305.6	Cocaine abuse
305.60	Unspecified
305.61	Continuous
305.62	Episodic
305.7	Amphetamine or related acting sympathomimetic abuse
305.70	Unspecified
305.71	Continuous
305.72	Episodic
305.8	Antidepressant type abuse
305.80	Unspecified
305.81	Continuous
305.82	Episodic
305.9	Other, mixed, or unspecified drug abuse
305.90	Unspecified
305.91	Continuous
305.92	Episodic

Residual Limb Skin Problem Severity (less severe/ severe/no treatment)

Table B18

Residual Limb Skin Problem severity

RLSPS	Residual Limb Skin Problem Severity (dependent/outcome variable)
Source:	NPCD Outpatient datafiles extracts, ICD9-CM codes.
Type:	Categorical
Values:	0.no treatment, 1.less severe, 2.severe
Comments:	This variable was derived from combining codes for less severe (Lseverex) and severe (Severex) ICD-9-CM codes as described in the tables following. The value 0.no treatment was assigned to those cases that did not have a severe or less severe code identified during the follow-up period. This variable was used in the study's statistical models.

Table B19

Less severe Residual Limb Skin Problems

Lseverex:	Less severe Residual Limb Skin Problems considered non-life threatening with minimal restrictions on artificial limb use
Source:	**NPCD Outpatient datafiles extracts, ICD9-CM codes**
Type:	Categorical, repeated measure
Values:	foreignbx, occlusionx, repetitivetx, surgicalx, otherlsx
	(*table continues*)
Comments:	Includes residual limb skin problems such as rashes, callouses, blisters, and other non-infectious dermatoses; Codes in parentheses indicate only select ICD9-CM codes were selected for this topic of diagnosis code. Codes were selected on the basis of recommendations from Bui et al., (2007). Code descriptions that included the terms head, neck, face, torso, arms, genitals, pelvis, or foot were excluded; those with the terms lower leg, stump or shank were included; codes with no body part mentioned were included if relevant to artificial limb use. Codes were first searched for by category (such as dermatoses) and then reviewed one-by-one, selected on the basis of description and definition. Codes were search for and retrieved using terms such as "dermatitis", "erresthema","blister", and callous, as well as within DISEASES OF THE SKIN AND SUBCUTANEOUS TISSUE (680-709) on the eICD website at http://www.eicd.com/EICDMain.htm.
Category definitions	
Foreignbx	Residual limb skin problem in reaction to foreign body.
ICD9-CM codes:	
706.2	Sebaceous cyst
709.4	Foreign body granuloma of skin and subcutaneous tissue
Occlusion	Residual limb skin problem in response to non-infectious occlusion.
ICD9-CM codes:	
(691)	Atopic dermatitis and related conditions
691.8	Other atopic dermatitis and related conditions
	(*table continues*)

Lseverex:	Less severe Residual Limb Skin Problems considered non-life threatening with minimal restrictions on artificial limb use
(692)	Contact dermatitis and other eczema
692.0	Due to detergents
692.1	Due to oils and greases
692.2	Due to solvents
692.3	Due to drugs and medicines in contact with skin
692.4	Due to other chemical products
692.8	Due to other specified agents
692.82	Dermatitis due to other radiation
692.83	Dermatitis due to metals
692.89	Other
692.9	Unspecified cause
694.5	Pemphigoid
(698)	Pruritus and related conditions
698.2	Prurigo
698.4	Dermatitis factitia [artifacta]
698.8	Other specified pruritic conditions
698.9	Unspecified pruritic disorder
(704)	Diseases of hair and hair follicles
704.0	Alopecia
704.00	Alopecia, unspecified
704.01	Alopecia areata
704.09	Other
704.1	Hirsutism
704.2	Abnormalities of the hair
704.8	Other specified diseases of hair and hair follicles
704.9	Unspecified disease of hair and hair follicles
(705)	Disorders of sweat glands
705.0	Anhidrosis
705.1	Prickly heat
705.8	Other specified disorders of sweat glands
705.81	Dyshidrosis
705.82	Fox-Fordyce disease
705.89	Other
705.9	Unspecified disorder of sweat glands
(706)	Diseases of sebaceous glands
706.1	Other acne
706.8	Other specified diseases of sebaceous glands
706.9	Unspecified disease of sebaceous glands
(708)	Urticaria
708.0	Allergic urticaria
708.1	Idiopathic urticaria
708.2	Urticaria due to cold and heat
708.3	Dermatographic urticaria
708.4	Vibratory urticaria
708.5	Cholinergic urticaria
708.8	Other specified urticaria

(*table continues*)

Lseverex:	Less severe Residual Limb Skin Problems considered non-life threatening with minimal restrictions on artificial limb use
708.9	Urticaria, unspecified
(709)	Other disorders of skin and subcutaneous tissue
709.8	Other specified disorders of skin
Repetitivetx	Residual limb skin reaction to repetitive injury (microtrauma).
ICD9-CM codes:	
(694)	Bullous dermatoses
694.0	Dermatitis herpetiformis
694.4	Pemphigus
694.5	Pemphigoid
694.8	Other specified bullous dermatoses
694.9	Unspecified bullous dermatoses
(695)	Erythematous conditions
695.0	Toxic erythema
695.1	Erythema multiforme
695.2	Erythema nodosum
695.8	Other specified erythematous conditions
695.89	Other
695.9	Unspecified erythematous condition
700	Corns and callosities
(701)	Other hypertrophic and atrophic conditions of skin
701.0	Circumscribed scleroderma
701.1	Keratoderma, acquired
701.2	Acquired acanthosis nigricans
701.4	Keloid scar
701.5	Other abnormal granulation tissue
701.8	Other specified hypertrophic and atrophic conditions of skin
701.9	Unspecified hypertrophic and atrophic conditions of skin
Surgicalx	**Residual limb complication directly consequent of limb surgery.**
ICD9-CM codes:	
997.61	Neuroma of amputation stump
997.6	Late amputation stump complication
998.3	Disruption of operation wound
Otherlsx	**Residual limb complication not otherwise categorized.**
ICD9-CM codes:	
683	Acute lymphadenitis
695.81	Ritter's disease
(696)	Psoriasis and similar disorders
696.0	Psoriatic arthropathy
696.1	Other psoriasis
696.2	Parapsoriasis
696.4	Pityriasis rubra pilaris
696.5	Other and unspecified pityriasis
696.8	Other
709.0	Dyschromia
709.00	Dyschromia, unspecified
709.01	Vitiligo

(table continues)

Lseverex:	Less severe Residual Limb Skin Problems considered non-life threatening with minimal restrictions on artificial limb use
709.09	Other
709.1	Vascular disorders of skin
709.8	Other specified disorders of skin
709.9	Unspecified disorder of skin and subcutaneous tissue
(739)	Nonallopathic lesions, not elsewhere classified
739.6	Lower extremities

Table B20

Severe Residual Limb Skin Problems

Severex	Severe Residual Limb Skin Problems that are life/limb threatening or infectious, and may require extensive restrictions on artificial limb use.
Source:	Data from NPCD outpatient file extracts; ICD9-CM diagnosis codes
Type:	Categorical, repeated measure
Values:	foreignb2x, occlusion2x, repetitivet2x, surgical2x, others
Comments:	Includes ulcers, infectious skin and bone conditions; codes in parentheses indicate only select ICD9-CM codes were selected for this topic of diagnosis code. Codes were selected on the basis of recommendations from Bui et al., (2007). Code descriptions that included the terms head, neck, face, torso, arms, genitals, pelvis, or foot were excluded; those with the terms lower leg, stump or shank were included; codes with no body part mentioned were included if relevant to artificial limb use. Codes were first searched for by category (such as dermatoses) and then reviewed one-by-one, selected on the basis of description and definition. Codes were searched for and retrieved using the terms “ulcer”, “infection”, “cellulitis”, and “osteomyelitis”, as well as within DISEASES OF THE SKIN AND SUBCUTANEOUS TISSUE (680-709) on the eICD website at http://www.eicd.com/EICDMain.htm. This variable was used only to describe the cohort.
Category definitions:	
Foreignb2x	Residual limb skin problem in reaction to foreign body.
ICD9-CM codes:	
006.6	Amoebic skin ulceration
037	Tetanus
040.3	Necrobacillosis
Occlusion2x	**Residual limb skin problem in response to infectious occlusion**
ICD9-CM codes:	
040.0	Gas gangrene
(680)	Carbuncle and furuncle
680.6	Leg, except foot
680.9	Unspecified site
(68)(	Other cellulitis and abscess
682.6	Leg, except foot
682.8	Other specified sites
682.9	Unspecified site
684	Impetigo

(*table continues*)

Severex	Severe Residual Limb Skin Problems that are life/limb threatening or infectious, and may require extensive restrictions on artificial limb use.
686.0	Pyoderma
686.8	Other specified local infections of skin and subcutaneous tissue
686.9	Unspecified local infection of skin and subcutaneous tissue
705.83	Hidradenitis
Repetitivet2x	**Residual limb skin reaction to repetitive injury (microtrauma)**
ICD9-CM codes:	
(173)	Other malignant neoplasm of skin
173.7	Skin of lower limb, including hip
173.8	Other specified sites of skin
(454)	Varicose veins of lower extremities
454.0	With ulcer
454.2	With ulcer and inflammation
707.1	Ulcer of lower limbs, except decubitus
707.8	Chronic ulcer of other specified sites
707.9	Chronic ulcer of unspecified site
Surgical2x	**Residual limb complication directly consequent of limb surgery**
ICD9-CM codes:	
997.60	Unspecified complication
997.62	Infection (chronic)
997.69	Other
998.0	Postoperative shock
998.5	Postoperative infection
Others	Residual limb complication not otherwise categorized
ICD9-CM codes:	
(038))	Septicaemia
038.0	Streptococcal septicaemia
038.1	Staphylococcal septicaemia
038.2	Pneumococcal septicaemia
038.3	Septicaemia due to anaerobes
038.4	Septicaemia due to other gram-negative organisms
038.40	Gram-negative organism, unspecified
038.43	Pseudomonas
038.44	Serratia
038.49	Other
038.8	ther specified septicaemias
038.9	Unspecified septicaemia
(172)	Malignant melanoma of skin
172.7	Lower limb, including hip
440.23	Atherosclerosis of the extremities with ulceration
440.24	Atherosclerosis of the extremities with gangrene
(451)	Phlebitis and thrombophlebitis
451.0	Of superficial vessels of lower extremities
451.1	Of deep vessels of lower extremities
451.11	Femoral vein (deep) (superficial)
451.2	Of lower extremities, unspecified

(*table continues*)

Severex	Severe Residual Limb Skin Problems that are life/limb threatening or infectious, and may require extensive restrictions on artificial limb use.
(730)	Osteomyelitis, periostitis and other infections involving bone
730.0	Acute osteomyelitis
730.06	Lower leg
(730.10)	Site unspecified
730.16	Lower leg
(730.2)	Unspecified osteomyelitis
730.26	Lower leg
730.28	Other specified sites
(730.3)	Periostitis without mention of ostemyelitis
730.36	Lower leg
730.38	Other specified sites)
730.5	Tuberculosis of limb bones
(730.8)	Other infections involving bone in disease classified elsewhere
730.86	Lower leg
730.88	Other specified sites
(730.9)	Unspecified infection of bone
730.96	Lower leg
730.98	Other specified sites
(733.4)	Septic necrosis of bone
733.43	Medial femoral condyle
733.49	Other

Table B21

Procedural Codes for Skin Problem Treatments

Drainx	Procedural codes for drainage of skin abscess or wound
Source:	**NPCD Outpatient data file extracts**
Type:	Binomial
Values:	1 = one or more codes present; 0 = no codes present
Comments:	CPT codes to be used for further categorization of severe and less severe skin problems, especially in the case of less severe problems transforming into severe skin problems. Codes provided courtesy of Laurel A. Copeland, Ph.D. And are in the form required by SAS statistical software. This variable was not used in the statistical analysis as only 5 cases were detected and to include was beyond the scope of the study (given skin problem categorization by etiology)
CPT Code	**Description**
10061	Drainage of skin abscess
10080	Drainage of pilonidal cyst
10081	DRAINAGE OF PILONIDAL CYST
10140	DRAINAGE OF HEMATOMA/FLUID
10160	PUNCTURE DRAINAGE OF LESION
10180	COMPLEX DRAINAGE, WOUND

(*table continues*)

Drainx	Procedural codes for drainage of skin abscess or wound
Woundx	**Procedural codes for wound treatment or debridement**
Source:	Npcd outpatient data file extracts
Type:	Binomial
Values:	1 = one or more codes present; 0 = no codes present
Comments:	Cpt codes to be used for further categorization of severe and less severe skin problems, especially in the case of less severe problems transforming into severe skin problems. Codes provided courtesy of laurel a. Copeland, Ph.D. And are in the form required by SAS statistical software. This variable was not used in the statistical analysis although 95 cases were detected. To include in analysis was beyond the scope of the study given categorization of skin problem codes by etiology.
Cpt code	**Description**
11000	Debride infected skin
11001	Debride infected skin
11010	Debride skin, fx
11011	Debride skin/muscle, fx
11012	Debride skin/muscle/bone, fx
11040	Debride skin, partial
11041	Debride skin, full
11042	Debride skin/tissue
11043	Debride tissue/muscle
11044	Debride tissue/muscle/bone
11055	Trim skin lesion
11056	Trim skin lesions, 2 to 4
11057	Trim skin lesions, over 4
12001-12002	Repair superficial wound(s)
12004-12007	Repair superficial wound(s)
12011	Repair superficial wound(s)
12013-12016	Repair superficial wound(s)
12020	Closure of split wound
12021	Closure of split wound
13100	Repair of wound or lesion
13101	Repair of wound or lesion
13102	Repair wound/lesion add-on
13120	Repair of wound or lesion
13121	Repair of wound or lesion
13131	Repair of wound or lesion
13132	Repair of wound or lesion
13133	Repair wound/lesion add-on
13150-13153	Repair of wound or lesion
15738	Muscle-skin graft, leg
15780-15783	Abrasion treatment of skin

(*table continues*)

Drainx	Procedural codes for drainage of skin abscess or wound
15781	Abrasion treatment of skin
15786	Abrasion, lesion, single
15999,	Removal of pressure sore
97597	Active wound care/20 cm or <
97598	Active wound care > 20 cm
97601	Wound(s) care, selective
97602	Wound(s) care non-selective
99183	Hyperbaric oxygen therapy
Lesionx	**Procedural codes for the treatment of skin lesion or sweat gland removal**
Source:	Npcd outpatient data file extracts
Type:	Binomial
Values:	1 = one or more codes present; 0 = no codes present
Comments:	Cpt codes to be used for further categorization of severe and less severe skin problems, especially in the case of less severe problems transforming into severe skin problems. Codes provided courtesy of laurel a. Copeland, Ph.D. And are in the form required by SAS statistical software. This variable was not used in the statistical analysis although 39 cases were detected. To include in analysis was beyond the scope of the study given categorization of skin problems by etiology.
Cpt code	**Description**
10120	Remove foreign body
10121	Remove foreign body
11450	Removal, sweat gland lesion
11451	Removal, sweat gland lesion
11462	Removal, sweat gland lesion
11463	Removal, sweat gland lesion
11470	Removal, sweat gland lesion
17000	Destroy benign/premalignant lesion
17001	Destruction of additional lesions
17003	Destroy lesions, 2-14
17004	Destroy lesions, 15 or more
17106	Destruction of skin lesions
17107	Destruction of skin lesions
17108	Destruction of skin lesions
17110	Destruct lesion, 1-14'
17111	Destruct lesion, 15 or more
17250	Chemical cautery, tissue
17260-17264	Destruction of skin lesions
17266	Destruction of skin lesions
17270-17274	Destruction of skin lesions
17280-17284	Destruction of skin lesions
17286	Destruction of skin lesions
17340	Cryotherapy of skin
64788	Remove skin nerve lesion

(table continues)

Drainx	Procedural codes for drainage of skin abscess or wound
96920	Laser treatment, skin < 250 sq cm
96921	Laser treatment, skin 250-500 sq cm
96999	Dermatological procedure

Rules for cohort inclusion/exclusion

Defining the Initial cohort.

The datafile extracts from the Fiscal Year (FY) 2007 National Patient Care Database (NPCD) Inpatient medSAS files, representing all Veterans admitted to a VA facility for treatment between October 1, 2006 through September 31, 2007, were searched for ICD-9-CM diagnostic codes for diabetes mellitus, peripheral arterial disease (PAD), and peripheral vascular disease (PVD).

All data manipulations were by a professional statistician (Shuko Lee, MS) using Statistical Analysis System (SAS) software, Version 9.4 (SAS Institute, Research Triangle, NC, and USA)

1. Codes were searched for in the following fields of the Inpatient files (bed section and full stay):

DXPRIME	Principal admitting ICD-9-CM diagnostic code; the condition which after study, is determined to be chiefly responsible for the admission of the patient to the hospital.
DXB2-DXB5, DXF2-DXF13, DXLSB, DXLSF	Primary and secondary ICD-9-CM diagnostic codes that apply to the bed section or full stay of the patient

Table B22

Initial Cohort Inclusion Criteria ICD-9-CM Codes for Diabetes Mellitus.

Code	Description
Diabetes	
250	Diabetes mellitus
Diabetes mellitus	Diabetes mellitus without mention of complication
250.00	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
250.01	Type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
250.02	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
250.03	Type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled
250.09	Unspecified whether adult-onset or juvenile type
250.1	Diabetes with ketoacidosis
250.10	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
250.11	Type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
250.12	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
250.13	Type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled
250.19	Unspecified whether adult-onset or juvenile type
250.2	Diabetes with hyperosmolarity
250.20	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
250.21	Type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
250.22	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
250.23	Type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled
250.29	Unspecified whether adult-onset or juvenile type
250.3	Diabetes with other coma
250.30	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
250.31	Type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
250.32	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
250.33	Type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled
250.39	Unspecified whether adult-onset or juvenile type
250.4	Diabetes with renal manifestations
250.40	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled

(table continues)

Code	Description
250.41	Type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
250.42	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
250.43	Type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled
250.49	Unspecified whether adult-onset or juvenile type
250.5	Diabetes with ophthalmic manifestations
250.50	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
250.51	Type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
250.52	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
250.53	Type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled
250.59	Unspecified whether adult-onset or juvenile type
250.6	Diabetes with neurological manifestations
250.60	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
250.61	Type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
250.62	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
250.63	Type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled
250.69	Unspecified whether adult-onset or juvenile type
250.7	Diabetes with peripheral circulatory disorders
250.70	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
250.71	Type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
250.72	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
250.73	Type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled
250.79	Unspecified whether adult-onset or juvenile type
250.8	Diabetes with other specified manifestations
250.80	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
250.81	Type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
250.82	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
250.83	Type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled
250.89	Unspecified whether adult-onset or juvenile type
250.9	Diabetes with unspecified complications
250.90	type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled

(table continues)

Code	Description
250.91	Type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
250.92	Type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
250.93	Type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled
250.99	Unspecified whether adult-onset or juvenile type

Table B23

Initial Cohort Inclusion ICD-9-CM Codes for Peripheral Arterial Disease.

Code	Description
440.2	[Atherosclerosis] Of native arteries of the extremities
440.20	Atherosclerosis of the extremities, unspecified
440.21	Atherosclerosis of the extremities with intermittent claudication
440.22	Atherosclerosis of the extremities with rest pain
440.23	Atherosclerosis of the extremities with ulceration
440.24	Atherosclerosis of the extremities with gangrene
440.29	Other
440.3	[Atherosclerosis] Of bypass graft of the extremities
440.30	Of unspecified graft
440.31	Of autologous vein bypass graft
440.32	Of nonautologous vein bypass graft
440.8	Of other specified arteries

Table B24

Initial Cohort Inclusion Criteria ICD-9-CM Codes for Peripheral Vascular Disease.

Code	Description
443	Other peripheral vascular disease
443.0	Raynaud's syndrome
443.1	Thromboangiitis obliterans [Buerger's disease]
443.8	Other specified peripheral vascular diseases
443.81	Peripheral angiopathy in diseases classified elsewhere
443.89	Other
443.9	Peripheral vascular disease, unspecified

2. Using the same dataset fields, cases that met the above inclusion criteria were then searched again for ICD-9-CM codes indicative of a unilateral below-knee amputation; codes indicative of any other level of amputation (other than “unspecified”) were ignored .

Because codes were search for in fields other than DXPRIME (the primary reason for the hospital stay), cases were not limited to those Veterans undergoing an index transtibial amputation in FY 2007.

3. In order to capture all possible transtibial amputations, the ICD-9-CM codes for “Traumatic amputation, unspecified level” was included in the search terms. Specifically, the codes searched for included:

Table B25

Initial Cohort Inclusion Criteria ICD-9-CM Codes for Transtibial Amputation

Code	Description
897	Traumatic amputation of leg(s) (complete) (partial)
897.0	Unilateral, below knee, without mention of complication
897.1	Unilateral, below knee, complicated
897.4	Unilateral, level not specified, without mention of complication
897.5	Unilateral, level not specified, complicated
CPT code	Description
278.80	Amputation of lower leg
278.81	Amputation of lower leg
278.82	Amputation of lower leg
278.84	Amputation of lower leg follow-up surgery
278.86	Amputation of lower leg follow-up surgery

4. The codes 896-896.9, “Traumatic amputation of foot (complete) (partial)” were not included to avoid partial foot amputations and Syme’s (through the ankle) amputations.
5. Similarly CPT codes275.98 and 278.89 were excluded to avoid knee disarticulation amputations and Syme’s through ankle amputations, respectively
6. The outcome from this search amounted to the “initial cohort’ - Veterans who during FY 2007 underwent a below-knee amputation and who also had a dysvascular condition.

7. The scrSSN codes from this initial cohort were then searched for and matched to cases in the NPCD Outpatient Event MedSAS datafiles for FY 2007, 2008, 2009, 2010, and 2011
8. Any matched scrSSN codes were extracted and merged with the initial cohort dataset establishing the clinical history of each case from FY 2007 to FY 2011.

Defining the study cohort

From the National Prosthetics Patient Database (NPPD) datafile extracts, cases for inclusion required the following:

1. Must have matching ScrSSN with initial cohort.
2. Must have HCPCSPSAS code for a prosthetic foot, socket suspension system, and definitive/permanent below-knee socket or socket replacement (codes L5301, l5100, l5700). Refer to Table B2 for HCPCS codes)
3. Must have a Delivery Date for each HCPCSPSAS that is on the same date or within 3 months of each other.
4. Text for Item and/or ConsultDesc must reflect HCPCSPSAS code or HCPCSDesc

Cases were excluded

1. Missing HCPCSPSAS code for a prosthetic foot, socket suspension system or socket type.
2. No Delivery Date provided.
3. Presence of HCPCSPSAS code for Above-knee socket (l5150, l5160, l5200, l5312 (knee disarticulate) or l5321 Indicates that individual is Above-

Knee/Below-Knee (AK/BK) amputee or revised to Above-Knee (AK)from Below-Knee (BK).

4. Presence of HCPCSPSAS code for Syme's amputation (through ankle) (l5010, l5050, or l5060) not a transtibial amputation.
5. Indicates bilateral or AK/BK amputee in Item or ConsultDesc (such as code for left foot and code for right foot).
6. Has appropriate HCPCSPSAS code but Item or ConsultDesc indicates not artificial limb for daily use (such as "swim leg" or "backup leg")
7. on the basis of the above criteria, cases were then categorized as follows:

1	useable (met all criteria)(N=282)
88	bilateral amputee (BK/BK or BK/AK)
92	not useable due to invalid data or missing Delivery Date
93	conversion to AK (presence of AK HCPCS limb codes);
94	missing the **HCPCSPSAS code** for prosthetic foot, suspension system or socket type;
95	Syme's amputation, not transtibial as indicated by **HCPCSPSAS code, Item and/or ConslutDesc.**

8. All data was manipulated using Microsoft Office Excel 2010.
9. scrSNN codes of cases that met inclusion/exclusion criteria were then matched and merged with those from the initial cohort using SAS statistical software as above.
10. These actions creating the study cohort dataset that was further manipulated for data analysis using SAS statistical software.

Healthcare Common Procedure Coding System (HCPCS).

HCPCS codes were identified from the Durable on the Centers for Medicare Medicaid Services website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html

Table B26

HCPCS Codes, Descriptions, and Costs.

Hcpcs code	Component	Long description	Cost (ea)
L5100	Definitive limb (BK)	- Below knee, molded socket, shin, sach foot	$2,859.38
L5301		- Below knee, molded socket, shin, sach foot, endoskeletal system	$2,824.77
L5321	Definitive limb (AK)	- Above knee, molded socket, open end, sach foot, endoskeletal system, single axis knee	$4,043.58
L5510	Temporary limb (BK)	- Preparatory, below knee 'ptb' type socket, non-alignable system, pylon, no cover, sach foot,	$1,791.14
L5520		- Preparatory, below knee 'ptb' type socket, non-alignable system, pylon, no cover, sach foot, thermoplastic or equal, direct formed plaster socket, molded to model	$1,769.22
L5530		- Preparatory, below knee 'ptb' type socket, non-alignable system, pylon, no cover, sach foot, thermoplastic or equal, molded to model	$2,125.00
L5540		- Preparatory, below knee 'ptb' type socket, non-alignable system, pylon, no cover, sach foot, laminated socket, molded to model	$2,226.77
L5560	Temporary limb (AK)	- Preparatory, above knee- knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, sach foot, plaster socket, molded to model	$2,391.16
L5570		-Preparatory, above knee - knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, sach foot, thermoplastic or equal, direct formed	$2,485.96
L5580		- Preparatory, above knee - knee disarticulation ischial level socket, non-alignable system, pylon, no cover, sach foot, thermoplastic or equal, molded to model	$2,902.18
L5585		- Preparatory, above knee - knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, sach foot, prefabricated adjustable open end socket	$3,147.76
L5647	Suction suspension (differential pressure; high tech)	- Addition to lower extremity, below knee suction socket	$978.64

(*table continues*)

Hcpcs code	Component	Long description	Cost (ea)
L5666	Cuff suspension (simple; Low-tech)	- Addition to lower extremity, below knee, cuff suspension	$86.12
L5670	Supracondylar (anatomical; mid-tech)	- Addition to lower extremity, below knee, molded supracondylar suspension ('pts' or similar)	$333.84
L5671	Sleeve, pin-lock mechanism (differential pressure; mid-tech)	- Addition to lower extremity, below knee / above knee suspension locking mechanism (shuttle, lanyard or equal), excludes socket insert	$611.95
L5680	Straps and belts (simple; low-tech)	- Addition to lower extremity, below knee, thigh lacer, nonmolded	$374.47;
L5682	Straps and belts (simple; low-tech)	- Addition to lower extremity, below knee, thigh lacer, gluteal/ischial, molded	$769.40;
L5684	Straps and belts (simple; low-tech)	- Addition to lower extremity, below knee, fork strap	$59.21;
L5685	Suspension sleeve (differential pressure; mid-tech)	- Addition to lower extremity prosthesis, below knee, suspension/sealing sleeve, with or without valve, any material, each	$141.59
L5688	Straps and belts (simple; low-tech)	- Addition to lower extremity, below knee, waist belt, webbing	$75.15
L5690	Straps and belts (simple; low-tech)	- Addition to lower extremity, below knee, waist belt, padded and lined	$120.38
L5700	replacement socket	- Replacement, socket, below knee, molded to patient model	
L5781	Vacuum assisted (differential pressure; High-tech)	- Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system	$4,423.02

(table continues)

Hcpcs code	Component	Long description	Cost (ea)
L5970	SACH foot (recommended for K1 functional level)	- All lower extremity prostheses, foot, external keel, sach foot	$249.86
L5972	SAFE foot ;flexible keel (recommended for K2 functional level)	- All lower extremity prostheses, foot, flexible keel	$433.59
L5973	Microprocessor-controlled ankle foot (recommended for k2/k3 functional Level)	- Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source	$19,290.71
L5974	Single axis ankle/foot (recommended for K1 functional level)	- All lower extremity prostheses, foot, single axis ankle/foot	$286.69
L5975	Multiaxis, flexible keel (recommended for K2/K3 Functional level)	- All lower extremity prosthesis, combination single axis ankle and flexible keel foot	$512.48
L5976	Energy-storing (dynamic response (recommended for K3 functional level)	- All lower extremity prostheses, energy storing foot (Seattle carbon copy ii or equal)	$688.99

(*table continues*)

Hcpcs code	Component	Long description	Cost (ea)
L5978	Multiaxial ankle/foot (recommended for K2 functional level)	- All lower extremity prostheses, foot, multiaxial ankle/foot	$359.04
L5979	Dynamic response/multiaxis (recommended for K3/K4 functional level)	- All lower extremity prosthesis, multi-axial ankle, dynamic response foot, one piece system	$2,807.21
L5980	Flex foot (recommended for K3 functional level)	- All lower extremity prostheses, flex foot system	$4,561.54
L5981	Flex-walk system (recommended for K3 functional level)	- All lower extremity prostheses, flex-walk system or equal	$3,543.43
L5987	Shank system with vertical loading pylon (recommended for K3/K4 functional level)	- All lower extremity prosthesis, shank foot system with vertical loading pylon	$7,952.18
L7510	Repair	- Repair of prosthetic device, repair or replace minor parts	Variable
L7520	Repair	- Repair prosthetic device, labor component, per 15 minutes	Variable

Code Sources

1. ICD-9-CM codes retrieved from:

Source:
Type:
Values:
Comments:

http://www.icd9data.com/2011/Volume1/default.htm

2. CPT codes provided by Laurel A. Copeland, PhD, Research Scientist, Associate Director, Center for Applied Health Research, Baylor Scot & White Healthcare, Central Texas Veteran Health Care System, Temple, Texas.
3. 2012 HCPCS codes for Durable Medical Equipment (DME) and Prosthetics Orthotics (PO) were provided in a searchable Excel file by Gordon W. Bosker, Chief Prosthetist, Prosthetics and Orthotics Service, South Texas Veterans Health Care System (STVHCS) – Audie Murphy Division, San Antonio, Texas. These codes were also available at the Durable on the Centers for Medicare Medicaid Services website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html. Long descriptions of the codes were searched for and retrieved from http://www.hipaaspace.com/Medical_Billing/Coding/Healthcare_Common_Procedure_Coding_System/HCPCS_Number_Lookup.aspx

Table B27.

Key Inpatient and Outpatient MedSAS Dataset Fields/Variables Used for Compiling the Study Dataset (VIReC, 2011a, 2011b)

Variable Name	Definition/label	Values	VHA database file
ADMITDAY	Date of admission of the inpatient stay	dd/mm/yyyy	Inpatient files, used to identify cases of severe infection and outcomes of residual limb during follow-up period.
AG8R	Categorical recoding of AGE (patient age in years	1 - Less than 25 years old; 2 - 25 – 34 years old; 3 - 35 – 44 years old; 4 - 45 – 54 years old; 5 - 55 – 64 years old; 6- 65 – 74 years old; 7 - 75 – 84 years old; 8 - 85 years old.	Inpatient and outpatient files; used to characterize the cohort and as covariate with dependent variable
DISTO	Type of location to which patient was discharged	-3 – Irregular, -2 – Death, -1 – Community, 0 - VA Hospital, 4 - Community Hospital, 5 - VA Nursing Home, 7 - Community Nursing Home, 9 - Same Community Nursing Home, 10 - Other Community Nursing Home, 11 - State Home Nursing, 12 - VA Domiciliary, 13 - State Home Domiciliary, 15 - Foster Home, 16 - Halfway House, 17 - Boarding House, 19 - Penal Institute, 20 - Residential Hotel/Reside, 21 - Other Placement, 22 - VA-Paid Home/Community, 25 - Home-Basic Primary Care, 27 - Sci Hcu Program, 29 – Respite, 30 – Hospice, 34 - Medicare Home Health, 35 - Other-Agency Home Health.	Inpatient files; used to characterize the cohort; potential covariate to explain variability.
DISTYPE	Type of discharge	1 – Regular; 2 – Non-Bedcare; 3 – 6-Mo Limit; 4 – Irregular; 5 – Transfer; 6 – Death-Autopsy; 7 – Death no autopsy	Inpatient files; used to characterize cohort

(*table continues*)

Variable Name	Definition/label	Values	VHA database file
DOD	Date of death	Mm/yyyy	Inpatient files; used to characterize cohort (estimate mortality rate)
DXPRIME	Principal admitting ICD-9-CM diagnostic code; the condition which after study, is determined to be chiefly responsible for the admission of the patient to the hospital.	ICD –9-CM codes	Inpatient and outpatient files; used to identify initial cohort (amputation due to dysvascular complications)
DXB2-DXB5, DXF2-DXF13, DXLSB, DXLSF	Primary and secondary ICD-9-CM diagnostic codes that apply to the bed section or full stay of the patient	ICD-9-CM code	In patient files; used to identify cohort (dysvascular amputation) as well as other comorbid conditions
MEANS	Means Test Indicator Code. The Means Test (MT) Indicator is used in determining a patient's eligibility to receive care. The assigned value reflects Veteran status and percent service-connected eligibility.	AS - Special category or Service Connected with at least 10% disability; AN – Poverty level Non-Service Connected or Service Connected with 0% disability (no copayment); CMT - Copayment required; N - Non-veteran; X - Not applicable; U – Means test not done or incomplete; G - Geographic-based Means Thresholds.	Outpatient files; used to characterize cohort and estimate SES; actual variable used to indicate VA Priority Status.
MS	Marital Status	D – Divorced; M – Married; N - Never Married; S - Separated; U – Unknown; W – Widowed.	Inpatient and outpatient files; used to characterize cohort, potential covariate to explain variance.
PROCDAY	Date of procedure or procedures performed at a given date and time combination	dd/mm/yyyyy	Inpatient files; used to determine date of procedures such as treatment for osteomyelitis.
PROCDE1-PROCDE5	ICD-9-CM Procedure Codes for 1st - 5th procedures performed on a given date and time. Procedures include dental services and are defined as either diagnostic or therapeutic and not occurring in an operating room.	ICD-9-CM codes	Inpatient files; used to identify severe residual limb conditions during follow-up period

(*table continues*)

Variable Name	Definition/label	Values	VHA database file
SEX	Gender of patient	M – Male; F – Female; O – Other	Inpatient and outpatient files; used to characterize cohort.
SURG9CD1-SURG9CD5	Surgical procedure codes	ICD-9-CM codes	Inpatient files; used to identify cohort with transtibial amputation, or revision during follow-up period
SURGDAY	Date of surgery	Dd/mm/yyyyy	Inpatient files; used to indicate when a surgical revision of residual limb occurred during follow-up period.
VISN	Veterans Integrated Service Network (VISN) where the hospital episode of care occurred	1 - VA New England Healthcare System; 2 - VA Healthcare Network Upstate New York; 3 - VA NY / NJ Veterans Healthcare Network; 4 - VA Stars & Stripes Healthcare Network; 5 - VA Capitol Health Care Network ; 6 - VA Mid-Atlantic Network; 7 - The Atlantic Network; 8- VA Sunshine Healthcare Network; 9 - Mid South Veterans Healthcare Network; 10 - VA Healthcare System of Ohio; 11- Veterans In Partnership; 12 - The Great Lakes Health Care System; 15 - VA Heartland Network; 16 - South Central VA Health Care Network; 17 - VA Heart of Texas Health Care Network; 18 - VA Southwest Healthcare Network; 19 - Rocky Mountain Network; 20 - Northwest Network; 21 - Sierra Pacific Network; 22 - Desert Pacific Healthcare Network; 23 - VA Midwest Health Care Network	Inpatient and outpatient files; used to characterize cohort and as proxy for prosthetist.
CPT1-CPT20	Services and procedures performed by a provider recorded in Current Procedural Terminology (CPT-4)	CPT codes	Outpatient files; used to identify residual limb procedures (e.g. wound debridement) during follow-up period.

(*table continues*)

Variable Name	Definition/label	Values	VHA database file
DXF2-DXF10	Secondary ICD-9-CM diagnostic codes for the visit	ICD-9-CM codes	Outpatient files; used to identify severe and less severe skin problems during follow-up period
DXLSF	Primary ICD-9-CM diagnosis code for this encounter	ICD-9-CM codes	Outpatient files; used to identify severe and less severe residual limb skin problems during follow-up period.
HOMLESS	Indicates the homeless status of veteran. Psychiatric and substance abuse disorders are prevalent among homeless Veterans	Character	Outpatient files; used as an indicator of SES, potential covariate to explain variance
RACE	Race or national origin	1 - Hispanic, White; 2 - Hispanic, Black; 3 - American Indian; 4 – Black; 5 – Asian; 6 – White; 7 – missing	Outpatient files; used to characterize cohort.
VIZDAY	Date of outpatient visit/encounter	Dd/mm/yyyy	Outpatient files; used to determine temporal aspects of residual limb skin problems during 6 month intervals of follow-up period.

Table B28

NPPD Available Variables. Retrieved October 20, 2011

Variable Name	Type	Description
VISN *	Integer	VISN where device was prescribed and dispensed
STATION	Text	Name of the VA facility
NPPD LINE *	Text	VA code that specifies the type of device within a category
PATIENT ID *	Integer	Patient identifier; unique to NPPD
SOURCE	Text	Commercial or VA issued
HCPCS – PSAS *	Text	Health Care Financing Administration Coding System (HCPCS) Prosthetic and Sensory Aids Service (PSAS) CODE
HCPCS CPT *	Text	HCPCS Common Procedure Code
NEW COST*	Currency	Commercial cost for item or service
USED COST	Currency	VA Cost for item or service
TYPE*	Text	Service type
ITEM *	Text	Description of service or item in IFCAP
CALCULATED COST	Currency	Cost of multiple line items linked to a single purchase order
QTY	Number	Number of items issued per transaction
VENDOR*	Text	Name of company providing device or service
FORM	Text	How item was procured or issued - VISA, Stock Issue, and so forth
SHIP COST	Currency	Cost of shipping
PRIORITY *	Integer	Priority Group of patient
CATEGORY	Text	Indicates where item was ordered for a Service Connected (SC) or Non Service Connected (NSC) Inpatient (IP) or Outpatient (OP)
SPECIAL CATEGORY	Text	NSC/OP fall within one of four special categories: Eligibility Reform, Post Hospital Care, Aid and Attendance, and Special Legislation
Vista ID	Text	Number assigned to a prosthetic order by the Vista Prosthetic Package
CREATE DATE	Date/Time	Date transaction entered into NPPD
DELIVERY DATE *	Date/Time	Date transaction completed with patient
ICD-9 *	Text	International Classification of Disease Code
HCPCS DESCRIPTION*	Text	Text description of HCPCS PSAS Code
PA NAME	Text	Name of VA staff member who generated the transaction

(*table continues*)

Variable Name	Type	Description
TRANSACTION ID	Text	Record number of purchase card order generated by station
GROUP ID *	Text	Number used to link multiple line items to a single purchase order
NPPD ID	Integer	Record number in the database
GENDER *	Text	Sex of patient
SERIAL NUMBER	Text	Unique ID of item
LOT NUMBER	Text	Unique ID of item
PRODUCT DESCRIPTION*	Text	Description of product
PRODUCT MODEL NUMBER*	Text	Model number of product
FISCAL YEAR*	Integer	Fiscal Year
SUSPENSE STATUS *	Text	Status of item - Open/Pending/Closed
SUSPENSE TYPE	Text	Not Linked/Contact Lens/Eyeglass/Manual/Oxygen/Routine
CONSULT DATE	Text	Date item/service prescribed
CONSULT DESCRIPTION *	Text	Free text description of item prescribed
CONSULT EXTENDED DESCRIPTION	Text	Free text description of item prescribed
WAIVER	Text	Indicates item has Waiver from purchasing off national contract
CONTRACT	Text	Contract #

* indicates those variables that will be used to identify the independent variable, artificial limb configuration as determined by HCPCS codes indicative of types of socket suspension systems and prosthetic feet. This table was derived from similar information provided at the VIReC Data Source and Description web page at http://www.virec.research.va.gov/DataSourcesName/NPPD/NPPD.html.

Appendix C: Copyright Letters of Permission

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Order Details
Licensee: Judith G Walden
License Date: Jan 27, 2014
License Number: 3317170612218
Publication: Archives of Physical Medicine and Rehabilitation
Title: Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050
Type Of Use: reuse in a thesis/dissertation
Total: 0.00 USD

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Sent: Monday, January 27, 2014 12:57 PM
To: Walden, Judith Gail
Subject: Thank you for your RightsLink / Elsevier transaction

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License Date: Jan 27, 2014
License Number: 3317181318157
Publication: Archives of Physical Medicine and Rehabilitation
Title: Reamputation, mortality, and health care costs among persons with dysvascular lower-limb amputations
Type Of Use: reuse in a thesis/dissertation
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Appendix D: Tables of Statistical Results

Section I: Characterization of the Cohort

Table D1

Derivation of the Artificial Limb Configuration Categories

Final ALC values			Derived from ALC values		
Category Value	Frequency	Percent	Category	Frequency	Percent
Transfer	12	3.81	K1 HV	2	0.63
			K1 L	2	0.63
			K1 M	2	0.63
			K1 LOCK	6	1.91
Household high-tech ss	10	3.17	K2 H	10	3.17
Household mid to low	16	5.08	K2 L	6	1.91
			K2 M	10	3.17
Household locking ss	25	7.94	K2 LOCK	25	7.94
Community high-tech ss	49	15.56	K3 H	7	2.23

(table continues)

Final ALC values			Derived from ALC values		
Category Value	Frequency	Percent	Category	Frequency	Percent
			K3 HV	1	0.32
			K34 H	37	11.74
			K34 HV	4	1.27
Community mid to low	53	16.83	K3 L	4	1.27
			K3 M	24	7.62
			K34 L	5	1.59
			K34 M	20	6.35
Community locking ss	150	47.62	K3 LOCK	50	15.79
			K34 LOCK	100	31.84

Table D2.

Distribution of cohort members and Artificial Limb Configuration Categories

	Region 1 - Northwest and Western U.S.		Region 2 - North- and South-Central U.S. (includes Texas)		Region 3 - Eastern Mid-West and Southern U.S. (Includes Ohio)		Region 4 - Mid-Atlantic and Northeast U.S. (includes Washington DC/Maryland)	
Cohort Members	**VISN**	**Frequency (percent)**	**VISN**	**Frequency (percent)**	**VISN**	**Frequency (percent)**	**VISN**	**Frequency (percent)**
	18	10 (3.58%)	12	7 (2.51%)	6	33 (11.83%)	1	9 (3.23%)
	19	1 (0.36%)	15	9 (3.23%)	7	9 (3.23)	2	4 (1.43%)
	20	18 (6.45%)	16	30 (10.75%)	8	19 (6.81%)	3	4 (1.43%)
	21	5 (1.79%)	17	11 (3.94%)	9	24 (8.6%)	4	15 (5.38%)
	22	14 (5.02%)	23	5 (1.79%)	10	12 (4.3%)	5	25 (8.96%)
					11	15 (5.38%)		
Totals		**48 (17.2%)**		**62 (22.2%)**		**112 (40.15%)**		**57 (20.43%)**
Artificial limb configuration	**Code**	**(Region 1) Frequency (percent)**		**(Region 2) Frequency(percent)**		**(Region 3) Frequency (percent)**		**(Region 4) Frequency (percent)**
1. Transfer	K1(All)	2 (3.7%)		3 (4.17%)		4 (3.25%)		3 (4.55%)
2. Household-high tech ss	K2H, K2Hv	1 (1.85%)		3 (4.17%)		2 (1.63%)		4 (6.06%)
Artificial limb configuration	**Code**	**(Region 1) Frequency (percent)**		**(Region 2) Frequency(percent)**		**(Region 3) Frequency (percent)**		**(Region 4) Frequency (percent)**
3. Household-mid-low tech ss	K2M, k2l	4 (7.41%)		4 (5.56%)		3 (2.44%)		5 (7.58%)

(table continues)

		Region 1 - Northwest and Western U.S.	Region 2 - North- and South-Central U.S. (includes Texas)	Region 3 - Eastern Mid-West and Southern U.S. (Includes Ohio)	Region 4 - Mid-Atlantic and Northeast U.S. (includes Washington DC/Maryland)
4. Household-locking ss	K2lock	1 (1.85%)	8 (11.11%)	15 (12.2%)	1 (1.52%)
5. Community-high tech ss	K3H, K3HV, K3-4H,K3-4Hv	6 (11.11)	11 (15.28%)	17 (13.82%)	15 (22.73%)
6. Community-mid-low tech ss	K3M, K3-4M, K3L, K3-4L	10 (18.52%)	13 (18.06%)	17 (13.82%)	13 (19.7%)
7. Community-locking ss	K3LOCK,K3-4LOCK	30 (55.56%)	30 (41.67%)	65 (52.85%)	25 (37.88%)
Total		**54 (17.14%)**	**72 (22.86%)**	**123 (39.05%)**	**66 (20.95%)**

Table D3.

Frequencies and Chi-Square Analyses per Study Cohort Variable Inclusion

Variable Name	Chi square p-value Frequency (percent) severe	Less severe	Variable used in Multivariate Analysis
Artificial limb configuration (ALC)	0.0428 150 (	0.2636146 (146	Yes
Major Depressive Disorder (MDD)	0.034 24 (8.6%)	0.0258 23 (8.2%)	Yes
Post traumatic stress disorder (PTSD)	0.2296 33 (11.3%)	0.0069 52 (18.6%)	Yes
Substance use disorder (SUD)	0.1888 24 ((8.6%)	0.1371 42 (15.1%)	Yes
Marital Status	0.0123 Married: 62 (22.9%) Other: 75 (27.7%	0.2544 Married: 66 (24.4%) Other: 63 (23.3%))	Yes
Age	0.1564 <55 y/o: 19 (9.9%) 55-74 y/o: 64 (33.3%) >74 y/o: 24 (12.5%)	0.6511 <55 y/o: 25 (13%) 55-74 y/o: 76 (39.6%) >74 y/o: 21 (11%)	Yes
Region	0.1651 Region 1: 27 (8.6%) Region 2: 29 (9.2%) Region 3: 56 (17.8%) Region 4: 33 (10.4%)	0.4357 Region 1: 29 (9.2%) Region 2: 30 (9.5%) Region 3: 65 (20.6%) Region 4: 34 (10.2%)	Yes

(*table continues*)

Variable Name	Chi square p-value Frequency (percent) severe	Less severe	Variable used in Multivariate Analysis
Socioeconomic status	0.9114 Unemployable: 86 (35.7%) Employable: 15 (6.2%) Co-pay eligible: 13 (5.4%)	0.9949 Unemployable: 95 (39.4%) Employable: 16 (6.6%) Co-pay eligible: 13 (5.4%	No
Race	0.632 White: 84 (32.8% Black: 39 (15.1%) Asian: 4 (1.5%))	0.0195 White: 85 (32.8%) Black: 44 (17%) Asian: 7 (2.7%)	Yes
Chronic obstructive pulmonary disease	0.014 45 (15.1%)	0.2293 40 (14.3%)	Yes
Congestive Heart failure (CHF)	0.0467 69 (24.7%)	0.0179 72 (25.8%)	Yes
Cerebral vascular disease (CVD)	0.462	0.5883 10 (3.6%)	No
Renal failure	0.0092 28 (10%)	0.1883 34 (12.2%)	Yes

Section II: Epidemiological analysis.

Table D4

General Estimating Equations Modeling Output for Research Question Four - the Interaction Of Mechanical (Household-Locking Suspension System Artificial Limb Configuration) with Behavioral Effects.

Less severe Residual Limb Skin Problems - Analysis Of GEE Parameter Estimates

Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		-2.0803	0.5527	-3.1635	-0.9971	-3.76	0.0002
Household-locking suspension system	1:yes	-0.7328	1.3166	-3.3133	1.8476	-0.56	0.5778
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Window	12 month	-0.2008	0.4487	-1.0802	0.6787	-0.45	0.6546
	18 month	0.0738	0.4102	-0.7302	0.8778	0.18	0.8572
	24 month	-0.3313	0.4444	-1.2022	0.5396	-0.75	0.4559
	30 month	-1.7618	0.6720	-3.0790	-0.4446	-2.62	0.0088
	36 month	-1.1098	0.5222	-2.1334	-0.0863	-2.13	0.0336
(reference)	6 month	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

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Less severe Residual Limb Skin Problems - Analysis Of GEE Parameter Estimates							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Age Group	55-74	-0.9513	0.3970	-1.7295	-0.1731	-2.40	0.0166
	74 older	-0.3555	0.4554	-1.2480	0.5371	-0.78	0.4351
(reference)	55 younger	0.0000	0.0000	0.0000	0.0000	.	.
Region	Region 1	-0.1238	0.4573	-1.0202	0.7726	-0.27	0.7866
	Region 3	-0.2903	0.3608	-0.9973	0.4168	-0.80	0.4211
	Region 4	0.1755	0.4616	-0.7292	1.0803	0.38	0.7038
(reference)	Region 2	0.0000	0.0000	0.0000	0.0000	.	.
Socioeco / VA Priority	co-pay eligible		0.7145	-2.9616	-0.1607	-2.18	0.0289
	Employable	0.2939	0.4328	-0.5545	1.1422	0.68	0.4972
(reference)	Unemployable	0.0000	0.0000	0.0000	0.0000	.	.
Marital Status	Married	0.1283	0.2969	-0.4535	0.7102	0.43	0.6655
	Others	0.0000	0.0000	0.0000	0.0000		.

(*table continues*).

Less severe Residual Limb Skin Problems - Analysis Of GEE Parameter Estimates

Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Race	Asian	0.3345	0.7150	-1.0669	1.7359	0.47	0.6399
	Black	0.2480	0.3282	-0.3952	0.8912	0.76	0.4498
(reference)	White	0.0000	0.0000	0.0000	0.0000	.	
Major depressive disorder	1:yes	-0.4741	0.4472	-1.3507	0.4025	-1.06	0.2891
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Post-traumatic stress disorder	1:yes	0.3192	0.3842	-0.4338	1.0722	0.83	0.4061
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Substance use disorder	1:yes	0.8734	0.4399	0.0112	1.7357	1.99	0.0471
	0:no	0.0000	0.0000	0.0000	0.0000	.	
Chronic obstructive pulmonary disease	1:yes	0.6967	0.3126	0.0841	1.3093	2.23	0.0258
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Congestive heart failure	1:yes	0.1689	0.3385	-0.4946	0.8325	0.50	0.6177
	0:no	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

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Less severe Residual Limb Skin Problems - Analysis Of GEE Parameter Estimates							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Cerebral vascular disease	1:yes	1.5114	0.4031	0.7212	2.3015	3.75	0.0002
	0:no	0.0000	0.0000	0.0000	0.0000	.	
Renal Failure	1:yes	0.2809	0.3092	-0.3251	0.8868	0.91	0.3636
	0:no	0.0000	0.0000	0.0000	0.0000	.	.

Severe Residual Limb Skin Problem- Analysis Of GEE Parameter Estimates							
Empirical Standard Error Estimates							
Parameter		**Estimate**	**Standard Error**	**95% Confidence Limits**		**Z**	**Pr > |Z|**
Intercept		-1.0247	0.4540	-1.9144	-0.1349	-2.26	0.0240
Household-locking suspension system	1:yes	-0.3293	0.4597	-1.2302	0.5717	-0.72	0.4738
	0:no	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

Less severe Residual Limb Skin Problems - Analysis Of GEE Parameter Estimates							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Window	12 month	0.0473	0.3277	-0.5949	0.6895	0.14	0.8852
	18 month	-0.2589	0.3421	-0.9294	0.4116	-0.76	0.4491
	24 month	-0.3302	0.3538	-1.0236	0.3631	-0.93	0.3506
	*30 month	-0.6158	0.3659	-1.3329	0.1013	-1.68	0.0924
	36 month	-1.6230	0.4838	-2.5712	-0.6747	-3.35	0.0008
(reference)	6 month	0.0000	0.0000	0.0000	0.0000	.	.
Age group	*55-74	-0.4929	0.2799	-1.0415	0.0556	-1.76	0.0782
	74 older	-1.1464	0.4049	-1.9400	-0.3528	-2.83	0.0046
(reference)	55 younger	0.0000	0.0000	0.0000	0.0000	.	.
*Region	Region 1	0.1553	0.3541	-0.5387	0.8492	0.44	0.6610
	Region 3	-0.2241	0.3156	-0.8426	0.3945	-0.71	0.4777
	*Region 4	0.6905	0.3640	-0.0230	1.4040	1.90	0.0578
(reference)	Region 2	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

.

Less severe Residual Limb Skin Problems - Analysis Of GEE Parameter Estimates

Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Socioeco / VA Priority	Co-pay eligible	-1.1994	0.4922	-2.1641	-0.2346	-2.44	0.0148
	Employable	-0.6472	0.4366	-1.5029	0.2085	-1.48	0.1382
(reference)	Unemployable	0.0000	0.0000	0.0000	0.0000	.	.
Marital status	Married	-0.2401	0.2373	-0.7051	0.2250	-1.01	0.3116
	Others	0.0000	0.0000	0.0000	0.0000	.	.
Race	Asian	-0.1486	0.8104	-1.7370	1.4398	-0.18	0.8545
	Black	-0.6053	0.2740	-1.1422	-0.0683	-2.21	0.0271
(reference)	White	0.0000	0.0000	0.0000	0.0000	.	.
*Major depressive disorder	1:yes	0.4338	0.2656	-0.0869	0.9544	1.63	0.1025
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Post-traumatic stress disorder	1:yes	-0.1065	0.2833	-0.6618	0.4487	-0.38	0.7069
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
*Substance use disorder	1:yes	0.5050	0.3055	-0.0937	1.1037	1.65	0.0983
	0:no	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

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Less severe Residual Limb Skin Problems - Analysis Of GEE Parameter Estimates							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Chronic obstructive pulmonary disease	1:yes	0.5935	0.2612	0.0816	1.1054	2.27	0.0231
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Congestive heart failure	1:yes	-0.1276	0.2551	-0.6275	0.3724	-0.50	0.6170
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Cerebral vascular disease	1:yes	-0.3756	0.6655	-1.6801	0.9288	-0.56	0.5725
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Renal failure	1:yes	0.0076	0.2785	-0.5383	0.5535	0.03	0.9781
	0:no	0.0000	0.0000	0.0000	0.0000	.	.

Estimate indicates direction of correlation; bolded text indicates statistical significance at 95% probability, alpha 0.05; * indicates statistical significance at 90% probability, alpha 0.10.

Table D5

General Estimating Equations Model Output for Research Question Four – the Interaction of Mechanical (Community-High Tech Suspension System) with Behavioral Effects.

Less severe Residual Limb Skin Problem - Analysis Of GEE Parameter Estimates

Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		-1.9411	0.5875	-3.0926	-0.7897	-3.30	0.0010
Community-high tech suspension system	1:yes	-0.4262	0.3651	-1.1418	0.2895	-1.17	0.2431
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Window	12 month	0.0382	0.4215	-0.7879	0.8644	0.09	0.9277
	18 month	0.1032	0.4005	-0.6818	0.8882	0.26	0.7966
	24 month	- 0.3402	0.4318	-1.1864	0.5061	-0.79	0.4308
	30 month	-1.5375	0.5942	-2.7021	-0.3730	-2.59	0.0097
	36 month	-1.0308	0.4940	-1.9990	-0.0626	-2.09	0.0369
(reference)	6 month	0.0000	0.0000	0.0000	0.0000	.	.
Age group	55-74	-0.9993	0.3883	-1.7603	-0.2382	-2.57	0.0101
	74 older	-0.4471	0.4405	-1.3104	0.4162	-1.02	0.3100
(reference)	55 younger	0.0000	0.0000	0.0000	0.0000		.

(table continues)

Less severe Residual Limb Skin Problem - Analysis Of GEE Parameter Estimates Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Region	Region 1	-0.2229	0.4742	-1.1523	0.7065	-0.47	0.6383
	Region 3	-0.3638	0.3693	-1.0876	0.3600	-0.99	0.3245
	Region 4	0.1397	0.4627	-0.7672	1.0467	0.30	0.7626
(reference)	Region 2	0.0000	0.0000	0.0000	0.0000	.	.
Socioeco / VA Priority	co-pay eligible	-1.5740	0.7146	-2.9747	-0.1734	-2.20	0.0276
	employable	0.2588	0.4569	-0.6367	1.1543	0.57	0.5711
(reference	unemployable	0.0000	0.0000	0.0000	0.0000	.	.
Marital status	married	0.1601	0.2864	-0.4012	0.7214	0.56	0.5761
	Others	0.0000	0.0000	0.0000	0.0000	.	.
Race	Asian	0.2809	0.7069	-1.1047	1.6665	0.40	0.6911
	Black	0.2400	0.3176	-0.3826	0.8626	0.76	0.4499
(reference)	White	0.0000	0.0000	0.0000	0.0000	.	.
Major depressive disorder	1:yes	-0.4542	0.4507	-1.3376	0.4292	-1.01	0.3136
	0:no	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

.

Less severe Residual Limb Skin Problem - Analysis Of GEE Parameter Estimates

Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Post-traumatic stress disorder	1:yes	0.2927	0.3742	-0.4407	1.0261	0.78	0.4341
	0:no	0.0000	0.0000	0.0000	0.0000	.	
*Substance use disorder	1:yes	0.8315	0.4294	-0.0101	1.6731	1.94	0.0528
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Chronic obstructive pulmonary disease	1:yes	0.6766	0.3136	0.0619	1.2912	2.16	0.0310
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Congestive heart failure	1:yes	0.1308	0.3386	-0.5329	0.7945	0.39	0.6993
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Cerebral vascular disease	1:yes	1.6301	0.4135	0.8197	2.4405	3.94	<.0001
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Renal Failure	1:yes	0.2523	0.3161	-0.3673	0.8719	0.80	0.4248
	0:no	0.0000	0.0000	0.0000	0.0000		.
							.

(*table continues*)

Less severe Residual Limb Skin Problem - Analysis Of GEE Parameter Estimates							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|

severe Residual Limb Skin Problem - Analysis Of GEE Parameter Estimates							
Empirical Standard Error Estimates							
Parameter		**Estimate**	**Standard Error**	**95% Confidence Limits**		**Z**	**Pr > |Z|**
Intercept		-1.0853	0.4764	-2.0191	-0.1515	-2.28	0.0227
Community-high tech suspension system	1:yes	0.2747	0.6176	-0.9357	1.4852	0.44	0.6564
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Window	12 month	0.1574	0.3583	-0.5449	0.8596	0.44	0.6605
	18 month	-0.3080	0.3926	-1.0774	0.4615	-0.78	0.4327
	24 month	-0.3295	0.3981	-1.1097	0.4507	-0.83	0.4078
	30 month	-0.4667	0.4024	-1.2555	0.3221	-1.16	0.2462
	36 month	-1.5233	0.5458	-2.5931	-0.4536	-2.79	0.0053
(reference)	6 month	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

.

Less severe Residual Limb Skin Problem - Analysis Of GEE Parameter Estimates Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Age group	*55-74	-0.5183	0.2902	-1.0872	0.0505	-1.79	0.0741
	74 older	-1.1831	0.4160	-1.9985	-0.3677	-2.84	0.0045
(reference)	55 younger	0.0000	0.0000	0.0000	0.0000	.	.
*Region	Region 1	0.1818	0.3469	-0.4981	0.8617	0.52	0.6002
	Region 3	-0.2258	0.3117	-0.8366	0.3851	-0.72	0.4689
	*Region 4	0.7119	0.3685	-0.0104	1.4342	1.93	0.0534
(reference)	Region 2	0.0000	0.0000	0.0000	0.0000	.	.
Socioeco / VA Priority	Co-pay eligible	-1.2037	0.4901	-2.1643	-0.2431	-2.46	0.0140
	Employable	-0.6627	0.4425	-1.5299	0.2045	-1.50	0.1342
(reference)	Unemployabl e	0.0000	0.0000	0.0000	0.0000	.	.
Marital status	Married	-0.2640	0.2353	-0.7252	0.1973	-1.12	0.2620
	Others	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

.

Less severe Residual Limb Skin Problem - Analysis Of GEE Parameter Estimates

Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Race	Asian	-0.1158	0.8139	-1.7110	1.4794	-0.14	0.8869
	Black	-0.6002	0.2759	-1.1409	-0.0595	-2.18	0.0296
*Major depressive disorder	1:yes	0.4370	0.2671	-0.0864	0.9605	1.64	0.1018
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Post-traumatic stress disorder	1:yes	-0.0878	0.2868	-0.6498	0.4743	-0.31	0.7595
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
*Substance use disorder	1:yes	0.5128	0.3124	-0.0995	1.1251	1.64	0.1007
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Chronic obstructive pulmonary disease	1:yes	0.6058	0.2658	0.0848	1.1268	2.28	0.0227
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Congestive heart failure	1:yes	-0.1316	0.2611	-0.6432	0.3801	-0.50	0.6142
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Cerebral vascular disease	1:yes	-0.3812	0.6462	-1.6478	0.8854	-0.59	0.5553
	0:no	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

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Less severe Residual Limb Skin Problem - Analysis Of GEE Parameter Estimates							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Renal failure	1:yes	-0.0019	0.2906	-0.5716	0.5677	-0.01	0.9947
	0:no	0.0000	0.0000	0.0000	0.0000	.	.

Estimate indicates direction of correlation; bolded text indicates statistical significance at 95% probability, alpha 0.05; * indicates statistical significance at 90% probability, alpha 0.10.

Table D6

General Estimating Equations Model Output for Research Question Four – the Interaction of Mechanical (Community-Mid-To Low-Tech Suspension System) with Behavioral Effects.

Less severe Residual Limb Skin Problem - Analysis Of GEE Parameter Estimates							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		-2.1945	0.5799	-3.3310	-1.0580	-3.78	0.0002
Community-mid to low tech suspension system	1:yes	0.2753	0.8375	-1.3662	1.9168	0.33	0.7424
	0:no	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

Less severe Residual Limb Skin Problem - Analysis Of GEE Parameter Estimates							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
	18 month	-0.0478	0.4459	-0.9217	0.8262	-0.11	0.9147
	24 month	-0.3061	0.4715	-1.2303	0.6182	-0.65	0.5163
	30 month	-1.5563,m	0.6698	-2.8691	-0.2435	-2.32	0.0202
	36 month	-1.1333	0.5541	-2.2193	-0.0473	-2.05	0.0408
(reference)	6 month	0.0000	0.0000	0.0000	0.0000	.	
Age group	55-74	-0.8884	0.4010	-1.6744	-0.1025	-2.22	0.0267
	74 older	-0.3293	0.4430	-1.1977	0.5390	-0.74	0.4573
(reference)	55 younger	0.0000	0.0000	0.0000	0.0000	.	.
Region	Region 1	-0.2375	0.4845	-1.1871	0.7121	-0.49	0.6240
	Region 3	-0.2105	0.3524	-0.9012	0.4803	-0.60	0.5504
	Region 4	0.1765	0.4620	-0.7289	1.0819	0.38	0.7024
(reference)	Region 2	0.0000	0.0000	0.0000	0.0000	.	.
Socioeco / VA priority	Co-pay eligible	-1.4777	0.7018	-2.8532	-0.1023	-2.11	0.0352
	Employable	0.2494	0.4606	-0.6533	1.1522	0.54	0.5882
(reference)	Unemployable	0.0000	0.0000	0.0000	0.0000		.

(table continues)

Less severe Residual Limb Skin Problem - Analysis Of GEE Parameter Estimates Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Marital status	Married	0.1689	0.2841	-0.3879	0.7258	0.59	0.5521
	Others	0.0000	0.0000	0.0000	0.0000	.	.
Race	Asian	0.1909	0.6856	-1.1529	1.5347	0.28	0.7807
	Black	0.2393	0.3148	-0.3777	0.8564	0.76	0.4471
(reference)	White	0.0000	0.0000	0.0000	0.0000	.	.
Major depressive disorder	1:yes	-0.4447	0.4517	-1.3300	0.4406	-0.98	0.3248
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Post-traumatic stress disorder	1:yes	0.3521	0.3787	-0.3901	1.0944	0.93	0.3524
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
*Substance use disorder	1:yes	0.8307	0.4365	-0.0247	1.6861	1.90	0.0570
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
*Chronic obstructive pulmonary disease	1:yes	0.5966	0.3091	-0.0093	1.2025	1.93	0.0536
	0:no	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

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Less severe Residual Limb Skin Problem - Analysis Of GEE Parameter Estimates							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Congestive heart failure	1:yes	0.1305	0.3378	-0.5314	0.7925	0.39	0.6991
	0:no	0.0000	0.0000	0.0000	0.0000		
Cerebral vascular disease	1:yes	1.5336	0.4161	0.7181	2.3490	3.69	0.0002
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Renal failure	1:yes	0.2826	0.3213	-0.3471	0.9124	0.88	0.3791
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Severe residual limb skin problems –Analysis of GEE parameter Estimates							
Intercept		-0.9679	0.4689	-1.8869	-0.0490	-2.06	0.0390
Community-mid to low tech suspension system	1:yes	0.2853	0.6301	-0.9495	1.5202	0.45	0.6506
	0:no	0.0000	0.0000	0.0000	0.0000	.	
Window	12 month	-0.0961	0.3598	-0.8014	0.6091	-0.27	0.7893
	18 month	-0.4483	0.3835	-1.2000	0.3035	-1.17	0.2425
	24 month	-0.5097	0.3999	-1.2935	0.2740	-1.27	0.2024
	*30 month	-0.6622	0.3990	-1.4443	0.1199	-1.66	0.0970
	36 month	-1.8656	0.5712	-2.9852	-0.7460	-3.27	0.0011
(reference)	6 month	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

Less severe Residual Limb Skin Problem - Analysis Of GEE Parameter Estimates

Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Age group	55-74	-0.6097	0.2834	-1.1650	-0.0543	-2.15	0.0314
	74 older	-1.2536	0.4205	-2.0779	-0.4294	-2.98	0.0029
(reference)	55 younger	0.0000	0.0000	0.0000	0.0000	.	.
Region	Region 1	0.1140	0.3699	-0.6109	0.8390	0.31	0.7578
	Region 3	-0.2107	0.3122	-0.8226	0.4012	-0.67	0.4997
	Region 4	, p	0.3587	0.0945	1.5005	2.22	0.0262
(reference)	Region 2	0.0000	0.0000	0.0000	0.0000	.	.
Socioeco – VA Priority	Co-pay eligible	-1.1494	0.4756	-2.0816	-0.2173	-2.42	0.0157
	*Employable	-0.8207	0.4483	-1.6993	0.0579	-1.83	0.0671
(reference)	Unemployabl e	0.0000	0.0000	0.0000	0.0000	.	
Marital status	Married	-0.2780	0.2347	-0.7380	0.1821	-1.18	0.2363
	Others	0.0000	0.0000	0.0000	0.0000	.	.
Race	Asian	-0.2966	0.8968	-2.0543	1.4610	-0.33	0.7408
	Black	-0.6006	0.2725	-1.1347	-0.0666	-2.20	0.0275
(reference)	White	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

Less severe Residual Limb Skin Problem - Analysis Of GEE Parameter Estimates							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
*Major depressive disorder	1:yes	0.5051	0.2697	-0.0235	1.0337	1.87	0.0611
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Pot-traumatic stress disorder	1:yes	0.0140	0.2831	-0.5408	0.5689	0.05	0.9604
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Substance use disorder	1:yes	0.4458	0.3195	-0.1804	1.0720	1.40	0.1629
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Chronic obstructive pulmonary disease	1:yes	0.4274	0.2694	-0.1006	0.9554	1.59	0.1126
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Congestive heart failure	1:yes	-0.1491	0.2640	-0.6665	0.3684	-0.56	0.5723
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Cerebral vascular disease	1:yes	-0.3699	0.7048	-1.7514	1.0116	-0.52	0.5997
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Renal failure	1:yes	0.0417	0.2926	-0.5318	0.6152	0.14	0.8867
	0:no	0.0000	0.0000	0.0000	0.0000	.	.

Estimate indicates direction of correlation; bolded text indicates statistical significance at alpha 0.05 (95%);
* indicates statistical significance at alpha = 0.10 (90%).

Table D7

General Estimating Equations Model Output for Research Question Four – the Interaction of Mechanical (Community-Locking Suspension System) with Behavioral Effects

Less severe Residual Limb Skin Problems - Analysis Of GEE Parameter Estimates

Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		-2.5098	0.7244	-3.9295	-1.0901	-3.46	0.0005
Community-locking suspension system	1:yes	0.6451	0.6190	-0.5681	1.8583	1.04	0.2973
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Window	12 month	0.6280	0.6110	-0.5696	1.8255	1.03	0.3041
	18 month	0.3640	0.5987	-0.8093	1.5374	0.61	0.5431
	24 month	-0.1717	0.6309	-1.4082	1.0649	-0.27	0.7856
	**30 month	-1.3543	0.8410	-3.0026	0.2941	-1.61	0.1073
	36 month	-0.4555	0.6615	-1.7520	0.8410	-0.69	0.4911
	6 month	0.0000	0.0000	0.0000	0.0000	.	.
Age Group	55-74	-0.9498	0.3978	-1.7296	-0.1701	-2.39	0.0170
	74 older	-0.3384	0.4401	-1.2009	0.5241	-0.77	0.4419
(reference)	55 younger	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

Less severe Residual Limb Skin Problems - Analysis Of GEE Parameter Estimates Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Region	Region 1	-0.1474	0.4629	-1.0547	0.7599	-0.32	0.7502
	Region 3	-0.3051	0.3792	-1.0483	0.4381	-0.80	0.4210
	Region 4	0.1599	0.4567	-0.7352	1.0550	0.35	0.7262
(reference)	Region 2	0.0000	0.0000	0.0000	0.0000	.	.
Socioeco / VA Priority	Co-pay eligible	-1.5827	0.7269	-3.0074	-0.1580	-2.18	0.0295
	Employable	0.2973	0.4459	-0.5766	1.1713	0.67	0.5049
(reference)	Unemployable	0.0000	0.0000	0.0000	0.0000	.	.
Marital status	Married	0.1511	0.2888	-0.4150	0.7172	0.52	0.6008
	Others	0.0000	0.0000	0.0000	0.0000	.	.
Race	Asian	0.3052	0.6895	-1.0461	1.6566	0.44	0.6580
	Black	0.2621	0.3189	-0.3629	0.8872	0.82	0.4111
(reference)	White	0.0000	0.0000	0.0000	0.0000	.	.
Major depressive disorder	1:yes	-0.4555	0.4491	-1.3358	0.4247	-1.01	0.3104
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Post-traumatic stress disorder	1:yes	0.2988	0.3940	-0.4735	1.0711	0.76	0.4482
	0:no	0.0000	0.0000	0.0000	0.0000		

(*table continues*)

Less severe Residual Limb Skin Problems - Analysis Of GEE Parameter Estimates							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Substance use disorder	1:yes	0.8611	0.4318	0.0149	1.7074	1.99	0.0461
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Chronic obstructive pulmonary disease	1:yes	0.7039	0.3129	0.0907	1.3171	2.25	0.0245
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Congestive heart failure	1:yes	0.1713	0.3318	-0.4791	0.8216	0.52	0.6057
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Cerebral vascular disease	1:yes	1.5273	0.3994	0.7445	2.3100	3.82	0.0001
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Renal failure	1:yes	0.2912	0.3094	-0.3152	0.8976	0.94	0.3466
	0:no	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

Less severe Residual Limb Skin Problems - Analysis Of GEE Parameter Estimates							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|

Severe Residual Limb Skin Problem - Analysis Of GEE Parameter Estimates							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		-0.8638	0.5058	-1.8551	0.1276	-1.71	0.0877
Community-locking suspension system	1:yes	-0.4282	0.4672	-1.3439	0.4875	-0.92	0.3594
	0:no	0.0000	0.0000	0.0000	0.0000	.	
Window	12 month	-0.1620	0.4670	-1.0773	0.7534	-0.35	0.7287
	18 month	-0.3969	0.4726	-1.3231	0.5293	-0.84	0.4010
	24 month	-0.5565	0.4883	-1.5136	0.4005	-1.14	0.2544
	30 month	-0.7721	0.5047	-1.7612	0.2171	-1.53	0.1261
	36 month	-1.8417	0.6471	-3.1099	-0.5734	-2.85	0.0044
(reference)	6 month	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

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Less severe Residual Limb Skin Problems - Analysis Of GEE Parameter Estimates							
Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Age group	*55-74 years	-0.5132	0.2851	-1.0720	0.0456	-1.80	0.0719
	74 older	-1.1785	0.3983	-1.9592	-0.3979	-2.96	0.0031
(reference)	55 younger	0.0000	0.0000	0.0000	0.0000	.	.
Region	Region 1	0.2043	0.3448	-0.4715	0.8800	0.59	0.5535
	Region 3	-0.2004	0.3345	-0.8560	0.4552	-0.60	0.5492
	Region 4	0.7279	0.3584	0.0255	1.4304	2.03	0.0422
(reference)	Region 2	0.0000	0.0000	0.0000	0.0000	.	.
Socioeco / VA Priority	Co-pay eligible	-1.1961	0.4943	-2.1650	-0.2273	-2.42	0.0155
	Employable	-0.6552	0.4351	-1.5079	0.1975	-1.51	0.1321
(reference)	Unemployable	0.0000	0.0000	0.0000	0.0000	.	.
Marital status	Married	-0.2621	0.2344	-0.7215	0.1972	-1.12	0.2634
	Others	0.0000	0.0000	0.0000	0.0000	.	.
Race	Asian	-0.1143	0.8323	-1.7456	1.5169	-0.14	0.8907
	Black	-0.6025	0.2776	-1.1466	-0.0584	-2.17	0.0300
(reference)	White	0.0000	0.0000	0.0000	0.0000		.

(*table continues*)

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Less severe Residual Limb Skin Problems - Analysis Of GEE Parameter Estimates Empirical Standard Error Estimates							
Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Major depressive disorder	1:yes	0.4302	0.2668	-0.0926	0.9531	1.61	0.1068
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Post-traumatic stress disorder	1:yes	-0.0697	0.2814	-0.6211	0.4817	-0.25	0.8044
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
*Substance use disorder	1:yes	0.5138	0.3102	-0.0942	1.1217	1.66	0.0977
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Chronic obstructive pulmonary disease	1:yes	0.5967	0.2597	0.0876	1.1058	2.30	0.0216
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Congestive heart failure	1:yes	-0.1377	0.2606	-0.6483	0.3730	-0.53	0.5973
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Cerebral vascular disease	1:yes	-0.3794	0.6496	-1.6527	0.8938	-0.58	0.5592
	0:no	0.0000	0.0000	0.0000	0.0000	.	.
Renal failure	1:yes	0.0037	0.2904	-0.5655	0.5729	0.01	0.9898
	0:no	0.0000	0.0000	0.0000	0.0000	.	.

Estimate indicates direction of correlation; bolded text indicates statistical significance at alpha = 0.05 (95%);
* indicates significance at alpha = 0.10 (90%).

Section III: NPPD Initial cohort analysis

Table D8

Initial Cohort Artificial Limb Prosthetic Foot Frequencies

HCPCSPSAS				
HCPCSPSAS	Frequency	Percent	Cumulative Frequency	Cumulative Percent
L5970 SACH	25	2.28	25	2.28
L5972 SAFE	89	8.12	114	10.40
L5973 Micro	2	0.18	116	10.58
L5974 Single-axis	90	8.21	206	18.80
L5975 Multitiaxis Flex	16	1.46	222	20.26
L5976 Energy-storing	188	17.15	410	37.41
L5978 Multiaxial Ankle	42	3.83	452	41.24
L5979 Dynamic response	67	6.11	519	47.35
L5980 Flex foot	192	17.52	711	64.87
L5981 Flex-walk	262	23.91	973	88.78
L5987 Shank	123	11.22	1096	100.00

Table D9

Initial Cohort Artificial Limb Suspension System Frequencies

Socsus	Frequency	Percent	Cumulative Frequency	Cumulative Percent
cuff suspension	70	4.00	70	4.00
suction socket	169	9.65	239	13.64
supercondyle suspension	77	4.39	316	18.04
BK suspension sleeve	658	37.56	974	55.59
VASS	12	0.68	986	56.28
Sleeve	698	39.84	1684	96.12
Straps	68	3.88	1752	100.00