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Ethics in Rehabilitation: Access to Prosthetics and Quality Care Following Amputation

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A Profile of Amputation

The most recent large-scale study of amputation in the United States found that 1.6 million people were living with limb loss in the country in 2005 [1]. With 185,000 amputations occurring annually [2], the total number of people with amputation in the US (accounting for mortality) is projected to double by the year 2050. The most common causes of amputation are vascular disease, trauma, cancer, and congenital malformation. Vascular disease and trauma account for 54 percent and 44 percent of the current prevalence, respectively, while less than 2.5 percent of people who have had amputations cite cancer or congenital deformity as the cause [3]. The rising incidence of amputations observed in the United States thus can largely be attributed to vascular disease and comorbid diabetes, the latter accounting for more than 60 percent of nontraumatic amputations in the United States today [4]. Furthermore, the number of people living with diabetes in the US in 2011—25.8 million—is predicted to double by 2030 [1, 5]. As a result, amputation presents an ever-increasing challenge to our health care system.

Those who sustain an amputation encounter multiple challenges during their recovery, rehabilitation, and reintegration into their homes and communities. Learning and adopting new strategies for basic mobility, personal hygiene, and activities of daily living with or without prosthesis is difficult. In prosthetic fitting, multiple attempts at socket fabrication are often needed to improve tolerance and comfort. Phantom limb and residual limb pain are extremely common and frequently require a multidisciplinary approach for optimal management [6-8].

Major limb amputation is associated with a higher incidence of secondary health complications, such as obesity, cardiovascular disease (CVD), peripheral vascular disease (PVD), renal disease, and diabetes [9, 10]. More than half of those who have a leg or arm amputated secondary to vascular disease and diabetes will require an amputation of the contralateral limb within two to three years [11]. And the five-year mortality rate for those who have lost limbs because of vascular disease is over 50 percent—the same or higher as that for prostate, breast, and colorectal cancer [10, 12, 13]. Despite advances in prosthetic technology, evidence still indicates that people who have had an

amputation (even those who use a prosthetic device) are at a biomechanical disadvantage that makes them more likely to develop musculoskeletal complications such as osteoarthritis, back pain, joint pain, and osteoporosis/osteopenia [14]. In addition, because of the challenges with socket interfaces, people with prosthetic limbs are likely to develop frequent skin complications, including irritation, breakdown, ulceration, cysts, and necrosis [15].

The psychological impact of amputation can be just as significant as the physical challenges. The perceived loss of ability to engage in previous vocational, avocational, social, sexual, and leisure activities can play a greater role in postamputation quality of life than the absence of the limb itself [16]. Body image, self-esteem, and quality of life can be significantly negatively influenced by amputation [17], and health survey scores are often far lower for patients who have had lower limb amputations than for control subjects. Ide et al. also found that nearly 50 percent of those who have had amputations are dissatisfied with their sexual life following limb loss [18]. Many of those surveyed reported that their interest in sexual issues deteriorated following amputation. Return to work following amputation can also be difficult and has been found to be dependent on a wide variety of factors such as amputation level, age, gender, level of education, and employer support [19]. Although reports vary, a large number of people do not return to work following amputation(s) and a significant percentage of those who do return to work change occupations [19]. As a result of these and other factors, depression and anxiety are significant concerns in the amputee population, with reports of as many as 20-30 percent of all amputees being diagnosed with major depressive disorder [20, 21].

The key to improving outcomes for those who have lost limbs is to ensure that they receive appropriate and comprehensive interdisciplinary care to address both their physical and psychosocial needs. Fundamental to the rehabilitative care and recovery of many people who have lost limbs is their fitting for and training on the use of prostheses. Increased prosthetic usage is associated with higher levels of employment [22], increased quality of life [23], decreased phantom limb pain [22], and lower levels of general psychiatric symptoms [24]. Additionally, prosthetic use has been shown to facilitate a reduction in secondary health issues [25] and therefore a larger degree of mobility and functional independence for those with amputation.

Even in the United States, patient access to appropriate rehabilitation and prosthetic care is still significantly limited. Geographical barriers, gender, age, socioeconomic position, race, education, and cost all contribute to health care disparities. These disparities may not only obstruct access to the most appropriate prosthetic and rehabilitative care but may contribute to prosthetic abandonment, psychological problems, reduced quality of life, and unsuccessful return to meaningful community participation.

Health Disparities

Race, socioeconomics, and gender. In the 2005 study mentioned earlier [1], 42 percent of those who had lost limbs belonged to a racial or ethnic minority group. Poverty, too, is a noted risk factor for amputation [26]. African Americans are four times more likely to undergo an amputation and 2.5 times as likely to have a second lower limb amputation than non-Hispanic white Americans, even controlling for age, sex, and diabetes severity [27, 28]. Similarly, Hispanic Americans are 1.5 times as likely to suffer an amputation as white Americans [29]. Non-whites, those with low income, and those without commercial insurance are more likely than members of other groups to undergo a lower limb amputation for PVD rather than revascularization (a limb-saving procedure associated with better outcomes), even controlling for the severity of disease [30]. In the rehabilitation period, those with an income at or near the poverty line are 2.5 to 3 times as likely as their peers who are not in poverty to perceive barriers in their access to work or community life, and some studies have found that a smaller percentage of women with limb loss remained employed following their amputation(s) than their male counterparts [31, 32].

Facility type. The type of rehabilitation facility a patient is sent to can have a tremendous effect on the eventual outcome for that patient. Following discharge from a hospital, rehabilitation typically occurs in one of three places—at home, at a skilled nursing facility (SNF), or at an inpatient rehabilitation facility (IRF). Per Medicare guidelines, IRFs provide, at minimum, physician services, onsite physical therapy, and social or psychological services [33]. They usually also provide access to prosthetic services or expertise. Rehabilitation physicians typically oversee day-to-day operations and medical procedures and create rehabilitation plans for each patient.

By contrast, SNFs are staffed by licensed nurses (RNs, LPNs, and LVNs) and nurse aides, with contracted physicians visiting the facility periodically. Rehabilitation often must begin or occur entirely without the input of a rehabilitation physician or physical therapist because regulations require that each patient see a doctor only once every 30 days for the first 90 days and once every 60 days after that [33]. DaVanzo et al. conducted a review of Medicare patient outcomes at these two types of facilities over a two-year period [33]. They found that people rehabilitating from amputations who were treated at an IRF returned home from their stays 16 days earlier, were able to live at home nearly 3 months longer, stayed alive more than 2.5 months longer, and experienced a 12 percent lower mortality rate. Hospital emergency room visits were reduced from 1,016.7 per 1,000 patients per year at SNFs to 861.3 per 1,000 patients per year at IRFs, while the number of hospital readmissions saw an even greater difference, with 1,966.6 per 1,000 patients per year at SNFs and 1,538.3 per 1,000 patients per year at IRFs. This is despite the fact that IRFs typically treat more severely affected patients who require more intensive rehabilitation efforts.

Prior to rehabilitation, the hospital where the patient undergoes initial treatment and receives acute care can impact recovery. Those patients who undergo amputations at a trauma center are 1.5 times more likely to be sent to an IRF for rehabilitation than those treated at hospitals without trauma centers [34]. Teaching hospitals are more likely than nonteaching institutions to attempt revascularization rather than amputation for patients with PVD [30]. Such limb-saving procedures also incur only one-third of the projected lifetime costs of amputation [35]. Less than one-fifth of all US hospitals are teaching hospitals, however, and less than 15 percent of hospitals qualify as level I, II, or III trauma centers [36, 37]. As recently as 10 years ago, more than 33 million people did not live within an hour of a level I, II, or III facility, and more than 45 million people did not have any access to a level I or II facility [38]. Those who do have access may simply be unaware of the differences between treatment at and referrals from teaching hospitals or trauma centers and hospitals that are neither. In either case, it is often the location and the physician at the bedside that determine the type of treatment (amputation or revascularization) and the success or failure of rehabilitation for many who have had an amputation.

Costs. Perhaps the greatest cause of prosthesis- and rehabilitation-related disparities in outcomes for those who have had amputations is cost, and there are also, in some cases, drastic limitations on insurance coverage of the necessary prosthetic devices and services. As many as 20 percent of nonmilitary amputees report an unmet need for rehabilitation services, largely because of inability to pay [39].

The costs related to amputation, prosthesis, and rehabilitation can be roughly divided into two categories: (1) those directly associated with the amputation event or surgery (including rehabilitation care, prosthetic fitting, and adjustment of devices) and (2) indirectly associated costs (including those for secondary health complications and their treatment). Costs in even one of these categories can be significant:

- On average, the two-year total cost of amputation exceeds $90,000 [35]. Rehabilitation care, fitting of prostheses, and adjustment of devices alone were the fifteenth most expensive condition treated in US hospitals in 2011, with a total cost of more than $5.4 billion for these services [40, 41]. Hospital charges for amputation procedures amounted to more than $8.3 billion in 2009, not including prosthetic or rehabilitation costs [13].
- Common secondary health conditions following amputation, including diabetes, are also among the top twenty most expensive conditions billed by hospitals in 2011. Osteoarthritis and back problems, also common, fall within the top six [40].
- Lifetime estimates for directly associated costs range from $345,000 to nearly $600,000, depending on how often the prosthesis is replaced and the age at time of amputation [10, 13, 35, 40].

- Based on the statistics available, direct and indirect health costs as a result of amputation could easily exceed $1 million for an individual *before* accounting for any loss of wages or salary due to an inability to work.

These costs are far outside the financial capabilities of most people. As a result, insurance providers (including Medicare, Medicaid, and private insurance) typically cover the majority of costs [42]. Insurance type also determines the patient's access to prosthetic components and services [42]. For those with Medicare, the prosthesis provided is based on the patient's rehabilitation potential as determined by a prosthetist and the ordering physician [43]. While a number of states have enacted laws to create parity and equal access to prosthetic devices for those who have had an amputation, many policies and laws still do not facilitate financial access to the most advanced prosthetic systems, despite the fact that such systems have become the clinical standard of care and have been shown to provide improved outcomes by reducing secondary health problems [44-46] and to decrease costs by improving quality adjust life years (QALYs) [43].

Prosthesis funding alone can independently influence both the selection and use of a prosthetic device [47]. Obtaining a second device for specific activities, such as work or avocational activities, can be difficult, requiring extended processes of verification and justification. Many private insurance providers have also added yearly and lifetime spending and visit caps in their policies, limiting the number of outpatient visits allowed as well as the covered costs of those visits. Yearly caps for prosthetic services ranged from $500 to $3,000 in 2012; lifetime maximums can be as little as $10,000 or only cover a single prosthetic device for a person's entire lifetime [39]. Given that, even without fitting and training services, a single prosthesis can range in cost from $3,000 to $100,000 for lower limbs and $4,000 to $75,000 for upper limbs and that even the most advanced and sturdy of these systems typically require replacement every two to five years [39], some patients face extreme costs not covered by insurance. That patients who undergo amputation are already likely to have financial disadvantages compounds the issue of ability to pay.

Discussion

Rehabilitation after amputation is a complex physical and psychological challenge. Obtaining access to appropriate prosthetic services is an important part of this process. Yet the disparities that exist in the current health care system pose substantial barriers for people who have lost limbs. For the reasons we have discussed, those with the least resources and education are disproportionately represented in the amputee population. Not only are they at higher risk for sustaining an amputation, but they often have less access to appropriate comprehensive care. Furthermore, there are no specific guidelines for standards of care or prosthetic management and there are great discrepancies in the competence and capacity of health care facilities across the nation, many of which lack

substantial experience and expertise in caring for people who have lost limbs. Finally, the costs of advanced prosthetic devices, training, and services continue to act as a significant barrier that a large majority of patients cannot overcome.

Over the past several decades, the US government has funded the development of model systems of care for complex debilitating disorders that are intended to stimulate research and improve quality of care [13]. Such models have been created for spinal cord injury, traumatic brain injury, and burn injury, and they have demonstrated encouraging results in their ability to influence and improve care [13]. It is apparent that such a model could have substantial benefits for postamputation rehabilitation.

The United States military's Military Amputee Treatment Centers (MATCs) are an example of such a model. These centers facilitate the coordination of the various services involved in rehabilitation for servicemembers injured in combat operations, including education, prosthetic services, surgery, physical therapy, occupational therapy, pain medicine, and psychosocial services. Studies show that Iraq and Afghanistan veterans treated at these centers have higher self-reported quality of life and health status, higher rates of prosthetic usage, and higher rates of satisfaction with the care received than Vietnam veterans [48, 49].

In 1984 Ham et al. reported on an overhaul at two hospitals performing amputations that did not have in-house prosthetic care [50]. This overhaul included standardizing physiotherapy for those who had had amputation(s), increasing patient education, enlisting the services of a surgeon trained in amputation techniques, encouraging vascular surgeons to use a standard protocol, using prosthetists and senior coordinating physiotherapists, and mandating prosthetic fitting before discharge. Four years of progressively increasing efforts resulted in a decrease of inpatient stays by 20 days, a 94 percent reduction in postdischarge physiotherapy, a fivefold increase in prosthetic fitting prior to discharge (17 percent to 100 percent), and a 150 percent increase in long-term prosthetic use (36 percent to 94 percent) from baseline. The majority of these gains were achieved in the first year of the system's implementation. Such success demonstrates the benefit that proper training, prosthetic devices, and coordination can provide for those who have had an amputation.

Pitfalls in education, treatment, costs, and care engender prosthetic abandonment, rehabilitation failure, and lower quality of life for those who have lost limbs, often without decrease in medical costs. The Davanzo et al. survey of Medicare patient outcomes at IRFs versus SNFs also tracked the cost incurred, per day and in total, for those who had had amputations at each facility type [33]. While the price for initial rehabilitation services was substantially higher per person at IRFs, the overall rehabilitation cost for an individual person at an IRF was not statistically different from rehabilitating him or her at an SNF, yet the outcomes were far superior.

It is worth asking if, in the current system of payment and insurance coverage, an initial prescription and training with advanced prosthetic devices would in fact result in overall cost savings for private insurance companies as it does for the military and Veterans Administration, by reducing the likelihood of secondary health issues. For example, those treated by the United States military or Veterans Health Administration are typically allowed to test multiple sockets and prosthetic devices to maximize their comfort and function [39]. Although comfort and fit remain two of the most significant prosthetic issues reported by those who have had an amputation, civilian insurance often only covers two test sockets and a single prosthesis [14, 39], despite the fact that no single prosthesis can achieve all the functions necessary for everyday life. A comprehensive cost analysis of Medicare patients who had had lower limb amputations within the previous year and had utilized orthotic and prosthetic services found that those who received physical therapy had fewer acute care hospitalizations and emergency room admissions and less facility-based health care than patients who had not [51]. Within a year, the prosthetic device cost was almost amortized by the other cost savings, and patients had higher quality of life and increased independence than the matched controls who did not receive a prosthesis.

The current access to prosthetic devices, prosthetic services, and rehabilitation services for the majority of those who have lost limbs leaves much to be desired. Model systems of amputation care and education would provide dedicated locations for assessing different treatment regimens, training protocols, and technology for caring for those who have had an amputation. A comprehensive investigation of cutting-edge prosthetic systems is necessary to establish not only their definitive clinical benefits, but also their impact on the overall cost incurred by a patient following amputation. These measures might make it possible to alleviate some of the health care disparities associated with geography, gender, socioeconomic status, and minority group membership that grip the prosthetic and amputation fields today.

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