Roadmap for Improving Patient-Centered Outcomes Research and Advocacy

Recommendations From the 2018 Limb Loss Task Force
May 2-4, 2018
Foreword

The Amputee Coalition is a 501(c)3 nonprofit organization whose mission is “to reach out to and empower people affected by limb loss to achieve their full potential through education, support and advocacy, and to promote limb loss prevention.”

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History of the Limb Loss Task Forces

The Amputee Coalition Limb Loss Task Force summits have traditionally served as an opportunity to convene a group of experts to discuss a particular issue or set of issues currently impacting individuals with limb loss and their family members and caregivers.

Limb Loss Task Force One

In 2010, the Amputee Coalition convened the inaugural Limb Loss Task Force summit in Washington, D.C. on April 16-18, which consisted of expert healthcare providers, healthcare researchers and consumer advocates in the field of limb loss. The goal was to develop general recommendations for improving the quality of care for people with limb loss and reducing the instance of preventable amputations. The summit produced the following four-point action plan for preventing limb loss and improving the quality of care for people with limb loss:

1. Develop and implement a blueprint for limb loss prevention.
2. Partner with professional organizations to develop practice guidelines for the care of people with limb loss.
3. Develop a national research agenda on limb loss prevention and amputation care.
4. Create and demonstrate a model system of care ranging from prevention through amputee rehabilitation and community integration that could be emulated by health systems throughout the country.

Further recommendations produced by the inaugural task force included developing a national research agenda on limb loss prevention and amputation care. Specifically, the task force recommended that the research agenda focus on: 1) quantifying the prevalence of limb loss and the burden of living with limb loss; 2) comparative effectiveness research on medical, surgical, prosthetic and rehabilitative care options; and 3) identifying determinants of quality of life and community reintegration.

Limb Loss Task Force Two

In 2012, the Amputee Coalition assembled a Limb Loss Task Force summit in Washington, D.C. on February 9-13, composed of a panel of leading experts on amputee care and rehabilitation, limb loss prevention, diabetes education and management, vascular disease management, healthcare policy, and health system-based care pathways. The goal of the summit was to identify paradigms and practices to reduce the incidence of preventable limb loss in the United States. It was determined that reducing healthcare costs while improving quality and outcomes drives much of the current healthcare policy debate. Implementing clinical models and guidelines that reduce preventable amputations is an integral part of achieving these goals. The task force broadly recommended: 1) creating competitive funding opportunities for demonstration projects in the civilian healthcare systems; 2) building interdisciplinary, coordinated care approaches that emphasize prevention; and 3) developing a media campaign to engage individuals most at risk for limb loss (e.g., African Americans and Latino/a/x) and their healthcare providers to raise awareness of evidence-based approaches to preventing amputations due to complications from diabetes and vascular diseases.
Limb Loss Task Force Three

In 2015, the Amputee Coalition gathered a Limb Loss Task Force summit which met from March 2-4, in Boston, Massachusetts as a group of experts on amputee care and rehabilitation, limb loss prevention, vascular medicine, diabetes education and management, healthcare policy, and current healthcare model systems administration. The goal of the summit was to develop strategies to address the lack of research about patients with limb loss, as the lack of evidence about limb loss frustrates current efforts to improve the quality of care and health outcomes for patients with limb loss. Recommendations produced by the task force included the following:

1. To improve the quality of patient care for amputees, a limb loss model system is needed. This model system will implement comprehensive care programs for patients with limb loss and provide data to support a longitudinal database to facilitate scientific research to improve outcomes for this understudied population.

2. Partner with existing model system programs to facilitate the development of a limb loss model system. Existing model system programs possess knowledge and experience in developing and maintaining a model system.

3. Incorporate advances in database management, data collection and management best practices and research interests (e.g., patient-centered research) in a data center to support a longitudinal database attached to a limb loss model system. These advances will contribute to efforts to address issues with maintenance costs and data quality, as well as enhance the usefulness of the database to researchers. Including validated instruments and measures within the database structure improves the availability of data to drive the development of evidence-based interventions and care guidelines for patients with limb loss.

4. Create competitive funding opportunities to support the development and implementation of a limb loss model system.

There is presently a lack of research and scientific evidence needed to inform the development of evidence-based care guidelines for the rehabilitation of patients who have an amputation. Addressing gaps in the quality, methodology, and accessibility of data and research is among the first steps in advancing the quality of patient care for people with limb loss.
Background of Limb Loss in U.S.A.

Impact of Limb Loss

There are currently 1.9 million people living with limb loss in the United States and this number is expected to nearly double by 2050 (1). With an average of 507 people losing a limb to amputation every day, limb loss has a momentous impact on the overall health and quality of life of the U.S. (2). The predicted escalation of limb loss is primarily tied to the increasing prevalence of diabetes and vascular diseases (1).

The review presented below is not intended to be comprehensive but to provide highlights regarding the background literature underlying the Limb Loss Task Force recommendations.

Direct Health-Related Costs

- In 2014, hospital charges for lower-limb amputation procedures accounted for more than $10 billion (3).
- In 2004, the total hospital costs associated with diabetes-related lower-limb amputations alone totaled more than $1.5 billion (4).
- Professional nursing care at home after losing a limb due to dysvascular disease costs a person with limb loss an estimated $100,000 per year (5).
- A below-knee amputation costs Medicare an average of $81,051 per person (6).
- Trauma patients who undergo attempts at limb salvage over the course of 18-24 months following their injury averaged 53.4 days in the hospital at a cost of $53,462 in hospital charges and, on average, underwent 6.9 surgical procedures with attendant personal and financial costs (7).

Employment and Social

- Less than half of those who experience amputation return to work. For those who return to work, the average time to return is approximately 14 months (8).
- People with limb loss perceive that they are participating less in recreational activities, are more dissatisfied at work, and are more impaired in community mobility relative to their premorbid status (9).
- Factors positively influencing amputees’ return to work include prosthetic use, access to vocational services, and age at the time of amputation. Factors negatively related to successful employment include residual and phantom limb pain, multiple limb amputations and significant psychological distress (10).

Disparity

- African-Americans are up to four times more likely to undergo an amputation than white Americans (11).
- Hispanic/Latino Americans are one-and-a-half times more likely than white Americans to undergo amputations (12).
- Poverty is an important risk factor for amputations (13).
- Amputees with a household income at or near the poverty line were two to three-and-a-half times more likely to perceive barriers to participation in work and community life than those who were not poor (9).

Approximately 85 percent of diabetes-related amputations are preceded by a foot ulcer.
**Diabetes is the leading cause of limb loss in the United States, accounting for more than 65,000 annual amputation procedures performed in the United States.**

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**Morbidity and Mortality**

- Survival rates after amputation vary based on a variety of factors. Those who have amputations from trauma tend to have good long-term survival, but those from vascular etiology (inclusive of peripheral arterial disease and diabetes) face a 30-day mortality rate reported to be from 9-15 percent and long-term survival rate of 60 percent at one year, 42 percent at three years, and 35-45 percent at five years (14).

- Nearly half of the people who lose a limb to dysvascular disease will die within five years. This is higher than the five-year mortality rate experienced by people with colorectal, breast and prostate cancer (15)-(16).

- Of people with diabetes who have a lower-limb amputation, up to 55 percent will require amputation of the second leg within two to three years (17).

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**Risk Factors for Limb Loss**

- Estimates show that 49-85 percent of amputations are preventable (18)-(19), clearly highlighting the importance of prevention of both dysvascular and traumatic amputation. A large number of preventable amputations is due to the increasing incidence of diabetes and peripheral arterial disease (PAD), and the related problems of obesity and smoking (20)-(21).

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**Dysvascular Amputation**

- 54 percent of amputations are related to peripheral vascular disease, most notably diabetes (1).

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**Diabetes**

- It is estimated that by 2025, there will be 250 million people with diabetes worldwide, compared to 120 million in 1996 (24).

- As many as one in four people with diabetes will develop a foot ulcer in their lifetime (25) and those who develop foot ulcers are at high risk for amputation within the subsequent year.

- 75 percent of nontraumatic amputations in people with diabetes would have been prevented by early identification and education of those at risk of ulceration (24).
Peripheral Arterial Disease

- A study from the National Health and Nutrition Examination Survey 1999-2000 data found that PAD affects approximately 5 million adults. Prevalence increases dramatically with age, and disproportionately affects African-Americans (26).
- PAD is a common cause of amputation; 1-2 percent of all people with PAD will progress to major amputation (26).

Obesity and Smoking

- Subjects who had ever smoked were twice as likely to have a lower-limb amputation as those who never smoked (27).
- Among people with a lower-limb amputation, smoking cigarettes has been associated with a re-amputation risk 25 times higher than of nonsmokers (28).
- People with lower-limb amputation had a higher baseline Body Mass Index (BMI) than those without a lower-limb amputation (27).

Traumatic Amputations

- Limb loss secondary to trauma accounts for 45 percent of all amputations in the U.S. (1).
- Over two-thirds of amputations due to trauma occur among adolescents and adults below the age of 45, with many years of productive life ahead of them.
- The most common causes of pediatric acquired amputations are lawnmower accidents, with an average of 600 children losing a limb to a lawnmower each year (29)-(30).

Prevention Opportunities

- In a 2001 study, only 49 percent of those receiving amputations related to dysvascular disease had any diagnostic vascular evaluation prior to amputation (31).
- Limb-preservation experts report a significant number of the 80,000-plus toe, foot and lower-limb amputations related to diabetes would be preventable if only patients received proper foot care and had improved diabetes control (33).
- Self-management education activities and programs can improve foot care behaviors, resulting in decreased lower-limb complications (34).
- The three most important contributors to amputation reduction in people with diabetes are: 1) education, 2) regular clinical visits, and 3) proper shoe wear (35)-(36) (37) (38).

Improved foot care for patients with diabetes may decrease the rate of lower-limb amputation.
Improving Patient-Centered Outcomes Research and Advocacy

Introduction

Limb Loss Task Force Four

The need for research on amputation care has been underscored by coverage and reimbursement policy decisions made by insurance companies that have restricted access to prosthetic care. Although the existing body of evidence is increasingly used to develop systematic reviews of evidence and clinical practice guidelines, the quantity and quality of scientific evidence available to advocate for policy changes is often limited. Recognizing how limitations in the evidence related to limb loss care and rehabilitation can adversely impact the quality of life of individuals with limb loss, the Amputee Coalition and the National Limb Loss Resource Center convened a fourth Limb Loss Task Force to address these issues.

On May 2-4, 2018, the Amputee Coalition held a Limb Loss Task Force in Washington, D.C. to discuss meaningful ways to improve the quality of evidence about individuals with limb loss and address gaps in available research. Prior to the discussion between participants, special guests Alison Cernich, PhD, director of the National Center for Medical Rehabilitation Research, and Erik Wolf, PhD, from the Clinical and Rehabilitative Medicine Research Program at the U.S. Army Medical Research and Development Command, gave brief presentations to the group. Dr. Cernich provided updates on the current research landscape, and together they presented updates on the Limb Loss and Preservation Registry, a new database supported by the National Institutes of Health and the Department of Defense. The goal of the Task Force was to bring together limb loss researchers, representatives from institutions that fund limb loss research, patient advocates, and policymakers to discuss strategies to improve the quality and availability of high-quality evidence to optimize functional outcomes for individuals with limb loss. Participants engaged in a day and a half of discussions and small group activities to achieve the following goals:

1. Define a research agenda that will provide the evidence needed to optimize functional outcomes for individuals with limb loss, improve quality of care provided to those who experience an amputation throughout the care continuum, and improve access to medically necessary prosthetic care and technology.

2. Develop a strategy to improve coordination of research efforts between clinicians, researchers, and funders in order to create better efficiencies in addressing current gaps in evidence.

3. Identify a list of research priorities to be commonly pursued across the research landscape.
Recommendations

1. Build Limb Loss Research Collaboratives

A research collaborative is needed to serve as a neutral/unbiased platform for research collaboration across interdisciplinary groups and stakeholders. Current barriers to knowledge and access include lack of communication within and between institutions, leading to knowledge gaps within the limb loss research community. This collaborative would identify needs and produce publications that include literature reviews, evidence summaries, outcome measure recommendations, overviews of current clinical trials, and clinical best practice guidelines.

2. Encourage Research That Addresses the Question: “What Is a Successful Outcome?”

Research efforts directed toward defining success and value are needed to advance awareness of stakeholder perspectives, improve clinical measurement and documentation, and inform future research study design and outcome measure selection. Studies should solicit input from a variety of stakeholders, including patients, caregivers, clinicians, funders and payers. Understanding different definitions of success may help to facilitate prosthetic prescription and corresponding measurement of outcomes based on important individual factors, such as whether and how much people are participating in activities that are meaningful instead of simply focusing on biomedical rationale like the presence of comorbidities.

3. Advocate for Increased Limb Loss Research Funding

Advocacy efforts are necessary to raise awareness about funding disparities for limb loss research initiatives compared to other health conditions; this will enhance awareness of the challenges and elevate the priorities currently faced by amputees. A briefing on Capitol Hill with key stakeholders is recommended to educate legislators about these disparities and to address the need to support limb loss research. It is paramount that legislators understand the importance of access to affordable and appropriate prosthetic care provided by qualified providers.
Build Research Collaboratives

Research collaboratives are common in medical research and intended to bring interdisciplinary scholars, clinicians, patients, caregivers and other stakeholders together for the purpose of advancing research in specific health conditions. It is not unusual to find collaboratives for complex or rare health conditions in which research from one specialty overlaps or connects to another specialty, such as multi-state Perinatal Quality Collaboratives, which include specialists in maternal and infant health, mental health, epidemiology, and emergency preparedness and response (CDC website).

Examples of current research collaboratives include:

- Traumatic Brain Injury Research Collaborative
- Pediatric Surgery Research Collaborative
- Geriatric Medicine Research Collaborative
- Patient-Centered Primary Care Research Collaborative
- Transplant Outcomes Research Collaborative
- Seattle Pediatric Concussion Research Collaborative
- Autism & Developmental Disorders Inpatient Research Collaborative.

The Osteosarcoma Collaborative was borne out of the need to develop new treatments with clinical researchers, including stakeholders like patients and families:

“We exist because new treatments for osteosarcoma don’t — there has been nothing new to treat this devastating disease in over 30 years. The Osteosarcoma Collaborative is recognized by the IRS as a 501(c)(3) public charity. To the extent contributions are tax-deductible under the new U.S. Tax Code, please consult an accountant. Created to identify, collaborate and fund new research and treatments in pediatric and adult osteosarcoma, the Collaborative also focuses on helping osteosarcoma families connect and interact with each other. Equally important, the Collaborative strives to educate the medical profession about long-term survivorship with osteosarcoma. With approximately 900 new cases a year, osteosarcoma is considered an extremely rare disease. By bringing together data, researchers, patients and family, we believe we can spur additional research and discovery for a very aggressive disease.”

What Is a Collaborative?

Unlike collaboration between research entities, a collaborative as an organization suggests an underlying culture of collaboration that drives all activity within the organization. Three important characteristics help define a collaborative organization:

1. A networked and nonhierarchical organization structure
2. A culture of openness, honesty and trust
3. An engaged and valued workforce.

Some groups combine a registry with the research collaborative, such as the Sudden Unexplained Death in Childhood (SUDC) Registry and Research Collaborative. Collaboratives may or may not include a repository in which members contribute data for the collective use of the membership as a whole.

2018 Limb Loss Task Force Comments

Discussion around the need for a Limb Loss Collaborative was a major player at the 2018 Limb Loss Task Force. Members felt that the lack of communication across specialties was a contributing factor to stagnant research in post-amputation outcomes:

“There really is a very low level of visible evidence published — we do a lot of research and try to figure out what’s out there but there really is a significant lack or gap in the literature as to what works and what may not work as well, and what’s marginal and what’s more significant...the industry is hungry for it but it’s not at a location that we can easily access and there’s not a dissemination platform that makes it easy to access...there are some incredible organizations in the country but they don’t always talk to each other.”
Currently, no coordinated plan exists for limb loss prevention in the civilian healthcare system.

The lack of evidence and a consistent repository for data, clinical studies, published research, white papers and conversations around knowledge gaps was duly noted:

“One of the things that’s needed as a consequence of this lack of evidence, we have an inability to put together meaningful practice guidelines. So you have this great variation in care, and that also complicates our ability to do real research, because when you actually get out to a prosthetics clinic, who knows what kind of care patients are getting, and what they’re not getting? So it’s real complicated.”

Suggestions were made for new directions in research that would advance technology in ways that were both affordable and timely for patients who needed it the most:

“To summarize the differences in technologies, patients who are limited in mobility are really technology-starved. That comes down to the cost of hydraulic and microprocessor knees and feet. It’s a two- or three-fold increase in cost, and payers have the perception that patients with limited mobility also have a shorter life expectancy, so an investment in two to three times the cost for a shorter amount of time may not be worth it. So there needs to be less expensive technologies that are smart technologies developed for that population, and that could be a priority.”

Stories shared about experiences with patients reiterated the need for consistent care grounded in evidence-based practices for quality of life outcomes in patient-centered care:

“This is a perfect example of why we’re here — and this is just one topic in this spectrum of people...and if you think of this, if you put someone who’s diabetic and the possibility that they’ll be dead — 50 percent of them — in five years — so I have someone who has an amputation in July of next year; I needed to battle to try to get the C-leg on him. And then he started to train but the prosthetist was horrific. And now it’s May and I have to start him all over again. That’s kind of classic, where this gentleman should have been out hiking in the woods last fall. So for those of you who weren’t here last night — we’ve been here before. Task Force One, we came out with — we needed research and a model system. And whether it’s a model system or not, without this research that really gets to the heart of what we’re trying to do. I understand this about payment and business and all that but when I see somebody in front of me who’s just walked into the room and the clock is ticking, I’ve got to get them back to life.”

Members discussed including a repository for clinical data but questioned the proverbial buy-in from stakeholders to share their data. Others suggested a fee-based consortium in which only paying members would have access, but there was no consensus. Future discussions should ensue to determine the direction and mission for a Limb Loss Research Collaborative.
Patient-Reported Outcomes on Success

While the body of literature includes a number of descriptions of post-amputation outcomes, studies often rely on biomedical outcomes when determining success. It is recommended that rehabilitation outcomes after amputation be defined in relation to an individual’s condition prior to the amputation, and that the patient’s perspective on their health be included in any assessment of success.

While a variety of patient-reported outcome measures are available to assess the impact of a health condition on an individual’s health, function and quality of life, little is known about how people with limb loss or limb difference view success. Because of this, outcomes most often reported in the literature are those that are prioritized by researchers, clinicians and policy-makers. While some of the outcomes valued by these stakeholders may be shared by patients, the Task Force felt that it would be important to assess which outcomes are valued by all stakeholders, and which ones may only be valued by some. Gaining a better understanding of “success” by all involved is critical to growing the body of evidence pertaining to post-amputation outcomes.

2018 Limb Loss Task Force Comments

“Discussion around the need to identify what success is for both the patient and the clinician was another major theme that emerged at the Task Force. Members felt that patients’ views on post-amputation outcomes were not well-documented in the body of literature, and saw an opportunity to better understand the patients’ values, perspectives on their health, and quality of life after receiving a prosthesis:

What is ‘satisfaction’ to the person that we serve? We should ask them: What do you care about? How do you measure quality? Because your indicators could all be excellent but then the patient says, ‘This is terrible.’ And then you can have the opposite, where the indicators are all terrible and the patient says, ‘This is awesome; it’s the best thing that ever happened to me!’”

Task Force members discussed the need for patient-reported outcomes research that extends beyond biomedical definitions of success. Unexpected outcomes in research have proven to be the most fruitful when compared to where their research efforts were focused:

“When we first started collecting data on catastrophic injuries and amputations, we focused 99 percent of our efforts on biomedical issues: limb size, age, comorbidities. Turned out that the biggest impact, the biggest driver, of outcome was really psycho-social stuff...many of the biological factors that I thought were going to be a contributor like diabetes didn’t really matter.” (50:00 LLTF 3)

Furthermore, members stressed that while strict recommendations for specific outcome measures might take the onus of evaluation off the provider, that does not come without its own inherent risks and often jeopardizes post-amputation outcome potential. For example, the K-Level system used by most insurers to classify the functional level of individuals is used to determine eligibility for prosthetics:

“There are conditions in which we want someone to tell us what to measure....K-levels came up as an example of trying to do this in the past. In my mind, the value of the K-level is that it’s a starting point; it was never meant to be the end-all/be-all. It’s supposed to be modified, and it’s supposed to be revisited.” (1:20 LLTF)

Attention to the impact of language and semantics when engaging with patients was also discussed. The perception of success and value can often be measured in how we frame post-amputation communication:

“We started calling them limb preservation centers instead of limb salvage, which makes patients feel like they’re going to the junkyard somewhere.”
Advocate for Increased Limb Loss Research Funding

There was an emphasis throughout the meeting on the need to educate policymakers and other decision-makers about research needs for the limb loss community. While people with limb loss are more prevalent in media and marketing campaigns than ever before, many people still connect limb loss with combat injuries. While this represents a unique and important population, the needs of combat veterans may differ significantly from those who experience limb loss due to many of the leading causes, such as complications from diabetes and vascular disease, trauma, and other conditions. Task Force members identified a need to change the overall perception of the limb loss community with respect to who is predominantly impacted so that research sponsors can make funding available to address issues of importance to all people with limb loss or limb difference. Members also discussed the challenges and frustration associated with serving a patient population that doesn’t have the same resources and support that other patient populations receive:

“In the rehab spectrum, we have model systems of care for brain injuries and spinal cord and burns. It’s very frustrating to know that our patients — the patients that we’re talking about — are just as important but we don’t have the type of infrastructure or the ability to do the things that they do. I admit it: I’m jealous. I’m frustrated and yet you still have to do things to make sure that our people are also getting what they need. I think we have to advocate very strongly for that.”

The 2015 Limb Loss Task Force members discussed the role that model systems have played in improving patient care and promoting research to improve the lives of other patient populations, and how a limb loss model system could benefit patients with limb loss. When comparing the three model systems that exist (Spinal Cord Injury, Traumatic Brain Injury, and Burn), and the populations that they serve, it’s clear that a similarly sized population like the limb loss community could benefit as each of these conditions have from improved research.

- Spinal Cord Injury — 17,700 new incidences each year, and approximately 288,000 people living with a spinal cord injury (39).
- Traumatic Brain Injury — An estimated 1.5 million Americans sustain a traumatic brain injury annually (40).
- Burn — Approximately 100,000 people experience burn injuries requiring medical treatment each year (41).
- Amputation — An estimated 185,000 Americans experience amputation annually and approximately 2.1 million people live with limb loss in the United States (1).

While there was a considerable dialogue about the need to invest in patient outcomes research for the limb loss community, there was also recognition of the disparate challenges individuals facing amputation have that can adversely impact their care and outcomes. We need to understand the needs of underserved populations as well as those engaged at major research centers and institutions.

“Getting the big centers involved is not necessarily the problem; it’s actually getting the patient who has fragmented care in (rural state) or wherever and collecting data on those. We need to continue the dialogue and figure out exactly what that would look like and how to capture viable and valuable data on those types of patients.”

Educating policy-makers, decision-makers, and patients about chances to elevate outcomes research in the limb loss community was seen as an opportunity. Stimulating public discussion was seen as a way to advance research opportunities to positively impact the community and initiate actions to address existing challenges.
Next Steps: Actionable Items
With the Amputee Coalition

Based on the discussion and recommendations of the 2018 Limb Loss Task Force, the following next steps are specific goals for the Amputee Coalition:

1. The Amputee Coalition will develop a strategic plan with key stakeholders for implementing and disseminating research by and for the community in a Limb Loss Collaborative. Actionable items include surveys and a focus group to identify data needs and to work actively with researchers for community buy-in to support an inaugural meeting in 2020.

2. The Amputee Coalition will work with researchers to identify ongoing outcomes that matter to those within the limb loss community through qualitative inquiries and analysis in surveys and focus groups. This item seeks to identify specific challenges from within the patient and caregiver population that might not otherwise be known to researchers.

3. The Amputee Coalition will organize a day on Capitol Hill for a briefing to raise awareness of the issues surrounding research disparities and access to care challenges. In addition to advocating for the community, members of the population will share personal stories to illustrate the impact of policy and regulation.

These three actionable items will be informed in part by the awardees of the newly launched Limb Loss and Preservation Registry, supported by the National Institutes of Health and the Department of Defense. Members and participants will be recruited from the database for the Collaborative, patient outcomes research, and advocacy efforts.
Diagnosing and treating potential risks for amputation in patients with diabetes and peripheral arterial disease should be the immediate focus of any project that seeks to prevent limb loss.
Works Cited


