



amputee
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Roadmap for Preventing Limb Loss in America

*Recommendations From the
2012 Limb Loss Task Force*

February 9–12, 2012

For print requests, please contact:

Amputee Coalition
900 E. Hill Ave, Suite 290
Knoxville, TN 37915
888/267-5669
amputee-coalition.org

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Foreword

The Amputee Coalition convened the 2012 Limb Loss Task Force to develop priorities for reducing the number of preventable amputations in the United States. The Limb Loss Task Force met from February 9-12 in Washington, D.C. The Task Force was comprised of experts on amputee care and rehabilitation, limb loss prevention, vascular medicine, diabetes education and management, health care policy and health system administration. They represented the following organizations and institutions: American Diabetes Association, Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality, American Academy of Orthotists and Prosthetists, Society for Vascular Nursing, National Institute on Disability and Rehabilitation Research, Duke University, University of Minnesota, Peripheral Arterial Disease (PAD) Coalition, Partners HealthCare, American Academy of Family Physicians, Durham Regional Hospital, Adventist HealthCare - Mid-Atlantic, the Institute for Preventive Foot Health, Blue Cross Blue Shield of North Carolina, Allina Health, Kessler Institute for Rehabilitation, Johns Hopkins School of Medicine, Harvard Medical School and Mount Sinai Hospital, and the Vascular Disease Foundation (Peripheral Arterial Disease Coalition). The goal of the summit was to identify paradigms and practices to reduce the incidence of preventable limb loss in the United States.

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.” The 2012 Limb Loss Task Force was supported by funding from the National Center on Birth Defects and Developmental Disabilities within the CDC (cooperative agreement #U59DD000347-05). Additional funding for the Limb Loss Task Force was provided by the Institute for Preventive Foot Health (IPFH). The contents of this report are solely the responsibility of the authors and do not necessarily represent the official views of the CDC.



Executive Summary

Problem

Currently, there are an estimated 1.9 million people living with limb loss in the United States, almost half of whom are non-white. At its peak, an estimated 185,000 amputations occurred in 1996 in the United States. While not all causes of limb loss are preventable, the leading causes of amputation - complications from diabetes and peripheral artery disease - can often be prevented through patient education, disease management and regular foot screening. The instance of preventable limb loss is especially important to racial and ethnic minority groups, where the amputation rate is up to four times that of white Americans.

Among people with diabetes and peripheral artery disease, early intervention and increased patient education has been associated with reducing the incidence of amputation. Recent research showing a 67% decline in the rate of lower-limb amputation from diabetes-related complications since 1996 demonstrates the potential efficacy of prevention efforts (1). Yet, the number of diabetes-related amputations remains high and the prevalence of diabetes and chronic kidney disease has grown tremendously. In 2009, there were an estimated 68,000 diabetes-related amputations performed in the United States, a 23% increase since 1988 (2). Amputation rates in the total population (including individuals without diabetes, or with PAD alone) are not known and active surveillance efforts do not exist. The CDC estimated that more than 20 million Americans had been diagnosed with diabetes in 2010, four times the number of Americans diagnosed with diabetes in 1980 (3). In 2010, nearly 70,000 Americans died due to diabetes, making it the seventh highest cause of death in the United States (4). Having diabetes is associated with a 55% increase in mortality in people who have a lower-limb amputation (5).

Costs

Preventing amputations could translate to a substantial reduction of health care costs in the United States. Annually, the immediate health care costs for the amputation of a limb - not including prosthetic costs or rehabilitation costs - total more than \$8.3 billion (6). Diabetes-related amputations alone account for nearly \$2 billion (7). The true health care costs associated with the amputation of a limb are likely to be significantly higher when prosthetic costs are included. While prosthetic costs are subject to much variation, the 5-year prosthetic costs are estimated to be as high as \$450,000 per person (8). Studies estimate that the lifetime health care costs for a person with limb loss are more than \$500,000 per person (8), nearly double the estimated lifetime health care costs of the average person (9). The lifetime health care costs for a person with limb loss are especially dramatic given the high 5-year mortality rates for this population.

The human toll associated with limb loss is significant. People with limb loss experience significantly lower health status and high rates of mortality. People with limb loss are at an increased risk for cardiovascular disease (10, 11), obesity (12) and joint and bone issues (13), as well as experience high rates of depression (14) and emotional distress (15). Studies estimate the 5-year mortality rate for people with an amputation to be between 50% and 74% (16, 17). For people 65 years or older with vascular disease, the 1-year mortality rate from the time of the initial amputation is estimated to be 36% (18). The mortality rate among people 65 or older with vascular disease increases according to the level of the initial amputation, with more proximal amputations associated with higher mortality rates (18). People with limb loss with diabetes are also more likely to experience subsequent amputation either to the ipsilateral or contralateral limb (5, 18).

Preventing amputations could translate to a substantial reduction of health care costs in the United States.

Strategies

Developing strategies to establish coordinated care paradigms and guidelines that reduce the instance of preventable amputation aligns with the current evolution of the United States health care system. Reducing health care costs while improving quality and outcomes drives much of the current health care policy debate. We believe that implementing clinical models and guidelines that reduce preventable amputations is an integral part of achieving these goals.

Current models for coordinating care of patients most at risk of amputation and clinical care guidelines for managing diabetes and peripheral arterial disease may offer some insight on how to create practice models that reduce preventable amputation. Clinical guidelines developed by organizations such as the American College of Cardiology (ACC) and American Heart Association (AHA) and the American Diabetes Association (ADA) supported establishing the Preservation-Amputation Care and Treatment (PACT) program in the Veterans Health Administration (VHA). Since implementing this program, the overall number of amputations performed at VHA medical centers has decreased by nearly 40% and the amputation rate among patients with diabetes by more than 50% (16). The VA's PACT program uses patient medical records to assess amputation risk based on the presence of particular conditions, diagnosis or procedure codes in the medical record.

The PACT program's use of patient medical records fits in well with the current evolution of the U.S. health care system set in motion with the inclusion of the Health Information Technology for Economic and Clinical Health (HITECH) Act within the American Recovery and Reinvestment Act of 2009 and the passage of the Patient Protection and Affordable Care Act (PPACA) in 2010. These initiatives emphasize the need to improve quality of patient care while reducing costs. Meaningful implementation of health information technology represents a key strategy for achieving these goals. The HITECH act made a significant investment in the implementation of health information technology throughout the U.S. health care system. In addition, numerous governmental agencies and private sector organizations have initiated funding for projects that use electronic medical records to achieve gains in care quality that reduce health care costs. One suggestion for accomplishing these goals is to embed evidence-based care guidelines within the electronic medical record to support clinical care decisions. This infrastructure could support the collaborative care model needed to prevent foot ulceration and subsequent limb loss.

Reducing health care costs while improving quality and outcomes drives much of the current health care policy debate. We believe that implementing clinical models and guidelines that reduce preventable amputations is an integral part of achieving these goals.



2012 LLTF recommendations

The Task Force made the following recommendations to reduce the number of preventable amputations in the United States.

- 1.** Create competitive funding opportunities for demonstration projects in the civilian health care system designed to reduce the number of preventable amputations, reduce the burden of disability and impairment on at-risk populations, improve health care quality and lower health care costs. The projects should consist of an interdisciplinary, coordinated care approach that emphasizes primary prevention to reduce the incidence of foot ulcers, lower cardiovascular risk, decrease functional impairment, lower amputation rates and prevent associated disability. The high 5-year mortality rate, due to a high rate of cardiovascular ischemic events (myocardial infarction and stroke) in people who develop a diabetic foot ulcer - estimated to be around 50% - underscores the importance of stressing primary prevention (17). This model has shown promise within the VA's system (19).
- 2.** Develop a media campaign engaging those individuals most at risk for limb loss (e.g., African Americans and Latino/as) and their health care providers to raise awareness about using established, evidenced-based approaches to preventing amputations due to complications from diabetes and vascular disease. This campaign would emphasize the importance of foot care for preventing limb loss among these populations.

Introduction

Background

On April 16-18, 2010, the Amputee Coalition convened the inaugural Limb Loss Task Force Summit, consisting of health care providers, health care researchers and consumer advocates in Washington, D.C., to discuss how to prevent limb loss and improve the quality of care for those with limb loss. This 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.

On February 9, 2012, the Amputee Coalition convened the second Limb Loss Task Force, consisting of a panel of leading experts on amputee care and rehabilitation, limb loss prevention, diabetes education and management, vascular disease management, health care policy, and health system-based care pathways, to focus on the topic of limb loss prevention. Over a three-day period, the Task Force discussed strategies for reducing the incidence of preventable amputation in the United States using the VA system's success as a model.

Overview of the Problem

The current state of limb loss in the United States

Population living with and at risk of limb loss

- Currently, there are an estimated 1.9 million people living with limb loss in the United States, a number that is expected to double by 2050, largely due to the rising diabetes epidemic (20, 21).
- In 2010, diabetes affected 25.8 million Americans, according to the CDC (22).
- 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 (2, 21, 23).
- It is estimated that 33% of Americans will have diabetes by 2050 (20).
- The increase in adult and childhood obesity over the last 20 years lies at the heart of the diabetes epidemic. Being obese or overweight substantially raises a person's risk of developing diabetes (24).

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.

Health care costs associated with limb loss

Immediate costs (i.e., surgical)

- In 2009, hospital charges for amputation procedures performed in the United States totaled more than \$8.3 billion (6).
- In 2006, health care costs associated with diabetes-related lower-limb amputations totaled more than \$1.6 billion (7).

Long-term costs (prosthetic devices)

- The lifetime health care costs for a person with an amputation (including prosthetic costs) are estimated to top more than \$500,000 (25).
- Prosthetic costs vary according to the level and complexity of the amputation. A recent study by the Department of Defense and the Department of Veterans Affairs estimated 5-year prosthetic costs to be as high as \$450,000 for a person with multiple limb amputations, \$230,000 for a person with a unilateral lower-limb amputation and \$117,000 for a person with a unilateral upper-limb amputation (8).

Health care costs associated with diabetes and diabetic foot complications

- In 2007, the treatment of diabetes and its complications resulted in \$174 billion in total health care costs, including \$116 billion in direct health care costs (26).
- Health care costs linked to the treatment of a diabetic foot ulcer comprise an estimated 33% of the direct health care costs associated with the treatment of diabetes and its complications (27).
- Studies have resulted in a wide variation of the average health care costs associated with individual ulcer episodes, with estimates ranging from as low as \$3,600/yr (28) to as high as \$28,000/yr (29).
- Despite these disparate cost estimates, studies consistently suggest that the severity of the ulcer significantly impacts the associated health care costs, with higher costs associated with increased severity of the ulceration (27).

Preventable limb loss in the United States

Limb loss risk factors

Diabetes

- 54% of people living with limb loss lost their limb due to complications related to vascular disease, including diabetes-related complications and peripheral arterial disease (21).
- In 2008, the age-adjusted amputation rate was approximately eight times higher among people diagnosed with diabetes than the non-diabetic population (1).
- It is estimated that as many as 60% of the amputations resulting from diabetes-related complications could have been prevented (30).

Approximately 85% of diabetes-related amputations are preceded by a foot ulcer.

Foot care and preventing foot ulcers

- Studies suggest that the presence of a foot ulcer is associated with a fivefold increase in amputation risk among patients with diabetes (31).
- Approximately 85% of diabetes-related amputations are preceded by a foot ulcer (32).
- Improved foot care for patients with diabetes may decrease the rate of lower-limb amputation (33).
- Simple steps such as routine foot inspection, fitting of appropriate shoes and orthotics, combined with patient education about the importance of self-care, can decrease the incidence of wounds in the diabetic population. Consistent follow-up with prompt treatment of wounds and management of callus formation to prevent further injury can result in fewer lower-limb amputations in the diabetic population(34).

Vascular disease

- Among people 65 and older, vascular disease, especially peripheral arterial disease, dramatically increases individual risk of amputation (23).
- The risk of amputation due to vascular disease is especially high among African Americans, where it is estimated to be more than 10 times that of their white counterparts (23).
- Among people with vascular disease, developing ischemic symptoms is a common pathway to the amputation of a limb (35).

Improved foot care for patients with diabetes may decrease the rate of lower-limb amputation.

Health disparities and amputation

Racial/ethnic disparities in amputation rates

- Non-whites comprise approximately 42% of the limb loss population in the United State (21).
- In 2008, the diabetes-related amputation rate (adjusted for age) among African Americans was nearly twice that of whites (1).
- Among Medicare beneficiaries, the lower-limb amputation rate within the African American community is nearly four times that of whites (36).
- The rate of peripheral arterial disease among African Americans is estimated to be three times that of whites (37).

Geographical disparities in amputation rates

- According to a study conducted by the California Healthcare Foundation, lower-limb amputation rates among Medicare beneficiaries varied by geographic location, with Louisiana, Mississippi and South Carolina having the highest rate (38).

Currently, no coordinated plan exists for limb loss prevention in the civilian health care system.

Current practices in amputee care and limb loss prevention

- Currently, no coordinated plan exists for limb loss prevention in the civilian health care system. Various recommendations and guidelines exist within the U.S. health care system. However, they are not consistently practiced within actual health care settings. Furthermore, these care practices are highly fragmented and do not encapsulate the totality of pathways to amputation and potential interventions (39).
- The VHA has established coordinated care programs designed to prevent amputation (PACT) and clinical practice guidelines for the rehabilitation of lower-limb amputation (40).
- The ADA's "Standards of Medical Care in Diabetes - 2012" contains recommendations for preventing amputations resulting from foot ulceration that closely resemble the guidelines adhered to within the PACT program (41).
- The American College of Cardiology (ACC)/American Heart Association (AHA) Guidelines for the Management of Peripheral Arterial Disease provide an evidence-based approach encompassing both diagnostic and therapeutic pathways that are intended to serve as a comprehensive disease management approach for individuals with critical limb ischemia, with or without diabetes as an etiologic factor (42).
- Additionally, the clinical guidelines developed by The Inter-Society Consensus for the Management of Peripheral Arterial Disease (PAD) (TASCII) also includes a discussion about limb loss, which combines the ADA and ACC/AHA management and prevention strategies (35).

Innovative Models & the Evolving Health Care Environment

Knowledge of evidence-based practice models supports efforts to develop, evaluate and disseminate paradigms and practices that lower the instance of preventable amputations in the United States. Current focus on developing care practices that reduce health care costs, improve quality of care and produce better outcomes underscores these efforts.

Evidence-based care models & clinical guidelines to prevent limb loss

The Department of Veterans Affairs Preservation - Amputation Care and Treatment (PACT) program: A potential model for using HIT to prevent diabetes-related amputations

The VHA as a health care innovator

- The VHA is recognized as a source of innovation within the health care arena, having incorporated evidence-based care practice guidelines to clinical care through its Quality Enhancement Research Initiative (QUERI) (43).

Overview and background on PACT program

- In response to the passage of the Veterans Medical Programs Amendments of 1992 (Public Law 102 - 405), which emphasized improving care for patients with amputations by designating veterans with limb loss as a special disability group, the VA's Preservation-Amputation Care and Treatment (PACT) program was established (16).
- The PACT program provides a model of care for patients at risk for amputation and for those who have already had an amputation, tracking these patients within the VA health care system. The PACT program incorporates an interdisciplinary care management approach using available resources, including primary care and diabetes, nurse, podiatrist, vascular surgeon and rehabilitation teams (16). This approach is supported by using the patient's electronic medical record to promote evidence-based interventions based on diagnostic and clinical information.
- The PACT program uses patient medical records to assess amputation risk based on the presence of particular conditions, diagnosis or procedure codes in the medical record. Specific care instructions are dispensed based on a patient's level of risk. The PACT program represents a unique method for harnessing electronic medical records to aid in disease diagnosis and management that improves care quality and patient outcomes while reducing overall health care expenditures.

Results of PACT program: Reducing diabetes-related amputations in the VHA system

- Within the VHA, rates of lower-limb amputation have decreased by almost 35% from 2000 to 2004 (44).
- The introduction of focused multidisciplinary foot care programs for patients with diabetes that use patient medical records to assess individual amputation risk has been associated with up to 80% reduction in number of lower-limb amputations performed (19).
- Other programs within the VHA system have achieved nearly 30% (45) and 50% (30) reduction in the amputation rate at their facilities.

Other models and guidelines

Organized diabetes foot care

A study of diabetes-related and non-diabetes-related lower-limb amputation rates in the U.K. demonstrates the positive impact that improving knowledge and practice of foot care in people with diabetes, the presence of a multidisciplinary diabetic foot care team and establishing care pathways and protocols for managing diabetic foot problems can have on diabetes-related lower-limb amputation rates, reducing the rate of diabetes-related amputations by nearly 30% (33).

Seven skills of a diabetic foot team

Members of the Southern Arizona Limb Salvage Alliance identified the following essential skills a Diabetic Rapid Response Acute Foot Team (DRRAFT) should possess in order to effectively manage the lower-limb complication of diabetes (46):

1. Perform a neurologic workup
2. Perform site-appropriate culture technique
3. Perform wound assessment and staging/grading of infection and ischemia
4. Perform site-specific bedside and intraoperative incision and debridement
5. Initiate and modify culture-specific and patient-appropriate antibiotic therapy
6. Perform appropriate postoperative monitoring to reduce risk of reulceration and infection
7. Perform hemodynamic and anatomic vascular assessment with revascularization as necessary.

Current perspectives on the U.S. health care system: Reducing costs, improving quality of care and outcomes

IOM report “Crossing the Quality Chasm (2001)” and recommendations to improve care and outcomes

- In order to improve health care quality and address delivery inefficiencies, the Institute of Medicine recommended that care processes be centered on best practices informed by evidence-based research and information technology be used to support clinical decision-making (43).
- Clinical decision support systems (CDSS) can assist clinicians and patients with three types of clinical decisions: preventive and monitoring tasks, prescribing or drug choices and diagnosis and management (43).

Affordable Care Act and the transformation of the American health care system

- With the passage of the Patient Protection and Affordable Care Act (PPACA), the Obama administration made a significant commitment to improving health care quality and reducing costs (47).
- The HIT provisions in PPACA reinforce the robust commitment to health information technology (HIT) made within the HITECH Act, part of the American Recovery and Reinvestment Act (ARRA) of 2009 (48).
- The HITECH Act set committed up to \$29 billion over 10 years to support the adoption and “meaningful use” of electronic health records, with the intent that the adoption of HIT improve quality of care and reduce costs, including supporting clinical care decisions (49, 50).

Current direction of health care

- Currently, a wide range of programs have been established to promote the meaningful use of HIT within health care system. These programs include:
 - o The Beacon Communities project, created by the Office of the National Coordinator for Health Information Technology, to demonstrate that HIT can improve the quality, cost and efficiency of care and demonstrate the ability of HIT to transform local health care systems (51)
 - o The Agency for Healthcare Research and Quality (AHRQ) has dedicated extensive resources to promoting the use of HIT that improves health care decision-making, supports patient-centered care and improves the quality and safety of medication management (52).

Toward a Demonstration Project to Prevent Amputations in the Civilian Population

Key elements

While the VHA's PACT program represents a useful blueprint for a similar system of amputation prevention in the civilian health care sector, some aspects of the VHA's program may not be suitable for a non-closed health care system. Certain elements of the VHA's program may be adapted to prevent amputations in the civilian health care system.

Within the VHA's program, the following items were demonstrated to have a statistically significant impact on reducing amputation rates (53):

- Address all patient foot care needs
- Refer patients to appropriate services/treatments
- Maintain stand-alone, specialized diabetic foot care services
- Diabetic foot care education for providers within the last 3 years.

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. Such projects should develop and employ a risk algorithm that uses information in the patient's medical records to assess individual risks of amputation and suggest interventions informed by guidelines developed from the best scientific evidence and agreed upon by the care team. Patient care should be multidisciplinary and coordinated throughout the system of care and include urgent care, primary care, infectious disease, podiatry, vascular surgery/medicine and prosthetic providers. However, it is imperative that such projects also address prevention of diabetes, peripheral arterial disease and other modifiable risk factors for amputation (45).

Additionally, a demonstration project testing the effectiveness of a care management model to prevent amputations in the civilian population should produce data that can be used to address the following questions:

- Does the presence of the program result in a statistically significant reduction in the rate of amputation?
- To what extent can the program improve amputation-free survival among individuals with diabetes or peripheral arterial disease and improve mortality rates within the current amputee population?
- Does the program improve patient-reported outcomes that measure treatment satisfaction, function and quality of life?
- To what extent does the program address health disparities regarding the rate of amputation?
- Are these results maintained for at least 5 years?
- What are the cost-benefits associated with the program?
- Can the program serve as a major national platform to improve amputee-related clinical research, by binding patients and providers together into a functional network?

Additionally, data collected during the course of a demonstration project to prevent amputation in at-risk populations would likely be able to address other research questions, including:

- What features contribute to racial disparities regarding incidence of amputation?
- What constellation of factors lead to amputation for one person but not another?

Resources required

- To recruit the best investigators and create innovative programs, significant resources will be needed to support a competitive funding for projects demonstrating the efficacy of prevention models.
- The resources necessary for a 5-year demonstration project are expected to be similar to those required for other model system programs. For example, each of the 16 centers with NIDRR's Traumatic Brain Injury Model System are supported by 5-year federal grants providing around \$500,000 per year per center (54). Thus, it is anticipated that resources on the order of \$300-500,000 per year for 5 years are required to support the development and implementation of limb loss prevention projects.
- Existing resources from the VHA's PACT programs, the Amputee Coalition and the Agency for Healthcare Research and Quality's Primary Care Practice-Based Research Networks (PBRNs) should be leveraged through partnerships with any institutions attempting to establish a demonstration project.
- The Amputee Coalition is a willing partner for any attempt to develop these resources and is uniquely positioned to address the subject of limb loss prevention.

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.

Recommendations

The Task Force made the following recommendations to reduce the number of preventable amputations in the United States.

1. Create competitive funding opportunities for demonstration projects in the civilian health care system designed to reduce the number of preventable amputations, prolong amputation-free survival among at-risk populations, reduce disability and impairment experienced by at-risk populations, improve health care quality and lower health care costs. The projects should consist of an interdisciplinary, coordinated care approach that emphasizes primary prevention to reduce the incidence of foot ulcers, impairment, amputation and disability. Appropriate funding opportunities would focus on improving patient outcomes among population at risk for amputation, work to prevent the development of amputation risk factors, and the use of health information technology to establish a comprehensive system of care for patients at risk of, and with, an amputation. Patients who develop a foot ulcer experience a 50% 5-year mortality rate, which underscores the importance of preventing diabetes (17). This model has shown promise within the VA's system (19).
2. Develop a media campaign encompassing all stakeholders, and engaging those individuals most at risk for limb loss (e.g., African Americans and Latino/as) and health care providers - especially primary care providers and those providers focusing on diabetes - to raise awareness about using established, evidenced-based approaches to preventing amputations due to complications from diabetes and vascular disease, emphasizing the importance of foot care. In order to be effective, such a media campaign would need to be a concerted effort encompassing multiple years and multiple media outlets, including traditional media (e.g., print advertising, radio, and TV) as well as new media (e.g., Twitter and other forms of social media). Emphasis would be placed on those media outlets that reach into racial and ethnic groups that experience higher incidence of diabetes and peripheral arterial disease, as well as amputation. Given the scope, this media campaign would require a substantial amount of funding.

2012 Limb Loss Task Force Participants

Thomas Biggs, MD	Physician Lead Vascular Medicine Program <i>Allina Health</i>
Marshall J. Cohen, PhD, JD	Chairman Board of Directors <i>The Amputee Coalition</i>
	Partner <i>Cohen & Perfetto, LLP</i>
David Crandell, MD	Physiatrist Spaulding Rehabilitation Hospital <i>Partners HealthCare</i>
	Instructor Department of Physical Medicine and Rehabilitation <i>Harvard Medical School</i>
	Member Scientific and Medical Advisory Committee <i>The Amputee Coalition</i>
Scott Cummings, PT, CPO, FAAOP	Prosthetist <i>Next Step Orthotics and Prosthetics</i>
	Past President <i>American Academy of Orthotists and Prosthetists</i>
	Member Scientific and Medical Advisory Committee <i>The Amputee Coalition</i>
Hugh J. Donohue, Jr., MD, MHA, FACS	Medical Director <i>Blue Cross Blue Shield of North Carolina</i>
Paulina N. Duker, MPH, RN, BC-ADM, CDE	Vice-President, Diabetes Education and Clinical Programs <i>American Diabetes Association</i>
Michael H. Fox, ScD	Associate Director for Science Division of Human Development and Disability (DHDD) National Center on Birth Defects and Developmental Disabilities (NCBDDD) <i>Centers for Disease Control and Prevention (CDC)</i>
Bruce M. Gans, MD	Executive Vice-President and Chief Medical Officer <i>Kessler Institute for Rehabilitation</i>
	National Medical Director for Rehabilitation <i>Select Medical Corporation</i>
	Professor Physical Medicine and Rehabilitation <i>University of Medicine and Dentistry of New Jersey</i> <i>New Jersey Medical School</i>

Alan T. Hirsch, MD	<p>Professor of Medicine, Epidemiology and Community Health Cardiovascular Division and Lillehei Heart Institute <i>University of Minnesota Medical School</i></p> <p>Director Vascular Medicine Program <i>University of Minnesota Medical Center</i></p> <p>Chair Science Committee and Critical Limb Ischemia Task Force <i>PAD Coalition, Vascular Disease Foundation</i></p>
Sue Kirkman, MD	<p>Senior Vice-President Medical Affairs and Community Information <i>American Diabetes Association</i></p>
Col. Tammy J. Lindsay, MD, FAAFP	<p>Clinical Associate Professor Family Medicine Residency <i>Saint Louis University</i></p>
Dina Moss, MA	<p>Program Analyst Center for Delivery, Organization and Markets <i>Agency for Healthcare Research and Quality</i></p>
Nancy Payne, RN	<p>Limb Loss Clinical Nurse Specialist Advanced Practice Nurse <i>Duke University Medical Center</i></p> <p>Member Scientific and Medical Advisory Committee <i>The Amputee Coalition</i></p>
Cindy Poorman, MSPT	<p>Rehabilitation Planning Specialist <i>U.S. Department of Veterans Affairs</i></p>
Kristjan Ragnarsson, MD	<p>Professor and Chair Rehabilitation Medicine <i>The Mount Sinai Hospital</i></p>
David Rippe, MD	<p>Physician Neuroscience Institute Abbott Northwestern Hospital <i>Allina Health System</i></p>
Jeffery M. Robbins, DPM	<p>Director Podiatric Service VACO <i>Louis Stokes Cleveland Veterans Administration Medical Center</i></p>
Carolyn Robinson, MSN, RN, CANP, CVN	<p>Nurse Practitioner <i>Veterans Administration Hospital - Minneapolis, MN</i></p> <p>President (Past) <i>Society of Vascular Nursing</i></p>
Theresa SanAgustin, MD	<p>Program Manager Spinal Cord Model Systems National Institute on Disability and Rehabilitation Research <i>U.S. Department of Education</i></p>

Mindy A. Smith, MD, MS	Professor Department of Family Medicine College of Human Medicine <i>Michigan State University</i>
Susan E. Spratt, MD	Assistant Professor of Medicine Department of Medicine Division of Endocrinology, Metabolism, and Nutrition <i>Duke University Medical Center</i>
Charlie Steele	Retired <i>IBM</i> Secretary Board of Directors <i>The Amputee Coalition</i> Member Scientific and Medical Advisory Committee <i>The Amputee Coalition</i>
Bob Thompson, CPed, BOCPD	Executive Director <i>Institute for Preventive Foot Health</i>
Kerry Watson, MBA	President Durham Regional Hospital
Joseph Webster, MD	Medical Director Servicemember Transitional Amputation Rehabilitation (STAR) Program <i>Hunter Holmes McGuire VA Medical Center - Richmond, VA</i>

Limb Loss Task Force Planning Committee

Terrence Sheehan, MD	Chief Medical Officer <i>Adventist Rehabilitation Hospital - Rockville, MD</i> Medical Director <i>The Amputee Coalition</i>
Stephen T. Wegener, PhD, ABPP	Associate Professor Director of Rehabilitation Psychology Department of Physical Medicine & Rehabilitation <i>Johns Hopkins University</i> Chair Scientific and Medical Advisory Committee <i>The Amputee Coalition</i>
Kendra Calhoun, MS	President & CEO <i>The Amputee Coalition</i>
Susan D. Stout, RN	Chief Communications Officer/Public Policy Director <i>The Amputee Coalition</i>
George Gondo, MA	Research and Analytics/Special Grants Manager <i>The Amputee Coalition</i>

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