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# Intervention to Decrease Race Related Disparities in Amputation Rates for Peripheral Arterial Disease

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## Introduction

Amputation is a devastating but preventable complication of diabetes and peripheral arterial disease (PAD). It is not only financially and emotionally costly, but it is also a marker for severe uncontrolled systemic disease. There is a significant racial disparity in amputation rates, with non-Whites comprising 42% of the limb loss population in the US (Coalition, 2012), and Blacks consistently undergoing leg amputations at rates that are 2-4 times higher than non-Hispanic Whites (Holman, Henke, Dimick, & Birkmeyer, 2011). Non-Whites are also more likely to present with critical limb ischemia (CLI), an end-stage form of PAD, and are more likely to present with gangrene, which increases the risk of amputation at least 10 fold.

In Chicago, the highly segregated nature of the city highlights this disparity issue. Chicago's South-side and West-side neighborhoods – with Black populations exceeding 50% – experience amputations for diabetes and vascular disease at rates that are 5 times higher than their North-side counterparts, where the non-Hispanic White populations exceeds 50% (Feinglass, Abadin, Thompson, & Pearce, 2008).

Current studies have not been able to fully elucidate the etiologies of this disparity, and at this point in time there have been no interventions designed at the community level to address it. Based on this information, we hypothesize that key interventions would decrease amputation rates and improve outcomes – specifically interventions directed at optimizing care for patients with diabetes and PAD and reducing delays in care for patients who have developed early symptoms of CLI. We also hypothesize that aiming such interventions at high-risk communities would significantly reduce the racial disparity in amputation rates.

As a team of vascular surgeons, medical specialists, and public health researchers dedicated to improving community health equity, we have a particular interest and stake in this

issue, particularly considering the *Healthy Chicago 2.0* goal to decrease the disparity in amputation rates in the city (Chicago Department of Public Health, 2016). Moreover, considering our location on the West/SouthWest side of Chicago, an area populated by Black and Hispanic patients, we are uniquely positioned to recruit and serve this particularly high-risk population.

The long-term goal of this research is to create an intervention that can be used in any high-risk community to effectively decrease amputation rates, thereby decreasing the overall amputation rate disparity. Other aims of this project include: increasing awareness of peripheral arterial disease and reducing its' prevalence in the community, collecting prospective data on vascular disease and critical limb ischemia, creating a self-sustaining intervention through community engagement.

## Background

### Epidemiology and Natural History of PAD and CLI

Peripheral arterial disease (PAD) is a chronic, disabling disease caused by the formation of atherosclerotic plaque (or blockages) in the lower extremities arteries. The disease affects 8 million men and women in the U.S. (Go, et al., 2013) and its' prevalence continues to grow as the population ages and risk factors persist. Risk factors for PAD include age, tobacco use, diabetes mellitus (DM), hypertension (HTN), hyperlipidemia, chronic kidney disease (CKD) and cardiovascular disease (CVD). Despite the ubiquitous nature of the risk factors for PAD in the U.S. population, there is a disparity in the prevalence of the disease between socioeconomic and racial groups. Data from the National Health and Nutrition Examination Survey (NHANES) demonstrated that the prevalence of PAD is significantly higher in individuals with low income

and lower education (Pande & Creager, 2014). Furthermore, NHANES also found that the prevalence of PAD is higher in non-Hispanic Black men and women and Mexican American women than in non-Hispanic White men and women (19.2%, 95% CI=13.7-24.6%; 19.3%, 95% CI=13.3-25.2%; and 15.6%, 95% CI=12.7-18.6% , respectively) (Ostchega, Paulose-Ram, Dillon, Gu, & Hughes, 2007).

According to the Trans-Atlantic Inter-Society Consensus (TASC) II document on the management of peripheral arterial disease, PAD presents in the following ways: It is asymptomatic in 20- 50% of patients; causes leg cramping during ambulation (known as claudication) with functional impairment and mobility loss in 10-40% of patients, and presents as critical limb ischemia (CLI) in 1-3% (Norgren, et al., 2007). CLI patients present with unremitting rest pain or tissue loss (ranging from a non-healing ulcer, to frank gangrene) of the affected extremity. The medical options for CLI are revascularization or amputation. Even with intervention, overall outcomes for CLI are dismal; at one year, 45% of CLI patients will be alive with both limbs, 30% will be alive with amputation and 25% will be dead (Norgren, et al., 2007). These outcomes denote the underlying severity of PAD in this patient population as well as the systemic underlying cardiovascular disease that is present (heart attack and stroke are the main causes of death in CLI patients). Unfortunately, PAD does not present in stages and there is no good data to predict which patients with PAD will progress on to CLI. However, patients who are able to modify their risk factors with smoking cessation, HTN, cholesterol and diabetes management are significantly more likely to have a benign course.

## CLI and Amputation Rate Disparities

Medical management for CLI is either revascularization using open or endovascular techniques, or amputation. For patients and practitioners, amputation is a highly undesirable outcome, leading to significant disability and psychological stress. Moreover, data in the vascular literature has found that long term survival for amputees is significantly less than in age matched controls, with approximate 1-year survival rates for below-the-knee amputations (BKA) cited at 65-80%, and 1-year survival rates for above-the-knee amputations (AKA) cited at 50% (Eidt & Kalapatapu, 2014).

As previously mentioned, there is a significant disparity in rates of major amputation (AKA or BKA) for PAD between non-Hispanic White patients and Black and Hispanic patients. Additionally, studies also show that non-Whites are significantly more likely to undergo primary amputation (that is, amputation without attempt at revascularization), rather than an attempt at revascularization, with odds ratios cited at 1.77 (95% CI, 1.23-1.65) (Durazzo, 2013) and 1.91 (95% CI, 1.65-2.20) (Eslami, Zayaruzny, & Fitzgerald, 2007).

The etiology of the racial disparity in amputation rates in patients presenting with CLI is multi-factorial and not fully understood. In a retrospective analysis of the National Inpatient Sample data from 2002-2008 by Durazzo, Frencher and Gusberg (2013), a multiple logistic regression analysis found that the following are independent risk factors for amputation versus revascularization (in descending order): The presence of gangrene (OR 11.22, 95% CI=10.89-11.56), redo of previous revascularization, non-Hispanic Black race (OR 1.77, 95% CI=1.72-1.84), Medicaid status, residence in poorest 25% of zip codes, Medicare status, CKD, Hispanic race (OR 1.09, 95% CI=1.03-1.15), DM and female sex (OR 1.04, 95% CI=1.01-1.07). The same

study found that non-Whites presenting with CLI are significantly more likely to present with diabetes and CKD, and to present with gangrene than non-Hispanic Whites (these findings have been corroborated throughout the literature).

## Conceptual Model

To fully understand the etiologies leading to the amputation rate disparity in patients presenting with CLI, a conceptual model is useful to focus on the multiple upstream and downstream factors leading to this outcome. In the upstream model (figure 1a), the social determinants of health, combined with potential genetic susceptibility lead to an increase in the incidence of chronic diseases and behaviors which are known risk factors for PAD. This model then demonstrates the role of access to care, delay in care and the non-adherence to risk factor modification in developing CLI. In the downstream model, the same risk factors play a role, however the factors that effect the risk of amputation versus revascularization come into play, these factors include the extent of disease at presentation (which is a delay of care issue) as well as the anatomic distribution of the disease (tibial disease is much more difficult to revascularize and are the main blood vessels affected by diabetes and CKD). Finally, the potential for physician and patient bias (Institute of Medicine, 2003) as well as access to care at a specialized center will affect the final pathway between CLI, amputation and revascularization.

## Methods

### Setting

This project will be focused on the Southwest and West Side communities of Chicago, which are among the highest risk communities for CLI and amputation. The intervention will be set both on the community level and at a major academic center (Rush University). Proposed

community partners include the Westside Health Authority (WHA) in the Austin community and Esperanza Health Centers on the Southwest side.

**Recruitment**

The recruitment process will occur at the community level and the provider level (both community and academic). In the community, recruitment efforts will be made at community centers, churches, health fairs, community hospitals and community health centers. Local radio and newspaper also are medium for recruitment. We will recruit patients with risk factors for PAD, a known diagnosis of PAD, a history of CLI or CLI related amputation, and diabetes.

For provider recruitment, visits and meetings will be coordinated with providers at WHA and Esperanza Health Centers. Each site will require a champion to create a quality improvement team consisting of clinicians, staff members and community members to lead the intervention. Further provider recruitment will be performed at the hospital level by creating specialty teams for limb salvage. These teams, referred to as "toe and flow" are anchored by podiatry and vascular surgery specialists and may be complemented by endocrinologists, infectious disease physicians and general surgeons.

**Measures**

Prospective data on patients recruited for the intervention will document co-morbidities, demographic data, age and race. The primary outcomes to be measured are hospitalization for vascular disease complications (typically hospitalization for PAD or CLI or diabetes-related leg wound), revascularization for CLI and major amputation. Secondary outcomes include occurrence of ulcers, hospitalization for ulcers, minor amputation, MI, stroke or death.

The proposed length of this study will be 4 years (to match the goal of the *Healthy Chicago 2.0*). At the end of the study time, the Illinois Department of Public Health (IDPH) database of hospital discharges in all 9 counties of Northern Illinois will be analyzed (in a retrospective fashion). This data will be categorized by zip code, allowing for an update of Feinglass et al.'s 2008 data. The amputation rates of the Southwest and West side patients in the IDPH data will be matched against the amputation rates of the patients in our intervention, allowing us to assess for efficacy of the intervention, decreases in amputation rates and disparity reduction.

## Intervention

Our intervention couples a preventative health care approach with a specialized, academic limb salvage center approach by using collaborative, community health strategies to coordinate care.

### Preventative Care

The preventative care program design combines the "comprehensive lower extremity amputation prevention (LEAP) program" designed by the U.S. Department of Health and Human Services (http://www.hrsa.gov/hansensdisease/leap/) with Rith Najarian et al's (1998) SDM (staged diabetes management) program.

The LEAP program is a 5-step program including:

1) An annual foot exam to identify neuropathy and vascular disease
2) Patient education
3) Daily self-inspection

4) Proper footwear selection
5) Early attention to simple foot problems.

Such a program was applied to low-income African American populations in Louisiana in the Louisiana state health system, resulting in a 79% decrease in amputations (Patout Jr., Birke, Horswell, Williams, & Cerise, 2000).

The staged diabetes management program complements and formalizes the LEAP initiatives by implementing screening, diagnostic, and treatment guidelines at each health center. The program provides criteria for risk factor assessment, diagnosis, treatment options, therapeutic targets, monitoring and follow up (see appendix A for a flow sheet from the original SDM). This program would run in conjunction with diabetes and cardiovascular risk factor modification and be part of the quality improvement teams at the community health centers.

**Specialty Care/Acute Care**

The vascular surgery and podiatry societies agree that the creation of a multidisciplinary limb salvage team at hospitals is key to reducing amputation rates. Studies have cited reductions in amputation rates by 36%-86% with multidisciplinary teams (Sanders, Robbins, & Edmonds, 2010). The team is anchored by a vascular and podiatry partnership, allowing for management of both the arterial and wound care aspects (also known as "Toe and Flow") of limb salvage. The team can also involve endocrinology, infectious disease and general surgeons and/or plastic surgeons. (Bharara, et al., 2010). In our intervention, our goal will be to build a strong anchor with podiatry and vascular, and add the above specialists as recruiting allows. Our team will also have a vascular team nurse and nurse practitioner (or physician assistant), as well as a nutritionist and social worker to coordinate resources for patients.

## Implementation

The model used to implement this intervention will follow the model used by Peek et al. for the South Side Diabetes Intervention (an application of the MacColl Institute's Chronic Care Model) which includes: Quality improvement collaborative, patient activation, provider training, community partnerships and outreach (Peek, et al., 2012).

### Quality improvement collaborative.

The first component of this model requires the creation of a quality improvement teams at each community health center site to implement the preventative care protocol and to ensure that best practices for risk factor modification is being followed at the center. The team will be supervised/"coached" by members of the research and implementation team of the project and is to be composed of clinicians, clerical staff members and leaders. The team will meet quarterly to assess progress, set goals and identify barriers. This is a natural fit for diabetic champion teams (as limb amputation is a quality measure that is being tracked by these teams) that already exist and can be created in conjunction with these programs.

### Patient activation.

This begins with basic foot care education for low risk patients, and intensifies with patients identified as high risk. High-risk patients are classified as those with evidence of neuropathy, foot deformity or ulcer history. These patients will be identified in annual diabetic and PAD foot care exams and will be put into a higher level of surveillance, given protective foot care and have more emphasis on risk factor modification. The high-risk patients will also be invited to participate in a diabetes and foot care educational program with other high-risk patients aimed at managing their risk factors (diabetes, HTN, hypercholesterolemia, tobacco use)

and providing cultural competent education. Part of the education program will also include training in shared decision making as this model has been shown to improve outcomes in diabetic patients and should be generalizable to the PAD population (Peek, et al., 2009).

**Provider training.**

This involves initial training and assessments at regular intervals led by the quality collaborative team. Provider training in improving communication, performing shared decision making and cultural competency (and bias) training also falls into this area. Both the hospital based and community based providers must be trained in these aspects.

**Community partnerships and outreach.**

This is the community engagement portion of the intervention and will engage the community at the following levels:

***Primary Care Providers.***

Outside of the health centers involved in the intervention, we will reach out to other primary care providers in the area to improve awareness and education on PAD and provide resources for preventative care, as well as referrals to our centers as needed.

***Community groups.***

We will reach out at health fairs and go out to community health centers (such as the diabetes empowerment center in Humboldt Park http://www.paseoboricua.org/member-businesses/greater-humboldt-park-diabetes-empowerment-center/) to do "save a limb/save a life" education (appendix B). We will also reach out to church groups and amputation support groups. In addition to education, we will also organize free screening programs for PAD to identify

people at risk. Ultimately, our goal is to build long-term relationships with strong community partners.

***Institutions.***

At Rush, we will partner with the Rush/DePaul Center for Community Health Equity (http://www.healthequitychicago.org) and the Rush Oak Park wound care center. At the community level, we are working with the WHA and Esperanza Health Centers to plan and execute the intervention. We will also reach out to Dr. Peek and Dr. Chin's team at the Southside Diabetes Initiative on the South side of Chicago (http://southsidediabetes.com/) as they have had significant success with their diabetes community intervention (Chin, Goddu, Ferguson, & Peek, 2014).

***Media.***

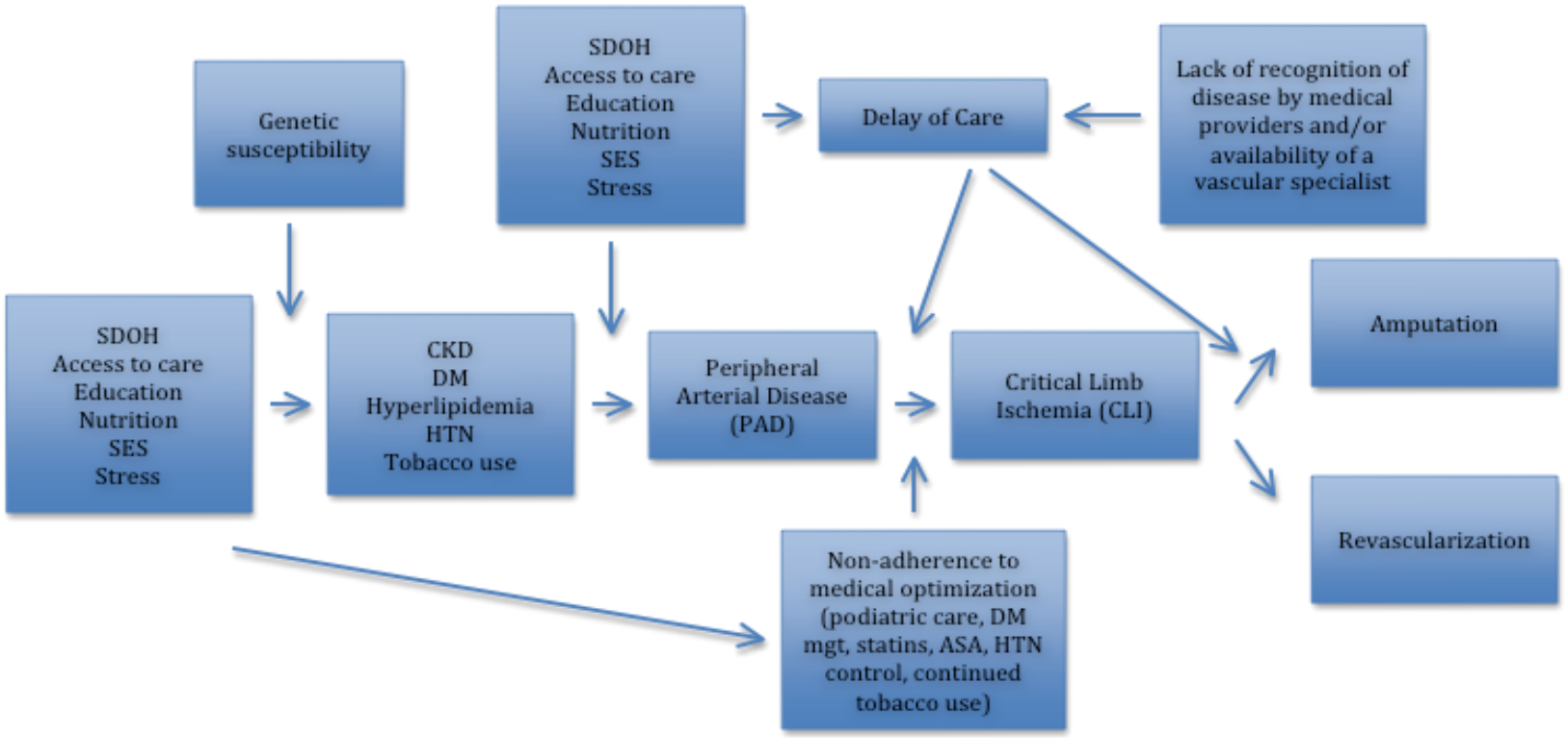
We will participate on panels on amputation prevention discussions on local radio stations such as WVON, as well as local television programming. Social media will also be addressed as a potential resource.

## Conclusions

The racial disparity in amputation rates in patients with PAD is a well-documented and significant issue in the United States. In order to reduce this disparity, aggressive preventative care plans must be in place in the community, and community providers must have ready access to specialized limb salvage teams in hospitals. The key to the success of this project is to bridge the communication gap between community providers and hospital providers while engaging the community to provide a more comprehensive and sustainable amputation prevention plan. With this comprehensive and integrative approach in place, we hope to significantly reduce the

disparity in amputation rates in the high risk communities of Chicago, and to create a model that can be applied to high risk communities across the country.

Figure 1a: Upstream Factors Leading to Critical Limb Ischemia
(SDOH: Social Determinants of Health, SES: Socioeconomic Status, CKD: Chronic Kidney Disease, HTN: Hypertension, DM: Diabetes)



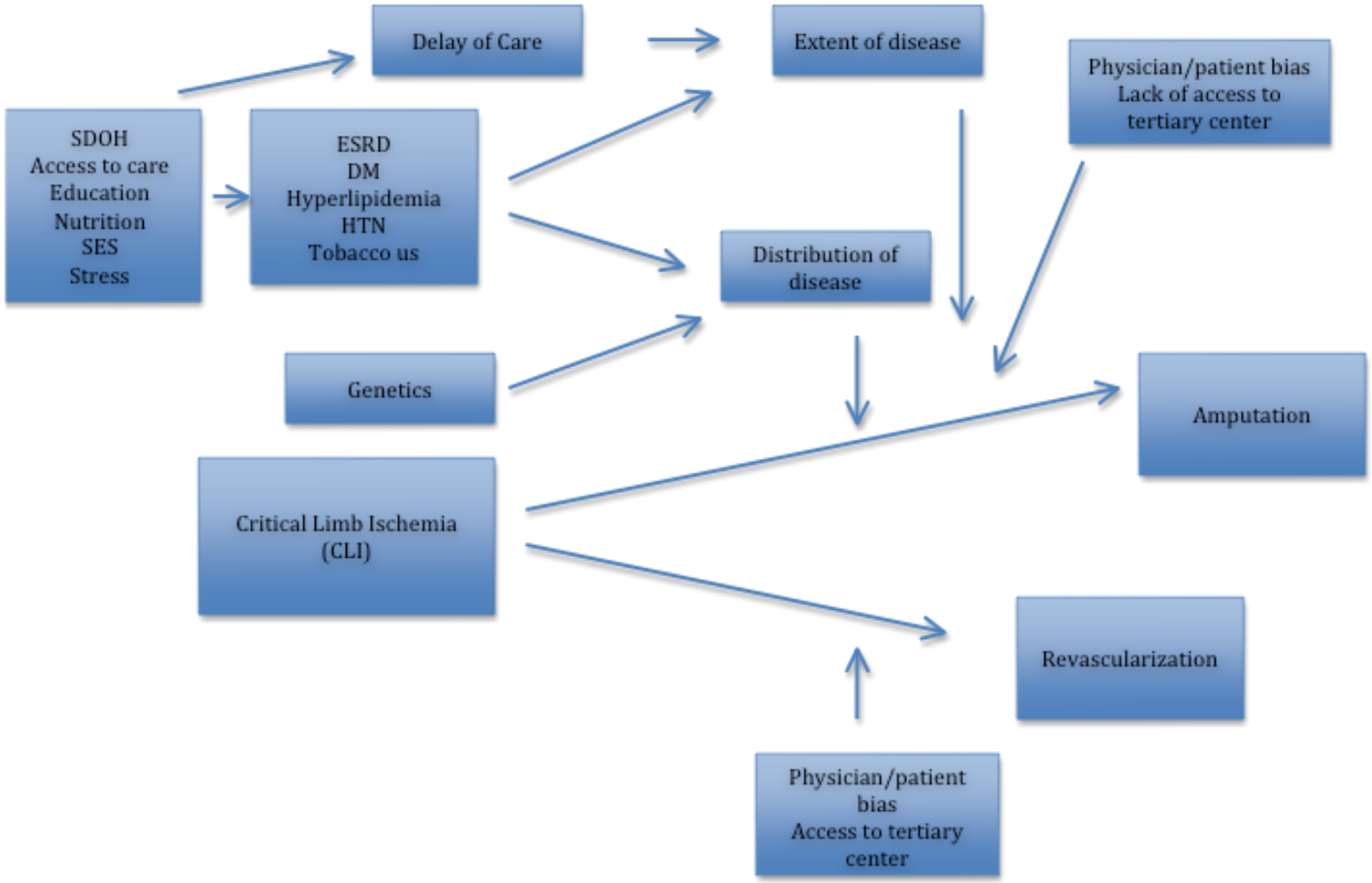
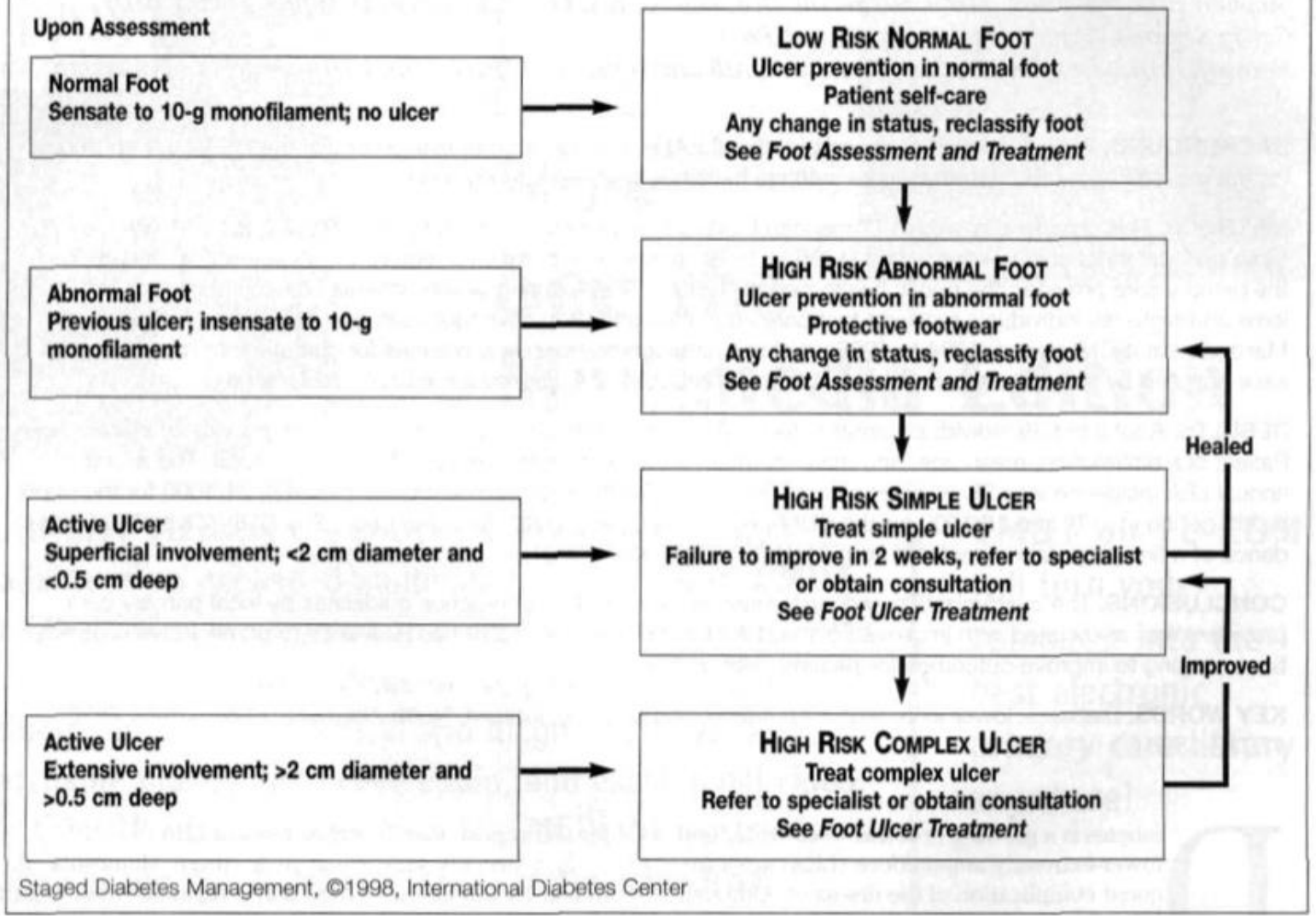



Figure 1b: Downstream Factors Leading to Amputation versus revascularization

**FIGURE**

**Practice Guidelines: Diabetic Foot Management**




Staged Diabetes Management, ©1998, International Diabetes Center

# LEGS FOR LIFE

**DO YOU OR SOMEONE *YOU* LOVE HAVE:**

- DIABETES
- HIGH BLOOD PRESSURE
- HIGH CHOLESTEROL
- HEART DISEASE
- A HISTORY OF SMOKING

**YOUR LEGS MAY BE AT RISK**

Vascular Surgeons are also experts in treating

- Peripheral Arterial Disease
- Carotid Stenosis
- Varicose Veins and Venous Ulcers
- Aortic and Arterial Aneurysms

THE UNIVERSITY OF CHICAGO MEDICAL CENTER

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