

a cascade of events

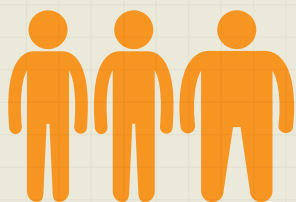
DIABETIC FOOT ULCERS

EVIDENCE-BASED MEDICINE

OBESITY IN AMERICA

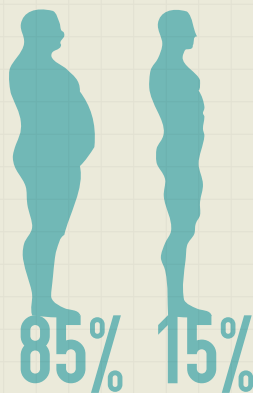
Obesity in the U.S. has reached epidemic levels and poses a continued threat to public health. For millions of Americans this condition leads to dangerous comorbidities and costly treatments. Because there is no single cause of obesity, the condition remains difficult to both prevent and treat.

About 1/3 of U.S. adults are OBESE¹



Obesity related conditions include^{3,4}

-  HEART DISEASE
-  STROKE
-  TYPE 2 DIABETES
-  HIGH CHOLESTEROL
-  SLEEP APNEA
-  OSTEOARTHRITIS
- & certain types of*
-  CANCER



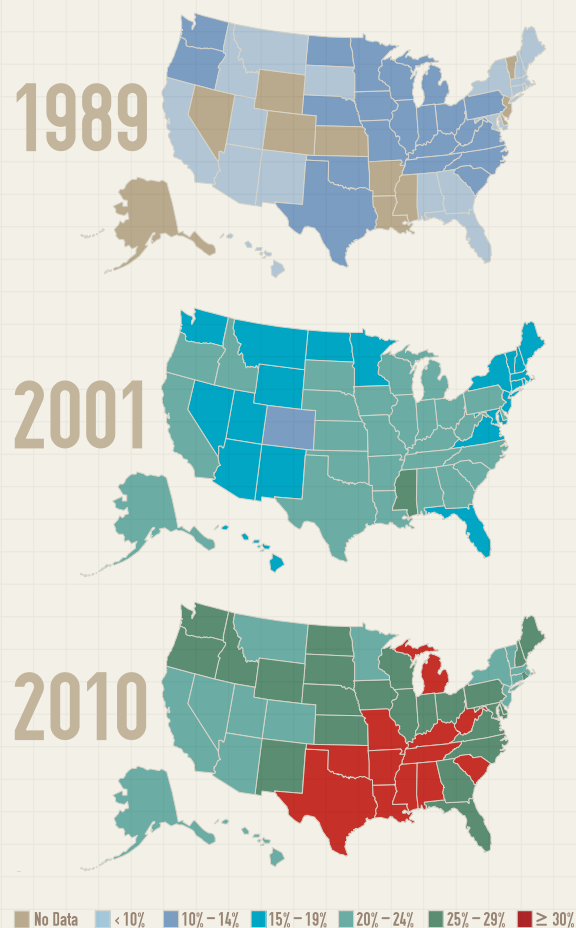
More than 85% of people who have TYPE 2 DIABETES are OVERWEIGHT⁵

In 2010, obesity prevalence was 30% or more in 12 states²

OBESITY TRENDS^{*} Among US Adults, BRFSS²

Behavioral Risk Factor Surveillance System

**BMI ≥ 30, or ~30 lbs. overweight for 5' 4" person*



AN EPIDEMIC OF DIABETES

There is a strong correlation between people who suffer from obesity and people who develop type 2 diabetes. Consequently, as the obesity epidemic has grown in recent years, the incidence of type 2 diabetes has also increased across populations. Those who develop this condition can be affected by debilitating complications, and higher health care costs.

Diabetes was the



in the U.S. in 2007³

In 2010, there were approximately
26 MILLION PEOPLE in the U.S. WITH DIABETES



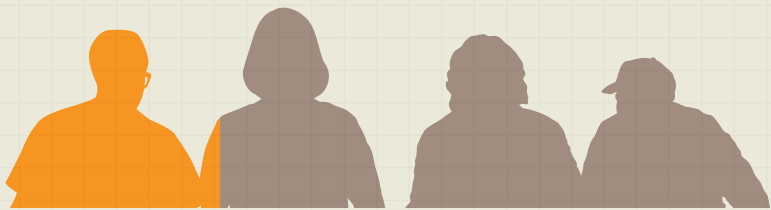
& nearly **7 MILLION** of those were **UNDIAGNOSED**³



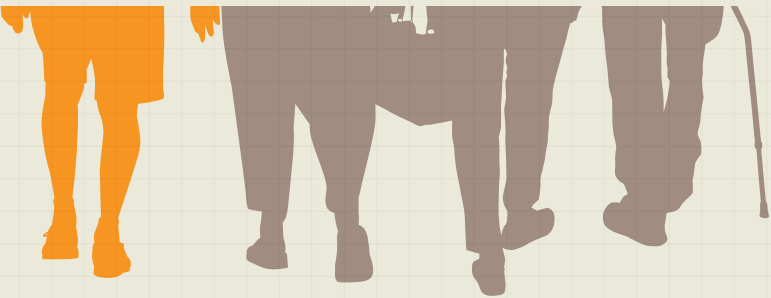
In 2011, in adults (20-79 years),
diabetes caused at least

\$465 BILLION
in HEALTHCARE EXPENDITURES

11% of TOTAL HEALTHCARE
EXPENDITURES⁵



26.9% U.S. residents
AGED 65 & OLDER HAVE DIABETES³



BY 2030 the number of
PEOPLE WITH DIABETES GLOBALLY

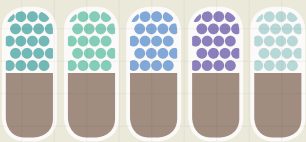


WILL RISE
to an estimated
552 MILLION⁶

Complications of diabetes include, but are not limited to³

HEART DISEASE & STROKE	Both the risk for stroke and heart disease related deaths are 2 to 4 times higher in adults with diabetes
HYPERTENSION	In 2005-2008, 67% of adults with diabetes had high blood pressure or used prescription medications for hypertension
BLINDNESS & EYE PROBLEMS	Diabetes is the leading cause of new cases of blindness among adults aged 20-74 years
KIDNEY DISEASE	Diabetes was the leading cause of kidney failure, accounting for 44% of all new cases of kidney failure in 2008
NERVOUS SYSTEM DISEASE	About 60% to 70% of diabetics have some form of nervous system damage
LOWER-LIMB AMPUTATIONS	Nearly 30% of all people with diabetes 40 years or older have impaired sensation in their feet

Patients with diabetes



take an average of **4-5 MEDICINES A DAY**^{10, 11}

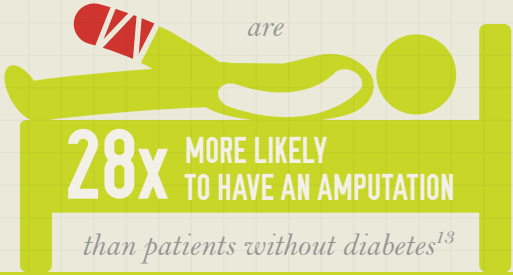


Diabetes greatly compounds
A POOR QUALITY OF LIFE
associated with other diseases^{8,9}



A person with diabetes
has about
TWICE THE RISK OF DYING
as a person of similar age
without diabetes³

Hospitalized Patients
WITH DIABETES
are

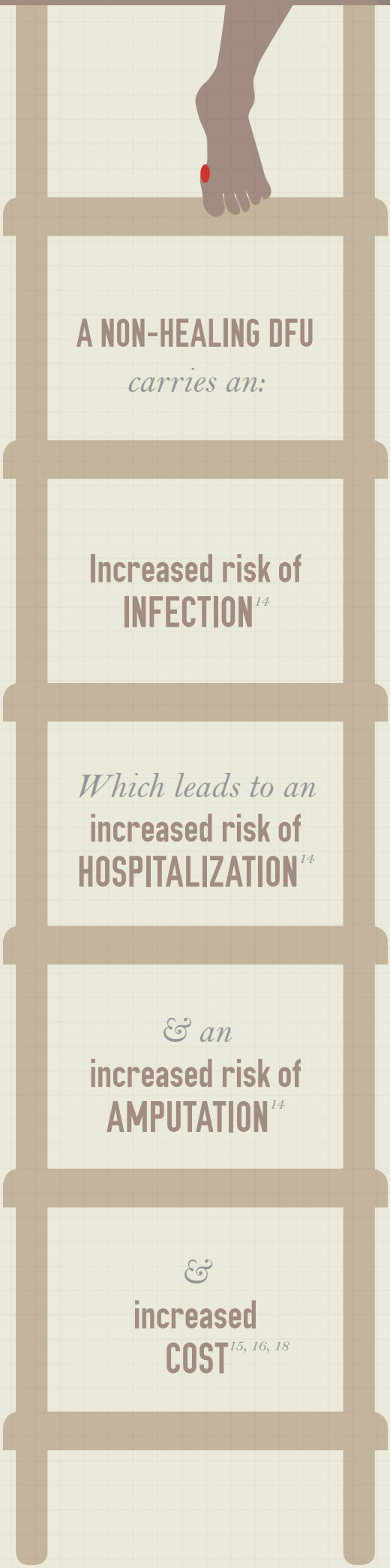


28x MORE LIKELY
TO HAVE AN AMPUTATION
than patients without diabetes¹³

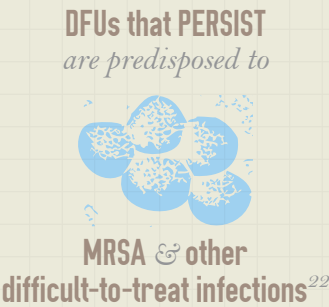
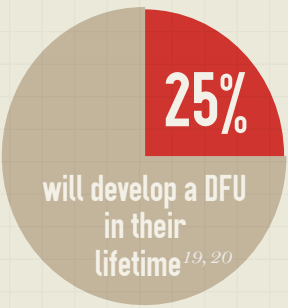
More than
60% of all non-traumatic LIMB AMPUTATIONS
in the U.S. occur in people WITH DIABETES³

A SERIOUS COMPLICATION

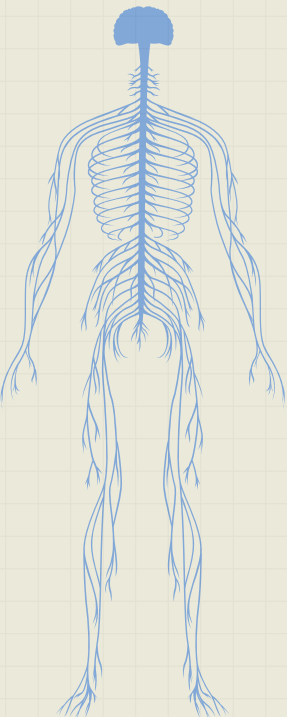
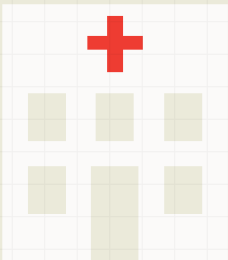
Nearly a quarter of people with diabetes will develop a diabetic foot ulcer (DFU). Despite the prevalence and disabling consequences of a DFU, many lack awareness of this serious diabetic complication. DFUs open the door for infection; the longer the DFU persists, the greater the risk of hospitalization and infections like MRSA. Diabetic patients with a DFU are at significantly increased risk for amputation and loss of life.



Among all people with diabetes, UP TO 4% ANNUALLY will develop a DFU &



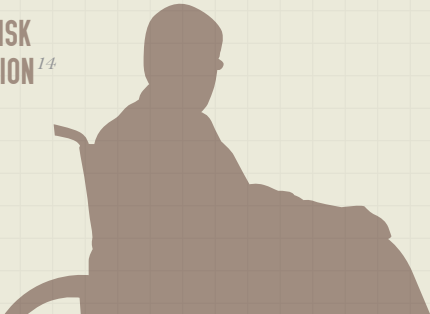
Patients who develop an INFECTED diabetic foot ulcer have a



PERIPHERAL VASCULAR DISEASE & NEUROPATHY are major contributing factors to diabetic foot ulcers¹⁷



Presence of a DFU for 30 DAYS or longer carries 4-fold risk of infection¹⁴

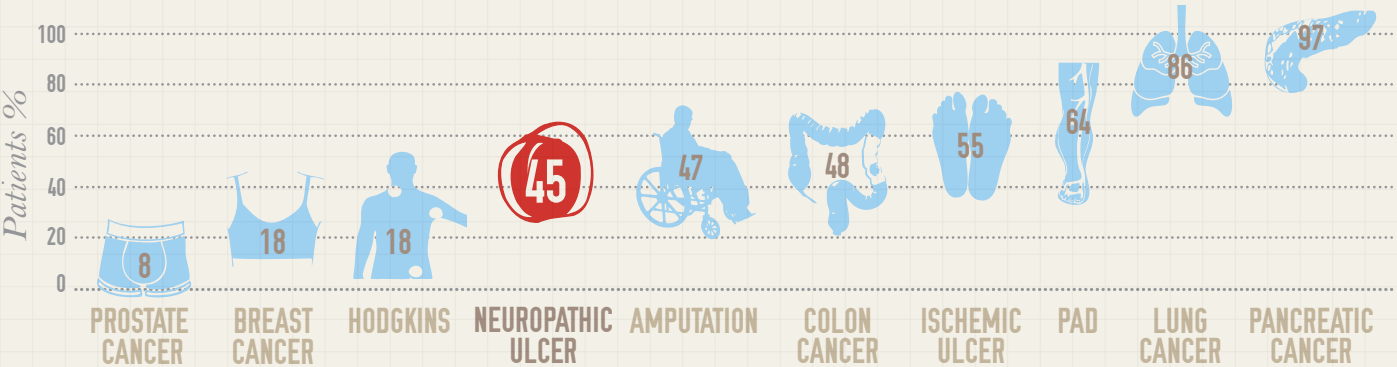


85% of lower limb amputations in patients with diabetes ARE PRECEDED BY ULCERATION^{19, 20, 23}



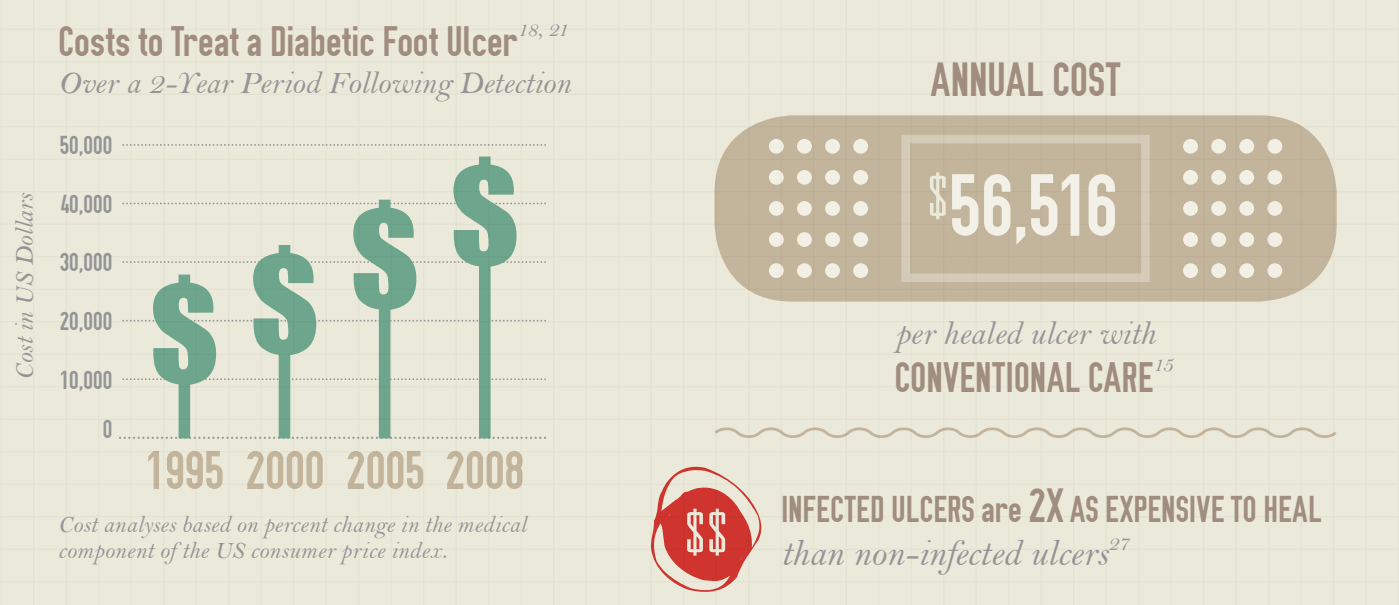
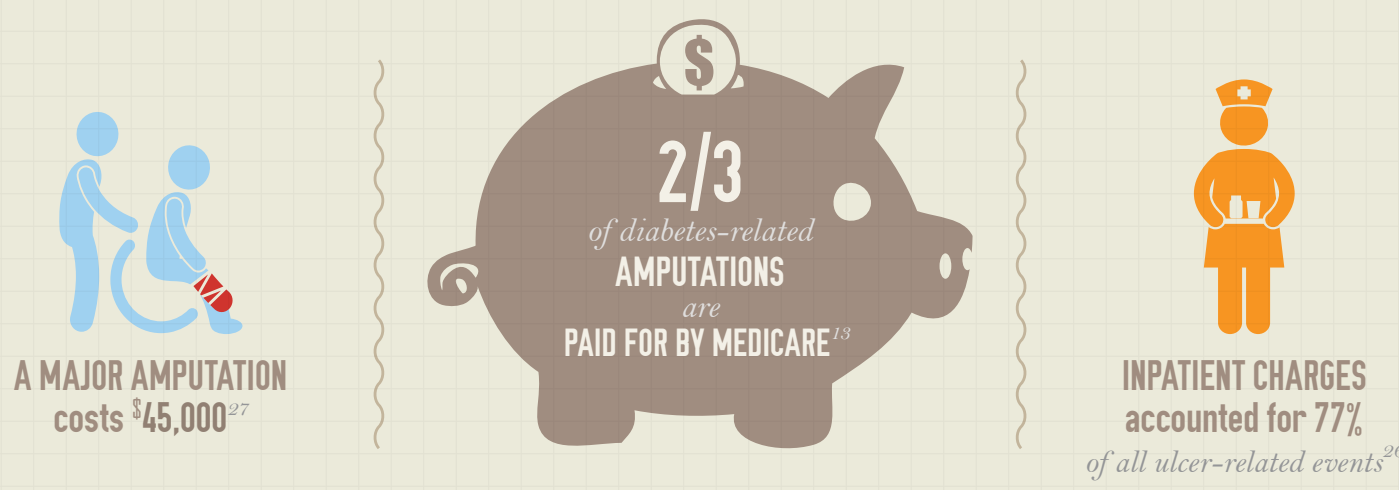
In patients with diabetes, HISTORY of a foot ulcer alone INCREASED MORTALITY RISK BY 47%²⁴

5-YEAR MORTALITY RATES²⁵



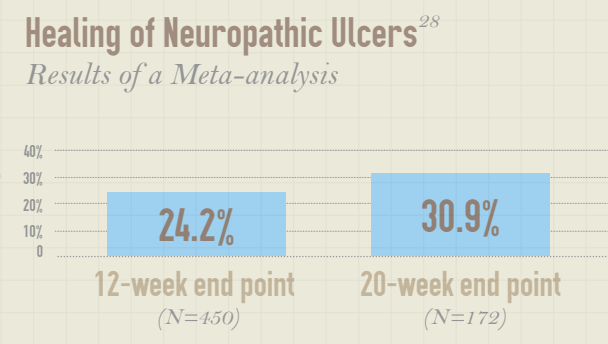
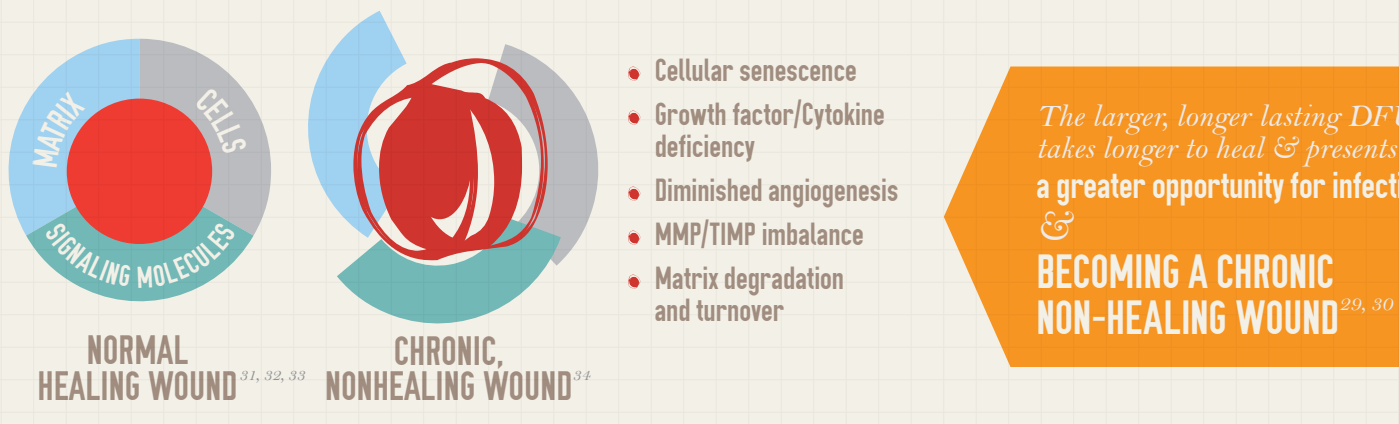
COST REALITIES

The magnitude of the challenge is reflected in the high cost of treatment. The economic burden of DFUs and the complications arising from them are enormous. One of the most important cost-saving considerations in caring for the patient with a DFU is expeditious and complete wound healing to avoid serious complications.



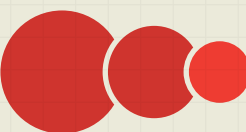
THE CHRONIC ULCER

Diabetic foot ulcers often fail to heal because persistently high concentrations of pro-inflammatory cytokines in the wound induce high concentrations of proteases, which degrade multiple growth factors, receptors, and matrix proteins that are essential for wound healing. Even with good, standard wound care, healing neuropathic ulcers in patients with diabetes continues to be a challenge.



A meta-analysis of 10 control groups in clinical trials evaluating treatments for diabetic neuropathic foot ulcers revealed that approximately 70% of DFUs are slow to heal (only 24% and 31% of ulcers heal after 12 and 20 weeks of good wound care, respectively).

CONSENSUS RECOMMENDATIONS³⁵



“Expeditious and complete wound healing is the definitive goal in treating diabetic foot ulcers.”

“The panel recognizes the prognostic value of 50% area reduction of the wound at four weeks and recommends utilization of this parameter as a clinical decision point.”

REFERENCES

- 1 Prevalence of Overweight, Obesity, and Extreme Obesity Among Adults: United States, Trends 1960–1962 Through 2007–2008. Centers for Disease Control website. Available at http://www.cdc.gov/NCHS/data/hestat/obesity_adult_07_08/obesity_adult_07_08.pdf. Accessed 8 February 2012.
- 2 Obesity Trends Among US Adults between 1985 and 2010. BRFSS, Centers for Disease Control website. Available at http://www.cdc.gov/obesity/downloads/obesity_trends_2010.ppt. Accessed 25 January 2012.
- 3 National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States, 2011. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011. Available at http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf. Accessed 8 February 2012.
- 4 F. Xavier Pi-Sunyer MD, MPH and the NHLBI Obesity Education Initiative Expert Panel on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults – The Evidence Report. The National Institutes of Health National Heart, Lung, and Blood Institute. NIH Publication No. 98-4083 September 1998. Available at: http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.htm
- 5 The Weight-control Information Network (WIN), National Institute of Diabetes and Digestive and Kidney Diseases. Do You Know the Health Risks of Being Overweight? US Department of Health and Human Services. 2007. Available at: http://win.niddk.nih.gov/publications/health_risks.htm#type2
- 6 The International Diabetes Foundation, IDF Diabetes Atlas, 5th ed.: <http://www.idf.org/diabetesatlas/5e/the-global-burden> (Accessed 2-23-12)
- 7 Adapted from the IDF Diabetes Atlas, 5th ed. International Diabetes Federation, 2011. Available at <http://www.idf.org/diabetesatlas/5e/the-global-burden>. Accessed 17 January 2012.
- 8 Sprangers MA, de Regt EB, Andries F, et al. Which chronic conditions are associated with better or poorer quality of life? *J Clin epidemiol*. 2000;53:895- 907.
- 9 Wee H-L, Cheung Y-B, Shu-Chuen Li I, Kok-Yong Fong K-Y, Thumboo J. The impact of diabetes mellitus and other chronic medical conditions on health-related Quality of Life: Is the whole greater than the sum of its parts? *Health and Quality of Life Outcomes* 2005, 3:2
- 10 Leichter S, Faulkner S, Camp J. On the Cost of Being a Diabetic Patient: Variables for Physician Prescribing Behavior. *Clinical Diabetes*. 2000;18(1):42-3.
- 11 Chester B. Good, MD, MPH. Polypharmacy in Elderly Patients With Diabetes. *Diabetes Spectrum*. 2002;15(4):240-248.
- 12 Diabetes Successes and Opportunities for Population-Based Prevention and Control, Centers for Disease Control website. Available at <http://www.cdc.gov/chronicdisease/resources/publications/AAG/ddt.htm>. Accessed 8 February 2012.
- 13 Economic and Health Costs of Diabetes. U.S. Department of Health & Human Services website. Available at <http://archive.ahr.gov/data/hcup/highlight1/high1.htm>. Accessed 8 February 2012.
- 14 Lavery LA, Armstrong DG, Wunderlich RP, et al. Risk factors for foot infections in individuals with diabetes. *Diabetes Care*. 2006;29:1288-93.
- 15 Zhang Y, Hogan P. Cost effectiveness of a human fibroblast-derived dermal substitute for the treatment of diabetic foot ulcers in Medicare and commercially insured populations. *Diabetes*. 2011;60(suppl 1A):LB15-LB16.
- 16 Harrington C, Zagari MJ, Corea J, Klitenic J. Cost Analysis of Diabetic Lower Extremity Ulcers. *Diabetes Care*. 2000;23(9):1333-1338
- 17 Ndip A, Rutter MK, Vileikyte L, et al. Dialysis treatment is an independent risk factor for foot ulceration in patients with diabetes and stage 4 or 5 chronic kidney disease. *Diabetes Care*. 2010;33:1811-6.
- 18 Ramsey SD, Newton K, Blough D, et al. Incidence, outcomes, and cost of foot ulcers in patients with diabetes. *Diabetes Care*. 1999;22:382-7.
- 19 Singh N, Armstrong DG, Lipsky BA. Preventing Foot Ulcers in Patients With Diabetes. *JAMA*. 2005;293(2):217-228
- 20 Reiber GE. Epidemiology of foot ulcers and amputations in the diabetic foot. In: Bowker JH, Pfeifer MA, eds. *The Diabetic Foot*. St Louis, Mo: Mosby; 2001:13-32.
- 21 Don Peltó, DPM, Central Massachusetts Podiatry, PC, Worcester, MA. Diabetic Foot Complications: Current Treatments and Advanced Therapies in Treating the Diabetic Foot. <http://www.slideshare.net/donpeltó/diabetic-foot-lecture-2010-3294772>
- 22 Yates C, May K, Hale T, et al. Wound chronicity, inpatient care, and chronic kidney disease predispose to MRSA infection in diabetic foot ulcers. *Diabetes Care*. 2009;32:1907-9.
- 23 American Diabetes Association. Consensus development conference on diabetic foot wound care, 7-8 April 1999; Boston, MA. *Diabetes Care*. 1999;22:1354-60.
- 24 Iversen MM, Tell GS, Riise T, et al. History of foot ulcer increases mortality among individuals with diabetes: ten-year follow-up of the Nord-Trøndelag Health Study, Norway. *Diabetes Care*. 2010;33:2365-9.
- 25 Armstrong DG, Wrobel J, Robbins JM. Guest editorial: are diabetes-related wounds and amputations worse than cancer? *Int Wound J*. 2007;4(4):286-287.
- 26 Stockl K, Vanderplas A, Tafesse E, et al. Costs of lower extremity ulcers among patients with diabetes. *Diabetes Care*. 2004; 27: 2129-34.
- 27 Kruse I & Edelman S. Evaluation and treatment of diabetic foot ulcers. *Clinical Diabetes*. 2006;24(2):91-93.
- 28 Margolis DJ, Kantor J, Berlin JA. Healing of diabetic neuropathic foot ulcers receiving standard treatment. A meta-analysis. *Diabetes Care*. 1999; 22(5):692-695.
- 29 Zimny S, Voigt A, Schatz H, Pföhl M. Prediction of Wound Radius Reductions and Healing Times in Neuropathic Diabetic Foot Ulcers. *Diabetes Care*. 2003;26(3): 959-960.
- 30 Sheehan P, Jones P, Caselli A, Giurini JM, Veves A. Percent Change in Wound Area of Diabetic Foot Ulcers Over a 4-Week Period Is a Robust Predictor of Complete Healing in a 12-Week Prospective Trial. *Diabetes Care*. 2003; 26:1879 –1882.
- 31 Falanga V. Wound healing and its impairment in the diabetic foot. *Lancet*. 2005;366(9498):1736-1743.
- 32 Barrientos S, Stojadinovic O, Golinko MS, et al. Growth factors and cytokines in wound healing. *Wound Repair Regen*. 2008;16(5):585-601.
- 33 Hunt TK, Hopf H, Hussain Z. Physiology of wound healing. *Adv Skin Wound Care*. 2000;13(Suppl 2):6-11
- 34 Menke NB, Diegelmann RF, Ward KR. Non-healing wounds. *Emer Med Rep*. 2007;28(4):38-48.
- 35 Snyder RJ, Kirsner RS, Warriner RA, et al. Consensus recommendations on advancing the standard of care for treating neuropathic foot ulcers in patients with diabetes. *Ostomy Wound Manage*. 2010;56(4 suppl):S1-S24.

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