

IMPORTANCE OF INCLUDING A WOUND CARE CLASSIFICATION ON THE USP DRUG CLASSIFICATION

PRESENTED TO USP BY THE ALLIANCE OF WOUND CARE STAKEHOLDERS

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October 6, 2020

ABOUT OUR SPEAKERS

➤ Marcia Nusgart R.Ph.

- Founder and Executive Director of Alliance of Wound Care Stakeholders and Coalition of Wound Care Manufacturers
- Highly regarded in the wound care industry- over 25 years experience in the wound care industry and is highly sought after speaker both at national and international conferences
- Worked in trade associations- AdvaMed and National Community Pharmacist Association and in the chain drug store industry
- Received Pharmacy degree from the Ohio State University; serves on many Boards

➤ Matthew G. Garoufalis, DPM, FASPS, FACPM,CWS

- Past President – American Podiatric Medical Association
- Past President – International Federation of Podiatrists
- Co-Chair and Board Member – Alliance of Wound Care Stakeholders
- Fellow Faculty of Podiatric Medicine – Royal College of Physicians and Surgeons of Glasgow
- An award winning researcher, author, and invited speaker, both nationally and internationally; He is considered a Key Opinion Leader in many areas

ALLIANCE OF WOUND CARE STAKEHOLDERS

➤ Who is the Alliance?

- *A non-profit multidisciplinary trade association of physician specialty societies, clinical associations and patient organizations whose members treat or are patients with wounds*
- *Created to have a unified voice for wound care when speaking with regulatory agencies and legislative bodies*
- *The go-to resource for government and private payers and decisionmakers to access knowledge from experts in complex chronic wounds*

➤ Mission of the Alliance:

- *To promote quality care and access to wound care products and services for people with wounds*
- *Focus on compelling issues of commonality to the organizations in the reimbursement, government and public affairs affecting wound care*

➤ www.woundcarestakeholders.org

- *Workplan, Comments, Achievements of the Alliance, COVID-19 Action Center*

CLINICAL ASSOCIATION MEMBERS

- Academy of Nutrition and Dietetics
- American Association of Nurse Practitioners
- American Board of Wound Medicine and Surgery
- American College of Foot & Ankle Surgeons
- American College of Hyperbaric Medicine
- American Diabetes Association® Interest Group on Foot Care
- American Physical Therapy Association
- American Podiatric Medical Association
- American Professional Wound Care Association
- American Vein and Lymphatic Society (formerly ACP)
- American Venous Forum
- Amputee Coalition
- Association for the Advancement of Wound Care
- Elevating Home (Visiting Nurses Association of America)
- National Lymphedema Network
- Society for Vascular Medicine
- Society for Vascular Surgery
- Undersea & Hyperbaric Medical Society
- Wound Healing Society
- Wound Ostomy and Continence Nurses Society (WOCN®)

FOUNDATIONS OF ALLIANCE WORKPLAN

- **Reimbursement Issues-** Coverage, Coding and Payment
 - Submit comments to CMS and its contractors (MACs)
 - Serve as resource to CMS coverage, coding and payment staff for education about wound care
- **Regulatory/Legislative Issues** – Work with Congress, FDA, MedPAC, AHRQ, PCORI, GAO
- **Wound Care Quality Measures**
- **Wound Care Research**
 - “An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds” (2017 Value in Health)
 - “Harnessing Big Data for Wound Healing Research” (2016 ISPOR presentation)
 - “Consensus Principles for Wound Care Research Obtained Using a Delphi Process” (the “POWER” paper, published in 2012)

AGENDA

- What Types of Wounds do Wound Care Practitioners Treat?
- Compelling Information About Wound Care
- Economic Impact of Chronic Wounds
- Importance of Continued Access to Wound Care Treatments from a Provider's Perspective
- Need for Including a Unique Wound Care Classification in the USP DC
- Questions/Discussion

CHRONIC VS. ACUTE WOUND

➤ Acute Wound

- Healing through the normal wound healing process

“The acute wound becomes a chronic wound when it does not follow the healing stages resulting in a lengthened recovery. On average, a chronic wound is classified as one that fails to heal within four weeks and shows no sign of improvement within eight weeks.”

➤ Chronic Wound

- Prolonged healing in any stage complicated by various factors- blood flow issues, edema, necrotic tissue, bacterial load, underlying medical conditions

SPECIFIC WOUND TYPES

➤ Acute Wounds

- Lacerations
- Abrasions
- Punctures
- Thermal burns
- Blisters
- Surgical Incisions

➤ Chronic Wounds

- Pressure Ulcers
- Diabetic/neuropathic ulcers
- Venous ulcers
- Arterial ulcers
- Atypical

COMPELLING INFORMATION ABOUT WOUND CARE

- Many different specialists treat patients with chronic wounds
- Having a chronic wound is usually a **symptom of underlying disease**
- Patients w/ chronic wounds often have co-morbidities:
 - Hypertension, CVD, diabetes, PAD, kidney disease, autoimmune deficiencies, infections, age-related immobility, etc.
- There are specific and different practice guidelines & treatment algorithms for each type of chronic wound
 - Venous or arterial, diabetic foot or pressure ulcers

COMPELLING INFORMATION ABOUT WOUND CARE (CONT.)

- Clinicians need flexibility to be able to treat the various diseases that wound care patients may have
- Wound healing is a complicated process
- Treating patients with chronic wounds is complex
 - Process involves metabolic, structural, biochemical and patient factors
 - Often overlapping processes
 - Chronic wounds are dynamic; require frequent changes and/or combinations of treatments. These vary based upon frequent wound assessments and which phase of the wound healing
- Chronic wounds may fail to heal, and even when they do, their recurrence rate approaches 80% since little can be done to mitigate the risk factors associated with their development.
- Wound care clinicians want what is best for their patients
 - Manufacturers develop products where the patient is their focus

ECONOMIC IMPACT OF CHRONIC WOUNDS

- Retrospective analysis of the 2014 Medicare 5% Limited Data Set
- Almost 2 million beneficiaries
- Nearly 15% (8.5 million) were diagnosed with at least 1 type of wound or infection (not pneumonia)
- Annual Cost: conservative est. **\$28 billion**, when the wound is the primary diagnosis on the claim
- Estimated at **\$31.7 billion** when analysis included wounds as a secondary diagnosis
- Surgical infections - largest prevalence category (4.0%)
- Diabetic wound infections (3.4%).
- Highest cost estimates site of service were for hospital outpatients demonstrating a major shift in costs from hospital inpatient to outpatient settings

"An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds," Published Jan 2018 *Value in Health*



CHRONIC WOUNDS ARE COSTLY - COSTLY IN QUALITY OF LIFE AND \$\$\$

- **Chronic Venous Disease affects nearly 30 million* people at a cost of more then \$24 billion**
- **Pressure ulcers affect 2 million people at a cost of \$1.3 billion**
- **Diabetic foot ulcers affect 1.5 million people at a cost of nearly \$10 billion**

* Rimedieka R, et al. Medicina (KUNAS). 2004; 40(8):731-9+Bradford Rice ,J; et al. "Burden of venous leg ulcers in the United States" Journal of Medical Economics, Vol.17, No. 5, 2014, 347-356

Lifetime cost of chronic ulcers requiring hospitalization in Ontario, Canada: A population-based study, Brian C.F. Chan et al. 2018

Lifetime Net Cost:

Pressure ulcer **\$98,500** (95% CI \$88,300–\$109,100)

Venous leg ulcer **\$548,100** (95% CI \$524,400–\$569,500)

Diabetic foot ulcer **\$619,300** (95% CI \$593,900–\$642,800)

Chronic ulcers present a **Substantial Economic Burden** to health care system



INCIDENCE OF VENOUS STASIS ULCERS (CONT.)

- Approximately 2.5 million patients, or 1% of the population are affected in the United States each year
- VLUs account for 75 % of all ulcerations
- 15% of individuals over 70 years of age
- O'Donnell, 2011, in *The Journal of Vascular Surgery* stated that VLUs “account for up to 1% of healthcare budgets in some industrialized countries”

DIABETIC FOOT COMPLICATIONS ARE INDEED GREATER THE 5 MOST COSTLY CANCERS - CDC

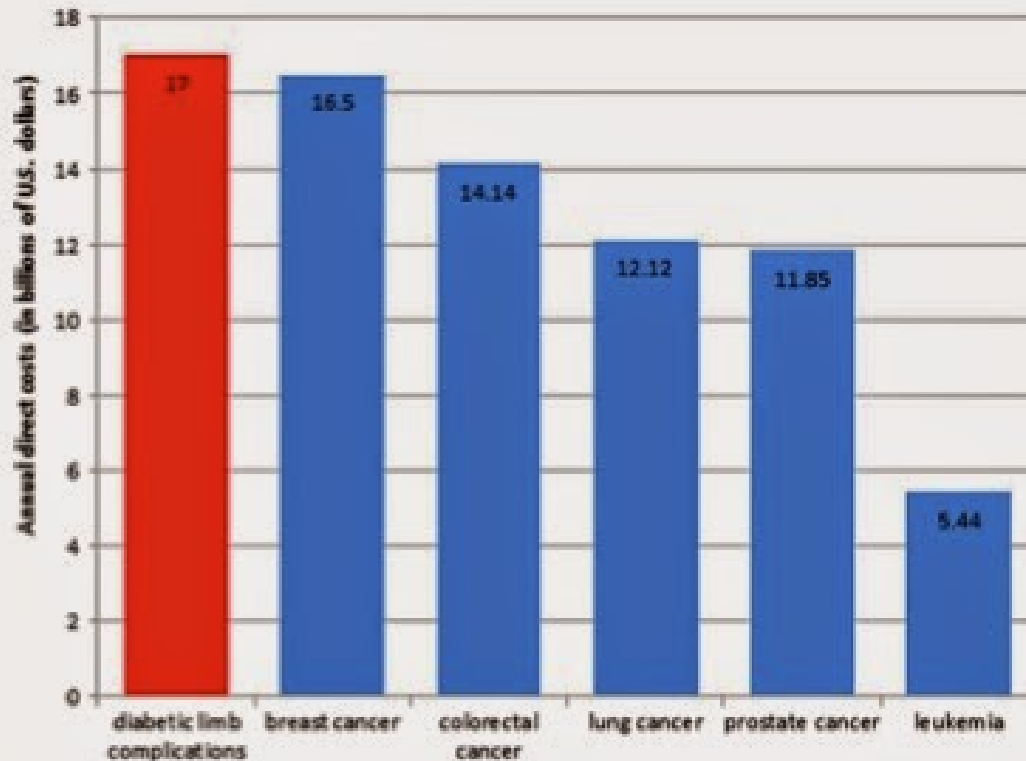
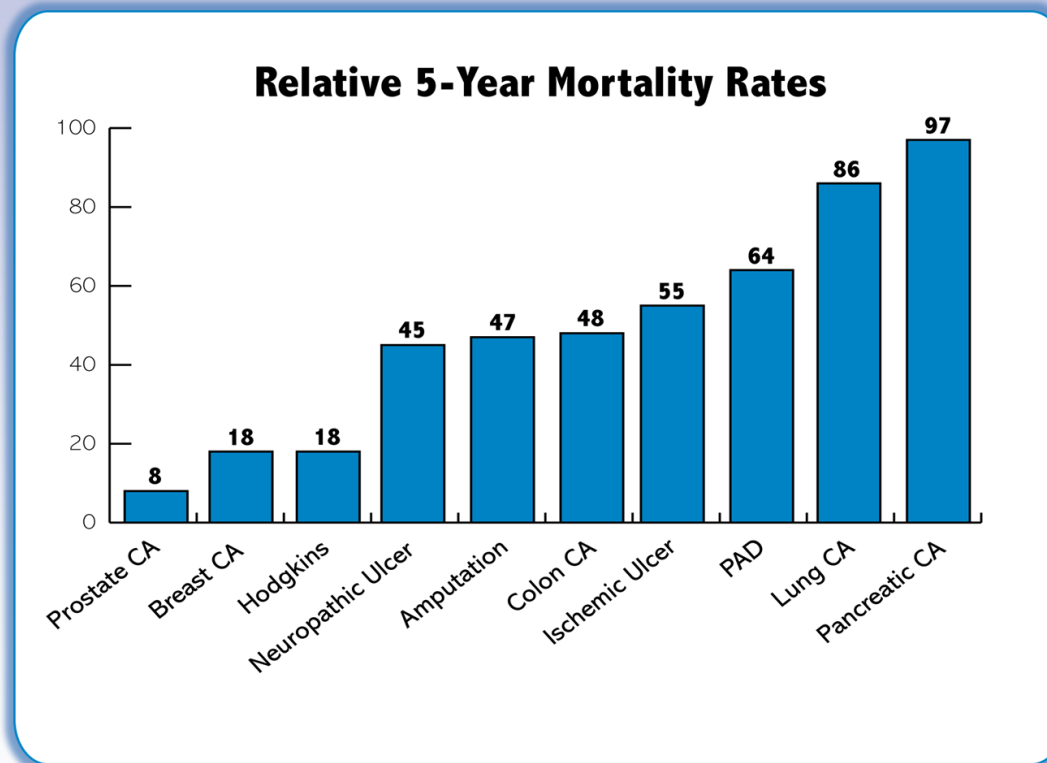


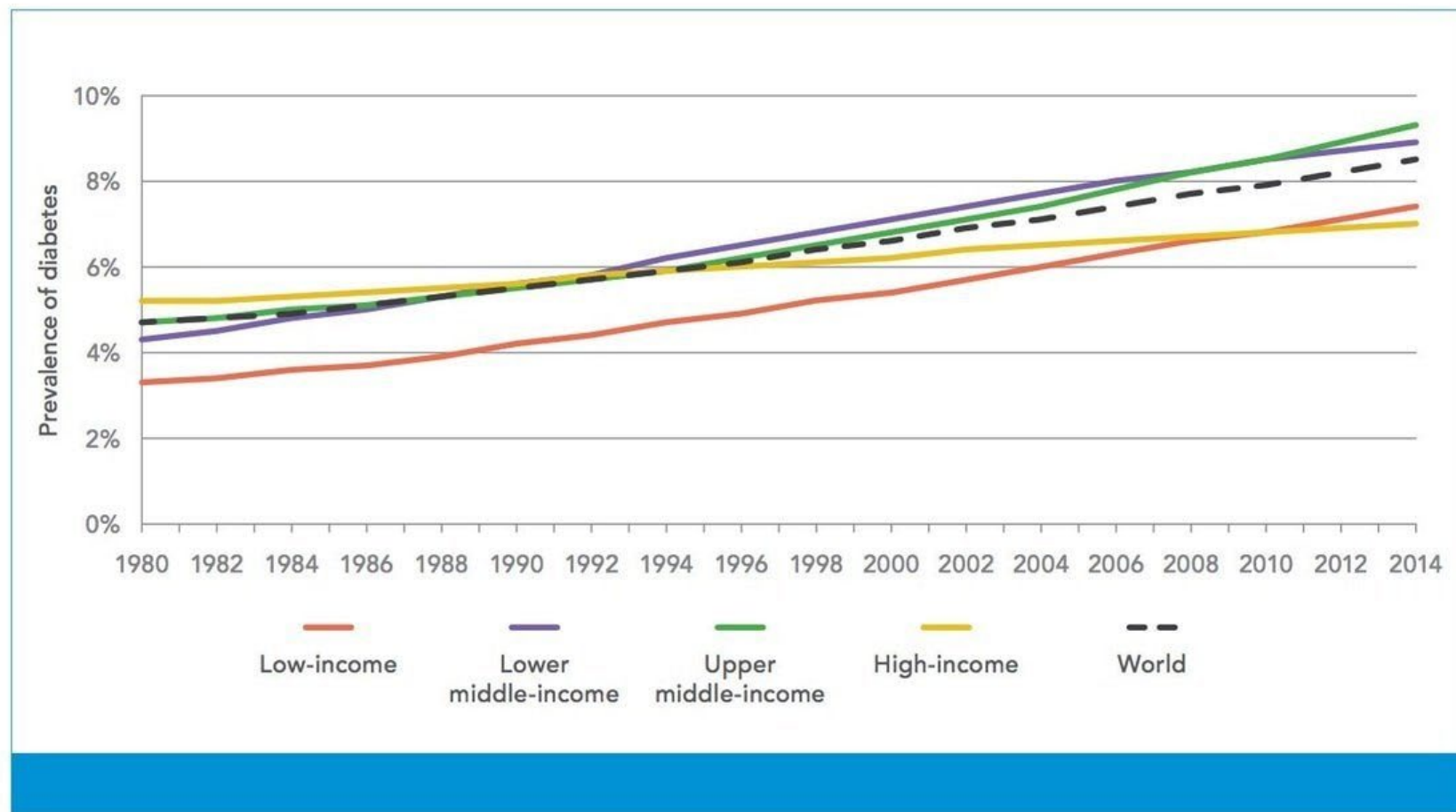
Fig. 2. The estimated annual direct costs of diabetic limb complications in comparison to the annual direct costs of the five most costly cancers in the United States.

THE CONSEQUENCES OF DIABETES IS WORSE THEN MANY CANCERS



Armstrong DG. *Int Wound J.* 2007;4(4):286-287.

FIGURE 4A. TRENDS IN PREVALENCE OF DIABETES, 1980–2014, BY COUNTRY INCOME GROUP



THE NEED FOR INCLUDING A UNIQUE WOUND CARE CLASSIFICATION ON THE USP DRUG CLASSIFICATION

- Currently wound care is under “Dermatology, Other” classification on the USP DC, which is large and diverse.
- Need for an unique subcategory titled “Wound Care” under Dermatology due to prevalence, variability, severity, morbidity and mortality and economic burden associated with chronic wounds.
- Wound care products are separate from products typically used in dermatology that often treat cosmetic and/or non-fatal conditions.
- Need to ensure patient access to these products and minimize discrimination in these fragile at risk patients.
 - Without a “Wound Care” classification it could result in a plan excluding all wound care products on its formulary

5 current USP DC Dermatology classifications include: Acne/Rosacea, Dermatitis and Pruritis Agents, Topical Anti-Infectives, Pediculicides/Scabicides and Dermatological, Other