



Emblem: "Soul Catcher" ...a Northwest Coast Indian symbol used to ward off spirits that brought physical or mental

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Northwest Center for Outcomes Research in Older Adults: A VA HSR&D Center of Excellence

Veterans Affairs Puget Sound Health Care System (VAPSHCS) and the Portland VA Medical Center (PVAMC)

Recent Article of Interest

Effectiveness of Diabetic Therapeutic Footwear in Preventing Reulceration

Matthew Maciejewski, PhD, Gayle Reiber, MPH, PhD, Douglas G. Smith, MD, Carolyn Wallace, PhD, Shane Hayes, CPed, Edward Boyko, MD, MPH

Preventing foot ulcers in persons with diabetes is a major clinical objective for diabetes care providers because foot ulcers can lead to lower limb amputations. Efforts to prevent ulcers and reulceration may avoid serious sequelae that reduce patients' quality of life and increase their health care costs. Therapeutic footwear was publicized as a way to prevent ulcers, amputations, hospitalizations and costs. Congress approved a footwear benefit based upon a demonstration study that showed cost neutrality but did not examine clinical effectiveness. Footwear benefits have been widely promoted and accepted in the clinical community despite limited experimental evidence on the ineffectiveness in preventing foot reulceration. The purpose of this paper is to review the evidence for the effectiveness of therapeutic footwear in preventing reulceration in people with diabetes and to discuss factors influencing study findings.

Methods

We conducted a structured literature review based on a MEDLINE search for studies of therapeutic footwear that examined preven-

tion of reulceration. Studies that examined surrogate outcomes such as plantar pressure reduction and ulcer treatment strategies (e.g. total contact casting, bivalve boots and healing sandals) or first ulcers were excluded. Studies were retained if the therapeutic footwear intervention included either off-the-shelf therapeutic shoes with custom or generic inserts or custom shoes with custom inserts. Nine published papers were identified. Characteristics of the study population, components of the intervention and level of adherence were evaluated. U.S. Preventive Services Task Force criteria for evaluating research were applied to rate each study on study design and internal validity.

Results

Two clinical trials found no significant protective benefit of therapeutic footwear while analytic and descriptive studies reported significant protective findings. There are six fundamental issues important in evaluating footwear and reulceration findings: 1) the heterogeneity in study design, 2) patient reulceration risk, 3) follow-up and study outcome criteria, 4) characteristics of intervention shoes and inserts, 5) adherence

Cover Story

Diabetic footwear (continued from Page 1)

with study footwear and foot protection when patients are out of their study footwear and 6) concurrent non-footwear interventions. Risk ratios in all studies assessing the association between therapeutic footwear and reulceration were below 1.0, suggesting some protective footwear benefit. However, in the most rigorous experimental study, no statistically significant benefit was observed between control patients wearing their own footwear and intervention patients wearing study footwear. Annual reulceration in these studies' control groups ranged from 8.4% to 59.3%. In patients with severe foot deformity or prior toe or ray amputation, observational studies suggested a significant protective benefit from therapeutic footwear.

Discussion

Therapeutic footwear has been used for decades as one of many strategies to prevent reulceration in patients with diabetes and foot risk factors. The findings of several studies reporting statistically significant protective effects from therapeutic footwear may have been unduly influenced by several design issues. When considering the appropriateness of therapeutic footwear recommendations for moderate risk patients, clinicians and patients should jointly explore individual strategies to decrease events that lead to foot ulcers. Results from the descriptive and alternate allocation studies are encouraging. However, after factoring in study design principles, appropriate comparison groups and complete follow-up, the evidence is less compelling. It is a popular belief that therapeutic shoes and inserts should be dispensed freely to all patients with diabetes; however, there is not consistent evidence to support this practice. The community concerned with the prevention and treatment of diabetic foot complications is faced with a dilemma. In light of evidence, health care providers should carefully evaluate the evidence

for footwear apart from foot care and education. Finally, providers and patients should jointly explore individualized strategies to decrease the events that give rise to foot ulcers.

Acknowledgements: This study was funded by the Department of Veterans Affairs. Helpful comments from Eric Johnson are greatly appreciated.

Maciejewski et al. "Effectiveness of Diabetic Therapeutic Footwear in Preventing Reulceration." *Diabetes Care*. 2004 Jul;27(7):1774-82.

Seattle HSR&D COE Moves

After much anticipation and planning, our HSR&D Center of Excellence moved to downtown Seattle in July 2004. This move gives us more space for our growing number of investigators and projects. Many thanks to HSR&D staff for their cooperation and hard work! Special thanks go to Greg Gilbo for his leadership in network and IT systems and to Jane Summerfield who orchestrated the HSR&D move for over a year! Our new location will encourage collaborative efforts with our neighbor, Group Health Cooperative's Center for Health Studies (CHS).

New address:

Department of Veterans Affairs
Northwest Center of Excellence
Health Services Research and Development
Metropolitan Park West
1100 Olive Way
Suite 1400
Seattle, WA 98101

Our old mailing address still works; however, mail is delivered much faster to our new address. All of our phone numbers remain the same.

Feature Article

Stephan D. Fihn, MD, MPH designated as VA's Acting Chief of Research and Development Officer (CRADO)



Dr. Stephan Fihn was designated as Acting CRADO in early summer 2004. Dr. Fihn's term of appointment is for six to nine months.

Dr. Fihn has served as Director of our HSR&D Center of Excellence since 1993. Dr. Fihn's other responsibilities are Co-director of the Ambulatory Care and HSR&D Fellowship Programs and Professor and Head of the Division of General Internal Medicine at the University of Washington (UW) and Professor in the Department of Health Services. His research interests include ambulatory care, cardiovascular diseases, evidence-based medicine, and cost-effectiveness of primary care.

Susan Hedrick, PhD is serving as Acting Director. Dr. Hedrick has assumed this responsibility twice before. Dr. Hedrick is our Associate Director for Seattle and Professor in the Department of Health Services at the University of Washington.

New Investigators to our COE: Welcome and Congratulations to Lisa Chew and Chris Bryson

Lisa Chew joined our HSR&D Center of Excellence at the VA Puget Sound Health Care System (VAPSHCS) as an investigator in July 2004. She attended University of California, Berkeley and received her medical education at the University of California, San Francisco. Wanting a change of scenery, she moved 900 miles north for her residency and chief residency in Internal Medicine at the University of Washington. Following residency, she joined the faculty at the University of Washington as a Clinician-Educator at Harborview Medical Center. After several years, Lisa became interested in research and improving care of vulnerable populations and chose to pursue formal research training. She completed the Robert Wood Johnson Clinical Scholars Program at the University of Washington and then joined the VAPSHCS for a two-year General Internal Medicine fellowship. During this time, she obtained

a master of public health degree in epidemiology. Lisa's research interests are focused on the study of low health literacy and its impact on chronic disease management. She has received a Career Development Award from VA to evaluate the relationship between inadequate health literacy and quality of diabetes care among VA patients. Recently, she completed a study demonstrating that low health literacy is associated with poorer adherence to preoperative medication instructions among VA patients. Also, in collaboration with Drs. Katharine Bradley and Ed Boyko, she developed a practical method of identifying identifying patients with health literacy.

Lisa enjoys living in the Pacific Northwest and likes to spend most of her free time running, snow-shoeing, cross-country skiing, traveling, watching movies, and spoiling her cookie-

Feature Article

New Investigators continued from Page 3)

loving dog.

Chris Bryson grew up outside of Dallas, Texas, and attended Austin College in Sherman, Texas, where he enjoyed pursuing a liberal arts education and received a BA in biology. His other interests in college included classical Greek (he served as President of the Classics Club for a year) and computer science, which have continued to be active hobbies as well as serendipitous resources. Continuing his education at the University of Texas Southwestern in Dallas, Chris completed medical school and a residency in internal medicine, training at Parkland Memorial Hospital and the Dallas VA Medical Center. In 2000, he then decided to seek further training in epidemiology and health services as a VA HSR&D ambula-

tory care fellow. He finished an MS in epidemiology from the School of Public Health at the University of Washington in 2002. Chris' research interests include the epidemiology and prevention of congestive heart failure, the treatment of hypertension and other cardiovascular risk factors, and pharmacoepidemiology. Other interests include the role of lifestyle factors in cardiovascular disease. He recently received a VA Career Development Award to continue the pursuit of these interests. After moving to Seattle, he was introduced to future wife, Jiho Huang, by another fellow at the time, Vince Fan. Chris and Jiho were married July 5th, 2003, recently celebrated their first anniversary. They enjoy spending time in their new home in Phinney Ridge, visiting family in New York, Texas, and Louisiana, and hiking.

New Fellows to our COE: Sasha, Leslie, and Rebecca

Sascha Dublin, MD, PhD is a first-year research fellow in HSR&D. She attended Brown University, where she majored in Renaissance Studies. She began her migration to the Pacific Northwest by spending a year in San Francisco working in a research laboratory and then moved northward to attend medical school at the University of Washington, where she earned an MD and PhD in epidemiology. After medical school, Sascha completed a residency in internal medicine at Oregon Health and Science University in Portland, Oregon. Sascha's research interests include women's health and pharmacoepidemiology. She is currently exploring research projects in several areas, including collaborating with Dr. Bessie Young of the Epidemiologic Research and Information Center (ERIC)



Feature Article

New Fellows continued from Page 4)

on a study of hypercalcemia and possible associations with calcium supplementation. She also plans to use her dissertation data to test a newly published hypothesis that chronic antibiotic use may be a risk factor for cancer. Sascha also has a strong interest in medical education and is currently serving as a board member for the Northwest chapter of the Society of General Internal Medicine.

Sascha is delighted to have returned to Seattle for her fellowship training, not least because her husband Mikael was commuting between Portland and Seattle throughout her three-year residency. Being married to a Swedish citizen, Sascha has become an expert on *sil* (pickled herring) and hand-blown glassware. In their free time, Sascha and her husband enjoy hiking, sailing (see photo), and running. They are also enthusiastic beginners in the sport of kiteboarding.

Rebecca Rudolph, MD also a first year research fellow in HSR&D. She has a B.S. from University of Puget Sound and completed her medical education and MPH at the University of Washington. Next, she completed a Preventive Oncology Fellowship program at the Fred Hutchinson Cancer Research Center. Rebecca is currently Clinical Instructor with the Division of Gastroenterology at the University of Washington and Staff Scientist with Fred Hutchinson Cancer Research Center.

Leslie Smithline Kinder, PhD is a first year research fellow in HSR&D. She completed her undergraduate education at Stanford University and her PhD in Clinical and Health Psychology at the University of Pittsburgh. At Pitt, she was part of the Cardiovascular Behavioral Medicine Training Program and studied psychosocial antecedents of cardiovascular disease. Her dissertation work focused on mechanisms linking depression to coronary heart disease development in patients with Type 1 diabetes. Leslie returned to the Bay Area where she completed her clinical internship at the Palo Alto VA and a postdoctoral

fellowship at the Stanford Prevention Research Center (formerly the Stanford Center for Research in Disease Prevention).

Leslie moved to Seattle with her family in 2002. For fun, she and her husband hang out at the Seattle Center, Barnes and Noble, and the neighborhood playground with their children, Samantha (3 yrs old) and Benjamin (12 months).

New Committee VA IRB formed

The University of Washington Human Subjects Division (UW HSD) has established a sixth Institutional Review Board (IRB) committee called Committee VA. This new committee will review all research conducted by VA appointed staff, studies which include VA patient populations, and studies being conducted at VAPSHCS or Boise VA Medical Centers.

Until now, VA research was reviewed by all five UW IRB committees. Committee VA was created due to increasing requirements of the Department of Veterans Affairs and to better streamline the review of VA specific research. By focusing an entire IRB on VA-related research, we can better follow VA specific regulations and help ensure compliance. This Committee will meet every other Wednesday, starting October 13, 2004. Amy Meadows is Committee VA's Human Subjects Review Administrator.

Contact information:

Human Subjects Division
Grants and Contract Services
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Fax: (206) 543-9218
E-mail: ameadows@u.washington.edu

Funding and Publication News

Funded Projects

Effects of Outlier Identification Strategy on Facility Profiling (IIR 00-077). PI: Kevin L. Sloan, MD. 2002-05

Telemedicine Intervention to Improve Depression Care in Rural CBOCs—Seattle site (IIR 00-078). Local PI: Matthew L. Maciejewski, PhD. 2002-06

Nurse Staffing and Patient Outcomes in VA (IIR 01-160). PI: Anne E. Sales, PhD, MSN. 2002-05

Evaluation of Community Based Outpatient Clinic Costs Using DSS Data (IIR 20-005). PI: Matthew L. Maciejewski, PhD. 2001-04

Audiology Visits after Screening for Hearing Loss: An RCT (IIR 99-377). PI: Bevan Yueh, MD, MPH. 2001-05

Improving Outcomes of Depression in Primary Care (MHI 20-020). PI: Steven K. Dobscha, MD. 2002-04

Well-being Among Veterans Enhancement Study (WAVES) (MHI 99-375). PI: Edmund F. Chaney, PhD. 2001-05

VA Nursing Outcomes Database Project (MRC 03-067). PI: Anne E. Sales, PhD, MSN, RN. 2003-04

Promoting Activity and Exercise in Chronic Pulmonary Disease: An Intervention Study (NRI 98-194). PI: Bonnie G. Steele, PhD, RN. 2000-05

Increasing Influenza and Pneumococcal Vaccinations in VA SCI&D Population (SCT 01-169). PI: Barry N. Goldstein, MD, PhD. 2002-04

Collaborative Cardiac Care Project (C3P) (IHI 02-062). PI: Stephan D. Fihn, MD, MPH. 2004-06

Assessing Practice Variation in Long Term Care Referrals (IIR 02-228). PI: Susan C. Hedrick, PhD. 2004-2006

Improving the Quality of End-of-Life Communication for Patients with Chronic Obstructive Pulmonary Disease (IIR 02-292). PI: David H. Au, MD, MS. 2003-07

VA Prescription Drug Company Copayments and Veterans with Diabetes or Hypertension (IIR 03-200). PI: Matthew L. Maciejewski, PhD. 2003-06

2004 Publications

Smith NL, Chen L, **Au DH**, McDonnell M, **Fihn SD**. Cardiovascular risk factor control among veterans with diabetes: the ambulatory care quality improvement project. *Diabetes Care*. 2004 May;27 Suppl 2:B33-8.

Curtis JR, Engelberg RA, Nielsen EL, **Au DH**, Patrick DL. Patient-physician communication about end-of-life care for patients with severe COPD. *Eur Respir J*. 2004 Aug;24(2):200-5.

Bradley KA, **Kivlahan DR**, **Zhou XH**, et al. Using alcohol screening results and treatment history to assess the severity of at-risk drinking in Veterans Affairs primary care patients. *Alcohol Clin Exp Res*. 2004 Mar;28(3):448-55.

Bridevaux IP, **Bradley KA**, **Bryson CL**, McDonnell MB, **Fihn SD**. Alcohol screening results in elderly male veterans: association with health status and mortality. *J Am Geriatr Soc*. 2004 Sep;52(9):1510-7.

Wiest FC, **Bryson CL**, **Burman M**, McDonnell MB, Henikoff JG, **Fihn SD**. Suboptimal pharmacotherapeutic management of chronic stable angina in the primary care setting. *Am J Med*. 2004 Aug 15;117(4):234-41.

Kanter JW, Epler AJ, **Chaney EF**, et al. Comparison of 3 Depression Screening Methods and Provider Referral in a Veterans Affairs Primary Care Clinic. *Prim Care Companion J Clin Psychiatry*. 2003 Dec;5(6):245-250.

Maynard C, **Chapko MK**. Data resources in the Department of Veterans Affairs. *Diabetes Care*. 2004 May;27 Suppl 2:B22-6.

Chew LD, **Bradley KA**, **Boyko EJ**. Brief questions to identify patients with inadequate health literacy. *Fam Med*. 2004 Sep;36(8):588-94.

Ioannou GN, **Dominitz JA**, Weiss NS, Heagerty PJ, Kowdley KV. The effect of alcohol consumption on the prevalence of iron overload, iron deficiency, and iron deficiency anemia. *Gastroenterology*. 2004 May;126(5):1293-301.

Fan VS, **Au DH**, McDonnell MB, **Fihn SD**. Intraindividual change in SF-36 in ambulatory clinic primary care patients predicted mortality and hospitalizations. *J Clin Epidemiol*. 2004 Mar;57(3):277-83.

Publication News

Publications continued from Page 6

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Helfand M. Screening for subclinical thyroid dysfunction in nonpregnant adults: a summary of the evidence for the U.S. Preventive Services Task Force. *Ann Intern Med.* 2004 Jan;140(2):128-41.

Chou R, Peterson K, **Helfand M.** Comparative efficacy and safety of skeletal muscle relaxants for spasticity and musculoskeletal conditions: a systematic review. *J Pain Symptom Manage.* 2004 Aug;28(2):140-75.

Liu CF, Sales AE, Sharp ND, et al. Case-mix adjusting performance measures in a veteran population: pharmacy- and diagnosis-based approaches. *Health Serv Res.* 2003 Oct;38(5):1319-37.

Maciejewski ML, Dowd B, O'Connor H. Multiple prior years of health expenditures and medicare health plan choice. *Int J Health Care Finance Econ.* 2004 Sep;4(3):247-61.

Maciejewski ML, Reiber GE, Smith DG, Wallace C, Hayes S, Boyko EJ. Effectiveness of diabetic therapeutic footwear in preventing reulceration. *Diabetes Care.* 2004 Jul;27(7):1774-82.

Maynard C, Cox GB, Hall J, Krupski A, Stark KD. Substance use and five-year survival in Washington State mental hospitals. *Adm Policy Ment Health.* 2004 Mar;31(4):339-45.

Weaver EM, **Maynard C, Yueh B.** Survival of veterans with sleep apnea: continuous positive airway pressure versus surgery. *Otolaryngol Head Neck Surg.* 2004 Jun;130(6):659-65.

Maynard C. Gender and place of death from coronary artery disease in Washington State. *Am J Cardiol.* 2004 May 15;93(10):1286-8.

Reiber GE, Au D, McDonell M, Fihn SD. Diabetes quality improvement in Department of Veterans Affairs Ambulatory Care Clinics: a group-randomized clinical trial. *Diabetes Care.* 2004 May;27 Suppl 2:B61-8.

Reiber GE, Boyko EJ. Diabetes research in the Department of Veterans Affairs. *Diabetes Care.* 2004 May;27 Suppl 2:B95-8.

Reiber GE, Koepsell TD, Maynard C, Haas LB, Boyko EJ. Diabetes in nonveterans, veterans, and veterans receiving Department of Veterans Affairs health care. *Diabetes Care.* 2004 May;27 Suppl 2:B3-9.

McGrath J, **Saha S, Welham J, El Saadi O, MacCauley C, Chant D.** A systematic review of the incidence of schizophrenia: the distribution of rates and the influence of sex, urbanicity, migrant status and methodology. *BMC Med.* 2004 Apr 28;2(1):13.

Nicolaidis C, Ko CW, **Saha S, Koepsell TD.** Racial discrepancies in the association between paternal vs. maternal educational level and risk of low birthweight in Washington State. *BMC Pregnancy Childbirth.* 2004 Jun 17;4(1):10.

Saha S, Hickam DH. Explaining low ratings of patient satisfaction among Asian-Americans. *Am J Med Qual.* 2003 Nov-Dec;18(6):256-64.

Sales AE, Plomondon ME, Magid DJ, Spertus JA, Rumsfeld JS. Assessing response bias from missing quality of life data: The Heckman method. *Health Qual Life Outcomes.* 2004 Sep;2(1):49.

Masoudi FA, Plomondon ME, Magid DJ, **Sales A, Rumsfeld JS.** Renal insufficiency and mortality from acute coronary syndromes. *Am Heart J.* 2004 Apr;147(4):623-9.

Amagada JO, Premkumar G, Myerson NA, Morgan RM, **Shannon JL.** Was it benign or malignant bleed? *J Obstet Gynaecol.* 2004 Apr; 24(3):329-30.

Schwartz SR, **Yueh B, Maynard C, Daley J, Henderson W, Khuri SF.** Predictors of wound complications after laryngectomy: A study of over 2000 patients. *Otolaryngol Head Neck Surg.* 2004 Jul;131(1):61-8.

Schwartz SR, McDowell J, **Yueh B.** Numeracy and the shortcomings of utility assessment in head and neck cancer patients. *Head Neck.* 2004 May;26(5):401-7.

Events and Other Information

National Meetings: Important Dates

February 16-18, 2005
HSR&D National Meeting
Washington D.C.

For questions concerning content or processing of abstract submission, contact Barbara Kimmel at (713) 794-8601 or Barbara.kimmel@med.va.gov
http://www.hsr.d.research.va.gov/about/national_meeting/

October 12, 2004

Abstract submissions **Due Date** for
HSR&D National Meeting

December 1-3, 2004
QUERI National Meeting 2004
Washington D.C.

For questions concerning content or processing of abstract submission, contact Linda McIvor, MHS, MS at Linda.mcivor@hq.med.va.gov
<http://www.hsr.d.research.va.gov/queri/meetings/national/2004/default.cfm>

Phone Listings for HSR&D Service, VA Central Office

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Director for QUERI: Joe Francis, MD, MPH
(202) 254-0289

Northwest HSR&D COE'S Newsletter

The Northwest HSR&D Center of Excellence Newsletter is trying on a new look. Let us know what you think.

Contact Connie Nakano if you have a newsletter topic or story and/or ideas and opinions about our new design and format.
(206) 277-5122; connie.nakano@med.va.gov

Funding: Important Due Dates and Change to LOIs

Immediate Changes regarding Letters of Intent (LOI)

Investigators planning to submit HSR&D Merit Review IIR proposals are no longer required to submit an LOI. Investigators submitting proposals for IIR review are to inform Monica Hayes at monica.hayes@med.va.gov. She will forward to Central Office all notifications to submit in one e-mail. This applies only to IIR submissions.

ORD-Wide Nursing Research Initiative (NRI) - administered by HSR&D: For NRI submissions, the LOI requirement is rescinded effective immediately.

Guidelines found in VHA Handbook 1204.01.
For current forms, refer to: <http://www.va.gov/resdev>

Dates

October 15, 2004
LOIs for HSR&D Career Development
Cut-off for December Proposals

December 15, 2004
HSR&D Merit Review IIRs and HSR&D Career Development
Proposals Due

December 15, 2004 and June 15, 2005
Merit Review Entry Program (MREP) Proposals Due

1st business day of March and September 1
Career Scientist Award Proposals Due

New website address for Northwest HSR&D COE:

<http://www1.va.gov/pshsr/>