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A Protocol for Primary Podogeriatric Assessment for Older Patients with Diabetes Mellitus

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1. Introduction

The Pennsylvania Department of Health's Diabetes Prevention and Control Program provided a contract to develop a Comprehensive Podogeriatric and Chronic Diseases Podogeriatric Assessment Protocol (Helfand Index – Appendix A). The goal was to provide a methodology to assess foot, ankle, and related structural problems in older patients; stratify those patients most at risk to develop complications; develop a surveillance instrument for patient care; and to serve as a public health data collection outcome measurement. The information obtained would also provide a protocol to develop prevention (primary, secondary and tertiary) and management programs for individual patients, institutions, and their communities, augment geriatric and chronic disease assessment, as well as stressing the need for appropriate patient management, professional, and patient education.

Foot problems identified in older diabetic patients are the result of the aging process, disease, disability, deformity, and complications associated with other chronic diseases. They are related to societal, environmental, and life style issues. Foot discomfort and pain or podalgia represent some of the most distressing, disabling, and known quality of life limiting conditions. Diabetic foot problems in the older patient are a major cause of morbidity, disability, and hospitalization and contribute to a lessening of the quality and independence of life, thus contributing to an earlier and higher mortality. The high prevalence of chronic diseases in the older population, such as, diabetes mellitus, arthritis, peripheral arterial disease as well as those conditions that produce sensory, peripheral vascular, musculo-skeletal, dermatologic, onychial, and neurologic deficits, lead to serious complications that increase morbidity, mortality, and health care costs. (1, 2, 3, 4, 5, 6)

Other life altering issues in the older patient include constipation, weakened muscle and bone structure, social isolation, mobility deficits, reduced Activities of Daily Living and

Instrumental Activities of Daily Living, sleep problems, agitation and compulsive disorders, increased perspiration, self mutilation and excoriation. The immobility that results from a local foot problem or as the result of a complication of a systemic disease can have a significant negative impact on the patient's ability to maintain a productive quality of life as member of society and to live life, to the end of life with dignity. The senior years should not become a period of "waiting for GOD". (17, 18, 19, 20, 21)

Diseases and disorders of foot and their related structures in the older patient and in particular diabetes mellitus and its neurovascular complications are a significant public health concern. The changes in the individuals' ability to maintain their independence become financial concerns for the individual, their families, and society in general. Two important factors involved in the older patient's ability to remain as a vital part of society are a keen mind and the ability to retain their mobility through ambulation. (5) There are many other factors, which also contribute to the development of foot problems of the adult population including the aging process itself as well as abuse and neglect. Some of these considerations include: the degree of ambulation, the duration of prior hospitalization, limitation of activity, prior institutionalization, episodes of social segregation, depression, prior care, emotional adjustments to disease and life in general, polypharmacy and drug interactions, and the complications and residuals associated with risk diseases. Other focused issues include a loss of tissue and joint elasticity; atrophy of fat and protective tissue; a weakening of the intrinsic muscles of the foot; a loss of balance and range of motion; an increase in foot size due to tissue laxity; a decrease in arch height; dry skin; and onychial dystrophies. (16, 18)

High risk factors for older diabetic patients include age itself, elevated blood sugar, hypertension, a history of a stroke, retinopathy, nephropathy, a history and duration of diabetes for more than ten years, delayed treatment, failure of diabetic foot health education, visual impairment, the inability to bend, living alone, a history of tobacco use, cognitive impairment, dementia, risk taking behavior, sensory loss, a loss of protective sensation, structural abnormalities, altered gait, ambulatory dysfunction, abnormal or excessive foot pressure, subkeratotic or subungual hematoma, a history of foot ulcers, decreased peripheral arterial pulses, peripheral arterial and vascular disease, diabetic neuropathy, soft tissue and plantar fat pad atrophy and/or displacement, deformities (limited joint mobility, hallux valgus, hallux limitus, hammer toes, prominent metatarsal heads and prolapse), xerosis, fissures, obesity, and other related chronic diseases, such as degenerative arthritis, rheumatoid arthritis, and gout. (9, 10, 22)

Additional systemic and/or life changes contributing to the development of high risk foot problems include impaired cardiovascular function, chronic constipation and incontinence, weakened muscle and bone structure, impaired cardiovascular function, diabetes mellitus, peripheral vascular and lower extremity arterial and venous disease, reduced interest and/or participation in social activities, decreased and/or loss of mobility, weakened muscle and bone structure, a reduction in independent activities of daily living and/or instrumental activities of daily living, sleep disorders, agitation, compulsive activities, increased foot perspiration, neurological and sensory deficits, neurotic excoriation, changes in mental status, and cognitive impairment. Self-mutilation, untreated and/or under treated hyperkeratosis, onychiauxis, onychomycosis, ulcers, tinea pedis, xerosis, abrasions and/or lacerations are also contributing factors. (25, 26, 27)

Older patients, especially those with chronic diseases, such as diabetes mellitus are usually taking more than one therapeutic drug at any given moment and may have increased sensitivity and they are usually more susceptible to infection because of the anatomic location of the foot itself. Associated avascularity, atrophy of soft tissue, muscle wasting, neuropathic changes, and a lack of concern for foot health, is associated with the aging and our society. They are concerned about life, as life in a sense is a terminal illness and they have a lower threshold of physical and emotional stress. They may have ambulatory limitation and usually have one or more chronic diseases. They are more prone to injury involving the lower extremity that additionally limits ambulation and mobility. And, they are prone to present with delayed or non-healing tissues. (12)

2. General information

The Assessment Protocol (Appendix A) reviews information related to demographics; primary medical facilities and management; a history of present problems; pertinent past medical history; a systems review; current medications; visual evaluation, foot dermatologic, foot orthopedic, peripheral vascular, and neurologic evaluation; neurologic risk stratification; peripheral arterial risk stratification; footwear evaluation; a primary assessment; an initial management plan; and referral direction; Medicare's class findings; risk stratification of onychomycosis, plantar pressure keratotic patterns, pre and ulcer classification, and the classification of mechanical or pressure hyperkeratotic lesions. (22, 23, 24)

The evaluation process is enhanced by the use of accessible instrumentation such as a C -128 Hz Tuning Fork; Neurologic Hammer; Percussion Hammer; Babinski Hammer; Neurothesiometer or similar instrumentation (Biothesiometer) to determine the Vibration Perception Threshold (VPT); Monofilament Sensory Testing (MST) devices such as the Semmes - Weinstein 5.07 nylon monofilament (SWM), Norton Monofilament, or the West Enhanced Sensory Test; Two Point Discriminator, Pinwheel, Tip-Therm, Tacticon; Doppler; Pulse Volume Recordings (PVR), Pressure-Stat, Temp-Stat, Radiometer - infrared surface temperature scanner for skin perfusion assessment; Ankle and Toe Brachial Index; Oscillometer; Transcutaneous Oxygen (TCPO₂); Radiography; MRI and CT Scans; and Contrast Arteriography as indicated.

The demographics, past medical history, system review, medications and therapeutic programs, current health conditions should be reviewed and noted from the medical record. Primary foot problems as well as their relationship to chronicity and activities, including; swelling, pain, hyperkeratosis, joint deformities, onychial diseases and disorders, infections, coldness, and other problems, as well as location, quality, severity, duration, context, modifying factors, and associated signs and symptoms, should also be noted from the institutional record.

The primary and secondary "at risk" diseases and disorders include complications associated with diabetes mellitus and metabolic disorders, peripheral vascular, lower extremity arterial and venous diseases, sensory and motor impairment, edema, degenerative joint changes and the residuals of arthritis and collagen diseases, ambulatory dysfunction, obesity, and cognitive impairment. (28)

In 1971, Medicare Regulations identified a number diseases and/or disorders that develop vascular insufficiency and neurological insensitivity and their complications as risk factors related to management. The primary examples include the following but are not exclusive:

- Amyotrophic Lateral Sclerosis
- Arteriosclerosis obliterans (A.S.O., arteriosclerosis of the extremities, occlusive peripheral arteriosclerosis)
- Arteritis of the feet
- Buerger's disease (thromboangiitis obliterans)
- Chronic indurated cellulitis
- Chronic thrombophlebitis
- Chronic venous insufficiency
- Diabetes Mellitus
- Intractable edema - secondary to a specific disease (e.g., congestive heart failure, kidney disease, hypothyroidism)
- Lymphedema - secondary to a specific disease (e.g., Milroy's disease, malignancy)
- Peripheral neuropathies involving the feet

Associated with malnutrition and vitamin deficiency

- Malnutrition (general, pellagra)
- Alcoholism
- Malabsorption (celiac disease, tropical sprue)
- Pernicious anemia
- Associated with carcinoma
- Associated with diabetes mellitus
- Associated with drugs and toxins
- Associated with multiple sclerosis
- Associated with uremia (chronic renal disease)
- Associated with traumatic injury
- Associated with leprosy or neurosyphilis
- Associated with hereditary disorders
- Hereditary sensory radically neuropathy
- Angiokeratoma corporis diffusum (Fabry's)
- Amyloid neuropathy
- Peripheral vascular disease
- Raynaud's disease

The secondary "at risk" list of diseases and disorders include the following as examples: Deficiency of B-complex components, Lipidoses, Amyloidosis, Peripheral autonomic neuropathy in disorders classified elsewhere, Hereditary and idiopathic peripheral neuropathy, Acute infective polyneuritis, Polyneuropathy in collagen vascular disease, polyneuropathy in malignant disease, Polyneuropathy in other diseases classified elsewhere, Alcoholic polyneuropathy, Inflammatory and toxic neuropathy, Inflammatory and toxic neuropathy, unspecified, Atherosclerosis of native arteries of the extremities, Generalized and unspecified atherosclerosis, Raynaud's syndrome, Other specified peripheral vascular diseases, peripheral vascular disease, unspecified, Stricture of artery, Other lymphedema, Postphlebitic syndrome, Compression of vein, Chronic venous

hypertension (idiopathic), Venous (peripheral) insufficiency, unspecified, Unspecified circulatory system disorder, Unspecified intestinal malabsorption, Chronic renal failure, Cellulitis and abscess of the toe (s), foot (feet) or leg (legs), prior foot ulceration, Hereditary edema of legs, Edema, and Injury to the knee, leg, ankle, and foot.

Examples of other significant at risk diseases and disorders include as examples: old age and frailty, Alzheimer's Disease, Cognitive dysfunction, Osteoarthritis (Degenerative Joint Disease), Rheumatoid Arthritis, Gout, Coagulopathies, Hemophilia, Prior Amputation, Reflex Sympathetic Dystrophy, Hansen's Disease, Mental Illness, the Mentally Challenged, Paralysis, Parkinson's Disease, visual impairment, physical impairment, ambulatory dysfunction, . In addition, patients with a history of vascular grafts, joint implants, heart valve replacement, active chemotherapy, renal failure and on dialysis, anticoagulant therapy, hemorrhagic disease, chronic steroid therapy, and immuno - compromised states (HIV - AIDS), pose additional risks when considering assessment, treatment and prevention. (52)

On June 16, 2009, the Department of Veterans Affairs (VHA Directive 2009-030) expanded the Medicare primary risk categories to appropriately include the following conditions: (50)

- Documented peripheral arterial disease
- Documented sensory neuropathy
- Prior history of foot ulcer or amputation
- Visually impaired
- Physically impaired
- Neuromuscular disease, i.e. Parkinson's disease
- Severe arthritis and spinal disc disease
- Cognitive dysfunction
- Chronic anticoagulation therapy
- >70 years old without other risk factors
- Diabetes without foot complications
- Obesity

3. Dermatological and onychial physical findings

The dermatologic section provides a focus on skin integrity and multiple changes that affect pressure, mechanical keratosis, onychial changes, infections, and pre-ulcerative states. (7, 8, 14)

The primary clinical signs and findings include the following: hyperkeratosis; keratotic lesions without hemorrhage or hematoma; tyloma; heloma durum; heloma milliare; heloma molle; heloma neurofibrosum; heloma vasculare; onychophosis; intractable plantar keratosis; sub-keratotic hematoma (pre-ulceration); xerosis; onychauxis; tinea pedis; bacterial infection; verruca; ulceration; onychomycosis; rubor; onychodystrophy; pre-ulcerative conditions; cyanosis; and discoloration.

Some examples of dermatologic symptoms and signs include the following: exquisitely painful or painless wounds, slow healing or non-healing wounds, trophic ulceration, necrosis, skin color changes such as cyanosis or erythema, changes in texture and turgor, inelasticity, tenting, pigmentation, hemosiderin deposition, pruritus, neurogenic, and/or

emotional dermatoses, contact dermatitis, stasis dermatitis, atopic dermatitis, nummular eczema, scaling, dehydration, xerosis or dryness, excoriations, verruca, moles, psoriasis, fissures, hyperhidrosis, bromidrosis, diminished or absent hair growth, diabetic dermopathy (shin spots), necrobiosis lipoidica diabetorum, bullous diabetorum, granuloma annulare, acanthosis nigricans, and poroma. Other factors include swelling, redness, an increase or decrease in skin temperature, and maceration.

Some examples of common onychial clinical changes include onycholysis, subungual hyperkeratosis, diabetic onychopathy, onychiauxis, onychogryphosis, onychocryptosis, onychomycosis, onychia, paronychia, subungual abscess, subungual heloma, subungual exostosis, onychomadesis, onychoschizia, onychophosis, subungual hematoma, splinter hemorrhage, periungual ulcerative granulation tissue, onychodysplasia, onychodystrophy, onychorrhhexis, Beau's Lines, pterygium, diabetic onychopathy, and hypertrophic onychodystrophy.

Onychomycosis evaluation includes: documentation of mycosis/dystrophy causing secondary infection and/or pain, which results or would result in marked limitation of ambulation and includes discoloration, hypertrophy, subungual debris, onycholysis, secondary infection, and limitation of ambulation and pain. The primary clinical presentation of onychomycosis include distal subungual, lateral subungual, superficial (white), proximal subungual, endonyx, total dystrophic and candida (14). The onychial grades at risk, which was modified and adapted from Strauss, Hart and Winant and recognizes earlier risk and includes the following: Grade - 1, normal; Grade - 2, mild hypertrophy, Grade 3, evidence of hypertrophy, dystrophy, onychiauxis, onychomycosis, infection, and/or onychodysplasia; and Grade - 4, evidence of hypertrophy, deformity, onychogryphosis, dystrophy, onychomycosis, and/or infection.

4. Hyperkeratosis classification

The major functions of the foot are static and dynamic. The foot is an organ of weight bearing, propulsion, and locomotion. The foot is relatively rigid and changes are related to the activities of daily living, excessive and repetitive stress, the normal aging process, degeneration, and disease, producing functional disability and ambulatory dysfunction. Repetitive stress, hard and flat surfaces, increased shock, tissue trauma, past occupational stress, and the environmental factors associated with ambulation that do not provide for a compensatory element for weight diffusion and/or weight dispersion. Examples of related complications include atrophy of the intrinsic foot muscles, atrophy, and anterior displacement of the plantar fat pad, morphologic changes, digital contractures and deformities, inflammation, pain, and the residuals of biomechanical, pathomechanical, and balance and gait change. The stress factors related to the development of hyperkeratosis include; force, compression, tensile stress, shearing, friction, elasticity, and fluid pressure. (29, 30)

The classification of mechanical or pressure keratosis is a modification of the program outlined by Merriman and Tollifield , includes the following grading descriptions as follows: 0 - no lesion; 1 - no specific tyloma plaque but diffuse or pinch hyperkeratotic tissue present or in narrow bands; 2 - circumscribed, punctate oval, or circular, well defined thickening of keratinized tissue; 3 - heloma milliare or heloma durum with no associated

tyloma; 4 - well defined tyloma plaque with a definite heloma within the lesion extravasation, maceration and early breakdown of structures under the tyloma or callus layer; and 5 -complete breakdown of structure of hyperkeratotic tissue, epidermis, extending to superficial dermal involvement. The plantar keratoma pattern is identified if present.

5. Ulcer classification

The Ulcer Classification was adapted from Simms, Cavanaugh and Ulbrecht and provides an earlier identification of risk given its ten grade classification and better identifies pre-ulcerative changes as follows: Grade - 0 - absent skin lesions; Grade - 1 - dense callus but not pre-ulcer or ulcer; Grade - 2 - pre-ulcerative changes (such as evidence of hemorrhage or hematoma in the keratotic lesion; Grade - 3 - partial thickness (superficial ulcer); Grade - 4 - full thickness (deep) ulcer but no involvement of tendon, bone, ligament or joint; Grade - 5 - full thickness (deep) ulcer with involvement of tendon, bone, ligament or joint; Grade - 6 - localized infection (abscess or osteomyelitis); Grade - 7 - proximal spread of infection (ascending cellulitis or lymphadenopathy); Grade - 8 - gangrene of forefoot only; and Grade - 9 - gangrene of majority of foot. A key factor in managing the diabetic is to prevent foot ulceration by finding clinical signs prior to skin breakdown. (13, 41, 41, 43, 44)

Other classifications include the Wagner Classification System (Grades 1-5) , the Liverpool Classification System for diabetic ulcers (Primary - neuropathic, ischemic and neuroischemic and Secondary - uncomplicated or complicated i.e., with cellulitis, abscess, or osteomyelitis, and the University of Texas Foot Ulcer Wound Classification Systems with Stages A, B, C, and D and Grades 1, 2, and 3 that encompass pre or post ulceration, superficial, penetration to tendon or capsule or penetration to bone, with no infection or ischemia, infection, ischemia, and infection with and ischemia. (46)

6. Foot orthopedic (musculoskeletal) physical findings

The foot orthopedic section highlights altered biomechanics and the most common foot and joint deformities and syndromes identified in the older patient and patients with chronic diseases, such as arthritis; Hallux valgus (bunion); anterior imbalance (identifies inappropriate weight bearing and correlates with the plantar keratoma pattern noted later in the examination); digiti flexus (hammer toes and rotational deformities); prominent metatarsal heads; Morton's Syndrome; improper weight distribution and pressure areas; soft tissues inflammation is also noted. Other primary findings include; diminished joint mobility (flexion, extension, inversion, and inversion); pes planus, pes valgo planus; pes cavus (equinus); hallux limitus or rigidus; bursitis; Charcot joints (neuropathic arthropathy); drop foot; osseous reabsorption; rear and/or forefoot varus; plantarflexed first ray; digital and or partial foot amputation; B/K and A/K amputation; and other clinical findings. (31, 33)

Other examples of musculoskeletal findings that should be considered include: gradual change in shape or size of the foot, decreased ranges of motion, a sudden and painless change in foot shape with swelling and no history of trauma, drop foot, "Rocker Bottom Foot" or Charcot foot, neuropathic arthropathy, elevated plantar pressure, limited joint mobility, abnormal foot pressure, atrophy of plantar fat pad, plantar fat pad displacement,

foot muscle atrophy, hallux limitus, hallux rigidus, tailor's bunion, plantar fasciitis, soft tissue inflammation, calcaneal spurs, decalcification, stress fractures, metatarsalgia, Morton's Syndrome, Haglund's, entrapment syndrome, neuroma, sesamoid displacement, joint deformities as residuals of arthritis, ambulatory dysfunction, pododynia dysbasia, biomechanical and pathomechanical variations, and footwear evaluation. Gait evaluation includes mobility, gait speed, and balance as it relates to fall risk that may be associated with foot deformity and inappropriate footwear. Ambulatory aids such as canes, walkers, etc, as well as physical activities are also a consideration. Mobility should consider independent activity, independence with assistance, homebound status, non-ambulatory status, and wheel chair use. The ranges of motion include dorsiflexion, plantar flexion, inversion, and eversion of the foot and ankle, flexion and extension of the great toe, and intrinsic foot muscles. (45, 47, 48, 49)

7. Peripheral vascular physical findings

The Vascular Evaluation identifies those symptoms associated with arterial insufficiency and ischemia. The primary findings include: coldness, trophic changes, diminished or absent pedal pulses, such as the dorsalis pedis pulse and posterior tibial pulses; night cramps; edema; claudication; varicosities; atrophy and amputation if present (noted as above the knee (AKA), below the knee (BKA), FF (forefoot), and T (toes), which are particularly important in patients with diabetes and arterial insufficiency. Other findings include: fatigue, rest pain, decreased skin temperature, burning, trophic changes, color and pigmentary changes, hemosiderin deposition, petechiae, hypoxia, cyanosis, rubor, absent or diminished digital hair, skin fragility, skin inelasticity (tenting), tingling, numbness, ulceration, history of phlebitis, cramps, edema, history of repeated foot infections, diminished or absent popliteal and/or femoral pulse change, femoral bruits, Ankle-Brachial Index ($ABI < 0.90$), Toe-Brachial Index, prolonged subungual capillary refill (> 3 sec), reduced claudication time, changes in skin perfusion, color changes (rubor, erythema, or cyanosis), temperature changes (cool and gradient), xerosis (atrophic and dry skin), atrophy of soft tissue, superficial infections, onychial changes, induration, blebs, delayed venous filling time, prolonged capillary filling time, femoral bruits, microcirculatory dysfunction, ischemia, telangiectasia, stasis, delayed and/or non-healing wounds and/or ulcers, necrosis, and gangrene. (15, 32)

The vascular and risk stratification includes the following as part of the initial assessment: 0, no change; 1, mild claudication; 2, moderate claudication; 3, severe claudication; 4, ischemic rest pain; 5, minor tissue loss; and 6, major tissue loss.

Medicare currently may provide payment for Therapeutic Shoes for patients with diabetes mellitus who meet specific criteria. The criteria include the following: a history of partial or complete amputation of the foot, a history of previous foot ulceration, a history of pre-ulcerative callus, peripheral neuropathy with evidence of callus formation, evidence of foot and/or osseous deformity, and evidence of poor circulation.

8. Neurological physical findings

The neurologic evaluation identifies primary reflex and sensory changes. Those findings include: the deep tendon reflexes – (DTR i.e. patellar and Achilles) and superficial plantar

reflexes, joint position, testing vibratory sensation, vibration perception threshold (VPT), sharp and dull reactions, evidence of paresthesia and burning. Other findings include: sensory changes (burning, tingling, and/or clawing sensations), pain and hyperactivity, two point discrimination variation, motor changes (weakness and /or foot drop), ankle clonus, autonomic changes (diminished sweating or hyperhidrosis), sensory vibratory deficits and/or proprioceptive, loss of protective sensation, changes in pain and temperature perception, and high plantar pressure areas as demonstrated by marked digital contractures, hyperkeratosis, metatarsal prolapse, prominent metatarsal heads, and plantar fat pad atrophy and displacement, bowstring tendons, muscle wasting, and Charcot foot (including rocker bottom deformity, erythema, heat, edema, fractures, neuropathy, swelling, bounding pulses, absent or diminished pain and proprioception, deep tendon reflex loss, anhidrosis, subluxation, the minus foot, equinus, hypermobility, ulceration, hyperkeratosis, and infection) . The use of monofilament testing and response are essential to measure sensory loss. Pinching the Achilles tendon and/or placing vertical pressure on a nail plate should demonstrate pain. The absence of pain is also an indication of sensory loss. Palpation of the common peroneal, posterior tibial and sural nerves may also demonstrate enlargement and tenderness. (34, 35, 36, 37, 38)

Medicare also provides a process for the evaluation and management of a diabetic patient with diabetic sensory neuropathy, resulting in a Loss of Protective Sensation (LOPS) to include the following: 1) a diagnosis of LOPS; 2) a patient history of diabetes mellitus; 3) a physical examination consisting of findings regarding at least the following elements, 3 a) visual inspection of the forefoot, hindfoot, and toe web spaces, 3 b) evaluation of protective sensation, 3 c) evaluation of foot structure, pathomechanics, and biomechanics, 3 d) evaluation of vascular status, 3 e) evaluation of skin integrity, 3 f) evaluation and recommendation of footwear, and 4) patient education.

The neurological risk stratification includes the following classification: 0, no sensory loss; 1, sensory loss; 2, sensory loss and foot deformity; and 3, sensory loss, a history of ulceration, and deformity.

9. Class findings

Medicare also has a series of Class Findings that need to be evaluated and documented as qualifiers for primary foot care for those patients with primary risk diseases noted. Those findings include the following: A - 1, nontraumatic amputation of the foot or part of the foot; B - 1, absent posterior tibial pulse; B - 2, advanced trophic changes; B - 2 - a, hair growth (decrease or absent); B - 2 - b, nail changes (thickening); B - 2 - c, pigmentary changes (discoloration); B - 2 - d, skin texture (thin, shiny; B - 2 - e, skin color (rubor or redness); B - 3, absent dorsalis pedis pulse; C -1, claudication; C - 2, temperature changes (cold); C - 3, edema; C - 4, paresthesia; and C - 5, burning.

10. Other findings

Other assessment areas include footwear, hygiene, and the type of stocking (nylon, cotton, wool, other), or none. Stockings or socks should also be inspected for staining and excessive wear (friction).The shoe or footwear evaluation includes the type of shoe, fit, depth, size,

last, flare, shoe-wear, patterns of wear, shoe lining wear, shoe wear pattern (outsole and upper counter distortion), foreign bodies, insoles, and orthoses. Where special shoes, such as those defined as “therapeutic” by Medicare, they should generally include a padded collar and tongue, laces, adjustable strap or “Velcro” closure, wide toe box to accommodate deformities, added depth in the upper section to accommodate deformities, orthotics, and /or padded inserts to evenly distribute plantar pressure, a steel shank for stability, cushioning, and a broad sole base for support and traction.

The mechanical factors leading to ulceration need to be reviewed and noted, such as: body mass; evidence of tissue trauma; weight diffusion; weight dispersion; pathomechanics (defined as structural change in relation to function); biomechanics (defined as forces that change and affect the foot in relation to function; imbalance (defined as the inability to adapt to alterations of stress); force (alteration in physical condition, either shape or position); compression stress (one force moves towards another); tensile stress (a pulling away of one part against another); shearing stress (a sliding of one part on the other); friction (the force needed to overcome resistance and usually associated with a sheering stress; elasticity (weight diffusion and weight dispersion); and fluid pressure (soft tissue adaptation and conformity to stress).

Given the fact that assessment and re-assessment should be completed on a regular basis, management can then be instituted to reduce the complications of chronic disease and subscribe to the principles of secondary prevention of disease. The plan for care includes the following, as an example: plan podiatric referral, patient education, medical referral, special footwear, vascular studies, clinical laboratory studies, imaging (including radiographs, sequential bone scans, computed tomography (CT), magnetic resonance imaging (MRI), and Duplex Ultrasound), prescriptions, and follow-up assessment and management. (39, 40)

11. Discussion

The evolution of this protocol began in 1959 as the number of older individuals and those with chronic diseases began to increase. Those diseases and disorders that presented with complications, such as diabetes mellitus, peripheral arterial disease, degenerative joint changes, collagen diseases, and neurosensory disorders were recognized as having a significant effect on the future quality of older citizens. A visit to the United Kingdom by the Commissioner and Deputy Commissioner of Health of the City of Philadelphia demonstrated a need for foot care that was a part of the British heral care system. A joint effort with the Philadelphia Department of Health and St. Luke’s & Children’s Medical Center in Philadelphia resulted in the first US Public Health Service funded program dealing with foot health for an aging population. “Keep Them Walking” provided a three years study involving information, education, screening, assessment and care for in excess of 16,000 citizens over the age of 65 in Philadelphia. The number of foot problems that were uncovered was so significant that Philadelphia established podiatric services as a part of it community health care program, that remain today as a vital part of providing care for older citizens.

About that same time, similar efforts were initiated at the Queensbridge Health Maintenance Program in New York, the ambulatory clinics of the Washington, DC Health

Department and by the Minnesota Department of Health for Long Term Care Programs. The data also demonstrated a similar high prevalence for diseases and disorders of the foot and related structures.

In 1963, the US Public Health Service and the Gerontological Society of America began to develop its first clinical geriatric practice guide that also included Podiatric programs. In 1966, the US Department of Veterans Affairs also identified a significant need for foot care programs, as a part of their long term care services, especially for older adults. It became clear that screening had to be replaced by Assessment, Identification, Risk Stratification, Education, and Treatment programs to enhance the concept of the secondary prevention of chronic diseases in older patients.

The presented Clinical Podogeriatric and Chronic Disease Protocol (Helfand Index) was developed through a coordinated effort by the Diabetes Control Program of the Pennsylvania Department of Health and Temple University School of Podiatric Medicine and provides a means to assess older patients with diabetes mellitus and other chronic diseases to develop proper and appropriate care prevention and care programs.

The most recent validation study of this protocol, Foot Problems in Older Patients – A Focused Podogeriatric Assessment Study in Ambulatory Care demonstrated the prevalence of foot conditions in older individuals and their association with chronic risk diseases such as diabetes mellitus, peripheral arterial disease, and arthritis, and to develop care plans to reduce complications from local foot problems and chronic diseases. One thousand individuals older than 65 years who were ambulatory and not institutionalized underwent a standardized and validated podogeriatric examination assessment protocol or index.

The Summary of the Data is attached as **Appendix B**. The findings demonstrated that foot problems in the older population result from disease, disability, and deformity related to multiple chronic diseases as well as changes associated with repetitive use and trauma. Older people are at a high risk of developing foot-related disease and should receive continuing foot assessment, education, surveillance, and care. (J Am Podiatric Med Assoc 94(3): 293-304, 2004). The data also demonstrated that 77% of all patients were deemed to be at risk for significant complications involving the foot and its related structures that could impair the quality of life and significantly increase the cost of care.

The development of this protocol (Helfand Index) provided a means to identify older and diabetic patients who were at risk for complications involving the foot and its related structures; to focus on educational needs for patients and professionals; to provide referral for the rapid treatment and management of foot problems; and to provide a forum to discuss the need for appropriate foot wear for patients at risk, as a means to secondarily prevent future diseases and disorders of the foot.

The protocol provided a focus on the current patients history, the past medical history, a system review, current and past medications, the assessment of skin and toe nail conditions, foot deformities, pathomechanical and biomechanical changes, vascular assessment, neurological assessment and sensory deficits, risk stratification (vascular, sensory, class finding, mycotic, hyperkeratotic, and ulcers), footwear and foot covering, assessment, and a

management plan. Examples for the reasons to refer patients for podiatric medical include but are not limited to the following:

- Signs suggesting generalized diseases that include neuropathy, vascular disease, diabetes mellitus, infection, ulceration, deformity, degenerative joint changes, focal neoplastic diseases, collagen diseases, and other conditions as indicated involving the foot and related structures in those cases where concomitant therapy is indicated where initial management is not effective:
 - In the presence of skin lesions involving the foot:
 - In the presence of postural deformities of the foot and related structures:
 - In the presence of diabetes mellitus, neurosensory, peripheral vascular, and other risk diseases:
 - In the presence of foot problems combined with ambulatory and/or walking difficulty and/or a history of or risk of falls:
 - Where orthotics are indicated:
 - If the patient is unable to obtain and/or provide foot care:
 - If the patient complains of a foot problem or has specific questions about care including information on footwear.

The assessment protocol clearly provided a means to identify the most significant risk factors. Although vascular and neurosensory deficits are usually thought of as most significant as to their potential impact for ulceration and amputation, class findings, mechanical or pressure keratosis, onychomycosis, onychial grades at risk, and pre-ulceration, become equally important in relation to prevention and a means to provide rapid and early treatment for conditions noted. The protocol does provide a means to identify previous amputations; past foot ulcer history, peripheral neuropathy, foot deformity including Charcot's Foot, peripheral vascular and arterial impairment, visual impairment, podalgia, pododynia dysbasia, and diabetic neuropath, especially in patient on dialysis. All of these factors increase the amputation risk for diabetic patients (1, 2). In addition, the assessment protocol is not time consuming.

There are a number of ulcer classifications in the literature including the Wagner Classification for Foot Ulcers, The University of Texas Diabetic Wound Classification, the National Pressure Ulcer Advisory Panel (NPUAP) Classification for Pressure Ulcers, as well as the one selected and described by Sims, Cavanagh, and Ulbrecht (46). This ten (10) grade classification provide three stages prior to a superficial ulcer that permitted earlier justification for treatment programs, associated with this assessment protocol.

The Loss of Protective Sensation was initially developed by Dr. Paul Brand at the Leprosy Mission in London and then for the USPHS National Hansen's Disease Program in Carville LA. With the recognition that the same findings were equal predictors of amputation in patients with diabetes mellitus, the use of the Semmes-Weinstein (5.07 gage) 10-gram monofilament has been defined universally in a consistent fashion to measure of light pressure. Vibration perception with the tuning fork 128 Hz (cps) and measurement of vibration perception threshold (Biothesiometer) were also employed. Pinching the Achilles tendon also provided a means to measure pain. Temperature perception, deep tendon reflexes and two-point discrimination are added procedures that provide additional assessment benefits.

By early recognition of foot and related problems, not as an initial assessment tool, but as a subsequent re-assessment tool, patient education and rapid treatment program can be instituted to prevent progressing complications and maintain a maximum quality of independent life for older diabetic patients.

Since this Protocol was introduced, it has been employed by a number of programs and institutions, included and identified in multiple presentations and publications. Examples include the following: Pennsylvania Department of Health; Pennsylvania Diabetes Academy; Temple University – School of Podiatric Medicine and Institute on Aging; University of Pennsylvania – School of Nursing; Griffin Hospital – Yale – Department of Veterans Affairs Health System; Geriatric Educational Resources for Residency Training in Family Medicine and Internal Medicine – The John A. Hartford Foundation Geriatric Education Consortium for Residency Training (Stanford University Geriatric Education Center, Baylor College of Medicine, Harvard University, Johns Hopkins University, Stanford University, University of California – Los Angeles, University of Chicago, University of Connecticut, University of Rochester, American Academy of Family Physicians); Pennsylvania Geriatric Education Center; Delaware Valley Geriatric Education Center; Thomas Jefferson University Hospital; American Medical Directors Association; American Podiatric Medical Association; as well as journals and texts; including the Geriatric Review Syllabus of the American Geriatrics Society, W B Saunders, Martin Dunitz, Elsevier, Wiley, McGraw-Hill, Health Professions Press, the American Public Health Association Press, Cambridge University Press, and Oxford University Press.

12. Concluding remarks

Much of the ability to remain ambulatory in the period of aging is directly related to foot health. In order to accomplish this aim, practitioners must think comprehensively, and recognize that team care must be an essential part of chronic disease management in the care of the older patient. Foot health education for patients and professionals should be employed. It is clear that adults with chronic diseases, such as diabetes mellitus, and older patients are a high risk for foot related disease and should maintain continuing foot assessment, education, surveillance, and care. The consequences of considering foot care for the older population as “routine” and a failure to prevent complications and maintain mobility and ambulation will result in ambulatory dysfunction, gait modification, podalgia, pododynia dysbasia, morbidity, mortality, increased health care costs, and will be reflected in the quality of life and the ability to remain mentally alert and active in their communities (51). For our future, the golden years must be more than aging in place, thinking of their residence as a waiting room, or waiting for God. We must recognize that aging is not a disease, that older individuals should be able to live life to the end of life with the dignity of age, and that we must protect what cannot be replaced.

13. Acknowledgment

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14. Appendix A

Assessment protocol

Date Of Visit	MR#	
Patient's Name	Age	
DATE OF BIRTH	SOCIAL SECURITY #	
ADDRESS		
CITY	STATE	ZIP CODE
PHONE NUMBER ()		
SEX M F	RACE B W A L NA	
WEIGHT LBS	HEIGHT IN	
SOCIAL STATUS	M S W D SEP	

Name of primary physician/health care facility

Date Of Last Visit

History Of Present Illness

SWELLING OF FEET	LOCATION
PAINFUL FEET	QUALITY
HYPERKERATOSIS	SEVERITY
ONYCHIAL CHANGES	DURATION
BUNIONS	CONTEXT
PAINFUL TOE NAILS	MODIFYING FACTORS
INFECTIONS	ASSOCIATED SIGNS &
COLD FEET	SYMPTOMS
OTHER	

Past medical history

HEART DISEASE	DIABETES MELLITUS
HIGH BLOOD PRESSURE	*IDDM
ARTHRITIS	*NIDDM
*CIRCULATORY DISEASE	HYPERCHOLESTEROL
THYROID	GOUT
ALLERGY	FAMILY AND SOCIAL HISTORY
	SMOKING
	ALCOHOL

System review

CONSTITUTIONAL		
ENT	CARD/VASC	GU
EYES	MUSCULO- SKELETAL	NEUROLOGIC

SKIN/HAIR	ENDOCRINE	GI
RESPIRATORY	GYN	IMMUNOLOGIC
PSYCHIATRIC	ALLERGIC	
HEMATOLOGIC	LYMPHATIC	

Medications

Dermatologic

*HYPERKERATOSIS		XEROSIS
ONYCHAUXIS	B-2-B	TINEA PEDIS
INFECTION		VERRUCA
*ULCERATION		HEMATOMA
ONYCHOMYCOSIS		RUBOR
ONYCHODYSTROPHY		*PREULCERATIVE
*CYANOSIS	B-2-E	DISCOLORED

Foot orthopedic

*HALLUX VALGUS	*HALLUX RIGIDUS-LIMITUS
*ANTERIOR IMBALANCE	*MORTON'S SYNDROME
*DIGITI FLEXUS	BURSITIS
*PES PLANUS	*PROMINENT MET HEAD
*PES VALGOPLANUS	*CHARCOT JOINTS
*PES CAVUS	OTHER

Vascular evaluation

*COLDNESS	C-2	*CLAUDICATION	C-1
*TROPHIC CHANGES	B-2-A	VARICOSITIES	
*DP ABSENT	B-3	OTHER	
*PT ABSENT	B-1	*AMPUTATION	
*NIGHT CRAMPS		*AKA BKA FF T	A-1
*EDEMA	C-3	ATROPHY	B-2-D

Neurologic evaluation

*ACHILLES		SUPERFICIAL PLANTAR	
*VIBRATORY		*JOINT POSITION	
*SHARP/DULL		*BURNING	C-5
*PARESTHESIA	C-4	OTHER	
LOSS OF PROTECTIVE SENSATION			

Risk category - neurologic

- 0 = No Sensory Loss
- *1 = Sensory Loss
- *2 = Sensory Loss & Foot Deformity
- *3 = Sensory Loss, Hx Ulceration, & Deformity

Risk category - vascular

- 0 - 0 No Change
- *I - 1 Mild Claudication
- *I - 2 Moderate Claudication
- *I - 3 Severe Claudication
- *II - 4 Ischemic Rest Pain
- *III - 5 Minor Tissue Loss
- *III - 6 Major Tissue Loss

Footwear Satisfactory		Hygiene Satisfactory	
YES	NO	YES	NO
Stockings: NYLON COTTON WOOL OTHER NONE			
YES		NO	

Assessment

Plan

- Podiatric referral
- Patient education
- Medical referral
- Special footwear
- Vascular studies
- Clinical lab
- Imaging
- Rx

Class findings

- A1 Nontraumatic Amputation
- B1 Absent Posterior Tibial
- B2 Advanced Trophic Changes
- B2A Hair Growth (Decrease Or Absent)
- B2B Nail Changes (Thickening)
- B2C Pigmentary Changes (Discoloration)
- B2D Skin Texture (Thin, Shiny)
- B2E Skin Color (Rubor Or Redness)
- B3 Absent Dorsalis Pedis
- C1 Claudication
- C2 Temperature Changes (Cold)
- C3 Edema
- C4 Paresthesia
- C5 Burning

Onychomycosis

Documentation of mycosis/dystrophy causing secondary infection and/or pain that results or would result in marked limitation of ambulation.

Discoloration
Hypertrophy
Subungual debris
Onycholysis
Secondary infection
Limitation of ambulation and pain

Classification of mechanical or pressure hyperkeratosis

Grade description

- 0. No lesion
- 1. No specific tyloma plaque, but diffuse or pinch hyperkeratotic tissue present or in narrow bands
- 2. Circumscribed, punctate oval, or circular, well defined thickening of keratinized tissue
- 3. Heloma milliare or heloma durum with no associated tyloma
- 4. Well defined tyloma plaque with a definite heloma within the lesion
- 5. Extravasation, maceration and early breakdown of structures under the tyloma or callus layer
- 6. Complete breakdown of structure of hyperkeratotic tissue, epidermis, extending to superficial dermal involvement

Plantar keratomata pattern

LT 5 4 3 2 1 RT 1 2 3 4 5

Ulcer classification

- Grade - 0 - Absent Skin Lesions
Grade - 1 - Dense Callus But Not Pre-Ulcer or Ulcer
Grade - 2 - Preulcerative Changes
Grade - 3 - Partial Thickness (Superficial Ulcer)
Grade - 4 - Full Thickness (Deep) Ulcer But No Involvement of Tendon, Bone, Ligament or Joint
Grade - 5 - Full Thickness (Deep) Ulcer With Involvement of Tendon, Bone, Ligament or Joint
Grade - 6 - Localized Infection (Abscess or Osteomyelitis)
Grade - 7 - Proximal Spread of Infection (Ascending Cellulitis or Lymphadenopathy)
Grade - 8 - Gangrene of Forefoot Only
Grade - 9 - Gangrene of Majority of Foot

Onychial grades at risk

- Grade I Normal
Grade II Mild Hypertrophy
Grade III Hypertrophic
 Dystrophic
 Onychauxis

Grade IV Mycotic
 Infected
 Onychodysplasia
 Hypertrophic
 Deformed
 Onychogryphosis
 Dystrophic
 Mycotic
 Infected

15. Appendix B

Summary of clinical findings in 1,000 older people (31)

Patients Percentage (%) of Clinical Findings:	%
History of present illness	
Swelling of feet	382
Painful feet	746
Hyperkeratosis	510
Onychial changes	895
Bunions	240
Painful toenails	357
Infections (bacterial)	37
Cold feet	197
Other	480
Past history	
Heart disease	258
High blood pressure	367
Arthritis	421
Circulatory disease	229
Thyroid disease	94
Allergy	53
Diabetes mellitus	572
Insulin-dependent	175
Non-insulin-dependent	397
Hypercholesterolemia	362
Gout	71
Smoking	63
Alcohol abuse	94
Systems review	
Constitutional	84
Ears, nose, throat	87
Eyes	487
Skin/hair	642
Respiratory	279
Psychiatric	242
Hematologic	21

Cardiac/vascular	410
Musculoskeletal	842
Gynecologic	420
Lymphatic	32
Genitourinary	273
Neurologic	124
Endocrine	619
Gastrointestinal	270
Immunologic	22
Dermatologic evaluation	
Hyperkeratosis	770
Onychauxis	470
Infection	42
Ulceration	24
Onychomycosis	590
Onychodystrophy	942
Cyanosis	42
Xerosis	652
Tinea pedis	137
Verruca	9
Hematoma	104
Rubor	61
Preulcerative	114
Discolored	89
Foot orthopedic evaluation	
Hallux valgus	527
Anterior imbalance	429
Digiti flexus	589
Pes planus	174
Pes valgoplanus	121
Pes cavus	192
Hallux rigidus/limitus	322
Morton’s syndrome, bursitis	107
Prominent metatarsal head	642
Charcot’s joint	46
Other	172
Vascular evaluation	
Coldness	483
Trophic changes	796
Dorsalis pedis pulse absent	347
Posterior tibial pulse absent	322
Night cramps	473
Edema	418
Claudication	223
Varicosities	181
Amputation	15
Above-the-knee	

Below-the-knee	4
Forefoot	3
Toes	6
Atrophy	689
Neurologic evaluation	
Achilles	42
Vibratory	721
Sharp/dull	432
Paresthesia	684
Superficial plantar	32
Joint position	214
Burning	621
Other	384
Risk category – neurologic	
No sensory loss	360
Sensory loss	217
Sensory loss and deformity	340
Sensory loss, history of ulceration, and deformity	83
Risk category – vascular	
No change	183
Mild claudication	133
Moderate claudication	90
Severe claudication	52
Ischemic rest pain	473
Minor tissue loss	6
Major tissue loss	9
Class findings	
A-1: Nontraumatic amputation	15
B-1: Absent posterior tibial pulse	322
B-2: Advanced trophic changes	796
B-2-a: Hair growth (decrease or absent)	780
B-2-b: Nail changes (thickening)	942
B-2-c: Pigmentary changes (discoloration)	89
B-2-d: Skin texture (thin, shiny)	473
B-2-e: Skin color (rubor or redness)	61
B-3: Absent dorsalis pedis pulse	347
C-1: Claudication	223
C-2: Temperature changes (cold)	483
C-3: Edema	418
C-4: Paresthesia	684
C-5: Burning	621
Onychomycosis	
Discoloration	590
Hypertrophy	590
Subungual debris	483
Onycholysis	521

Secondary infection	104
Limitation of ambulation and pain	107
Classification of pressure keratosis	
Grade 0: No lesion	230
Grade 1: Diffuse or pinch	78
Grade 2: Circumscribed oval or punctate	147
Grade 3: Heloma milliars or durum	204
Grade 4: Tyloma with heloma	203
Grade 5: Extravasation or maceration	114
Grade 6: Tissue breakdown	24
Ulcer classification	
Grade 0: Absent skin lesions	230
Grade 1: Dense callus	632
Grade 2: Preulcerative changes	114
Grade 3: Partial-thickness (superficial)	22
Grade 4: Full-thickness (deep)	2
Grade 5: Full-thickness (deep) with involvement of tendon, bone, ligament, or joint	0
Grade 6: Localized infection (abscess or osteomyelitis)	0
Grade 7: Proximal spread of infection (cellulitis)	0
Grade 8: Gangrene of forefoot	0
Grade 9: Gangrene of majority of foot	0
Onychial grades at risk	
Grade I: Normal	58
Grade II: Mild hypertrophy	888
Grade III: Hypertrophy, dystrophy, onychauxis, mycosis, infection, onychodysplasia	355
Grade IV: Hypertrophy, deformity, onychogryphosis, dystrophy, mycosis, infection	235
Footwear satisfactory	
Yes	637
No	363
Hygiene satisfactory	
Yes	972
No	28
Stockings	
Nylon	587
Cotton	302
Wool	93
Other	12
None	7
Plan	
Podiatric referral	1,000
Medical referral	272
Vascular studies	104

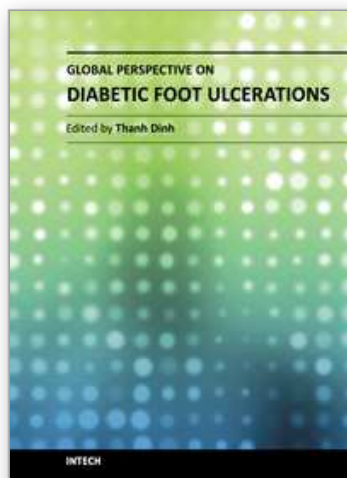
Imaging	123
Patient education	1,000
Special footwear	425
Clinical laboratory evaluation	36
Medication	824

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Global Perspective on Diabetic Foot Ulcerations

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Over the last decade, it is becoming increasingly clear that diabetes mellitus is a global epidemic. The influence of diabetes is most readily apparent in its manifestation in foot complications across cultures and continents. In this unique collaboration of global specialists, we examine the explosion of foot disease in locations that must quickly grapple with both mobilizing medical expertise and shaping public policy to best prevent and treat these serious complications. In other areas of the world where diabetic foot complications have unfortunately been all too common, diagnostic testing and advanced treatments have been developed in response. The bulk of this book is devoted to examining the newest developments in basic and clinical research on the diabetic foot. It is hoped that as our understanding of the pathophysiologic process expands, the devastating impact of diabetic foot complications can be minimized on a global scale.

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