Assessment of Painful Diabetic Peripheral Neuropathy (pDPN):
An Essential Part of the Diabetic Foot Exam

Pfizer Medical Affairs
Objectives

• Review the epidemiology, burden, pathophysiology, and clinical features of DPN and pDPN
• Review components of the comprehensive foot examination for patients with diabetes
• Review risk classification based on the comprehensive foot examination
• Review current guidelines for the screening, diagnosis, and management of DPN and pDPN
• Provide patient education for appropriate diabetic foot care
Prevalence of Diabetes in the United States

- Diabetes affects 29.1 million people in the US (9.3% of the population)\(^1\)
- Prevalence of diabetes by age group\(^1\):
  - ≥20 years: 28.9 million (12.3%)
  - ≥65 years: 11.2 million (25.9%)
- Diabetes is the 7\(^{th}\) leading cause of death in the US (2010)\(^1\)
- Diabetes is the leading cause of kidney failure, nontraumatic lower-limb amputations, and new cases of blindness among adults in the US\(^2\)
- A major cause of heart disease and stroke\(^1\)

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2. CDC. National Diabetes Fact Sheet: Atlanta, GA: Department of Human Services, Centers for Disease Control and Prevention; 2011.
Diabetes and Associated pDPN Are Prevalent\textsuperscript{1,2}

- Up to 50% of patients with diabetes have DPN\textsuperscript{2}
- \textasciitilde20% of patients with diabetes have pDPN\textsuperscript{2}

DPN = diabetic peripheral neuropathy
pDPN = painful diabetic peripheral neuropathy

Scope of the Problem
The Diabetic Foot

- One of the most common complications of diabetes in the lower extremity is the diabetic foot ulcer
  - An estimated 15% of patients with diabetes will develop a lower extremity ulcer
  - 7% to 20% of patients with foot ulcers will subsequently require amputation
  - Foot ulceration is the precursor to approximately 85% of lower extremity amputations (LEAs) in people with diabetes

- Diabetes is the main initiating factor for foot ulceration and the most common cause of nontraumatic LEA in the Western world
  - Approximately 45% to 60% of all diabetic ulcerations are purely neuropathic
The Diabetic Foot

- Patients who have chronic neuropathic pain associated with DPN are also at risk for foot ulcers and subsequent infections.¹
- Ritzwoller and colleagues demonstrated a higher prevalence of limb complications in pDPN patients compared to matched diabetes controls²:
  - >2 times as many limb infections (\(P<.001\))
  - A nearly 10-fold increase in limb amputations (\(P<.001\))
- The annual cost of foot ulcer care in the US is estimated at $5457 per patient (total annual cost = $5 billion)³
- Direct and indirect costs of LEA range from $20,000 to $40,000 per event³

pDPN Impacts Physical and Mental Health Status

SF-12v2 Scores for Study Subjects and Normative Groups (N=255)

<table>
<thead>
<tr>
<th>SF-12v2 Scores</th>
<th>General US Population</th>
<th>Patients with Diabetes</th>
<th>pDPN Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Functioning</td>
<td>50</td>
<td>45</td>
<td>50</td>
</tr>
<tr>
<td>Role Physical</td>
<td>50</td>
<td>45</td>
<td>50</td>
</tr>
<tr>
<td>Bodily Pain</td>
<td>50</td>
<td>45</td>
<td>50</td>
</tr>
<tr>
<td>General Health</td>
<td>50</td>
<td>45</td>
<td>50</td>
</tr>
<tr>
<td>Vitality</td>
<td>50</td>
<td>45</td>
<td>50</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>50</td>
<td>45</td>
<td>50</td>
</tr>
<tr>
<td>Role Emotional</td>
<td>50</td>
<td>45</td>
<td>50</td>
</tr>
<tr>
<td>Mental Health</td>
<td>50</td>
<td>45</td>
<td>50</td>
</tr>
</tbody>
</table>

SF-12v2 = Short Form Version 2 health form. Higher scores correlate to better health status.

Relationship Between Pain Severity and Impact of pDPN on Daily Function

![Bar chart showing the relationship between pain severity and impact on daily activities]

<table>
<thead>
<tr>
<th>Activity</th>
<th>Mild Pain (n = 50)</th>
<th>Moderate Pain (n = 149)</th>
<th>Severe Pain (n = 194)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep</td>
<td>82%†</td>
<td>57%</td>
<td>42%</td>
</tr>
<tr>
<td>Walk</td>
<td>50*</td>
<td>49%†</td>
<td>42%</td>
</tr>
<tr>
<td>Drive</td>
<td>28*</td>
<td>34%</td>
<td>42%</td>
</tr>
<tr>
<td>Exercise</td>
<td>52*</td>
<td>79%†</td>
<td>70%†</td>
</tr>
<tr>
<td>Work</td>
<td>20%</td>
<td>20%</td>
<td>16%</td>
</tr>
<tr>
<td>Perform Daily Activities</td>
<td>69%†</td>
<td>42%*</td>
<td>42%*</td>
</tr>
</tbody>
</table>

*P ≤ 0.05 versus mild; †P ≤ 0.05 versus mild and moderate.

Impact of pDPN on Annual Health Care Costs

Annual health care costs for patients with pDPN were up to $7200 higher when compared to patients with diabetes but no pDPN.

Patients with pDPN were selected from 2 different administrative databases of health care claims and matched to control subjects with a diagnosis of diabetes but no pDPN. Multivariate regression analyses were used to estimate the differences in health care costs between cases and control subjects.

Economic Burden of pDPN Increases With Greater Pain Severity


* Average annualized total direct cost per pDPN subject was significantly different by pain severity (P <0.0001). Direct costs include physician visits, other healthcare provider visits, prescription medications, TENS device, outpatient tests/procedures, emergency room visits, hospital outpatient visits, hospitalizations, direct medical costs to subjects, and direct non-medical (child care, help with house and/or yard work, and help with activities of daily living) due to pDPN.

** Average annualized total indirect cost per pDPN subject was significantly different by pain severity (P = 0.0003). Total indirect costs include overall work impairment, activity impairment, disability, unemployment, early retirement, and reduced work schedule due to pDPN.

- Scores on the BPI Pain Severity Index were used to classify average pain severity as mild, moderate, or severe.
Overview of pDPN
Diabetic Peripheral Neuropathy

- A symmetrical, length-dependent sensorimotor polyneuropathy attributable to metabolic and microvessel alterations as a result of chronic hyperglycemia exposure and cardiovascular risk covariates\(^1\)
  
- The most common presentation of neuropathy in diabetes\(^2\)
  
- Insidious in onset\(^2\)
  
- Up to half of patients may be asymptomatic, with the diagnosis made during a routine neurological exam or when the patient presents with a painless foot ulcer\(^2\)

Pathophysiology of DPN

- Small fibers (Aδ and C)$^{1,2}$
  - Pain and hyperalgesia (first)
  - Loss of sensitivity (later on)
  - Autonomic symptoms
  - Electrophysiology may not detect nerve damage

- Large fibers (Aα/β)$^{1,3}$
  - Sensory and/or motor nerves
  - Loss of vibration perception and proprioception
  - Wasting of small muscles in hands/feet
  - Abnormalities readily detected by electromyography

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It is not known why some patients experience neuropathic pain and others, with similar nerve lesions, do not\(^2\)

- Sensory and/or motor nerves
- Loss of vibration perception and proprioception
- Wasting of small muscles in hands/feet
- Abnormalities readily detected by electromyography

Result of sensory nerve damage\(^2\)
Sock-and-glove distribution very common\(^1\)
Both small and large fibers can be affected\(^1\)

Duration of Diabetes and Poor Glycemic Control Increase Risk for DPN

Severity of DPN correlates with duration of diabetes

Prevalence of DPN is related to glycemic control

**SD = standard deviation**


**Severity of Diabetic Neuropathy**

- 0: 10.3 (±7.7)
- B: 10.1 (±8.1)
- 1: 12.4 (±8.4)
- 2: 13.3 (±8.2)
- 3: 15.6 (±9.7)

**Prevalence of DPN (%)**

- < 7: 17%
- 7-8: 24%
- 8.1-9.5: 29%
- ≥9.6: 41%

(A1C (%) Adjusted for Duration of Diabetes)
Duration of Diabetes and Poor Glycemic Control Increase Risk for DPN

Severity of DPN correlates with duration of diabetes

Prevalence of DPN is related to glycemic control

Although poor glycemic control is a risk factor for pDPN, patients who have good glycemic control are still at risk for developing pDPN

SD = standard deviation

Odds Ratios for Key Risk Factors for Development of DPN\textsuperscript{1}

Clinical Presentation pDPN

- Up to 50% of patients with DPN experience painful symptoms\(^1\-^4\)
  - Burning
  - Sharp pain
  - Electric shocks
  - Shooting
  - Stabbing
  - Deep aching
  - Numbness
  - Prickling
  - Tingling
  - Pins and needles
  - Allodynia
  - Hyperalgesia

Clinical Presentation of pDPN

- First affects the feet and lower limbs, with the hands affected later
- Symptoms occur symmetrically in a “stocking and glove” pattern
- Symptoms tend to be worse at night
- Pain may be constant or intermittent
- Patients often find it difficult to describe the symptoms, which may differ from the pain they've previously experienced

Clinical Presentation of pDPN

- The majority of patients report their pain as moderate or severe\(^1,2\)
- Limited data on the natural history of pDPN\(^3\)
  - Some studies report no appreciable occurrence of remission or improvement in pain severity over time
  - Other studies suggest painful symptoms may improve with the worsening of sensory loss
- There is no correlation between the intensity of pain symptoms and the severity of sensory loss\(^4\)

The Comprehensive Foot Exam
All patients should be assessed annually for DPN using medical history and simple clinical tests:

- Patients with type 1 diabetes for five or more years
- All patients with type 2 diabetes

Perform a comprehensive foot evaluation each year to identify risk factors for ulcers and amputations.

Patients with a history of ulcers or amputations, foot deformities, insensate feet, and peripheral arterial disease should have their feet examined at every visit.
Key Components of the Foot Exam

• Patient History
  – Includes assessment for neuropathic pain symptoms

• General Inspection
  – Dermatologic
  – Musculoskeletal

• Vascular Assessment

• Neurological Assessment

Past History

- Ulceration
- Amputation
- Charcot foot
- Angioplasty or Vascular surgery
- Cigarette smoking
- Foot care practices

Neuropathic symptoms

- Positive (eg, burning or shooting pain, electrical or sharp sensations etc.)
- Negative (eg, numbness, feet feel dead)

Vascular Symptoms

- Claudication
- Leg fatigue
- Rest pain
- Decreased walking speed
- Nonhealing ulcer

Other Diabetic Complications

- Renal disease (dialysis)
- Retinopathy (visual impairment)

General Inspection¹

• Careful inspection of skin integrity and musculoskeletal deformities performed in a well-lit room with shoes and socks removed

• Inappropriate footwear and foot deformities are common contributory factors in the development of foot ulceration
  – Inspect the shoes. “Are these shoes appropriate for these feet?”

• **Dermatologic**
  – Skin status: color, thickness, dryness, cracking
  – Sweating
  – Infection: check between toes for fungal infection
  – Ulceration
  – Calluses (particularly with hemorrhage), blistering, abnormal erythema

• **Musculoskeletal**
  – Deformity (eg, claw toes, prominent metatarsal heads, Charcot foot)
  – Muscle wasting (guttering between metatarsals)

Vascular Assessment$^{1,2}$

- Peripheral arterial disease (PAD) is a component cause in approximately 1/3 of foot ulcers and is often a significant risk factor associated with recurrent wounds.
- Assessment of PAD is important in defining overall lower extremity risk status.
- Assess for symptoms of vascular disease: claudication, rest pain, leg fatigue, decreased walking speed, nonhealing ulcers.
- Vascular examination should include:
  - Palpation of the posterior tibial and dorsalis pedis pulses.
  - Ankle-brachial index testing in patients with signs or symptoms of PAD.

Loss of Protective Sensation

- 5 simple clinical tests available*
- Ideally 2 of these should be regularly performed during the screening exam
  - Normally the 10-g monofilament and 1 other test
- One or more abnormal tests would suggest LOPS
- At least 2 normal tests (and no abnormal test) would rule out LOPS

Clinical Tests

- 10-g monofilament
- Vibration using 128-Hz tuning fork
- Pinprick sensation
- Ankle reflexes
- Vibration Perception Threshold (VPT)

* Temperature sensation included as a testing option in the Standards of Medical Care in Diabetes – 2016. The testing procedure was not specified.


LOPS = Loss of Protective Sensation
# ADA Risk Classification Based on the Comprehensive Foot Exam

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Definition</th>
<th>Treatment Recommendations</th>
<th>Suggested Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No LOPS, no PAD, no deformity</td>
<td>• Patient education including advice on appropriate footwear</td>
<td>Annually (by generalist and/or specialist)</td>
</tr>
</tbody>
</table>
| 1 | LOPS ± deformity | • Consider prescriptive or accommodative footwear  
• Consider prophylactic surgery if deformity is not able to be safely accommodated in shoes. Continue patient education | Every 3–6 months (by generalist or specialist) |
| 2 | PAD ± LOPS | • Consider prescriptive or accommodative footwear  
• Consider vascular consultation for combined follow-up | Every 2–3 months (by specialist) |
| 3 | History of ulcer or amputation | • Same as category 1  
• Consider vascular consultation for combined follow-up if PAD present | Every 1–2 months (by specialist) |

LOPS = Loss of Protective Sensation

American Society of Pain Educators Consensus Guidelines: Key Elements in the Diagnosis of pDPN


- Establish presence of neuropathy
  - Use validated questionnaires to identify painful symptoms
  - Perform neurological assessment (10-g monofilament, 128-Hz tuning fork)

- Assess pain characteristics
  - Distal, symmetrical
  - Numbness, tingling vs. burning, aching, throbbing pain
  - Spontaneous pain (continuous or intermittent) vs stimulus-evoked pain

- Rule out nondiabetic causes for neuropathy and/or pain
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- Rule out nondiabetic causes for neuropathy and/or pain

There is no correlation between the intensity of pain symptoms and the severity of sensory deficit

Validated Questionnaires to Identify Neuropathic Pain\textsuperscript{1-3}

- Patients often find it difficult to describe the symptoms of pDPN as they are different than the pain they have previously experienced\textsuperscript{1}
- Use of validated questionnaires that can distinguish neuropathic from non-neuropathic pain is recommended in routine clinical practice\textsuperscript{1}
- Examples of validated questionnaires\textsuperscript{1-3}:
  - ID Pain
  - Leeds Assessment of Neuropathic Symptoms and Signs\textsuperscript{©} (LANSS and S-LANSS)
  - Neuropathic Pain Questionnaire\textsuperscript{©} (NPQ and NPQ-SF)
  - Neuropathic Pain Diagnostic Questionnaire\textsuperscript{©} (DN4 and DN4-Interview)

ID Pain: Patient-Reported Screener

• A 6-item validated screening tool that accurately indicates the presence of a neuropathic component of pain

• Validated using data from 2 independent multicenter study samples and a statistical and psychometric methodology informed by expert clinician review

• Self-administered or administered by staff

• Scores range from -1 to 5 with a higher score indicative of pain that contains a neuropathic component

ID Pain: Patient-Reported Screener Neuropathic vs Nociceptive Pain

Mark “Yes” to the following items that describe your pain over the past week and “No” to the ones that do not.

<table>
<thead>
<tr>
<th>Question</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did the pain feel like pins and needles?</td>
<td>1</td>
</tr>
<tr>
<td>2. Did the pain feel hot/burning?</td>
<td>1</td>
</tr>
<tr>
<td>3. Did the pain feel numb?</td>
<td>1</td>
</tr>
<tr>
<td>4. Did the pain feel like electrical shocks?</td>
<td>1</td>
</tr>
<tr>
<td>5. Is the pain made worse with the touch of clothing or bed sheets?</td>
<td>1</td>
</tr>
<tr>
<td>6. Is the pain limited to your joints?</td>
<td>-1</td>
</tr>
</tbody>
</table>

A score of 3, 4, or 5 (indicating the likely presence of a neuropathic component) may justify a more detailed evaluation.

Electronic Chronic Pain Questions (eCPQ)*

**CHRONIC PAIN?**
Have you had pain most days in the past 3 months? (Y/N)

**PAIN INTENSITY & LOCATION**
- What was your average pain over the last week? (0–10 NRS Scale)
- Where is your pain? (Diagram)

**IMPACT ON FUNCTION, SLEEP, & MOOD**
Thinking of the past week...
- How much did pain interfere with your usual activities?
- How much did pain interfere with your sleep?
- How much did pain interfere with your mood?
  (0–10 NRS Scale for each item)

**PAIN QUALITY & TYPE**

**ID PAIN® Screener**
- Did the pain feel like pins and needles? (Y/N)
- Did the pain feel hot/burning? (Y/N)
- Did the pain feel numb? (Y/N)
- Did the pain feel like electrical shocks? (Y/N)
- Is the pain made worse with the touch of clothing or bed sheets? (Y/N)
- Is the pain limited to your joints? (Y/N)

**“Sensory Hypersensitivity” or Fibromyalgia-like Pain**
- Did you have trouble thinking or remembering in the past week?
- Were you sensitive to bright lights, loud noises, or smells in the past week?
  (0–10 NRS Scale for each item)

Other information to help diagnose sensory hypersensitivity can be derived from medical history and other eCPQ questions. It includes:
- Widespread pain from body map image / locations? (Y/N)
- Marked impairment of mood, sleep, and function? (Y/N)
- Medical history of ≥1 other sensory hypersensitivity condition? (Y/N)

**Score:**
- Score: < 3
  Consider Nociceptive Pain
- Score: ≥ 3
  Consider Neuropathic Pain

*For the purposes of this presentation, the eCPQ questions have been paraphrased.

NRS = numeric rating scale

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2016 Diabetes Physician Quality Reporting System (PQRS) Measures

Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation (#126)

Percentage of patients ≥18 years with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months
- 10-g monofilament plus one of the following: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold

Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear (#127)

Percentage of patients ≥18 years with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing
- Foot exam documenting vascular, neurological, dermatological, and structural/biomechanical findings;
- Foot measured using a standard device;
- Footwear counseling based on risk categorization.

Diabetes: Foot Exam (#163)

Percentage of patients aged 18-75 years with diabetes who had a foot examination during the measurement period
- Examination through visual, pulse, and sensory foot exams

(Reportable via EHR only in 2016; Claims/Registry Reporting Method Removed)

Providers who do not satisfactorily report data on quality measures for covered professional services will be subject to a 2% negative payment adjustment to Medicare Part B Physician Fee Schedule covered services beginning in 2015. Program participation during a calendar year will affect payments after two years (i.e., 2016 program participation will affect 2018 payments).

Clinical Quality Measures (CQMs) for Meaningful Use

• Beginning in 2014:\(^1\):
  – Eligible professionals must report on 9 of the 64 approved CQMs
  – Recommended core CQMs are encouraged but not required
  – Selected CQMs must cover at least 3 of the National Quality Strategy domains
• EHR Incentive Programs in 2015 through 2017: CQM reporting for both eligible professionals and hospitals/CAHs remains as previously finalized.\(^2\)

**Diabetes: Foot Exam (CMS 123v4; NQF #0056)**\(^3\)

**DESCRIPTION:**
Percentage of patients aged 18–75 years of age with diabetes mellitus who had a foot exam (visual, pulse, and sensory foot examinations) during the measurement period.

**DOMAIN:** Clinical Processes/Effectiveness

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Management of pDPN
Therapeutic strategies for the relief of symptoms related to pDPN can potentially reduce pain and improve quality of life.

- Assess and treat patients with a tailored and stepwise pharmacological strategy with careful attention to symptom improvement, medication adherence, and side effects.

- Provide general foot self-care education to all patients with diabetes.

- Refer patients who smoke, have LOPS, structural abnormalities, PAD, or prior lower extremity complications to foot care specialists for ongoing preventive care and lifelong surveillance.

- Multidisciplinary approach recommended for those with foot ulcers and high-risk feet.
American Society of Pain Educators Consensus Guidelines: pDPN Treatment Goals

<table>
<thead>
<tr>
<th>Goal</th>
<th>Recommendation</th>
</tr>
</thead>
</table>
| **Primary:** Zero pain | • Be realistic  
• Many patients only achieve 30% to 50% pain reduction  
• Aggressive pursuit of maximum relief is recommended |
| **Secondary:** Restoration or improvement in functional measures and quality of life | • Pain relief may translate to an ability to return to work or social activities and improved quality of life and mood  
• Hopefully, improved function will follow pain relief  
• If improved function does not follow, take measures to help patients optimize function in the presence of residual pain |

Management of Pain Associated with pDPN

- Neurostimulatory
- Interventional Regional Anesthesia
- Pharmacotherapy
- Physical Rehabilitation
- Psychologic
- Lifestyle

References:
Commonly Prescribed Classes of Medications for the Management of pDPN¹,²

- Anticonvulsants*
- Serotonin-norepinephrine reuptake inhibitors*
- Tricyclic antidepressants
- Opioid analgesics*
- Dermal and topical treatments

*FDA-approved treatment available within these classes.

Objective: To develop a scientifically sound and clinically relevant evidence-based guideline for the treatment of pDPN

Addresses the efficacy of pharmacologic and nonpharmacologic treatments to reduce pain and improve physical function and quality of life in patients with pDPN

Classified studies according to the AAN classification of evidence scheme for a therapeutic article. Recommendations were linked to the strength of evidence
Impact of pDPN on Diabetes Care

• Regular exercise is an important part of the diabetes management plan:\(^1,2\):
  – Improves blood glucose control
  – Reduces cardiovascular risk factors
  – Contributes to weight loss
  – Improves well-being

• “The inclusion of an exercise program or other means of increasing overall physical activity is critical for optimal health in individuals with type 2 diabetes”\(^2\)
  – American College of Sports Medicine and American Diabetes Association 2010 Joint Position Statement on Exercise and Type 2 Diabetes

• pDPN negatively impacts walking ability and mobility\(^3\)

• Guidelines recommend aerobic exercise (eg, brisk walking) as part of the diabetes management plan:\(^1,2\)

Patient Education
Management of the Diabetic Foot: Patient Education


- Control DM
- Check feet every day
- Wash feet every day
- Keep skin soft, smooth, and dry; smooth corns and calluses gently
- Trim toenails each week or when needed
- Wear shoes and socks at all times
- Protect feet from hot and cold
- Keep blood flowing to the feet
- Be active
- Check with your doctor
Management of the Diabetic Foot: Footwear Assessment

• Examine the inside of the shoes
• Look at the type of footwear
• Look at the fit of the footwear
• Avoid pointed-toe and open-toe shoes, high heels, thongs and sandals
• Shoes should accommodate any deformities
• Should corrective shoes or inserts be prescribed?

Summary

- pDPN is a prevalent chronic complication of diabetes that is associated with significant health and economic burden\(^1\).
- According to the ADA, an annual comprehensive foot exam and assessment for DPN are standards of medical care for patients with diabetes\(^2\).
- The American Society of Pain Educators recommends the use of validated questionnaires to identify and assess neuropathic pain in patients with diabetes\(^3\).
- The ADA recommends both pharmacologic and nonpharmacologic therapies to help patients manage and treat symptoms of pDPN\(^2\).