



## Effective Health Care

### Prevention of DM Related Foot Complications with Comprehensive Diabetic Lower Extremity Exam (CDLEE)

#### Results of Topic Selection Process & Next Steps

The nominator, The American Podiatric Medical Association (APMA) is interested in a new evidence review on Prevention of DM Related Foot Complications with Comprehensive Diabetic Lower Extremity Exam (CDLEE) to inform clinical practice.

Because no original research addresses the nomination, a new review is not feasible at this time. No further activity on this nomination will be undertaken by the Effective Health Care (EHC) Program.

#### Topic Brief

**Topic #:** Prevention of DM Related Foot Complications with Comprehensive Diabetic Lower Extremity Exam (CDLEE) Comprehensive Diabetic Lower Extremity Exam (CDLEE)

**Nomination Date:** July 1, 2018

**Nominator:** The American Podiatric Medical Association (APMA)

**Topic Brief Date:** December 26, 2018

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**Conflict of Interest:** None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

**Background:** According to an estimate from the Centers for Disease Control (CDC), 29.1 million people, or 9.3 percent of the U.S. population, have diabetes mellitus (DM). The most common complications of DM are microvascular and macrovascular damage and manifest as peripheral neuropathy and vascular disease. Thirty to 50 percent of patients with diabetes will eventually develop nerve damage called neuropathy. Diabetic peripheral neuropathy is usually described as glove-stocking distribution of numbness, sensory loss, paresthesia (abnormal sensation) and/or pain (shooting or stabbing). Sensory loss from neuropathy and decreased blood supply from vascular disease increases risk for foot injury, foot and leg ulceration and infections. Recurrent ulcers and infections may eventually lead to amputation of the lower extremities. Altered proprioception causes imbalance and increased risk for falls. <sup>1</sup>

Comprehensive Diabetic Lower Extremity Exam (CDLEE) helps to identify DM patients at risk for diabetic foot complications, such as foot infection, ulceration, hospitalization and amputation. CDLEE consists of visual inspection of the feet and legs for evidence of skin lesions or changes, evaluation of blood flow via pedal pulses, examination of the overall structure of the feet and their relation to the legs as well as determination of the status of peripheral nerve function in the diabetic patient<sup>1,2</sup>.

**Nominator and Stakeholder Engagement:**

The nominator is American Podiatric Medical Association (APMA) interested in using the systematic review evidence to educate doctors of podiatric medicine, other healthcare providers on the importance of CDLEE to reduce the burden of diabetic foot complications. They are also interested in whether the delivery personnel affects the effectiveness of CDLEE, in particular if delivered by a podiatrist.

**Key Questions:**

KQ 1. What are the benefits and harms of Comprehensive Diabetic Lower Extremity Exam (CDLEE) to prevent the foot complications among adults age 18 or older with type 1 or type 2 diabetes mellitus?

KQ 1a: Could CDLEE risk stratification and subsequent follow-up planning reduce the incidence of complications as described above?

KQ 2. What is the comprehensive effectiveness and harms of CDLEE done by podiatrist or other health care providers to prevent foot complication among adults age 18 or older with type 1 or type 2 diabetes mellitus?

**Table 1. Key Questions and PICOTS**

<b>Key Questions</b>	What are the benefits and harms of Comprehensive Diabetic Lower Extremity Exam (CDLEE) to prevent the foot complications among adults age 18 or older with type 1 or type 2 diabetes mellitus?	What is the comparative effectiveness and harms of CDLEE done by podiatry or other health care providers to prevent foot complication among adults age 18 or older with type 1 or type 2 diabetes mellitus?
<b>Population</b>	Patients with DM Type 1 and Type 2	Patients with DM Type 1 and Type 2
<b>Interventions</b>	Comprehensive Diabetic Lower Extremity Exam (CDLEE)	CDLEE done by podiatrist (DPM)
<b>Comparators</b>	Active interventions, usual care	CDLEE done by other health care providers
<b>Outcomes</b>	<p><b>Benefits (KQ1):</b></p> <ul style="list-style-type: none"> <li>- Incident or recurrent foot ulcer</li> <li>- Falls</li> <li>- Perceived fall risk</li> <li>- Amputation</li> <li>- Health-related quality of life</li> <li>- Physical activity level</li> <li>- Peripheral vascular interventions</li> </ul> <p><b>Harms (KQ1):</b></p> <ul style="list-style-type: none"> <li>- Cost</li> <li>- Discomfort</li> <li>- Dropouts</li> </ul>	<p><b>Benefits (KQ1):</b></p> <ul style="list-style-type: none"> <li>- Incident or recurrent foot ulcer</li> <li>- Falls</li> <li>- Perceived fall risk</li> <li>- Amputation</li> <li>- Health-related quality of life</li> <li>- Physical activity level</li> <li>- Peripheral vascular interventions</li> </ul> <p><b>Harms (KQ1):</b></p> <ul style="list-style-type: none"> <li>- Cost</li> <li>- Discomfort</li> <li>- Dropouts</li> </ul>
<b>Setting</b>	Ambulatory care  Outpatient	Ambulatory care  Outpatient

Abbreviations: CDLEE: Comprehensive Diabetic Lower Extremity Exam, KQ: Key Question, DPM: Doctor of podiatric medicine

## Methods

We assessed nomination “Prevention of DM Related Foot Complications with Comprehensive Diabetic Lower Extremity Exam (CDLEE)” for priority for a systematic review or other AHRQ EHC report with a hierarchical process using established selection criteria. Assessment of each criteria determined the need to evaluate the next one. See Appendix A for detailed description of the criteria.

1. Determine the *appropriateness* of the nominated topic for inclusion in the EHC program.
2. Establish the overall *importance* of a potential topic as representing a health or healthcare issue in the United States.
3. Determine the *desirability of new evidence review* by examining whether a new systematic review or other AHRQ product would be duplicative.
4. Assess the *potential impact* a new systematic review or other AHRQ product.
5. Assess whether the *current state of the evidence* allows for a systematic review or other AHRQ product (feasibility).
6. Determine the *potential value* of a new systematic review or other AHRQ product.

## Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

## Desirability of New Review/Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last three years from September 19, 2015 and September 19, 2018 on the key questions of the nomination. See Appendix B for sources searched.

## Impact of a New Evidence Review

The impact of a new evidence review was qualitatively assessed by analyzing the current standard of care, the existence of potential knowledge gaps, and practice variation. We considered whether it was possible for this review to influence the current state of practice through various dissemination pathways (practice recommendation, clinical guidelines, etc.).

## Feasibility of New Evidence Review

We conducted a literature search in PubMed from September 19, 2013 and September 19, 2018. We reviewed all titles and abstracts for inclusion and classified identified studies by study design, to assess the size and scope of a potential evidence review. (7 SRs, 77 RCTs and 148 other types of titles and abstracts reviewed for the feasibility scan) See Table 2, Feasibility Column, Size /Scope of Review Section for the citations of included studies. See Appendix C for the PubMed search strategy and links to the ClinicalTrials.gov search.

## Compilation of Findings

We constructed a table with the selection criteria and our assessments (Appendix A).

## Value

We assessed the nomination for value. We considered whether or not the clinical, consumer, or policymaking context had the potential to respond with evidence-based change; and if a partner organization would use this evidence review to influence practice

## Results

See Appendix A for detailed assessments of all EPC selection criteria.

### Appropriateness and Importance

Approximately 50% of diabetic population develops peripheral neuropathy and is at risk for foot complications.

## Desirability of a New Review/Duplication

A new evidence review would not be duplicative of an existing evidence review. We found no systematic reviews directly relevant to KQ1 and KQ2. See Table 2, Duplication column.

## Impact

A new review may have low impact. The standard of care for lower extremity exam in people with diabetes has been described in multiple national and international guidelines.

## Feasibility of New Evidence Review

A new evidence review is not feasible.

We found no studies for KQ1 (effectiveness of CDLEE) or for KQ2 (CER of CDLEE done by podiatrist versus other health care workers) See Table 2, Feasibility column.

**Table 2.** Key Questions and Results for Duplication and Feasibility

Key Question	Duplication (09/2015-09/2018)	Feasibility (09/2013-09/2018)
KQ 1: Benefits and harms of CDLEE to prevent the foot complications among adults with type 1 or type 2 diabetes mellitus?	Total number of identified systematic reviews: #0	<p><u>Size/scope of review</u></p> <p>Relevant Studies Identified: #0</p> <p><u>Clinicaltrials.gov</u></p> <ul style="list-style-type: none"> <li>• None</li> </ul>
KQ 2: Comparative effectiveness and harms of CDLEE done by podiatry or other health care providers to prevent foot complication among adults age 18 or older with type 1 or type 2 diabetes mellitus?	Total number of identified systematic reviews: #0	<p><u>Size/scope of review</u></p> <p>Relevant Studies Identified: #0</p> <p><u>Clinicaltrials.gov</u></p> <ul style="list-style-type: none"> <li>• None</li> </ul>

## Summary of Findings

- Appropriateness and importance: The topic is both appropriate and important.
- Duplication: There is no SR directly related to KQ1 and KQ2. Multiple clinical practice guidelines by major national and international organizations consistently recommend annual diabetic foot exam for every diabetic patient<sup>3</sup>.
- Impact: A new systematic review has unclear impact potential.
- Feasibility: A new systematic review is not feasible due to limited number of published studies on KQ1 and KQ2.

## References

1. Dy SM, Bennett WL, Sharma R, et al. AHRQ Comparative Effectiveness Reviews. Preventing Complications and Treating Symptoms of Diabetic Peripheral Neuropathy. Rockville (MD): Agency for Healthcare Research and Quality (US); 2017.
2. CADTH Rapid Response Reports. Delivery of Podiatry Care for Adults with Diabetes or Chronic Foot Conditions: A Review of the Clinical Effectiveness. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health. Copyright (c) 2013 Canadian Agency for Drugs and Technologies in Health.; 2013.
3. Hingorani A, LaMuraglia GM, Henke P, et al. The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. J Vasc Surg. 2016 Feb;63(2 Suppl):3s-21s. doi: 10.1016/j.jvs.2015.10.003. PMID: 26804367.

## Appendix A. Selection Criteria Summary

Selection Criteria	Supporting Data
<b>1. Appropriateness</b>	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the U.S.?	Yes this nomination represents a health care intervention (CDLEE) available in the U.S.
1b. Is the nomination a request for a systematic review?	Yes, this topic is a request for a systematic review.
1c. Is the focus on effectiveness or comparative effectiveness?	The focus of this review is on both effectiveness of CDLEE and comparative effectiveness of CDLEE done by podiatrist versus other health care (HC) providers.
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes, it is biologically plausible. Yes, it is consistent with what is known about the topic.
<b>2. Importance</b>	
2a. Represents a significant disease burden; large proportion of the population	Yes, this topic represents a significant burden. Approximately 50% of diabetic population develop peripheral neuropathy and at risk for foot complications.
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the US population or for a vulnerable population	Yes, this topic affects health care decisions for a large, vulnerable population.
2c. Represents important uncertainty for decision makers	Even though high quality RCTs are missing to show the effectiveness of CDLEE on health care outcomes, in clinical practice CDLEE is well accepted and it is part of annual routine diabetic exam.
2d. Incorporates issues around both clinical benefits and potential clinical harms	Yes, this nomination incorporates both benefits and potential harms of CDLEE for adult patients with DM.
2e. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	KQ-1: CDLEE is part of annual diabetic exam. KQ-2: Annual podiatric evaluation done by podiatrist for every diabetic patient may be costly for the HC systems and payers. Evidence is lacking.
<b>3. Desirability of a New Evidence Review/Duplication</b>	
3. Would not be redundant (i.e., the proposed topic is not already covered by available or soon-to-be available high-quality systematic review by AHRQ or others)	KQ-1 : no SRs KQ-2: no SRs
<b>4. Impact of a New Evidence Review</b>	

Selection Criteria	Supporting Data
<p>4a. Is the standard of care unclear (guidelines not available or guidelines inconsistent, indicating an information gap that may be addressed by a new evidence review)?</p>	<p>The standard of care is clear for KQ-1: Multiple national and international guidelines and recommendations consistently support annual CDLEE for every diabetic patient.</p> <p>For KQ-2. Clinical practice guidelines do not recommend one type of provider over another for the CDLEE. The most recent CPG by Society for Vascular Surgery (SVS), American Podiatric Medical Association (APMA) and Society for Vascular Medicine (SVM) recommend that patients with diabetes undergo annual interval foot inspections by physicians (MD, DO, DPM) or advanced practice providers with training in foot care (Grade 1C)</p>
<p>4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?</p>	<p>KQ-1: There is no practice variation. Diabetic foot exam is performed by podiatrists, primary care/general practitioners, endocrinologists and other HC practitioners trained for DM foot exam during routine annual DM exam. DM patients with abnormal foot exam findings referred to podiatrist or other specialists for further management.</p> <p>KQ-2: Clinical practice guidelines do not recommend one type of provider over another for the CDLEE.</p> <p>Most clinicians do not refer low risk for diabetic foot complication patients for CDLEE done by podiatrist.</p>
<b>5. Primary Research</b>	
<p>5. Effectively utilizes existing research and knowledge by considering:</p> <ul style="list-style-type: none"> <li>- Adequacy (type and volume) of research for conducting a systematic review</li> <li>- Newly available evidence (particularly for updates or new technologies)</li> </ul>	<p>A new systematic review is not feasible. We identified no studies relevant to KQ 1 or 2.</p>



**Appendix B: Search of Evidence Reviews (Duplication)**  
**Comprehensive Diabetic Lower Extremity Exam (CDLEE). Evidence Searched on September 27, 2018**

<b>Duplication</b>
<b>Source Searched</b>
<b>AHRQ</b>
<b>VA HSR&amp;D</b>
<b>Cochrane Library - Reviews</b>
<b>Cochrane Library - Protocols</b>
<b>York Center for Reviews and Dissemination (CRD)</b> [No longer updated as of 31 March 2018]
<b>CRD PROSPERO (protocols only)</b>
<b>Pubmed Health</b>
<b>MEDLINE(PubMed) searched on September 19, 2018</b>

### Appendix C: Search Strategy Results (Feasibility)

MEDLINE(PubMed) searched on September 19, 2018	
Concept	Search String
Diabetic Complications of the Foot	(((((("Diabetes Mellitus"[Mesh] OR "Diabetes Insipidus"[Mesh] OR "Diabetes Complications"[Mesh])) OR diabetes[Title])) AND (((("Podiatry"[Mesh] OR ("Lower Extremity"[Mesh] OR "Foot Diseases"[Mesh])) OR (foot[Title] OR feet[Title] OR lower extremity[title]))) OR "Diabetic Foot"[Mesh]
AND	
Examination	("Physical Examination"[Mesh] OR ((exam[Title] OR examination[Title]))
Limits, 5 years, English	Filters activated: published in the last 5 years, English
SR N=7	Systematic[sb] URL: <a href="https://www.ncbi.nlm.nih.gov/sites/myncbi/r.relevo.1/collections/56582546/public/">https://www.ncbi.nlm.nih.gov/sites/myncbi/r.relevo.1/collections/56582546/public/</a>
RCT N=77	((((((((groups[tiab]) OR (trial[tiab]) OR (randomly[tiab]) OR (drug therapy[sh]) OR (placebo[tiab]) OR (randomized[tiab]) OR (controlled clinical trial[pt]) OR (randomized controlled trial[pt]) URL: <a href="https://www.ncbi.nlm.nih.gov/sites/myncbi/r.relevo.1/collections/56582578/public/">https://www.ncbi.nlm.nih.gov/sites/myncbi/r.relevo.1/collections/56582578/public/</a>
Other N=148	URL: <a href="https://www.ncbi.nlm.nih.gov/sites/myncbi/r.relevo.1/collections/56582587/public/">https://www.ncbi.nlm.nih.gov/sites/myncbi/r.relevo.1/collections/56582587/public/</a>

#### Additional Searches

Resource	
ClinicalTrial.gov	

## Appendix C. Original Nomination

Topic Suggestion Description

Date submitted: July 1, 2018

Briefly describe a specific question, or set of related questions, about a health care test or treatment that this program should consider.

Comprehensive Diabetic Lower Extremity Exam (CDLEE). For diabetic patients, what are the risks and benefits of incorporating a CDLEE by a podiatrist (doctor of podiatric medicine) on at least an annual basis in order to risk stratify patients to guide treatment and follow-up planning? The CDLEE consists of visual inspection of the feet and legs for evidence of skin lesions or changes, evaluation of blood flow via pedal pulses, examination of the overall structure of the feet and their relation to the legs as well as determination of the status of peripheral nerve function in the diabetic patient. The CDLEE is performed in order to risk stratify patients with the resultant risk category (based on the results of the exam) guiding follow-up planning in order to monitor those at risk and reduce or prevent complications, such as ulceration, infection, hospitalization and amputation. Could CDLEE risk stratification and subsequent follow-up planning reduce the incidence of complications as described above? Could CDLEE risk stratification prevent complications in the diabetic population? Could the CDLEE improve quality of life in diabetic patients?

### Importance

Describe why this topic is important.

Close to 10 percent of the United States population has diabetes. Twenty-five percent of diabetic patients will experience a foot ulceration in their lifetime. There is an increased risk of infection with an open ulceration, especially in diabetic patients as they experience reduced innate immune system function. Diabetic foot infections are associated with poor clinical outcomes (hospitalization and amputation), significant cost to the patient (morbidity, ambulatory and psycho-social/mental health), society (absenteeism) and to the healthcare system (financial cost). An open ulceration precedes non-traumatic amputation in more than 80 percent of cases. For diabetic patients with peripheral arterial disease, the risk of amputation is even greater. If the CDLEE identifies patients at differing levels of risk, complications (ulceration, infection, hospitalization, and amputation) could be avoided, allowing patients a better quality of life and reduced financial burden on the healthcare system.

### Potential Impact

How will an answer to your research question be used or help inform decisions for you or your group?

An evidence-based report and subsequent resources related to the CDLEE would be beneficial for providers, patients and policy makers. With the information, there could be more of a push for coverage of such screening/prevention services being provided, especially as we move toward value-based care. If the benefits of the CDLEE outweigh any risks and the exam proves successful in reducing and preventing diabetic foot complications, it could result in better outcomes, a healthier population and lower costs associated with diabetic foot complications. The American Podiatric Medical Association will use the information from a new evidence report relating to the CDLEE and diabetic foot complications to educate not only doctors of podiatric medicine on the importance of such an exam, but also other healthcare providers on the importance of early identification/screening to reduce the burden of diabetic foot complications. The information from such a report would be disseminated to our membership (the vast majority of the 15,000 practicing podiatric physicians and surgeons in the country), to other healthcare providers/organizations, and to the public, especially those with diabetes and those who care for

people with diabetes. Information goes out via a number of channels including print, online and social media outlets.

#### Technical Experts and Stakeholders

Are there health care-focused, disease-focused, or patient-focused organizations or technical experts that you see as being relevant to this issue? Who do you think we should contact as we consider your nomination? This information will not influence the progress of your suggestion through the selection process, but it may be helpful to those considering your suggestion for further development?

The American Diabetes Association guidelines recommend performing a comprehensive foot evaluation at least annually to identify risk factors for ulcers and amputations. Diabetic patients are being evaluated and risk stratified in clinical practice, however, the interval of CDLEE and outcomes directly related to such an exam are unclear. A new evidence report would allow for more information on the benefits of a CDLEE, including the cost-savings of such an exam, and thus better implementation of and possibly payment for the exam at intervals recommended by the risk stratification.

Alliance for Patient Access - The AfPA has the Diabetes Therapy Access Working Group focused around public policy surrounding access to treatments for diabetes. The information from a report on CDLEE could be beneficial for the AfPA to share with its stakeholders. The American Podiatric Medical Association would implement the findings as stated above.

#### Nominator Information

Other Information About You: (optional)

Please choose a description that best describes your role or perspective: (you may select more than one category if appropriate)

The American Podiatric Medical Association (APMA) is the national organization representing podiatric physicians and surgeons.