

Technical Expert Panel (TEP) – Meeting 4 (Session 1 – Diabetes Measures to Prevent Amputation)

**Electronic Clinical Quality Measures
Development and Maintenance for Eligible
Clinicians (EC eCQM) Project**

Contract number: 75FCMC18D0032;
Task number: 75FCMC19F0004

March 3, 2022

Agenda

- **Welcome, introductions, and conflict-of-interest disclosures**
- **Meeting objectives**
- **Overview of project and task**
- **Information gathering and measure scan**
- **Review concepts for amputation process measure**
- **Review composite measure quality construct**
- **Wrap-up and next steps**

Introductions

TEP member name	Organization/location
Donald Casey, M.D., M.B.A., M.P.H.	American College of Medical Quality; Chicago, IL
James Colbert, M.D.	Blue Cross Blue Shield of Massachusetts; Boston, MA
Fran Cunningham, Pharm.D.	Department of Veterans Affairs; Hines, IL
Barbara Kivowitz	San Francisco, CA
Luming Li, M.D.	Yale New Haven Psychiatric Hospital; New Haven, CT
Bridget Lynch, M.D., M.P.H.	Presbyterian Medical Group; Albuquerque, NM
Precious McCowan	Dallas, TX
Robert McClure, M.D.	MD Partners, Inc.; Lafayette, CO
Michael Perskin, M.D.	American Geriatrics Society; New York, NY
Lori Popejoy, Ph.D., R.N., F.A.A.N.	University of Missouri; Columbia, MO
Christa Starkey	Lone Oak, TX

Introductions

Guest attendees	Organization/location
Vickie Driver, D.P.M., M.S., FACFAS	Wound Care and Hyperbaric Centers at INOVA Healthcare
Jennifer Green, M.D.	Duke University School of Medicine

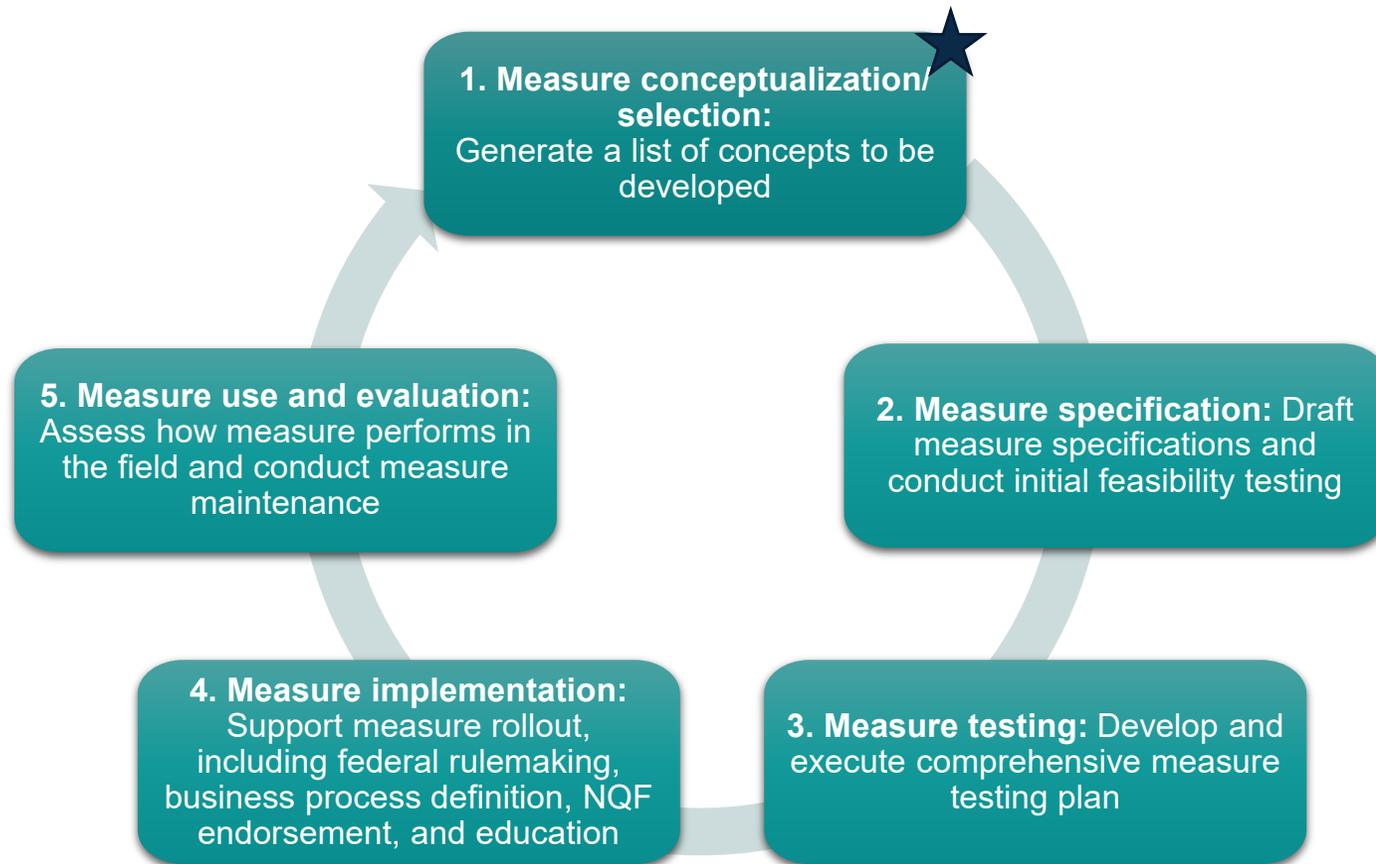
Meeting objectives

- **Review the background and intent of the diabetes-related amputation measures (CMS priority)**
- **Solicit input on the importance, usability, and feasibility of the potential measure concepts**
- **Discuss potential unintended consequences**
- **Solicit feedback on the proposed composite measure quality construct and potential component measures**

Project environmental scan task overview

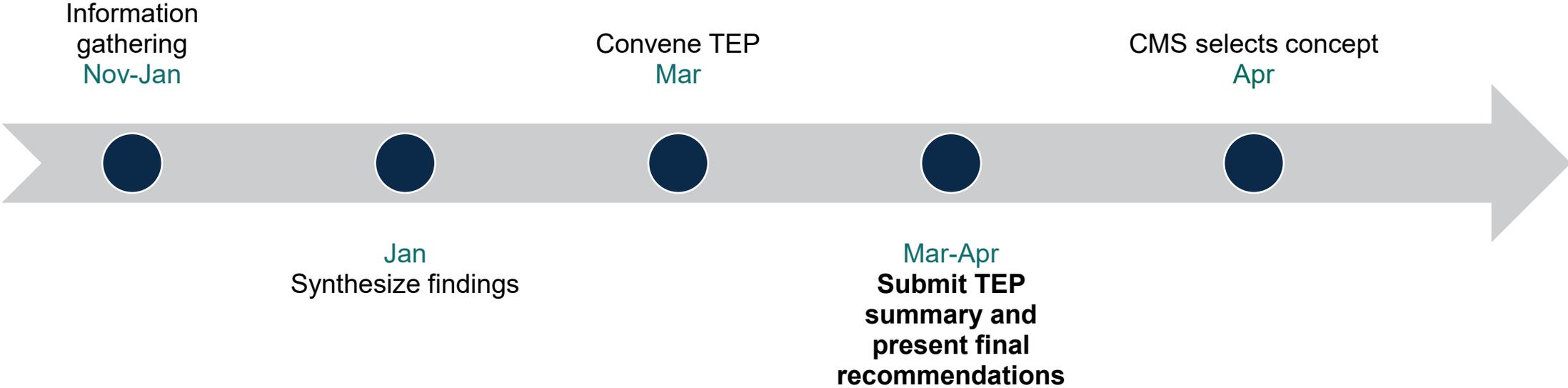
- / As directed by CMS, Mathematica and its partners develop and maintain clinical quality measures for CMS's Merit-based Incentive Payment System (MIPS)**
- / Mathematica helps CMS prioritize new measure concepts**
- / CMS guidance: Develop a process and a related composite measure focused on diabetes-related amputations for MIPS and MIPS Value Pathways (MVPs)**

Measure development life cycle





Current work timeline



Preventing diabetes-related amputation: why is it important?

Diabetes-related amputation is prevalent

- Diabetes affects **34 million, 13% of, U.S. adults**
- Lower extremity amputations occur at a rate of **5.6 per 1000** persons with diabetes (approx. 130,000 hospitalizations in 2016)
- Diabetes-related amputation is not experienced equally across the population, with significant disparities in rates observed by **race, ethnicity, income, and geography**

Diabetes-related amputation is serious

- **15% of people** with diabetes will develop a foot ulcer at some point. 5-year rate of LEA following an ulcer is 12%
- 5-year mortality following LEA is **estimated to be 50%**

Diabetes-related amputation is preventable

- Amputation **can be prevented** through adequate hemoglobin (A1C) control, management of diabetes complications, comprehensive foot care, timely and appropriate treatment of ulcers, and revascularization efforts to restore blood flow to the limbs for patients with vascular compromise

Diabetes-related amputations

- **Lower extremity amputation (LEA) refers to the removal of all or part of a lower limb (leg, foot, toe)**
- **LEA can be major or minor**
- **LEA frequently results from an infected wound (ulcer) on the foot, and/or loss of blood flow to the limb (ischemia)**
- **Complication resulting from diabetes and/or peripheral arterial disease (PAD)**

An Equity Concern

/ Growing concern over disparities in diabetes-related amputations

- Disparities documented by race, ethnicity, income, geography
- Patients of Color experience higher amputation rates than White patients
- Patients in rural areas exhibit higher amputation risk compared to those living in urban areas
- American Diabetes Association Health Equity Bill of Rights underscores the need to avoid unnecessary amputations for all

Momentum to Reduce Amputations

Reducing Nontraumatic Lower-Extremity Amputations by 20% by 2030: Time to Get to Our Feet: A Policy Statement From the American Heart Association

Mark A. Creager, Kunihiro Matsushita, Shipra Arya, Joshua A. Beckman, Sue Duval, Philip P. Goodney, J. Antonio T. Gutierrez, John A. Kaufman, Karen E. Joynt Maddox, Amy W. Pollak, Aruna D. Pradhan, Laurie P. Whitsel,
On behalf of the American Heart Association Advocacy Coordinating Committee

Originally published 25 Mar 2021 | <https://doi.org/10.1161/CIR.0000000000000967> | Circulation. 2021;143:e875–e891

The Amputation Reduction And Compassion (ARC) Act



Objectives and Data | TOOLS FOR ACTION | ABOUT | Custom List

 **Healthy People 2030**

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Reduce the rate of foot and leg amputations in adults with diabetes

Concept Prioritization: Process Measure Concepts to Reduce Diabetes-Related Amputation

Environmental Scan Process



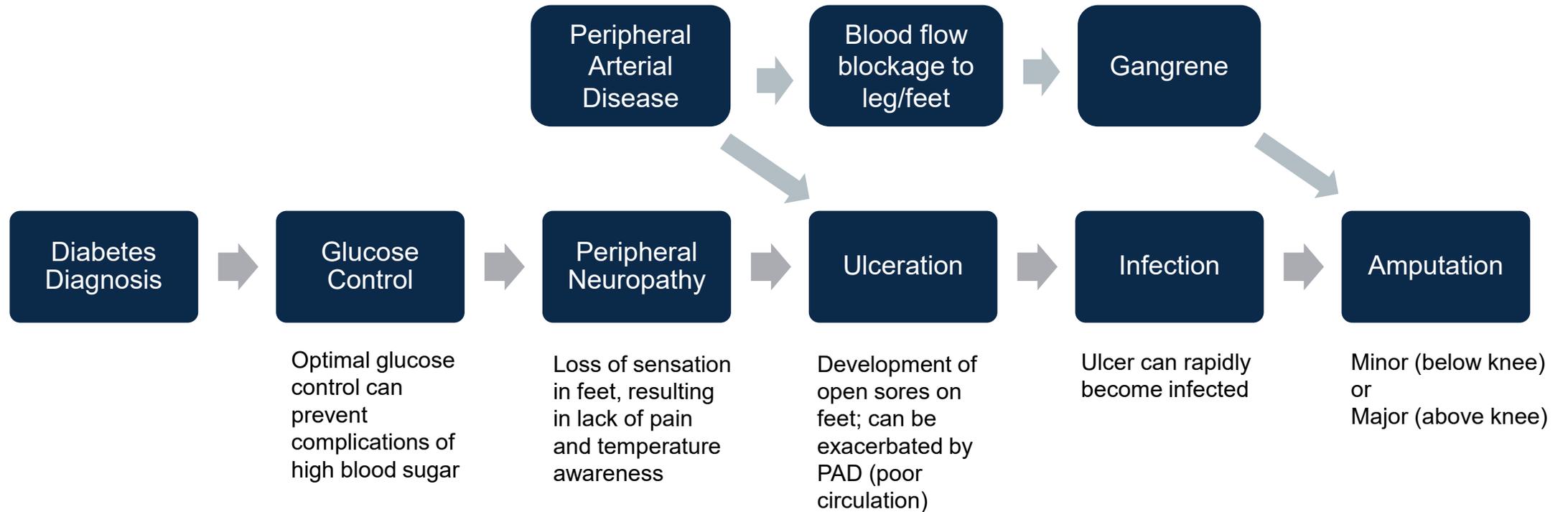
Literature review findings

- **Amputations are a major equity concern in terms of race/ethnicity (higher risk among patients of Color)**
- **Lack of peripheral arterial disease (PAD) screening is associated with preventable amputations**
- **Patient education on self-management is a crucial component of amputation prevention**
- **Foot exams are important in managing amputation risk**
- **Improved footwear- especially in ulcer treatment- can help reduce amputation risk**

Relevant Guidelines

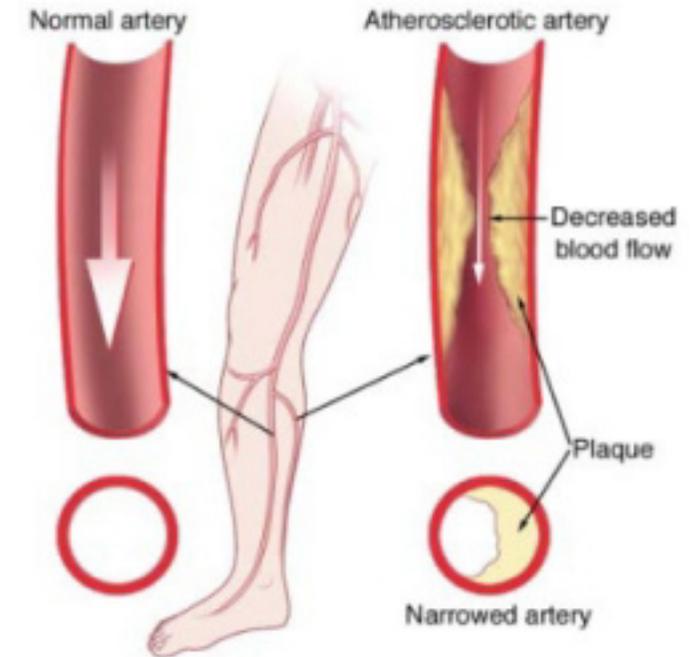
- / American Diabetes Association (ADA) Standards of Medical Care in Diabetes (2021) and Comprehensive Foot Exam Guideline (2008)
- / American Academy of Family Physicians (AAFP) Diabetes-related Foot Infections: Diagnosis and Treatment (2021)
- / International Working Group on the Diabetic Foot (IWGDF) Guidelines on the Prevention and Management of Diabetic Foot Disease (2019)
- / American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) Clinical Practice Guidelines for Diabetes Mellitus (2015)
- / American College of Foot and Ankle Surgeons Diabetic Foot Guideline (2006)
- / Society for Vascular Surgery/American Podiatric Medical Association/Society for Vascular Medicine Diabetic Foot Guideline (2016)
- / Veteran's Affairs/Department of Defense Diabetes Guideline (2017)

Understanding the Pathway to Amputation



Clinical Topic 1: Peripheral Arterial Disease (PAD)

- / PAD is a disease in which blood flow to the legs and feet is reduced, due to narrowed arteries.
- / Approximately 50% of patients with diabetic foot ulcer also have PAD.
- / Half of LEA are attributed to concomitant diabetes and PAD
- / Many patients with PAD go undiagnosed; late presentation contributes to amputation risk.
- / PAD can be treated.



Clinical Topic 1: Peripheral Arterial Disease

- / **Guidelines support vascular assessment for patients with diabetes and risk factors for ulcer, as well as vascular intervention for those with PAD.**
- / **Existing Measures:**
 - 3 QCDR measures: *Arterial Assessment of patients with lower extremity wounds or ulcers; Arterial Assessment of patients with intermittent claudication; Structured Walking Program for Patients with Claudication*

Potential Measure Concept

/ PAD screening for Patients with Diabetes

Percent of patients with diabetes who received a vascular assessment (e.g., pulses in feet, and ankle-or toe-brachial index for those with abnormal pulses), with potential to also assess follow up based on findings.

- Could respecify existing QCDR measures
- Could also entail adding vascular assessment to existing neuropathy screening measure

Pros

Guideline supported.
Opportunity to address equity issue.

Cons

No RCTs demonstrating improved amputation outcomes from screening asymptomatic diabetic patients; low quality evidence.

Potential Measure Concept

/ Arterial Testing Prior to Amputation

Among patients who received a lower extremity amputation, whether there was an arterial assessment in the year prior to amputation.

Pros	Cons
Accountability for evaluating viability of other treatment prior to recommending amputation.	Assesses quality after the fact, rather than preventively.
Opportunity to address equity concern.	

Clinical Topic 2: Diabetes foot exam critical to managing amputation risk.

/ Guidelines note annual foot exam as critical to diabetic foot care and managing amputation risk, particularly in order to screen for peripheral neuropathy and assign ulcer risk category.

/ **Components of Comprehensive Foot Exam:**

- History and General inspection
- Dermatological assessment (assessment for ulcer)
- Musculoskeletal assessment (assessment for ulcer risks)
- Neurological assessment (screening for peripheral neuropathy)
- Vascular assessment (screening for PAD)

Level	Ulcer Risk	Follow up Frequency
0	Very Low	Annually
1	Low	6-12 mo
2	Moderate	3-6 mo
3	High	1-3 mo

/ **Exam informs assignment of ulcer risk category**

Clinical Topic 2: Diabetes foot exam critical to managing amputation risk.

/ Existing Measures:

- 1 Existing MIPS measure: Peripheral Neuropathy - Neurological Evaluation
 - Percentage of patients who had a lower extremity neurological exam:
 - **Neurological exam:** Consists of a documented evaluation of motor and sensory abilities and should include: 10-g monofilament plus testing any one of the following: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold
 - Measure suggests risk categorization but doesn't require assignment of risk level or measure that follow up occurred.

Potential Measure Concept(s)

/ Assessment of Ulcer Risk and Follow-up for High-Risk Patients

Assess whether patients were assessed for ulcer risk and assigned a risk level using a standardized risk assessment tool and received appropriate follow-up if identified as high-risk.

Pros

Guideline supported.

Addresses gap in current foot exam measure – foot exam measure only measures peripheral neuropathy screening, not assessment of ulcer risk and corresponding follow up.

Cons

May be considered duplicative of current foot exam peripheral neuropathy screening measure.

Clinical Topic 3: Footwear can prevent and treat ulcers

- / **Poorly fitting footwear can contribute to ulcer risk. Guidelines recommend therapeutic footwear for high-risk patients.**
- / **Therapeutic footwear can help prevent ulcers in high-risk patients and promote healing in patients with ulcers, contributing to reduced amputation risk.**
 - **Therapeutic footwear:** Shoes that offer support and protection and reduce risk of ulcer.
 - **Offloading:** Technique of reducing pressure on an ulcer by removing or redistributing weight, often done through a removable or nonremovable cast.

Clinical Topic 3: Footwear can prevent and treat ulcers

Literature Review Findings:

- Therapeutic Footwear:
 - A systematic review of 72 studies found moderate quality evidence that therapeutic footwear is effective at reducing mechanical pressure (which can lead to ulcer).
 - A systematic review 74 studies found moderate quality evidence that therapeutic footwear can prevent plantar ulcer recurrence.
- Offloading:
 - A systematic review of 165 studies found strong evidence supporting non-removable knee-high offloading devices for healing of diabetic foot ulcer.

Existing Measures:

- 1 existing MIPS measure related to footwear: Ulcer Prevention - Evaluation of Footwear
- 2 QCDR measures related to offloading:
 - Off-loading of Diabetic Foot Ulcer
 - Offloading with Remote Monitoring

Potential Measure Concept(s)

/ Therapeutic Footwear for High-Risk Patients

Assess whether patients at high risk for ulcer received therapeutic footwear.

Pros

Guideline supported.

Addresses important step in pathway – preventing development of ulcer.

Cons

There is already a MIPS measure that addresses at least one dimension of footwear.

Challenge of defining therapeutic footwear.

Potential Measure Concept(s)

/ Offloading for Diabetic Foot Ulcer

This concept would involve potential re-specification of existing measure:

- Adequate Off-loading of Diabetic Foot Ulcer [CDR1]
- Offloading with Remote Monitoring [REGCLR5]

Pros

Guideline supported.

Addresses important step in pathway – preventing ulcer from leading to infection/amputation.

Cons

May be unable to receive permission to respecify measures from owners.

Clinical Topic 4: Patient education and self-management

Guidelines support providing education to patients on foot self care practices.

Literature Review Findings:

- A systematic review of 74 studies found moderate quality evidence that daily skin temperature checks can reduce recurrent plantar ulcer.
- A systematic review of 72 studies found low quality evidence supporting the link between foot education and increased adherence to self care behaviors.
- Little evidence demonstrating that education, knowledge or self care alone reduce foot ulcer or amputation.

Existing Measures:

- 1 non-MIPS measure: *Diabetic Foot Care Patient/Caregiver Education*

Potential Measure Concept(s)

/ Patient-reported Knowledge of or Engagement in Foot Self Care

This measure would assess patient reported level of knowledge of foot self care or engagement in foot self-care practices, such as daily foot inspections.

Pros	Cons
Guideline supported. Assesses patient engagement vs simply provision of education (higher bar)	Literature doesn't demonstrate strong evidence of linkage specifically between patient knowledge or self-management and ulcer/amputation reduction.

Summary of Concepts and Discussion

Concepts

PAD Screening

Arterial Assessment Prior to Amputation

Ulcer Risk Assessment and Follow-Up

Therapeutic Footwear for High-Risk Patients

Offloading for Ulcer

Patient-reported Knowledge/Engagement in Foot Self Care

- **What concepts should be prioritized or deprioritized? What other potential concepts should we consider?**
- **What are your thoughts on stratification by race and ethnicity?**

Diabetes Composite Measure to Prevent Amputation

Composite Measure

- / A combination of multiple individual measures which are packaged together, resulting in a single score.**
- / Enables holistic measurement of high-quality care across an entire care episode or condition.**
- / Diabetes composite measure aimed at preventing amputation could evaluate how well clinicians are providing care, across multiple dimensions of health, necessary to prevent amputation in their diabetic patients.**

Existing Diabetes Composite Measure

Optimal Diabetes Care/Diabetes Composite

The percentage of patients 18-75 years of age who had a diagnosis of type 1 or type 2 diabetes and whose diabetes was optimally managed during the measurement period as defined by achieving ALL of the following:

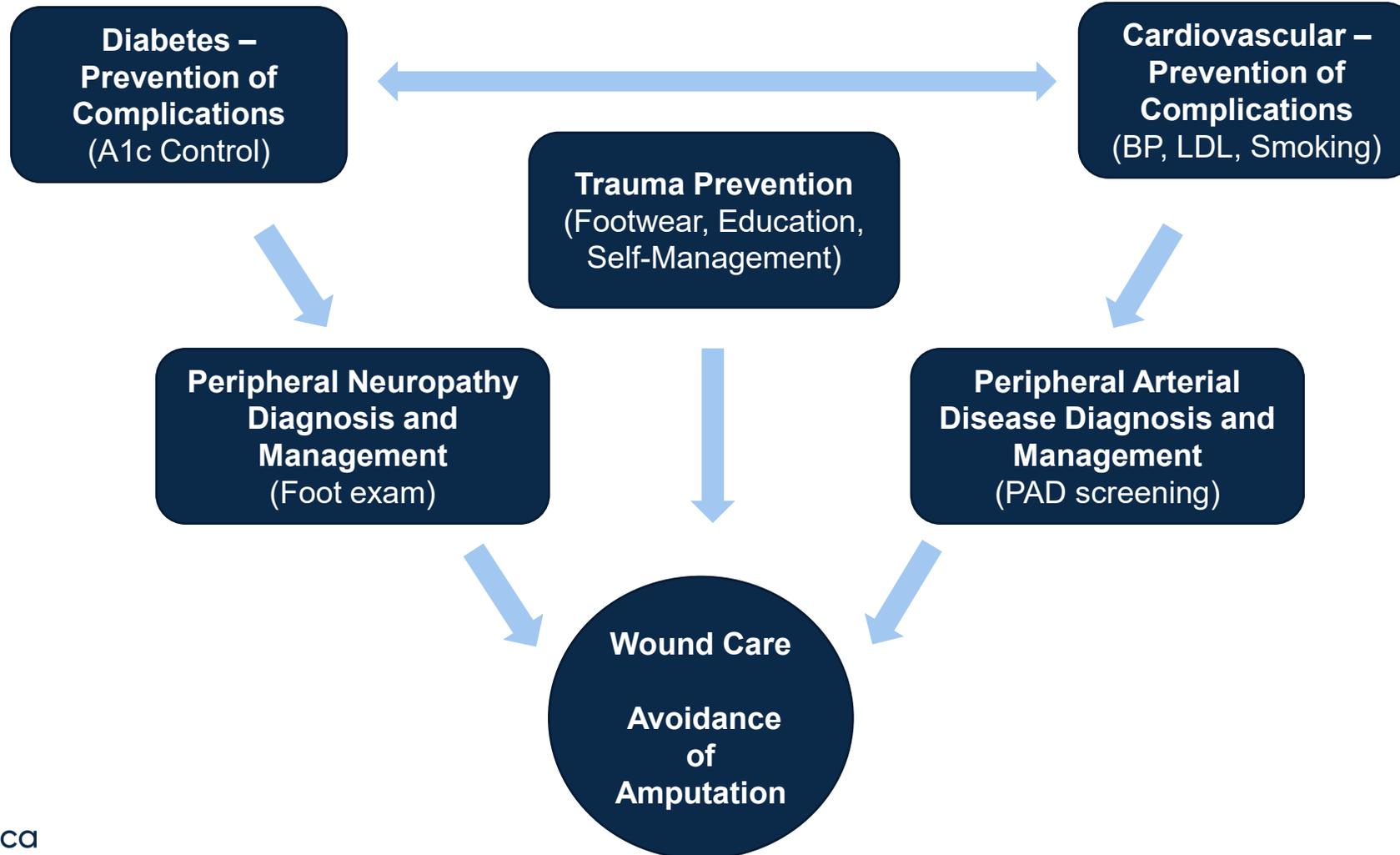
- HbA1c less than 8.0 mg/dL
- blood pressure less than 140/90 mmHg
- on a statin medication
- non-tobacco user, and
- patient with ischemic vascular disease is on daily aspirin or anti-platelets

/ Composite measures have a single underlying *quality construct* which informs the *goal* of the composite and *component measures* which work together to achieve the goal.

Diabetes Composite Measure Intent

- / The intent of a diabetes composite measure to prevent amputation would be to assess how well clinicians provide the necessary preventive care to avoid unnecessary lower extremity amputations in their patients with diabetes.**

Potential Quality Construct for Composite



Discussion

- / How adequately do you think the proposed quality construct captures the optimal care pathway for preventing amputation?**
- / What are your thoughts on the development of a diabetes composite measure to prevent amputation?**
 - **Important to report?**
 - **Gap in care**
 - **Variation in care**
 - **Supported by evidence**
 - **Feasible to report?**
 - **Usable to improve quality of care?**
- / What gap could the new process measure we are developing fill in this composite measure?**

Wrap-up and next steps

- / Review and summarize TEP feedback**
- / Conduct any follow-up outreach if needed**
- / Use feedback to prioritize list of measure concepts and recommend final concept(s) to CMS**

Appendix

Measure Scan Process

- / Searched CMS Measures Inventory Tool (CMIT) and NQF Quality Positioning System (QPS) for measures related to diabetes, ulcer, foot care, amputation.
- / Measures fall into the following types:

MIPS Measure	QCDR Measure	Non-MIPS Measure
An existing measure already specified in the MIPS program.	A <i>Qualified Clinical Data Registry</i> measure.	Used in another program or specified for another level of accountability.
Can easily be packaged into composite with potentially minimal adjustments.	Owned by registry organization, would need to obtain permission and respecify measure for MIPS.	Would need to respecify measure for MIPS.

Measure Scan Results

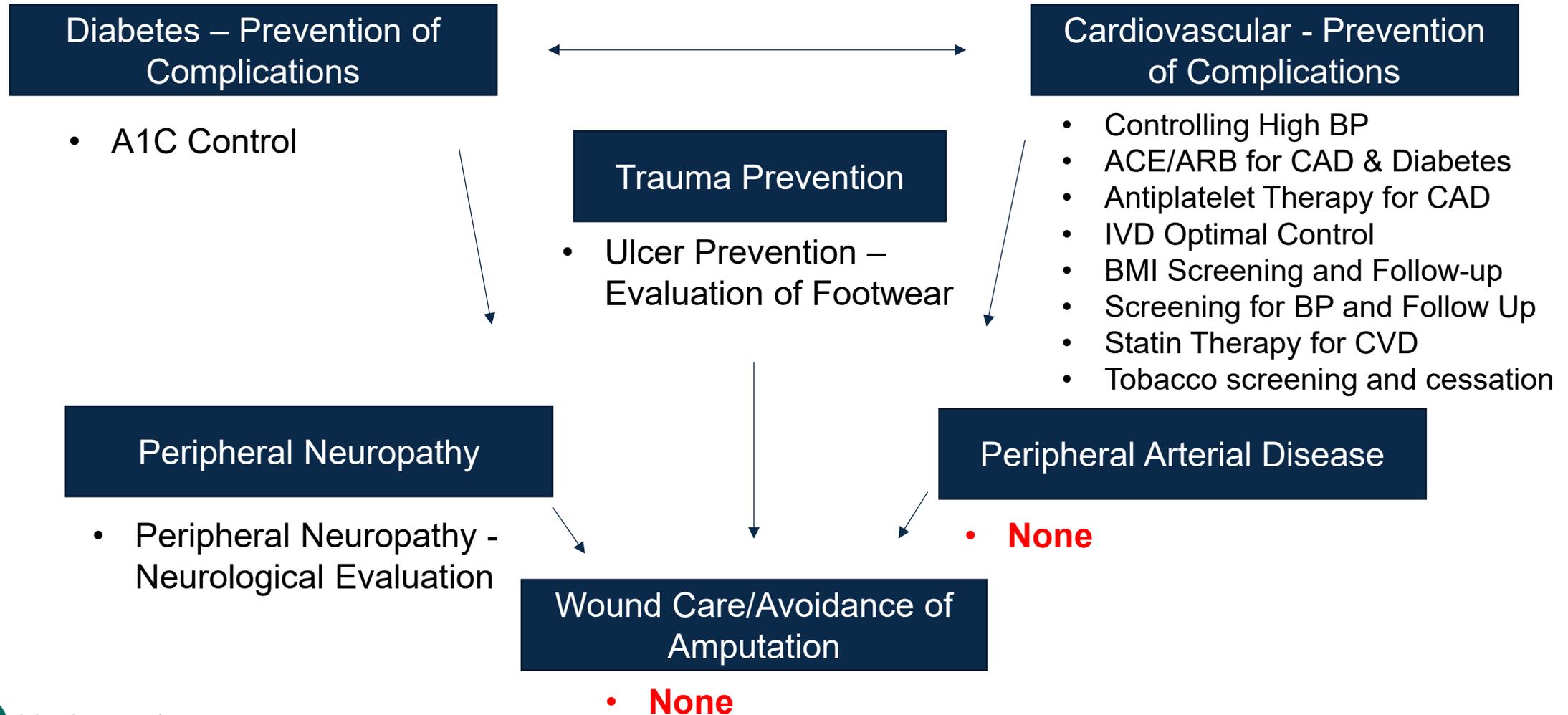
/ 3 related composite measures identified

- Diabetes Composite
- Optimal Diabetes Care
- Optimal Vascular Care

/ 32 potential component measures identified:

MIPS Measure	QCDR Measure	Non-MIPS Measure
10 existing MIPS measures	15 QCDR measures, which would need to be re-specified	7 non-MIPS measures, which would need to be respecified

Potential Component Measures - MIPS



Potential Component Measures - QCDR & Non-MIPS

Wound Care/Avoidance of Amputation

- Appropriate Use of HBOT
- Compression for Patients with VLU
- Diabetic Ulcer Healing or Closure
- Digital Imaging to Improve Treatment Outcomes in Chronic Wound Healing
- Nutritional Assessment in Patients with Wounds and Ulcers
- Off-loading of Diabetic Foot Ulcer
- Offloading with Remote Monitoring
- Patient Reported Wound Outcome
- Venous Leg Ulcer Healing or Closure

Peripheral Arterial Disease

- Arterial Assessment of patients with lower extremity wounds or ulcers (QCDR)
- Arterial Assessment of patients with intermittent claudication (QCDR)
- Structured Walking Program for Patients with Claudication (QCDR)
- Statin Therapy after Lower Extremity Bypass (retired MIPS)