Welcome to PCORI

Please be seated by 8:50 AM ET. The webinar will start at 9:00 AM ET.
Restrooms are located outside near the elevators. Key fobs are available at our front desk.

As webinar participants will join us online and by telephone, please state your name and title before speaking.

Please stand your name tent up to let the moderator know that you are interested in speaking.

To use the push-to-talk microphones, please press the button on the lower right-hand side and speak into the microphone when red circle lights up around microphone.
Clinical Interventions to Reduce Lower-Extremity Amputation Disparities Workgroup

November 4, 2013
Welcome and Introductions

Romana Hasnain-Wynia, PhD, MS
Program Director
Addressing Disparities Program, PCORI
Introductions: Moderator and Chair

David G. Armstrong, DPM, MD, PhD
Director, Southern Arizona Limb Salvage Alliance (SALSA)
Professor of Surgery, University of Arizona College of Medicine
Introductions: Workgroup Participants

Harry Glauber, MD
Endocrinologist, Kaiser Permanente Northwest
America’s Health Insurance Plans (AHIP) Representative
Introductions: Workgroup Participants

Michael Herndon, DO
Senior Medical Director, Oklahoma Medicaid
Medical Directors Network
Carolyn Jenkins, DrPH, APRN, LD, RD, FAAN
Ann Darlington Edwards Endowed Chair and Professor, Medical University of South Carolina, College of Nursing
Introductions: Workgroup Participants

Lawrence Lavery, DPM, MPH
Professor, UT Southwestern Medical Center
Co-Director, Plastic Surgery Research Division
Joseph W. LeMaster, MD, MPH
Primary Care Physician and Associate Professor,
The University of Kansas School of Medicine
Introductions: Workgroup Participants

Gayle E. Reiber, PhD, MPH
Senior VA Career Scientist
Professor, Department of Health Services and Epidemiology, University of Washington
Introductions: Workgroup Participants

Reva Mariah S. ShieldChief
AIS Chair, Pawnee Nation College
Patient Representative
Introductions: Workgroup Participants

Charlie Steele
Board of Directors, The Amputee Coalition
Introductions: Workgroup Participants

Carl D. Stevens, MD, MPH
Health Sciences Clinical Professor, David Geffen School of Medicine at UCLA
# Workgroup Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Agenda Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00 AM</td>
<td>Welcome and Introductions</td>
</tr>
<tr>
<td>9:15 AM</td>
<td>Introduction to PCORI and Workgroup</td>
</tr>
<tr>
<td>9:30 AM</td>
<td>Setting the Stage</td>
</tr>
<tr>
<td>9:50 AM</td>
<td>Perspectives on Priority Topics: Patients, Stakeholders, and Researchers</td>
</tr>
<tr>
<td>10:30 AM</td>
<td>Break</td>
</tr>
<tr>
<td>10:40 AM</td>
<td>Perspectives on Priority Topics: Patients, Stakeholders, and Researchers (Continued)</td>
</tr>
<tr>
<td>11:45 AM</td>
<td>Lunch</td>
</tr>
<tr>
<td>12:30 PM</td>
<td>Recap of Priority Topics in Lower-Extremity Amputations</td>
</tr>
<tr>
<td>12:45 PM</td>
<td>Discussion and Consensus around Key Research Gaps</td>
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<tr>
<td>2:15 PM</td>
<td>Break</td>
</tr>
<tr>
<td>2:25 PM</td>
<td>Identification and Refinement of Comparative Effectiveness Research Questions</td>
</tr>
<tr>
<td>3:55 PM</td>
<td>Next Steps and Wrap-Up</td>
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<td>4:00 PM</td>
<td>Adjourn</td>
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</tbody>
</table>
Introduction to PCORI and Workgroup

Romana Hasnain-Wynia, PhD, MS
Program Director
Addressing Disparities Program
Overview

- Background on PCORI
- Addressing Disparities Program Mission and Goals
- PCORI’s Process for Identifying Research Topics and Gaps
- Identification of Current Workgroup Topic
- Managing Conflict of Interest
An independent non-profit research organization authorized by Congress as part of the 2010 Patient Protection and Affordable Care Act (ACA).

Committed to continuously seeking input from patients and a broad range of stakeholders to guide its work.
PCORI’s Mission and Vision

Mission
The Patient-Centered Outcomes Research Institute (PCORI) helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

Vision
Patients and the public have the information they need to make decisions that reflect their desired health outcomes.
Knowledge Gaps and Research questions should:

- **Be patient-centered**: Is the proposed knowledge gap of specific interest to patients, their caregivers, and clinicians?
- **Assess current options**: What current guidance is available on the topic and is there ongoing research? How does this help determine whether further research is valuable?
- **Have potential to improve care and patient-centered outcomes**: Would new knowledge generated by research be likely to have an impact in practice?
- **Provide knowledge that is durable**: Would new knowledge on this topic remain current for several years, or would it be rendered obsolete quickly by subsequent studies?
- **Compare among options**: Which of two or more options leads to better outcomes for particular groups of patients?
Cost-effectiveness: PCORI will not answer questions related to cost-effectiveness, costs of treatments or interventions. However, PCORI will consider the measurement of factors that may differentially affect patients’ adherence to the alternatives, such as out-of-pocket costs.

Medical billing: PCORI will not address questions about individual insurance coverage or about coverage decisions from third-party payers.

Disease processes and causes: PCORI will not consider questions that pertain to risk factors, origin, and mechanisms of diseases or questions related to bench science.

Lacking comparative nature or foundation: PCORI will not consider questions that lack any comparative aspect.
Addressing Disparities Program Mission Statement

PCORI’s Vision, Mission, Strategic Plan

Program’s Mission Statement
To reduce disparities in healthcare outcomes and advance equity in health and health care

Program’s Guiding Principle
To support comparative effectiveness research that will identify best options for eliminating disparities
### Addressing Disparities: Program Goals

<table>
<thead>
<tr>
<th>Identify Research Questions</th>
<th>- <strong>Identify</strong> high-priority research questions relevant to reducing and eliminating disparities in healthcare outcomes</th>
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<tbody>
<tr>
<td>Fund Research</td>
<td>- <strong>Fund</strong> comparative effectiveness research with the highest potential to reduce and eliminate healthcare disparities</td>
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<tr>
<td>Disseminate Promising/Best Practices</td>
<td>- <strong>Disseminate</strong> and facilitate the adoption of promising/best practices to reduce and eliminate healthcare disparities</td>
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PCORI’s Process for Identifying Research Topics and Gaps

Topics come from multiple sources

- Board topics
- Workgroups, roundtables
- 1:1 interactions with stakeholders
- Guidelines development, evidence syntheses
- Website, staff, Advisory Panel suggestions

Gap confirmation

- (PCORI staff in collaboration with AHRQ and others)

Priority topics/questions

- Eliminating non-comparative questions
- Aggregating similar questions
- Assessing research gaps
- Preparing topic briefs

Topics/Questions proposed for further consideration

(Multi-stakeholder Advisory Panels and Workgroups)
Identification of Workgroup Topic on Clinical Interventions to Reduce Disparities in Lower-Extremity Amputations

- PCORI’s Addressing Disparities Advisory Panel prioritized 12 topics in April 2013.
- One of the top five topics was reducing lower-extremity amputations (LEA) in populations that experience disparities.
- Next step is to better understand the research gaps.
How PCORI Gathers Input

PCORI seeks input on topics to determine specific research gaps on comparative effectiveness research questions.

- The researchers, patients, and stakeholders who’ve been invited to this workgroup give input during the workgroup.
- The broad community of researchers, patients, and other stakeholders can give input via our website.
- Webinar participants can provide input via the webinar “chat” feature.
How PCORI Manages the Potential for Conflict of Interest

- Participants in this workgroup will be eligible to apply for funding if PCORI decides to produce a funding announcement.
- The Chair(s) of the workgroup will be eligible to apply for funding should they not participate in any subsequent discussions with PCORI following the workgroup.
- Input received during the workgroup deliberations are broadcast via webinar, and the webinar is then archived and available to other researchers, patients, or stakeholders on the website.
- PCORI does not have subsequent discussions with the participants after this workgroup.
- Participants have been explicitly instructed and are expected to address a set of questions we’ve asked – not to tell us about their research.
- There should be no “influence advantage” to being a workgroup member, or any knowledge advantage by participating in the workgroup.
Setting the Stage

David G. Armstrong, DPM, MD, PhD
Director, Southern Arizona Limb Salvage Alliance (SALSA)
Professor of Surgery, University of Arizona College of Medicine
Setting the Stage

- Lower-Extremity Amputation Overview
- Lower-Extremity Amputation Burden and Disparities
- Workgroup Objectives
- Collaborative Workgroup Discussion
Lower-Extremity Amputation: Definition

Lower-extremity amputation (LEA) refers to the total loss of any part of the lower limb and can range from minor (i.e., an amputation performed below the ankle) to major (i.e., an amputation performed above the ankle).
Risk Factors for LEA

- Diabetes is the leading cause of non-traumatic LEA in the United States
- 29.1 million Americans (9.3%) have diabetes, with an additional 86 million Americans estimated to have prediabetes
- Diabetes is the 7th leading cause of death in the United States

Risk Factors for LEA (cont’d)

Diabetes Prevalence

<table>
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<tbody>
<tr>
<td>non-Hispanic Whites</td>
<td>7.60%</td>
</tr>
<tr>
<td>Asian Americans</td>
<td>9%</td>
</tr>
<tr>
<td>Hispanics</td>
<td>12.80%</td>
</tr>
<tr>
<td>non-Hispanic blacks</td>
<td>13.20%</td>
</tr>
<tr>
<td>American Indians/Alaska Natives</td>
<td>15.90%</td>
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</tbody>
</table>

Division of Diabetes Translation National Center for Chronic Disease Prevention and Health Promotion, ‘National Diabetes Statistics Report, 2014’
Foot Ulcers and LEA

Diabetic patients carry a 25% risk of developing a foot ulcer within their lifetime.²

Foot ulcers are the leading cause of amputations in diabetics, preceding over 85% of these surgeries.³

Inadequate diabetes control, smoking, neuropathy, prolonged hyperglycemia, and peripheral artery disease are risk factors that predispose diabetic patients to the development of foot ulcers.¹

If a diabetic foot ulcer is left untreated, a patient may have to undergo amputation.


Foot Ulcers and LEA (cont’d)

On Remission:
Cumulative recurrence rates following initial healing
Comparision of study results (via S. Morbach)

Recurrence is Likely

* at least one recurring ulcer episode among those under risk (i.e., alive and with at least on leg);
10-year data unpublished
Effects of LEA

- In 2010, diabetic complications resulted in over 73,000 non-traumatic LEAs, accounting for 60% of surgeries of this type.
- 42% percent of patients with LEA require having their opposite limb amputated within the subsequent one to three years.
- Within five years of the first LEA surgery, the mortality rate for patients ranges from 39% to 80%.

LEA Disparities

As of 2009, African Americans experienced an amputation rate almost 50% greater than that of non-Hispanic whites.¹

Medicare data from 2008 show that American Indian/Alaska Natives had an incidence rate double that of non-Hispanic whites.²

Disparities also exist in regard to the severity and level of amputation.¹


Contributing factors to LEA disparities:

- Impaired access to multicomponent, interdisciplinary care (e.g., podiatrists, vascular surgeons, dietitians, educators)\(^1\)

- At-risk patients are often treated at safety-net hospitals, which may be inadequately equipped to provide the high-quality care needed by these individuals.\(^2\)

- Greater reliance might be placed on amputation procedures, as opposed to less invasive, limb-sparing treatment options.\(^2\)

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Strategies for Prevention of LEA

Prevention Strategies

- Increased use of screening examinations by physicians and daily self-examinations by patients
- Referral of at-risk patients to a specialist
- Smoking cessation
- Maintenance of glycemic control
- Management of hypertension, renal disease, and peripheral arterial disease
- Clinician and patient education

Strategies for Prevention of LEA (cont’d)

Beyond prevention, a number of interventions exist to spare a patient’s limb.

**Revascularization** procedures restore and increase circulation and blood flow to the affected limb.

- **Angioplasty**, the insertion of a stent to open the blocked artery.
- **Lower-extremity bypass**, where an alternate passage for blood flow is created to bypass the blockage.

Strategies to Reduce LEA

Multicomponent, multidisciplinary interventions that follow standardized guidelines show the most promise for reduction in the rate of LEAs

- However, there are no agreed-upon guidelines for the treatment of diabetic foot ulcers or for determining when an LEA is necessary

Programs for increasing patient knowledge and engaging patients in preventive self-management have also shown promise.

Addressing Disparities in LEA

The US Department of Health and Human Services “Healthy People 2020” report specifically calls for the reduction in the rate of LEA in persons diagnosed with diabetes.

There are few studies focusing on reducing disparities among those at risk for LEA.
LEA Workgroup Goal

Identify high-priority comparative effectiveness research questions on interventions that, if addressed, could reduce disparities in LEA among racial and ethnic minorities and low-income populations.
Examples of Comparative Effectiveness Research Questions

- Compare the effectiveness of interventions to help eliminate healthcare system barriers that may disproportionately affect outcomes for racial and ethnic minorities and low-income populations at risk for LEA.

- Compare the effectiveness of treatments with significant potential to improve health care and quality of life for racial and ethnic minorities and low-income populations at risk for LEA.

- Compare the effectiveness of strategies to improve screening, increase access to quality care, and reduce risk factors for racial and ethnic minorities and low-income populations at risk for LEA.
Obtain a diversity of perspectives and input on important patient-centered research gaps and topics in LEA;

Identify high-impact CER questions that will result in findings that are likely to endure and that are not currently studied;

Seek consensus on identified LEA research gaps and specific comparative effectiveness research questions that address those gaps.
Collaborative Workgroup Discussion

**Focus:** Provide targeted input on priority topics.

**Honor Timelines:** Provide brief and concise presentations and comments.

**Level the Playing Field:** Use language that is familiar to all (e.g., explain any acronyms before using them)

**Participate:** Encourage exchange of ideas among diverse perspectives that are present today:
- Patients
- Clinicians
- Researchers
- Other Stakeholders
Perspectives on Priority Topics: Patients, Stakeholders, and Researchers
Perspectives on Priority Topics

Presenter: Carolyn Jenkins, DrPH, APRN, LD, RD, FAAN
Ann Darlington Edwards Endowed Chair and Professor, Medical University of South Carolina, College of Nursing
Potential Topics/Questions to Explore to Reduce Disparities in LEA:

- Compare the effectiveness of strategies to improve screening, increase access to quality care, and prevent/reduce risk factors for racial and ethnic minorities and low-income populations at risk for LEA.
Perspectives on Priority Topics

Potential Topics/Questions to Explore to Reduce Disparities in LEA:

- Compare the effectiveness of interventions to help eliminate healthcare system barriers that may disproportionately affect outcomes for racial and ethnic minorities and low-income populations at risk for LEA.

Examples:
- Accountable Care Organization vs. Fee for Service vs. Expanded Medicaid
- Transportation vs. No Transportation
- Rapid Access vs. Traditional Appointment
- Integrated vs. Non-Integrated Healthcare Systems
Perspectives on Priority Topics

Potential Topics/Questions to Explore to Reduce Disparities in LEA:

- Compare the effectiveness of different systems approaches to reducing diabetes-related foot ulcers and amputation in high-risk racial and ethnic minorities and low-income populations at risk for LEA.

Examples:

- Patient-centered medical home management (with training in quality diabetes care and foot care) vs. specialty care management (to be defined).
- Comprehensive clinical care system (LEAP) vs. comprehensive community care system vs. integrated community and clinical care systems (REACH)
Perspectives on Priority Topics

Potential Topics/Questions to Explore to Reduce Disparities in LEA:

- Compare the effectiveness of different approaches/delivery of self-management training/education for prevention and early identification/treatment of foot lesions in racial and ethnic minorities and low-income populations at risk for LEA.

Examples:
- Traditional Classroom DSME vs. Group Visits
- In-person Educator(s) vs. Tele-Health
- Synchronous vs. Asynchronous Technology
Perspectives on Priority Topics

Presenter: Charlie Steele
Board of Directors, The Amputee Coalition
Potential Topics/Questions to Explore

- **Significant Racial Disparities**
  - 42% of all amputations are performed on minority populations

- **CARE Disparity**
  - Lack of coordinated TEAM approach and poor outcomes – especially in large urban areas

- **Secondary Limb Loss Disparity**
  - Significant disparity with minorities losing the other leg; again, lack of team approach

- **Acute Rehab vs. Nursing Home**
  - Recent study showed that treatment in in-patient rehab facilities (INF) provided better long-term outcomes than in skilled nursing facilities (SNF)
Perspectives on Priority Topics

Presenter:
Gayle E. Reiber, PhD, MPH
Senior VA Career Scientist
Professor, Department of Health Services and Epidemiology, University of Washington
To what extent can patient coaches assigned to patients at very high risk of limb loss (high psychiatric comorbidity, prior ulcer, current ulcer, amputation) decrease the risk of lower-limb ulcers/amputations?

To what extent can electronic medical record templates improve ulcer outcomes? (Simple care templates would monitor delivery of evidence-based components of care, healing progress, and facilitate dual care communication and coordination)
Perspectives on Priority Topics

Presenter:
Carl D. Stevens, MD, MPH
Health Sciences Clinical Professor, David Geffen School of Medicine at UCLA
Perspectives on Priority Topics

- Income-related amputation rate disparities: the view from Los Angeles
- CER target areas and study questions
  - “Supply-side” factors: access and quality of care
  - “Demand-side” factors: patient and household education, self-efficacy and “activation”
Perspectives on Priority Topics
Income-related disparities in diabetic LEA rates: possible CER target areas

“Supply-side” factors

- Access barriers
  - Safety-net providers by neighborhood: Patient-Centered Medical Home (PCMH) up and running?
  - Long wait times for ED visit vs. available PCP appointments?
  - Primary care “gate-keeping” when urgent specialty care needed?

- Quality of care in the “safety net”
  - Standardized secondary prevention protocols including foot care
  - Access to expert, limb-sparing wound care for foot ulcers

“Demand-side” factors

- Patient activation, education, self-efficacy
- Immediate care-seeking plan of action for foot concerns
Perspectives on Priority Topics
Income-related disparities in diabetic LEA rates: possible CER study questions

“Supply-side” study questions:
- PCP vs. dedicated foot care (podiatry/orthopedic)
- Clinical pathways in safety-net EDs and clinics (standardized initial management and referral protocols)
- Team-based primary and secondary prevention of ulcers
- Identification of providers with low severity-adjusted amputation rates from public and Managed Care Organization (MCO) data sets

“Demand-side” study questions:
- Comparison of patient education/“activation” strategies
- Intensive disease management/adherence after first ulcer or distal amputation
BREAK

- Visit us at www.pcori.org
- Submit comments via Chat
Perspectives on Priority Topics

Presenter:
Joseph W. LeMaster, MD, MPH
Primary Care Physician and Associate Professor,
The University of Kansas School of Medicine
Perspectives on Priority Topics
Endovascular procedural disparity reduction

Reducing disparities in access to limb-sparing vascular procedures (PubMed lit-review):

- Amputation risk higher for:
  - Non-white race/ethnicity: Hispanics and Hispanics have greater rates and critical ischemia (Morrissey 2007; Amaranto 2009; Rowe 2010; Hughes 2014)
  - Medically underserved counties (by 29%) (McGinigle 2014)
  - Low income: Income < 100% poverty 16X greater risk, more advanced presentation, older age, less statin use (Durham 2010)

- Endovascular/limb-sparing procedures increasing, but some groups less likely to receive
  - Women: fewer procedures (Egorova 2010)
  - Non-white race/ethnicity: Blacks have less limb-related admissions, revascularization, wound debridement, or toe amputation (Holman 2011)
Perspectives on Priority Topics
Endovascular procedural disparity reduction

Randomized studies or outcome studies demonstrating interventions to reduce risk in most at-risk disparity groups are lacking.

Large databases previously used for analysis:
- National Inpatient Sample
- Inpatient Medicare data
- State-based Medicaid (not easily compatible across states)
- These analyses will be subject to limitations in recorded data (e.g., patient self-report of race/ethnicity is a fairly recent addition to many hospital-based databases)
Perspectives on Priority Topics
Endovascular procedural disparity reduction: possible strategy

- Hospital-Practice networks documenting procedures
  - PCORI Clinical Data Research Networks: ongoing discharge data stream

- System, hospital, or practice surveys exploring patient, provider, and systemic policies and/or programs to eliminate healthcare disparities and increase access to care for groups at high risk

- Studies could link these data streams to identify system-, clinic-, or provider-based best practices associated with improved outcomes for groups experiencing disparities (identifying candidate disparity-reducing interventions for CER)
Perspectives on Priority Topics

Presenter:
Harry Glauber, MD
Endocrinologist, Kaiser Permanente Northwest
America’s Health Insurance Plans (AHIP) Representative
Potential Topics/Questions to Explore

- What are the primary drivers of differences in LEA rates in different ethnic groups?
  - Inherent biologic variability in pathophysiology of DM and its complications
  - Differences in self-care (medication adherence, diet/exercise adherence, clinic visits, foot self-care, footwear quality, etc.)
  - Differences in health system management of DM minority patients (treatment goals, testing rates, choice of medications, use of referrals, etc.)
  - Differences in access to primary and specialty care (variance in insurance coverage, convenient availability of care)
Perspectives on Priority Topics

- Compare different strategies to improve frequency of foot exams at routine primary care visits, and to assess impact on ulcer rates, and ultimately amputation rates
  - Clinician education
  - Patient education (comparing culture-/language-specific print, online, one-on-one vs. group, lay-provided vs. professional)
  - Electronic Medical Record (EMR) prompts or other real-time clinical decision support
For patients with sensory loss or peripheral vascular disease (PVD), what is the effect of referral to a “high-risk foot” case management program on participation, self-care measures, and diabetic foot ulcer (DFU)/amputation rates in different ethnic groups?
Perspectives on Priority Topics

Presenter:
Reva Mariah S. ShieldChief
AIS Chair, Pawnee Nation College
Patient Representative
Perspectives on Priority Topics

Potential Topics/Questions to Explore

- How to communicate pertinent medical information to Tribal Nations’ members in a manner that “speaks” to them?
  - Asking patients to participate rather than telling them what you, as medical staff, want/expect.
Perspectives on Priority Topics

Michael Herndon, DO
Senior Medical Director, Oklahoma Medicaid
Medical Directors Network
Potential Topics/Questions to Explore

- Do practices that utilize team-based care and standing orders have a lower incidence of lower-extremity amputation compared to traditional healthcare delivery models?
Is the current delivery system, which is designed to reimburse providers based upon encounter, a barrier to diabetic patients and those at risk of LEA receiving adequate education regarding their disease and risk of morbidities including LEA?
If practice redesign strategies are taught and implemented within a practice setting, including:

- Team-based care
- Utilization of standing orders to ensure standards of care are being delivered
- Appropriate educational materials given to the patient

Would patients at high-risk for LEA have fewer LEA procedures?
Perspectives on Priority Topics

Lawrence Lavery, DPM, MPH
Professor, UT Southwestern Medical Center
Co-Director, Plastic Surgery Research Division
Perspectives on Priority Topics

Prevention vs. Treatment

- Multiple factors that contribute to ulcer prevention
- When evaluated individually…. inconsistent outcomes

Education: patients, family, physicians, staff
  - Quality, content, frequency

Education: global and foot specific

Therapeutic shoes and insoles: quality, replacement

Regular foot care: consistent monitoring

Innovation: self-monitoring, iphone monitoring & trending

CER: systems of care, continuity, quality,

High risk population: dialysis, amputees, history of ulcer
Perspectives on Priority Topics

Treatment: ulcers, infections, PAD

Peripheral vascular disease: endovascular vs. bypass

Ulcer treatments: standards are low, inconsistent

Infection treatments: by convention not evidence
  - Antibiotics are over used: resistance, AE
  - ill-defined starting and stopping parameters

Collaborative teams vs. stand alone

Long-term care because recurrence & risk are high.
LUNCH

- Visit us at www.pcori.org
- Submit comments via Chat
Recap of Priority Topics in Lower-Extremity Amputations
Discussion and Consensus around Key Research Gaps
PCORI Criteria for Comparative Effectiveness Research Questions

Questions should:

- **Be patient-centered**: Is the proposed knowledge gap of specific interest to patients, their caregivers, and clinicians?

- **Assess current options**: What current guidance is available on the topic and is there ongoing research? How does this help determine whether further research is valuable?

- **Have potential to improve care and patient-centered outcomes**: Would new knowledge generated by research be likely to have an impact in practice?

- **Provide knowledge that is durable**: Would new knowledge on this topic remain current for several years, or would it be rendered obsolete quickly by subsequent studies?

- **Compare among care options**: Which of two or more approaches leads to better outcomes for particular groups of patients?
BREAK

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Identification and Refinement of Comparative Effectiveness Research Questions
PCORI Criteria for Comparative Effectiveness Research Questions

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Next Steps and Wrap-Up
Thank You for Your Participation