



Rationale and Intended Uses for RAPID

An Industry Perspective

The Heart House 11/6/15

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Real World Examples of How Industry May Benefit

Real World Examples

Clinical and Economic Data Supports Procedures

Addresses FDA's focus areas

Safe, effective and patient-centric outcomes

Addresses CMS's focus areas

Reasonable and necessary

Patient Population Currently Treated Expands

Indications for Use for Technologies Expand

Practice Guidelines Updated to Reflect Real World Data

Cost of Healthcare Driven Down



How Can A Registry Do That?

Let's Look at Diabetes and PAD

Confidential

CSI. | CARDIOVASCULAR
SYSTEMS, INC.



29.1 million

people in the U.S. have
diabetes mellitus¹

9.3%

of the population

\$245 Billion

spent on diabetes and its
complications,
direct and indirect costs¹

Most Serious and Expensive Sequelae

160,000-180,000²
amputations annually

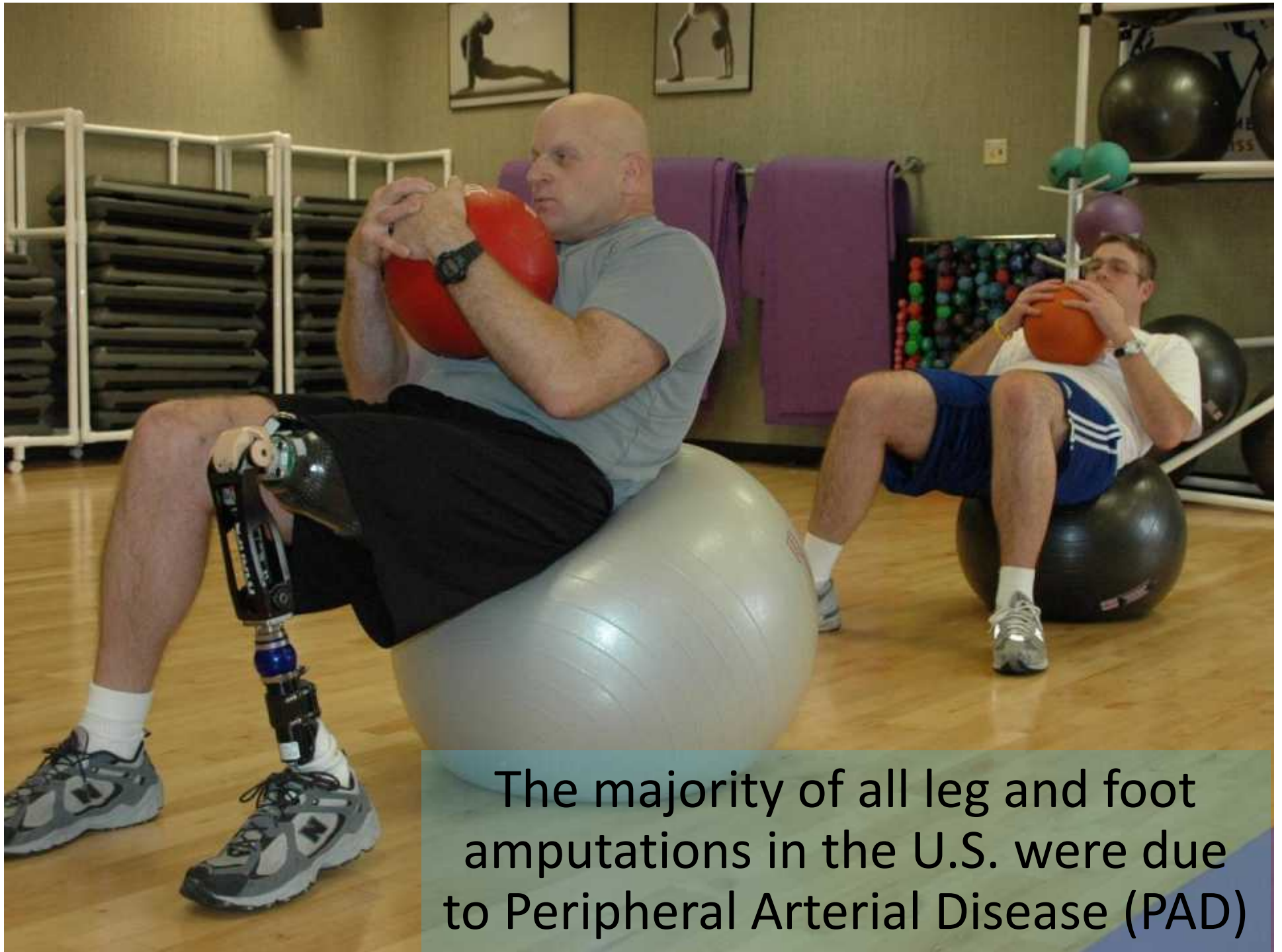
(73,000 amputations per year are **patients with Diabetes**¹)

50,000

new cases ESRD annually³

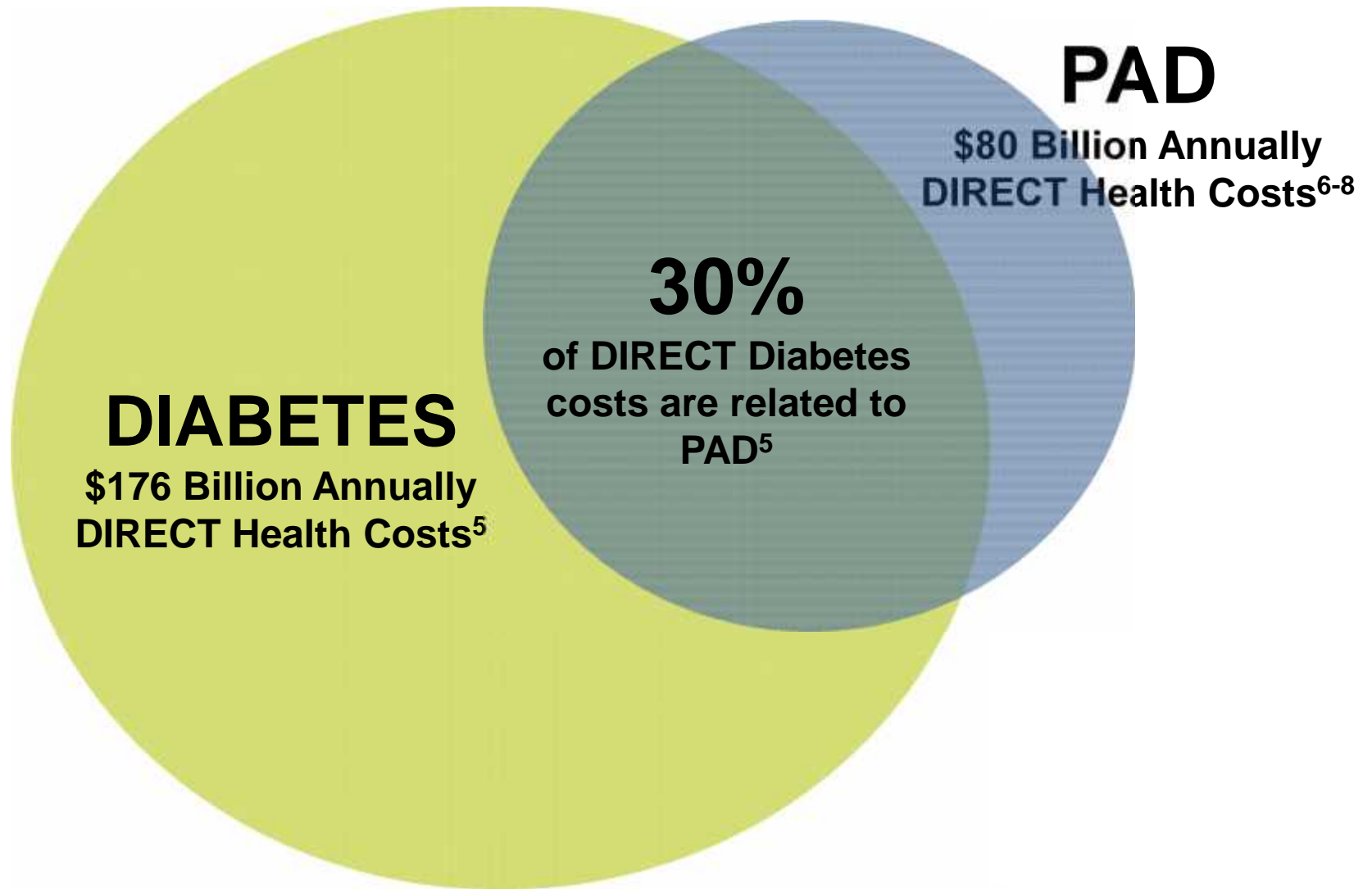
24,000

new cases of blindness annually⁴



The majority of all leg and foot amputations in the U.S. were due to Peripheral Arterial Disease (PAD)

PAD - Costly Sequelae of Diabetes





PAD - Costly Sequelae of Diabetes

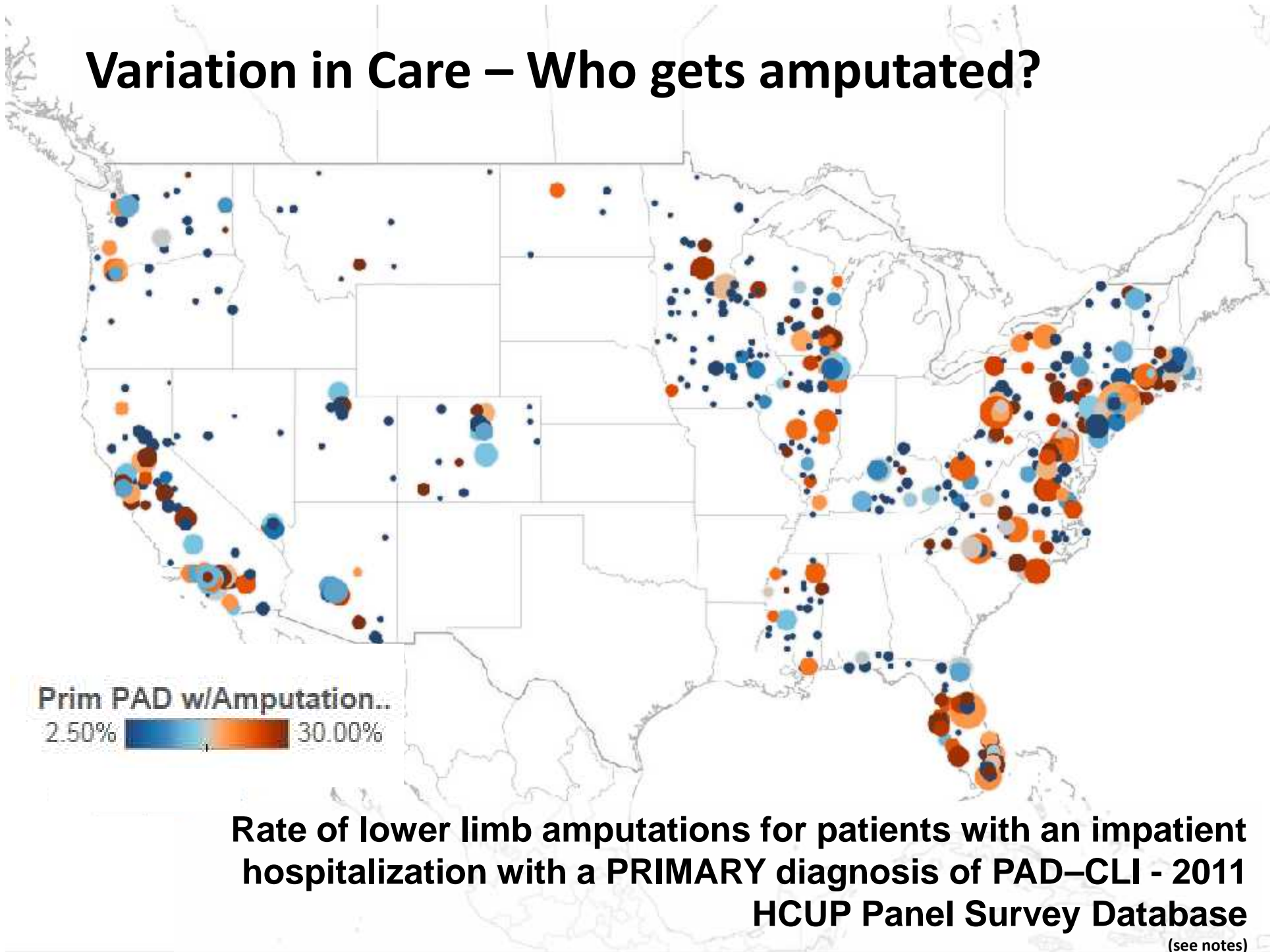
Estimated prevalence of PAD in US varies from 12 to 19.5 million⁹⁻¹⁰

Hospital costs represent majority of PAD burden¹¹⁻¹²

Amputations are the most expensive of all PAD-related hospitalizations¹²⁻¹³

The average rate of amputation among PAD patients with critical limb ischemia (CLI) is estimated to be ~25%¹⁴

Variation in Care – Who gets amputated?



**Rate of lower limb amputations for patients with an inpatient hospitalization with a PRIMARY diagnosis of PAD-CLI - 2011
HCUP Panel Survey Database**

(see notes)

Limited consensus on
amputation vs. limb salvage
for target populations

No **formal guidelines** in place

Key decision-making is left to a
physician's discretion

PAD has a significant

Clinical,

Economic

& Human

Burden



In 2015, an estimated **1.3 million Americans** are living with a lower extremity amputation (LEA)¹⁵



Clinical Burden of Amputation

Following
an initial
LEA due to
dysvascular
causes

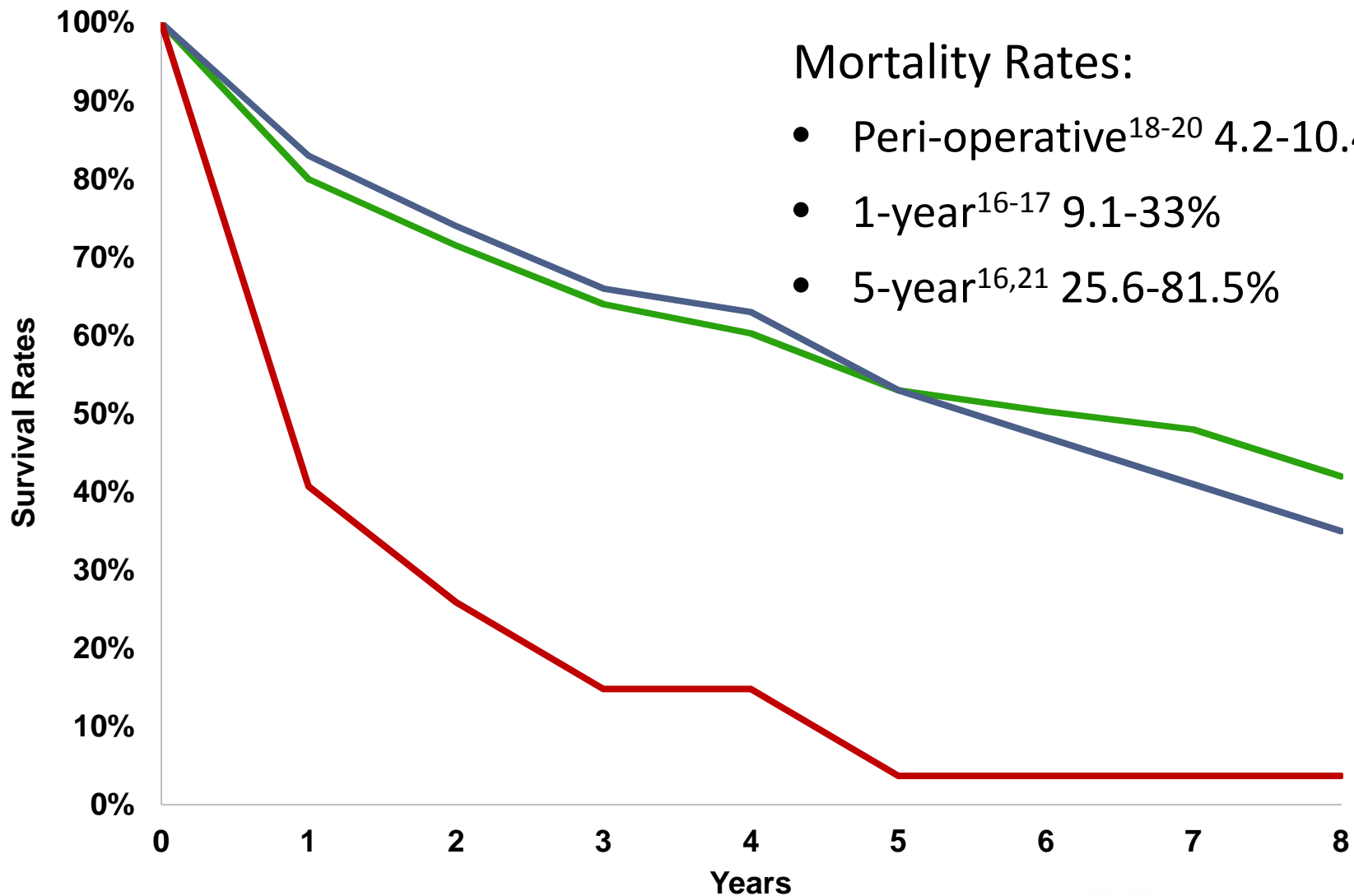
27% will have 1 or more re-amputation(s)
within 1 year¹⁶⁻¹⁷

40% progressed to a higher level of limb loss
within an year of an initial toe, foot or ankle
amputation¹⁷

This rate rises to 62% among those with comorbid DM

55% get an opposite limb amputation
within 2-3 years among those with
comorbid DM¹⁸

Poor Outcomes Post-Amputation²¹⁻²²



Mortality Rates:

- Peri-operative¹⁸⁻²⁰ 4.2-10.4%
- 1-year¹⁶⁻¹⁷ 9.1-33%
- 5-year^{16,21} 25.6-81.5%

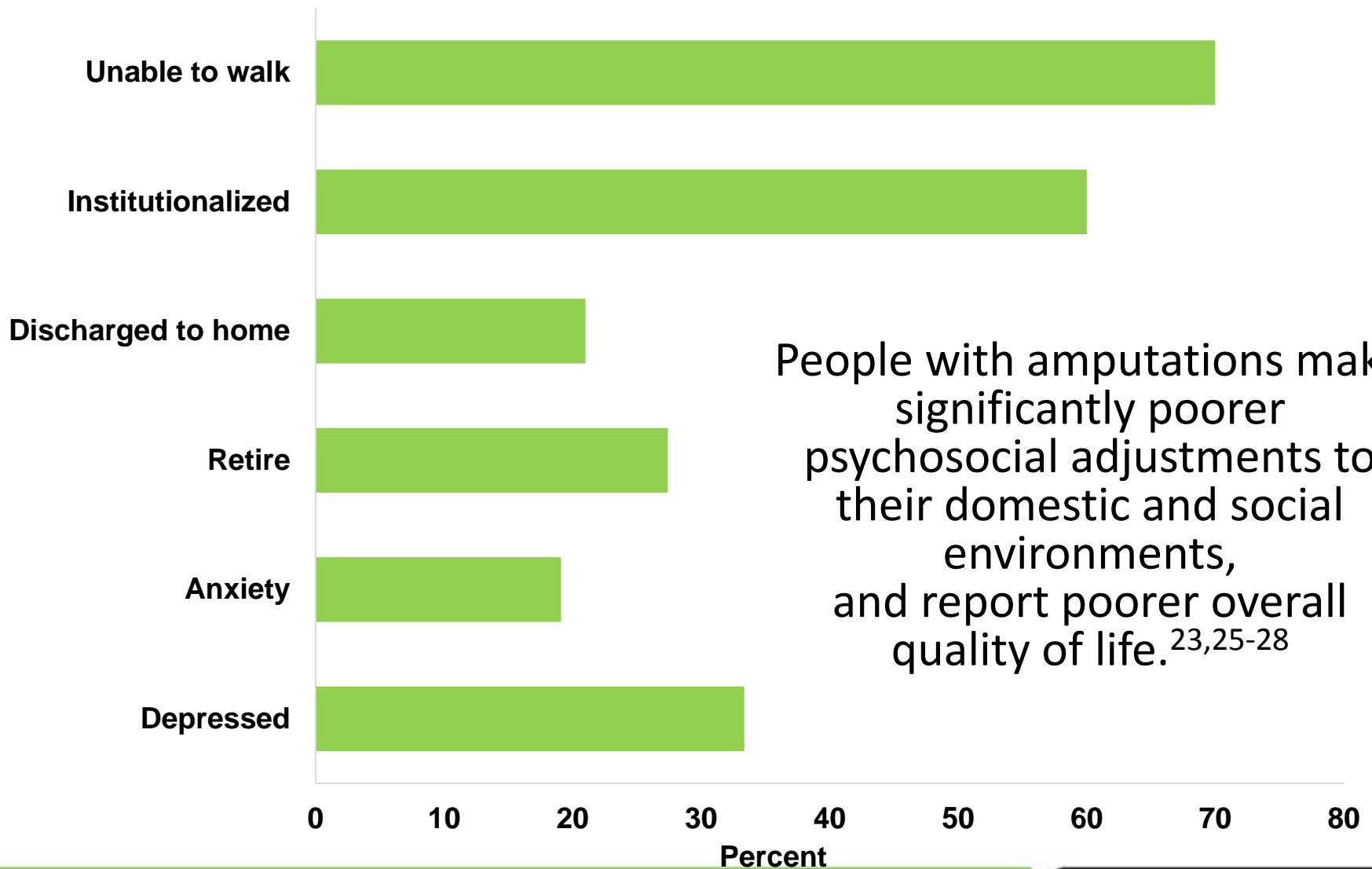
— No Diabetes/PAD — w/ Diabetes — w/ Diabetes, PAD



\$509,275

Lifetime Post-LEA per capita
Costs^{23,24}

Psycho-social Impact of Amputation



People with amputations make significantly poorer psychosocial adjustments to their domestic and social environments, and report poorer overall quality of life.^{23,25-28}



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Thank you!



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