



LIMB LOSS *and*  
PRESERVATION  
REGISTRY

*Activity is health.* —————

# CREATING THE LIMB LOSS AND PRESERVATION REGISTRY: *Lessons Learned & Wisdom Earned*

**Kenton R. Kaufman, PhD, PE**

Principal Investigator/Project Director: Limb Loss and Preservation Registry

Hall Wendel Jr Musculoskeletal Research Professor

Professor of Orthopedics

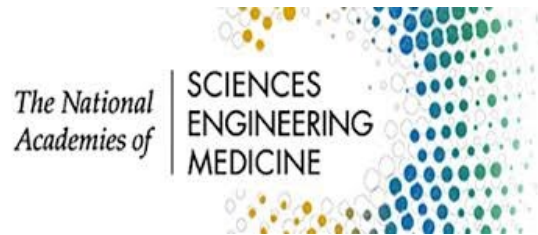
Professor of Biomedical Engineering

Director, Motion Analysis Laboratory

Consultant, Departments of Orthopedic Surgery, Physiology, and Biomedical Engineering

**Mayo Clinic**

Rochester, MN, USA



May 29, 2024

**CONSENSUS STUDY**

Principles and Framework to Guide the  
Development of Protocols and Standard  
Operating Procedures for Face and Hand  
Transplants

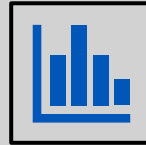
# ACKNOWLEDGMENT



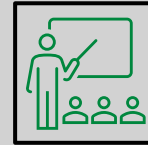
*Eunice Kennedy Shriver*  
National Institute of  
Child Health and  
Human Development



# OUTLINE



Data



Lessons  
Learned



Clinical  
Trials



Framework

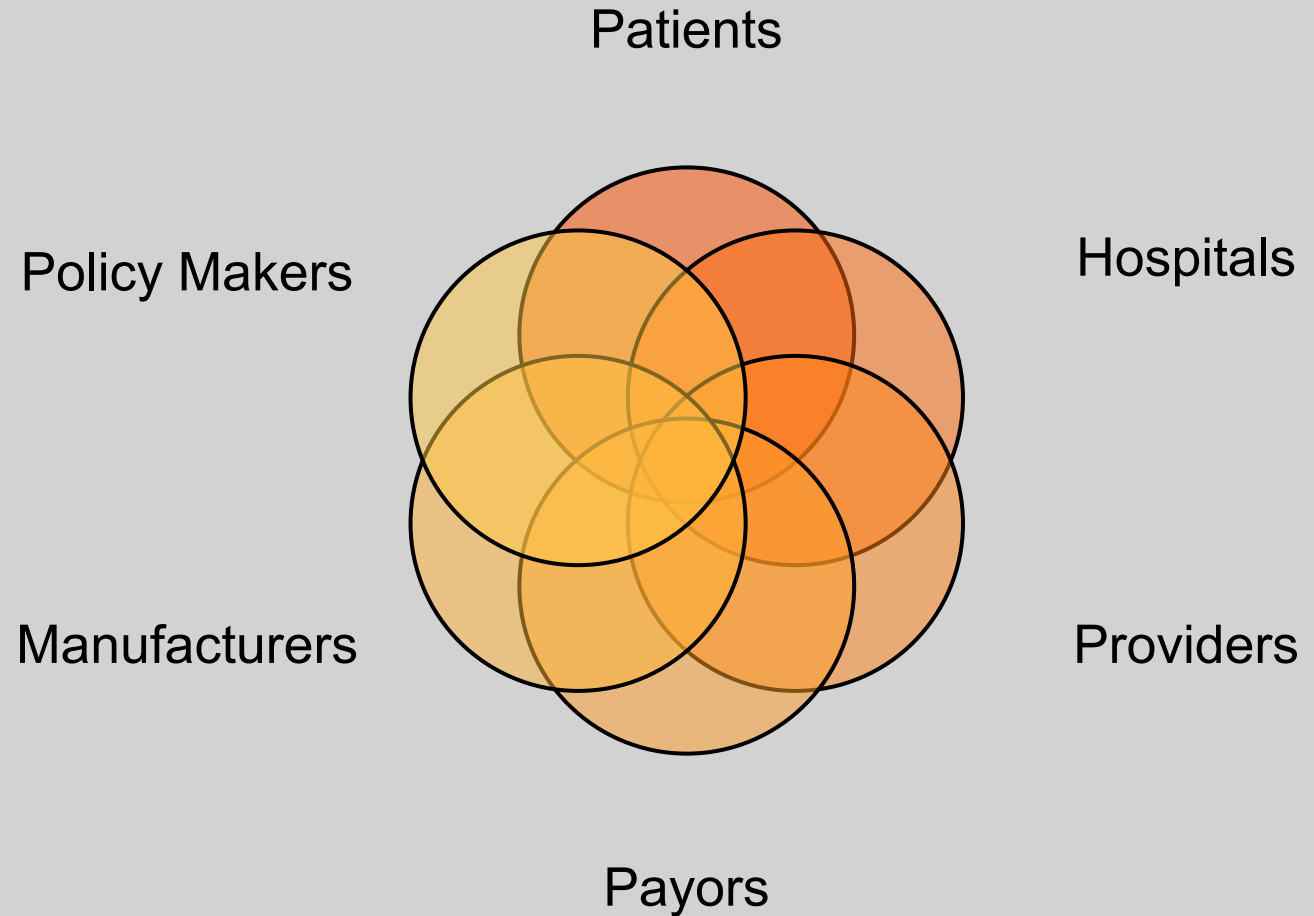


- Over 5 Million People in the US with Limb Loss or Limb Difference Struggle with Significant Life Challenges
- Lack of data on effective clinical practices and technologies to guide patients, care providers, payers, and policy makers
- Think differently. Challenge the status quo by collecting data to document better care.
- Measurement is the step that leads to improvement.

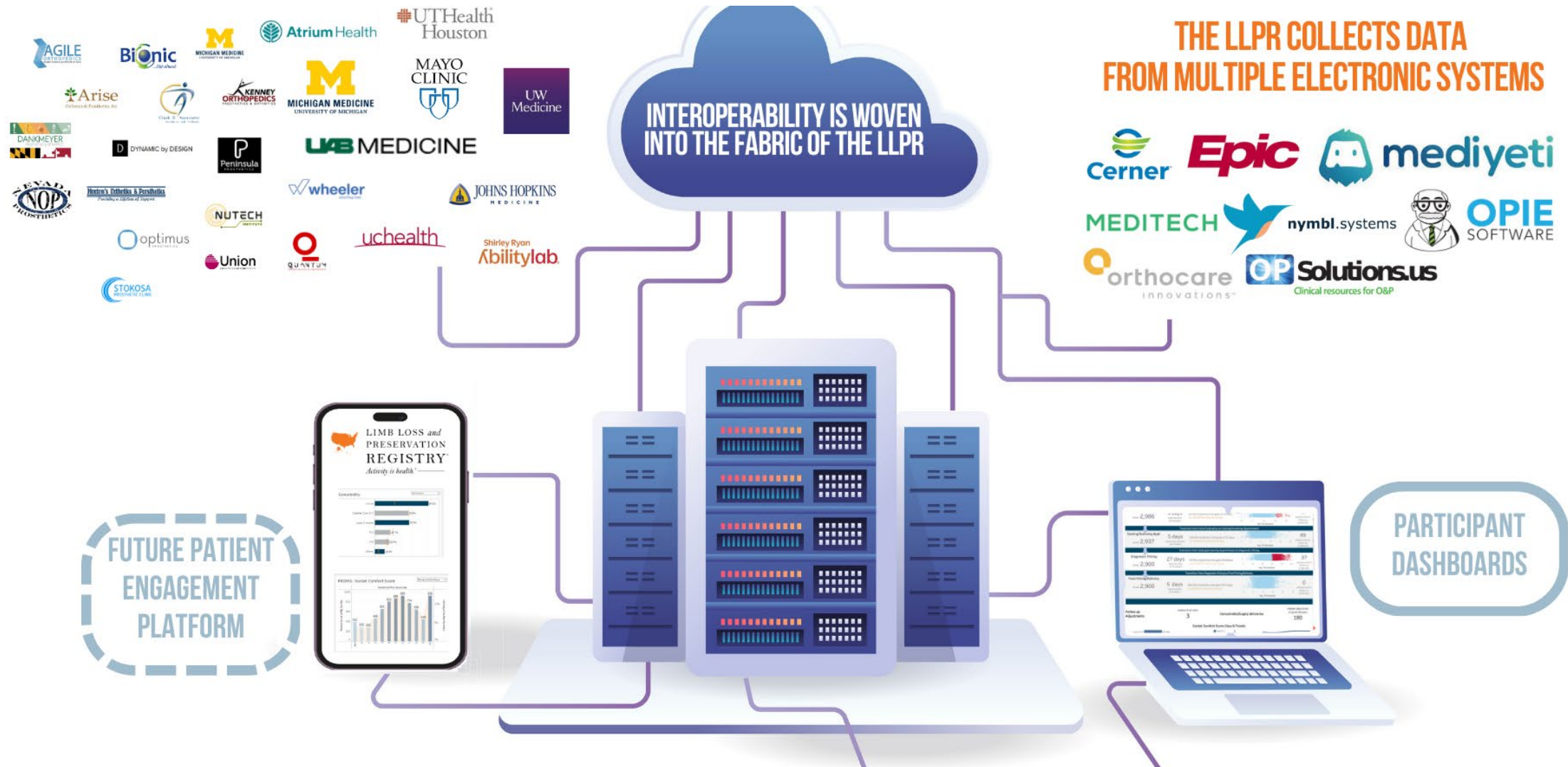


# LIMB LOSS *and* PRESERVATION REGISTRY

*Activity is health.* —————



# CURRENT OPERATIONAL SYSTEM VIEW



IMPROVE PATIENT CARE BY CREATING UNIQUE INSIGHTS FROM QUALITY DATA

# DATA COLLECTION

## DATA ELEMENTS

- Type I – Amputation/Hospitalization
- Type II – Provider/Prosthetic Fitting
- Type III – Patient Reported Outcome Measures
- Type IV – Objective Functional Outcome



# DATA ELEMENTS

## TYPE I – HOSPITALIZATION

- ***Patient***

- Name
- DOB
- Sex
- Race
- Ethnicity
- Marital Status
- Veteran Status
- Zip Code
- Tobacco use
- Alcohol use
- Education level

- ***Amputation***

- Level
- Side

- ***Facility***

- ***Provider***

- ***Payer***

- ***Patient Encounters***

- Height & Weight
- ICD10 code(s)
- CPT code(s)
- Z Codes
- Co-morbidities
- Rehabilitation Services

- ***PROMIS Physical Function***



# DATA ELEMENTS

## TYPE II – PROVIDER/PROSTHETIC/ORTHOTIC FITTING

- Patient name
- Gender
- Date of birth
- Height/weight
- Amputated side/level
- Reason for amputation
- Date of delivery
- Clinic location
- Activity Level
- Prescription(s)
- L-Codes
- Hip joint type  
(by classification/description)
- AK pylon type
- Knee type  
(by classification/description)
- BK pylon type
- Foot type  
(by classification/description)
- Ankle type  
(by classification/description)
- Prosthetic sock type
- Socket design
- Suspension method
- Exoskeleton/Endoskeleton

# DATA ELEMENTS

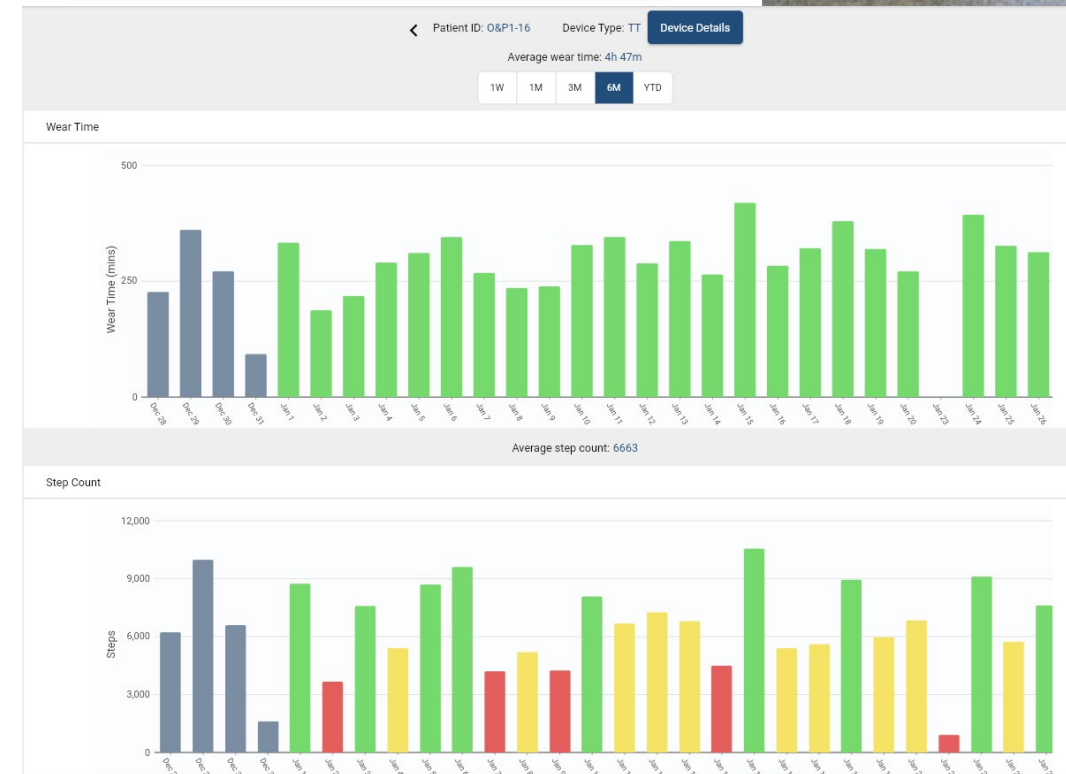
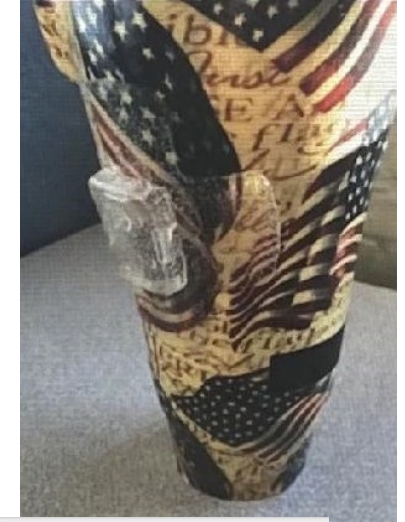
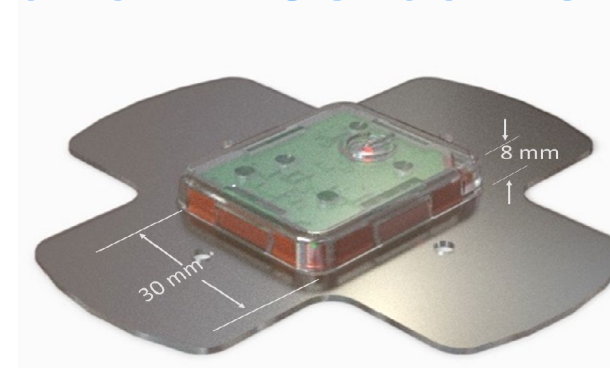
## TYPE III – PATIENT REPORTED OUTCOMES

Category	Lower Extremity	Upper Extremity
<b>Mobility &amp; Functional Status</b>	Prosthetic Limb Users Survey of Mobility (PLUS-M)	Orthotics and Prosthetics User's Survey (OPUS) Upper Extremity Functional Status (UEFS)
	Patient-Reported Outcomes Measurement (PROMIS®) Physical Function	PROMIS UE Physical Function - Custom
	Activity Specific Balance Confidence (ABC) Scale	Disabilities of the Arm, Shoulder, and Hand (DASH)
<b>Socket Comfort Limb Health</b>	Expanded Socket Comfort Score (E-SCS)	Expanded Socket Comfort Score (E-SCS)
<b>Quality of Life</b>	PROMIS®-Preference (PROPr)	PROMIS®-Preference (PROPr)
<b>Safety</b>	Fall History	
<b>Prosthesis Use</b>	Day per week Hours per day Satisfaction – TAPES-R LL SAT	Day per week Hours per day Satisfaction – TAPES-R UL SAT

# DATA ELEMENTS

## TYPE IV – OBJECTIVE FUNCTIONAL OUTCOMES

- Wearable sensor
- Cloud based data collection
- Real-world evidence
- Disposable
- Dashboard
- Reimbursable service - CPT code

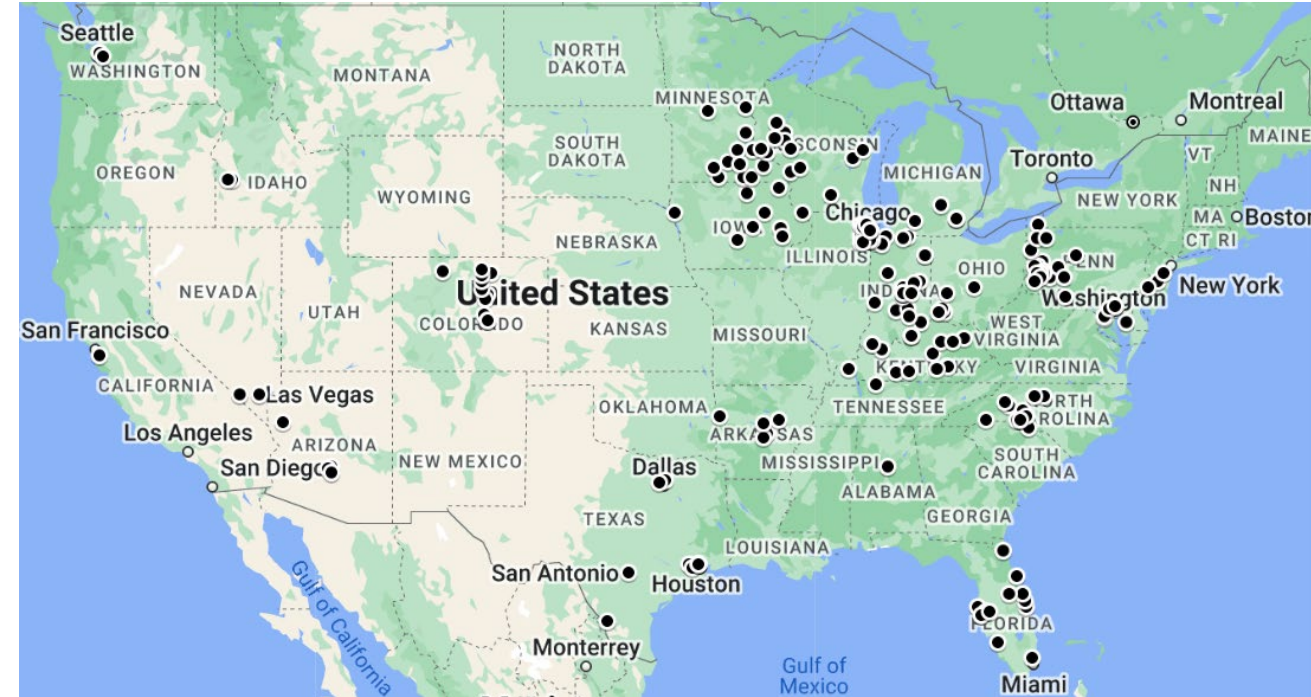




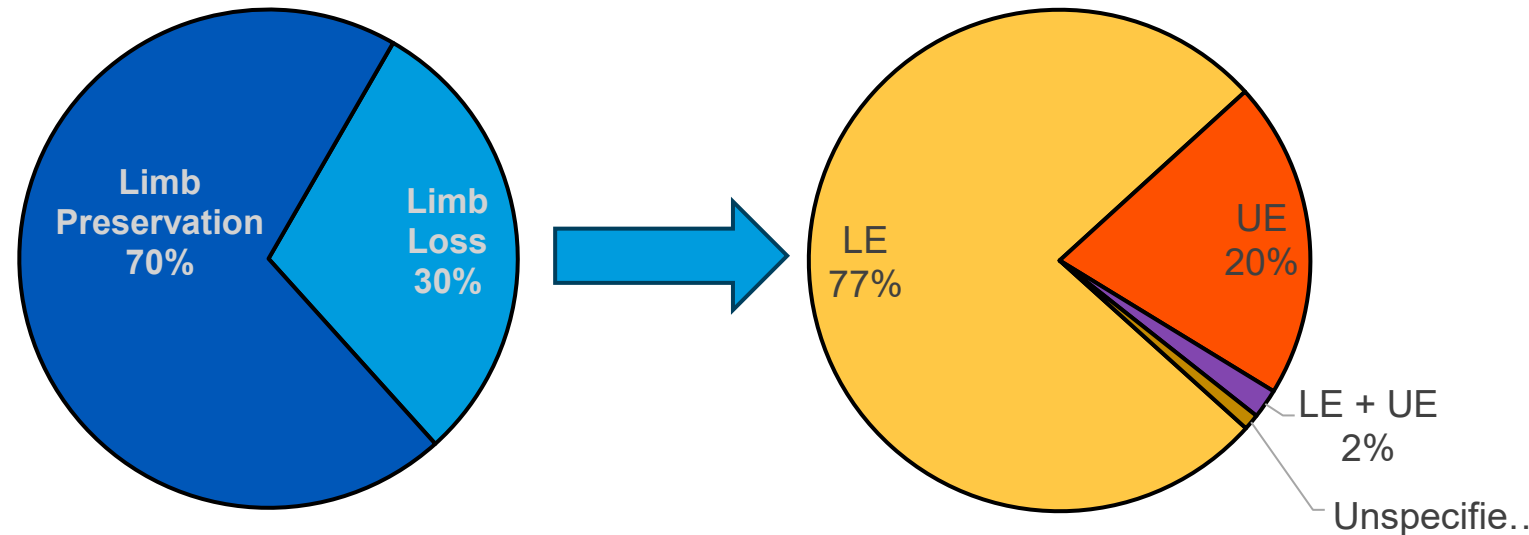
# PARTICIPATION

## Collecting Data from 221 Locations

- 10 Medical Systems with 69 Facilities
- 23 O&P Businesses with 151 Clinics and 1 Mobile Clinic

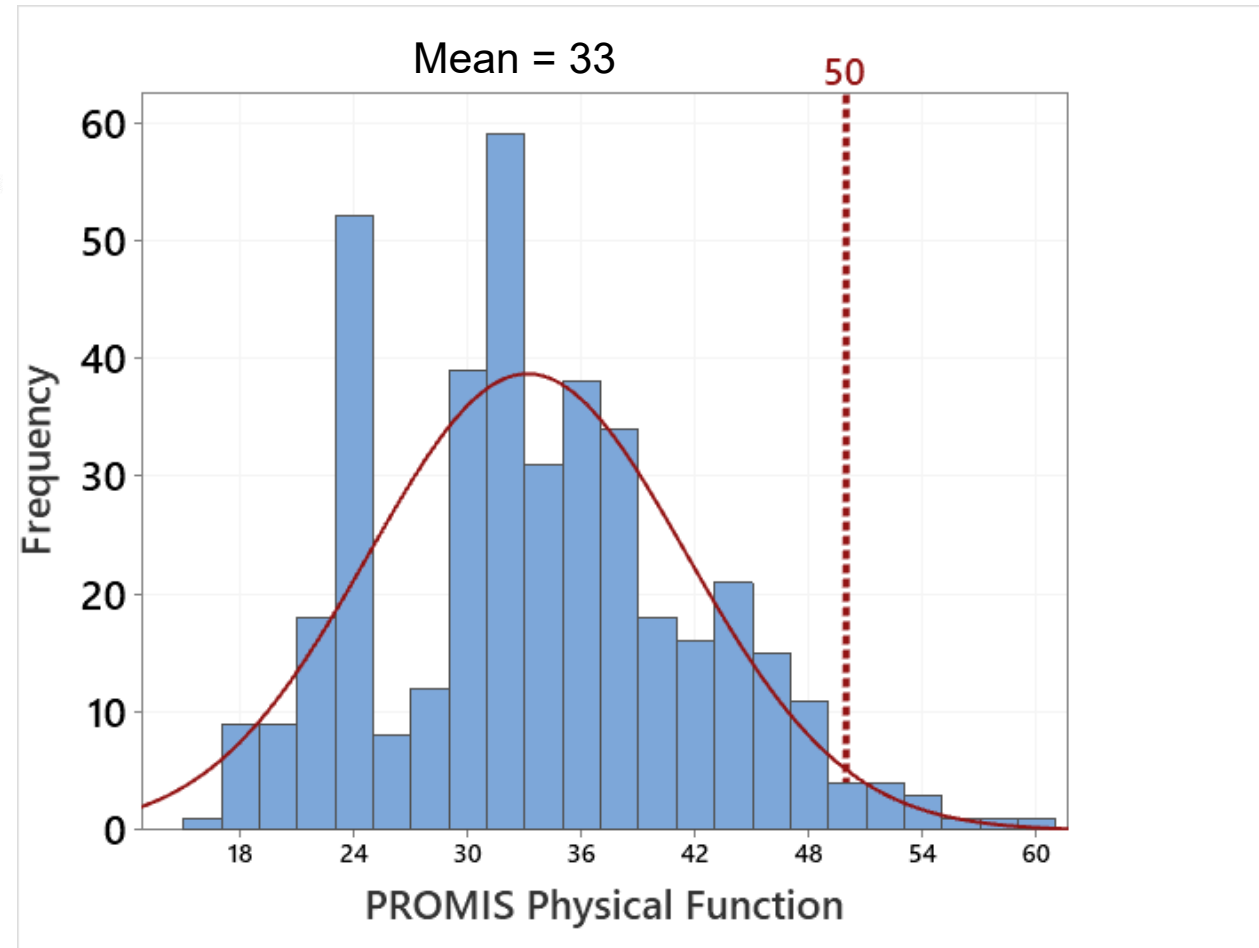
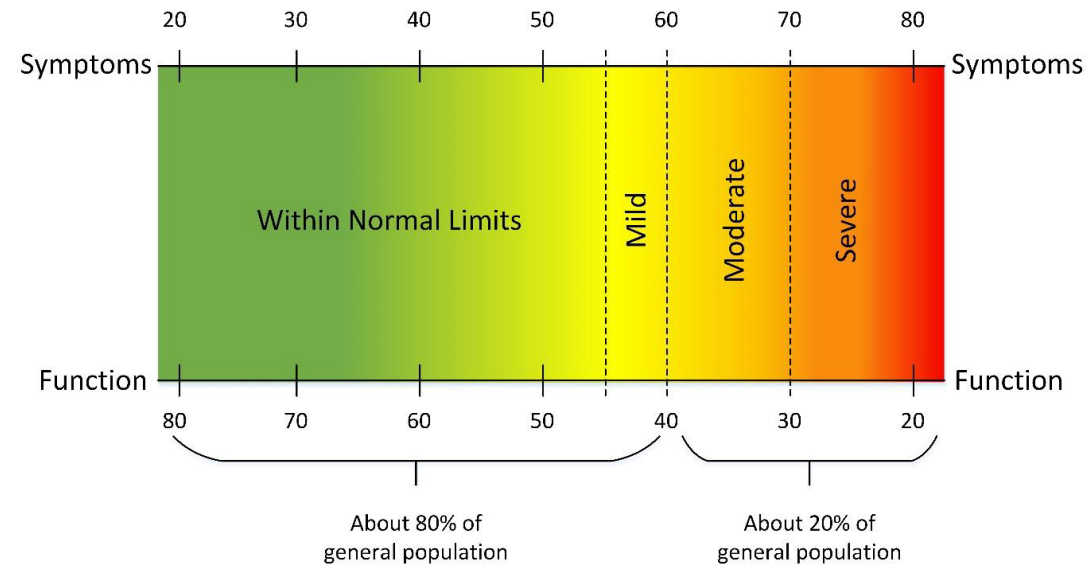


- Patients: 435,979
- Patient Encounters: 11,579,020



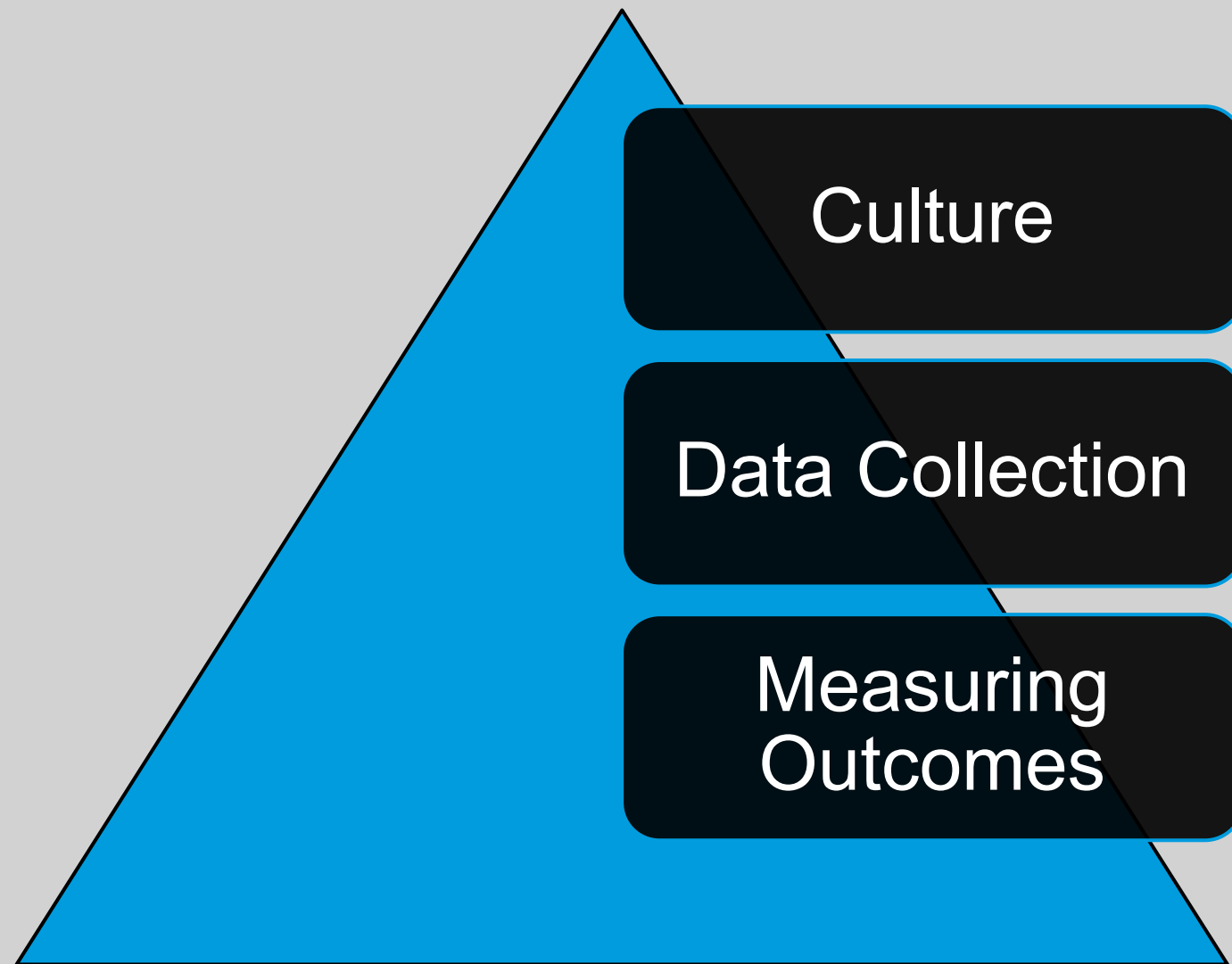


# PROMIS PHYSICAL FUNCTION



39 - Joint Arthroplasty pre-op  
39 - Rheumatoid Arthritis  
35 - Heart Transplant

# LESSONS LEARNED





# CULTURE



1972



1977



1981



1988



1994



2001

# CULTURE CHANGES

- Poorer Speed
- Poorer Graphics
- Poorer Sound
- DIFFERENT
- Movement
- Within 3 years outsold all previous gaming consoles combined

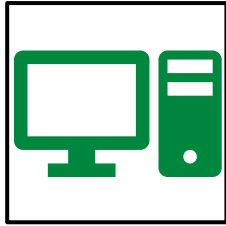


2006

## CULTURE CHANGES

Evidence-Based Practice  
Practice-Based Evidence

# DATA COLLECTION



## AVAILABLE IN EHR

- No Additional Time
- Data Quality
- **Data Granularity**



## DATA EXTRACTOR

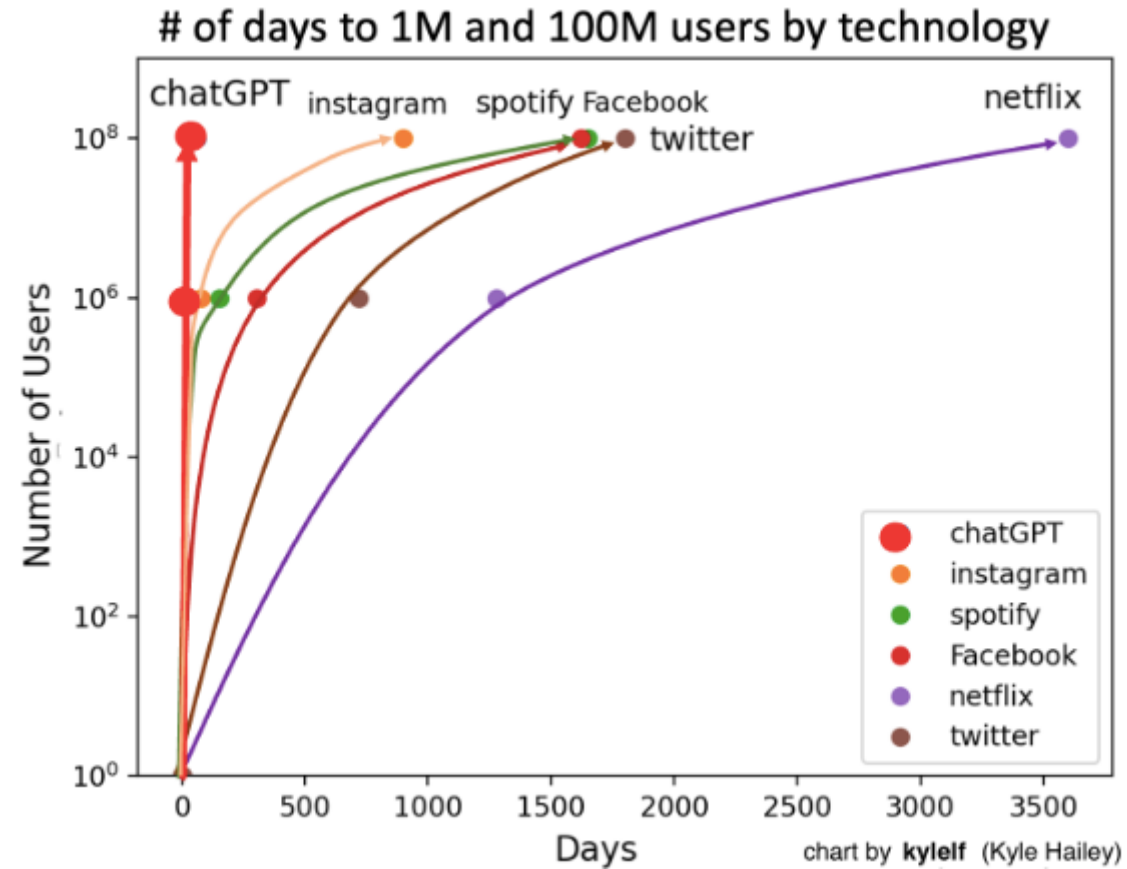
- Extended Dataset
- Data Granularity
- **Additional Time & Cost**
- **Scalability**



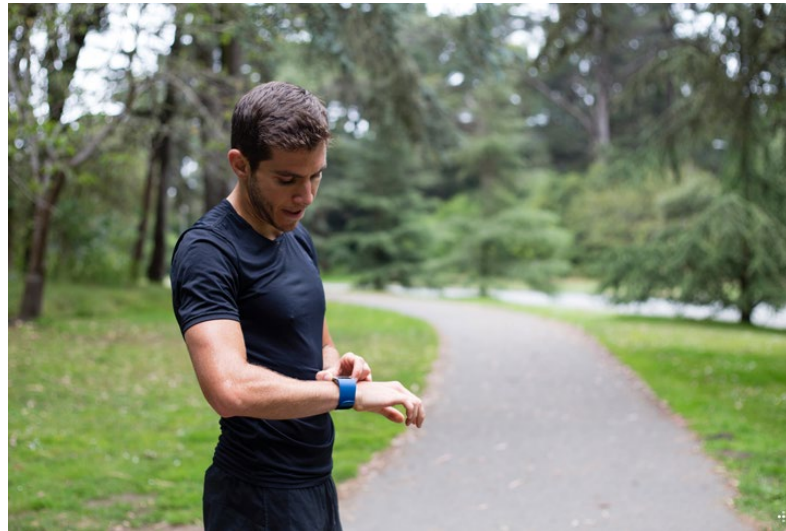
## NATURAL LANGUAGE PROCESSING (NLP)

- Emerging Technology
- Unstructured Data
- **Reliability and Accuracy**

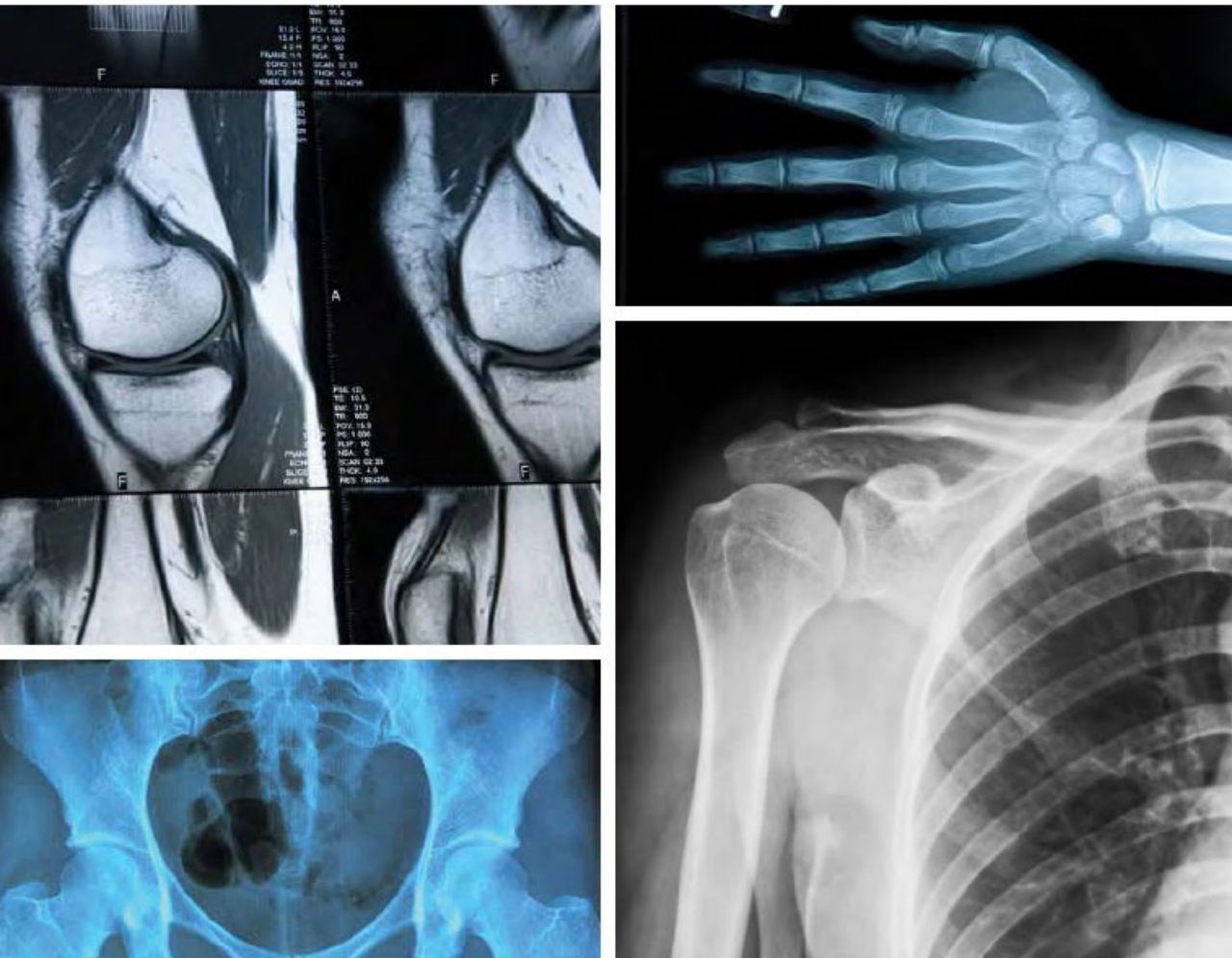
# RATE OF TECHNOLOGY ADOPTION



# MOST IMPORTANT REASON TO MEASURE OUTCOMES



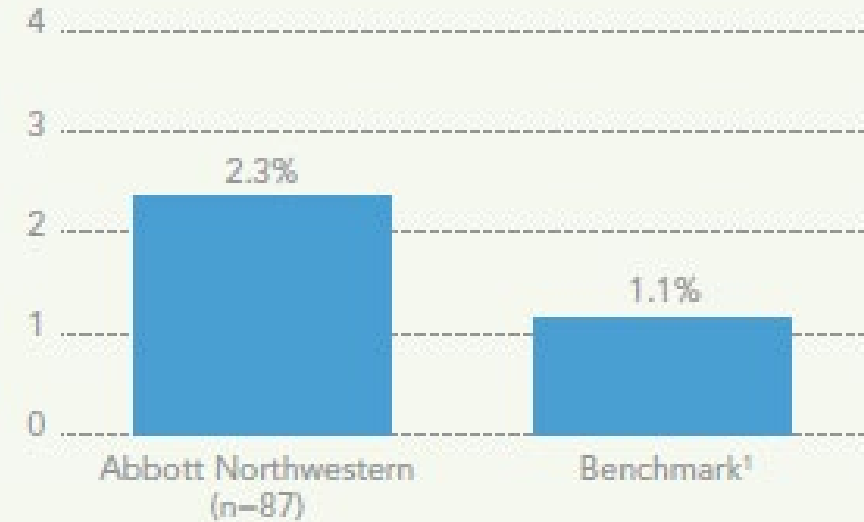




# REVISION HIP REPLACEMENT COMPLICATIONS 2012

## Deep infection rate

Patients  
5%



Overview and Outcomes Report 2012

¹Phillips CB et al. JBJS 85-A(1):20-26, 2003





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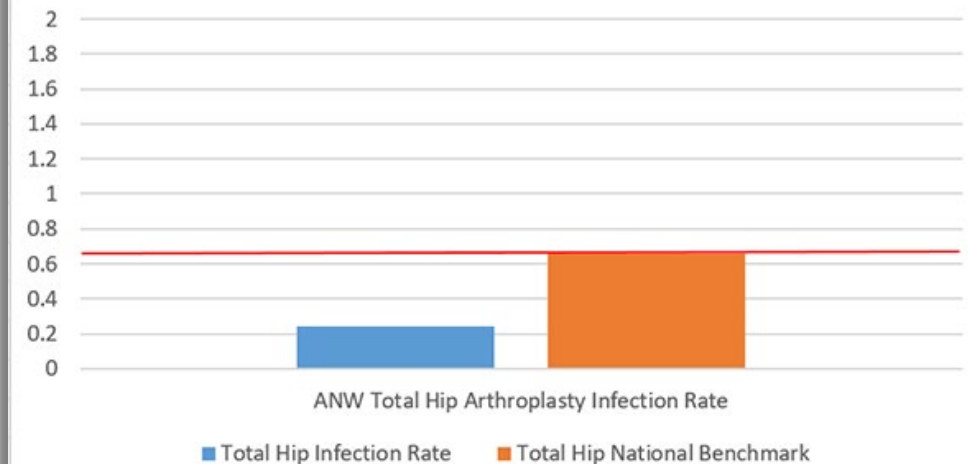
## 100 hospitals and health systems with great orthopedic programs | 2023

Anna Falvey, Claire Wallace and Zoe McClain - Updated Tuesday, October 17th, 2023

**Allina Health (Minneapolis).** Allina Health Orthopedics provides multidisciplinary care across three hospitals. Allina is investing in minimally invasive robotic technology, with providers recently completing the 1,000th hospital-based orthopedic robotic case. The orthopedic program's joint replacement services feature expertise in injury prevention, pre-surgery education, medical imaging and radiology, minimally invasive robotic-assisted surgery and more. The shoulder program, which boasts one of the highest-volumes in the nation, has become a regional destination for care. Allina Health Orthopedics is also in the process of developing a hip preservation program. From fall 2023 onward, care accessibility will increase via a virtual orthopedic urgent care platform.

*healthcare providers. Organizations cannot pay for inclusion on this list. Organizations are presented in alphabetical order. We extend a special thank you to Rhoda Weiss for her contributions to this list.*

ANW Total Hip Infection Rate in 2020





You can't manage what  
you don't measure.

Peter F. Drucker

quotefancy



## **PERFORM CLINICAL TRIAL USING REGISTRY**

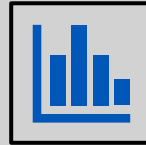
- 1) Avoid duplicative data collection
- 2) Identify and recruit patients more efficiently
- 3) Reduce time to database lock
- 4) Accelerate time to critical decision-making
- 5) Reduce clinical trial costs
- 6) Easily perform post-trial surveillance

# SHARED FRAMEWORK

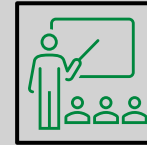
- Technical Platform
- Trigger Codes
- Data Dictionary
- FedRAMP security



# SUMMARY



Data



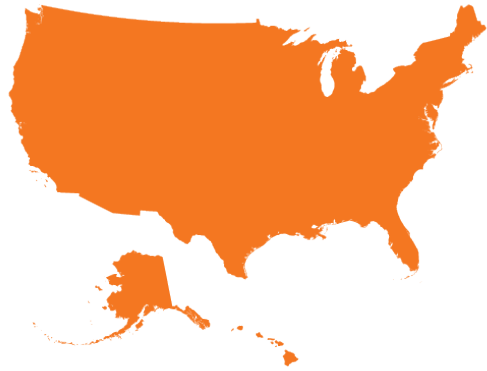
Lessons  
Learned



Clinical  
Trials



Framework



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**[www.llpr.org](http://www.llpr.org)**

[kaufman.kenton@mayo.edu](mailto:kaufman.kenton@mayo.edu)

# THANK YOU!





# **BACKUP SLIDES**

# REGISTRIES IMPROVE QUALITY OF CARE



- Collect unique clinical information demonstrating ***real-world practice***
- Facilitate registry-driven ***quality improvement*** programs
- Establish and disseminate ***clinical guideline*** for clinicians
- Support novel scientific ***research***
- Evidence development for ***national coverage determinations***