Limb Loss and Preservation Registry (LLPR)
Frequently Asked Questions

What is the Limb Loss and Preservation Registry?

The Limb Loss and Preservation Registry (LLPR) is a national program to improve the quality, safety, effectiveness and cost of limb loss treatment and limb loss preservation. Mayo Clinic is undertaking a five-year plan to develop, establish and populate a multi-stakeholder national registry. The LLPR is a centralized data warehouse designed to collect relevant patient data and perform analysis to improve the quality of care and patient outcomes. The project is part of a competitive contract funded by the National Institutes of Health and Department of Defense.

What is the long-term vision for the Registry?

Ideally, five years from now, the LLPR data set will help patients make decisions based on their specific circumstances. The data analytics will forecast probabilities on what is possible given a patient's functional status. The LLPR will provide education and generate knowledge and discovery.

Who has oversight for the Registry?

Registry oversight includes a committee with members from the National Institutes of Health, the Department of Defense, the Veterans Administration, the Center for Medicare and Medicaid Services, and the Food and Drug Administration. Mayo Clinic's principal investigator, Kenton Kaufman, Ph.D., P.E., will lead the project with a team of subject matter experts, including subcontracts with the American Academy of Orthopaedic Surgeons, Prometheus Research, and the Thought Leadership & Innovation Foundation.

Mayo Clinic will also receive guidance from an independent panel of specialists with diverse expertise, ranging from medicine and science to manufacturing and defense. These individuals will act as champions for the LLPR providing influence and communication within and between the various professional organizations and societies they represent.

Who are the participants (or stakeholders) in the Registry?

The Registry is a multi-stakeholder model including a broad group of participants: patients, providers (OT, PT, physicians, prosthetists etc.), care sites (hospitals, clinics wound centers), payors, manufacturers, supplies, and regulatory agencies.

What is the value to participants?

The Registry's primary value is to enhance treatment and care for limb preservation and patients with limb loss. In addition, the multi-stakeholder model highlights secondary value streams from the LLPR data will serve to:

- Create a unified voice for all stakeholders uniting together for a common purpose
- Identify and support underserved populations
- Drive enhanced reimbursements

- Validate design concepts, test new devices, and accelerate time to market
- Offer a timely and direct feedback channel about how product works for the patient
- Provide key data needs: billing data, component device, objective non-biased measures of patient outcomes
- Provide a tool for education and self advocacy
- Generate real-time outcomes – the ' lived experience'
- Provide data points for evidence-based medicine and aftercare:
    - Validate providers belief in how to care for patient and how to inform patient expectations
    - Risk factor modeling
    - Anticipate clinical trajectory
    - Optimize resources – helping understand who needs what device
    - Inform standards of care –i.e., validate surgeon expertise, objective data on provider performance /outcomes

What data will be collected?

Three data sources will be sought:

1. Hospitals,
2. Providers, and
3. Patients.

Data will be collected on limb preservation, amputation and nerve surgical procedures being performed in hospitals. Patient demographic information, co-morbidities, clinical treatments received, length of stay, payers, service locations will also be collected. Details on prosthetic fittings and the providers of those prosthetics will be collected. Patient-reported outcomes will also be collected. Eventually, objective functional data from wearable devices will also be collected to document how well patients are functioning. This is considered quality improvement data that will help improve practice standards across the country.

How will the data be used?

The de-identified data will be used by clinicians and researchers working in surgery, wound care, physical and rehabilitation medicine, biomechanics, physical therapy, occupational therapy, prosthetics, orthotics, podiatry, and psychiatry. It will also be used by engineers, industrial scientists and manufacturers who are working to create improved prosthetic and orthotic devices. In the long term, the data will also help health care providers, patients and families, all of whom need up-to-date, reliable information and resources. Health economists, public regulatory agencies, policy makers, advocacy groups and payer organizations will also benefit from the data.

Registry data will be use to:

- enhance the quality of life for patients with limb loss or limb preservation based on their goals and what they value
- enhance shared decision making between patient and the care provider
- develop quality measures and inform clinical practice guidelines
- assist providers and healthcare systems in meeting regulatory and certification requirements
- advance scientific developments in treating limb difference, limb preservation and limb loss

What prosthetic and/or orthotic components will be tracked and how?

Initially, prosthetic and orthotic components will be tracked using the existing L-code system. Unfortunately, this will only allow general categories of components to be identified. Eventually, it is hoped that greater detail will be provided by manufacturers sharing data with the Registry which will be kept confidential and allow a conversion between serial numbers and components with greater detail.

How much effort will it take to participate?

It is hoped that data from hospitals and providers can be obtained from the electronic health record. Data from patients will be collected by manual entry via a web portal or mobile app. It is anticipated that the first time a patient enters data into the LLPR it may require up to 20 minutes, followed by a 10 minute quarterly update.

How much does it cost to participate?

There will be a fee structure to make the LLPR sustainable. It is anticipated that there will be a fee for stakeholders to join the registry and then there will be costs associated with reports that will be generated from the data.

What is the role of patients? And, how will their confidentiality be assured?

Patients will be a driving force in developing and sustaining the LLPR. Information will be collected, stored and analyzed under the highest security. Data will be in a well-protected repository that meets the highest Federal requirements for non-classified data. Patients will be asked to input data.

What is the current status of the Registry?

LLPR is initially conducting a pilot study to learn about the feasibility and logistics of collecting clinical information about lower limb loss. The LLPR Pilot will allow us to learn and problem-solve around the data capture needed to both decrease data burden, as well as to maximize the data quality. The LLPR pilot study will work with three health systems to collect procedural, post-operative and patient reported outcomes data.

The pilot will allow us to understand care in the intraoperative phase that is currently anecdotal. LLPR Pilot data re-use will be critical. The LLPR research team will evaluate the data set to ensure that the data elements are reliable, actionable, and provide feedback on how to improve patient care and understand payer and certification program needs.

What is the trigger to be included in the pilot study?

During the pilot study, only patients with a lower limb amputation or limb preservation procedure code (plus trauma diagnosis) will be included. Eventually, it is planned that the LLPR will also include upper extremity preservation and limb loss.

How do I become an active participant in the Registry?

Please contact us using the email below so that we can begin to form a list of individuals who we can contact to participate in building the registry and providing data.

How do registry participants get recognition for their involvement?

By necessity, all data entered into the LLPR needs to be kept confidential. Participants will only see their individual data compared to national data. It is hoped that a recognition process will be developed in the future whereby outstanding care providers will allow themselves to be identified so that other providers can discuss strategies with them to achieve better outcomes.

Where do I go to get more information?

Visit us on the Web:
https://www.mayo.edu/research/labs/motion-analysis/research/limb-loss-preservation-registry

Contact us: limblosspreservationregistry@gmail.com