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WHAT IS THE LLPR?

The Limb Loss and Preservation Registry is the first hospital systems and prosthetic/orthotic facilities collaborative database to focus on the acquired and congenital limb difference, as well as, limb preservation, populations.

HOW WILL THE REGISTRY IMPACT THE COMMUNITY?

- The Registry addresses a substantial public health knowledge gap for a population that has no current reliable data repository.
- The information housed in the Registry will help to prevent limb loss, influence clinical practice guidelines, refine rehabilitation approaches, and guide development of more optimal care plans for people living with limb loss.
- As a collaborative data hub, the Registry collects data from hospital and O&P EHR systems and other outcomes measuring systems, to create a longitudinal view of a patient's care journey.
- This dataset will be made available to researchers studying medical conditions that contribute to limb loss, such as diabetes and vascular disease, enhance their functionality and quality of life.

WHO WE SERVE

PATIENTS  CLINICIANS  MANUFACTURERS  HOSPITALS  RESEARCHERS  PAYERS
Since the LLPR received Authority to Operate in February 2022, the LLPR has ingested data from participating sites.

The LLPR receives data from its participating sites on a quarterly basis. Therefore, the numbers below and on the following pages will continue to change over time.*

**SNAPSHOT OF DATA IN THE LLPR DATABASE**

- **Visits**: 11,579,020
- **Patients**: 435,979
- **States**: Patients in all 50 States, DC, Canada, Mexico, Virgin Islands, and Puerto Rico

*Data as of 4/22/2024.

**HOW SECURE ARE THE DATA?**

The LLPR environment is compliant with FedRAMP moderate, HIPAA, and NIST 800-53 requirements. Because the LLPR is funded by the NIH and DOD, the LLPR is obligated to meet NIH and DOD security requirements. That means your data is as protected as US military data.
SNAPSHOT OF DATA IN THE LLPR DATABASE

**LLPR Summary Information**

- **Number of Patients**: 304,563
- **Number of Encounter Visits**: 10,597,758

**Hospital Patient Cohorts**
- 88,499 Patients

**O&P Patient Cohorts**
- 216,074 Patients

---

Data as of 2/21/2024.
SNAPSHOT OF DATA IN THE LLPR DATABASE

**Encounters**

<table>
<thead>
<tr>
<th>Year</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021</td>
<td>478,877</td>
<td>500,621</td>
<td>586,416</td>
<td>552,142</td>
<td>597,504</td>
<td>552,878</td>
<td>581,289</td>
<td>638,779</td>
<td>668,787</td>
<td>780</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Comorbidities Per Patient**

| Comorbidities | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | >15 |
|---------------|---|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|-----|
| Percentage    | 36%| 12%| 7% | 6% | 4% | 4% | 4% | 3% | 2% | 2% | 2% | 2% | 1% | 1% | 0% | 0% | 0% | 0% |

**Sex**

- Male: 54.7%
- Female: 45.3%

**Social Determinants of Health**

- Problems related to housing and economic circumstances: 55.0%
- Problems related to social environment: 16.7%
- Other problems related to primary support group, including family circumstances: 11.8%
- Problems related to other psychosocial circumstances: 6.7%
- Problems related to employment and unemployment: 5.1%
- Occupational exposure to risk factors: 1.6%
- Inadequate parental supervision and control: 1.4%
- Problems related to upbringing: 1.2%
- Problems related to education and literacy: 0.4%
- Problems related to certain psychosocial circumstances: 0.1%
- Problems related to physical environment: 0.0%

**Prevalence of Elixhauser Comorbidities in Patient Population**

- No Comorbidities: 36.7%
- Heart disease: 22.0%
- Hypertension, uncomplicated: 28.1%
- Peripheral vascular disorders: 26.4%
- Hypertension, complicated: 22.4%
- Renal failure: 20.8%
- Fluid and electrolyte disorders: 19.5%
- Congestive heart failure: 19.3%
- Valvular disease: 18.7%
- Obesity: 17.7%
- Chronic pulmonary disease: 15.8%
- Diabetes, uncomplicated: 15.3%
- Depression: 13.6%
- Solid tumour without metastasis: 9.0%
- Hypothyroidism: 9.7%
- Coagulopathy: 8.5%
- Pulmonary circulation disorders: 8.3%
- Liver disease: 8.1%
- Deficiency anaemia: 8.1%
- Weight loss: 7.8%
- Rheumatoid arthritis/collagen vascular disorders: 6.6%
- Other neurological/psychiatric disorders: 6.4%
- Metastatic cancer: 3.5%
- Alcohol abuse: 3.5%
- Drug abuse: 2.7%
- Paralysis: 0.2%
- Peptic ulcer disease, excluding bleeding: 1.9%
- Blood loss anemia: 1.8%
- Lymphoma: 1.0%
- Psychoses: 0.5%
- AIDS/HIV: 0.1%
- Diabetes, complicated: 0.1%

Data as of 2/21/2024.
Since the LLPR received Authority to Operate in February 2022, hospitals and O&P practices have participated in this national initiative.

23 O&P practice systems participating.

10 Hospital systems participating.

221 Total Sites Participating

PARTICIPATING HOSPITALS

- Atlantic Health System
- Atrium Health
- Mayo Clinic
- Shirley Ryan AbilityLab
- University of Alabama at Birmingham Medicine
- University of Colorado Health
- University of Michigan Health
- University of Texas Health Houston
- University of Washington Medicine
- The Johns Hopkins University Health System Corporation
WHAT KIND OF DATA ARE AVAILABLE FOR ME?

SEE HOW YOU COMPARE

PATIENT POPULATION

With the data from the LLPR, hospitals are able to critically evaluate the types of patients their facility is treating in comparison to others regionally and nationally.

The below shows where your hospital system or site compares to others.

![Clinical Case Mix - Patient](image-url)
WHAT KIND OF DATA ARE AVAILABLE FOR ME?

SEE HOW YOU COMPARE

PATIENT OUTCOMES

With the data from the LLPR, hospitals are able to critically evaluate how their facility is performing in comparison to others regionally and nationally.

The below shows where your hospital system or site compares to others.
### WHAT DATA ARE COLLECTED?

#### patients
- Address
- Alcohol Frequency
- Alcohol Use
- Allergies
- Date of Birth
- Date of Death
- Deceased Indicator
- Education Level
- Ethnicity
- Marital Status
- Name
- Occupation
- Patient ID
- Race
- Sex
- Sex at Birth
- Smokeless Tobacco Use
- Smoking Tobacco Use
- Veteran Status

#### patient visit
- Admission Date
- Assistive Device Type
- Assistive Device Use
- Discharge Date
- Discharge Location
- DX Codes
- Encounter Date & Time
- Encounter Number
- Facility ID
- Height
- ICD-10 Codes*
- CPT Codes**
- Patient ID
- PROMIS Physical Function
- PT/OT Therapist Training Indicator
- PT/OT Therapist Training Visits
- SDOH Codes
- Weight

#### payer
- Cardinality
- Patient ID
- Payer Type
- Payer Status
- Payer Status Effective Date

#### limb amputation
- Amputation Date
- Amputation Level
- Amputation Reason
- Amputation Reason Description
- Amputation Side
- Encounter Date & Time
- Encounter Number
- Patient ID
- Prior Amputation
- Procedure Name

#### facility
- Facility Address
- Facility Name
- Facility NPI
- Facility Phone Number

#### comorbidity
- Comorbidity
- Date of Presentation
- DX Code
- Encounter Number
- Patient ID
- Present on Admission

#### prosthetic prescription
- Encounter Number
- Patient ID
- Prosthetic Prescription
- Prosthetic Prescription Value

*ICD-10 Codes include codes for limb difference and congenital limb difference

**CPT Codes include codes for limb amputation and limb preservation
The LLPR is exempt from the requirement for IRB approval per 45 CFR 46.104d, category 4. This was reviewed by the NIH.

Read the summary below and 45 CFR 46.104d, category 4 on the next page.

Summary of IRB Exemption

- The LLPR is a clinical data registry, designed to standardize, measure, and report patient outcomes data, support evidence-based decision making, enhance health care delivery, and establish and disseminate best practices. This purpose is reflected in the registry protocol and participation agreement. The registry is not a research registry aimed at development of generalizable knowledge.
- Each LLPR participant submits Protected Health Information to Mayo, which acts as a business associate for each covered entity participant in conducting data analyses that relate to the participant’s health care operations (as defined under HIPAA at 45 CFR 164.501), including data aggregation, quality assessment and improvement, and peer review functions. The business associate agreement is attached to and part of the LLPR participation agreement.
- Mayo Clinic sought IRB review for creation of the clinical data registry because one of the downstream goals of LLPR is use of de-identified clinical data collected in the registry in research. OHRP guidance has suggested that creation of a clinical data registry that might be used downstream for research should be reviewed and approved by an IRB (even if any data that might be used for research would be de-identified). (See OHRP guidance at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/june-25-2015-letter-to-robert-portman/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/guidance/regarding-application-of-45-cfr-46-to-national-health-registry/index.html.)
- OHRP guidance linked above provides that “institutions that are providing data to the clinical data registry, but are not engaged in the research activity, do not need any IRB review.” For this reason, many LLPR participants have not sought IRB review. Some participants have submitted for IRB review nonetheless, and IRBs have typically either (1) confirmed that the downstream research use of de-identified data from the clinical registry does not constitute human subjects research because no identifiable information is used, or (2) have determined that the downstream research use is exempt from IRB review under exemption 4, which exempts research involving information recorded in such a manner that the identity of the subject cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify the subjects (45 CFR 46.104(d)(4). (This is the exemption that the Mayo IRB determined was applicable.)
Integration testing.

We will work with your IT team to confirm data transfer. We will also confirm that data files (JSON files) are correctly formatted and the data are valid.

Live data transmission & receipt.

After testing is complete, it is time to send live data. Your IT team will send bulk data (2017 and onward when possible).

After bulk data, we request incremental data loads every 3 months.

IRB EXEMPT

The LLPR is exempt from the requirement for IRB approval per 45 CFR 46.104d, category 4. This was reviewed by the NIH.


45 CFR 46.104d, category 4

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
40–55 business days. After your hospital signs a Participation Agreement, we are ready to receive your data!

Please note the timeline below is an estimate and may vary by institution.
Because LLPR was created by contract from NICHD in partnership with DoD as a quality registry for the purpose of improving patient care for the limb loss and limb difference community, participation in LLPR is a quality improvement practice for your hospital system—not just one department at one hospital. We encourage you to share the benefits of LLPR analytics with other departments in your hospital and hospital system and propose to your hospital administration that LLPR should be paid for by the system and not your department.

*LLPR can be used as part of quality improvement initiatives for CARF accreditation.*
<table>
<thead>
<tr>
<th>Service</th>
<th>Base Reporting Organization</th>
<th>Each Additional Organization (up to 9 additional organizations)</th>
<th>Each Additional Organization (more than 9 additional organizations)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base Subscription</td>
<td>$5,000</td>
<td>$4,000</td>
<td>$3,500</td>
</tr>
<tr>
<td>Analytic Dashboards</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>What’s included:</td>
<td>Data Quality dashboards summarize data for completeness and accuracy. Case Mix dashboards give descriptive summaries and unadjusted benchmarks about patient demographics and healthcare experiences of the limb loss and preservation patient population.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expanded Population Analysis Add-On</td>
<td>$2,000</td>
<td>$1,700</td>
<td>$1,500</td>
</tr>
<tr>
<td>What’s included:</td>
<td>The patient journey dashboards deliver insights into patient care pathways including unadjusted benchmarks.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subpopulation Analysis Add-On</td>
<td>$2,000</td>
<td>$1,700</td>
<td>$1,500</td>
</tr>
<tr>
<td>What’s included:</td>
<td>These enhanced dashboards enable deeper delivery of care insights along with unadjusted benchmarks through added global filters. Individual provider-specific insights are included as well.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk-Adjusted Benchmarking Add-On</td>
<td>$2,400</td>
<td>$2,250</td>
<td>$2,000</td>
</tr>
<tr>
<td>What’s included:</td>
<td>Advanced risk modeling methodology applied to contributor data to support comparisons across entities of similar size and type to yours.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- New participants are invoiced for the annual subscription fee at the time of their first data transmission; subscription renewals are processed annually
- Each organization includes 2 user licenses, additional licenses are available for $250 each, per subscription cycle
- Organization is defined by you; it can be one or all of your locations, or somewhere in-between
- There is a 3-month lag for report availability from the time of data transmission to the Registry
- You do not need to subscribe to contribute data, non-subscribing data contributors will receive 2 reports annually; one is aggregated data for the entire Registry population, and one specifically generated from your organization’s data

Visit: www.llpr.org
Follow us: @llpregistry
## How the LLPR Saves Your Hospital Money

<table>
<thead>
<tr>
<th>2018</th>
<th>2021</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3.8 MILLION</strong> adult hospital readmissions within 30 days</td>
<td><strong>1.8 MILLION</strong> adult hospital readmissions within 30 days</td>
</tr>
<tr>
<td><strong>14%</strong> average readmission rate</td>
<td><strong>11.67%</strong> average readmission rate</td>
</tr>
<tr>
<td><strong>$15,200</strong> average readmission cost</td>
<td><strong>$22,944</strong> average readmission cost</td>
</tr>
<tr>
<td><strong>57 BILLION</strong> spend for hospital readmissions</td>
<td><strong>41.3 BILLION</strong> spend for hospital readmissions</td>
</tr>
</tbody>
</table>


### Annual Subscription Cost of the LLPR is as little as $5,000

- The LLPR determines common risk factors for readmission within its patient population so that you can flag these risk factors and identify your patients who meet these criteria and are a high risk for readmission.
- The ability to identify patients at high risk for readmission allows your organization to be proactive with enhanced patient education prior to discharge, and post-discharge follow-up which are both known to reduce the rate of 30-day readmissions.
- The annual subscription cost of the LLPR can be recouped if the information it provides prevents 1 readmission per year.
# How the LLPR Can Save Your Hospital Money

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult hospital readmissions within 30 days</td>
<td>3.8M</td>
<td>1.8M</td>
</tr>
<tr>
<td>Average readmission rate</td>
<td>14%</td>
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<tr>
<td>Average readmission cost</td>
<td>$15,200</td>
<td>$22,944</td>
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<tr>
<td>Spend for hospital readmissions</td>
<td>$57B</td>
<td>$41.3B</td>
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</table>


## Annual Subscription Cost of the LLPR

is as little as $5,000.00

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- The annual subscription cost of the LLPR can be recouped if the information it provides prevents 1 readmission per year.
WHAT DO I TELL MY IT?

DATA TRANSFER DOCUMENTATION

LLPR HAS THE FOLLOWING DOCUMENTATION TO SEND TO YOUR IT:

- Hospital Data Dictionary (Excel spreadsheet with each tab representing a table in LLPR’s database)
- Trigger Codes List
- Example JSON files
- Data Intake Onboarding One Pager and File Naming Convention
- Bucket Upload Instructions

THEN WHAT?

NEXT STEPS FOR YOUR IT TEAM

- Review the Hospital Data Dictionary and determine where those data elements are mapped in your EHR system. Please note for each tab/table in the data dictionary, Column K lists Epic fields. We are working with CERNER sites to develop a similar listing for data elements.
- The patient cohort is identified using trigger codes. Once a patient is triggered, then LLPR receives all subsequent episodes of care. For example, if a patient has an amputation and then a year later is admitted for COVID, LLPR receives data regarding the COVID admission.
- LLPR receives data for each table (each tab in the data dictionary) as flat files called JSON files. LLPR has example JSON files that can be provided.
  - Note: LLPR’s ingestion routine relies on the file naming convention for the JSON files. LLPR has a file naming convention that can be provided.
- LLPR requests bulk data (2017 and onwards) with subsequent incremental data feeds once per quarter. Prior to receiving bulk data, LLPR requests test JSON files be sent first. Please send sample data for each table with no more than 10 entries. This allows LLPR developers to test the formatting of your files prior to receiving large files.
- You will be able to upload your data to a private Google bucket. To do that, LLPR needs the email address(es) of the individuals that will be uploading data to the bucket (no general use emails permitted). Please note these email addresses should be Google accounts. If your hospital does not use Google accounts, then LLPR requests IT to federate identities with Google. This is Google’s way of ensuring no one else is impersonating your accounts.
  - If your hospital does not allow IT teams to send data to an external source, then LLPR requests hospital IT to create an SFTP server and grant LLPR access to pull files from that server.

*LLPR is ready to receive your data at any time once we receive the email addresses of the persons submitting data.*
WHAT IS THE FUTURE OF THE REGISTRY?

2022
- Hospital Collection of Lower and Upper Limb Amputation and Preservation Clinical Procedure Data Begins
- Hospital Focus Group

Q1 2023
- O&P Provider Market Analysis
- Hospital Market Analysis

Q2 2023
- O&P Dashboard Subscription Model
- O&P Subscription Model Limited Release
- Patient Self-Reported Outcomes Finalized

Q3 2023
- Hospital Dashboard Subscription Model & Limited Release
- Manufacturer Market Analysis
- O&P EHR Data Collection of All Visits Begins
- O&P Dashboard Focus Group and Ongoing Development

Q4 2023
- Manufacturer Dashboard Subscription Model
- Manufacturer Focus Group
- O&P Full Subscription Model Release
- Hospital Dashboard Development & Full Release of Subscription Model

Q1 2024
- Manufacturer Dashboard Subscription Model Release
- Engagement with Accrediting and Credentialing Organizations

Q2 2024
- Researcher Market Analysis & Data Requests Pricing Model
- Manufacturer Dashboard Development & Full Release of Subscription Model

Q3 2024
- Patient Engagement Platform Design
- Researcher Focus Group Kickoff
- Researcher Dashboard Development & Full Pricing Release

Q4 2024
- Payer Market Analysis & Focus Group Kickoff
- Government Policy Engagement
STAY IN TOUCH

www.llpr.org

info@llpregistry.org

@llpregistry

Limb Loss and Preservation Registry