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Methodology and Research Protocols

Creation of a Limb Loss and Preservation Registry for Improving the Quality of Patient Care in the United States

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KEYWORDS
Clinical Data Registry;
Limb Loss and Preservation Registry;
Rehabilitation

Abstract *Objective:* To describe the development of a national Limb Loss and Preservation Registry (LLPR) designed to collect, standardize, and report patient outcomes data on limb loss and limb difference in the United States.
Design: Clinical Data Registry
Setting: The LLPR was developed through consensus of key stakeholders from academia, industry, patient advocacy, and payers as well as the available scientific evidence. Data are collected from multiple sources, including hospitals, providers, and patients.
Participants: Data are collected from all 50 states.
Interventions: Not applicable.
Main Outcome Measures: More than 1100 trigger codes are used to identify patients who have limb difference or have received a limb preservation or amputation procedure. Once a patient is identified, all subsequent episodes of care are collected for the life of the patient. An integrated model is used for collecting, validating, cleaning, transforming, aggregating, and storing the data received from all sources. The information contained is then provided in a thorough and easily comprehensible manner.

List of abbreviations: ATO, authority to operate; EHR, electronic health record, EMR, electronic medical record, IRB, institutional review board; LLLD, limb loss and limb difference; LLPR, Limb Loss and Preservation Registry; PHI, protected health information; PROMIS, Patient-Reported Outcome Measures Information System; RoPR, Registry of Patient Registries; US, United States.

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Results: To date, the LLPR has captured data from >435,000 patients and >11.5 million episodes of care.

Conclusions: The LLPR creates opportunities to apply large-data analytical methodologies to provides caregivers, researchers, manufacturers, payers, and policy makers the tools needed to improve the quality of clinical care, quantify patient-centric outcomes, develop clinical practice guidelines, assess patient quality of life, identify appropriate technology, and guide creation of national policies to allocate scarce sources appropriately.

There is no reliable source of comprehensive data on limb loss and limb difference (LLLD) in the United States (US). No data are available to provide information on incidence, prevalence, cost, and quality of life for these individuals. National-level health outcomes data are vital to identify health problems, develop clinical practice guidelines, determine barriers to accessing care, provide cost-effective care, and study health-related disparities.[1-4] According to the Amputee Coalition, there are an estimated 5.7 million people in the US, living with LLLD[5] and an estimated 465,000 amputations occur every year.[5] Although informative, these numbers are only gross estimates. Although limb loss was included in the National Health Interview Survey in the early years of the project, the health condition was not included after 1996. In each case, data were general and did not consistently include reasons for limb loss, information on surgical care, or any data related to follow-on care, prosthetic or assistive device provision, or patient quality of life. At present, there is no feasible means to gather this data through existing national surveys or existing health interviews owing to the nature of the distributed health care for this population in the US.

The lack of comprehensive, national outcomes data for people with LLLD hampers prevention, treatment, and rehabilitation efforts. Outcome measures are not routinely collected and used in clinical practice.[6-8] This results in a significant public health gap and inhibits policy creation[9] to address the potential causes or effective postamputation rehabilitation to optimize health and wellness of those who experience limb loss. Without this data, it is not possible to define effective postamputation rehabilitation and recovery efforts to optimize the health and wellness of those who experience limb loss. Payors increasingly demand objective measurements of a patient's functional status and improvements to be measured to facilitate funding of rehabilitation services such as prosthetic components.[10] It is also imperative that caregivers, researchers, payers, and policymakers have standardized data from which they can develop clinical practice guidelines, perform research, draw conclusions, and create national coverage determinations that will move the field forward.

The overall objective of this project was to address this public health gap by establishing a national Limb Loss and Preservation Registry (LLPR). This LLPR was designed to collect, standardize, and report patient outcomes data, support evidence-based decision-making, and enhance health care delivery. The LLPR provides the tools needed to compare patient care approaches, quantify patient-centric outcomes, develop clinical practice guidelines, assess patient quality of life, and assess fitness for return to work. Ultimately, the LLPR will provide the data needed to improve patient care, reduce disability due to limb loss and preservation, and allocate scarce sources appropriately.

Technical design

The LLPR integrates data from the electronic health records (EHRs) of hospitals and orthotic and prosthetic providers (fig 1). The LLPR is designed with the goal of collecting health outcomes data that can be used to guide care for patients with or at risk of limb loss. The 21st Century Cures Act,[11] signed into law on December 13, 2016, requires EHRs to share data with registries, making the LLPR a way for EHRs to be compliant with this act. A patient engagement platform is planned to acquire patient-reported outcome

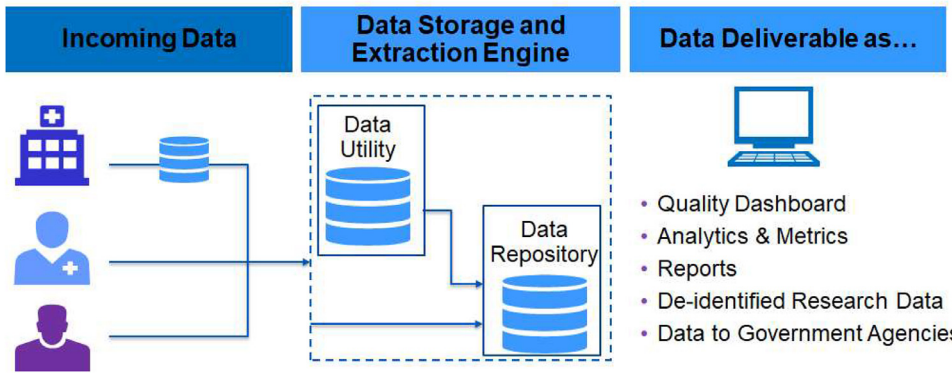

Fig 1 Limb Loss and Preservation Registry national data flow.

measures (PROMs). In the future, the LLPR will also acquire data from other external data sources at the patient level (ie, Medicare and Medicaid claim data for longitudinal follow-up) and the prosthesis level (ie, prosthesis components characteristics from manufacturers). PROMs data are essential for evaluating the effectiveness of surgical approaches, rehabilitation programs, and prosthetic and orthotic components.

The LLPR stores data in the Google Cloud Platform using a scalable system architecture to assure end-state data flow (see fig 1). The LLPR uses a web-based user interface to provide a diverse stakeholder community with access to role-based standardized and customized reports and data to answer research questions efficiently and effectively. The online advanced platform is customized for data queries and reporting. Dashboards offer user-specific filters to guide cohort creation, comparison with regional and national benchmarks, and nonrisk-adjusted, and in the future, risk-adjusted results. Participants can easily create reports detailing patient demographics, outcomes, and performance on process measures. Drill-down reporting allows users to instantly examine data from the macroscopic national outcome level to the microscopic level perspective.

Data collection

A landscape analysis was performed to identify valid administrative and clinical data about limb amputation and limb preservation patients in the US. The LLPR team created data dictionaries to capture the various aspects of clinical care. Our team consisted of medical professionals and people trained in diagnosis and procedure codes (International Classification of Diseases, Current Procedural Terminology, Healthcare Common Procedure Coding System codes) typically used in the US. The LLPR also adopted the recommendations provided by the International Society of Orthotics and Prosthetics for a Lower Extremity Amputation Dataset.[12] The LLPR uses industry-accepted methods[13] to collect clinical data to evaluate outcomes of individuals with limb loss, limb difference, and limb preservation and perform clinical trials. These data can be used for clinical, scientific, and policy purposes. The integrated information provides information on patient function, quality of life, safety, and cost-effectiveness achieved in current clinical practice. There are 1122 trigger codes that have been selected to identify individuals with limb preservation procedures, limb loss, and limb difference (supplemental appendix S2 and S3, available online only at http://www.archives-pmr.org/). The trigger codes include both upper and lower limbs. The trigger codes encompass both vascular and orthopedic surgeries. Trigger codes include ICD-10 diagnosis or procedure codes, CPT codes, or HCPCS codes. The trigger codes can be present in an inpatient or outpatient facility. Once a trigger code is activated for an individual patient, all subsequent episodes of care are collected.

The data collected from participating hospitals, clinics, and patients are robust, authenticated, and linked so that a complete representation of all patient care delivered in a community, state, or region can be analyzed. Data elements reflect the characteristics of the individuals, interventions, and outcomes. The LLPR has taken a four-tiered approach to the data collection. Protected health information (PHI) is collected in each tier so that the data from an individual can be linked together across the tiers. The first tier is data collected from hospital systems (table 1). These data include patient demographics, amputation/preservation side/level, facility, provider, payor, patient comorbidities, z-codes (social determinants of health), physical and/or occupational therapy (PT/OT) visits, and Patient-Reported Outcomes Measurement Information System physical function.[14,15] The comorbidities are those used to define the Elixhauser Comorbidity Index.[16] The second tier is data collected from prosthetic clinics (table 2). This dataset is based on the recommendations from the International Society of Orthotics and Prosthetics.[17] The data include patient demographics and information on the prosthetic/orthotic device,

Table 1 Hospital data collected by the LLPR.

Category	Data Elements
Patient demographics	Name, address, date of birth, deceased indicator, date of death, alcohol use, alcohol frequency, allergies, education level, ethnicity, marital status, occupation, patient ID, race, sex, sex at birth, smokeless tobacco use, smoking tobacco use, veteran status
Limb amputation	Date, level, side, encounter date and time, encounter number, patient ID, prior amputation, procedure name
Comorbidities	Comorbidity, date of presentation, Diagnosis codes, encounter number, patient ID, present on admission
Patient visit	Admission date, assistive device type, assistive device use, discharge date, discharge location, DX codes, encounter date and time, encounter number, facility ID, height, ICD-10 codes*, CPT codes†, patient ID, Patient-Reported Outcomes Measurement physical function, PT/OT therapist training indicator, PT/OT therapist training visits, SDOH codes, weight
Provider	Encounter number, patient ID, provider Name, provider National Provider Identifier, provider specialty, taxonomy code
Payer	Cardinality, patient ID, payer type, payer status, payer status effective date
Facility	Facility address, facility name, facility National Provider Identifier, facility phone number
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.

Table 2 Orthotic and prosthetic data collected by the LLPR

Category	Data Elements
Patient demographics	Name, address, date of birth, deceased indicator, date of death, alcohol use, allergies, education level, ethnicity, marital status, occupation, patient ID, race, sex, tobacco use, veteran status
Comorbidity	Comorbidity, date of presentation. Diagnosis code
Patient visit	Assistive device type, assistive device use, discharge location, Diagnosis codes, encounter date and time, function level, height, HCPCS codes, pain level, patient goals, PT/OT therapy, residual limb characteristics, SDOH codes, socket comfort score, weight
Provider	Credential number and type, credentialing state, organization name, provider name, provider National Provider Identifier, provider specialty, taxonomy code
Payer	Cardinality, payer type, payer status, payer status effective date
Facility	Facility address, facility ID, facility name, facility phone number
Orthosis	Orthosis*, manufacturer, manufacturer year, orthosis experience, orthosis type and use, hours of use, suspension type
Upper limb prosthesis	Prosthetic prescription, capability, control mechanism, hand dominance, wrist*, elbow*, shoulder*, joint range of motion§, delivery date, interface material, prosthetic average hours of use, prosthetic use, prosthetic prescription fulfillment, prosthetic prescription fulfillment reason, socket‡, suspension type, suspension type additional, termina device
Lower limb prosthesis	Prosthetic prescription, capability, delivery date, fabrication location, foot, knee, hip, laterality, liner material, liner size, prosthetic average hours of use, prosthetic description, prosthetic use, sock†, socket‡, structural design, suspension, suspension type, suspension type additional

* Brand, lot number, manufacturer, serial number, SKU UPC code.
† Ply, size, use.
‡ Design, composition, manufacturer.
§ Shoulder, elbow, wrist.

socket design, suspension method, and components. The third tier is patient-reported outcomes (table 3).[18-27] These PROMs were selected based on recommendations by the Registry Advisory Board (supplemental appendix S1). The fourth tier is objective functional outcomes collected from wearable devices. When a trigger code is activated, all subsequent patient encounters thereafter are collected.

LLPR data security

The Federal Government has stringent requirements for holding PHI. The LLPR is required to meet NIST 800-53[18] and Federal Risk and Authorization Management Program[19] security requirements for Moderate Impact. This impact level is defined as data where the loss of confidentiality, integrity, and availability would result in serious adverse effects on an agency's operations, assets, or individuals. To meet these security requirements for processing, storing, and exchanging sensitive data, the LLPR system and software have undergone a security assessment and accreditation by the National Institute of Child Health and Human Development. The LLPR was granted authority to operate (ATO) by the Federal Government before data could be loaded into the database. The LLPR processes, stores, and exchanges the following types of sensitive information: (1) patient information; (2) health/physical condition; and (3) diagnostic information. Precautions have been taken to ensure that PHI is encrypted and sent using industry-standard, Health Insurance Portability and Accountability Act, and Federal Risk and Authorization Management Program compliant methods. With the ATO received, the LLPR can hold federal medical data, which means that it can hold Department of Defence, Veterans Affairs, and civilian data.

Access to the LLPR is controlled and managed to ensure that only authorized devices or persons have appropriate access in accordance with business needs. Using a standard Google utility, authenticated and authorized LLPR users upload their data to their exclusive Google Cloud Platform Storage Bucket over a secure port. There are 2 following methods for transmitting data to the LLPR: (1) a Google utility command is executed locally on the user's device as an installed application, or (2) users can execute the command using Google Cloud Shell in their browser, whichever aligns with the participants' internal security policies. All Application programming interface and utility calls are encrypted HTTPS requests originating from the authenticated and authorized user's device. The LLPR leverages Google's Transport Layer Security encryption to ensure data are encrypted during transmission and at rest. All computers that are permanently or intermittently connected to the LLPR have an approved credentials-based access control system.

The LLPR architecture supports secure sharing of data (fig 2). All information required for analysis and research purposes is deidentified. Only select LLPR staff members, such as biostatisticians or data analysts, have access to identified data. All LLPR staff are trained and certified on privacy and security issues. Owing to the nature of the LLPR dataset, all users are set up with an account within the system to qualify for legitimate data usage. These accounts are centrally controlled. The accounts are secured using current security requirements including unique usernames and passwords, password complexity requirements, and multifactor authentication. LLPR users are required to agree to the data

Table 3 Patient-reported outcomes collected by the LLPR.

	Patient-Reported Outcome	
Category	Lower Extremity	Upper Extremity
Mobility and functional status	Prosthetic Limb Users Survey of Mobility[18]	Orthotics Prosthetics User Survey-Upper Extremity Functional Scale[19]
	Patient-Reported Outcomes Measurement Information System physical function[14]	Patient-Reported Outcomes Measurement Information System-13 Upper Extremity Amputation[20]
	Activity Specific Balance Confidence Scale[21]	Disabilities of the Arm, Shoulder, and Hand[22,23]
Socket comfort-limb health	Expanded Socket Comfort Score[24]	Expanded Socket Comfort Score
Quality of life	Patient-Reported Outcomes Measurement Information System-Score for the PROMIS measurement system[25]	Patient-Reported Outcomes Measurement Information System-Score for the PROMIS measurement system
Safety	Fall history	
Prosthesis use	Day per week	Day per week
	Hours per day	Hours per day
	Satisfaction — Trinity Amputation and Prosthesis Experience Lower Limb Satisfaction[26]	Satisfaction —Trinity Amputation and Prosthesis Experience Scales Upper Limb Satisfaction[27]

sharing terms and conditions of use including terms of use, privacy requirements, data retention policies, collection of information on users of the site, liability, and termination terms. Security measures protect the confidentiality of the patients by not exposing their PHI and Personally Identifiable Information to end users of the LLPR.

Quality assurance

A critical factor in the ultimate success of the LLPR is how data quality issues such as missing, out-of-range, or logically inconsistent data values, are handled. The LLPR has taken into consideration the known challenges, desired quality characteristics, and qualities that add value and combined them to assure data quality. Planning, control, and assurance are the primary methods employed to uphold the standards of the registry information. The following steps have been taken: (1) staff training is achieved by guidance on data standards and validation rules for new hires and an annual refresher course for all staff; (2) data completeness from participating sites is gained by constructive feedback when issues such as missing data or out-of-range values and logical inconsistencies are present in the data provided; (3) data consistency is assessed by observing data trends across participating sites to determine if the data are uniform; (4) audits of sample sites are performed according to written review procedures to guide data sampling from sites to assess quality; and (5) triggered audits are performed based on detected data inaccuracies or anomalies exceeding a threshold (as computed from the data distribution of other sites).

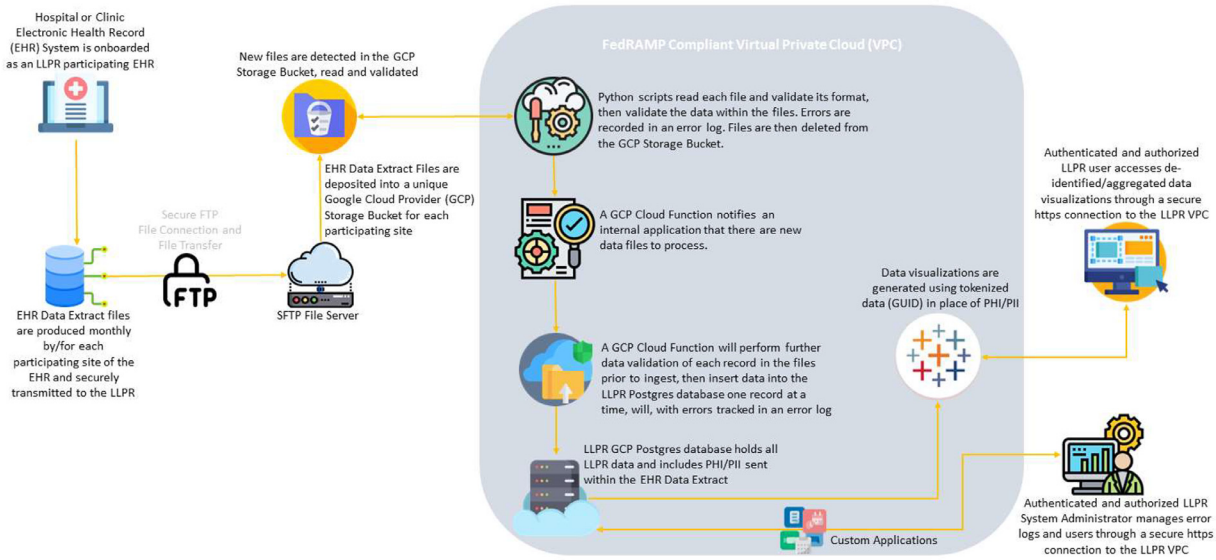

Fig 2 Limb Loss and Preservation Registry data architecture plan.

Principal measures have been adopted to achieve data transparency, integrated care/transition, and data interoperability. In addition, the ecosystem/workflow and security/privacy compliance auditing were designed to ensure that the data quality is sufficient for the intended registry purposes.

Recruitment and retention

Recruitment and retention are based on a well-designed strategy to minimize burdens and maximize rewards of participation as well as avoid biases that may risk the validity and quality of the registry. The burden of participation is minimized by only collecting data that is already in the EHR. No additional tests or data entry is required. Incentives for hospitals and providers include membership in a community of dedicated caregivers, access to useful data, ethical incentives, compliance with quality improvement requirements, and public recognition. Incentives for patients include insight into their personal level of mobility, the ability to determine their own best care pathway based on access to aggregated data from individuals just like themselves, and the awareness that they are providing data to advance care for all individuals with limb loss and limb preservation.

Institutional review board approval

The LLPR is a quality improvement registry. The system is designed for efficient collection of clinical data for quality improvement purposes. Sites (including hospitals, providers, and prosthetists) submit data in a batch format via the Registry's secure site. LLPR data are deidentified after the 3 sources of data are matched. Registry data that is deidentified may be used for research purposes after undergoing appropriate review. Formal procedures for data protection and privacy have been established. The LLPR has a participation agreement and business associate agreement with each site.

The Common Rule[20] applies to research involving human subjects, which includes the collection of identifiable patient information for research purposes. The Department of Health and Human Services Office for Human Research Protections has clearly stated that health care providers' submission of data collected during clinical care to a registry established by external researchers is not considered human subjects research and therefore is not subject to the Common Rule. Specifically, the Office of Human Research Protection provides guidance that "institutions that are providing data to the clinical data registry, but are not engaged in the research activity, do not need any institutional review board (IRB) review."[21] Participating sites that provide identifiable clinical data to the registry for quality improvement purposes enter a business associate agreement that specifies that the LLPR will collect identified data and then deidentify the data. As a covered entity, the participating site may use and disclose PHI for health care operations, which includes quality improvement activities. Data are handled in a Health Insurance Portability and Accountability Act-compliant fashion. A nonconsent approach is used for patient data in the registry. The nonconsent approach is used because the registry data falls outside of federal research regulations, ie, quality improvement activities (and thus is not subject to the Common Rule).[21] This protocol was reviewed by the IRB and determined to be exempt from the requirement for IRB approval (45 CFR 46.104d, category 4). An IRB exception was issued on December 29, 2020. Only deidentified registry data may be used for research, and further IRB approval will be required for research studies using the registry data.

Current status

The LLPR received ATO on February 26, 2022. Within the first 2 years, it has accumulated hospital data on >435,000 patients from all 50 US states and >11.5 million episodes of care. The dataset collected is a convenience sample and, as the volume of patients and participating sites continues to grow, can be analyzed to make national estimates. Although these data are not yet nationally representative of the population of interest, they soon will be based on the current rate of growth. Current data in the LLPR contain patients with limb preservation procedures (70%) and patients with limb loss (30%). The patients with limb loss comprise patients with lower limb loss (80%), upper limb loss (17%), both upper and lower limb loss (<2%), and unknown limb loss (<2%). The patients are from all decades of life (fig 3) with the greatest number of patients (27.3%) in the 7th decade of life. There are slightly more men (55%) than women (45%). Most of the patients (63%) have at least one comorbidity, with 23% having 5-10 comorbidities, and 8% having >10 comorbidities. The most common comorbidities are cardiac arrhythmias (32%), uncomplicated hypertension (28%), peripheral vascular disorders (26%), complicated hypertension (22%), and renal failure (20%). The registry is accumulating >600,000 episodes of care per quarter. When reported, the most common social determinant of health is "Problems related to housing and economic circumstances" with 54% of the patients listing this as a problem in their lives.

Discussion

The LLPR is a repository of health information that can improve the standard of care and inform research for patients with limb loss. In today's health care environment, it is becoming more important to measure and report the quality of health care among various institutions. The quality of health care delivery can be measured by structural data (characteristics of physicians and hospitals), process data (components of the encounter between patients and clinicians), or the outcome of the care delivered to the patient (patient's health status).[22] Measuring outcomes in patients with limb loss is particularly suitable for quality assessment because the care of the patient involves an intervention (eg, surgery, rehabilitation, and/or a device) with an expected outcome—the patient is expected to have improved function. The LLPR is designed to provide this quality assessment. It can be used to start answering questions regarding appropriate coverage of prosthetic and/or assistive technologies provided to patients who experience amputation or live with limb differences.[23]

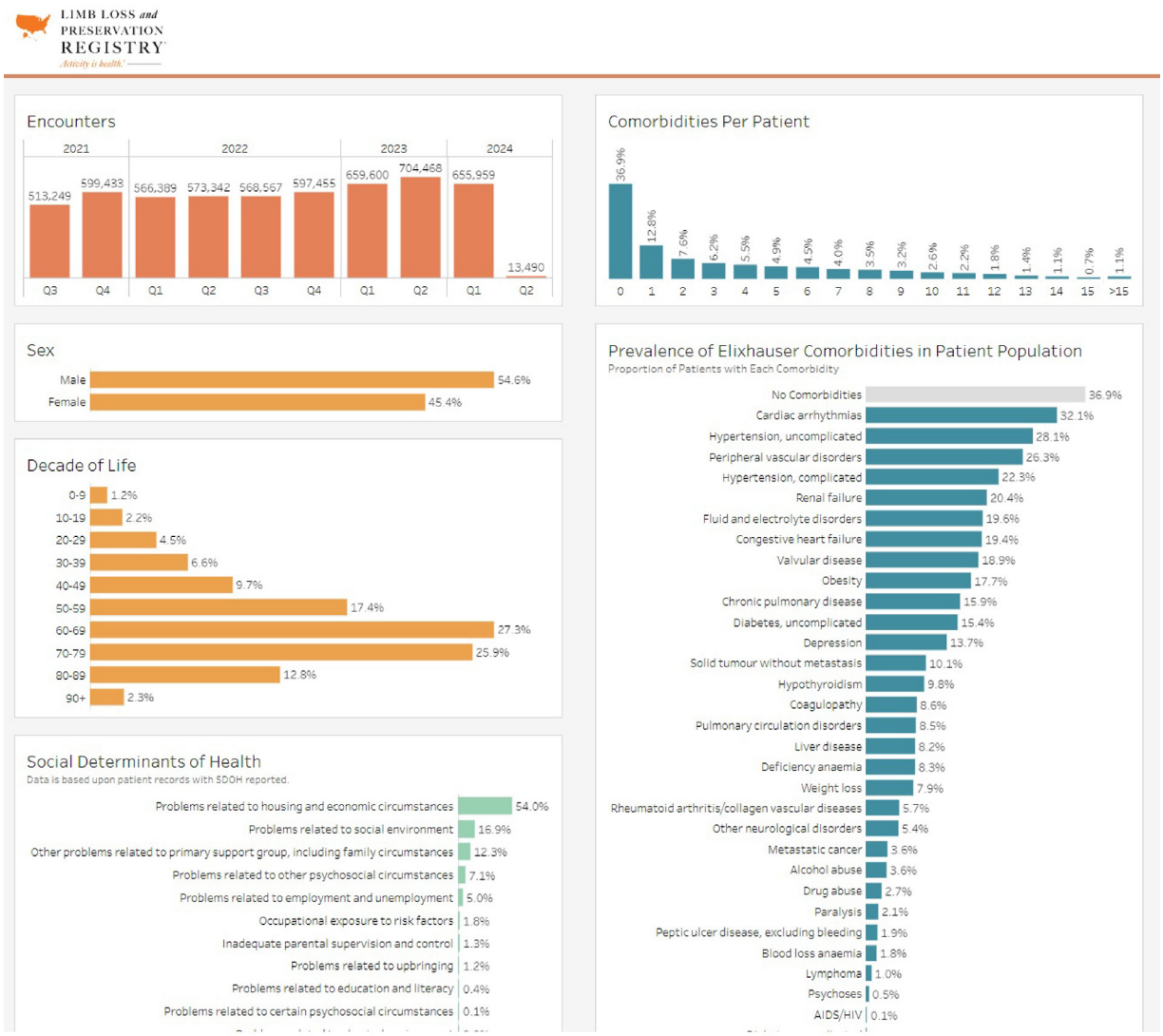

Fig 3 Characteristics of patients in the Limb Loss and Preservation Registry accumulated over the first 2 years. The registry contains >435,000 patients and >11.5 million episodes of care.

The comorbidities collected by the LLPR are those previously identified to influence healing and functional outcomes after an amputation.[24,25] The comorbidity prevalence reported by the LLPR agrees with a previous report.[26] The influence of patients' comorbidities on function after amputation requires additional investigation. Although some authors have documented that comorbidities explain a portion of function after amputation,[27,28] others have demonstrated that there is no association with physical activity.[29] The importance of linking patient comorbidities to patients' function is critical. A recent study has shown that a patient's overall comorbid health is not a factor that affects the patient's mobility with a lower limb prosthesis.[30] Yet, comorbid disease is a factor in referral for a prosthetic fitting.[31-33]

Although many studies have established the relation between comorbidities and clinical risk factors for amputations, much less is known about the effect of health disparities on outcomes in patients with limb preservation. Treatment disparities exist owing to the lack of a standardized approach for treating diseases such as peripheral artery disease.[34] Unconscious bias or barriers to health care access for certain populations are to blame.[35] Social determinants of health provide a framework to understand the social, economic, psychological, and environmental effects on limb loss/preservation. There is emerging evidence that barriers to accessing the health care system may be contributing to disparities in major amputation rates.[36,37] The LLPR collects data on social determinants of health, which might affect outcomes of patients with lower extremity arterial reconstruction.

The most rigorous type of outcome evaluation and the highest level of evidence is provided by a randomized controlled clinical trial. In a randomized controlled trial a causal relation between a treatment and an outcome is studied. There are clear enrollment criteria and active treatment is provided in a controlled manner. Although traditional clinical trials test the efficacy of an intervention in carefully selected patients with a carefully controlled protocol, a registry collects national population-based

observations on how well a device or intervention performs in a general population of patients under the chaos of clinical practice. Registries provide more generalizable data to describe patterns of care, access to care, quality of care, and treatment effectiveness.[38] Moreover, information collected in clinical registries, such as medical history, demographics, disease diagnosis, and outcomes data, often overlap with data gathered for clinical trials. Thus, integrating clinical trials within registries may offer opportunities to (1) avoid duplicative data collection, (2) Identify and recruit patients more efficiently (3) reduce time to database lock, and (4) accelerate time to critical decision-making, while (5) potentially reducing clinical trial costs.[39]

As part of the Affordable Care Act (HR 3590), health care providers were mandated to convert their medical charts to electronic medical records (EMRs). Providers must now demonstrate meaningful use of EMRs.[40] Because EMRs have gained increasing use in hospital systems, they have provided a means to collect vast amounts of information. The goal of this legislation is to not just employ EMRs, but also demonstrate improvements in health outcomes. Reform is needed to transform our current inefficient and expensive health care system into a more evidence-based system of effective patient-centered care.[41] The Patient-Centered Outcomes Research Institute was formed to generate high-quality evidence to help patients and physicians make informed evidence-based health care decisions for ethnically and geographically diverse populations. The new health care era is calling for not only more population-based research but also more registries to demonstrate their importance.[42] To support this growing demand, the Registry of Patient Registries has now launched to provide a searchable central listing of patient registries. Registry of Patient Registries' primary objective is to promote collaboration, reduce redundancy, and improve transparency in the use of registries.[43]

Improving health care outcomes requires changes in hospital systems and provider care pathways. Although evidence has confirmed that improvements in health care quality reduce cost,[44] the ability to achieve these changes has proved to be challenging. Most work in hospital systems has focused on reporting and preventing medical mishaps. Voluntary systems of reporting are incomplete and lead to underreporting of complications.[45] Quality assurance or professional review organizations are similarly limited in their ability to identify flawed institutional systems.[46] Engagement of all stakeholders involved in the care of patients with limb loss and limb preservation and mediation of their conflicting goals is necessary to transform the barriers into incentives in favor of participating in the LLPR.

In forming the LLPR, several factors were identified that have contributed to a successful startup. First, a diverse group of stakeholders which represented various aspects of limb loss/preservation care were assembled to guide the formation of the registry (see supplemental appendix S1). Second, the registry is designed to gather data elements with minimum burden to the participants. Minimal changes in workflow are needed to participate in the registry. The data being collected in routine clinical care are gathered from the EHR and transferred to this LLPR. This maximizes voluntary participation and minimizes demands on frontline staff. Third, most of the data are required for billing/administrative purposes and thus are already being routinely entered into the EHR. This assures data quality. Fourth, dashboards are provided so that each participating site can benchmark the quality of their data submitted to regional and national standards. Finally, the registry participation provides valuable insights that contribute to improving patient care and future success.

Conclusions

The LLPR has been developed to collect, standardize, and report patient outcomes, support evidence-based decision-making, enhance health care delivery, and establish and disseminate best practices. The LLPR is an organized system that will make critical data available to hospitals, clinics and individual providers, manufacturers, payers, scientists, clinical researchers, and policymakers. The LLPR has major practice, payor, and policy implications. Currently, the LLPR contains >435,000 patients from throughout the US.

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Disclosures

None.

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