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How Registry Data Will Change Our Approach to Lymphedema Research and Clinical Management

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Abstract

In 2018 the American Physical Therapy Association officially launched the *Physical Therapy Outcomes Registry* (PTOR). The purpose of the registry is to accumulate clinical data from therapists around the country in order to analyze aggregate information on patient populations. Such an approach can help our profession better understand how to optimize treatment outcomes and can enhance data-driven clinical decision making. Additionally, a recent collaborative effort between Stanford University and the Lymphatic Education & Research Network (LE&RN) has created *The International Lymphatic Disease and Lymphedema Patient Registry and Biorepository*, a patient registry that aims to collect information about individuals who are diagnosed with a lymphatic disease or lymphedema. While these efforts are both Registries of condition-specific data, they are different in how they collect data and produce information. Researchers and clinical providers should have an understanding of what registry data currently exists and what the opportunities are to support clinical lymphedema management and lymphedema-focused research efforts by leveraging registry data.

APTA PTOR*

The PTOR is designed to capture a core set of data about a patient and their episode of care in physical therapy. In addition to the core set of data, the registry is seeking to develop additional clinical modules that identify a specific set of data elements for a defined population. These modules will collect data for a specific group of patients. For example, APTA's Orthopedic Section has developed a module specific to neck pain and collects data elements that focus on classification, diagnosis, and treatment. The registry procures data from clinical providers in outpatient-based practices through their existing Electronic Health Records (EHR). Ideally, this is information you are already capturing and documenting during your clinical encounters. If your clinic or system participates in PTOR data collection, the registry connects directly to your EHR and securely collects and transfers only the data elements identified as required in the module.

By leveraging the registry, a module can potentially collect a large amount of data about the patient population and the analysis of this data can help to describe optimal patterns of practice and outcomes. Overtime, with a substantial amount of data on a clinical population, registry data could be analyzed to better understand the effectiveness, or lack thereof, of specific interventions for a population.

*<http://www.ptoutcomes.com/Home.aspx>

The community of lymphedema researchers should consider working with the PTOR team to identify what data elements could help to answer important research questions for this population. A module dedicated to lymphedema could be a collaborative effort between the Oncology Section and other Sections with an interest in this condition, specifically Women's Health and Clinical Electrophysiology and Wound Care. The effort would need to identify common data elements that would be valuable to collect in order to understand the classification and treatment of the condition. The PTOR currently uses outcomes instruments that are familiar to physical therapist practice and are recommended by the EDGE Taskforce for lymphedema including the Disability of Arm, Shoulder, and Hand (DASH), Neck Disability Index (NDI), and Activity Measure- Post Acute Care (AM-PAC), as well as the National Institutes of Health (NIH) Patient-Reported Outcomes Measurement Information System (PROMIS), Focus on Therapeutic Outcomes (FOTO), Care Connections and others.

Some possible research questions that a well-orchestrated registry data collection effort could help to answer include: for a given severity of lymphedema what clinical interventions contribute to the greatest patient-reported functional outcomes?, based on the severity of lymphedema, what is an optimal number of visits to achieve the best functional outcomes, and what level of variance exists across providers regarding visits within an episode of care? The registry can help to provide insight on optimal clinical interventions, quality improvement, health service delivery, and improve clinical decision making.

The International Lymphatic Disease and Lymphedema Patient Registry and Biorepository[†]

This registry aims to include a representative population of patients with lymphedema who self-report on their clinical condition as well as provide blood and tissue samples to the repository. The data collection in this registry is completely driven by patients who volunteer to participate and provide information from their own medical records. The registry is operated and secured by Stanford University and participants consent to participate, just as they would in a research study, and sign medical record release forms. The data elements that are captured are based on the patient's response to survey forms that they fill out on-line at the time they sign up to participate and at six-month intervals, as well as information procured from the individual's medical record. This project is a registered clinical trial (NCT01336790).

Researchers will be able to leverage the data from this registry to answer important questions about the natural history of lymphatic diseases and how they relate to the onset of lymphedema and to quantify biological factors associated with the condition. This data set is unique in that it is structured at the individual level and matches the person with their unique biological, clinical, and self-reported data. The opportunities here are extremely interesting to understand genetic and biomarker profiles of individuals with lymphedema and to be able to match those data with their subjective self-reported condition. Important research

[†]<https://lernregistry.stanford.edu/>

questions could include understanding how the biomarker profile of an individual changes over time if they experience condition management, in aggregate how does this population present with specific genetic or biomarker profiles, and what other biological markers can help us classify severity of the condition and predict progression of the condition?

Registry-based Research

Registry data is different than clinical trial data. A clinical trial seeks to structure data collection around a specific research question, often studying the direct effect of an intervention on an outcome. Registries focus on a specific disease or condition and take a population-based approach to understanding the multiple factors associated with condition development, detection, classification of severity, treatment interventions, response to treatment, and outcomes. Registries often have similar ethical and legal considerations to clinical trial data including consent, IRB approvals, protection of private health information, and disclosures of conflict.

Researchers can often obtain access to registry data by establishing agreements with the organization or entity responsible for the registry data. Data Usage Agreements (DUA) outline the parameters for use of the data for research purposes including; who may use the information, data sharing restrictions, assurance of safeguards for the data, and other restrictions regarding access and use of the data.

Access to registry datasets typically requires the researcher to pay a fee to obtain the data. There are hundreds of highly reputable medical registries in the United States, and the majority of them require fees ranging from several hundred dollars to tens of thousands of dollars, often depending on the volume of data you seek to obtain. As registry-based research is advancing in popularity, funding mechanisms are becoming more available through NIH and other federal and non-federal sources to help researchers explore population-based registry data to answer important research questions. Recently, the National Cancer Institute issued a Funding Opportunity Announcement (FOA) to leverage registry data to study health disparities, and the NIH has recently provided guidance to researcher's *frequently asked questions* regarding registry research. [‡]

Cloud-based analytics are a significant driver in the advancement of registry data analysis trends. Registry data collection enables a large number of variables to be collected on entire populations yielding huge volumes of data. In the past, data sets of this size were too large to be handled by traditional server-based data storage systems and traditional statistical analysis methods could not fully provide insight on a large data set. This evolution towards the collection, analysis, and interpretation of Big Data has accelerated the movement towards the development of registries. Big Data analytics also enable us to look at data differently and find associations and relationships that traditional statistical methods could not identify.¹ It also enables us to frame our research questions differently and to learn from populations of real patients, rather than from only those who have qualified for and enrolled into a clinical trial. However, there are shortcomings and limitations to registry data.

[‡]<https://www.nih.gov/health-information/nih-clinical-research-trials-you/list-registries>

Consideration should be given to the data quality, potential sources of bias in procuring and analyzing large data sets, and missing data.² Understanding the lineage of how the data was obtained and processed is critical to ensuring the integrity of research assumptions and findings.

The emergence of registry data specific to physical therapist practice and lymphedema management offers unprecedented opportunities for researchers and clinicians. Both researchers and clinicians will have to think differently in the future about how to ask research questions and how to interpret research findings based on registry data. The specific details of constructing a research proposal using registry data is beyond the scope of this article, however excellent resources and references exist to support researchers moving towards using clinically captured data for research purposes. The new RECORD statement (**RE**porting of studies **C**onducted using **O**bservational **R**outinely-collected health **D**ata) offers a reporting checklist to guide researchers in sound methodology in constructing research using these data.³

Clinicians will need to think differently about prescribing interventions and will need to consider more than just the clinical diagnosis of lymphedema. Understanding risk clusters based on comorbidities and biomarker profiles will become an inherent part of developing a treatment plan. Outcomes from large scale registry data will be just as valuable to help us identify which patients will not have a good clinical response based on factors beyond the therapists control. Biologically, some patients may be inherently poor responders to lymphedema therapy. Registry data outcomes may help us better identify this group of individuals in the future and triage them for more appropriate interventions such as surgery.

The first and most important step that our research community can take is to engage with APTA PTOR around the potential interest in developing data modules that can support our understanding of lymphedema as a condition and how it responds to standardized therapy interventions. Lymphedema is one area of physical therapist practice where there are defined interventions and parameters for condition management. Leveraging a registry approach to understanding treatment outcomes will become the next wave of innovative research in our field.

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