Outcomes Research in Psoriasis and Psoriatic Arthritis Using Large Databases and Research Networks: A Report from the GRAPPA 2013 Annual Meeting

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ABSTRACT. Advances in healthcare informatics have increased the ability to address real-world, clinically relevant questions using large databases. When examining data sources, researchers and clinicians need to consider data validity, potential sources of misclassification, whether the source is sufficiently powered to detect clinically relevant differences, ability to obtain longitudinal data, containment of patients within a database, and ability to obtain structured point-of-care data. Population-based databases create opportunities for characterizing natural history of psoriatic diseases, conducting comparative effectiveness research, determining comorbidities, and providing epidemiology-based rational approaches to mechanistic investigations. Herein, we discuss the major data sources for clinical research in psoriasis, including electronic medical records, research networks, disease registries, and others. (J Rheumatol 2014;41:1233–6; doi:10.3899/jrheum.140178)

Key Indexing Terms:
PSORIASIS PSORIATIC ARTHRITIS OUTCOMES RESEARCH
REGISTRY ELECTRONIC MEDICAL RECORDS LARGE DATABASE RESEARCH

At the 2013 Annual Meeting of the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) in Toronto, Ontario, Canada, members explored opportunities for outcomes research using large databases and research networks. To address real-world, clinically relevant questions in psoriasis and psoriatic arthritis (PsA), we examined the advances in healthcare informatics and the features of data sources (e.g., strengths, limitations, and appropriateness for a given research question) that enable us to conduct such investigations.

How to Evaluate Large Databases for Research in Psoriasis and Psoriatic Arthritis

When examining data sources, researchers and clinicians must consider 6 major factors:

(1) Are the data valid? Do they accurately represent the information sought by the investigators? What are potential sources of misclassification? Is misclassification differential?

(2) Are the data sufficiently powered to detect a clinically relevant effect? Sample sizes must be sufficiently large to detect small, but clinically relevant, differences. Data collected from diverse practice settings may increase the generalizability of the findings.

(3) Can patients be followed longitudinally? The ability to ascertain time-series data on a population is critical for understanding disease progression and following response to treatment over time.

(4) Are patients contained within the same healthcare system? When patients move in and out of health systems that do not have shared or linked health records, clinically relevant events occurring outside the examined health system could be missed.

(5) Does the database incorporate various perspectives, e.g., conventional health-provider, patient-reported outcomes, and robust linkage to pharmacy, laboratory, and pathology data?

(6) Does the database have efficient, point-of-care data entry? Can novel or confounding outcome measures (e.g., smoking, obesity) be easily incorporated into the data collection process? A key factor is the ability to engage users to enter structured, clinically relevant information efficiently.

Examples of Data Sources and Their Application in Psoriasis and Psoriatic Arthritis Research

Population-based databases create opportunities for various types of investigative endeavors, including characterizing

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natural history of psoriatic diseases, conducting comparative effectiveness research, determining comorbidities, and providing epidemiology-based rational approaches to mechanistic investigations[1]. However, depending on the purpose and scope of the database, they are variably suited to answer specific research questions. Described below are major types of data sources available for clinical research and their associated advantages and disadvantages.

Electronic medical records (EMR). EMR have been widely adopted in the past few years and present a remarkable opportunity for clinicians to enter visit information at point of care; laboratory and imaging data are also readily available. However, challenges exist for extracting EMR data for population research: medical records housed on different electronic health record platforms create difficulties for combining data; and despite technological advances such as natural language processing, extracting valid responses from nonstructured data elements is problematic[2]. Despite these challenges, however, real-world data obtained at point of care presents appealing opportunities for generating "large" data to power hypothesis-driven, patient-oriented research.

In the simplest form, a single practitioner through his or her practice generates clinical care data based on individual patient encounters. Alternatively, a single institution can combine patient data from multiple practitioners to create larger datasets that reflect more diverse patient populations and a wider range of clinician practice patterns. In multi-institutional or multicentered datasets, data are combined from several groups that usually share a common EMR platform.

For example, in the United States, several EMR systems exist. To date, EMA is the largest dermatology-specific EMR system in the United States[3], whereas Epic[4] and Cerner[5] are non-specialty-specific EMR systems used widely in academic institutions and healthcare maintenance organizations. The Veteran's Affairs[6] Healthcare System uses a centralized EMR for all its US sites, which makes extraction of EMR data possible for research across large populations. There are different approaches to validating diagnostic codes for psoriasis and PsA, including in-person examination by dermatologists or rheumatologists, chart reviews, and retrospective surveys of practitioner and patients. Validation of diagnostic codes for psoriasis and PsA was performed in the Kaiser Permanente EMR as well as databases from the UK, including the General Practice Research Database and The Health Improvement Network (THIN[7,8,9,10]). THIN, for example, allows investigators to obtain additional information such as body surface area affected by psoriasis by surveying the patient's general practitioner[11,12]. Thus, validation of outcomes, examination of data availability, extraction of structured data, and handling of unstructured data are important considerations when using data extracted from EMR.

Research networks and disease registries. While research networks and disease registries differ in scope, mission, and patient population, many were created to evaluate effectiveness and monitor safety of systemic medications among patients with moderate-to-severe psoriasis and/or PsA. Research networks and disease registries often collect granular and relevant data, but their setup and sustainability costs continue to be challenging.

Psonet[13] is a European system of independent registries that monitors longterm efficacy of systemic medications for treatment of psoriasis[14]. Currently participating countries include the UK, Portugal, Spain, France, The Netherlands, Germany, Switzerland, Italy, Denmark, Sweden, Israel, and Australia. Psonet researchers collect data on effectiveness and adverse events related to biologics or other systemic medications in patients with psoriasis and/or PsA. Similarly, the German Psoriasis Registry collects data from patients with psoriasis and PsA to determine the longterm safety, tolerability, and efficacy of biologics and other systemic medications that are used in Germany[15]. The Australasian Psoriasis Registry (APR) established an analogous database of patients with psoriasis in Australia, New Zealand, and New Guinea[16]. The Dermatology Clinical Effectiveness Research Network in the United States is a system of multiple dermatology practices that conducts clinical research studies of comparative effectiveness to help inform treatment decisions, and currently maintains a database of over 1700 patients with moderate to severe psoriasis evaluated during routine clinical followup care[17,18,19,20,21,22].

Members of the International Psoriasis and Arthritis Research Team (IPART), which includes several groups in Canada and the United States, have developed a large database of well-phenotyped patients with PsA and/or psoriasis based on an observational cohort at the University of Toronto. The international collaboration aims to use the IPART database to perform genome-wide association studies, in addition to studying disease progression, severity, and comorbidities[23].

Government-mandated postmarketing registries can provide valuable data regarding longterm medication safety[21,24], and many registries also collect additional information to help inform comorbidities research. For example, the Psoriasis Longitudinal Assessment and Registry is a 10-year study evaluating the longterm safety of the biologic therapies ustekinumab and infliximab[24] in 12,000 US patients with moderate to severe plaque psoriasis. Researchers are also collecting other important outcomes data, e.g., patient quality of life, clinical outcomes, and comorbidities.

While a number of other registries and research networks exist that are not specific to psoriasis or PsA, they often include those populations in their mission of evaluating patients receiving biologic treatments or those with rheumatologic diseases. The British Association of Dermatologists

Biologic Interventions Registry (BADBIR) houses observational data from a large cohort of patients with psoriasis, rheumatologic conditions, and/or inflammatory bowel diseases being treated with biologics or other systemic medications to determine the longterm safety of biologics in the UK and Ireland[25]. Another example is the Consortium of Rheumatology Researchers of North America (CORRONA), a registry that houses data from patients with rheumatologic conditions (primarily rheumatoid arthritis, but also PsA) from the United States[26].

Other data sources: National healthcare data and surveys, administrative databases, and crowdsourced data. Various regions of the world have different standards for collecting population-based healthcare data. For example, whereas nationalized and centralized databases for healthcare records exist in countries such as Israel[27], Denmark[28], and Taiwan[29], many countries lack such databases. In the United States, the Centers for Medicare and Medicaid Services house centralized data for individuals ≥ 65 years as well as those enrolled in the Medicaid program (the federal healthcare program for those who cannot afford health insurance)[30]. Other federally funded databases such as the National Ambulatory Medical Care Survey/National Hospital Ambulatory Medical Care Survey[31] and National Health and Nutrition Examination Survey[32,33,34,35] obtain nationally representative data, but their utility is limited by the number and type of questions specific to psoriasis and PsA. In the UK, practitioners have an incentive to put data into the Clinical Practice Research Datalink to yield more granular data for outcomes assessment and other research purposes[36].

Administrative and claims databases such as Truven Health Analytics MarketScan are helpful in providing aggregate data on diagnosis and medication use[37]. However, those data are derived for the purposes of billing and may be more prone to misclassification that could threaten data validity.

Finally, crowdsourcing-generated data also provide valuable information[38,39,40,41,42]. In healthcare research, crowdsourcing is the act of outsourcing data collection to patients. Potential advantages include recruitment of larger patient populations, lower cost for data collection, obtaining patient-centered perspectives, and the ability of patients to contribute through the Internet, providing ongoing opportunities for patients from diverse backgrounds to contribute to the collective patient experience.

The opportunities for conducting outcomes research using the various large databases and research networks are becoming more abundant. Aligning the research question with the appropriate database and analytical approach, however, is key to addressing clinically relevant questions appropriately. Although access to the various databases may be limited by cost and procedural challenges, the future for outcomes research in psoriasis and PsA is promising. With continued improvements in healthcare informatics, creation of more psoriasis and psoriatic disease-specific research networks, and advancements in analytical approaches, we will be able to increasingly use real-world observational data to perform quality research that informs clinical decisions and improves patient outcomes.

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