The National Data Bank for Rheumatic Diseases

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ABSTRACT

The National Data Bank for Rheumatic Diseases (NDB) is a longitudinal observational patient-driven database, founded as a non-profit research organisation in 1998 by Dr Frederick Wolfe. Patients are sent a primary questionnaire twice a year. More than 50,000 patients with more than 100 various rheumatic diseases under the care of more than 1,500 rheumatologists have completed at least one 6-month questionnaire. Many important publications concerning rheumatoid arthritis, osteoarthritis, systemic lupus erythematosus, fibromyalgia, and pharmaco-epidemiology have resulted from NDB research.

The National Data Bank for Rheumatic Diseases (NDB) is a longitudinal observational patient-driven database, in which patients with rheumatic diseases answer comprehensive self-report questionnaires to monitor responses to therapies and long-term outcomes. These patient data have been analysed by researchers around the world to better understand the real-world burden of people who live with rheumatic diseases.

The NDB was founded as a non-profit research organisation in 1998 by Dr Frederick Wolfe, MACR, initially from patients cared for in his rheumatology private practice in Wichita, Kansas USA, with the addition of more than 10,000 interested patients recruited from rheumatologists in the US and Canada. Since 1998, more than 100,000 patients have consented to participate, more than 50,000 of whom have completed at least one 6-month questionnaire. Continual enrolment and attrition has occurred since 1998; more than 10,000 active patients have participated every year.

Participating patients are under the care of more than 1,500 rheumatologists from every region of every US state and Canadian province. Primary recruitment comes from generous rheumatologists and rheumatology health professionals, who promote the NDB in their clinics to their patients, ideally through a 1-page "clinic quest" that is given to all patients over about a month, or less ideally through brochures in the clinic waiting room. The only information provided by participating clinics are confirmation of primary diagnoses of included patients. No reimbursement is provided for involvement of the clinic, and workflow impact is kept to a minimum. Patients who enrol online (http://ndb.org) also have their diagnosis validated by their physician.

More than 100 various rheumatic diseases are included in the NDB, although the published research has focused primarily on those most represented: rheumatoid arthritis (RA), osteoarthritis (OA), lupus (SLE), and fibromyalgia (FM). Patients are sent a primary questionnaire twice a year (January and July); as researchers analyse NDB data, the questionnaires have become more tailored to specific conditions over time. For July 2016, approximately 40 different NDB 6-month questionnaires were developed, with varying length, disease-focus (RA/default, OA, SLE, gout, etc.), media (paper, online, telephone interview), and language (English and Spanish).

A multitude of research studies using NDB data are conducted at any one time. The reason for "Data Bank" in the project title is to emphasise the multiple uses and wider scope than a single registry study with a specific disease or treatment outcome of interest (1). First, the NDB collects a wide range of information from patient participants – medical history, medical events, all treatments and side effects, health-related quality of life, symptoms, standardised clinical questionnaires, employment productivity and medical utilisation. While collected prospectively, the collection of these data allows for continual testing of

new hypotheses. Also, several items or questionnaires are completed for specific sub-group studies, such as a parity and pregnancies questionnaire given to women with RA and SLE in 2009 (2) or a subset who completed items for a PROMIS pain study (3). Physician data also are collected by participating clinics and clinical registries that overlap with NDB participation (4, 5). Some NDB participants contribute biosamples that are also available for analysis (6) and some have contributed to smartphone studies (7).

Additionally, the NDB patient research infrastructure is being used to: collect data on first degree relatives of RA patients as possible recruitment into the STOP RA NIH trial, collect longitudinal data for the International Dupuytren's Data Bank (IDDB), and enrol those infected with Chikungunya, Zika, and other infectious agents noted to induce changes in function and health-related quality of life. All projects are initiated by interested researchers, physicians, and organisations; the many projects are a testament to the multifaceted aspect of NDB activities.

Funding for the NDB is derived from individual donations, public and private research grants, and from pharmaceutical companies for conducting large post-marketing drug safety registries. To validate medical events, the NDB collects medical records for important medical events in addition to confirmatory patient/family interviews. Death records are collected for all participants through linkage with the National Death Index. Recent links with Medicare provide additional event validation. These efforts also resulted in several important pharmaco-epidemiological publications (8-15).

This brief summary of the NDB covers a small part of what has been accomplished over the past 18 years. Additional activities have included efforts to provide education in research methods for rheumatology fellows and clinicians and development of optimised (shorter) questionnaires, as described in greater detail in a prior review (1). The NDB plans to connect to with the American College of Rheumatology RISE registry to provide collected patient measures to the patient rheumatology clinics as additional value to their participation. Its future depends upon what new questions arise for research using NDB data and the continued willingness of rheumatology professionals to help recruit and patients to continue to volunteer their time in helping their voices be heard through this research-promoting non-profit project.

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