A short history of data banking in the United States from 1974 to 2003.

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ABSTRACT. There have been 4 major longitudinal data banking efforts within the United States: ARAMIS, the Western Consortium, and the individual data banks of Drs. Ted Pincus and Fred Wolfe. ARAMIS began in the 1970s, and helped to develop the language and methodology of rheumatology data banks using biannual surveys. The National Data Bank for Rheumatic Diseases used the ARAMIS model beginning in the late 1990s to form a very large contemporary rheumatology data bank. Hybrid models using both survey data and clinical data were put into practice by Pincus and Wolfe, and by Paulus at the Western Consortium. (J Rheumatol 2004;31 Suppl 69:41–45)

Key Indexing Terms:
DATA BANKS RHEUMATOLOGY ARAMIS
NATIONAL DATA BANK FOR RHEUMATIC DISEASES

The formal start of data banking in the United States began with the proposal by James Fries for a common language of rheumatology that might be used in data banking[1]. This was followed closely by the founding by Fries of the ARAMIS (American Rheumatism Association Medical Information System — later the Arthritis, Rheumatism and Aging Medical Information System)[2-4]. Although Fries put together the first computer-based rheumatology data bank, the first true data collectors were Donald Mitchell, MD, of Saskatchewan and Joseph Levinson, MD, of Cincinnati. Mitchell was an adult rheumatologist who in the 1960s began collecting on paper exquisitely detailed data on all of his patients and clinical encounters[5-7]. Levinson, a pediatric rheumatologist, collected similar paper data on his patients[8].

Fred Wolfe, a rheumatologist in Wichita, Kansas, was the first rheumatologist (1974) to collect computerized data on patients seen in a clinical practice. In Pittsburgh, Dr. Tom Medsger brought his previously defined scleroderma data bank into the ARAMIS envelope in the decade of the 1970s with publications generally beginning in the 1980s[9-11].

ARAMIS

It was Fries and his colleagues at Stanford University, however, who built the ARAMIS computerized data bank, making it accessible to multiple users throughout the US by the use of telephone networks. In addition, they incorporated into ARAMIS programs for data analysis. ARAMIS also attempted to implement a standardized language that could be used by all rheumatologists[1,4]. However, this attempt at a *lingua Franca* was not successful as there were many different methods for assessments, and the newly proposed methods were not universally agreed on or backward compatible. Major changes in the direction of compatibility came about later with the incorporation of self-report measures and standardized examination measures into the American College of Rheumatology core criteria for clinical trials[12,13].

Supported by US National Institutes of Health (NIH) grants for more than 25 years, ARAMIS was the first research rheumatology data bank. Around 1980, funding from an outside source, the manufacturer of auranofin, provided enough supplemental funds to bring together online, as part of ARAMIS, the data banks of Mitchell, Levinson, Wolfe, and Sanford Roth of Phoenix. These were known as the Saskatchewan, Cincinnati, Wichita, Phoenix, and Pittsburgh data banks. Together with the data bank from the Stanford clinics (Stanford) and a community data bank formed by the Stanford group (Santa Clara), these sources formed more than 90% of the activity and data encompassed in the ARAMIS system over most of its life[14,15]. There was a small contribution from Cincinnati adult rheumatology, and in the mid 1980s Phoenix stopped its primary data collection. ARAMIS might be thought of, then, as an adult, primarily rheumatoid arthritis (RA) data group composed of Stanford, Santa Clara, Saskatchewan, and Wichita through the late 1990s. Wichita left ARAMIS at that time, while another RA group from Pittsburgh joined to contribute data.

Although the ARAMIS system worked well in RA, none of the other centers could supply enough patients with scleroderma, juvenile RA (JRA), or systemic lupus erythematosus — except Pittsburgh (scleroderma) and Cincinnati (JRA) — to make a substantive consortium; gradually these specialty data banks faded away within the ARAMIS system. The major accomplishment of ARAMIS in these areas was to provide motivation and expertise that allowed the specialty centers to develop their own data banks. Although a number of "ARAMIS publications" followed

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from the specialist data banks, these were specialty reports rather than ARAMIS consortium reports.

In contrast to work by the early contributors to ARAMIS whose data sets contained physical examination, laboratory, and radiographic data, the ARAMIS assessment model utilized only questionnaire data that was obtained at 6-month intervals. Hence one of the limitations of ARAMIS (and all data banks that followed on this model) was the lack of clinical data. It became impossible to measure or document the kind of changes that occur in the clinic, or to link results to physical examination or laboratory data. By contrast the biannual questionnaire was superbly positioned to measure costs and longterm outcomes.

CLINICAL DATA MODELS

In the 1980s Ted Pincus started data collection using primarily the clinical model[16-30]. He and Fred Wolfe stayed with the clinical data model[31-52], although Wolfe also participated in the biannual data collection of ARAMIS[53-61]. The ARAMIS model was enormously successful, producing a series of important papers in rheumatology. The clinical model was pursued by Pincus and Wolfe, who also published many influential reports[16-52].

In 1992, Dr. Hal Paulus at UCLA incorporated the ARAMIS survey methods and the clinical practice method. The Consortium of Practicing Rheumatologists (The Western Consortium) was formed in 1992 as part of an NIH-sponsored Multipurpose Arthritis and Musculoskeletal Diseases Center grant to study early severe RA. The description that follows was provided by Paulus and modified by the author as necessary.

At the inception of the Western Consortium 51 community physician-investigators were recruited, while an additional 20 have joined subsequently. Forty-four have enrolled at least one patient, while 40 physicians in 25 geographical locations in the Western United States have actively followed patients through June 2002.

Physicians in the study regularly see and treat patients at the onset of their RA. Information is collected about these patients as they are treated by their physicians, from the beginning of their RA for 2 to 5 or more years (up to 15 or 20 years, if possible), to see whether joint damage is related to the presence of certain characteristics within one year of the start of the RA, and whether treatment can prevent joint damage. This evaluation is based on radiographs of hands, wrists and feet, physical examination of the joints, recording of RA symptoms, and functional status and erythrocyte sedimentation rate (ESR) at the beginning of the study, after 6 and 12 months, and yearly thereafter. All of these are a part of ordinary RA care and are done by the patient's personal rheumatologist and paid for by the patient or the insurer. The Western Consortium merely collects the information and compares it among patients. In addition, they collect extra blood for genetic testing to see if the inherited rheumatoid epitope can be used to predict joint damage, and for storing in freezer banks for future evaluation of new tests. The rheumatologists can treat their RA patients however they choose. The physician and the patient decide which treatment to use and when to change treatments, depending on their individual assessments of the benefits and risks.

By mid 2002, 326 patients had been enrolled. The first patient entered January 28, 1993, and the most recent on April 1, 2002. A total of 70 patients have withdrawn at their own request or because their consortium doctor moved or stopped participating in the study. Patients who enter the study receive individualized "best care" by their personal rheumatologists, which includes evaluating at entry, 6 months, 12 months, and yearly thereafter (and whenever the initial treatment regimen is stopped): radiographs of hands, wrists, and feet; physical examination to evaluate joint tenderness and swelling, and hand grip strength (measured by squeezing a partially inflated sphygmomanometer bag); history of morning stiffness, hours to onset of fatigue, subjective pain intensity, and functional status by health assessment questionnaires; and Westergren ESR. In addition to these items involved in rheumatologic care of RA, the Consortium asks for 30 cc of heparinized blood at baseline to be used to test for the genetic "susceptibility epitope" and to be used to establish a freezer bank. Information is collected by direct patient questionnaire and followup telephone calls regarding RA status, functional status, ability to work, dependence on others, and RA-associated costs.

The Western Consortium has been a successful project, with a continuing publication record[62-68]. However, the 71 rheumatologists have enrolled only 326 patients in a 10-year period. This illustrates the difficulty that many have found in relying on community physicians to enroll and follow patients in the detail required.

LIMITATIONS

Problems also occurred with the ARAMIS model and the clinical model of Pincus and Wolfe. The ARAMIS experiment might have been expected to stimulate others to build additional large data banks in the 30 years that it has been in existence. But this did not occur. Similarly, Pincus and Wolfe engendered no followers.

Other defects occurred with these systems. Although ARAMIS was designed to be a national data base system, it really had only a few active centers, as noted above. With time, patients registered within the system aged or died, and the average age and duration of disease of the patients in the data bank rose. Only a small percentage of those enrolled in the ARAMIS data banks remain active participants. The idea that longitudinal survey data banks could answer many questions of importance was most true in eras when therapy was not very effective so that one could infer results from decade to decade. With the introduction of cyclooxygenase-2 inhibitor drugs and then anti-tumor necrosis factor (TNF)

agents much of the older data in longitudinal data banks lost most of its value. What good, for example, was the enormous experience with gold therapy if it was no longer a viable therapy? These problems also were noted with the Pincus and Wolfe clinical models, where aging populations and changes in therapies and laboratory tests created the same problems as in the ARAMIS system.

In the late 1990s, Wolfe developed in ARAMIS an inception cohort of almost 1000 patients. But unlike the original ARAMIS model, where the data bank managers were patients' physicians, this inception cohort made use of referring rheumatologists. This method did not work well, and within 5 years only 35–40% of the inception cohort remained in the study, despite intensive effort to retain them[69,70]. Recently, Pincus and Sokka started an early RA data bank, and are actively enrolling new patients.

In 1998, Wolfe started the National Data Bank for Rheumatic Diseases (NDB)[71]. The goal of the NDB was to enroll a large number of patients from a group of geographically diverse rheumatologists. By 2003, the NDB had enrolled 23,319 patients, including 18,501 with RA, 3774 with osteoarthritis, and 1044 with fibromyalgia. Each of these patients had completed at least one detailed survey questionnaire. These patients came from the practices of 904 US rheumatologists and had, as might be expected, had wide exposure to contemporary therapy with anti-TNF and coxib agents. The NDB questionnaires have as their original model the ARAMIS type questionnaire, but in the NDB administration the questionnaire had been expanded to incorporate additional cost and outcome items, all drugs, and a variety of detailed quality of life instruments. The large cross-sectional data bank together with the contemporary longitudinal data have made the NDB a valuable public health and clinical research tool[33,72-84]. The NDB has also been used for teaching rheumatology fellows using programs written by NDB staff to mine the data.

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