

THE Arthritis Research NEWSLETTER

WINTER 2001

Looking back at 25 years of data bank research

WITH THE MAILING OF THE JANUARY 2001 questionnaire, we begin a new millennium and at the same time celebrate 25 years of data bank research. Twenty-five years ago there were few computers, no internet, and some people were just beginning to think about trying to understand arthritis by talking to people who had arthritis. Talking to you was a good idea, and 25 years later what we began in a small clinical setting and with a primitive computer is being used all over the world.

Making some progress with your survey questionnaire

There are a couple of new things in this year's questionnaire. First, we have tried to make it easier by having special sections that you only have to answer if this is your first time, if things have changed, or if you have skipped one or more questionnaires. After all, how many times do we have to ask you your date of birth or years of schooling, anyway? Doing it this new way makes the questionnaire look longer, but there are actually fewer questions for you to answer.

Arthritis at work

This year we have added a newly developed 'Work Limitations Questionnaire.' With it we are trying to learn about the difficulties that employed people with arthritis have doing their work. It is an important subject about which there is almost no information. We need your help with this one. If you are not employed, then just skip those question (and it'll be faster).

We have also added questions about high blood pressure and

edema (swelling in the feet and ankles). Recently there has been concern that some arthritis drugs might bring on such problems or make them worse. Truthfully, no one knows if this is so. But your answers can help in determining whether there is any truth here.

We were surprised to learn how many of you use the internet regularly. We have some good news for those of you who do. We hope to have an internet-based questionnaire on our web site by the time of the next questionnaire. We'll let you know about this the next time around.

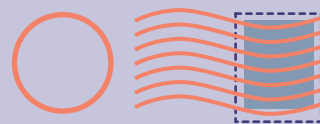
As the world becomes smaller, we hope to expand some of our research activities to Europe this year, working together with our European colleagues.

National Data Bank (NDB) research: year 2000 results

The NDB presented more research results to the American College of Rheumatology (ACR) 2000 annual meeting than any research center in the United States. For this meeting where more than a third of submitted research is not judged good enough for presentation, 100% of NDB submissions were accepted.

One of these presentations (about infection) was described in the Summer 2000 newsletter. It was submitted to the ACR in June and presented at the annual meeting in November. If you don't have a copy of the

Summer 2000 newsletter, give us a call or send us an email. We'll send you one. We thought that in this newsletter we'd spend a little time telling you about some research that is not yet published, as well as some additional studies presented at the last ACR meeting.



WIN \$1000

Return your research questionnaire within two weeks of receiving it and be eligible for one of three \$1,000 awards. The research data bank can best contribute to research when the mailed questions are completed and returned as soon as possible. All persons who complete the questionnaire within two weeks of receiving it will be eligible for the drawing for the award – given as a token of our gratitude in help with arthritis research. **The winners from the last questionnaire were Muriel Haberkamp, Garner IA; Linda Henry, Ambler PA; and James Sears, Elkview WV.**

What it means to have arthritis or fibromyalgia: The costs of arthritis

ALTHOUGH ARTHRITIS CAUSES PAIN AND DIFFICULTY in function, it also has other consequences. One of those consequences is economic (money!). It is harder to do your job if you have arthritis, and many may become disabled. Even while you may be earning less, your medical costs go up. This is really an important issue for many people with arthritis, and one that we have been interested in studying.

You may not know it, but we ask you many questions about what having arthritis costs you. Here are some of the ways.

- **Drug costs.** We calculate the cost of every drug you take.
- **Hospital/doctor visits and tests.** We calculate the dollar costs associate with these events.
- **Work disability.** We find out how much income was lost because you can't work.
- **Income.** By your family income we are able to compare income of people with arthritis with that of those without arthritis. We are also able to see how the severity of arthritis affects income.
- **Days lost from work.** We can tell how much it costs you and society to have arthritis.
- **Loss of productivity.** The work limitations questionnaire allows us to understand how you may be limited in your ability to be fully productive.

Here are a few results in this economic area. A few years ago we asked people about how well they could afford their medications. We were reminded about this when we came across a story from ABC news that shows how people are crossing the border into Mexico to purchase drugs at much lower costs than in the



United States. Rheumatologists know drug prices are of concern to most people with arthritis.

Because of this story we went into the data bank and analyzed the results of a few questions we had asked you. About 3,500 persons with arthritis supplied information for the table below. Overall, about 68% of those with arthritis had 'no problem' in paying for medications. But when we looked in detail at the replies, we saw another picture. Only 41% of people who paid for their own medication had felt drug costs were a financial problem compared to 77% whose insurance paid for their medication costs. So it depends on how good your insurance is. If it is not so good or you are on Medicare, most people have a problem.

How much of a financial problem is getting prescribed medications?

	Paid by insurance	Part pay by insurance	Paid by self	Total
No problem	94%	77%	41%	68%
Somewhat of a problem	2%	21%	31%	22%
Major problem	1%	3%	24%	9%
Unable to get medications	3%	0%	4%	2%

Some facts about arthritis and income

The more severe your arthritis, the lower your income. Although that is not a surprise to most people with arthritis, it is not known in the medical literature or among insurance companies or even governmental policy makers. Using data from your surveys, we reported at the 2000 American College of Rheumatology annual meeting that among 7,218 people with rheumatoid arthritis between the ages of 18 and 65, each unit increase in the HAQ score was associated with \$16,890 less income, even after adjusting for age. The HAQ (Health Assessment Questionnaire) score goes from 0 to 3. It is one part of the larger questionnaire we mail to you, and it asks about your functional ability.

One reason that this information is so important is to convince insurance companies and the government that having arthritis (not just having pain) constitutes a severe economic burden on people with arthritis as well as on our society, which has to take up some of these costs. We often hear that certain treatments are not 'cost effective.' But it seems as if your data show that it depends on whose costs you are talking about. For arthritis patients, the burden can be very heavy.

Income of Rheumatoid Arthritis Patients According to X-Ray Score

Many of the newer treatments for rheumatoid arthritis seem to slow down or halt x-ray damage. These drugs are expensive, and insurance companies ask whether it makes any difference to slow down X-ray damage. From the data bank, we found the following and reported it at the ACR annual meeting.

X-RAY SCORE	INCOME
Best (Upper third)	\$31,204
Middle (Middle third)	\$25,469
Worst (Lower third)	\$23,527
Upper and lower third difference:	\$7,677



More Research Results from the Databank

In the last newsletter, we promised to tell you this time about some other studies we would be presenting at the ACR meeting. Here are the results, in brief.

When 'worse?'

Is arthritis or fibromyalgia better or worse in the winter or in the summer? We found that the months for 'worse' symptoms were December and January, and for 'best' symptoms was July. However, when actual pain and global severity measurements obtained over a 19-year period were analyzed, pain was slightly increased in the summer and global severity was not related to season at all. Even when patients who specifically reported worse symptoms in winter and best symptoms in summer were examined, no effect of season could be found. We concluded that seasonal arthritis and fibromyalgia symptoms are commonly reported across all rheumatic diseases, but appear to reflect perception rather than reality since reported symptoms do not agree with measured clinical

scores. In addition, regardless of seasonal complaints, measured pain and global severity scores are not worse in winter. Bottom line: we all feel more comfortable in the warmer, pleasant months, but arthritis is really much the same in all months of the year.

Ulcer link reviewed

The new COX-2 drugs and the risk of ulcers. From the information you provided about side effects to medication, we studied whether the new COX-2 drugs (Celebrex and Vioxx) reduce the rate of ulcers. We found that people taking these drugs had their ulcer rate reduced by half. During a one year period, about 1.6% developed ulcers taking regular anti-inflammatory drugs, but only 0.7% developed ulcers while taking the COX-2 drugs.

OSTEOARTHRITIS: A New study on the safety and effectiveness of Glucosamine and Chondroitin Sulfate

In 1997 the #1 New York Times Bestseller entitled The Arthritis Cure was published. This book recommended the use of glucosamine and chondroitin sulfate as the therapeutic foundation of a nine step approach to treating OA. Since that time, however, the Arthritis Foundation has cautioned patients about the use of these dietary supplements, stressing the lack of clinical research to support these claims. Similarly, doctors have been warned about the lack of data demonstrating the effectiveness of these products, as well as the lack of control over the purity of products available in the United States.

To help address this problem, in the fall of 2000 a new national research study of Glucosamine and Chondroitin Sulfate for the treatment of osteoarthritis began. Our National Data Bank in Wichita is one of 13 sites around the country participating in this study which is funded by the National Institutes of Health.

Glucosamine and chondroitin sulfate are both components of cartilage. These dietary supplements are being widely recommended, especially in the lay media, as safe and effective alternatives in the treatment of osteoarthritis. While several small studies suggest that glucosamine may be effective in treating OA, no large-

scale, well-designed studies have ever been performed. This is mostly because nutritional supplements are not required to meet the extensive testing of the FDA approval process (we described this process in our last newsletter)

This new study is set up in the following way. Patients who participate will be randomly divided into 1 of 5 groups. Group 1 will take glucosamine only. Group 2 will take chondroitin sulfate only. Group 3 will take a combination of glucosamine and chondroitin sulfate. Group 4 will take Celebrex, an anti-inflammatory medication currently being used in the treatment of

osteoarthritis. Group 5 will take a placebo (a sugar pill). Patients will not be able to choose which group they are in, but will be assigned at random (by chance). Neither the patient or the study doctor will know which group they are in.

During the first 6 months of the study, patients will visit their study site office at 1 month, 2 months, 4 months, and 6 months after start. The purpose of these visits is to see if glucosamine and/or chondroitin is safe and effective in controlling pain. At seven of the sites, patients will continue on in the study for a total

How to participate

A list of all the sites is provided below. If you would like to find out more about the requirements or how to participate, please call the site closest to where you live. The general requirements are that you be at least 40 years old, and have had knee pain at least half of the days during the previous month.

- ▶ **Wichita, KS**, National Data Bank for Rheumatic Disease, 316-263-2125 ext. 117.
- ▶ **Birmingham, AL**, University of Alabama at Birmingham, 205-934-7754.
- ▶ **Los Angeles, CA**, Cedars-Sinai Medical Center, 310-358-5757.
- ▶ **San Francisco, CA**, University of California San Francisco, 415-648-8644.
- ▶ **Indianapolis, IN**, Indiana University School of Medicine, 317-278-0555.
- ▶ **Omaha, NE**, University of Nebraska Medical Center, 402-559-4873.
- ▶ **New York, NY**, Hospital for Joint Diseases, 212-598-6650.
- ▶ **Cleveland, OH**, Case Western Reserve University, 216-844-5253.
- ▶ **Philadelphia, PA**, Hospital of the University of Pennsylvania, 215-823-4480.
- ▶ **Dallas, TX**, Presbyterian Hospital, 214-345-8067.
- ▶ **Pittsburgh, PA**, University of Pittsburgh, 412-692-4346.
- ▶ **Salt Lake City, UT**, University of Utah, 801-581-4911.
- ▶ **Seattle, WA**, Virginia Mason Research Center, 206-223-6836.

of 24 months (2 years) during which time a series of x-rays will show if glucosamine and/or chondroitin sulfate is effective in stopping the progression of the disease.

Nutritional supplements are not required to meet the extensive testing of the FDA approval process.