

# THE Arthritis Research

WINTER 2001 **NEWSLETTER**

## 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

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# What it means to have arthritis or

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- **Hospital/doctor visits and tests.** We calculate the dollar costs associate with these events.
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- **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.
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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.

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	Paid by insurance	Part pay by insurance	Paid by self	Total
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# Fibromyalgia: The costs of arthritis

## 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)

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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

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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.

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# The Fibromyalgia Newsletter

WINTER 2001 FROM THE NATIONAL DATA BANK FOR RHEUMATIC DISEASES

## A Fibromyalgia Data Bank is Born: We Need You

With the coming availability of new treatments for fibromyalgia, this year we have started a special fibromyalgia data bank. With this start we are changing our usual NDB newsletter to reflect a greater interest in fibromyalgia. In all, we expect to have as many as 5,000 persons with fibromyalgia helping us to learn more about the illness and its treatment. This new interest has come about, in part, because ongoing research by major pharmaceutical companies is finally leading to the development of new and more effective drugs for fibromyalgia treatment. These drugs are not released yet, but they are on their way as more and more drug companies are sensing the importance of effective fibromyalgia treatments.

As part of the National Data Bank's commitment to fibromyalgia, we are adding discussions of fibromyalgia research and articles of special interest to those with fibromyalgia.

People with fibromyalgia have pain, fatigue, and difficulty with function, much as those who have rheumatoid arthritis and osteoarthritis. Many of our evaluations are common to all of these illnesses. But there are many differences, too. There are no laboratory tests that show the severity of fibromyalgia, nor can we demonstrate fibromyalgia problems by x-ray.

The lack of good tests to describe fibromyalgia problems has been a major impediment to fibromyalgia research. In our discussion with drug companies about how best to determine improvement in fibromyalgia, the problems with our sometimes inadequate assessment tools come up over and over again. In our new fibromyalgia research questionnaire that is being mailed with

this newsletter, we are adding a special questionnaire section to better document a number of fibromyalgia features. You will note special questions on pain, difficulty with work, fatigue, and sleep problems. We are trying to find out in a better way just how much trouble people with fibromyalgia have in these areas. Based on

your responses, we believe some of these question will be used in evaluation of new drugs. So your help is important, and will aid in the speedy development of new treatments and in bringing information about fibromyalgia to the medical and non-medical community. We hope you will give this new effort your full support. As we said above, we need you.

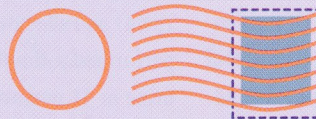
### Chiari Malformation and Fibromyalgia

It wasn't too long ago that this rare neurological problem was heralded on the ABC Nightline television program as a major cause of fibromyalgia. More than that, a neurosurgeon described major improvement in fibromyalgia symptoms after neurosurgery to correct the Chiari malformation.

The Chiari malformation occurs when there is extra cerebellum (brain tissue) crowding the outlet of the brainstem/spinal cord from the skull on its way to the spinal canal. People with this extra pressure on the spinal cord often complain of headaches, neck pain, numbness and other strange feelings in their arms and/or legs, and may have stiffness and other difficulties.

One of the ideas about the cause of fibromyalgia is that there is some abnormality of the nervous system. The Chiari malformation seemed like a perfect candidate. At the 2000 meeting of the

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## Continued from first page

American College of Rheumatology (ACR) in November, Dr. Dan Clauw of Georgetown University and his associates presented a study in which they determined how often Chiari malformation occurred in persons with and without fibromyalgia (FM). If Chiari malformation (CM) was a cause of fibromyalgia then it would be expected to be much more common in persons with fibromyalgia. What they found was the opposite.

The researchers studied 39 consecutive fibromyalgia patients, and a group of 23 sex-matched asymptomatic individuals served as the control group. All subjects completed symptom questionnaires, had an extensive neurological examination, and underwent an MRI of the brain and cervical spine. The MRIs were evaluated by two radiologists who did not know the diagnoses. What they found was that there were no consistent differences between groups in the size of the spinal cord, or in the number of individuals who would be judged to have narrowing of the cervical spinal cord. Of the subjects who had technically adequate studies, 8 of 26 FM and 11 of 15 controls had evidence of abnormality. This study, they concluded, did not support the notion that there is an increased prevalence of CM in individuals with FM. There is another important message here. It is that uncontrolled studies rarely yield scientifically valid information. So what about Nightline? We'll leave it to you to make a judgment about medical information provided by television.

## How do we hurt?

A number of years ago Dr. Dan Wallace, a lupus and fibromyalgia expert, advanced an interesting idea about fibromyalgia. He noted that people with fibromyalgia often report that they feel as if they had 'the flu.' Wallace knew that flu-like symptoms are caused in part by particles circulating in the blood called cytokines – substances that are used by cells to communicate to each other. At the 2000 ACR annual meeting, Dr. Wallace and his colleagues from the Cedars-Sinai Medical Center in Los Angeles presented results of their studies of cytokines in 56 fibromyalgia patients and in 36 age and sex matched controls (persons who did not have fibromyalgia).

The found no differences between fibromyalgia patients and controls in five of the cytokines (IL-1, IL-10, sIL-2r, IFN- $\gamma$ , TNF- $\alpha$ ). But two cytokine levels (IL-1Ra and IL-8) were significantly higher in sera, and two (IL-1Ra and IL-6) in stimulated and unstimulated fibromyalgia cells compared to controls. They concluded that soluble factors (cytokines) whose release is stimulated by substance P were found to be increased in FM patients. Since IL-8 promotes a kind of nerve pain and IL-6 decreases sensitivity to pain, it was hypothesized that they may play a role in modulating FM symptoms.

These data are very interesting because it is now well established that substance P (a substance that is related to pain and is abnormal in fibromyalgia), sympathetic nervous system abnormalities, and hyperalgesia (a general increase in pain) are all part of fibromyalgia pain. Dr. Wallace's data help to explain how these fibromyalgia abnormalities might be brought about by increased levels of cytokines. Like many abnormalities in fibromyalgia, this one is not the cause of the syndrome, but may be one of the ways (mechanisms) by which fibromyalgia pain may be brought about.

## Serotonin Again

Professor Jon Russell from San Antonio has been among the first to be interested in serotonin in fibromyalgia. At the 2000 ACR meeting, Chi-Lun Rau working with Russell pointed out once again that low serotonin availability at critical places in the brain may contribute to FMS symptoms by failing to regulate nociception (pain) and affective (depressive) manifestations. In this study, they performed a simple test. They measured serotonin levels in the urine in 31 persons with fibromyalgia and in an equal number of controls. The average serotonin was significantly lower for all fibromyalgia patients than for all healthy normal controls. They concluded that their findings support the serotonin deficiency hypothesis as a potential contributor mechanism for fibromyalgia development. One of the reasons that anti-depressant drugs are often used in fibromyalgia is not so much for their anti-depression properties as for their ability to alter serotonin levels in the brain.

## Zinc?

Here's another study from Dr. Russell's group. The level of zinc found in the blood is known to be related to pain in animals. This study sought evidence to implicate zinc in the mechanism of fibromyalgia pain in humans. Thirty patients with fibromyalgia and 30 healthy control subjects were studied. The researchers studied zinc and three measures of pain severity including the average pain threshold (amount of pain in the tender point regions). Zinc levels were lower in fibromyalgia, and rose somewhat after treatment. But clinical measures of pain did not improve with zinc treatment. Russell's group concluded that Zinc is physiologically related to the mechanism of fibromyalgia pain. They concluded further that zinc deficiency may contribute to the pain of FMS, but warned that Zinc therapy for FMS symptoms cannot yet be recommended with confidence. This is an important warning. Zinc treatment has been around for a long time and there is still no evidence that taking zinc helps. But if Dr. Russell's work holds up after further investigations, we may be able to understand better why there is so much pain in fibromyalgia.

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