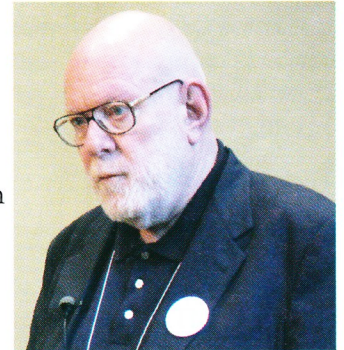


# THE Arthritis Research

NEWSLETTER

July 2005

## Notes from the Director: New Directions



NDB Director Dr. Frederick Wolfe

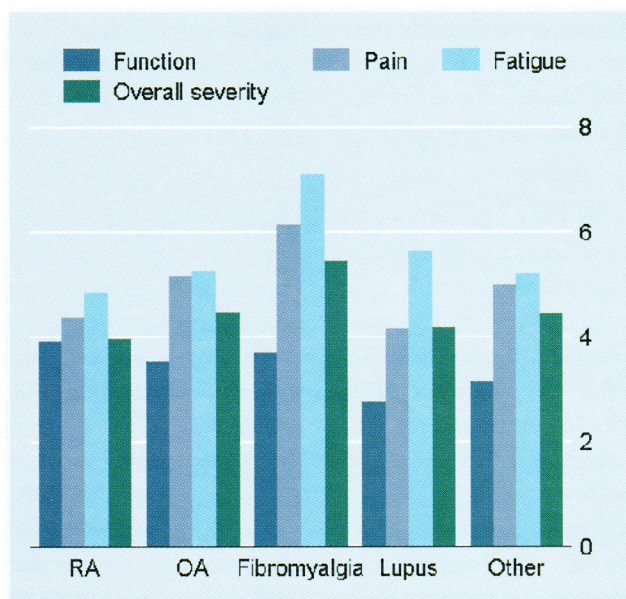
Over the last few years the NDB has expanded its role by actively including people who have less common rheumatic illnesses like Lupus and others. After rheumatoid arthritis, these other illnesses make up the second largest population that we study, followed by osteoarthritis and fibromyalgia.

Rheumatic illnesses are really quite different. Many affect the joints, some don't. Some cause skin or bowel problems, most don't. How can we study all of these different problems with one questionnaire? One reason that we can do it is because almost all illnesses produce functional loss (or the inability to work fully), pain, fatigue and an overall level of severity.

The graph below provides an illustration that you might find interesting. All of the scales in the figure run from 0 to 10, with higher values being worse. Notice that persons with RA, on average, have the highest

levels of functional loss. Even so, it is hardly more severe than in persons with OA or fibromyalgia. Pain scores are highest in fibromyalgia and lowest in lupus, reflecting the differences in these illnesses. You might also notice that lupus and fibromyalgia have the most fatigue, reflecting their similarities. I find it intriguing that it is possible to understand illnesses that have different causes and courses by a few simple questionnaire items like these.

*On average, you spend \$774 per year traveling and waiting. That's a lot of time and a lot of money.*



If you are like me, you don't like traveling to the doctor and waiting in the waiting room. About a year ago we spoke to many of you on the telephone and asked about these issues. We asked you about how many miles you were from your doctor and laboratory, how much time you spent going to the doctor or laboratory, and whether people accompanied you. Here's what we found from this information and from the number of medical visits you make after converting this information to dollar costs, based on how much money your time was worth. On average, you spend \$774 per year traveling and waiting. That's a lot of time and a lot of money. I knew there was more than just one reason for not liking doctor visits!

There is a lot of interesting information in this newsletter. Hope you enjoy it. And, as always, thanks for your help!



# Meet the Participants

## Anita K Hansen, Participant since 1998

I thought a bee had stung me in my left shoulder when walking in the field at a friend's farm. The pain was awful and lasted for many hours. A few days later my right wrist began slowly to throb and reached an unbelievable crescendo of pain that lasted for 6 hours. Several days after that, the same thing happened in my ankle. I was frightened and perplexed, so I called my doctor. He said, "It sounds like you have rheumatoid arthritis."

That was 32 years ago. We moved from our small town to Minneapolis in 1978 and found a Rheumatologist. After much trial and error we settled on Methotrexate as my primary treatment. MTX gave me my life back. I could now turn over in bed and brush my hair and wake up with no stiffness. I stopped walking like Tim Conway on the Carol Burnett Show.

I developed Dyspnea, and my Pulmonologist diagnosed Pulmonary Hypertension. My new internist took me off the MTX and put me back



on Prednisone, 7.5 mg daily. Now I'm back to morning stiffness and horrible pain on awakening. The upside is that my hair is now more luxurious and thicker!

The dyspnea prevents me from walking even a block. I lap swim 3 times a week; breast stroke, crawl and butterfly for a total of 3/4 mile. Unless people see my hands, which are very deformed, they can't tell I have RA. I have had synovectomy surgery twice to remove inflamed joint tissue. Once for 4 trigger fingers.

All in all, having just passed my 70th birthday I feel blessed to get along this well. I do most anything I want except sky diving, bowling, tennis, and triathlons. I push myself to the limits, suffer the pain and accept the tiredness and exhaustion that follows a day of doing what I want to do.

I am thankful for the NDB research. I feel privileged to participate, thus helping science to conquer this disease and to further the research to help others. I understand it has helped doctors a great deal.

## Fibromyalgia, Research and Getting on with Life!

### Michelle Millar, Participant since 2004

Like most others with Fibromyalgia Syndrome, I was both shocked and overwhelmed when I received my diagnosis in January 2003, aged only 25. Luckily, unlike many others, my diagnosis was swift, coming within 4 months of the first symptoms. Sufferers of FMS experience a range of diverse symptoms of varying degrees. My own over-riding symptoms are extreme pain in the back, hips and legs, a heavy fatigue, migraines and disrupted sleep. It is life-changing when you are first told that these symptoms are of a chronic nature though thankfully I am an extremely strong-willed young woman and was determined from the outset that FMS would not control my life. I was resolute that I would control it!

I started by investigating how I could best manage my own condition. I became an expert in my own illness through online research and contact with the local charity here in Northern Ireland (FMSNI). Although I tried many treatments I found most produced no real tangible benefits or offered relief on only a short-term basis. And then I was referred for Cognitive Behavioral Therapy (CBT)!

CBT literally changed my life. By the time I started this therapy, I was well aware that there was no magic cure to FMS and this had left me feeling quite despondent. CBT dealt with all the issues surrounding my illness, physical and emotional,

and encouraged me to look at life from another perspective. With my therapist I worked to identify the thought patterns that were causing problematic feelings and behavior in my life. We also structured pacing into my daily activities more effectively and I began setting long and short-term goals. After a brief period, I began to notice small improvements that eventually added up to huge changes. Before I knew it I was living life fully again. The pain, tiredness and illness are all still there – the difference is that nowadays I control FMS like I always said I would!

During my online research, I came across the NDB website. This site caught my eye, specifically because it was research based and included FMS. Currently a lot of FMS literature is completely contradictory and there are hugely varying medical explanations for the condition. There is also little research carried out into the condition. We need to know exactly what the root cause of FMS is. Are there any drugs out there that could be of real benefit to sufferers? What is the most effective treatment for FMS? So many questions and as yet, so few answers. It is for this reason I support the NDB and other FMS research and encourage all those I know with FMS to also enroll as research participants. I feel it is our duty to participate and help with any research we can. I think it's about time we FMS sufferers got some answers!



# Latest Research

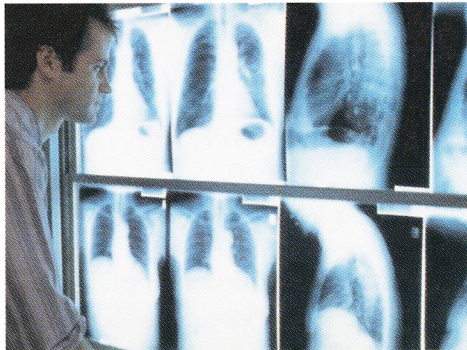
Each year the NDB presents the results of our research at the annual scientific meetings of the European League Against Rheumatism and the American College of Rheumatology. Here are some of the important findings we're reporting this year.

## *Biologics don't increase breast cancer rates*

Good news for women with RA! We found no evidence to date that rheumatoid arthritis therapy, particularly the newest medications, increases the risk of breast cancer.

These new medications include Remicade (infliximab), Enbrel (etanercept) and Humira (adalimumab), and are known as biologic response modifiers, or biologics. They were of special interest because many older treatments do increase the risk of some cancers in rheumatoid arthritis (RA) patients. A previous NDB study found an association between the biologics and non-melanoma skin cancer.

However, because the drugs have only been on the market for a few years, patient exposure to the therapy may be too short for a firm conclusion and further study will be necessary.



We also found no significant relationship between breast cancer and any RA treatments, including biologics and the more common methotrexate and corticosteroid treatments. The only measure that predicts breast cancer among RA patients is age, with the highest rates occurring between the ages of 55 and 70.

## *RA does not increase lung cancer risk*

One benefit of having such a large group of participants is the ability to compare our results with those of other studies from around the world. We recently did this and found that RA does not increase the risk of lung cancer. A previous European study showed an increased risk but could not assign the blame to RA because of lack of data.

We found that the increased risk is associated with smoking, age, low levels of education and dyspnea (breathing discomfort or significant breathlessness), but not with the disease itself.

## *RA and preventative aspirin*

Remember the question about aspirin? Here's something we did with your answers. Researchers already know that inflammatory diseases are associated with a higher risk of heart disease, and low-dose aspirin is recommended for adults with an increased risk of having a heart attack. We wanted to know if RA patients were taking preventative aspirin. It turns out that about six percent fewer RA patients take it compared to non-RA patients. We couldn't find any explanation for the difference in the data. However, several possibilities exist. Doctors may feel that complicated RA treatments weigh against additional therapies. In addition, package inserts and pharmacists recommend against using aspirin with methotrexate or NSAIDs. Finally, rheumatologists, as sub-specialists, might not address primary prevention issues. Although further studies are needed to understand this discrepancy, we think that rheumatologists should be aware that RA patients, on average, receive less than the recommended care for prevention and treatment of heart disorders.



**FOR MORE INFORMATION OR TO PARTICIPATE**

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Please call 1-800-323-5871 ext. 140 or [www.arthritis-research.org](http://www.arthritis-research.org)



## *Fibromyalgia causes and risks in RA patients*

Everyone wonders “What is it about me that made me get this disease?” When looking at a group of FMS patients at one point in time it can be almost impossible to separate the symptoms of the disease from the signs that say someone may get it. They are often the same. However, by looking at people over time, specifically people with RA, we are able to draw some conclusions about who will meet FMS diagnosis criteria. Unfortunately, we can’t answer the question for any individual in particular. Using recently published criteria for diagnosing FMS we found that disease in about 17 percent of RA patients. Interestingly, patients may meet the criteria at times and fail to meet them at other times. The following characteristics may predict FMS: lower levels of education, being black or Hispanic (as compared to white), being divorced or separated, having

FMS symptoms, poverty, low function in daily activities, pain, sleep disturbance, a lack of general well-being and having other medical problems. FMS is more likely to occur in women. Again, we studied RA patients to get these results, and they may not apply to the general population.



## *A new measure of Fibromyalgia symptoms?*



If you have Fibromyalgia (FMS), you might find it hard to imagine that there’s a measurement of the syndrome that can say you either have it or you don’t. Yet that’s how researchers classify FMS patients. In reality, we think FMS is better judged on a continuous scale that can show varying levels of severity. We developed a scale of Fibromyalgia Intensity (FI) using existing pain and fatigue scales, and found that it works pretty well in identifying key FMS symptoms such as mood, memory, depression and headaches. We think the new FI scale will be useful for doctors and researchers in measuring the intensity of FMS symptoms no matter what the diagnosis.

## *The NDB welcomes Lupus and FCAS patients*



We recently began a few new projects:

Lupus, or Systemic Lupus Erythematosus (SLE), is a chronic inflammatory disease that can affect various parts of the body. In the US, there are about 500,000 to 1.5 million people with this autoimmune disease.

FCAS, or familial cold autoinflammatory syndrome, is a rare genetic condition caused by a genetic mutation. FCAS is characterized by fever, rash, chills, joint and muscle pain and fatigue brought on by exposure to cold. For now, the FCAS study is short-term and uses its own questionnaire.

The NDB is wrapping up a project called HERO we did with the RA medication Humira, and we’ve invited all HERO study participants to join the NDB and take our regular questionnaires as an ongoing follow-up.

If you’re new to the NDB, we welcome you! You are making a valuable contribution to medical research, and we sincerely appreciate the effort, time and attention it takes.



# Top 10 Comments and Questions about the Questionnaires

We've been making an effort to reply to your comments and questions that you give us about the questionnaire. This is easy for us to do for those of you who use WebQuest, while those of you using the paper quest may get a phone call to answer your questions or clarify something you told us.

Here are some of the most common things we hear about.

## 1. TOO LONG!!

Yes, it's true that the questionnaire is long. We try to make it as easy as possible for you, but we must ask these questions in order to understand what effects you are getting from your treatment. You might try doing one page a day so that it doesn't wear you out.

## 2. TOO Repetitive!

But if we're trying to make it easy why do we include so many repetitive questions? Good point. Some of the questions are very similar or repetitive, but they are scored in different ways and are worded slightly differently. These questions originally come from standardized arthritis questionnaires. In order for the answers to be meaningful we have to leave all the questions in.

## 3. What if I can't remember?

We understand that it may not always be possible for everyone to remember something that happened or started a long time ago. If you can't remember the answer to a question or how you felt in the past, please give us your best guess.

## 4. What about my other disease?

The comments section is really the best place for any information you want to give us that we don't ask about on the questionnaire. There are many, many diseases and conditions that people in the study have in addition to their rheumatic diseases. However, be sure to tell us ALL of the medications, supplements and treatments you are taking for ALL illnesses you have. We are able to learn a lot about your other conditions by knowing what you are taking.

## 5. This question does not apply to me

If you find a question that doesn't seem to apply to you, you simply have to make the best choice, even though it may not seem completely correct for you. We try to make sure that the questions make sense for everyone and that all appropriate answers are listed. The answers are still useful to us. One of the big challenges of this kind of study is measuring subjective answers, which may explain why it's sometimes hard to find just the right answer in the 3 or 4 choices available.

## 6. I can't enter the right date

We ask about a few different time periods in the questionnaire. First, the main six-month period matches how often we give the questionnaire. The shorter periods, one week and four weeks, come from standard arthritis questionnaires. This time, for example, we don't ask about hospitalizations after June 30th because 1) we hope that

everybody does the questionnaire as soon as possible after the 30th, 2) we assume and hope that we will learn about the problem in the next questionnaire, and 3) it would be difficult for us to keep track of all the information from outside the date range. On WebQuest, the computer will not let you enter an incident that is out of the date range for that question. If you have a surgery in July, you'll need to enter that in the next questionnaire. Please don't use a wrong date.

## 7. My medications are not listed in WebQuest

WebQuest will only save medication information from one questionnaire to the next, so if you skip doing a questionnaire, you will need to re-enter your medications.

This is the only way we can make sure that we have the latest information for each medication. Medications are perhaps the most important part of the questionnaire, so we can't afford to risk having outdated information.

## 8. Why do you need to know my income?

Having a rheumatic disease can often limit your earning power by restricting the type of work you can perform and the amount of time you are able to work. By tracking income we can see the relationship between the severity of the disease, the effect of treatment and the ability to maintain your usual lifestyle. Income is also related to the quality of care received. The research we conduct with this information is very useful to health authorities as they make funding decisions and set public policy. Like all the other information in the survey, your income is confidential and is never visible to anyone outside the NDB in an identifiable way.

## 9. What if I don't have "arthritis"?

Participants in the NDB can have any rheumatic disease, including Rheumatoid Arthritis, Osteoarthritis, Lupus, Scleroderma, Fibromyalgia, Ankylosing Spondylitis, and so on. For most of these conditions we need to ask the same questions, so it doesn't make sense for us to create separate questionnaires for each disease. We use "Arthritis" as an umbrella term that really means any rheumatic disease. Also, some of the questions we ask come from standardized questionnaires, and we are not allowed to change the wording.

## 10. Pain levels vary too much to answer

Knowing how to mark pain severity or function can be difficult. If the question asks for a specific time period, such as the last 4 weeks, you should try to focus on that. If it asks about the last 6 months, it may be harder to remember, but you're looking for an average of how you were over that period. It's also perfectly normal to have high function at one point in the day and then worse function later or the next day. In the end, these kinds of questions are about your impressions about yourself, so there is no right or wrong answer. You just have to go with what you feel is right.



## How YOU can help the NDB

### Refer a Friend



Here's a really easy way to let a friend with arthritis know about the NDB. Just give us your friend's email address and we'll send out an email invitation to join the study. Go to

<http://www.arthritis-research.org/enrollfriend.htm>

### Three \$1,000 Awards to Arthritis Research Participants:

Return your research questionnaire within two weeks of receiving it and be eligible for one of three \$1,000 awards. The research databank can best contribute to research when the questionnaires are completed and returned as soon as possible. Anyone who completes the questionnaire within two weeks of receiving it will be eligible for the award – given as a token of our gratitude in help with arthritis research.

The winners from the last questionnaire were Elta Sutton, Plattsburg, MO; Irene Lawn, Jamestown, NY; and Max Hall, Elm Grove, LA. Winning smaller amounts were Faye Day, Kansas City, KS; George McIver, Summerville, SC; Janet Henton, Santa Cruz, CA; and Linda Roberts, Muncie IN.

*Congratulations to all!*

## Can you use our new pamphlet?

Now available for your support group or arthritis meetings....Our new pamphlets explain what we do and how you and can help. Each one has a postage-paid postcard to request more information or join the project. The pamphlets and a small table-top stand are available free from the NDB. Just contact us at [info@arthritis-research.org](mailto:info@arthritis-research.org) or 800-323-5871 ext. 133 or 140. Thank you!



#### Join a long-term

The National Databank (NDB) is a non-profit study of arthritis and NDB research advances causes, costs, treatments related to rheumatoid research and study making NDB data

#### How to enroll

Fill out the attached (no stamp needed) send you enrollment allow one month

### Arthritis Research needs your help

If you have any form of arthritis, muscle or back problems, immunological disorders or any condition that you would see a rheumatologist or joint specialist about, you can help improve the treatment and outcomes of these conditions.

#### Answers to common questions about NDB research:

##### Why should I participate?

People volunteer to participate in research for a variety of reasons. The primary reason people give for NDB participation is that they want to contribute to medical research that may help others with their disease. With a debilitating disease like arthritis or other rheumatic conditions it can sometimes be difficult to volunteer in a traditional setting. NDB research allows you to volunteer in an important way.

##### How often will I get a questionnaire?

Every 6 months. Questionnaires take approximately 30 to 60 minutes to complete. Returning your questionnaire within two weeks makes you eligible for a \$1,000 prize given to three people chosen at random. You will also receive a biannual newsletter and access to an online discussion group.

##### Does it cost anything to participate?

No. We pay all of the postage and have a toll-free phone line for questions.