

THE NDB Research NEWSLETTER

News for Participants in the National Data Bank for Rheumatic Diseases

July 2009

Notes from the Director

Frederick Wolfe, MD

NDB Current Activities: Fibromyalgia

As many of you know, fibromyalgia is a somewhat controversial and difficult condition. Treatments are not always as helpful as physicians and patients would hope. Sometimes doctors are not even sure when to diagnosis it or how to evaluate it when diagnosed.

During the first part of this year the NDB has been working with fibromyalgia experts throughout the US and Canada to try to develop criteria for diagnosis that are easier to use and to develop a method to measure its severity. Almost a thousand patients and around 50 physicians participated in the new study. Half of the patients had fibromyalgia and were evaluated when they were seen by their physician. The other half didn't have fibromyalgia but had other painful conditions (e.g. osteoarthritis). These "control" subjects also were evaluated during their regular medical appointment.

Currently, fibromyalgia is diagnosed by noting that patients with it are tender to pressure in most areas of their body — much more tender than those without fibromyalgia, and also noting that they experience pain in many non-joint areas of the body.

That's the way to diagnosis it according to the American College of Rheumatology, but that's not all there is to fibromyalgia. There are high levels of pain. Many people who have it experience symptoms of fatigue, headaches, difficulty with memory or thinking, bowel problems, difficulty with sleep, and many other symptoms. If you have enough of these symptoms and if they are severe enough, you can have a lot of troubles.

In our study we wanted to find out if there were any other factors that might be useful in diagnosing and evaluating fibromyalgia.

You might think that the amount of pain that people with fibromyalgia suffer might best distinguish them from those without fibromyalgia. But we found that was not the case because the control subjects (those without fibromyalgia) also had pain. What we found that best distinguished fibromyalgia from

non-fibromyalgia were four symptoms. First was the severity of a sleep problem called non-restorative sleep —or waking up unrefreshed. It's a common enough symptom to be sure, but persons with fibromyalgia report it to occur frequently and to be severe. A second symptom was difficulty remembering things or thinking clearly. That's another symptom that many experience, but it was common, frequent and severe in fibromyalgia. The third symptom was fatigue, clearly much more of a problem in fibromyalgia than in the control subjects. Finally, people with fibromyalgia just had more symptoms. If you think of the long list of symptoms we ask you with our questionnaire, people with fibromyalgia just have more of these symptoms, often a lot more.

Well, maybe you can guess the problem. If everyone can have these four symptoms at some time and sometimes people with fibromyalgia have few of the symptoms, how can you tell who has and who does not have fibromyalgia? And how can you tell how severe it is? One way is to try to make a score of these symptoms, that is, to add them up. You may notice that we have

added a few questions to the current NDB questionnaire that deal with unrefreshed sleep, memory and thinking problems and fatigue. To make room for these questions we removed a few older questions, so the overall NDB questionnaire is slightly shorter. These questions, together with the number of symptoms that people

have make up a **Symptom Severity Scale**. The fibromyalgia experts thought that this scale might help to measure fibromyalgia severity. Of course, you don't need to have fibromyalgia to have these common symptoms, but if your score on the symptom scale is very high, it is likely that you have fibromyalgia.

The fibromyalgia experts said that to have fibromyalgia you had to have a certain minimum symptom severity score, but you also had to have many painful non-joint areas in your body. In June the experts submitted their recommendations as a report to the American College of Rheumatology annual meeting. The NDB will try to use some of these new ideas to measure and diagnose fibromyalgia, and we will report the result to you early next year.

"People with fibromyalgia have more symptoms in the long list of symptoms in our questionnaire. Often, a lot more."

Notes from the Director (continued)



Lupus

Over the last year the NDB helped lupus experts to develop a questionnaire version of a lupus severity scale called the *Lupus Damage Index Questionnaire*. Our first scientific paper using this index will soon be published in a journal called *Lupus*, and we expect NDB results of using this scale to be published next year. Early this year we also published the results of NDB experience with a lupus activity index. These two new scales will help physicians better evaluate and treat lupus. The NDB presented three papers on lupus at the European EULAR rheumatology meeting in Copenhagen (June 2009).

Rheumatoid Arthritis

The big news in RA this year is new treatments. Earlier this year two new biologics were approved by the US Food and Drug Administration (FDA) for the treatment of rheumatoid arthritis. These treatments are Simponi (golimumab) and Cimzia (certolizumab). These 2nd or 3rd generation treatments are given just once a month by injection. We have added them to the questionnaires and will be interested in your experience with them. The NDB published a few papers about RA this year, including reports about remission, measuring treatment success and failure, and depression.

Osteoarthritis and other conditions

Those of you with other conditions were also reported in some of the above studies. In addition, NDB is preparing studies on joint surgery and less common rheumatic conditions. We'll let you know as soon as the results are ready.

Welcome New Participants!

Everyone who works for the NDB and all of the doctors and researchers who benefit from our research are extremely grateful for the dedication of you, the participants, to helping with this project. Many of you have been with us for several years or more. But every 6 months we are also glad to see many new people join us. Here is a quick primer on the NDB for the new and a refresher for the seasoned experts.

The NDB is a non-profit organization that performs research in rheumatoid arthritis, osteoarthritis, fibromyalgia, lupus and other rheumatic diseases. The research is designed to improve the treatment and outcomes of these conditions.

The NDB is an independent organization that conducts its own research without influence from pharmaceutical, insurance, financial or other outside interests. Our research is so well respected that we are often hired to provide independent drug safety verification to the FDA.

Your personal information will always remain private. We do not sell or share any identifying information about NDB participants. Before we work with researchers or collaborate with other research groups we remove any of your answers that could be used to identify you.

Nearly all of our research is available for you to read on our website.

We are glad to answer your general questions about rheumatic diseases and treatments, but we are not able to give personal medical advice.

NDB research is different in an important way: Participants report on themselves; data is not collected by doctors or medical staff. With patient-reported data, researchers get a perspective that short, small clinical trials cannot provide. Our long-term study offers a much broader view of treatment and results. Clinical trials are good at identifying common side effects, but rare or subtle problems, or problems that take longer to develop,

are better detected by studies like the NDB. The same is true of long-term effectiveness of a treatment.

So, welcome to the NDB, or thanks again for your continuing participation! If you ever have any questions or need help with your questionnaire, feel free to contact us.

FOR MORE INFORMATION OR TO PARTICIPATE

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LATEST RESEARCH

RA and Work Disability

A new NDB report published in the journal *Arthritis & Rheumatism* considers whether new medications have reduced work disability for persons with RA. Our research found differences from previous studies: For most people with RA who stopped working, neither disease severity nor the physical demands of work were significant risk factors for having to stop work. Older age, lower income from employment, fewer hours worked per week, and preference not to work were the major risk factors for work disability.

Improved treatments might be one explanation for this result, but more research is needed before drawing a final conclusion.

When you also have another medical condition

We studied the presence of other medical conditions in NDB participants with lupus, RA, fibromyalgia and non-inflammatory rheumatic disorders (NIRD) such as osteoarthritis. Having more than one condition at a time is called comorbidity. We found that comorbid conditions are most common in fibromyalgia, followed by lupus. Hypertension and stomach disorders are the most common current physical conditions, and depression is the most common mental condition. Depression affects 15% of persons with RA or NIRD and 34 to 39% of people with lupus and fibromyalgia.

It's important for doctors to know about likely comorbid conditions so they may be detected and treated.

How does the NDB distinguish between multiple conditions?

A common question we hear from people who complete the questionnaires is, "How can you use my answers when I'm not sure if the problem is my arthritis or something else?" One way we can tell is by comparing groups of participants



with conditions to see if the questions we ask still apply. In a recent article in the *Journal of Rheumatology* we looked at groups of participants with lupus and fibromyalgia. We wanted to make sure that our lupus results

were not being affected by fibromyalgia symptoms. To do this we compared NDB participants with lupus, fibromyalgia and other rheumatic diseases.

We found that fibromyalgia and symptoms of fibromyalgia are slightly increased in people with lupus compared to patients with arthritis. Our results show that lupus disease activity reports strongly reflect fibromyalgia and its symptoms in

people with both. However, there is no evidence that fibromyalgia or increased levels of fibromyalgia symptoms distort the measures of lupus activity.

What is remission in RA?

We've reported in this newsletter about efforts to describe remission. Until there is a cure, everyone desires remission for people with RA. Remission is the term to describe some significantly lowered level or absence of RA activity and symptoms. How do people with RA and their doctors know when there is a remission? Some of you may remember answering our recent questions on this topic at your recent rheumatologist visit.

Now we've published further results in the *Journal of Rheumatology*. Eight hundred of you completed the remission questions at a rheumatologist visit. Roughly 35 percent of you were in remission according to your doctors. But just 31 percent were by your own perspective. To make matters more complicated, when we looked at disease activity measured at the same time, it appears that neither doctors nor patients were completely correct. Previous studies have shown lower rates of remission. So, we conclude in these new results that we're really measuring low disease activity rather than genuine remission. The search for a definition continues.

Instant reports coming to WebQuest!

The NDB is taking steps to offer you access to reports on your answers to questionnaires. We hear your requests for copies of your answers and more information about what they mean.

Starting with this July's WebQuest we'll begin testing some reports for you. Some of you will see a summary report indicating a selection of clinical scores from the questionnaire. You can share this report with your rheumatologist or just keep it for your personal records. Usually a rheumatologist likes to know how you are doing at the time of your visit, so he or she may not be able to use these reports. We currently plan to provide a summary of clinical measures such as the HAQ, pain, global health, etc. as you've reported them in the NDB over time. We also hope to include other information and we welcome your feedback on this optional "benefit" from contributing to the NDB.



Other ways to save your answers

If you want to save your answers but don't get our test reports this time, you can still save them by printing out each completed page as you go. You may also contact the NDB for a copy of your answers.



While working on your questionnaire, if you have ANY questions about the questionnaire, please contact us right away by email or phone. These might be about technical difficulties or how to interpret a question. If you put your immediate questions in the comments section we probably won't see it in time to answer.

Please use the comments section for any information you think we should have that isn't covered in the questionnaire. This could be about a change in medication that needs explanation or information about other considerations of your condition that you think we need to know. You may also ask general questions that don't require an immediate answer.

Support rheumatic disease research with a financial donation

As a non-profit project conducting ongoing research to improve conditions for people with arthritis, fibromyalgia, lupus and other conditions, the NDB is an organization with ongoing financial needs. If you would like to make a tax-deductible monetary donation to the NDB to help support this research, we would be very appreciative of your support. If you would like to make your donation in memory of or honor of someone please let us know. We will send a card to the person of your choice to acknowledge your gift.

Donations should be payable to The Arthritis Research Center Foundation Inc. and sent to:

The Arthritis Research Center Foundation Inc.
1035 N Emporia Ste 288
Wichita, KS 67214

Lottery Winners!

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 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 rheumatology research. The \$1,000 winners from the last questionnaire were Janice Severin, Omaha NE; Justin Prentiss, Bloomington GA; Sharon Chapman, Wichita KS. Winning smaller amounts were William Rosenthal, Warren OH; Alice Musgrove, Elba AL; Ronald Nix, Valley Center KS. Congratulations to all!

Refer a Friend

Here's a really easy way to let a friend 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>



Helping the NDB in other ways

Achieving the NDB's goals of telling the rheumatology community about patient experience depends on a large group of participants. Here are a couple of ways you can help.

Now available for your support group or arthritis, fibromyalgia or lupus meetings.... Our pamphlets explain what we do and how you can help. Each one has a postage-paid postcard to request more information or an enrollment form to 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 or 800-323-5871 ext. 133 or 140. Thank you!



WebQuest

WebQuest is the online version questionnaire. The questions are the same as what you get on the paper questionnaire. People who are comfortable using computers should find it easier than the paper version. If you would like to try it, follow the links from our home page, www.arthritis-research.org and make the request, or send us an email at webquest@arthritis-research.org.

Important Information about Email

For patients using WebQuest, email is our primary method of getting in touch with you. Even if you're not using WebQuest, we'd like to be able to send you important information by email.

We cannot emphasize enough how important it is for you to let us know whenever you change your email address. To update your email address go to our website and look in the participant's links, or call us.

Here's a VERY IMPORTANT step you can take to make sure our email gets to you: Add us to your email address book. Our address is webquest@arthritis-research.org. This will ensure that our mail makes it through the spam blockers. You will need to do this every time you change your email address. Thank you!