

## 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](mailto:info@arthritis-research.org) or 800-323-5871 ext. 133 or 140. Thank you!



## 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 participants' 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](mailto: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!



## WebQuest

WebQuest is the online version questionnaire. The questions are the same as what you get on the paper questionnaire, and people who are comfortable using computers for things like paying bills and shopping 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](http://www.arthritis-research.org) and make the request, or send us an email at [webquest@arthritis-research.org](mailto:webquest@arthritis-research.org).

## 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 [www.arthritis-research.org/enrollfriend.htm](http://www.arthritis-research.org/enrollfriend.htm)

### FOR MORE INFORMATION OR TO PARTICIPATE

**Arthritis Research Center Foundation, Inc.**

1035 North Emporia • Suite 288 • Wichita, KS • 67214

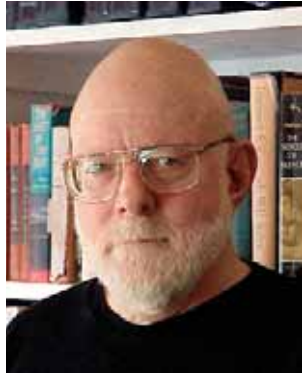
Frederick Wolfe, MD, Director    Rebecca Schumacher, Executive Director

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

# THE NDB Research NEWSLETTER

News for Participants in the National Data Bank for Rheumatic Diseases July 2006

## Risks and benefits Notes from the Director



NDB Director Dr. Frederick Wolfe

It seems like a week does not pass without some discussion appearing in newspaper and television reports of the risk of taking a medicine and the benefit that medicine provides. Two risk/benefit issues appeared in the media during the last six months that are of interest to people with arthritis and rheumatic disorders: a report that said Remicade™ and Humira™ increased the risk of cancer and serious infections, and a report of jury trials regarding whether Vioxx™ caused heart attacks.

When we take drugs for our illnesses we take risks. So it might be useful to examine the issue of risk in a little more detail. There are two parts to understanding risk. The first is the "absolute risk." For example, the absolute risk of being killed by a tornado in a single year is around 0.6 in a million (about 1 in 1,700,000). "Relative risk" lets us compare how the risk affects different groups of people. For example, the relative risk of being killed by a tornado is 10.6 for people who live in a trailer park compared with those who don't. Or as the media might put it, your risk is increased by more than 10 times if you live in a trailer park. So why would anyone

**"...we found the risk of malignancy was not increased in people who had used these drugs."**

want to live in a trailer park? For one thing the absolute risk is still very small, 6 in a million. For comparison, the annual death rate from motor vehicle accidents is 150 per million, or 25 times greater.

Why would people want to engage in what scientists call "risky behaviors" such as driving or living in a mobile home? For one thing, by taking on these risks, we receive benefits. Mobile homes are less expensive, and cars get you from place to place very conveniently. For most of us the risks associated with these behaviors are acceptable given the benefit. All risks must be

thought of in terms of risk and benefit. When it comes to treatment for arthritis and rheumatic disorders, or any medical treatment for that matter, we need to pay attention to absolute and relative risks, too.

We can make some simple rules to help guide us.

- No risk is acceptable if there is no benefit.
- No risk is acceptable if you don't need the benefit.
- No risk is acceptable if there is another treatment that is equally effective but does not carry risk.
- Risks have to be evaluated while considering all possible benefits.

You and I might be interested in the issue of risk because of an article that appeared in May in the *Journal of the American Medical Association* (JAMA). The article brought together cases of cancer and infection from all clinical trials of Remicade™ (infliximab) and Humira™ (adalimumab). The researchers found 24 cases of malignancy, and from those concluded that there was an increased chance of developing cancer and serious infections for people who used the drugs for rheumatoid arthritis compared with those who didn't use such drugs. The increased risk was 3.3 times for malignancy and 2.0 times for serious infection.

The number of cases of cancer that are found depends upon the number of persons taking a treatment and how long they take the treatment. Scientists tend to add up the number of persons treated and the number of years treated. They come up with a number called "patient-years" of treatment. The larger the patient-years the more reliable or believable are the study results. In the JAMA article, about 2,500 patient-years were found. You could think of this as meaning that 2,500 patients used the treatment for 1 year.

The NDB also has been studying the risk of malignancy and infection, based on information you provided. Because we have a much larger group of participants to study, we found many

*continued page 2*

## Risks and benefits (continued)

more malignancies. In fact, we found 543. However, we had 41,912 patient years. You could think of this as 10,000 patients followed for about 4 years. By having a larger group to study we can reach conclusions with a lot of confidence. We are planning to publish our analyses soon, but I want to share with you some preliminary results. In contrast to the JAMA study, we found the risk of malignancy was not increased in people who had used these drugs.

We are in the process of analyzing infections, but those results are not yet available. These results are another example of the way in which your self-reported data can clearly illuminate the issues that come up with these powerful medicines and potential side-effects. It's important to remember that because the drugs are still relatively new, neither study should be considered to be the final word.

In the current questionnaire we ask you if you have had some infections that we have not asked about before. Some are rare infections that most people have never heard of. Some are infections that people don't like to talk about, including genital warts. We are trying to find out if use of rheumatology drugs increases the risk of these infections. We hope you are

not offended by such questions, but your replies are important in helping us assess risk and benefit. Remember that your answers are always confidential and are never shared with anyone in a way that allows you to be identified.

As long as we are at it, I thought I'd tackle another interesting but hard



question. Do drugs cause side effects? Didn't we just say they do? We did, and you may have had side effects yourself. But the complete answer is that while we can say they cause side effects in groups of people we can almost never say that with confidence about one individual person. Let's use an example. Teenagers are twice as likely as older persons to die in auto accidents. Can we conclude that being a teen-ager caused a specific accident? No. In recent law suits discussed in the media, the arthritis drug Vioxx™, was found to "cause" heart

attacks by some juries and not by others. Can we conclude that Vioxx™ caused an individual person to suffer a heart attack? No. All we can say is that it might have. But perhaps it might not have. We really can't tell in the individual user, and millions of people all over the world who never used Vioxx™ also have heart attacks. However, we can use the information about Vioxx™ risk to guide our individual decisions about using that treatment.

In closing, let's make it even more difficult. Risk is rarely from one cause. Automobile accident risk increases when the driver is a male teenager, it is night, he is speeding, visibility is poor, and so on. Heart attacks come about from many risk factors that can be added together: cholesterol, weight, age, family history, other illness and medicines such as Vioxx™. Our role at the NDB is to measure the risk and benefit – with your help. Should you take any drug? Only if you need it. Should you take a drug with a known risk? Only if the benefit it gives is greater and more important to you than the possibility of a side effect. Think of that the next time you get into your car. And, by the way, buckle up. There is no benefit in not buckling up but there is risk.

## Welcome New SLE Participants!

About a year ago the NDB began enrolling people with lupus in order to study the outcomes of treatments of that auto-immune disorder. So far we've seen about 500 people with lupus join the NDB, and we expect to have more as the project continues. If you're one of those 500, welcome to the NDB! If you know someone with a doctor's diagnosis of lupus, please ask him or her to consider enrolling in the NDB. Every lupus patient enrolled will help with the success of this project.

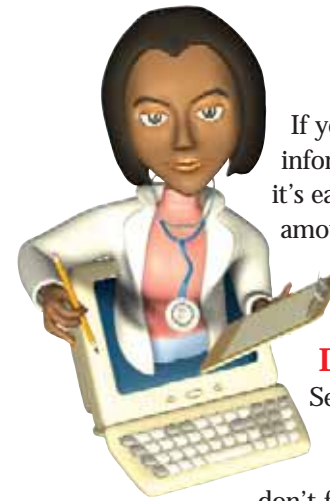
Lupus, or Systemic Lupus Erythematosus (SLE), is a chronic inflammatory disease that can affect various parts of the body. In the U.S., there are about 500,000 to 1.5 million people with this disease.

Our project is called SLE in the Community, or SLEC for short. We began the project because much of what is known and published about SLE comes from the work of a small number of academic centers. But we are also interested in the experience of people with the disease and the community rheumatologists who provide most lupus care. Because the NDB is a patient-centered data bank, it is well suited to the task.

## Questionnaire changes

We're always glad when we have an opportunity to shorten or simplify the questionnaire, and we know you are, too. This six-month questionnaire is once again shorter than the previous. We've also simplified the questions about medication cost. However, we want to know if you've enrolled in the new Medicare drug plan, sometimes called Medicare Part D Prescription Drug Plan, and how you picked your plan. As always, your answers remain confidential.

## Internet health information



If you've ever tried to find health information on the internet, you know that it's easy to be overwhelmed by the vast amount of conflicting answers to what seems to be a simple topic. Here are some tips for staying afloat while surfing the web.

### Don't believe everything you see.

Search websites like Google are popular and easy tools for finding health information on the internet. But they don't filter out the good from the bad. They just give you exactly what you ask them for. If you search for "arthritis cure" you'll see hundreds of web pages offering a cure or guaranteed relief. But we know that while there are good treatments, there are no cures yet. Likewise, if you search for side effects to your medications, you'll find horror stories and plenty of lawyers ready to help you sue drug manufacturers, even though we know that such cases are usually rare.

### What's the motivation?

Is the website trying to sell you something, whether a book, supplement or exercise program? Be suspicious. Consider the source. Are you looking at the website of a news organization you trust? Ask yourself, "How can I confirm this?"

### Do your own research.

Once you've found some information that seems useful to you, investigate it further. Do a search on the organization that is offering the information to see what other people say about it. Do a search on the key points of the information to see if you can confirm what you've found or to see what differing views may be.

### Ask your own trusted network.

The best resources are often the people you trust most and who know you best. Your doctor will be able to explain how information you find may apply to you. Your local support group or your friends may have some direct experience.

Medical information websites that are run by large news companies can be helpful. Advocacy associations for particular diseases have good depth of knowledge and can point you to further resources you may need. Pharmaceutical companies often have detailed information about individual medications, but they also serve as marketing tools.

Here is a list of some sites that we like, but there are many more good ones out there.

- arthritis.about.com
- webMD.com
- Healthday.com
- Patientlinx.com
- hopkins-arthritis.som.jhmi.edu  
(Johns Hopkins Arthritis Center)
- arthritis.org (The Arthritis Foundation)
- rheumatology.org  
(The American College of Rheumatology)
- arthritis.ca (The Arthritis Society of Canada)
- www.nlm.nih.gov/medlineplus/arthritis.html  
(MedlinePlus - Arthritis)
- lupus.org (Lupus Foundation of America)
- faware.org (National Fibromyalgia Association)

**Government and educational resources, such as medical schools and universities, are often safe bets. They aren't trying to sell you anything, and they usually have your own best interests in mind.**

### Keep in mind...

Don't forget that science moves forward, and what is accepted today may be refined, revised or refuted by future research. This is especially true of new conclusions and new treatments.

Of course, don't miss the NDB's own blog, [ndb.blogspot.com](http://ndb.blogspot.com), where we direct you to some of the latest rheumatology information after searching through the above sites and more.

## The NDB celebrates 25 years (continued)

individuals. That cannot be done with the paper versions because of bulk mail regulations and costs.

### Accomplishments

Since the beginning of the NDB in 1998, the NDB has claimed several accomplishments. Generally, it has created the methods for letting people tell doctors the way things really are. Doctors don't necessarily understand what it's like to have a disease, even if it's a problem they see and treat regularly. Specifically, the NDB has given doctors the tools to understand issues like how disease severity affects work disability, the long-term effectiveness of particular medications, the rate of problems like tuberculosis and other infections. This knowledge helps people get the most effective and safest care.

And now the Federal Drug Administration (FDA) is seeing the value of studies like the NDB to evaluate long-term drug

safety. In a new study required by the FDA, the NDB will follow as many as 20,000 people to evaluate the new drug Orencia™ (abatacept), starting in July 2006. Using a new enrollment system, each person in the study taking Orencia™ will be matched for disease severity and other factors with someone who is not taking it. This matching will allow even more accuracy when conclusions are made.

The NDB owes its longevity to the hard work of its staff, the support of the rheumatology community, and most importantly, the dedication and generosity of you, the participants in the NDB, who have continued to share a bit of your time and yourself to help others like you.

Again, thank you so much for all the time you've given us over the last 25 years. It would not have been possible without you!

*Every six months the NDB staff process thousands of questionnaires using high-speed scanning equipment and handwriting recognition software. Every questionnaire is tracked from the moment it enters the building. After all the answers have been saved on computers and backed up, the stacks of forms are shredded and recycled. Completed WebQuests go directly into the NDB's computer system.*



### 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 Elizabeth Pall, Overland Park, KS; Chloie Luckow, Bear Creek, WI; Jeanie Beal, Frisco, TX. Winning smaller amounts were Geraldine Green, Overland Park, KS; Carolyn Dinkins, Valdosta, GA; Evelyn Kreutz, Golden, CO; Evelyn Beluzo, Heights, MI.

***Congratulations to all!***

## The NDB celebrates 25 years of research

Although the NDB has existed in name just since 1998, it contains self-reported information from patients seen in Dr. Wolfe's clinic going back much further. In fact there are some NDB participants who've been with the NDB for 25 years without missing a questionnaire. We knew that people with arthritis and other rheumatic diseases had very important information to share with doctors and researchers. However, we could not have wished for more dedication and help than we've received.

"I didn't imagine that people would stick with it for as long as they have. I think there's a sense of camaraderie, of wanting to help contribute to making life understandable to doctors, that keeps people doing it. Rheumatologists around the world owe NDB participants a debt of gratitude," Dr. Wolfe explained.

### Data collection starts

Data collection began in 1974 with WANG mini-computers. Dr. Wolfe systematically recorded clinical data from every patient at every visit to his Wichita, KS clinic. He continued this until 2004, when the growth of the NDB didn't allow him to give patients the attention they needed. His focus then turned full-time to developing the NDB.

In 1981 the Wichita clinic began working with ARAMIS (Arthritis, Rheumatism and Aging Medical Information Systems) of Stanford University in California. ARAMIS broke new arthritis research ground by collecting patient-reported data at a time when clinical trials dominated the research world. ARAMIS introduced the familiar six-month questionnaires, a pattern still used at the NDB.

### The NDB is formed

But ARAMIS collected data only from a few locations in the US and Canada, and this limited the usefulness of its research conclusions. A wider, more general approach to collecting data was needed, and in 1998, the National Data Bank for Rheumatic Diseases was founded. The goal was to allow any physician and his or her patients to participate.



*Dr. Wolfe discusses NDB research with other rheumatologists at one of the many conferences he attends every year to bring research results to the rheumatology community.*

Since 1998 more than 900 doctors and 20,000 patients have participated in the NDB. It was at about the same time, that new drugs for rheumatoid arthritis were being introduced. There had been little change in medications available for 20 years. But the the Cox-2 inhibitors like Vioxx™ and Celebrex™, and the first biologic medicines like Enbrel™ were starting to become available. The NDB was perfectly suited to conduct long-term research into the effectiveness and safety of these new medicines.

### Why the NDB is different

With patient-reported data, researchers gained a perspective that short, small clinical trials could not provide. The NDB started answering questions like: Does it work? How much better is it?

What are the side-effects? How long are patients staying on the treatment? This was a real-life look at the course of patients' experience with a medication and it included everyone, not just people in clinical trials.

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.

The NDB also started to show rheumatologists what patients really thought about problems like pain and fatigue, because the research results are based on how people say they are feeling, not how doctors believe people feel.

However, as time went by the NDB learned of an important challenge with patient-reported data, one that now has become a major portion of the data bank's work. Journals would only accept NDB research if incidents like heart attacks, cancers and infections were confirmed. So the NDB now spends considerable time on the phone with participants, their doctors and hospitals to double-check and get more information about what people say has happened with them in the last six months.

The NDB has been able to streamline some of the work by constantly looking for new and faster ways to get the answers into the computer. These ways have included high-speed scanners, special hand-writing recognition software, and using the web. Web-based questionnaires have been particularly beneficial because many people find them easier to use, and the web allows the NDB to customize questionnaires for

*continued other side*