THE
Arthritis Research
NEWSLETTER

July 2003

Research Notes from the Director

So far 2003 has been a very exciting and busy year. Earlier this spring, we presented NDB data at two meetings of the FDA. At the first meeting, NDB results for lymphoma, a kind of lymph cancer, were discussed. NDB research showed that lymphoma was rare among persons with RA, occurring in about 90 persons with RA and 69 patients without RA each year. NDB research did not show evidence of increased risk with Enbrel® or Remicade®, the TNF drugs. These results have been submitted for publication. The 'bottom line' is that this is a very rare condition, and it does not seem to be associated with RA treatments.

The NDB also presented safety data on Arava® at the FDA meeting. NDB research, in agreement with a number of other studies, found no evidence of increase in acute liver failure among persons using Arava®.

We did find, however, that the risk of another rare condition, tuberculosis, was increased among persons treated with Remicade®. This information has been submitted for publication and to the American College of Rheumatology (ACR) meeting in October 2003. Tuberculosis may occur shortly after starting Remicade® in a very few persons who have a positive skin test for tuberculosis. The actual rate was 53 cases for every 100,000 persons exposed to Remicade® for one year. It appears, however, that this rare condition can be prevented by skin testing for previous tuberculosis infection before starting Remicade®.

In some other breaking research, the NDB and the 2002 CHORD fellowship program reported to the ACR that the risk of recurrence of cancer was reduced among persons receiving anti-TNF therapy. We also found no association between heart failure and the use of TNF agents.

The NDB has just submitted its research on fibromyalgia using newly developed criteria. This work is in progress and we hope to give you more details in our next newsletter.

One last research result, that may be of interest among the many items now being submitted for publication, is that we have determined the actual medical cost of RA. This information will soon be published in the medical journal, "Arthritis and Rheumatism". It may help establish the need for financial support of arthritis treatment.

As always, we extend our thanks to all of you who by participating in NDB research advance knowledge of arthritis and arthritis treatment.

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 data bank can best contribute to research when the mailed 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 Ella Williams of Raysal, WV; Donald Mead of Wichita, KS; Judd Pickering of Brookhaven, MS.

Congratulations to all !

Costs of Medications.

If you have been following the debate just starting in congress about payment for drugs under the Medicare program, you may also have seen articles about people buying their medications from Canada. Some state legislatures, congressmen and patient organizations have strongly supported purchasing drugs from Canada. However the US Food and Drug Administration (FDA) and drug manufacturers are opposed. How much of a problem are costs for people with arthritis? Who has the problem?

During the last 18 months we have been asking about your ability to pay for medications in our NDB questionnaires. Overall, about 20% of persons with arthritis or fibromyalgia did not get some medications because of cost and 3% didn't have surgery because of costs. The graphs on this page provide some insight into possible reasons. Figure 1 shows that the worse function you have the more difficulty you have obtaining medications or having surgery. Almost 30% of persons in the worst category did not get some medications because of cost. Figure 2 gives some further insight into the issue. It shows that total family income is a major factor in the ability to get needed medical services. Function and income go together. The more difficulty you have with function, the less likely you are to be working, the lower your salary if working, and the higher your medical bills.

20% of persons with arthritis or fibromyalgia did not get some medications because of cost

And the situation is getting worse. To cut their costs, insurance plans are covering less and insurance rates and Medicare premiums are going up. Are their any villains? Certainly many drugs cost too much – thus the reason people are trying to buy medications from Canada. A second serious problem in the US is the inability to get insurance for many people whose work ability is limited because of arthritis or who are not working. Still another problem is the higher insurance costs that are sometimes charged to those who are ill with arthritis. These types of problems are societal, although they affect each of us individually. If you see this as a problem, you might want to let your congressman know.

Over the last year we have been doing additional research into arthritis costs and will be publishing these results soon. For this information see the "Notes from the Director" section on page one.

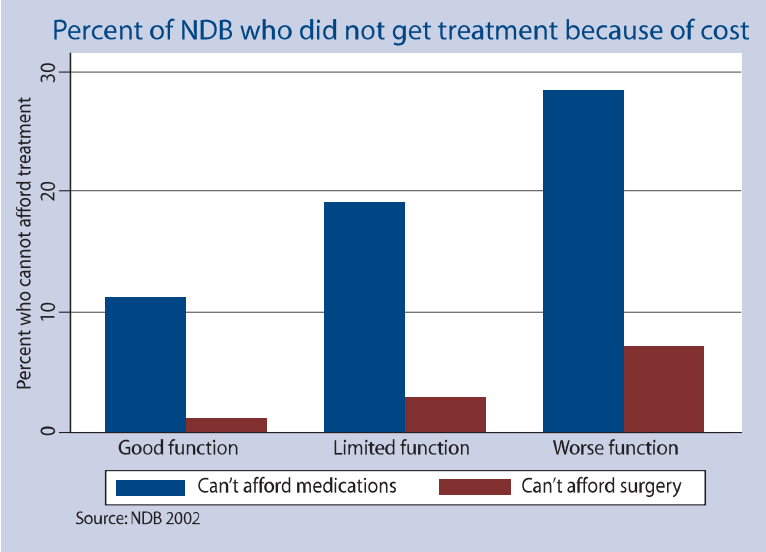


Figure 1

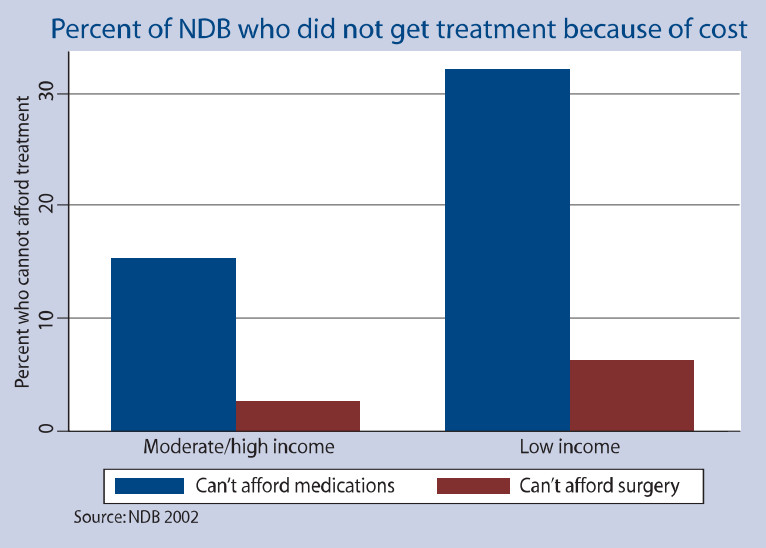


Figure 2

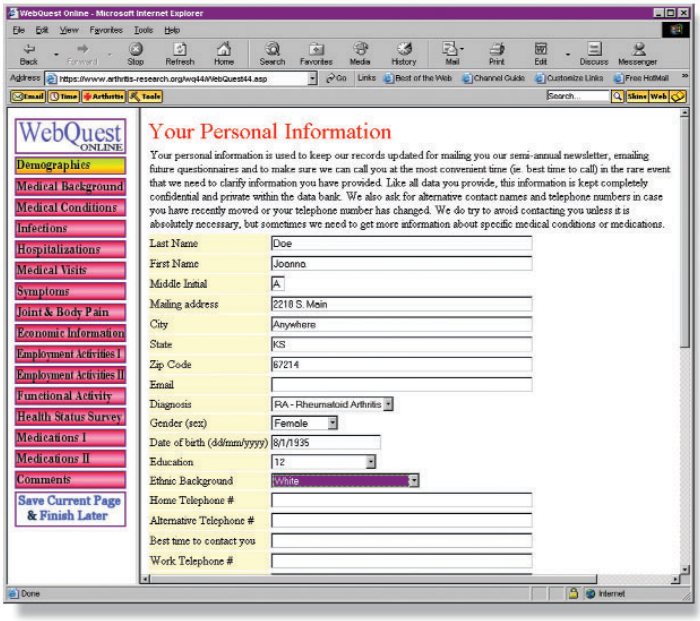
FOR MORE INFORMATION OR TO PARTICIPATE

Arthritis Research Center Foundation, Inc.
1035 North Emporia • Suite 288,
Wichita, KS • 67214
Director -- Frederick Wolfe, MD
Executive Director -- Kathleen Urbansky

please call 1-800-323-5871 ext. 133
or email info@arthritis-research.org

WebQuest: Trying the Questionnaire on the Internet

Two years ago, at the request of many of you, we launched an Internet version of the NDB research questionnaire. We call it `WebQuest.' Most people who have used it were quite pleased. In many respects, it is easier to use than the larger paper questionnaire. Here are some of its features.



WebQuest is smart. Depending on your answers, WebQuest can skip many unnecessary questions. This makes the questionnaire shorter and filling it out quicker. WebQuest also makes sure you don't inadvertently miss some questions, which limits having to call you about missing items.

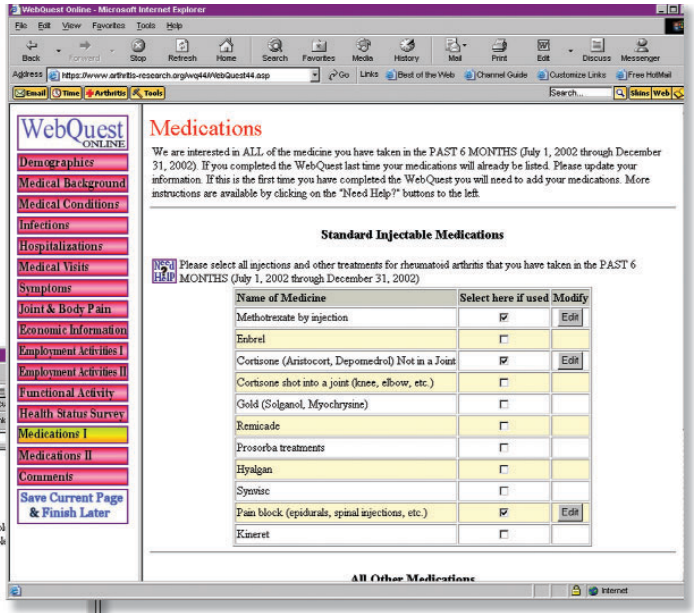
WebQuest remembers your answers from questionnaire to questionnaire. When you use the WebQuest, it shows the treatments you reported last. That makes it easier for you to identify changes, or even to correct errors.

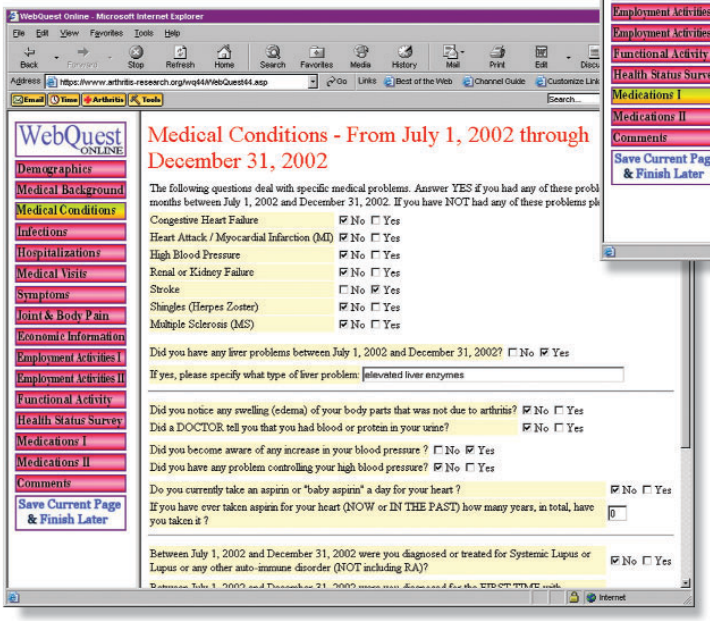
You don't have to do WebQuest all at once. If you log off, WebQuest remembers where you stopped and starts you there again.

On the [right] are some actual pictures of WebQuest from the Internet to show you how simple and friendly it is to use. Even if you have received a paper questionnaire, you can do WebQuest instead.

If you are interested in trying the on-line questionnaire for the first time, or if your email address has changed, please let us know at webquest@arthritis-research.org or call us at 1-800-323-5871. We will send you everything you need to get started. If you completed the WebQuest last time you will be automatically emailed a new invitation.

Thanks again for your feedback and patience. We expect this version of the WebQuest to be the best yet.





CHORD Health Outcomes in Rheumatic Diseases Fellowship Program Update

CHORD is a program sponsored by Centocor, Inc. and directed by NDB director, Frederick Wolfe, Theodore Pincus of Vanderbilt University, and Hyon K. Choi of Harvard. Physicians who were named as fellows in this program are training to be rheumatologists. During the yearlong fellowship training, CHORD fellows will study with Drs. Wolfe, Pincus and Choi using the research data from the National Data Bank.

In the last newsletter we listed the physicians participating in the 2002 program. Many of these fellows have already submitted their research results to the 2003 American College of Rheumatology meeting. We will report more information on their research in the January 2004 newsletter.

The figure below is a list of the fellows and their affiliations for both the 2002 and 2003 programs.

Congratulations to Rheumatology Fellows associated with the

CHORD
Fellowship Program

The CHORD Fellowship Directors are proud to acknowledge the outstanding contributions of the outgoing 2002-2003 CHORD Fellows

We hope that your experience has provided a solid foundation for continued growth and accomplishment in rheumatology

WELCOME 2003-2004 CHORD FELLOWS

Now incoming CHORD Fellows can have this same opportunity for broad experience in clinical epidemiology and outcomes research

We welcome you... and look forward to a dynamic and challenging year!

2002–2003 CHORD FELLOWS

Shahin Bagheri	University of Iowa
Victoria Cartwright	Seattle Children's Hospital, University of Washington
Elizabeth Benito Garcia	Brigham & Women's Hospital, Harvard University
Jeffrey Greenberg	New York University
Abha Gupta	Yale University
Melissa Hawkins-Holt	University of Maryland
Dinesh Khanna	UCLA
Sung Lim	Emory University
Richard Stern	University of Texas Southwestern Medical Center
Kent Ta	University of Washington
Sergio Toloza	Catamarca, Argentina
Nancy Walker	University of Massachusetts
David Wu	Massachusetts General Hospital, Harvard University
Yusuf Yazici	New York City

2003–2004 CHORD FELLOWS

Mir Asgar	Wayne State University (SPLIT FELLOWSHIP)
Michael Cassetta	Mt. Sinai Hospital, New York
Eliza Chakravarty	Stanford University
Laura Davies	Oregon Health Sciences Center
Esi Dewitt	Children's Hospital of Philadelphia, University of Pennsylvania
Sherry Guardiano	The George Washington University
Andrew Head	University of Tennessee
Eric Hochman	Washington University, St. Louis (SPLIT FELLOWSHIP)
Diane Kamen	South Carolina Medical School
Liron Kaplan	Washington University, St. Louis (SPLIT FELLOWSHIP)
William Kcomt	University of Indiana
Eric Lieberman	Massachusetts General Hospital, Harvard University
Jag Mangru Lor	University of Iowa
Ioana Moldava	State University of N.Y. – Downstate Med Center
Mihail Moroianu	Wayne State University (SPLIT FELLOWSHIP)
Paola de Pablo	Brigham & Women's Hospital, Harvard University
Johnny Su	University Hospital, Cleveland
Brian Wallitt	Georgetown University

The Centocor Health Outcomes in Rheumatic Diseases (CHORD) Fellowship Program is sponsored by the Arthritis Research Center Foundation and Vanderbilt University, under a grant from Centocor, Inc.

Centocor

HIPAA and the NDB - Frequently Asked Questions:

The Heath Insurance Portability and Accountability Act went into effect April 14, 2003. The law covers several elements of healthcare information transfer, but the most important element to most people is the Privacy Rule. This rule protects your health information from being shared with anyone unless you give authorization. This law protects the information that we collect from the NDB. Below are some frequently asked questions about how the NDB uses and shares your information.

Does the NDB share information and if so what information will be used or disclosed?

The NDB uses your health information related to this study in specific research projects. The information we use includes, but is not limited to, your medical history, symptoms, treatments, side effects, hospitalizations, infections, and work history. In addition, information from hospital or physician records is used to clarify the information you provide.

Who may use and disclose the information?

The following parties are authorized to use and disclose your health information in connection with this research study:

- The Director of the National Data Bank for Rheumatic Diseases (NDB), Frederick Wolfe, MD, and the research and data collection staff of the NDB.
- A legally constituted review board charged to protect the safety of human subjects in medical research, called the Via Christi Institutional Review Board (IRB).

Who may receive / use the information?

The parties listed above may disclose your health information to the following persons and organizations for their use in connection with this research study:

- Qualified medical researchers at other universities.
- The US Food and Drug Administration (FDA)
- Sponsors of the research study.
- Your rheumatologist or physicians.
- A legally constituted review board charged to protect the safety of human subjects in medical research, called the Via Christi Institutional Review Board (IRB).

If I have already signed an authorization or consent do I need to sign another one?

No. Anyone who signed a consent form for the NDB before April 14, 2003 does not need to fill out an additional form.

Can I be identified personally?

No, with 3 exceptions: 1) we may share identifying information with your rheumatologist or physicians if, for example, we contact your physicians to clarify information you have provided; 2) if requested by the human subjects safety board (IRB); 3) if ordered by a court. Otherwise, information that will allow you to be identified personally (e.g., name, address, social security number, etc) will be removed from all information used by 1) medical researchers at other universities, 2) FDA, and 3) study sponsors.

New Arthritis Drug Released.

Earlier this year, Abbott Laboratories released Humira® (generic name: adalimumab) for treatment of rheumatoid arthritis. Humira® is an anti-TNF agent that appears to be as effective as the other two anti-TNF agents, Remicade® and Enbrel®. One advantage of Humira® is that it is given by self-injection every two weeks, compared with Enbrel® that requires two injections per week, and Remicade® that requires intravenous infusions. Like Enbrel®, Humira® will not be covered under Medicare reimbursement; and like the other TNF agents it is expensive with costs in excess of $15,000 per year. Other biologic agents are also being tested, including CTLA4ig and Rituxan. These drugs may be available starting in 2005.

News from the NDB Staff:

Celebrating our 5th Year!

The NDB has reached the 5-year mark. A lot has changed through 10 questionnaires, and we are continuing to make the questionnaire as simple and straightforward as possible without losing any critical information needed for our research.

Below are a few changes you can expect to see in July's questionnaire:

1). The questionnaire has been reorganized so that questions dealing with specific types of information (i.e. medical conditions, economic information, medications) are grouped within a few pages. This means you won't have to flip back and forth from one part of the questionnaire to another to make sure you answered questions consistently.

2). The Injectable Medication page has been eliminated. All injectable drugs are VERY important to us, but to help shorten the questionnaire we removed this page. Now ALL injectable drugs should be written in like your other medications. There are special instructions on the first page of the drug section. PLEASE review these instructions to make sure we collect the dosage and frequency of use accurately.

3). You will also see some new questions associated with a new osteoporosis study. The questions ask for information about fractures, bone density tests, and a special "Women's Only" section. Since osteoporosis largely affects post- menopausal women this section is very important.

In Brief, What's Coming...

Many of you have asked for information about new medications or treatments, and what other things are happening in arthritis research. So, we have added this section to the newsletter hoping these items will be of interest to you.

- The American College of Rheumatology News reported in the May 2003 issue that new biologic agents have been developed for the treatment of psoriasis which may greatly improve the quality of life for patients living with psoriasis and psoriatic arthritis. Alefacept is the first biologic to be approved by the FDA for this treatment. Etanercept (Enbrel®), efalizumab, and infliximab (Remicade®) are other biologic agents that are in the final phases of testing to be approved for psoriasis treatment.
- The National Institute of Environmental Health Sciences (part of NIH) has created a new group called the Environmental Autoimmunity Group (EAG) that will conduct pioneering research in the area of genetic and environmental risk factors that may result in autoimmune diseases such as rheumatoid arthritis. The EAG is is currently enrolling patients for a new study. Additional information can be found at their website www.nih.gov/news/pr/apr2003/niehs-21.htm or by calling the NIH directly at 800-411-1222.
- Teriparatide (Forteo) was approved by the FDA in late November 2002. Forteo is used to treat osteoporosis in postmenopausal women. It is also used to increase bone mass in men with osteoporosis who are at high risk of fracture.
- Earlier this year Etanercept (Enbrel®) was submitted to the FDA for the treatment of ankylosing spondylitis. If approved, Etanercept would be the first medication used for this disease that is not a non-steroidal anti-inflammatory drug (NSAID).

If you have any questions or would like to contribute information please contact us at 800-323-5871 x124 or email us at info@arthritis-research.org.