THE NDB Research NEWSLETTER

News for Participants in the National Data Bank for Rheumatic Diseases July 2008

Notes from the Director

Frederick Wolfe, MD

Addressing your important questions

Two recent comments we received from NDB participants were right on the mark. The first asked, "What is this survey accomplishing to make things better and to provide better general medical care. What is the goal of this survey?" The second admonished us to be concerned about personal medical costs.

Among our goals, we work to provide information to participants, doctors and health planners about safety and effectiveness of treatments, costs and cost-effectiveness, outcomes, symptoms and diagnosis. Below are some of our current activities that we thought might be of interest.

In the next few months, two important NDB articles will be published in major medical journals. They deal with risk of heart attacks and strokes, and the effect of medications that are used in arthritis treatment. We found that people with rheumatoid arthritis (RA) have an increased risk of these events. We discovered that prednisone (cortisone) use seemed to increase the probability of developing high blood pressure and diabetes, illnesses that do have increased probabilities of heart attack and stroke. About 35% of people with RA and 50% of those with lupus in the NDB use prednisone. Prednisone is a complicated issue, as it has both good and bad effects. With NDB data in mind, we expect that other studies will further clarify its effect.

One of you wrote to us about Sjögren's Syndrome, a condition of severe dryness of the mouth and eyes. It is often seen in lupus and rheumatoid arthritis. Well, we didn't have data on Sjögren's Syndrome, but we did have information on dryness. This information is now being published in the Journal of Rheumatology. About 30% of you have either dry eyes or dry mouth symptoms. These symptoms are caused in part by medications used for high blood pressure, sleep problems, muscle relaxants, analgesics, and drugs used to treat anxiety and depression. Alas, they are also caused by aging, and by the severity of your rheumatology problem. It's a complicated study, but if you would like a copy of it, send us an email, write or call.

We also have exciting results from our work with fibromyalgia.

One of the most important ways the NDB advances treatment is to aid in the development of new criteria for the diagnosis of fibromyalgia. Fibromyalgia, a disorder of chronic body-wide pain, has been a controversial condition. In 1990 I helped to develop the American College of Rheumatology (ACR) criteria that are used everywhere in diagnosing fibromyalgia. Over the years it became apparent that extensive revisions of the criteria were needed. But where to start? What would work? We used data from the NDB to identify characteristics of fibromyalgia that provided a start to the criteria development process. We did this by comparing information supplied by those of you with fibromyalgia and those that did not have fibromyalgia. We are going to present some of this information at the American College of Rheumatology annual meeting this fall. Write us if you want some additional details.

> *"...It became apparent that the fibromyalgia criteria need extensive revisions."*

One of you wrote to us commenting about the cost of medical care, particularly out-of-pocket costs, and said we needed to address this issue. The NDB is not an advocacy group, but you might have guessed that we share many of your concerns about getting and paying for medical care. There are two components of costs that you experience, the cost of medical insurance and out-of-pocket costs. Out-of-pocket costs are what you pay after your insurance has paid all it will. Sometimes these costs are known as co-pay or co-payments. For most people figuring out co-pay is difficult because the insurance forms and letters can seem endless, and new bills can come in before the old ones are reimbursed or paid. One of the tactics that insurance

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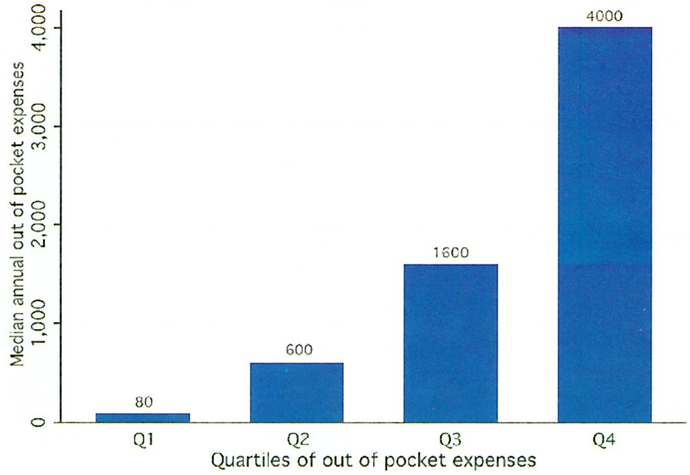
Notes from the Director (continued)



companies use to keep their premiums from sky-rocketing even more than they are already doing is to increase the out-of-pocket amount that you have to pay.

We analyzed your replies about out-of-pocket costs, and will be reporting this information at the American College of Rheumatology annual meeting in the fall. But here are some of the results. Half of you have trouble with out-of-pocket costs and have to defer other purchases or put off obtaining medical care because of such costs. About a quarter of you pay about an average of $4,000 a year in out-of-pocket costs (Figure 1), or about $80 per week after your insurance has paid all it will pay. The more severe your rheumatic illness is the greater are the out-of-pocket costs, the lower your household income, and the more likely the costs will be an important burden to you.

While it will be the case that the people with lower incomes will find it more difficult to pay, our research suggests that lower household income correlates with more severe illnesses. People of working age with rheumatic diseases earn less and are not as often able to purchase affordable insurance. In addition, people with more severe illnesses require more treatments and usually more expensive treatments – all of which lead to greater out-of-pocket costs. Rheumatologists often see people who cannot obtain insurance, cannot afford it, or have huge premiums just because they became sick.

In the next four years there will be much discussion of reforming the US health care system. Universal health coverage can go a long way toward reducing the financial burden surrounding medical care for those who are sick or poor. It can solve some but not all of our problems. Medical care in the US is much more expensive than in any other industrial country, and our health outcomes are not as good as those obtained in a number of other countries. As the debate about health care goes forward we should ask why costs are so high and where the money is going. As I noted above, the NDB cannot be an advocacy group, although many of us have strong opinions. We'd be interested in your thoughts and experiences. Just send us an email.

> *"...In the next four years there will be much discussion of healthcare reform in the U.S."*

FOR MORE INFORMATION OR TO PARTICIPATE

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Frederick Wolfe, MD, Director Rebecca Schumacher, Executive Director
Please call 1-800-323-5871 ext. 140 or visit www.arthritis-research.org

The NDB wants to know:

Who is getting total joint replacements and why, or why not?

By Debra Bergman, University of Nebraska Medical Center MPH candidate

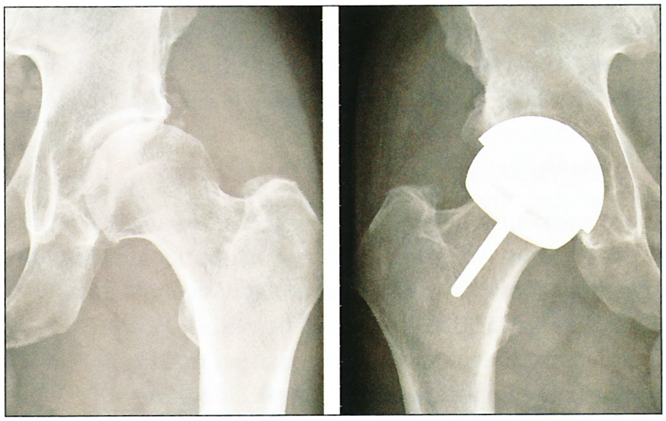
For many people with arthritis, a total replacement of a severely affected joint offers a significant reduction of pain and increase in function. In 2003, approximately 418,000 total knee replacements and over 220,000 hip replacements were performed in the U.S. And in the NDB, 20% of all participants received a joint replacement in the past 10 years. Now we want to know more about how TJR works for you.

While we have always asked about your experience with total joint replacement (TJR) surgery, we're asking some new questions about your perception of TJR. Have you ever been told you need a TJR? What factors influenced your decision?

> *"...it is important that patients learn the likely personal consequences (good and bad) of the surgery."*

In 2003, the National Institutes of Health concluded that because TJR is an elective procedure with risks and a range of possible outcomes, it is important that patients learn the likely personal consequences (good and bad) of the surgery. Both patient and doctor need to express any goals and expectations, hopes and fears, before the surgery to determine what outcomes are attainable and which expectations are realistic. Any discrepancies between the patient's expectations and the likely surgical outcome should be discussed in depth before surgery.

What is total joint replacement?



(R) Xray of hip with TJR *Photo by Tom Gotchy*

In general terms, a joint is the junction of two bones separated by cartilage and lubricating fluids, and held together with muscle and connective tissue. In damaged joints the bones can rub together, which may be very painful. Modern joint replacement replaces the damaged or worn cartilage (and sometimes some of the bone) with a metal, ceramic or plastic implant. The implant resembles and functions similarly to a normal joint. Most joints in the body can be replaced, but hip and knee replacements are most common.

> *"More than 20% in the NDB had a total joint replacement in the past ten years."*

Joint replacement surgery is often recommended to patients who have tried non-surgical treatment but still experience significant joint pain. Total joint replacement may be the last, rather than the first, treatment option for patients with advanced arthritis of the hip, knee, or shoulder. According to the Federal Drug Administration, for knees, the procedure usually means 3 or 4 days in the hospital. Recovery period at home depends on patient health, age and other factors. Most people return to normal activities in 4 to 8 weeks. Infection at the site of the replaced joint is one risk of the surgery, not only as an immediate effect, but also later in life. Another concern is the durability of the new joint. Materials are improving, but it's possible for replacements to wear out and need to be replaced in what is called revision surgery.

Total Joint Replacement (continued on page 4)

How many people receive total joint replacement?

In 2003, approximately 418,000 total knee replacements and more than 220,000 hip replacements were performed in the US, according to the American College of Rheumatology. These numbers will continue to grow as the population ages. In a 25-year follow-up study of patients with RA, more than a fourth (27%) of patients underwent either total hip or knee replacement surgery. And over the past 10 years in the NDB, more than a fifth of NDB research participants have had a TJR, specifically 29% with osteoarthritis and 23%.with RA.

What influences the choice to receive a TJR?

Joint replacement is a "preference-sensitive" medical treatment option, which means that as an optional procedure with risks and both pros and cons, an individual needs to consider whether a TJR is appropriate. Within a consumer-minded health care system, shared decision making is becoming more important. But those decisions are still affected by patient attitudes and perceptions. Gillian A. Hawker wrote in *Current Opinion in Rheumatology* in September 2006 that research shows patients' willingness to consider total joint replacement varies by sex, race/ethnicity, and socioeconomic status as a result of what people know and believe about the procedure. Willingness decreases with increasing age. In addition, patients' expectations and self-confidence are important potential predictors of postoperative outcome.

> *"Research reveals that doctors under-prescribe total joint replacements."*

Who is getting TJR in the US?

Research reveals that doctors under-prescribe replacements for severe arthritis in both sexes, but the degree of underuse is more than three times as great in women as in men. Studies have shown that Caucasian women are twice as likely to undergo total knee replacement arthroplasty (TKA) as African-American women, and Caucasian men are as much as 5 times more likely to have TKA than African-American men. Another study found that Hispanic patients receive joint arthroplasty approximately two-thirds less often than did Caucasian patients.

Gender and race treatment differences have received national attention in the United States. The reasons for these disparities are complex and not well understood. Treatment preference, physician-patient communication style and access to specialist care affects patient knowledge of the procedure, as does having a family member or friend who had undergone the surgery. Pain is the primary patient-reported reason for undergoing TJR, followed by difficulty walking.


Knee implant
Photo by Matt Burke

What does the National Data Bank (NDB) know about TJR?

We conducted a study looking at the impact of total knee replacement on patient-reported pain and health-related quality of life in patients with arthritis. The findings were presented at last year's national scientific rheumatology meeting. We identified 656 of you who received total knee replacements (TKR) for the first time while participating in NDB research. As expected, we showed that before TJR, patients had increased disability, pain and disease severity compared to those who did not receive joint arthroplasty. After the procedure, TKR produced important reduction of pain in the affected knee and overall improvement in most outcome measures. The improvement was greater in osteoarthritis than rheumatoid arthritis patients. Further, the primary outcome of TJR may be to stabilize function, but not to return it to pre-disease levels.

Studies consistently indicate that among people living with disabling arthritis in which TJR would be helpful, there is significant unwillingness to consider TJR as a treatment option. The NDB is interested in understanding how well TJR works or doesn't work for some people. Additional information on patients' perceptions of TJR is necessary to allow the healthcare system to improve a person's ability to make an informed decision about receiving a TJR. The goal is to reduce pain and improve quality of life for patients with arthritis.

We hope that our new questions will be part of an increase in research on TJR. In particular, patients and doctors need to know more about quality of life and complications from TJR in people with RA so that everyone who needs the procedure understands it and makes a personally appropriate choice.

LATEST RESEARCH

Out-of-pocket medical expenses hit women hardest

We often receive questions, and sometimes complaints, about our questions on financial information. People want to know why we need that information and how it helps. This new piece of research shows just how useful it is. Ideally, this information could help direct healthcare decision makers and reformers.

To evaluate the financial burden of out-of-pocket expenses (OOP) we studied 5,665 NDB participants aged 18 to 65 years, including 3,825 with rheumatoid arthritis (RA), 618 with lupus, 804 with fibromyalgia, and 418 with other non-inflammatory rheumatic disorders.

It turns out that the burden has more to do with the disease and the person than how much is actually spent OOP, and it has even less to do with the type of insurance or total medical expenses.

We found that 50% of participants experience financial burden because of OOP medical expenses. Worse yet, 12% reported not being able to purchase all the care they needed. Financial burden hits women the hardest, especially if they are unmarried. Lower education levels are also related to increased burden, as is disease severity.

Looking at diseases themselves, financial burden is not affected by rheumatic disease type except in fibromyalgia. People with that disease reported significantly worse financial burden.

Participants reporting severe financial burden spend less in drug costs, but have greater hospital and outpatient costs, lower education levels and more severe illness.

Financial burden in Rheumatoid arthritis

Applying some of the above questions to RA, we found that almost half of people with RA have difficulty in paying for medical care, and 12.2% are unable to purchase all the medications or care they need. In terms of yearly out-of-pocket expenses, the top 25% of people with RA spend approximately $4,000. The prime determinant of financial burden is household income, and for many this is determined by RA severity and disability, both of which directly affect income. People with the most severe RA are least likely to receive biologic therapy.

What about those work-related questions?

As you know, we ask a lot of questions about work and time off work because of your rheumatic disease problems. We want to know how the overall costs of rheumatic diseases affect society at large. In other words, societal cost is the sum of time off work and money spent on treatment, including hospital and outpatient expenses. Of course there are other effects on families and communities that are hard to measure and are not covered by our questionnaires. Looking at RA, lupus and fibromyalgia, here's what we learned.

Average yearly direct medical costs per person were:

- Fibromyalgia — $5,953
- Lupus — $8,124
- RA — $15,895
- Other rheumatic diseases — $5,671

Among working age adults, the societal impact of work disability is greatest for fibromyalgia because of the higher occurrence of the disorder in the general population. Annual direct costs are very high in RA because of expensive drug therapy. But the societal direct costs of the larger number of people with fibromyalgia make the costs equal.

LATEST RESEARCH

Muscle pain helps identify fibromyalgia

You may be aware, especially if you have fibromyalgia, that diagnosing the disease is somewhat problematic. Many general practitioners aren't familiar with the disease, and not all rheumatologists agree on what it is and how to treat it.

The American College of Rheumatology, the national scientific organization for rheumatologists, has long-established guidelines for making a fibromyalgia diagnosis, but they are often not used in doctors' clinics.

We decided to look at what factors are common to fibromyalgia compared to other rheumatic diseases and see if there were any predictors that could help doctors make a diagnosis.

By comparing 1,688 people with fibromyalgia to the same number of people with RA and again to people with other rheumatic diseases, we learned that muscle pain is the top difference. Compared to RA, people with fibromyalgia have noticeably more muscle pain, chest pain and irritable bowel syndrome. Compared to other diseases in the NDB the differences are muscle pain again, the count of painful body areas, and age.

We think that using these indicators doctors can develop simple measures for diagnosing fibromyalgia.

A new way to measure the effects of lupus

People with lupus may be familiar with the SLICC/ACR damage index (SDI). It's a road-tested index developed by international consensus to measure systemic lupus erythematosus (SLE) damage. But it's hard to administer, requiring a well-trained physician.

We developed a patient self-administered version of the SDI. We call it the Lupus Damage Index Questionnaire (LDIQ), and it has been validated by simultaneous administration of the SDI and LDIQ in 1,281 people world-wide.

After comparing results of the LDIQ from the NDB survey, we think it can be used as a clinical and research questionnaire, but more study will be needed to confirm that.

Doctors and patients mostly agree on RA remission

One of our newer questions asked people with RA if they were in remission. We compared the answers with their doctors' answers and found pretty good agreement. Doctors reported that 35% of patients were in remission, and patients reported a 31% remission rate.

However, there were many people reporting more than minimal levels of activity, pain and functional limitation, and some with high levels. This suggests that patient and physician assessments are both incomplete, and that no gold standard definition of remission yet exists.

In Memoriam

After a long and courageous battle, cancer claimed the life of one of our co-workers, Debbie Esslinger, who had been with the NDB for nearly 11 years. A beautiful person both inside and out, Debbie was dedicated to her work of making sure everything was accurate and complete. If you ever neglected to sign your questionnaire, you may have received a call or letter from Debbie. She will be truly missed by us, her family and all who knew her.

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 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 old timers.

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 government.

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 can not 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.

Questionnaire changes

The NDB will investigate a few new topics starting with the current questionnaire. As reported in the article in this newsletter about total joint replacements (TJR), we want to know your experiences with TJR, even if you decided not to have the procedure done to you.

Hair loss is an important side effect for many people. We're asking you to report your experience with it and how it affects you.

Also, you will see new questions on eye problems and mouth problems.

If injected or infused medications are a treatment option for your condition, we're interested in whether you've ever had injection site reactions, and if so, what the effects were.

If you have any questions about these new topics as you go through the questionnaire, please send an email or give us a call.

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 Valerie King, Granton, WI; Robert Chambers, Lincoln, NE; Virginia Barker, Caldwell, KS. Winning smaller amounts were Nancy Frost, Elkhart, IN; Stephen Smith, Camden, TN; Sharon Wallace, Yucaypa, CA; Connie Fisher, Henderson, NV. Congratulations to all!

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!

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

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.

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!

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.