

THE NDB Research NEWSLETTER

News for Participants in the National Data Bank for Rheumatic Diseases January 2015

Notes from the Directors

Kaleb Michaud, PhD

Why questionnaires?

When I visit my rheumatologist, I am always handed a paper questionnaire to fill out. This has been true for me for as long as I can remember (more than 35 years!), and I've visited several different rheumatologists during this time. Each form has been different, although they often asked about the same things. And each doctor was different about how they used these forms – some went through them carefully (yay!) and others ignored them completely (ugh).

Why have questionnaires in the clinic? Because rheumatologists, before many other doctors, figured out that watching how the answers to these questions change over time was very important in determining how their patients with arthritis were doing (again, I'm using "arthritis" to cover for RA, OA, JIA, lupus, and lots of other chronic rheumatic diseases). They developed many questionnaires to determine our level of physical function, pain, mood, and many other aspects of our health affected by arthritis. Once we had new and better treatments, doctors learned that our responses also improved.

But some of these questions created in the 60's and 70's are no longer as useful either because of changes in our culture and homes (e.g. most people have showers instead of bath tubs), or because the questions did not take into account that some arthritis patients were doing much better than ever before (e.g. folks who run 20 miles a week got the same scores as folks who could only run 2 blocks). So now we're trying to create new questionnaires that work for us now in 2015. Some of these were created in the last 10 years as part of a multi-million dollar NIH initiative called PROMIS, and some were created here at the NDB. Some require using a computer or smartphone to answer since the next question depends on the answer of prior questions, and some are simply lines that you checkmark.

With all of these questions that we ask, we learn A LOT! But just like our "15 minutes" of seeing the doctor, we rarely have enough time to communicate all that is going on with our health. These questionnaires have to summarize our answers into specific areas so we can better comprehend what is happening to us. The NDB provides an online report that you can see some of these summaries in graph and number form from over the past 10+ years. I've included mine as an example—I can tell you that my sleep quality (the orange line) was much worse last July as I was usually stressed preparing grants and an important personal event (my wedding!). Another example of the online report can be seen on page 7.



Unfortunately some doctors don't think that what we, as patients, have to report on questionnaires are useful because it is subjective. I would argue that it is exactly this personal perspective that makes our answers important! If I'm feeling miserable, yet the doctor doesn't think it's important because my joints are fine or lab results didn't change—then we have a communication issue (and I may be looking for a new doctor). While our blood tests are getting better, they still aren't as powerful as our personal and individual responses to questionnaires.

These questionnaires have to summarize our answers into specific areas so we can better comprehend what is happening to us.

So, just like when I was a kid, I'll continue to fill these out in the clinic, and I and many other staff and researchers across the world thank you for doing the same with our questionnaires from the NDB.

LATEST RESEARCH

In November 2014 at the Annual American College of Rheumatology (ACR) Meeting, the NDB was involved in 12 research abstracts and talks on various subjects that used the data that you have provided to us over the years. The majority of these will end up as papers published in medical journals. This meeting allows rheumatologists, researchers, organizations, patients, and companies to get together and learn about the new research and treatments related to all rheumatic diseases.



Once again, the NDB had a booth at the conference to be able to visit with other researchers, participants and other non-profit groups that we currently work with and hope to work with in the future. We were pleased to be visited by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (www.niams.nih.gov), CreakyJoints (www.creakyjoints.org), OTIS/Mother-ToBaby (www.mothers-to-baby.org), the Arthritis Foundation (www.arthritis.org)

and the International Foundation for Autoimmune Arthritis (www.ifautoimmunearthritis.org)—all great organizations that we are pleased to work with and/or have participants in our research.



Cindy Crowson, MS, from the Mayo Clinic and Dr. Kaleb Michaud after moderating their 90 minute session on drug safety. The color purple was not planned in advance.



"RA Warrior" and Patient, Kelly Young, with her daughter and Dr. Kaleb Michaud catching up between scientific sessions.

We thank each and every one of you—it could not be done without you!

Here are some overviews of the research from the meeting:

Test of the NIH Patient-Reported Outcomes Measurement Information System (PROMIS) 29-Item Profile in RA, OA and Fibromyalgia Patients

The NIH PROMIS questions have been asked for many 6-month phases and the data collected over this time were used as an initial evaluation of these measures in RA, OA and Fibromyalgia patients. Results overall were similar for all groups and showed a strong support for the use of the PROMIS short forms. Validating these questions lays the foundation for future use of the PROMIS measures, which will allow us to cover more areas related to the quality of life in patients without increasing the number of questions.

Comparing Patients with RA initiating a TNF biologic compared to Patients with RA initiating a non TNF biologic

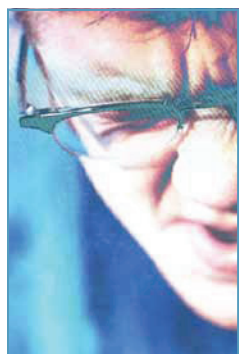
Patients enrolled into the NDB and RAlly that responded to the 6-month questionnaires from 2005 through 2013 allowed us to compare baseline characteristics of RA patients receiving abatacept, other non TNF, or TNF as their first biologic medication. TNF biologics considered were: etanercept, infliximab, adalimumab & certolizumab pegol. Non TNF biologics were: abatacept, rituximab, tocilizumab & anakinra. Abatacept and other non TNF were statistically the same except that abatacept patients were less likely to be current smokers. When comparing all of the non TNF to TNF biologics, non TNF tended to be older, and had significantly higher pain, fatigue and activity scores.

Patient Reported Outcomes following Total Knee Arthroplasty (TKA) in RA and OA patients

Researchers at the University of Nebraska and the NDB evaluated and compared the effects of TKA in RA and OA patients since there are very few studies pertaining to TKAs effect on a patient's health related to quality of life and are limited to just OA patients. This comparison was able to show that reduction in pain and overall improvement in all outcome measures was most striking in the first 6-12 months after the TKA for all patients, yet OA patients had better response than RA patients.

Symptoms Increase in Fibromyalgia is not Consistent with the Current Hypothesis Explaining Fibromyalgia

The current dominant hypothesis explains fibromyalgia as a centralized pain state in which the Central Nervous System (CNS) originates or amplifies pain, which is then accompanied by fatigue, memory problems, and sleep and mood disturbances. The review of symptoms is being attributed to central hyperresponsiveness and not to psychological factors or "somatization." In reviewing the data collected on fibromyalgia patients and mixed



rheumatic disease patients, the data showed no increase in non-pain symptoms in subjects with high widespread pain. Alternative hypotheses for increase in

symptoms should include factors such as non-Central Nervous System pain and psychological variables.

Mortality Trends in Rheumatoid Arthritis compared to NIRD during the Biologic Era, 1998 to 2011

RA has consistently been associated with increased mortality risk and appears to be linked with greater disease activity. With the improvements of treatment, data was looked at to see if these advancements have improved RA-related survival. When comparing the trends of RA and non-inflammatory diseases (NID, OA, back pain, tendonitis), overall RA-related mortality risk remained significantly higher than NID mortality risk through 2011. So despite important advances in treatments for RA, no meaningful improvement has yet been made in RA-related mortality.

Smart Phones and Rheumatic Disease Patient Outcomes

Last year we started a new project using a smartphone app for iOS (e.g. iPhone) or Android (e.g., Droid, Samsung, HTC, Pantech, or LG). The data has shown to be very useful along with the survey data and as we stated in the last newsletter, we are seeing some items that may become very useful for patients and doctors. We plan to continue this research study and will be inviting more patients to participate this year and to also start testing it with a couple of clinics and their patients and see what other advances and improvements we can make to help the doctors and patients with treatments and care. If you are interested in participating and have not received an invite email, you can also sign up via our online form: <http://www.ndb.org/participate/your-consent-join-smartphone-research>

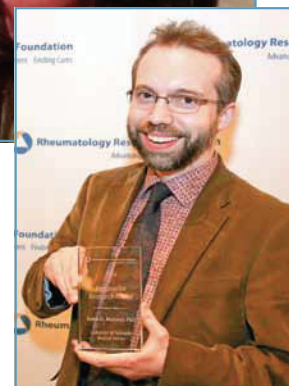
We thank all of you that have been able to help and continue to do the smart phone study!

Family Research Project

The other new project we noted in the last newsletter is also moving forward out of its pilot stage to the full project—the Family Research Project. There is great interest from patients, doctors and researchers to try to find and understand the effect of genetics and other measures in aiding in the diagnosis, treatment, and eventual cure of RA and other diagnoses. We have created a new Family Medical History questionnaire where you can answer questions about your close biological relatives (father, mother, brothers, sisters, and children) and build a family tree. For adult relatives (18 and older) who are alive and willing, you can then invite them to enroll in the NDB to answer a few questions about themselves.

To complete your family medical history form online, please see our enrollment page at: www.familyhistory.ndb.org

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Here are a couple more pictures from the annual ACR Meeting: left is Rebecca Schumacher, NDB Executive Director, and Dr. Fred Wolfe, NDB Co-Director in the NDB Booth. Right is Dr. Kaleb Michaud, NDB Co-Director, receiving his award from the Rheumatology Research Foundation for the Innovative Research Grant that supported the pilot study for the Family Research Project.

Arthritis Internet Registry (AIR) News



AIR is a groundbreaking internet-based patient registry and biospecimen collection using the combination of the patient-study infrastructure of the NDB, the nation-wide availability of Quest Diagnostics blood collection sites and the patient outreach of the Arthritis Foundation. Participants in AIR complete the same questionnaires as the participants in the NDB, but are noted as AIR participants due to the way they enrolled into the data bank. Some AIR participants consent to donate blood samples for the biospecimen collection. We currently have had over 5,800 participants join and we have collected over 1,000 biospecimens on a variety of rheumatic diseases.

AIR recognizes the importance of research to improve the lives of arthritis patients and the needs of patients to discuss their disease with other patients. The purpose of AIR is to bring together a community of arthritis patients to enable discovery research and social networking via the internet.

Latest Research from AIR

Data and biospecimens from AIR patients are currently being looked at internally by Quest Diagnostics and NDB to see if they could help in future research on another biomarker to help aid in the diagnosing and/or prevention of rheumatoid arthritis and psoriatic arthritis. We will keep you posted in future newsletters on if this becomes a new research study from AIR.

AIR is a partnership between leading academic researchers, the Arthritis Foundation, and Quest Diagnostics. The main researchers and advisors working on and supporting AIR are the following:

Kaleb Michaud, PhD

NDB and the University of Nebraska Medical Center

Peter Gregersen, MD

The Feinstein Institute for Medical Research

Stanley J. Naides, MD

Quest Diagnostics Nichols Institute

Csaba Siffel, MD, PhD, PMP

Arthritis Foundation

NDB Questionnaires and Primary Diagnosis

We are asked a couple times each phase “Why did I get a questionnaire for RA/Fib, but my diagnosis is Psoriatic Arthritis (or many other diagnoses)?” As you may see on the cover of the paper questionnaires that are mailed out, it states a diagnosis on the cover, i.e. RA/Fib, OA, Lupus and Gout. The NDB Questionnaires first started out with only one version to cover all diagnoses, which was called “RA/Fib”. But over the years, as the NDB has been able to work with experts in other diagnoses, we have added on other questionnaires geared to ask more specific questions for certain diagnoses. The main one is still called “RA/Fib” to keep the questionnaire naming consistent over all the years of data collection. We wish we could have a questionnaire for each and every diagnosis, and might in the future, but currently we have the following questionnaires:

- **RA/Fib** is sent to all RA, fibromyalgia and all other diagnoses (i.e. psoriatic arthritis, ankylosing spondylitis, lower back pain, polyarthralgia, etc.). This questionnaire asks all the questions that will help aid the researchers to see the entire view of how a patient’s disease affects their lives.
- **OA** is sent to all osteoarthritis patients and asks the majority of the questions in the RA/Fib questionnaire and an extra set of questions that are used by rheumatologist’s to help with OA patient care.
- **Lupus** is sent to all lupus patients and has majority of the questions in the RA/Fib questionnaire and asks specific questions for understanding how lupus affects patients.
- **Gout** is sent to all gout patients. Dr. Ted Mikuls and other researchers at the University of Nebraska Medical Center have helped to design this shorter and unique questionnaire specifically for patients with gout.

This is the reason we ask on the enrollment forms for your primary diagnosis, so we can make sure that we are sending you the correct questionnaire that will ask you the questions that would best reflect how your disease is affecting your life. Please let us know at any time if your primary disease changes or if you have any questions about this by emailing us at webquest@ndb.org or calling us at 1-800-323-5871.

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 participant, in 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

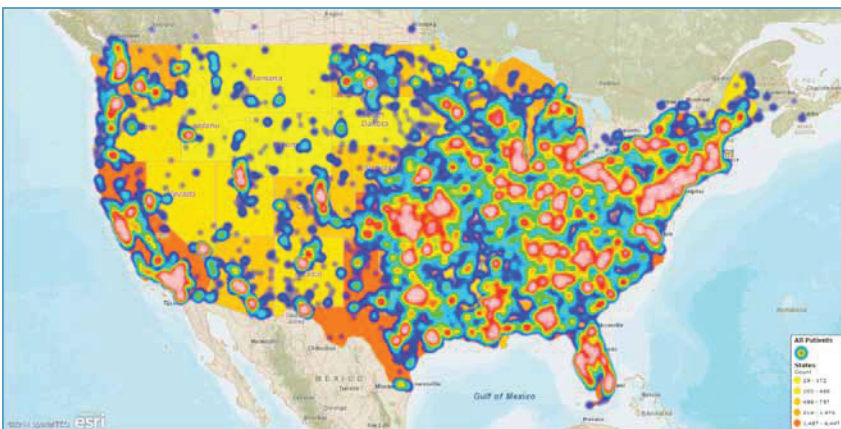
diseases and treatments, but we are not able to give personal medical advice.

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 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.

NDB Participants on the Map

Participants who have set up an account on our website will be able to see maps that show where participants are from and overall pain scores for each US state and also per specific diagnosis groups. The maps are set up for the following diagnosis groups: rheumatoid arthritis (RA), fibromyalgia, lupus, other inflammatory rheumatic diseases (which include psoriatic arthritis, ankylosing spondylitis, etc.) and non-inflammatory rheumatic diseases (which include osteoarthritis, osteoporosis, etc.).



You can view this map by logging into your account on our website or if you don't already have an account on our website, you can set one up by going to this page on the web: <http://www.ndb.org/user/register>



WebQuest is the online version of our questionnaire. The questions are the same as what you see 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.ndb.org and make the request, or send us an email to webquest@ndb.org.

Meet the Staff: Sofia Pedro, MS



Sofia Pedro, MS, Biostatistician, has been working with the NDB since June 2012 and previously had worked for BioEpi in Portugal, the organization that ran the Portugal Data Bank that NDB had helped with forms, data collection, and analysis.

Sofia has been working in statistics and research for over 10 years and the NDB was very excited when we were able to have her join us. Sofia brings great talent and knowledge of statistical analysis to the NDB team. She works on the various research projects and studies of the NDB and helps write and produce the abstracts and manuscripts from the data collected from the NDB questionnaires. She has also presented abstracts for the NDB at the annual American College of Rheumatology Meeting. Sofia is currently very busy

with a new addition to her family—a healthy baby boy!



Prize Drawing Winners!

The research data bank can best contribute to research when the questionnaires are completed and returned as soon as possible. We conduct the prize drawings as a token of our gratitude in help with rheumatology research.

Our prize drawings consist of:

2 drawings for \$1,000 each for those who complete a large questionnaire via mail, web or phone within the first 4 weeks.

2 drawings for \$500 each for those who complete a large questionnaire via mail, web or phone any time within the 5 ½ months.

4 drawings for \$50 each for those who complete a shorter questionnaire via mail or phone anytime within the 5 ½ months.

The \$1,000 winners from the last questionnaire were a participant from Denver, CO and a participant from Taylor, ND. Winning smaller amounts were a participant from Cookeville, TN; Ileen Swelland, Peoria, AZ; Jerry Garrett, Livingston, TN; Bobby Moon, Calhoun, GA; Diana Alferi, Maryland Heights, MO; a participant from Maryville, TN. Congratulations to all!

Donate Blood for Research!



You can help advance arthritis research by donating a blood sample. By analyzing your blood in combination with your answers to the NDB questionnaires, we hope to discover

biological reasons why some treatments work better and why some are more toxic to an individual.

As always, your privacy is protected and there is absolutely no cost to you. Your lab results will be available directly to you through a secured login on our website. You can also print out the lab results and take them with you to your next doctor appointment.

Blood collection takes place only at Quest Diagnostics laboratory sites, which are located in many cities across the US.

To donate blood, you must first sign a consent form—which we will mail to you. If you are interested in donating a blood sample, please contact Kimberly Harp by email at kim@ndb.org or by phone at 1-800-323-5871 ext. 143.



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.ndb.org/participate/tell-friend>.

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. Available for your support group or arthritis, fibromyalgia or lupus meetings, our pamphlets explain what we do and how you and others 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@ndb.org or 800-323-5871 ext. 133. Thank you!



Join
Us on
Facebook
& Twitter



You can find us on Facebook as "National Data Bank for Rheumatic Diseases." We will try to keep you up to date with any news items that occur between questionnaires. You can also connect with other participants and NDB staff who have joined our group.

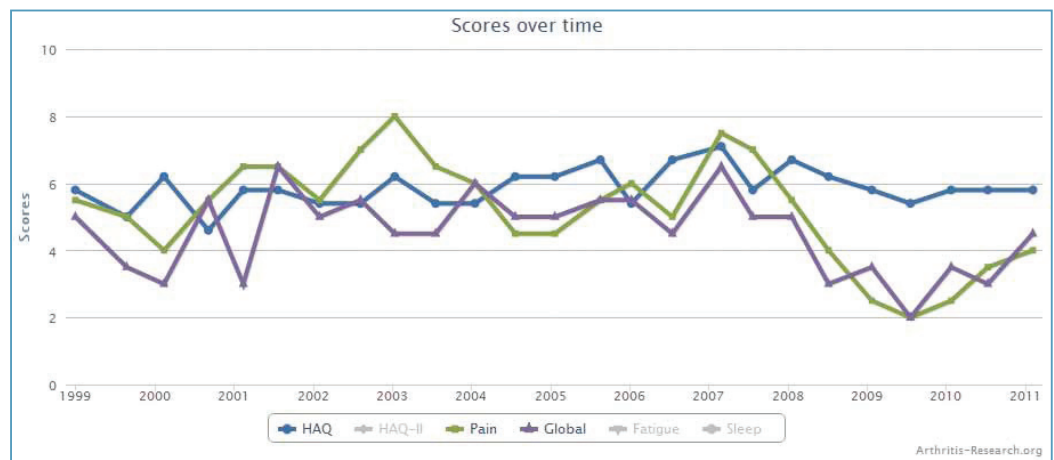


We have just started our new Twitter account and you can find us as "@ndb_org". We have added this for those that may be on Twitter but not on Facebook and we will be tweeting news items to start with.

View Your NDB Results Online

Many of the questions we ask every six months give researchers and doctors scores that show how you're doing. We have heard from many of you that you want to see your results. You can now get these scores any time you need them on our website. If you don't already have an account on our website, start on this page: <http://www.ndb.org/user/register>. Having an account protects your privacy and lets you access your scores.

You will be able to see scores for every questionnaire you've ever completed for the NDB, and print them for your own information or to show to your doctor. Please email us at webquest@ndb.org if you have any questions about the website or your scores.



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@ndb.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!



Reminders

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:

Arthritis Research Center Foundation Inc.

and sent to:

Arthritis Research Center Foundation Inc.

1035 N. Emporia, Suite 288

Wichita, KS 67214

Or you can donate online by visiting www.JustGive.org and type in Arthritis Research Center Foundation.

For more information please contact Rebecca Schumacher at 1-800-323-5871, ext. 119 or Rebecca@ndb.org.

Thank you very much for considering a donation to support this important research.

FOR MORE INFORMATION OR TO PARTICIPATE

Arthritis Research Center Foundation, Inc.

1035 N Emporia | Suite 288 | Wichita, KS 67214

DIRECTORS: Frederick Wolfe, MD | Kaleb Michaud, PhD

EXECUTIVE DIRECTOR: Rebecca Schumacher

Please call 1-800-323-5871

or email info@ndb.org

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