



# Lupus News

Tips and information from the BWH Lupus Center

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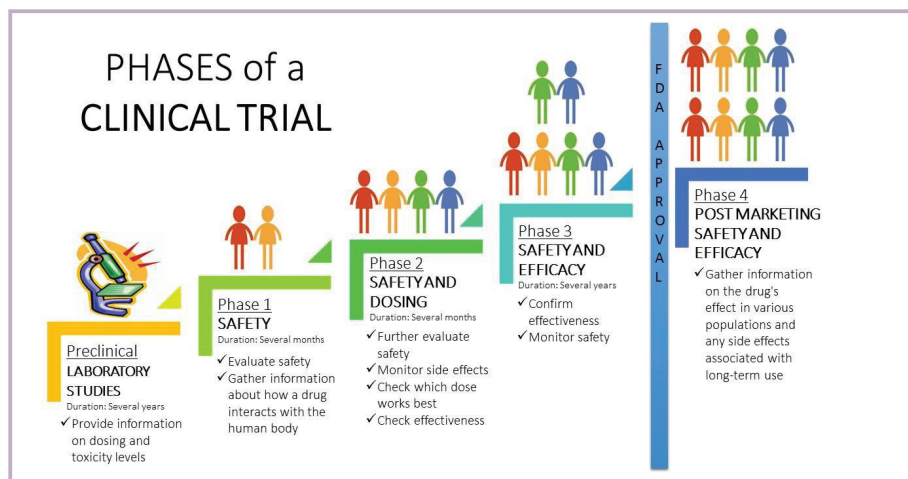
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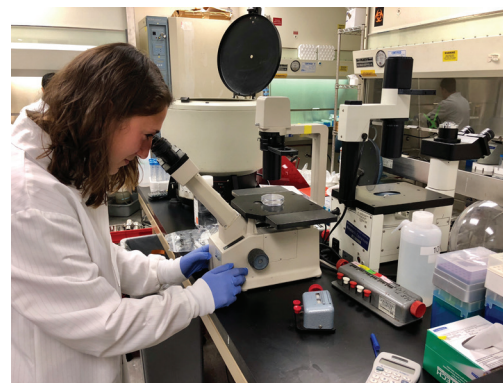
Source: Columbia University

## What's New in Lupus Research?

### 2018 Updates in Lupus Clinical Research

Over the last few years, the amount of funding going to lupus research has grown tremendously, which has allowed for lupus research to grow as well! For fiscal year 2019, the government approved funding for lupus research programs, including \$5 million to the Lupus Research Program at the Department of Defense, \$39.1 billion for the NIH, which is expected to provide nearly \$110 million for lupus research and \$2 million for the Office of Minority Health's National Health Education Lupus Program.<sup>1</sup>

While lupus is still relatively rare, the Lupus Foundation of America estimates that 1.5 million Americans have some form of lupus. Lupus, especially systemic lupus erythematosus (SLE), can be difficult to diagnose and presents in a wide range of ways in different people. It predominantly impacts young women of child-bearing age, and individuals who are of African or American Indian/Alaska Native descent.<sup>2</sup> Scientists and clinicians have many questions about lupus: What causes it? Why does it affect people so differently? While progress has been made over the years, there remains a lot of room for future research findings.



Physician-researchers here at BWH, with the help of research assistants like Rachel Blaustein (pictured), are working toward advances in lupus research

In 1955, hydroxychloroquine (Plaquenil) was FDA-approved to treat lupus. Since then, only one additional drug, belimumab (Benlysta), has been approved specifically for lupus treatment. It is primarily used with disease-modifying antirheumatic drugs (DMARDs) to treat skin and joint disease. While patients receive many other drugs to manage their lupus symptoms and complications, none of these are specific to lupus.

In this issue, we will provide information on ongoing and new SLE clinical trials and epidemiologic studies. While we are not endorsing any of these specific trials, we encourage you to please discuss with your treating rheumatologist if you have any questions.

**Brigham and Women's Hospital**  
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**<https://tinyurl.com/DonateBWHLupusCenter>**

**To learn more about our**  
**Lupus Research Program:**  
**<https://lupus.bwh.harvard.edu/>**

### What's new in Lupus Research? (cont.)

#### Clinical Trials-What new drugs are being studied?

Clinical trials are research studies in which the researcher or scientist intervenes to prevent or treat a disease. This kind of study offers an opportunity to see how different interventions, like a medication or device, works for a group of people over some period of time. There are five different phases to a clinical trial: preclinical or laboratory studies (non-human), Phase 1 focuses on safety, Phase 2 focuses on dosing, and Phase 3 measures efficacy, or how well the drug or device works. Phase 4 is completed once the drug has been FDA-approved and becomes available to multiple populations, while monitoring continues.

Currently, there are 10 active Phase 3 clinical trials in the US (listed on ClinicalTrials.gov) examining the roles of specific medications in treating lupus disease.

Drug	Trial	NCI#
Voclosporin	Aurinia Renal Assessments 2: Aurinia Renal Response in Lupus With Voclosporin	03597464
Baricitinib	A Study of Baricitinib in Participants With Systemic Lupus Erythematosus	03616964
Voclosporin	Aurinia Renal Response in Active Lupus With Voclosporin	03021499
Belimumab   Rituximab	A Study to Evaluate the Efficacy and Safety of Belimumab Administered in Combination With Rituximab to Adult Subjects With Systemic Lupus Erythematosus (SLE) - BLISS-BELIEVE	03312907
Baricitinib	A Study of Baricitinib (LY3009104) in Participants With Systemic Lupus Erythematosus	03616912
Ustekinumab	A Study of Ustekinumab in Participants With Active Systemic Lupus Erythematosus	03517722
Drug: IPP-201101	Study of Repeated Administration of a 200-mcg Dose of IPP-201101 Plus Standard of Care in Patients With Systemic Lupus Erythematosus	03427151
Belimumab	Belimumab Treatment Holiday and Treatment Re-start Study in Lupus Patients	02119156
Anifrolumab	Efficacy and Safety of Anifrolumab Compared to Placebo in Adult Subjects With Active Systemic Lupus Erythematosus	02446899
Belimumab	Efficacy and Safety of Belimumab in Patients With Active Lupus Nephritis	01639339

#### Epidemiologic Studies

Epidemiologic (or observational studies) are another type of clinical research. They differ from clinical trials in that the researcher usually does not intervene. Rather, these studies examine questions about the causes of a disease, which exposures contribute to disease development, and which groups of individuals are more affected than others. Like clinical trials, the researcher can follow the participants over a short or long period of time. As of August 28, 2018, there were 29 active observational studies on **ClinicalTrials.gov** in the US examining a range of questions related to lupus disease. The future of lupus research in the United States remains hopeful! There are over 20 drugs that are currently in phase 2 trials, meaning they will take a few years but are in the pipeline. All of these studies are active, with results for some of them potentially being published as in the next 1-2 years. Epidemiologic studies continue to provide much insight and additional context for understanding how to prevent and treat lupus. Investigators continue to examine how obesity, smoking, post-traumatic stress disorder and poverty affects both the onset of lupus and its manifestations among those afflicted with the disease.

At the BWH Lupus Center we have several ongoing active studies, some of which are led by our own clinician-investigators. Our studies are examining risk factors for developing lupus, changes seen in immune cell types in early lupus, imaging to detect early heart disease in lupus, questions on patients' opinions of their lupus medications, and methods to train community leaders and physicians to help disseminate information about lupus.

To learn more about our research and the BWH Lupus Program, please visit our website: [www.lupus.bwh.harvard.edu](http://www.lupus.bwh.harvard.edu)

#### References:

- 1 <https://www.lupus.org/general-news/entry/house-sends-lupus-research-funding-to-presidents-desk>
- 2 <https://www.cdc.gov/lupus/facts/detailed.html>

# Ask the Doctor!

Up to 20% of patients with lupus develop the disease in childhood or adolescence. As SLE is a chronic, life long disease, people with childhood onset SLE will need to transition their care from their pediatric rheumatologist to an adult doctor, typically between the ages of 16-24.

Mary Beth Son, M.D., a pediatric rheumatologist and lupus specialist at Boston Children's Hospital, answers some questions about how patients who developed Lupus in childhood or adolescence can successfully transition to adult care.

**Q: What happens when I want to change doctors?**

A: There are many things to consider when going through the transition from pediatric to adult doctors. First, there are the logistics of finding a new doctor. A good place to start in finding a new doctor is to talk to your pediatric doctor. He or she should be able to provide the name of a rheumatologist, or the name of a practice of rheumatologists. Additionally, you could ask your rheumatologist if there are materials regarding transition that you could review. Your primary care doctor may also be able to provide input. There are a few things to take into account when looking for an adult doctor.

(1) Location, location, location! Where do you want to see your doctor? Is there a nearby medical center with rheumatologists?

(2) Can you go to one center to see all your specialists, like your kidney doctor or eye doctor, to make life easier?

(3) Are you looking for a doctor who is male or female, or does it not matter to you? Do you want them to do research in lupus?

Once you have determined where you would like to transfer your care, the next step is to transfer your medical records so your new doctor can learn about you. This usually

entails signing a medical release such that your pediatric doctor's office is permitted to send your records. You should also ask your pediatric doctor for a letter of introduction that you have a copy of, and that should be sent to your new doctor before your first visit. You shouldn't hesitate to contact your pediatric rheumatologist if you have questions after the first visit with the adult doctor.

**Q: What are possible issues I should be aware of when transitioning care?**

A: It is critically important that you have enough medications so that you don't run out while transitioning. It is also very important that there aren't gaps in your care, meaning you are seeing all of your doctors in a timely manner. People who develop lupus earlier in life tend to have more severe disease and may have multiple specialists. For all these reasons, working closely with your pediatric rheumatologist to ensure that the transition goes smoothly and you don't have a flare of disease is so important. You should have a discussion with your doctor about who to call if you need refills or aren't feeling well during transition.

There are also important, age specific issues to consider. People in late adolescence/early adulthood are undergoing a lot of changes, emotionally and mentally. Some are working, some are going to college, some are doing both. There are decisions to be made regarding where

to live and how to live independently. There are also insurance issues to consider. Will you remain on your parents' insurance, or do you need to make a change? Will your doctor be in network, and will there be co-pays for medications? These issues can be complicated, but made much easier by working with someone, for example a social worker in your doctor's office. Additionally, if you are feeling stressed about these changes, please reach out to your support network. Getting more social support will make your transition go smoothly and feel easier. Never hesitate to ask for help on these issues, as they impact your health.

Q: Will my adult doctor manage my lupus as my pediatric rheumatologist did?

A: Yes. Treating lupus across the age spectrum is tailored to the specific patient, but the approach to controlling the disease is usually similar. You should see your new doctor regularly for clinic visits to check in and to manage medications. Routine health maintenance, including vaccines like the flu shot, is really important and your new doctor can help. Although it may feel difficult to move on from your pediatric rheumatologist, you can develop a great relationship with your new doctor who will help you manage your lupus and thrive!

## Lupus Conversations with the Boston Butterflies: A Project Update

by Courtnie Phillip

Lupus is twice as likely to occur among individuals of African descent than among Caucasian patients. Additionally, studies have shown that African-Americans not only have a higher prevalence of the disease, but also experience a higher burden of adverse outcomes. Delays to high quality rheumatology care may play a role in these disparities. To begin to address this, two rheumatologists, Dr. Candace Feldman (BWH) and Dr. Rosalind Ramsey Goldman, (Northwestern University, in Chicago), launched "Lupus Conversations." The project, funded by the U.S. Office of Minority Health, was designed to train individuals active in their Boston or Chicago communities ("Popular Opinion Leaders") and healthcare providers to increase awareness and understanding about lupus, and to promote early access to care among individuals of African descent.

### The Boston Butterflies

This past winter, our research team began our Popular Opinion Leader (POL) trainings for the project. Eighteen members of the greater Boston community, eleven of whom had lupus, were recruited to be POLs and chose the name "Boston Butterflies." Over a one-month period we held four training sessions at Sportsmen's Tennis and Enrichment Center in Dorchester. They included PowerPoint presentations, videos, case scenarios and discussions and focused on various topics including: lupus signs & symptoms, health disparities, research methods, and strategies for sharing lupus information within their communities to promote earlier access to care. During the training sessions, POLs shared their thoughts with each other and the group leaders, on a range of issues including challenges with patient-provider communication, experiences of racial and gender discrimination in healthcare, and the role of support networks for lupus patients. In addition, they helped to develop the curriculum for healthcare providers.

After completing their training, the Boston Butterflies engaged over 300 individuals in the greater Boston area in conversations about lupus, raising overall awareness about the disease and stressing the importance of early access to medical care. They visited different venues such as hair salons, banks, schools, churches, community health centers, and neighborhood fairs and distributed cards that contained information about lupus signs and symptoms and contact information for the Lupus Foundation of America.

We plan to present the accomplishments of the Boston Butterflies and their Chicago counterparts at the American College of Rheumatology meeting in October and continue to refine our educational materials with a plan for national dissemination.



Courtnie Phillip (L) and Dr. Candace Feldman (BWH) with Ernestine Washington and Gail Granville (Women of Courage support group) at the Center for Community Health Education Research and Service 2018 conference.



# Raising Lupus Awareness in Nigeria

A conversation with lupus advocate and BWH Patient Advisory Board member Chisa Nosamiefan

## Tell us about your work in lupus advocacy in Nigeria.

On my lupus fact finding trip to Nigeria, I met, Dr. Ayesha Akinkugbe, a dermatologist who works at the Lagos University Teaching Hospital. She's always had a passion for working with lupus patients. Until very recently, within the past 10 or 15 years, there were very few trained rheumatologists in practice, because few trainee doctors chose the specialty. Consequently, dermatologists managed many lupus patients who initially presented as a result of their skin manifestations and stayed on in the practice. She told me that she had always wanted to do more for her lupus patients. Meeting her was like an answer to a prayer for me, and together, we started *The Labalaba Foundation* for Lupus Awareness and Advocacy in Nigeria. The word "Labalaba" means butterfly in two main Nigerian languages. Our mission is to improve the quality of life of all people affected by lupus through programs of education, advocacy and support that will engage the healthcare community and the society at large.

On May 10<sup>th</sup>, 2018, in collaboration with the Rheumatology and Dermatology clinics of the Lagos University and Lagos State University Teaching Hospitals, we hosted a health symposium to mark World Lupus Day. There were over 130 people including lupus patients, their family members and caregivers, faculty and trainee doctors from both participating universities, and other interested members of the public. The event was widely covered by the local media and followed up by interviews on a number of very popular radio shows. The event was also a learning opportunity for us, especially listening to the patients and others impacted by lupus, who shared a lot of things we hadn't heard before.

## What motivated you to become actively involved?

I got into this is because we know that lupus is 2 times more likely to affect people of African descent. I thought to myself that Nigeria is the most populous country in Africa, with almost 200 million people, so lupus must be a major problem in Nigeria. Yet I, who am originally from Nigeria, had never heard of anyone who had lupus.

I've had a very challenging journey with lupus, many times not knowing if I would pull through another flare. Grateful that I had become stable and well managed at last, I began to think of what I could do to give back, to help others with lupus.

## How does the experience of individuals living with lupus in Nigeria compare to your experience here in Boston?

In Nigeria, I found there is a lack of awareness in the public sphere. The frontline doctors are not sensitized to consider the possibility of lupus when confronted with some of its signs and symptoms, because they mimic those of many other more common diseases. If you're in a place like Nigeria and you have a fever, you most probably have malaria. After ruling out malaria the next possible culprit is typhoid, and down the list. If the problem is unexplained weight loss, the first thought is HIV. Many patients report multiple rounds of testing for these conditions, and for the fortunate few, a final chance diagnosis of lupus.

All of this combined with the fact that there is a culture of silence when it comes to disease, so they don't talk about what's going on. Not just by the patient, but even the family members. It is all just shoved under the rug like nothing's happening, as though if you don't pay it any attention, it will all go away. All these things lead to late diagnosis which, in turn leads ultimately to untold suffering and unnecessary and otherwise avoidable fatality.



Chisa Nosamiefan is a member of our BWH Lupus Center Patient Advisory Board and has lived with lupus for over 20 years. She is an Intercultural Relations Consultant. She holds degrees in Chemistry (B.Sc.) and Intercultural Relations (M.A.). This year, she co-founded *The Labalaba Foundation*, with Dr. Ayesha Akinkugbe (MB;BCh;FWACP) in Nigeria and it is the first lupus non-profit foundation of this kind there.

## How can the BWH lupus community, both patients and providers, help with your work in Nigeria?

Two things immediately come to mind. *The Labalaba Foundation* began a lupus support group in June and we are thinking of having monthly discussions where we put out articles and information on a particular subject, and also invite patients and their families to ask questions. Hopefully doctors who are subject matter experts could help by providing materials and answering questions by video or slide presentations or written responses.

The other thing is thinking of the BWH Lupus Center community as a resource in terms of the skill sets and personal networks of the members. A lot of this is new to me, for example, how to apply for grants is a new area for me. It would be great if I could tap into the collective wisdom of the community. We have many program ideas in the works, so hopefully as they crystalize I can turn to my BWH Lupus community for help, and perhaps we could go to Nigeria as a team to support the work someday.



## LUCIN—Clinical Research Network

The BWH Lupus Center is pleased to participate in the Lupus Research Alliance's clinical research network called LUCIN (Lupus Clinical Investigators Network). We are one of many nationally renowned lupus centers represented in the network. A major goal of LUCIN is to facilitate lupus clinical trials and studies, including trials of new therapies and to find better treatment options for lupus patients. To learn more, you can contact Corine Sinnette, [csinnette@bwh.harvard.edu](mailto:csinnette@bwh.harvard.edu)

## Upcoming Local Events

10/06/2018  
**Lupus Medical and Educational Symposium**  
[www.lupusne.org](http://www.lupusne.org)

10/15/2018  
**10th Annual Runway for a Cure**  
[www.runwayforacure.com/](http://www.runwayforacure.com/)

10/20/2018  
**Lupus Foundation of America Walk To End Lupus Now**  
[www.supportlupus.org](http://www.supportlupus.org)