

In Conversation: Dr. Kari Nadeau

A view into Stanford Allergy Center's vision, goals, and research priorities

Fundraising efforts are underway to establish an interdisciplinary and integrated Allergy Center at Stanford. Directed by Dr. Kari Nadeau, the Center will bring together top-ranked scientists, physician-scientists, and research teams in an effort to expand the scientific understanding of allergies and develop a long-lasting cure for patients everywhere. By uniting leaders from multiple disciplines—scientists, nurses, physicians, counselors and other health professionals—the Center will concentrate on the cause, diagnosis, counseling of patients and families, and treatment of allergies.

In this interview, Stanford Allergy Center News contributor Angela Evans sits down with Dr. Nadeau to learn more about the Center's model of patient care, research priorities, and community outreach efforts.

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What led to the creation of the Stanford Allergy Center?

Dr. Nadeau: It's really exciting for me because my vision for an allergy center was inspired by patients and families. All of this came about in 2003 when I was training as a fellow. I was asked to consult on a little boy in the intensive care unit who had, unfortunately, accidentally ingested milk. He was terribly milk allergic. But when I got to the ICU to see him for the first time, he had died just moments earlier. When I spoke to his family in the ICU, it really made an impact on me as an unnecessary death that could have been completely prevented. It was no one's fault, but it spoke to the need for stronger food allergy education to prevent death. That compelled me to

work in the field of allergy. I became interested in doing research, and I focused in on what could cause allergies and how could we possibly cure them. I then began putting together collaborations at Stanford and around the country to do so. Since 2003, the clinical and research teams at Stanford across different departments have made great strides in allergy research and clinical care. Yet, we only had about \$3.2 million (over 95% of which came from individual donors) to spend on our work thus far. We've accomplished a great deal with those funds considering that we've treated over 300 patients a year, patented new allergy diagnostics, developed a prognostic based on DNA changes in oral immunotherapy patients, and discovered epigenetic markers to food allergy. We've done an incredible job as a team to push this forward with very little resources, but there is so much more to be done. We need more resources to move forward. Over 25% of the population (adults and children) are affected by environmental allergies. With an average of 6% of the population affected by food allergy and a doubling of prevalence over the last ten years, the food allergy disease has become an epidemic. The causes of allergies are still unknown,



and there are no effective cures available. We need a cure approved by the Food and Drug Administration (FDA) and by insurance companies to get patients reimbursed for treatments.

Upon visiting some allergy centers around the country, I thought about how Stanford could have its own allergy center. I believed that we could lead the way because of our incredible collaborative nature, teams of well-renowned scientists, and outstanding community involvement. I thought this was a perfect time for Stanford to make a mark in history in a highly impactful way for patients and families living with allergies. We approached the Dean with an Allergy Center proposal, and it was approved last year.

And what does it mean? We've formalized a Center that already exists in terms of its laboratories and space in the Stanford hospital, but we can now build and develop the Center's resources in a very professional, official way. It means that for perpetuity, Stanford will now consider the Center a high priority for adult and pediatric allergy patients.



Stanford Allergy Center Team

Can you describe your vision for the Center?

Dr. Nadeau: The overall vision is to create an interdisciplinary and interdependent Center that makes transformative changes in the field of allergy by uncovering the causes of allergies and developing a cure. The Center aims to become the leader in allergy research by attracting world-class researchers and local, national, and international patients. Physicians at the Center will employ this research in a fully integrated patient care setting. The Center will simultaneously undertake major investments in training, education and community outreach.

I understand that the Center will offer a multi-disciplinary model of patient care. Can you explain what this means for allergy patients walking through your doors and how this will differ from other models of allergy care?

Dr. Nadeau: Let's talk about the ambulatory clinic at the Center. This will be an outpatient clinic with one-stop shopping. Sometimes people with allergies and sensitivities have other symptoms related to the disease such as eczema, asthma, abdominal pain, and anxiety. If you have celiac disease, for example, there are a lot of issues related to autoimmune disease that need to be addressed.

So here's what happens now, and I describe this as a parent, myself: if you have a child who is sick with a complex illness, you may have to get many different referrals and go in on many different days stretched over many months due to lag times for available appointments. Then you have to gather all of the plans, and then all of the plans might not line up because the doctors don't have the opportunity to talk to each other. So, you're just going around and around until you can get people to agree on the same plan.

What I thought is this: let's do one-stop shopping. Let's have people come into an ambulatory care unit, and they'll see a doctor who's an allergist for all their allergies and asthma, an otolaryngologist for sinusitis, a dermatologist for eczema, a gastroenterologist for gastrointestinal diseases, and other physician specialists as needed to meet their individual needs. They'll also see a nutritionist, a wellness counselor, and a nurse for education and prevention. By the end of the day, they will also meet with the scientists who are working to develop a cure and understand the causes of the disease. We then all come into the room and develop the patient's plan together, and then it's written up and given to the patient that day.

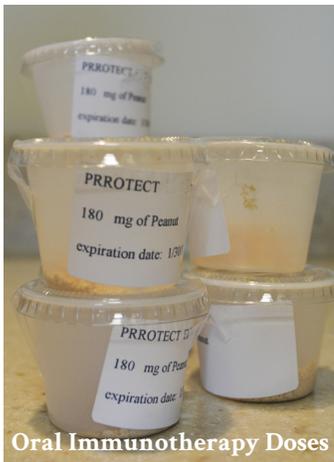
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By August 1st, we hope to have an ambulatory clinic in place if we obtain the resources to do so. We are trying to start this type of clinic in California Pacific Medical Center (CPMC) first. We are going to set up some prototypes first, but we plan to deliver on this promise through our satellite network of allergy centers throughout the country.

Can you describe the Center’s research priorities and explain how it will drive interdisciplinary allergy research? What specialists do you expect will be involved in this research and why?

Dr. Nadeau: The Center will have an interdisciplinary focus that combines the efforts of multiple programs at Stanford, such as allergy and immunology, epigenetics, statistics, chemical engineering, pathology, biotechnology, bio-engineering, and others.

Physicians and scientists across disciplines will collaborate to identify the causes of allergies and discover new methods to prevent the onset of the disease. We have already made substantial progress on this front but still have much more work to do.



The interdisciplinary research team will also evaluate new diagnostics to predict allergies, including severity and longevity in all age groups (as early as one week of life). We currently have three patented diagnostics that we are working to bring forward.

Most importantly, we are collaborating to find cures for all allergies. We want to deliver new combination therapies and new cures for food allergy that go beyond oral immunotherapy. We know that one size does not fit all in the food allergy context; we have to create different lines of therapeutic regimens that don’t have to be taken orally. Similar to other subspecialties such as HIV, cancer, or autoimmune disease, the field of allergy should offer safe and effective therapy choices that meet patients’ individual needs.

Can you briefly explain the concept of computational biology and how it will be applied to Stanford’s allergy research at the Center?

Dr. Nadeau: Computational biology is critical to allergy research because it’s about collecting data from around the world in a shared, digital database. Currently, that’s lacking in this field, and that’s a barrier to uncovering the causes and cure for allergies. In fact, biomedical research and the practice of medicine are reaching an inflection point: the capacity for collecting data is expanding dramatically, but the efficiency of doing so to understand biological processes in human disease has not kept up pace. We need better integration of information between research and clinical studies to be able to use all of the information we gather carefully and productively.

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We want to create a digital system that allows trained professionals to enter in data themselves and access data through a data server. Data will be privacy-protected, of course. For instance, if someone in Sweden collects data from a group of 20 or so children who have just become allergic to peanut and finds that all of those children were born by C-section, that person can go onto our server and seek thousands of more data points related to that issue to help determine if there is a connection.

How will the Center’s allergy research play into patient care?

Dr. Nadeau: I think it all comes down to wanting to provide the best, state of the art patient care. Our research findings allow us to provide data to companies that want to get approval by the FDA for food allergy therapy regimens. We work closely with Genentech and Allergy Research Corporation to

share protocols (dosing – what works, what does not) and safety and efficacy data to enable these companies to work together toward approval of therapies by the FDA. We don't get any funds from these companies at all, but we're working collaboratively and objectively so that we can get things approved and have it tangible and available to patients in hopefully about nine years.

We are also working to expedite the availability of combination therapies like Xolair and food immunotherapy for everyone in the country by getting insurance companies to approve these therapies and reimburse allergy patients for them. Doing so would help bypass the long FDA approval process and can be accomplished with two Phase 2 trials published in a peer-reviewed journal.

Do you expect the Center to accommodate more patients interested in participating in Stanford's allergy clinical trials than before?

Dr. Nadeau: Historically we have undertaken about 300 patients a year for clinical trials. We've collected exciting initial data on sustained response, in which many children and adults are now eating ad-lib. The FDA and National Institute of Health (NIH) have been very thoughtful and extremely supportive of moving this forward. They understand that allergy is a disease that needs to be addressed and needs clinical trials. They've approved many trials that are ongoing in the U.S. and around the globe.

We absolutely can accommodate more patients if we get the financial resources to do so. We do not charge patients. We need to raise the money through private philanthropy since the grants we receive from outside organizations are quite small.

Among the 13 allergy clinical trials currently at Stanford, two active Phase 2 multiple food allergy immunotherapy studies will be launched at the

Center if enough resources are obtained in the next year. We would be able to accommodate 120 children across the U.S. and the globe, and the Stanford site would be able to enroll 40 of the 120 patients.

A main goal of the Center is to collaborate with other hospitals throughout the country and the globe so that more children and adults across all socioeconomic levels have access to our novel clinical research trials. We have already started a network of satellite sites that we are training over the next four months. Currently, there are more than 1,600 adults and children on our waitlist for clinical trials, and we need to offer new and innovative therapies not only at Stanford but also at other institutions. Many adult and pediatric patients from Europe, Asia, the Middle

East, Australia, and India have inquired about our clinical trials at Stanford. With the appropriate resources, we plan to set up additional sites throughout the U.S. and the globe to perform trials.

How does the Center intend to educate and train its community of scientific and medical professionals? What results does the Center hope to achieve by investing

in this education effort?

Dr. Nadeau: Training and education of the community and of the new generation of scientists and researchers are critical. We need to attract the best scientists, the best researchers, and the best doctors to combat this disease because allergies represent 20-30% of people around the world. Food allergies, specifically, are up to 17 million people in the U.S. and 18 million in Europe, Russia, and from what we know, China. This disease does not seem to be going away. It seems to double every ten years. We need to get new people trained, we need to be able to establish endowments for them to stay in science, and we need to work collectively as a community because that's the only way we are going to be able to move forward.

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We are currently training visiting scholars from other countries who are funded by their countries to come to Stanford and undergo training at our Center. We recently had a scholar from Italy conducting quality of life research. We currently have a visiting scholar from Canada pursuing research in multi immunotherapy and in immune research studies. We will be hosting visiting scholars from Korea and Israel this coming year.

As NIH funding has declined in recent years throughout the country, it has become increasingly difficult for young physician-scientists to obtain funding, despite the fact that these future leaders are often pursuing the most innovative treatments and cures in the field of allergy. We aim to help address this problem. Early career faculty and fellowship endowments in the Division of Allergy and Immunology at the Stanford School of Medicine will enable the Center to train the next generation of physician-scientists in this field. We plan to recruit and train the most promising physician-scientists to obtain cutting edge skills necessary to succeed and become leaders in the field of food allergy. Our goal is to establish at least four endowed fellowships or early career faculty positions for allergy research that will last in perpetuity at the Stanford School of Medicine.

It's important to note that we train at all levels – elementary school, high school, undergraduate, graduate, post doc, MD, fellowship. I teach undergraduate and graduate level courses at Stanford in which we focus on allergies and how translational science is conducted to help find the cures and causes of diseases. I always accept 2-3 high school students in my lab during the summer to get them excited about scientific research.

How will the Center raise awareness of allergies in the local community? What types of activities and opportunities will the Center create to support families affected by allergies?

Dr. Nadeau: Together with the Stanford Allergy Center Community Council, the Center plans to educate and train the general public, school

administrators and teachers of all grade levels, health professionals, and policy-makers about the epidemic level that allergy disease has reached. We believe that this focused outreach will help to create safer environments and improve lifestyles

for patients with allergies. Examples of current outreach and plans for the future include: seminars at hospitals around the country about our progress, advocacy for allergy-related policies such as keeping stock epinephrine in schools and restaurants, a health van that educates underserved communities about allergies and provides them with free epinephrine auto-injectors, a “buddy” program connecting newly-diagnosed patients with existing ones, as well as additional activities that will support patients and their families.



What next steps are needed to make the Center's vision a reality?

Dr. Nadeau: Most of what we do is funded by private philanthropy (about 95%). We receive grants from the NIH and Food Allergy Research and Education (FARE), but we rely heavily on donations from individuals and families. We need to raise approximately \$38 million in private funds to make the Center's vision a reality; over \$12 million of these funds has been raised since 2012.

I'm really excited to be working with the community to get this Center moving forward, and only through your support can we continue to do that. It has been such a wonderful opportunity to work with the community, and we want to foster that always, allowing for continued dialogue. Thank you.

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