A Newsletter from the Glomerular Disease Collaborative Network

Kidney Care

Fall 2019

Approved by the UNC-CH Institutional Review Board

Patient Perspective: Journey To Transplant

In this article, Lauren Creecy, a PharmD/MPH candidate, shares her own story about living with Focal Segmental Glomerulosclerosis (FSGS) and receiving a kidney transplant.

The Need: Currently, there are over 113,000 people awaiting lifesaving organ transplants.[1] This number includes men, women, and children. About 20 people die each day waiting for a transplant.[1] The number of people added to the waiting list continues to rise each year, with the number of donors and transplants growing at a much slower rate. In fact, 36,528 transplants from about 17,500 donors were performed in 2018.[1] One donor is able to save up to 8 lives by providing their kidneys, intestine, liver, lungs, pancreas, and heart, while also restoring sight in 2 people.[2]

About 83% of patients on the waiting list are awaiting a kidney, with an average wait time of 3-5 years for a kidney from a deceased donor.[2] This wait time can be even longer for people with blood type O, which is able to give to all the other blood types, but is only able to receive from blood type O. With only 3 in 1,000 people dying in ways that allow for deceased organ donation, there exists a large need for living donors.[1] Living donors on the other hand, are able to donate one of their kidneys or a portion of their liver, intestine, lung, or pancreas, while still functioning normally.[2] Donor registration at the DMV does not include living donation, which has a different process of matching individuals to recipients.[2]

Myths about Donation: There are several myths about organ donation that discourage individuals from being living or deceased donors. For one, several people fear that becoming an organ donor will change the measures and decrease the efforts medical professionals take to save their lives. This is NOT true. Medical professionals are trained to take every step necessary to save your life regardless of donation status. The same is true for African American patients. Also, financial status does not play a part in who receives a transplant first. The United States has laws in place prohibiting the buying and selling of organs.[3] Waiting time for recipients is based on blood type, severity of illness, time spent on the waitlist, and other medical factors. If you are unsure if you are able to become a donor, medical professionals can evaluate your ability to donate safely. It does not cost money to donate your organs or tissue.

My Journey: My journey begins when I was diagnosed with FSGS at the age of four years old. This is a form of kidney disease that causes scarring over time, to where your kidneys are not able to filter and function properly. By the age of 18, I was on my way to kidney failure in which I was very tired and sleeping most of the day. I was starting college and had to schedule my classes throughout the day to accommodate my new sleeping schedule. Luckily, my doctors anticipated kidney failure the year before from changes in my creatinine levels, an indicator of kidney function, and I went through evaluations to be placed on the pediatric waiting list.

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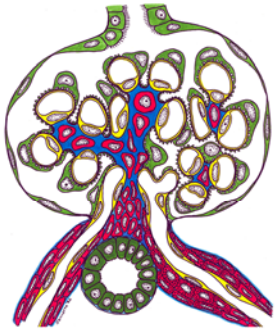
Lauren Creecy



Health care professionals and patients working together to learn more about diseases that affect the filters (glomeruli) in the kidney.

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Patient Perspective Continued from page 1

Because higher priority is given to children, especially if you have accumulated time, I received my first call to the hospital in October of my first semester of college. I was 18 years old. I prepared and waited for a few hours, but the doctors were not happy with the condition of the deceased donor's kidney and did not think it was a good fit for me.

I did not lose hope since I knew what was meant for me would be. On Christmas day of the same year, I received that call again and rushed to UNC hospitals again. After waiting and preparing a few hours, this was the one! I was taken to surgery immediately and the next thing I knew I was waking up to a kidney ultrasound with mild pain. I spent a week in the hospital and started my new regimen of immunosuppressive pills I would be taking for the rest of my life. I instantly felt better: no more sleeping all day! In those first few months, I was extra careful about what I ate and stayed away from people who may be sick. By May, I was back in school, continuing my college studies.

About 2 years into my transplant, I began to feel out of the ordinary, experiencing night sweats, chills, and pain in my spleen. After a few emergency room visits, my doctors diagnosed me with post-transplant lymphoproliferative disorder (PTLD), a form of lymphoma cancer. This is a rare condition caused by too much immunosuppression. I had lesions in my chest and my abdomen, requiring 6 months of chemotherapy. It was a difficult time for my family and me; I lost all my hair and now had to see an oncologist. The combination of the chemotherapy and immunosuppressive drugs weakened my immune system to the point where I could no longer fight common infections, with one infection taking over my kidney. I learned my new kidney had endured too much and I was preparing for another transplant. This did not discourage me from transplantation, I just knew this is what I had to do if I wanted to get better and live.

This time I was no longer a pediatric patient and would have a longer waiting time, especially since I had blood type O. I could wait, but my best option to avoid dialysis again, would be a living donor, versus a deceased donor like the first time. My mother and her side of the family were not able to donate since hypertension (high blood pressure) runs on their side of the family. My father had died of cancer before my first transplant, so I turned to his side of the family who of course were fearful at first. My uncle decided to step up to the plate and undergo testing to see if he was a match for donation. He was in fact a match and we were able to schedule my transplant for a few weeks after my college graduation. As a word of advice, try to stay as healthy as possible before your transplant, because if you are sick, the doctors will reschedule. After sitting in the rain at my graduation, I became sick with a sinus infection and had to move my surgery to the next month.

This time when I woke up, I did not feel any pain and was talking and taking pictures like nothing ever happened. The surgeons tell me that as soon as they got the kidney in place, I urinated on his foot. The doctors did not remove any of my other kidneys, but placed the new kidney on the opposite side of my lower abdomen. Again, I was back to class starting my new journey in pharmacy school within 2 months. My uncle was back to work in no time and has been a living healthy life with one kidney. Currently, I still have the same kidney. There have been a few minor ups and downs, but overall, I am doing great under the care of wonderful UNC doctors. There is a possibility I will need another kidney, but I am prepared and never fearful because I know what to expect. I am a strong believer that we are only given a journey that we are strong enough to bear and sometimes our journey is a little harder to help those after us. Please do not be afraid to share with others that you are in need of a transplant. You will be surprised by the amount of people that want to support you and donate their organ to you. I encourage everyone that is able, to become living and deceased organ donors. For those awaiting or in need of a transplant, do not lose hope. Be willing to do what you have to in order to become healthy and live your life.

References

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BEYOND SALT: ADDED SUGAR 101

Anne Froment, Study Coordinator

> "Don't add salt to your food." "Look at the sodium content on the package." "Rinse the beans from the can to reduce the salt content before using them"

If you have high blood pressure, you have probably heard this from your doctor or your nutritionist. All eyes on the salt!

But sugar is another player you need to be careful about. We need sugar in our daily diet to fuel our bodies, as UNC nutritionist Judy Lester explained in the fall 2018 newsletter [1]. However, the sugar we need is the one that occurs naturally in fruits, vegetables, milk, whole grain, brown rice.

Free sugar – the sugar added to a drink or a food- is another story. Evidence is mounting that too much added sugar is definitely not good for you. Recent reports have found that regular consumption of sugary drinks increases the risk of tooth decay, obesity, fatty liver disease, type 2 diabetes, heart disease and premature death.[2]

Added sugars can harm your health but they are everywhere as manufacturers add extra sugar to 68% of packaged foods and beverages sold in the US. [3] Did you know that, "On average, Americans eat 23 teaspoons of added sugars a day".[4] A key recommendation from the 2015-2020 Dietary Guidelines for Americans is to "consume less than 10% of calories per day from added sugar"[5], about 12 teaspoons.

Added sugar comes under different names. If a label mentions one of the following items, your food/drink does contain added sugar: glucose, fructose, high-fructose corn syrup (HFCS), agave nectar, molasses, fruit juice, golden syrup, sucanat, sorghum syrup, barley malt, brown rice syrup, corn syrup, dextrin, dextrose, diastatic malt, ethyl malitol, lactose, malt syrup, maltodextrin, maltose, galactose, and the list is not complete.

Since soda and other sugary drinks –energy, sports and fruit drinks, and sweetened teas- account for about half (46%) of the added sugar we consume, a great way to decrease our added sugar intake is to remove those liquid calories from our menu –and our kids menu. See page 4 in this newsletter for recommendations from a chef and kidney patient on how to drink less sugar in your beverages.

Test your knowledge of sugar in food and rink by trying out the Sugar Overload calendar here: www.healthyfoodamerica.org/sugar_calculator

To conclude: it's OK to enjoy the sugars that are naturally present in fruits, vegetables and dairy products. But beware of the massive amount of ADDED sugar present in our diet. Look at the salt content of what you buy– but don't forget to check the sugar, too!

Make your own sugar free beverage: Add a couple of (washed) orange, lemon, lime, or cucumber slices to a quart of water. Or add herbs: mint, rosemary, lavender. Refrigerate or add ice cubes. Enjoy!

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Patient Voice: Diet & Risk for Developing Kidney Disease

By Diane Sunwold, Instructor, Inland Northwest Culinary Academy, Spokane, WA

I was diagnosed with minimal changes disease, and I am very interested in research that shows lifestyle patterns that affect kidney disease. I was diagnosed 18 years ago and have spent the past two decades successfully experimenting with food and how protein affects my kidney disease. By replacing animal protein with plant-based protein, I was able to put my CKD into remission.

In Issue 14 (2019) of the Clinical Journal of the American Society of Nephrology, Rebholz et al.[1] research the effect of sugar-sweetened beverages on kidney disease risk. Important studies, such as this one, motivate me to restrict my consumption of sugar-sweetened drinks and help educate other patients with kidney disease on the affect that sugar-sweetened beverages have on kidneys.

It is common practice in restaurants to allow employees to drink sodas for free. During the hot summer months, I was drinking more sodas per shift. This increase in sugar-sweetened beverages made me less tolerant of the heat in the kitchen. I appreciate my physical response, because it motivated me to change my beverage consumption from sodas to fruit-infused flavored water. Chances are I could have decreased my kidney function even more if I had not made this lifestyle change. I look back on that situation and realize that my experience does support these research findings: a higher intake of soda could be associated with greater odds of decreasing kidney function.

Living in the Pacific Northwest, I have great empathy for people who live in the southern region of the United States. Their climate is very similar to the working conditions in a commercial kitchen; it can be sweltering. I understand why people would be drinking more liquids in this environment. As a chef, we spend our lifetime developing flavors, which people want to enjoy when eating and drinking. However, this desire for flavor can easily lead people, like me, down the path of sugar-sweetened drinks. It can be standard practice in some food establishments to give the kitchen staff an after-shift beer, which seems like a double dose of trouble for people's kidneys, because this research also indicates a higher association with CKD in people who consume more tea and beer.

As a chef, what recommendations do I give patients with kidney disease trying to decrease their consumption of sugar-sweetened drinks?

1. I educate patients. I remind them to read nutritional labels and record the amount of sugar that they consume in a day from beverages. I had to learn how addictive sugar is for me; the more I consume, the more I crave it. If I start drinking a soda with lunch, I will start craving a soda at every lunch.
2. I explain to patients that eating is a journey with kidney disease. How can I make this journey as enjoyable and healthy as possible? People look at food and beverage as a one-time event, a meal that we sit down and enjoy. As a patient, I had to teach myself to look at my consumption accumulatively. This helped motivate me to make changes with my diet for my kidneys. I slowly made changes every day and built on my successes. To change my beverage consumption, I just slowly started removing a small number of sugar-sweetened beverages each day and built on it.
3. I tell patients that we can re-educate our palate. Instead of drinking sweet tea, I replaced it with a drink called an Arnold Palmer: 50% unsweetened iced tea and 50% lemonade. The unsweetened iced tea dilutes the sugar in the lemonade. Then, over time, as my tastes change, I decreased the lemonade and added more unsweetened iced tea.
4. I like to use Stevia; it is a natural sweetener from the leaves of the rebaudiana plant. The leaves have a sweeter taste on our tongue. I drink a green tea that has a small number of stevia leaves mixed in with the tea leaves. The tea has a mildly sweet flavor without the addition of sugar.
5. Be careful of natural sweeteners. Some health-conscious people replace sugar with honey, maple syrup, agave nectar, and molasses. These sweeteners are digested like sugar. ***Continued, next page...***

KEEPING UP WITH THE KEOP

The KEOP has had a fun and active year. From education talks to screenings to working with students, the KEOP is working hard to spread the word about kidney health.

Early in the year, we visited barbers in Edgecombe County and talked to them about how kidneys work, and how kidneys can be affected by conditions such as diabetes and high blood pressure. We worked hard to empower them with health information they can pass onto their patrons.

Our screening events took us to Cumberland, Orange, Lenoir, and Edgecombe County where we talked about kidney health and screened community members for indicators of kidney disease. We look forward to several more screening events this fall.

Through all our efforts, in the office and out in communities, we have had the pleasure of growing our team and working with both graduate and undergraduate students to provide opportunities for professional growth in many different ways.

Mark your calendars! The 2019 Triangle Kidney Walk, put on by the National Kidney Foundation, will be in Durham, NC on Sunday – November 17, 2019! Come walk and join the UNC team, Carolina Kidney! For more information, visit www.kidneywalk.org

Make sure to stay up to date with the KEOP: https://unckidneycenter.org/outreach/
You can also follow us on twitter at: https://twitter.com/UNCKidney

Diet and Risk for Developing Kidney Disease **Continued from page 4...**

6. Take a lesson from the spa; they offer fruit-infused water. You can make your own for pennies and put it in your water bottle. I like a few pieces of fresh pineapple and strawberries. Some people like slices of cucumber. When I make an infused water, I do it the night before and keep it in my refrigerator; it is chilled and tastes great the next day.
7. When dining in restaurants, I always ask for a wedge of lemon in my water. It motivates me to drink water, the lemon keeps the water tasting fresh, and it keeps me from ordering a soda.

Patients with kidney disease have many challenges; I try to reward myself with healthy flavor wherever I can. I believe that patients can successfully add healthy flavor, and this research supports why patients with CKD need to decrease the number of sugar-sweetened beverages.

References: 1. Rebholz CM, Young BA, Katz R, Tucker KL, Carithers TC, Norwood AF, Correa A: Patterns of beverages consumed and risk of incident kidney disease. Clin J Am Soc Nephrol 14: 49–56, 2019

This article was reprinted, with permission, from the Clinical Journal of the American Society of Nephrology (Rebholz CM, Young BA, Katz R, Tucker KL, Carithers TC, Norwood AF, Correa A: Patterns of beverages consumed and risk of incident kidney disease. Clin J Am Soc Nephrol 14: 49–56, 2019).

Study Spotlight: Tailoring Maintenance Therapy in ANCA Vasculitis

Clinical study title: "Tailoring Maintenance Therapy to Cluster of Differentiation 5 Positive (CD5+) Regulatory B Cell Recovery in ANCA Vasculitis"

Funding: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Principal investigator: Vimal Derebail, MD, University of North Carolina (UNC), Chapel Hill

Co-investigators at UNC: Donna O'Dell Bunch, PhD; Ronald Falk, MD; John Schmitz, PhD; Shannon Mahoney Murphy, MD; Koyal Jain, MD; Manish Saha, MD

Statistician: Susan Hogan, PhD

Study coordinators: Anne Froment and Sandy Grubbs, MSN, RN; sandy_grubbs@med.unc.edu (919) 445-2657

Sponsors/collaborators; University of North Carolina, Chapel Hill; National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Study location: University of North Carolina, Chapel Hill

Study timeframe: May 2019–December 2022

Q&A with Sandy Grubbs (SG), Nurse Research Coordinator

Most patients with ANCA (anti-neutrophil cytoplasmic antibody) vasculitis make antibodies to either myeloperoxidase (MPO) or proteinase 3 (PR3) that can attack certain white blood cells called neutrophils and monocytes and cause inflammation in their blood vessels (vasculitis). Other white blood cells (B cells) produce these autoantibodies against "self" proteins. Our previous research with samples from patients in the GDCN has shown that some B-cell abnormalities are associated with a higher frequency of relapse. We found that a special type of B cell called "CD5+" was decreased during active disease and returned to normal levels during remission. We think these cells indicate the level of "regulatory" B cells that help keep the autoantibody-producing B cells in check. These findings have now led to the current proof-of-concept clinical trial.

What are the goals of this new clinical trial?

SG: Patients with ANCA vasculitis (GPA, MPA and EGPA) are routinely treated with immunosuppressants—medications that decrease their immune system function. The treatment lasts several months with an initial "induction" phase aimed at stopping the inflammation and a "maintenance" phase aimed at decreasing risk of relapse. The risk of relapse varies considerably between patients, and we believe that some patients have a relatively low risk of relapse and may not need continued maintenance immunosuppression.

The purpose of this research study is to learn if a special blood test can help us identify which patients could be closely monitored without additional immunosuppressive maintenance treatment during remission. By collecting health information and laboratory samples, our goal is to learn more about this disease and find better ways to tailor treatment of ANCA vasculitis to an individual's needs.

How will the study be conducted?

SG: Patients will be enrolled in this study after they have completed the initial phase of treatment for ANCA vasculitis and they are in remission. We will monitor patients' blood for return of B cells and treat according to whether the CD5+ B cell levels are low or at a normal level, using the same medications they would receive if they were not participating in this trial. We believe that the number of these B cells can give us an indication of the risk of having a relapse of ANCA vasculitis in the future.

Continued on next page….

KidneyTalk™ is an informative online talk show hosted by Renal Support Network's Founder & President Lori Hartwell. Each half-hour show features a special guest who has first-hand knowledge, an inspirational story or decades of wisdom to share with listeners on how to survive and thrive with kidney disease. Hundreds of shows available 24/7 at RSNhope.org and on iTunes.

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To Be Young and Dating with Kidney Disease Web ID: 948 · The Kidney Project Update Web ID 3023
Cooking for your Kidneys Web ID 3037 · Dialysis Basics of Dry Weight and Fluid Management Web ID 3035
Having a Baby on Dialysis Web ID 3038 · What is a Preemptive Kidney Transplant? Web ID 3021

RENAL SUPPORT NETWORK RSNhope.org

Study Spotlight Continued…

How is this study different from other studies on this subject?

SG: This study is not testing new medications. Treatment will use the same medications that are routinely used for maintenance treatment in ANCA vasculitis. We're testing whether some patients whose CD5+ B cells return to normal levels can be followed closely without receiving additional maintenance treatment.

Are there any potential benefits to patients who enroll in this trial?

SG: Depending on their CD5+ B cell levels, patients may be randomized to stop immunosuppressive therapy with close monitoring. Being off therapy would likely reduce the risk of infections and other side effects of standard therapy. Patients will be seen in clinic by UNC nephrologists and have frequent phone check-ins with the study nurse. This careful surveillance by study personnel is intended to detect any signs of relapse or active disease early, so that appropriate therapy can begin as soon as possible.

How will this study help people with vasculitis?

SG: If measuring the CD5+ B cell levels to guide decisions about immunosuppressive medication brings good results, we will have a new tool to better tailor treatment to each patient's individual needs, avoid unnecessary treatment and potentially avoid relapse.

Do you have any concluding remarks?

We are grateful to the patients who contribute research blood samples—without their participation, there would be no research and no progress. We also want to express our appreciation to GDCN physicians who refer patients for our studies. We thank the Vasculitis Foundation for funding early B cell studies that were the foundation for subsequent work that has now led to this "proof of concept" trial.

For more information on this trial, please visit: https://clinicaltrials.gov/ct2/show/NCT03906227

Recent Publications Using GDCN Registry Data

Thanks to your generous participation in our patient registry, we are able to conduct a wide range of studies to help further our understanding of glomerular (kidney) diseases. See below for some of our most recent publications. To read more, you can look up these articles on www.pubmed.com.

Understanding ANCA patients who remain in remission off therapy

Clinical data from 427 people with ANCA vasculitis was reviewed to investigate who reached disease remission and stopped all immunosuppressive therapy, and to understand if they relapsed more than people who stayed on treatment continually. A total of 277 (65%) subjects were able to stop all immunosuppressive treatment at least once during follow up, with half staying off for two years or more and a subset of those (22%) staying off for 5 or more years . More women and those who had been treated with intravenous (IV) steroids stopped treatment more often, although investigators are not sure why. There was a higher risk of disease relapse over the first two years of stopping all immunosuppressive therapy (compared to staying on treatment continually), but for those who made it beyond two years, their risk of relapse was similar to those on treatment continually. In a subset of those who stopped treatment, relapses while off immunosuppressives were evaluated, and remission was reached swiftly with a new course of immunosuppressive treatment. Breaks in therapy may help the immune system to recover and reduce long-term risks of infections and other treatment-related problems, but this must be weighed against the risk of disease relapse. More research is needed on who can safely stop treatment and when, and the information learned from this study provides an important foundation to learn more.

Publication Details: Hogan SL, Nachman PH, Poulton CJ, Hu Y, Blazek LN, Free ME, Jennette JC, Falk RJ. **Understanding Long-term Remission Off Therapy in Antineutrophil Cytoplasmic Antibody-Associated Vasculitis.** Kidney Int Rep. 2019 Jan 28;4 (4):551-560. Link: ncbi.nlm.nih.gov/pmc/articles/PMC6451087/

How does the immune system attack myeloperoxidase (MPO) in patients with anti-neutrophil cytoplasmic autoantibody (ANCA) vasculitis?

Using blood samples and clinical data from GDCN participants, investigators looked at the responses of two different immune cells in patients with ANCA vasculitis. B cells are known to make antibodies—the Y-shaped proteins that target bacteria and viruses normally. However, in ANCA vasculitis, these B cells make antibodies that target MPO or proteinase-3 (PR3). This study focused just on those MPO-ANCA vasculitis patients. The other cell type investigated were T cells. T cells tell the immune system to respond in a pro-inflammatory or anti-inflammatory manner. This study analyzed B and T cells to determine if there were certain regions within MPO that stimulated the immune system more in patients. The data suggested that in a group of patients (about 50% of MPO-ANCA patients), there is a restricted region within MPO that triggers the immune response in both T and B cells. Interestingly, this MPO region is normally "hidden" from the immune system under normal circumstances. Therefore, future studies will try to determine what triggers may "open up" MPO to permit this immune response.

Publication Details: Free ME, Stember KG, Hess JJ, McInnis EA, Lardinois O, Hogan SL, Hu Y, Mendoza C, Le AK, Guseman AJ, Pilkinton MA, Bortone DS, Cowens K, Sidney J, Karosiene E, Peters B, James E, Kwok WW, Vincent BG, Mallal SA, Jennette JC, Ciavatta DJ, Falk RJ. **Restricted myeloperoxidase epitopes drive the adaptive immune response in MPO-ANCA vasculitis**. J Autoimmun. 2019 Aug 2 . Link: ncbi.nlm.nih.gov/pubmed/31383567

CURE GLOMERULONEPHROPATHY (CUREGN) UPDATES

The Cure Glomerulonephropathy Network (CureGN) is a study of 2,400 children and adults with glomerular disease. **238** subjects have now been enrolled from UNC and there are 2362 subjects enrolled overall. Now that we have a few years of data under our belts, studies are taking shape and data is being analyzed. See below for some recent papers using CureGN data, and thank you for your participation! If you would like to see if you are eligible for this study, please contact Maggie D'Angelo at Maggie_dangelo@med.unc.edu or by phone at 919-619-1773.

Health-related Quality of Life in Glomerular Disease: Using data from the Patient Reported Outcomes (PRO) questionnaire of 478 children and 1115 adults from their enrollment visit, researchers have begun to analyze some of the effects of glomerular disease on patient well-being. Among other findings, researchers note that the factor most closely associated with patient reported quality of life at time of enrollment is swelling. These findings can help doctors and other members of the health care team address and manage the most concerning issues for patients diagnosed with glomerular disease. Follow up visit PROs and additional clinical values may be used for further analysis of the impact of glomerular disease on participant's lives.
Link to abstract: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5220669/

Prevalence of Cardiovascular Disease Risk Factors in Childhood Glomerular Diseases: Data from 761 CureGN pediatric participants was analyzed to better understand the frequency of risk factors for cardiovascular disease (diseases effecting the heart or blood vessels). Compared to the general pediatric population, researchers found that the risk factors for cardiovascular disease are found more often in children with glomerular disease, especially dyslipidemia (too many lipids in the blood). Rates of high blood pressure and obesity are also increased. This study highlights the need for standardized screening guidelines for cardiovascular risk factors in children with glomerular diseases. Link to article: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6662122/

Differences between IgA Nephropathy or IgA Vasculitis: Published in *Kidney International Reports*, this study describes the clinical characteristics and treatment patterns of the IgA cohort. Data from a total of 667 adult and pediatric subjects was used. Differences between the IgA Nephropathy (IgAN)cohort and IgA vasculitis (IgAV) cohort were analyzed. Compared to subjects with IgAN, subjects with IgAV were younger, more frequently white, had better kidney function at the time of biopsy, and were more likely to have been treated with immunosuppressants at or prior to study enrollment. This study can be used as a baseline for future CureGN studies.
Link to article: ncbi.nlm.nih.gov/pmc/articles/PMC6224619/

NEPHROTIC SYNDROME STUDY NETWORK (NEPTUNE) UPDATES

What is NEPTUNE Made Of? NEPTUNE is made of over 750 participants. 44% of our participants are children, but NEPTUNE is made up of participants from a wide range of ages. In fact, our youngest participant is only 4 months old, and our oldest participant is 85 years old! Thanks to your time and efforts, NEPTUNE participants have completed over 6,400 study visits at our 37 study sites since our start in 2011

So, what does this mean? This means that researchers are using the over 195,000 blood and urine samples collected to learn how to better treat people with FSGS, minimal change disease, and membranous nephropathy. There are over 110 research projects underway, and we have published more than 44 articles.

You can search for NEPTUNE publications yourself using PubMed:

Site: www.ncbi.nlm.nih.gov/pubmed
Search: Nephrotic Syndrome Study Network (NEPTUNE)

STUDIES CURRENTLY RECRUITING GDCN PATIENTS

The GDCN and the UNC Kidney Center are actively recruiting patients into the studies listed below and on the next page. Please contact the study coordinators listed at the bottom of page 11 if you are interested in learning more.

NEPHROTIC SYNDROME (FSGS, MEMBRANOUS, MINIMAL CHANGE DISEASE, IGAN)

Study name and sponsor	*Study Doctor*	*Study coordinator*	*More about the study*
C-NEPTUNE (NIH)	Keisha Gibson	Sandy Grubbs	Observational study of children newly diagnosed with Nephrotic Syndrome. Before renal biopsy and < 30 days of treatment.
CureGN (NIH/NIDDK)	Ronald Falk/ Amy Mottl	Maggie D'Angelo	Observational study of children and adults with MN, FSGS, IgA, or Minimal Change Disease biopsied in the last 5 years.

FSGS

Study name and sponsor	*Study Doctor*	*Study coordinator*	*More about the study*
DUPLEX (Retrophin, Inc)	Vimal Derebail	Anne Froment	Patients aged 8-75 with FSGS will be treated either with sparsentan, a dual endothelin receptor and angiotensin receptor blocker or with irbesartan.
Aurona (Aurinia)	Amy Mottl	Sandy Grubbs	Patients with FSGS who have > 2 grams of proteinuria will be treated with Voclosporin over 24 weeks.
PODO (Pfizer)	Amy Mottl	Anne Froment	Patients with FSGS will receive a new investigational drug called PF-06730512 to test for safety, efficacy, and tolerability.

ANCA Vasculitis

Study name and sponsor	*Study Doctor*	*Study coordinator*	*More about the study*
Maintenance therapy based on CD5+ regulatory B cell recovery (NIH)	Vimal Derebail	Sandy Grubbs	Patients with ANCA will be assigned to maintenance therapy or no maintenance therapy based on the level of a type of B cells in their blood.
IFX-1-P2.6 (InflaRx GmbH)	Vimal Derebail	Sandy Grubbs	Patients with GPA or MPA will be given a dose of a monoclonal antibody called IFX-1 or placebo. The study investigate the safety and tolerability of two dose regimens compared with placebo.

STUDIES CURRENTLY RECRUITING GDCN PATIENTS

LUPUS

Study name and sponsor	*Study Doctor*	*Study coordinator*	*More about the study*
MSCs in SLE Trial	Sarah Sheikh Manish Saha Keisha Gibson	Sandy Grubbs	Patients with moderate to severely active treatment refractory lupus (renal and non-renal) will receive an infusion of mesenchymal stromal cells (stem cells known to possess significant immunosuppressive properties) or placebo.

IGA NEPHROPATHY

Study name and sponsor	*Study Doctor*	*Study coordinator*	*More about the study*
Nef-301 (Calliditas)	Amy Mottl Manish Saha	Anne Froment	Patients will receive Nefecon (a special formulation of budesonide) or placebo to evaluate the safety and efficacy of Nefecon.

CHRONIC KIDNEY DISEASE

Study name and sponsor	*Study Doctor*	*Study coordinator*	*More about the study*
EMPA-Kidney (Boehringer Ingelheim)	Amy Mottl	Emmie Cole	Patients will received empagliflozin or placebo to assess if empagliflozin prevents kidney disease progression and heart problems.

DIABETES

Study name and sponsor	*Study Doctor*	*Study coordinator*	*More about the study*
TRIDENT (Boehringer Ingelheim, GSK, Regeneron)	Amy Mottl	Emmie Cole	Observational study of patients with Type 1 or Type 2 diabetes who are about to have a kidney biopsy. A piece of the kidney biopsy will be collected along with clinical information.
NeoKidney Augment Study (inRegen)	Randy Detwiler	Paula Steele	Patients with moderate to severely active treatment refractory lupus (renal and non-renal) will receive an infusion of mesenchymal stromal cells (stem cells known to possess significant immunosuppressive properties) or placebo.

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