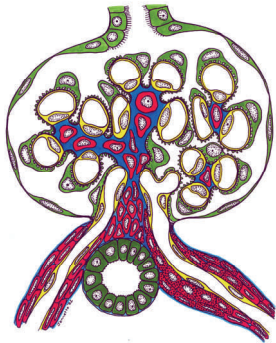


KIDNEY CARE

This Newsletter was approved by
the Committee on the Protection
of the Rights of Human Subjects
University of North Carolina
11/29/04



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

Co-Directors:

Ronald J. Falk, MD, and
J. Charles Jennette, MD

Research Director:

Susan Hogan, PhD

Pediatric Research Director:

Debbie Gipson, MD

Study Coordinators:

Caroline Jennette
Marcus Johnson
Trevor Presler

Research Assistants:

Sheri Kremer
Michelle Mitchell

In This Issue:

- **Study Updates**
- **How to be a kidney patient advocate.**
- **Tips on Transplants**
- **Useful websites and kidney support group information.**

ANCA-GLOMERULONEPHRITIS ENVIRONMENTAL STUDY: SOME INTERESTING FINDINGS

The Glomerular Disease Collaborative Network has recently completed collecting information on occupational and environmental exposures as well as on other factors that may cause or contribute to the development of vasculitis in the kidney. This is an important study because the cause of this disease is unknown.

The study conducted was a case-control study and was supported by a research grant from the National Institutes of Health. "Cases" included people from the GDCN vasculitis registry who were diagnosed with vasculitis in their kidney by a renal biopsy during or after 1998. "Controls" were identified from the general population through random telephone calls, a common method for obtaining a comparison group of people who do not have the disease being studied. Both cases and controls participated in a lengthy telephone interview that collected detailed information on lifetime occupations, a wide variety of tasks and hobbies, certain medical conditions and drugs, smoking history and many other items. A total of 260 people completed the interview: 161 with vasculitis and 99 from the general population, which is the largest study of this type that has ever been conducted to learn more about causes of vasculitis.

The information from the study is currently being evaluated. Preliminary results on one specific area of interest were reported at the October 2004 American Society of Nephrology meeting in St. Louis, Missouri. This evaluation suggested that exposure to silica dust over many years is likely to trigger the development of vasculitis in the kidney. Silica refers to the chemical compound silicon dioxide. One of the most common forms of silica is quartz, which is an ordinary component of soil and rock. Occupations and tasks within dusty environments, especially those with dust from soil or rock, or that involve heating silica (foundry and some manufacturing occupations) can lead to exposure to silica. Evaluation of silica exposure for our study has been done by an Industrial Hygienist who is familiar with types of jobs and environments that are likely to include silica exposure. Much of the silica exposure in our study sample was due to certain types of farming tasks, although more evaluation is needed to thoroughly evaluate all types of occupations and tasks and to determine if certain occupations put people at higher risk for the development of vasculitis in the kidney. Overall, the results from this study are in agreement with other smaller and less thorough studies of this type.

There are many additional research questions that we will learn more about using the information from this study. For example, does exposure to silica dust influence the involvement of different organs with vasculitis, the loss of renal function and the development of disease relapses? Although the evaluation of silica dust was a primary goal for the study, the impact of other occupational exposures, smoking and certain drugs on the development of vasculitis of the kidney will also be studied.

We appreciate the time and willingness that so many of you have already given to make this and other studies of this type possible. We will continue to keep you posted as we learn more from this study. We also hope to do more of this type of study to learn about the risk factors for other kidney diseases.

For more information on health effects and the definition of silica, please see the website prepared by the Center for Disease Control and the National Institute for Occupational Safety and health: <http://www.cdc.gov/niosh/02-129E.html#oneone>, or call us and we will print and mail a copy of the information to you.





NATIONAL, MULTICENTER CLINICAL TRIAL NOW ENROLLING FOR PATIENTS WITH STEROID-RESISTANT FSGS

The FSGS Clinical Trial (FSGS-CT) is a research study being carried out in hospital clinics and doctors' offices in the United States, Mexico, and Canada in an attempt to improve therapy for patients 2-35 years old with focal segmental glomerulosclerosis (FSGS) and persistent proteinuria.

Focal Segmental Glomerulosclerosis (FSGS) is a disease of the glomeruli, which are the filtering units of the kidney. This disease causes scarring in the kidneys. The scarring causes kidneys to lose protein in the urine (proteinuria) and reduces the kidneys' ability to function.

Individuals may be eligible to participate in this study if they have FSGS and have had some therapy (corticosteroids such as prednisone) to decrease the amount of protein in their urine. If this therapy has not worked and a different therapy is needed, individuals may qualify for this study. About 500 children and adults in North America (ages 2-35) will take part in this study.

The UNC-CH Division of Nephrology & Hypertension is one of the 5 core coordinating sites for this study. For more information, please contact Trevor Presler, Michelle Mitchell, Cathy Lambeth, or Caroline Jennette at (919) 966-2561. You can also leave a message on our toll-free patient line (1-866-462-9371) or visit www.fsgstrial.org.

This study is sponsored by the National Institutes of Health (NIH) and the National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK).

CLINICAL TRIALS: FAQ

(REPRINTED WITH PERMISSION FROM WWW.CLINICALTRIALS.GOV)

What is a clinical trial?

A clinical trial (also clinical research) is a research study in human volunteers to answer specific health questions. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people and ways to improve health. Interventional trials determine whether experimental treatments or new ways of using known therapies are safe and effective under controlled environments. Observational trials address health issues in large groups of people or populations in natural settings.

What are the phases of clinical trials?

Clinical trials are conducted in phases. The trials at each phase have a different purpose and help scientists answer different questions:

- In **Phase I trials**, researchers test a new drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- In **Phase II trials**, the study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.
- In **Phase III trials**, the study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
- In **Phase IV trials**, post marketing studies delineate additional information including the drug's risks, benefits, and optimal use.

What kind of preparation should a potential participant make for the meeting with the research coordinator or doctor?

- Plan ahead and write down possible questions to ask.
- Ask a friend or relative to come along for support and to hear the responses to the questions.

Every clinical trial in the U.S. must be approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits. An IRB is an independent committee of physicians, statisticians, community advocates, and others that ensures that a clinical trial is ethical and the rights of study participants are protected.

For more information check out www.clinicaltrials.gov or call 1-800-411-1222

“Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people.”

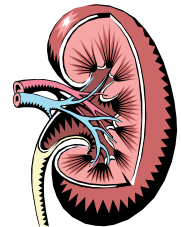
LUPUS STUDY UPDATE

This is a very busy time for lupus research within the GDCN. There are several ongoing research projects, including clinical trials and the *Carolina Lupus Follow-up Study*, sponsored by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and the National Institute of Environmental Health Sciences (NIEHS). Lupus patients are more likely than others to develop kidney involvement and progression of kidney disease. Some of the exposures we want to examine as “risk factors” for lupus include medical history, work history, exposure to smoking and environmental agents, medications, hobbies, and the presence or absence of certain inherited genes. Information from lupus nephritis patients will be compared to information from people living in the same communities who do not have this disease and to lupus patients without nephritis. We are in the telephone interview phase of this study, which means that subjects are being contacted and asked questions regarding medical history, pregnancies, places they’ve lived, and family history of certain diseases.

Another lupus project that is underway is *The Systemic Lupus International Collaborating Clinics Registry For Artherosclerosis*. The Systemic Lupus Erythematosus International Collaborating Clinics (SLICC) is a group of rheumatologists from 30 international centers who have been working together to carry out research in Lupus. The SLICC group has established an international registry of patients to look at the importance of heart disease and nervous system involvement in SLE. The purpose of this study is to develop a registry or database of information on a large number of newly diagnosed SLE patients and to follow these patients over time. SLE is associated with increased risk for coronary artery disease (CAD). This can occur at younger ages and more frequently than the general population. While lupus patients may have more risk factors (diabetes, high blood pressure, increased cholesterol levels, etc.) it is also a concern that lupus itself may be a risk factor. This study allows researchers to determine the prevalence and nature of early atherosclerotic coronary artery disease, identify associated risk factors and gain important insight into the prevalence, causes and management of CAD and nervous system involvement in lupus.

For more information about either of these studies, please contact Marcus Johnson, Lupus Research Coordinator at UNC, at 919-966-2561 ext. 227, or leave a message on the GDCN Toll-free patient line (1-800-462-9371).

THE TRUTH ABOUT TRANSPLANTS



By Clara Neyhart, RN, UNC Kidney Transplant Coordinator

Receiving a kidney transplant is often a joyous occasion for patients and their families. Receiving a kidney transplant can mean more independence and a return to normal life activities, but it is not a cure for kidney disease. It is important to understand both the risks and benefits of transplantation. Nephrologists, transplant nurses, social workers, and surgeons at the transplant center can help patients understand risks and benefits in more detail, but here are some things to consider:

- Transplant centers have individual differences, but most centers do not offer kidney transplantation to patients with the following health problems: active cancer, active infection, untreatable heart or blood vessel disease, severe blood clotting disorders, current alcohol or drug abuse or severe lung disease. These conditions put patients at risk for severe complications during or following transplantation.
- Transplant patients have to take anti-rejection medications every day, for the life of the kidney. These medications have side effects that may affect one's quality of life, but are essential to maintain the transplanted organ. Patients should talk with the transplant team and have a good understanding of these medications before being listed for a transplant.
- Anti-rejection medications are very expensive. Medicare will pay a part of the cost, but not the whole cost, and presently, only for three years. Private insurance will pay for these medications, but will often require a copay by the patient. Medicaid is also a means of obtaining medication coverage, but patients must qualify for Medicaid, and Medicaid does not provide free care. Patients should have a clear understanding of how they will pay for their medications.
- Transplantation is a great option for patients who want to be independent and participate in their care. It is the patient's responsibility to monitor themselves for complications, call the transplant team for help, go to all clinic appointments, have lab work drawn as prescribed, never run out of medications, and take medications correctly and consistently.

For more information on the transplant process, check out www.transplantliving.org, a patient information site sponsored by the United Network for Organ Sharing (UNOS). You can also call their toll-free patient line at 1-888-894-6361.

A whole new way to think about mouthwash!



Scientists can now analyze the genetic make-up of a patient by simply performing tests on mouthwash samples. This involves analyzing the genetic material (DNA) contained in cells shed from the mouth when you gargle with mouthwash.

These genetic tests will help to determine whether there are certain genes that make some people more likely to develop kidney diseases, or whether there are genes that are expressed more in patients with certain diseases or symptoms than in people without these disease and symptoms.

Carla Nester, MD, a nephrology fellow that works at UNC, has already gotten mouthwash samples from 87 GDCN patients, and plans to branch out into other types of glomerular disease.

ATTENTION:

What would you like to see in the next newsletter?

Please let us know at 1-866-462-9371 or by e-mailing gdcn@med.unc.edu.

PAIRS STUDY: NOW RECRUITING COUPLES WITH VASCULITIS AND LUPUS

Partners Adjusting to Illness with Relationship Support

The Thurston Arthritis Research Center at the University of North Carolina at Chapel Hill is conducting a research study specifically for couples living with vasculitis, or related conditions. The purpose of this study is to examine support and coping in married couples where one spouse has vasculitis, or a related condition. This study will examine the different ways couples communicate with one another, and how this might be related to coping with vasculitis. We hope to gain a better understanding of how communication and support affect coping when one spouse has a chronic condition like vasculitis. The recruitment goal for this study is 150. Eighty-five couples have been screened and enrolled.

Do You Qualify?

You may qualify for this study if:

- You are married; and
- You have been diagnosed with a form of vasculitis, such as:
 - Wegener's Granulomatosis
 - ANCA Disease
 - Microscopic polyangiitis,
 - Lupus Nephritis
 - Several others (ask us if you are not sure!)



What Does the Study Involve?

In this study, couples will be asked to complete three sets of mailed surveys at home. They will also be asked to complete two separate in-person interviews. The interviews will be conducted at several locations, including UNC-Chapel Hill and other satellite offices across the southeastern United States. Couples who complete the study will receive \$150 for their participation.

TO FIND OUT MORE:

If you would like more information about this study, **please contact Tracy Barrett at (919) 843-9256, or toll-free at (866) 827-2862 (please ask for Tracy Barrett), or via email at: tmbarr@email.unc.edu.**

THE VASCULITIS SELF-MANAGEMENT STUDY

Help us understand how individuals living with vasculitis manage their condition!

The Vasculitis Self-Management Study is a research study for individuals who are living with vasculitis (or related conditions). We hope to learn more about the experiences that individuals with vasculitis have with carrying out the treatment plans suggested by their doctors. If you decide to participate, we will ask you to complete a survey that asks you about your feelings about your vasculitis and the tasks you perform to manage your illness. Participants will receive \$10 for completing the survey.

Do You Qualify?

You may qualify for this study if:

- You are over 18 years of age
- You have been diagnosed with a form of vasculitis, such as:
 - o Wegener's Granulomatosis
 - o ANCA Disease
 - o Microscopic polyangiitis,
 - o Glomerulonephritis,
 - o Churg-Strauss syndrome,
 - o Several others (ask us if you are not sure!)

To Find Out More: Please call us at 919-966-7538 or toll free at 1-866-827-2862 if you would like more information about this study. You may also email us at ckalino@email.unc.edu. Your participation will help us better understand how individuals living with vasculitis manage their illness.

You are the expert about your condition, and we want to learn from you!

PATIENT ADVOCACY: TAKE ACTION AND HELP SUPPORT BILLS FOR KIDNEY PATIENTS!

In the fight for health awareness and disease prevention, it is important and empowering for patients to get involved in political decisions that may affect them and the future of their disease. Kidney patients know, like no other person can, the challenges and triumphs of living with kidney disease. Your local, state, and national representatives are accountable to you and are available to listen to your thoughts, ideas, and concerns. The following are some ways to make your voice heard and help support kidney disease prevention, early detection, and research.

- Write a letter to the editor of your local paper.
- Call or e-mail your local and state representatives.
- Raise awareness of kidney disease by speaking at your church or at a town hall meeting.
- Schedule a visit to meet with your local elected leaders; bring a group of friends, family members, or patients to talk about their experiences with kidney disease.

For more information and resources on how to be a kidney advocate, contact Caroline Jenette, MSW, at 919-966-2561 ext. 263 or leave a message on the toll-free GDCN patient line (1-866-462-9371). Caroline can also help you figure out who represents you on the national and state level.

HOUSE BILL 3635: MEDICARE CHRONIC KIDNEY DISEASE MANAGEMENT ACT OF 2003

Clinical research has indicated that appropriate medical treatment, education and counseling programs furnished during the early stages of kidney disease can help prevent and/or slow down the progression to end-stage renal disease.

House Bill 3635 was created to provide coverage under the Medicare Program for chronic kidney disease patients who are not end-stage renal disease patients. If this bill is passed, Medicare would be responsible for expanding services to cover patients with advanced, chronic kidney disease. This bill would pay for patients with chronic kidney disease to receive individual or group nutritional counseling services by a registered dietician or nutrition professional, disease counseling from a qualified health provider to ensure active participation in disease management, and items and services to help patients prepare for the possibility of kidney transplant or dialysis.

This bill is currently being reviewed by the House Subcommittee on Health.

H.RES 610: AUTOIMMUNE RESEARCH BILL

Right now, many patients with autoimmune diseases like Lupus and ANCA take medicines on a daily basis to treat vasculitis or to keep it in remission. But there could be a day when patients might not have to maintain a daily regimen. It's possible as science makes advances in understanding how autoimmune diseases work.

The National Institutes of Health (NIH) Autoimmune Diseases Research Plan is the first federal initiative to cover all autoimmune diseases and investigate them as an interrelated group. In autoimmune diseases, the immune system goes awry and damages a patient's own body organs and system. They are a common cause of disability and are one of the top ten leading causes of death in children and women in all age groups up to 64 years of age.

Because these diseases cross many specialties and can affect all body organs, an integrated approach to research is critical. The NIH research plan calls for such an approach. The Resolution expresses the sense of Congress that this interrelated family of diseases deserves the integrated research proposed in the Autoimmune Diseases Research Plan.

For more information, contact Dianne Shaw, Wegener's Granulomatosis Association Advocacy Chair, at dgs@med.unc.edu or 919-929-9134



*Want to contact your
State Representatives
and urge support for
S.1114 and H.B.3635?*

On the web:

<http://www.house.gov>

<http://www.senate.gov>

<http://www.statelocalgov.net>

By Phone: 1(800) 333-4636

Use these resources to find out who represents you and how to contact them. If you need help locating your representative, leave a message on the GDCN patient line with your name, address, and telephone number and Caroline will let you know who they are :
1-877-462-9371

**A Newsletter from the
Glomerular Disease Collaborative Network**

345 MacNider Building, CB#7155
Chapel Hill, NC 27599-7155

Phone: 919-966-2561 ext. 263
Toll-Free: 1-866-462-9371
Fax: 919-966-4251
Email: gdcn@med.unc.edu



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

**RESOURCE CORNER:
SUPPORT GROUPS AND USEFUL ORGANIZATIONS**

National Kidney Foundation
30 East 33rd St.
New York, NY 10016
Phone: (800) 622-9010

Website: www.kidney.org
E-mail: info@kidney.org

The NKF offers many services for patients and their families, including education, emergency assistance, and a kidney early evaluation screening program.



National Kidney and Urologic Diseases
Clearinghouse (NKUDIC)
3 Information Way
Bethesda, MD 20892-3580
Phone: 1-800-891-5390

Website: <http://www.kidney.niddk.nih.gov/>
E-mail: nkudic@info.niddk.nih.gov

Connects to patient organizations,
government agencies, and the National
Kidney Disease Education Program.

Renal Support Network
1102 N. Brand Blvd., Box 74
Glendale, CA 91202
818/543-0896 Phone
818/244-9540 Fax

Website: www.renalnetwork.org
E-mail: info@renalsupportnetwork.org

Identifies and meets the non-medical needs of those affected by chronic kidney disease. Services include an annual Renal Prom for teenagers and a renal support network directory.



Wegener's Granulomatosis Association
P.O. Box 28660
Kansas City, MO 64188-8660
Phone: 1-800-277-9474

Website: <http://www.wgassociation.org>
E-mail: wga@wgassociation.org

The Wegener's Granulomatosis
Association offers comfort and support to WG
patients and families through
education, awareness and research.

The American Kidney Fund
Helpline: 1-800-638-8299
1-866-300-2900 (spanish)

Website: www.akfinc.org
E-mail: helpline@kidneyfund.org

The American Kidney Fund was founded in 1971 and has since become the nation's leading non-governmental source of direct financial assistance for needy kidney patients. Each year, AKF helps thousands of dialysis and transplant patients pay for treatment necessities.



American Association of Kidney Patients
3505 E. Frontage Rd., Ste. 315
Tampa, FL 33607-1796
Phone: 1-800-749-2257

Website: www.aakp.org
E-mail: info@aakp.org

The AAKP is the only national kidney patient organization directed by kidney patients for kidney patients. Services include a patient magazine, an online newsletter, and patient support and education.

