

THE M.U.S.C.L.E.

Medical University of South Carolina LUPUS Erythematosus Research Group,
Division of Rheumatology & Immunology

M.U.S.C.L.E



Welcome

Welcome to the Fall 2009 edition of the M.U.S.C.L.E. Group Newsletter. We at the **M**edical **U**niversity of **S**outh **C**arolina **L**UPUS **E**rythematosus Group are working extremely hard to identify causes and better treatments for Systemic Lupus Erythematosus. We are pleased to have had the opportunity of working with patients with lupus, their families, and friends over the years. It is because of you that we are able to do what we do. Many thanks and we hope that this newsletter is both informative and motivating in regards to the fight against lupus.

Lupus Clinical Research at MUSC

Community enthusiasm for the SLE (“lupus”) studies at MUSC has been tremendous, leading to several community-based initiatives to promote early screening and diagnosis for people at risk for lupus. Members of the MUSCLE group are active in education and research programs locally, nationally, and internationally. This is an exciting time in lupus research with many new discoveries in the field of autoimmunity and potential new therapies being developed. One drug developed for treating lupus, called Benlysta (full story on page 5), has shown significant benefit in two large clinical trials and has the potential to become the first approved drug in 50 years for people living with lupus!

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Lupus Investigators:

- Gary S. Gilkeson, MD (Rheumatologist)
- James C. Oates, MD (Rheumatologist)
- Diane L. Kamen, MD, MSCR (Rheumatologist)
- Holly C. Mitchell, MD (Rheumatologist)
- Natasha Ruth, MD, MSCR (Pediatric Rheumatologist)
- Melissa Cunningham, MD, PhD (Rheumatology Fellow)
- Marina Pulini-Franks, MD (Rheumatology Fellow)
- Hazel Breland, PhD (Occupational Therapist)
- Lee Moultrie (Community Research Associate)
- Brandi Eastman and David Gray (Medical Students)

Lupus Study Coordinators:

- Liezl de la Cruz-Tracy, CCRC
- LoriAnn Ueberroth
- Anna Meyer, PhD
- Christina Demos, MS
- Imani Fickling (Intern)



From Left to Right: Holly Mitchell, Hazel Breland, Diane Kamen, Anna Meyer, Christina Demos, LoriAnn Ueberroth, Liezl de la Cruz-Tracy, Imani Fickling. 2nd Photo: Lee Moultrie, Diane Kamen, Gary Gilkeson, Liezl de la Cruz-Tracy, LoriAnn Ueberroth, Anna Meyer, Jim Oates, Melissa Cunningham, Christina Demos, Brandi Eastman, David Gray.

Meet Imani Fickling, Our M.U.S.C.L.E. Group Intern



In 2005 I lost one of my aunts to lupus. In 2008 I lost a second aunt to lupus. It was at that point that I decided to learn more about the disease. Most people do not understand how life-threatening this disease is. I now know how debilitating it can be. The M.U.S.C.L.E. Research Group has been very active in the community helping to educate and build awareness. They have created a great program to assist patients with lupus. I am committed and enthusiastic about being a part of this initiative. My goal is to help build a focus on increasing healthy lifestyles for lupus patients.



Recent Accomplishments of the M.U.S.C.L.E. Group!

SWEET SIXTEEN! MUSC Division of Rheumatology was ranked #16 in the Country by U.S. News and World Report 2009

Congratulations to Liezl and LoriAnn for being awarded
Department of Medicine 2009
Employees of the Quarter!



Dr. Kamen was elected as a member of The Systemic Lupus International Collaborating Clinics (SLICC). This was a big accomplishment for M.U.S.C.L.E. to be included in this international collaboration of researchers from 30 major lupus centers - all fighting lupus together.



Our own LoriAnn Ueberroth was among the 10 nominees for MUSC Employee of the Year. What an Honor!

We are so lucky to have her on our the M.U.S.C.L.E. TEAM!

M.U.S.C.L.E. Group in the Community

One of the goals of our group is to build awareness of lupus and provide resources about early diagnosis and treatment of lupus to the public. We offer educational programs for patients with lupus on how to maintain a healthy lifestyle. For more information visit our website at www.musc.edu/lupus or contact us by email or phone.



Pictured left to right at a Health Fair in Beaufort, SC: Anna Meyer, Imani Fickling, Dr. Diane Kamen and Garrett Mann

Lupus Support Group and Local Chapter of the Lupus Foundation of America

For information on the "Lupus: Listening and Learning Group" in Charleston, please contact **Alice Burress at 843-886-5859**. All patients with lupus, family members, friends and supporters are invited!

DATE of NEXT MEETING: Monday, January 11, 2010 (meetings are the 2nd Monday, every other month)

TIME: 5:45 to 7:30pm

WHERE: Fellowship Hall - Mount Pleasant Presbyterian Church, Mt. Pleasant, SC

TOPIC: Georgia Roane, M.D., a rheumatologist with Rheumatology Associates, will discuss "Manifestations of Lupus: Monitoring Labs and Symptoms."



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Clinical Studies in Lupus at MUSC

Systemic Lupus Erythematosus in Gullah Health (SLEIGH)

The Systemic Lupus Erythematosus (SLE) in Gullah Health, or SLEIGH, study is an observational study enrolling African Americans from the Sea Island communities of South Carolina and Georgia. We are enrolling patients, family members of patients, and unrelated community members. The main purpose of this study is to find genes that, along with factors from the environment, result in the development of SLE. Initial findings from the SLEIGH study were recently published in the journal *Arthritis and Rheumatism*. These data indicate that lupus in the African American Gullah community is similar in severity to that in other African American populations, while skin disease and familial prevalence are increased. These findings suggest an increased genetic influence on overall disease.

For more information contact

Anna Meyer at 843-792-8997.

Urine Protein Markers in Lupus Nephritis

The purpose of this study is to identify components of urine called "markers" that can help to predict whether a patient is more or less likely to have kidney damage as a result of lupus kidney disease. Subjects can participate if they have lupus with associated lupus kidney disease and are undergoing a kidney biopsy (needle placed into the kidney to obtain tissue to look at under the microscope) as part of their routine care. Participants will be evaluated with a history, physical exam, blood draw, and urinalysis at study entry, 3 months, 6 months, and at 1 year. The goal of this research is to develop tests for these markers and then use these tests in the clinic to replace the kidney biopsy in diagnosing and monitoring lupus kidney disease. Results from this study published in *Arthritis and Rheumatism* report that blood markers of nitric oxide production associate with lupus kidney disease activity.

For more information contact

Lori Ueberroth 843-792-0549.

Systemic Lupus Erythematosus Database Project

The purpose of the Database is to compile information from patients with lupus seen by MUSC physicians. This is not a drug study. Information about medical and family history, medications, physical exam findings, laboratory tests and work or environmental exposures will be collected for analysis. We will collect data from all enrolled patients with

lupus, adding to the database as new patients are seen making this a long-term, open-ended project. We hope that information gathered in the database combined with biomarkers from blood and urine samples will provide more information about the causes and treatments of lupus. This study will involve approximately 400 volunteers.

For more information contact

Christina Demos at 843-792-6864

Biomarkers of Atherosclerosis in Systemic Lupus Erythematosus (SLE)

Cardiovascular disease (CVD) is a slowly advancing hardening of the arteries that leads to strokes, heart attacks, and loss of blood flow to limbs. To reduce the number of patients who suffer from strokes and heart attacks, people who are in the early phases of CVD should be identified for treatment. CVD is much more common in patients with diseases such as lupus (SLE) and the risk for CVD among patients with SLE is up to ten times that of the general population. However, markers that identify early CVD in the general population do not work as well in SLE patients. Early markers (biomarkers) of CVD are needed for SLE patients so that those at risk for CVD can have treatment to prevent heart attacks and strokes. This study is being undertaken to identify such markers of early CVD in SLE.

For more information contact

Lori Ueberroth at 843-792-0549



An Investigation of of NNC 0152-0000-0001 in Patients With Systemic Lupus Erythematosus (SLE)

The purpose of this research trial is to determine if the study drug NNC 0152-0000-0001 (Anti-IFN-alpha), a drug that has not been approved by the FDA, is a safe and effective treatment for adults between the ages of 18-65 who have been diagnosed for at least 6 months with SLE. This study is sponsored by Novo Nordisk in the US and abroad, but will be conducted at the Clinical Translational and Research Center. Each qualified participant will be randomized to either placebo or study drug. The entire study is estimated to last at least two years, but individual participation may be shorter. All participants will either receive study drug or placebo at no cost. Participants will be compensated.

For more information contact

Liezl de la Cruz-Tracy at 843-792-2668



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Effect of Vitamin D on the IFN-alpha Signature in Patients with SLE

Vitamin D plays a role in bone health as well as in immune health. Many people are deficient in vitamin D. In patients with SLE, vitamin D deficiency may play a role in the disease and contribute to the presence of an interferon (IFN) signature in the blood. The 1st phase of the Vitamin D Trial was completed in the Fall of 2008 and we found that daily doses up to 4000 IU / day for up to 12 weeks were safe and well-tolerated. The purpose of this 2nd phase study is to determine if vitamin D replacement can lower or eliminate the IFN signature. Patients with SLE may qualify if they have low vitamin D levels (< 20 ng/ml), stable disease activity, and the IFN signature present in their blood - all of which will be tested at a screening visit. Patients who qualify are randomized to placebo, 2000 IU / day, or 4000 IU / day of vitamin D to take by mouth for 12 weeks. There are a total of 4 study-related visits.



For more information contact
Anna Meyer at 843-792-8997.

A phase II randomized, double-blind, placebo-controlled, study to evaluate the efficacy and safety of Rontalizumab (rhuMab IFNalpha) in patients with moderately to severely active Systemic Lupus Erythematosus (SLE).

The purpose of this research trial is to determine if the study drug Rontalizumab (rhuMab IFNalpha), is a safe and effective treatment for adults (men or women) between the ages of 18-65 who have SLE. This study is sponsored by Genentech and will be conducted on the MUSC campus at the Clinical Translational and Research Center (CTRC). Each qualified participant will be assigned to either placebo (non-study drug) or Rontalizumab (study drug). Study participation may last approximately 18 months (72 weeks), including follow-up. Study participants will receive study-related health examinations at no cost and compensation for time and travel may also be available.

For more information contact
Lori Ueberroth 843-792-0549.



The Sierra Leone Project By Natasha Ruth, M.D.

Sierra Leone, officially the Republic of Sierra Leone, is a country in West Africa. Sierra Leone covers a total area of 71,740 km² (27,699 sq mi) - about the size of South Carolina- and has a population estimated of about 5.7 million. Over two decades of government neglect of the interior followed by the spilling over of the Liberian conflict into its borders eventually led to the Sierra Leone Civil War which began in 1991 and was resolved in 2000 after the United Nations led by Nigeria defeated the rebel forces and restored the civilian government elected in 1998 to Freetown. This brutal war ended in 2002. Since then, almost 72,500 former combatants have been disarmed and the country has reestablished a functioning democracy. The West Africa Institute (WAI) is dedicated to empowering the people of Sierra Leone and West Africa to be healthy, economically secure, and autonomous. It creates and implements programs that will achieve this goal by promoting healthcare, micro credit financing, appropriate technologies and sustainable agriculture.



Dr. Gilkeson and I have been invited by Dr. Darius Maggi, a retired obstetrician and founder of the fistula foundation to come and see what is being done in Bo by this foundation for the people of Sierra Leone in hopes that we will bring knowledge back to the western world. We hope to better describe the needs of these people that have been through so much. Also, we have a special interest in the people of this region of the world because they are the true ancestors of slaves that came over to the Sea Islands of South Carolina and Georgia in the 1700s; the Gullah people. This unique group of people has a very homogenous admixture of genes and appear to have a high incidence of autoimmunity, specifically lupus. Interestingly, there is not a high incidence of lupus in the people of Africa leading us to the possibility that there is an environmental trigger to this very complex disease.

It is truly unimaginable to those of us that live in this country how much the people of this region of the world are in need of adequate healthcare. Personally, I am hoping to enhance my knowledge of these needs and bring this information back to the West, specifically the United States, and even more specifically, MUSC so that we can find ways to help the people of this country in the future.



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LUPUS IN THE NEWS

NEW POSITIVE FINDINGS FROM LUPUS CLINICAL RESEARCH !

BENLYSTA (belimumab) Phase 3 Trial Results

"The lack of a gold standard to measure SLE disease activity endorsed by international rheumatology societies or national health authorities has impeded the development of SLE therapies," said Richard A. Furie, M.D., Chief, Division of Rheumatology and Allergy-Clinical Immunology, North Shore Long Island Jewish Health System, and Professor of Medicine, Albert Einstein College of Medicine. "In other diseases where manifestations are heterogeneous, combined responder instruments have been used to assess disease activity. We believe the SLE Responder Index may play an important role in drug development for this potentially devastating disease."

In July 2009, Human Genome Sciences (HGS) and GlaxoSmithKline (GSK) announced that belimumab met this primary endpoint in BLISS-52, the first of the two Phase 3 trials. In November, similar encouraging results were announced from BLISS-76, the second Phase 3 trial.

Belimumab is an investigational human monoclonal antibody drug that specifically recognizes and inhibits the biological activity of B-lymphocyte stimulator, or BLYS®. BLYS is a naturally occurring protein discovered by HGS that is required for the development of B-lymphocyte cells into mature plasma B cells. Plasma B cells produce antibodies, the body's first line of defense against infection. In lupus and certain other autoimmune diseases, elevated levels of BLYS are believed to contribute to the production of autoantibodies - antibodies that attack and destroy the body's own healthy tissues. The presence of autoantibodies appears to correlate with disease severity. Preclinical and clinical studies suggest that belimumab can reduce autoantibody levels in SLE. BLISS-52 and BLISS-76 results suggest that belimumab can significantly improve SLE disease activity while being safe and well-tolerated.

"The lupus community has waited for decades for one positive Phase 3 trial of an investigative drug developed for lupus. Now we have two. Based on the data we now have in hand, we have cause for hope that belimumab may emerge as a significant new treatment for lupus," said Joan T. Merrill, M.D., Professor of Medicine, University of Oklahoma Health Sciences Center and Oklahoma Medical Research Foundation.

Source: Human Genome Sciences

UCB and Immunomedics Announce Positive Results for Epratuzumab Phase IIb Study in SLE

In August 2009, UCB and Immunomedics announced Phase IIb trial results comparing epratuzumab to placebo in patients with SLE. The data from the 12-week dose and regimen-ranging study demonstrated clinical meaningful treatment effect of epratuzumab over placebo. The 227 patients in this study had moderately (30%) to severely (70%) active disease in multiple organ systems. Treatment advantage of epratuzumab over placebo reached 24.9% at week 12.

"Epratuzumab is the most advanced pipeline program in UCB's immunology disease portfolio and the positive results are significant for UCB as we continue to move our antibody based programs ahead", said Roch Doliveux, Chief Executive Officer of UCB. "These results may provide new hope for the hundreds of thousands of people around the world living with SLE as no new treatment has been approved for this life altering disease for over five decades."

Source: Lupus Foundation of America



Save the Date!

**The Lupus Foundation Lowcountry Walk 2010
will be Sunday, April 18th, 2010**

More details to come...

Contact LoriAnn at 843-792-0549

or email us for more information or to volunteer!

lupusresearch@musc.edu



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Lupus and Osteoporosis

By Hazel L. Breland, PhD, OTR/L

Did you know that systemic lupus erythematosus (SLE) and osteoporosis both disproportionately affect women compared to men? Actually, SLE is more common among female ethnic minorities, particularly African Americans (AA). Did you know that although osteoporosis is more common among Caucasian women, there is a growing awareness that a large proportion of AA women with SLE also develop osteoporosis with an increased risk of fracture? In fact, the increasing prevalence is multifactorial in part due to the effects of corticosteroid therapy used to manage their SLE, vitamin D deficiency, and lack of emphasis on preventative measures. Both conditions have tremendous impact on the individual's life, their families, and society. Despite the trend of increased risk, impact, and burden of osteoporosis among AA women with SLE, there is a lack of awareness, knowledge, or prevention strategies for AA women. Therefore, Hazel L. Breland, PhD is conducting and actively recruiting African American females between the ages of 35-65 who have been diagnosed with SLE (lupus) and are at-risk for developing osteoporosis. The overall objective of the "Lupus and Osteoporosis Education/Prevention Intervention" pilot study is to develop a culturally sensitive education/prevention intervention designed to reduce the burden of osteoporosis among AA women with SLE.

FIVE STEPS TO BONE HEALTH AND OSTEOPOROSIS PREVENTION

EAT RIGHT: Get your daily-recommended amounts of Calcium and Vitamin D.

EXERCISE: Engage in regular weight bearing and muscle strengthening exercise.

MAINTAIN A HEALTHY LIFESTYLE: Avoid smoking and excessive alcohol consumption.

TALK TO YOUR HEALTHCARE PROVIDER:

Talk to your healthcare provider about bone health.

GET TESTED: Have a bone density test and take medication when appropriate.

Five Steps to Bone Health accessed from the National Osteoporosis Foundation: <http://www.nof.org>



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Risks of Atherosclerosis and Lupus

By James C. Oates, M.D.

Heart attacks and strokes occur more often in lupus patients than in the general population. Predicting who will develop atherosclerosis, or "hardening of the arteries", that leads to these events has been a challenge to researchers and practicing rheumatologists alike. Doctors would like to identify those lupus patients with atherosclerosis early in the disease to prevent heart attacks and strokes rather than waiting to treat them when they have already happened. The problem for clinicians is that traditional risk factors for atherosclerosis (obesity, diabetes, high blood pressure, high cholesterol, smoking, and family history of heart attacks and strokes) do not predict who is at risk in lupus patients as well as they do in the general population. Our research group is looking at markers in the blood of lupus patients that may predict who needs more aggressive medical therapy to prevent heart attacks and strokes. We believe that markers of oxidative stress from lupus disease activity, obesity, and diet will aid in predicting who is at risk.

What should you do to reduce your risk? It is believed that modifying traditional risk factors is as important in lupus patients as the general population. Therefore, maintaining a healthy body weight, exercising 30 minutes a day, consuming a healthy diet (high fruit and vegetable, low saturated/trans fat, high omega 3 fatty acid), stopping smoking, and controlling blood pressure and cholesterol all are important in preventing disease. Ongoing research will identify the best approach.

If you are interested in participating in research into atherosclerosis in lupus, please contact one of the M.U.S.C.L.E. coordinators at 1-866-859-6107.

Tips for a Healthy Heart

1. Make sure you eat lots of fruits and veggies
2. Eat whole grains every day
3. Eat fish with healthy oils (omega-3 fatty acids)
4. Get 30 minutes of moderate exercise everyday
5. Limit Alcohol and Sodium in your diet
6. Stop smoking

Adapted from American Heart Association Guidelines

Important Information for Parents of Children with Lupus

Educating Your Child

The feeling of being overwhelmed can be very real for both parents and children. However, educating yourself and your child can help to alleviate many of the worries and concerns. Of course no two children are the same, but these general guidelines can help. For children younger than age 10, excessive explanations aren't very helpful. While your child should know that they have lupus, you don't need to spend a lot of time trying to explain it. They will need to understand that lupus is a disease, and that it's not their fault. They need to know they didn't get lupus from doing something wrong, that it is not something they caught from someone, and that they cannot "give" lupus to anyone else. It is important that your child understands the need to take the prescribed medicine. For older children you can begin to explain the names of the medicines and the doses. For smaller children this isn't helpful. Sometimes well-intentioned parents go to great lengths to explain every detail to their children as if they were small adults. Under the age of 10 this information is often misunderstood and despite the best intentions it may do more harm than good. For children 10 and older it is important to begin explaining the nature of lupus. The transition from a small child who must simply do what they are told, to a mature self-reliant adult, may be a difficult one under the best circumstances. Thus it is important that children with lupus be allowed to assume a progressively greater role in taking their medications and making choices about their care.

Coping with a Sick Child

It is important to remember that most children hate being sick. Improperly dealt with, a child or young adult's resentment about having lupus may result in risky behavior that can be disastrous. Don't be afraid to ask the doctor for help if you are having trouble getting through to your child. If you believe your child needs help, the child's doctor can help you find an experienced psychologist in your community. Even children who appear to be doing well may have questions they are afraid to ask. Young people in their middle and late teenage years are beginning to think about their life as adults. Children with lupus will wonder if they are going to be able to get married, have kids, and make a living. The answer should always be that you expect them to lead productive lives. Since most children with lupus will live well into adulthood, it is important to make sure they understand the importance of doing all the things necessary to achieve their goals.

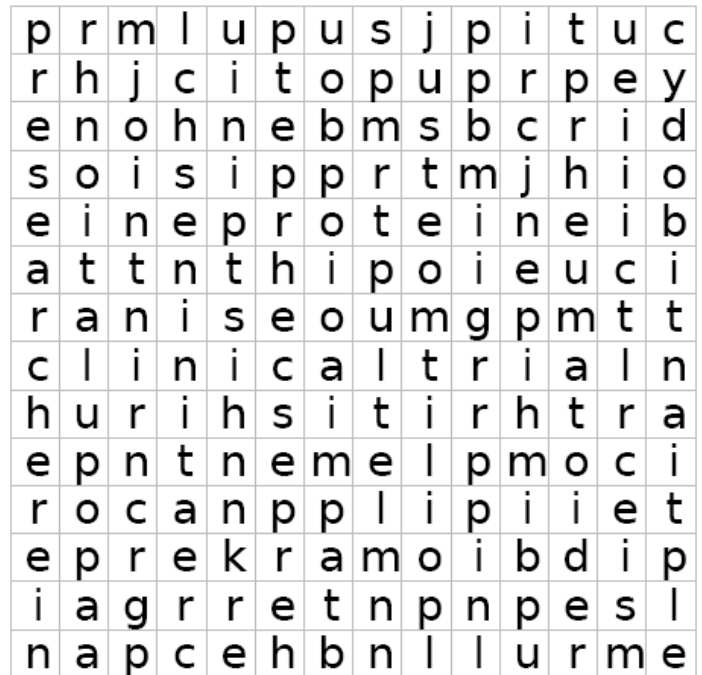
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KID'S CORNER



Lupus Word Find

antibody
rheumatoid
arthritis
complement
gene
biomarker
protein
creatinine
lupus
phospholipid
clinical trial
research
subject
population
joint

Lupus affects children, too. Usually, it is found in young adults and adolescents as they go through puberty. Kidney disease and Central Nervous System manifestations of lupus can be more severe in children. Early diagnosis with close monitoring with a pediatric rheumatologist is critical to successful treatment.

MUSC Pediatric Rheumatology Contact Information:

Charleston, SC office: 843.792.5696
Columbia, SC office: 803.434.5989
Drs. Natasha Ruth and Murray Passo

Thank you for being an MUSC HERO!

Many of you receiving this newsletter have made the important personal decision to participate in a clinical research study. You may be participating in one of the database studies which are helping us discover important aspects of lupus including its causes. Or you may be participating in one of the therapeutic trials that are bringing us closer to approval of effective new therapies to make living with lupus easier.

Thank you!

For more information about clinical trials and being a HERO visit: MUSChero.org or call 843-792-8300.

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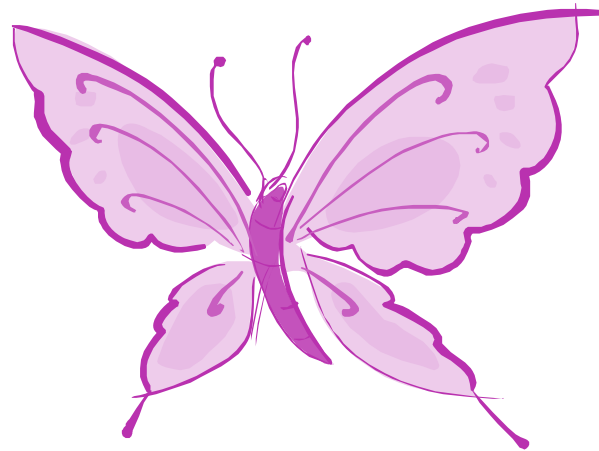
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