

The University of Connecticut Health Center

GENERAL CLINICAL RESEARCH CENTER NEWSLETTER

PERIODONTITIS AND RENAL DISEASE: THE ROLE OF A GCRC PILOT STUDY IN THE CAREER DEVELOPMENT OF A CLINICAL RESEARCHER



Featured PI

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Sciences
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My exposure to clinical research began with my participation as a co-investigator in a NIH/NIDCR funded clinical research project that explored the association of oral infections and systemic inflammation in solid organ transplant recipients. The grant was awarded to Dr. Anna Dongari-Bagtzoglou that has been my mentor since that time. Later on, my first investigator-initiated research project "Periodontal Infections, Depressive Symptoms and Systemic Inflammation In Renal Patients" as a PI was

funded by the GCRC through the Clinical Research Feasibility Funds program. This was a pilot study examining the link between periodontal and systemic inflammation in chronic kidney disease patients.

Our Research Team: Drs. Effie Ioannidou (PI), Anna Dongari-Bagtzoglou (periodontist/inflammation biologist), Andre Kaplan (nephrologist), Mark Litt (psychologist), Joseph Burleson (statistician), Ms. Megyn Clement (research assistant), and two post graduate students, Drs. Eric Choudhury and Dongha Oh.

Background and Significance: Chronic kidney disease is characterized by a state of chronic inflammation that has been associated with high mortality rates (Stenvinkel et al. 2002). Elevated levels of inflammatory markers such as C-reactive protein (CRP) and interleukin 6 (IL-6) are known predictors of cardiovascular outcomes in the general population as well as in the HD population (Rao et al., 2004), where they are linked to hypoalbuminemia, malnutrition, erythropoietin resistance and



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increased mortality (Bergstrom et al., 1996; Arici et al., 2001). Periodontitis is a polymicrobial and predominantly Gram negative infection affecting over 70% of the adult population (Albandar et al., 1999) and is recently associated with formation of atherosclerotic plaques and an elevated risk for myocardial infarction, ischemic stroke and peripheral arterial disease (Beck et al., 2001; Joshipura et al., 2003). The involvement of systemically elevated inflammatory mediators has been proposed as a possible mechanism. Elevated serum levels of IL-6 and CRP are present in individuals with severe periodontal disease (Ebersole et al., 1997; D'Auito et al., 2005). Although, there are a few studies exploring the prevalence of periodontitis in chronic kidney disease (CKD) population on hemodialysis (HD), the results are conflicting.

Depression, that is the most common psychological disorder among patients with end-stage renal disease, is associated with increased mortality in HD patients (Kimmel 2001) and may predispose these patients to periodontitis (Johanson et al., 2006). Depression is also associated with elevated levels of systemic inflammatory markers (Dentino et al., 1999).

This pilot investigation enters a novel multidisciplinary research field with the main objective being to explore the relationship between chronic periodontal infection, systemic inflammatory markers and depressive symptoms in chronic kidney disease population. We will determine the prevalence of periodontal infection in our HD and pre-dialysis CKD population and examine related mechanisms of increased systemic inflammation levels. Moreover, this pilot study investigates the association between depressive symptoms and the periodontal and systemic inflammatory status. Data from this pilot project will be used to further explore the relationship between periodontal and systemic inflammation in this population by designing

prospective controlled studies monitoring periodontal status, inflammatory markers, cardiovascular events and HD survival in CKD populations.

Specific Aims: Specific Aim 1: to compare the prevalence of periodontal infection between CKD (HD and pre-dialysis) and systemically healthy populations. Specific Aim 2: (a) to assess the levels of the systemic inflammatory markers, IL-6 and CRP, in the presence or absence of periodontal infection in HD and pre-dialysis CKD populations and (b) to test the hypothesis that periodontal tissues are a possible source of these inflammatory mediators in HD and pre-dialysis CKD patients. Specific Aim 3: (a) to compare the levels of proinflammatory markers, CRP and IL-6, in the HD population with high vs. low levels of depressive symptoms and (b) to compare the periodontal status in CKD populations with high vs. low depressive symptoms.

Based on the above proposed work, I received the 2007 University of Connecticut Faculty Development Award that was awarded for the first time to a faculty (either junior or senior) showing evidence of development in the area of either clinical or basic science research. Moreover, I received the 2008 American Academy of Dental Research Neal W. Chilton Fellowship on design and analysis in oral clinical research. The award is decided through a peer-reviewed process by the AADR Task Force on Design and Analysis in Dental and Oral Research based on a clinical research development plan that each candidate submits. Moreover, the AADR Task Force has recognized the importance of this research effort and has invited me to speak at the annual AADR Task Force meeting in May 2009.

In September 2008, at the annual American Academy of Periodontology meeting, I was selected as the winner of the 2008 Tarrson Fellowship, which is awarded to a junior

faculty committed to an academic career, having an exceptional achievement record in teaching and research.

Preliminary data of this project has been analyzed and presented in the NIDCR K23 patient-oriented clinical research application titled, "Periodontal Infection and Systemic Inflammation In Renal Patients" with Drs. Ioannidou and Dongari-Bagtzoglou as PI and mentor, respectively. This application has received excellent score and is awaiting funding decision.

The preliminary results of this work have been accepted and will be presented at the International Association of Dental Research in Miami in April 2009 and at the International Society of Nephrology in Milan, Italy in May 2009.

GREETINGS FROM THE NEW GCRC PROGRAM DIRECTOR



Cheryl Oncken, M.D., M.P.H.
Associate Professor of Medicine
GCRC Program Director

I assumed the role of GCRC Program Director on April 1, 2009. I am looking forward to the opportunity of continuing the scientific and educational missions of the GCRC and improving the GCRC's available services in clinical and translational research. The GCRC will continue to prioritize its support for NIH and investigator-initiated research. However, with reductions in funding levels and changes in funding sources, going forward most

investigators using the GCRC may be required to pay a portion of the cost of the services requested.

In addition, we have partnered with the Clinical Trials Unit (CTU) to form a combined GCRC/CTU Clinical Research Center which broadens the availability of clinical research services available and allows us to become more cost efficient. Tom Kiely, R.N. is the nurse manager for both units. This effort leads to a single pool of nurses, research assistants, and medical assistants available for clinical research studies. Further, we are in the process of streamlining the scheduling procedures and documentation of patient visits for both units; this work will result in a single set of forms and procedures to serve investigators in the GCRC and the CTU. The GCRC/CTU integration over the coming months will enable us to be more efficient, cost effective, and competitive as we move towards the goal of Clinical and Translational Science Award (CTSA) funding.

A FAREWELL FROM THE DEPARTING GCRC PROGRAM DIRECTOR



Henry R. Kranzler, M.D.
Professor of Psychiatry
GCRC Program Director

It is with regret that I bid farewell as Program Director of the GCRC, relinquishing that position to my able colleague, Dr. Cheryl Oncken. Although I will continue to work with the GCRC in my capacity as a clinical

investigator, I have ended my administrative service to this institution. I want to thank all of the wonderful colleagues and friends with whom I have worked during the past 12 years, since I began as an Associate Program Director at the behest of Dr. Larry Raisz. I spent the past four years as Program Director. My tenure has been a challenging one, with efforts by the Health Center administration to move the GCRC to Dowling North threatening its viability. Fortunately, wisdom prevailed and the GCRC continues to occupy the location established with its first successful funding cycle, beginning in 1994. The grant was renewed twice competitively and, although scheduled to end on March 31, 2009, it will continue through a no-cost extension and Health Center support as efforts continue to obtain funding for a Clinical and Translational Science Award (CTSA). I applaud the institutional commitment to clinical investigation that, although substantially diminished over the past decade, has been rekindled in the CTSA effort. I am grateful for the fruitful and enjoyable collaborations that my involvement with the GCRC has provided. Having worked closely with Dr. Oncken for the past decade, I am confident that she will bring a new vitality to the GCRC, ably supported by the staff and faculty who conduct clinical investigations at UCHC and its collaborating institutions.

CERTIFICATE OF CONFIDENTIALITY

by **Kathleen Salomone, APRN**
GCRC Research Subject Advocate

Does your IRB approved research study collect personally identifiable and sensitive information? If so, a Certificate of Confidentiality (CoC) may be helpful in protecting the privacy of study participants. Under section 301(d) of the Public Health Service Act {42 U.S.C. 241(d)} the Secretary of

Health and Human Services may authorize persons engaged in biomedical, behavioral, clinical, or other research to protect the privacy of individuals who are the subjects of that research. This authority has been delegated to the National Institutes of Health (NIH). If your study is funded by NIH, you may apply for a CoC through the funding NIH Institute/ Center. However, a CoC can be awarded even if your research study is not supported with NIH funding. Application contact information is available on the website noted below.

CoCs are usually granted for studies collecting information that, if disclosed, could have adverse consequences for participants, damage their employability, insurability or reputation. Examples of studies that may be eligible for a CoC are:

- Research on HIV, AIDS or other STDs
- Studies on the use of alcohol, drugs or other addictive products
- Studies that collect information on illegal conduct
- Studies collecting information on participant's psychological well being or mental health
- Genetic studies, including those that collect and store biological samples for future use

The Informed Consent Form (ICF) must include language describing the protection that the CoC provides and its limitations. For example, the ICF should address how the investigator will handle information regarding child abuse or the intent to harm self or others. The ICF template on the University of Connecticut Health Center Human Subjects Protection Office's website includes language regarding CoCs.

A CoC can be useful in promoting study participation by providing assurance to participants that confidentiality and privacy will be protected.

This information was obtained from the Certificate of Confidentiality Kiosk located at: <http://grants.nih.gov/grants/policy/coc/>

Check it out for additional information!

NEW SPACE FOR DENTAL CLINICAL RESEARCH

by **J. Robert Kelly, DDS, MS, DMedSc**
Dental Core Director

Dental clinical research will be occupying newly renovated space in LM006 by late summer 2009. This renovation was necessary due to this GCRC core facility being moved last year to make way for the Dental Implant Center. As with many GCRC cores, the DCRC is also using a service center model where investigators will pay a portion of service costs. University-wide, industry- and NIH-sponsored trials will become jointly administered under the Connecticut Institute for Clinical and Translational Science. In order to enhance service center activity in the future, the DCRC will expand and become a dual-use facility with an enhanced revenue stream from off-hours continuing clinical education. The LM006 renovation will represent Phase 1 in the development of a combined clinical research facility and the Center for Prosthodontic Technology Integration (**CpTi**). Few dental educators have routine access to emerging technologies and, therefore, are not in a position to teach the next generation of dentists about them. Industry has limited access to private practices and dental laboratories for the purpose of distributing technologies more broadly. Emerging technologies are certain to change the practice of dentistry, but industry has yet to

embed such advanced systems into educational and research centers.

CpTi will be composed of three integrated facilities:

- Research Dental Clinic (GCRC)
- Integrated Dental Laboratory
- Dedicated Educational Facility

The UConn Health Center has already committed over \$300,000 and space for phase one of the Research Dental Clinic. An architectural drawing of this Phase 1 clinic appears below, and includes:

- Two large operatories (facing large windows)
- In-office CAD/CAM dental laboratory
- Study coordinators/assistants office
- Patient waiting area
- Dirty prep/sterilization room
- Clean preparation area



An additional 2400 square feet is becoming available adjacent to the Phase 1 research clinic beginning in the summer of 2010. In Phase 2 the **CpTi** proposes two additional operatories, space for a behavioral sciences/medical research suite, an integrated automated dental laboratory and state-of-the-art training facility. As of this writing UConn has nearly \$1.0 M in pledges and gifts for the combination Dental Clinical Research Center and the **CpTi**.

**MASTERS PROGRAM IN
CLINICAL AND
TRANSLATIONAL RESEARCH**

by **Anne Kenny, M.D.**
Program Director

I am pleased to announce that we have two students graduating from our program this month. They are: Dr. Christopher Carroll, who is an Assistant Professor of Pediatrics at Connecticut Children's Medical Center; and Ms. Kathryn Papp, a Ph.D. candidate in the Department of Psychology at UConn-Storrs. Congratulations Chris and Kate!

**UPCOMING
GCRC SEMINARS**

Tuesday, June 9, 2009

Lee M. Pachter, D.O.

Professor
Pediatrics and Anthropology
University of Connecticut School of Medicine
Connecticut Children's Medical Center
Hartford, CT

“The Development of an Instrument to Measure Perceptions of Racism in Minority Children”

12:00 noon –1:00 p.m.
Academic Research Building - EG-013

Monday, June 22, 2009

Paul S. Appelbaum, M.D.

Elizabeth K. Dollard Professor of Psychiatry,
Medicine, and Law
Director, Division of Psychiatry,
Law and Ethics
Department of Psychiatry
Columbia University College of
Physicians and Surgeons
New York, NY

“Assessing Competence to Consent
to Research”

12:00 noon –1:00 p.m.
Academic Research Building - EG-013

All GCRC seminars are sponsored by the University of Connecticut School of Medicine Office of Continuing Medical Education. You can receive one hour per session of category 1 credit for attending this educational session.

**NEW CLINICAL RESEARCH
IN THE GCRC**

Ancillary Study to the Hepatitis C Antiviral Long-term Treatment against Cirrhosis (HALT-C) Trial: Long-term Follow-up of HALT-C Sustained Virologic Responders
P.I. – Herbert Bonkovsky, M.D.

The Genetics of Severe Asthma in Children.
P.I. – Christopher Carroll, M.D.

Follow-up Study on CML Patients Treated with Imatinib Mesylate and HSP70 Vaccine
P.I. – Zihai Li, M.D., Ph.D.

Effects of Aromatase Inhibitors on Blood Pressure and Forearm Vascular Reactivity In Postmenopausal Women With Breast Cancer
P.I. – Faryal Mirza, M.D.

Pilot Study of Nicotine Replacement for Smoking Cessation During Pregnancy
P.I. – Cheryl Oncken, M.D., M.P.H.

Behavioral Intervention for Reducing Obesity
P.I. – Nancy Petry, Ph.D.

Effects of Vitamin D Supplementation on Hemodialysis End Stage Renal Disease (ESRD) Patients with Vitamin D Insufficiency
P.I. – Wilner Samson, M.D.

Stress-Related College Drinking: Learning and Genetic Vulnerabilities
P.I. – Howard Tennen, Ph.D.

RECENT GCRC PUBLICATIONS

Barry D, Sullivan B, Petry NM. Comparable Efficacy of Contingency Management for Cocaine Dependence among African American, Hispanic, and White Methadone Maintenance Clients. *Psychol. Addict. Behav.* 23:168-174, 2009.

Dongari-Bagtzoglou A, Dwivedi P, Ioannidou E, Shaqman M, Hull D, Burleson J. Oral Candida Infection and Colonization in Solid Organ Transplant Recipients. *Oral Microbiol. Immunol.* 24:249-254, 2009.

Fontana RJ, Bonkovsky HL, Naishadham D, Dienstag JL, Sterling RK, Lok AS, Su GL; Halt-C Trial Group. Serum Fibrosis Marker Levels Decrease after Successful Antiviral Treatment in Chronic Hepatitis C Patients with Advanced Fibrosis. *Clin. Gastroenterol. Hepatol.* 7:219-226, 2009.

Gelernter J, Kranzler HR, Panhuysen C, Weiss RD, Brady K, Poling J, Farrer L. Dense Genomewide Linkage Scan for Alcohol Dependence in African Americans: Significant Linkage on Chromosome 10. *Biol. Psychiatry.* 65:111-115, 2009.

Kenny AM, Smith J, Noteroglu E, Waynik IY, Ellis C, Kleppinger A, Annis K, Dauser D, Walsh S. Osteoporosis Risk in Frail Older Adults in Assisted Living. *J. Am. Geriatr. Soc.* 57:76-81, 2009.

Kranzler HR, Gelernter J, Anton RF, Arias AJ, Herman A, Zhao H, Burian L, Covault J. Association of Markers in the 3' Region of the GluR5 Kainate Receptor Subunit Gene to Alcohol Dependence. *Alcohol Clin. Exp. Res.* 33:925-30. 2009.

Lalla RV, Pilbeam CC, Walsh SJ, Sonis ST, Keefe DM, Peterson DE. Role of the Cyclooxygenase Pathway in Chemotherapy-induced Oral Mucositis: A Pilot Study. *Support Care Cancer.* Apr. 29, 2009 [Epub ahead of print] PMID: 19404685

Oncken C, Dornelas E, Greene J, Sankey H, Glasmann A, Feinn R, Kranzler HR. Nicotine Gum for Pregnant Smokers: A Randomized Controlled Trial. *Obstet. Gynecol.* 112:859-867, 2008.

Swede H, Rohan TE, Yu H, Anderson, JC, Stevens, RG, Brokaw J, Levine J, Brenner BM, Malchoff CD, Duffy VB, Pleau DC, Rosenberg DW. Number of Aberrant Crypt Foci Associated with Adiposity and IGF1 Bioavailability. *Cancer Causes Control,* Dec. 9, 2008 [Epub ahead of print] PMID: 19067190



REMINDER TO INVESTIGATORS

Remember to acknowledge the GCRC grant on all manuscripts and abstracts as follows:

This research was supported in part by a General Clinical Research Center grant from NIH (M01RR006192) awarded to the University of Connecticut Health Center, Farmington, CT

STUDIES THAT ARE ACTIVELY RECRUITING PARTICIPANTS

ARE YOU A CANCER PATIENT WITH A PICC LINE OR “PORT”?

If so, you are invited to participate in a research study which is being done to see if having a dental procedure increases the chances of bacteria from the mouth getting into the blood stream.

The study will involve:

- Blood draws through the Port or PICC for blood cultures
- Two visits to the health center, one day apart

The benefit you will receive from the study:

- A professional dental cleaning done by a Registered Dental Hygienist

If you are interested, please contact Dr. Saad Usmani or Dr. Robert Bona

Phone: (860) 679-2000
Monday-Friday, 9 AM-5 PM.

(IRB #09-059-2)



ARE YOU AN AFRICAN AMERICAN WOMAN WITH DIABETES?

If you are a White or an African American woman with diabetes, then you may be eligible to participate in a research study at the UConn Health Center in Farmington. The study, being conducted by Julie Wagner, Ph.D., investigates the effects of stress on blood pressure and blood sugar levels in women with diabetes. If you are eligible and choose to participate you will be asked to:

- Complete some questionnaires
- Give a blood sample
- Wear portable monitors that check your blood glucose and blood pressure at home for several days.

Participants will be receive up to \$175 for completing the study and free screenings of blood sugar, cholesterol, and blood pressure.

If you would like to learn more about this study or think that you might want to participate, please call the University of Connecticut Health Center at

(860) 679-7692 or (800) 535-6232

(IRB #07-017-01)

DO YOU WANT TO QUIT SMOKING?

A research study at the University of Connecticut Health Center is evaluating whether adding an exercise or relaxation program along with Varenicline (Chantix) and counseling helps women quit smoking. All visits and medication are **free of charge**. You will be involved in the study for 15 months. For the first 6 months, you will be seen up to 2

visits/week. For follow-up, you will have one visit at 9 months, 12 months, and 15 months.

We are seeking female smokers who are:

- **50 years of age or older**
- **Smoke at least 10 cigarettes per day**
- **Postmenopausal**

This research is under the direction of Dr. Cheryl Oncken, Associate Professor of Medicine.

Please call (860) 679-3136 for more information about this study.

(IRB #09-097-2)

**TEAM UP WITH US!
KEEP YOUR BONES
HEALTHY
while receiving treatment for
breast cancer**

**Are you OR is someone you know
planning to begin treatment with
ANASTROZOLE (ARIMIDEX) or
LETROZOLE (FERMARA) for
breast cancer.
*Bone Health Study***

Medications for breast cancer such as anastrozole (Arimidex) or letrozole (Femara) are often used for the treatment of breast cancer. These medications lower the levels of the female hormone estrogen and as a result may result in bone loss and increased risk of fractures. We are studying the early effects of this treatment on bone health. Benefits for participants include monitoring

of their bone health during the first year of treatment with anastrozole or letrozole.

There are 6 study visits over 1 year.

If you, or someone you know, is considering taking anastrozole (Arimidex) or letrozole (Femara) and would like to know more about participation in this research study, please contact the principle investigator, Dr. Pamela Taxel at (860) 679-4743.

(IRB #07-043-2)

DENTAL IMPLANT AND BONE HEALTH RESEARCH STUDY

The purpose of the research study is to understand the relationship between general bone health and the rebuilding of shrunken jaw bone before an implant is placed.

To be considered for this research study you must be:

- A woman
- Postmenopausal
- Between 55 and 80 years old
- Be missing at least one tooth for more than three months
- Have at least 12 of your own teeth
- Be willing to commit to a 26 month study with approximately 11 visits.
- Require bone grafting

If you are eligible for this standard of care research study you may receive:

- An implant, bone grafting, and a crown for a total of \$800 per each missing tooth area. (The study will treat up to two areas only if they are next to each other or in a three unit bridge)

Additional research related activities include:

- Filling out health and behavior surveys
- Having five fasting blood draws
- Having pictures taken of your face and inside your mouth
- Bone scan to determine bone health status
- Additional diagnostic x-rays

This research study intends to continue to enroll participants through 2010 or until 120 participants are enrolled, whichever comes first.

**For more information please call:
860 679-1658 or 860-679-2022**

(IRB #07-016-1)

INDIAN MEN NEEDED FOR BONE HEALTH STUDY

Osteoporosis is a condition that results in weakening of the bones in your body. It can cause bone fractures. In the United States and in many European countries, it is most often seen in elderly women. However, there are reports that suggest that East Asian (Indian) men may be susceptible to this condition.

The University of Connecticut Health Center is conducting a study to examine the status of bone health and vitamin D and calcium metabolism in East Asian Indian men. The aim of the study is to determine whether Indian men who have immigrated into the United States are also susceptible to osteoporosis.

If you are an East Asian Indian male age 50 or older, and are interested in finding out more about your current bone health, please contact Dr. T. V. Rajan at the University of Connecticut Health Center (Tel: 860-679-3221 rajan@neuron.uchc.edu) or

Ms. Harriet Zawistowski (Tel: 860-679-1658; zawistowski@nso.uchc.edu) for further information.

(IRB #08-303)

HEALTHY MEN WHO DRINK 3 TIMES PER WEEK NEEDED FOR ALCOHOL STUDY

Healthy males, 21-45 years old, who consume alcohol at least 3 times a week, and have no history of substance dependence or psychiatric illness, are needed for a UConn Health Center study to evaluate an FDA approved medication, Dutasteride, and common genetic variation on the effects of a moderate dose of alcohol.

Dutasteride (Avodart™) is not FDA approved for the purpose of this study.

Participation involves blood samples, interviews, questionnaires, 7 brief study visits and 4 full day laboratory sessions where you will be asked to consume placebo or alcohol drinks based on your body weight. \$555 paid for full participation.

For information call 860-679-4186 or go to www.uchcalcoholstudy.com (refer to study #2)

(IRB #06-218S-2)

GCRC PHONE NUMBERS

(860) 679-4145 - ADMINISTRATION

(860) 679-3666 - CLINIC

(860) 679-1636 - STUDY LINE

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by the Staff of the GCRC*

General Clinical Research Center Newsletter

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