

News from

The Osteopathic Research Center

Fostering nationwide collaborative OMM research

From the Executive Director

Dear Friends,

The Osteopathic Research Center (ORC) got off to a busy start in the new year.

On January 4, the ORC provided a presentation and tour of the ORC to members of the

American Association of Osteopathic Examiners and to members of the American Osteopathic Association traveling with the group.

On January 18, ORC faculty, staff and dual-degree students presented a three hour session on developing and conducting student research to the Council of Osteopathic Student Government Presidents.

Read more about both of these events on page 2 of the newsletter.

The ORC is happy to develop presentations about the Center and about osteopathic manipulative medicine research geared toward specific groups as part of a site visit. Please give us 30 days notice if you would like to visit the ORC and to have us work with your group to share more information about the ORC's mission and projects, or to talk about research in general.

Over the next few months, the ORC will be exhibiting at several conferences including the American Academy of Osteopathy Convocation March 26-30 in Dallas, Texas, and the American Association of Colleges of Osteopathic Medicine/ Association of Osteopathic Directors and



Licciardone



Plans Progress for March International Research Symposium at UNTHSC

Plans continue to progress for the international, interdisciplinary research symposium on somato-visceral interactions that will be held March 31-April 1, 2008 at the University of North Texas Health Science Center in Fort Worth, Texas, which is home to The Osteopathic Research Center (ORC).

This conference, "Delineating the Evidence Base for Somato-Visceral Interactions and Autonomic Mechanisms of Manual Therapy," will feature leading researchers in this area from the United States, Sweden, Germany and Canada.

The symposium, which is part of the Osteopathic Collaborative Clinical Trials Initiatives Conference (OCCTIC) series, immediately follows the American Academy of Osteopathy Convocation, which will be held in Dallas, Texas March 26-30, 2008.

Sponsors for the event include the American Association of Colleges of Osteopathic Medicine, the American Osteopathic Association, the Osteopathic Heritage Foundation, the American Academy of Osteopathy, The Osteopathic Research Center, the University of North Texas Health Science Center, NCMIC Insurance, the Canadian Memorial Chiropractic College, the American Academy of Orthopaedic Manual Physical Therapists, the Orthopaedic Section of the American Physical Therapy Association and the Massage Therapy Association.

A preliminary program is now available for download on the registration website listed below.

The hotel room block expires March 10. Visit the site listed below for a direct link to the Hilton Fort Worth for room reservations.

For more information about the symposium, please visit the ORC website at <http://www.hsc.unt.edu/orc/services/occtic.asp> or contact Cathleen Kearns by email at ckearns@hsc.unt.edu, or by phone at 817.735.0515.

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Two National Osteopathic Medical Groups Visit ORC

Two national osteopathic medical groups visited The Osteopathic Research Center in January.

The American Association of Osteopathic Examiners visited the ORC on January 4. John Licciardone, DO, MS, MBA, executive director, Hollis King, DO, PhD, associate executive director, and Cathleen Kearns, administrative director, presented information about the ORC, its research endeavors and sponsors to the group. Following the presentations and questions, the group toured the ORC's research facilities.

On January 18, several members of the ORC faculty and staff provided a presentation and workshop on developing student research to approximately 60 members of the Council of Osteopathic Student Government Presidents (COSGP). COSGP is a council of the American Association of Colleges of Osteopathic Medicine, one of the ORC's sponsoring organizations.

Dr. Licciardone, des Angles Crusier, PhD, MPA,

research education director, Scott Stoll, DO, PhD, founding executive director, Olive Chen, PhD, coordinator of research studies for the Texas College of Osteopathic Medicine Physician Assistant Program, DO/MS student Elizabeth Bah, and DO/PhD student Kari Guinn, made presentations to the student government representatives. Dr. King and Rita Patterson, PhD, director of the Osteopathic Heritage Foundation Physical Medicine Core Research Facility were on-hand to answer questions about student research. Ms. Kearns coordinated the event.

Members of the group received a research manual produced by the ORC, other information about the ORC and a 15 minute PowerPoint presentation to take back to their respective colleges of osteopathic medicine to answer questions about developing student research projects and initiatives.

DIRECTOR ————— *Continued from Page 1* —————

Medical Educators Annual Meeting April 9-12 in St. Louis, Mo. We hope that those of you who are planning to attend these conferences will find some time to stop at our exhibit to visit with us as well as to learn more about the ORC and the research that it is conducting to advance osteopathic medicine. We want to hear how we can help you with your research goals.

Plans for the upcoming international research symposium on somato-visceral interactions are progressing well. The ORC is excited to be able to host this groundbreaking research conference on the University of North Texas Health Science Center campus. For more detailed information about the conference and for registration information, please see the article in this newsletter on page 1.

It is my pleasure to be able to share information about the ORC and its research endeavors with you through this newsletter. The ORC has been doing a tremendous job of building a research enterprise as it was charged by the profession to do in 2002. One of the key goals for the ORC this year is to enhance and increase communication across the wide range of audiences we serve.

We are here to lead the profession in developing studies that explore the efficacy of osteopathic manipulative treatment, to help document the mechanisms of action of osteopathic manipulation, and to help train the next generation of osteopathic researchers. Join us as we work to expand research in the osteopathic profession.

Sincerely,
John C. Licciardone, D.O., M.S., M.B.A.
Executive Director

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ORC Executive Committee

John C. Licciardone, DO, MS, MBA
*Executive Director and Osteopathic
Heritage Clinical Research Chair*

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Hollis H. King, DO, PhD
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Lessons Learned:

Recruitment, Compensation are Keys to Success

Conducting a successful clinical trial relies on a number of factors. The Osteopathic Research Center is committed to sharing its experiences with other individuals and centers interested in developing clinical trials in osteopathic manipulative treatment.

One of the keys to successful management and completion of this type of research endeavor is to find enough qualified subjects to enroll in and complete the study. Subject compensation may play a significant role in meeting the recruitment goals for the study.

In general, having a diverse pool of subjects who complete the study is desirable. Even within narrowly defined subject groups, such as women in their third trimester of pregnancy, having racial, ethnic and socioeconomic diversity across the study ensures more generalizability of the findings.

Some of our clinical trials have very rigid inclusion criteria. The carpal tunnel syndrome study is one example where subjects must pass a phone screening, have a diagnosis of carpal tunnel syndrome verified through a nerve conduction study, and also have a MRI to determine if there are any physical changes that would exclude the subject from participating in the study.

Other studies, such as the chronic low back pain study, have less rigid inclusion criteria. In this case, the phone screening used at the beginning of the study did ask subjects if they had chronic low back pain (> 3 months), but did not specifically ask subjects to define the length of time they have experienced the pain, or other characteristics of the pain. Potential subjects in this study undergo an osteopathic structural examination, but that exam is geared more toward ruling out herniated discs, nerve impingement and other criteria that may impact the subject's ability to improve during the course of the study, or that would be safety factors in allowing the subject to participate in the study.

Recently, the ORC addressed an issue relative to the impact of subject compensation on recruitment. Over the course of several weeks, one of our clinical research coordinators noticed that several subjects that had called had learned about the low back pain study from the same person. Following a phone conversation with one prospective subject, the research coordinator reviewed several charts and noted that a handful of subjects used the address of a local homeless shelter in their questionnaires.

Our primary concern in addressing this issue was that we maintain a diverse population in the subjects recruited for the low back pain study, and that we not have a large number of subjects from one particular population that could potentially skew the data collected during the study.

At the time this situation occurred, the ORC was compensating the subjects in the low back pain study with cash, which made the study attractive to this homeless population. The compensation system, combined with less rigid inclusion criteria for this study compared to other clinical trials under way at the ORC, could have had a significant impact on the outcome of the study had the problem not been discovered and rectified.

Since this situation occurred, the compensation for this study has been changed, and subjects will now be given gift cards instead of cash.

In addition, we were able to work with our institutional review board to revise the phone screening in order to obtain more information from prospective subjects, and we feel, to make a better decision as to whether the person does indeed meet the criteria of the study.

We hope these lessons learned have been valuable to those of you who may be designing or conducting clinical trials to evaluate the efficacy of osteopathic manipulative treatment.



Licciardone Presents Keynote Address at International Symposium

John C. Licciardone, DO, MS, MBA, executive director of the ORC, delivered the Keynote Address at the 4th International Symposium on Advances in Osteopathic Research in Schlangenbad, Germany on October 6, 2007. The symposium was part of "Osteopathy Today," the 10th International Congress sponsored by the German Osteopathic Association (VOD). His presentation, entitled "Evidence-Based OMTology" focused on the current state of evidence-based medicine, with particular emphasis on osteopathic manipulative treatment (OMT). Dr. Licciardone also gave a second lecture as part of the symposium, entitled "Osteopathic Manipulative Treatment of Back Pain and Related Symptoms during Pregnancy: A Randomized Controlled Trial." He presented the final results of this study of 144 subjects at the ORC, which found that OMT significantly improved the functional status of women during pregnancy.

Licciardone Presents Grand Rounds, Seminar at Colleges of Osteopathic Medicine

John C. Licciardone, DO, MS, MBA, executive director of the ORC, presented Grand Rounds at the Kansas City University of Medicine and Biosciences on November 16, 2007. His presentation, entitled "Osteopathic Research: A Strategic Tool for Defining and Promoting Osteopathic Medicine," provided an update on osteopathic clinical research and views on how such research could promote the osteopathic profession in the United States. Dr. Licciardone also presented a research seminar on the evidence base for osteopathic manipulative treatment (OMT) at the A.T. Still University on November 19, 2007. Following his seminar, he met with ATSU faculty and toured the A.T. Still Research Institute.

ORC Research Provides Evidence for Clinical Practice Guideline

Research conducted at The Osteopathic Research Center contributed evidence to support the efficacy of spinal manipulation in treating chronic low back pain. The systematic review and meta-analysis of osteopathic manipulative treatment (OMT) conducted by John C. Licciardone, DO, MS, MBA, Angela Brimhall, DO, MS, and Linda King, MLS, was one

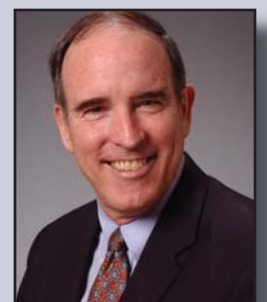
of only ten studies involving spinal manipulation that met the inclusion criteria established by an expert panel convened by the American Pain Society and the American College of Physicians. It was the only study that specifically evaluated osteopathic manipulation. The panel used these studies to guide recommendations for a clinical practice guideline on nonpharmacologic therapies in the management of low back pain. The panel's findings were reported in the October 2, 2007 issue of the *Annals of Internal Medicine*, and the original ORC research was published on August 4, 2005 in *BMC Musculoskeletal Disorders*.

ORC Contributes to Research Workshop at Osteopathic Leadership Conference

V. James Guillory, DO, MPH, associate dean for research at the Kansas City University of Medicine and Biosciences, and John C. Licciardone, DO, MS, MBA, executive director of the ORC, presented a workshop entitled, "Research Strategies to Enhance Academic and Clinical Activities," on January 11 as part of the 18th Annual Osteopathic Medical Education Leadership Conference in Scottsdale, Ariz. The workshop focused on osteopathic, patient-oriented research and on funding mechanisms to support such research and its related academic and clinical activities. Conference attendees included deans of colleges of osteopathic medicine (COMs), Osteopathic Post-doctoral Training Institute (OPTI) officers, hospital and COM administrators, directors and administrative directors of medical education, residency program directors and specialty college representatives.

King Assists UNECOM with Research Development

On November 19-20, 2007, Hollis King, DO, PhD, visited the University of New England College of Osteopathic Medicine to facilitate the Research Summit, which was developed by Kenneth Johnson, DO, associate dean for clinical affairs, in an effort to bring focus to the college's expanding efforts related to the construction of new research facilities on campus.



King