



From the Executive Director

Dear Friends and Colleagues:

Greetings from your Osteopathic Research Center. The first few months of the year have been very busy and productive for The Osteopathic Research Center, and I am delighted to have this opportunity to share our news with you.

Our four-year renewal grant from the Osteopathic Heritage Foundation (OHF) started January 1. While this grant was announced in last year's fourth quarter newsletter, we are pleased to provide more details of the projects funded through the grant in this issue of our newsletter. The ORC is very grateful to OHF for its continued support of osteopathic research and of the ORC. To date, OHF has provided approximately \$9 million of support to the ORC and the University of North Texas Health Science Center (UNTHSC). UNTHSC provided matching funds for the OHF grant. To learn more about the most recent grant, please see page 1.

Our practice-based research network (PBRN), the Consortium for Collaborative Osteopathic Research Development (CONCORD) is beginning to recruit its first class of PBRN fellows, who will start training in February 2011. Cathy Kearns and I had the opportunity to share information about the training and research components of the network with attendees of the recent American Association of Colleges of Osteopathic Medicine (AACOM) Annual Meeting in Bethesda, Md., where we made a brief



Licciardone

See *DIRECTOR*, Page 2

OHF Awards Four-Year Renewal Funding to ORC

The Osteopathic Heritage Foundation has awarded The Osteopathic Research Center \$2,000,000 over four years in a grant to continue to build its research infrastructure, and to advance several major projects. The University of North Texas Health Science Center and the Texas College of Osteopathic Medicine committed \$1,000,000 in matching funds for the grant.

Through the grant titled, Partnership to Enhance the Evidence for Osteopathic Medicine, the ORC will:

- Maintain and expand clinical research under the leadership of John C. Licciardone, DO, MS, MBA, the executive director of the ORC, and the Osteopathic Heritage clinical research chair;
- Maintain and expand basic science research under the leadership of Lisa Hodge, PhD, the ORC's Osteopathic Heritage basic science research chair;
- Fully implement and expand the emerging health services and policy research area, which includes conducting OSTEOSURV 2010;
- Develop and implement an osteopathic clinical research training program to establish a cadre of osteopathic researchers to conduct clinical research within the framework of the Consortium for Collaborative Osteopathic Research Development (CONCORD) and its affiliated primary care Practice-Based Research Network (PBRN) for osteopathic medicine. This initiative aims to provide a mechanism for practicing osteopathic physicians to acquire clinical research training at no cost and minimal disruption to their clinical practices, and to then engage them in substantive clinical research using their clinical practice patients;

See *OHF RENEWAL GRANT*, Page 3

presentation about the program and had a poster that featured highlights of the CONCORD-PBRN. To learn more about the fellowship and the opportunity to conduct clinical research with the ORC as a member of the CONCORD-PBRN, please see the story on page 4.

Related to the PBRN, a small group of key individuals will be on campus June 2 to discuss PBRN development throughout the osteopathic profession. The meeting is being sponsored by the Osteopathic Heritage Foundation and the ORC.

You may recall from the 2009 fourth quarter newsletter, that several authors from the ORC had a paper on the use of osteopathic manipulative treatment in the third trimester of pregnancy published in the *American Journal of Obstetrics and Gynecology*. It is my pleasure to report that this article was also featured by the National Institutes of Health-National Center for Complementary and Alternative Medicine (NIH-NCCAM) as a Research Spotlight in January. This is indeed an honor, and it helps promote awareness of the high caliber of research being conducted at the ORC. For more information, please see story on page 6.

I am delighted to report that the Multicenter Osteopathic Pneumonia Study in the Elderly (MOPSE) paper has been published in *Osteopathic Medicine and Primary Care*. Cathy Kearns has worked closely with MOPSE investigators to help promote the article to the national and regional news media. For more information, please see the story on page 6.

In January, the Agency for Healthcare Research and Quality's National Guideline Clearinghouse accepted the American Osteopathic Association (AOA) guidelines for the use of osteopathic manipulative treatment for patients with low back pain. These guidelines were largely based on the meta-analysis and systematic review that I completed for the AOA in 2007. The guidelines are currently listed as "in progress" on the National Guideline Clearinghouse site. To check the status of the guidelines, please visit the AHRQ National Guideline Clearinghouse website at <http://www.guideline.gov/browse/workqueue.aspx>.

It is my pleasure to welcome Robert J. Gatchel, PhD, to the ORC as our director of biopsychosocial research. Dr. Gatchel joined our faculty part-time in February. The chair of psychology at the University of Texas at Arlington, Dr. Gatchel's expertise focuses on interdisciplinary treatment approaches to chronic pain, including cognitive behavioral therapy (CBT). To learn more about Dr. Gatchel and his work with the

ORC, please see the story on page 5.

Beginning with this issue of our newsletter, we will be mailing printed copies in addition to sending out an electronic version. If you've received this from a colleague and would like your own copy, please send your contact information to Cathy Kearns via email at Cathleen.Kearns@unthsc.edu.

You may also notice that email addresses at UNTHSC have changed. The new email convention is firstname.lastname@unthsc.edu. If you are having difficulty locating someone on our campus, please visit the website at <http://www.hsc.unt.edu/> and click on "Find People" in the box at the right side of the page.

I hope that you enjoy this edition of the ORC newsletter.



The Osteopathic Research Center Newsletter is published quarterly by The Osteopathic Research Center at the University of North Texas Health Science Center, Fort Worth, Texas.

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- Develop, implement, and host the “Osteopathic Research” conference series. This initiative aims to revitalize osteopathic research conferencing by providing an annual three-day event in the Dallas-Fort Worth metroplex that is aimed at national and international researchers in osteopathic medicine and related fields. The inaugural conference will be “Osteopathic Research 2012.” Tentative conference dates are April 27-29, 2012 in Fort Worth, Texas;
- Promote the growth and visibility of *Osteopathic Medicine and Primary Care* (OMPC), an open-access journal under the umbrella of BioMed Central; and
- Provide consultation to OHF and other relevant organizations in establishing another center within the United States to conduct osteopathic research. The leadership of the ORC will provide consultation in identifying promising candidate sites for the center, develop the framework for and review candidate applications, make recommendations on site selection, and assist the new center in start-up activities, as requested by OHF.

The centerpiece of the ORC’s focus on clinical research is the OSTEOPATHic Health outcomes In Chronic low back pain (OSTEOPATHIC) trial, a study of 488 subjects that compares the efficacy of osteopathic manipulative treatment (OMT), ultrasound and placebo control in the treatment of chronic low back pain. This study currently has 417 subjects enrolled, and is scheduled to conclude later this year. In expanding this area of research, the ORC has applied for funding for a pragmatic trial of the use of OMT to treat chronic low back pain. Clinical research will also be significantly enhanced through the Consortium for Collaborative Osteopathic Research Development: A Practice-Based Research Network (CONCORD-PBRN). To learn more about CONCORD-PBRN, please see page 4. Funding for the pragmatic trial and for the PBRN are being sought through the National Institutes of Health-National Center for Complementary and Alternative Medicine (NIH-NCCAM) under R01 and K24 mechanisms. John Licciardone, DO, MS, MBA, leads the clinical research area through his role as the ORC’s executive director and as the Osteopathic Heritage clinical research chair.

Development of mechanistic research through the ORC’s basic science area continues to advance through the work of Lisa Hodge, PhD, who serves as the Osteopathic Heritage basic science chair. One aspect of Dr. Hodge’s work assesses the effect of

OMT on the immune system in specific conditions and diseases such as respiratory infections and cancer. She also evaluates the impact of OMT on the immune system by studying the response of cytokines and other biomarkers in the OSTEOPATHIC Trial. Another mechanistic research focus of the ORC includes work in conjunction with the University of North Texas Health Science Center’s Institute for Investigative Genetics that determines if there is any difference in genetic composition between responders to OMT and non-responders to OMT.

In addition to its efforts in the clinical and mechanistic research areas, the ORC has expanded the scope of its research in the past year by launching its health services and policy area. “For years, people have been saying that osteopathic distinctiveness is more than just OMT,” said Dr. Licciardone. “Through our health services and policy area, we now have the opportunity to conduct research that looks at distinctive patterns of osteopathic medical practice.”

One of the first major projects that will be undertaken through this area of the ORC is the OSTEO-SURV 2010, a national 1,000 respondent, random digital survey that will assess such topics as awareness of osteopathic medicine, the use of osteopathic physicians, the extent of patient-centered care and opinions on health care reform. The survey will be conducted under the auspices of the ORC, using trained interviewers at the University of North Texas Survey Research Center in Denton, Texas. Another recent health services and policy project that has been conducted through the ORC includes, “A National Study of Ambulatory Medical Care Provided by Osteopathic Physicians: 2002 to 2006.” Data analyses were completed last year through a \$152,610 grant from OHF. An article discussing the results of that study is being submitted for publication.

Another significant initiative that will be advanced under this OHF renewal is the increased effort to promote the growth and visibility of the journal *Osteopathic Medicine and Primary Care*. Dr. Licciardone serves as the editor-in-chief of the journal. The OHF renewal grant provides funding to waive publication fees for authors who may otherwise be discouraged from publishing in this open-access journal, which is published by BioMed Central. OMPC is peer-reviewed and indexed in PubMed. The journal’s mean time from submission to publication is 118 days.

Richard Vincent, president and chief executive officer of the Osteopathic Heritage Foundation, said, “We are pleased to award this renewal funding to the ORC. I am extremely proud of the research that has come out of UNTHSC and the ORC. We have been very pleased and proud of our association with Texas.”

CONCORD-PBRN Opens Recruitment for 2011

The Osteopathic Research Center has opened recruitment for the first class of fellows to join the Consortium for Collaborative Osteopathic Research Development: A Practice-Based Research Network (CONCORD-PBRN). The first class of eight fellows is scheduled to start research training in February 2011.

CONCORD-PBRN is a new pathway for physicians who have been interested in conducting clinical research, but who do not have the training needed to conduct patient-oriented research.

Historically, the osteopathic profession has struggled with conducting large clinical studies to evaluate the processes and outcomes of osteopathic medical care, including osteopathic manipulative treatment.

Currently, The Osteopathic Research Center is the only research center in the world that is conducting clinical studies that are large enough to potentially demonstrate definitive results.

A network of trained physician researchers working in partnership with the ORC would substantially increase the impact of our clinical research on developing an evidence base for osteopathic medicine. For example, one major study that will be conducted through the CONCORD-PBRN will look at how OMT is used in clinical practice to treat patients with chronic low back pain. Over a period of five years, the ORC, working with 24 physician researchers trained through the CONCORD-PBRN, anticipates recruiting and collecting data on more than 5,000 subjects. Having a network of trained physician researchers means that no one practice or individual bears an unrealistic burden to recruit subjects for a study.

“CONCORD-PBRN is a unique approach to developing a practice-based research network for the osteopathic profession because it focuses on a realistic pathway for training physician researchers,” said John C. Licciardone, DO, MS, MBA, ORC executive director and director of the CONCORD-PBRN network. “Such training is critical for ensuring the validity and reliability of data collected at disparate sites throughout the nation.”

CONCORD-PBRN uses Extended Weekend Seminars as the foundation of its training component. Each fellow selected for the program will commit to attending six Extended Weekend Seminars at the ORC, located on the University of North Texas Health Science Center campus in Fort Worth, Texas. Seminars will begin Thursday at noon and end Sunday at noon. The six seminars will be held in February, April, June, August, October and December. Eight fellows will be recruited each year for the next three years to develop the core group of 24 physician researchers for the PBRN.

Topics covered during each annual cycle of six

Extended Weekend Seminars include:

- Biostatistics - 24 hours
- Clinical Epidemiology - 24 hours
- Data Management - 16 hours
- Evidence-Based Medicine - 16 hours
- Genetics - 8 hours
- Human Subjects Protection - 10 hours
- Immunology - 8 hours
- Low Back Pain and Other Musculoskeletal Conditions - 16 hours
- Practice-Based Research Network Structure and Operations - 26 hours
- The Osteopathic Research Center - 12 hours
- Psychosocial Issues - 8 hours
- Osteopathic Manipulation - 16 hours

In addition to the 184 hours of classroom training, the PBRN fellows will work closely with the ORC for at least two years to collect data on patients with chronic low back pain.

The ORC will conduct a site visit at each fellow's practice location during their first year of data collection, and will guide fellows throughout the project period and publication of results.

Applications for the program will be accepted from osteopathic physicians who have a practice large enough to allow them to recruit six to eight new research subjects per month that would be treated with OMT in accordance with a specific project protocol.

Physicians on faculty at osteopathic medical schools, at medical centers or hospitals with ambulatory practices or in private practice will be considered.

CONCORD-PBRN has seed funding from the Osteopathic Heritage Foundation, and the ORC has applied for NIH funding to advance the major objectives of taking the network to the next level.

Contingent on grant funding, it is anticipated that there would not be any costs to fellows to attend the training sessions as long as they honor all commitments to the PBRN as agreed when they are selected.

If no additional funding is received for the project by Fall 2010, fellows could still begin the training component of the CONCORD-PBRN by asking their institutions to cover travel and lodging costs.

Travel and lodging costs per fellow are estimated at \$1,200 per Extended Weekend Seminar, with an additional one-time expense of \$400 for books. The total estimated cost for the entire six session cycle is \$7,600. The ORC would cover the cost of meals for the Extended Weekend Seminars.

To download an application, or for more information, please visit the website at <http://www.hsc.unt.edu/orc/CONCORD-PBRN.htm>.

Gatchel Joins ORC Part-Time

Robert J. Gatchel, PhD, has joined The Osteopathic Research Center part-time as the director of biopsychosocial research.

Dr. Gatchel serves as professor and chairman of the psychology department at the University of Texas at Arlington. He is also a clinical professor and clinical director of the Eugene McDermott Center for Pain Management at the University of Texas Southwestern Medical Center at Dallas.

Dr. Gatchel has a long track record of funding from the National Institutes of Health, the United States Department of Defense, and many other funding organizations. One of his major areas of expertise is in treating low back pain, and he was instrumental in developing cognitive behavioral therapy and functional restoration as treatment modalities for pain.

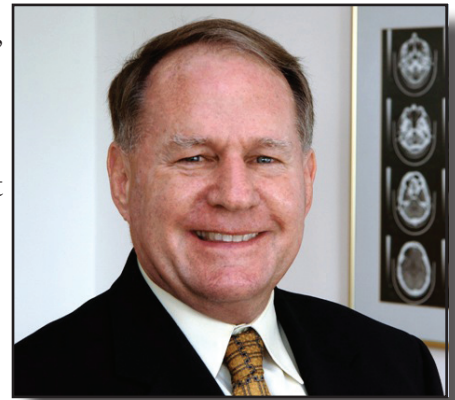
He has served as an editor and a member of editorial boards for numerous journals, and has published more than 400 scientific journal articles and abstracts, as well as 23 books and 103 book chapters.

At the ORC, Dr. Gatchel will work with leaders, faculty and staff to complement the work that is already under way to assess psychosocial aspects of chronic pain.

“I am excited to to join the research team at at

The Osteopathic Research Center,” Dr. Gatchel said. “We know from years of research that one treatment modality frequently does not work when you are treating pain. The osteopathic approach to treating the whole person, and treating both the mind and body offers an exciting path to help people get better. I am pleased to be part of the research efforts under way at the ORC, and to help develop projects that reflect this mind-body model of treatment.”

John Licciardone, DO, MS, MBA, executive director of the ORC, said, “It is a privilege to have someone with Dr. Gatchel’s research experience and credentials join our research team. He adds another important dimension to our research capabilities.”



Gatchel

News From The Osteopathic Research Center



**will be distributed electronically and in print
beginning with this issue.**

If you have received this document from a colleague and would like to receive your own copy, please contact Cathleen Kearns, at Cathleen.Kearns@unthsc.edu to be added to the mailing list.

ORC Research Shines in NIH-NCCAM Spotlight

The Osteopathic Research Center's research efforts recently garnered national recognition when an article published in the January issue of the *American Journal of Obstetrics and Gynecology* was featured in the January Research Spotlight on the National Institutes of Health-National Center for Complementary and Alternative Medicine (NIH-NCCAM) website.

The article, titled "Osteopathic Manipulative Treatment of Back Pain and Related Symptoms During Pregnancy: A Randomized Controlled Trial," was authored by John C. Licciardone, DO, MS, MBA, Steve Buchanan, DO, Kendi L. Hensel, DO, PhD, Hollis H. King, DO, PhD, Kimberly G. Fulda, DrPH, and Scott T. Stoll, DO, PhD.

The Phase II randomized controlled trial of 144 subjects showed that women in the usual obstetric care+osteopathic manipulative treatment group reported less deterioration of back-specific function on the Roland-Morris Disability Scale than women in the usual obstetric care+sham ultrasound and the usual obstetric care only groups when these groups were compared using an intention-to-treat analysis. Women were excluded or dropped from the study if they were determined to be at high risk by their obstetrician. The median age for women included in the study was 24 years. This study is the first major randomized, placebo-controlled trial to explore the potential effects of any type of manual therapy during prenatal visits.

Dr. Licciardone noted that outcomes were statistically significant for improved low back function in the OMT group. "The results also showed a trend toward pain reduction in the group that received OMT,

Preliminary Trial Finds Possible Benefits of Osteopathic Treatment for Back Pain During the Third Trimester of Pregnancy [NCCAM Research Results]



research spotlight Preliminary Trial Finds Possible Benefits of Osteopathic Treatment for Back Pain During the Third Trimester of Pregnancy

Most pregnant women experience low-back pain, which often is associated with sleep disturbance and can affect daily activities. Because of possible risks associated with many pain medications, pregnant women and their prenatal care providers often consider using complementary and alternative medicine (CAM) therapies, such as massage and spinal manipulation, for back pain. In a recent NCCAM-funded study, researchers at the University of North Texas Health Science Center investigated the effects of osteopathic manipulative treatment on back pain during the third trimester of pregnancy.

In this exploratory trial, 144 women in weeks 28-30 of pregnancy received usual obstetrical care only, usual care plus a systematic osteopathic manipulative treatment protocol provided by an osteopathic specialist, or usual care plus a sham treatment in which the specialist applied pressure with a nonfunctional ultrasound instrument. At each of seven 30-minute weekly sessions, researchers measured back-specific functioning (Roland-Morris Disability Questionnaire) and level of back pain (an 11-point scale). At the end of 7 weeks, back-specific functioning deteriorated significantly less in the osteopathic manipulative treatment group than in the other two groups. Average level of back pain decreased in the osteopathic manipulative treatment group, remained unchanged in the sham ultrasound group, and increased in the usual-care-only group; however, the between-group differences were not statistically significant.

Although the results of this preliminary study suggest that osteopathic manipulation may have benefits for back-specific functioning, but not pain, in the third trimester of pregnancy, larger trials are needed before definitive conclusions can be drawn about its efficacy or effectiveness for this purpose. An NCCAM-funded study of the physiological and clinical effects of osteopathic manipulative treatment during pregnancy is under way at the University of North Texas.

As with any CAM therapy, pregnant women should consult their health care provider before using osteopathic treatment.

Reference

Licciardone JC, Buchanan S, Hensel KL, et al. Osteopathic manipulative treatment of back pain and related symptoms during pregnancy: a randomized controlled trial. *American Journal of Obstetrics and Gynecology*. 2010;202(1):43.e1-43.e8.

Additional Resource

<http://nccam.nih.gov/research/results/spotlight/032210.htm>[4/21/2010 5:39:07 PM]

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but pain remained the same or increased in the other groups."

Usual obstetric care was defined in this study as the conventional prenatal care received during pregnancy. Osteopathic manipulative treatment is generally considered a complementary treatment that is not included as part of routine prenatal care.

MOPSE Paper Published in International Open-Access Journal

The Multicenter Osteopathic Pneumonia Study in the Elderly (MOPSE) paper was published March 30 in *Osteopathic Medicine and Primary Care*.

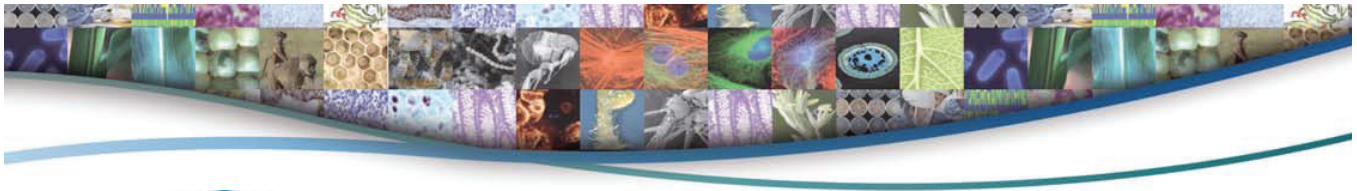
MOPSE was a clinical trial of 406 subjects 50 years of age and older who were hospitalized with pneumonia. The study showed a one-day reduction in the length of hospital stay in those patients who received osteopathic manipulative treatment (OMT) in addition to conventional medical care when compared to patients who received only conventional medical care. A per protocol analysis also showed a significant reduction in the duration of intravenous antibiotics and in respiratory failure or death in the group that received OMT when compared to the conventional care only group.

The study was conducted between March 2004 and February 2007 at seven hospitals in five states: Michigan, Missouri, New Jersey, Ohio and Texas.

MOPSE was funded by a consortium of

osteopathic supportive foundations including the Brentwood Foundation (Ohio), the Colorado Springs Osteopathic Foundation (Colorado), the Foundation for Osteopathic Health Services (Maryland), the Muskegon General Osteopathic Foundation (Michigan), the Northwest Oklahoma Osteopathic Foundation (Oklahoma), the Osteopathic Founders Foundation (Oklahoma), the Osteopathic Institute of the South (Georgia), the Osteopathic Heritage Foundation (Ohio) and the Quad City Osteopathic Foundation (Iowa). The Osteopathic Research Center at the University of North Texas Health Science Center in Fort Worth, Texas, was contracted by these foundations to provide administrative, fiscal and scientific oversight of the A. T. Still University's Kirksville College of Osteopathic Medicine in Kirksville, Mo., in its primary role of coordinating this multicenter clinical trial.

To access the article, visit <http://www.om-pc.com/>.



OSTEOPATHIC MEDICINE
AND PRIMARY CARE



www.om-pc.com

Editor-in-Chief: John Licciardone (United States)

***Osteopathic Medicine and Primary Care* is an open access, peer-reviewed online journal that encompasses all aspects of osteopathic and allopathic treatment as well as research relevant to the provision of primary care services at the level of the individual patient or entire population.**

Primary care articles may address any aspect of family medicine, internal medicine, pediatrics, and obstetrics and gynecology. The journal also covers health service and public health research that addresses primary care issues.

In addition to the aforementioned themes, osteopathic medicine articles may also cover uniquely osteopathic topics, such as osteopathic manipulative treatment and its mechanisms of action, reliability of palpatory findings, clinical outcomes, and efficacy in treating a variety of musculoskeletal conditions or related disorders.

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News Briefs

OMPC Announces Article of the Year

The article titled, "Muscle Functional Magnetic Resonance Imaging and Acute Low Back Pain: A Pilot Study to Characterize Lumbar Muscle Activity Asymmetries and Examine the Effects of Osteopathic Manipulative Treatment," has been selected by the editorial team of *Osteopathic Medicine and Primary Care* as the article of the year. The authors of the article are: Brian C. Clark, PhD, Stevan Walkowski, DO, Robert R. Conatser, MS, David C. Eland, DO, and John N. Howell, PhD, from the Ohio University

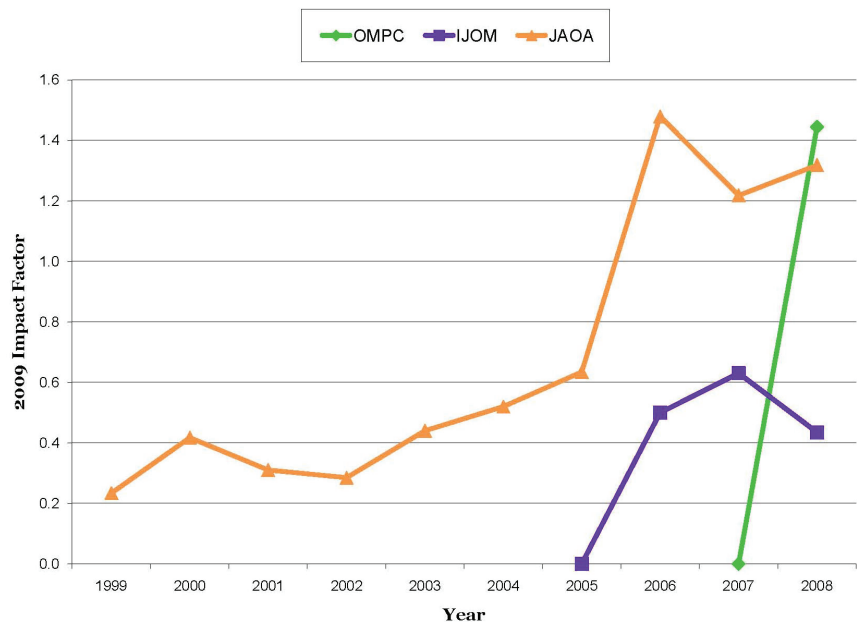
College of Osteopathic Medicine. To read the full-text article, please visit the OMPC website at <http://www.om-pc.com/>.

Save the Date for Osteopathic Research 2012

Mark your calendar for the launch of the new osteopathic research conference series, Osteopathic Research. The three-day conference is tentatively slated for April 27-29, 2012 in downtown Fort Worth, Texas. Watch the ORC website at <http://www.hsc.unt.edu/orc/events.aspx> for more information.

SCImago Computes Journal Impact Factors

Osteopathic Medicine and Primary Care has achieved the highest impact factor among three osteopathic journals in the first year during which it was eligible to receive an impact factor. The 2009 impact factor is based on the total number of times that the journal's articles published during 2007-2008 were cited by journals in 2009. *Osteopathic Medicine and Primary Care* began publishing in 2007. The methodology used by SCImago Journal & Country Rank (SJR) plots the 2009 impact factor in the year 2008 because it reflects the impact of the journal's articles that appeared in the 2007-2008 biennium. Impact factors were available for *Osteopathic Medicine and Primary Care* (OMPC), the *Journal of the American Osteopathic Association* (JAOA), and the *International Journal of Osteopathic Medicine* (IJOM).



Support uniquely osteopathic research with a donation to The Osteopathic Research Center



Where Science Meets Practice™

Now more than ever, your contribution helps us conduct clinical trials that look at the efficacy of osteopathic manipulative treatment, basic science research that explores the underlying mechanisms of action of OMT, and health services and policy research that helps highlight the distinctive ways in which osteopathic physicians provide patient care.

Please send contributions to The Osteopathic Research Center, UNTHSC, 3500 Camp Bowie Boulevard, Fourth Floor, Center for BioHealth, Fort Worth, TX 76107. Attn: Cathleen Kearns