Researchers and Select Principle Investigators:

Andrea Amalfitano, DO, PhD:
Chair Holder, Osteopathic Heritage Foundation Endowed Chair in Osteopathic Medicine; Michigan State University College of Osteopathic Medicine

Brian J. Balin, PhD:
Chair Holder, Osteopathic Heritage Foundation Endowment for Aging Research, in Honor of Ruth Purdy, DO, George Faerber, DO and Peter Johnston, DO; Philadelphia College of Osteopathic Medicine

Thomas A. Cavalieri, DO, FACOI, FACP, AGSF:
Chair Holder, Osteopathic Heritage Foundation Endowment for Primary Care Research in Aging, Dean; Rowan University School of Osteopathic Medicine

Brian C. Clark, PhD:
Professor of Physiology in the Department of Biomedical Sciences & Executive Director of the Ohio Musculoskeletal and Neurological Institute (OMNI); Ohio University Heritage College of Osteopathic Medicine

Brian F. Degenhardt, DO, C-SPOMM, C-OFP & OMT:
Chair Holder, Osteopathic Heritage Foundation Endowment for Research in Osteopathic Diagnostic and Therapeutic Palpation, in Honor of John Auseon, DO and Boyd Bowden, DO; A.T. Still University of Health Sciences, Kirksville College of Osteopathic Medicine

Ken H. Johnson, DO:
Executive Dean, Ohio University Heritage College of Osteopathic Medicine

John C. Licciardone, DO, MS, MBA:
Chair Holder, Osteopathic Heritage Foundation Distinguished Chair, in Honor of David Richards, DO and Benjamin Cohen, DO; Executive Director, the Osteopathic Research Center; University of North Texas Health Science Center at Fort Worth, Texas College of Osteopathic Medicine

Robert G. Nagele, PhD:
Professor of Medicine; Rowan University School of Osteopathic Medicine

Michael M. Patterson, PhD:
Conclave Facilitator; Nova Southeastern University College of Osteopathic Medicine –Retired

Frank Schwartz, MD:
Chair Holder, James O. Watson, DO Endowment and Director of the Diabetes Research Center; Ohio University Heritage College of Osteopathic Medicine

Richard J. Snow, DO, MPH:
Vice President of Clinical Effectiveness, OhioHealth

Unable to attend this year:

Frances Daly, PhD:
Director, J. Richard Costin, DO Institute for Osteopathic Medical Educators; Midwestern University Chicago College of Osteopathic Medicine

OHF Leadership and Board of Directors:

Richard Vincent, President/CEO
Terri Donlin Huesman, Vice President, Programs
Renée Gifford, Executive Assistant
Kerry Shaw, Program Officer

Tom Anderson, DO, Director
J. Richard Costin, DO, Director
Rebecca deVillers, DO, Director
Peter Johnson, DO, Director
Osteopathic Heritage Foundation

The Osteopathic Heritage Foundation
2013 Research and Education Conclave

Foundation President Richard Vincent opened the Osteopathic Heritage Foundation (OHF) 2013 Research and Education Conclave on Friday, July 26 at the Doubletree Suites in downtown Columbus, Ohio. Mr. Vincent introduced the OHF Board of Directors who were present, conclave guests and OHF staff. The first afternoon of the conclave featured updates from participants on their research and scholarly activities. The conclave resumed on July 27 at approximately 8:00 a.m. with remaining updates followed by open discussion regarding a number of research issues, including the annual American Osteopathic Association research conference and the strategic plan for osteopathic research.

Osteopathic Heritage Foundation Updates

Terri Donlin Huesman, Foundation Vice President, provided a brief update on Foundation activities during the past year. The Osteopathic Heritage Foundation and the Osteopathic Heritage Foundation of Nelsonville are currently managing $149,000,000 in active grants, which includes $12 million in awarded endowments. During the past year Robert G. Nagele, PhD was awarded a grant for his research activities in the area of mild cognitive impairment and Alzheimer’s. The Osteopathic Heritage Foundation of Nelsonville continues its active involvement in southeastern Ohio supporting a number of health and quality-of-life issues.

Mr. Vincent reminded the participants of the Foundation’s priority to advance the educational and scientific opportunities within Ohio, through its support of the Ohio University Heritage College of Osteopathic Medicine. It is the intent of the Foundation to continue its support of compelling research projects and looks forward to its continuing relationships with the institutions represented by the Conclave participants. The investment portfolios remain strong which bodes well for future funding.
Summary of Participant Presentations:

Ken Johnson, DO, Executive Dean, Ohio University Heritage College of Osteopathic Medicine (OU-HCOM)

Dr. Johnson provided a brief statement regarding the state of the college. Of the $105 million grant provided by the Osteopathic Heritage Foundation, about $25 million has been allocated for the development of the new branch campus in Dublin, Ohio. Work has begun on the renovation of the first buildings that will house the major teaching facilities of the new campus. This campus is scheduled to open in 2014. Plans are also underway for the opening of a second branch campus in 2015 in Warrensville Heights, near Cleveland. The Heritage College has affiliated with OhioHealth in central Ohio and the Cleveland Clinic in northern Ohio for student clinical rotations and postgraduate educational opportunities. The remaining funds from the Foundation’s grant are allocated to expanding the research capabilities, educational facilities and medical student scholarships. The college is actively seeking research collaboration opportunities with other institutions, especially with those in the central Appalachian region. One of the objectives of the Heritage College is to become the premiere center for educating primary care physicians.

Andrea Amalfitano, DO, PhD, Michigan State University College of Osteopathic Medicine (MSU-COM)

Dr. Amalfitano discussed a few of the research initiatives being undertaken at Michigan State. One initiative includes a new treatment for Pompe disease, also known as glycogen storage disease type II, acid maltase deficiency and glycogenesis type II. This disease is a metabolic myopathy caused by a lack of adequate intra lysosomal acid-alpha glucosidase (GAA) activity. The disease occurs in infants and causes early death, usually by five years of age, depending upon the severity of the disease. Dr. Amalfitano has many such children under his care and has proposed using gene therapy to treat the disease. Using adenovirus infected with the required gene, he proposes to inject the virus and expects the virus to position the gene in cells throughout the body. Along with Dr. Phil Ng, Baylor College of Medicine, he has initiated studies of this therapy in baboons. Initial results are promising with large increases in GAA activity in the baboons. He hopes to begin clinical trials in the near future. In another study he is using the adenovirus to induce T-cell responses in patients with advanced colorectal cancer. The results of this study are also promising with injected patients far outliving the usual life expectancy for this type of cancer. The first report of this study will be published in the August 2013 issue of Cancer Immunology and Immunotherapy. He is working on a two-year phase III clinical trial of 300 colorectal cancer patients, the cost of which is estimated to be $15 million, with partial funding by the National Cancer Institute. There are many potential uses for the adenovirus therapy since it can be the carrier for many different genes, with few side effects.

Dr. Amalfitano then addressed the issue of research funding. He pointed out that the greater the scholarly activity at an institution the more likely it was to be able to attract research funding. Since MSU-COM has the highest level of research funding of any college of osteopathic medicine, he feels the school is truly in a unique position to provide a leading role in promoting research in the osteopathic profession. The school
has a long history of producing DO-PhD graduates and is now developing a program to accept DO students from other colleges of osteopathic medicine into the PhD program. In addition Michigan State has recently founded the Clinical Translational Sciences Institute to promote translational research efforts at all levels of the university. Dr. Amalfitano has been named director of the Institute.

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**Brian J. Balin, PhD, Philadelphia College of Osteopathic Medicine (PCOM) Center for Chronic Disorders of Aging (CCDA)**

Dr. Balin summarized the development and purpose of the CCDA. Planning for the center was initiated in 2002 and in 2007 the Osteopathic Heritage Foundation endowed the center, whose purpose is focusing aging research at PCOM. This past year six small research grants were funded at an average of $15,000, with each satisfying the requirement to have external collaboration. Another initiative of the Center is to bring together clinicians and basic scientists to work on mechanisms of osteopathic manipulative treatment and other related topics, collaboratively applying for extramural funding. Center activities during the past year have included three symposia and lectureships, 14 peer-reviewed publications and numerous presentations and collaborations.

One of the major research areas of the Center is evaluating how infectious agents may be involved in Alzheimer’s and other similar diseases. Dr. Balin pointed out that 95% of Alzheimer’s disease patients do not have a genetic cause. Two specific infectious agents under study are *Chlamydia pneumoniae* and herpes simplex virus type one. One potential mechanism of chlamydia infection is through the olfactory vector. The infection occurs in the olfactory system and affects the sense of smell and the limbic system. Other proposed routes of infection include the respiratory system and systemic infection via the bloodstream. Infectious mechanisms of Alzheimer’s disease may be analyzed with human brain tissues and fluids, cell culture models using human cell lines, and animal models using normal non-transgenic mice. A promising line of research includes autophagy, which cells use to defend against pathogens. If autophagy is stopped, pathogens can accumulate in the cell, resulting in amyloid accumulation and finally the formation of Alzheimer’s tangles. Other areas of research within this project are an analysis of inflammasome gene regulation and changes in calcium-associated gene expression in infected cells. Another promising research area is detection of chlamydia pneumoniae in blood samples as a diagnostic screen for Alzheimer’s disease. The infection hypothesis for the beginning of Alzheimer’s disease suggests that infection leads to neuroinflammation and oxidative changes in the nerve tissue resulting in the formation of amyloid plaques. Dr. Balin suggested that chlamydia and other infections may lead to atherosclerosis, diabetes, neurotrauma and other diseases and thereby linking Alzheimer’s disease with many of these other conditions.

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**Thomas A. Cavalieri, DO, FACOI, FACP, AGSF, Dean Rowan University School of Osteopathic Medicine (RUSOM)**

Dr. Cavalieri discussed the New Jersey Medical and Health Sciences Education Restructuring Act and its implications for research at the school of osteopathic medicine (SOM). He briefly outlined the effects of the OHF endowment on the research at the school. Numerous funded projects have resulted from the endowment along with various published papers, abstracts, presentations,
The endowment has been a very significant factor in promoting scholarly activities in research at the school. Research funded by the endowment always includes student scholars and the endowment provides infrastructure such as statistical and grant writing assistance that leads to larger projects. Dr. Cavalieri emphasized the importance of research to the future of the osteopathic profession.

The restructuring of the educational system in New Jersey is the largest such undertaking within higher education in the United States. The shift occurred on July 1, 2013. Initially viewed with some concern by the osteopathic profession, the restructuring is proving to have positive implications for osteopathic education and research. In this restructuring, the University of Medicine and Dentistry of New Jersey (UMDNJ) was disassembled and redistributed. The School of Osteopathic Medicine and the Stanford campus Graduate School of Biomedical Sciences were transferred to Rowan University. Seven of the UMDNJ schools, the Cancer Institute of New Jersey and the University Behavioral Health Care were transferred to Rutgers University. The University Hospital in Newark became a freestanding academic medical center. Rowan University, founded in 1923, now has both osteopathic and allopathic medical schools. The university has campuses in both Glassboro and Camden. It offers bachelors through doctoral degrees to 12,200 students in 57 disciplines in nine academic colleges. It is ranked by the U.S. News & World Report and the Princeton Review as among the best Northern regional colleges. Its engineering and business programs are nationally ranked. The plan also calls for a partnership between Rowan and Rutgers – Camden to create a new College of Health Sciences in the city of Camden. As a result of the restructuring, Rowan University increased its student body by 650 osteopathic students and 190 biomedical graduate students and increased it sponsored research funding by $13 million. The restructuring has increased the opportunities for interdisciplinary research, increased state appropriations for the school and provides for enhanced educational opportunities for the osteopathic medical students. Rowan’s vision for the next decade includes increasing enrollment to 25,000, increasing the operating budget to $1 billion, increasing sponsored research to $100 million and increasing the endowment to $500 million. To achieve this vision the University will add new programs, particularly in health, science, engineering and business. The university plans to develop additional research collaborations and SOM researchers have initiated research collaborations with their colleagues at Rowan. A vibrant Glassboro – Camden – Stratford research triangle is envisioned, along with the South Jersey Technology Park being developed. The park will be an incubator for start-up companies and development of increased collaboration with industry. This educational restructuring has already had a positive impact on the SOM and will provide many more opportunities for research among its students and faculty.

Robert G. Nagele, PhD, Rowan University School of Osteopathic Medicine Biomarker Research Project

Dr. Nagele reported on his research on the early diagnosis of Alzheimer’s disease at the mild cognitive impairment (MCI) stage. Currently there is no consistent or affordable method available to accurately diagnose Alzheimer’s disease in its early phases. It is estimated the annual world market for an early diagnostic test for Alzheimer’s is approximately $3 billion. The ideal criteria for such a test indicate it must be: specific; reliable and reproducible; non or minimally invasive; simple
to perform, and affordable. Early detection of the disease would potentially allow greater treatment possibilities. Dr. Nagele and his team have discovered that autoantibodies are very numerous in human serum. Autoantibody counts generally increase with age and are slightly higher in females than males. The hypothesis is that autoantibodies are involved in clearance of debris generated by the body. If this is the case, the presence of disease should lead to a production of excessive debris from the organs affected and to an increased abundance of autoantibodies responsible for the clearance of disease-associated debris. The Nagele team has developed protein microarray plates that can be used to detect the presence of various autoantibodies from a single drop of serum. They have detected 451 autoantibodies that show significantly higher prevalence in patients with mild-moderate Alzheimer’s disease compared with controls. From this list, they selected the top 10 autoantibodies in sera from Alzheimer’s patients and, using these, were able to distinguish Alzheimer’s disease patient sera from controls with 96% sensitivity and 92.5% specificity. These results were published in 2011. These methods were also used with very high sensitivity and specificity in the diagnosis of mild-moderate Parkinson’s disease patients. More recently, the team has shown that autoantibody biomarkers useful for detection of early-stage Parkinson’s disease are different from the biomarkers previously reported to diagnose Parkinson’s disease, suggesting this diagnostic strategy can be used to detect diseases with minimal pathology.

Recent studies from clinical trials of potential Alzheimer’s disease drugs have been disappointing. Dr. Nagele suggests that, in these trials, the disease is being treated when it is far too advanced and thus early diagnosis would be useful in testing proposed drugs. Dr. Nagele’s research is partially funded by the OHF and has three specific aims: a biomarker discovery study; a larger scale verification study; and seeking FDA approval for the diagnostic test. An ongoing, longitudinal, multicenter study, the Alzheimer’s disease Neuro Imaging Initiative (ADNI) has been developed and funded by the National Institute on Aging. The purpose of this study is to enroll clinically well-characterized normal subjects, minimal cognitive impairment subjects and full Alzheimer’s disease subjects, following them with various clinical tests for as long as possible. Dr. Nagele’s group has initiated a study that will utilize sera from 100 minimally cognitive impaired subjects and 100 control subjects from the neuroimaging study. Thus far, 50 MCI and 50 normal subjects have been tested with the autoantibody array system. The team is also testing the system for the early detection of multiple sclerosis, traumatic brain injury, autism, and early-stage breast cancer. One of the long-term goals is to construct a multi-disease diagnostic blood test using these microarrays. Because each array can currently hold 23,000 protein targets, there could be hundreds of diagnostic tests performed with a single microarray. In addition, microarrays could test for the decrease in antibody biomarkers of various diseases following therapy, thus showing the therapeutic efficacy of treatment. Tests of the array in multiple sclerosis patients suggests that an accuracy of 96.8% may be achieved in diagnosing early-stage multiple sclerosis. Likewise results for detection of early-stage breast cancer suggest greater than 95% accuracy. A further hypothesis is that maternal brain-reactive antibodies passed to the infant from the mother may cause autism. Thus the diagnostic strategy with the microarrays may be used to identify autistic-specific antibodies in both the mother’s and child’s blood as risk factors for autism, and to identify autoantibodies in the child’s blood that diagnose the presence of ongoing autism neuropathology.
The development of these biomarker microarray diagnostic systems is an extremely exciting and potentially groundbreaking development.

**Brian C. Clark, PhD, Ohio University Heritage College of Osteopathic Medicine and the Ohio Musculoskeletal and Neurological Institute**

Dr. Clark discussed the mission and structure of the Heritage College of Osteopathic Medicine’s Ohio Musculoskeletal and Neurological Institute (OMNI). Its mission is to improve the diagnosis, treatment, and prevention of musculoskeletal and neurological disorders. The Institute has two programmatic foci; 1. musculoskeletal and neurological pain disorders research and; 2. healthy aging research. The pain disorders division aims to elucidate the causes, effects, and psychological aspects of musculoskeletal and neurological pain disorders. The healthy aging division aims to understand the biologic mechanisms behind reductions in neuromuscular and musculoskeletal form and function in seniors. Both divisions conduct clinical trials in their respective areas. OMNI has over 25 affiliated scientists from four colleges and eight departments. It incorporates a facility designed to facilitate interdisciplinary research. There are six scientific core areas within the Institute: the human neurophysiology core; the human motor and muscle performance core; the medical imaging core; the physical and metabolic function core; the bioanalytics core; and the complex systems, theoretical and data analytical core. One of OMNI’s major initiatives in 2013 is to develop centralized core medical imaging facilities. Currently, the institute’s active extramural research grant funding is $3,776,530. OMNI’s seven principal investigators published 70 Medline referenced articles in 2011 and 2012.

One of the major research efforts is looking at the neurophysiologic determinants of muscle strength/weakness. A major question in this research is in understanding the role of the brain and contributing to muscle activation. The research has shown that seniors with weak muscle strength exhibit dramatic deficits in voluntary muscle activation. These weak seniors also exhibit increased levels of intracortical inhibition. Research has also shown that in an immobilization model that induced muscle weakness in young, healthy adults that mental imagery training attenuates muscle weakness and eliminates the prolongation in the muscle silent period following immobilization. Another research area has been looking at the effectiveness of lumbar interventions in enhancing function. This NIH R01-funded study is comparing muscle energy interventions to high velocity-low amplitude interventions and laser therapy interventions as it relates to enhancing physical function and reducing pain. Additionally, this study is examining the physiological effects of these interventions at the cortical, spinal, and muscular levels. OMNI scientists are also conducting a multi-site proof of mechanism study on a novel pro-myogenic compound. This study is evaluating the effectiveness and safety of this novel compound when administered with and without exercise (compared to a placebo) as it relates to skeletal and cardiac muscle structure and function.

Dr. Clark pointed out that among OMNI’s challenges are federal funding level decreases and the historic reputation of research at osteopathic medical schools. He presented data showing that schools of osteopathic medicine have less National Institutes of Health (NIH) funded research than all other professional schools. Thus, the osteopathic profession must significantly enhance efforts to strengthen its research programs and increase extramural funding.
Dr. Schwartz reported on current activities of the Diabetes Institute research programs. The Institute is currently in the third year of a five-year, NIH funded study of the relationship between diabetes and depression in conjunction with Indiana University and West Virginia University. There is also a $350,000, two-year National Science Foundation grant for predicting future glucose levels in diabetics. A five-year $150,000 Medtronic grant is supporting development of a smart phone app for use with diabetics. The diabetics and depression grant is a four-arm study comparing usual care, talk therapy, supervised exercise, or a combination of talk and exercise. Thus far the interventions appear to be working. However, recruitment of patients is difficult due to changing models of patient care in the Appalachian region. The development of intelligent decision-support software for diabetes management is progressing well. The eventual outcome will be a continuous monitoring of patient glucose levels with a sensor that transmits data through an iPhone to the cloud-based information system. Abnormalities in glucose levels can be detected and advice relayed to the patient by text messaging. The team has developed the 4DSS software program (patent pending) which is a case-based reasoning software program designed to manage patients with type 1 diabetes on insulin pump therapy. They have developed a consensus glycemic variability metric to help predict individual patient risks for developing long-term complications in diabetes. They are also developing machine-learning techniques to predict hyper and hypoglycemia 30 to 60 minutes before it occurs. Current prediction programs do not detect hypoglycemia before it occurs. By using machine-learning paradigms it should be possible to predict hypoglycemia based on not only current glucose levels but also on past patient events. Hypoglycemia is a potentially severe syndrome that can cause cognitive disorders, seizures, coma, and irreversible brain damage or death. Currently with present programs the team is predicting hypoglycemia 30 minutes before it is detected by sensors with a 96% accuracy.

In another of the institute's research programs, the role of toll like receptors (TLR) in the pathogenesis of diabetes and the commercial development of C10 are being studied. TLR activation converts dendritic cells to antigen presenting cells. This conversion is a major mediator in the pathogenesis of many inflammatory, autoimmune and oncologic diseases. C10 is a derivative of methimazole and an inhibitor of environmentally-induced TLR expression in non-immune cells. Beta cell destruction in the pancreas results over time in type 1 diabetes. C10 affects TLR signaling pathways in the pancreas and inhibits beta cell death. In mouse studies C10 has been shown to inhibit the induction of type 1 diabetes. Also deleting the TLR3 gene protects mice from induction of type 1 diabetes. In addition, C10 protects mice from viral-induced type 1 diabetes. TLR4, another toll like receptor, appears to play a role in the pathogenesis of type 2 diabetes by inducing insulin resistance at the post receptor level. C10 reverses high-fat diet-induced insulin resistance in mice but is less effective in the prevention of type 2 diabetes. It is apparent that C10 may have a positive effect on fatty liver disease. Fatty liver disease often progresses to cirrhosis and hepatocellular cancer. Mice fed a high-fat diet have been shown to have much less fatty accumulations in the liver if given C10. The group is attempting to work through licensing agreements so the compound can be commercially produced. Approximately 20 additional compounds derived from C10 have been created that will soon screen for use in diabetes and fatty liver disease.
John C. Licciardone, DO, MS, MBA, University of North Texas Health Science Center, Texas College of Osteopathic Medicine, Osteopathic Research Center

Dr. Licciardone reported on activities of the Osteopathic Research Center (ORC). In September 2012, the Texas College of Osteopathic Medicine (TCOM) clinical research administration and functions were unified and consolidated under the ORC. All TCOM clinical research is now overseen by Dr. Licciardone. The center will continue its focus on osteopathic and primary care research with additional research and scholarly activities relating to osteopathic medical education. The Osteopathic Research Center has three major research foci: basic science research on mechanisms of osteopathic manual medicine; clinical trials of osteopathic manual treatment; and health services research to inform health policy, regulatory and reimbursement issues. Much of the center's research is funded by the OHF, the National Institutes of Health and other agencies. The focus areas are headed by Drs. Licciardone, Hodge and Gatchel, and with Dr. Aryal serving as biostatistician. One of the center's accomplishments was presenting five articles in a theme issue of the September 2012 Journal of the American Osteopathic Association. These articles originated from the research symposium that the center had previously organized.

Also in September 2012, Dr. Licciardone presented in London, England the results of the OSTEOPATHIC Clinical trial at the 9th International Conference on Advances in Osteopathic Research. Utilizing a multidimensional assessment model, this 455 patient study of the impact of osteopathic manipulative treatment (OMT) on low back pain showed a significant alteration in low back pain when compared with a sham control. It also showed a significant decrease in the use of prescription drugs in the OMT group. Utilizing these results, including meta-analysis, the center has participated in writing the first clinical practice guideline for recommending OMT in the care of patients with low back pain. In association with the American Osteopathic Foundation and Purdue Pharma, the center is distributing copies of its primary article on the OSTEOPATHIC trial to college of osteopathic medicine deans and directors of approved Osteopathic residency programs. Three secondary articles on the trial were published during 2012 in the Journal of the American Osteopathic Association (JAOA). These articles as a group received the 2013 JAOA Northup Medical Writing Award. An application has been submitted to the National Institutes of Health to conduct an OSTEOPATHIC-II trial. The proposed clinical trial on low back pain would involve 576 subjects, be conducted over five years and have an estimated budget of $3.5 million. The proposal was well received and well scored by NIH, but due to funding restrictions, has not been funded. It also appears the NIH is interested in partially funding a much larger trial of manual therapy on low back pain, involving osteopathic physicians, chiropractors and physical therapists. NIH believes that such a large trial, incorporating a collaborative of providers could be significant for manual medicine.

Dr. Licciardone has established the Consortium for Collaborative Osteopathic Research Development - Practice Based Research Network (CONCORD-PBRN), designed to train DOs in research techniques and to administer a practice-based research network. The CONCORD is establishing a network of office-based research centers across the country. A card study has just been conducted to collect
Glycogen storage disease type II (GSD-II)
Acid maltase deficiency (AMD)
Amylase deficiency (AMD)
patient demographics, primary diagnosis, structural exam findings and OMT techniques used on patients at these centers. A manuscript presenting these findings is in process. It is hoped that each PBRN site will recruit additional sites to participate in the research that is rapidly expanding the PBRN’s reach.

Dr. Licciardone specifically thanked the Osteopathic Heritage Foundation for its funding of research activities. Total funding awarded to the center from 2002 through 2012 has been $23,400,000 including $9 million from OHF.

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**Brian F. Degenhardt, DO, C−SPOMM, C−OPP & OMT, A.T. Still University of Health Sciences (ATSU), Kirksville College of Osteopathic Medicine (KCOM), A.T. Still Research Institute**

Dr. Degenhardt discussed the various research initiatives at the A.T. Still Research Institute. Established in 2001, the A.T. Still Research Institute's mission is to advance whole person healthcare and wellness through the development and support of premier clinical and translational research. Within the Institute there are four centers: the center for advancement of osteopathic research methodologies; the center for mechanistic studies; the center for clinical outcome studies; and the center for research in osteopathic manipulative medicine education. Among the institute's goals is the determination of the validity of osteopathic palpatory diagnostic processes. The classes of diagnostic tests utilized by osteopathic physicians include tissue texture abnormalities, asymmetry, restricted motion, and tenderness. There is good evidence showing that interobserver reliability of osseous and soft tissue pain is clinically acceptable, but that most other palpatory procedures are either not reproducible or that evidence for their reproducibility is either conflicting or preliminary. The center is developing methods to determine reliability for the localization of lumbar landmarks. The evidence to date shows that first-year osteopathic students through practicing clinicians show a great deal of variability in locating lumbar landmarks.

Another long-term goal is to advance the palpatory skills of future osteopathic physicians through feedback from instruments and protocols that objectify palpation. The team has developed calibrated palpatory models to assess the identification of bony asymmetries. These various models can be set to different levels of asymmetry, thus providing an accurate way of determining the palpator's ability to discriminate bony asymmetries. Also utilized is a Vicon position recognition system to determine medical student position accuracy during asymmetry assessment. Data at present suggest that asymmetries as small as 2 mm can be correctly detected on the models with about 90% accuracy after students have had some experience with palpation. The first of these models was constructed in 2006 and by 2011 were used in standardized testing for first through third year medical students at Kirksville. 250 of these models have been constructed and disseminated to the profession over the last year. Currently 2,555 students with 187,642 observations have been accumulated within a database from those models.

A digital camera measurement system is being developed to aid in training students in the art of palpatory analysis. The system and its associated software accurately provide the relative position
of hand placement that can be analyzed. Evidence to date shows a great deal of variability between camera and examiner findings. In addition, the data show excellent Kappa values between camera and examiner if there is a 4 to 6 mm or greater asymmetry in several tests, such as standing anterior iliac crest and standing anterior AC joint tests. Supine pelvis exams generally showed poor Kappa values at practically all asymmetries.

The use of skin radiopaque markers to identify L1 through L4 vertebra by x-ray showed that accuracy and inter examiner reliability gets better with experience. Faculty examiners were more accurate than medical resident examiners and accuracy was higher in male participants than female.

The Institute is also conducting research to advance the clinical identification and quantification of musculoskeletal pain in collaboration with Thomas Graven–Nielsen, PhD, of Aalborg University. Using sensitive sensors they measure thumb angle, rotation and orientation during palpation. These measurements are displayed graphically over time. These graphs show the patterns of palpatory pressures and orientations within and between palpators.

The Institute is also developing a PBRN called “Doctors of Osteopathy Treating with OMM – Usefulness in Current Healthcare” or DO-TOUCH.NET. A network of participant sites is being developed across the country. The initial data collection is aimed at determining the use and effectiveness of osteopathic manipulative medicine (OMM) in the clinical setting. The aims are to identify conditions that appear to be responsive to osteopathic manipulative treatment (OMT), determine if certain patient characteristics are present in those who are most responsive to OMT, determine which physicians utilizing OMT demonstrate positive outcomes and to identify and accurately describe techniques that are most beneficial when using OMT. Data collection tools include office visit questionnaires, physical examination and treatment forms, post treatment questionnaires, daily and one week follow-ups. To date, 532 unique patients have been enrolled at the various centers.

Dr. Degenhardt pointed out that currently medical students are not sufficiently trained in palpatory accuracy and that the educational system must improve in this regard. If students are not doing palpation accurately, many will recognize the inconsistencies and will not utilize it in their practice, or if they choose to use it, they will achieve highly variable results.
RESEARCH & EDUCATION

CONCLAVE 2013

DISCUSSION
General Discussion

The general discussion session began with the group questioning whether, in research of manipulative treatments, only those who had shown actual proficiency in palpation should be used as treatment providers. Those to be used as treatment providers could be tested on Dr. Degenhardt’s models and be required to meet certain standards of proficiency and accuracy to qualify. Dr. Licciardone pointed out that his research showed a definite correlation between somatic dysfunction and low back pain. There was discussion of how the profession could achieve better outcomes in its manipulative treatment research studies. Such measures would have to include more stringent palpatory requirements, screening of patients and treatment providers and demonstrate quantifiable outcome measures. It was pointed out that the National Institutes of Health (NIH) lumps manual medicine modalities together rather than recognizing, for example, osteopathic physicians separately from chiropractors or physical therapists. In addition, the National Center for Complementary and Alternative Medicine (NCCAM) is looking for pragmatic trials of manual therapies. In the clinical world there is a push for an interdisciplinary team approach to healthcare and the concept seems to work well. Therefore NCCAM seems to be looking for a pragmatic study including all manual medicine practitioners. If such a study was done and the results were negative it would be difficult to justify the utilization of manual medicine, even by osteopathic physicians. It was suggested that if such a study were undertaken, the osteopathic profession would have to mount a large-scale trial of osteopathic manipulative treatment to counter the possibility of an NCCAM negative result. It was pointed out that the osteopathic profession has little funding from the NIH and in effect is not on the NIH radar. There was a discussion of funding patterns across the health professions. As has been shown in the talks, the osteopathic profession has less NIH research funding than practically any other health profession.

Dr. Degenhardt then presented the strategic plan for research in the osteopathic profession that has been formulated by a sub-committee of the AOA Council on Research. The strategic plan has evolved over a few years with the input from many in the osteopathic research community. At the 2012 American Osteopathic Association (AOA) research conference there was a session devoted to the strategic plan. The plan has been approved by the AOA Board of Directors. The plan contains 13 specific recommendations. These include increased funding for research, increased research education and a restructuring of the annual research conference. The challenge now is to determine how to implement the recommendations. Dr. Cavalieri mentioned that the Commission on Osteopathic College Accreditation (COCA) is planning to review the research standards for accreditation of osteopathic schools. There was discussion that little emphasis is placed on research in the osteopathic schools compared to that for allopathic schools. It would be desirable for the colleges of osteopathic medicine to increasingly emphasize research in faculty decisions such as hiring, promotion and tenure. With respect to research, this would help in gradually changing the reputation and culture of the schools and hence the profession. It was emphasized that research should be included during advanced training of research oriented osteopathic clinicians. It was further stated that during such training, the emphasis must be on quality research. The group discussed how

One of the major research areas of the Center is evaluating how infectious agents may be involved in Alzheimer’s and other similar diseases.
individuals are selected for NIH study sections. Those who hold NIH grants are generally selected for study sections, resulting in the osteopathic profession having little presence on NIH study sections. This is a concern because when a study section reviews an osteopathic manipulative treatment grant, there is no expertise on the treatment.

Discussion ensued regarding the strategic plan recommendation on the research conference. Dr. Degenhardt described the history of the research conference, indicating it had started as a standalone conference of osteopathic researchers and had only in recent years been incorporated into the general AOA convention, the Osteopathic Medical Conference and Exposition (OMED). The goals of incorporating the research conference into the Osteopathic Medical Conference and Exposition had been to expose osteopathic researchers to the osteopathic profession and DO’s to the research being conducted in the profession. These goals have not been substantially met under the present structure. The osteopathic profession should reconsider the structuring and purpose of the research conference. One suggestion is to develop a portfolio of conference types that are provided on a rotating basis. For example, the 2013 conference will not be a single meeting, but presenters will be integrated into other meetings at the OMED. A stand-alone research conference, outside of OMED, should also be considered. Further, the profession should consider external sources to help sponsor research conferences, thus promoting integration of osteopathic medicine into those conferences. It was indicated by one who has chaired the research conference that the AOA expects the organizing work for the conference to be performed by the conference chair and the association does not promote the research conference well. However, there is, of course, the issue of how to promote interest in the research conference in the busy venue of the OMED. The central question is to determine the true goal of the osteopathic research conference. If it is to bring together the researchers of the profession, then a standalone conference would be preferable, with students being included in such a conference. It was suggested the AACOM should be more fully engaged in planning the research conference. Perhaps a research session could be included in the annual AACOM educational conference. Further, the research deans at the osteopathic schools should be more involved. It was suggested having a profession wide research day, perhaps rotated among the osteopathic schools. A participant then questioned whether it is truly feasible to have an osteopathic research conference at all. He explained that most of the researchers attend their own specific research meetings and a general research conference may not be a priority for them. There must be demonstrated benefit to attract researchers to an osteopathic research conference and he suggested that more emphasis on the osteopathic schools for osteopathic research may certainly help. Additionally, emphasizing enhanced linkage between osteopathic physician researchers and basic scientist researchers might be beneficial. It was suggested there should be more cooperation and collaboration in research among the various osteopathic schools. It was mentioned that care should be taken in collaborating with non-osteopathic large research institutions because the collaboration may only benefit the larger institution.

It was questioned if there is in fact a critical mass interested in an osteopathic research conference. Dr. Cavalieri advised he has appointed a task force on osteopathic research that has defined osteopathic research as anything contributing to the uniqueness of the osteopathic profession. Dr.
Patterson mentioned that perhaps we need to rethink our role as Osteopathic Heritage Foundation Scholars, perhaps acting more in the role of mentors for research. Dr. Licciardone suggested bringing together a group three times as large as the present OHF group to discuss potential directions for osteopathic research. Dr. Degenhardt agreed, suggesting that such an osteopathic research summit could help create roadmaps for research in the profession. The group agreed on an action step to give input to Mr. Vincent and Ms. Donlin Huesman to plan the next Heritage Conclave and suggest who could be invited to attend. Some suggestions were surfaced, including representatives from COCA, AACOM, the AOA Board of Trustees, and the Council on Research. In addition, past AOA President Ray Stowers, DO and Mike Clearfield, DO were suggested as potential invitees. The goals for such a meeting could be to develop plans for getting more funding and more research in the profession, determining a roadmap for encouraging holistic thinking in osteopathic research. There was a group consensus to dedicate more Conclave time for productive discussions on directions and means for osteopathic research.

Mr. Vincent indicated an OHF Conclave session will not be held in 2014, providing an opportunity for researchers to complete their considerations for implementing the osteopathic profession's research strategic plan. The Foundation will consider participating in a research planning meeting should one be organized in 2014. Otherwise, the Foundation will plan for a new Conclave structure for 2015.

Dr. Patterson ended the meeting with a short presentation on the direction and goals of the Journal of the American Osteopathic Association (JAOA). He pointed out the entire look and feel of the JAOA had recently been updated. While the journal does not currently have an impact factor, it rates above other osteopathic oriented journals in the SCImago journal and country rankings. The JAOA will soon apply for an impact factor.

At present the JAOA has a monthly printing of 38,600 copies while its electronic table of contents is sent to approximately 80,500. The JAOA’s online edition was accessed by 363,000 the last year, while about 445,000 PDF downloads occurred. Another example of the JAOA’s reach is that since published in January 2000 one of its articles was accessed over 1,000 times in the first half of 2013. In addition the JAOA can be accessed through the AOA’s mobile website. In the past year the JAOA has decreased its submission to publication time dramatically. The average time from submission to first decision is approximately 1.5 months and from decision to publication approximately 5.5 months. The number of manuscripts submitted in 2012 was 299 and 330 thus far in 2013. Dr. Patterson pointed out that Dr. Licciardone had won the 2013 George W Northup DO Medical Writing Award for his recently published articles. In addition the journal is publishing a series of articles aimed at providing information on research design and medical writing. The journal has recently added several new sections aimed at increasing its usability and general appeal. Finally, the current editor-in-chief, Dr. Gilbert D’Alonzo, has announced his retirement and a search is underway for a new editor-in-chief.

At meeting conclusion, Mr. Vincent commended the Conclave participants for their attendance and congratulated them for their work in advancing biomedical and clinical research.