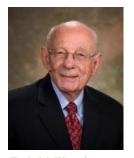


Research Matters February 2016

Research Matters is an internal monthly newsletter published by Marshfield Clinic Research Foundation.

Director's Report



Frederick Wenzel, Interim Executive Director

At the time of my writing this, last night the response to the RFA for the NIH Precision Medicine Initiative was sent out. Sometimes these things don't work like clockwork and the submission of the proposal for the Initiative was no exception. There were technical problems on the NIH side which caused some of our forms to be rejected. With due diligence however and great patience on the part of the investigators the project was submitted and accepted. I want to thank all of the members of the staff for their hard work on this project which is one of the largest and perhaps most significant for the Foundation for a long time. Dr. Brilliant, Dr. Peissig and Marlene Stueland worked very hard to prepare the basic document and coordinate the information from our partners at the University of Wisconsin and the Medical

College of Wisconsin. I want to thank them along with the staff in Grants Management for sticking with the job until it was done.

The meeting of the recent Board of Trustees sparked a great deal of interest when Dr. Murali discussed the situation related to St. Joseph's Hospital and the Clinic's/System plans for the future. This discussion included a number of questions and comments from the community members of the Trustees. The financial report indicated that the Foundation is in a good financial position. Teri and the Development staff presented an overview of that Department's plans for the future which will be submitted to the System Board in March. I had an opportunity to outline some of the priorities for the future stressing the importance of planning in sync with the System and the Clinic while at the same time carrying out an in-depth review of the Foundation and each of our Centers. The first Center has been reviewed and work is being done to help make that Center more efficient. The planning process is already beginning in several of the Centers and we will look toward a coordinated effort on that process in the next two months.

We have prepared a one page document which outlines the goals, activities and accomplishments of each of the Centers. That document will be available to the members of the System Board at their meeting in March. Copies will also be sent to the Center Directors and the members of the Board of Trustees.

On Saturday, February 20th the Wenzel Science Conference was held in cooperation with the Department of Education. The two keynoters were Dr. Jeff Grossman, the CEO of the University of Wisconsin Healthcare Authority and Dr. Murali, the Executive Director of the Clinic. There was a record attendance of over 150 students and faculty from all over the state of Wisconsin. I want to thank the presenters and the Department of Education for their work on the seminar.

Associate Director's Report



Steve Ziemba, Associate Director

It's still February, but the weather is starting to look more like spring. In fact, this past weekend the temperature rose above 50 degrees. We have not had a terrible winter, all things considered, but it is still nice when we can start to see the turnaround to warmer temperatures. I for one, am going to be tapping maple trees for the first time, and am very much looking forward to getting the garden started. And cycling to work, of course...

Speaking of things turning around to something better, we as a group have been tasked with making improvements in the Foundation overall, and the individual Centers. This will not be a quick process, or necessarily, a smooth

one. We've been reviewing one Center in detail, and will be working with the Center's staff and leadership to improve efficiency and productivity. Other Centers will follow. The intention is to improve the overall work we do as the Research Foundation. To that end, not only are the Centers being reviewed, but also the Research Administration and Resources offices, which provide the support needed in the conduct of our work. Much as I said above that part of the weekend will be warm, however, part of it will be back at the freezing mark as well. Your dedication and cooperation as we engage each Center and Office in making improvements will go a long way to ensuring the long term success of MCRF. Thank you again for all you do.

CCEPH Welcomes Back Research Scientist



David L. McClure, PhD rejoined CCEPH this winter as a Senior Project Scientist. David previously worked in CCEPH as a clinical epidemiologist working with MESA, regional and national collaborative such as ICTR, and collaborated with clinicians and other scientists conducting epidemiologic research. David's new role will be as a collaborator and co-investigator on epidemiologic research with the CDC funded Vaccine Safety Datalink project.

David received his PhD in Analytical Health Sciences (epidemiology/biostatistics) from the University of Colorado in 2005, and is

coming to MCRF from CVS Health where he was a Health Outcomes Research Advisor conducting program evaluation of medication adherence. Previously, David worked for Kaiser Permanente- Colorado (KPCO), Institute for Health Research. At KPCO, David participated in Comparative Effectiveness Research studies, the CDC funded Vaccine Safety Datalink project, and served as an epidemiologist and biostatistician on other vaccine related studies. David has a strong foundation in public health, health services, comparative effectiveness, and pharmacoepidemiology.

"We're delighted that Dave has returned to MCRF," said Dr. Edward Belongia, Director of CCEPH. "He brings a great deal of expertise and will be a tremendous asset for our vaccine safety research program."

Institute for Oral and Systemic Health (IOSH) Welcomes Intern



The Institute for Oral and Systemic Health (IOSH) welcomes Jacob Blamer as a writing intern. Jacob is currently finishing his undergraduate work at the University of Wisconsin-Stevens Point, where he is working towards two degrees; a Bachelor Degree in Biology, as well as a Bachelor Degree in English. He has an emphasis in Biomedical Writing and is on track to graduate in May of 2016. A native of Milwaukee, Wisconsin, Jacob is looking to earn a Graduate Degree in Science Journalism sometime in the near future. He will be interning with IOSH through May of 2016 and assisting with editing and developing partial drafts of manuscripts on the knowledgeability of patients and medical providers surrounding oral cancer.

MCRF On The Move

In this issue, we're introducing "MCRF On The Move", a recurring section of *Research Matters* where you can find information about the new roles, new locations, and new opportunities for MCRF staff.

The staff of BIRC and IOSH have settled-in at their new location and can now be found at ML8.

Marla Ripp Fischer in ORIP is the new point of contact for questions about Conflict of Interest disclosures and Data/Material Transfer Requests.

Please visit HR's <u>Employment Center</u> website to learn more about these positions currently available: Clinical Projects Manager, Lab (<u>ERP bonus-eligible</u>) and Grant & Contract Specialist.

Recent Publications, Grants, and Awards

This column is to highlight recent accomplishments of MCRF researchers and MC clinical investigators.

Please select the hyperlinks to view recent publications and grants for the first quarter.

If you have recently published an article or received a grant or an award and want it included in the next issue of *Research Matters*, please contact Patti Baer at baer.patricia@mcrf.mfldclin.edu

For more, please visit http://www.marshfieldresearch.org/

100th Anniversary Celebration to Include Research Day



Maree Stewart, Development Special Events Coordinator

Since I started as Development, Research, and Education Coordinator for Marshfield Clinic's 100th anniversary, I have heard over and over that what has set Marshfield Clinic apart for the past 100 years, and what will continue to distinguish us, is our research program. I am thrilled to have the opportunity to showcase research in 2016 as we celebrate our rich history and look forward to the future of Marshfield Clinic.

Throughout 2016, our Development special events will focus on celebrating the Clinic's 100th anniversary. In addition to our annual events, we have added a Historical Artifacts Exhibit in June as well as Legacy Week in October, which will feature a special Research Day.

Visit https://www.marshfieldclinic.org/giving/100-years for updates.

100th Anniversary Development Events:

<u>Historical Artifacts Exhibit</u> New Visions Gallery, Marshfield Clinic Campus June 6-17, 2016

Exhibit Open House New Visions Gallery, Marshfield Clinic Campus Wednesday, June 15, 2016, 4:00-6:00pm

<u>Legacy Week</u> Marshfield Clinic Campus October 10-14, 2016



Activities will be held throughout the week at Marshfield Clinic Campus and the Laird Center for Medical Research, including history exhibits, clinic tours, and city tours.

Wednesday, October 12, 2016: Education Day Thursday, October 13, 2016: History Day Friday, October 14, 2016: Research Day

Research Day on Friday, October 14 will include a combination of scientist-focused and community-focused events to feature the groundbreaking, cutting-edge research programs taking place right here at Marshfield Clinic. In addition, research messages will be woven throughout all our 100th anniversary activities. We are also exploring options for research-focused 100th anniversary events at some of our regional centers.

Research has proven our commitment to innovation and progress over the past 100 years. Our 100th anniversary is an opportunity to showcase this commitment and share our vision for the future.

We welcome your feedback and suggestions as we plan specific activities for Research Day, as well as work on ways to incorporate research into all 100th anniversary events. Please send your ideas to Maree Stewart, Development Special Events Coordinator, at stewart.maree@marshfieldclinic.org, or give me a call at 715-389-3257.

Collaboration Between MCRF Centers Results in Successful Enrollment for Innovative Oral Health Study

Through a collaboration between CCEPH, IRDL & IOSH, Dr. Timothy Rhoads and Dr. Katherine (Katie) Overmyer, Oral Health Informatics Postdoctoral Fellows*, have conducted the innovative study Proteomic/Metabolomic Profiles of the Oral Microflora. Working under the mentorship of Dr. Amit Acharya and Dr. Sanjay Shukla from MCRF and Dr. Joshua Coon from UW-Madison, the Investigators' study has endeavored to learn more about how the oral bacteria (microbiome) influence human health. To do this, with the assistance of CCEPH staff, they successfully collected plaque samples from 97 diabetic and non-diabetic patients with and without periodontal disease at the Marshfield Dental Center. The plaque samples are currently being analyzed by Drs. Rhoads and Overmyer to identify bacterial proteins, fats, and metabolites present in the plaque samples, and possibly identify biomarkers. In addition, they plan to explore ways to translate the microbial information into the electronic health records to be used by the medical/dental providers to make decisions.

Study Team Members include:

- CCEPH: Deanna Cole, Becky Pilsner, Maddie Minervini, Terry Foss, DeeAnn Polacek, Jackie Salzwedel, Yvonne Cerne, Jillette Petersen, Kristja Vittallo, and Matthew Rehlinger
- IRDL: Le Thao
- IOSH: Dr. Timothy Rhoads, Dr. Katie Overmyer, Dr. Amit Acharya, Dr. Sanjay Shukla (Secondary Appointment) & Dixie Schroeder

Study-Related Presentations and Publications:

- Rhoads TW, Prasad A, Kwiecien NW, Merrill AE, Zawack K, Westphall MS, Schroeder FC, Kimble J, Coon JJ. NeuCode Labeling in Nematodes: Proteomic and Phosphoproteomic Impact of Ascaroside Treatment in Caenorhabditis elegans. Mol Cell Proteomics. 2015 Nov; 14(11):2922-35.
- Rhoads TW, Kwiecien NW, Merrill AE, Westphall MW, Shukla S, Acharya A, Coon JJ.
 "Dental plaque meta-omics for diagnosis of oral and systemic disease." American Society for Mass Spectrometry Annual Conference, June 2015. Poster.
- Rhoads TW. "Quantitative Proteomics of Nitroxidative Post-translational Modifications."
 Academic Employment Initiative, American Chemical Society National Meeting, Boston, MA, August 2015. Poster.
- Rhoads TW, Overmyer KA, Merrill AE, Westphall MS, Shukla SK, Acharya A, Coon JJ.
 "Quantitative Proteomic Strategies for Investigating the Oral Microbiome." CIBM Annual Retreat, Madison, WI, October 2015. Poster.
- Overmyer KA, Rhoads TW, Merrill AE, Westphall MS, Shukla SK, Acharya A, Coon JJ.
 "Metabolomics approach to elucidate oral microbiota interactions." CIBM Annual Retreat, Madison, WI, October, 2015. Poster.

^{*}Dr. Rhoads and Dr. Overmyer are NIDCR funded oral health informatics post-doctoral fellows, who are jointly trained by the Institute for Oral and Systemic Health at the Marshfield Clinic Research Foundation and the Computational and Informatics in Biology and Medicine program at University of Wisconsin-Madison.

RE-POWER Study Launch

On February 5th, CCEPH researchers hosted a staff training meeting to launch the "RE-POWER" (Rural Engagement in Primary Care for Optimizing Weight Reduction) trial at Marshfield Clinic. The study is funded by a grant from the Patient Centered Outcomes Research Institute (PCORI). This PCORI funding mechanism is designed to test meaningful translational research (bench to bedside) for Marshfield Clinic's rural patients who face obesity challenges.

The project is led by Christie Befort, PhD at the University of Kansas Medical Center (KUMC), along with scientists from both the University of Nebraska Medical Center and Marshfield Clinic. Jeff VanWormer, PhD is serving as the Marshfield Clinic PI in CCEPH, along with co-investigators Ram Pathak, MD from Endocrinology and Peggy Peissig, PhD from BIRC. Epidemiologist Tenisha Hill, MPH is the Study Manager, and Jen Meece, PhD, oversees lab portions of the study in IRDL.

RE-POWER will compare three different behavioral weight loss interventions, including: (1) a fee-for-service (FFS) model that emulates the current CMS standard of obesity treatment, offering usual office visits with individual counseling, (2) a patient-centered medical home (PCMH) model offering group-based counseling at participating clinics, and (3) a disease management (DM) model that provides group-based obesity counseling over the phone with a remote team of counselors based at



RE-POWER Feb 5th meeting attendees, bottom to top rows, left to right: 1st row: Jeff VanWormer, PhD (CCEPH), Christie Befort, PhD (KUMC), Danielle Christifano, PhD (KUMC); 2nd row: Karen Shulman, MD (MC-Stratford), Tenisha Hill, MPH (CCEPH), Paula McIntyre, RD (MC-Merrill); 3rd row: Kelley Natzke, RN (MC-Merrill), Heidi Stuttgen, MA (MC-Colby), Nicole Bargender, RN(MC-Stratford), Kandise Sporer, RN (MC-Stratford); 4th row: Linda Daubner, RD (MC-Park Falls), Sharon Scherwinski, NP (MC-Park Falls), Jackie Kundinger, RN (MC-Park Falls); 5th row: Brenda Halverson, MA (MC-Colby), Dawn Decker (MC-Stratford), Debra Boilesen (MC-Merrill), Kathleen Franke, MA (MC-Park Falls)

KUMC. All intervention arms utilize Care Coordinator trained in comprehensive lifestyle and behavioral coaching techniques. Each participating clinic is randomized to use one of these three specific interventions, and each will enroll 40 participants. Body weight, lipids, and other outcomes will be compared between study arms over 2 years.

RE-POWER will be the largest rural weight management trial conducted to date, including nearly 1,500 patients across four Midwestern states. Ten Marshfield Clinic centers will participate, and recruitment efforts have started in four centers so far (Merrill, Park Falls, Stratford, and Colby). Additional centers, including several in Marshfield, will begin later in 2016.

More information can be found at the RE-POWER website: http://www.kumc.edu/school-of-medicine/preventive-medicine-and-public-health/repower.html

Updates from ORIP/IRB

PARTICIPANT COMPENSATION AND INCENTIVES - INFORMED CONSENT REVISIONS AND INCOME TAX NOTIFICATION REQUIREMENT

Federal Guidance (45 CFR 46.116 and 21 CFR 50.20) states that IRBs are responsible for ensuring that research participation is voluntary, and consent is sought under circumstances that minimize the possibility of coercion or undue influence, thus proposed compensation must receive IRB review and approval. MCRE IRB considers compensation or incentives on a



review and approval. MCRF IRB considers compensation or incentives on a study-by-study basis, considering variables such as patient population, time to be spent and inconvenience. Participant compensation should be based upon a reasonable amount for time spent in preparation for, participation in, and recovery from a particular research intervention, including time as well as any potential discomfort they may experience and not to be so great as to influence them to participate in research when contrary to their interest or values. The amount should not be based upon the degree of risk of the study. Proposed compensation and incentives should be described in the informed consent document, however not be given more emphasis during the informed consent process than discussion of the purpose, risks, benefits and alternatives of the study.

The Internal Revenue Service (IRS) regulations consider payments for research participation as income. If Marshfield Clinic anticipates participant payments will **reach or exceed \$600 in a calendar year**, **in any or all studies**, participants will be asked to complete a Form W-9. If the total amount of payment made equals or exceeds \$600 then an IRS Form 1099-MISC will be issued by January 31 of the following year by MCRF Fiscal.

Although reaching or exceeding \$600 is rare, participants may enroll in multiple studies within our MC system in a given year and need to be made aware of this information therefore, ORIP effective immediately is requesting the following:

- Notify all participants currently receiving compensation at their next visit using the IRB prepared document entitled, "Research Study Payment Tax Information Document". The information document could also be mailed to participants provided that a contact for questions is available. The document can be obtained from ORIP staff.
- Revise all existing open to enrollment study informed consents where participants are receiving compensation to include IRS applicable information, using the revised <u>Informed</u> <u>Consent Template</u> located in the Forms Library.
- Document in the study records once achieved that information and discussion has occurred relative to IRS information.
- For all new study submissions, use the newly revised <u>Informed Consent Template</u>, which has applicable language to be incorporated.
- Note if an existing study is closed to enrollment with participants being compensated, the Informed Consent doesn't need to be revised. However participants are to be informed of IRS information if being compensated.

CCEPH Scientists Present Research at ID Week

Dr. Ed Belongia, Director of CCEPH, Jennifer King, Masters Prepared Epidemiologist, and Dr. Huong McLean, Associate Research Scientist, attended and presented scientific posters at



IDWeek in San Diego, Oct 26-30. IDWeek is an international infectious disease meeting sponsored by the Infectious Disease Society of America (IDSA) and three other professional organizations. Also presenting posters were Dr. Holly Frost, a pediatrician at the Minocqua Center, and Dr. Pamela Talley from the Minnesota Department of Health. Dr. Talley is a CDC Epidemic Intelligence Service Officer who conducted an influenza vaccine study in collaboration with CCEPH investigators. Poster presenters and associated Marshfield Clinic authors include:

<u>Variable Influenza Vaccine Effectiveness by Type and Subtype: Meta-analysis of Studies Using</u> the Test-negative Design

 Authors: Edward Belongia, Melissa Simpson, Jennifer King, Maria Sundaram, and Huong McLean

Association of Spontaneous Abortion and Receipt of Inactivated Influenza Vaccine Containing H1N1pdm09 in Early Pregnancy

 Authors: James Donahue, Burney Kieke, Jennifer King, Maria Mascola, and Edward Belongia

Priming History and Risk of H3N2 Vaccine Failure Among Young children

Authors: Huong McLean, Jennifer King, and Edward Belongia

Effect of Prior Season Vaccination on Serologic response to Live Attenuated and Inactivated Influenza Vaccine in Children During 2014-2015

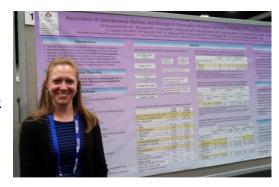
Authors: Pamela Talley, Jennifer King, Huong McLean, and Edward Belongia

Blastomycosis in Children: An analysis of the clinical, epidemiologic, and genetic features

Authors: Holly Frost, Jennifer Meece, Jennifer Anderson, and Lynn Ivacic

The presentations attracted the media coverage from STAT news, Wired, and Boston Globe:

- Getting a flu shot every year? More may not be better, STAT news.
- Scientist found a flu vaccine flaw Now they have to fix it, Wired.
- Weak link discovered in flu vaccine, Boston Globe.



Upcoming Talks and Presentations

Scientific Seminar (Froehlke Auditorium)

Wednesday, March 30th

12:00pm-1:00pm - hosted by Dr. Sanjay Shukla (CHG)

"Fecal Microbiota Therapeutics to Treat Recalcitrant, Recurrent, and Often Severe GI Diseases" Dr. Michael Sadowsky, Director BioTechnology Institute/Distinguished McKnight Professor, University of Minnesota

PreventionGenetics Seminar Series

Save the date! PreventionGenetics will be offering a Seminar Series in 2016. The following speakers and topics are currently scheduled with additional seminars to be announced in the future.

April 22: Dr. Hassold - Aneuploidy & Sex Development

June 30: Dr. Eichler - Homology

Sept TBD: Dr. Shapiro – Ciliopathies

Grand Rounds (12:00 - 1:00 p.m. in the Froehlke Auditorium)

Friday, March 4:

Osteopathic Manipulative Treatment (OMT) for Cervicogenic Headache: An Osteopathic Manipulative Medicine Approach

Jonathon R. Kirsch, D.O., C-NMM/OMM, Associate Physician, Neuromusculoskeletal Medicine, Marshfield Clinic Stevens Point Center

Friday, March 11:

Professionalism in a Small Town

Edward J. Krall MD MS FAPA, Marshfield Clinic

Friday, March 18:

Pending

Friday, March 25:

Resiliency 101: Transitioning Adolescents with Type 1 Diabetes to Adult Practice through a Self-Management Insulin Adjustment Educational Program

Angela Mojica, MD & Brianna Czaikowski, DNP, Pediatric Endocrinology, Marshfield Clinic

Infectious Disease Journal Club

If you are interested in this noontime journal club and are not currently on the club's email list, please contact Ms. Brenda Potts.

In Addition:

- The next Full Foundation meeting is scheduled for March 17, 2016 at 2PM in the Froehlke Auditorium. Questions can be routed or emailed to Jeanette Normington at 1R3 or normington.jeanette@mcrf.mfldclin.edu.
- The next Board of Trustees meeting will be held on May 26, 2016 at 6PM in the Laird 50 conference room.
- For the latest issue of the UW-Madison newsletter, ICTR Today, please click here: https://ictr.wisc.edu/Newsletters.
- For updates on the Wisconsin Network for Health Research (WiNHR), please visit: https://ictr.wisc.edu/winhr
- The Marshfield Clinic Research Foundation website can be accessed through this link: http://marshfieldresearch.org/. You will find in depth articles, news about upcoming presentations, and achievements by the staff. There are also links to each Center, with detailed information about the staff and projects.
- Research Matters is always accepting announcements. Your contributions are greatly appreciated.

<u>Contributors to this issue</u>: Bobbi Bradley, Dixie Schroeder, Lori Scheller, Maree Stewart, Frederick Wenzel, Dr. Steve Ziemba

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