RESEARCH *Matters*

SPRING 2021

IN THIS ISSUE...

Association for the Accreditation of Human Research Protection Programs, Inc. *Full* Accreditation

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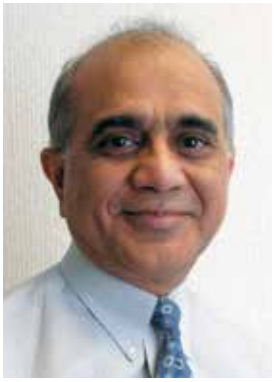
RESEARCH AROUND McLAREN

DR. REHAN MAHMUD COMPLETING INVESTIGATOR-INITIATED PROJECT



Rehan Mahmud, MD

Please join McLaren Center for Research and Innovation in congratulating Dr. Rehan Mahmud, Electrophysiologist from McLaren Bay Region, on his successful investigator-initiated study, *Characteristics of Left Ventricular Activation in Non-Selective HIS Bundle Pacing: Its Effect on Left Axis Deviation and Left Bundle Branch Block*. Dr. Mahmud secured funding and support for his project from Medtronic and put together an expert team to conduct the study. Shakeel Jamal, MD, Brenda Harris, RN, and Stacy Kukla, RN, all from McLaren Bay Region, worked closely with Dr. Mahmud to collect and analyze their data. "There is growing awareness that the site of the left bundle branch block is usually distal to the pacing site, and therefore not amenable to correction with selective HIS bundle pacing," Dr. Mahmud notes, "This realization has led to considerable interest in pacing the left bundle itself." Dr. Mahmud and his research team are preparing for publication and look forward to sharing their results with McLaren and the medical community.

NEW RESEARCH FUNDING FOR INVESTIGATORS

McLaren Health Care has formed a corporate level Research Funding Committee. This committee has been created to establish a system-wide strategic plan and process for awarding research funding to investigators. One goal of this committee is to support and strengthen investigator-initiated research within the corporation. Awards of up to $5,000 will be presented to individuals involved in Graduate Medical Education research (Residents and Fellows). Awards of up to $20,000 will be presented to non-GME individuals interested in pursuing investigator-initiated research. Non-GME awards are open to all McLaren employees or affiliated providers. These funds are to be used for the conduct of observational or interventional research studies and will be awarded on a quarterly basis. Due dates for application submissions are January 1st, April 1st, July 1st, and November 1st of each year. The application process is now open for the July 1st deadline at www.McLaren.org/FundingApplication. Required information for the application includes a detailed description of the research project, as well as a proposed budget. Research Matters will publish awardee information in future issues. Good luck to all applicants.

NEUROSCIENCE RESEARCH AT McLAREN RECEIVES NATIONAL ATTENTION

Despite the unique challenges of 2020, McLaren Center for Research and Innovation (MCRI) is proud to celebrate a number of milestone achievements in our Neuroscience Research program. Neuroscience Research flourished in 2020 and is currently the most rapidly growing therapeutic area of MCRI. While navigating the newfound challenges of conducting clinical trials during a pandemic, in 2020 neuroscience clinical trial enrollment grew by 186 percent over the previous calendar year. Additionally, MCRI has 67 percent more open and enrolling neuroscience studies than in 2019. Dr. Aniel Majjhoo and his team at McLaren Flint opened and enrolled in the MOST trial, our first interventional in-patient stroke trial with investigational treatment starting in the emergency department.

Many of our neuroscience clinical trials are conducted in partnership with the NIH funded StrokeNet. StrokeNet is a network of 27 regional centers across the US, involving approximately 500 hospitals. This serves as the infrastructure and pipeline for exciting new potential treatments for patients with stroke and those at risk for stroke. MCRI currently participates in eight StrokeNet clinical trials across two research sites: McLaren Flint and McLaren Macomb. McLaren neurointerventionalists Dr. Aniel Majjhoo, Dr. Bharath Naravetla, and Dr. Mahmoud Rayes serve as Principal and Sub-Investigators on these neuroscience studies.

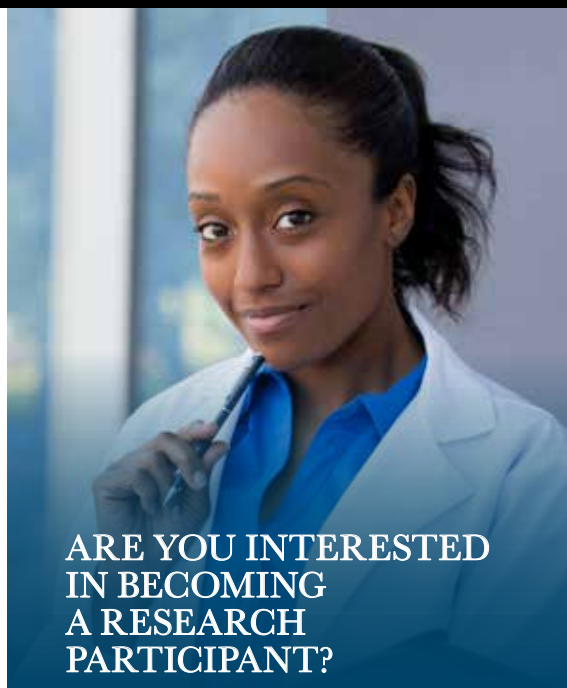
Neuroscience clinical trials are complex and often require a great deal of collaboration to achieve success. McLaren's efforts involved in conducting these trials has recently been recognized by StrokeNet. Congratulations were extended to Dr. Rayes and the McLaren Macomb research team for their successful enrollment and randomization of the 600th patient study-wide for the ARCADIA trial. A member of the StrokeNet team reached out to congratulate the team on this success and "the cutting-edge care that you deliver".

Accolades from StrokeNet were communicated globally for Dr. Aniel Majjhoo and the McLaren Flint research team for reaching the top 5 percent of enrolling sites in the MOST trial.

Marci Roberts, Clinical Research Coordinator at McLaren Flint, was named SleepSMART coordinator of the month for her extraordinary efforts to enroll patients, including traveling back to the hospital after hours during a snowstorm. She was recognized by StrokeNet for helping to turn McLaren Flint into a top randomizing site for this study.

Aside from the immense success with StrokeNet studies, McLaren remains the number one enroller globally in the ASSIST registry with Stryker. Dr. Naravetla and his team have enrolled over 100 patients between McLaren Flint and McLaren Macomb.

MCRI is excited to continue partnering with StrokeNet and industry sponsors to grow Neuroscience research at McLaren.



ARE YOU INTERESTED IN BECOMING A RESEARCH PARTICIPANT?

For information on enrolling in a clinical trial please visit our website at https://www.mclaren.org/main/research-trials1.aspx . Here you will find a list of open enrolling studies at McLaren, including which hospital the research is being done at and contact information for each study.

We have enrolling studies for the following conditions (not a complete list):

- **Diabetes**
- **COVID-19**
- **High Blood Pressure (Hypertension)**
- **Stroke**
- **Heart Attacks / Heart Failure / Heart Disease**
- **Kidney Diseases**
- **Lung Diseases**
- **Peripheral Artery Disease**
- **Carotid Artery Disease**
- **Mastectomy**
- **Various Cancers**
  - **Breast**
  - **Lung**
  - **Prostate**
  - **Multiple Myeloma**
- **Patients who underwent intracranial aneurysm coiling**
- **Drug study for patients with recent acute coronary syndrome**

For a complete list of conditions, please visit our website listed above.

RESEARCH AROUND McLAREN

CLINICAL TRIALS DAY

Clinical Trials Day is celebrated internationally on May 20 of each year to commemorate the date that English surgeon Dr. James Lind began the first randomized clinical trial to combat scurvy in 1747. Dr. Lind's research took place on a British naval ship where he divided ill soldiers into six groups, provided each group with various dietary supplements, and was able to determine a positive connection between Vitamin C and scurvy. This clinical trial laid the foundation for modern clinical research.

Clinical Trials Day is a celebration of clinical research professionals and participants by recognizing their contributions to public health and medicine. It is a well-deserved time out to honor those who make clinical trials possible and raise awareness of clinical trials in the community. Clinical Trials are research studies with human volunteers that are intended to add to overall medical knowledge. Behind every medication and medical intervention are thousands of patients that volunteered to participate in Clinical Trials. Without Clinical Trials, devastating diseases like polio would not be all but eradicated in the United States. Nor would we have seen a 50 percent decline in coronary artery mortality rates between 1980 and 2000. Clinical Research professionals and patients are the unsung heroes in the development of new drugs, devices, biologics and treatments to improve the care of all Americans.

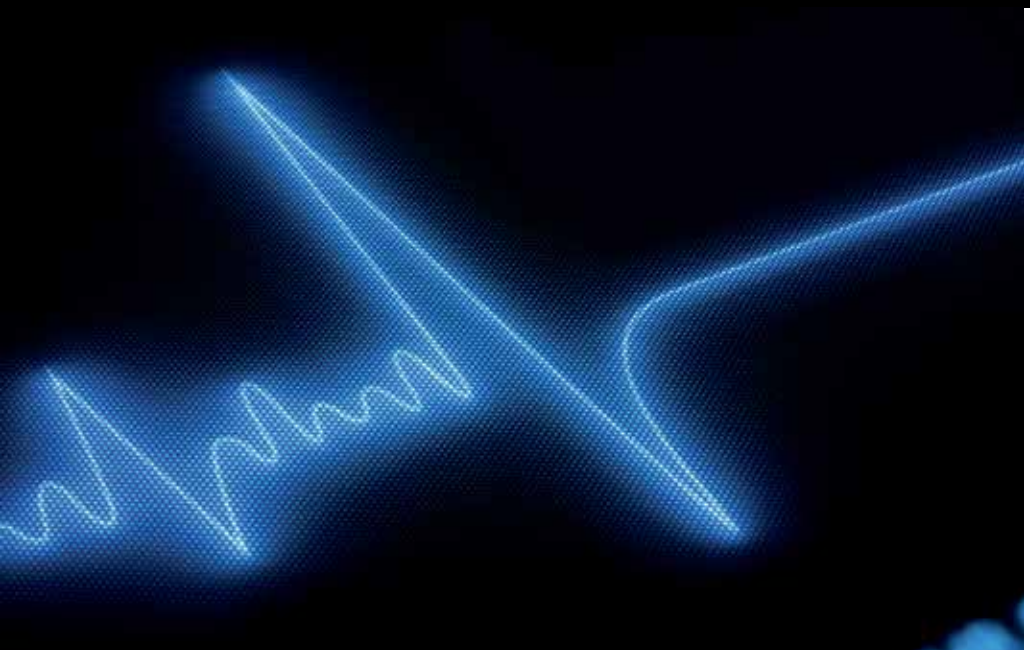
McLaren Health Care would like to take this time to thank our clinical research professionals for their tireless efforts to advance medical science, as well as improving the health and well-being of our patients. McLaren patients involved in clinical trials are often provided choices for their care beyond the standard available treatment. This care is coordinated and provided by our highly skilled clinical research professionals. At McLaren, research matters for our patients, our organization, and our physicians. Growing our research program gives our patients access to the latest clinical trials and the confidence they are receiving the best treatments, proven by research conducted in our own hospitals, by physicians they know and trust.

Clinical Trials at McLaren Health Care are conducted by the McLaren Center for Research & Innovation and the Karmanos Cancer Institute.

IMPORTANT REMINDERS FOR MCRI INVESTIGATORS

You may be receiving email reminders from our regulatory staff when you are within 90 days of your CITI training expiring. Please log in to www.citiprogram.org as soon as you receive your reminder to complete the refresher training. Please note, you are not permitted to do any research activity with expired CITI training.

The MHC IRB has a new submission system, and all PI signatures will now be obtained electronically. You will receive emails from our regulatory staff when you have a submission waiting to be signed, and those emails will include instructions. Please reach out for help if you are having trouble **research.regulatory@mclaren.org**.



ELECTROPHYSIOLOGY PROGRAM COMMITTED TO SCHOLARLY ACTIVITY

By Khalil Kanjwal MD, FACC, FHRS
Clinical Associate Professor of Medicine, Michigan State University
Director of Cardiac Electrophysiology, McLaren Greater Lansing

The electrophysiology (EP) program at McLaren Greater Lansing (MGL) was rebuilt in July of 2017. A new electrophysiology laboratory was established with an advanced mapping and ablation system along with a new fluoroscopy unit. While maintaining the active clinical volume and providing cutting edge technology in the treatment of various complex arrhythmias to our patients, the cardiology division and section of electrophysiology has been actively involved in various scholarly activities. These activities have not only involved the local physicians, residents, fellow and some staff members from the electrophysiology (EP) laboratory at MGL, but a collaboration with physicians from other centers across the country including University of Toledo, Central Michigan University, University of Florida, Hackensack University NJ, George Washington University, Walter Reed Medical Center and Johns Hopkins.

The division has published 20 peer reviewed papers in various journals in the last year. The papers included invited reviews, national guideline reviews, analysis of national databases such as national inpatient Sampling (NIS) database, case reports and various hands-on papers explaining various electrophysiological techniques in complex arrhythmia management. The EP laboratory of MGL was highlighted in the *EP Lab Digest* twice in the last two years. Recently, *EP Lab Digest* published the zero-fluoroscopy technique being used at MGL. In another invited peer reviewed article, the technique was highlighted (along with the one used at Walter Reed Military hospital) in Current Cardiology Reviews.

Our program also published on arrhythmia management in COVID times and, in collaboration with University of Toledo and Hackensack Medical Center in New Jersey, reported a first case of Postural Orthostatic Tachycardia Syndrome (POTS) following COVID infection.

While committed to providing the best clinical care to our patients, the cardiology group at MGL is eager to collaborate with other cardiologists and electrophysiologists within the McLaren Health system and publish original research.

Khalil Kanjwal,
MD, FACC, FHRS

"Our goal is to start Investigator-initiated original studies from McLaren Health System. We hope to continue to involve our medical students, residents, and fellows in various original research projects from the group. Our goal for the next few month is to submit various study proposals and protocols for IRB approval. We believe that there are ample opportunities for physicians at McLaren Health Care to be productive both clinically as well as academically."

– Khalil Kanjwal, MD
Director of Cardiac Electrophysiology
McLaren Greater Lansing

RESEARCH AROUND McLAREN

THE KARMANOS CANCER INSTITUTE CLINICAL TRIALS OFFICE REGULATORY TEAM IS ELECTRONIC!

As you may have seen in past Karmanos email notifications, eREG™ is the new electronic regulatory binder system that the KCI Clinical Trials Office is using. The system went live in August 2019 for oncology. Users will be required to complete several online training modules in order for us to set up your eREG account. This account will allow you to electronically sign regulatory documents and confirm protocol training through eREG for clinical trials that you are listed as key personnel on.

The training is a one-time requirement done online through Advarra University. This training is required in order to participate on KCI trials managed by the Clinical Trials Office. Utilization of the eREG system is now mandatory. Failure to complete the Advarra University training may result in the inability to participate in future research. If you haven't yet completed your training or eREG account set up, you will be contacted by someone in the Clinical Trials Office with further instructions.

Please contact **CTOeREG@karmanos.org** with any questions.

Lauren Hamel, PhD

LAUREN HAMEL, PhD, PUBLISHED IN *CANCER*

Congratulations to Lauren M. Hamel, PhD, assistant professor Department of Oncology, WSU School of Medicine, whose research on "Examining the Dynamic Nature of Nonverbal Communication Between Black Patients with Cancer and Their Oncologists" was published, in *Cancer,* an interdisciplinary journal of the American Cancer Society. Alongside of her team, Hamel used a newly developed and theory-guided network analysis to examine the dynamic interplay and behavioral convergence and divergence between Black patients with cancer and their oncologists during cancer treatment discussions. The study identified patterns of modifiable behaviors that can potentially inform interventions to reduce disparities in clinical communication and, in turn, treatment and mortality disparities. Co-authors on this study from the Department of Oncology at Karmanos and WSU School of Medicine are Felicity W. K. Harper, PhD, Louis A. Penner, PhD, Terrance L. Albrecht, PhD, and Susan Eggly, PhD; and from the University of Virginia, Robert Moulder, PhD.

STUDY SHOWS SOCIAL NEEDS LINKED TO LOW HEALTH-RELATED QUALITY OF LIFE AMONG AFRICAN AMERICAN CANCER SURVIVORS

Theresa Hastert, PhD

Social needs, such as food and economic insecurity, poor housing and neighborhood conditions and lack of access to transportation, were common in a group of African American cancer survivors in Detroit. These factors were associated with lower health-related quality of life (HRQOL) according to a study conducted by a team of researchers led by Theresa Hastert, PhD, assistant professor in the Department of Oncology at the Barbara Ann Karmanos Cancer Institute and Wayne State University School of Medicine. Findings are published early online in *Cancer*, a peer-reviewed journal of the American Cancer Society (ACS).

Among cancer survivors, HRQOL–or individuals' perceived well-being regarding their mental, physical and social health status–tends to be significantly lower among African Americans compared with other groups. Investigators looked to see if social needs may play a role in this disparity.

The analysis included 1,754 participants in the Detroit Research on Cancer Survivors (ROCS) cohort, a population-based study of African American survivors of breast, colorectal, lung and prostate cancer. Social needs are those related to food insecurity, utility shut-offs, housing instability, avoidance of health care due to cost or lack of transportation, and negative perceptions of neighborhood safety. HRQOL was measured using a questionnaire called the Functional Assessment of Cancer Therapy–General (FACT-G).

Researchers found that more than one-third (36.3 percent) of survivors reported social needs, including 17.1 percent who reported two or more. Prevalence of social needs ranged from 8.9 percent for utility shut-offs to 14.8 percent for food insecurity.

Dr. Hastert noted that a link between social needs and lower HRQOL among cancer survivors is not surprising; however, the association had not been quantified before. Additionally, the study was conducted in a population of African American cancer survivors, a population that is often under-represented in cancer research. The prevalence of social needs in this population may be higher than in cancer survivors more broadly but the results likely apply to other populations as well.

"My hope is that these findings raise awareness among cancer care providers and cancer researchers by showing that many patients face substantial social and financial difficulties and that these have real impacts on patients' health-related quality of life on top of cancer and cancer treatment," Dr. Hastert said. "Cancer care and survivorship settings may represent an opportunity to screen for social needs, to connect patients and survivors with programs and services to address those needs, and to implement innovative interventions to reduce health disparities by addressing social needs among Black cancer survivors. These findings also highlight the need for and importance of having a social safety net in advancing population health and health equity."

RESEARCH AROUND McLAREN

Elisabeth Heath, MD, FACP

ABOUT THE PCF CHALLENGE AWARDS

PCF Challenge Awards fund international, multi-institutional, cross-disciplinary teams of investigators conducting highly innovative research with the greatest potential for accelerating new and improved treatments for advanced prostate cancer. Following a rigorous peer-review process that assessed each project's scientific merit and potential patient impact, 12 highly coveted PCF Challenge Awards totaling $11 million were granted to teams at some of the world's leading cancer research institutions.

ELISABETH HEATH, MD, FACP RECEIVES 2020 PROSTATE CANCER FOUNDATION (PCF) CHALLENGE AWARD

Congratulations to Elisabeth Heath, MD, FACP, associate center director of Translational Sciences and leader of the Genitourinary Oncology Multidisciplinary Team at Karmanos Cancer Institute and professor at Wayne State School of Medicine, for receiving the 2020 Prostate Cancer Foundation (PCF) Challenge Award. Dr. Heath serves as principal investigator, alongside Peter Nelson, MD of the University of Washington, on the project titled PC-REACTR: A Multidimensional Tumor Atlas to Overcome Prostate Cancer Therapy Resistance. Wael Sakr, MD, member of the Genitourinary Oncology Multidisciplinary Team at Karmanos Cancer Institute and Chairman of the Pathology Department at Wayne State School of Medicine, serves as a co-investigator.

Through this project, a team of investigators will create a multidimensional tumor atlas to investigate tumor biology and predict improved treatment combinations that can overcome treatment resistance.

"We've made great progress in treatments for metastatic prostate cancer, but resistance to current therapies and disease progression inevitably happens," Dr. Heath said. "We need to get a better understanding of the variability and complexity of advanced prostate cancer so we can create new treatment strategies that will overcome resistance and lead to better tumor control for our patients. This atlas will create a broader, more comprehensive view of cases and give us the ability to devise new treatment combinations."

The tumor atlas will contain data on genomic alterations, gene expression and imaging of the tumor microenvironment over time in patients treated with standard of care and emerging therapeutics for advanced prostate cancer. This "4-D" information will be used in mathematical models to identify the mechanisms by which prostate cancer becomes drug-resistant and to predict new treatment approaches that can overcome resistance. These models will aid in the design of clinical trials directed toward overcoming therapy resistance for standard and experimental treatment modalities. The atlas will be made available as an open-access resource for the scientific community.

DR. GEN SHENG WU PROPOSED STUDY RECEIVES NCI AWARD

Gen Sheng Wu, PhD

Ovarian cancer is the deadliest female reproductive tract cancer with a 29 percent five-year survival rate in late stages, at which more than 60 percent of cases are diagnosed. It is estimated that in 2020, about 21,750 new cases of ovarian cancer will be diagnosed and 13,940 women will die of ovarian cancer in the United States. The standard first line chemotherapy to treat this deadly disease includes platinum-based treatments, but the development of drug resistance presents a significant clinical problem that needs to be addressed.

Gen Sheng Wu, PhD, proposed a study that identifies a gene called autophagy-related gene (Atg) 5 as important to development of platinum resistance. The project is titled "Targeting Atg5 in platinum-resistant ovarian cancer." Atg5 plays an important role in regulating a process called autophagy, which is a key process to sustain cancer cells. Dr. Wu's lab previously found that blocking autophagy overcomes platinum resistance in ovarian cancer. However, direct blocking autophagy with drugs has undesired side effects because this process is also needed for normal cell function. In this application, Dr. Wu found that high Atg5 protein levels lead to platinum resistance and poor patient survival in some ovarian cancer patients. Based on these novel observations, the hypothesis of this application is that higher Atg5 levels help ovarian cancer cells by promoting cell survival and drug resistance.

NIH
NATIONAL CANCER INSTITUTE

This project will define the role of Atg5 in platinum resistance. Successful results from this study could lead to the development of novel therapeutic strategies for treating ovarian cancer patients.

EQuIP CORNER

Andrea Klaver, MBA, CHRC

AAHRPP ACCREDITATION: WHY DO WE DO WHAT WE DO?

By Andrea Klaver, MBA, CHRC

Many of you know of AAHRPP (pronounced "ay-harp"), the Association for the Accreditation of Human Research Protections. However, you might not know exactly what they do, why McLaren strives for this accreditation, or how their guidelines benefit researchers whose projects come under McLaren Institutional Review Board (MHC IRB) review.

AAHRPP is an organization, founded in 2001 by seven national organizations committed to the ethical conduct of human research, whose mission is to offer a voluntary accreditation program for research institutions responsible for overseeing research involving human subjects. AAHRPP was created in response to the intense scrutiny research programs were experiencing at the time.

According to AAHRPP, all major U.S. independent IRBs are AAHRPP accredited, and more than 60% of U.S. research-intensive universities and 65% of U.S. medical schools are either AAHRPP accredited or have begun the accreditation process.

Why are AAHRPP and their Standards Good for Research?

You might also wonder how another level of oversight could be a good thing for your research, or how AAHRPP accreditation and its accompanying institutional self-evaluation could benefit your studies.

The accreditation process involves extensive fact-finding and self-assessment, for which AAHRPP offers guidance to promote high-quality human research protection program (HRPP) practices. Institutions can, therefore, improve their practices on the way to accreditation and through the reaccreditation process. (Accredited organizations renew their accreditations three years after the initial accreditation and every five years afterwards.)

When examining the broad research study portfolio of an organization like McLaren, the AAHRPP site visit team considers several issues, including how the MHC IRB interprets the accreditation standards according to the different types of research being conducted. The AAHRPP team examines the way the MHC IRB

reviews the informed consent process and documentation requirements, and the use of the expedited review process for research involving no more than minimal risk – among other things.

AAHRPP accreditation benefits research organizations, study participants, and the research process. It requires organizations to take a comprehensive look at their HRPP to identify and address any weaknesses and to build upon their strengths. The result is a more cohesive HRPP, with the systems in place not only to protect study participants but also to develop better research.

Advantages and Benefits to AAHRPP Accreditation

The following are just some of the advantages of AAHRPP accreditation:

- **An assurance of the highest quality research.** AAHRPP accreditation is evidence of a high-quality research program. The AAHRPP "golden seal" that you see on many of the McLaren Research web pages and documents indicates not only that our organization safeguards study participants but also that data are reliable and credible and we have made a commitment to continuous quality improvement.
- **The highest possible standards and protections.** AAHRPP's high ethical and professional standards provide the most comprehensive protections for study participants. AAHRPP standards exceed federal requirements, which often represent the minimum required. Institutional IRBs like the MHC IRB may set more stringent criteria to suit their locale and research portfolio.
- **Improved efficiency and effectiveness.** AAHRPP requires research organizations to take an extraordinarily detailed view of their HRPP to make sure that policies and procedures are in place and that they are translated into practice. As a result, accredited organizations tend to have more streamlined and effective policies and procedures. They also typically keep better records and are more likely to avoid costly or problematic project stoppages or inspections.
- **Government recognition.** Federal agencies acknowledge the value of AAHRPP accreditation. They seek accreditation for their own HRPPs and use accreditation status to guide their decisions.
- **Competitive funding edge.** Sponsors and other funding sources recognize that AAHRPP-accredited research organizations have more efficient processes, provide more comprehensive study subject protections, and produce higher-quality data. More and more, AAHRPP accreditation is expected to be a condition of research support.
- **Public trust and confidence.** Prospective study participants, and the public in general, look to the McLaren IRB to take responsibility for ensuring that research is conducted safely and ethically. Since AAHRPP accreditation is voluntary, study participants may be more likely to select research organizations that have chosen to earn the AAHRPP golden seal.

Site Visits During COVID: AAHRPP Perspective

During a recent virtual meeting of a professional network I belong to, we were fortunate enough to hear from an AAHRPP Site Visitor regarding remote site visits during the Covid-19 pandemic.

Particularly during remote site visits, technology and communication are key, including access to documents, screen sharing, and availability of site staff to be reached during the audit (e.g., a standing zoom meeting, exchanging cell phone

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EQuIP CORNER

UPCOMING RESEARCH EDUCATION 2021

SOCRA

Please visit the SOCRA Events Calendar at https://www.socra.org/conferences-and-education/events-calendar/ for virtual continuing education and training opportunities.

MAGI's Clinical Research Conference – Spring

ONLINE
April 26 – 29, 2021
and May 3 – 6, 2021

ACRP 2021

Due to COVID-related concerns and government regulations, ACRP will not proceed with hosting ACRP 2021 in Toronto, Canada as planned. ACRP is excited to see everyone at ACRP 2022 in Orlando, Florida, April 22 – 25, 2022.

Online conference options are available. For virtual program schedule and registration, see www.2021.acrpnet.org.

BROWN BAG SERIES

Our next Brown Bag Session is tentatively scheduled for June 8, 2021. Please watch your email for more details as the time approaches. The Research Integrity team hopes you can attend.

For more information, contact Andrea Klaver at (248) 484-4987 or andrea.klaver@mclaren.org.

AAHRPP ACCREDITATION: WHY DO WE DO WHAT WE DO?

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numbers). He also stressed to make it as casual, informal, and communicative as possible. It is especially critical during a remote site visit to make it as simple as possible for auditors to identify the information (e.g., highlighting key information, being specific in directions and responses).

When providing access to information, sites may choose to provide visitors with access to their systems, or to download documents to share. Downloading documents may be easier than trying to teach a site visitor to use your system. In any case, make documents readily available, with as few complications as possible.

To facilitate meaningful remote communication, make sure people have the right technology, including cameras, and the time/space to have a focused discussion. A more formal structure may benefit remote meetings. The site visitor must play a more active role in monitoring and structuring the conversation than is the case with in-person meetings.

It is harder for the site visitors to communicate among themselves because they are not in the same room and they are not debriefing informally as they would when travelling together. Although AAHRPP provides remote options for this, if the site provides a way for site visitors to communicate among themselves easily (such as a breakout room within the platform being used for the rest of the audit), it is very helpful.

While it may be possible for a site to request a remote visit post-Covid, AAHRPP is looking forward to resuming in-person site visits when it is safe to do so. Overall, remote audits enable site visitors to get an understanding of the site and to get the job done. However, it is much harder to get a feel of the site remotely. It is a different experience and lacks the informal communication and connections which in-person visits support.

Conclusion

Voluntary AAHRPP accreditation leaves the research oversight process in the hands of institutions and researchers. The research community's willingness to meet a set of voluntary national standards is likely to convince federal regulators and the public that more regulation or guidance is not needed.

Although AAHRPP accreditation is another layer of oversight and does require a wealth of time and human resources, its benefits may make it a worthy return on investment. In addition to improved HRPPs, assurance that accredited organizations like McLaren are in full regulatory compliance, and ultimately, increased public trust in our research, the accreditation process allows the research community to define and aspire to its own best practices.

BECOME AN IRB MEMBER – WE ARE RECRUITING!

The McLaren Health Care Institutional Review Board (MHC IRB) is looking for new members to serve one of its two boards. Membership requires careful review of research protocols with emphasis on human subject protections issues. The IRB review process is designed to protect the rights and welfare of human subjects by ensuring:

1. the research design is sound and study hypothesis is reasonable,
2. selection of subjects is equitable,
3. risks to subjects are minimized,
4. risks to subjects are reasonable in relation to anticipated benefits,
5. informed consent is obtained or appropriately waived from all prospective subjects and documented,
6. the research protocol includes a plan for data and safety monitoring,
7. subject's privacy and confidentiality are protected, and
8. appropriate additional safeguards are incorporated for any vulnerable subjects.

We need scientific members from all clinical specialties. Scientific members bring their respective discipline expertise for clinical protocols. Non-scientific, community, or lay members each bring a different voice and set of life experiences to the discussion of human subject research.

If you are interested in becoming an IRB member, please contact Patricia Ivery, Research Integrity Manager, at (248) 484-4955.

FACULTY, FELLOWS & RESIDENTS

SCHOLARLY ACTIVITY NEWS

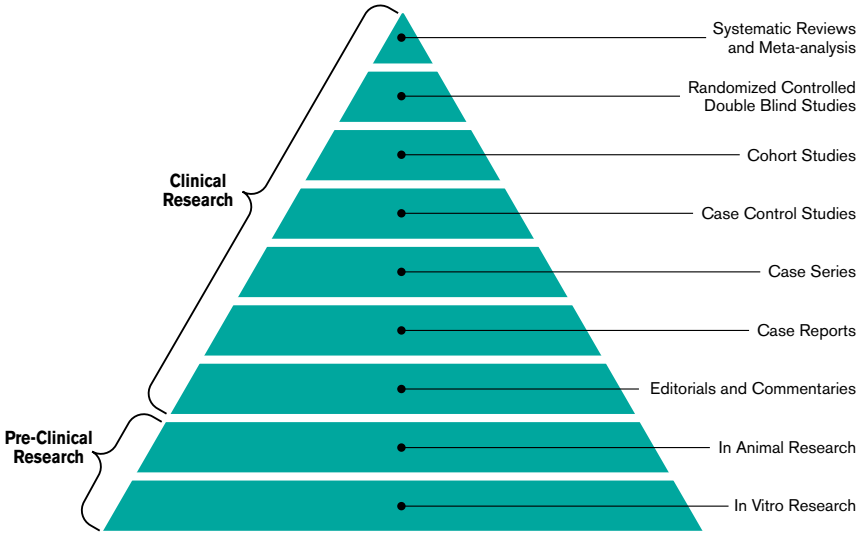
Carlos F. Rios-Bedoya, ScD

SYSTEMATIC REVIEWS & META-ANALYSIS: SHOULD THEY REMAIN AT THE TOP OF THE TRADITIONAL EVIDENCE-BASED MEDICINE PYRAMID?

Traditional evidence-based medicine (EBM) uses the type of research study design to determine the quality of the evidence (see Figure 1).

At the top of the pyramid (i.e., best quality of the evidence) systematic reviews & meta-analysis (SRMA) are found. Originally, most SRMA only included several randomized control trials. The main reasons for selecting only randomized control trials (RCTs) were the reduced biases and comparability of study results among RCTs. Merging and summarizing results from different RCTs to calculate a pool estimate of the effect of interest provided an extremely useful and quantitative

Figure 1. Evidence-based Medicine Pyramid



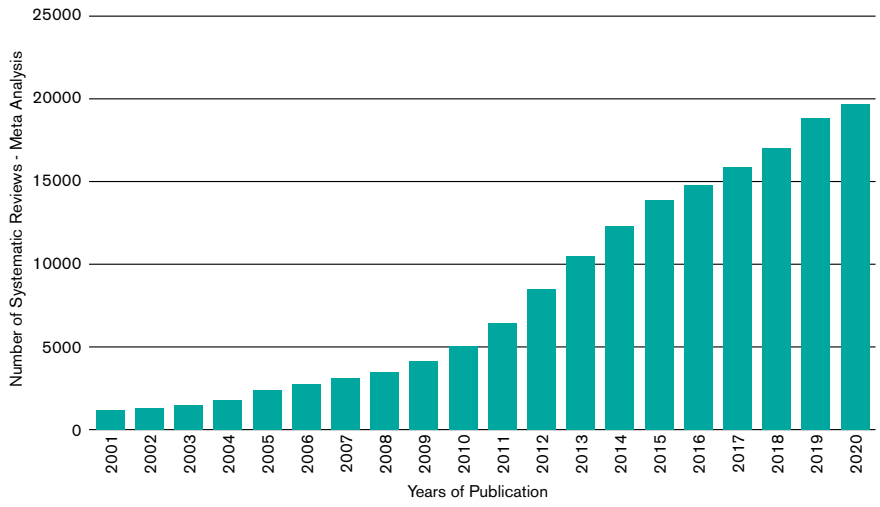
REFERENCES:
1. Borenstein M. Common mistakes in meta-analysis and how to avoid to them. First edition. New Jersey: Biostat Inc., 2019.

way of evaluating the available evidence. Placing SRMA at the top of the pyramid was appropriate. However, the proliferation of SRMA manuscripts together with the calculation of pool estimates derived from findings from observational study designs or from combining study designs might require re-evaluating placing SRMA at the top of the EBM pyramid.

A quick PubMed search using the terms "systematic reviews, meta analysis" found that during the past 20 years (2001-2020) there has been a 1705.6% increase in the number of this type of publications. From 1,103 articles in 2001 to almost 20,000 (19,916) in 2020 (see Figure 2).

This incredible proliferation raises questions about the quality and value of SRMA. Access to medical literature electronic databases combined with the availability and easy to use software for pool estimation of results could explain

Figure 2. Systematic Reviews - Meta Analysis Articles found in *PubMed* by Year of Publication (2001-2020)



this proliferation. However, theoretical frameworks, statistical assumptions, and adequate selection and merging of studies are not usually followed on many of today's SRMA. Consequently, consumers of medical literature need now to critically appraise SRMA implementation, analysis, and results when several years back SRMA results were trusted as valid and reliable without much thought.

Dr. Michael Borenstein in his book *Common Mistakes in Meta-Analysis and How to Avoid Them* (Biostat, Inc., 2019)[1] identifies and explains 42 mistakes researchers usually make when designing, implementing, and analyzing meta-analysis. Those most frequently found in the medical literature include choosing between random effects and fixed effects, interpretation of the I^2 statistic and classifying heterogeneity as low, moderate, or high, and combining observational and RCTs to obtain a pool estimate. Therefore, it is extremely important that those wanting to do this type of scholarly activity seek advice or collaborate with someone with a quantitative background and training before conducting this important type of scholarly activity. Furthermore, an EBM critical approach should be used when reading meta-analysis from the medical literature.

In the Division of Scholarly Inquiry, we have a commitment and responsibility to promote, expedite, facilitate, and support scholarly activity productivity among McLaren residents, fellows, and teaching physicians. For additional information or questions contact Dr. Carlos F. Ríos-Bedoya at **carlos.rios@mclaren.org**.

McLAREN OAKLAND RESIDENT PUBLICATIONS AND AWARDS

Publications

C. Byrd, E. Keidar, O. Santiago, et al. (March 31, 2021). "The Loudness of Suctioning in the Ear Canal." *Cureus* 13(3): e14208. doi:10.7759/cureus.14208.

Colin Byrd, DO

Eytan Keidar, DO

Eytan Keidar, Jeffrey Singh, Olga J. Santiago-Rivera, Brent Wilkerson, Seilesh Babu. "Utility and value of pre-operative CT and MRI for cochlear implantation in the elderly" (2021). *American Journal of Otolaryngology*, 42 (3). doi.org/10.1016/j.amjoto.2020.102853.

Christopher Lenkeit, DO

C. Lenkeit, J. Bank, M. Shirazi. "Renal Cell Carcinoma in the Head and Neck: Case Presentation of a Patient With a Rare Metastatic Pattern." *Cureus*. 2020;12(12):e11894. Published 2020 Dec 4. doi:10.7759/cureus.11894.

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ANNOUNCEMENTS AND WHAT'S NEW

Stephanie Bruma

McLaren Center for Research and Innovation is pleased to introduce our newest Clinical Research Nurse, **Stephanie Bruma**. She started her career with McLaren in 2016 as a Patient Service Representative with the Karmanos Cancer Institute while working toward her bachelor's degree in Nursing. Stephanie recently worked as a registered nurse in a telemetry unit at McLaren Flint. By joining MCRI at McLaren Flint, Stephanie will primarily be working with cardiovascular, neuroscience and COVID-19 clinical trials.

Hannah Ardelean

Karmanos Cancer Institute Clinical Trials Office is pleased to introduce **Hannah Ardelean**, Research Nurse. Hannah is an experienced Oncology Certified Registered Nurse with a Bachelor of Science in Nursing from University of Detroit Mercy. Hannah has more than six years of oncology patient care and nurse navigator experience. We are excited that Hannah has joined our team and will be extending her oncology expertise and support to the Karmanos Cancer Institute at McLaren Flint clinical research program.

Mahjabeen Waris

Mahjabeen Waris joined the McLaren Research Integrity department in January 2021 as the new IRB Analyst. She obtained her medical degree from Dow University of Health Sciences in Karachi, Pakistan, and pursued residency at Beaumont Hospital (Dearborn). Having a keen interest and passion for research, she went on to work as a Clinical Research Coordinator at Henry Ford Hospital and has now joined McLaren to continue her research career. She is very excited to bring her medical and research experience to McLaren Health Care.

We sincerely regret if we left out any fellow or resident, due to our publication deadline. Nevertheless, our congratulations to all of you that received any recognition for your scholarly activity work. We also would like to recognize faculty, program directors, and all medical education staff for their support and assistance. Without you, none of this would have been possible.

RESIDENT PUBLICATIONS AND AWARDS

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Awards

Dr. Cody Ingram presented at the annual Michigan Podiatric Medical Association/Great Lakes Conference and was awarded Third Place for an oral case study out of 19 presentations in February 2021. The presentation was titled "Non-Diabetic Charcot in the Presence of Total Aorto-iliac Occlusion."

Cody Ingram, DPM

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