Ascension St. John Hospital

Research Vitals

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Welcome to all our new residents and fellows! On behalf of the Research Department and the IRB, we want to extend our assistance and support as you work on your research endeavors and scholarly activity.

There are many educational opportunities for Ascension St. John personnel at all levels of training. For residents and fellows, there will be a lecture given to every program regarding the research process, support available to you and research compliance. For faculty investigators and staff, we will be offering a series of lunchtime learning sessions during the upcoming year.

New trainees, please stop by the library and meet our librarians, Karin and Debbie. They provide assistance to you with literature searches and with obtaining copies of articles that are not in our electronic collection.

During 2018-19, Ascension St. John Hospital had over 150 publications in journals indexed in PubMed. These include journals such as the Journal of the American Medical Association (JAMA) and the Journal of the American College of Cardiology. I hope that we will all keep up this fantastic research scholarship in the coming year.

Research compliance is an especially important topic that we review every year. **Patient data should never be removed from hospital premises, stored on the hard drive of a personal computer or emailed without encryption.** HIPAA violations are costly to our patients, our reputation and to our hospital finances! If you have any questions about how to safely handle research data, please feel free to contact me.

Once again, welcome!

Dr. Susanna Szpunar

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Fast Stats

Superiority, Equivalence and Non-Inferiority

When you are reading a journal article about a randomized controlled clinical trial (RCT), you will come across the words "superiority", "equivalence" and "non-inferiority." So, what's the difference?

1. Superiority trials: Superiority trials are the types of RCTs that we are most familiar with. The goal in these studies is to determine if an experimental treatment is ***superior*** to a placebo or to an existing treatment. The primary objective is to determine the magnitude of increased benefit of the experimental intervention over standard therapy on effectiveness outcomes.

2. Equivalence trials: These RCTs seek to determine that an experimental treatment is "***neither better nor worse"*** (beyond a pre-specified margin) than the standard.

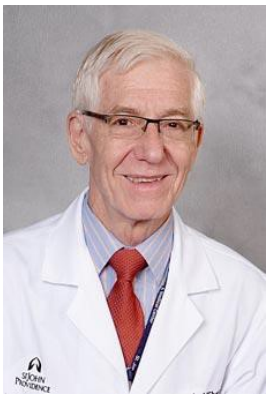
    - These trials require an *a priori* definition of the smallest difference in outcomes between the interventions that patients would consider large enough to justify a preference for the superior.

    - For the researchers to claim equivalence, the confidence interval (CI) for the estimated treatment effect at the end of the trial should exclude that difference.

3. Non-inferiority trials: These RCTs try to establish whether an experimental treatment is ***"not much worse"*** than a standard treatment, i.e. not so inferior that it would cause a concern. Non-inferiority is of interest if the new intervention has some other advantage, such as lower costs or fewer side effects, that mitigate the trade-off in effectiveness.

Remember that one of the determinants of sample size is the magnitude of the difference you are trying to detect. In both equivalence and non-inferiority trials, the magnitude of the difference will be very small, so these studies typically require large sample sizes. Thus, they are often multi-site, even multi-national studies.

Ascension St. John Kudos!



Dr. Riad Khatib retired from Ascension St. John Hospital after 29 years of service. Dr. Khatib led the Infectious Diseases division from 1991 to 2011. He established the Infectious Diseases Fellowship program at Ascension St. John Hospital, training 32 fellows over the span of 25 years.

Dr. Khatib was a dedicated researcher, making a substantial contribution to the medical literature on infectious diseases. He authored more than 100 original research papers and presented more than 200 abstracts at national meetings, many with trainees.

Dr. Khatib has touched the lives of many trainees, colleagues and patients. While he will be terribly missed, we hope that Dr. Khatib will have a healthy, happy retirement.

Recent Publications

Patel VH, Vendittelli P, Garg R, Szpunar S, LaLonde T, Rosman H, Mehta RH, Othman H. Neutrophil-lymphocyte ratio: a prognostic tool in patients with in-hospital cardiac arrest. World J Crit Care Med 2019 Feb; 8(2):18-21.

Hamza A, Khawar S, Sakhi R, Alrajjal A, Miller S, Ibrar W, Edens J, Salehi S, Ockner D. Factors affecting the concordance of radiologic and pathologic tumor size in breast carcinoma. Ultrasound 2019 Feb; 27(1):45-54.

Sall L, Hayward RD, Fessler MM, Edhayan E. Between-hospital and between-neighbourhood variance in trauma outcomes: cross-sectional observational evidence from the Detroit metropolitan area. BMJ Open 2018 Nov 25;8 (11): E022090.

Crisher MA, Giuliano CA, Hartner CL. Insulin detemir versus insulin glargine in the hospital: do hypoglycemia rates differ? Clin Diabetes 2019 Apr;37(2):167-71.

Valenti S, Johnson L, Szpunar S, Hilu R, Saravolatz L. Training internal medicine residents to provide care and treatment for human immunodeficiency virus-1-infection patients. Open Forum Infectious Diseases 2019;6 (4): ofz093.

Youssef D, Bhargava A. *Escherichia coli* bacteremia with secondary seeding in the sternoclavicular joint: A case report and literature review. Germs 2019 March;9(1):43-46.

Venditelli P, Botros B, Rosman, H, Govindaraju V, Zaitoun A, Marroush T. Coronary artery embolism: two case reports and a review of the literature. Am J Med Sci 2019 Apr;357(4):333-337.

Rock K, Hayward R, Edhayan, E. Obesity and hospital outcomes following traumatic injury: Associations in 9 years of patient data from a single metropolitan area. Clin Obes 2019 Apr;9(2):e12293.

Please inform the Research Department of any publications, including abstracts.
We will enter them into our database. Send information to Susan Szpunar or Alice Mar.

Institutional Review Board Updates

Changes in Research:

Federal regulations (21 CFR 56.108(a)(3) and 45 CFR 46.103(b)(4) and hospital policies require "prompt reporting to the IRB of changes in research activity." The completion of a study and changes in research personnel are examples of changes in research activity.

IRB Process Update:

Research activities limited to changes in study team members will be reviewed within one business week. PI changes for more than minimal risk studies are reviewed at a convened meeting. To facilitate processing these changes, ensure that all study team members have current CITI training.

Regulatory Update:

In July 2019, the FDA released a draft document E8(R1) General Considerations for Clinical Studies (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e8r1-general-considerations-clinical-studies). This document focuses on designing quality into clinical trials. "Quality" is defined as "fitness of purpose", i.e. that the study is designed such that high-quality, reliable information is generated. The FDA welcomes public comments to this draft by September 30, 2019.

Did you know?

The **Belmont Report** is one of the leading works concerning ethics and health care research. Its primary purpose is to protect subjects and participants in clinical trials or research studies. This report consists of 3 principles: beneficence, justice, and respect for persons.

Beneficence: The philosophy of "do no harm."

Justice: Ensure that reasonable, non-exploitative and well-considered procedures are administered fairly — the fair distribution of costs and benefits to potential research subjects.

Respect for persons: Protect the autonomy of all people and treat then with courtesy and respect — allowing for informed consent.

Upcoming CME Events

- November 6, 2019 Family Medicine Seminar
- December 4, 2019 Hematology & Oncology Seminar
- March 26, 2020 Radiology Seminar
- April 29, 2020 Pediatric Seminar
- June 3, 2020 Nephrology Seminar

Physicians wishing to complete their mandatory requirements for CME go to WWW.MI.CME.EDU to access the courses.

For information about the CME program at Ascension St. John Hospital, click here:

http://www.stjohnprovidence.org/sjhmccme

Consent for Case Reports

Many journals now require that patients or their legally authorized representatives provide consent for a case report. This is a relatively new trend, resulting primarily from evolving information technology and social media that make it easier to identify people with very little information.

At Ascension St. John Hospital, we have published guidelines for obtaining informed consent for a case report as well as a standard case report consent form and a consent for photography or videos, if needed.

The policy and forms can be found on PolicyStat at https://ascensionsemichigan.policystat.com/. Once you access PolicyStat, search for "informed consent for case reports." The policy and forms are also available on the research page on the intranet https://medicaleducationsjp.com/medical-education .

Because it is often difficult to contact patients or their families after they leave the hospital, if you are caring for a patient and think there is a possibility that you will write a case report, please obtain the consent while you are with the patient. If you don't use it, that's okay. But, if you decide to write a case report, you have saved yourself the hassle of trying to track down the patient later.

Cryptoquiz—the definition of **RESEARCH.**

Research is:

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z
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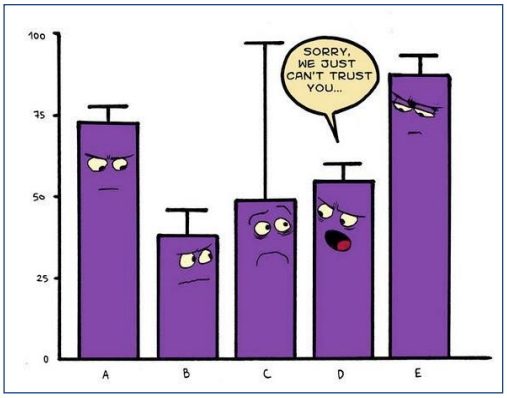

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So long summer…hello,