Ascension St. John Hospital

Research Vitals

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At the outset of 2020, none of us could have imagined how different our world would become. So much has changed. As *Chris Rock* said on Saturday Night Live (10/3/2020), "we used to make plans." And we did! We made plans for dinner *at a restaurant (!)*, movies and concerts, visits with family, vacations (not in the back yard!)

But to quote another popular icon, *John Lennon*, "life is what happens to you while you're busy making other plans." So, life has gone on.

Everywhere you look, you can see how people have adapted to this changing world. Before, if you walked into a bank wearing a mask, the police would be called. Now, security is called if you don't wear a mask. No one needs to dress up for Hallowe'en, we've already been wearing masks for months!

So, too, in research, much has changed. Our focus has changed to all things COVID-19—from research assessing outcomes, treatments and risk factors—to the exciting vaccine trials that will soon be coming to Ascension St. John Hospital.

The one thing that has stayed the same, though, is the dedication and devotion of the Ascension St. John personnel who participate in conducting or regulating research. The other constant, whether we are on-campus or remote, is our care for each other and our membership in the Ascension St. John family.

As the holiday season approaches, we will have to find new and safe ways to celebrate—and we will! Best wishes for your health and safety!

Dr. Susanna Szpunar

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Efficacy and Effectiveness

We often see these two words used interchangeably, when reading about the effects of new drugs or treatments. In the world of scientific investigation, however, efficacy and effectiveness are two distinctly different entities. Often, investigators use the word "efficacy", when they really mean "effectiveness". So, what is the difference?

In short, efficacy trials assess how well an intervention works under ideal circumstances, i.e. in the context of a well-controlled clinical trial. In converse, effectiveness look at how well an intervention works in real-world practice. Most of the time, we find that the effectiveness of an intervention will be less than its efficacy.

While efficacy research demonstrates the highest likelihood of showing the effect of an intervention if one exists, effectiveness research takes into account factors (provider, patient, environment) that may blunt an intervention's effect.

Efficacy Study:

Question: Does the intervention work under ideal circumstances?

Setting: Resource-intensive "ideal setting".

Study group: Highly selected, homogenous population.

Providers: Highly experienced and trained.

Intervention: Strictly enforced and standardized. No concurrent interventions.

Effectiveness Study:

Question: Does the intervention work in real-world practice?

Setting: Real-world everyday clinical setting.

Study group: Heterogeneous population; few to no exclusion criteria.

Providers: Representative usual providers.

Intervention: Applied with flexibility, concurrent interventions and cross-overs permitted*

*Singal AG, Higgins PDR, Wajee AK. A primer on effectiveness and efficacy trials. Clin Transl Gastroenterol 2014 Jan; 5(1):e 45. doi: 10.1038/ctg.2013.13

Michigan ACP

Ascension St. John Hospital's resident abstracts chosen by the American College of Physicians for the October judged competition:

Oral Presentations

- **Sana Jaffery, MD:** Precipitation of Sweet's Syndrome after Granulocyte Colony Stimulating Factor (G-CSF) Administration to a Patient with Felty's Syndrome
- **Abdulla Nasser, MD:** COVID-19 Induced Focal Encephalitis
- **Omama Siddiqui, MD:** Compliance with American Diabetes Association's Recommendation on Urinary Albumin Screening in Resident and Faculty Clinics
- **Claudia Villatoro-Santos, MD:** Chronic Urticaria and CVID: An Association to Remember
- **Jose Zamora-Sifuentes, MD:** Hepatitis A Immunization Rates in Patients with Underlying Chronic Hepatitis C Infection in Community Hospital-based Clinics

Poster Presentations

- **Hiba Al Jammala, MD:** Cavitary Lesion in *Legionella* Pneumonia Serotype 1 in an Immunocompetent Host
- **Rahmah Aldoulah, MD:** Primary Autoimmune Myelofibrosis With Severe Anemia. A Steroid-Responsive Cause of Bone Marrow Fibrosis
- **Khalid Alfares:** Hypertensive Emergency Secondary to Renal Artery Stenosis Due to Antiphospholipid Syndrome
- **Muneer Al-Husseini, MD:** Left Flank Pain in a Recently Recovered COVID-19 Patient, a Case Report
- **Mohamad Ayas, MD:** Malignant Psoas Syndrome: A Rare Case of Endometrial Carcinoma with Psoas Muscle Metastasis Mimicking a Psoas Abscess
- **Mujtaba Cherri, MD:** The Great Escape: A Drug-Induced Junctional Rhythm
- **Jacob Compton, MD:** Occam's Razor Except in Human Immunodeficiency Virus (HIV): A Case of Sepsis Resulting from *Salmonella Eustacian* Valve Endocardia
- **Nikhil Gandhi, MD:** Destruction of the Ferrous Wheel: An Acquired Methemoglobinemia
- **Harish Gidda, MD:** Coronary Artery Ectasia
- **Madhav Kapila, MD:** Suspected Metastatic Adrenocortical Carcinoma
- **Thomas Loss, MD:** Acute Necrotizing Pancreatitis Complicated by Sepsis and Adult Respiratory Distress Syndrome as a Result of a Dime Ingestion
- **Beshoy Nazeer, MD:** Achy Breaky Stent: Persistent Angina Due to Coronary Stent Fracture
- **Theodoor Roverts, MS4** Is Itraconazole Superior to Fluconazole in Treating Acute Septic Coccidioidomycosis Monoarthritis?
- **Sara Samaan, MD:** Cryptococcemia Secondary to Corticosteroid Use in Metastatic Non-Small Cell Lung Carcinoma
- **Heidi Stoute, MD:** Primary Pulmonary Angiosarcoma: A Rare Malignancy with a Poor Prognosis
- **Jordan Swisher, MD:** Once, Twice, Three Times a Dissection...
- **Neil Umles, MD:** Calciphylaxis Causing Systemic Emboli Mimicking Vasculitis
- **Wei Zhao, MD:** Rituximab-Associated Posterior Reversible Encephalopathy Syndrome

Recent Publications

- Bhargava A, Sharma M, Riederer K, Akagi E, Szpunar S, Saravolatz L. Risk factors for In-hospital mortality form COVID-19 infection among black patients—an urban center experience. Clin Infect Dis 2020 Sept. https://doi.org/10.1093/cid/ciaa1468
- Neu R, Leonard MA, Dehoorne ML, Scalia SJ, Kale-Pradhan BP, Giuliano CA. Impact of pharmacist involvement in heart failure transition of care. Ann Pharmacother 2020 Mar;54(3):239-46.

Institutional Review Board Update

In 2004, Congress created the Emergency Use Authorization (EUA) to allow access to a range of medical products during a declared emergency. During a declared emergency or public health crisis, under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of medical products.

During crises such as the COVID-19 pandemic, there is an urgent need to have products available that may diagnose, prevent, or treat the public health threat. EUAs are one of several tools the FDA can use to help make these tools available during a pandemic.

The FDA is relied upon to evaluate whether medical products (i.e. drugs, diagnostic tests, medical devices), have been shown to be safe and effective. During a declared emergency, the FDA may revise or revoke an EUA to protect public health. It is also important to note that even if a medical product is granted EUA status by the FDA, if a researcher uses the medical product under the intent of research, **research regulations apply.**

The lists below compare EUA and investigational new drug (IND) or investigational device exemption (IDE) mechanisms on key regulatory points.

EUA: The EUA mechanism provides appropriate participant protections based on the circumstances of the emergency. EUAs are intended to allow for faster use of a product than under an IND/IDE.

FDA Approval: FDA approval is required to review and approve an EUA request.

IRB Approval: IRB review and approval is **not** required.

Informed Consent: Informed consent is not automatically required but may be required at the discretion of the FDA commissioner. If an informed consent is required, it should be stipulated in the FDA approval letter granting the EUA.

Otherwise, the distribution of information (e.g., fact sheets) for healthcare professionals and recipients that contains information on product safety, available alternative products, and the right to refuse administration of the EUA product is required.

Duration of Approval: Typically, EUAs are approved for up to one year from the date of the declaration of emergency or for as long as section 564 is in effect.

Adverse Event Reporting: At the discretion of the FDA Commissioner.

Record Keeping: Recordkeeping and access to product distribution and administration records is required at the discretion of the FDA commissioner.

IDE and IND: The objective of the IND/IDE is to assess the safety and efficacy of an investigational drug/biologic/device (hereafter "investigational product") while ensuring that human subjects are protected during the research study of the investigational product. Investigational protocols specify requirements to ensure participant protection and the validity of the data collected during the clinical trial.

FDA Approval: FDA review and agreement that the study may proceed.

IRB Approval: IRB review and approval is required.

Informed Consent: Is required.

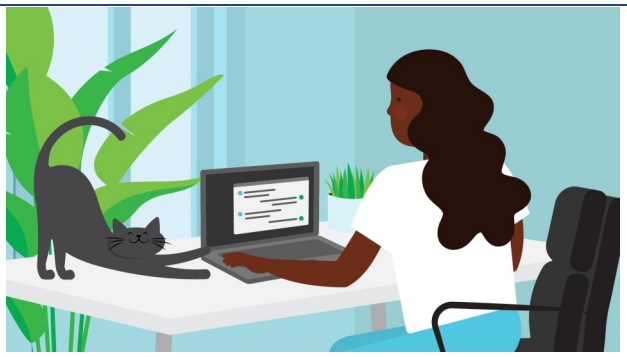
Duration of Approval: Length of the clinical trial.

Adverse Event Monitoring & Reporting: Requires monitoring and reporting of adverse events.

Recordkeeping & Access: Requires recordkeeping and access to distribution and administration records.

FDA Approval: FDA review and agreement that the study may proceed.

IRB Approval: IRB review and approval is required.



During this time, the Research and IRB staff are working remotely. The best way to contact us is by email.

Upcoming CME Events

December 2, 2020: Family Medicine Seminar

(CME Zoom webinar)

For more information:

Nancy DeRita, CME Specialist

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Coming Soon: Our own in-house medical journal!

Ascension St. John Advances in Research & Quality Improvement

SEMCME Research Workshop Series 2020

Webinars on Wednesdays, Noon - 1 p.m.
now through December 9th.

Each resident completing the Workshop Series during the course of his/her residency program will receive a certificate of completion.

SEMCME Faculty Development

Fostering Civility, Resilience, Mindfulness and Supportive Teams

Presented by Dr. Jillian Horton, via Zoom
Four one-hour sessions 1:00-2:00 pm EST
September 25th,
October 16th,
October 30th and
November 13th

Self Directed Learning

Three one-hour sessions 1:00-2:00 pm EST
Presented by Gloria Aquino Sosa, PhD, via Zoom
November 20th, December 4th and December 11th 1-2 pm EST via zoom

For more information on these events, visit:
https://semcme.org/

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