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RCTs: 'Gold Standard' for Medical Research Targets Improved Outcomes

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Changing Lives Through Research



Drs. Hitoshi Hirose, Jordan Winter, and Harish Lavu are among the many clinician researchers in the department conducting randomized clinical trials to investigate and improve treatment options for their patients.

RCTs: 'Gold Standard' for Medical Research Targets Improved Outcomes

For decades, prospective randomized clinical trials (RCTs) have been the "gold standard" for medical research. These studies randomly assign patients to one of two groups: half receive the standard treatment, and half undergo the experimental approach. As Associate Professor of Surgery Harish Lavu, MD, FACS, explains, randomly assigning patients helps eliminate even subconscious bias on the part of researchers. Dr. Lavu notes that while there is widespread agreement that RCTs are the best way to conduct research, these studies are complex and often costly. Funding often comes from institutional sources, government sponsored research grants, philanthropic organizations, or pharmaceutical companies.

"From conception to completion, a high-quality prospective RCT can take two to 10 years. By contrast, retrospective studies – in which researchers analyze an existing data set, such as a large collection of patient charts – are typically much faster and easier," Dr. Lavu says. He adds that while retrospective studies can provide early findings suggesting that a new method may be beneficial or merits further investigation, the gold standard to test the hypothesis is often a full-scale RCT.

Jefferson's Department of Surgery has a number of RCTs in various stages – including the HYSLAR (Hypertonic

Saline) Trial and the Celiac Nerve Block trial for pancreatic cancer patients as well as a trial analyzing sternal pain after cardiac surgery.

The 264-patient HYSLAR Trial studied the type of fluid used during the Whipple procedure (pancreaticoduodenectomy). The standard approach is to administer Lactated Ringer's solution for fluid replacement. The study hypothesized that with a more concentrated saline, surgeons could administer less fluid and improve outcomes.

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"In our trial, surgeons used the standard amount of Lactated Ringer's solution with half of the patients, while the other half received the concentrated form of intravenous fluids known as hypertonic saline," he says. "We found that with hypertonic saline, we were able to get patients through surgery and the recovery period with less total fluid administered. In fact, reducing fluid by several liters resulted in a 25-percent reduction in post-surgical

On the Job



Renee Juliano (center) and her colleagues – including Operations Manager, Beverly Kelter (fifth from right) – keep the department's SMOB outpatient clinic at 11th and Walnut running smoothly.

Renee Juliano

Whether seeking an initial consultation or receiving post-surgical care, patients of Jefferson's cardiothoracic, colon and rectal, general, transplant and trauma surgeons will see their physicians at Jefferson Hospital's Medical Office Building at 11th and Walnut. A team of about 20 administrative professionals helps keep the "MOB" humming. A key part of that team is Practice Manager Renee Juliano, who supports general surgeons Karen A. Chojnacki, MD, FACS, and Ernest L. Rosato, MD, FACS.

Renee joined Jefferson's Department of Surgery in 1996, working in the Gibbon Building until the surgical practices came together in the MOB in 2001. She has been supporting Dr. Chojnacki and Dr. Rosato for the last 12 years – and has become a go-to resource for her peers.

She enjoys helping her colleagues tackle everything from computer glitches to patient relations. To be sure, Renee takes

pride in assisting patients – serving as an administrative advocate as they schedule a range of procedures. When cancer patients are referred by other doctors, she's the one who ensures that the surgeons see them as quickly as possible. Since Renee isn't a clinician, she doesn't address patients' medical questions. But she is quick to provide a listening ear and a kind word to individuals who are feeling anxious about their diagnosis or upcoming procedure.

"I get to interact with our patients every day, and I always try to make their situation a little bit better," Renee says. "I listen to them and assure them that they're in good hands – that the people in our office are here to help them."

With daily patient volume as high as 90, Renee admits that the MOB can sometimes get hectic. Even so, she always operates by her own golden rule: "Treat your patients and co-workers the same way you'd like to be treated. It really does make a difference."

complications such as edema and fluid build up in the lungs." Dr. Lavu and colleagues published the results in the September issue of *Annals of Surgery*.

From 2008 to 2013, Jefferson also enrolled pancreatic cancer patients in the Celiac Nerve Block Trial. All told, 485 individuals enrolled and have

forward to presenting our findings in December at the Annual Meeting of the Southern Surgical Association."

In the Division of Cardiothoracic Surgery, an analysis of patients who underwent coronary artery bypass showed that compared to conventional sternal wire, rigid fixation using sternal plates led to a reduction in postoperative pain and shortened ventilation time, ICU stay and hospital stay. Hitoshi Hirose, MD, PhD, FACS, led the RCT that further investigated those outcomes – and confirmed a trend of shorter intubation time and lesser narcotic requirements with rigid fixation versus wire closure.

These trials are just a sample of the gold-standard research at Jefferson. As Dr. Lavu notes, numerous other RCTs are ongoing and in development – including studies of vaccines and neoadjuvant treatment in both melanoma and pancreatic cancer and the efficacy of fibrin sealants to control blood loss during surgery.

been helping researchers understand whether or not injecting concentrated ethanol into the celiac nerve during surgery lessens severe abdominal pain and improves quality of life.

"This is a double-blind placebo-controlled trial – meaning that neither the researchers nor the patients know who has received the ethanol nerve block and who has received the saline as a placebo," Dr. Lavu says. "We are currently analyzing the data and look