



Small



Madara

SPOTLIGHT ON CLINICAL RESEARCH

Family Medicine, Cardiology, Cardiothoracic Surgery

Roy S. Small, M.D.

Medical Director of Clinical Research

Heather Madara

Clinical Research Coordinator

Penn Medicine Lancaster General Health Research Institute

Editor's note: This is the fourth in a series of articles from the Penn Medicine Lancaster General Health Research Institute that describes ongoing research studies, with a focus on those actively enrolling patients. Other active studies have been described in previous issues of this Journal.^{1,2,3}

Physicians who wish to refer patients for any of the studies mentioned below are encouraged to contact the Penn Medicine Lancaster General Health Research Institute at 717-544-1777.

Other members of the Penn Medicine LGH staff who are conducting research and wish to have their studies described here are encouraged to contact the offices of JLGH at 717-544-8004.

FAMILY MEDICINE

IMPLICIT ICC

Interventions to Minimize Preterm and Low birth weight Infants using Continuous Techniques (IMPLICIT) Interconception Care (ICC)

Principal Investigator: Corey Fogleman, M.D.

Summary by Maha Shafqat

Approximately 50% of pregnancies in the United States are unintended, and the incidence of preterm birth and birth defects remains unacceptably high. The preterm birth rate in Lancaster is 9.2%. Many modifiable risks for adverse birth outcomes occur prior to pregnancy.

The IMPLICIT ICC project is an evidence-based approach that screens mothers during well child visits (WCVs), addresses maternal risks such as tobacco use, maternal depression and family planning, and provides multivitamins with folic acid. Data collected over the past seven years indicates that moms are present at approximately 93% of the WCVs. This makes WCVs an opportune time to

assess and address maternal needs and risks. This project aims to improve maternal health and to reduce the incidence of prematurity and low birth weight infants.

INTERVENTIONAL CARDIOLOGY

PERT

Consortium Registry

Principal Investigator: Todd Wood, M.D.

The PERT (Pulmonary Embolism Response Team) Consortium was developed by a group of physicians at Massachusetts General Hospital in 2012 to identify patients with pulmonary embolism (PE), and improve their survival rates through increased awareness and more effective treatment. The PERT Consortium Registry is a multi-center registry of patient-level data from patients admitted to the hospital with PE for whom the PERT team has been consulted. Since LGH joined the Consortium in 2016, our site has enrolled 220 patients to the nationwide registry.

HEART FAILURE

GUIDE-HF

Hemodynamic GUIDEd Management of Heart Failure

Principal Investigator: Tareck Nossuli, M.D.

The CardioMEMS HF system is an FDA-approved device that measures pulmonary artery pressure in heart failure (HF) patients. It is currently approved for use in HFrEF and HFpEF patients with NY Heart Association (NYHA) Class III symptoms. The Guide-HF study is an interventional

randomized clinical trial that seeks to expand the indications for the CardioMEMS HF system by assessing its benefits in HF patients in NYHA Class II, III, or IV who have an elevated NT-proBNP and a recent prior HF hospitalization. LGH is one of 140 participating sites across North America.

ELECTROPHYSIOLOGY

MORE-CRT MPP

MORE Response on Cardiac Resynchronization Therapy (CRT) with MultiPoint Pacing (MPP)

Principal Investigator: Sandeep Bansal, M.D.

Cardiac resynchronization therapy (CRT) using biventricular (BiV) pacing can restore synchrony in HF patients with delayed left ventricular (LV) activation.

The MORE-CRT MPP clinical trial aims to determine the efficacy of Multi Point Pacing (MPP) in non-responders to CRT. MPP is performed with a multi electrode coronary sinus lead. Patients with an implanted MPP compatible CRT device are randomized to having MPP turned on or off. At the six-month study visit, patients determined to be responders to CRT will be removed from the study, while those determined to be non-responders will have the MPP feature activated per randomization results and will be followed until the 12-month study visit.

The primary endpoint of this study, assessed at 12 months after enrollment, is the percentage of non-responder CRT patients who converted to responders after six months with the MPP feature turned On. "Response" is defined as a reduction of at least 15% in Left Ventricular End Systolic Volume (LVESV).

Roy S. Small, M.D.
The Heart Group of Lancaster General Health
217 Harrisburg Ave.
Lancaster, PA 17603
717-544-8300
Roy.Small@pennmedicine.upenn.edu

CARDIOTHORACIC SURGERY (CTS)

TAVR PREHAB

PreHabilitation for patients undergoing Transcatheter Aortic Valve Replacement

Principal Investigator: Rahul Jhaveri, M.D.

In this pilot study, initiated by WellSpan Health, investigators aim to identify patients undergoing TAVR for severe aortic stenosis. Investigators also aim to determine if monitored pre-procedural physical therapy is safe in these patients and whether "pre-habilitation" to improve physical functioning can sustain benefits through 30 days post-procedure.

Patients randomized to the intervention arm will receive eight to twelve physical therapy visits before the surgery date, while the control group receives none (which is standard of care). Post-procedural length-of-stay and clinical outcomes will be compared. The evaluations include a six-minute walk test, "time up and go" test, a four-square step test, and changes in quality of life (Kansas City Cardiomyopathy Questionnaire score). LGH collaborates with WellSpan Health on this innovative study, which aims to enroll 70 patients across the two health systems.

REFERENCES

1. Small RS, Madara H. Spotlight on clinical research: cardiology and neurology. *J Lanc Gen Hosp.* 2018; 13(4): 100-101.
2. Small RS, Madara H. Spotlight on clinical research: nephrology, cardiology, radiology, neurology. *J Lanc Gen Hosp.* 2019; 14(1): 4-5.
3. Small RS, Madara H. Spotlight on clinical research: cardiology, cardiothoracic surgery, and trauma. *J Lanc Gen Hosp.* 2019; 14(3): 88-89.

Heather Madara
Penn Medicine LG Health Research Institute
131 E. Frederick St.
Lancaster, PA 17602
717-544-1777
Heather.Madara@pennmedicine.upenn.edu