

Cardiovascular Update

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A newsletter from the BayCare Cardiovascular Service Line

Cardiovascular and Surgical Outcomes | 2015



As a system of community hospitals within West Central Florida, BayCare is committed to being a leader in providing superior heart care. The BayCare Cardiovascular and Surgical Outcomes book for 2015 is available, detailing our volume and outcomes data as well as highlighting some of our world-class programs including our heart failure clinics, fast-growing structural heart and arrhythmia programs, and the many clinical research trials available across the system. [Download](#) a copy of our 2015 outcomes book today.



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Clinical Research

By Leslie W. Miller, MD



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Health care is an issue that impacts a growing number of people, especially as the population increases in age. The field of medicine is responding with expanding efforts to translate the discoveries made in laboratories to the clinic. There have been many new therapies introduced in the past several years, particularly in the field of cardiovascular medicine, including significant technical advances to treat structural problems with heart valves, and ways to ablate or treat heart rhythm problems without surgery. In addition, there are many new oral medications, including so-called biologics which includes antibodies, as well as stem cell and gene therapy. Collectively, these advances offer real hope for improved quality of life for many patients with previously limited options.

However, none of these advances would be possible without the therapies going through the rigorous process of FDA approval, which can take eight to 10 years and cost hundreds of millions of dollars to

achieve. The central requirement for FDA approval is to demonstrate both the safety and efficacy of each new therapy. This requires clinical trials be conducted, that enroll patients before the treatment has been approved in the U.S. Importantly, in order for a trial to be conducted in the U.S., it has to have already been conducted in patients outside the U.S., typically Europe, and found to be both safe and effective. That assures potential patients that they are not being exposed to untested risk, but have an opportunity to access the latest advances in the field, often years before being commercially available.

There are several phases of clinical trials, starting with the earliest Phase I, which tests primarily the safety and ideal dose to be used, up to the final or pivotal Phase III, which if positive, leads to FDA approval and commercialization. The FDA mandates that there is a placebo option in the more advanced trials. This is to compare the outcomes to the agent being studied. This process is not under any control of the doctors conducting the trial, and is called blinded, meaning that neither the patient nor the doctor know what treatment the patient will receive.

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BayCare has made a significant commitment to expanding the clinical research trials now available to patients in Tampa Bay. The trials are currently being led at Morton Plant Hospital, with an increasing availability at St. Joseph's Hospital in Tampa and Winter Haven Hospital in Polk County. The outcomes achieved in these trials are some of the best reported in the country. There are many different trials now actively open and enrolling patients with a variety of cardiovascular conditions including:

Structural Heart Disease

- **Aortic stenosis:** Including several new types of nonsurgical valve replacement and repair, as well as high-caliber valve surgery
- **Mitral regurgitation:** New nonsurgical clip procedure to reduce the leak and symptoms

Peripheral Vascular Disease

New gene therapy to help generate new blood vessels and help heal areas of tissue loss and reduce pain and limitations, as well as new stents to improve blood flow and improve symptoms with and without surgery

Heart Failure

There is a trial using the latest stem cell to help regenerate heart function and improve functional status.

Acute MI

There is a trial of a novel stem cell that is designed to also generate new blood supply and regenerate heart tissue and function.

Stroke

A trial is scheduled to start by March 2017 to treat patients who suffer a stroke, using the same stem cell as is now being tested for acute MI. The goal is to minimize the damage of the stroke and improve blood flow to that part of the brain.

It's important for the team conducting the study to obtain previous medical records to help them assess eligibility criteria. At the appointment, the potential patient is given the details of what would be required for their participation and the expected benefits and risk for that study. This is a no-obligation appointment and the cost is often covered by the study. If someone enrolls in a clinical trial/study, all of the tests and procedures costs related to the study are completely covered by the study, with no expense to the patient or their insurance.

All the exciting potential advances in the field of medicine are very dependent on the conduct of clinical trials. These trials represent the cutting edge of the newest science and are made available to potential patients who enroll years ahead of the trials' access by the general population. Participation is free and easy. The goal of all these studies is to improve the outcomes for each patient, especially quality of life and functional capacity.

To see a full listing of our cardiovascular clinical trials, visit our [Research and Clinical Trials](#) page.

For additional information on cardiovascular clinical trials, including eligibility and assistance in setting up an appointment with the study lead, contact Kathryn Gloer at kathryn.gloer@baycare.org.