



EFS EXPRESS

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How One Site Innovated to Keep EFS Going During COVID-19

Site: Northwestern University
Site type: Academic medical center
Device Type: Cardiovascular devices

This is Part 1 of a 3-part series on the impact of COVID-19 on US EFS.

When the COVID-19 pandemic struck in March 2020, new enrollment in EFS was suspended, research staff were deployed to emergent care, and early patient access to life-saving cardiovascular devices was delayed nationwide. At the [Bluhm Cardiovascular Institute](#) at Northwestern Medicine, three EFS for tricuspid valve repair and replacement were suspended for almost five months.

“There was almost no way to enroll new patients and limited ability to follow up with patients,” says Charles J. Davidson, MD, FACC, FAHA, FSCAI, medical director at the Bluhm Cardiovascular Institute. Dr. Davidson is also vice chairman of clinical affairs in the Department of Medicine, clinical chief of cardiology, and professor of medicine at Northwestern University Feinberg School of Medicine.

Dr. Davidson and other investigators were able to explain what sites were facing to FDA and industry during MDIC’s regular meetings about the EFS program. These discussions and MDIC’s advocacy resulted in regulatory changes to protect subjects, such as remote monitoring through telehealth.

Researchers at the Bluhm Cardiovascular Institute used telehealth for follow up and to evaluate potential subjects. Follow-up was limited, since it was challenging to do exams, imaging, and other tests. The imaging laboratories were operating at limited capacity statewide while stay at home orders were in effect. Even after clinic visits and tests were allowed, many patients were reluctant to visit the hospital.

But telehealth emerged as a better way to do the initial screening for EFS. “Many patients come from three to five hours away. We try to get as much clinical information ahead of time as we can through telehealth,” says Dr. Davidson. The Bluhm Cardiovascular Institute also began allowing patients to have imaging done closer to their homes and scheduled other tests at the hospital on a single day.

Even when clinical trials resumed in July, limits on the number of procedures and industry personnel in the hospital, and patient fear about coming to the hospital, made conducting EFS challenging. Patients who weren’t urgent in March became urgent as their symptoms and medical conditions progressed. Dr. Davidson and his colleagues developed a priority list for EFS enrollment based on patients’ medical condition.

The Bluhm Cardiovascular Institute streamlined the EFS process by:

- Working with local and internal heart failure specialists to ensure that patients were as healthy as possible before considering a procedure
- Scheduling pre-op COVID testing and bloodwork to occur on the same day
- Scheduling industry representatives for case support to perform multiple procedures on the same day.

By fall 2020, volume for EFS procedures was at about 80% of pre-pandemic. “Our overall interventional procedure volume is lower than it would have been if the pandemic had not occurred. Once we have some degree of herd immunity, probably this Fall, I think we can return to normal,” says Dr. Davidson.

Also read about how the Bluhm Cardiovascular Institute uses the [MDIC EFS Master Clinical Trial Agreement \(MCTA\)](#) template to complete contract negotiations faster.

MDIC thanks Dr. Charles J. Davidson, Vice Chairman of Clinical Affairs, Department of Medicine; Clinical Chief, Cardiology Bluhm Cardiovascular Institute; and Professor of Medicine, Northwestern University Feinberg School of Medicine, for sharing the site’s EFS COVID-19 Story.

Join us April 21 for the 3D-EFS MDIC Symposium. In partnership with The Dartmouth Device Development Symposium Office, MDIC will host a 3.5-hour interactive virtual meeting focused on the Early Feasibility Study (EFS) Initiative to facilitate the first clinical use studies in the United States, providing updates and examining the current roadblocks. Learn more and register [here](#).

Have an EFS success story? In support of our Strategic Priorities, we want to publish success stories to help further the mission and vision of this project. If you would like to share, please send us an e-mail at efspilot@mdic.org with your contact information and a 2-3 sentence summary of your project/story and we will contact you to set up a time to discuss further. Success stories may be written up and published in the EFS Express and across general MDIC channels and industry channels.

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