MDIC MEDICAL DEVICE INNOVATION CONSORTIUM

EFS EXPRESS

Edition 29 • June 8, 2021

Pandemic Leads to Advances in the EFS Process

This is Part 3 of a 3-part series on the impact of COVID-19 on US EFS. Read Part 1 and Part 2.

While the COVID-19 pandemic created massive disruptions to EFS, it also led to advances in the EFS process. “The pandemic accelerated the changes that needed to happen. That is the little silver lining to all of this,” says Michael J. Mack, MD, director of the cardiovascular service line at Baylor Scott & White Health System and president and chairman of the Baylor Scott & White Research Institute.

Changes to the EFS process made to protect subjects and continue studying innovative devices during the pandemic include:

- More use of remote technology
- Less data
- Fewer study visits
- Increased efficiency

The Rise of Telehealth

Researchers used telehealth for follow-up visits with patients who had received a device through an EFS and to screen potential subjects. While tele-health was insufficient for follow-up visits, it became a valid way to screen patients for an EFS.

“Many patients come from three to five hours away and only about one third of patients qualify for an EFS. Tele-health makes sense for the screening initial visit,” 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.

Emergence of Other Remote Technologies

Point-of-care diagnostic devices and remote proctoring are other advances in the EFS process. Remote diagnostic testing enables echocardiograms to be done at the patient’s home by a home health agency nurse instead of in the hospital.

Remote proctoring, or supervision, of procedures by a physician who is familiar with the new device solved the problem of travel restrictions during the pandemic. Proctoring is required by the FDA or the sponsor. Going forward, remote proctoring will enable more experts to proctor procedures without the time and expense required to travel to clinical research sites.

Optimized Data Collection and Study Visits

MDIC provided a forum for FDA, industry, and investigators to coordinate the response to the pandemic

and re-evaluate the necessary data and frequency of study visits. “The pandemic caused a significant re-engineering of EFS trials and reduced the amount of information necessary to be gathered both before and after procedures,” says Dr. Mack.

Increased Efficiency at Sites

The Bluhm Cardiovascular Institute streamlined its EFS process by:

- Working with 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 to work with surgeons to perform more surgical cases in a day

“We learned how to prioritize patients and use hospital resources more strategically,” says Dr. Davidson.

Read more about the response to the pandemic at the Bluhm Cardiovascular Institute and the Baylor Scott & White Research Institute.

MDIC thanks Dr. Charles J. Davidson and Dr. Michael J. Mack, for sharing their EFS Stories. Dr. Davidson is Vice Chairman of Clinical Affairs, Department of Medicine; Clinical Chief, Cardiology, Bluhm Cardiovascular Institute; and Professor of Medicine, Northwestern University Feinberg School of Medicine. Dr. Mack is Director of the Cardiovascular Service line, Baylor Scott & White Health System and president and chairman, Baylor Scott & White Research Institute.

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.

Looking for more information? Consult our EFS Tool Kit.

Interested in participating in the EFS Initiative as a sponsor or site? Email us today for more information.