24 Hour Summary of the Circulatory System Devices Panel Meeting
November 3, 2021

Introduction:

The Circulatory System Devices Panel of the Medical Device Advisory Committee met on November 3, 2021 to discuss and make recommendations on the continued safety and effectiveness of endovascular stent grafts used to treat abdominal aortic aneurysms (AAA) and ways to improve real-world data collection on long-term device performance (for both currently marketed devices and future technologies). The FDA requested panel input on the clinical outcomes that are most relevant to capture in the real world. Additionally, the FDA sought Panel recommendations on data collection platforms and incentives to optimize real-world data capture.

FDA Questions

QUESTION #1. Safety and Effectiveness

Please discuss the safety and effectiveness of endovascular stent grafts in the treatment of abdominal aortic aneurysms stratified by near-term and long-term outcomes.

> ***Panel Consensus*: The short-term benefits of endovascular aortic repair (EVAR) vs. open surgery are well-established. However, although newer generation EVAR devices perform better than first generation devices, EVAR benefits vs. open surgery may not be maintained in the longer term, due to higher rates of aortic reintervention and other device and aortic complications in EVAR patients.**

QUESTION #2. Clinical and Imaging Event Surveillance

A. Available long-term data demonstrate that adverse events continue to accrue post-EVAR. Please discuss which of the following real-world clinical outcomes should be assessed in a long-term EVAR surveillance system:

- All-cause mortality
- Aneurysm-related mortality
- Aortic rupture
- Aortic reinterventions
- Others

> ***Panel Consensus:* A real-world surveillance system should assess endpoints of all-cause mortality, aneurysm-related mortality, aortic rupture, and aortic reintervention. The reintervention endpoint should capture the reason for reintervention and type of reintervention performed.**

B. Although imaging outcomes are collected in pre-market and FDA-required post-market studies, these studies have a modest sample size, and it is challenging to collect serial imaging data in real-world surveillance. Please discuss the importance and feasibility of the capturing the following imaging outcomes in real-world surveillance:

- Endoleaks
- Loss of device integrity
- Aortic enlargement
- Device migration
- Device patency

> ***Panel Consensus:*** **Real-world imaging surveillance should assess endoleaks, aneurysm size, and device patency because these endpoints are clinically important and can be reliably captured. Loss of device integrity and device migration are less feasible to evaluate at all sites but could be assessed at a subset of centers using standardized imaging protocols with core lab review. Along with the need for long-term imaging data, a change in culture among patients, health systems, and physicians is required to increase patient compliance with follow-up imaging recommendations post-EVAR.**

QUESTION #3. Real-world Surveillance

Please discuss whether strengthening existing real-world surveillance is needed to evaluate long-term EVAR performance.

> ***Panel Consensus:*** **Strengthening real-world surveillance is needed to evaluate long-term EVAR performance.**

A. If so, please discuss the key attributes that should be included in a real-world surveillance infrastructure to assure high quality and clinically useful long-term EVAR device evaluation (e.g., enrollment strategies to address potential selection bias, data monitoring and auditing, event adjudication, core labs, major endpoints, statistical analysis plan).

> ***Panel Consensus:*** **A real-world surveillance infrastructure should capture data on a diverse patient population and should not be limited to academic medical centers. Serial enrollment reduces selection bias, and data monitoring and auditing plans are required. At present, there is no single real-world surveillance infrastructure that can meet the needs of all stakeholders; collaboration among data collection platforms will be needed.**
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> **The surveillance system should collect information on the specific device model(s) used and baseline patient clinical and anatomic characteristics. These data are needed to identify early safety signals. Ease of use by physicians and incorporation of data from multiple data collection systems are important considerations.**

B. Please discuss the frequency and duration of surveillance for patients post-EVAR that would be clinically meaningful and feasible to capture through a real-world surveillance infrastructure, including recommendations for patients who undergo aortic reintervention.

> ***Panel Consensus:*** **Patients should complete follow-up visits 30-days post implantation and annually thereafter. As is outlined in the current professional society guidelines, concerning findings from 30-day imaging should prompt a 6-month follow-up visit. The proposed surveillance infrastructure should collect data through 10 years post-EVAR.**

C. Please discuss strategies that can incentivize relevant stakeholders to participate in real-world data collection on a routine basis.

> ***Panel Consensus:*** **Support is needed for data entry, which is a burdensome rate-limiting step. Voluntary participation would not likely lead to a successful real-world data collection system. A surveillance system that provides value to participating health systems would be needed. A tiered approach could be considered so that health systems can choose to participate to a greater or lesser degree.**

D. Please comment on how device manufacturers, health care systems, professional societies, individual providers, and other stakeholders should collaborate to maximize long-term follow-up compliance and data quality on EVAR device performance.

> ***Panel Consensus:*** **The FDA should act as the convening party and encourage data sharing and active participation among stakeholders. Patients and patient advocacy groups should be involved in this collaboration, and patient input should be considered in the design of real-world data collection platforms.**

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