SUMMARY MINUTES

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

CIRCULATORY SYSTEM DEVICES PANEL

November 3, 2021

Via Zoom Videoconference

Attendees:

Chairperson

Richard A. Lange, M.D.
Texas Tech University Health Sciences Center
El Paso, TX

Voting Members

Randall C. Starling, M.D.
Cleveland Clinic
Cleveland, OH

Jason T. Connor, Ph.D.
ConfluenceStat, LLC
Cooper City, FL

James C. Blankenship, M.D.
University of New Mexico
Albuquerque, NM

Robert W. Yeh, M.D.
Beth Israel Deaconess Medical Center
Boston, MA

Keith B. Allen, M.D.
St. Luke's Mid America Heart & Vascular Institute
Kansas City MO

Temporary Non-Voting Members

Keith A. Horvath, M.D.
Association of American Medical Colleges (AAMC)
Washington, D.C.

Ralph G. Brindis, M.D., M.P.H.
AC Wellness Network
San Francisco, CA

Minhaj S. Khaja, M.D., M.B.A.
University of Virginia
Charlottesville, VA

Edwin C. Gravereaux, M.D.
Brigham and Women's Hospital
Boston, MA

Karen Woo, M.D., Ph.D.
University of California
Los Angeles, CA

Ben Starnes, M.D.
University of Washington School of Medicine
Seattle, WA

Alex D. Shepard, M.D.
Henry Ford Health System
Detroit, MI

Joaquin E. Cigarroa, M.D.
Oregon Health & Science University
Portland, OR

Albert G. Hakaim, M.D.
Mayo Clinic
Jacksonville, FL

Matt J. Eagleton, M.D.
Massachusetts General Hospital
Boston, MA

Industry Representative

Gary J. Jarvis, B.S.
Alfa Medical
Eden Prairie, MN

Patient Representative

Paul T. Conway, B.A.
Conway Strategies Global
Falls Church, VA

Consumer Representative

Jacqueline S. Alikhaani, B.A.
Healthcare Consumer/Volunteer
Los Angeles, CA

Food and Drug Administration

Bram Zuckerman, M.D.
Director, Office of Health Technology 2 (OHT 2: Cardiovascular Devices)
Office of Product Evaluation and Quality

Akinola A. Awojope, Dr.PH, M.P.H.
Designated Federal Officer

CALL TO ORDER
PANEL INTRODUCTIONS

Panel Chairperson Richard A. Lange, M.D., MBA, called the meeting to order at 9:02 a.m. He noted the presence of a quorum and affirmed that the Panel members had received training in FDA device law and regulations. He announced that the Panel would be discussing and making recommendations on the continued safety and effectiveness of endovascular stent grafts, and how to strengthen real-world data collection on long-term performance of the devices, both for currently marketed products and future technologies.

He then asked the Panel members and the FDA staff to introduce themselves.

CONFLICT OF INTEREST STATEMENT
TEMPORARY NON-VOTING MEMBER STATUS STATEMENT
GENERAL ANNOUNCEMENTS

Akinola A. Awojope, Dr.PH, M.P.H., Designated Federal Officer, read the Conflict of Interest statement and reported that conflict of interest waivers had been issued to Drs. Albert Hakaim, Alexander Shepard, Randall Starling, Matt Eagleton, and Robert Yeh.

He noted for the record that the invited guest speakers, Drs. Rodney White, Gustavo Oderich, and Tara Mastracci, had acknowledged interests with affected firms.

He announced that Jacqueline Alikhaani, the consumer representative, had been appointed to serve as a temporary non-voting member, and that Gary Jarvis would be serving as the industry representative.

He then made general announcements regarding speaker identification and transcript availability, and introduced Shirley Simson as the press contact.

FDA PRESENTATION

Background and Current Status of Endovascular AAA Repair

Ron Fairman, M.D., presented an overview of abdominal aortic aneurysms and therapies and discussed the history and current status of endovascular abdominal aortic aneurysm repair, as well as the following topics: currently approved AAA endovascular grafts, benefits and disadvantages of EVAR, current realities, EVAR outcomes of interest, and the role of long-term surveillance.

Current Regulatory Paradigm for AAA Endovascular Devices

Gordon Bryson, B.S., specified that FDA utilizes least burdensome principles, and balances pre- and postmarket data requirements in order to facilitate timely approval of devices with data demonstrating reasonable assurance of safety and effectiveness. He informed the Panel that the current approval requirements for a new EVAR device is typically one-year safety and effectiveness data from a pivotal study and five-year follow-up data after the device is marketed, and that new enrollment post-approval studies can also be required. He noted that essential data on how devices perform in the real world are underutilized, particularly key outcomes beyond five years, as well as device use outside the

approved indications, and that there are several mechanisms to facilitate real-world data collection.

Conclusion of FDA Presentation

Dr. Fairman summarized the following conclusions:

- Pivotal study outcomes at five years and long-term real-world data indicate that significant adverse events continue to occur after EVAR procedures.
- There is uniform agreement that long-term follow-up is indicated post-EVAR.
- While surveillance is critical to understanding long-term real-world device performance, clinical and imaging outcomes have been challenging to capture by current surveillance methods.
- Patients and physicians would benefit from knowing the rates of important clinical adverse events to an adequate degree of precision. This would require large numbers of patients to be followed post-market.
- A high-quality, robust post-market surveillance system is aligned with FDA's mission to protect public health and its total product life-cycle approach for device regulation.

Questions for the Panel

Mr. Bryson then presented an overview of the FDA discussion questions.

Q&A

Questions and Comments from the Panel:

Ben Starnes, M.D., asked for further comment on what the 522 process involves.

Alexander D. Shepard, M.D., asked why lower extremity ischemia or limb loss is not considered a major adverse event as a primary safety endpoint for EVAR trials.

Paul T. Conway, B.A., Patient Representative, asked what other current mechanisms besides MDRs are in place to capture patient-reported outcomes or insight data relative to long-term surveillance.

Answers and Responses from FDA:

Carmen Gacchina Johnson, Ph.D., provided information on Section 522 of the Food, Drug, and Cosmetic Act. She also confirmed that patient-reported outcomes are currently not procured in the Agency's AAA endovascular graft studies, but that it ~~has~~ is ~~become~~ a CDRH priority.

Dr. Fairman explained that lower extremity ischemia and limb loss is captured in all of the pivotal trials as a secondary endpoint, if not primary. He pointed out that it is

uncommon for lower extremity ischemia to result in limb loss in the majority of pivotal trials conducted in the United States.

COMBINED INDUSTRY PRESENTATION

Medtronic

Jean Starr, M.D., presented a clinical perspective of endovascular aneurysm repair. She provided a brief background on aortic aneurysm disease and shared how she discusses treatment options with patients. She noted that device improvements have allowed a broad range of patients to be treated more safely over time, that EVAR devices have been found to be safe and effective after extensive testing in clinical studies with follow-up out to five years, and that the potential need for reintervention persists, supporting the need for long-term follow-up. She further noted that the key objectives are to build off existing large sources of relevant data where possible and to optimize data collection, allowing for quick and reliable detection of safety and effectiveness signals.

Cook Medical

Scott Williams, M.S., RAC, focused on industry's proposal for strengthening real-world data collection on longer-term performance of endovascular stent grafts. He stated that EVAR patients may require reintervention at any time for a variety of reasons, supporting the need for long-term follow-up; that industry proposes vital status, reintervention, and aneurysm rupture to 10 years as the most relevant endpoints to assess in a real-world setting for this patient population; and that linking established registries with claims as an initial step to enhancing long-term data collection is currently the optimal approach for timely assessment.

COMBINED PHYSICIAN PRESENTATION

Society for Vascular Surgery

Ronald L. Dalman, M.D., introduced the professional society consensus presentation speakers and also M. Ashraf Mansour, Professor and Chair of Surgery at Michigan State University and president-elect of the Society for Clinical Vascular Surgery.

He outlined the presentation, noting that the group would be providing input on the following topics:

- Overall safety and effectiveness of endovascular graft technology in the longer term.
- Clinical events associated with endovascular repair that are most relevant and feasible to capture in a real-world setting.
- Potential platforms available for real-world data collection.
- Ways to overcome low patient compliance in real-world data collection and the role of professional societies in ensuring compliance.

American College of Cardiology

Marc Bonaca, M.D., stated that robust long-term follow-up of data, risk-benefit, and associated patient characteristics after AAA repair are critical for optimum maintenance and shared decision making. Data collection should be balanced with practical realities and should be multidisciplinary, objective, and precise with regard to key outcomes. It should also be open and available for appropriate evaluation of publications and should include all centers. He noted that the merging of the NCDR PDI registry with the Vascular Quality Initiative provides a good opportunity for long-term reporting.

Society for Interventional Radiology

John Fritz Angle, M.D., discussed methods for identifying trends in late EVAR failure and of data collection for registries. He emphasized the need for periodic reporting of national-level analysis, as well as definition of thresholds and accountability reporting of potential endograft issues.

Society for Vascular Surgery/VQI-VISION

Philip Goodney, M.D., provided an overview of VQI-VISION and described its methodology for leveraging linked datasets for long-term EVAR surveillance. He noted that with more contemporary data updates, a near real-time national EVAR surveillance program is a plausible next step.

Society for Vascular Surgery

Dr. Dalman summarized the presentation:

- The group feels that the VQI-VISION methodology represents the most realistic option available to capture real-world outcomes for aortic endograft procedures up to a decade or more after device deployment.
- Mortality and secondary interventions, identifiable through the VQI-VISION methodology, are realistic and relevant data points for evaluating long-term device performance.
- Future iterations in the VQI data collection system may provide opportunities to obtain more granular surveillance from a smaller number of high-volume sites which will supplement, rather than replace, VQI-VISION. Also, the ACRIN model is scalable and could augment VQI-VISION.
- Incentivizing and ensuring patient follow-up should be everyone's responsibility.
- The resources required to ensure enhanced surveillance and patient education initiatives to identify unexpected device failures should be provided by device manufacturers as a requirement for market approval.

Q&A

Dr. Goodney provided details on the consolidation of VQI with Medicare data,

matching exercises, and the advantages of the Patient Safety Organization setup. He informed Mr. Conway that patients do not attend steering committee calls but have participated in several projects. He addressed questions regarding the permeation of VQI across hospitals for aortic aneurysm surgery, how the VQI is audited, the adjudication process, potential delays in examining Medicare claims, and the impact of Medicare Advantage.

A discussion then ensued regarding barriers to imaging follow-up. **Dr. Dalman** mentioned that device development, marketing, implementation, and follow-up needs should be considered as a whole to ensure appropriate follow-up.

Minhaj S. Khaja, M.D., M.B.A., asked why the imaging portion can't be done from the beginning. Dr. Goodney agreed, noting that the ultimate goal of collecting imaging more extensively is a matter of which iterative step to take first.

Mr. Williams and **Dr. Goodney** addressed a question posed by Dr. Starnes as to whether reporting of anatomical data and IFU compliance should be a condition of PMA approval for new devices. Dr. Goodney stated that some aspects that would inform IFU adherence is already being collected and that there is room to grow.

FDA PRESENTATION

Relevant Infrastructure

Li Wang, Ph.D., M.B.A., M.S., gave an introduction to real-world data use in the regulatory space and an overview on the growing need in the evolving AAA ecosystem. He then discussed prominent cases where real-world evidence was utilized in both the AAA and general cardiovascular space. He noted that data accessibility can be impacted by important considerations to patient privacy protection, and that navigating pre-existing data use agreements may need further exploration. Also, many outcomes necessary for the evaluation of AAA-specific devices are impacted by a lack of longer-term follow-up and low imaging compliance. He concluded that there has been successful incorporation of real-world evidence in the regulatory space, that the existing real-world data infrastructure provides multiple modalities for data capture, and that the main challenges include navigating data-use agreements, low imaging compliance, more reliable long-term follow-up, and ensuring patient privacy protection.

Q&A

Questions and Comments from the Panel:

Karen Woo, M.D., Ph.D., asked if other claims data sources have been looked at, and **Mr. Conway** asked if the VA database and Tricare have been considered.

Answers and Responses from FDA:

Dr. Wang affirmed that other RWD sources have been evaluated depending on the question that is being asked.

Dr. Johnson specified that ~~alternative care-based registry and/or data systems have not been explored~~the infrastructure discussed by FDA was regional or national infrastructure that capture AAA specific outcomes. She noted that ~~information from~~ there is ongoing ~~coverage~~ research ~~of~~ utilizing the VA database ~~will be publicly presented at a future date~~.

Answers and Responses from Physicians:

Dr. Goodney explained that New York All Payer datasets are used to run similar analyses to check how well the methodology works in those datasets and that the results have been almost identical to what is observed in regular claims.

GUEST SPEAKER PRESENTATIONS

Gustavo S. Oderich, M.D., discussed the reasons for EVAR failure, noting that it is often caused by a combination of device, patient, and physician-related factors. He then gave examples from his own experience. He emphasized that patients can go undetected for years or decades with ineffective repairs before clinically significant events such as reintervention, rupture, or death take place. He further noted that the reporting of EVAR failure is inconsistent and is usually left to single-center retrospective reviews that vary widely and are generally not reported for community based outcomes.

Tara M. Mastracci, M.D., discussed the overall safety and effectiveness of EVAR, clinical and imaging outcomes, and the strengths and limitations of platforms for data collection. She recommended detailed anatomical data, machine learning whenever possible, device-specific data, and platforms that do not require a fee to participate.

Rodney A. White, M.D., discussed five-year surveillance, real-world imaging, and imaging techniques. He showed examples of non-contrast CT, noting that relevant information can be obtained from it, and stressed the importance of getting patients closely involved in the process from the beginning to help alleviate compliance issues.

Q&A

Questions and Comments from the Panel:

Mr. Conway asked Dr. White if he uses non-contrast to avoid any potential detrimental issues with contrast load.

Dr. Khaja agreed that a contrast-enhanced study is ideal with a non-contrast phase followed by CT angiogram and delayed venous stages, and with acquiring contrast-enhanced or non-contrast ultrasounds at stable time points.

Answers and Responses from Guest Speakers:

Dr. White expounded on how he engages his patients' families, and on the use of non-contrast imaging. He also stated that same-center imaging is not of the utmost

importance, but having a protocol that outlines short-interval, high-contrast CT imaging is a critical component.

OPEN PUBLIC HEARING

Gary Lemmon, M.D., discussed the drawbacks of endografts and of changes that need to be made going forward. He recommended a lifetime surveillance platform for EVAR patients that would house pertinent information such as survival data, type of surveillance, aneurysm size and changes, endoleak type, and reintervention or new aneurysm treatment info. He also suggested the inclusion of emergency repairs, all ruptures, explantations, and sac pressurization in adverse event monitoring.

Mattias Andersson, M.D., referred the Panel to a recently published study that used national registers to assess the occurrence of post-procedural rupture among all EVARs performed in Sweden between 2001 and 2015. He provided background information on the registers and defined what the limitations are in connection to their use. He noted that they are highly useful for identifying patients who have had primary EVAR, for estimating survival, and for assessment of some complications as well as reinterventions. He revealed that a validation method of the register data was used to create an index of complications and reinterventions of 1800 consecutive standard EVARs at five Swedish vascular centers.

Art Sedrakyan, M.D., Ph.D., shared results from national and international initiatives of the Medical Device Epidemiology Network. He stated that continuous global evaluation of long-term outcomes will aid in gaining a comprehensive understanding of the performance of this technology, especially in subgroups where there is potential for harm.

Jens Eldrup-Jorgensen, M.D., discussed optimization of real-world data. He provided details on enhancement of the current VQI registry, data improvement strategies, and the creation of a vascular research collaborative (VRC). He noted that the VRC will focus on high-quality data and longer follow-up of three to five years, and will consist of 40 to 50 preselected centers.

Eric A. Secemsky, MD., M.Sc., discussed the use of real-world evidence for analysis of aortic device safety. He addressed concerns regarding the evaluation of rare or infrequent indications, and the lack of a systematic approach in assessing post-approval safety. He noted that real-world evidence has an opportunity to play a significant role in device safety evaluation by providing timely assessments at a lower cost, and that the linkage of limited device files to insurance data can also provide a cost-effective, flexible approach to evaluating the safety of aortic implants and other medical devices.

Matt Waltham described the concept and design of Cydar EV, an intelligent mapping system intended for use in planning and guiding endovascular surgery. He affirmed that the system can provide a robust platform to aggregate and analyze high-quality data for the improvement of patient outcomes.

Meg Seymour, Ph.D., spoke on behalf of the National Center for Health Research.

She expressed concern about conflicting data on EVAR devices and reliance on five-year studies that include different device iterations. She pointed out that a considerable amount of time can pass before problems with altered devices can be verified, and asked how many patients are harmed before updated data on new device versions have enough follow-up information to be useful. She insisted that clinical trials be required for all revisions of high-risk devices and that they should not be approved if they are only effective for small subgroups of patients.

Q&A

Dr. Eldrup-Jorgensen addressed a question posed by **Ralph G. Brindis, M.D., M.P.H.,** regarding the VQI's ability to detect EVARs that are not in compliance with the IFU. He specified that some identification of IFU conformity can already be done and will be further considered as upgrades and revisions continue. He affirmed that audits are done every three years at all sites for completeness of data entry, and discussed the costs associated with setting up the VRC. He also mentioned that a fair amount of resources and support would be needed to set up a sampling methodology, and that DELTA is currently being integrated into VQI to aid in early signal detection.

Dr. Secemsky expounded on the process of linking UDI to insurance claims, acquisition of registry data, the main strengths of the VQI, and the use of complementary data. He apprised Mr. Conway of accessibility issues with the VA dataset and told Dr. Woo that there are future plans for collecting more than just basic limited patient information.

Mr. Waltham provided detailed information on leveraging artificial intelligence and using imaging interpretation to retrospectively retrieve CT scans from preoperative and surveillance phases to better understand and gain more information on why devices fail. He informed Dr. Starnes that prototypes have been developed for using machine-learning computer vision to identify when devices are being introduced on fluoroscopy images, what devices they are, and who the manufacturer is. He explained that aggregated analytical data of all procedural events and post-operative follow-up is being collected in a patient-centric vault that can be linked together and viewed as a whole to better understand device failure.

PANEL DELIBERATIONS

Dr. Goodney discussed the logistics of longer follow-up. He informed Chairperson Lange that the VQI has already been extending one-year follow-up using Medicare claims and that there have been initiatives to add further in-person follow-up visits.

Dr. Eldrup-Jorgensen addressed questions raised by Mr. Conway concerning transparency issues. He explained that members in his organization are required to participate in biannual regional quality meetings to review data and discuss matters related to compliance. He highlighted the importance of patient input and provided details on a new experimental project aimed at collecting patient-reported outcomes through various means.

A discussion took place regarding longer-term follow-up. **Mr. Williams** confirmed that industry agrees with the proposal of looking at information over an extended period of 10 years.

Other topics discussed by the Panel included industry's responsibilities with respect to IFU compliance, information that can be obtained from device representatives, data entry agreements, and patient privacy.

FDA QUESTIONS

Chairperson Lange read Question 1: 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.

There was general consensus that there are still unanswered questions about the long-term safety of EVAR compared to open surgery, even though the newer devices are safer and more effective.

Dr. Shepard pointed out that there are now many vascular surgeons who are not comfortable or experienced with open surgical repair.

Edwin C. Gravereaux, M.D., emphasized the importance of long-term results. He pointed out that there is still a lot of uncertainty about what is happening in the anatomy.

Chairperson Lange noted that EVAR has a purpose and is here to stay. The longer-term benefits are not as good as the shorter-term benefits and the reintervention rate of 30% is widely acknowledged.

Bram Zuckerman, M.D., asked Dr. Starnes for his perspective on the impact of off-label use on the 10-year results. **Dr. Starnes** prognosticated that the long-term outcomes will be worse.

Chairperson Lange read Question 2a: 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. They include:

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

A straw poll taken by Chairperson Lange indicated almost unanimous agreement that the first four outcomes should be included.

Dr. Starnes commented that vital status, aortic rupture, and aortic reinterventions would be adequate data points for long-term outcomes.

Mr. Conway suggested the inclusion of patient survey information.

Jacqueline S. Alikhaani, B.A., Consumer Representative, proposed patient-reported outcomes, quality of life and lifestyle related issues, and outcomes from ethnically diverse studies.

Dr. Zuckerman asked Panel members if the three data points recommended by Dr. Starnes would be adequate or if more granularity is needed.

Dr. Woo stated that she would prefer a more highly detailed analysis of the outcomes that had been discussed.

Joaquin E. Cigarroa, M.D., emphasized that they would be insufficient for detecting signals of potential harm over a long period of time. He stressed the importance of increased granularity.

Dr. Gravereaux opined that the outcomes suggested by Dr. Starnes are easily obtainable and would be good measures for data collection that can be linked to registries.

Mr. Bryson read Question 2b: Although imaging outcomes are collected in premarket and FDA-required postmarket 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 capturing the following imaging outcomes in real-world surveillance:

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

There was general consensus that endoleaks, aortic enlargement, and patency are fairly easy to capture. **Matt J. Eagleton, M.D.,** commented that identifying loss of device integrity and migration are more problematic. **Dr. Khaja** recommended having cardiovascular imaging specialists involved who can perform center-line measurements and determine angular changes by comparing pre- and post-op imaging.

Dr. Eagleton pointed out that a single radiologist at a small community hospital may not be able to detect these issues as readily as an academic medical center.

Dr. Starnes advised collection of data that can be generalized and looking for sac regression instead of aortic enlargement.

A discussion took place regarding additional burden on patients, inconsistency in imaging types, and the need for centralized core labs. **Drs. Woo** and **Shepard** highlighted the difficulty in getting images on remote patients and of interpreting outside CT scan reports. **Robert W. Yeh, M.D.,** recommended a dedicated research study to generate the type of data that central labs would need for comprehensive follow up, and **Dr. Cigarroa** maintained that changing the industry and health systems, and identifying what can be done to improve imaging is achievable.

Chairperson Lange summarized the discussion:

- Imaging is important and there are two times when it should be done: (1) on an annual basis, and (2) whenever there is a reintervention.
- All of this data is available and should be analyzed to provide insight as to why

reinterventions occur.
- Trials for new devices should have adequate and regular imaging follow-up.
- Addressing these issues at a system level will require regular reporting and tracking of data.
- Participating VQI centers could be used as pilots in determining what can be done to improve imaging compliance.

Mr. Bryson read Question 3: Please discuss whether strengthening existing real-world surveillance is needed to evaluate long-term real-world EVAR performance.

Dr. Eagleton pointed out that the Panel had just discussed this topic and that the answer is yes, it is needed. No one disagreed.

Mr. Bryson read Question 3a: 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, and statistical analysis plans).

Dr. Eagleton asked if the new infrastructure will actually be "real-world" if it is only given to selected sites.

Jason T. Connor, Ph.D., opined that the key is obtaining appropriate sites that are representative, weighting them, and understanding the bias in what is being measured.

Dr. Yeh pointed out that the objective is completeness of data, baselines, and follow-up. He stressed the importance of having endpoints that are significant to patients, of making valid inferences that speak to study population bias and potential treatment selection bias, and of catching signals at the earliest possible time. He made the following recommendations:

- The system should not be too onerous for participating sites.
- It should not be too expensive nor should it be dependent on extensive volunteerism.
- It needs to be transparent and should not rely on a single organization or system.

He voiced doubts as to whether there is one real-world surveillance infrastructure that can accomplish all of these goals, and that the question is which ones are needed and how can they be accomplished.

Dr. Shepard stated that the infrastructure already exists in the VQI and that the VRC plan will be exceptional going forward.

Ms. Alikhaani emphasized the importance of ethnic diversity, collaboration with federally funded community health centers, and further participation in enrollment strategies.

Dr. Connor remarked that it would be a good idea to have multiple data collection sites. He also recommended long-term evaluation of open procedures.

Dr. Brindis observed that the VQI has most of the key attributes and that it is already

in operation.

Dr. Woo briefly discussed the reasons why it would be difficult to track or compare the outcomes of open surgery, and pointed out that the VQI could be criticized for not being generalizable.

Mr. Bryson read Question 3b: 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.

Chairperson Lange noted that 10 years had been proposed by FDA and asked if there were any dissenting opinions.

Dr. Starnes specified appropriate 30-day imaging followed by an interval of six months for patients with endoleaks and then annually out to 10 years. He further stated that lifelong surveillance is paramount, that annual imaging is part of the process, and that diligence is essential

Dr. Shepard opined that this would be clinically meaningful and would provide value for a better postmarket surveillance system, but that he does not believe it is doable.

Mr. Bryson read Question 3c: Please discuss strategies that can incentivize relevant stakeholders to participate in real-world data collection on a routine basis.

There was general discussion about data entry support for physicians and financial stimulation.

Dr. Brindis mentioned that the value of the data will breed continued enrollment and **Dr. Starnes** emphasized that as a busy clinician, he would want it to be easy.

Dr. Yeh opined that incentivizing long-term follow-up is probably not feasible and that the tiered approach is the right option.

Randall C. Starling, M.D., asserted that everyone who provides this therapy should have the incentive to support whatever needs to be done to ensure the highest quality.

James C. Blankenship, M.D., suggested the creation of a reimbursable CPT code.

Chairperson Lange summarized the Panel's recommendations:

- Ease of use.
- Showing value to organizations for quality and measures of performance.
- Having a tiered approach so that anyone can participate.
- Creating systems integration within organizations so that everyone can be involved.

Mr. Bryson read Question 3d: Please comment on how device manufacturers, healthcare systems, professional societies, individual providers, and other stakeholders should collaborate to maximize long-term follow-up compliance and data quality on EVAR device performance.

There was discussion regarding who would serve as a moderator to keep the different

entities aligned with acceptable priorities and strategies. **Mr. Conway** suggested having FDA continue in that role and also proposed the inclusion of patient stakeholder organizations. **Dr. Cigarroa** agreed with the suggestion of having FDA as the facilitator. **Ms. Alikhaani** articulated her support of a collaborative effort to address this issue.

FINAL COMMENTS

Ms. Alikhaani remarked that the discussions were very productive. She encouraged a more accelerated pace in dealing with these issues, expressed optimism about new and proactive approaches, and emphasized that patients, families, and caregivers are the top priority.

Gary J. Jarvis, B.S., Industry Representative, observed that everything is moving in the right direction and that with the involvement of all stakeholders, these goals can be achieved regardless of the expense and amount of time.

Mr. Conway thanked everyone who participated, noting that there are consensus points and a shared sense of urgency.

Chairperson Lange thanked the Panel, FDA, and all of the participants for their contributions to the meeting.

Dr. Zuckerman thanked Chairperson Lange for his leadership and expressed his appreciation to everyone who contributed to the two-day meeting.

ADJOURNMENT

Chairperson Lange then adjourned the meeting at 5:10 p.m.

I certify that I attended this meeting on November 3, 2021 and that these minutes accurately reflect what transpired.

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Akinola A. Awojope, Dr.PH, M.P.H
Designated Federal Officer

I approve the minutes of this meeting as recorded in this summary.

_____/S/_____
Richard A. Lange, M.D., M.B.A.
Chairperson

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