VISION CRN Meeting  
Thursday September 5, 2019  
White Oak Campus, Silver Spring, MD  

Translating Data into Action for Device Research and Surveillance  

Meeting Presentations  

VISION: Building CRN Infrastructure and Capacity  

Brief overview of VISION:  
  Phil Goodney welcomed attendees to the 2nd annual VISION meeting. The themes of the meeting included fostering and communicating ideas as well as sharing successes. He introduced the history and mission of the Vascular Quality Initiative (VQI) and their work in studying major vascular procedures and evaluating treatment successes in the short and long term.  

Comments:  
  Scott Berman commented that using commercial insurance data may help answer some important questions in addition to the current Medicare linkage work (at Duke University and Weill Cornell Medicine). The long-term plan is to include all datasets and payers. Danica Marinac-Dabic underlined that all payers are invited to move the field forward.  

Coordinated Registry Network Maturity:  
  Art Sedrakyan presented the role of the MDEpiNet Coordinating Center at Weill Cornell Medicine and its objectives towards Coordinated Registry Network (CRN) Maturity. Implementing Artificial Intelligence and deep/machine learning to support real world evidence methodologies is an important next focus in moving the data infrastructure forward.  
  Art Sedrakyan also briefly introduced the steps of CRN development, Delphi Process, and the importance of identifying core minimum datasets leading up to data nesting in HIVE. There are several pilot projects that have taken this process, with next steps in HIVE to democratize data sources. Linkage projects, developing objective performance criteria for devices, and the overall CRN development process was showcased within the VISION CRN model. VISION CRN has created a national repository of linked data sources to obtain long-term outcome data (e.g. VQI registry linked with Medicare claims), published a series of studies documenting the data quality within this collaboration, and have used it to support quality improvement and regulatory decision making. VISION CRN is advancing towards high maturity.  

Comments:  
  Danica Marinac-Dabic commented on the importance of recreating the system so data can be used by multiple stakeholders. Phil Goodney agreed and commented that VQI has been providing platforms for all collaborating units and more.  

What is in VISION-VQI Data? How can they help evaluate long-term device effectiveness and safety? Council Chair Presentations
Jens Jorgensen framed the data available in VISION-VQI data for real world evidence. Grace Wang (on behalf of Edith Tzeng and the Society for Vascular Surgery (SVS) Research Council) presented research council goals relevant to VISION CRN, which included engaging vascular surgeons and exploring additional methods. Many of the SVS Research Council’s priorities can be studied utilizing VQI-Medicare matched data and almost all involve device utilization. Andrew Hoel (Chair of VISION Abdominal Aortic Aneurysms (AAA) Council) on Peripheral Vascular Intervention presented key issues, which include continuous innovation in technology, technique, and patient selection for treatment of AAA as robust and clear data lags in this intervention.

Comments:

Art Sedrakyan commented how this highlights an opportunity to used linked data to advance the quality of care, cost, and value analyses. There are not many studies that highlight the value of linked data so this can be helpful for other networks and stakeholders to understand the greater societal value of sharing data. Phil Goodney says that VQI data starts in 2002 and is matched to Medicare claims at that date; the patient is followed forward in time so every year the data gets richer. Jens Jorgensen said that device data for Peripheral Vascular Interventions (PVI) started collection in fall 2016 and balloon data started in 2012. The FDA’s GUDID has incomplete data and missing information so it is important to collaborate with industry to help fill in data to track down missing information. More people who help support GUDID would be very helpful. Pablo Morales commented that the database can be refined for use to make regulatory decisions.

There is a digital extraction and digital trend analysis software that is designed for early detection (created by Fred Resnic at Lahey); Danny Bertges has a project to use this for paclitaxel. Danica Marinac-Dabic said that Data Extraction and Longitudinal Analysis (DELA) is open sourced and was developed using NLM/FDA funding; however, the important part is for stakeholders to come together to talk about data transparency and determine a democratized approached to look into signals by those who have access to the data, determine who needs to be at the table, and study how it affects MAUDE. VISION cannot act on this alone, so the Active Surveillance Task Force (through NESTcc) can be utilized to engage stakeholders.

Are there models where industry is inputting data into the registry for better device identification? Since 2011, this issue has been researched in orthopedics to understand what registries did globally and many established their own mini GUDID which were harmonized so the devices matched across countries.

Danny Bertges spoke about the goals to have long-term follow-up in data for PVI space. Individual device class comparison has become increasingly important and the future of device evaluation of the total product life cycle will help with registry post-market surveillance. Patient reported outcome (PRO) data is a blind spot in the registry which has not been implemented. Nicholas Osborne spoke about how the vein registry captures PRO and where a lot of the signals will be. Scott Berman spoke about how there are lot of patients who benefit from more aggressive treatments than people may be trained to do, so VISION is an improvement to assess
the quality part and deliver long term results for patients. There is a need to have validation measures in PRO so short and long term outcomes can be adequately measured.

Comments:
Art Sedrakyan said that many surgeons can participate in primary care clinician efforts through Medicare Access and CHIP Reauthorization Act (MACRA)/Merit-based Incentive Payment System (MIPS) but not through VQI so CMS needs to emphasize payment levels for participation in quality initiatives such as VQI.

Grace Wang on Thoracic Endovascular Aortic Repair (TEVAR) spoke about the VQI TEVAR surveillance project, which is to study the safety and efficacy of TEVAR in the treatment of Type B dissection and set up to evaluate real-world application of TEVAR as a surveillance project. TEVAR patients are not infrequently undergoing reinterventions and are highly resource-intensive, so studying this issue is challenging.

Comments:
Phil Goodney said that the goal is for data sources is to allow the committees to answer the questions they want and prioritize the appropriate variables. Art Sedrakyan said that there is existing infrastructure to share expertise and have wider committees to have folks collaborate.

Benjamin Brooke on Carotid Endarterectomy (CEA) and Carotid Artery Stenting (CAS) presented a patient case with left CEA with patch and discussed the procedures for patching. He discussed the questions which arise after CEA with patch, such as the durability of patch materials and incidence of complications. These are high risk patients, which raises the question of if they even benefit from any carotid interventions so this would be an important area to track readmission and other outcomes. Nicholas Osborne on Venous Interventions said that much of data is industry sponsored data or single-center series and administrative data fails to capture most variables important to venous disease.

FDA Update on Coordinated Registry Networks Maturity; PCOR Trust Fund
Danica Marinac-Dabic provided an update on PCORI funding, where Phase 1 is developing a strategic CRN for Women’s Health Technologies (WHT) and Phase 2 is the CAPSTONE project in bridging the PCOR and technological innovation through the CRN community of practice (COP). The CAPSTONE project advances CRN COP by implementing the following 7 attributes of CRN maturity: patient engagement, device identification, data quality, efficiency, governance, sustainability, fitness for use during total product life cycle. VISION and its priorities in utilizing the funding is one of the aspects of the framework that would be important to assess.

Comments:
Andrew Hoel emphasized that all aspects of the framework need prioritization and equal focus. It’s important to ensure data quality in terms of extraction, usage, accuracy and completeness. It is essential that there is proper training for the data team to achieve this. Michael Dalsing commented on patient engagement and how the information is being collected. The information is going to be collected in clinics and research settings, as well as by involving patients in meetings
when feasible with proper representation to get a direct input from their end. Benjamin Brooke commented that approaching caregivers can help get some information in this regard.

Art Sedrakyan commented that anything that’s developed through this effort can be applied to all CRNs (e.g. app for Patient reporting (FHIR can be connected to various vendors) can be utilized in VQI setting in entering data and collaborating in that environment). Danny Bertges noted that it would be important to elaborate on what has been done already in this area in terms of data collection. Danica Marinac-Dabic elaborated on the current efforts including the app that is being developed for Women’s Health Technologies CRN. Jens Jorgensen commented on the importance of harmonizing variables as well as public-private partnerships to develop common data elements, which has been achieved. As the project moves onto phase 2 and 3, the focus is to collaboratively move forward the effort towards maturity.

VISION Data Core – Expanding the Impact of CRN Datasets to Measure Quality and Cost

Jessica Simons on Research Aimed at Improving Quality and Cost of Vascular Care said that the scale is challenging as there are a lot of variables to consider and this will take time; however, as it is built, it should get better. Jens Jorgenson on feedback reports to VQI centers spoke about VQI data limitations, such as compliance issues (needs personnel, requires cost and effort), data is mostly 1 year follow-up (but ideal is total product life cycle), and there is no follow-up if seen at a non-VQI site, so VISION is the solution using claims linkage.

Comments:

Phil Goodney commented that feedback reports have traction and are disseminated to membership, which leads to behavior change.

Phil Goodney and Shipra Arya on feedback reports to industry said that this doesn’t exist yet but they are presenting this information to show a case study example. Monitoring high risk cases for reinterventions post-endovascular aneurysm repair (EVAR), over the long term after EVAR is not cost effective mainly due to re-intervention costs and impact on quality of life. Adherence to surveillance has mixed results in terms of survival and re-interventions. This demonstrates the need for better measurement and improvement overall.

Comments:

Michael Dalsing commented about EVAR cost, survival, and re-intervention report; there is a good idea of what happens at 5-year reintervention after EVAR and freedom from 5-year late mortality after EVAR. VQI data was linked to hospital data for cost and the differential costs across hospital was large, but what happens over the 5-year period is where larger costs would come in. For quality, where cost is the denominator, it is important to know the cost too. Nicholas Osborne said that what we consider cost is different (cost of EVAR, patient experience, cost of device) so acute costs may not have any signal. Diagnosis-related group payments may be different between teaching institutions and non-teaching institutions so it may be difficult to use data. As a result, it will be important include all-payment data (include acute and long term care data).

Case Studies: Maximizing VISION to Generate RWE for Device Evaluation - Novel Cases to Test VISION Fitness for Use for Regulatory Decision Making:
PAD/RAPID, Surveillance of Paclitaxel Coated Peripheral Devices, Review of SAP using VISION Data:

Daniel Bertges introduced RAPID and its mission to improve evaluation and total product life cycle that partners with a number of institutions in public-private partnerships (including industries). He introduced the possible use case of discernment of the paclitaxel mortality signal as well as the limitations of VQI PVR registry in terms of mortality of data and aligning with SSDI as data source. He shared three analyses which are planned with three comparators, drug, treatment vs none, and discussed the proposed variables for the study.

Comments:

Art Sedrakyan noted that this is a novel way to design the studies as most robust analyses can be done. With claims it isn’t possible so this allows analyses that can answer important questions. Misti Malone also noted that this showcases multiple methods to capture real world settings. This is a project that can move the effort forward in terms of value. One aspect of RAPID that can be underlined is how this project can be a learning process for other CRNs. Misti Malone would be open to discussing how FDA can support without getting in the way of such effort. Jennifer Brown agrees that this important effort brings the FDA, industry and institutions together to discuss the signals. Despite previous challenges in signals, having stakeholders at the table to discuss the possibility has been a good experience from an industry perspective and can be used as a model going forward for other projects.

Brian Nolan brought up questions to address VQI’s process in data analysis and wanted to know how to prevent counting patients twice in terms of procedures and others, noting that it’s especially difficult from claims perspective. He emphasized the challenges of patients who have already been exposed raises the question of increased mortality risk, which is important to underline for future trials and analysis. Others agreed that this is important to look into and helpful to know if there are double exposures and how to analyze such cases. Danny Bertges shared that RAPID is round table collaborative effort and has leadership representation from all spaces so this model is important to apply in other efforts.

Trans Carotid Artery Revascularization (TCAR):

Brian Nolan shared his project on TCAR outcome analysis. He discussed the use, growth, and short-term outcomes of TCAR; outlines the need for long term outcome evaluation of carotid stenting, for stroke risk, stent fracture, and other potential adverse outcomes; highlights the advantages of claims-based surveillance mechanisms to accomplish these goals. There are still questions to be answered in terms of long-term neurologic outcomes of TCAR, medical outcomes of high risk TCAR patients, as well as associated readmissions, stent durability, associated reinterventions.

Comments:

This is a good opportunity for VISION to help propose questions. Kenneth Cavanaugh underlines that the use of common data elements is a better approach. Jens Jorgensen commented that data audit and integrity are important to focus on.
Impact of Gender on Quality and Durability of EVAR: Expanding the impact of an FDA initiative:

Niveditta Ramkumar elaborated on her study on gender evaluations in EVAR procedures that uses VQI Medicare linked data with both men and women in the cohort. The anatomy varies in genders with AAA diameters between being significantly different in the two. She highlights the fact that the procedure is more difficult to perform on women and there are more deaths in women during procedures compared to men. Niveditta Ramkumar also discussed the limitations in the study in terms of match rate, administrative data errors, and clinical information on outcomes. It is important to highlight the risks in women and study ways to improve the procedures that can have huge impact in women.

Comments:

This represented 5-year data, but in a few years (with 10-year data), we will have acquired more data and can project better. There are fewer female subjects, which may be attributed to the selection criteria in randomized control trials studies. This is an important study to focus the growing need and interest in EVARs in women as there are gaps which exist

NESTcc Test Case: Gore Excluder Iliac Branch Endoprosthesis

Sreekanth Vemulapalli spoke about the NESTcc test case which attempts to combine EHR data with existing registry infrastructure (VQI) to expand the utility of VQI for devices/uses not addressed by current modules/data capture.

Comments:

This project is taking longer than expected, but the results will be very fruitful. Having targeted efforts will be important to identify hot spots and problems. This is an incremental process and there is a potential way to identify a larger cohort and extract additional patients for the cohort as well as the ability to develop OPC/OPGs. Manufacturers want to take action before FDA takes regulatory actions so it is relevant for both new technologies and multi-generational devices and is important for research and development.

Priority Setting: What will be next for VISION’s sustainability?

Phil Goodney summarized some of the discussions from the meeting and said there was a clear group interest in long-term outcomes, a need for clear interoperability in data points, and the importance of sharing plans with relevant stakeholder and regulatory groups. Specific areas of interest include: PROs, device specific investigations, and the role of gender. Lower priorities include venous work (PROs, gender, sample size) and developing alternative payment models using claims data (for example, for PVI and open/lower extremities intervention: 90 days after intervention, 50% of patients require readmission or intervention but it is unknown if this is due to device failure or patient characteristics) as an important use case for VQI data to determine patient characteristics for bundled payments. Additionally, there is interest in paclitaxel, outcomes in high risk individuals (e.g. disparity populations), machine learning, and getting imaging into VISION.