VISION CRN 2020 Meeting: What we've done, and what lies ahead
Wednesday, September 2, 2020
Meeting Minutes

Session 1 – VISION Impact from the Past Year
Moderator: Philip Goodney, Dartmouth-Hitchcock

Philip Goodney opened with an introductory speech, mentioning the origins of Vascular Quality Initiative (VQI) and VISION. VQI was launched by the Society for Vascular Surgery (SVS) in 2011 and continues to grow with an additional 8,000 procedures per month. The VQI VISION Coordinated Registry Network (CRN) allows for comparisons of device types and treatment methods in the short and long term. The CRN consists of low cost but high-quality data for generalizable research. Art Sedrakyan also led with an opening statement on the meeting and community.

Gender Differences: Niveditta Ramkumar, Dartmouth-Hitchcock

Niveditta Ramkumar spoke about gender differences. Since women are often underrepresented in randomized control trials, there is a large disparity in their appearance in trials versus amount of surgery they receive. In the OVER trial on aneurism repair, less than 1% of the study participants were women, and the majority of deaths were women receiving EVAR (endovascular aortic repair). VISION data consisting of VQI data linked to Medicare claims were used to determine long term outcomes. Overall, women were typically sicker and less likely to receive newer devices. Limitations in the study included laterality of outcomes, racial diversity (approx. 10-15% of patients were minorities as compared to 30% industry standard), and missing data.

Danica Marinac-Dabic provided the commentary. She spoke on championing women's health. VISION is the most mature CRN due to the implementation of unique device identifiers (UDI), implementation of the RAPID minimum core data set, and linked registry data with Centers for Medicare and Medicaid Services (CMS) and plans to add private health insurance data. VISION also plays a prominent role internationally. VISION is the first CRN piloting blockchain technology. Danica highlighted two initiatives. First, the Food and Drug Administration's Center for Devices and Radiological Health (FDA CDRH) has been focusing on important issues specific to women's health by harmonizing data between various registries and sources. Secondly, the CDRH has created the Health of Women Program, focusing on analysis of sex and gender analysis. This has formed an integrated approach for current and emerging issues as a research roadmap. Danica also described future goals for gender outcomes studies.

Long-Term Surveillance After EVAR – Philip Goodney, Dartmouth-Hitchcock

Philip Goodney spoke on behalf of Jesse Columbo on long term surveillance after EVAR. Following-up with imaging after EVAR is important and recommended every 12 months. However, many patients don't undergo recommended surveillance. Marrying VQI data and Medicare data is key to determining follow up rates. In terms of findings, 1/3 patients needed

reintervention after 10 years, and chances of late rupture were about 5%. The association between reintervention and late rupture needs further study. Overall, reintervention is costly, and we are unsure of its effectiveness.

Scott Williams provided the commentary, speaking on the importance of devices from the patient side. He affirmed the importance of follow up and intervention if necessary. Some patients range in age, and therefore have varying follow up procedures. Overall, active surveillance is essential.

VQI Center Specific Survival Reintervention and Surveillance (SRS) Reports – Philip Goodney, Dartmouth-Hitchcock

He gave a brief overview of the center-specific report format and what each report includes (5-year freedom from death, reintervention and imaging surveillance failure). The reports were disseminated to all sites with sufficient matched data (per CMS suppression requirements), with goals to reach all 800 sites in the future.

Jens Jorgenson provided the commentary. EVAR is neither permanent nor durable, and therefore requires ongoing surveillance. Endovascular Abdominal Aortic Aneurysm (AAA) repair is an important alternative to open repair, as ruptures have incredibly high mortality rates. Jens noted that the importance of the reports was quality assurance and quality improvement. The reports compare a given center to an overall benchmark figure. The benchmark, while not the standard of care, is composed of data from the community.

Discussion pertaining to Session 1:

- Danny Bertges: what implications do the data have for public health particularly for our most common open procedures? Were you able to tease out the etiology of late strokes?
    - Niveditta Ramkumar: We were unable to distinguish stroke etiology using Medicare claims for the 2015 dataset
- Andrew Hoel: So what is next? What do you think you will find with comparison within gender, i.e. women with and without adverse outcomes? Do you think you can make new observations with an exposure variable other than gender?
    - Niveditta Ramkumar: Within-sex comparison is the next step to really assess the causality of different treatments and their outcomes by sex.
- Jens Jorgensen – Any thoughts on why women are underrepresented in randomized control trials? Or how to address this issue?
    - Niveditta Ramkumar: The prevalence of some of these vascular conditions is lower in women, making them harder to recruit. Perhaps one way to increase that consideration is using pragmatic trials to really leverage real-world data.
- Peter Henke – Was the periprocedural mortality higher for women with EVAR compared with open repair?
    - Niveditta Ramkumar: Periprocedural mortality was lower in EVAR but only until about 6 months post-procedure.

- Daniel Bertges – How can the reintervention be the same? That doesn't seem plausible when you consider initial device cost, or are we incorrect assuming an embolization is cheap?
    - Art Sedrakyan: It would probably be good to do focused economic analyses.
- Peter Henke – Are you able to determine if those undergoing reintervention were mostly off IFU?
    - Philip Goodney: The IFU variable is not available in VQI yet. This has been previously discussed, but it is difficult to get this right.
- Gary Lemmon – Can VISION parse out reintervention between device failure versus incomplete aneurysm treatment by device?
    - Philip Goodney: This is a great question about extent of treatment. The data is not this granular yet, but endoleak (a variable present in the registry) could provide some insight into this.
- Andrew Hoel commented that multiple RCT's included a high proportion of VA patients. This was a criticism of the paper, but he thinks the original response is still valid: the study site dose does not absolve the study of responsibility to accurately reflect the population.

Session 2 – VISION Project Summaries from Investigators with Ongoing Projects

Moderator: Philip Goodney, Dartmouth-Hitchcock

Outcomes of Paciltaxel coated devices vs. non-drug – Daniel Bertges, University of Vermont Medical Center

Daniel Bertges spoke on outcomes of Paclitaxel coated devices vs. non-drug coated devices. He summarized analysis assessing the mortality and reintervention rates after paclitaxel treatment in VISION. Daniel reviewed the exclusion criteria used, the crosswalk between the identification of devices in the Peripheral Vascular Intervention (PVI) dataset and Medicare claims, the comparators between balloon vs. balloon, stent vs. stent, and paclitaxel and non-paclitaxel. The outcomes were mortality, major amputation, and reintervention. He also reviewed methods to help address some of the biases that could occur within the data (i.e. misclassification bias). Outcomes were measured at 6 months and 1 year. Findings revealed mortality, major amputation, and reintervention saw a benefit for paclitaxel-coated devices (unadjusted). There was a 10% increase in survival and 10% decrease in reintervention. The 4 different methods produced similar results throughout which is reassuring. In conclusion, there was no increase in mortality, and a benefit in reduced reintervention for paclitaxel coated devices.

Misti Malone provided the commentary, elaborating that these findings demonstrate the capability to quickly respond to the signals that are identified. The FDA is interested in utilizing this data for early signal detection and assessing the signal. The FDA appreciates the transparency and the methods used to attempt to account for biases. She posed a question regarding the inclusion of disease severity in the analysis and added additional commentary regarding the

discussion of the limitations of randomized control trials (RCT), FDA/RAPID. There is a planned future publication discussing RCT limitations.

EVAR conversion events - Salvatore Scali, University of Florida, Gainesville

Salvatore Scali spoke on EVAR conversion events. The review study focused on international trends of EVAR – intact vs. ruptured. VQI has added a significant proportion of cases within the International Consortium of Vascular Registries in recent years. The findings in a literature review revealed late failure in EVAR is not insignificant and rupture risk increases over time. EVAR conversion is increasingly being reported, showing a knowledge gap: the frequency of EVAR conversion nationally is largely unknown and the natural history of EVAR and conversion are unknown. The purpose of this study was to determine rates of open conversions after EVAR in VQI, examine temporal trends and geographic variation, and identify predictors and examine outcomes of EVAR. Conversion and non-conversion groups were very similar other than in sex. A higher proportion of conversion events occur in the later events, regional variation is present, and graft differences are present. Non-elective EVAR is correlated with higher likelihood that the patient undergoes a conversion as compared to elective EVAR. Next steps include assessing complications related to EVAR conversion, identify predictors, and performing a survival analysis of EVAR conversion.

Brian Pullin and Carmen Gacchina Johnson provided the commentary, emphasizing the importance of this type of infrastructure and study.

Comparison of event calculation with and without claims-based follow-up - Livia de Guerre, Beth Israel Deaconess

Livia de Guerre spoke on comparison of event calculation with and without claims-based follow-up. This work utilized VQI and Medicare data. She reviewed how mortality rates were calculated in the VQI and Medicare data, assessing follow-up until 2016. She also assessed mortality status in VQI: 100% of patients alive in VQI data were also alive in Medicare. When only using the VQI death variable, a third of potential deaths would be missed. In comparing the exact follow-up data of those who were marked as dead in both VQI and Medicare, research showed 2.8% had a VQI death event, while 2.7% had a Medicare death date before VQI. The absolute numbers with discrepancies are very low between VQI and Medicare. As a whole, findings suggest that if only VQI data were used, one third of potential deaths would be missed. Additionally, this would result in low false negative rates, but low sensitivity and patients need to be adequately censored for accurate death analyses. With only Medicare death data, an additional 50% of death would be captured, causing low false negative rates.

Jacqueline Major provided the commentary, clarifying that not all patients can be linked to Medicare, and generation metrics and analysis is needed to ensure that the data quality remains high and misinterpretation or inaccurate findings do not occur. It is important to understand the limitations of the data, reconcile these limitations, and validate outcomes when possible. Transparency and collaborations are needed to help navigate data quality considerations.

VISION Value-Driven Sustainability

Moderator: Art Sedrakyan, Weill Cornell Medicine

Art Sedrakyan provided an overview of MDEpiNet offerings, including the organizational structure, coordinating center services, various coordinated registry networks and the High-performance Integrated Virtual Environment (HIVE) for secure data hosting. MDEpiNet has been thinking about a maturity model for partners to build better systems. Domains include: device identification; patient reported outcomes and patient engagement; data quality; efficiency; governance and sustainability; healthcare quality improvement; total product lifecycle.

Disparities in diffusion of endovascular devices – Philip Goodney, Dartmouth-Hitchcock (VQI) / Shipra Arya, Stanford
This is an R01 proposal to examine disparities associated with device use in EVAR. The goal is to examine factors contributing to these disparities using long-term data elements in VISION.

Use of post-acute care and frailty – Shipra Arya, Stanford/ Philip Goodney, Dartmouth-Hitchcock (VQI)
This is a proposal aimed at understanding the feasibility of studying post-acute care use and frailty, with an interest in what happens to patients after discharge as there are differences in long-term mortality between those who are discharged to home and non-home. Surgeons are seeing a boom in older patients and there has been an endovascular technology boom for the treatment of older and sicker patients. The aim is to use the VQI-Medicare linkage to understand what happens after surgery, such as determinants and variation in post-acute care use.

Outcomes of dialysis access procedures – Karen Woo, UCLA
This is an RO1 proposal that focuses on vascular dialysis decision making. The US set utilization guidelines for fistula first and catheter last. In 2019, the guidelines were revised and moved to a patient-centered individualized plan. The objective of the RO1 proposal is to build a personalized decision-making tool.

Using registry-claims linkages for randomized trial long-term follow up, including in VA population – Alik Farber, Boston Medical Center
This is an R01 proposal to use real world data to complete a National Heart, Lung, and Blood Institute trial for best endovascular vs. best surgical therapy in patients with clinical limb ischemia (BEST-CLI) looking at clinical, quality, and cost outcomes. The plan is to link data from the BEST-CLI trial to participants' real world data (e.g. Medicare, VA and insurance claims). One of the aims is to use this real-world data for long-term follow-up of RCT patients after trial completion.

NOSI-120, COVID-19 Testing – Salvatore Scali, University of Florida, Gainesville
The project is collaborating with MDEpiNet, FDA (SHIELD data harmonization infrastructure), and VQI but will not be using claims data. This is a special emergency supplemental funding opportunity to understand and scale up testing for COVID-19 among vulnerable patient populations. There will be 5 pilot sites.

VISION and VQI: Potential Future Opportunities – Jack Cronenwett, Dartmouth-Hitchcock (VQI)
The VISION CRN is a success story that demonstrates the value of CRNs for merging granular clinical data from a registry and late outcomes from Medicare claims. There is substantially lower cost than in-person follow-up with data entry through the use of Medicare claims data. There are potential opportunities to include additional data sources (e.g. long-term outcomes for non-Medicare patients, patient reported outcomes, data extraction from electronic health records (EHRs), Veterans Affairs (VA) data, clinical trial data). Another opportunity is to broaden the vascular device types being evaluated and expand the use of VISION combined clinical-claims data. This requires stable funding for sustainability and increased funding for expansion.

Art Sedrakyan highlighted one project that was not covered today was the collaboration between NEST and VISION to collect data from EHRs that may be relevant for regulatory science.

Greggory Papas provided the commentary. Jack Cronenwett has authored a paper that calculated the return on investment and time saved by using the VQI instead of traditional data for collecting follow-up. Jack Cronenwett, Danica Marinac-Dabic, and Greggory Papas provided a review to the team at the Center for Biologics Evaluation and Research (CBER) about VISION and the work of the VQI, as CBER has the first candidate for biological product for use by vascular surgeons. The hope is that this discussion will move forward and work with the VQI.

Breakout Sessions

Breakout Session 1: Developing Technologic Solution and Future Directions for VISION
Moderator: Danica Marinac-Dabic, FDA

Integration with PROs: Michelle Tarver, FDA

They are striving for the timely integration of Patient-Generated Health Data (PGHD) into existing registry infrastructure, as standardization and consensus on definitions is needed for the pooling of data and seamless integration. In terms of PROs, it is known that complementary information is collected by patient-generated datasets and registries. However, reciprocity is needed as sharing of the data can help all groups advance their efforts. It is important to determine what outcomes are important to regulatory, clinical, and patient-shared decision making.

Linkages to under-65 data: Jesse Columbo, Dartmouth-Hitchcock

The practical next steps needed to move forward with the linkages include: 1) taking into account the motivation and incentive of the private payer to participate, as the more groups that are behind the ask the more likely it is to happen with a pilot project; 2) providing leverage, incentive, and pressure to share this data, leveraging existing efforts (such as Sentinel) to apply in the device world and link with registries. In terms of the expansion with VISION, they are leverage existing efforts to scale the linkages to private health insurance data – including those under the age of 65 (state claims or leveraging Sentinel that are working directly with payers). This gives

disconnected data sources of insurers. The current work is to address challenges such as the time lag in between the release of the data and incorporating UDI.

NESTcc Partnerships: Sandi Siami, NESTcc

This presentation highlighted the value of leveraging MDEpiNet and the VISION data to not only get a snapshot of a procedure but also be able to follow the patient longitudinally, as this is necessary for active surveillance and more robust data. NEST is working on how to link data and integrate UDI. It is important to ensure that MDEpiNet future contributions to NEST are maximized, including aiding in the access to additional claims data, accessing the data available to MDEpiNet to help answer research questions, and aiding in international collaborations.

Potential for expansion to other medical products (e.g. biologics): Jack Cronenwett, Dartmouth-Hitchcock

MDEpiNet is strengthening the CRN data architecture by (1) implementing state of the art block-chain framework to provide provenance and to support consent-based contractual agreements for traceable and auditable data and by (2) developing the infrastructure to advance the application of artificial intelligence/machine learning methodologies. To this end, MDEpiNet had launched its multi-stakeholder BAIT Task Force (Blockchain and Artificial Intelligence Task Force) as one of the steps to diversify the input. It is important to consider approaches to achieve proper balance between novel technological, clinical and partnership approaches to prepare MDEpiNet for the tasks ahead.

Breakout Session 2: Operationalizing your research plan
Moderator: Andrew Hoel, Northwestern

How do I work with VISION Data from Start to Finish: Kayla Moore, Dartmouth-Hitchcock and Jialin Mao, Weill Cornell Medicine

Kayla Moore presented a brief overview of the process for obtaining access to VISION data. She highlighted the special nature of working with VISION data given the Medicare + registry components; reviewed the Medicare-derived late-outcomes variables; the rules governing CMS DUAs; and the additional screening done by the VISION Priorities Committee prior to moving a project to the "on-deck" list for analyses. She emphasized that projects must be device-specific in order to fit with the scope of the MDEpiNet DUA, have a clear need for Medicare claims, and be feasible. The VQI VISION page contains helpful information for investigators wishing to use VISION data (https://www.vqi.org/data-analysis/blinded-datasets/).

Jialin Mao, then provided insight on what makes a project successful from the perspective of the analytic team. Investigators are asked to complete a full research memorandum, and then meet with the analytic team to ensure the research question can be asked with the available data. Prior to starting their project, investigators are encouraged to consider: potential sample size limitations, the CMS claims data lags two years behind, what the inclusion/exclusion criteria is,

what are the important covariates, and preliminary thoughts on statistical analyses. Any publications describing similar studies are helpful to pass along to the analytic team as reference, as are definitions of variables from the VQI, and specific outcomes you are looking for in the claims. The team will work with you to refine the analytic plan based on the data and information you provide.

Prioritization of Research Projects: Andrew Hoel, Northwestern Medicine

Dr. Hoel summarized the additional vetting which projects undergo after receiving approval from the VQI Research Advisory Council to ensure the projects are a fit for VISION data. Specifically, Dr. Hoel engages in direct conversation with investigators to ensure the needed variables are in the Medicare derived datasets, that the research question cannot be addressed with VQI-data alone, and that the project has a device-specific component. He also works to streamline the work by identifying opportunities for potential collaboration.

Prioritization of research projects: What is FDA's Perspective? Carmen Gacchina Johnson, FDA

Dr. Gacchina Johnson recapped the mission of the CDRH to protect and promote health and ensure access to safe and effective medical devices, provide consumers with science-based information about products, and advance regulatory science. FDA uses RWD to monitor post-market safety and adverse events and to make regulatory decisions. The 21st Century Cures Act passed in 2016, places additional focus on the use of these types of data to support regulatory decision-making. The projects that are of most interest to the FDA are those that address safety signals, are intended to support regulatory decision-making, enhance the RWE eco-system (validation studies), and improving understanding of the effectiveness of devices. The Office of Cardiovascular Devices has a mechanism, known as the Q-Submission Pathway that investigators can use to get FDA feedback on proposals.

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Breakout Session 3: Regulatory Science, Stakeholders, and Policy
Moderator: Misti Malone, PhD, MS, FDA

Mahmoud Malas, Industry representatives Scott Williams from Cook, Roberta Bloss and Keely Scamperle from Gore, and Tiessa Simoes from Medtronic participated in a discussion on the potential for VISION data to be used for regulatory decision making. Dr. Bertges also shared the example from RAPID highlighting the device evaluations that have been performed with VISION data. Dr. Goodney also shared the update from an industry-MDEpiNet project, EDUCATE, to assess the feasibility of linking claims data with data from pre-market clinical trials. Overall, the discussion revealed that VISION provides several examples of real world evidence use, but the precise nature for how the data will be used for regulatory science is still in the nascent phase.

Breakout Session 4: VISION Next Steps for Priority Areas in Disparities and Expansion of Indications
Moderator: Shipra Arya, Stanford

The Role of Gender in Device Use: Shipra Arya, Stanford

Shipra Arya presented that women have a much higher disease burden as they grow older according to peripheral artery disease and gender specific risk factors include higher inflammatory markers. Women also have higher mortality rates and also have lower use of EVAR devices, which is the current focus of the grant. Current device trial reporting has minimal reporting of outcomes by gender, however that fact will be changing in the future.

Ted Heise added that additional factors for enrolling women can be anatomical differences due to thinner vein size, in elderly women in particular.

Venous Linkages and Development – Nicholas Osbourne, University of Michigan

Nicholas Osborne stated that there exist many unanswered questions centered around venous disease and its treatments. There are several venous disease registries, including: Varicose vein registry (~40,000 cases), Inferior Vena Cava (IVC) filter registry (~15,00 cases), and the Venous stenting registry (currently starting up). Data limitations include lack of long-term data, lack of a control group, and lack of minority recruitment in existing randomized control trials. Additionally, CMS data lacks granularity. The VQI offers large cohorts of patients treated for venous insufficiency but is struggling with long-term data. There is a need for data comparing device types and treatment types. To create synergy, possible data sources include New York State Data – SPARCS, California patient data, and possible private payers (i.e. United Healthcare).

Leila Mureebe stated that Illinois has a similar data set compared to the New York data set and combining it with New York and California could give a large portion of the population. Illinois data was quite well organized and free. Shipra Arya commented that it is important to consider what the FDA could do to help with their role of working with devices pre-deployment.

Veterans Affairs: Opportunities for Collaborations – Emily Spangler, University of Alabama, Birmingham VA Medical Center and Leila Mureebe, Duke, Durham VA Medical Center

Emily Spangler's presentation commented about how vascular disease is prevalent with the VA population. Data tends to be free text forms and not standardized data fields but can be strengthened by linkage to systems such as VISION. The VA has a national device surveillance program and is hoping to implement structure of VQI fields in day-to-day operations for the VA. The data environment is rich enough to perform population-based research as opposed to procedural based work.

COVID Collaboration – Max Wohlauer, University of Colorado

Max Wohlauer looked at impact of COVID-19 on vascular disease broken into 5 different modules. They used the Aortic module as a base for the other 4 modules in order to ensure common data elements amongst modules. This allowed for analysis that VQI is unable to do. Dr. Wohlauer led the breakout room through an example displaying survey and fields of information collected.

Shipra Arya asked about the challenges of linking between the data on COVID-19 and VQI. Max Wohlauer said that it is the same challenges as integrating any large database, such as buy-in and participation.

Report Back

Breakout 1: Laura Gressler reported the main highlights of the discussion were patient reported outcomes, linkage of data, NESTcc and expansion of VISION. There needs to be standardization and consensus of definitions as well as the importance of patient reported outcomes (PROs) as complementary data to registry, and reciprocity is needed. They discussed the incentives for private payers to provide data for those under 65 and take into account existing data such as from SENTINEL who work with payers as complementary data sources as well as including UDI. MDEpiNet and VQI data is valuable to answer important research questions, aid in active surveillance, and international collaborations that are of use to NEST. Danica Marinac-Dabic discussed the balance between technological advancements providing complementary support to clinical and partnerships efforts and ensuring that there is multi-stakeholder input.

Breakout 2: Andrew Hoel recapped the discussion about prioritization and execution of research projects with a focus on the analytic bandwidth and current list of projects. There are multiple opportunities to expand access to data. Kayla Moore and Jialin Mao outlined the steps for the development and execution of an analytic plan and the importance of communication for developing a suitable plan for data. Dr. Carmen Gacchina Johnson shared the perspective of the FDA with respect to research priorities, which focus on safety signals and early detection, promotion of public health and regulatory decision making. She discussed both overlap and differences between FDA and investigators' priorities, acknowledging the importance of different viewpoints. They also discussed future opportunities for expanding access to data.

Breakout 3: Misti Malone spoke about how both FDA and Industry value linkages to understand long-term outcomes, and how these collaborations may offer opportunities for more affordable, quicker trials. There is value in validating clinical trial data in a real world patient population, strengthening clinical decisions, generating metrics for healthcare delivery to understand payment, quality, and patient experience which is important for understanding the total product lifecycle. There is also an opportunity to improve long term data and maintain an open discussion about the need of IRBs and informed consent, understanding missing information in registries, and affirmed that there is interest in embedding trials in the future.

Breakout 4: Shipra Arya spoke about the discussion of disparities in gender and minority groups and differences in outcome and emphasized the importance of VISION to be involved early-on with sampling and enrollment of trials. She also spoke about venous disease and work by other registries which have been ongoing; these registries have been instrumental in collecting PROs. There is opportunity for improved collection of PROs across all procedural datasets. It is important to combine the procedural data along with the patient data to understand the patient lifecycle and make it more patient-centric. This is important for leveraging head-to-head comparisons and linkages to state and payer databases to understand outcomes for those under 65. There is also an opportunity to link VA data and pick use-cases that are of interest to the VA/FDA/SVS PSO, such as community care of complex device use for veterans and tracking device outcomes across different healthcare systems. There is also opportunity through linkages of the data from COVID collaborative to VQI.

Art Sedrakyan summarized that there is a need to emphasize value for stakeholders and having more sustainable efforts, such as enhancing data linkages further as a strategic priority. State data linkages are making progress but there also needs to be stronger demonstration projects with EHRs to cover some gaps

that real world evidence could provide. In both the regulatory and manufacturing communities, there are certain limitations of real world evidence so more needs to be done to address these issues and enhance the quality of the data. Another important issue is the inclusion of UDI for active surveillance and evaluative studies. MDEpiNet recently launched a patient-facing mobile app that enhances coordination between patient reported data entry and clinical data entry, with plans to showcase the app to the VISION community to see if there can be greater application. In terms of collaboration with manufacturers, the ability to obtain longer-term follow-up can enhance value and make research more efficient.

Philip Goodney summarized three main messages: 1) improve data through linkages for those under 65, to the VA, and patient reported data; 2) disseminate data using new technologies and share data through SENTINEL, blockchain or improving the current capacity; 3) interact with stakeholders to understand how to use data successfully.

Please visit mdepinet.net to learn more about the capacities of the MDEpiNet coordinating center and resources available. Please email Art Sedrakyan (ars2013@med.cornell.edu) about any questions you may have about leveraging MDEpiNet resources.