ICVR Meeting Summary

Thursday 18.5.2017 Helsinki University Hospital Tower Hospital 15th floor

Attendees: Martin Björck, Jack Cronenwett, Daniel Bertges, Larry Kraiss, Mike Clark, Gabor Menyhei, Kevin Mani, Art Sedrakyan, Georg Heller, Adam Beck, Nikolaj Eldrup, Martin Altreuther, Christian Behrendt, Sebastian Debus, Cristina Isaia, Zoltan Szeberin, Gerold Labek, Maarit Venermo, plus Danica Marinac-Dabic (by teleconf).

1. Discussion of Potential New Projects

A. AAA: analyze variation in threshold diameter for elective repair, including center volume and economic influences. Currently, data are available from Sweden, Hungary and UK. Denmark, Finland, Norway and Germany have agreed to provide the required data by August 15. Project leads TBD.

B. AAA: compare in-hospital mortality of open vs EVAR treatment of ruptured AAA using 2010-2016 data, comparing trends over time and differences in men/women. In light of the recent publication by Vascunet on this topic using 2010-2013 data, it was agreed to wait until all 2016 data are available before re-doing and expanding this project to include VQI data. This is estimated to be able to start late 2017 or early 2018. Project Leads: Drs. Beck and Mani

C. AAA: analyze effect of center volume on outcome for open and EVAR treatment of elective and ruptured and all AAA using 2010-2013 Vascunet plus VQI data. It was agreed that Cornell would work with Drs. Mani and Beck (Project Leads) to analyze Vascunet and VQI data for those years.

D: Carotid: analyze variation of interval from symptoms to treatment across countries. Time from symptoms to treatment is currently collected in UK, Sweden, Germany, Finland, Denmark, Hungary and VQI. It was agreed that this project would await collection of 2016 data in Vascunet so that years 2011-2017 could be used. Key outcome would be 30-day stroke/death, with covariate analysis of anesthesia, center volume and changes over time based on new recommendations for more rapid treatment. This is estimated to be able to start late 2018 or early 2019. Project leads: Dr. Venermo plus TBD.

E. Carotid: analyze effect of center volume on outcome of CEA and CAS, which would be possible to do already from the existing data. Project leads TBD.

F. Transfusion threshold: analyze the variation in transfusion rate across ICVR countries based on blood loss and Hb level. This was viewed as a valuable project. Additional details will need be presented in November, including availability of data elements in various registries. Project Leads: Dr. Eldrup plus TBD.

2. Periodic Objective Performance Goal Publications

The idea of an annual publication of "State of the art" or objective performance criteria, alternating between AAA, carotid and PAD was thought to be valuable. Each area would then be updated every 3 years, and would provide an international standard using real world evidence for expected outcome of major vascular procedures. The first analysis will be for AAA in 2017, carotid in 2018, and PAD in 2019. Project leads TBD.

4. Risk Factor Harmonization across Registries

The group agreed to recommend 3 levels of detail for risk factor variables to be harmonized across registries: 1-basic data, 2- intermediate, 3-very detailed data. Dr. Eldrup presented recommendations for the risk factors and these were discussed and agreed upon. All registries are encouraged to adopt these standards, as attached.

5. PAD Projects

A. A Delphi survey to select core data elements for registries. Dr. Behrendt presented the results of the 4th Delphi round, and discussion focused on variables for which consensus about inclusion had not been reached by the final round of the survey. After discussion, it was agreed that these variables would be recommended for "potential" inclusion in registries, for those that could consider a more complete dataset, analogous to Levels of detail in the core variables. The final set of PAD recommended variables will be harmonized with the RAPID project recommendations and with the risk factor harmonization across registries (see also topic 4) and distributed by Dr. Behrendt. The writing committee (Dr. Behrendt, Betges, Debus) will develop a manuscript draft before the next meeting.

B. International Variations in PAD Treatment Project (InVASC PAOD)**.** The aim of this study is to compare international practice patterns for the revascularization of intermittent claudication and critical limb ischemia across several countries using the VQI and VASCUNET registries and available claims data Dr. Behrendt sent a short questionnaire prior to the meeting to get an overview on already existing registry data and claims considering this topic, and all members are urged t0 complete this. The study team of Drs. Behrendt, Bertges, Sigvant and Debus will reach out for data before the next meeting.

6. International Medical Device Regulators Forum (IMDRF)

A. European Device Regulations

Dr. Gerold Labek, Director Clinical Market Surveillance for the TÜV SÜD Product Service GmbH presented information about new European device regulations (slides attached). Highlights included:

- In the EU, registries are increasing in importance for device evaluation, as noted in Medical Device Regulation (MDR; published May 2017) and guidance document for clinical evaluation and assessment for manufacturers and Notified Bodies (MEDDEV 2.7.1. rev 4; published June 2016).
- A key incentive for manufacturers to finance clinical studies is for generation of clinical data for market approval and post market surveillance in order to fulfill regulatory requirements.
- Requirements in EU and US now include:
    - Formal introduction of registries as new data source to be considered.
    - New requirements which can hardly be fulfilled without registry data, like life cycle monitoring or identification of previously unknown risk.

B. IMDRF Update

Dr. Marinac-Dabic presented the essential principles in the use of international medical device registry data, and emphasized the importance of registry data for world-wide device evaluation (slides attached). She indicated that the IMDRF will consider supporting a pilot project proposed by ICVR to study EVAR device performance for treating ruptured AAA, which could potentially lead to inclusion of rAAA treatment in indications for use of EVAR devices, which are currently being used off-label in all countries (see below). A meeting to discuss this further was planned for the SVS VAM meeting in San Diego in early June, and will be presented to the IMDRF in mid-June.

7. Prospective AAA Project (IPAP)

A summary of prior discussions was presented and it was ultimately agreed to start with a focused project to evaluate EVAR treatment of ruptured AAA (with a contemporary comparison to open repair), since the key outcome of in-hospital mortality is available in all registries. Secondary outcomes of death and re-

intervention at one year could be accomplished in many centers since the number of ruptured cases to track from each participating center is small. Further, this project has value to industry, for potential expansion of indications to include EVAR for ruptured AAA, and might attract industry funding for participating registries and centers. Drs. Beck and Mani will develop a detailed protocol, including required data elements, and circulate this to invite each registry to participate. Participating registries will implement required data elements and invite sites that will agree to collect one-year data. Foundational data for this project will be generated once updated Vascunet data are available in the beginning of 2018.

8. Next Meeting / Workgroup Members

Discussion was held about potentially holding ICVR meetings in association with ESVS and SVS annual meeting to reduce travel, but it was agreed that adding a day to these already long meetings would be difficult. Accordingly, the next ICVR meeting will be during the VEITH conference in New York, on Tuesday, November 14, 2017.

There are many new project lead opportunities outlined above for ICVR members, and others from each involved country to participate. Please reply to the Co-Chairs if you or someone from your countries registry would like to be involved in a specific project. We are hoping to attract new work group members!