

**Aortic Valve Research Network Meeting**  
**Saturday, February 15, 2020**  
**1:00PM – 1:50PM**  
**Cleveland Clinic Abu Dhabi**

**MINUTES**

Introductions

1. **Database update** - *Nienke Adriaens*

**Inclusion**

Nienke updated the group on the database. There are 56 centers who are including patients in the database. Up until December 2019, there are 7267 patients included in total, and on average there are about 500-600 patients included per year. The majority of the procedures have been valve repairs (89%).

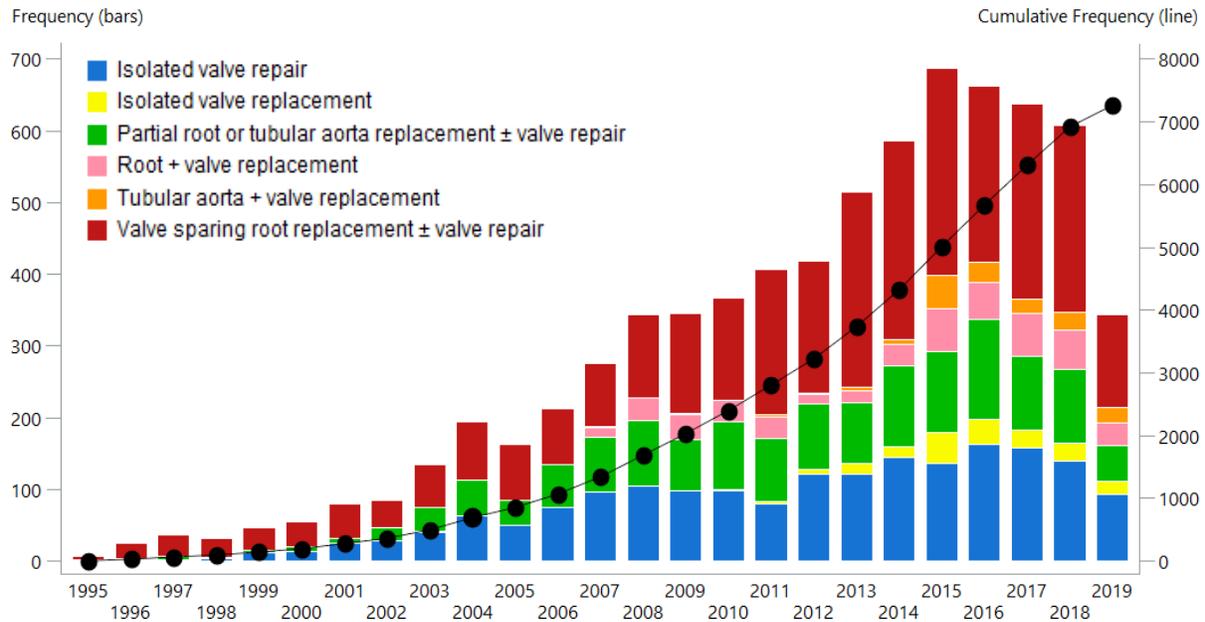


Figure 1 Inclusions AVIATOR

**AVIATOR kids**

The CRF for AVIATOR kids is finished. It is now ready to be built into an online eCRF and database.

**Data completeness report**

Nienke has sent data completeness reports to all participating centers. The aim of this is to encourage centers to increase their data completeness. In this report, information can be found on the overall completeness of the operative variables. Furthermore, there are tables on patient-

level, which show the variables missing per patient, as well as the presence of echo's and follow-up visits in several timeframes.

There has been a discussion regarding the frequency of follow-up visits and echo's. Currently, the aim is to have one echo and follow-up visit every 2 years, regardless of the time after surgery. It was suggested to enlarge this timeframe after 10 years after surgery, to one echo and follow-up visit every 5 years. However, it has been decided to keep the frequency at one echo and follow-up visit every 2 years, and not enlarge this timeframe to 5 years. Reason for this is that we may lose valuable information when enlarging the timeframe.

An important message to all participating centers is that when entering data in the online database, is it important to also select 'no' when a certain procedure or event is not applicable. If this is not done, the variable will occur as missing.

## **2. HVS Aortic Valve data platform -> LIVE - *Thierry Bourguignon***

The HVS Aortic Valve data platform has been launched. This data platform is a combination of the already existing AVIATOR registry, complemented with the new LEOPARD registry. Both registries will use the same database, which will allow comparison. With the addition of the LEOPARD registry, a new patient population has been added: patients with aortic stenosis. The inclusion criteria for the HVS Aortic Valve data platform are AV disease (aortic stenosis, aortic regurgitation, mixed AV disease, or aortic aneurysm), and a minimum age of 18 years at the time of surgery. For the stenosis patients there is an additional maximum age limit of 65 years. The objective is to complete one yearly clinical follow-up and echo evaluation every two years for a direct comparison between techniques and devices.

For the LEOPARD Registry there is a funding plan and dozens of patients have been included so we are ready to invite other centers. Of course, there are still challenges and questions, including which database to use (which is a VRN-wide question as all should use the same platform). Thierry reported that there are concerns about Telemedicine. As it is expensive and not everyone finds it user-friendly, especially the extraction of the data. Another option which could be explored is REDCap. It is a free software tool, user-friendly and has an easy data extraction-module. We have to explore this in more detail and need to find out about compliance to the EU regulations.

Ismail said that having done quite a bit of extraction and one project within Telemedicine, he can say with certainty that there are many meaningless columns in the Telemedicine extraction, plus the costs are very high. He said that when we decide on a platform, whether staying with Telemedicine or migrating to REDCap (or something else) we must stick to it so we are not constantly moving around.

Many of the European investigators have little to no experience with REDCap. There was much discussion around both databases. Emmanuel pointed out that with a migration, we could potentially lose data and participants, but the decision must be made soon so that the mitral database can move forward, as they should use the same database as aortic.

Bart noted that you have to manage REDCap yourself, Telemedicine on the other hand manages the database so when something goes wrong, and they are able to assist.

**Conclusion:** We need to get a group of people together with experience in both REDCap and Telemedicine, and make a decision to move forward.

The table below summarizes the given arguments on both database providers.

*Table 1 Summarization of arguments on REDCap and Telemedicine*

	<b>REDCap</b>	<b>Telemedicine</b>
<b>Advantages</b>	<ul style="list-style-type: none"> <li>• Software is free</li> <li>• user-friendly</li> <li>• Easier to extract data</li> </ul>	<ul style="list-style-type: none"> <li>• Compliant with EU regulations</li> <li>• Telemedicine manages the database</li> </ul>
<b>Disadvantages</b>	<ul style="list-style-type: none"> <li>• Uncertainty about compliance to EU regulations</li> <li>• Data team would have to manage the database, and therefore solve any problems</li> <li>• Risk of losing data and participants during transfer</li> </ul>	<ul style="list-style-type: none"> <li>• Data extraction is more difficult (there are possibilities to simplify this)</li> <li>• Expensive</li> </ul>

### 3. **Mitral valve database** – *Evaldas Girdauskas*

Emmanuel noted that the principal of VRN’s is that anyone interested in a topic can join to stimulate the discussion. Everyone has seen the presentation on AVIATOR and LEOPARD, and now we are introducing the Mitral VRN with the Functional Mitral Regurgitation, REFORM 2 database. It will be set up like the aortic database.

Evaldas reported that there are different treatment options for functional mitral regurgitation, on both the catheter based and surgery-based sides. The idea behind Mitral VRN projects is to implement interdisciplinary strategy in the establishment of mitral/tricuspid database where the focus is on the outcomes of diseases and not on one specific treatment strategy. That means, all types of treatment should be analyzed in the mitral/tricuspid projects, including best-medical-treatment, catheter-based approaches, and surgical options. This will apply to all new projects in the Mitral VRN, including REFORM2, CAUTION and TRICUSPID.

The goal of REFORM 2 is to establish an international registry to evaluate treatment outcomes in functional mitral regurgitation. The HVS has approved support of this project under the Valve Research Networks, and as mentioned previously, it will use the same platform as AVIATOR to create a common database. Evaldas reported that the variable list is complete for mitral VRN, it’s

been announced to HVS members via email blast and discussion has occurred with industry regarding financial support. The goal is to start by mid-year.

REFORM 2 is for functional MR only, there is the CAUTION database too, though, but degenerative MR has not been included yet.

Emmanuel recommends including everything and then launch, and Evaldas added that CRF is ready and but we need to decide on platform. Jolanda noted that AVIATOR started alone and then added LEOPARD so the mitral database can move forward in the same fashion, doesn't necessarily have to include everything at the outset.

#### 4. **News from the Scientific committee** – *Laurent de Kerchove*

Ismail noted that the key to gaining industry support is to publish, and so Laurent reported on the scientific committee, ongoing projects and proposals.

Ongoing research projects:

1. Aortic valve repair using external aortic ring annuloplasty: a multicentric analysis of outcomes (Emmanuel Lansac, IMM). Data is provided and analysis started.
2. The Role of Aortic Root Remodeling with Annuloplasty for the Management of Patients with Connective Tissue Disorders (Vincent Chauvette, Montreal). Data is provided, results were presented at AV repair summit, Paris 2018. Completed manuscript and internal reviewing is almost finished (EACTS2019). Thereafter it will be send to the authors for review and to the scientific committee. It will be submitted to JACC.
3. Determinants of conversion to aortic valve replacement in patients selected for valve repair (Frederiek de Heer, Amsterdam). Data is provided and investigation of data completeness started.
4. Early and mid-term clinical and echocardiography outcomes in patients undergoing aortic valve repair / replacement for isolated aortic regurgitation from AVIATOR database (Maciej Matuszewski, Wolverhampton, UK). Data is not provided yet. New investigation of data completeness will be done.
5. Valve related outcome after aortic valve and/or root repair and valve replacement: short term follow-up on the AVIATOR registry. The coordinating investigator Bardia Arabkhani (Leiden UMC, Netherlands) and the PI is Prof. Robert Klautz (Leiden UMC and Amsterdam UMC). Data is provided and abstract is presented at HVS2020.

New research proposals approved by Scientific Committee:

1. Impact of preoperative aortic regurgitation and leaflet repair on immediate and long term outcomes of valve sparing root replacement in patient with TAV (Laurent de Kerchove).
2. One-year clinical and hemodynamic outcomes in patients treated for aortic insufficiency and ascending aorta aneurysm. The one-year flight of AVIATOR (Ismail El-Hamamsy).

3. Aortic valve reparability in aorta dissection patients: insight from the AVIATOR registry (Matteo Pettinari).

How to submit a research proposal:

- Send in a proposal to the Scientific Committee ([AVIATOR@HeartValveSociety.org](mailto:AVIATOR@HeartValveSociety.org)) at least 1 month before EACTS or HVS
- Proposals will be reviewed by the Scientific Committee
- Presentation of proposal at EACTS/HVS
- Discussion & approval of research proposal
- Data extraction
- After data extraction, the team will be given a deadline of 6 months to perform the analysis and write a draft publication that should be presented at the next meeting. When the deadline is exceeded, the topic can be passed on to another group.

#### **4. Other announcements**

Due to a time constraint, the topics ‘Regulations & Ethics’, ‘AVIATOR bylaws’ and ‘Strategies for sustainable fundings’ were not discussed. These will be postponed to EACTS2020.