Heart Valve Society Valve Research Networks

Instructions for researchers

29th of January 2025
Version 1.2024

Table of Contents

1. Introduction

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1.1   Foreword

The following guide contains practical information for researchers that utilize data from the Heart Valve Society (HVS) Databases.

The HVS fosters a collaborative community dedicated to advancing heart valve research across basic, translational and clinical disciplines. To support this mission, HVS hosts an annual meeting where scientists, cardiologists and cardiac surgeons gather to exchange ideas and insights. Additionally, HVS has established Heart Valve Research Networks (VRNs) to stimulate international collaboration and further heart valve research, the Mitral and Tricuspid VRN and the Aortic VRN, which have respectively led to the development of the HVS Mitral Tricuspid Valve (MTV) Database and the HVS Aortic Valve (AV) Database.

Participating centers can conduct research using data from these HVS Databases. While regulations are outlined in formal protocols and legal agreements, this guide offers practical information and specific guidelines to support researchers in their work.

1.2   Contact information

For any questions about these instructions or inquiries regarding the databases, please reach out to the database managers at:

HVS MTV Database: mitralvalvedatabase@heartvalvesociety.org

HVS AV Database: aorticvalvedatabase@heartvalvesociety.org

2.   Data access management

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In this section, the way data is accessed, stored and removed by researchers is laid out, including securing data storage, handling data within the scope of research and sharing data.

2.1   Data access request

Researchers can submit a research proposal to the relevant Scientific Committee, either for the HVS MTV Database or the HVS AV Database, to request access to the data for scientific research. A research proposal template is available at the [HVS MTV Database](#) and [HVS AV Database](#) websites. Details on this process and instructions for data access are outlined in the Registry Project Plans.

2.2   Data transfer

Once approved, the relevant database manager will create a (time-stamped) copy of the database (including only required variables) and will send the copy to the researchers via SURFfilesender, an approved secure file-transfer system. The datasets provided are pseudonymized, with all patient- and center-identifying variables removed. Each patient is assigned a new pseudonymous ID, created specifically for the research proposal.

The patient identification log will never be shared with the researcher. When necessary for the analyses, the center identification log may be shared with the researchers if approved by the Scientific Committee in the research proposal or after secondary consultation with the Scientific Committee. The center identification log may only be published after approval from all centers concerned and the Scientific Committee.

In case the data is sent back to the relevant database management team – for example to request support with data analysis – this must be done using a secure file transfer system to ensure safe data transfer.

2.3   Secure data storage

Researchers receiving a copy of the dataset are expected to handle and store the datasets in a secured space. This implies that the datasets should be stored in a secure folder on the institutional server and must not be stored on a personal computer.

2.4   Data usage and access

The provided dataset may only be used to answer the research questions outlined in the research proposal. Reuse of the data for research projects or questions other than those approved by the Scientific Committee is prohibited. Researchers wishing to repurpose the data for additional projects or questions must submit a new research proposal for continued access, which requires approval from the Scientific Committee.

Only individuals actively involved in the research project or data analysis should have access to the datasets. Sharing the datasets with unauthorized individuals is strictly prohibited.

2.5   Archiving data

After the manuscript is published and no further revisions will be made to the data analysis, researchers are requested to send the final analysis and processed data back to the database management team and delete the copy dataset, along with any related data, from all locations where it is stored, including their hospital. This should be done within one month of publication. If someone requests access to the dataset to verify the accuracy of your analysis, please refer them to the relevant database management team, who will determine if the dataset or analysis can legally be shared with the requesting party.

3. Research output requirements

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Throughout the research project, researchers are encouraged to present and publish their work. Since the data involves multiple centers, there are specific regulations. Whenever you plan to produce any type of research output, whether this is a presentation, abstract submission for a conference or congress, or a manuscript submission, please inform the relevant database manager in advance. They will explain the exact requirements regarding the authorship list and approval from the Scientific Committee.

3.1   Contributing centers

In addition to those who have executed and supervised the research project, individuals who contributed to the data analysis or provided data for the specific research proposal should also be acknowledged. This means that any center contributing data must be included in the authorship list of the manuscript. Each participating center may propose one author for studies using its data.

Authors' order will be established based on a ranking of data completeness (*data completeness X volume*"), from high to low. The total number of authors will depend on the requirements of the journal, conference or congress. Ideally, all participating centers in the dataset will be represented. If there are limits on the number of authors, centers with the highest ranking of data completeness will be prioritized. The ranking will be determined by the relevant database manager.

The method for calculating data completeness is specific to each research proposal and primarily depends on the outcomes outlined in the research proposal. The first two and last authorships will be decided by the researchers of the research proposal. Once the data analysis is complete, the relevant database manager will provide the names of the principal investigators of all contributing centers, which will also serve as the proposed order in which the authors should appear on the authorship list. The researchers should then contact each principal investigator to inquire about the proposed authors from their respective centers.

3.2   Approval by Scientific Committee

After the research output has been approved by all (co-)authors, it must be sent to the relevant database manager, who will forward it to the relevant Scientific Committee. The research output will be reviewed by at least one member of the Scientific Committee. When submitting any research output – whether it is for example a presentation, abstract submission for a conference or congress or a manuscript submission – approval from the

relevant Scientific Committee is required. The members of the Scientific Committee review the manuscript to ensure alignment with the protocol and perform a basic check for methodological issues.

3.3 Requirements per research output

For each type of research output, different regulations have been put in place:

Manuscript

- o Contributing centers: all centers that have contributed data to the research project should be acknowledged in the authorship list, as described in section 3.1, and in accordance with and limited to the journal's authorship requirements. Each selected center can propose one author for studies using its data. The relevant database manager will provide you with the ranked list of contributing centers, along with their respective principal investigators. The researchers should contact the principal investigators themselves to inquire about their proposed author.
- o It is mandatory to acknowledge the HVS Databases, and their funder(s). In the acknowledgement section of the manuscript, please write the following:
  - ▪ HVS Mitral Tricuspid Valve Database: "The research project has been made possible thanks to the HVS Mitral Tricuspid Valve Database management team, funded by Edwards Lifesciences."
  - ▪ HVS Aortic Valve Database: "The research project has been made possible thanks to the HVS Aortic Valve Database management team, funded by Vascutek Limited, trading as Terumo Aortic."
- o Approval from Scientific Committee: approval from the Scientific Committee is required prior to submitting the manuscript to any journal.

(Abstract) Presentation at international congress

- o Contributing centers: the authors as proposed by the principal investigators of the first 6 – 10 contributing centers should be acknowledged in the authors list for any (abstract) presentation at an international congress. They should give their approval prior to submission of the (abstract) presentation.

Approval from Scientific Committee: approval from the Scientific Committee is required prior to submitting the (abstract) presentation to any international congress.

(Abstract) Presentation at national congress

- o Contributing centers: the authors as proposed by the principal investigators of the first 4-6 contributing centers should be acknowledged in the authors list for any (abstract) presentation at a national congress. The contributing

centers may be notified/informed *after* submission of the (abstract) presentation.

- o Approval from Scientific Committee: approval from the Scientific Committee is *not* required prior to submitting the (abstract) presentation to any national congress.

Non-peer reviewed (medical) journals/newspapers.

Please consult with the relevant database manager what the regulations are for any submission to a non-peer reviewed (medical) journal or newspaper.