



SINGLE VENTRICLE RECONSTRUCTION EXTENSION STUDY (SVR II) PUBLIC USE DATASET

ABOUT THE STUDY

The NHLBI Single Ventricle Reconstruction (SVR) Trial was conducted by the Pediatric Heart Network (PHN) at 15 centers from 2005 to 2009. There were 555 participants randomized. The primary aim of the trial was to compare one-year transplant-free survival of newborns randomized to receive either a modified Blalock-Taussig shunt (MBTS) or a right ventricle to pulmonary artery shunt (RVPAS) as part of the Norwood procedure. The protocol, public use datasets, and documentation are available at <https://www.pediatricheartnetwork.org/datasets/?selectedStudy=438>.

The SVR Extension Study collected data annually between ages 2 and 6 years, as well as before and after Fontan surgery. Data were obtained through medical record review, phone interview with parents/guardians, ECG, core laboratory analysis of echocardiographic images and Holter monitors, and completion of questionnaires regarding neurodevelopmental outcomes, behavior, health-related quality of life, and family functioning. The primary outcome was freedom from death or cardiac transplantation at 6 years post-randomization. The protocol and 6-year main results are provided along with the public use datasets (available to users with approved logins). Additional publications on specialized topics are summarized at <https://www.pediatricheartnetwork.org/studies/single-ventricle-reconstruction-follow-up-2-svr-ii/>.

DATA AND DOCUMENTATION

The following datasets and descriptor files are available for download. A login and password (request access via <http://www.pediatricheartnetwork.org>) are required for download capability. The lock date used for creation of the public dataset is August 2, 2020. Privacy protection of these data is described in Appendix A.

1. Study data collection forms
2. SAS version 9.4 datasets
3. Excel datasets (with variable formats applied) – These data have a .csv extension, which means that the file may also be opened either in Excel, OR in a text editor, appearing as a comma-delimited file.
4. Codebooks for each dataset – These contain variable names, labels, and descriptive statistics for each variable on the data collection forms. Key created variables are included as well.
5. The files *svrfmts_combined.sas7bcat* – Include this file in your program using:

```
options fmtsearch = (fmtlib.svrfmts_combined);
```

where *fmtlib* is specified using a *libname* statement as the path name.
6. Code lists B, D, F, M

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STUDY RESOURCES

Resources posted on the pediatricheartnetwork.org website include:

- SVR II protocol (with login access)
- SVR II Main Results paper (with login access)
- SVR II bibliography (<https://www.pediatricheartnetwork.org/studies/single-ventricle-reconstruction-follow-up-2-svr-ii/>)
- SVR Trial documents (<https://www.pediatricheartnetwork.org/datasets/?selectedStudy=438>)

DATA USE POLICY

- **REQUIRED ACKNOWLEDGEMENTS:** All presentations and publications using these data must include the following statement: *“The NIH/NHLBI Pediatric Heart Network Single Ventricle Reconstruction Extension Study dataset was used in preparation of this work. Data were downloaded from www.pediatricheartnetwork.org on mm/dd/yyyy.”*
- **PAPER, ABSTRACT, and PRESENTATION TITLES:** Titles may, at the authors’ discretion, mention the PHN database but should not imply that the work is from the PHN. An example of an acceptable phrase would be, “an analysis of the Pediatric Heart Network public database.” Whether or not the title makes mention of the PHN, acknowledgement should be made as described above.
- All users are requested to send a copy of published abstracts and articles to the PHN Data Coordinating Center at New England Research Institutes (PHNpubs@neriscience.com) within one month of publication. This will allow the PHN and the NHLBI to document the continued impact of this study on the field.
- The login and password to access the public dataset is provided to a single user. If a colleague would like to access the public dataset for a different analysis topic, a separate request for login and password should be submitted via the www.pediatricheartnetwork.org website.
- As an approved user, you agree that you will not attempt to establish the identities of research participants through use of this dataset.
- As an approved user, you agree to not place these data in other public locations.

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TIPS ON USING THESE DATA

- Identification numbers for study subjects have been re-assigned for privacy protection. IDs are consistent with those used in SVR Trial public use datasets.

subj_id: Subject ID ranging from 1 to 920

- The study data are contained in a large number of individual forms. These may be used jointly by merging on *blind_id*.
- SVR II data can be merged with SVR Trial data using *blind_id*. SVR Trial data (available at <https://www.pediatricheartnetwork.org/datasets/?selectedStudy=438>) contain important variables, such as demographics and treatment arm.
- The ND_scores dataset contains scored neurodevelopmental data.

ADDITIONAL ASSISTANCE

If you have questions about the study dataset that this documentation and the above resources (protocol, articles) have not answered, please email the PHN Mailbox at PHNmailbox@neriscience.com.

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APPENDIX A

Implementation of Privacy Protection Rules for Public Use of the PHN SVR Trial Dataset

Variables that could lead to subject identification were eliminated in the public dataset. Steps included:

1. Removal of original study ID number (replaced with *blind_id*, a random consecutive numbering ranging from 1 to 920), and removal of acrostic. Of note, no names, addresses, zip code, or medical record numbers were ever contained in the original study dataset.
2. All dates in the original datasets were removed, and replaced with subject age on that date, in years with at most 2 decimal places. Dates of form completion were removed.
3. Free (write-in) text variables were generally removed from the public datasets. When included as clinically relevant, they were first scanned for any identifying information (e.g., dates, places) and edited accordingly.
4. Variable groupings with low frequencies were combined.

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APPENDIX B

Special Value Codes

-9 = missing

-8 = don't know/indeterminate

-7 = refused to answer

-6 = not recorded

-5 = measurement could not be reliably recorded or is not interpretable (study technically inadequate)

-4 = illegible

-2 = programmed skipped field based on results of or response to a previous question

-1 = not applicable/structure not present