PEDIATRIC ECHOCARDIOGRAPHY Z-SCORE AND ELECTROCARDIOGRAM DATABASE PROJECT
(Echo-Z and Normal ECG)
PUBLIC USE DATASET

Pediatric Heart Network (PHN)

ABOUT THE STUDY

The NHLBI Echo-Z and Normal ECG Studies were conducted by the Pediatric Heart Network (PHN) at 19 North American centers. The study objectives were:

1. To establish a Z-score database for common echocardiographic (echo) measurements based on a uniformly defined and racially diverse population of normal children from multiple centers over a wide geographic area
2. To collect electrocardiograms (ECG) from the same population of normal children for establishment of ECG reference values

Thirty-six study groups were created from 3 race, 6 age, and 2 sex categories. Self-reported race/ethnicity information was divided into 3 categories: whites, blacks, and others (Hispanics, Asians, Pacific Islanders, Native Americans, and Multiracial). Age was divided into 6 categories (<1 month, 1 month–3 years, 3-6 years, 6-12 years, 12-16 years, 16-18 years).

Of the 3566 echos collected, 3215 (90%) had adequate images. Race data revealed 35% whites, 31% blacks, and 34% others. Ethnicity data revealed 25% Hispanic, 70% non-Hispanic, and 5% unknown. All study groups reached complete enrollment (≥80 subjects with measurable images) except black girls age <1 month, 3 to 6 years, and 16 to 18 years, black boys age <1 month, and other girls age 16 to 18 years.

Among 2619 ECGs collected, 219 were excluded because of inadequate quality of waveforms, leaving 2400 for analysis.

Additional information about the Echo-Z and Normal ECG studies can be found at https://www.pediatricheartnetwork.org/studies/echo-z-score-normal-electrocardiogram/.

Details on calculation of echo Z-scores based on study results can be found at https://www.pediatricheartnetwork.org/forresearchers/echo-z-scores/.

An online Z-score calculator can be found at https://www.pediatricheartnetwork.org/z-scores-calculator/.

DATA AND DOCUMENTATION

The following datasets and descriptor files are available for download. A free login and password are required for download capability. The lock date used for creation of these public use datasets was February 1, 2016. Privacy protection of these data is described in Appendix A.

1. Study protocol

2. Echo-Z published main results

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3. Normal ECG published main results

4. Study data collection forms

5. SAS datasets

6. 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.

7. 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. Categorical variables are listed first, with frequencies; continuous variables are listed next, with mean, SD, median, interquartile range, and range.

DATA USE POLICY

- REQUIRED ACKNOWLEDGEMENTS: All presentations and publications using these data must include the following statement: *"The NIH/NHLBI Pediatric Heart Network Echo-Z/Normal ECG 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 HealthCore, Inc (PHNpubs@healthcore.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 participants have been re-assigned for privacy protection. A blinded ID ranging from 1 to 3566 (number of echos in the database) has been assigned.

- The study data are contained in a large number of individual forms. These may be used jointly by merging on *blind_id*.

- An analytical dataset of variables created for the study, including PHN z-scores, is included.

- An analytical dataset from the Z-score comparisons paper is also included. This dataset contains other echo Z-scores that were compared to the created PHN z-scores:

  - <u>Detroit:</u> Pettersen MD, Du W, Skeens ME, Humes RA. Regression equations for calculation of z scores of cardiac structures in a large cohort of healthy infants, children, and adolescents: an echocardiographic study. J Am Soc Echocardiogr 2008;21:922-34. doi: 10.1016 / j.echo.2008.02.006.
  - <u>Italy:</u> Cantinotti M, Giordano R, Scalese M, Murzi B, Assanta N, Spadoni I, et al. Nomograms for two-dimensional echocardiography derived valvular and arterial dimensions in Caucasian children. J Cardiol 2017;69:208-15. doi: 10.1016/j.jjcc.2016.03.010.
  - <u>Boston:</u> Boston Children's Hospital Z-Score Calculator: http://zscore.chboston.org/ (accessed July 2020).

- An Eligibility dataset was not included because only eligible participants were data entered; all other data from the form were considered possibly identifying.

- An Adjudication dataset was not included as only one case required adjudication; it was adjudicated as 'include'.

- There were no withdrawals from the study.

ADDITIONAL ASSISTANCE

If you have questions or concerns about the study datasets that this documentation and the above resources (e.g., protocol, case report forms) have not answered, please email the PHN Mailbox at PHNmailbox@healthcore.com.

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APPENDIX A

Implementation of Privacy Protection Rules for Public Use

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 3566). Of note, no patient names, addresses, zip code, or medical record numbers were ever contained in the original study dataset.

2. Physician names were removed.

3. All dates in the original datasets were removed. Of note, age at echo and ECG were already in the dataset; all other dates were not scientifically relevant.

4. 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.

5. Variable groupings with low frequencies were combined, e.g., 'other' race groups.