A Novel Approach to Enhance the Enrollment of Under-represented Groups in Clinical Trials Using a Site Selection Tool

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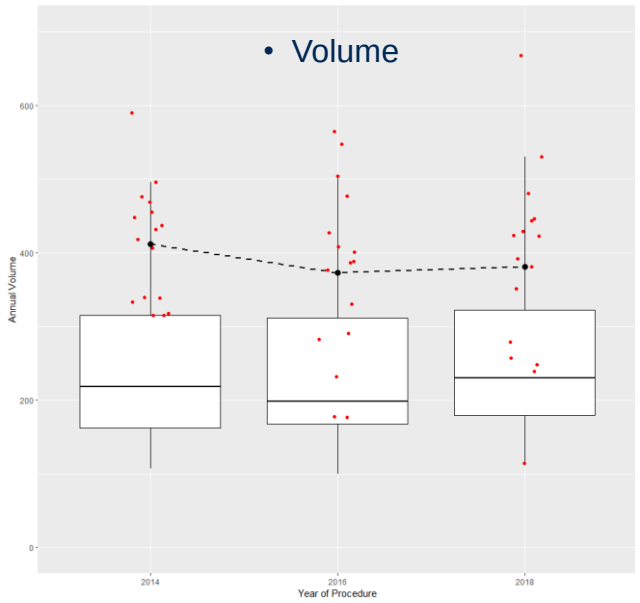
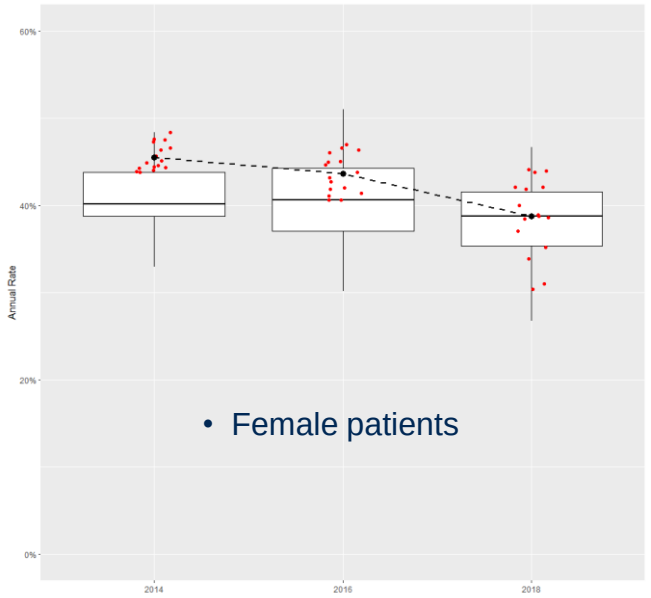
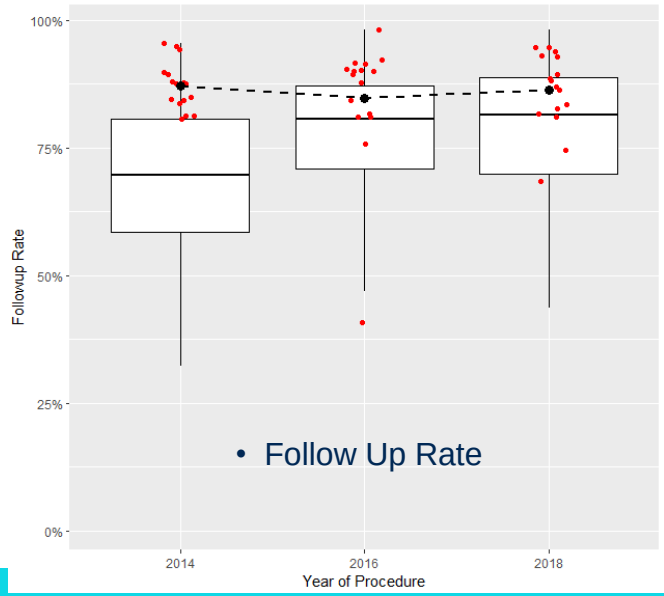
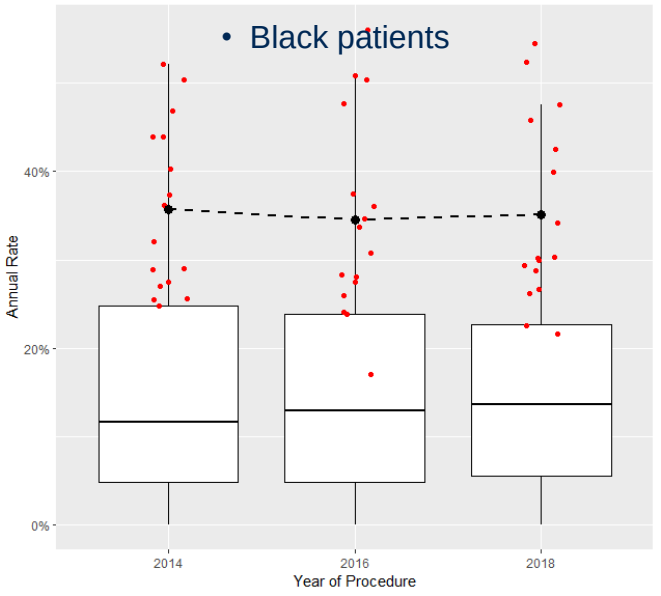
- **Objective:** The selection of clinical sites is a key step in starting a clinical trial. Usually, site selection is based on a survey that is subjective, anecdotal, and does not mirror eventual enrollment. We describe a novel site selection tool (SST) and its possible application in clinical trials.

- **Methods: A)**The SST used the SVS Patient Safety Organization, a national registry of deidentified vascular surgery data, to select diverse sites. **B)** Goal was to pick sites with high clinical volume and enrollment of under-represented cohorts for a planned PVI trial. **C)** We assessed sites chose top quartile sites for multiple variables including clinical volume, female, and Black patients. **D)** We compared 3 time periods: complete year 2014 to 2016 and 2018 data. **E)** All analyses were performed in RStudio (version RStudio 2023.06.1+524) running R (version 4.2.2). Institutional Review Board approval and informed consent requirements were not necessary as the data were deidentified.









- **Implications**

SST allows for precise data assessment on clinical sites

SST allows trialists to focus on variables of interest (i.e. female or minority patients)

SST may increase predictability in enrolling in clinical trials

- **Conclusions**

The SST provides granular, longitudinal verified data on sites performing PVI. This tool can be used predictively to recruit sites that can have robust enrollment of historically under-represented groups in a clinical trial.