Statistical Considerations

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Importance of Data Quality

- **Ability to derive reliable statistical conclusions from this registry will depend heavily on data quality (completeness, consistency, and reliability)**
  - "Garbage in --- Garbage out"
  - Good statistical analysis cannot magically salvage (transform) bad data into good data
- **Achieving desired level of quality will require implementing some of the organizational features/processes and rigor of a well-designed randomized clinical trial**

Data Quality- Principles to Consider

- **Prospective specification of the hypotheses and primary questions to be addressed (this stage of the planning is crucial)**
- **In developing the data collection forms and choice of variables, consider carefully**
  - how the data will be used
  - what questions it will answer
  - how it will be analyzed
- **Less data collected well is preferable to collecting more extensive data and compromising the quality**

Data Quality (cont.)

- **A Data Coordinating Center to measure and monitor data quality, manage the information, provide timely reports, and coordinate the analysis is essential**
  - "Where quality is measured, quality improves"
- **Involve data management and statistical thought leadership during the planning stages**
- **Length and extent of f/u data collection is a critical consideration (e.g, re-do's, patterns of afib recurrence, adverse outcomes)**

What Can Be Done Statistically With A High-Quality AF Ablation Registry?

- Large numbers of patients will permit estimating event rates (safety outcomes, adverse events) with a high degree of precision (narrow confidence intervals)
- A registry is not an RCT (all pts will undergo ablation), so comparative effectiveness of ablation with other treatment approaches will not be possible

What Can Be Done Statistically? (cont.)

- **Broad representation of patients and participating sites will permit observational comparisons among**
  - Important patient subgroups
  - Types of sites (e.g. community v. academic)
  - Level of experience of ablation operators
  - Different ablation strategies/techniques
- **Assess factors predictive of various adverse outcomes and characterize those relationships (through careful statistical modeling) (i.e., develop risk models)**
  - Missing data will be a problem--Quality is key!

What Can Be Done Statistically? (cont.)

- Characterize patterns of drug use (rhythm control (antiarrhythmic), rate control, anticoagulation, etc.
- Adequately characterizing A-fib recurrence will depend on the length of f/u and how pts are monitored
- The registry will generate useful hypotheses that will motivate future clinical trials, and event rate data to aid in the design of those trials

What Can Be Done Statistically? (cont.)
CABANA and the AF Ablation Registry

- **With CABANA now being launched, the trial and registry should be designed to complement one another and have as much consistency in definitions and comparable data collection as possible**
- **Characteristics of pts in the RCT can be compared to pts in the registry**
  - Help define generalizability of CABANA

CABANA and the AF Ablation Registry

- **Short-term outcomes of pts in CABANA and the registry can be compared**
  - Will require careful statistical modeling to adjust for baseline differences (confounders)
- **Registry can be used to describe outcomes of ablation in pts excluded from or not well represented in CABANA or other clinical trials**
- **Long-term outcomes of registry pts might be obtained through Medicare claims data and/or NDI and compared with CABANA pt outcomes**

Other Points to Consider

- **First do a pilot registry (like a pilot trial). Start small, develop some experience, and then expand**
- **Take advantage of the registry's data collection framework and embed RCTs within that framework**
  - Consistent data collection across trials
  - Mechanism for enhancing/ensuring data quality
  - Will provide stronger evidence for answering key questions and changing practice