

# Priorities and Objectives for an Atrial Fibrillation Ablation Safety Registry

## NHLBI view

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# Priorities and Objectives for an Atrial Fibrillation Ablation Safety Registry

## Some General Objectives

An NHLBI-sponsored Safety Registry?

*The “yin” without the “yang”?!?*

An NIH supported Registry should:

- Follow patients both for complications AND freedom from events in general population
- Identify patients most likely to benefit from treatment
- Follow compliance with guidelines
- Reduce risk of selection/reporting bias

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## Background

- Limitations of current registries
  - Lack of valid “control” group (historical control not appropriate)
    - Selection of patients
    - Selection of intervention
    - Inconsistent enrollment/definition of outcomes
  - Small size: inadequate to evaluate uncommon but serious side effects
  - Bias (conflict of interests)
- Need for a National Registry (with NIH participation)
  - Best mechanism to gather and share post-market real world data in broader population
  - Include longitudinal follow-up to evaluate short AND long term risk-benefit (cost?) of AF ablation

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## Some Priorities

- Do not reinvent the wheel!
  - NCDR
  - STS
  - ICD Registry
- Key issues
  - Definition of technical ablation techniques components: changes over time
  - Definition of short and long term complications
  - Definition of factors (procedures/patients) influencing outcome (both risk and benefit)
  - Address confidentiality: IRB and HIPAA issues (“tracking” of patients for longitudinal Follow-up)

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## Key requirements of a National Registry

- Public, private and academic partnership:
  - Protect patients interest/privacy
  - Minimize bias (collection and reporting of data)
  - Governance structure?
- Independent Data Coordinating and Analysis center
- Universal participation of public/private institutions
- Common definition of:
  - Data elements
  - Outcome measures
  - Analytical techniques

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## Key requirements of a National Registry

- A national registry need to provide patients with complete information on the short and long term risk-benefit of the procedure
- As indications/patients changes so does the Registry
- A Registry is NOT a substitute for well designed, well controlled, large RCTs!
- Government participation/funding will guarantee integrity and transparency

## Conclusion

### Registries?

They're not just for weddings anymore!

*(E Clarke Haley Jr. Neurology 2008; 70: 1508)*

### Provided they include:

- Well defined research questions
- Standard definitions of data elements and outcomes
- Rigorous data collection
- Training of investigators/data abstracters
- Auditing
- Universal participation
- Well defined governance and public support