

ACADEMIC / PROFESSIONAL SOCIETY PERSPECTIVE

Background

- Rapid increase in AF ablation procedures
- Diffusion to diverse clinical settings and operators, with different levels of experience and volume
- While variety of tools and strategies exist, some convergence on basics of indications, technique, endpoints, and follow-up
- Limited data on outcomes, risks, and target population beyond single high volume centers and a few small multicenter trials
- Significant gaps in knowledge base regarding disease mechanisms, progression, and response to therapy, particularly with respect variations between individuals

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Objectives / Needs

- Assure adequate training of membership, without undue restriction of eligibility
- Objective credentialing process of both centers and operators
- Assure availability of procedure to patients in need, commensurate with adequate evidence base supporting benefit
- Assure reasonable compensation available appropriate to level of effort and resources required
- Ongoing high level input, participation in design and management of registry, and subsequent use of data

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What Would We Like to Know?

- Best procedural strategies and endpoints for individual scenarios (symptom control, QOL)
- Long-term risk of death, stroke, heart failure, and relationship to AF control
- How does new technology impact outcomes and safety? What increment of benefit at what cost?
- How does volume (both operator and center) relate to outcome and risks
- Optimal use of adjunct strategies (drug therapy, anticoagulation)

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Potential Opportunities and Impact

- “real life” snapshot of AF ablation: number of procedures, techniques employed, characteristics of operators, procedural settings, target populations
- Answer questions not possible with clinical trials
 - Durability of outcome over several years
 - Generalizability of outcomes to less experienced centers (complications, symptom control, long term AF sequelae - stroke, HF, death)
- Ongoing quality assurance – de facto credentialing and “standard of care”
 - both individual operators and centers
 - availability of data to consumers, credentialing bodies, insurers, and other health care organizations

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Implementation: Issues and Uncertainties

- Requires significant infrastructure both centrally, and at individual centers
- Who pays? (hospitals/providers, insurers, industry)
- How much data?
 - Tradeoff between granularity of data and quality/verifiability
 - Burden of data collection and analysis
- How to incorporate data from other health care agencies?
- Mandatory, voluntary, evolutionary approaches
 - Tiered approach (small amount of mandatory data from all centers, more extensive data from selected centers)