Variation in Outcome Measures in Atrial Fibrillation Registries and the Need for Harmonization

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Background

Atrial fibrillation (AF) affects more than 3 million adults in the US, leading to increased risk of stroke, heart failure, cognitive impairment and death. Many AF patient registries exist, but the ability to link and compare data across registries is hindered by the differences in outcome measures collected by each registry and a lack of harmonization.

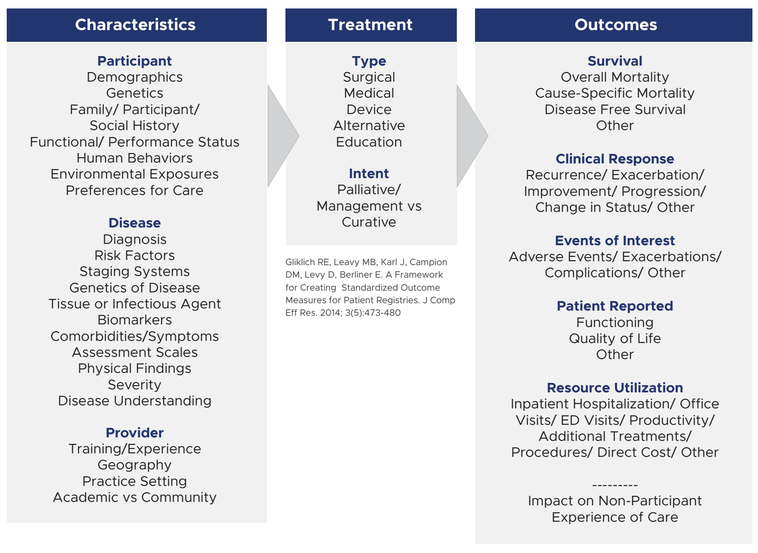
Objective

The purpose of this analysis and initiative was to develop a minimum set of standardized outcome measures for utilization in AF patient registries and clinical practice.

Methods

AF patient registries were identified through multiple sources and invited to join the workgroup and submit outcome measures. Additional outcome measures were identified through literature searches and reviews of consensus statements. Outcome measures were categorized using the gency for Healthcare Research and Quality's supported Outcome Measures Framework (OMF), a conceptual model for classifying outcomes that are relevant to patients and providers across most conditions (**Figure 1**).

Figure 1: Outcome Measures Framework (OMF)



Gliklich RE, Leavy MB, Karl J, Campion DM, Levy D, Berliner E. A Framework for Creating Standardized Outcome Measures for Patient Registries. J Comp Eff Res. 2014; 3(5):473-480

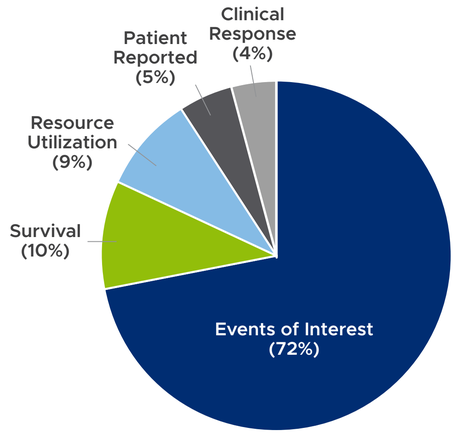
Table 1. Participating Registries

Registry Name	Sponsoring Organization
A Novel Healthcare Information Technology Tool to Improve Care in Patients With Atrial Fibrillation (AFCare)	Biosense Webster, Inc.
Does Atrial Fibrillation (AF) Termination Without Additional Ablation Influence Outcome? (TARGET)	Texas Cardiac Arrythmia Institute
Get With The Guidelines - Afib	American Heart Association
Global Anticoagulant Registry in the Field (GARFIELD-AF)	Thrombosis Research Institute
GLORIA-AF: Global Registry on Long-Term Oral Anti-thrombotic Treatment In Patients With Atrial Fibrillation	Boehringer Ingelheim
LAAO Registry	American College of Cardiology
Outcomes Registry for Better Informed Treatment of Atrial Fibrillation I & II (ORBIT-AF I &II)	Janssen
PaTH Clinical Data Research Network (CDRN) Atrial Fibrillation (AF) Clinician-Patient Partnership Cohort	Patient-Centered Outcomes Research Institute (PCORI)
PINNACLE Registry	American College of Cardiology
Postmarket Evaluation of the Phased Radio Frequency Ablation System (GOLD AF Registry)	Medtronic
Registry on WATCHMAN Outcomes in Real-Life Utilization (EWOLUTION)	Boston Scientific Corporation
Retrospective Evaluation and Assessment of Therapies in AF (TREAT-AF)	American Heart Association, Veterans Health Administration
Reveal LINQ Registry	Medtronic

Table 2: Examples of Harmonized Measures for Atrial Fibrillation

OMF Category	Outcome Measure	Definition	References
Survival	Cardiovascular Death	Cardiovascular death indicates cause of death was sudden cardiac death, MI, unstable angina, or other coronary artery disease; vascular death (e.g., stroke, arterial embolism, pulmonary embolism, ruptured aortic aneurysm, or dissection); congestive heart failure; or cardiac arrhythmia.	2004 ACC/ AHA Key Data Elements
Clinical Response	AF/AFL/AT Recurrence	Recurrent AF/AFL/AT is defined as AF/AFL/AT of at least 30 seconds' duration that is documented by an ECG or device recording system and occurs following catheter ablation or drug therapy. In the setting of catheter ablation, recurrent AF/AFL/AT may occur within or following the post ablation 3-month blanking period. Recurrent AF/AFL/AT that occurs within the post ablation blanking period is not considered a failure of AF ablation.	2017 HRS Consensus Statement
Events of Interest	Transient Ischemic Attack (TIA)	Transient episode of focal neurological dysfunction caused by brain, spinal cord, or retinal ischemia without acute infarction and with signs and symptoms lasting less than 24 hours.	2014 ACC/AHA Key Data Elements
Patient Reported	AF-Related Quality of Life	AF-related quality of life should be measured using an AF-specific quality of life instrument that is validated and commonly used, such as AFEQT.	Workgroup Recommendation
Resource Utilization	Cause-Specific Hospitalization	Hospitalization for which the primary admitting diagnosis was for heart failure, stroke, bleeding, atrial fibrillation, repeat AF-ablations, periprocedural complication, other cardiovascular causes.	Workgroup Recommendation

Figure 2: Categorization of Outcome Measures using OMF



Results

Thirteen registries (**Table 1**) participated and submitted 112 outcome measures. The majority (72%) represented events of interest, such as bleeding, stroke, and myocardial infarction (**Figure 2**). Eleven measures examined survival outcomes, including all-cause mortality, cardiovascular death, and sudden cardiac death. The measures were harmonized into a minimum set of 18 measures. The harmonized definitions build on existing consensus statements and are intended to apply across treatment pathways (**Table 2**).

Conclusions

AF registries collect a wide range of outcome measures, with a focus on short-term events of interest. Many registries measure similar concepts but use different definitions. Consistent collection of outcome measures in registries and in other systems would support the creation of a national research infrastructure to efficiently address new questions and improve patient outcomes.

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