

NCDR[®] Atrial Fibrillation Ablation Dataset Development

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Workgroup Members

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Workgroup Members

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- **FDA:** Ben Eloff, Randy Brockman, Jun Dong
- **CMS:** Marcel Salive; JoAnna Baldwin
- **AHRQ:** Elise Berliner
- **ACC:** Nancy Smith, Susan Fitzgerald, Christie Lang, Kristi Mitchell

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AF Ablation Workgroup Objective

- Develop a dataset to measure and report the safety and efficacy of AF ablation procedures

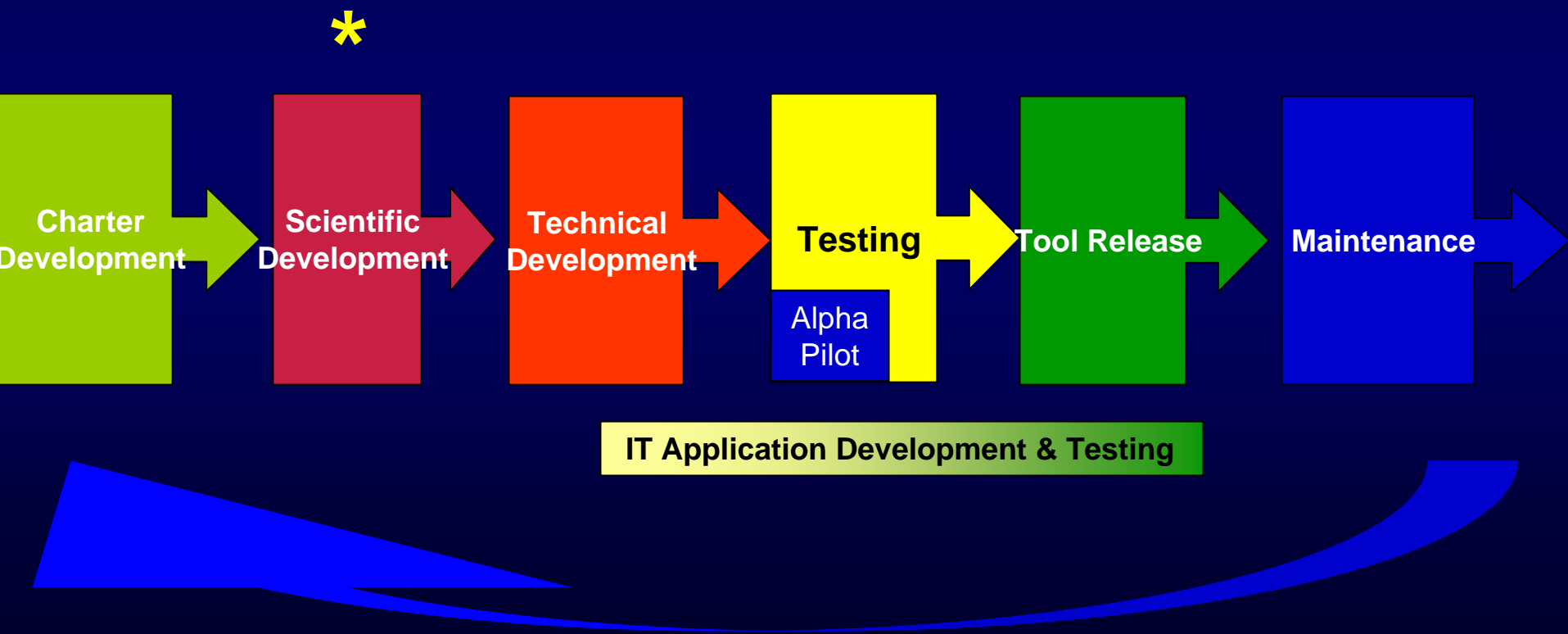
Workgroup process

Draft metrics and data collection form

Conference calls

Email review

Registry Development Timeline



AF Ablation Outcome Metrics During Hospital Stay

During Hospital Stay
Outcome Metrics:
1. Proportion of patients with an absence of atrial fib/flutter without antiarrhythmic drugs at discharge.
2. EP Endpoints –
a. Achievement of bidirectional cavotricuspid isthmus block (if performed)
b. Achievement of pulmonary venous entrance and exit block in patients with a pulmonary vein isolation procedure
3. Proportion of patients with fluoro dose >600 rads
4. Proportion of patients with at least one adverse event
5. Proportion of patients with at least one bleeding and/or vascular event
6. Proportion of patients with cardiac perforation with tamponade requiring pericardiocentesis or surgical intervention
7. Proportion of patients with cerebrovascular accident
8. Proportion of patients with pneumothorax
9. Proportion of patients with phrenic nerve damage
10. In-hospital Mortality – unadjusted and risk adjusted

Process, Utilization and Data Quality Metrics During Hospital Stay

Process Metrics:

1. Warfarin prescribed at discharge
2. Membrane active anti-arrhythmic drug prescribed at discharge
 - a. Prescribed as per procedure routine
 - b. Prescribed because of a recurrence of AFib/flutter post-procedure

Utilization Metrics:

1. Median post procedure length of stay (patients admitted for this procedure)
2. Median procedure duration (catheter placement to removal)

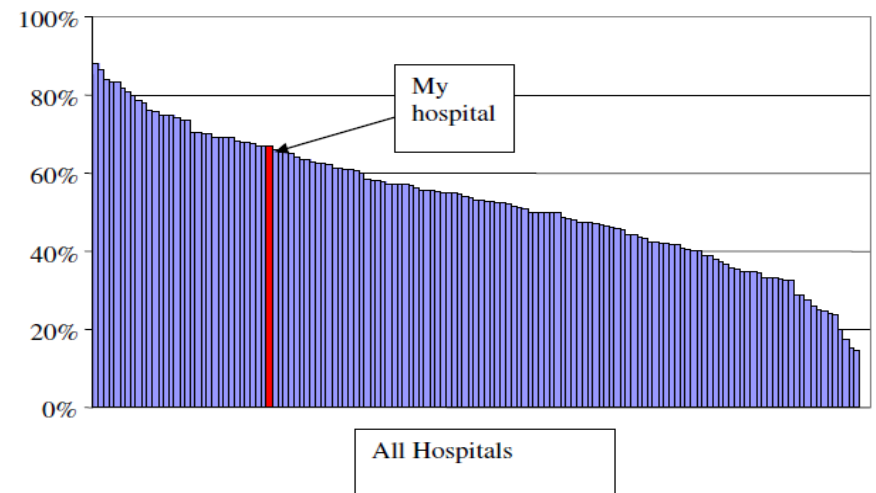
Data Quality Metrics:

1. Proportion of patients with pulmonary vein isolation performed as part of the AFib Ablation procedure

Process Comparison Metrics During Hospital Stay

Process Comparisons:
1. Use of trans-esophageal echocardiogram prior to procedure
2. Use of heparin therapy during procedure
3. Use of warfarin therapy during procedure
4. Use of general anesthetic during procedure
5. Use of intracardiac echo during procedure
6. Use of low molecular weight heparin therapy post-procedure

**Atrial Fib Ablation - Process Comparison
Use of Warfarin Therapy During the Procedure**



Metrics – After Hospital Discharge

Outcome Metrics:

1. Proportion of patients with minimal or no symptoms of AFib (CCS Severity of Atrial Fibrillation (SAF) is Class 0 or 1)
2. Freedom from documented AFib/Flutter (minimum duration >30 second episode) on 48 hour holter or any other ECG (event recorders, 12 lead ECG)
 - a. All patients
 - b. Patients without membrane active anti-arrhythmic drug
 - c. Patients with membrane active anti-arrhythmic drug
3. Readmission (all cause)
 - a. Atrial fib or atrial flutter
 - b. Other cardiovascular event
 - c. Complication of the procedure
 - d. Repeat ablation procedure for recurrent Afib/flutter
 - e. Surgical procedure (MAZE, etc) for recurrent Afib/flutter
 - f. Other
4. Proportion of patients with CVA
5. Proportion of patients with permanent pacemaker implanted
6. Proportion of patients with esophageal perforation or fistula with demonstrable ulceration
7. Proportion of patients with persistent phrenic nerve injury
8. Proportion of patients with pulmonary vein stenosis $\geq 75\%$
 - a. Requiring intervention
9. Proportion of patients with vascular injury - AV fistula
10. Proportion of patients with vascular Injury - Pseudoaneurysm
11. Mortality

Metrics – After Hospital Discharge

Data Quality Metrics

1. Proportion of patients who receive follow-up 3 months following the procedure
2. Proportion of patients who receive follow-up one year following the procedure

Data Collection Form

A. DEMOGRAPHICS	
Last Name ^{2010.}	First Name ^{2012.}
SSN ²	(auto)
Admission Date ^{3000.}	
Birth	
Race	Asian ²⁰⁷²
Hispanic	Hawaiian
Admission	
Insurance	
Diabetes	
Esophageal	
Hypercholesterolemia	
Hypertension	
Sleep Apnea	
Termination	
B. EPISODE OF CARE	
C. HISTORY AND RISK FACTORS (PRIOR TO THE PROCEDURE)	
General History:	
Cancer	C. HISTORY - RHYTHM HISTORY
Chronic Atrial Fibrillation:	<input type="radio"/> No <input type="radio"/> Yes Date of Onset:
Current	D. PHYSICAL EXAM AND LABS:
Cerebrovascular	E. DIAGNOSTIC TESTS:
Blood Pressure	12 Lead ECG With Automated Measurements: <input type="radio"/> No <input type="radio"/> Yes → If Yes, Date
Pulse:	Heart Rate ___ bpm; QT Interval: ___ msec; Qtc Interval: ___ msec
	PR Interval Obtainable: <input type="radio"/> No <input type="radio"/> Yes → If Yes, PR Interval: ___ (msec) No
	QRS Duration (Non-Ventricular Paced Complex) ⁵¹⁷⁰ : ___ (msec) <input type="checkbox"/> Only V
	Cardiac Rhythm (check all that apply) <input type="checkbox"/> Sinus <input type="checkbox"/> Atrial tach <input type="checkbox"/> Atrial fib
	<input type="checkbox"/> 3rd degree heart block <input type="checkbox"/> Junctional
	→ If Paced Rhythm, Pacing Type ⁵¹⁹⁰ : <input type="radio"/> Atrial pacing <input type="radio"/> Vent pacing <input type="radio"/> Both

Data Collection Form—Challenges

E. PROCEDURE INFO:

Date Procedure: mm / dd / yyyy : Operator Name and NPI: _____

Total Fluoro Time: _____ minutes or Total Fluoro Dose _____,mGy

Time of Catheter Placement: hh/mm Time of Catheter Removal: hh/mm

Indication: Symptoms; Desire for drug-free lifestyle; Stroke prophylaxis; Redo

Pulmonary Vein Anatomy: Typical Four PV: No Yes

Presence of Left Common PV: No Yes

Presence of Right Middle PV: No Yes

Phrenic Nerve Evaluated By: Not evaluated; Pacing maneuvers; Other

Esophagus Location Evaluated By (check all that apply): Not evaluated; CT/MRI; ICE; Barium swallow; Temperature Probe

Type of Anesthesia: Moderate sedation; General sedation; Combination

Primary Ablation Strategy (check all that apply): Lasso – type catheter guided; Wide area circumferential ablation;
 Antral isolation; Complex fractionated atrial electrogram;

Secondary Ablation Strategy (check all that apply): Linear lesions; Ganglion plexus ablation;
 Complex fractionated atrial electrogram; Other

Challenge #1:
Defining what
procedure was
done

Not Release

Data Collection Form—Challenges

Challenge #2:
Documenting
procedure success
(short and long
term)

E. PROCEDURE INFO:			
Vein Isolation: Right Antrum Present: <input type="radio"/> No <input type="radio"/> Yes Left Antrum Present: <input type="radio"/> No <input type="radio"/> Yes			
	Right Pulmonary Vein		
	Superior	Inferior	Medial
Ablation:	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Present	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Present	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Present
Location: (Check all that apply)	<input type="checkbox"/> Circumferential <input type="checkbox"/> At Orifice <input type="checkbox"/> Outside orifice	<input type="checkbox"/> Circumferential <input type="checkbox"/> At Orifice <input type="checkbox"/> Outside orifice	<input type="checkbox"/> Circumferential <input type="checkbox"/> At Orifice <input type="checkbox"/> Outside orifice
Entrance Block Achieved:	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Tested	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Tested	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Tested
Exit Block Achieved:	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Tested	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Tested	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Tested

Data Collection Form

Challenge #3:
Establishing
follow-up (what to
collect and who
is responsible)

E. FOLLOW-UP:

Date of follow-up: mm / dd / yyyy

Mortality: No Yes if yes, Date: mm / dd / yyyy Cause of Death: Cardiac Non-Cardiac

CCS Severity of Atrial Fibrillation: Class 0 Class I Class II Class III Class IV

Post Procedure Events (check all that apply): AV fistula CVA, Esophageal Fistula or Perforation; Phrenic nerve injury,
 Pulmonary vein stenosis → If Yes, % Stenosis ____; Requiring intervention: No Yes, Pseudoaneurysm

Readmission: No Yes if yes, Date: mm / dd / yyyy

Reason for Readmission: AFib/Flutter Complication of the procedure; Other cardiac problem; Other

Repeat Ablation Procedure: No Yes if yes, Date: mm / dd / yyyy

Surgical Procedure (MAZE, etc) Since Catheter Ablation: No Yes if yes, Date: mm / dd / yyyy

Permanent Pacer Implant: No Yes if yes, Date: mm / dd / yyyy

ICD implant: No Yes if yes, Date: mm / dd / yyyy

Rhythm Testing: No Yes;

→ If Yes, **Method of Assessment:** 24 hour holter 48 hour holter Event monitor 12 lead Other

→ If Yes, **>30 Seconds of Recurrent AF/Aflutter Documented:** No Yes

Conclusions – Dataset Requirements

- Ask appropriate questions
- Collect appropriate data
- Accurate, reliable data
- Clear, consistent definitions
- Data form completed by an abstractor
- Collaboration and teamwork

