

# **SAFARI** **NCDR**<sup>®</sup> **Dataset Development**

## **Progress since April ThinkTank and Results of Beta Testing**

**Stephen Hammill MD**

# Workgroup Members

## At- large Members:

- Steve Hammill, chair (Mayo)
- Sana Al-Khatib (Duke)
- Hugh Calkins (Hopkins)
- Alan Kadish (Northwestern)
- Peter Kowey (Main Line Health – Philly)
- Fred Masoudi (U Colorado)
- Doug Packer (Mayo)
- Jeremy Ruskin (MGH)
- Paul Varosy (UCSF)

## Workgroup Members

- **HRS:** Kathy Pontzer
- **FDA:** Ben Eloff, Randy Brockman, Jun Dong
- **CMS:** Marcel Salive; JoAnna Baldwin
- **AHRQ:** Elise Berliner
- **Industry:** Marcia Yaross (Biosense), Ruey Dempsey (AdvaMed)
- **ACC:** Susan Fitzgerald, Kristyne McGuinn  
Christie Lang, Kristi Mitchell

# Workgroup process- Update

**Forms and metrics reviewed at the April ThinkTank were revised**

- Conference Calls**
- Email feedback**
- Beta testing**

# AF Ablation Metrics

## Atrial Fibrillation Ablation Study Draft Metrics

### 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 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

# AF Ablation Metrics

## Outcome Metrics:

- |    |  |
|----|--|
| Pr | 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) <ul style="list-style-type: none"> <li>a. All patients</li> <li>b. Patients without membrane active anti-arrhythmic drug</li> <li>c. Patients with membrane active anti-arrhythmic drug</li> </ul>     |
|    | 3. Readmission (all cause) <ul style="list-style-type: none"> <li>a. Atrial fib or atrial flutter</li> <li>b. Other cardiovascular event</li> <li>c. Complication of the procedure</li> <li>d. Repeat ablation procedure for recurrent Afib/flutter</li> <li>e. Surgical procedure (MAZE, etc) for recurrent Afib/flutter</li> <li>f. Other</li> </ul> |
|    | 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 $\geq 75\%$ <ul style="list-style-type: none"> <li>a. Requiring intervention</li> </ul>   |
|    | 9. Proportion of patients with vascular injury - AV fistula  |
|    | 10. Proportion of patients with vascular Injury - Pseudoaneurysm   |
|    | 11. Mortality  |

## 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

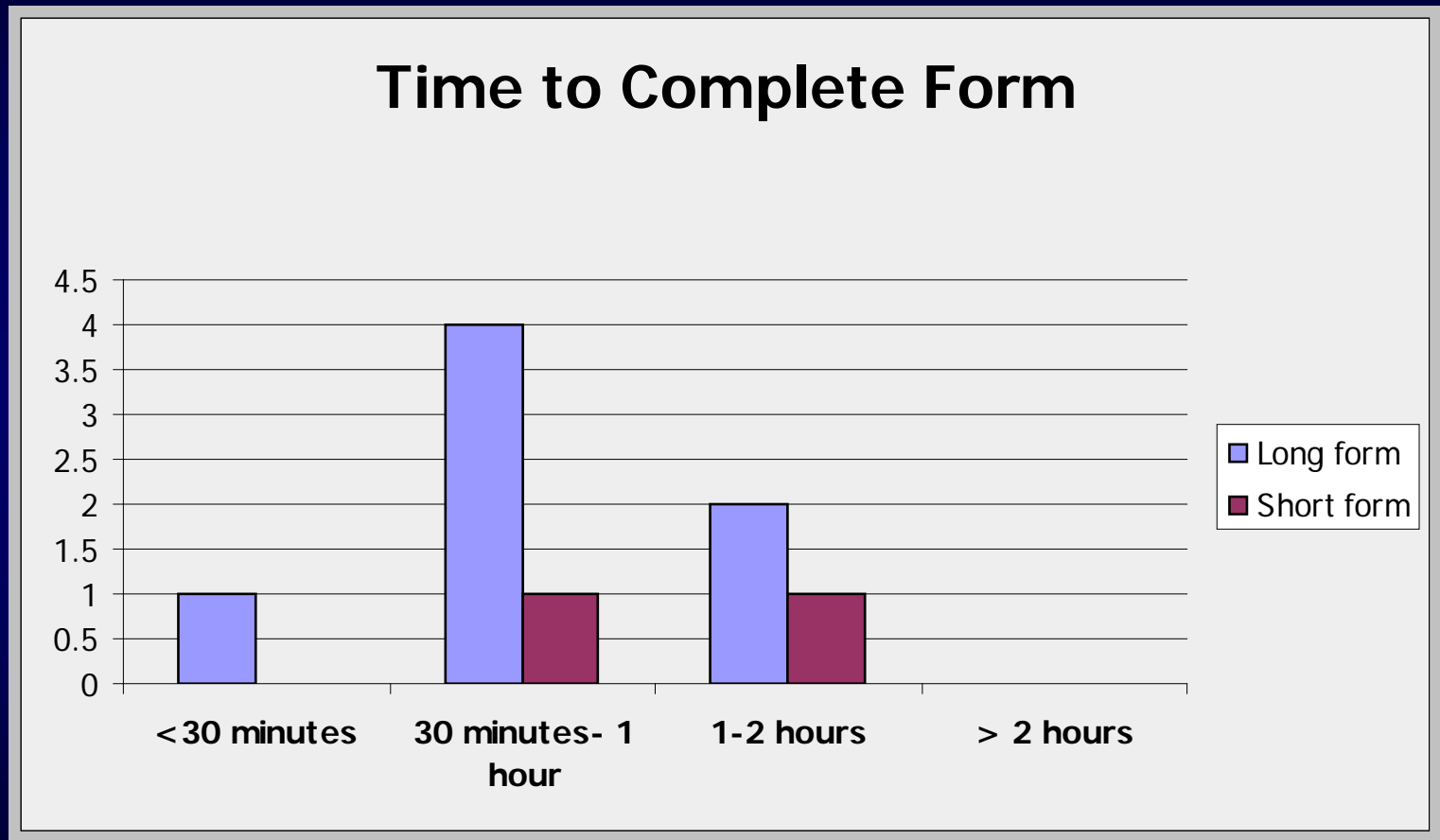
A. DEMOGRAPHICS		
Last Name <sup>2000</sup> :	First Name <sup>2005</sup> :	Middle Name <sup>2010</sup> :
B. EPISODE OF CARE		
Admission Date <sup>3000</sup> : mm / dd / yyyy	Patient Zip Code <sup>3005</sup> :	<input type="checkbox"/> Zip Code NA <sup>3006</sup>
Admitted For This Procedure <sup>3010</sup> : <input type="radio"/> No <input type="radio"/> Yes		
C. HISTORY AND RISK FACTORS		
G. PROCEDURE INFORMATION:		
E. DIAGNOSTIC TESTS		
12 Lead ECG With	Date of Procedure <sup>8000</sup> : mm / dd / yyyy	Operator Name and NPI <sup>8005</sup> : _____
Indications (check all that apply): <input type="radio"/> Symptoms <sup>8010</sup> <input type="radio"/> Desire for drug-free lifestyle <sup>8011</sup> <input type="radio"/> Stroke prophylaxis <sup>8012</sup> <input type="radio"/> Redo <sup>8013</sup>		
J. DISCHARGE:		
Cardiac Rhythm (check all that apply): <input type="checkbox"/> Sinus <sup>10000</sup> <input type="checkbox"/> Atrial tach <sup>10001</sup> <input type="checkbox"/> AFib <sup>10002</sup> <input type="checkbox"/> AFlutter <sup>10003</sup> <input type="checkbox"/> 2nd degree heart block <sup>10004</sup> <input type="checkbox"/> 3rd degree heart block <sup>10005</sup> <input type="checkbox"/> Junctional <sup>10006</sup> <input type="checkbox"/> Idioventricular <sup>10007</sup> <input type="checkbox"/> Paced rhythm <sup>10008</sup> <input type="checkbox"/> Other <sup>10009</sup>		
→ If Paced Rhythm, Pacing Type <sup>10010</sup> : <input type="radio"/> Atrial pacing <input type="radio"/> Vent pacing <input type="radio"/> Both → If Vent Pacing: Vent Paced QRS Duration <sup>10011</sup> : ____ msec		
→ If Paced Rhythm, Underlying Atrial Rhythm <sup>10012</sup> : <input type="checkbox"/> Sinus rhythm <input type="checkbox"/> Atrial fib/flutter <input type="checkbox"/> Sinus arrest <input type="checkbox"/> Unknown		
Intraventricular Conduction (check all that apply):		
Type of Anesthesia <sup>8040</sup> : <input type="radio"/> Moderate sedation <input type="radio"/> General sedation <input type="radio"/> Combination		

# Beta Testing

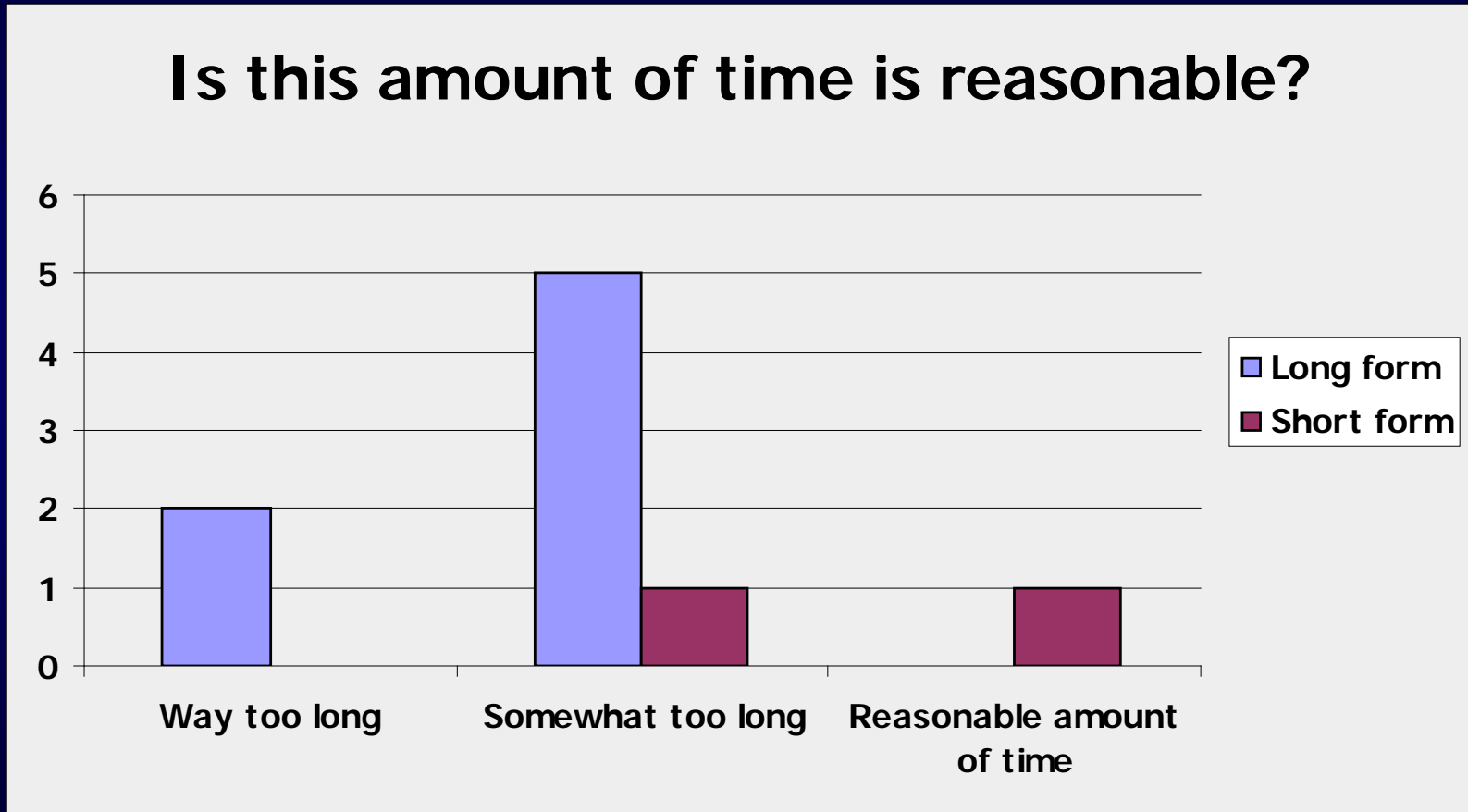
- **9 Beta Testing Sites**
- **Long, Short, and Follow-Up Forms**
- **All ablations during Dec. 1-15**
- **Most Sites Completed 1-5 data collection forms, 1 more than 20**



# Beta Testing- Survey Results



# Beta Testing- Survey Results



# Beta Testing- Survey Results

## Resources Required- Other Staff

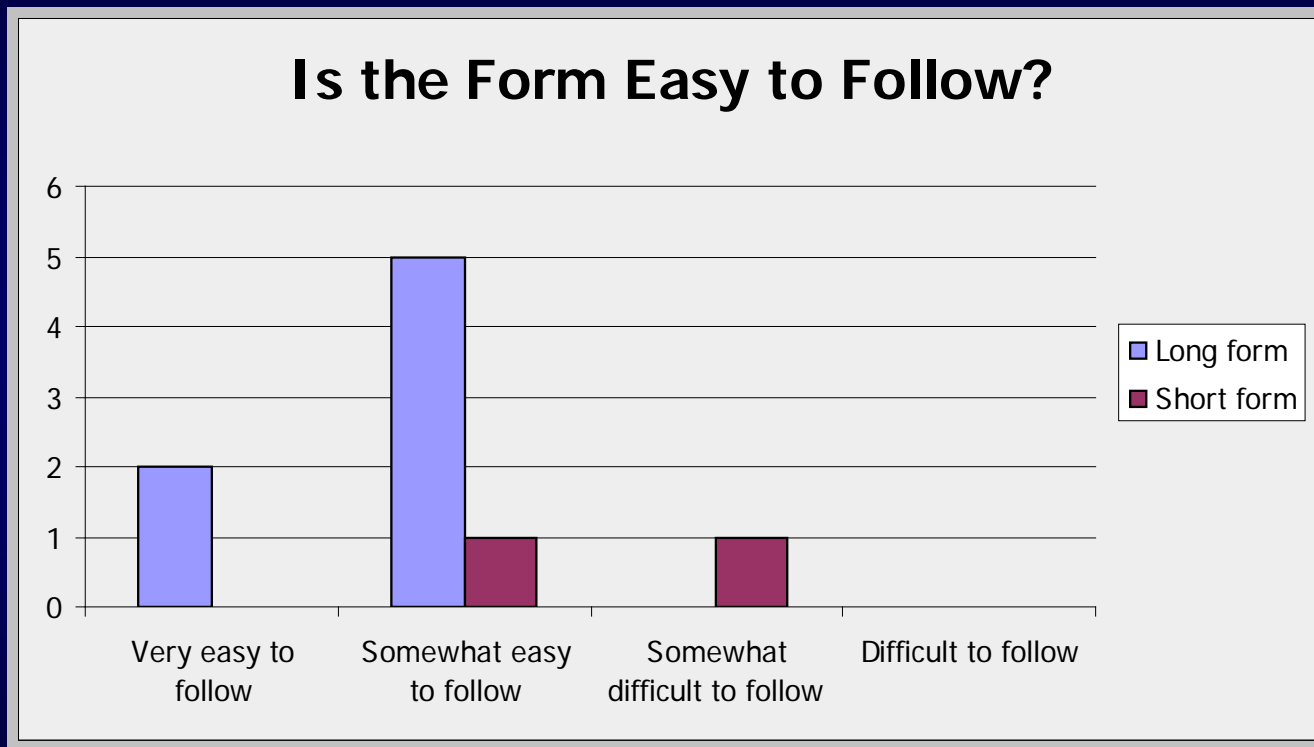
	Most of the time	Some of the time	Never
Demographics	0	1	7
Episode of Care	1	3	3
History and Risk Factors	0	2	5
Physical Exam and Labs	0	2	5
Diagnostic Tests	0	6	2
Procedure Information	5	1	1
Discharge	1	1	5
Post Procedure	1	2	4
Follow-up	0	4	1

# Beta Testing- Survey Results

## Could not Complete Data Elements

	Most of the time	Some of the time	Never
Demographics	0	0	6
Episode of Care	0	0	7
History and Risk Factors	0	3	4
Physical Exam and Labs	0	2	5
Diagnostic Tests	0	5	2
Procedure Information	1	5	1
Discharge	2	0	5
Post Procedure	2	0	5
Follow-up	1	2	2

# Beta Testing- Survey Results



# Beta Testing- Feedback

## Procedure Section:

- Too long
- More clear and concise definitions needed
- Variation in interpretation of elements
- Information not readily available from medical record/dictated reports.

# Beta Testing- Feedback

## Follow-up form:

- Timing?
- Who is responsible?
- How to get information if performed at another facility?
- Is information obtained in-person, or is a phone/mail survey OK?

# Inclusion Criteria

## Better age and rhythm definition needed

### Suggested inclusion criteria:

*Patients undergoing a left atrial catheter ablation procedure to treat atrial fibrillation*

### Suggested exclusion criteria:

*Patients with A. Flutter unless this is a “recurrent” arrhythmia following AFib ablation*



## Next steps

- **Review ThinkTank comments and revise form accordingly**
- **Shorten the “short form”**
- **Expand and enhance the data dictionary**

***Thanks for your attention***