

# Review of CMS MEDCAC Meeting & Impact on SAFARI

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# Background

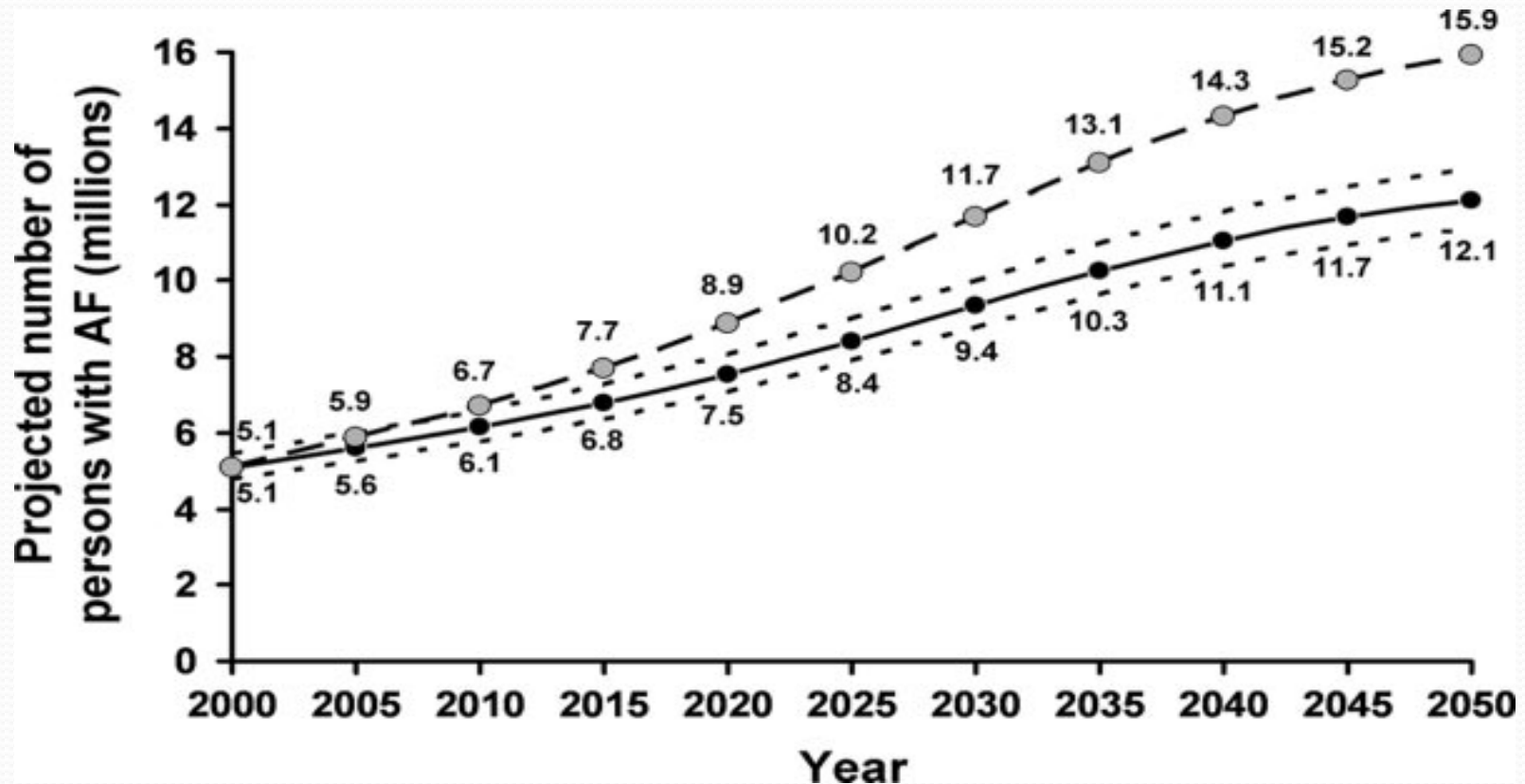
- Atrial fibrillation prevalence high in the Medicare population
- Complex management options and strategies for prevention of adverse health effects
- Interest and utilization of catheter-based therapy for AF has been growing

# MEDCAC Meeting

- Oct 21, 2009
- Committee comprised of:
  - Chair & Vice Chair
  - 7 Voting members
  - Industry representative
  - Patient Advocate
  - 2 Guest Panel members
- Speakers
  - 1 Guest speaker;
  - 2 Tech Assessment presenters
  - 6 public commenters

# The Burden of AF

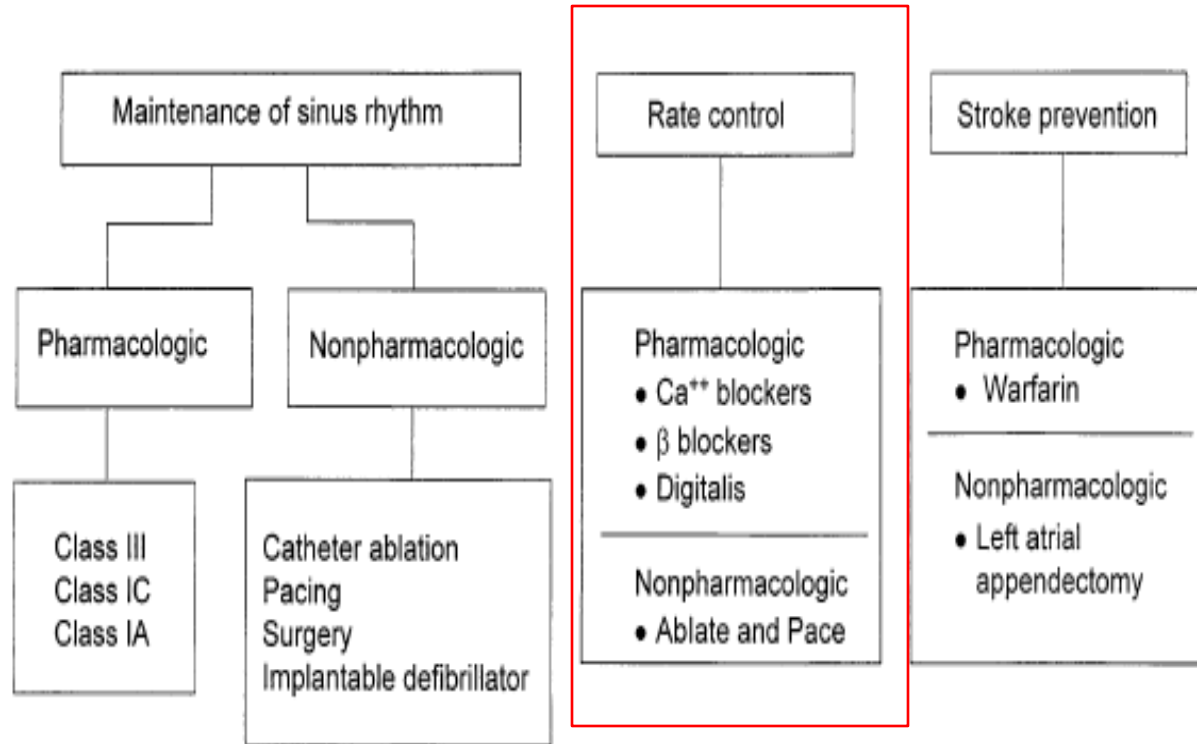
## Projected AF Prevalence in the USA in the Next 50 years



Projected number of persons with AF in the United States between 2000 and 2050, assuming no further increase in age-adjusted AF incidence (solid curve) and assuming a continued increase in incidence rate as evident in 1980 to 2000 (dotted curve).

*Go A. et al. JAMA. 2001;285:2370*

# Treatment Strategies for AF



# Comparative Effectiveness of Radiofrequency Catheter Ablation for Atrial Fibrillation

S. Ip, T. Terasawa, E. Balk, M. Chung, A. Alsheikh-Ali, A. Garlitski, J. Lau  
Tufts Medical Center Evidence-based Practice Center

Comparative Effectiveness Review, 2009  
Funded by the Effective Health Care Program at the  
Agency for Healthcare Research and Quality

# Summary

- moderate level of evidence that RFA is effective as a 2<sup>nd</sup> line therapy but short follow-up ( $\leq 12$  mo)
- insufficient data on 1<sup>st</sup> line therapy
- major clinical complications  $< 5\%$ , but quality of data is poor
- need more data on the elderly, patients with multiple co-morbidities, long term (years) rates of AF recurrence, effects from radiation exposure, quality of life, and mortality

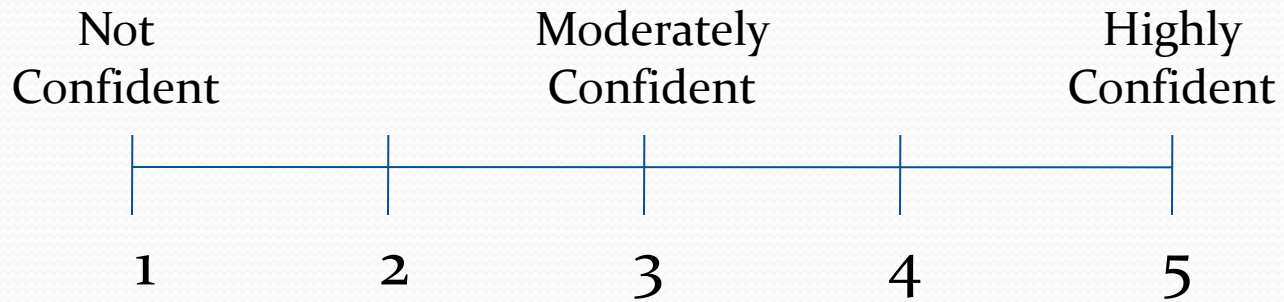
# Discussion Questions

- Clinical comparators
- Population
- Outcomes of interest
- Duration of follow-up
- Device characteristics
- Physician training



# Voting Scale

How confident are you...



# Voting Questions

1. How confident are you that the evidence is adequate to draw conclusions about the health outcomes of interest to patients treated with catheter ablation for atrial fibrillation?
  - a. Recurrence of Arrhythmia 4.0
  - b. Symptom relief 3.8
  - c. Stroke 2.0
  - d. Survival 1.4

# Voting Questions

2. How confident are you that catheter ablation for the treatment of atrial fibrillation improves health outcomes compared to other therapies or treatments in the following populations:
  - a. As first-line therapy? 1.8
  - b. As second-line therapy? 4.2
  - c. For first detected atrial fibrillation? 1.2
  - d. For long-standing (greater than 1 year) atrial fibrillation? 2.9
  - e. For paroxysmal atrial fibrillation? 4.0
  - f. For persistent atrial fibrillation? 3.1

# Voting Questions

3. How confident are you that ablation improves long-term (greater than 1 year) health outcomes?

Score: 2.3

# Voting Questions

4. How confident are you that the outcomes can be extrapolated to:
  - a. Patients outside a controlled clinical study? 2.8
  - b. The Medicare beneficiary population (age 65 years and older, 56% female)?  
Score 2.6

# Voting Questions

5. How confident are you that additional evidence is needed?
  - a. Recurrence of Arrhythmia 2.4
  - b. Symptom relief 2.8
  - c. Stroke 4.7
  - d. Survival 4.7

# Discussion Questions

## Addition evidence, if needed

- What type of additional evidence is needed to determine health outcomes?
- What study designs are most appropriate to obtain this additional evidence?