



U.S. Department of Health and Human Services
National Institutes of Health
National Heart, Lung, and Blood Institute

SAFETY EVALUATION OF ATRIAL FIBRILLATION FDA THINK TANK

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National Heart
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People Science Health

DISCLOSURES

- ▣ No financial conflicts of interest
- ▣ Views expressed are my own and do not represent the NIH view nor the NHLBI view

▣ Diagnosing recurrence of arrhythmia

- Time dependent
 - ▣ Early recurrence
 - ▣ Late recurrence

At what point does one declare success and when does progressive disease take over?

- ▣ Does the PCI analogy hold?
- Sampling issues for asymptomatic episodes
 - ▣ Need easy to tolerate, cheap, non-invasive diagnostics

▣ Diagnosing new arrhythmias

- Atypical atrial flutter/proarrhythmia

- ▣ Issue of anticoagulation continuation/termination
 - May be a large determinant of outcome
 - Decision often not based on evidence or extrapolation of known data
 - Need for better anticoagulants
- ▣ Issue of unreported or underreported serious complications
 - A-E fistulae
 - PV stenosis
 - Tamponade
 - ?Radiation exposure