

Updating Systematic Reviews: Treatment of Atrial Fibrillation

A PCORI Virtual Multi-Stakeholder Workshop

December 7, 2016



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Agenda

- Welcome
- Background and goals for the day:
 - PCORI's Evidence Synthesis Program
 - AHRQ's Evidence-based Practice Center (EPC) Program
 - Prior Atrial Fibrillation Review Key Questions
 - Questions to guide the discussion
- Discussion
- Summary and closing remarks



Welcome

Housekeeping

- Participants' lines are live
 - Please mute your line when you are not speaking to reduce background noise
- Today's conversation is being recorded and will be posted to the PCORI web site
- We will take comments in the order indicated on the agenda
- Comments and questions from the public may be submitted via the chat window
 - We will attempt to include these submissions in the discussion when feasible
 - We cannot guarantee a question will be addressed



PCORI's Evidence Synthesis Program



PCORI and Evidence Synthesis

- *PCORI's authorizing legislation states that evidence synthesis is a core function of PCORI:*

“(C) PURPOSE.—The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations....”



PCORI's Evidence Synthesis Program

- Initial goals:
 - Research to address heterogeneity of treatment effects, more personalized individual health care choices
 - More rapid deployment of actionable CER evidence in context
- We are focusing on short-turnaround, rigorous, relevant products
 - Strategic, selective focus on generating new research products (IPD MA, other research “re-use” opportunities)
 - Locating and qualifying existing CER SR products for targeted updating through a partnership with the Agency for Healthcare Research and Quality



Decision Tree for PCORI CER Systematic Review Topic Selection

Relevance

- Common, costly, or contentious clinical area
- Stakeholders have expressed interest in topic
- Synthesis will inform decision-making and/or change practice
- Meets PCORI's mission and scope

Yes

Gap test: Has the evidence previously been synthesized?

Work collaboratively with CER SER authors/funders to avoid duplication of efforts before proceeding

Yes

No

Strength of evidence

High or moderate

Low or insufficient

Candidate for new systematic review

Urgent issue of potential harms?

Yes

No

Recency: Search dates within 1 year?

Yes

No

Candidate for dissemination work

Candidate for updating

Consider update and/or dissemination work; develop framework to inform future research

Is there sufficient intervening research since completion?

Yes

No

Candidate for updating or other analysis

Future research or no further action



Planned Targeted SER Updates in Collaboration with AHRQ

- **Treatment of Atrial Fibrillation**
- Treatment of Rheumatoid Arthritis
- Treatment of Post-Traumatic Stress Disorder
- Nonsurgical Treatments of Urinary Incontinence



AHRQ's EPC Program



Prior Key Questions



Prior Key Question 1

What are the comparative safety and effectiveness of pharmacological agents used for ventricular rate control in patients with atrial fibrillation?

Do the comparative safety and effectiveness of these therapies differ among specific patient subgroups of interest?



Prior Key Question 2

What are the comparative safety and effectiveness of a strict rate-control strategy versus a more lenient rate-control strategy in patients with atrial fibrillation?
(HR <80 or <110)

Do the comparative safety and effectiveness of these therapies differ among specific patient subgroups of interest?



Prior Key Question 3

What are the comparative safety and effectiveness of newer procedural and other nonpharmacological rate-control therapies compared with pharmacological agents in patients with atrial fibrillation for whom initial pharmacotherapy was ineffective?

Do the comparative safety and effectiveness of these therapies differ among specific patient subgroups of interest?



Prior Key Question 4

What are the comparative safety and effectiveness of available antiarrhythmic agents and electrical cardioversion for conversion of atrial fibrillation to sinus rhythm?

Do the comparative safety and effectiveness of these therapies differ among specific patient subgroups of interest?



Prior Key Question 5

What are the comparative safety and effectiveness of newer procedural rhythm control therapies, other nonpharmacological rhythm-control therapies, and pharmacological agents (either separately or in combination with each other) for maintenance of sinus rhythm in atrial fibrillation patients?

Do the comparative safety and effectiveness of these therapies differ among specific patient subgroups of interest?



Prior Key Question 6

What are the comparative safety and effectiveness of rate-control therapies versus rhythm-control therapies in patients with atrial fibrillation?

Do the comparative safety and effectiveness of these therapies differ among specific patient subgroups of interest?



Questions to Guide the Scoping Discussion



Scoping Question 1

The prior review provided a comprehensive summary of available pharmacological and interventional approaches to both rate and rhythm control strategies.

Is there a rationale to **prioritize** updating the review of the evidence to **one strategy or the other** at this time (i.e., reviewing just **rate control** strategies, **or** just **rhythm control** strategies)?

If so, why?

Similarly, is there a case to be made for limiting the review to only **pharmacological interventions or non-pharmacological interventions** for either strategy?



Scoping Question 2

The prior review directly compared the effectiveness of rate control strategies versus rhythm control strategies in improving a number of outcomes among patients with atrial fibrillation **(key question 6)**.

To your knowledge, are there new studies addressing this question of the direct comparison of the two control strategies that would be important to include in an update of the evidence?

Are there remaining uncertainties associated with this question (e.g., specific subpopulations that might benefit more or less from the two strategies) which would make it important to retain in this updated review?



Scoping Question 3

The prior review found moderate to high strength of evidence for a fair number of treatment comparisons of various electrical or pharmacologic methods of cardioversion to restore normal sinus rhythm (**key question 4**), although the evidence was less certain regarding maintenance of sinus rhythm and recurrence of atrial fibrillation.

Would you retain this question as being of high priority in the updated review?

If so, **would you refocus it** in any way given the prior findings?



Scoping Question 4

Is the issue of **strict versus lenient rate-control** (i.e., heart rate <80 versus <110 BPM) still strongly debated (**key question 2**)?

Is there new evidence that you are aware of since the prior review that would definitively add to our knowledge on this issue?



Scoping Question 5

Is there anything that is emerging in the area of atrial fibrillation treatment since the prior review that you feel needs to be addressed by this update?

Is something critical missing?



Scoping Question 6

Do you have any other comments for us on behalf of your organization?



Discussion



Order of Comments

- Patients and Patient Representatives
- Clinicians
- Industry
- Research
- Patients and Patient Representatives

**Comments are not required of participants. Any participant may pass on the opportunity to comment.*



Order of Comments

Patients and Patient Representatives

- American Heart Association
 - Mark Estes
- Stop Afib.org
 - Mellissa Moss
- WomenHeart
 - Susan Campbell

Clinicians

- American Geriatrics Society
 - Michael Rich
- American Academy of Family Physicians
 - Kenny Lin
- American College of Cardiology
 - Paul Varosy



Order of Comments

Industry

- Advanced Medical Technology Association
 - Karen Nordahl
- Bristol-Myers Squibb
 - Priti Jhingran
- Biotechnology Industry Organization
 - Cheng Wang

Research

- Centers for Disease Control and Prevention
 - Mary George
- National Heart, Lung and Blood Institute
 - David Lathrop
- Alliance for Aging Research
 - Sue Peschin



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Patients and Patient Representatives

- American Heart Association
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Summary and Closing Remarks



THANK YOU!

