

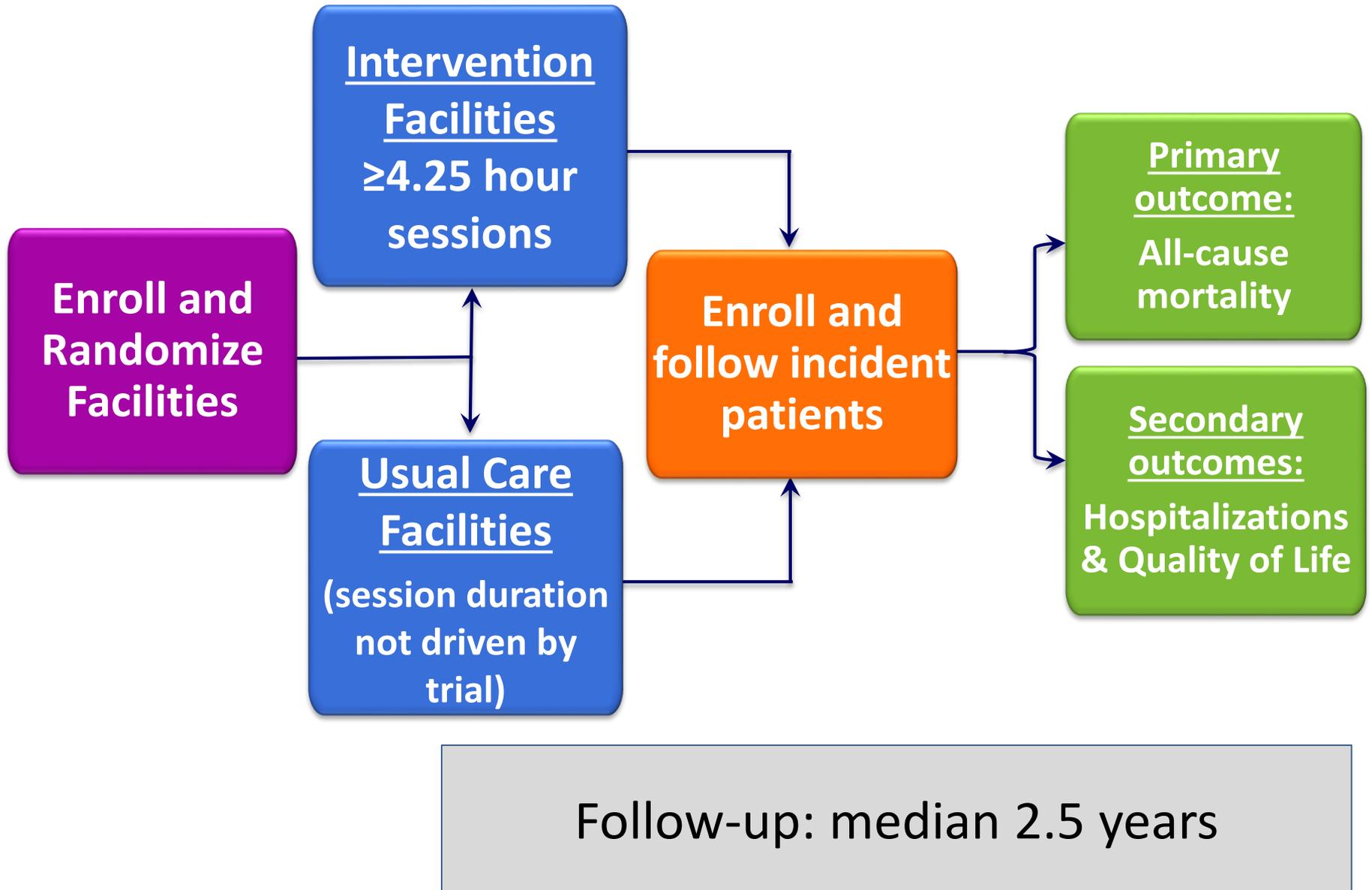
# Barriers, Challenges, and Lessons Learned from TiME

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Steering Committee Meeting  
May 23, 2017

**TiME**

# TiME Trial Design



Barrier	Level of Difficulty				
	1	2	3	4	5
Enrollment and engagement of patients/subjects	x				
Engagement of clinicians and Health Systems			x		
Data collection and merging datasets	x				
Regulatory issues (IRBs and consent)		x			
Stability of control intervention			x		
Implementing/Delivering Intervention Across Healthcare Organizations					x

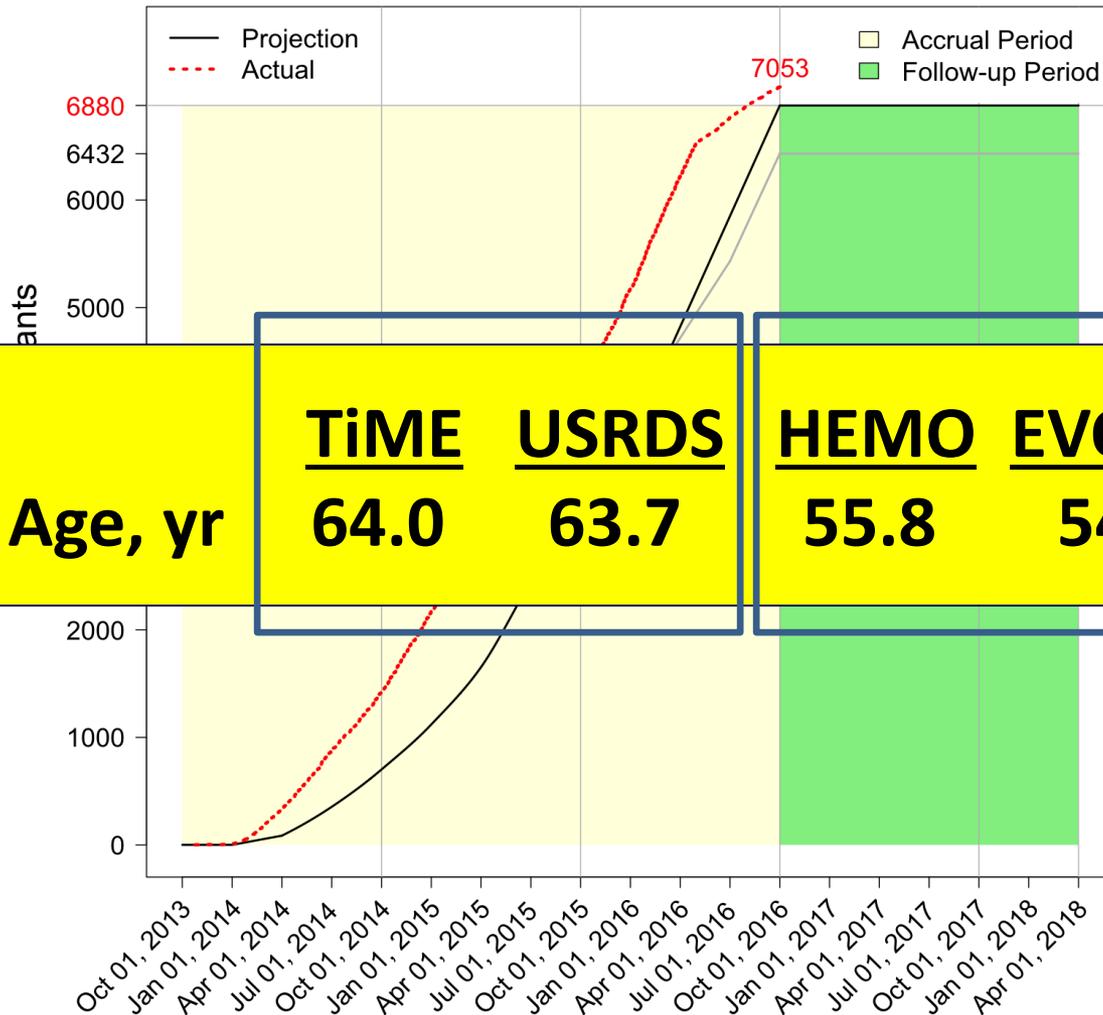
# Patient Enrollment

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## Lesson:

People are less likely to opt out than to opt in.

# Patient Enrollment



**Mean Age, yr**

**TiME**

**64.0**

**USRDS**

**63.7**

**HEMO**

**55.8**

**EVOLVE**

**54.5**

# Patient and Clinician Engagement

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## Lesson:

Difficult without either research staff on site OR health system staff who view themselves as part of the research team

- Active, ongoing interaction with clinicians and health system staff is critical – need systems for this
- Staff turnover, changing priorities need to be anticipated

# Data Collection and Merging Datasets

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## Lessons:

- Collaborative approach between IT teams at DCC and health system is important during both trial planning and conduct
- Ongoing data review useful

# Regulatory / IRB Issues

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## Lesson:

There are many experts and many strongly held views -- do not be intimidated; conversations help.

# Stability of Control Intervention

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## Lessons:

- Enthusiasm about the trial question can be a double-edged sword
- Stability of control intervention more likely if trial can be completed quickly

# Stability of Control Intervention

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- Lots of national attention to dialysis session duration
  - 4-hour treatments *almost* became a CMS clinical performance measure
  - New clinical practice guidelines include a maximum ultrafiltration rate (usually necessitates a longer session duration)
- We could not have dictated Usual Care session duration and still viewed trial as minimal risk

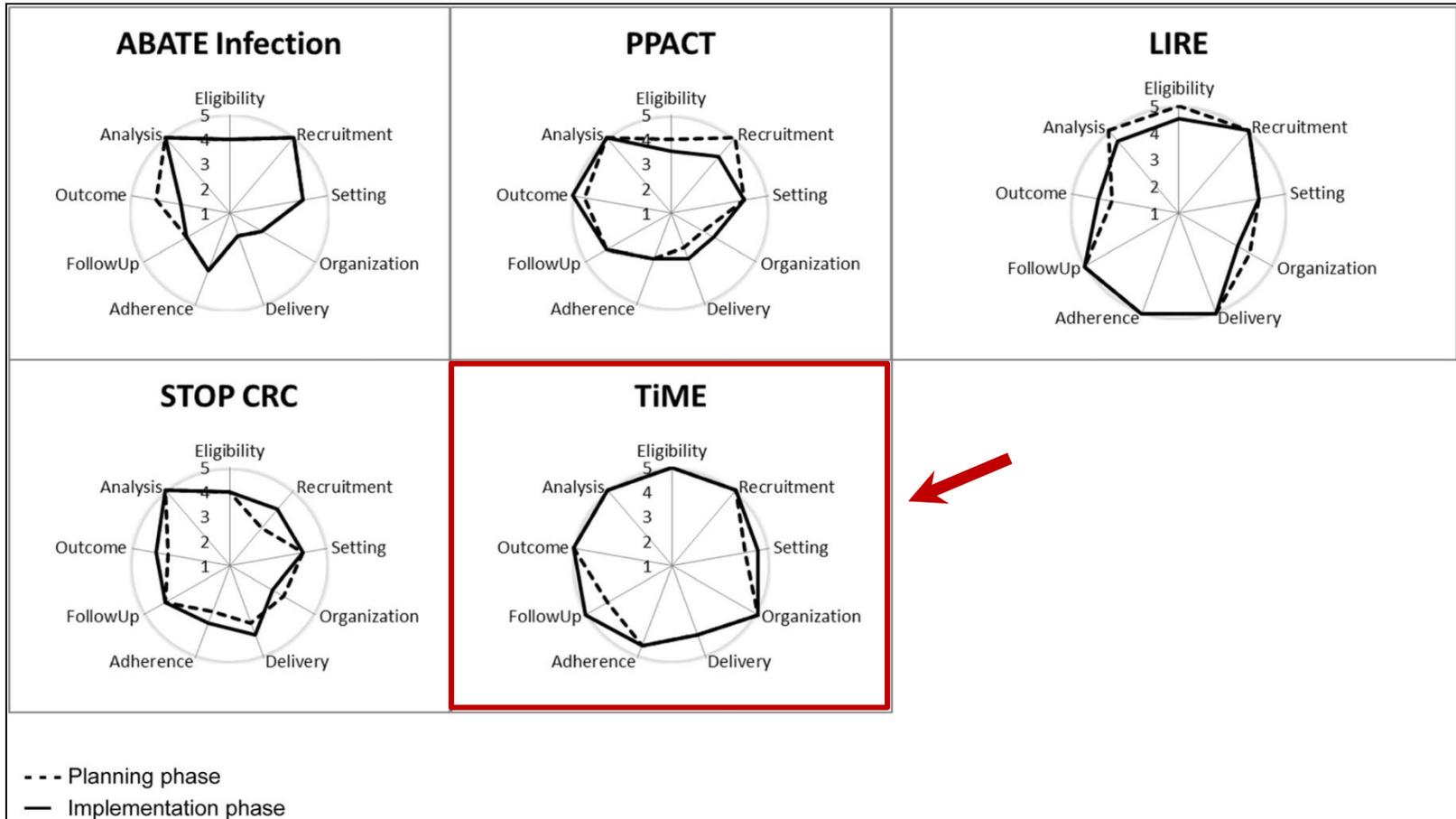
# Implementing / Delivering Intervention Across Health Systems

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## Lessons:

- Not all interventions are the same
- Important to be able to track delivery of intervention
- Maybe a trial can be too pragmatic

# PRECIS Scores



# Most Important Lessons

- Progress is incremental
- Not all problems can be solved on the first try
- Celebrate successes, learn from challenges
  - First trial conducted under true partnership between LDOs, academia, NIH
  - Largest dialysis trial to date
  - Navigated regulatory challenges for waiving consent in high risk patient population, mortality trial
  - Use of single IRB for hundreds of sites
  - TiME has generated tremendous interest in moving forward with this approach to evaluate other interventions in dialysis