TiME Trial: Challenges and Insights

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TiME

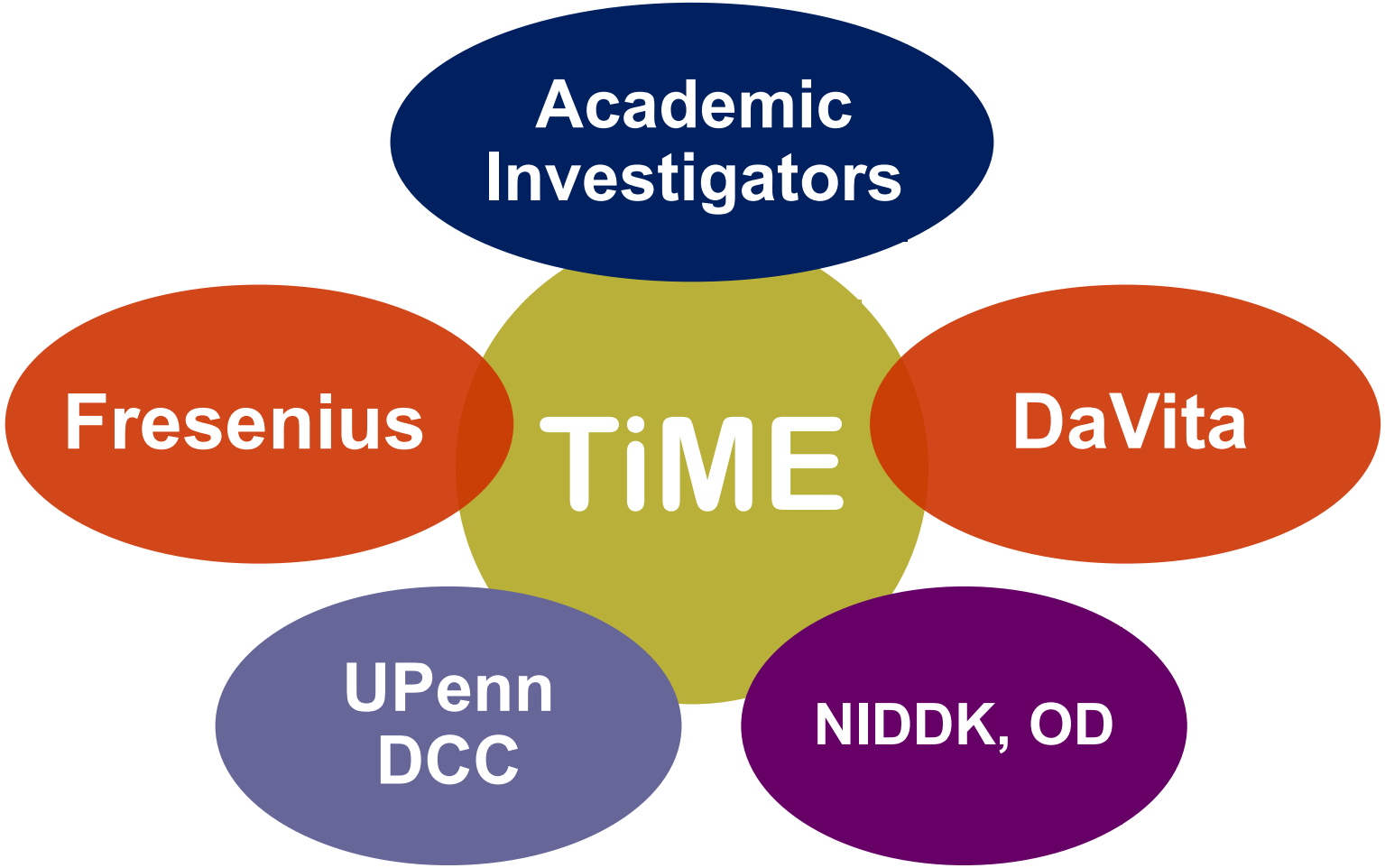
Trial Hypothesis

For thrice-weekly maintenance hemodialysis, treatment with session durations >4 hours will improve outcomes compared with usual care.

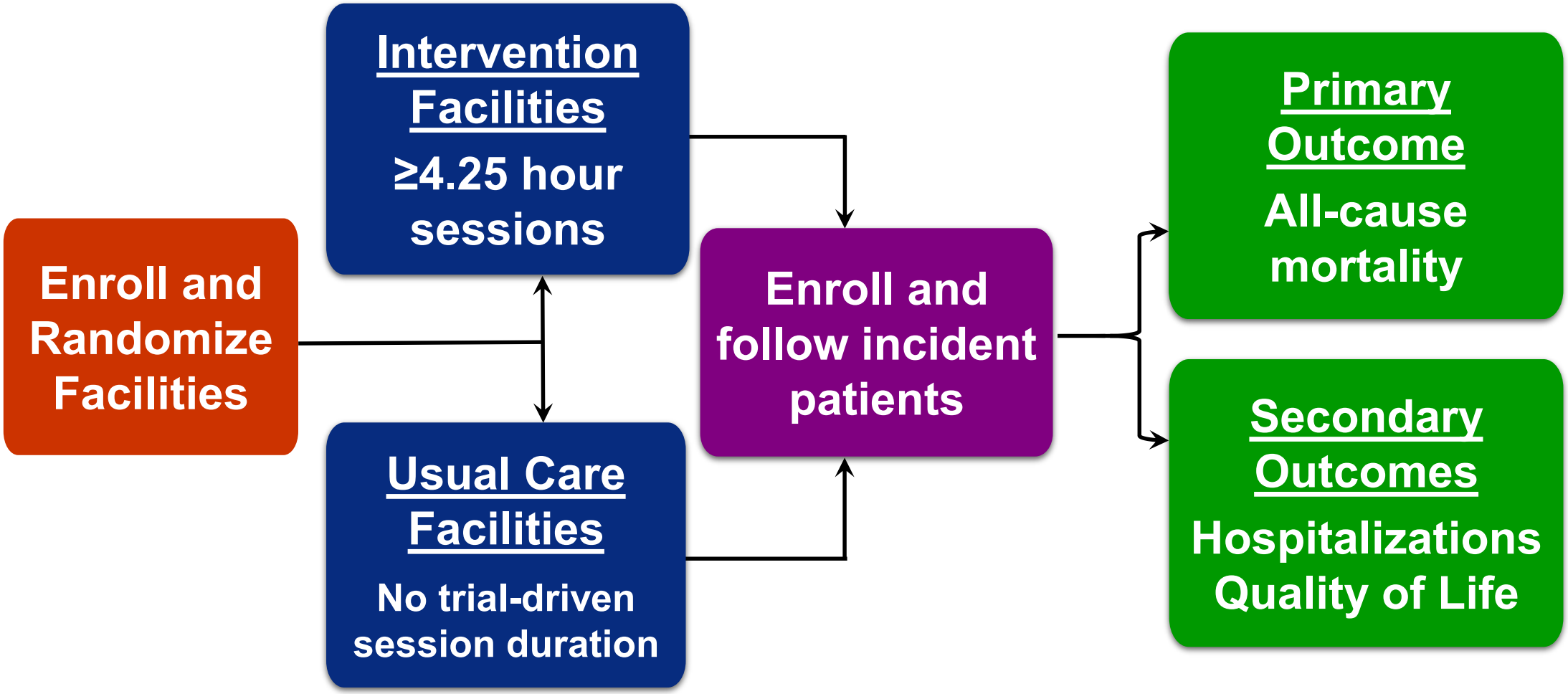
Slower removal of fluid will result in:

- Less intra-dialytic hypotension
- Less myocardial “stunning”
- More consistent attainment of target weight

TiME Trial Team



Trial Design



Demonstration Project Objectives

1. Partner with multiple health systems and leverage their clinical care infrastructures to conduct a large pragmatic trial
2. Navigate regulatory and ethical challenges for waiving consent
3. Use a single academic IRB to oversee hundreds of study sites
4. Enroll thousands of incident patients who are highly representative of US hemodialysis population (largest trial in dialysis)
5. Harmonize highly granular clinical data from multiple health systems and achieve high degree of data completeness
6. Monitor trial conduct and safety using an efficient centralized approach
7. Determine the effect of longer session duration on important clinical outcomes by implementing sessions >4 hours in the Intervention facilities

Factors Contributing to Intervention Implementation Challenge

- Required buy-in from all levels of health system
- Intervention was burdensome for patients
- Required uniform messaging from full clinical team
- Implementation affected by high rate of staff turnover
- Multiple health system initiatives competed for staff attention
- Clinicians were placed in a somewhat uncomfortable position

Observations about Intervention Implementation

- Some dialysis units had outstanding adherence to the intervention
  - Nearly 100% of sessions for all participants throughout entire duration of trial were at target
- Facility was a major contributor to the overall variance in achieved target session duration
- Session duration decreased over time (both patient-time and calendar-time)

What I Wish I Knew Then….

- Engagement, engagement, engagement!
- Clinician willingness to participate is not the same as buy-in and commitment
- Active, ongoing interaction with clinicians and health system personnel is critical but systems for interacting with clinicians are poorly developed
- Waiving consent can make it difficult to engage with patients

Advice for New Project Teams

- A highly developed and centralized health care delivery infrastructure does not obviate the need for activity at the local level
- What we view as a small change to work flow may be viewed by health system personnel as prohibitively burdensome.
- Questions that can be answered quickly reduce threat of competing initiatives or policies, secular changes, clinician burn-out
- Interventions that do not require buy-in from “all parties” are easier to implement
- **Have fun!!!!**

What the Collaboratory Has Allowed

A whole that is greater than the sum of the parts

- Sharing of experiences
- Group efforts to tackle big challenges: e.g., regulatory issues
- Messaging to broader research and health system communities