Lessons Learned (so far) from the TiME Trial

Laura Dember, M.D.
University of Pennsylvania

HCS Research Collaboratory
Steering Committee Meeting
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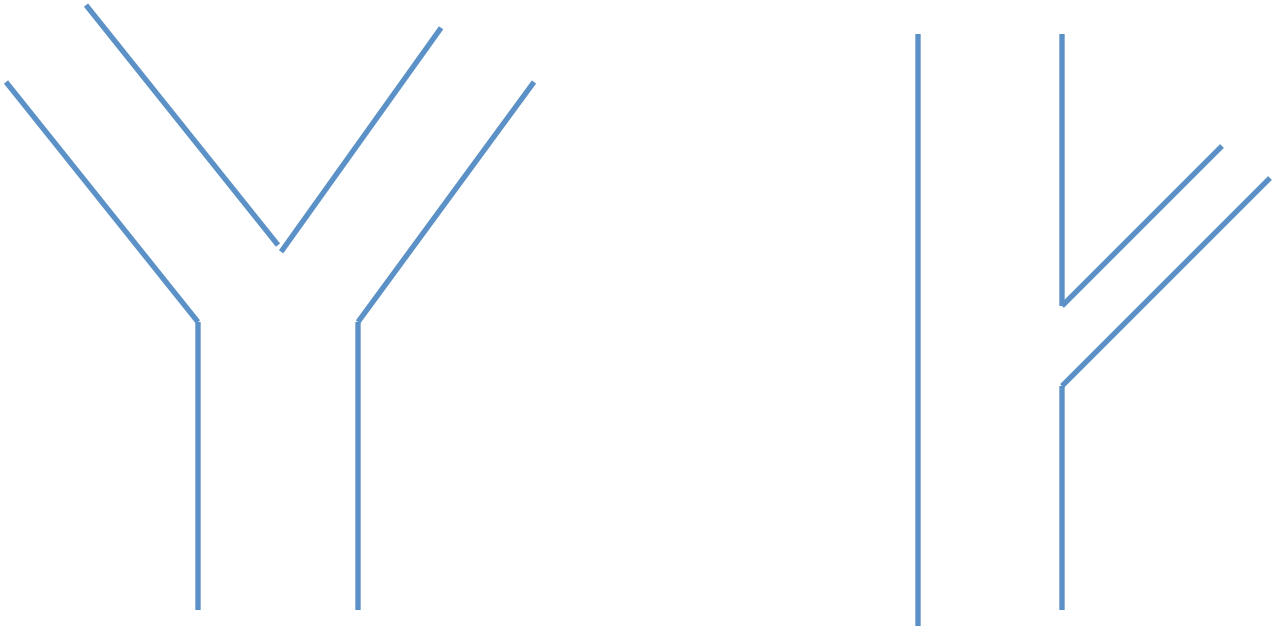
My Father's Favorite Yogi Berra Quote

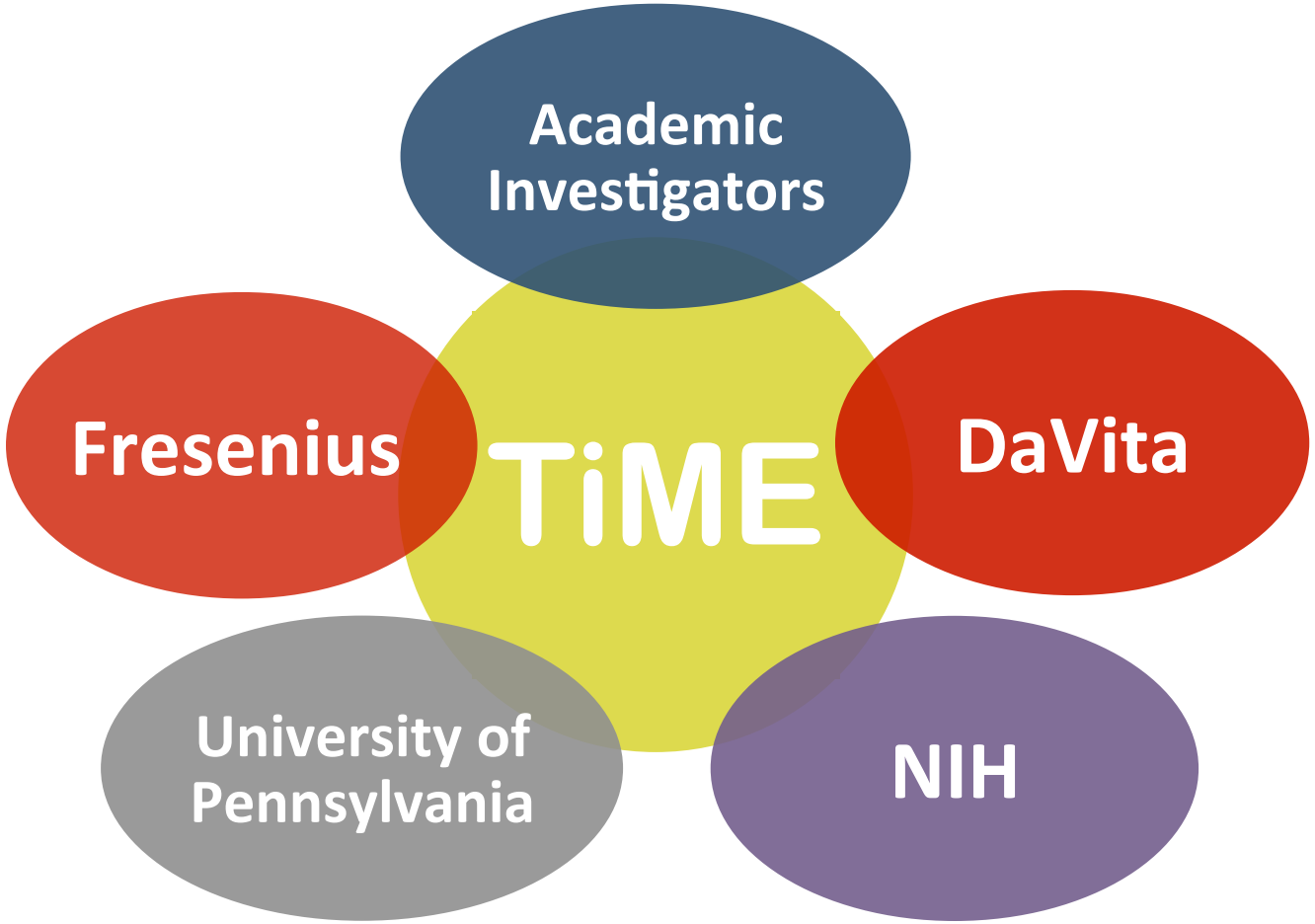
If you come to a fork in the road, take it.



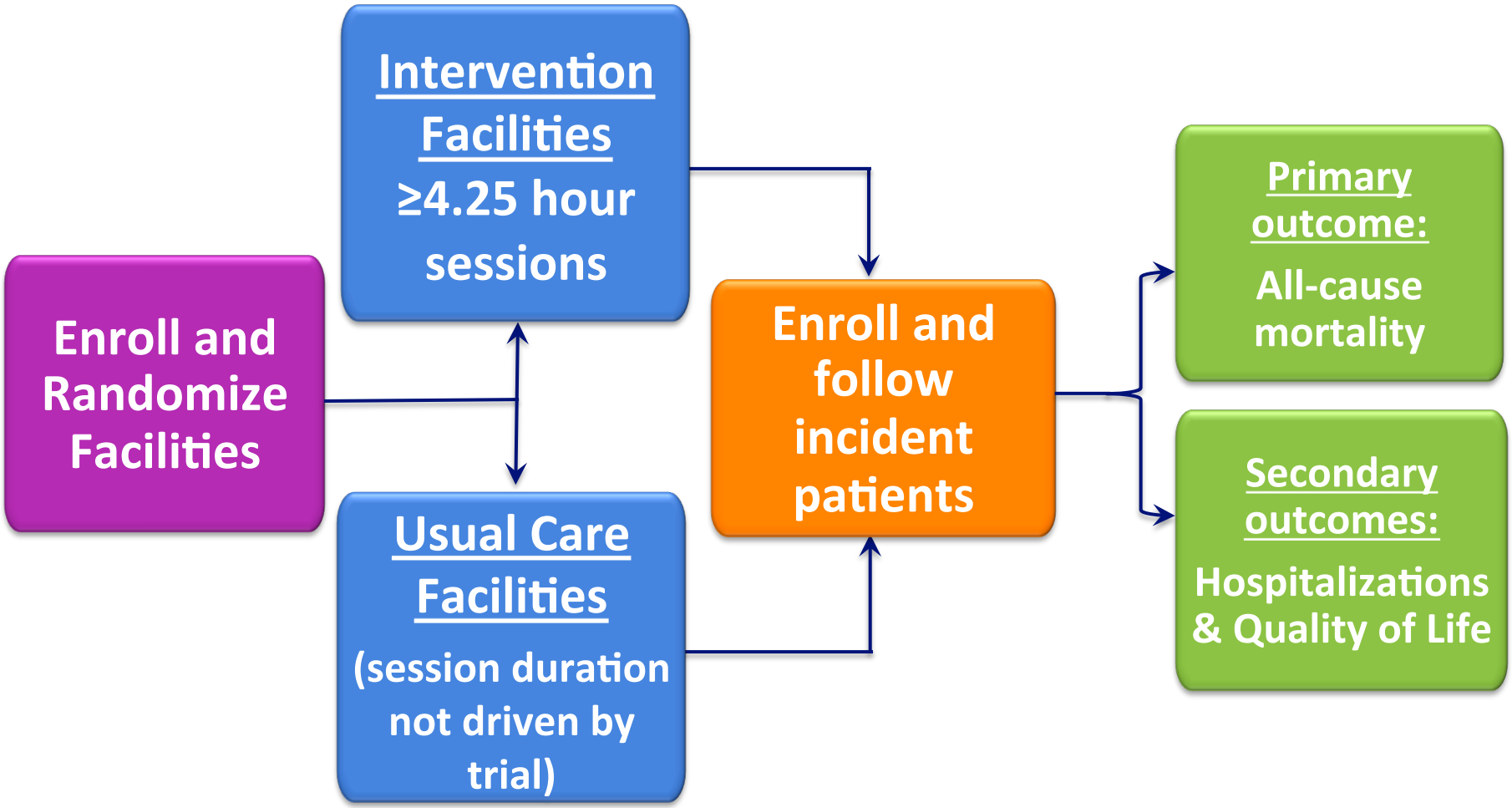
Lessons Learned

1. A highly developed and centralized health care delivery infrastructure does not obviate the need for activity at the local level and with individual practitioners and administrators.
2. What we view as a small change to work flow or IT system is often viewed by health system personnel as a large change.
3. There are many things we cannot control.
4. Not everything will work as initially planned.
5. Seemingly insurmountable problems usually have solutions.

TiME Trial Team



TiME Trial Design



Follow-up: 2-3 years

Eligibility Criteria

Facility

- Capacity to accommodate 4 hr, 15 minute treatments for incident patients
- Agreement by nephrologists and facility leadership to implement intervention

Patient

- Age >18 years
- Initiation of maintenance dialysis within past 120 days
- Ability to provide consent for dialysis care

Opt-Out Approach

- Patients are given a brief information document that includes
  - Purpose of the trial
  - How session duration will be affected by the trial
  - Toll-free telephone number to obtain additional information and to opt-out of participation
- Informational posters with research team contact information are posted in dialysis facilities throughout duration of the trial.

Sample Size and Power

- 402 facilities, 6432 patients
- Average cluster size: 16 patients
- 80% power for HR 0.85

Data Acquisition

- Clinical and administrative data are transmitted electronically from individual facilities and centralized laboratory to dialysis provider data warehouses (as in clinical care)
- De-identified data are transmitted from dialysis provider data warehouses to UPenn Data Coordinating Center

Pragmatic Features of the TiME Trial

- All patients starting dialysis are eligible unless they cannot provide consent to clinical care
- Intervention is delivered by clinicians
- Outcomes and all data elements are obtained through routine clinical care
- Adherence to intervention at the patient level is promoted using systems already in use
- Highly centralized implementation approach
- Single IRB of record
- Testing effectiveness rather than efficacy

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One Health Provider Organization = Thousands of Health Care Providers

- Buy-in and support from leadership is necessary but not sufficient
- Enrollment sites (400!) are made up of individuals with:
  - Different opinions
  - Different concerns
  - Different personalities
  - Different roles
- At facility level we need buy-in from:
  - Administrator
  - Medical Director
  - Every nephrologist
  - Patients

Small Changes to Us = Big Changes to Provider Organization and/or Facility

- Addition of 2 questions to CMS-mandated quality of life assessment

- Electronic documentation of eligibility and notification

We Cannot Control Everything

- Secular trend: longer dialysis

Not Everything Will Work as Initially Planned

- This should be expected and is okay.
- Example: change in approach to facility selection at one provider organization

"Insurmountable" Problems Usually Have Solutions

- CMS research tags for billing
- OHRP concerns
- FDA oversight

It is possible, and very helpful, to talk to individuals at these regulatory agencies

The TiME Trial is an Experiment

- Does longer session duration provide important benefits to patients?

- How can we conduct pragmatic clinical trials in the dialysis setting: what works and what doesn't work?

TiME Trial Team

Academic Investigators

Laura Dember – U Penn
Alfred Cheung – U Utah
John Daugirdas – U Illinois
Tom Greene – U Utah
Czaba Kovesdy – U Tenn
Dana Miskulin – Tufts
Ravi Thadhani – MGH
W. Winkelmayer - Stanford

Dialysis Provider Organizations

Steven Brunelli – DaVita
Amy Young – DaVita
Mary Burgess - DaVita
Eduardo Lacson, Jr – Fresenius
Christina Kahn – Fresenius
Leland Brown - Fresenius

NIDDK

Michael Flessner
Paul Kimmel
Kevin Abbott

Penn CRCU / CCEB

J. Richard Landis
Jesse Hsu
Susan Ellenberg
Denise Cifelli
Steve Durborow