

Lessons Learned from the TiME Trial

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TiME

Lessons Learned

1. What we view as a small change to work flow or IT system is often viewed as a large change by the health system personnel.
2. 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.
3. Not everything works as initially planned.
4. Seemingly insurmountable problems usually have solutions.

Challenges in (somewhat) Chronological Order

- UH2 Phase
 - Contracts
 - Data element selection
 - Data sharing plan
 - CMS requirements, research billing
 - Documentation, eligibility and distribution of information sheet
 - g dialysis unit recruitment

Regulatory and ethical considerations

Challenges continued

- UH3 Phase
 - Engagement of key stakeholders
 - Secular changes in dialysis session duration

Relatively Non-Challenging Elements

- Establishing single IRB of record
- IRB view about consent waiver
- Engagement by research teams at dialysis provider organizations
- Data completeness

Challenges

- UH2 Phase
 - Contracts
 - **Data element selection**
 - **Data sharing plan**
 - **CMS requirement for research billing**
 - Documenting eligibility and distribution of information sheet
 - Initiating dialysis unit recruitment
 - **Regulatory and ethical considerations**
- UH3 Phase
 - **Engagement of key stakeholders**
 - **Secular changes**

Data Element Selection and Data Sharing

- Data elements necessary for research questions
- Ensure appropriate masking of facility identity

CMS Billing Code Requirement

- Are all dialysis related claims subject to this if there is no cost to CMS associated with research?

Regulatory and Ethical Considerations

- Can a trial be minimal risk if the outcome is mortality?
- Does trial require FDA oversight

Engagement: Who are the Key Stakeholders?

- Corporate office (medical, business, operations)
- Regional operations groups
- Regional administrators
- Facility nephrologists
- Facility staff: administrators, nurses, patient care technicians, dietitians, social workers
- Patients

One Health Provider Organization but Thousands of Health Care Providers

- Buy-in and support from corporate 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
 - **And....the patients**

On the Surface, Intervention is Simple

- Admission order set: “4.25 hours”

R_x
Name: _____
Dialysis Time: <u>4.25 hours</u>

But Implementation is Complex

- Impact on facility productivity?
- Personnel changes

Implementation is Complex

- Applicable to incident patients only..... but incident patients sit next to prevalent patients
- Delicate relationship between nephrologist (prescriber) and patient

What We're Doing to Improve Implementation

- Participation by investigators in facility multi-disciplinary facility meetings
- Leveraging culture of friendly competition to motivate facilities
- Involving Quality Assurance teams from provider organizations

Secular Changes

- Dialysis session duration is increasing nationally in response to general view that longer is better
- CMS is considering a clinical performance measure of upper limit for ultrafiltration rate (translates often into increased session duration)

Barriers Scorecard

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

1 = little difficulty

5 = extreme difficulty

Lessons Learned

1. What we view as a small change to work flow or IT system is often viewed as a large change by health system personnel.
2. 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. *(Perhaps a pragmatic trial can be too pragmatic?)*
3. Not everything works as initially planned.
4. Seemingly insurmountable problems usually have solutions.

The TiME Trial is an Experiment

- Does longer session duration provide important benefits to patients?

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

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