Decision Autonomy in Pragmatic Clinical Trials

Supplement to the TiME Trial

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Goals of Supplement Project

Context: In the service of learning, clinical trials curtail autonomy of individual patients and physicians to choose specific treatments

We seek to learn:

– How patients and physicians view treatment autonomy

– How these valuations differ in the contexts of research versus clinical care

– Whether limitations on treatment autonomy should influence approach to informed consent
Motivated by the TiME Trial

Enroll and Randomize Facilities

Intervention Facilities
≥4 hr, 15 min. sessions

Usual Care Facilities
(duration not driven by trial)

Enroll incident patients

Primary outcome: All-cause mortality

Secondary outcomes: Hospitalizations & Quality of Life
Aims

Aim 1: Assess qualitatively how patients treated with hemodialysis and their providers value physician autonomy to choose among treatment strategies that are within the range of the standard of care.

Aim 2: Quantify how curtailing treatment autonomy influences patients’ and providers’ willingness to participate in RCTs, and whether these influences differ in research vs. clinical care settings.

Aim 3: Measure the extent to which requirements for informed consent modify patients’ and providers’ concerns regarding the curtailment of treatment autonomy in research and clinical care.
Mixed Methods Approach

• Phase 1 (Aims 1 and 3): Semi-structured interviews
  – Patients: dialysis units in Philadelphia area (urban and suburban) not participating in the TiME Trial
  – Nephrologists: TiME Trial facilities

• Phase 2 (Aims 2 and 3): Conjoint analysis
  – Patients: dialysis units in Philadelphia area not participating in the TiME Trial
  – Nephrologists: TiME Trial facilities

Phase 1 informs Phase 2
Semi-Structured Interviews

• 2 vignettes presented to each participant, sequence varied
  – Research vignette: similar to TiME Trial
  – Clinical vignette: new facility policy
• Followed by open-ended questions
If you were asked to participate in this study, what would your initial thoughts and reactions be?

- What factors would be important in your decision to participate or not?
- What do you like about the study, and what might motivate you to participate in it?
- In what ways might participating in this study benefit you?
- Are there any reasons that you might not want to participate in this study? What are they?
- What other concerns might you have about participating in this study?
Prompts (if needed)

Further prompts (only provide if needed)

— Would participating in this study affect your relationship with your doctor? If so, how?

• Suppose you were asked to help someone else decide whether to participate in this study. What would you tell this person in order to help them decide?

• Are there other things you would want to know about the study before deciding whether or not to participate? What are these?

Further prompts (only provide if needed)

— What else, if anything, would you like to know about the risks of being in the study?

— What else, if anything, would you like to know about the benefits of being in the study?

— How comfortable are you with the way patients are told about the study?
  • Do you have suggestions for a better way to inform and enroll patients?
  • Do you think it is appropriate that if patients do not want to participate, they can make a phone call to ask to be removed from the study?
Phase 2: Conjoint Analysis ("Discrete Choice Experiment")

• Experimental design forces participants to reveal preferences rather than to state preferences

• Use questionnaires to present multiple hypothetical RCTs to assess how attributes identified as important in Phase 1 influence willingness of patients/nephrologists to participate in RCTs
  – Restrictions on autonomy
  – Rationale for restriction: RCT participation vs adoptions of clinical practice guidelines
  – Burdens of trial participation for patients or providers
  – Inclusion of processes for informed consent, notification or neither

• Attributes presented to participants are systematically varied

• Evaluate main effects and interactions
Hypothetical RCTs

• Restrictions on autonomy
  – Longer without individualization
  – Longer with individualization

• Rationale for restriction on autonomy
  – RCT vs Clinical Practice Guideline
  – Hypothesized benefit

• Burdens of trial presentation
  – Extra tests

• Informed consent process: traditional, streamlined, none
## Timeline and Progress

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<thead>
<tr>
<th>Task Description</th>
<th>Year 1</th>
<th>Year 2</th>
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<tr>
<td>Develop and finalize interview guides</td>
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<td>IRB documentation and approval</td>
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<td>Complete semi-structured interviews</td>
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<td>Develop codebook, code interviews</td>
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<td>Qualitative data analysis</td>
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<td>Develop conjoint analysis surveys</td>
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<td>Participant recruitment, questionnaires</td>
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<td>Quantitative data analyses</td>
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<td>Integrate qualitative &amp; quantitative data</td>
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<td>Manuscripts and dissemination</td>
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Discussion

• Content linked tightly to the TiME Trial
• TiME Trial nephrologists included as participants