Supplemental Appendix

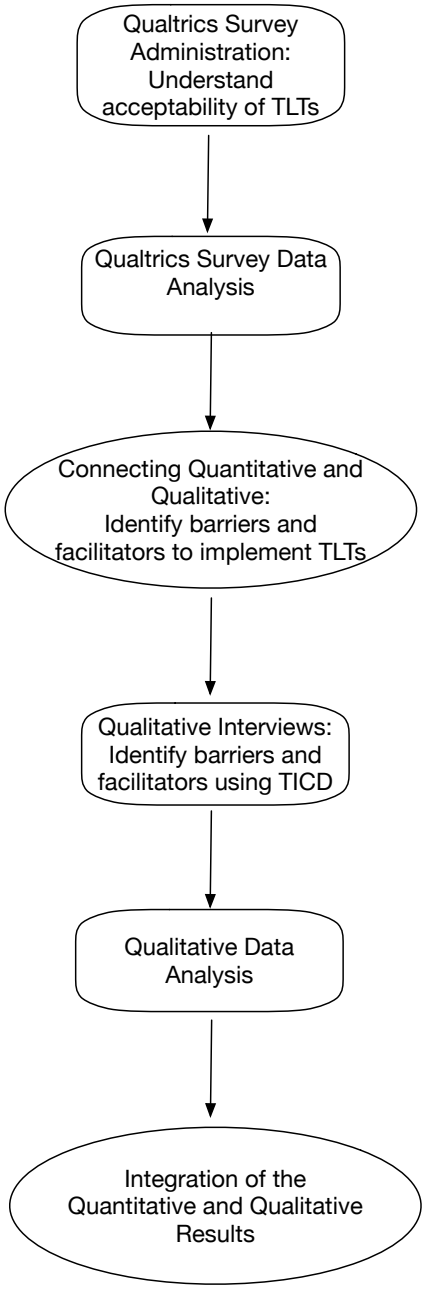
Supplemental Appendix A**:** Sequential Explanatory model

Supplemental Appendix B: Clinical Vignettes Survey Instrument

Supplemental Appendix C: Interview guide based on the TICD framework

Supplemental Appendix D: Exploratory analysis of physician factors associated with implementation of a TLT in the following treatments IMV, CRRT, HHFNC

Supplemental Appendix A: The Sequential Explanatory model



TLT: Time-limited trial
TICD: Tailored implementation of chronic diseases

Supplemental Appendix B
The physicians were provided the following 3 clinical vignettes in random sequence.

Survey Instrument
I invite you to participate in a brief research survey. You will review 3 brief patient vignettes and will be asked about what you believe the best management of these patients would be. The survey will not take more than 5 minutes.

This study is about time limited trials. Time limited trials are an agreement between clinicians and patients/surrogate decision makers to use medical therapies of uncertain benefit over a defined period of time to see if the patient's condition improves based on certain agreed upon clinical milestones. There are no right answers—we want to hear how you would treat these patients.

All of your answers will be completely anonymous. You can exit the survey at any time. This study was deemed exempt from review by the University of Michigan Institutional Review Board (HUM00169627). If you have any trouble with the survey, email me at eviglian@umich.edu.

Thank you again for taking the time to complete this survey!
- The Time-Limited Trials Research Team

Prior to this survey, have you heard of time limited trials?
Yes
No

Have you been involved in a time limited trial?
Yes
No

Case 1:
Time limited trials are an agreement between clinicians and patients/surrogate decision makers to use medical therapies of uncertain benefit over a defined period of time to see if the patient's condition improves based on certain agreed upon clinical milestones.

A 79-year-old male with severe idiopathic pulmonary fibrosis was admitted to the medical ICU for acute hypoxic respiratory failure 3 days ago. Upon arrival to the ICU, he was intubated for worsening hypoxemia.

His ventilator settings are currently: Tidal volume 450 mL, respiratory rate 18, FiO2 70%, PEEP 14 cm H2O. Over three days, his condition has neither improved nor worsened while on appropriate treatment. He has not tolerated any spontaneous breathing trials.

Is the patient's condition **appropriate** for a time-limited trial with **mechanical ventilation**?

Yes
No

If no was selected, the following question appeared: why is the patient's condition **not appropriate** for a time limited trial with mechanical ventilation?

Please rank by importance the specific clinical milestones you use to assess whether the following interventions are working.

1 is the most significant and 5 is the least significant clinical milestone. You can move each choice up or down.

Successfully pass spontaneous breathing trial
Decreasing oxygen or ventilatory requirement
Able to communicate
Other:
Secretions can be managed without frequent suctioning

Assuming no change in a patient's clinical status (i.e., no improvement and no worsening), after how many days would you feel comfortable telling a patient or their surrogate decision-makers that mechanical ventilation is not working?

Case 2
Time limited trials are an agreement between clinicians and patients/surrogate decision makers to use medical therapies of uncertain benefit over a defined period of time to see if the patient's condition improves based on certain agreed upon clinical milestones.

A 56-year-old female with alcoholic cirrhosis was admitted to the medical ICU four days ago for septic shock from spontaneous bacterial peritonitis. Her last drink was four months ago. She is not currently a transplant candidate but may be in the future.

Over four days, her renal function has worsened, and she was started on continuous renal replacement therapy (CRRT) yesterday.

Is the patient's condition **appropriate** for a time-limited trial with **CRRT**?

Yes
No

If no was selected, the following question appeared: why is the patient's condition **not appropriate** for a time limited trial with CRRT?

Please rank by importance the specific clinical milestones you use to assess whether renal replacement therapy is working.

1 is the most significant and 7 is the least significant clinical milestone. You can move each choice up or down.

Improving metabolic acidosis
Alert and able to communicate
Decreasing oxygen or ventilatory requirement
Other
Decreasing vasopressor requirements
Improving fluid status
Increasing urine output

Assuming no change in a patient's clinical status (i.e., no improvement and no worsening), after how many days would you feel comfortable telling a patient or their surrogate decision-makers that renal replacement therapy is not working?

Case 3
Time limited trials are an agreement between clinicians and patients/surrogate decision makers to use medical therapies of uncertain benefit over a defined period of time to see if the patient's condition improves based on certain agreed upon clinical milestones.

A 77-year-old female with acute myeloid leukemia was admitted to the medical ICU with hypoxic respiratory failure 3 days ago.

She is on heated high flow nasal cannula with an FiO2 of 85%. Her pulse oximetry is 92% at rest and drops to the mid 80s with any activity. She has stated that she does not want to be intubated. Over past three days, she has not improved despite appropriate treatment. During this time, her condition has neither improved nor worsened.

Is the patient's condition **appropriate** for a time-limited trial with **heated high flow nasal cannula**?

Yes
No

If no was selected, the following question appeared: why is the patient's condition **not appropriate** for a time limited trial with heated high flow nasal cannula?

Please rank by importance the specific clinical milestones you use to assess whether treatment with heated high flow nasal cannula is benefitting a patient.

1 is the most and 5 is the least significant clinical milestone. You can move each choice up or down.

Decreasing oxygen requirement
Improved oxygenation
Other:

Reduced respiratory rate
Improved ventilation

Assuming no change in a patient's clinical status (i.e., no improvement and no worsening), after how many days would you feel comfortable telling a patient or their surrogate decision-makers that heated high flow nasal cannula is not working?

Supplemental Appendix C:
Interview guide used for the semi-structured interviews.

Interview Guide: Implementing Time-limited trials

Introduction

Before we begin I want to let you know that we are interested in your comfort in this interview and we are here to talk about anything related to time limited trials that you would like to talk about. By time limited trials, we are referring to an agreement between clinicians and patients/surrogate decision makers to use medical therapies of uncertain benefit over a defined period of time to see if the patient's condition improves based on certain agreed upon clinical milestones.

Construct/Concepts[1]	Questions	Probes
Warmup / Rapport Building	1. To start, what is your experience with using time-limited trials?	• How do you decide to use them? • Is there a certain type of patient or family that you tend to provide TLTs to? • When is the best time to initiate a TLT? • How long do your TLTs typically last?
Guideline factors	2. Are clinicians aware of and familiar with time-limited trials? (K/S)	
	3. Is it feasible to conduct time-limited trials, in your opinion? (E/R/ci/b)	• **Who do you think should initiate TLTs?**
	4. In your opinion, how much effort is required to conduct TLTs? What factors make them difficult (or easy)?	• **Who should be involved in conversations intended to create and/or follow up on TLTs?**

[1] Constructs and concepts come from the Tailored Implementation in Chronic Disease project: http://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-8-35; notes in parentheses provide keys to possible areas for coding responses using the TICD checklist/framework.

Construct/Concepts[1]	Questions	Probes
	(E/R/ci/b)	
	5. Are there guidelines and/or standardization in creating TLTs or handling conflict with patients/families? (Cog)	• In your opinion, what knowledge or expertise do clinicians need in order to use TLTs appropriately? (K/S) • What skills are needed to use TLTs appropriately, and do clinicians here have those skills? (K/S) • Are there any guidelines in place right now for shared decision-making with patients and families?
Individual health professional factors	6. How do your colleagues think TLTs might affect outcomes (for patients, providers, the health system? For better or worse? (Cog)	• Do you or your colleagues intend to conduct TLTs? What concerns do they have about conducting it? (Cog)
Patient factors	7. What perceptions do you and your colleagues have about patient knowledge, needs and expectations related to TLTs and shared decision-making? (Pat Fac)	• How might values between you or your colleagues and patients differ with regard to TLTs? (Pat Fac) • What difficulties do you or your colleagues anticipate in obtaining support from patients and/or their caregivers in the use of TLTs? • What issues may TLTs cause patients and/or their caregivers? (Pat Fac)
Professional interactions	8. Are there specific individuals, organizations, or norms/values that you are aware of that affect how you perceive the use of TLTs? (Prof	• Are changes needed in referral processes, or interactions with other systems or groups, such as consults, to be able to use TLTs effectively? (Prof Interac)

Construct/Concepts[1]	Questions	Probes
	Interac)	• How do perspectives on TLTs differ between ICU physicians and other types of doctors?
	9. Are there team or workflow issues that affect your use of TLTs? (Prof Interac)	
Incentives and resources	10. What resources would be helpful in getting you or your colleagues to use TLTs fully? (include financial incentives, human resources, facilities, equipment and supplies, technical capacity, patient information, other ideas….) (Inc/Res)	• What incentives do you have to engage in TLTs? (Inc/Res). • How does the information system/EHR (Epic) help or hinder use of TLTs? (Inc/Res) • How are TLTs best documented? • How do the quality improvement/quality assurance systems help or hinder use of TLT? (Inc/Res) • Do you or your colleagues have the assistance they need (checklists, patient information, decision aids, decision support, clinical supervision)? (Inc/Res)

Construct/Concepts[1]	Questions	Probes
Capacity for organizational change	11. What leadership or management support is needed to assist you or your colleagues in using time-limited trials? In your opinion, is this available, and do clinicians know how to access it? (Org Chg) 12. How much of a priority is use of TLTs, compared with other initiatives and activities going on in your setting? (Org Chg) 13. How useful is monitoring and feedback? Is it available? (Org Chg)	• Is the style of leadership being used helpful in initiating TLTs? (Org Chg) • Who supports use of TLTs, and who doesn't (or supports it less)? (Org Chg) • How do internal and external rules, regulations, policies or procedures help or hinder use of TLTs? (Org Chg)
Social, political and legal factors	14. What is your understanding of why TLTs are implemented/are being encouraged? 15. Are there any payer or funder policies or issues that you're aware of that either help or hinder use of TLTs? (Soc/Pol/Leg)	• Do real or perceived risks of malpractice complaints help or hinder use of TLTs? (Soc/Pol/Leg) • Do influential people or groups outside UMHS help or hinder use of TLTs? (Soc/Pol/Leg)
Wrap-up	16. Are there any issues we should talk about that haven't come up yet?	•

Supplemental Appendix D: Exploratory analysis of physician factors associated with implementation of a TLT in the following treatments IMV, CRRT, HHFNC

E-Table 1. No specific physician factors are associated with the implementation of a TLT in the each of the three hypothetical scenarios. A) TLT with IMV. B) TLT with CRRT. C) TLT with HHFNC.

A)

	Odds Ratio	*95%CI*
Age (vs 25-35) years		
36-45	3.50	0.61-20.00
>45	1.46	0.19-11.11
Gender (vs Male)		
Female	2.60	0.33-20.48
Institution (vs UM)		
UT Southwestern	3.73	0.50-27.99
Participated in a prior TLT (vs No)		
Yes	3.36	0.44-25.66

B)

	Odds Ratio	*95%CI*
Age (vs 25-35) years		
36-45	2.54	0.46-14.15
>45	1.98	0.24-16.57
Gender (vs Male)		
Female	1.30	0.18-9.26
Institution (vs UM)		
UT Southwestern	2.08	0.29-14.71
Participated in a prior TLT (vs No)		
Age (vs 25-35) years	0.40	0.04-4.49

C)

	Odds Ratio	*95%CI*
Age (vs 25-35) years		
36-45	0.23	0.01-4.54
>45	1	
Gender (vs Male)		
Female	0.90	0.05-17.64
Institution (vs UM)		
UT Southwestern	0.12	0.01-2.62
Participated in a prior TLT (vs No)		
Age (vs 25-35) years	0.48	0.01-16.05

*UM= University of Michigan; UT Southwestern= University of Texas Southwestern; CI= Confidence interval

E-Table 2. No physician factors were associated the recommended duration (e.g., days) of TLT for the three different hypothetical scenarios. A) TLT with IMV. B) TLT with CRRT. C) TLT with HHFNC.

A)

	Coefficient	*95%CI*
Age (vs 25-35) years		
36-45	3.23	-2.37-8.83
>45	0.52	-7.08-8.12
Gender (vs Male)		
Female	-1.34	-7.65-4.96
Institution (vs UM)		
UT Southwestern	0.87	-5.34-7.08
Participated in a prior TLT (vs No)		
Age (vs 25-35) years	0.49	-6.34-7.32

B)

	Coefficient	*95%CI*
Age (vs 25-35) years		
36-45	-1.95	-7.23-3.32
>45	-3.48	-10.64-3.68
Gender (vs Male)		
Female	-2.00	-7.94-3.94
Institution (vs UM)		
UT Southwestern	0.09	-5.76-5.95
Participated in a prior TLT (vs No)		
Age (vs 25-35) years	-2.45	-8.89-3.99

C)

	Coefficient	*95%CI*
Age (vs 25-35) years		
36-45	3.47	-2.25-9.19
>45	-0.46	-8.22-7.30
Gender (vs Male)		
Female	0.13	-6.31-6.57
Institution (vs UM)		
UT Southwestern	1.48	-4.87-7.82
Participated in a prior TLT (vs No)		
Age (vs 25-35) years	1.12	-5.86-8.10

*UM= University of Michigan; UT Southwestern= University of Texas Southwestern; CI= Confidence interval