

**FAST FACTS AND CONCEPTS #401**  
**TIME-LIMITED TRIALS FOR SERIOUS ILLNESS**  
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**Background:** Patients, families, and clinicians often struggle when deciding on potentially life-sustaining therapies. On the one hand, they do not want to “give up” too soon; yet, they worry about burdensome treatment if there is little chance of recovery (1). Moreover, prognostication is an inexact science and both clinicians and patient/families may want to see how the treatment will affect them (2,3). Experts have long recommended time-limited trials to offer a compromise in such situations, a way to experience a treatment’s impact over a specified period and then allow patient, families, and clinicians to re-evaluate if it is achieving the patient’s goals.

**What is a time-limited trial (TLT)?** An agreement between clinicians and a patient/family to use certain medical therapies over a defined period to see if the patient improves or deteriorates according to prespecified clinical outcomes. If the patient improves, disease-directed therapy likely would continue. If the patient deteriorates, treatment goals would be re-evaluated, often to focus more on comfort. If significant clinical uncertainty remains, another TLT might be renegotiated (1). Examples of TLTs include mechanical ventilation after severe stroke; dialysis in a patient with limited functional status; and medically administered nutrition for a delirious patient recovering from sepsis (1).

**When is a time-limited trial appropriate?** TLTs should be utilized when the outcome or potential benefit of aggressive interventions is unclear, and more data is needed to inform complex treatment decisions both for family members and care teams. This may occur when an invasive treatment (e.g. mechanical ventilation) is being provided for a potentially reversible condition (e.g. ARDS) often in a patient with an underlying serious illness (e.g. heart failure). A TLT may allow a patient/family more data to process such difficult decisions; it may also allow clinicians to better understand the patient’s wishes and values that should guide their medical decision-making (3,4).

**How do you talk to a patient or family about a time-limited trial? (1,3)**

1. Acknowledge the uncertainty and difficulty of the decision. Respond to the underlying emotion in what may be the most difficult time of the patient/surrogate’s life. *“I cannot imagine how difficult it is to see your dad so sick, and not know what the future might bring.”*
2. Explore patient goals, values and priorities. Clarify what outcomes might be considered acceptable or unacceptable. *“Given this situation, what would be most important to your dad?”*
3. Suggest a TLT of a specific intervention. Suggest a TLT to meet a patient’s specific goals (i.e. life prolongation, improved function/mental status, allowing a peaceful death) (3, 5). *“It may be helpful to try medically administered nutrition and see if that meets his goal of getting stronger.”*
4. Negotiate clinical markers of improvement or decline. Definitions of success should be negotiated with the patient or family based on their values and the intervention being considered (i.e. if offering medically administered nutrition/hydration by gastric tube, families may define success differently, such as the patient being more interactive, living longer, or less frequent hospitalizations) (1). These outcomes should be identifiable by the patient and family and should be communicated clearly, enabling all involved to know what to watch for and what determines improvement (i.e. more awake or functional) or decline/burden (i.e. more sleepy or in pain). *“It sounds like being independent is important to your dad and he would want to be able to care for himself. I know you are optimistic that tube feeds could help him get stronger and care for himself. If he gets more confused or sicker, I worry that tube feeding would not really help him. What do you think?”*
5. Negotiate a specific and medically reasonable time frame to evaluate the effect of the treatment. Often, the optimal durations of therapies are unknown and depend on the underlying disease and the specific presentation (2). Resources are available which offer reasonable TLTs based on expert opinion for commonly encountered scenarios such as mechanical ventilation after a stroke, critical care for patients with cancer, or dialysis trials for the frail (2,3,5). Obtaining an expert consensus from relevant clinicians and specialists can help identify the most reasonable timeframe.
6. Arrange a follow-up family meeting for the middle and/or end of the trial to discuss progress or failure and next steps (5). This provides opportunities for clinicians and patients or their families to talk

about how they feel things are going, and what, if any, changes should be made. *"I would expect some progress of strength and weight gain after 2 weeks of tube feeds. What do you think about us meeting in two weeks to see how he is doing? If something new happens, we can talk earlier."*

7. **Negotiate potential actions at the end of a time-limited trial.** Define next steps such as continuation or cessation of a therapy based on defined goals. Time during a trial is valuable not just for information on treatment benefit, but it also can allow families or patients an opportunity to process difficult information or prepare themselves for cessation of life-sustaining therapies applicable to the situation. *"You've said that Dad would define an acceptable quality of life as being independent at home, and he wouldn't want tubes attached to him for the rest of his life. I think these tube feeds might help him to get stronger and get to his goal. But if we don't make progress after a few weeks, we should re-evaluate and consider the option of taking the tube out and focusing primarily on his comfort, which sounds like something he would prefer in that situation. What do you think?"*
8. **Document the discussion:** Who was present? What information was discussed? What was the reason for the time-trial? What was negotiated regarding standards for success, the length of the trial and the potential actions at the end of the trial? Clear documentation regarding these crucial elements will guide other clinicians if transitions or hand-offs in care occur.

**Re-evaluating a time-limited trial:** First, assess the patient/family's perspective of success or failure of the TLT. *"It has been two weeks. How do you think your dad is doing? We said that success was defined as him being able to take care of himself and gain weight. Do you think these things are better?"* If there is disagreement amongst clinicians and patient/family on the clinical progress, further discussion is necessary before any continuation, cessation, or change in treatment should be pursued. If all agree that the patient is improving, the intervention likely would be continued or transitioned to the next recommended treatment. If the situation has not changed significantly, or worsened, then a new plan would need to be developed with strong consideration of discontinuation of the life-prolonging intervention and pursuit of the best comfort-focused treatment options.

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