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MANAGEMENT DILEMMA

# Management dilemmas in pediatric nephrology: time-limited trials of dialysis therapy

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**Abstract**
*Background* Time-limited trials of dialysis have been proposed as a third option in addition to initiation of treatment and comfort-care only in the setting of high uncertainty or discordance between the treating team and child/family or among the treating team.
*Case-diagnosis/treatment* The index case was noted antenatally to have severe kidney disease and pulmonary hypoplasia. In light of the guarded, but uncertain prognosis and a lack of consensus among the treating team, as well as between the treating team and the family, a time-limited trial of dialysis was initiated. Six days later the child developed bacteremia due to infection of the dialysis catheter. The treating team felt this was a failure of the trial and that future dialysis should be withheld, the family disagreed.
*Conclusion* A time-limited trial is a problematic option. Providers may be better suited by returning to the dichotomous choice of withholding or initiating treatment.

*Key management points*
- *Time-limited trials offer potential benefits in terms of alleviating the burden of decision-making in the setting of uncertainty, offering an opportunity to forecast a poor prognosis, help avoid interprofessional conflict, and providing support for patients, their families, and staff.*
- *Time-limited trials have important limitations, including the use of time limits, difficulty in determining clear, meaningful endpoints, and different interpretations of a trial of therapy between parents and providers.*
- *Decisions regarding the initiation, withholding, and withdrawal of dialysis should be made based on regular assessments of the benefits and burdens of the intervention for the child.*
- *Pediatric nephrologists are better served to abandon the concept of time-limited trials.*

**Keywords** Time-limited trial · Ethics · Withhold · Withdraw · Dialysis · Child · Infant

## Case report

An outside neonatal intensive care unit (NICU) refers for possible dialysis a 4-day-old girl born with severe kidney disease due to a presumed solitary dysplastic kidney. The birth weight was 1.8 kg. The neonate has had no urine output. She remains critically ill, but her pulmonary status is stable on high-frequency jet ventilation. The pediatric pulmonologist has evaluated the child's pulmonary hypoplasia and believes that the child will likely require prolonged mechanical ventilation, but may eventually be able to be extubated. The cranial ultrasound shows a unilateral grade 2 intraventricular hemorrhage. Since birth the child has slowly developed volume overload, now estimated to be about 10%. Serum creatinine has trended upwards (7 md/dl, 619 μmol/L) as has serum potassium (7.0 mEq/L).

**Relevant international guidelines** Renal Physicians Association (RPA) (2010) Shared decision making in the appropriate initiation of and withdrawal from dialysis, 2nd edn. RPA, Rockville
Zurowska AM, Fischbach M, Watson AR, Edefonti A, Stefanidis CJ, European Paediatric Dialysis Working Group (2013) Clinical practice recommendations for the care of infants with stage 5 chronic kidney disease (CKD5). Pediatr Nephrol 28:1739–1748

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The parents were aware of severe renal disease antenatally and met with a neonatologist as part of a prenatal clinic earlier in the pregnancy. The neonatologist informed the parents that it was unlikely their child would survive the neonatal period due to concerns of severe pulmonary hypoplasia and renal failure. The family was offered therapeutic termination, which they declined expressing instead their desire to pursue life-sustaining interventions if the child appeared vigorous at birth. As a result the child was born with a neontatologist present, intubated in the delivery room, and transferred to the NICU prior to transfer to the referral center.

The neonatology team recommends withholding dialysis and a focus on comfort-care measures because of concerns over the life-long burdens of severe kidney and lung disease, as well as the high mortality rate in neonatal end-stage renal disease (ESRD). The nephrology team shares the neonatology service's concerns over possible mortality, but notes emerging evidence of improving outcomes of neonates with severe kidney disease, including a 3-year survival of 78.6% in neonates (<30 days) initiating peritoneal dialysis in the North American Pediatric Renal Trials and Collaborative Studies cohort [1–3]. The family is uncertain how to proceed, but "want everything done" for their child.

After a series of conferences which include the parents, nephrologist, neonatologist, surgeon and chaplain, a consensus was reached to pursue a time-limited trial of renal replacement therapy (RRT). A plan was made to initiate continuous RRT rather than peritoneal dialysis due to the child's size and based on the center's experience and to re-evaluate the plan in 2 weeks. The team-identified criteria for the trial included improvement of the ventilator settings, toleration of dialysis, and improvement in volume overload. It was made clear to the family that the dialysis catheter would not be replaced if it failed or became infected.

## Time-limited trials in pediatric dialysis

Medical and technical advances over the last 50 years have contributed to a new paradigm in pediatric dialysis. Dialysis has become a standard treatment for most—but not all—children with renal failure [4, 5]. Negative factors can include poor prognosis, coexisting disease, neurologic damage, or age [4–6]. Decisions to initiate dialysis are not made lightly, in part because the initiation of dialysis, under any circumstance, confers significant burden and harm on a child. This burden is justified by the expected benefit of the therapy. If dialysis will not benefit a child, then it should not be pursued, as it only exposes the child to increased levels of harm and a potentially shorter and more burdensome remaining life than conservative comfort-care measures [7]. The European Paediatric Dialysis Working Group Guidelines (EPDWGG) reflect such a sentiment, recommending shared decision-making among a multidisciplinary team, including the parents, to consider short- and long-term prognosis, medical care issues, and the predicted quality of life (QoL) for the child and the family [8]. Similarly, Lantos and Warady recommend that in situations of uncertain outcome treatment decisions be made through "a process of shared decision-making between doctors and parents that aims to come up with the best decision for the individual child and family" [9]. Both the EPDWGG and Lantos and Warady [9] focus primarily on the decision to either withhold or initiate dialysis treatment. In settings of prognostic uncertainty or lack of consensus among family members and/or care teams about the initiation or withholding of dialysis treatment, a time-limited trial offers a third option to providers and families to move forward.

Time-limited trials are defined as "an agreement between clinicians and patient/surrogate decision-makers to use medical therapies—such as mechanical ventilation, enteral feeding, or dialysis—over a defined period of time to determine if the patient improves or deteriorates according to agreed-upon clinical outcomes" [10]. Quill and Holloway proposed a five-step framework for initiating time-limited trials consisting of a meeting between the care team and patient/surrogate decision-makers to: (1) define the patient's acute care needs and prognosis, (2) clarify the patient's goals and preferences, (3) identify objective markers for improvement or deterioration, (4) suggest a time frame for re-evaluation of the patient's condition, and (5) define potential actions to take at the end of the trial or, if complications arise during the trial, actions that should be taken.

Dialysis represents a life-saving or life-sustaining treatment, but provision of dialysis can also inflict indefinite suffering. A time-limited trial is a response to a "technological imperative", a claim that because a treatment such as RRT is technically possible, then initiation of treatment is the morally correct response [11, 12]. In the setting of organ failure, time-limited trials offer the opportunity to learn more of the benefits and burdens of dialysis treatment for a child without committing to a possible lifetime of organ replacement therapy [13]. Time-limited trials have been described as "a patient-centered ethical process incorporating the best estimate of prognosis, QoL factors, and patient values" [12]. They offer several potential advantages, including alleviating some of the burden experienced by families asked to choose a treatment course in the face of uncertainty, offering an opportunity for forecasting a poor prognosis, thereby giving families time to emotionally prepare before the death of a loved one, and helping avoid interprofessional conflict and provide support for children, families, and staff [14–16]. Time-limited trials may be especially helpful in settings of prognostic uncertainty or a lack of consensus among the medical team and family [14]. Some have argued that a trial of therapy may even be preferential to the initiation or withholding of life-sustaining treatment as it allows for a true assessment of the benefits and burdens of therapy rather than relying on speculation [13]. In settings where withdrawal of a life-sustaining treatment could be justified, a time-limited trial of treatment should also be legally

permitted and accepted by most major religious groups; however, specific differences among groups may exist [17–20].

Multiple groups have endorsed the use of time-limited trials when dialysis is considered in settings of prognostic uncertainty or lack of consensus. The 2010 Renal Physician Association's Guideline on 'Shared Decision Making in the Appropriate Initiation of and Withdrawal from Dialysis' recommended consideration of "the use of a time-limited trial of dialysis in neonates, infants, children, and adolescents with AKI or ESRD to allow for the assessment of extent of recovery from an underlying disorder" [15]. The authors provide the example of initiation of dialysis in conjunction with extracorporeal membrane oxygenation (ECMO). The authors claim that such a trial is "time-limited in that dialysis is most often discontinued when ECMO is withdrawn due to patient non-viability" [15]. A trial of dialysis therapy was also recommended by Dionne and d'Anningcourt-Canning in the setting of parental disagreement or lack of consensus among the medical team for children with multiorgan system dysfunction who develop renal failure [5]. Rinehart argued that a time-limited trial of dialysis "may provide an acceptable option if a patient's response to treatments is uncertain and persistence with burdensome treatments seems undesirable" [21]. Scherer and Holley recently recommended a time-limited-trial of dialysis for critically ill adults as an appropriate choice in the setting of prognostic uncertainty or lack of consensus among the treating team or patient/surrogate [12]. In addition to RRT, time-limited trials have been advocated as a useful tool for complex decision-making in a variety of adult disease states [10, 22–26].

In situations of prognostic uncertainty pediatric nephrologists may psychologically hesitate to choose to initiate life-sustaining treatment in circumstances where they may ultimately have to withdraw that treatment. A time-limited trial may provide the opportunity to initiate treatment for a short period without committing to long-term therapy. In ethics, it is well established that there is no moral difference between withholding and withdrawing treatments; however, to many providers withdrawal feels worse. As a result, healthcare providers may be more inclined to pursue a time-limited trial with an endpoint rather than agree to initiating treatment [27–30]. Scribner described this feeling well: "It really isn't fair to a person to prejudge his ability to cope with dialysis. And yet we do this because we are afraid to get locked into a situation we won't know how to handle. We can't get out once we start. But for some reason, if you don't start a guy, if you don't get really involved with him, the fact you know he is going to die, and then does, doesn't seem to bother you so much. But once you've seen him on the machine and walking around, then the thought of not dialyzing him and having him die just becomes overpowering" [31]. A time-limited trial may provide an alternative option for the physician experiencing moral distress at the prospect of initiating dialysis, as there is not an agreement to chronic treatment. This perception among providers of a difference between withholding and withdrawing treatment is problematic and may result in the creation of an implicit barrier to treatment, resulting in undertreatment of children who could benefit from dialysis and overtreatment from the continuation of treatment that is no longer beneficial or is even harmful.

In the case presented here, prognostic uncertainty over the degree of lung disease and a lack of consensus between the treating teams and family precipitated the use of a time-limited trial of 2 weeks defined by outcomes of improvement of the ventilator settings, toleration to dialysis, and improvement in volume overload. An additional provision was made to discontinue dialysis in the setting of infection or catheter failure. Analogous cases with high uncertainty could include a child with relapsed leukemia who develops renal failure due to thrombotic microangiopathy or a child with multiorgan failure due to meningococcal sepsis who develops renal failure.

## Case continued

After placement of a dialysis catheter, the patient was started on continuous RRT. The dialysis treatment was successful in improving the child's fluid and metabolic balance. During treatment the respiratory status also began to slowly improve, however on day 6 of the dialysis treatment the child developed fevers and was found to have bacteremia, presumably related to the dialysis catheter. This resulted in increased hemodynamic instability, worsened volume overload, and increased respiratory support requirements. At a care conference the neonatology team suggested that future dialysis be withheld and that the child be transferred to comfort-care measures only as the time-limited trial failed; however, the parents requested treatment with antibiotics and continued RRT.

## Limitations of time-limited trials in pediatric dialysis

While intuitively appealing, the application of time-limited trials in pediatric dialysis engenders several concerns, including the use of time limits, difficulty in determining clear, meaningful endpoints, and differing interpretations of a trial of therapy between parents and providers (Table 1).

One concern with a time-limited trial is the role of time as the limiting factor of the trial. The use of a time limit ensures a period of review during which time the family and medical team must review the child's progress and decide whether to continue the chosen therapeutic strategy. In the case of neonatal dialysis, use of a time limit may also identify the significant minority of neonates who will be able to come off dialysis and may allow further time for strengthening of the parent–child bond [2, 32]. Despite these potential benefits, the use of a time

**Table 1** Five-step framework for initiating time-limited trials

| Step | Limitation in pediatric dialysis |
|---|---|
| 1. Define the clinical problem and prognosis | |
| 2. Clarify the patient's goals and priorities | The patient's goals and priorities are often unknowable and parent surrogate |
| 3. Identify objective markers of improvement or deterioration | Dialysis will almost always be effective in treating metabolic derangement or volume overload. Other potential markers may reflect random treatable events or a technical criterion fallacy. |
| 4. Suggest a time for reevaluation | Time period chosen for a trial is arbitrary |
| 5. Define potential actions at the end of the time-limited trial | |

Framework is derived from Quill and Holloway [10]

limit is problematic as the duration of time chosen for a trial is ultimately an arbitrary decision. In the case described here, it is unclear why 2 weeks rather than 1 week or 4 weeks is significant.

Another concern with a time-limited trial is the difficulty in meeting the requirement for clear, meaningful endpoints [12, 15]. Organ replacement therapies, such as dialysis, ECMO, and a respirator, are almost always successful if the focus is on volume and electrolytes, perfusion, or oxygenation. Therefore, their utility as endpoints is limited. Other potential endpoints in a time-limited trial of dialysis could include catheter failure, infection such as peritonitis or central line-associated bacteremia, failure to wean off of a ventilator, failure to recover renal function, abnormal cranial imaging, and/or progression of a concomitant disease, such as leukemia. Catheter failure and infection are both common complications of pediatric dialysis, especially in the neonatal period [33]. They are also largely random events, which in many circumstances can be and are successfully treated by antibiotics, with or without catheter replacement, allowing dialysis to continue. Moreover, endpoints such as failure to wean off of a mechanical ventilator or findings of abnormal cranial imaging may reflect a technical criteria fallacy. A technical criteria fallacy involves the medicalization of decisions that are inherently value-based [34]. Seemingly objective criteria, such as failure to wean off of a ventilator, failure to recover renal function, or abnormal brain injury, may implicitly reflect the providers' value judgments of the QoL of a person on a ventilator or on dialysis, or of an individual with intellectual disability [34]. Such criteria fail to engage with the key ethical arguments that would justify their use [35]. When using such endpoints, providers must provide clear reasons why a particular set of criteria are chosen, why a particular probability of poor outcome is sufficient, and/or why a certain level of disability should be determinative [35]. In the case discussed here, the specific criteria used, namely, stabilization of electrolytes and improved volume status, will almost certainly be achieved with provision of dialysis. Criteria of improvement in respiratory status may reflect a technical criteria fallacy. Finally, criteria of infection or catheter failure are based on common, treatable complications of dialysis. None of these criteria *alone* account for a justifiable cause to initiate, withhold, or withdraw life-sustaining treatment.

This critique of time-limited trials of dialysis is not a claim that dialysis should be pursued in every case or that healthcare provider values should play no role in medical decision-making. In settings where dialysis access cannot be obtained or resources are not available (e.g., financial, professional expertise, etc.) to provide treatment, dialysis cannot be offered, either as a time-limited trial or as treatment. More importantly, there are situations, such as progression of cancer, where it is entirely possible that the benefits of continued life-sustaining dialysis treatment will not exceed its associated burdens for a particular child. This global assessment is traditionally focused on a child's QoL. Generally, such an assessment is made by a child's informed parents, in deference to parental medical decision-making authority and as an acknowledgment of their role as the best advocates for their child. This does not mean the provider's values play no role. A central duty of a physician is to provide recommendations of the best option for the child, citing reasons for their recommendations based on medical, experiential, and moral factors [36]. Any such recommendation is inherently value-based. Importantly, changes in a patient's prognosis may change the nephrologist's recommendations. The family should be informed of this change without delay [15]. Decisions regarding life-sustaining treatments like dialysis can and should be made based on a global assessment of the benefits and burdens of the treatment for that child at the present time and in the future and re-evaluated regularly as a child's medical status changes [37]. This is true of any medical treatment.

An additional objection to a time-limited trial is that parents may have a different understanding of the meaning of a "trial" than the medical team. Parents consider a time-limited trial of dialysis as treatment until a complication occurs which results in greater burdens (generally pain) for the child that exceed the

benefit of continued life-sustaining dialysis. If such a complication does not occur, treatment continues indefinitely. In the case discussed here, it appears there was a misunderstanding between the medical team and the family. The medical team believed they had reached an agreement where if certain markers occurred within a designated time then treatment would end, whereas the parents believed that treatment would begin and the benefits and burdens of continued life-sustaining treatment would be regularly re-evaluated. Time played no role in the parent's understanding. This interpretation is the same as initiating any life-sustaining treatment. With a life-sustaining treatment such as dialysis, providers may be better suited by returning to the dichotomous choice of withholding or initiating treatment, similar to the guidelines on withholding and withdrawing dialysis proposed by Fauriel and colleagues, among others [38].

## Conclusion

A time-limited trial of therapy is a problematic option lacking clear, meaningful endpoints. Organ replacement therapies, such as dialysis, ECMO, and a respirator, are almost always successful if the focus is on electrolytes, perfusion, or oxygenation. Other potential endpoints of a trial may reflect random occurrence (e.g., infection) or an implicit value judgment by the treating team (e.g., inability to wean off of a ventilator, need for tracheostomy, or brain injury resulting in intellectual disability) rather than an objective criterion. Time-limited trials have different meanings to the medical team and families, with the latter viewing the trial simply as treatment. In these situations a trial of therapy may represent a false third choice between life-sustaining dialysis treatment and comfort-care only. Pediatric nephrologists and families would be better served by abandoning this "third option" and acknowledge that it is simply treatment, the provision of which should be based upon repeated assessments of benefits and burdens to the child.

#### Compliance with ethical standards

**Conflict of interest** The author declares that there are no conflicts of interest.

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