Rapid Implementation of an On-site CRRT Dialysate Production System during the COVID-19 Pandemic

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Introduction

On December 29, 2021, during the local delta wave of the Coronavirus Disease 2019 (COVID-19) pandemic, the stock of premanufactured solutions used for continuous renal replacement therapy (CRRT) at the University of New Mexico Hospital (UNMH) was nearly exhausted with no resupply anticipated due to supply chain disruptions. Within hours, a backup plan, devised and tested 18 months prior, to locally produce CRRT dialysate was implemented. This report describes the emergency implementation and outcomes of this on-site CRRT dialysate production system.

Emergency CRRT Fluid Production

- In July 2020, the UNM Nephrology Division developed a backup plan to generate CRRT dialysate locally based on protocols previously published in the medical literature.
- The equipment and supplies [**Figure**] used included:
  - Traditional hemodialysis machines (Gambro Phoenix, Baxter, Deerfield, IL)
  - Revaclear dialyzers (Baxter)
  - Naturalyte hemodialysis concentrate (Fresenius Medical Care, Waltham, MA)
  - Sterile 3-L and 4-L bags (Exactamix Empty EVA Bag, Baxter) typically used for total parenteral nutrition (TPN)
  - Connectors – non-sterile but designed to not come into contact with the dialysate – made of 3-D printed biocompatible rigid material (Figure 4 MED-WHT 10, 3D Systems, Rock Hill, SC) by Sandia National Laboratories (Albuquerque, NM)
- Testing of fluid samples generated at this phase revealed appropriate electrolyte composition and undetectable bacterial growth and endotoxin levels [**Table 1**]
- After learning of the impending CRRT fluid shortage on the morning of December 29, 2021, UNMH leadership was contacted and, after considering the alternatives, approval to proceed was obtained and the first batch of dialysate was prepared.
- The first patient was transitioned to locally produced fluid that same afternoon. After observing the first patient for approximately an hour, the remaining six patients on CRRT were transitioned to the new solutions.
- UNMH utilizes Prismaflex and PrisMax CRRT machines. As per the manufacturer's recommendation, we infuse a minimum of 200 mL/h of fluid into the post-filter deaeration chamber to prevent clot formation in the chamber. Locally produced fluid – as it is not technically sterile – was used as dialysate only. Therefore, we continued to run our machines in CVVHDF mode, but using mostly dialysis, with replacement fluid limited to 200 mL/h of post-filter saline or isotonic sodium bicarbonate.
- Rather than adjusting the potassium concentration, we opted to use our available supply of 3K concentrate and generate all CRRT dialysate with 3 mEq/L of potassium.
- A system for fluid tracking, inventory, and testing was rapidly devised and implemented. Initially all locally produced fluid was used within 24 hours, but we ultimately extended the shelf-life to 48 hours based on results of testing at 72 hours [**Table 1**].

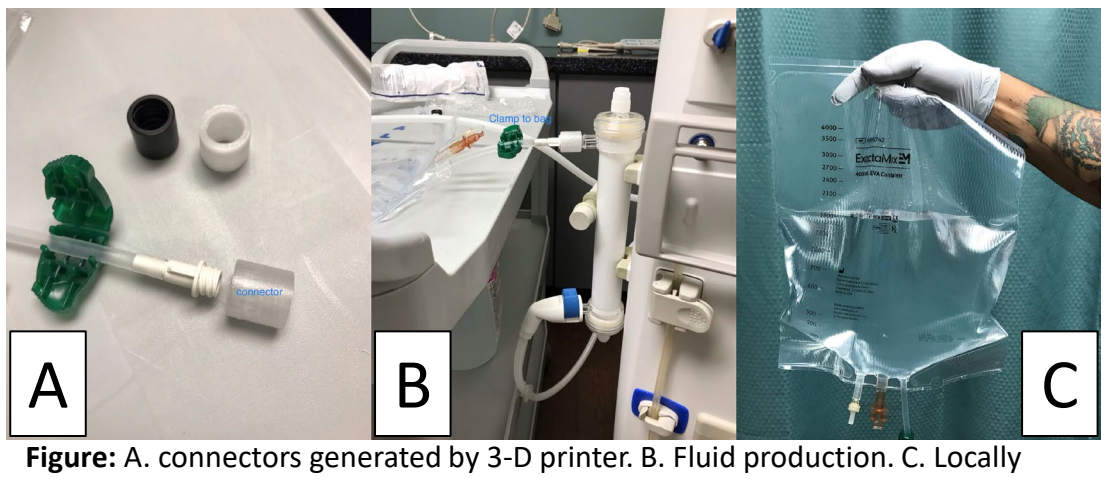

Figure: A. connectors generated by 3-D printer. B. Fluid production. C. Locally produced dialysate collecting in a TPN bag.

Methods

All adults treated with locally produced CRRT dialysate were included in this retrospective case series. Outcomes analyzed included fluid testing for composition and microbiologic contamination, CRRT prescription elements, patient mortality, sequential organ failure assessment (SOFA) scores, and catheter-associated bloodstream infections (CLABSIs).

Results

- Over 13 days, 22 patients were treated with 3,645 liters of locally produced dialysate.
- The indication for CRRT was AKI in 68.2%, AKI on CKD in 22.7%, and ESKD with critical illness in 9.1%. The primary admission diagnosis was COVID-19 in 50%.
- Mean CRRT dose was 20 mL/kg/h actual body weight or 28.8 mL/kg/h ideal body weight (IBW). Anticoagulation was provided with prefilter or systemic unfractionated heparin (UFH) in 11, regional citrate (RCA) in 4, and both UFH and RCA in 4.
- Fluid testing at 48 and 72 hours revealed appropriate electrolyte composition and endotoxin levels and bacterial colony counts below the lower limit of detection [**Table 1**].
- No CLABSIs occurred within 7 days of exposure to locally produced dialysate.
- In-hospital mortality was 81.8% and 28-day mortality was 68.2%, though illness severity was high, with a median SOFA score at CRRT initiation of 14.5 [**Table 2**].

Table 1: Testing for composition and microbiologic contamination of locally produced CRRT dialysate

	Trial Phase (July 2020)		Implementation Phase	
Fluid Incubation Period (hours)*	0	0	24	48
Approximate Testing Interval (hours)*	24	48	48	72
Sodium (mEq/L)	140	141	142	143
Potassium (mEq/L)†	2.3	2.3	3.0	3.0
Chloride (mEq/L)	110	110	110	110
Calcium (mEq/L)	2.5	2.5	2.6	2.6
Bicarbonate (mEq/L)	34	33		
Magnesium (mEq/L)	1.0	1.0		
Glucose (mg/dL)	110	109		
Colony Count (CFU/mL)	<2		<2	2
Endotoxin Level (EU/mL)	<0.010		<0.010	<0.010

†We used 2K hemodialysis concentrate in the trial phase but used 3K concentrate in the implementation phase. Abbreviations: CFU, colony forming units; EU, endotoxin units

Table 2: Patient Characteristics and Illness Severity

	Mean ± SD (Range) or *N* (%)		Mean ± SD (Range) or *N* (%)
Age (years)	51.3 ± 12.5 (26-74)	SOFA score	14.5 ± 2.4 (9-19)
Female gender	2 (9.1%)	Invasive mechanical ventilation	18 (81.8%)
Weight (kg)	100.1 ± 33.2 (50.2-183)	Non-invasive ventilation	1 (4.5%)
IBW (kg)	71.5 ± 7.9 (57-85)	Vasopressor use	19 (86.4%)
Height (cm)	176.6 ± 8.5 (160-191)	Length of hospital stay (d)	31.4 ± 22.9 (0.3-80.2)
BMI (kg/m^2)	31.8 ± 9.5 (19.0-57.7)	28-day mortality	15 (68.2%)

Conclusions

Though producing CRRT fluid with intermittent hemodialysis machines is not novel, we report the first description of the rapid and successful implementation of an emergency backup plan for local production of CRRT dialysate at a large academic medical center in the US during the COVID-19 pandemic. Our experience could serve as a model for other centers navigating similar severe supply constraints in the future.

References

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