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Meeting the Demand for Renal Replacement Therapy during the COVID-19 Pandemic: A Manufacturer's Perspective

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Introduction

As experience managing coronavirus disease 2019 (COVID-19) increased in early 2020, it became evident that patients infected with severe acute respiratory syndrome coronavirus 2 were at increased risk of developing AKI. In large United States cohorts studied at the beginning of the pandemic, 28%–46% of those hospitalized with COVID-19 developed AKI, and rates were markedly higher among patients requiring admission/transfer to the intensive care unit (ICU; 61%–78%) (1–5). In a retrospective study in New York, patients admitted with COVID-19 were at 130% increased risk for AKI compared with a historical cohort in the same centers (6). The burden of COVID-19–associated AKI is superimposed upon the nearly 4 million cases of AKI reported annually among United States adults in a pre–COVID-19 environment (7).

Given the absence of uniformly effective therapy directed against severe acute respiratory syndrome coronavirus 2, supportive management and RRT are the primary treatments for AKI (8,9). For hemodynamically unstable and critically ill patients, continuous RRT (CRRT) is generally the preferred RRT (9). Alternative modalities for hemodynamically unstable patients include sustained low-efficiency dialysis (SLED), prolonged intermittent RRT (PIRRT), and peritoneal dialysis (PD), whereas intermittent hemodialysis (IHD) is a primary option for more hemodynamically stable patients.

The widespread nature of the current pandemic placed enormous demands on the need for RRT across the United States. In the pre–COVID-19 era, 23,105 patients were treated for AKI with RRT annually (7). The need for RRT among patients with COVID-19 appears to be five-fold higher than that observed in historical populations (4.9% versus 0.9%) (6). In datasets of community cohorts, 5%–15% of patients hospitalized with COVID-19 required dialytic support (1,2,5). In certain United States centers, the population requiring CRRT increased 370% over typical levels (10). During the first 6 months of the pandemic, the United States is believed to have experienced a shortage of 1088 CRRT machines, with demand outweighing supply in up to eight states (11). The extraordinary demand for RRT put strains on the delivery of all dialysis therapies across the entire United States health care system. Manufacturers of RRT often became the determinants of delivery of care in the face of these unprecedented challenges. The ability of manufacturers to alter supply enabled individual practitioners, hospitals, and local communities to adapt to increased demand and reduced supply of RRT equipment and consumables (10,12–14). Such a response, however, could not adversely affect continued delivery of chronic dialysis to patients with ESKD. This article details the response of one manufacturer, Fresenius Medical Care North America (FMCNA), to meet the RRT-related needs of patients, clinicians, and institutions. It is hoped that the lessons learned to date can help inform future strategies.

FMCNA is the world's leading provider of dialysis products and services, operating across 150 countries. In 2019, FMCNA completed acquisition of NxStage Medical, Inc. (NxStage), now part of Fresenius Renal Therapies Group. In 2019, FMCNA manufactured 167 million dialyzers (57.6 million in the United States) and approximately 50% of the world's dialysis machines. Additionally, FMCNA manufactures PD cyclers and solutions, hemodialysis concentrates, and solutions. FMCNA also operates a network of approximately 4000 outpatient dialysis centers (>2500 in the United States). Presently, the company has 45 production sites across >20 countries and has over 120,000 employees.

Equipment Needed for RRT

Dialysis Fluid

As the COVID-19 pandemic spread in March 2020, demand for bagged dialysate fluid, most frequently used in the ICU setting, surged 38% and continues to remain increased. To meet such increased demand for dialysis fluids, production of bicarbonate-based solutions was increased at manufacturing facilities. A supply of lactate-based fluids, which had typically been used for home-based dialysis, was released for in-

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hospital CRRT and PIRRT to supplement the increased manufacturing of bicarbonate-based solutions. Release of these reserves did not affect the availability of fluids for patients receiving home dialysis, most (approximately 85%) of whom have a home dialysis machine system that produces ultrapure product water from ordinary tap water that is then mixed with concentrate to produce quality dialysate. The net result of these efforts was a 75% increase in premixed dialysate fluid capacity for ICUs. Additionally, emergency use authorization (*i.e.*, regulatory authorization of medical products to be used in an emergency when there are no adequate approved and available alternatives) allowed dialysate solutions not approved in the United States (*i.e.*, multiBic/multiPlus solutions) to be supplied to United States institutions. In addition to the actions taken by FMCNA to increase supply, some hospitals, on their own initiative, produced their own RRT bagged fluids (15). However, the production of dialysate fluids is regulated by the Food and Drug Administration, and FMCNA only operates within its regulated quality system in manufacturing and supplying dialysate fluids.

Given changes in supply and availability, many institutions increased their reliance on using lactate-based fluids for CRRT (9). Such fluids can allow for stable control of acid-base balance and cardiovascular stability (9,16). Although guidelines suggest using bicarbonate rather than lactate as a buffer (9), a systematic review found no differences in mortality between patients treated with either type of solution (17). Notably, lactate-based solutions should be avoided in patients with liver failure, patients with lactic acidosis, and those with "lactate intolerance" (9). Some institutions reduced fluid consumption to manage supply needs by decreasing CRRT dialysate flow rates (*e.g.*, from 25 to 15–20 ml/kg per hour) (10).

Dialysis Machines

At its peak, the demand for dialysis machines for the management of AKI (*e.g.*, CRRT) increased 279% over baseline. The changing geography of COVID-19 "hot spots" required the ability to deliver RRT equipment where it was needed while simultaneously avoiding a surplus of unused equipment elsewhere. To that end, a pool of equipment capable of being rapidly shipped to areas of increased need was developed. This National Intensive Renal Care Reserve was formed by FMCNA in April 2020 and included devices that can deliver CRRT, IHD, and SLED/PIRRT on the basis of the needs of the patient and the institution. With the use of bagged dialysate fluids, these machines did not require a water hookup, making dialysis available in multiple hospital locations. This equipment was made available to institutions in need of supplies regardless of whether they previously used FMCNA equipment, and this program continues to be refined to protect against future surges in demand.

To further increase RRT capacity for the management of AKI, equipment typically deployed for home use (*e.g.*, NxStage System One and Cartridges) was allocated to ICUs. Such devices are designed to be user friendly. This was a particularly important consideration given that some hospital staff have had limited experience managing AKI and dialysis devices. Finally, emergency use authorization allowed a CRRT system previously approved and used in Europe (*i.e.*, multiFiltratePRO system) to be used in the United States. Provision of such equipment to hospitals did not require sites having a prior contractual relationship with the manufacturer. The use of extended RRT may provide several advantages over IHD for the management of critically ill patients with AKI (18). Offering improved hemodynamic stability while also allowing for the treatment of more than one patient per 24-hour period, SLED or PIRRT combines the benefits of CRRT and IHD (19–22).

Despite the above actions, demand for RRT machines outweighed inventory for the 2-month period between March and April 2020. To coordinate distribution of equipment in a fair and informed manner, a team was formed that included members of our sales, operations, logistics, supply chain, customer service, and contracts departments. Coordination was further enhanced by the development of a pandemic-informed inventory tracking tool that provided real-time data regarding orders, demand, and machine availability.

Following initial efforts to meet demand, numerous additional adjustments have been implemented to allow for improved response to future surges in RRT demand. Specifically, we maintained high levels of production, allowing an increase in on-hand inventory. Refurbishment of NxStage System One machines has allowed for an additional reserve of equipment should RRT needs increase beyond the supply of new equipment. Closer management of third-party distributor inventory and enhanced hospital census tracking will allow for improved decision making regarding equipment allocation. Finally, we will continue to refine our methods for communication with customers to safeguard against uncertainties regarding the status of shipments.

Additional Equipment

Increases in manufacturing and delivery of single-use renal care products furthered the goal of increasing RRT availability for ICUs. The manufacturing capacity for tubing sets and filters was doubled and made possible by synergies in a uniquely shared supply chain for both critical care and home products. Such action helped meet the 45% increased demand for disposable cartridges for RRT (*i.e.*, those used with the NxStage System One) during this period.

FMCNA also increased the availability of supplies needed for acute PD, an RRT option for some patients with COVID-19, including patients who are hemodynamically unstable, those who exhibit hypercoagulability, and those without vascular access (9). In a series reported by Vigiola Cruz *et al.* (23), bedside placement of PD catheters offered a safe and effective option for establishment of access for RRT. Hospitals, including those in New York City, relied on low-volume, rapid-start acute PD in nonobese patients with COVID-19 on positive end-expiratory pressure that was not >10 cm (10). During the COVID-19 surges in New York, at some sites, acute PD was initiated in up to 20% of patients with AKI requiring RRT (24,25). In cohorts detailed by Shankaranarayanan *et al.* (24) and El Shamy *et al.* (26), patients were treated with PD for a median of 14 days and a mean of 8 days, respectively. To aid in the ordering of PD equipment, FMCNA staff supported hospital staff with

Table 1. Solutions implemented by the manufacturer to address RRT shortages and lessons learned to improve preparedness for future surges in demand

Challenge	Solutions	Lessons Learned (*i.e.*, Preparations for Future Surges in Demand)
Shortage of bagged bicarbonate RRT fluids due to patient surge	Increased bagged RRT fluid availability by 75% Bicarbonate-based fluid production increased to capacity Reserve of lactate-based fluids typically used for home-based dialysis released to the ICU environment Sought and received Emergency Use Authorization of multiBic RRT fluids for use in the United States	Increase inventory position as a reserve Patient census tracking to better estimate customer demand; important commercial discussion with customers Need for closer management of distributor inventory by expanding contractual data agreements Improve management of shipment tracking Development of team to manage pandemic demand Development of inventory tracking system that incorporates multiple systems within the organization
Shortage of HD disposables	Doubled manufacturing capacity for tubing sets and filters Reserve of cartridges used in the home environment released to ICU setting	
Shortage of HD machines	Created pool of unused equipment across the United States that could be rapidly deployed to surging locations Release of NxStage home equipment to ICUs Sought and received Emergency Use Authorization of multiFiltratePRO system for use in the United States Increased training resources for PIRRT therapy, which may enable treatment of more than one patient per 24-h period Increased the availability of supplies needed for acute PD	Increase inventory position as a reserve Refurbishment of traded hemodialysis machines as a reserve Development of new and unique business agreements for use in emergent situations Quickly deploy PIRRT training as a means to treat more than one patient with one machine during a 24-h period
Maintenance of adequate staffing across the company	Employees involved in manufacturing, distribution, pharmacy, and laboratory work were deemed essential health care workers Protocols developed to require PPE (including assurance of adequate equipment), daily symptom screening (increased after a known exposure), best practices for hygiene, contact tracing, social distancing, and protocols for return to work after infection	Maintaining up-to-date emergency preparedness plans are essential to supply and care continuity

ICU, intensive care unit; HD, hemodialysis; PIRRT, prolonged intermittent RRT; PD, peritoneal dialysis; PPE, personal protective equipment.

(*1*) ordering and receiving PD products, (*2*) training to enable the safe use of and troubleshooting for the PD products, and (*3*) properly directing inquiries related to medical interventions and off-label or alternate product use requests. A new set of order forms for PD equipment/supplies was developed to allow for rapid processing and fulfillment, whereas contracts were expedited for customers without existing contracts.

Personnel and Education

The increases in equipment production and allocation described above were wholly dependent on the efforts of our employees and maintenance of adequate staffing across the company. Employees involved in manufacturing, distribution, pharmacy, and laboratory work were deemed essential health care workers, and multiple steps were taken to ensure their continued safety and well-being. Protocols developed early in the pandemic required workers to wear masks, complete daily symptom questionnaires, and undergo temperature screenings. Hand sanitizer, gloves, gowns, and face shields were deployed and required in appropriate settings, and equipment was delivered in trucks disinfected twice a day. In addition, appropriate distancing between personnel was emphasized, and close contact tracing and appropriate quarantining and screening were employed for those exposed to infected individuals.

The allocation of new (and in some cases, previously unavailable in the United States) RRT equipment necessitated the development and deployment of nationwide educational and training initiatives. A company-wide tracker was established to document training for accounts on the basis of their modality and prescription choice. Virtual sessions were conducted to train on equipment, and expanded support options, including virtual and on-demand offerings, were also made available. Not all training was carried out remotely. For example, the clinical staff aboard United States naval hospital ships docked in cities with high infection rates received hands-on training with CRRT equipment. To ensure appropriate functioning of RRT equipment, additional service and installation assistance was made available to institutions. PD nurse trainers conducted virtual training on PD products and troubleshooting, and assistance with programming the cycler was conducted *via* phone or video support. Virtual "medical office hours" allowed for the communication of information specific to the management of AKI in patients with COVID-19. Additional education/training was provided *via* Advanced Renal Education Program seminars and webinars from other online sources. In total, FMCNA increased the number of staff trained in a typical year by 300%.

In addition, areas of surge also experienced a lack of personnel due to increased demand and decreased supply as COVID-19 illness affected health care workers. FMCNA increased training in some institutions for non-ICU personnel to provide care with CRRT and PIRRT. Operating room nursing and cardiac perfusionists were reassigned and trained to manage the patients on CRRT or PIRRT and their treatments. Additional ICU nurses were also rapidly trained to increase ability to care for these patients. Despite these processes to increase capable personnel, there were still deficits. FMCNA moved volunteer personnel from areas of decreased need to areas of higher need. Acute nurses moved to support hospitals, and a workforce of home dialysis nurses was also employed to assist with PIRRT with home dialysis devices as well as CRRT devices.

Key Learnings

The COVID-19 pandemic has placed an unprecedented strain on our health care system and resulted in a dramatic demand for RRT across geographically distant "hot spots." These areas were faced with limited staffing, supplies, equipment, and in some cases, physical space to manage the influx of patients with COVID-19 and AKI. Responding to these needs required a coordinated effort across all aspects of the health care system. As a manufacturer of RRT products and services, numerous steps were taken to ensure the efficient distribution of resources (*i.e.*, training, equipment, and staff) to respond to surges in demand while simultaneously safeguarding continuity of resources for maintenance RRT (Table 1). These steps were carried out with a commitment to protecting the safety of our employees, our suppliers, and the patients and caregivers with whom we interact. Manufacturers play a critical role in health care delivery, and it is hoped that the lessons learned from the current pandemic can serve as a blueprint to help prepare for future disasters.

Disclosures

All authors are employees of FMCNA. R.J. Kossmann and C. Mullon own stock in FMCNA. R.J. Kossmann is on the board of directors of Advanced Renal Technologies. M.A. Kraus reports scientific advisor or membership as Associate Chief Medical Officer for Fresenius Kidney Care, Critical care Scientific Advisory Board for Fresenius/NxStage, and Home Scientific Advisory Board for Fresenius/NxStage.

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Author Contributions

M.S. Anger, L.H. Ficociello, R.J. Kossmann, M.A. Kraus, C. Mullon, P. Newcomb, and D. Thompson conceptualized the study; M.S. Anger and R.J. Kossmann provided supervision; C. Mullon was responsible for investigation; L.H. Ficociello was responsible for project administration; M.A. Kraus, P. Newcomb, and D. Thompson were responsible for resources; and M.S. Anger, L.H. Ficociello, R.J. Kossmann, M.A. Kraus, C. Mullon, P. Newcomb, and

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