

Kidney Disease: Evolving the Standard of Care

Franklin W. Maddux, MD, FACP

Fresenius Medical Care (FME) is a leader in addressing complex health challenges and is working to meet the complex needs of individual dialysis patients. People living with kidney disease deserve more personalized and targeted therapy choices, better clinical outcomes, and the greatest possible quality of life, no matter where they are in their treatment journey.



The future of healthcare will be personalized within a standardized framework and approach. For global health conditions like chronic kidney disease (CKD), genetic and genomic information will one day influence prescriptions and treatment decisions for an individual. Data and Artificial Intelligence (AI) will accelerate connecting care to not only the **right person** at the right time, but the **right treatment** at the right time. People will have greater access to better and diverse targeted therapies, giving them more power and choice.

For Fresenius Medical Care (FME), evolving the standard of kidney disease care toward this personalized future goes beyond a mere “box checking” exercise. Addressing the global expansion of recognized kidney disease while improving clinical outcomes, health, well-being, and quality of life for people living with advanced kidney disease requires a focus on meaningful measures that underpin what high-quality and efficient effective care looks like.

Clinical and Quality Agenda: A Structured Focus on Excellence in Kidney Care and Science

FME's Clinical and Quality Agenda (CQA) is the foundation of the company's global medical strategy and provides focus on several aspects required to deliver high-quality dialysis care today, and the research needed to advance quality care for the future.

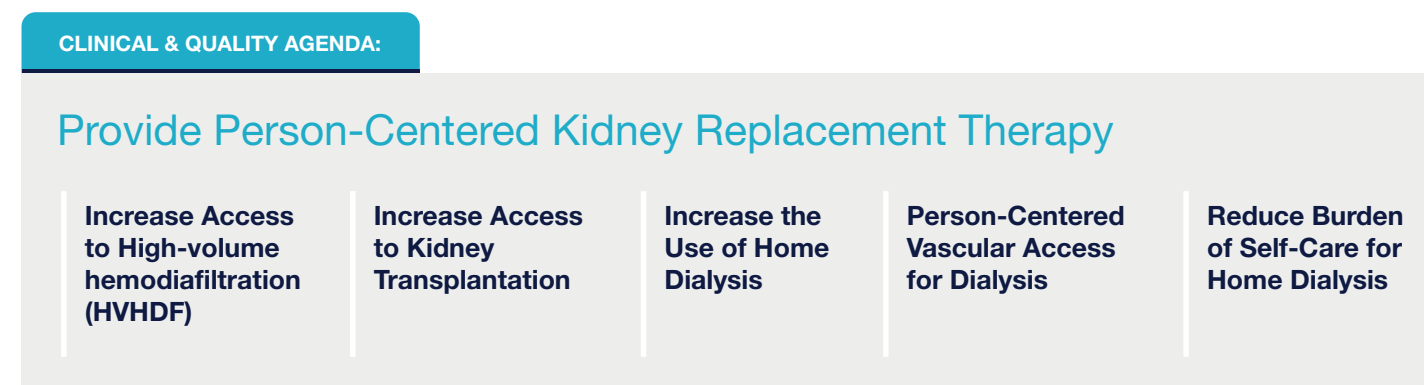
First, the CQA articulates key areas of care with a focus on improving clinical outcomes and reducing complications (Figure 1).

FIGURE 1 | PURSUING CLINICAL EXCELLENCE REQUIRES CONTINUOUS QUALITY IMPROVEMENT FOCUSED ON THE MOST IMPORTANT ASPECTS OF CARE AND OUTCOMES.



The CQA also seeks to increase the use of individualized kidney replacement therapies and aims to work with people to identify the therapy that will help them achieve the best outcomes and experience (Figure 2).

FIGURE 2 | PERSON-CENTERED KIDNEY REPLACEMENT THERAPY INVOLVES TAILORING TREATMENTS TO INDIVIDUAL NEEDS AND PREFERENCES.



For people on dialysis, integrating patient-reported measures into care is necessary to improve the quality of care (Figure 3).

FIGURE 3 | FME SEEKS TO IMPROVE EACH PERSON'S OUTCOMES AND EXPERIENCE BY INTEGRATING PATIENT-REPORTED MEASURES INTO THEIR CARE.



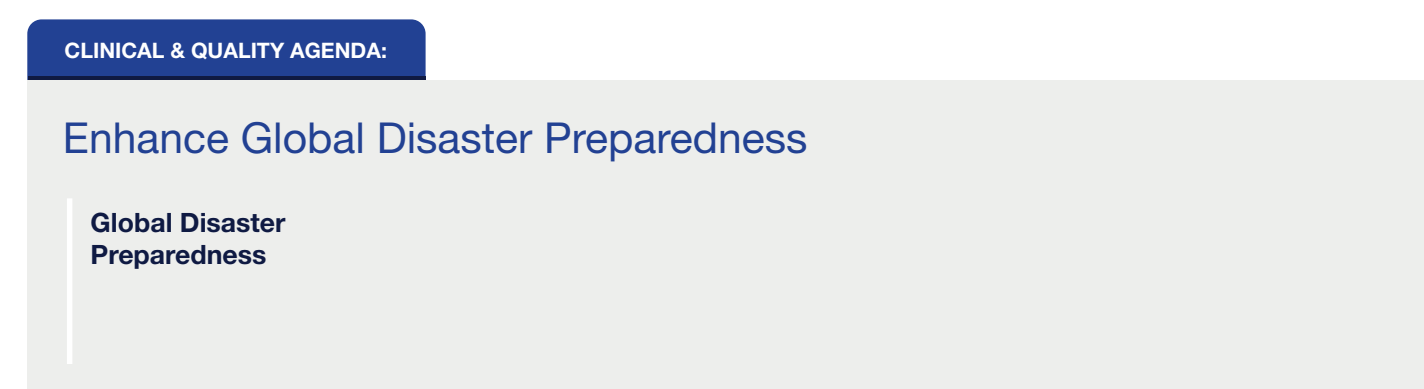
We are sharpening our focus by increasing global access and diversifying therapeutic options for people with critical illnesses (Figure 4).

FIGURE 4 | INCREASING THERAPEUTIC OPTIONS FOR PEOPLE WITH CRITICAL ILLNESS IS IMPORTANT FOR IMPROVING CLINICAL OUTCOMES.



As significant weather events increase in strength and frequency, pandemics and epidemics occur, and geopolitical conflicts impact key regions of the world, the need to solidify our emergency preparation and response plans to support people on dialysis, as well as our clinic staff and physicians, is evident. Whether it's a natural disaster, epidemic, pandemic, or geopolitical conflict, we need to be ready to respond efficiently and effectively (Figure 5).

FIGURE 5 | FME HAS DEVELOPED A GLOBAL DISASTER RESPONSE FRAMEWORK DESIGNED TO SUPPORT DIALYSIS TREATMENTS DURING CRISES AND EMERGENCIES.



FME takes pride in its strong collaboration with leading researchers in the field of kidney disease and uses the findings to innovate and improve care (Figure 6).

FIGURE 6 | ADVANCEMENTS IN KIDNEY DISEASE RESEARCH LEAD TO BETTER TREATMENTS, IMPROVED OUTCOMES, AND PERSONALIZED CARE.



We are committed to reducing health disparities and advancing health equity (Figure 7).

FIGURE 7 | TO REDUCE HEALTH DISPARITIES AND ACHIEVE HEALTH EQUITY, FME IS EXPANDING ITS FOCUS ON IDENTIFYING AND ADDRESSING HEALTH-RELATED SOCIAL NEEDS.



Innovating Optimal Therapies: Power and Choice for People

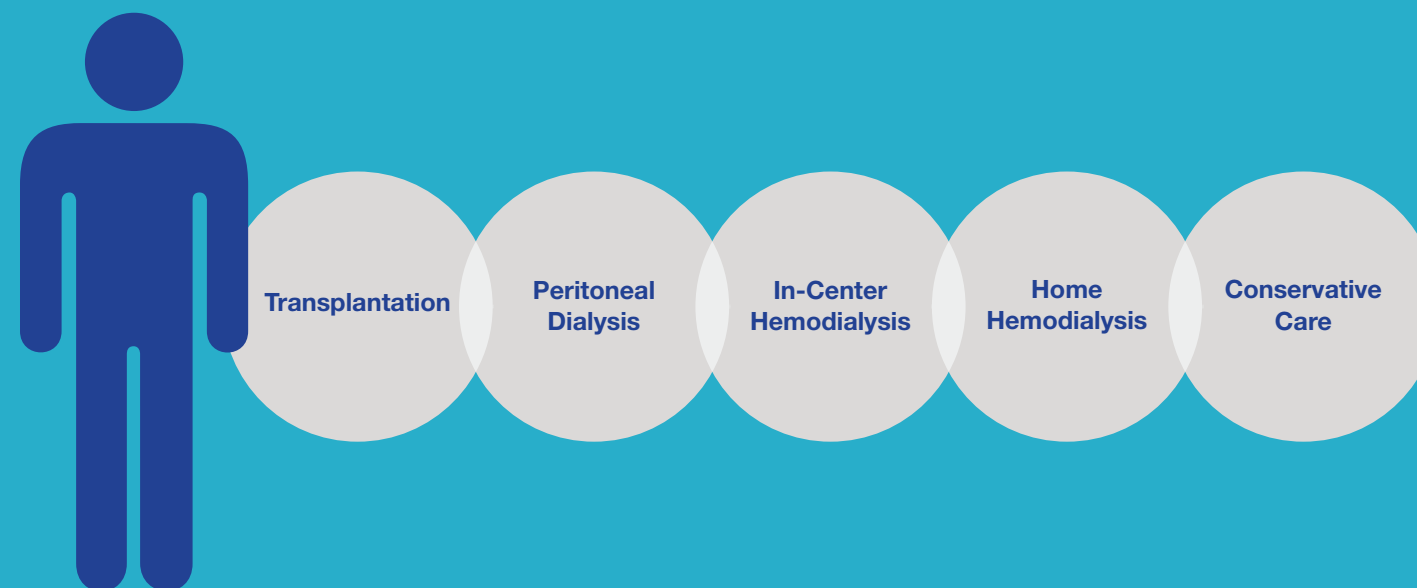
Achieving the best health outcomes, with the greatest independence and highest quality of life, requires diverse therapies that can meet each person's complex and unique needs. Therapies should help people feel better and live more productive lives on their own terms, while spending less time in healthcare facilities. Creating new therapies that continually improve the quality and efficacy of existing treatments is central to evolving an improved standard of care. Whether a person chooses in-center hemodialysis, peritoneal dialysis, or home dialysis, or is a candidate for a kidney transplant, FME provides therapy options that meet each individual's needs based on where they are in their care journey (Figure 8).

Evolving the Care Standard in Action: Introducing High-Volume Hemodiafiltration Dialysis to the United States

FME's leadership in medical device engineering and expertise in membrane technologies create opportunities for the Care Enablement MedTech division to lead the way in developing the most reliable and innovative machines and therapies to enhance our kidney replacement treatments which expand the duration and quality of life for people without kidney function.

Our 5008 & 6008 series machines and companion FX-CorAL dialyzers can deliver high-volume hemodiafiltration (HVHDF) for kidney replacement therapy. These innovations are great examples of FME's potential to evolve the standard of kidney care and expand the availability of these enhanced therapies.

FIGURE 8 | PEOPLE WITH KIDNEY DISEASE MAY ENCOUNTER ONE OR MORE OF THESE THERAPIES ALONG THEIR TREATMENT JOURNEY.



FME is both a longtime advocate as well as a global innovator for HVHDF as an improved dialysis therapy over conventional high-flux hemodialysis (HF-HD), utilizing physical principles of both diffusion and convection to modify blood in people with kidney failure. These techniques are used widely in many parts of the world and are being introduced in the United States.



5008 series dialysis machine

In 2023, the results of the European Union-funded CONVINCe study comparing the efficacy of HVHDF against HF-HD were released. The results showed a remarkable 23% decrease in all-cause mortality for patients treated with HVHDF, and an improvement in patient-reported outcomes.

In 2004, the use of online HDF in FME's EMEA-based NephroCare clinics was limited in general. After 2004, online HDF increased its share continuously among the dialysis techniques prescribed in the network. By June 2024, more than 61% of patients in our European Union clinics were treated by HVHDF.

In 2023, the U.S. Food and Drug Administration approved the 510(k) clearance for FME's 5008X dialysis machine to be used for HVHDF therapy in the United

States. This milestone clears the way to bring this improved dialysis therapeutic alternative to people across the U.S. who did not previously have access to this form of therapy. FME leads through innovating improvements in care standards.

In our chapter "[Strategy to Expand High-Volume Hemodiafiltration Worldwide](#)," our authors provide a detailed look at the clinical benefits and challenges to adopting HVHDF and provide recommended strategies to aid in broader implementation.

Expanding Access to Kidney Transplants

For many patients with end-stage kidney disease (ESKD), kidney transplantation is the optimal therapy for improving survival and quality of life. In addition to the shortage of available kidneys for transplantation, patients face several barriers and delays in navigating the transplant referral and evaluation process, culminating in reduced access to the transplant waiting list.

The evaluation, testing, and waitlisting practices of transplant centers are heterogeneous and are frequently not transparent to patients nor referring physicians. As a result, reliably tracking the progress of patients through the evaluation toward waitlisting remains difficult, with ample opportunities for patients to get stuck or simply lost in the process. At FME, we are working to identify process gaps for targeted interventions, so that more people who are referred for transplant complete their evaluation and are added to the waiting list when they are deemed acceptable by the transplant centers.

FME Signs Zero Health Gaps Pledge at 2023 World Economic Forum



On behalf of FME, Helen Giza, Chief Executive Officer, signed the Zero Health Gaps Pledge at the World Economic Forum in Davos, Switzerland in January 2023.

The Zero Health Gaps Pledge is part of the Global Health Equity Network (GHEN), which brings together key stakeholders from the public and private sectors to advance a collective vision of Zero Health Gaps, in line with the UN Sustainable Development Goals. In total, 36 companies from eight countries committed to sign the first-in-kind global pledge. By taking the pledge, FME is declaring its commitment to meaningful action and collaboration toward health equity.

“We believe that access to equitable and high-quality health care is a fundamental human right, and we are committed to working with global leaders and organizations to improve the lives of millions of people throughout the world,” said Helen Giza. “We will also look inward and achieve clear, actionable steps to make our processes economically and environmentally sustainable, while increasing access to the care we provide in the global communities we serve.”

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Reducing Disparities of Care for People Living with Kidney Disease

The World Health Organization defines social determinants of health as “the non-medical factors that influence health outcomes.” These can include the set of factors and circumstances that shape a person’s daily life, such as socioeconomic condition, location, and economic, social, and political policies and systems.

In 2024, FME launched the Global Health Equity steering committee to examine and evolve our approach to identifying and addressing health disparities.

Read more about our efforts to reduce health disparities and address health-related social needs in our chapter entitled, “[Improving Food Security in People with End-Stage Kidney Disease](#)”.

Policies

FME continues to play a crucial role in providing expert comment on proposed policies affecting patients with kidney disease, as well as promulgating new and innovative ideas for future value-based care payment models. For example, FME has submitted [extensive commentary](#) on recent proposals by Centers for Medicare & Medicaid Services (CMS) to reform the

organ procurement and kidney transplant system in the United States, [incentive payments to increase access to home dialysis modalities](#) and, most recently, [a proposal by CMS](#) to create a mandatory enrollment model for kidney transplant programs to incentivize increasing the total volume of kidney transplants.

Looking forward to the future structure of value-based care payment models after the Kidney Care Choices (KCC) model expires at the end of 2027, FME clinical leaders have proposed an “[end-to-end](#)” payment model that is fully “transplant inclusive”.

Looking Ahead

As we consider additional ways to evolve the standard of care for kidney disease, it is important to recognize that new classes of drugs, such as glucagon-like peptide 1 (GLP1) receptor agonists and sodium-glucose transport protein 2 (SGLT2) inhibitors on those living with CKD and ESKD. In the chapter entitled “[Interventions to Improve Survival in People with End-Stage Kidney Disease on Dialysis](#),” our authors note: “There is increasing interest in whether the

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benefits of SGLT2 inhibitors realized in patients with CKD provide mortality benefits in ESKD, and several studies examining this question are ongoing.”

Artificial intelligence has the potential to have a profound impact on how healthcare is delivered. In our chapter entitled “[The Challenges and Benefits of Generative AI in Kidney Care](#),” you can learn more about the potential that “may revolutionize several aspects of healthcare,” including:

- Clinical insights and powerful prognostic tools
- Personalized care
- Efficiency and cost savings
- Tailored medical education
- Comprehensive use of data and knowledge

The content of the 2024 Annual Medical Report highlights the expertise and singular focus of FME employees in delivering our mission to *provide the best possible care to a growing number of people across diverse healthcare systems worldwide, sustainably.*



Franklin W. Maddux, MD, FACP
Global Chief Medical Officer, Member of the Management Board

Franklin W. Maddux oversees the delivery of high-quality, value-based care for the world’s most expansive kidney care organization. His distinguished career encompasses more than three decades of experience as a physician, expert nephrologist, technology entrepreneur, and healthcare executive.

Dr. Maddux joined Fresenius Medical Care’s (FME) North America region in 2009 after the company acquired Health IT Services Group, a leading electronic health record (EHR) software company, which he founded. He developed one of the first laboratory electronic data interchange programs for the U.S. dialysis industry and later created one of the first web-based EHR solutions, now marketed under Acumen Physician Solutions.

He previously served as chief medical officer and senior vice president for Specialty Care Services Group and is the former president of Virginia’s Danville Urologic Clinic, where he was a practicing nephrologist for nearly two decades. His writings have appeared in leading medical journals, and his pioneering healthcare information technology innovations are part of the permanent collection of the National Museum of American History at the Smithsonian Institution.

An alumnus of Vanderbilt University, Dr. Maddux earned his medical degree from the School of Medicine at the University of North Carolina at Chapel Hill, where he holds a faculty appointment as clinical associate professor.