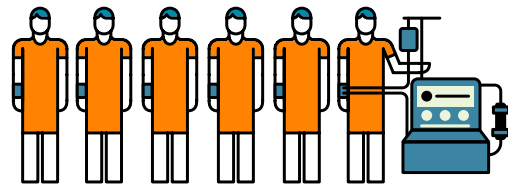


Fostering Innovation in Fluid Management

JULY 2019

About this Report

The importance of fluid management



For patients with end stage renal disease (ESRD), renal replacement therapy (RRT) partially replaces the functions of a normal kidney, including maintaining volume balance. Proper volume balance is critical: either too much volume (hypervolemia) or too little volume (hypovolemia) can lead to complications, ranging in severity from headache and fatigue or cramping and edema, to intradialytic hypotension (IDH) and hospitalization. In fact, IDH—which is associated with morbidity and mortality—occurs in an estimated 15%–30% of all maintenance hemodialysis sessions. Optimizing volume balance can help prevent these complications and improve blood pressure, which in some cases may eliminate the need for antihypertensive medications.

Despite the critical need for fluid management approaches that can improve patient quality

of life, there are currently no U.S. Food and Drug Administration (FDA) approved devices for objectively measuring volume status in dialysis patients. The nephrology community also lacks agreement on the best methods to accurately assess volume status to avoid hypervolemia and hypovolemia.

Currently, fluid regulation is based on an estimate of an individual patient's dry weight—commonly defined as the weight below which patients become hypotensive on dialysis. It is typically estimated by incrementally adjusting the patient's prescribed (target) weight at the conclusion of hemodialysis and assessing the clinical response. A more holistic definition of dry weight is the post-dialysis weight that enables the patient to remain close to normal hydration between dialysis sessions, with minimal use of antihypertensive medications and without experiencing discomfort or compromising residual function. Without precise, standardized methods or technologies for assessing volume status, estimating an individual's dry weight is often subject to trial and error.

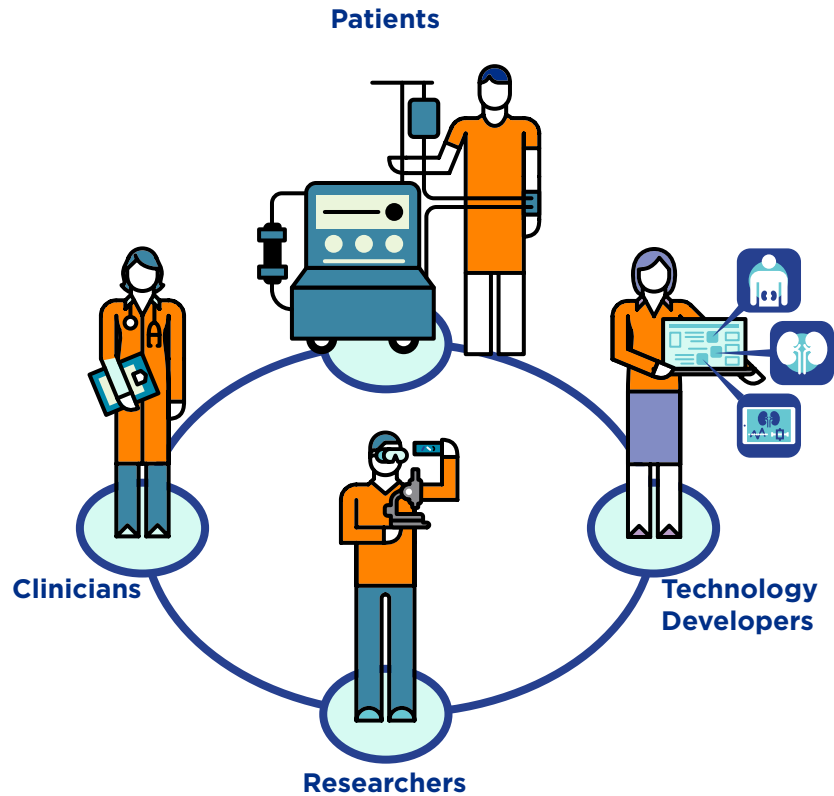
What this report aims to accomplish

Innovative advances to improve fluid management could have a significant impact on not only morbidity and mortality rates but also quality of life among patients on maintenance dialysis.

Motivated by the initial work of [The Technology Roadmap for Innovative Approaches to Renal Replacement Therapy](#), the Kidney Health Initiative organized a working group composed of patients, clinicians, researchers, and technology developers. This group was tasked with producing **guidance to spur innovation in fluid management devices and techniques—from both inside and outside of the nephrology community—that will improve the quality of life of ESRD patients.**

Leveraging the research activities outlined in the RRT roadmap as well as technologies from other application areas (e.g., wearable devices like glucose monitors, ultrasonography), this report:

- Outlines **patient priorities**
- Assesses **currently available devices and techniques**
- Identifies **gaps and challenges** that must be overcome
- **Recommends design specifications needed** for near- and long-term solutions that can overcome those challenges and meet patient expectations



Defining Success

The guidance in this report will better prepare innovators to develop much-needed new or enhanced devices or techniques that will allow patients and clinicians to respond more quickly and accurately to volume status.

To significantly improve patient experiences and outcomes, all solutions must strive to achieve the following high-level objectives:

- Accurately assess volume status
- Help patients safely achieve dry weight
- Be easy for patients to use and accommodate into their daily lives

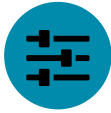
Additionally, developers and innovators must coordinate their efforts with regulatory bodies and payers throughout the entire product development lifecycle to facilitate more widespread availability, adoption, and patient access to innovative fluid management solutions. To this end, KHI has created a resource guide—[Guide to Regulatory Resources for the Product Developer](#)—to increase awareness and understanding of:

- Communication mechanisms that enable developers to obtain early, non-binding, regulatory advice from the FDA
- Available programs intended to facilitate development and review of eligible fluid management products

This coordination with both patients and regulators will ensure that future solutions meet the goals of all key stakeholder groups.

Patient Priorities

Improving the lives of ESRD patients is the ultimate focus of this report. As patient contributors envisioned the future state of fluid management, they expressed a desire for the following:



Personalization

Each patient's individual needs are different, so solutions should be customizable and easy to use.



Interactivity

Solutions should provide real-time helpful feedback or alerts, as well as offer an improved ability for patients to monitor and self-manage their fluid status.



Freedom

Devices or techniques that can be used outside of a clinic setting will offer patients greater ability to work, travel, and live a more "normal" life.



Improved Outcomes

As innovators create new devices/techniques to help achieve improved fluid balance, they should strive to design solutions that will achieve the following outcomes for patients:

- ➔ **Reduced patient mortality**
- ➔ **Reduced intradialytic and interdialytic symptoms (e.g., thirst, fatigue, cramping)**
- ➔ **Optimized medication management (e.g., reduced use of antihypertensive medications)**
- ➔ **Hemodynamic stabilization to avoid large variability in blood pressure and improve cardiovascular health**
- ➔ **Reduced healthcare utilization costs**

Improving patient quality of life and patient outcomes must be the focus of technology development.

Current Fluid Management Devices and Techniques

While it is widely accepted that better fluid management could reduce mortality and morbidity in dialysis patients, current devices and techniques—including monitoring and tracking tools—for improving fluid management are either inadequate or unproven, leaving no practical way to consistently maintain optimal volume status.

To best determine where gaps and challenges exist and how new tools or techniques could help address them, it is first important to understand the **current tools and techniques for fluid monitoring that are on the market, in development or in clinical trials, or that were unsuccessful**. This section provides a high-level overview of the following categories of fluid management devices and techniques:

- Physical exam
- Biomarkers
- Absolute blood volume measurement techniques
- Relative blood volume monitoring
- Invasive hemodynamic monitoring
- Bioimpedance spectroscopy
- Ultrasound techniques
- Biofeedback
- Sodium alignment techniques
- Telemonitoring techniques/devices
- Dietary intake apps
- Additional devices in development
- Additional devices in clinical trials

This overview is not intended to be a comprehensive literature review or an assessment of the state of the evidence. Rather, it intends to provide innovators of future technology with important information to better understand each category of current tools and techniques. A complete list of the resources consulted to assemble this overview is included in Appendix B: Sources.

Physical Exam

This approach involves using aspects of physical examination to estimate volume status.



CURRENT STATE

Physical examination elements are often used to estimate volume status, but studies show that physical examination findings do not correlate well with objective measures of volume status.



EXAMPLES

Evaluations of blood pressure, lung auscultation, jugular vein distension, peripheral edema

Biomarkers

This approach involves evaluation of specific biomarkers (e.g., B-type natriuretic peptide [BNP] and N-terminal pro hormone BNP [N-terminal pro-BNP]) whose levels can help assess patient fluid status, often by providing a direct correlation to overhydration.



CURRENT STATE

Measured through simple blood tests, results can be delivered in fewer than 15 minutes. While BNP and N-terminal pro-BNP may predict cardiovascular death in the dialysis population, baseline levels are higher for those on hemodialysis, with no established range for normal for this population. This approach is still being assessed.



EXAMPLES

BNP, N-terminal pro-BNP

Absolute Blood Volume Measurement Techniques

There are a variety of techniques for measuring volume, including dye dilution, radioactive labeling of biomarkers (e.g., albumin), and saline dilution. These techniques do not provide real-time continuous data.



CURRENT STATE

Dye dilution and radioactive labeling techniques are largely impractical for use in hemodialysis settings; for example, while BVA-100 is FDA-approved for measuring blood volume using radioactive iodinated serum albumin (RISA) and is considered a “gold standard,” it is time-consuming, expensive, and not preferred because it involves radioactivity.



EXAMPLES

COstatus, BVA-100, Evans Blue Transonic and indocyanine green (ICG) dyes

Relative Blood Volume (RBV) Monitoring

RBV monitoring involves real-time monitoring of total protein concentration, blood water content, and hematocrit, which all serve as surrogates for changes in intravascular blood volume. The monitors also record oxygen saturation.



CURRENT STATE

Devices available in the United States for RBV are noninvasive and allow real-time intradialytic monitoring. Some studies indicate that RBV may reduce hospitalization, IDH, and intradialytic morbid events. However, one randomized controlled trial showed harm with RBV use. Additional studies are being conducted to gather more evidence.



EXAMPLES

CritLine, Hemocontrol/Hemoscan

Invasive Hemodynamic Monitoring

Monitoring technologies are implanted to collect patient data that can then be analyzed by decision-support software systems.



CURRENT STATE

This technique is invasive and therefore impractical for routine use in the outpatient hemodialysis setting. It is also largely used and tested with heart failure patients and is currently not reimbursable by the Centers for Medicare & Medicaid Services for kidney disease applications.



EXAMPLES

Arterial lines to monitor blood pressure, V-LAP (Israel), CardioMEMS HF System, Swan-Ganz catheterization, Transonic ELSA Monitor

Bioimpedance Spectroscopy (BIS)

BIS devices send an electrical current into the body and measure tissue resistance to assess intracellular and extracellular fluid, which can then be used to assess hydration status. There are several types of BIS, including whole body, segmental, single frequency, and multifrequency.



CURRENT STATE

Simple and noninvasive, whole-body BIS is used in dialysis settings, with some evidence indicating that it can guide target weight assessment to help decrease use of antihypertensive medications and predict mortality in ESRD patients. However, assessments can be affected by factors such as extreme obesity or over-eating, physical activity, postural changes, hemodynamic shifts during dialysis, and fluid intake prior to assessment. BIS is also less accurate in children and pregnant women.



EXAMPLES

Fresenius Body Composition Monitor (not approved in the United States), BodyStat MultiScan 5000, impedance cardiography (e.g., Non-Invasive Cardiac System [NICaS], Task Force Monitor)

Ultrasound Techniques

Ultrasound techniques can noninvasively detect changes in inferior vena cava (IVC) diameter and amount of extravascular lung water, both of which correlate to some degree with volume status.



CURRENT STATE

Measurements can be affected by factors other than volume status. Findings may be interpreted/reported differently by different ultrasonography technicians (lack of consistency/objectivity) and may be inaccurate in patients with other conditions (e.g., morbid obesity, emphysema).



EXAMPLES

Lung ultrasound, ultrasound of IVC diameter

Biofeedback

Ultrafiltration (UF) biofeedback devices are often integrated into hemodialysis machines, coupled with relative blood volume monitoring devices, to automatically guide UF rates, dialysate sodium, or dialysate temperature, in response to changes in relative blood volume, blood pressure, or body temperature.



CURRENT STATE

A recent randomized trial indicated no reduction in the rate of IDH events using UF biofeedback. Additional studies that investigate different feedback algorithms are needed; however, the need for tight integration with the hemodialysis machine can be a hurdle.



EXAMPLES

Computer-assisted UF control software designed to work with devices such as CritLine or CLiC

Sodium Alignment Techniques

Statistical models, based on a series of past measurements, are used to help achieve sodium alignment (aligning dialysate sodium to a patient's serum sodium) during dialysis either in-machine or through manual adjustment.



CURRENT STATE

The most common technique requires daily manual measurement of pre-dialysis sodium. One promising technique (in proof-of-principle stage) is an electrolyte balancing control (EBC) algorithm that attempts to achieve zero diffusion sodium balance automatically during a hemodialysis session by individualizing the dialysate sodium to the patient's plasma sodium without having to measure or calculate predialytic plasma levels.



EXAMPLES

In-center pilot at Renal Research Institute (New York, NY), Diacontrol module of the Hospal/Gambro Integra (Medolla, Italy)

Telemonitoring Techniques/Devices

Home monitoring of blood pressure or other key data points can help assess changes and are a potential precursor to other in-home techniques for fluid management.



CURRENT STATE

In-home blood pressure monitors are commonplace and easy to use. Newer devices in development (e.g., GraftWorx Smart Patch System) may be able to collect more accurate and meaningful data.



EXAMPLES

At-home blood pressure monitoring, telehealth-monitored scales

Dietary Intake Apps

Readily available health and fitness apps may be used to help track sodium intake.



CURRENT STATE

Although popular and widely available, most are activity and dietary trackers without enough feedback around sodium intake.



EXAMPLES

MyFitnessPal, Spire, My Food Coach, My Net Diary, Fooducate

Additional Devices in Development

- [KidneyX Redesign Dialysis Phase 1 Winners](#)
- Skin-based sensors from Microdermics that can monitor key electrolytes and metabolites in the body in real time
- Non-invasive monitor from InteloMed that uses pulse waveforms to monitor cardiovascular status via a forehead sensor
- A wearable wrist watch from Heart Beat Technologies that uses infrared to measure heart rate, oxygen saturation, blood pressure, and cardiac output
- Portable device from Bitome that uses MRI-based fluid status monitoring and predictive analytics
- Wearable bioimpedance device from GE Global Research that uses multi-channel electrical impedance tomography (EIT) to differentiate impedance at different tissue levels; understanding the spatial resolution of fluid location will aid in fluid removal

- Fresenius Medical Care's CLiC-based computer-assisted ultrafiltration control software, intended to improve fluid management during hemodialysis and allow for personalized treatments, has been granted FDA breakthrough device designation
- GraftWorx Smart Patch System, a band-aid-sized patch containing a sensor suite that collects acoustic, mechanical, optical, and thermal data from the fistula/graft at multiple timepoints over the course of a day. Data is analyzed in the cloud, and clinically actionable alerts can be sent to physicians via a web portal.

Additional Devices in Clinical Trials

- Clinical trial for using low-frequency radio frequencies to assess lung water (ClinicalTrials.gov Identifier: NCT03476187)
- Clinical trial for an automated auscultatory device that detects low-frequency sound waves/pressure waves and responds to elevated left ventricular end-diastolic pressure (LVEDP) (ClinicalTrials.gov Identifier: NCT03203629)

Gaps and Challenges

To improve fluid management and, ultimately, patient outcomes, a variety of challenges must be overcome, including:

- Very limited selection of relevant devices and techniques
- Lack of standardized measurement techniques
- Lack of device personalization and real-time responsiveness
- Dependency on in-clinic treatment and clinicians

Based on the landscape assessment and feedback from both patients and clinicians, the following barriers must be overcome to ensure objective and reliable estimates, maintenance, and monitoring of patient volume status.



Lack of standard techniques, measurement approaches, and interpretation of measurements to assess both volume status and product accuracy

- Physical exam is the most common and widely accessible approach for assessing volume status, but it is not always accurate.
- Methods for assessing volume status are not sufficiently objective (e.g., variations in interpretation of findings across ultrasonography technicians).
- While other techniques or devices exist and may be used in other countries (e.g., bioimpedance spectroscopy), lack of evidence from clinical trials and the lack of FDA approval prevents their widespread clinical use in the United States.



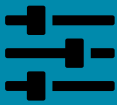
Difficulty of using current devices/techniques

- Lack of home-based volume status assessment techniques makes it difficult for patients to self-manage volume.
- In-center techniques are often cumbersome or uncomfortable (e.g., wires, electrode stickers), not designed for patient self-operation, and may require additional time spent in center (e.g., end-of-treatment refill test).
- It can be challenging for patients to stay motivated to use devices that require regular input or attention (e.g., 24-hour blood pressure monitors).



Inadequate automation of devices/techniques to allow for home use

- Most devices are designed for in-center use; while they may automatically take measurements or collect data, interpretation of those results often requires nurse or clinician expertise.
- Many measurement techniques (e.g., direct measurements, biomarkers) require in-clinic injections or timed blood draws.



Insufficient device/technique personalization and lack of real-time responsiveness

- Patients are unable to make micro-adjustments or respond quickly to changes in volume status, which puts them at greater risk of hypervolemia or hypovolemia.
- Algorithms in devices are not calibrated to the individual patient, which can affect accuracy.
- Invasive techniques cause patient discomfort without yielding real-time results (i.e., must wait for resulting data).
- Measurements are taken too infrequently to provide effective feedback for predictive management.



A fully-informed approach to treatment management is impeded by insufficient integration and communication among devices, as well as limited data sharing

- Medical records and other protected patient data are often captured and stored separately, preventing access to all the data sets necessary to understand an individual patient's disease state.
- Devices associated with different aspects of fluid management (e.g., detection of fluid overload, measurement of blood pressure, and management of sodium) may be difficult to integrate due to incompatibilities among equipment, software, algorithms, and data infrastructure.



Adoption of newer devices/techniques is limited due to high cost (and lack of reimbursement), lack of kidney-specific parameters, or insufficient success data

- Patients and clinicians lack confidence in many devices without longitudinal studies to assess long-term outcomes; they may also be reticent to embrace new products or processes—even if technically superior—if the use of the new techniques requires retraining.
- Devices or techniques designed for multiple uses/purposes (e.g., biomarkers, sodium intake apps) are not kidney-specific.
- Some techniques used to treat other conditions that could be used for fluid management have limited adoption because they are only covered for reimbursement for the officially designated use (e.g., invasive hemodynamic monitoring is covered for heart failure but not volume assessment).
- The need for tight integration of the new device/technique with the hemodialysis machine can be a hurdle.




Innovative fluid management advances that address these challenges could significantly impact patients on maintenance dialysis.



























Device Design Guidance




























Based on patient priorities, the current state of devices and techniques, and challenges that must be overcome, this document establishes a set of **specifications that any new device or technique should strive to achieve to improve fluid management** for ESRD patients.

Because patients desire both incremental improvements and innovative game-changers, fluid management approaches may not meet all of these requirements, particularly in the short term. Whether for developing new sensors and home-based devices or standardizing in-clinic protocols and techniques, the purpose of these specifications is to **provide design/functionality guidance**. This guidance will aid in the development of devices and techniques that can optimize the amount and rate of fluid removal for an individual patient, resulting in stable blood pressure and less thirst and cramping.

Design Specifications

 Volume status measurement
  Analysis and real-time feedback
  Fluid removal

Design Requirement	Function			Development Timeframe	
				Near (1-5 yrs)	Long (5+ yrs)
Between Treatments					
Assess relevant volume metrics, including interdialytic fluctuations, to provide estimate of volume status					
Capture and record relevant patient symptoms					
Provide interactive prompt or warning based on device measurements (e.g., blood pressure, weight, volume) to inform decisions on dietary sodium, fluid intake, etc.					
Record 24-hour urine measurements (e.g., attachment to home toilet for frequent and longitudinal assessment of urine output)					
During Treatments					
Integrate treatment data (e.g., blood pressure, ultrafiltration rates, volume removal, symptoms during treatment)					
Provide recommendations to optimize amount and rate of volume removed during dialysis					
Provide clinician with information needed to recommend modifications to the dialysis regimen if volume is under or over the target based on input					

Design Requirement	Function			Development Timeframe	
				Near (1-5 yrs)	Long (5+ yrs)
Innovations Beyond Dialysis					
Can remove excess volume and be adjusted based on the needs of the patient					
Allows patient to self-manage and monitor volume status separate from monitoring of other functions (electrolyte and toxin removal)					
Does not require in-clinic treatment					
Is durable, with a long lifespan					
Monitors volume status and has automatic feedback mechanism (i.e., closed-loop algorithms)					
Monitors tissue sodium and provides feedback for clinician or patient use					
Monitors and informs patient of key biomarkers					
Alerts clinician of issues with closed-loop system and need for intervention					

Improved Patient Outcomes

By striving to create or improve devices/techniques that address these specifications to improve fluid balance, developers will be helping to achieve the following **significant outcomes for patients**:

- Reduced hospitalizations and patient mortality, and overall improved patient quality of life
- Reduced intradialytic and interdialytic symptoms (e.g., thirst, fatigue, cramping)
- Optimized medication management (e.g., reduced use of antihypertensive medications)
- Hemodynamic stabilization to avoid large variability in blood pressure and improve cardiovascular health
- Reduced healthcare utilization costs

Appendix A: Report Contributors

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