

# **Additional Abstracts**

## **2019 KidneyX Summit**

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United States Institute of Peace  
2301 Constitution Avenue, NW  
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# **patientMpower for Hemodialysis - A Digital Therapeutic to Empower Self-Care for Hemodialysis Patients**

For patients with end-stage kidney disease, poor adherence to their hemodialysis regimen and essential fluid and dietary restrictions causes many complications, resulting in increased morbidity and mortality. Furthermore, missed dialysis treatments, or extended / additional sessions to manage the consequences of fluid overload, causes significant difficulties for dialysis service providers.

Patients have indicated that trying to adhere to all of their lifestyle restrictions and care regimens is extremely challenging, and a significant source of distress, affecting their mental wellbeing and quality of life. The reasons for poor adherence are multifactorial. Patients lack the tools to help them understand and manage the many aspects of their life on dialysis.

Our proposal, patientMpower for Hemodialysis, is a patient-centered, holistic solution that addresses barriers to adherence in all aspects of dialysis care. patientMpower for Hemodialysis is a digital therapeutic care package which empowers patients to achieve better outcomes by improving adherence to dialysis and associated lifestyle restrictions. This is achieved by helping patients better understand their own health goals, and giving them tools to better manage their own care and achieve those goals. It reduces the burden of adherence to dialysis and lifestyle restrictions, enables informed support by family or friends, supports attendance at planned dialysis sessions and captures holistic information to enable dialysis clinics to improve patient care.

A prototype of patientMpower for Hemodialysis has entered an early phase clinical trial (NCT03403491) and patient feedback from this trial is a key element in the product development plan. Future clinical studies, which are due to complete by early 2020, will compare the impact of patientMpower for Hemodialysis on patient outcomes versus usual care. The fully developed solution could be available for all patients by Q3 2020 and therefore represents an opportunity to improve dialysis patients' quality of life in the very immediate future.

The patientMpower team has considerable experience in both product development and clinical trial management, and has already produced award-winning technology solutions to empower patients to better manage their care in the fields of idiopathic pulmonary fibrosis and transplant.

Hemodialysis patients need a patient-centric solution to make it easier for them to adhere to their dialysis schedule and associated lifestyle restrictions. Working with KidneyX we believe that we can deliver a novel solution that helps patients to take control of their life on dialysis, improving their quality of life and empowering better outcomes.

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## **Reducing hospitalizations in hemodialysis patients through the use of a kidney disease management platform**

Dialysis patients frequently experience disease and treatment complications which result in hospitalization, negatively impacting their quality of life. A growing body of evidence is demonstrating that many of these hospitalizations could be prevented through improved management for end-stage renal disease (ESRD) and comorbid conditions [1]. **In order to provide direct solutions to the challenges of disease management for kidney disease patients, a committed team of nephrologists, patients, researchers, software developers, data scientists and healthcare industry thought leaders has come together to develop a mobile and web-based platform called CarelogiQ™.** The platform includes three integrated components which collectively target the management problems that contribute to high hospitalization rates for hemodialysis patients:

### **1. Advanced Fluid Management Tool**

Suboptimal fluid management contributes to cardiovascular complications which often precipitate hospitalization [2]. To provide decision support to dialysis staff, this tool analyzes patient data and outputs a concise summary along with a suggestion for fluid management for a clinician to review in conjunction with patient symptoms.

### **2. Patient Engagement Tools**

CarelogiQ empowers patients by providing an educational module with customized content, a calendar tool for appointments, and a symptom tracker. Together, these tools reduce hospitalizations by giving patients the knowledge and support they need to follow their care guidelines and by promptly alerting providers about their patients' critical symptoms.

### **3. Patient-Centered Provider Network**

Careful and timely coordination among specialists and other providers is often required to care for dialysis patients, who experience a high rate of comorbidities [3]. This tool enables providers to collaborate with one another in the context of their patients' data, as well as message patients and their care givers directly. As a result, specialists can make proactive, coordinated and personalized adjustments to their patients' treatment plans, thus reducing the rate of health complications which lead to hospitalizations.

A basic version of the CarelogiQ platform is currently being tested in a private nephrology practice and is providing integral feedback from both patients and care providers, allowing the team to continuously refine each tool (see video link, [4]). However, a large-scale study is necessary to formally evaluate the accuracy of the advanced fluid management tool and to assess its impact on the rate of health complications and hospitalizations. Such a study is being designed in collaboration with the Medical College of Wisconsin, Milwaukee

The most significant challenge to CarelogiQ's success is its adoption by providers and institutions. However, the substantial financial incentives inherent to reducing the rate of expensive health complications and hospitalizations will help overcome reluctance to adopting a new platform.

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# Changing Dynamics of Hemofiltration and/or Hemodiafiltration

## IDEA:

To introduce the flow dynamic-dual technique in hemodialysis filter to achieve maximum clearance and filtration resulting in the decrease in therapy time from 3-4 hrs to just 45mins-1hr or less.

To implement this technique creating micro or biologically compatible and implantable artificial kidneys.

## METHADODOLOGY:

1. Introduction of idea of spiral flow of dialysate with opposite flow human blood flow v/s flowing treated water (DNA Spiral flow).
2. Introduction of 3 chambered /partitioned filters with flow control and possible serum separation technique hence introducing "Plasma Exchange Controlled Mechanism".
3. Pro-biotic controlled calculation and introduction during "DNA Spiral Flow" in intervals.
4. Calcium and Phosphate chelators/dispensers chambers in dialysis filters.
5. Hemoglobin sensors and automated erythropoietin dispenser technique for last 15 mins of dialysis session (DNA Spiral Flow session).

## EXPECTED OUTCOMES:

1. Reduced therapy time.
2. Less visits to dialysis centers.
3. More effective clearance.
4. Achieving Hemoglobin targets.

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## **MQ-7 drug candidate for treatment of vascular calcification and associated loss of arterial flexibility in chronic kidney disease patients**

Kaydence Pharma is developing menaquinone-7 (MQ-7), a drug candidate to treat vascular calcification, the leading cause of medical hardship and mortality among chronic kidney disease (CKD) patients. Vascular calcification, and the associated loss of arterial flexibility, is highly prevalent in later stage CKD patients. MQ-7 has the potential to slow, prevent and potentially reverse the process of vascular calcification and the associated loss of arterial flexibility, an outcome which could have a profound impact on the quality of life for these patients.

Our objective is the development and registration of an orally-administered menaquinone-7 (a form of vitamin K2) to slow or prevent the decline of kidney function first in renal transplant patients, and ultimately across multiple stages of CKD. In broader CKD we believe MQ-7 will improve patient outcomes by extending the life of the kidney and reducing complications from cardiovascular disease caused by calcification.

There are currently no available treatments to address vascular calcification. Aortic and central arterial stiffening driven by calcification is directly implicated in impaired renal function. A strong body of clinical and scientific understanding supports the causal pathway and potential for intervention. A proof-of-concept study in renal transplant patients has already demonstrated the ability of MQ-7 to reduce arterial stiffness at a clinically significant level. In November 2018 we successfully completed a face-to-face Pre-IND meeting with the FDA. Our regulatory progress, proof-of-concept data in renal patients, IP protection (including FDA status as a New Chemical Entity) and a reduced risk profile create what we believe is a compelling case. We have the additional advantage of having established safety data and a highly focused patient group, factors that can enable us to gain conclusive Phase 2 clinical data at relatively low expense over a relatively short time-frame. Our current focus is on our upcoming IND submission and preparation for the Phase 1b trial.

The Kaydence team has decades of pharmaceutical experience, including successful FDA drug registrations. We are advised by several of the world's leading experts in vascular calcification, nephrology, cardiology and biochemistry. Our goal is to provide CKD patients with a potentially life-changing tool that does not exist today.

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## The Modern Dialysis Unit

Our vision of newly designed dialysis unit includes different domains that make the dialysis experience more enjoyable and less traumatic. The idea of these modern dialysis session is to integrate dialysis more into the lifestyle and thus can increase compliance and diminish the psychological adverse effects of feeling bound to fixed dialysis machine

1) The shape of the dialysis machine is different from the current version. The main unit of the dialysis machine will be behind the patient instead of being beside him.

2) The machine will be mobile and allow patients to walk during the dialysis sessions allowing exercise during the sessions and also giving more freedom. To render dialysis machines mobile they could be connected through hydraulic wires that could be hanging from the ceiling or the walls.

3) The machines will have a simulator that tells the story of the patient and his progress over months in term of phosphorus, anemia, body weight management and urea reduction over time. The simulator will have multiple visual functions and can be used as an educational tool for the patient, for example if a patient is hyperkalemic over the preceding time it could give quizzes and regimen for suggested diet modifications.

4) Dialysis you do recreational activities: new dialysis units could be built as ambulatory units in large vans that can tour around the cities or even go to beaches. Each patient can opt into one (dialysis during a tour) every certain time, for example weekly or fortnightly.

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# **The ULTRADIALYZER a new dialyzer design that upgrades the quality of hemodialysis to a new standard**

The Ultradyalyzer is a modification to the current Hollowfiber dialyzer design upgrading it to achieve maximal convection and diffusion.

The first section or compartment of the ultradyalyzer will achieve hemofiltration by separating the plasma ultrafiltrate from the blood.

The second compartment is a dialyzer that will dialyze the plasma ultrafiltrate and the hemoconcentrated blood separately, in a separate hollowfiber bundle.

The hemoconcentrated blood with its higher hematocrit and higher plasma proteins concentration will create significant backfiltration into this bundle. Those backfiltration forces will create negative pressure that will augment the transmembrane pressure exerted on the plasma ultrafiltrate bundle leading to more convection in this bundle. The plasma ultrafiltrate being protein free will perform physically as a Ringers solution compared to whole blood. This will allow larger uremic molecules to cross the membrane freely into the dialysate side with no obstructive forces. Clearance of middle molecules will be significantly enhanced.

The Ultradyalyzer design emulates the function of the human Nephron as it starts first by ultrafiltration as in the glomerulus followed by clearance and backfiltration as in the tubules and adjacent interstitium.

The Ultradyalyzer can achieve a superior hemodialysis comparable to hemodiafiltration by significantly enhancing the convection and removal of the middle molecules. It will be easy to upgrade the quality of dialysis for every dialysis patient whether in center or home hemodialysis with this new design. It will achieve treatments comparable to Hemodiafiltration without the need to change or upgrade the dialysis machines, without the need to create large volumes of ultrapure fluid, without the need to upgrade the water filtration system and without the need to retrain the staff.

A minor change in the dialyzer design and cost can go a long way in achieving better quality of life for our patients with the added benefits that we started to recognize for Hemodiafiltration such as cardiovascular benefits, hemodynamic stability, better middle molecules clearance, better phosphorus clearance, less ESA resistance and others.

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## **Subcutaneous, Long-term On/Off Vascular Access Device**

For hemodialysis patients their vascular access is their lifeline, without which they could not survive. Pharmateck, LLC is working on the Pharmateck Vascular Valve (PVV) to offer these patients a superior approach to reliable vascular access. The PVV is a device that consists of two identical elements surgically placed wholly under the patient's skin. One element allows arterial blood to flow to a dialysis machine while the second allows blood to return from the dialysis machine to a vein. The 2 implanted elements are completely independent of one another. Each element is comprised of three components; 1) a palpable subcutaneous needle entry mechanism, 2) a flexible blood lumen which extends from the subcutaneous needle entry system to a surgical anastomosis with a native vessel (either artery or vein) and 3) a clamp which is affixed externally to the blood lumen at the surgical anastomosis to the native vessel. The clamp opens or closes the surgical anastomosis, on demand, when a portion of the subcutaneous needle entry mechanism is compressed thereby permitting or preventing blood flow into the PVV blood lumen.

The PVV design offers the following benefits:

- 1) No direct connection between an artery and vein so no "arterialize" the venous system,
- 2) No high flow AV fistulas/grafts so no cardiac decompensation issues,
- 3) No persistent arterial steal syndrome as clamp is only open during a dialysis session,
- 4) Minimal post dialysis bleeding as clamp is closed to blood flow when dialysis is completed,
- 5) Reduced biofilm production as minimal foreign material is in direct contact with blood and no portion of the device protrudes into the lumen of the native vessel when the clamp is closed,
- 6) Reduced infection rates as heparin or a concentrated antimicrobial solution can be locked into the small blood lumen of the device when the clamp is closed,

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# Dermodialysis

Chronic Kidney Disease (CKD) is a debilitating and widespread illness affecting millions of lives globally, with the United States Renal Data System estimating that over 30 million Americans may be in one of CKD's five stages. Kidney disease results in compromised Glomerular Filtration Rates (eGFR) and decreased Renal Blood Flow (RBF), and culminates in End Stage Renal Disease, the last and final stage in which the kidney is no longer viable and is unable to perform its crucial functions.

Subsequently, toxic byproducts of metabolism accumulate in the blood, excess water and salt disrupt homeostasis, and acid-base and electrolyte imbalances occur. Among the primary contributors to the high prevalence of CKD are conditions like hypertension and Diabetes Mellitus.

Patients suffering from End Stage Renal Disease (ESRD) face increased risk of cardiovascular and infectious mortality, leaving dialysis or kidney transplantation as the sole options for extending their lives. In many cases, when preemptive kidney transplantation is not possible, hemodialysis and peritoneal dialysis are considered. Yet, hemodialysis and peritoneal dialysis treatments are not without complications. In addition to being time-consuming and costly, these exhaustive and invasive treatments introduce a number of complications, including infection, hemodynamic instability, electrolyte imbalances, pain, and in some cases, mortality.

Alternative treatments have been sought since existing treatments were introduced. "Dermodialysis" is a refined solution to an approach attempted for many years, and results from five years of now patented work by three passionate and dedicated individuals: Steven Sable, MSci + MBA (a former dialysis patient for seven-and-a-half years); Sundar Nadarajan, PhD, Material Science (Principle Scientist); and Tarun Marwaha, MD, Nephrologist.

Given the extent, severity, and potential adverse outcomes of kidney disease, the need for improved, intuitive, streamlined treatment options cannot be overemphasized. Dermodialysis aims to meet these needs and mitigate tangible and potential problems by introducing a noninvasive, affordable, pain-free, user-friendly, and effective home treatment therapy. Dermodialysis offers simple, efficacious solutions aimed at decreasing the disease burden and minimizing the time patients spend undergoing current renal replacement therapies, thereby increasing and maximizing the quality of life. Dermodialysis presents a unique approach to kidney care that specifically and effectively targets existing physiological bodily processes and functions, working to enhance their efficacy through a viable, affordable, painless home treatment system.

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# **Novel “Enteric Dialysis ®” technology using Probiotics product formulation as live bio therapeutics towards dialysis and predialysis patients with standard care of therapy**

The concept of “Enteric Dialysis” evolved a long time ago in China as early as the 1950s where traditional Chinese medicine used various decoctions of different herbs to treat uremia via the intestinal tract. Then in 1983, the use of oral sorbents in uremia was discussed in depth by Dr. Eli Friedman. The original concept “WILL THE BOWEL BE THE KIDNEY OF THE FUTURE?” was proposed and discussed at the International/European Artificial Internal Organs Society Congress held in Aug 1999 at Edinburgh, Scotland. Thus the concept of substituting the failing Kidney functions by the bowel; the “Enteric Dialysis ®” platform technology emerged and has been scientifically and systematically advanced by Kibow Biotech Inc. This technology uses the bowel or colon as a surrogate kidney to metabolize several uremic toxins like urea, uric acid, creatinine etc., with the aid of highly strain specific well researched and documented probiotics and specifically chosen prebiotic product formulation named RENADYL™. This product is marketed as a dietary supplement with a structure-function claim as per USFDA/FTC regulations for the past nine years. A similar product formulation is also marketed as “AZODYL®” by our veterinary partners Vetoquinol SA for cats and dogs with moderate to severe kidney failure problems since July 2006.

In 2006 the gut flora and its contents “Gut Microbiota” was recognized based on numerous studies on their role in health and disease. With the exponential advances in the field of Gut Microbiome, it is becoming more and more apparent that almost all disease conditions are the result of “dysbiosis in the Gut”. This is a term for microbial imbalance or maladaptation of the gut microbiome. Only in 2010, the gut was recognized as an important but as the forgotten organ in uremia. Vaziri and his group in 2013 showed that CKD patients have an imbalance in their gut microflora as a consequence of their kidney failure. All CKD patients have a higher percentage of bad bacteria (known as pathogens) present as compared to good bacterial populations in healthy individuals.

In CKD dysbiosis, these pathogenic bacteria generate uremic toxins such as indoxyl sulfate and p cresyl sulfate by putrefaction of proteins. Thus renal failure patients have scores of known and unknown uremic toxins such as urea, uric acid, creatinine (Millimolar concentrations), several other metabolites such as indoxyl sulfate, para-cresyl sulfate, oxalate, trimethylamine N oxide (TMAO) and others termed middle molecules (Nano/Pico molar concentration). Some of these toxins are protein bound uremic metabolites which are not generally removed by conventional dialysis treatment modalities.

The use of probiotics to modulate an unhealthy gut microbiome in CKD is a promising intervention giving their easy availability, innocuous nature; potential to reverse multiple CKD associated metabolic derangements, and ability to preserve renal function. This offers the opportunity for therapeutic intervention by either diet modification, modifying the gut microbiota, decreasing uremic toxin production by microbiota, increasing toxin excretion or targeting specific uremic toxins, to halt or slow down the progression of CKD. Our R&D efforts are focused on the catabolic pathways to reduce major uremic toxins like urea, uric acid and creatinine and also to reduce the bacterial putrefaction cardiovascular nephrotoxins generated. The aforementioned information provides a conceptual framework that allows the development of novel Live Bio-Therapeutic (BLT) approaches. This in essence opens a newer approach to reduce the duration or frequency of Dialysis therapy with improved Quality Of Life and better outcome measures and thus can reduce the healthcare expenses by several billions of dollars associated with DIALYSIS therapy.

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## **Tandem dialysis proposal**

There is abundant excess kidney function all around us. ESRD, at a population level, can be viewed as a problem of distribution of resources. ESRD patients have exhausted their renal clearance, while the friends and family members surrounding them may have 4 to 5 times the renal reserve needed to sustain life. What if we allowed sharing of renal clearance?

Additionally, what about the middle molecule clearance, endocrine functions of the kidney, and other physiologic roles that are not addressed by dialysis as we know it? Transplant can replicate many of these non-clearance roles. However, our current model of high efficiency dialysis, focused on biochemical parameters, cannot replicate myriad important functions of the kidney.

Finally, what if we reimagined dialysis to cut down on the expense of dialysate generation or delivery, and let a more elegant model do what current technology cannot?

Tandem dialysis is a concept in which we replace artificial dialysate with the serum of a bed partner, be that a healthy spouse or other life partner. Instead of generating artificial dialysate to serve as the diffusion medium, we can use in vivo serum from the bed partner as a diffusion medium. This would redistribute the small molecule clearance to the healthy bed partner, add middle molecule clearance, and restore renal endocrine function that is impossible with current dialysis, and allow for slower and safer ultrafiltration (UF).

This paper will demonstrate that adequate small molecule clearance is both possible and safe. It will lay out the case for a more physiologic solution to ESRD that addresses aspects of ESRD that are not treated by our current dialysis paradigm.

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## **Novel Modeling and Anemia Management Replacement Therapy Technology to Improve Patient Quality of Life and Reduce the Cost of Care for End Stage Kidney Disease Patients**

The kidney function impairment in ESRD patients often leads to anemia due to the fact that the kidneys are no longer able to manage red blood cell homeostasis through the production and secretion of the red blood cell stimulating erythropoietin. The advent of erythropoiesis-stimulating agents (ESA) in the 1990s provided hope to ESRD dialysis patients that their anemia could be managed without direct intervention (transfusion). Yet, due to long-endured complexities in determining proper dosing for ESA administration, there is a prevalence of harmful up and down swings in ESRD patient hemoglobin (Hgb) levels that leads to comorbidities, increased hospitalizations, and even death.

Currently anemia management in ESRD patients utilizes traditional protocols like the Kidney Disease Outcomes Quality Initiative (KDOQI) to assess high Hgb changes and prescribe ESAs. However, patients respond differently to similar ESA doses leading to a wide fluctuation in Hgb levels that often ends up in hospitalization. Additionally, this also leads to unnecessary high ESA dosages that have adverse effects while significantly impacting the quality of life in ESRD patients.

Physician Software Systems (PhySoft), in cooperation with the Mayo Clinic, proposes to deploy a software tool called PhySoftAMS™ that provides decision support to medical professionals managing anemia in ESRD patients treated with ESAs. When PhySoftAMS™ individualized dosing recommendations are followed, it has proven to stabilize Hgb levels in ESRD patients receiving ESAs as well as reduces overall ESA dosages. This leads to a significantly improved quality of life for these patients and reduced hospitalizations, alongside substantial savings for dialysis centers and the healthcare system. The system reduces the use of expensive ESAs by 30 – 50 % while also enabling providers to manage

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## Changing the Properties of Water to Reduce the Duration of Hemodialysis

We have developed a novel technology to increase the effectiveness of current hemodialysis. We propose that this new technology will substantially reduce the time it takes a patient to complete a dialysis session, thereby increasing the patient's quality of life. Current hemodialysis relies on a concentration gradient to diffuse toxins from the blood. Our novel approach uses a function generator and Helmholtz coil to alter the magnetic properties of purified water. We hypothesize that by introducing this magnetic gradient to dialysate it will speed the removal of toxins such as Urea, a polar molecule, from the blood by a paramagnetic attraction. The paramagnetic effect will attract toxins to the dialysate while the magnetic property of blood [1, 2] will induce a diamagnetic effect to prevent accumulation of water. Based on our data we expect a 40% decrease in the time of a single hemodialysis session, thereby improving patient quality of life. We are currently near completion of a prototype magnetic resonator-function generator that can be used in a clinical setting or used by patient at home. Our next step is to collaborate with the Nephrology Department at the University of Oklahoma on a series of clinical trials to test our hypotheses.

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## **Artificial Intelligence Driven System to Enhance ESRD Care Delivery and Improve Outcomes**

Due to strains on nephrology workforce, today's clinicians often struggle to deliver comprehensive care that addresses all the domains of ESRD care on time and provide the necessary education support that results in a better-engaged patient. To address these issues, Gurdye.com have developed artificial intelligence (AI) driven clinical pathways (aka 'SuperPathway') to replace traditional clinical protocol to improve outcomes and 'MyCare portal' to accomplish goals of delivering comprehensive care, reduces treatment complications and provides for better patient engagement.

Five SuperPathways in development are 1) Mineral Bone Disorder (MBD) SuperPathway, 2) Anemia SuperPathway, 3) Nutrition SuperPathway, 4) Dialysis Adequacy & Efficiency SuperPathway and 5) Ultra-Filtration Rate & Dynamic Estimated Dry Weight SuperPathway.

MyCare Portal is the patient engagement platform that gives patients the digital experience and on-demand multimedia education platform. MyCare seeks patient's input (example medication adherence and affordability) and provides them with focused education and information on their ongoing care. This portal will be integrated with electronic medical records (EMR) and the SuperPathway platform to deliver a frictionless, personalized and fully integrated experience.

Data from the completed pilot project on MBD SuperPathway with 166 ESRD patients demonstrated a remarkable acceptance (98.3%) of Gurdye's AI engine's care recommendations by the rounding nephrologist and showed improving MBD lab outcomes over a 7-month duration (KDIGO 2017 CKD-MBD guideline targets). More patients were

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## **ON DEMAND SCHEDULING APPLICATION TO IMPROVE PATIENT QUALITY OF LIFE AND OUTCOMES**

End stage renal disease (ESRD) patients on in-center hemodialysis (ICHD), experiences a substantial impairment in quality of life (QOL). Also noted is the association between dialysis treatment non-adherence and increase the risk of hospitalization and out-of-hospital sudden death. We believe the inflexibility of the ICHD schedule and the inefficiencies in the transient dialysis setup contributes to poor QOL and treatment non-adherence. Mobile-HD is a technological platform of an on-demand marketplace for dialysis treatment schedule with a bi-directional communication tool that will in near-realtime connects an ESRD patient who is looking for ICHD treatment(s), temporarily to an outpatient hemodialysis clinic ('host HD clinic').

Many of the existing processes and trends in today's healthcare has provided us the impetus to envision Mobile-HD. The standardization of dialysis clinic operations, the existence of transient dialysis setup program, lessons learned from ESCO care model and telehealth, as well as the improving environment of clinical data sharing, are among the many motivators for us to consider realizing our project.

Mobile-HD will be a location-based application that will utilize industry standard security protocols to protect user data. One of the key goals would be to efficiently and timely complete (<30 min) the entire process of a patient requesting an appointment to the host HD clinic providing confirmation. Patient and host HD clinic on the Mobile-HD's platform will complete all the scheduling process and perform the exchange of clinical data including the dialysis prescription. The system will follow complete event procession (CEP) workflow pattern with the goal of complex event processing of locating a host dialysis clinic, real-time exchange of data between users and relationship management system to monitor

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# Information Technology Platform for Expanded Comprehensive End-Stage Renal Disease Care

We are proposing an information technology (IT) platform permits data informing pertinent quality metrics to be gathered, collated and tracked for all end-users. The most recent iteration of Centers for Medicare and Medicaid Services (CMS) Conditions for Coverage includes a transplant based metric applicable to dialysis facilities, the Percentage of Prevalent Patients Waitlisted (PPPW). The IT platform will allow facilities to track their PPPW rates in real time. In addition to the PPPW, the IT platform will offer a novel tool dialysis facility can use to design and implement quality improvement projects around all steps of transplantation. Transplant centers can also make use of the IT platform to inform quality improvement projects around waitlist criteria and waitlist management. Nephrology practices can make use of the IT platform to actualize population-health level tracking the transplant education, referral, evaluation and listing of prevalent patients with advanced chronic kidney disease (CKD) and/or end-stage renal disease (ESRD).

## Technical Requirements:

1. Active on the federally certified Health IT product list.
2. Linked to a patient record with unique patient identifier (UPI).
3. Facilitates instant and bi-directional communication capabilities among the patients, payers, providers, and other Health IT systems:
  - a. Videos/Pictures/Files/Medical Imaging
  - b. Recorded audio and video calls
  - c. Text messaging
  - d. Customizable Notifications
  - e. Delivered/Read receipts
  - f. Acknowledgment emojis
  - g. Patient record data fields (e.g. Seven Steps to Transplant, Labs, order entry, test results, evaluation results)

This proposal includes organ transplant with metrics and IT infrastructure/platform to support the communication and coordination of the patients and providers in the network. The OmniLife platform provides the infrastructure supporting all technical requirements above, including an upcoming interface with BlueButton 2.0. OmniLife leverages existing IT systems partnerships to accelerate implementation throughout the provider network. Existing centers and dialysis units are already customers of OmniLife can be implemented relatively quickly. **Aim 1:** implement the IT platform among an ESRD care provider network. **Aim 2:** reduce cost of care for patient population through better coordination of patients among treatment providers.

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## **Intelligent PD catheter allowing for remote monitoring of device performance**

Catheter obstruction is a serious complication of peritoneal dialysis (PD). Unfortunately, the current ineffective monitoring for complications in catheter-based treatments results in morbidity, hospitalizations and huge costs. This is especially evident for patients undergoing treatment for end stage renal disease (ESRD), where complications drive over \$2 Billion annually in preventable costs. Patients with kidney failure who opt for PD as their preferred modality of treating their condition need to be aware of the complications that come with the procedure. PD is one way of doing dialysis at home and therefore involves transference of a certain degree of health responsibility, from the nephrologist to the patient. Importantly, it is not just infections like peritonitis that one needs to guard against in ESRD patients with PD catheters. Other so-called "mechanical" and other non-infectious complications are possible as well. Blockage in PD catheters is a serious problem that has not been adequately addressed in current practice. In fact, PD catheter occlusion, is a very common complication with up to 36% of catheter obstructions described in the literature.

Senseer is addressing this unmet need by developing a sensor-enabled digital platform for peritoneal dialysis patients to provide early PD catheter complication detection while safely reducing the number of monthly patient visits. Our digital platform allows dialysis providers to safely monitor treatment efficacy, catheter blockages and patient compliance via access to our cloud delivered patient data live stream.

Our hardware acts as a gateway between the indwelling abdominal catheter and external dialysate discarding method. The fluid channel in the device houses several sensors that measure various metrics of the dialysate solution as it is drained from the peritoneal cavity. This data is then transmitted to cloud-based servers where our proprietary algorithms alarm dialysis providers in real-time when complications are detected. Our software interface will be designed to consolidate all communication between dialysis providers and patients in a single platform.

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