

Human Centered Design Toolkit :

Treating Kidney Failure



2022
Version 1



What is this?

You are reading the Kidney Health Initiative (KHI) Human Centered Design Toolkit for Treating Kidney Failure. It is a draft release, containing tools to help developers of kidney replacement therapy technology connect with people with kidney failure and begin to better understand the bigger picture of the needs within that community.

Developing and applying that bigger picture of the lives of people with kidney failure to product design is the key to accelerating commercialization of innovative kidney medical products. Using an empathic approach, guided by this toolkit, will direct your technology development towards a better defined market and help you understand when your product is clearly defined enough to meet the holistic needs of people with kidney failure.

This toolkit will help you build an empathetic understanding of people’s lives that you can apply to product design. Your first empathy tool is an innovation scale that describes the relationship among the needs of people with kidney failure in a way that avoids tradeoffs and prioritization. Three ambassadors representing the lives and aspirations of people with kidney failure on dialysis are your

next empathy tool. They will give you a more tangible representation of the innovation scale and help you envision the context in which your product must work. The final empathy tool that ties the innovation scale and ambassadors to product development are design principles and metrics to help you demonstrate that your product meets needs described in the ambassador’s stories. The empathy created by these three tools will help you communicate with people with kidney failure as consumers. Consumers expect the products they use to meet their needs and work in their context or they will not adopt them.

This toolkit cannot replace actual engagement with the community. Instead, it is meant to help open a dialog so that the next generation of kidney replacement therapies have a deeper and more meaningful impact. The only path to achieve that goal is to have actual conversations with people living with this chronic condition and use that knowledge to build empathy driven innovations. It is the best path we know for product developers to create disruptive innovations that are the foundation for great companies.

Why we created this:

Our goal for this work is to promote connection between medical product innovators and the people who need transformational innovation: people with kidney failure. Our belief is that when these two groups connect on the basis of empathy, transformational clinical outcomes and disruptive technology become possible. This toolkit is the beginning of an important empathy journey for the innovators and offers the opportunity to reset the definition of innovation within the kidney disease space.

This project started with a question: how might we identify and compare the best possible technologies for treating kidney failure? Taken at face value, it is not an easy question to answer. For example, an electro-mechanical pump is not directly comparable to a xeno-kidney transplant. They approach treating kidney disease in very different ways and both have good reasons to be pursued as well as potential drawbacks that color their impact on people with kidney failure.

If we step back and reframe the question slightly, we can get a better result: how might we identify innovations with the most impact on people’s lives? By refocusing on the problems experienced by people with kidney failure, all of the technology elements become secondary and the scale becomes clear: what has the most impact on the person. Measuring innovation starts to become intuitive and simple at a qualitative level.

This question also sets up the opportunity to rethink the definition of innovation. As you will learn in this work, the experience of people with kidney failure is often shaped by the medical products used in their care. Those products have been designed with a bias toward patient survival rather than the bigger picture of the patient experience. This has resulted in incremental improvements in technology with very few disruptive innovations in the market that have the potential to drastically change the experience

of people with kidney failure. Listening to people with kidney failure will help you to understand that the technology advancements in the last 50 years have failed to meet their broader needs. Embracing our new question is the path to the most impactful innovation that meets the comprehensive needs of people. By using a broader range of problem statements beyond survival, we can better understand the experience of people with kidney failure. These problem statements were collected from people with kidney failure and used to create a new framework: the innovation scale. That innovation scale resets the definition of innovation and transformation by attacking problem statements that address “quality of life” and needs arising from the context in which people live in addition to survival. Resetting our definitions is critical to a new era of innovation.

This project started with a question:

How might we identify and compare the best possible technologies for treating kidney failure?

Reframed question:

How might we identify innovations with the most impact on people’s lives?

Start here.

The toolkit is nonlinear and can be explored as your curiosity drives you. It has been structured in four related and interdependent sections:

- An introduction to working with empathy (Intro)
- A revised framework for innovation (Innovation Scale)
- A conversation with Marianna, Luke and Anthony (Stories)
- Connecting design principles and metrics (Metrics)

Despite its nonlinear design, the heart of the toolkit is a journey getting to know three hypothetical ambassadors: Marianna, Luke and Anthony. They are fictional people who share insights gathered from interviews of real people with kidney failure. While they do not cover all of the experiences present in the community, their stories are representative of people with kidney failure on some form of dialysis and will help you to understand some of the individual journeys that do exist. Hearing their real world challenges and experiences is intended to help you connect empathetically to the innovation scale, the design principles, and the associated design metrics we have created to get you started.

The empathetic connections you build will help you understand the “why” behind the innovation scale and help you retarget what innovation and transformation really means. Once you understand Marianna, Luke, and Anthony, you can follow the interactive connections from their stories into the design principles and finally to measurement metrics. Metrics function as specific calls to action that can help you measure the impact of your innovation.

Understanding kidney disease & designing for chronic conditions

Kidney failure is about losses. A loss of independence, a loss of wellness, a loss of financial stability, a loss of available life choices. Kidney failure can consume most of the conscious life moments of the people living with it. It also takes over how society views people living with the condition and shifts how they define themselves.

Chronic conditions are defined by the fact there isn’t an outright cure. **Often, the best case scenario for people with kidney disease is a stalemate where symptoms and progression are held at bay.**

Chronic Conditions

People with kidney failure have had to learn to live with the daily reminders of their health condition. Many have found hope and thrive despite the limits of current therapy options. For many people with kidney diseases, it is tough to identify a moment of daily life where they are not facing a reminder of their health condition. Disrupting this reality remains a huge unmet opportunity.

Your job as product developers is to support the needs of people with kidney failure as they rebuild what they have lost. The losses associated with kidney failure are major opportunities for disruptive innovation that extend well beyond treating the symptoms and side effects of kidney failure. Looking past symptoms and survival reveal opportunities to address the needs of the whole person.

When innovators look at the quality of life losses as a ripe target to differentiate and transform the health experience for people with kidney failure, it’s not just an altruistic goal to relieve patient burdens. In the US, treating kidney failure is a multi-billion dollar market with significant investments from Centers for Medicare & Medicaid Services. Giving people with kidney failure a break from constant immersion in their health condition increases their engagement in society and improves their health outcomes.

Chronic conditions are defined by the fact there is not an outright cure. Often, the best case scenario for people with kidney failure is a stalemate where symptoms and progression are held at bay. The reality is that most people with kidney failure must spend a significant amount of time attached to a machine and physically altering their bodies to accommodate technology. Even the current gold standard, kidney transplants, require significant medication and lifestyle choices in an effort to reduce the chances of organ rejection.

Designing products for people with chronic conditions requires a different mindset. We need to think beyond treating the illness and consider the whole person. Treating quality of life and survival as tradeoffs is not an acceptable outcome for people with kidney failure. Survival on dialysis was a technological innovation decades ago and has become a table stake while quality of life issues are often neglected.

The conflict between survival and quality of life is intimately tied to the treatment options available to people with kidney failure. Dialysis will filter waste from the blood but comes with its own side effects, consumes significant amounts of dedicated time and is cost intensive. While it is the optimum treatment for kidney failure, a kidney transplant presents significant qualification challenges and costs to maintain the graft without restoring a person to full health.

The drawbacks associated with the standard of care are well documented elsewhere. What is less understood is the relationship between those drawbacks and how product developers should choose their product opportunities.

Seeking a holistic understanding of the life of people with kidney failure is necessary to design products that meet their complete needs. Like any other product, innovators should think of people with kidney failure as a diverse group of consumers who live in different contexts with diverse needs and aspirations. Embracing a consumer mindset will help innovators design the next generation of medical devices that can both disrupt and transform the healthcare experiences for people with kidney failure.

Redefining innovation with a new framework

In order to meet the urgent market demand for innovation, we must use a

Innovation Scale

value proposition of innovation that goes beyond technological advancement. A pure focus on technology without an underlying human centered problem statement is rarely disruptive, and often a primary root cause of failure in the marketplace.

We have created a new framework based on a model from psychology that has been applied in multiple areas: Maslow's Hierarchy of Needs. This is intended to help guide innovators to redefine the range of the problem space available for innovative solutions.

A traditional presentation of Maslow's Hierarchy of Needs functions like a ladder: the lower rungs are the basics of survival. These include: food, shelter, and water.

Without achieving these goals, it is difficult to focus on the next rungs above them. People progressing through all of the rungs in our ladder would have achieved full self-actualization.

We are adapting this model to communicate the broader set of problems faced by people with kidney failure. This model acknowledges an opportunity space for innovators that includes both survival and a return to life moments that are freed from the burdens imposed by kidney failure. The higher up the ladder a kidney replacement therapy reaches, the more it delivers health and life experiences more similar to curing kidney failure. Layered on top of this new model are targets to communicate a revised definition for scaling innovation: incremental, innovation

and transformational. An incremental range achieves near-term improvements to healthcare experiences that have aged out of being innovations, such as conventional dialysis. Dialysis, as a standard of care, has existed for decades with small improvements. Its primary benefit of extending life has become an expectation for any new product addressing the needs of people with kidney

failure. The innovation range delivers a product experience that solves the expected product benefits in the incremental range while starting to deliver solutions to unaddressed kidney failure experience opportunities. These mid range problems do not fully achieve the urgently needed freedom from the burden of kidney disease, but they are achievable within

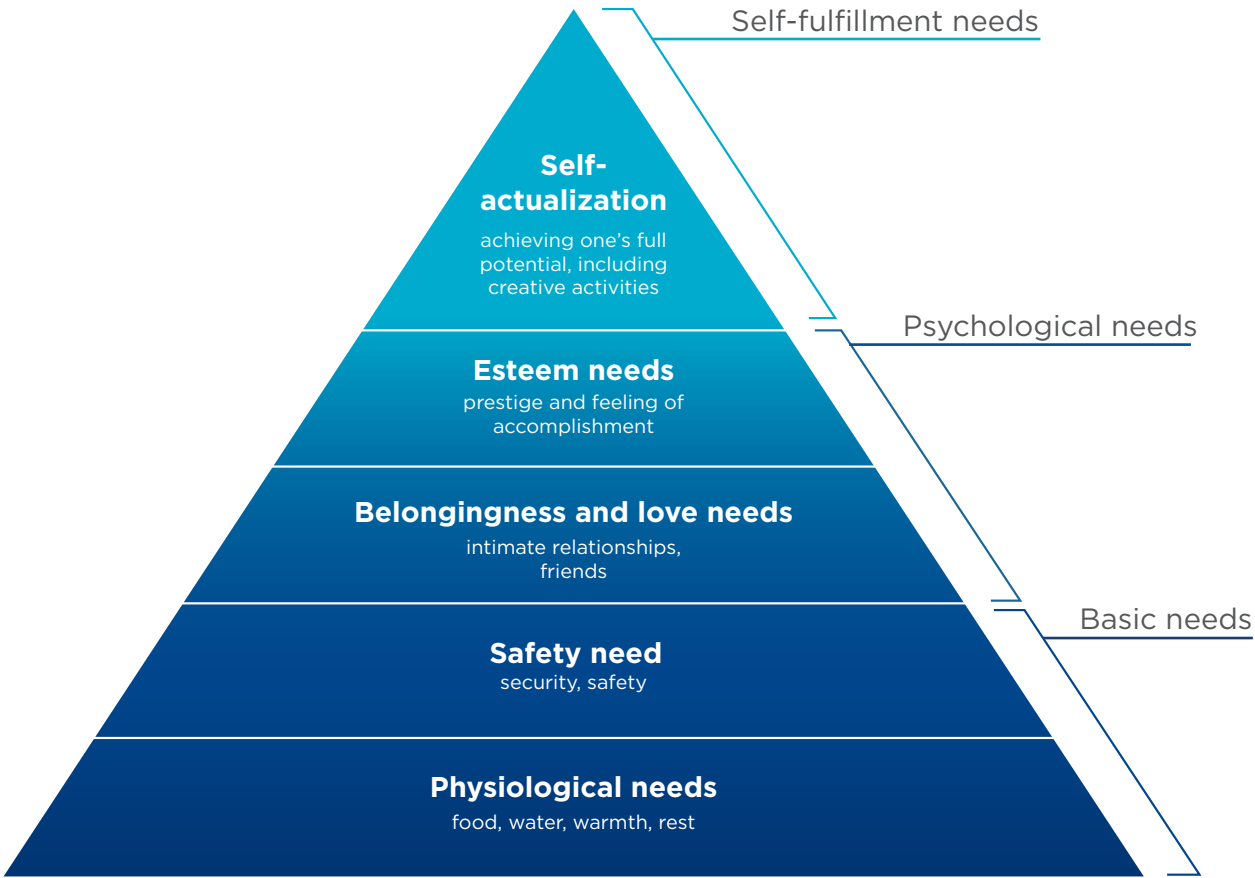


Figure 1: Maslow's Hierarchy of Needs

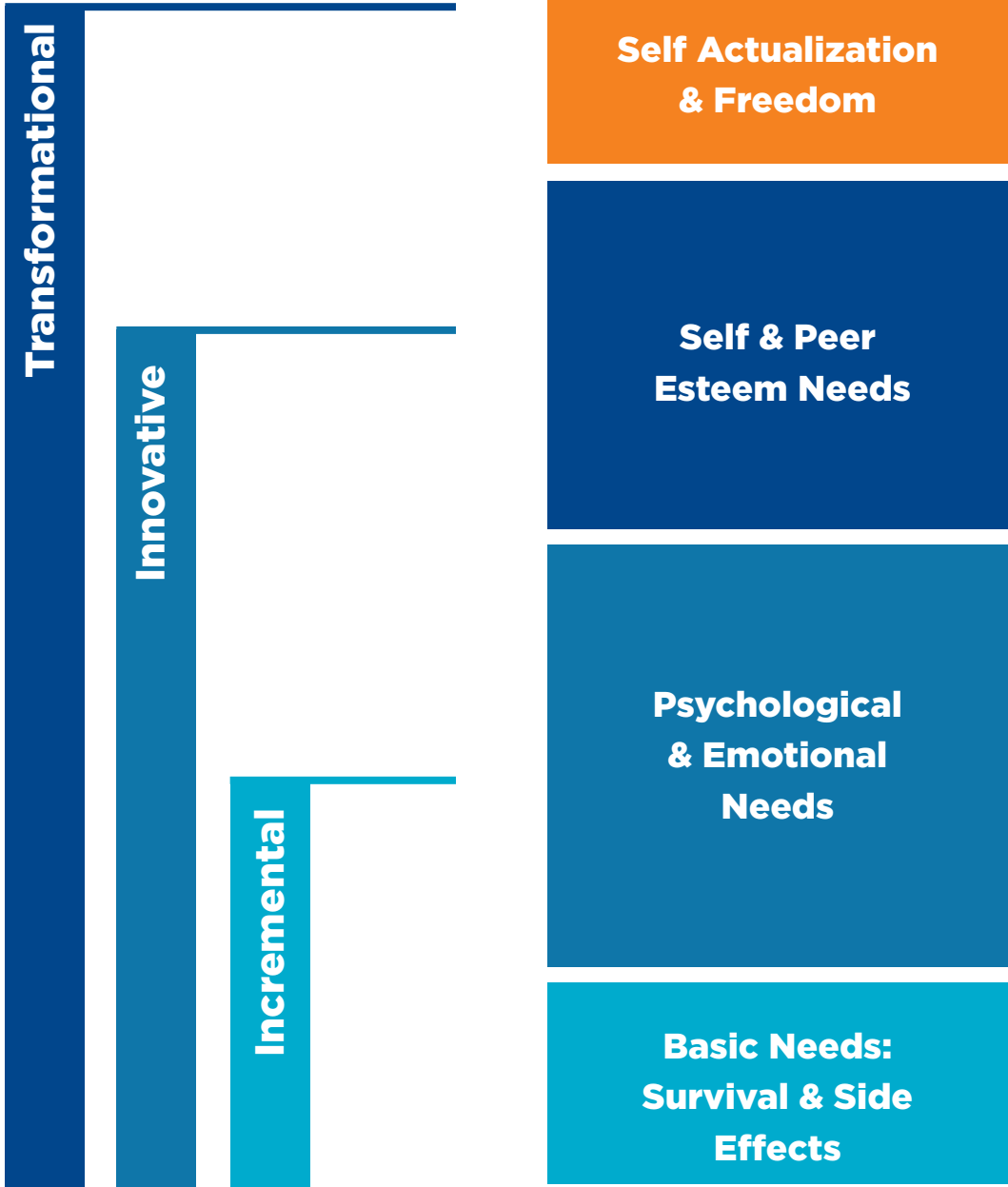


Figure 2: The Innovation Scale and Human Needs

Innovation Scale

a near-term window for medical product innovation.

The transformational range establishes a “moonshot” target for changing the patient experience. At the top, it sets the aspirational goal of an experience free of sensory/mental/emotional burden from kidney failure. The daily life experience should be difficult to discern from a life lived after a true cure for chronic kidney disease is achieved. The challenge within this range is realizing the

result within a meaningful timeline. Our goal as human-centered innovators is the delivery of real solutions into the hands of the people we seek to serve. Scientific discovery is a step in that journey, but we should keep pressure on ourselves to ship a transformational product that is holistically life-changing for people with kidney failure.

The final diagram helps to clarify this point about the tension between innovation and timeline to product. A classic square diagram

with two axes: level of innovation and likelihood for near term delivery. Quadrant #1 should be avoided (lower left), it is incremental and unlikely to be launched in a meaningful timeline. Quadrant #4 is highly attractive because it is transformational and has high confidence that it will ship within a meaningful timeline. Quadrants #2 and #3 are attractive but product developers should look for opportunities to improve the innovation level of user centered problems addressed (quadrant #3) or opportunities to improve

the meaningful timeline for delivery (quadrant #2). Moving past the midpoint on both axes places innovators in the position to have impact for the people with kidney diseases and generate a market transformational product.

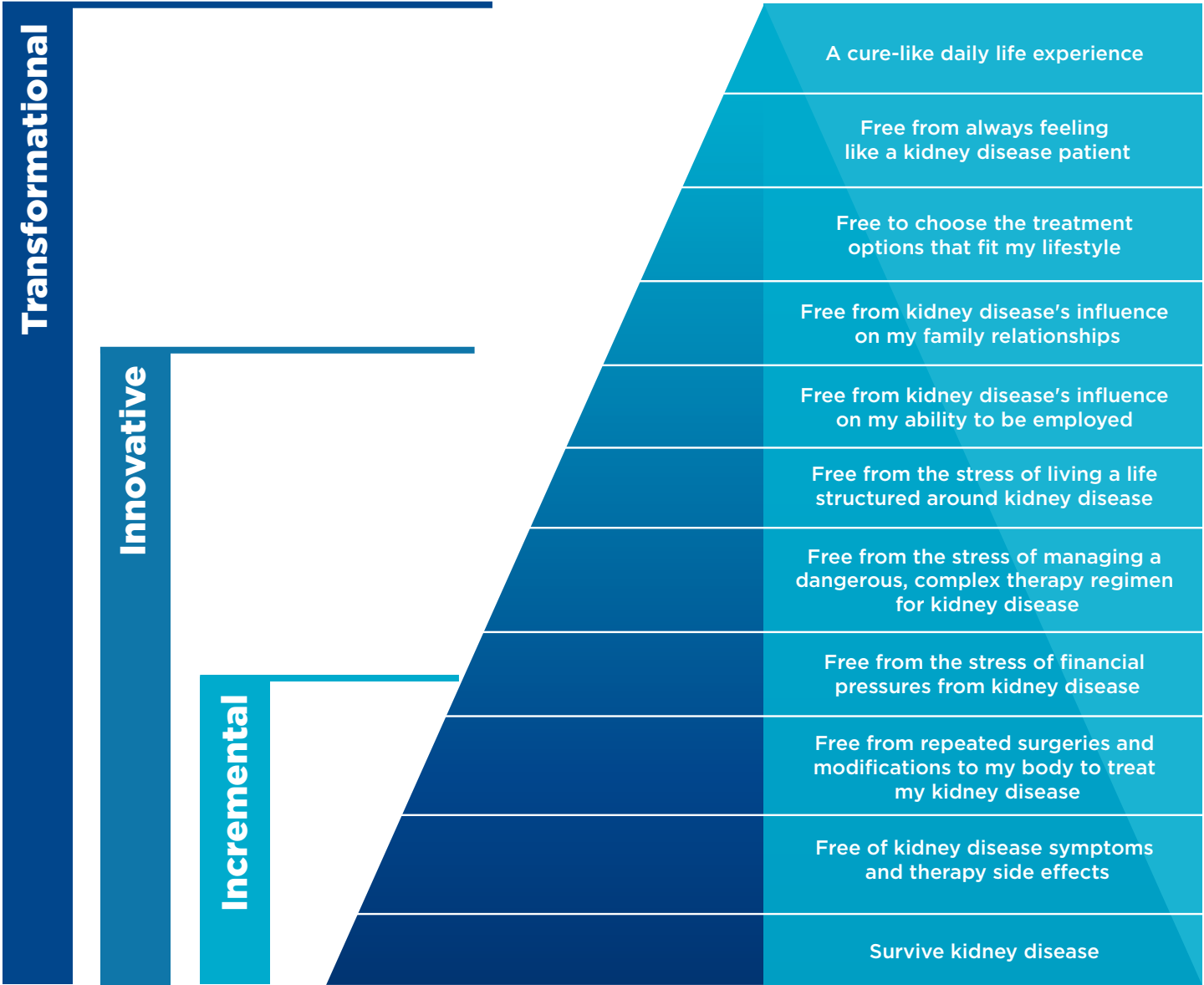


Figure 3: The Innovation Scale and Problem Statements

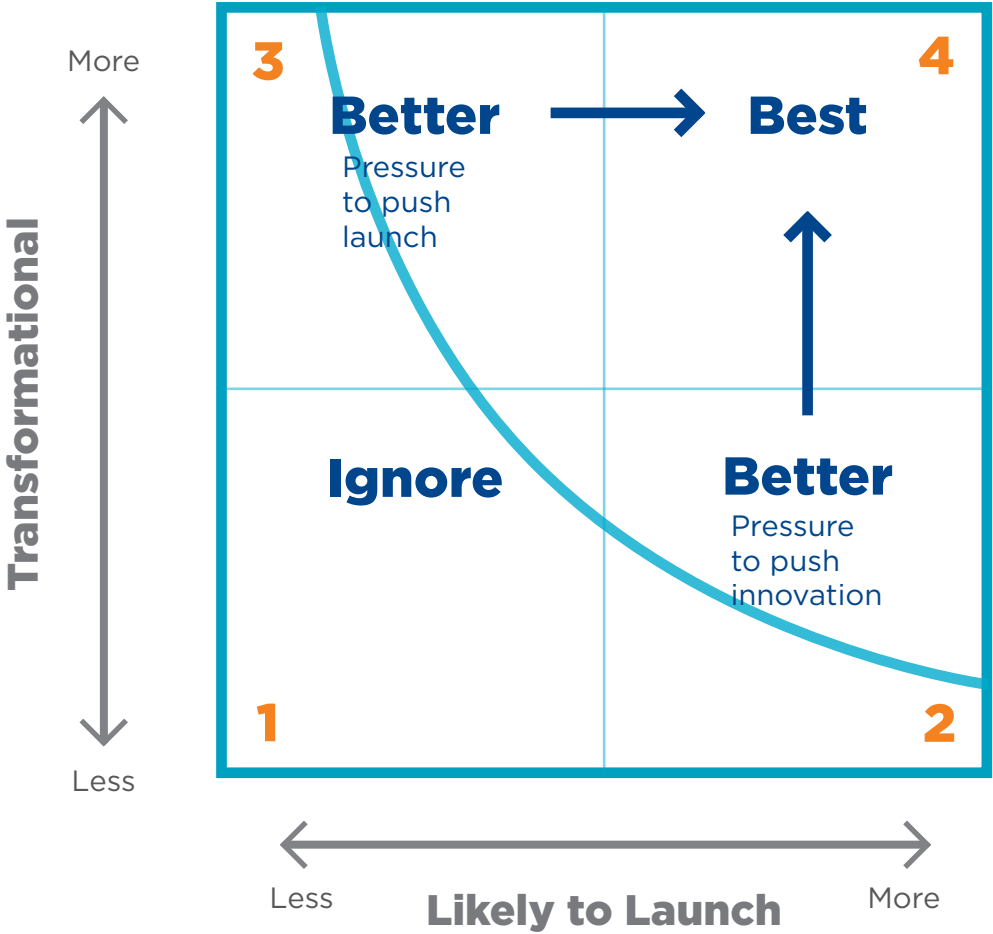


Figure 4: Innovation and Commercialization

Ambassadors



Marianna



Luke



Anthony

Introduction to the ambassadors

This section describes three fictional life stories that capture honest moments from patient experiences with kidney failure. We would like you to meet Marianna, Luke, and Anthony. Think of them as ambassadors on your journey to better understanding the types of experiences that exist when living with kidney failure. Their stories are the primary method to immerse you within the lived experience of people with kidney failure so you can empathetically assess whether your product will solve the problems the Ambassadors describe.

Each ambassador’s story is based in information gathered through qualitative research interviews. We identified problem statements in those interviews before organizing and verifying them in a quantitative research survey. This ensured that the problem statements used as the basis for these three stories honestly reflected the lives of real people with kidney failure.

As you read Marianna, Luke, and Anthony’s

stories, you will note a series of design principles listed within each one. Interacting with these design principles will highlight related problem statements embedded within the story. Use these design principles as a guide to help understand the emotional result of solving the problem. Thinking of your outcome as an emotional result is an important part of the process since it forces us to step back from a technology focus and embrace the nuances of the problems we are trying to solve.

Once you have internalized the connection between the desired emotional outcome (the design principle) and the problem statements, follow the navigation link to the section we are calling “Metrics”. The metrics are designed to complete the journey from a human centered problem statement to a measurable call to action. They trace connections between design principles and a set of human centered metrics. These key performance indicators are designed to clarify

the emotional truth written into the design principles with qualitative evaluation criteria.

They follow a formula you can use to craft your own: each statement includes a directional change (increase, decrease,

eliminate) and a unit of measure (time, perception, etc.).

The design principles and metrics in this toolkit are presented as a starting point for meaningful discussions between innovators and people with kidney diseases. Innovation is expected to be unique and requires us to spend time with people with kidney diseases educating ourselves. As you explore the problem space you are targeting, we are confident that you will identify new design principles to expand on this baseline set. We celebrate this independence and share this toolkit as a starting point. Jump in and embrace the emotional truth you will discover. Once you have it, come back to these materials and use them as a reference to build your own palette of design principles and metrics.

Hearing their real world challenges and experiences is intended to help you connect empathetically to the innovation scale.



Marianna

Age: 29
Job: Hourly Retail
Location: Rural Oklahoma
Family: Single
Therapy: Hemodialysis In Center
Length: 3 to 5 years on Therapy
Children: No

Everything I'd built my life around began to fall away. Despite working hard at the grocery store, I wasn't getting rich, but I was earning enough money to cover my basic needs. In spite of my illness, I tried to keep going to work, but after a few weeks my manager suggested I step down. I believe they couldn't work around my dialysis schedule. My body just can't sustain a job where I am on my feet for 6 hours a day. Unfortunately, I can't work retail jobs because I'm too sick to do so. Eventually, the little bit of savings I had ran out. I got on Medicaid and disability insurance, but that's barely enough for me to survive. After seeing an ad about working from home, I tried to earn more money doing data entry and taking surveys. The work didn't pay well and I almost lost my Medicare. It's tough to find any way to earn extra money without losing Medicaid coverage.

I was working on my future by studying for a nursing certification in community college. Just like work, I couldn't keep up with school. Following dialysis sessions, I felt so drained that I couldn't concentrate on my coursework at community college. Realistically, I couldn't afford tuition anyway without my job. I was watching my life going into free fall.

I left my apartment and moved back in with my parents. Being home makes me feel like a kid again. It's a lot of work for them to fit my needs into their schedule, but they know I am relying on them for survival. They take me to dialysis sessions 30 minutes away, because I can't drive myself. I feel bad because even though it's kind of on the way to their jobs, they both have long commutes already. My parents are anxious about me. I get the sense that they are afraid to let me do normal things around the house. I'm supposed to be an adult but I feel like I'm back to being a high school kid. They care but don't really understand. Most of my day is spent traveling to a clinic, sitting in a dialysis chair, or waiting for a ride home. It's frustrating because I want to be doing something else with my life. It's scary and uncomfortable being at a dialysis clinic. I'm the youngest person there. I've seen people show up in chairs one day and not be there the next. Some of the people I've talked

to in the chair next to me are nice, but it's easier to find people like me online.

New Normal

Dialysis at home is possible as well as kidney transplants, but no one at my dialysis clinic has addressed either with me. When I see a kidney doctor, it's usually for a short time. If someone spoke to me about other options, I wouldn't know which one is right for me. I see what the nurses and techs do to give me dialysis. It's intimidating to think of doing all that at home. After being hospitalized for the infection, it's frightening to think of doing dialysis on my own. Who knows what could go wrong and who would help me if something did. In some ways, it's nice to have someone else handle it and not think about it.

Right now, I'm in survival mode. Everything beyond getting through today is too much. I need to figure out what my new normal is. I want to be independent, to live on my own, be able to work and study, and for my family not to worry about me. The way I crashed into dialysis scarred me. Anything new I'd try will have to provide me peace of mind that something won't happen that will send me to the hospital. Going to a dialysis center makes my health condition impossible to ignore. I don't want my health or treatment to take as much space in my mind as they do now. Dialysis treatment that I didn't have to think about and wasn't in my face would be great.

I don't want kidney failure to dictate everything going forward. I need kidney replacement therapy that supports the life I want and doesn't limit my aspirations.

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My life used to be full of possibilities, but kidney disease has limited my options.

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Design Principles

Don't add to my financial burden

Kidney disease is isolating, help me be a contributing member of my community

Relieve my family of the burdens of being a care partner

Kidney disease limits my life, give me back options

I'm a person, don't make my life revolve around being a patient

Hide All

Select All

The Crash

It all happened so fast. It's hard to describe how terrifying it is to go from thinking that you're healthy and not really caring about your health to knowing you're sick and facing the serious limitations that a disease without a cure places on your life. My new reality is a shorter life spent attached to a machine. There is so much to process and I am not sure if I have accepted it yet.

The day I crashed into kidney failure was pretty normal. I was working as a cashier at a local grocery store. That day, I collapsed and lost consciousness as I was conversing with a customer. I remember very little afterward. I woke up in a hospital and the doctor told me my kidneys had failed. The people in the ER said high blood pressure could have caused it.

I had never heard of kidney disease before I was hospitalized. To survive, I needed dialysis, so I had a temporary central venous catheter inserted. The surgery didn't go well and I had to be hospitalized for another week because of an infection. When the hospital cleared me, I was discharged and given instructions to go home and call a dialysis clinic thirty minutes from home. The catheter was just the first of several surgeries. I had to go back to create a fistula in my arm. The fistula had to heal before the catheter could finally be removed.



Luke

Age: 42

Job: Multi-Sourced

Location: New Jersey

Family: Married

Therapy: Peritoneal Dialysis
At Home

Length: 5+ years on
therapy

Children: Yes

Design Principles

Kidney disease is isolating, help me be a contributing member of my community

Managing my kidney disease shouldn't require an advanced degree

I'm a person, don't make my life revolve around being a patient

Treating my kidney disease should make me feel better not worse

Kidney disease limits my life, give me back options

Hide All

Select All

The Inevitable

I've worked hard to live with kidney disease. I was diagnosed with IgA Nephropathy in high school. From then on, I had to eat well and try to stay healthy so my kidneys would last as long as possible. In college and my twenties, I managed my kidney disease with diet and exercise to make my life look similar to my peers. I looked healthy to everyone else but knew in the back of my mind where things were going. Because of this, I got on the transplant waitlist. Although I endured lots of testing and paperwork, I could afford to wait for a preemptive transplant. Eventually, I got a transplant through a paired kidney donation. It was an exciting time, enabling me to live an almost normal life, but my IgA Nephropathy came back and my graft failed after a couple of years.

Finding out my kidney was failing again was traumatic. My desire was to avoid in-center dialysis, but to remain alive I had to do it while I was being trained to do home dialysis. The final blow was when my nephrologist told me that I would unlikely qualify for another transplant due to the risks of my disease recurring and being over-sensitized by the immune regimen required by my previous transplant.

It was devastating, depressing, and frustrating to imagine a future on dialysis where I would not live the life I was used to. I felt for the first time that kidney disease would significantly disrupt my life. So, I chose a kidney replacement therapy that would still allow me to live my life and I made it work for me.

Home hemodialysis is an option, but the risks of needle sticks made my spouse anxious. I didn't want to choose a modality that forced my family into a medical role they didn't choose. The continuous cycling peritoneal dialysis machine was best for me since I can do it at night without interruption.

New Life Style

I'm invested in my health and treatment because I want the freedom I had with a transplant, or even just the life I had before my kidneys failed. Currently, none of the options available are ideal, since I have a catheter in my stomach, I must be in one place for several hours at a time, and my peritoneum will eventually deplete, requiring a different therapy. I have to hyper-manage my therapy/diet/lifestyle to minimize the side effects and even then it doesn't always work. We don't have a ton of room in a three bedroom house with five people living together. The gallons of dialysis solution and other medical supplies we have around the house blur the lines between home and hospital.

I know I have chosen the best option out there for me but I still wish there were better options available. A large external machine keeping me alive is a visible reminder that I'm sick. Despite managing kidney disease for decades, I never had an external sign that I was sick. It's been a grind to master very complex machines to get my health to the best state it can be. It's mentally exhausting to always be "on." My first consideration is always my health. I am constantly thinking about my body, staying up to date on research, and talking to doctors.

Fortunately, this life change happened when my kids were a little older and my career was more established. Peritoneal dialysis offers me freedom, but it still costs time with my family.

It is difficult to have a vacation without detailed logistics. My entire life has to be planned: Travel, friends, romantic relationships. All of these things are made more difficult by kidney failure and my treatment. It is really difficult to be spontaneous when living with kidney failure. Today, I am able to administer my therapy on my own. In the future, though, I will need more help from my spouse and children than now.

I'm lucky my employer has given me a ton of accommodations to make it easy for me to stay employed. I am proud of my career advancement and don't want to think about what might happen if my kidney disease forces me to leave the workforce.

I've accepted that I will never have fully functioning kidneys, but I haven't accepted that it will define my life. I will need different kidney replacement therapy eventually. My hope is that whatever is next will let me enjoy life like a person, not a perpetual patient so I can relax and not worry about my health. I'm good at taking care of myself, but I've got too much going on in my life to be thinking about kidney disease as much as I do.

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I'm amazing at managing my CKD...It is still limiting. I am fighting against it being "my normal".

”



Anthony

Age: 62
Job: Retired
Location: Atlanta Metro Area
Family: Married
Therapy: Hemodialysis In Center
Length: 1.5 years on therapy
Children: Yes

Design Principles

Don't add to my financial burden

Kidney disease is isolating, help me be a contributing member of my community

I'm a person, don't make my life revolve around being a patient

Relieve my family of the burdens of being a care partner

Treating my kidney disease should make me feel better not worse

Kidney disease limits my life, give me back options

Hide All

Select All

Onset of Sickness

Despite my illnesses, I enjoy a full and happy life. I never thought of myself as a sick person, but diabetes, hypertension, and finally kidney disease have slowly taken over my life. For years, I've been dealing with heart problems and diabetes. I felt powerless as I watched my kidneys gradually fail. Nothing worked to help me escape these diseases. It's too much, and I cannot handle yet another illness. I don't want kidney failure to stop me from having a fulfilling life, but I can't ignore what's happening inside my body.

I had to retire because I don't have the time to work. Three times a week, I'm at the dialysis center, I'm tired and weak afterward, and in between sessions I feel bad.

It feels like I have a doctor for everything now. I see specialists for diabetes, heart issues, and kidneys now. My family and I have to coordinate my care between all of them, which is a lot of work. There are more restrictions, pills, procedures, and pharmacy bills each year. I take more than 100 pills a week. That's a lot to handle.

The doctors say that I'll never qualify for a new kidney because of my heart disease and weight. My insurance would not cover the drugs I'd need to keep a new kidney working long-term, even if I got a transplant. The

insurance company says I'm too much of a risk. I feel like this is my life now

Staying positive is hard. Retirement isn't what I thought it would be: relaxing at home, maybe a little golf, playing with the grandkids, and big family reunions. I just want to play with my grandkids and watch them grow up. Having dialysis three times a week and feeling lousy between means I can't give my grandkids the attention they deserve.

Family and Community

It is a family effort to manage my kidney disease. My wife keeps track of my food, medications, and activities. My kids keep me on track with dialysis and doctor appointments. I'm used to being the king, but now I'm being told what to do most of the time.

My wife and I used to argue about my health when I started dialysis. I think she was just so terrified that she took over. She wants me to be there to see our grandkids grow up. It took me a while to accept the changes in our relationship, but once I did, it got easier.

I feel sick before dialysis and too weak afterwards so my family doesn't trust me to drive anymore. My children take me to in-center dialysis three times per week. It's hard to stay on schedule and I need the help. I feel like a passenger in my own life. It's nice that they help me, but I know it's an additional burden they didn't ask for. I want to be more independent because they should be focusing on their lives and their kids. I wish this never happened.

My grandkids don't understand what's going on. During the summer, when they catch a glimpse of my vascular access, they are often scared because the veins bulge out like snakes. I didn't want to do home dialysis because I want my grandkids to feel comfortable at my house. I don't want them to be scared or worried. They know I am sick, so seeing their grandpa hooked up to a dialysis machine would worry them more. Starting dialysis made me feel defeated. It wasn't just the side effects wearing me down,

it was the finality of my kidneys failing. It felt like everyone thought my choices caught up to me. I could tell that people around me thought I could have avoided dialysis if I had taken better care of myself. It hurt to see that, especially when it felt like I lost a battle. You can't stay in that mindset though. It's a bad space to be in. You need a reason to keep going. My reasons to keep going are my wife and my family. I want to see my grandkids grow up and share that with my wife. My people? I found them too. I have made friends with some of the other people on dialysis at the clinic. We can talk to each other more easily because we understand our anxieties and don't need to explain everything to each other. We already get it.

I'm not going to lie, in between dialysis sessions I feel bad. I feel sick. I'm fatigued, crampy, and dehydrated so I just don't have the energy or strength to do what I want to do. I'm still holding out hope that my body gets used to dialysis so that I can get back some of my independence.

I wish there were more options for people like me. I don't need some fancy Iron Man solution. I just want something that makes me feel better, and doesn't make me look like I'm a sick person. I don't want to spend my golden years tied to a machine away from my family. I just want my family to stop seeing me as a sick person. It doesn't have to be any more complicated than that.

“

“I've lost a lot with CKD and Diabetes. I'd just like to be in a place where I can play with my grandkids again.”

”

Why Metrics?

Welcome to the final section of the toolkit. The Design Principles shared in previous sections are intentionally interpretable but at their core is an emotional truth. This section provides additional clarity on the intent behind that emotional truth. The Metrics are crafted following a loose formula: a type of change + a direction of change + a unit of measure. You are free to expand on these clarifying metrics within your own work, just try to follow the template to ensure

compatibility. These metrics are not intended to be seen as comprehensive and your interviews with the kidney disease community may uncover new nuances to these Design Principles as well as entirely new Design Principles.

Review the metrics and use them to measure how much your innovation is likely to change the story for people with kidney failure. These metrics tie back to the problem statements

shared in Marianna, Luke, and Anthony’s stories. Use those design opportunities to ensure your product goals stay grounded in the way they will change the life experience of people with kidney failure. A large story change will increase the potential for a shared win: a market disrupting product and a significant improvement to the experience of people with kidney failure.

Metrics provide clarity on a Design Principle’s emotional truth.

DESIGN PRINCIPLES:

Relieve my family of the burdens of being a care partner

METRICS:

Provide options that allow patients to honor their chosen responsibilities:

- Reduce or eliminate the kidney disease symptom/therapy side effect/therapy time burdens that limit patients from being engaged in their responsibilities

Therapy options which instill/increase confidence in family members:

- Increase care partner confidence that the patient’s therapy is improving their health outcome
- Increase care partner confidence that they and the patient can manage the therapy and any side effects

Functioning kidneys “just work”. Meeting that gold standard will reduce care partner anxiety:

- Reduce or eliminate the need for skilled use/training for therapy success
- Reduce or eliminate the opportunity to be injured or killed receiving therapy
- Reduce or eliminate supporting medications from therapy (e.g. heparin, anti-rejection/immunosuppressant medications, etc)
- Reduce or eliminate any interaction with medical equipment. People don’t have “kidney time” like patients have “treatment time”

Minimize or eliminate the impact of kidney disease and its treatment on the patient’s ability to manage the activities of daily life:

- Would a patient be able to drive a car safely (e.g. without passing out from weakness)?
- Would a patient have the stamina to grocery shop/wash laundry/supervise their children/prepare food?

Therapy options which do not require skilled or trained users:

- Reduce or eliminate the need for skilled use/training for effective therapy
- Reduce or eliminate the opportunity to be injured or killed receiving therapy

DESIGN PRINCIPLES:

Treating my kidney disease should make me feel better not worse.

METRICS:

Minimize or eliminate therapy side effects or symptoms related to kidney failure:

- Reduce time spent feeling weak or exhausted
- Reduce the necessity of stacking medications to manage symptoms or side effects.

Change the mindset from “Physically altering the persons body to work with technology” to “altering technology to work with a persons body”:

An example list of changes necessary to make dialysis work (illustrating this mindset):

- **Hemodialysis:** Surgery to alter the vasculature in the patient’s arm (create a fistula), heparin doses for every treatment to avoid clotting, maintenance surgeries to keep alterations viable
- **Peritoneal dialysis:** Surgery to mount a permanent plastic port creating a passage from the peritoneum through the abdominal wall, filling the peritoneal cavity with dialysate

Kidney disease is isolating, help me be a contributing member of my community

Minimize or eliminate the physical presence of kidney failure on a patient’s body:

- Could a patient be confident facing a romantic partner for the first time without worrying about their appearance?
- Are there aspects of their illness or its treatment which can make them stand out in society (examples: access sites, surgical scars, ports into their bodies)?

Reduce or eliminate situations where a person would have to decide between quality of life and their survival to get kidney replacement therapy.

Minimize or eliminate the impact of kidney disease and its treatment on the patient’s life:

- Maintain their ability to earn a living.
- Increase their ability to participate in educational opportunities
- Increase their ability to take on societal roles outside of their illness
- Increase their ability to spend time with friends/family/society without increased risk of infection or illness

Minimize or eliminate the impact of kidney disease and its treatment on the patient’s ability to work:

- Minimize or eliminate the impact of kidney failure symptoms, treatment side effects and treatment time commitments on the the patient’s ability to stay financially secure
- Minimize disruptions to people’s ability to work in a retail environment or pursue education.

Minimize or eliminate the perceivable presence of kidney disease and its treatment in the patient’s home:

- Minimize or eliminate the presence of treatment (devices, accessories and supplies) within the patient’s living environment
- Minimize or eliminate the time spent in or traveling to clinical environments (clinician offices, treatment spaces, etc.)

DESIGN PRINCIPLES:

Don't Add to My Financial Burden

METRICS:

Give me options that allow me to stay employed/earn an income:

- Reduce or eliminate the amount of dedicated time patients have to spend receiving therapy
- Reduce or eliminate interruptions to the activities of daily life because of routine maintenance
- Reduce or eliminate therapy side effects that impact the ability to earn a living

Reduce or eliminate direct costs to patients for therapy access:

- Ensure eligibility for CMS coverage

Reduce in-direct cost impacts:

- Reduce the likelihood of maintenance surgeries
- Reduce the number of medications needed by patients
- Reduce or eliminate the sources of recurring costs (e.g., accessories, disposables, supporting medications, etc.)

Reduce total cost of product:

- Demonstrate that product can be manufactured at scale
- Maximize the number of commercial off the shelf components (reduce number of customizable components)

Kidney Disease Limits my life, give me back options.

Increase kidney replacement therapy options beyond the three available modalities. While there are three options, most patients are limited to a single option: hemodialysis:

Hemodialysis: easiest to qualify for, provides the least amount of lifestyle flexibility

- Peritoneal: only a small percentage of kidney failure patients can qualify (gated by evaluations for effectiveness for their illness and patient skills)
- Kidney transplant: most difficult option to access without directed donation

Increase therapy options that are easier to access than transplantation:

- Therapy options which have an easily understood & streamlined pathway into the therapy (Clinician prescribes => Payor approves => Access is provided) with the fewest patient touch points
- New treatment options should not be precious resources with limited access.
- Commodity level production to alleviate availability concerns

Functioning kidneys “just work”. How close can you get to that gold standard?

- Reduce or eliminate the need for skilled use/training for therapy success
- Reduce or eliminate the opportunity to be injured or killed receiving therapy
- Reduce or eliminate supporting medications from therapy (e.g. heparin, anti-rejection/immunosuppressant medications, etc.)

Therapy options which do not require skilled or trained users:

- Reduce or eliminate the need for skilled use/training for effective therapy
- Reduce or eliminate the opportunity to be injured or killed receiving therapy

DESIGN PRINCIPLES:

I'm a person, don't make my life revolve around being a patient.

METRICS:

Patients spend a large amount of time being forced to “live” in their illness. Change the ratio by reducing or eliminating:

- The amount of time spent in clinical spaces (dialysis centers, clinician visits, personal spaces filled with medical equipment, out patient surgeries)
- The dedicated time spent receiving therapy
- The amount of medications required to treat kidney disease or manage side effects
- The frequency of therapy sessions or the amount of time spent experiencing clinical or therapy focused moment moments

Ability to perceive their current therapy in their lives:

- Reduce the amount of side effects that limit patient activities
- Reduce the amount of restrictions in the patient’s life (dietary, activity, etc.)
- Reduce the number of decisions patients need to make that relate to their therapy
- Increase the patient’s ability to act spontaneously

Increase therapy options that focus on quality of life and not just survival:

- Has the patient been able to return to pre-illness daily life activities?

Reduce/remove physical presence of kidney failure on a patient’s body:

- Could a patient be confident facing a romantic partner for the first time without worrying about their appearance?
- Are the effects of illness & therapy visible to children or family members?

Reduce/remove visible artifacts of their current therapy in their lives:

- The need to damage the patient’s body for therapy access (e.g. rerouting vascular structures, access site scarring)
- Physical ports entering the body
- Devices placed in the home environment

Managing my kidney disease shouldn't require an advanced degree

Functioning kidneys “just work”. How close can you get to that gold standard?

- Reduce or eliminate supporting medications from therapy (e.g. heparin, anti-rejection/immunosuppressant medications, etc.)
- Reduce or eliminate any interaction with medical equipment. People don't have “kidney time” like patients have “treatment time”

Therapy options which do not require skilled or trained users:

- Reduce or eliminate the need for skilled use/training for therapy success
- Reduce or eliminate the opportunity to be injured or killed receiving therapy

Conclusion

We hope this toolkit inspires you to answer the call for innovation from people with failure. We are invested in supporting your efforts to address their needs.

We believe this draft toolkit can inspire you to identify and meet the needs of specific groups of people with kidney failure and develop technology to solve their problems. Identifying and prioritizing peoples' problems before designing solutions that work for those people in their context is the process at the core of human centered design.

As you take your next steps towards innovation, please reflect on the three following ways the toolkit can help you start by:

- Providing language, in the form of design principles, to describe how a product can meet the needs of people with kidney failure.
- Offering a way to avoid the false dichotomy between survival and quality of life needs by acknowledging the importance of both along a spectrum from incremental to transformational.
- Providing a basis for you to evaluate when a product, requirement, or specification is good enough by comparing it to the emotional outcome captured in a design principle, measured in by a metric, and linked back to the context captured in a patient story.

Embrace the process and prioritize the aspirations faced by a person with kidney failure. They will lead you to market disrupting solutions that bring us ever closer to restoring the whole person.

How will your product change Marianna's, Luke's, or Anthony's story?



Contact Information

khi@asn-online.org
www.kidneyhealthinitiative.org

