The Kidney Project

FAQ

Frequently asked questions sourced from and designed for patients living with end stage renal disease (ESRD) answered by Dr. Shuvo Roy and Dr. William Fissell.

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The Basics

Will this device be a replacement for transplantation or will there be risks equivalent to immunosuppression?
At least at first, the bioartificial kidney will not provide all the functions of a real kidney, such as blood pressure regulation through the renin-angiotensin system, or erythropoietin production. For now, transplant remains the best treatment available for end-stage renal disease.

Has this device been proven to work yet by implanting it into a test subject?
We have done some testing of our device components in animals for short periods of time. For the next phase of work, we will build large-scale prototypes for longer testing.

Is there a demonstration of how this device works?
We have a video that shows how the bioartificial kidney functions on our website: http://kidney.ucsf.edu.

Are there other groups working on artificial kidneys as well?
A few groups are working on next-generation renal replacement devices, including wearable and portable dialysis machines. There are some efforts on “growing” kidneys, but these are still in the early concept stage. To our knowledge, we are the only group working on an implantable device that will provide kidney replacement beyond dialysis.

What challenges are you working on?
We are currently working to build more prototypes for testing and for evaluating their performance. It is an ongoing process, but necessary to ensure we arrive at a functional device that will be safe for patients.

The Specifics

How long are the cells able to last in the bioreactor before they need to be replaced?
We know a fair amount about cell lifetime from our colleague, David Humes, and pioneering work on the Renal Assist Device (RAD), where cells survived for many months in cell culture without loss of function. In our work, we are targeting years of life before replacement.

Would it be possible to use the bioreactor for Chronic Kidney Disease (CKD) and dialysis patients to slow the progression to End-Stage Renal Disease (ESRD)?
We would love to be able to prevent progression, but we don't see a clear path to using the bioreactor alone for that purpose. Unfortunately, there is very little evidence that starting treatment with dialysis earlier does anything to preserve renal function.

Will this device be a solution for recurrent disease processes, specifically Focal Segmental Glomerulosclerosis (FSGS)?
We hope that we can provide a good treatment option for patients with FSGS or Membranoproliferative Glomerulonephritis (MPGN) who sometimes struggle with transplant. Our big goal is a better therapy for everyone.

Will the device address the anemia and hyperparathyroidism that accompany renal failure?
We do not anticipate any effect on anemia. We expect that the bioreactor will generate vitamin D and the entire device should have excellent phosphate removal, both of which will help with secondary hyperparathyroidism.

The Funding

How do you plan to market the bioartificial kidney?
To ensure that the bioartificial kidney is available to all patients, we will need to partner with industry leaders experienced in medical device production and distribution. From there, we expect that the process will be similar to other medical devices already on the market.

Will insurance carriers pay for the bioartificial kidney?
In the US, Medicare covers the cost of ESRD treatment. After our device passes clinical trials, we anticipate that Medicare will cover the bioartificial kidney as well, and private insurers will follow suit.

Is it difficult and cost prohibitive to produce the artificial kidney on a large scale?
We are using established manufacturing techniques for the production of our device components. Therefore, we expect that the device will be cost-effective; while it is hard to put a price on the device prospectively, it will likely be similar in cost to other long-term medical implants.

How long do clinical trials usually take before Medicare will approve the treatment?
We do not have a concrete timeline at this point, but The Kidney Project was one of three programs chosen by the FDA for inclusion in their Innovation Pathways program, which aims to reduce time and cost of bringing safe and effective, breakthrough technologies to patients. We are optimistic that by working with the FDA now, we can facilitate a quicker and more efficient approval process after clinical trials.

What are the guidelines to becoming a candidate?
We hope that there will be no special barriers to candidacy. The limits on transplant today are (1) supply of organs, which we address by manufacturing the artificial kidney, (2) risk of immunosuppression (cancer, infection), which we address by isolating cells within the bioreactor from the body, and then finally (3) risk of surgery itself, which we address in the same way we address risk of any surgery for a kidney patient.

Is there advice for potential recipients in terms of a "clinical pathway" or other protocol to be followed now in order to be considered later?
It's very early to say, but we imagine that once approved the process will work in the same way the transplant process works now: patients will be referred by their nephrologist to a specialty center where they will undergo operative risk stratification to determine that surgery is medically safe. Once cleared, the patient will undergo a short operation to implant the device followed by some post-operation monitoring. At that point, the patient goes back to their original nephrologist for all their care.

What medications would be required after transplant of the device?
This is not a transplant, it is a medical device, and as such, we do not expect any immunosuppression. The cells in the bioreactor are protected from the patient's immune system by the device itself. However, we do not expect as much function as a native kidney or transplant, so some blood pressure medicines, erythropoiesis stimulating agents, and some phosphate binders might be needed.

Will the device require maintenance or need to be replaced after a certain length of time?
While the device is designed to be a permanent implant, it is possible that certain components will need to be replaced. The internal components could be exchanged (filter) or refreshed (cells) via minimally invasive surgical techniques if such a situation arises depending on individual patient needs.

Getting Involved

Will there be routine updates regarding the progress of the project?
Our Facebook page is a great place to stay informed about our progress: http://facebook.com/ArtificialKidney. In addition, we keep an archive of news stories on our site: http://kidney.ucsf.edu

Is there a way to help get the artificial kidney closer to reality?
There are two main ways: firstly, raising awareness by sharing our website and Facebook page, publicizing our efforts in the press, and reaching out to interested people or communities. Secondly, by directly helping with funding either through organized fundraisers in your community or direct donations to the project. You can donate on our website: kidney.ucsf.edu.

How will the first group of people for clinical trials in 2017 be selected?
For the first studies, we are focused on safety. Need will likely not play a large role in selection. While we do not have an official “clinical trial candidate list,” we are keeping track of all interested parties. Please send an email to sara.getz@ucsf.edu.