# Accelerated placement of hard-to-place kidneys: Answers to frequently asked questions from kidney transplant candidates and caregivers

# Protocol 1: Pre cross clamp placement of KDPI 75-100 Kidneys

#### What is a "rescue pathway" protocol? Is this a permanent policy change?

A rescue pathway is a test approach meant to get more organs accepted and transplanted that might otherwise go unused. It involves some change to the normal sequence of organ placement, and it is meant to get organ offers more quickly to transplant programs and patients willing to accept them.

Rescue pathway protocols are not a permanent change to OPTN policy in how organs are allocated and matched with transplant patients. They are short-term trials to study whether new placement methods get more people transplanted successfully, with organs that are less likely to be used in the current allocation system.

### What protocol is being tested first, and how will it work?

The first protocol will study the benefit of speeding up the placement process for kidneys that are harder on average to match with candidates based on the Kidney Donor Profile Index (KDPI) scale. (To learn more about KDPI and how it is used, <u>watch this video</u>.) It will focus on kidneys with a KDPI value of 75% to 100%.

Kidneys with a high KDPI percentage score may function very well if transplanted, but they are not expected to function quite as long as kidneys with a lower KDPI score. These organs can help many people, especially those who are likely not to do well on long-term dialysis and may do better with a timely transplant. Yet kidneys with a KDPI of 70% or greater are the least likely to be accepted and used.

The goal of the trial is to see whether more high-KDPI kidneys can be successfully used if they are offered early in the organ placement process. Early placement should mean they spend less time being preserved and transported for a transplant, and thus they are more likely to work well.

This early placement will only be offered to patients listed at a hospital taking place in the trial, and only for those transplant candidates who have consented in advance to be considered for high-KDPI kidney offers.



#### Who is developing and testing these ideas?

The OPTN Expeditious Task Force is creating protocols with input from organ donation and transplant professionals as well as patient and donor family representatives. The OPTN Executive Committee must review and approve any proposed trial.

The Task Force aims to have multiple, short-term trial protocols in testing and study at the same time. If a protocol shows promising results, it may be considered for a permanent policy change. If it does not show better results, it will be ended and not pursued further.

#### Will high-priority kidney transplant candidates be bypassed for offers in the trial?

No. OPTN kidney allocation policy gives immediate priority to a few different groups of candidates, including people who:

- have lost the ability to have dialysis
- have a very highly sensitized immune system
- have been a prior living organ donor
- are younger than age 18 at the time of the match

Under the trial, kidney offers will always be made first to people who meet one or more of those requirements. After that, if the kidney has a KDPI value of 75% or higher, it could then be offered for candidates who are listed at a transplant program taking part in a trial **and** who have consented to getting offers from high-KDPI donors. These matches may happen earlier in the kidney placement process than they usually would for these patients.

There will be no change to the placement process for kidneys from any donor with a KDPI less than 75%. In addition, not all organ procurement organizations (OPOs) and transplant programs will take part in the trial. If they are not part of the protocol, they will place high-KDPI kidney offers by the standard sequence in OPTN kidney allocation policy.

## How long will the trial last? What if it doesn't work as planned?

The trial period is planned to run at least 60 days. It could be extended if either:

- not enough organs have been placed to see the effect, or
- the results are promising enough that a longer time could help more patients

The OPTN will carefully study the results of the trial. It may stop the trial early and not pursue it further if early results show that it is harming transplant access for key groups of people based on things such as their age, their race or ethnicity, or other medical factors that make them hard to match for a kidney.



#### How much could this change my chance to get a kidney transplant offer?

This should not change any person's overall kidney transplant access in a major way. This trial will only be done in select areas of the country, and only for kidneys with a KDPI of 75% or higher. Given that many of these kidneys are not used for transplant, any increase in their use should mean more transplants for more people overall. There will be no change to the sequence of offers to the highest priority kidney candidates, and no change to the offer process for any kidneys with a KDPI less than 75%.

If you and your transplant program have agreed to consider accepting a high-KDPI kidney, and if your program is one of the trial participants, your program may get the kidney offer earlier in the placement process than they might through the standard OPTN policy. This could mean they can transplant the kidney with less preservation and travel time, and that may increase the likelihood of a successful transplant.

#### Who should I contact if I have more questions?

Your transplant team will have the most complete information about your health and about your treatment options. They can let you know if their program is part of the protocol. They can also discuss with you whether you are already listed to be considered for a higher-KDPI kidney. If you are not, they can discuss whether that may be an option for you.

In addition, the OPTN Patient Services information line can address many questions about the OPTN and the transplant process. You can reach them by phone at (888) 894-6361 or by e-mail at <a href="mailto:patientservices@unos.org">patientservices@unos.org</a>.

