Trillium Gift of Life Network

Frequently Asked Questions for Healthcare Providers

Toolkit to Assist Transplant Programs in the Use of Increased Risk Donors for Organ Transplantation

What is the Increased Risk Donors Toolkit?

The *Toolkit to Assist Transplant Programs in the Use of Increased Risk Donors for Organ Transplantation* (IRD Toolkit) was first distributed to transplant programs in February 2016 to provide guidance on the utilization of Increased Risk Donor (IRD) organs for transplantation. The Trillium Gift of Life Network (TGLN), in consultation with transplant programs, created the IRD Toolkit based on a framework developed by the Canadian Society of Transplantation and the Canadian National Transplant Research Program.

What has been updated in the IRD Toolkit?

New advancements in treatment for Hepatitis C Virus (HCV) provide the transplant community with opportunities to increase the utilization of organs from HCV Antibody (Ab) positive and HCV Nucleic Acid Testing (NAT) positive donors. The toolkit has been revised to include: guidance on the management of HCV NAT positive or HCV Ab positive organs, new risk profile tables and recommended follow-up testing protocols, a HCV Donor Algorithm for physician decision-making, and materials for transplant programs that will assist in facilitating discussions with patients regarding HCV NAT positive donor organs. The IRD Toolkit has also been updated to reflect current Canadian Standards Association (CSA) standards in the identification and testing of increased risk donors (IRDs).

What is an Increased Risk Donor?

IRDs are donors who may or may not test positive for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and HCV and/or identify certain lifestyle behaviours that are of higher risk who may transmit infectious diseases to transplant recipients. Donors who test negative for HIV, HBV, and HIV are still at risk for transmitting HIV, HCV, or HBV to recipients, due to a window period of time where infection is not detectable. A donor is identified as IRD based on the *Factors and behaviours associated with higher risk of HIV, HBV, and HCV*, (see Table 1 of section 2.3 of the IRD Toolkit as identified by CSA).

Is an Increased Risk Donor the same as an Exceptional Distribution Donor?

IRDs are a subset of Exceptional Distribution Donors. Exceptional distribution is a process for distributing organs from donors who are at risk of transmitting disease to a recipient. Use of organs under exceptional distribution is permitted if another organ is not immediately available and the accepting transplant physician authorizes use of the organ based on their clinical judgment. It is a transplant program responsibility to communicate the risk or any potential risk to the recipient so they can make an informed decision about whether to consent.

How do I know if my patient is being offered an organ from an Increased Risk Donor?

When an organ from an IRD is offered to a transplant program, it will be offered under exceptional distribution and the program will be notified of the reasons why exceptional distribution has been applied. This will include, if applicable, any positive serology and/or NAT testing results and any factors and behaviours associated with an increased risk for transmission of HIV, HBV and HCV.

What is Nucleic Acid Testing (NAT)?

Nucleic Acid Testing (NAT) is a molecular technique used to detect a virus or a bacterium. It detects viruses earlier than other screening methods; thus, narrowing the detection window period.

What is the risk of receiving an IRD organ and what do I tell patients?

Physicians should consider the following factors when identifying potential candidates for organ transplant from an IRD:

1. Estimated time the patient may be on the wait list if he/she waits until the next offer.
2. Estimated wait-list mortality if he/she waits until the next offer.
3. Risk of becoming too sick that a transplant may not be possible.

The appendices in the toolkit include scripts, patient FAQs, and informed consent forms that can be used to tell a patient about the risk of receiving an IRD organ, a HCV NAT positive organ, or a HCV Ab positive organ, NAT negative organ with unknown history or recent treatment of HCV.

In general, the patient should be informed of the risks and statistics pertaining to the donor specific high risk behaviours identified. It is not necessary to name the behaviour, only the risk. This information can be obtained from Table 2 and Table 3 under section 3.2 of the IRD Toolkit. If the donor has tested HCV antibody positive, NAT negative, and all history is unknown or there are no high risk behaviours, read out the highest risk rate which is IV Drug Use (liver patients are exceptions, who may be a higher risk).

Please note that the transplant physician makes the ultimate decision on whether it is in the best interest of the patient to be considered for an IRD organ. Information on the use of organs from IRDs should be provided to potential recipients at the time of listing and again at the time of offer.

Do I have to use the script or forms that are provided in the IRD Toolkit?

The scripts and forms included in the toolkit were developed as templates to guide healthcare professionals with providing ethical and accurate information to patients. Please refer to section 4.3 of the IRD Toolkit on how to adapt these forms in your organization.

What happens after a patient receives an IRD organ?

It is a transplant program responsibility to test recipients after their transplant surgery, provide them with the appropriate follow-up treatments, and monitor these recipients. The following post-transplant testing schedules are **recommended**.

1) Post-Transplant Testing for Recipients Who Receive IRD Organs

Post-Transplant Test	Timing of Test
• HIV NAT, HIV Serology • HCV NAT, HCV Serology • Anti-HBc, HBsAg (± HBV NAT)	• At 1 month and at 3 months post-transplant
• Anti-HBs, Anti-HBc, and HBsAg	• At 12 months post-transplant

2) Post-Transplant Testing for Recipients who receive HCV NAT +ve and HCV Ab +ve Donor Organs

Post-Transplant Test	Timing of Test
• HCV NAT	• At 2 Weeks • At 6 weeks
• HIV NAT • Anti-HBc, HBsAg (± HBV NAT)	• At 1 month and at 3 months post-transplant
• Anti-HBs, Anti-HBc, and HBsAg	• At 12 months post-transplant