

When it comes to the time of transplant, you **may** be offered an organ from a deceased donor that has certain types of increased medical risk (Called “Exceptional Distribution”). **There is always some risk with every donor.**

The increased risk does not affect how well the organ works. It may include a risk of transmitting cancer or infection. You need to balance the slightly increased risk of accepting this organ with the likely benefits of being transplanted at this time instead of waiting for another organ. We encourage you to read the information in this handout and consider whether you would be willing to accept an organ like this.

A transplant physician at your hospital will carefully review the information about an Exceptional Distribution donor before recommending that you accept that donor.

They will only recommend an Exceptional Distribution Donor if the potential benefits of accepting the organ outweigh the risks.

If you decide to accept an Exceptional Distribution Donor, your doctor will discuss with you what, if any, additional testing you may need after transplant. If you get an infection, treatments are available and will be provided.

Everyone has a different level of how much risk they are willing to accept for themselves. The decision to accept an Exceptional Distribution organ is yours. If you decide NOT to accept the organ, you will not lose your place on the waiting list.

Some Exceptional Distribution Donors have specific increased infectious disease risks. This is discussed in detail on the next two pages.

You do not need to make a decision now; we will always discuss this again with you at the time of transplant, if this is the type of donor you are being offered.

WHAT IS AN EXCEPTIONAL DISTRIBUTION DONOR (EXD) ORGAN?

This is a donor organ that is otherwise suitable for transplantation but where it may carry an increased risk of certain infections or cancer compared to a typical donor. Your doctor will discuss the specific risks with you at the time of a transplant offer including the follow-up testing that might be needed.

Some types of Exceptional Distribution Donors have a **specific increased risk for Hepatitis C, Hepatitis B, or HIV.** These are called Increased Risk Donors (IRD); information about these donors is provided below.

WHAT IS AN INCREASED RISK DONOR ORGAN?

This is an organ from a donor who identifies certain lifestyle behaviours that are of higher risk of transmitting infectious diseases to transplant recipients. **These donors test NEGATIVE for infections at the time of donation**, but they may still be a small risk for spreading Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), and Hepatitis B Virus (HBV) to transplant recipients. This is due to a window period where the infection(s) cannot be detected from the blood tests. Organs are considered an increased risk if the donor has identified the following behaviours:

- persons who have injected non-medical drugs into the blood, muscles, or under the skin in the last 5 years;
- persons who have used intranasal cocaine in the last 6 months
- men who have had sex with another man in the last 12 months;
- persons who have had sex in exchange for money or drugs in the last 5 years;
- persons who have had sex with any persons described above or with a person who has or may have HIV, HBV, or HCV infection in the last 12 months;
- persons who have been in contact with the blood and/or bodily fluids of a person who has or may have HIV, HBV, and/ or HCV in the last 12 months;
- persons who have been in prison, lock-up, jail, juvenile detention for greater than 72 hours in the last 12 months;
- persons with a tattoo or piercing where sterile procedures were not used in the last 12 months; and,
- persons who have had close contact with another person having clinically active viral hepatitis (e.g., living in the same house where kitchen and bathroom are shared) in the last 12 months.

You will be informed if you are being offered an increased risk organ by your doctors at the time the organ is offered.

WHAT IS THE DIFFERENCE BETWEEN AN ORGAN FROM AN INCREASED RISK DONOR AND ONE FROM A STANDARD DONOR?

The increased risk from the donor does not affect how well the organ will work. It means that the donor engaged in activities before their death that increase the chances of having an infection. All donors are screened for infectious diseases. This includes testing for HIV, Hepatitis B, and Hepatitis C. Even with negative test results, there is still a very small chance that an organ from an increased risk donor has an infection such as HIV or Hepatitis. There are treatments available for these diseases but they are not curable. On average, increased risk donors tend to be of younger age with better organ function.

WHY WOULD I THINK ABOUT ACCEPTING AN ORGAN FROM AN INCREASED RISK DONOR?

Deciding to accept an organ from an IRD may increase your chance of getting a transplant.

These are the facts:

There is a constant shortage of organs and tissues that can be used for transplant.

There are nearly 1,500 Ontarians waiting to get life-saving organ transplants.

Every three days, someone dies while waiting for an organ transplant.

The waiting times for organ transplants can be up to several years depending on the organ.

You will only be offered an increased risk organ if a transplant doctor at your hospital feels that the benefits of transplanting you with the organ are greater than the risks. Otherwise the organ will not be offered to you. A transplant doctor will speak to you about the risks and benefits of accepting the increased risk organ versus waiting for another organ.

HOW WILL I KNOW IF I DEVELOP AN INFECTION?

If you decide to accept the organ, you will be monitored after your transplant to be sure that you did not get an infection. In the unlikely case that you do get an infection, treatments are available. The infectious disease doctors will treat you, if needed.

WHO DECIDES IF I SHOULD RECEIVE AN INCREASED RISK DONOR?

The decision to accept the increased risk organ is YOURS. The right choice for you depends on the state of your health. You need to talk about this with your medical team and all your doctors. The best answer for you may change if the state of your health changes.

If you have questions about organs from IRDs, talk with a member of your healthcare team while you are waiting for your transplant. If you are offered an organ from an increased risk donor, it will be helpful to have already thought about this information.

IF I DO NOT AGREE TO ACCEPT AN INCREASED RISK ORGAN, WILL IT HURT MY CHANCES OF GETTING A STANDARD ORGAN?

No. Everyone has a different level of how much risk they are willing to accept for themselves. The decision to accept the organ is yours. If you decide NOT to accept the organ, you will NOT lose your place on the waiting list.

INFORMATION ABOUT HEPATITIS C POSITIVE ORGANS

Organs from these donors have a 100% chance of transmitting hepatitis C, for which treatment can be given after transplant with a very high chance of complete cure.

You may be offered a donor organ that is Hepatitis C positive if:

- a) You have hepatitis C ,
- b) You are participating in a clinical trial of transplant of Hepatitis C positive organs, or
- c) Your doctors think the benefit of the transplant in you will outweigh the risks of hepatitis C transmission and treatment.

The use of a hepatitis C positive organ will always be discussed with you before transplant and you have the right to accept or refuse the donor organ. Some frequently asked questions about Hepatitis C positive organs are answered below.

WHAT IS A HEPATITIS C POSITIVE ORGAN?

Hepatitis C is a virus that enters through a person's blood stream and can affect the liver. This is an organ from a donor who has tested negative for Human Immunodeficiency Virus (HIV), and Hepatitis B Virus (HBV) and fits one of the following two profiles:

- A. HCV antibody positive, NAT negative results with recent or unknown history of treatment: The donor is currently on HCV treatment, less than 12 weeks have elapsed since completion of HCV treatment, or HCV treatment history is unknown.
- B. Donor NAT test results are positive for HCV

A patient may be asked to consider an organ from a deceased donor that is HCV NAT positive by either of the above definitions if they fit into one of the following categories:

- 1) HCV NAT positive recipient
- 2) Participant in clinical trials for HCV NAT negative recipients
- 3) Selected cases and special recipient considerations

The risk of transmission from a donor who tested HCV NAT positive is 100%.

WHAT IS THE DIFFERENCE BETWEEN AN HCV POSITIVE ORGAN AND A STANDARD DONOR ORGAN?

An organ that comes from an HCV positive donor does not affect how well the organ will work (however, the risk of transmission may be higher for liver transplant recipients).

The difference is that by receiving an HCV positive organ, a post-transplant treatment protocol will be required. The evidence shows that HCV treatments are effective in 95 to 99% of the HCV population (Feld, et al., 2015; Levitsky, et al., 2017). New therapies called direct acting antivirals (DAAs) are pills that act on the virus itself to get rid of it from the body. The new treatment requires a shorter time (between 8 to 24 weeks), has reduced side effects, and appears to be effective at all stages of the disease.

After your surgery, an infectious disease physician and/or hepatologist (liver doctor) may also be involved in your care and you will require some additional blood work at 1 week, 2 weeks, 6 weeks, 1 month, 3 months, and 1 year to track the Hepatitis C virus in your blood. All other care will be the same.

WHY WOULD I THINK ABOUT ACCEPTING AN HCV POSITIVE DONOR?

Deciding to accept an organ from an HCV positive donor may increase your chance of getting a transplant. These are the facts:

- There is a constant shortage of organs and tissues that can be used for transplant.
- There are nearly 1,500 Ontarians waiting to get life-saving organ transplants.
- Every three days, someone dies while waiting for an organ transplant.
- The waiting times for organ transplants can be up to several years depending on the organ.

You will only be offered the consideration of an HCV positive organ if :

- a) A transplant doctor at your hospital has identified you in one of the three categories of patients listed above,
- b) You have consented, and
- c) Appropriate HCV drugs to treat transmission are available.

There will be no charge to you for the HCV drugs.

Otherwise, the organ will not be offered to you. A transplant doctor will speak to you about the risks and benefits of accepting the HCV positive donor organ versus waiting for another organ.

WHAT ARE THE RISKS OF RECEIVING AN HCV POSITIVE ORGAN AND HOW WILL I KNOW IF I DEVELOP AN INFECTION?

In the case of HCV NAT positive donors, if you decide to accept the organ, there is a 100% chance you will get HCV. The infectious disease doctors in partnership with the transplant physicians will treat you accordingly based on the access to drug coverage and perform regular blood tests.

WHO DECIDES IF I SHOULD ACCEPT AN HCV POSITIVE ORGAN?

The decision to accept the HCV positive organ is YOURS. The right choice for you depends on the state of your health. You need to talk about this with your medical team and all your doctors. The best answer for you may change if the state of your health changes.

If you have questions, talk with a member of your healthcare team while you are waiting for your transplant. If you are offered an HCV positive organ from a donor, it is because you consented to consider this type of organ at the time of listing.

IF I DO NOT AGREE TO ACCEPT AN HCV POSITIVE DONOR ORGAN, WILL IT HURT MY CHANCES OF GETTING A STANDARD ORGAN?

No.

Everyone has a different level of how much risk they are willing to accept for themselves. The decision to accept the organ is YOURS.

If you decide NOT to accept the organ, you will NOT lose your place on the waiting list.

If you decide NOT to accept an organ offer, you have the right to change your mind in the future and accept one at a later date should you choose. The choice will always be offered to you.