

What is hepatitis?

Hepatitis means inflammation of the liver. Non-infectious causes of liver inflammation, such as diabetes and alcoholism, are not transmissible thru organ or tissue donation. Infectious causes of liver inflammation, like bacteria, viruses, parasites and fungi, present a real risk for disease transmission. Hepatitis B (HBV) and hepatitis C (HCV) are examples of liver viruses that that can be transmitted thru organ and tissue donation. They are of particular risk because they can cause chronic liver disease. Other infections, like hepatitis A (HAV), are screened for but are rarely tested for unless there is clinical evidence for possible active infection.

HAV is a mild form of hepatitis compared to other viral infections. It tends to occur in outbreaks and is primarily spread by ingestion of contaminated food or water or by person to person contact. Laboratory testing can be done to determine if someone has a recent or past infection. This is important because while an active infection will preclude organ or tissue donation a past exposure will not. This is because HAV infections usually result in long term immunity but not long term chronic liver infection. Vaccines are currently available.

HBV is easily spread through sexual contact, transmission from mother to her fetus or child, cohabitation with someone with active disease or exposure to contaminated blood and blood products. Most infected adults develop antibodies and usually recover with long term immunity to the virus. However, others will develop a chronic form of liver disease that can lead to fibrosis or scarring of the liver, severe liver failure (cirrhosis) and even liver cancer. Vaccines are currently available.

HCV is also spread through sexual contact, contaminated blood and blood products, and is associated with risk taking behaviors that have the potential for sharing of needles, piercings or inks. This includes intravenous drug use, tattoos and body piercings. HCV is referred to as the “silent disease” or the “silent killer”. Many people do not know that they have the disease until signs or symptoms of chronic liver disease manifest themselves. It is a leading indication for a liver transplant. Though treatment is available there is currently no vaccine available.

Is transmission of hepatitis through an allograft possible?

HBV and HCV are cause for significant concern in organ and tissue transplantation. The U.S. Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB) require screening and testing on every donor using only approved screening test kits. LifeNet Health utilizes CLIA certified laboratories to test blood samples from each donor for these and other viral pathogens.

How does LifeNet Health screen and test for hepatitis viruses?

LifeNet Health screens each potential donor utilizing the Donor Risk Assessment Interview (DRAI) with the Next of Kin. This interview is designed to reveal any medical or social behaviors that would put the potential donor at risk for infection. This rigorous screening combined with highly sensitive laboratory screening tests exceeds the requirements set forth by the FDA and the AATB.

How does LifeNet Health’s Allowash XG[®] process reduce the potential risk of hepatitis transmission?

LifeNet Health’s Allowash XG[®] technology encompasses a comprehensive patented and validated process during which greater than 99% of bone marrow and blood elements are removed from the internal bone matrix. This process, along with subsequent chemical treatment and sterilization steps, has been shown to render tissue sterile to a Sterility Assurance Level (SAL) of 10^{-6} . This means that there is a probability that no more than one allograft per one million allografts processed will contain a live organism. It also inactivates enveloped and non-enveloped viruses, without compromising the biomechanical or biochemical properties of the tissue as needed for its intended surgical application.

Since 1995 millions of bio-implants processed using Allowash Technology have been distributed by LifeNet Health, with no disease transmission.