



NOTES FOR HELPING WITH INFORMED CONSENT FOR IMMUNOGLOBULIN THERAPY

POTENTIAL TRANSMISSION OF INFECTIOUS AGENTS

Immunoglobulin replacement therapy is a life long treatment to replace low antibody levels in the blood. There are many benefits to be gained from this treatment. It replaces the low antibody levels in the blood reducing the risk of frequent infections. It will improve quality of life and in the majority of cases increase energy and ability to lead a normal life (normal to the individual). It is important to remember that immunoglobulin is a blood product derived from antibodies in the plasma. Antibodies found in normal plasma are concerned with fighting infection. Whilst it may not look like a blood product there is still a potential risk of transmission of blood borne infections.

The manufacturers of immunoglobulins take stringent steps to remove and inactivate known viruses; nevertheless there remains the potential for transmitting certain types of viral infection. The virus that most people worry about is HIV (the cause of AIDS). All plasma donations are screened for the presence of HIV. Intravenous immunoglobulin has been used for at least thirty years to treat primary immune deficient patients and to date there have been no reported cases of patients developing HIV from any Immunoglobulin product.

Another group of viruses, which can be transmitted through the blood or plasma, are the hepatitis viruses. Hepatitis is a viral infection, which causes inflammation of the liver. There are a number of different viruses that can cause inflammation of the liver. The three main hepatitis viruses are: **hepatitis A**, which is rarely caused by blood or plasma transfusion. **Hepatitis B** is not now transmitted through immunoglobulin preparations, as we have very reliable tests to detect the presence of hepatitis B in donated plasma.

However a different virus known as **hepatitis C** (previously classified as non-A, non-B hepatitis) has been previously transmitted through immunoglobulins. Most outbreaks were centred around the mid-1980s, before the hepatitis C virus had been properly identified and also before laboratory screening tests had been developed. Unfortunately, despite this, there have been three significant outbreaks and all the products that have transmitted the virus in these outbreaks are no longer available. As a result of this outbreak all manufacturers of immunoglobulin are required to include specific virus inactivation steps during the manufacturing process and all plasma donations are now screened for hepatitis C.

This now means that the available immunoglobulin products are much safer than ever before, however, as a result of past experience we cannot give a guarantee that any immunoglobulin we currently use will not transmit viruses that may cause hepatitis or other viruses not yet known to us.

Nonetheless, all patients receiving immunoglobulins will be screened before receiving this treatment and at regular intervals to ensure that there is no damage to the liver. This is achieved by obtaining blood and measuring chemicals in the blood known as enzymes, which are released into the bloodstream if the liver becomes damaged. If there are signs of damage to the liver due to viruses this may be treated through a course of anti-viral injections and tablets.

It should be emphasised that, although there is a possible risk of developing hepatitis, none of the currently available immunoglobulin products are known to transmit hepatitis.

There is speculation that **mad cow disease**, known as variant and new variant CJD, may be transmitted through immunoglobulins. Although limited, currently available literature suggests that transmission of vCJD is unlikely to occur with immunoglobulin preparations. However, such transmission cannot be completely excluded and we cannot give a categorical assurance that immunoglobulins are completely safe in respect of this until laboratory screening tests for vCJD become available.

If you have any other concerns regarding your treatment please do not hesitate to discuss your concerns with your Consultant Clinical Immunologist or Immunology Nurse Specialist.

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