Who is the leaflet for? What is its aim?

This leaflet is for all patients who receive immunoglobulin therapy by intravenous injection, either to support an immune system that is not effective (immunodeficiency) or to help treat a condition resulting from an overactive immune system. It aims to explain treatment related topics such as 1) what immunoglobulin therapy is and 2) how it affects immune medical conditions. The leaflet also aims to explain how we use patient data to increase patient safety and provide assurances that patients can access appropriate treatment.

About immunoglobulin therapy

Immunoglobulins are naturally occurring blood proteins made in the body and are an important part of the human immune system. Antibodies are made when the immune system comes into contact with foreign substances such as bacteria or viruses. These antibodies are important to kill or neutralise these foreign substances to prevent disease. In rare circumstances, people can develop antibodies to their own cells. This can lead to the immune system attacking body tissues such as nerves, muscles, skin or blood cells and the development of an ‘autoimmune’ condition. ‘Autoimmune’ conditions can manifest in a number different ways which make you feel unwell. If you are recommended immunoglobulins for an ‘autoimmune’ condition, this is termed immunomodulatory – that means that this treatment will modulate the immune system and ease some or all of the symptoms of the condition.

Additionally, some people who develop an infection or recurrent infections may have too little immunoglobulin to effectively fight the infection. Giving immunoglobulin can help the body to overcome or prevent serious infections.

Immunoglobulins can regulate the body’s immune response:
- Where the body makes too little immunoglobulin
- Where the immune system requires help to fight certain types of infection
- Where the immune system becomes overactive and starts to attack the body’s own tissues such as nerves, muscles, blood cells or skin.

Immunoglobulin is usually given as an intravenous infusion where it is called Intravenous Immunoglobulin (IVIg). It is used as a treatment for these conditions by reducing, altering or augmenting the response of the immune system. This in turn helps to limit or prevent longer-term
damage to the organs of the body. It may also be given as an injection under the skin where it is called subcutaneous immunoglobulin (SC Ig).

As immunoglobulins are prepared from human blood donations, demand to treat patients is often greater than the available supply. Care must be taken to ensure treatment is directed to those who derive the greatest benefit and to reduce any potential for waste.

Before your treatment

Treatment with immunoglobulins in the NHS needs to be ratified by a regional panel of experts in immune therapies. This panel is populated by a broad range of clinicians and pharmacists from across each hospital in the region, but is hosted by a specialist hospital. In the East of England, Cambridge University Hospitals is the host of the Immunoglobulin Assessment Panel. Following recommendation for treatment by your clinician, clinical and appropriate personal information (see the ‘Use of Data’ paragraph for more information) is provided to the panel in order to ensure treatment requested is appropriate. The panel may advise on factors such as the dose to be given, tests required to monitor efficacy, duration of therapy and dates for future reviews by panel if there is a continuing need for treatment.

We will need to know if you have been given IV Ig in the past. We may wish to give you the same brand as you have previously had, although this is not always the case. If you are admitted to hospital specifically to receive IV Ig, we may wish to correct dehydration with intravenous fluid before your treatment. If you have an immune deficiency, you may need to take medicines to reduce your risk of reacting to the immunoglobulin treatment. You will be asked if you take any tablets, remedies or use any other types of medication either prescribed by a doctor, bought over the counter in a pharmacy or from an alternative health practitioner. Please bring any repeat prescription forms and medicines packaging with you if we have not already been provided with this information, or if there have been changes to your medicines.

During the treatment

Treatment for an immune disease with IV Ig is usually given based on your body weight and spread over two to five days, although occasionally it is given on a single day. Subsequent doses, if required, may be given in the outpatient clinic or day-case unit. If it is given in hospital, it is most frequently given straight into your blood stream via an intravenous drip of immunoglobulin (IV Ig). It takes a few hours per day of treatment and should not be painful.

Replacement immunoglobulin therapy for immunodeficiency is usually given subcutaneously (under the skin, but not into a vein) under the advice of a specialist immunology service. Usually you will be trained to self-administer this at home.

After the treatment

No other special precautions are necessary after the treatment unless you are advised otherwise.
Who will perform my treatment?

Intravenous immunoglobulin will be administered by a nurse and your response to treatment will be monitored by a doctor with experience with this therapy and the condition requiring treatment.

Intended benefits

To regulate the immune system and alleviate symptoms arising from an atypical immune reaction, or, to prevent damage to one or more of the body organs or limit the duration of an infection.

Alternative procedures or treatments that are available

Often there are no alternative treatments to IVIg, but this depends on the condition to be treated. Alternatives, if available, will not work in the same way as IVIg. Your doctor can speak with you about the possibility of alternative treatments.

Significant, unavoidable or frequently occurring risks of this procedure/treatment

Immunoglobulin is a human blood product and there is therefore a risk of infection. This is eliminated as much as possible by donor screening for Hepatitis B, C and HIV and the manufacturing process which inactivates infective agents. Plasma for making immunoglobulin is sourced from outside the UK to minimise potential risk of CJD (Creutzfeldt-Jacob Disease). However, the potential risk of acquiring infection cannot be completely eliminated.

Rarely blood clots can form in arteries or veins (thrombosis) in patients receiving IVIg. This is a very rare complication and has mainly been reported in patients who have received high doses of IVIg, or, by mistake received immunoglobulin products which are not licensed for intravenous therapy. If you develop any unusual symptoms including chest pain, breathlessness or weakness in any part of your body, pain and swelling of a limb after the procedure contact your own doctor without delay.

Adverse reactions can occur during infusion, such as headaches, shivering, wheezing, back pain, low blood pressure or dizziness. These can be managed by stopping or slowing the infusion or giving appropriate supportive medications.

Precautions

IVIg has not been specifically studied for safety in pregnancy. IVIg will cross the placenta, particularly in the third trimester though clinical experience to date suggests that no harm to the developing or newborn baby is to be expected. The IVIg that crosses the placenta will protect your baby from infectious diseases in first six months of life. IVIg does not transfer into breast milk and does not affect fertility.

If you are at a higher risk of developing a blood clot in light of other medical problems you have, your doctor may recommend giving a medicine to reduce the risk of a blood clot forming.
What will I feel like afterwards?
You should not feel unwell after IVIg therapy

Will I always be able to receive immunoglobulin therapy when I need it?
There have been short-lived global shortages in supply of immunoglobulins in recent years. This is because:
- There are fewer blood donors worldwide
- There are sometimes difficulties in production
- There are an increasing number of conditions that may respond to immunoglobulin therapy

The Department of Health and NHS England have produced national guidelines to help advise doctors and hospitals how patients should be treated when immunoglobulin supply is low. These guidelines give priority to treatment of conditions that are life-threatening without treatment with immunoglobulin, or where there is a serious risk of lasting harm.

For other medical conditions there may be alternative treatments available. For such patients, immunoglobulin may not be used at times of shortage, so that IVIg can be reserved for those patients where no alternative is available

Use of data – demographic and other patient data used by the regional panel and recorded on the national immunoglobulin database.

A national database for immunoglobulin treatment is maintained by NHS hospitals. The purpose of this database is to demonstrate efficacy of treatment so that immunoglobulin treatment is available on the NHS for current and future patients, and secondly to track batch numbers of immunoglobulins given. As there is a small risk of a blood infection, if a potential case of infection resulting from immunoglobulin use is identified, the national database would be used to identify all other patients who have been exposed to a potentially contaminated batch of product.

Patients who are believed to be at risk following the identification of a potentially contaminated batch of immunoglobulin may be contacted, as may the registered GP of that patient, the treating consultant and representatives of the Immunoglobulin Assessment Panel. Anonymised data may also be shared with the Medicines and Healthcare Products Regulatory Agency (MHRA), with NHS England, with the manufacturer of the affected product and with the European Medicines Agency (EMA).

Access to the national immunoglobulin database is restricted to the hospital which enters the data, the local Sub-Regional Immunoglobulin Assessment Panel who is responsible for immunoglobulin use within the healthcare region for the hospital and the host / designer of the software that supports the database. The company that designed and maintains the software is called MDSAS. MDSAS holds a contract with the Department of Health and includes data protection requirements. All hospitals in the East of England have signed a legal 'data sharing agreement' which has been ratified by the Caldicott Guardians within each hospital.
The patient-related data reported to the national database are as follows:

**Demographic data:**
- Hospital number and NHS number
- Date of birth
- Gender
- Height and weight (including changes in weight)
- Registered GP
- The diagnosis for which immunoglobulin therapy is required, and any relevant other diagnoses which affect treatment.
- Other treatments provided which may affect the immune system or treat the diagnosis for which immunoglobulin therapy is required.
- Results from blood tests and clinical assessments
- Care provided by other hospitals – if associated with the use of immunoglobulins

**Other data recorded:**
- Dates associated with treatment given, clinic appointments or communications with the GP.
- Intended dose and brand of immunoglobulin.
- How the immunoglobulin is given – e.g. at home or in hospital, by intravenous drip or subcutaneously.
- Batch numbers from vials of immunoglobulin administered / supplied.
- The name of the treating consultant.
- Details of any adverse reactions to immunoglobulins.
- Immunoglobulin Assessment Panel decisions relating to the immunoglobulin therapy

Although this list is complete at the time of writing, the design of the database is continually being improved and may be subject to change.

All information we hold about you is stored according to the Data Protection Act 1998.

**References/ Sources of evidence**
The Electronic Medicines Compendium (www.medicines.org.uk)

**Information and support**
If you have any questions please ask your specialist nurse or doctor or call the local hospital contact centre.

The East of England Immunoglobulin Assessment Panel may be contacted via: ivig-coordinator@addenbrookes.nhs.uk
If you would like this information in another language or audio, please contact Interpreting services on telephone: 01223 256998, or email: interpreting@addenbrookes.nhs.uk
For Large Print information please contact the patient information team: patient.information@addenbrookes.nhs.uk

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Contact number: 01223 245151
Publish/Review date: 14th Jan 2020
File name: PIL_Immunoglobulin_therapy_data_management_EOEIAP_2019
Version number/Ref: 1.0