People who have thrombosis risk factors (increased risk of clot development) are also at increased risk of developing a clot while on these treatments.

What follow up is required following administration of CFCs?

- A blood sample may be required after the administration of CFCs in hospital, to confirm that the correct response to treatment has been achieved.
- If you are on Home Treatment you are required to track exactly what CFCs you use. This can be captured by scanning (an electronic system to aid tracking of the product) the CFC from your mobile phone or else by filling out the pink sheets manually and returning them to the Data Manager in the NCC at the end of every month.

The reasons we ask for this information are firstly to track product in the case of a recall and secondly to identify your bleeding patterns when you attend for your out patient visit.

It is recommended that all patients with inherited bleeding disorders are tested for HIV, Hepatitis A, B and C. If patients are not immune to Hepatitis A and B they should be offered vaccinations against these agents. The vaccinations for Hepatitis A and B protect most people from infection against Hepatitis A and B.

If you have a bleeding disorder and happen to attend an ED or another hospital for treatment:

-Always show your bleeding disorders card to the treating doctor or nurse.
If you don't have your card with you always identify you have a bleeding disorder to the healthcare professional.

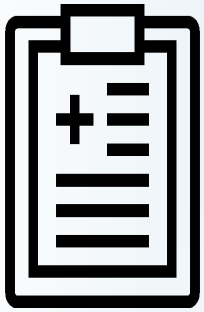
- If possible you or a relative should phone the NCC to inform us of your admission/ treatment in ED or in another hospital.

Contact Details:

National Coagulation Centre (NCC), St James's Hospital, Dublin 8.
-Mon-Fri 08:30 -17:00hrs
Phone: (01) 416 2141
or
-Mon-Fri 08:00 -17:00hrs call (01) 4103000 and ask for the nurse on Bleep # 721.

-**After 17:00hrs , at weekends and bank holidays**
please phone the H&H ward on (01) 4103132.

Clotting Factor Concentrates



Patient Information Leaflet

What are Clotting Factor Concentrates?

The best way to treat an inherited bleeding condition is to replace the missing blood clotting factor so that the persons bleeding will stop more quickly.

Clotting Factor Concentrates (CFCs) are one of these types of treatment . These are made up of individual clotting factors or groups of clotting factors which are freeze dried. The patient then mixes them into a solution and gives it through a vein. They provide convenient high doses of clotting factors for the rapid treatment of bleeds and also for some people in the prevention of bleeds .

Are there different types of Clotting Factors Concentrates (CFCs)?

CFCs are divided into two main types:

- **Recombinant factor concentrates:**

are genetically engineered using minimal or no material from human plasma donors. This product does have a viral inactivation step included as a safety measure in its manufacture.

- **Plasma derived factor concentrates:**

are prepared from plasma which has been collected from many donors. All donors are selected and screened rigorously. The plasma undergoes viral inactivation and is then freeze dried however this does not completely rule out the risk of a patient contracting a viral infection.

Extended half life product is a new treatment feature which keeps the factor concentrate in a persons system for longer . For many people this means that if they receive prophylaxis (prevention of bleed treatment) the frequency of infusions on a weekly basis has reduced. Examples of this are Elocta for Factor VIII deficiency and Alprolix for Factor IX deficiency

Risks associated with CFCs

Infection

Plasma derived factor concentrates for rare bleeding disorders are usually made from human plasma and are treated to eliminate viruses like HIV and Hepatitis B and C however the risk of Parvovirus and Hepatitis A transmission remains, even though very rare. There is also the theoretical risk of contracting Transmissible Spongiform Encephalopathy (TSE) (which is the human form of nvCJD).

Recombinant factor concentrate VIII, IX and VIIa are also available. They are made in the laboratory and not from human plasma, so they carry no risk of infectious disease. Factor concentrates are administered intravenously.

Inhibitors

Some patients with haemophilia develop antibodies as a complication of their condition and treatment. These antibodies to factor VIII or IX are called “inhibitors.”

Inhibitors knock out the effect of the administered clotting factor treatment resulting that the bleeding does not stop.

Inhibitors represent the most significant risk factor for patients requiring treatment with CFCs to stop their bleeding.

The incidence of inhibitors in individuals with factor VIII deficiency is estimated to be as high as 33%, but only 1-6% in patients with Factor IX deficiency.

While inhibitors are more common in those with factor VIII deficiency, they is more clinical significant for those with Factor IX deficiency Factor IX inhibitors increase the risk of people developing anaphylactic reactions to factor IX treatment during or shortly after the infusion. These people can then go on to have a measurable antibody titre to Factor IX concentrate thus complicating their treatment and prophylaxis.

Allergic Reactions

Signs of an allergic reaction include hives, swelling, itching, and tightness of the chest. Pre medication may be required. This is rare but may be life threatening and must always be reported to your treatment centre.

Thrombosis

Thrombosis (abnormal clotting) can occur as a result of treatment with certain clotting factors eg (Novoseven, activated Factor VII or FEIBA, Factor VIII inhibitor bypassing agent) in high doses.