



Haematology Directorate - Gene therapy cabinet in aseptic unit

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Haematology Directorate - Gene therapy cabinet in aseptic unit

S SITUATION

We cannot currently support a gene therapy trial, X due to lack of cabinet available for preparation of the gene therapy infusion. Prof X is very keen to take part in the trial as licenced gene therapies for haemophilia will be upon us soon and it would be beneficial for the department to gain experience in the context of a clinical trial before then. There are also substantial savings in Factor VIII concentrate requirements if patients are successfully treated with this gene therapy.

B BACKGROUND

It is recommended that where possible gene therapy products are handled and prepared in pharmacy departments to minimise the risk of environmental contamination, product microbial contamination and also medication errors, there are 4 levels of containment required for handling gene therapy products. The level of containment depends on the hazard group classification (class) of the gene therapy medicine, as applied by the HSE.

This particular trial vector is Class 2. It needs to be handled in at least containment level 2.

There are a number of licenced and NICE approved gene therapies now available, several planned to be reviewed by NICE in the next few years and many in trials. Having a suitable isolator would mean we could prepare licenced therapies and also support gene therapy trials for other directorates.

A ASSESSMENT

The Principal Pharmacist Aseptics has confirmed that there is a room where a gene therapy isolator could be placed at the current Pharmacy aseptic unit. However a new isolator is required for the room which will be designated for Gene therapies.

R RECOMMENDATION

We have a quote for a suitable isolator for just under £XK. It is recommended that the Directorate/Trust pay for this piece of equipment as each successfully treated patient will realise savings of at least £30K per annum recurrent on factor VIII products and will also enable experience of these products in a trial setting.