Professor Ian M Hann - Response to Penrose Inquiry Dated 5/6/2010

Please note that I regard all my responses to enquires as being in the public domain

I have been asked to respond to three main points and the responses should thus be added to my previous detailed document submission and e mails. Throughout I will do my best to recall these events of the distant past, although I have to admit that my recall is very limited with regard to many of these episodes, other than the general ethos and feelings surrounding those times which were very difficult, fraught and busy for everyone. I would like to express from the outset my heartfelt sympathies for those families who have suffered from the events of the time which inspired me for the next two decades to ensure that such events could never recur ; as I believe now to be the case in relation to most of the bleeding disorders. In this respect, Great Ormond Street (to which I moved as Director in 1987) was the first or one of the first units in the world to offer all children recombinant therapy prophylaxis,which has revolutionized the lives of many families. It is important to understand that paradigm as it was always the motivation of Haemophilia Directors ; we just didn't have the tools at our disposal to achieve such aims until some years later.

My Title, Position, Area of Responsibility and Time Frame

I took up work at Royal Hospital for Sick Children Yorkhill on January 1st 1982 and moved to Great Ormond Street Childrens' Hospital in late 1987.My post was as the sole Cosultant Paediatric Haematologist and Oncolgist. I was Head of the West of Scotland Paediatric Haematology- Oncology - Leukaemia and Bone

Marrow Transplant Centre. I was Consultant in Administrative Charge of the haematology labs and blood transfusion labs and service at Yorkhill and The Queen Mothers' Hospital. I was Director of The West of Scotland Childrens' Comprehensive Care Haemophilia Centre. This was an extremely burdensome role which was partially recognized by the appointment of Dr Gibson within the next year - I believe that my post is now performed by at least 3 consultants.

The points to be addressed are as follows

- **Q :- Systems regarding blood products used –did clinicians decide for each patient and, if so, what types of regimen typically operated for patients? How did patients get their medication and what type of product would they receive? For patients receiving commercial product, how were decisions reached as to which make of product?**
- Answer :- There was indeed an individual approach for patients depending upon the diagnosis and severity.Dr Peter Kernoff (for whom I worked at The Royal Free) had consistently warned during this period of the very high risk of transmission of what was known as non-A non-B hepatitis, from non-virally-inactivated plasma products. We thus avoided them wherever possible, even though at the time we had very little inkling of the extent of the long-term problem which was developing under the surface. Thus for instance we used topical thrombin, tranexamic acid and DDAVP in most instances of bleeding and procedures for patients eg with von Willebrand disorder and 'mild' haemophilia. Thus, dental extractions were to be avoided by excellent dental care and if this failed or there was gum bleeding from deciduous teeth, then tranexamic acid was the next resort, with plasma products being reserved

for multiple extractions or uncontrolled bleeding.

- Within a few days of taking over my post I produced a protocol and guidelines for therapy of bleeding disorders as such documents had not previously existed. I noted that my predecessor had what appeared to be a preference for commercially (as opposed to NHS-produced) products, and I did not express that preference to the best of my knowledge, preferring to assess the products by availability and safety record (eg via reporting to the Haemophilia Directors Organisation UKHCDO which I attended rehularly) so far as one could in those days before testing for anything relevant other than HepB. These protocols were printed and in folders at several locations eg Ward, Day Care, Department etc. Those documents may still exist. Therapy was organized via the excellent Clinical Assistant under my supervisio, and administered aither od Day Care or the Haematology-Oncology Ward.
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- Patients with severe haemophilia were considered for short-term prophylaxis if they had troublesome joints and multiple bleeding episodes. Routine prophylaxis was very controversial in the UK at the time and no Centre was using it routinely. In addition, the resources with regard to supply would not have been anywhere near adequate at the time, and insertion of indwelling catheters was then thought to be associated with unacceptable risk. Thus, all patients received their intravenous therapy through short-term catheters, unless they were admitted for surgery when a longer term 'drip' would be used.
- When it came to the use of commercial product, the plan would always to be to use that which was available and which had a good track record. I cannot remember how payment for such products was actually organized

within the Health Service at the time in Scotland, but that would **not** to the best of my knowledge have been a deciding factor in any treatment decisions

- **Q :- Systems for introduction of new products- who received new product and what happened to stocks of older product ?**
- Answer :- I am not absolutely sure what is meant by this question. To an extent we were supplied by SNBTS on the basis of what we ordered for the needs of regular treatment/prophylaxis/surgery/emergency supplies. Different batches were logged in books which were either kept in blood bank or the Haematology Department, and individual therapies and supplies were detailed in that book by batch number, volume, name, case number and clinical indication. Annual returns on usage of product were made to the UKHCDO and published by category (eg 'commercial' versus NHS) in their annual reports. If supplies were insufficient then product was ordered in ; I think that this usually occurred for specific instances eg synovectomy, compartment syndrome and other major needs. My recollection which could well be wrong is that the supplies were kept in Blood Bank rather than pharmacy - whatever the system, my memory is that it worked well as a supply/storage/stock control/product liability-type chain. As stated above, it is likely that commercial product was used for specific major events or when supply demanded rather than tailoring pooled concentrate product to a patient.
- As a matter of principle, pooled concentrate factor therapy was expensive and in relatively short supply and so good stock control was essential. I think that at that time the shelf-life was relatively long and so it would be rare to return product. To my recollection, if outdating did rarely occur,

or if 'reactions' of any type to any product occurred then we followed a protocol similar to that which had existed for many years with blood transfusion ie we would return the product along with clinical details and details of the reaction to the manufacturer, usually SNBTS. If, as occurred at some later stage with Hep A in Ireland, a Director noticed any pattern of problems then we reported those to the UKHCDO which had its protocols to follow up in these instances via various standing committees.

- **Q :- Systems for dealing with recall of products by SNBTS or by manufacturers?**
- Answer:- *Vide supra*
- Recall of products was not uncommon in this era, as some batches appeared to be more likely to be associated with transmission of non-A-non-B hepatitis or to transfusion infusion reactions than others. As stated, the blood transfusion type of approach would be taken and I certainly do recall that we assiduously followed every single such episode with a return of product. In the case of non-idiosyncratic reactions eg hepatitis, then whole batches would be returned unused. At some stage, and I cannot recall when, the UKHCDO began to collect detail of reactions and episodes of hepatitis. I cannot recall if such episodes were cross-referenced to manufacturers/batches etc or whether they were simply numerical exercises. It would be necessary to look at the UKHCDO records in order to determine those facts.