

# Submission to the Infected Blood Inquiry

The infected blood scandal remains one of the most devastating public health crises in modern history. This submission aims to provide a focus on areas of concern that remain and sit heavily with those impacted . This document is structured to address key aspects of concern offering suggested solutions to those concerns.

## 1.Speed of Delivery of Compensation

There is clearly a need for faster delivery with many different valid calls from the infected and affected community. It is disappointing that it has taken too long to implement a process of consideration for those who may be in or approaching palliative care but the process is right that these people should be prioritised.

As for compensating those in other groups it might well be appropriate to address those who are older first rather than a random selection.

However I believe that there should be a different approach to the affected community. As we know the affected community is much more widespread and can range from the very young to the very old , from the very healthy to the very ill . What we do know is that every affected claim will have to emanate from an infected person , dead or alive. In most cases the affected claims are likely to be primarily an administrative effort . As the government are publicly acknowledging that technology can speed up government work surely this is a prime example of where the technology can be put in place to speed up the administrative process with the appropriate safeguards in place. Assuming an average infected case will spawn maybe 3 to 4 affected cases under the current core route of regulations, a vast number of claims could be considered in an efficient manner and led by applications process rather than a one to one claim manager approach. The choice of application – manual or technology driven could be given to the applicant.

Recommendation;

Prioritise payments to those who may be in their final days or months

Rather than random selection of victims prioritise by age in all cohorts.

Adress affected claimants associated with the infected person in the one process or in a parallel process.

## HCV Tariffs

Individuals infected through tainted blood products have faced severe health challenges, ranging from progressive liver damage and extra hepatic illnesses caused by Hepatitis C. Many have endured years of uncertainty, chronic pain, and the side effects of treatment regimens.

As admitted to by James Quinault in his oral evidence to the inquiry on May 8<sup>th</sup> 2025:

- The tariffs and eligibility prior to June 2023 was 'a decision taken by the Government at the time and ministers '
- The Government decided in 2023 to establish an expert group in October 2023 and the ministers made those appointments and the ministers took the decision not to appoint someone with psychosocial expertise , clinicians who specialise in bleeding disorders or specialists in blood transfusions.
- One single law firm was appointed by the Cabinet office to provide advice. A firm who works predominantly in defending NHS cases and whose paymasters are the government not just for this contract .
- These processes were 'not what the inquiry recommended' and it wouldn't of have been transparent.
- In conclusion we believe that the design of these tariffs have been flawed and in no way recognise the harm done .

### Recommendation:

We believe that a review of the current system should be undertaken with a panel of lawyers , an inclusive group of medical opinions and community members. Essentially what the inquiry recommended but was not followed. This exercise should be independent of IBCA and whilst it is being undertaken IBCA should continue their processes of rolling out under the current compensation framework.

## Widows Pensions

Throughout the inquiry Government officials repeatedly stated that no-one would be worse off as a result of the compensation process. In the case of the spouses/partners of those who are currently infected the 75% of the monthly payments needs to be re-introduced . There is absolutely no justifiable reason for taking this away and most who are receiving 'low' compensation figures are taking the monthly payments it is unfair that these die with the person without leaving spouses/partners with financial security .

Recommendation:

Re-instate the 75% protection of the monthly payments for those infected spouses/partners upon the death of an infected person

## Supplementary Regulations

We were told that the supplementary regulations would be an additional route for those who have suffered above and beyond what the core route covers. It is clear that the Government have used these regulations to save money and only to recognise those who have many severe conditions. When giving evidence ministers and government officials continually refer to core route covering impacts such as fatigue, brain fog etc.

I refer to the impacts of the treatment regimens that many undertook and the report that the expert group on Hepatitis produced in 2020 . Partly copied below.

We have never seen any specific criteria that the core route is covering so after listening to the evidence it is clear in my mind that the core route is in place to address the harm done for the very common and common impacts of the treatment. The government have used the regulations that only addresses a small amount of the very rare impacts. No where is there recognition of the rare and uncommon impacts . This needs redressed as the typical impacts of these treatments have been lifelong in many cases.

It is clear that the Jonathon Montgomery expert group have clearly missed the real input of psychosocial experts. In the real world you do not get to see a psychiatrist , you see your GP and psychologists and those impacted by this illness have been totally neglected. Psychologically, victims and their families have grappled with feelings of betrayal, isolation, and grief. For some, the stigma associated with these conditions exacerbated their suffering, leading to strained relationships and diminished quality of life.

The regulations do not address the potential of those who have had careers 'halted' and capped limiting their potential earning powers. Many people tried to keep their life as normal as possible albeit hiding secrets from their employees but frequent time off and illnesses will have meant that their career would not have developed as it would have done had they not been infected.

Individual centres have been highlighted as centres of unethical research. We know that documents have been destroyed, we know that Doctors worked informally and created 'blood clubs'. We have clear evidence that unethical experimentation was going on in Belfast as highlighted in the Belfast presentations when the Chair noted in that 'dare he say it - -treated as guinea pigs'. Some patients also received F8 bottles labelled as for clinical trials only. We also know that data was exchanged continually with Dr Craske and in the 1960S AND 1970S Belfast was not a reference centre but attached to Oxford centre. Irrespective of dates and whether it was experimentation or research in the balance of probabilities Belfast centre was part of a nationwide program of testing of patients unknowingly which is unethical. For the government to dismiss these facts is just another cost saving exercise.

"All patients attending the Centre were aware of the existence of UKHCDO."

Top of the next page:

"They were aware that the secretariat collected and compiled stats on an annual basis relating to their treatment and they realised the procedures were necessary in order to estimate changes in treatment product availability year by year. In those circumstances it was a matter of implied, rather than express, consent."

Now, it may be right that patients had knowledge of UKHCDO. It may be right, I know not one way or another, that patients were aware of UKHCDO's secretariat collecting and compiling statistics.

It doesn't, I think, follow as a matter of logic or inference that patients must be taken to have been aware that named data, in particular sensitive data about matters such as HIV status or the progression of medical conditions, was also being provided to UKHCDO.

Again, we've seen this is not an issue unique to Belfast. It's an issue that's arisen in relation to many centres, probably all of them, and one which UKHCDO itself was attempting to wrestle with at some stage.

154

noted that 25 years ago there was a lot of ignorance and fear associated with HIV and hepatitis and it was felt to be an act of humanity not to use those terms on the death certificate in order to protect the deceased and their relatives. Very often ..."

She doesn't say "always", but:

"Very often this was at the specific request of the patient or their family and was not done in any underhand way"

So that's the evidence from those two clinicians about the approach taken to the completion of death certificates.

Can I then turn relatively briefly to evidence relating to Dr Mayne's involvement in research. She describes in her evidence having undertaken some full-time research in the course of the 1960s and early '70s but she says in her statement once she returned to Northern Ireland and took up her post in the Haemophilia Centre she had little, if any, time or opportunity to carry out meaningful research.

There are examples of Dr Mayne participating in some studies, trials or pieces of research. There are the two papers we've looked at in the Ulster Medical Journal in relation to hepatitis B and patients with HIV. There's some work and publications in relation

156

(39) Pages 153 - 156

INQY1000116\_0039

1 to porcine products. Dr Mayne and I think Dr McNulty  
2 had some involvement in a study in relation to the  
3 purity of NHS Scottish concentrates or at least some  
4 anticipated involvement in that issue.

5 If we have a look at MACK0001300\_002, we can  
6 see Dr Mayne being sent a copy of a protocol for a PUP  
7 study in December 1988 and that appears to be from  
8 other documents in relation to a further Scottish  
9 product said to be purer than Z8. It's not clear what  
10 happened in relation to that study, I should say.

11 Some other handful of examples of Dr Mayne's  
12 involvement OXUH0000451, if we go to the second page  
13 we can see this is a reference to UKHCDO's Factor VIII  
14 inhibitor working party and there is a trial of  
15 Factor VIII versus Autoplex and it says a meeting of  
16 the participants in this trial was held in  
17 February 1982 in London and then a number of  
18 participants are listed including Dr Mayne.

19 If we look further down the page there's  
20 reference to a discussion about a draft clinical  
21 protocol and then the trial comprising a double-blind  
22 random allocation assessment of Factor VIII versus  
23 Autoplex. So that's again one example at least of  
24 anticipated involvement in a trial.

25 If we then look at BHCT0000951, there's some

157

1 whether it's -- I think it is made in life actually.

2 If we look further up the page, first paragraph on  
3 that page, the last four lines, it says:

4 "... he had liver failure related to his  
5 carrier status for Hepatitis B and Hepatitis C ..."

6 So again, that may be an indication which casts  
7 some further light upon what Dr Mayne is elsewhere  
8 saying about the serious or otherwise nature of  
9 hepatitis C at this time.

10 There's a reference -- we can take that down,  
11 thank you -- there's a reference again in one of the  
12 documents to Dr Mayne receiving some modest funding,  
13 £500, for a piece of work on the immune response for  
14 patients with haemophilia. That's from The  
15 Haemophilia Society. It's not known what that work  
16 then entailed.

17 Then if we look at BPLL0005964, this is about  
18 provision of clinical data and not participation in  
19 any specific trial as far as I can tell, but it's an  
20 internal memo, BPL memo, 19 April 1991, and it says:

21 "I attach up-to-date lists of users of products  
22 formerly issued from PFL, mostly without charge on the  
23 understanding that clinical data would be provided."

24 Again, we've seen I think an example of this in  
25 relation to another clinician. There appears to have

159

1 evidence of involvement in a clinical trial, so this  
2 is the Concorde trial, and there's a request there by  
3 the Medical Research Council for information relating  
4 to the patient's death. That's a request in  
5 September 1992. Dr Mayne's response, we should  
6 perhaps go to this for what it may indicate more  
7 generally about her knowledge, is at BHCT0000948.

8 If we go to the second page, we can see in the  
9 first paragraph -- so it's a letter 30 November 1992.  
10 She refers to or she says -- apologises for the delay  
11 in responding to the letter regarding the patient  
12 involved in the Concorde trial. She then gives  
13 a detailed description of his admission to the  
14 haematology unit.

15 If we go over the page or rather back a page,  
16 these letters are in the wrong order, again she gives  
17 further details leading up to the patient's death. If  
18 we just look at the third paragraph it says this:

19 "In summary, severe haemophilia who was  
20 a carrier for Hepatitis B and Hepatitis C who  
21 developed HIV illness ..."

22 And then gives details of that illness.

23 So again we can see in relation to this patient  
24 at least a diagnosis of hepatitis C having apparently  
25 formally been made by -- it's not clear I think

158

1 been some arrangement whereby some products were  
2 provided free of charge to clinicians in return for  
3 the provision of clinical data.

4 Then if we go two pages further on, there's  
5 a list of some 52 clinicians, but bottom of the page  
6 we see there listed Dr Mayne as one of them.

7 I want to move next to a separate topic which  
8 now postdates Dr Mayne's retirement which is in  
9 relation to the vCJD notification exercises. There is  
10 a very detailed account from Dr Anderson in her recent  
11 witness statement which I'll come to in a moment and  
12 it was just one contemporaneous document that I'm  
13 going to invite you to look at now, sir.

14 It's at DHNI0000049\_036, so this is a letter  
15 dated 22 January 2001. It's from Dr Anderson to  
16 a Dr Carson, Medical Director, Royal Group of  
17 Hospitals, and this concerns the first notification  
18 exercise with which Dr Anderson had any involvement,  
19 so the 2001 notification. She provides a useful  
20 summary in this letter:

21 "I am writing to update you on the current  
22 situation at the Northern Ireland Comprehensive Care  
23 Centre. I have now identified six patients who have  
24 been affected with the implicated batch ... this  
25 includes two adults and four children."

160

(40) Pages 157 - 160

INQY1000116\_004



# Interferon and PEG-interferon

PEGylated interferon is a modified form of the drug where a large polyethyleneglycol (PEG) molecule is attached. The advantage of "PEGylation" is that drug levels in the patient stay higher for a longer period, reducing the need for dosing from 3 times/week to weekly, improving efficacy and reducing adverse events. PEG-interferon was approved by the FDA in 2002 and, where interferon is still used, remains the preferred treatment choice. Two versions were widely used – PEG-IFN-2b (trade name PEGIntron) and peginterferon alfa-2a (trade name Pegasys). Despite improvements with PEGylation, the side effects of prolonged interferon use remained a major barrier to many patients completing treatment and for many, knowledge of the adverse events was a deterrent to starting therapy.

There is a long list of contraindications to PEG-interferon including: potential hypersensitivity to the active substance; autoimmune hepatitis; severe liver dysfunction or decompensated cirrhosis of the liver; severe pre-existing cardiac disease, including unstable or uncontrolled cardiac disease in the previous six months; HIV-HCV patients with cirrhosis and a Child-Pugh score  $\geq 6$  (see Q15.11) combination with telbivudine (see above); neonates and young children up to 3 years old; and in paediatric patients; the presence of, or history of severe psychiatric condition, particularly severe depression, suicidal ideation or suicidal attempt.

Given the widespread use of interferon and its associated toxicity, the adverse events are reproduced here in more detail than for other drugs (Table 15.13a) as a common challenge in practice is determining the extent to which symptoms experienced by individuals after cure can be attributed to treatment.

Body system	Very common ( $\geq 1$ in 10)	Common ( $\geq 1/100$ to $< 1/10$ )	Uncommon ( $\geq 1/1,000$ to $< 1/100$ )	Rare	Very rare	Frequency not known
<b>Infections and infestations</b>		Bronchitis, upper respiratory infection, oral candidiasis, herpes simplex, fungal, viral and bacterial infections	Pneumonia, skin infection	Endocarditis, otitis externa		Sepsis
<b>Neoplasms benign and malignant</b>			Hepatic neoplasm			
<b>Blood and lymphatic system disorders</b>		Thrombo-cytopenia, anaemia, lymphadenopathy		Pan-cytopenia	Aplastic anaemia	Pure red cell aplasia
<b>Immune system disorders</b>			Sarcoidosis, thyroiditis	Anaphylaxis, SLE Rheumatoid arthritis	Idiopathic or thrombotic TCP	Liver and renal graft rejection, Vogt-Koyanagi-Harada disease
<b>Endocrine disorders</b>		Hypothyroidism, hyperthyroidism	Diabetes	Diabetic ketoacidosis		
<b>Metabolism and nutrition disorders</b>	Anorexia		Dehydration			
<b>Psychiatric disorders</b>	Depression*, anxiety, insomnia*	Aggression, mood alteration, emotional disorders, nervousness, libido decreased	Suicidal ideation, hallucinations	Suicide, psychotic disorder		Mania, bipolar disorders, homicidal ideation

Body system	Very common (≥1 in 10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥1/1,000 to < 1/100)	Rare	Very rare	Frequency not known
<b>Nervous system disorders</b>	Headache, dizziness*, concentration impaired	Syncope, migraine, memory impairment, weakness, hypoaesthesia, hyperaesthesia, paraesthesia, tremor, taste disturbance, nightmares, somnolence	Peripheral neuropathy	Coma, convulsions, facial palsy		Cerebral ischaemia
<b>Eye disorders</b>		Vision blurred, eye pain, eye inflammation, xerophthalmia	Retinal haemorrhage	Optic neuropathy, papilloedema, retinal vascular disorder, retinopathy, corneal ulcer	Vision loss	Serous retinal detachment
<b>Ear and labyrinth disorders</b>		Vertigo, earache	Hearing loss			
<b>Cardiac disorders</b>		Tachycardia, oedema peripheral, palpitations		Myocardial infarction, congestive heart failure, cardiomyopathy, angina, arrhythmia, atrial fibrillation, pericarditis, SVT		
<b>Vascular disorders</b>		Flushing	Hypertension	Cerebral haemorrhage, vasculitis		Peripheral ischaemia
<b>Respiratory, thoracic and mediastinal disorders</b>	Dyspnoea, cough	Dyspnoea exertional, epistaxis, nasopharyngitis, sinus congestion, nasal congestion, rhinitis, sore throat	Wheezing	Interstitial pneumonitis including fatal outcome, pulmonary embolism		Pulmonary arterial hypertension
<b>Gastrointestinal disorders</b>	Diarrhoea*, nausea*, abdominal pain*	Vomiting, dyspepsia, dysphagia, mouth ulceration, gingival bleeding, glossitis, stomatitis, flatulence, dry mouth	Gastrointestinal bleeding	Peptic ulcer, pancreatitis		Ischaemic colitis, tongue pigmentation
<b>Hepato-biliary disorders</b>			Hepatic dysfunction	Hepatic failure, cholangitis, fatty liver		
<b>Skin and subcutaneous tissue disorders</b>	Alopecia, dermatitis, pruritis, dry skin	Psoriasis, urticaria, eczema, rash, sweating increased, skin disorder, photosensitivity reaction, night sweats			Stevens-Johnson syndrome, toxic epidermal necrolysis, angioedema, erythema multiforme	

## Infected Blood Inquiry

Body system	Very common (≥1 in 10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥1/1,000 to < 1/100)	Rare	Very rare	Frequency not known
Musculoskeletal and connective tissue disorders	Myalgia, arthralgia	Back pain, arthritis, muscle weakness, bone pain, neck pain, musculoskeletal pain, muscle cramps		Myositis		Rhabdo- myolysis
Renal and urinary disorders				Renal insufficiency		
Reproductive system and breast disorders		Impotence				
General disorders and administration site conditions	Pyrexia, rigors*, pain*, asthenia, fatigue, injection site reaction*, irritability*	Chest pain, influenza like illness, malaise, lethargy, hot flushes, thirst				
Investigations		Weight decreased				
Injury, poisoning and procedural complications				Substance overdose		

Table 15.13a Adverse events associated with pegylated interferon (including when used with ribavirin) for HCV treatment. Those marked with \* have been associated with treatment for HBV. Adapted from SPC for Pegasys [www.medicines.org.uk/emc/product/1697/smpc](http://www.medicines.org.uk/emc/product/1697/smpc)

### Ribavirin

Ribavirin is a prodrug, a nucleoside analogue of guanosine. Although its effects on HCV are likely to be, in part, a consequence of inhibiting the HCV viral polymerase enzyme, its mechanisms of action remain the subject of some debate (for example it also appears to induce mutations in the virus which limit the virus' ability to replicate).

The main challenge of using ribavirin therapy, particularly for long periods, is toxicity. Until recent years ribavirin was only used together with interferon for the treatment of hepatitis C and establishing which of the medications was responsible for individual side effects could be challenging. The most common challenge specific to ribavirin is anaemia, resulting from the breakdown of red blood cells (haemolysis). Other very common side effects include neutropaenia (a low level of the white cells-neutrophils), depression, insomnia, headache, dizziness and impaired concentration. There is a long list of common side effects, including thyroid disorders, mood alteration, emotional disorders, anxiety, aggression, memory impairment, visual blurring, vomiting, rash, photosensitivity back pain, impotence and weight loss. The drug is contraindicated in pregnancy due to risk of foetal abnormalities and male partners of women wishing to become pregnant should also avoid the use of ribavirin. It is also contraindicated in those who may have hypersensitivity, women who are breast-feeding, and individuals with severe cardiac disease or haemoglobinopathies (such as sickle cell disease).

In general, ribavirin still has a role in a limited number of patients for treatment, though as other treatments have improved it has begun to fall out of favour.

### Recommendations:

Recognise those that have had to undergo multiple toxic treatments with additional tariffs.

Include conditions listed above in the special Medical conditions that are uncommon, rare and very rare as identified by a broad base of experts .

Recognise and compensate those that have had to receive medical intervention from a GP and/or psychologists over and above those that were impacted in the core route.

Include those with SCM associations in these regulations with an additional tariff.

Enable those whose career earnings were restricted to demonstrate the impact of becoming infected on their potential earnings and recognise as such.

Recognise Belfast as a centre where unethical testing and research took place.

Paul Kirkpatrick

Chair Family and Friends Haemophilia NI