

REPORT FOR MEETING TO REVIEW OUTPUTS ON vCJD AND BLEEDING DISORDER PATIENTS

Batches of vCJD implicated clotting factor

23 batches of implicated products have been identified by BPL(9 of 8Y,4 of 9A, 2 High Purity VIII,4 Replenate,4 Replene) and SNBTS have identified 3 batches(1 of HT Defix,2 of Z8).BPL have provided data about the batches so that we have the quantity released nationally and by centre. That sent to centres has been recorded on the NHD and data is available matching the amounts received by each centre to the amounts recorded on the notification forms following the 2004 notification exercise.

For each implicated batch the TMER implicated donor number is known as is the date of donation and the time from donation to vCJD diagnosis.

Total units of implicated product is 23.2million units and only 12.7million units have been recorded as used on notification forms. Data is available that has allowed the percentage of each batch used to be derived.

It has not been possible to improve the information about product issued through consignees.

The extent and years of patient exposure has been established by collaboration of the staff of the NHD and the HPA(Akram Zaman)

ACTION taken to improve further notifications:

1.Online notification set up.

2.NHD have produced lists of current patients at each centre and provided information for each patient with regard to treatment with UK plasma products 1980-2001 or an implicated batch irrespective of where this batch was given. Centres were also provided with units of implicated batches issued to them and asked to look into any under accounting. It is hoped that this will improve the level of implementation of public health measures as well as leading to further notifications of implicated batch recipients. This was effected with the help of Charles Hay, Chairman of UKHCDO.

BIOPSY and POST MORTEM STUDY

Information on at risk status, receipt of implicated batch and quantity, time from first exposure dose to death, samples tested and findings are now held on the NHD

Considerable time was spent investigating the patient who was PrPsc positive only on splenic samples. Issues arising from these investigations are being addressed.

STILL TO BE COMPLETED

1.Finalising format and implementation of an annual report on mortality associated with complications of treatment.

2. PM held can be recorded on NHD but procedure for review needs to be agreed. This is separate to those on PM study.

3 .Produce a final report.

4. Produce a guidance procedure document on actions when a patient with a bleeding disorder dies .

5. Produce a guidance procedure document in the event that a bleeding disorder patient develops vCJD.

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Batch Number	Brand Name	Timer No	No. of patients treated	Sum of Units used	Average dose per patient (Units)	Units released	% Units accounted for
FHB4116	8Y	124	34	280,710	8,256.18	775,000	36
FHB4189	8Y	454	71	735,725	10,362.32	1,233,500	59
FHB4419	8Y	125	55	656,600	11,938.18	1,022,000	64
FHB4547	8Y	123	61	873,821	14,324.93	902,000	94
FHB4596	8Y	396	93	1,054,410	11,337.74	1,398,500	75
FHC0059	8Y	315	10	58,560	5,856.00	528,720	11
FHC0289	8Y	124	46	266,960	5,803.48	633,500	42
FHC0369	8Y	454	52	199,060	3,828.08	604,500	32
FHC4237	8Y	123	117	982,977	8,401.51	1,268,500	77.4
FJA0020	9A	315	10	88,025	8,802.50	533,500	16
FJA0092	9A	124	18	92,990	5,166.11	511,800	18
FJA4239B	9A	123	9	141,435	15,715.00	251,000	56
FJA4308	9A	454	20	379,540	18,977.00	573,000	66
FHM3900	High Purity F8	454	11	169,055	15,368.64	812,000	20
FHM4054	High Purity F8	454	33	304,500	9,227.27	905,500	33
3502-70210	HT DEFIX	313	26	216,220	8,316.15	230,184	93.9
FHE4437	REPLENATE	454	73	818,095	11,206.78	1,547,000	52
FHE4536	REPLENATE	396	97	1,224,270	12,621.34	2,069,000	59
FHE4548	REPLENATE	123	88	965,400	10,970.45	1,690,000	57
FHF4625	REPLENATE	448	47	1,035,900	22,040.43	2,290,000	45
FJM4327	REPLENINE	454	80	1,139,915	14,248.94	1,607,500	70
FJM4437	REPLENINE	454	29	379,380	13,082.07	832,500	45
FJM4596	REPLENINE	396	49	592,380	12,089.39	838,500	70
FJM4625	REPLENINE	448	4	22,145	5,536.25	875,000	2.5
0304-70510	Z8	313	3	16,150	5,383.33	123,690	13
0301-70320	Z8	313				125,440	0