

6c.

INCIDENT REPORTS

Summary 1986

Plasma

There were 463 units implicated in plasma reports in 1986, making a cumulative total of 1538. Occasionally, one report may cover more than one pack/donation/product, thus the numbers given are for the number of packs/donations/products concerned and not the number of reports.

Of these 463 units, 94 had been fractionated. The increase in the number of units having already been used at the time of reporting (in 1985 only 18 units had been used) is due to the fact that the past donations of donors now Anti-HIV positive have been treated as plasma incidents. These donations could have been given upto six years ago.

The only batches recalled in this year were four Anti-VZ batches that were implicated in a case of a haemonetics donor becoming Anti-HIV positive (ref.W86/11). Currently there are 425 reports still open, but of these, 221 are concerned with plasma that was not screened for Anti-HIV at the RTC. As such untested plasma is not being fractionated at BPL, there has been no opportunity to discard these packs.

Product

There were 35 complaints from users concerning product in this year. Five cases of adverse reactions occurring in patients receiving BPL products were reported : Two HAS 4.5%; one normal immunoglobulin; one Anti-D immunoglobulin and a heat-treated Factor IX.

The largest product problem concerned the quality of overseals on HAS 4.5% (400ml). Numerous users reported that the overseals came away from the bottle when they attempted to remove the flip-off cap (ref.PR86/13). So far there have been complaints from 28 users concerning 30 batches. This report is still open.

There were 15 other complaints about packaging, e.g. 400ml bottles falling out of cartons, ill designed slings for HAS etc.

cc: Dr T J Snape

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PLASMA INFECTION REPORTS

REGION	HBs	GF	AIDS	HIV	HRA	VD	HZ	RB	MP	ML	T/M	SP	RTC	C	S	UF	Doc	NT	NS	DAM	MISC.	TOT
BPL	2	0	0	0	0	0	0	0	0	0	0	0	0	0	29	0	0	6	0	23	5	65
YORKSHIRE	1	1	0	5	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	1	11
TRENT	4	2	0	1	0	2	0	1	0	0	0	4	0	2	0	0	0	0	0	0	5	21
OXFORD	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
EAST ANGLIA	1	0	0	1	0	0	0	0	0	0	3	0	0	1	0	0	0	0	0	0	1	7
W. MIDLANDS	1	0	0	10	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	12
N.E. THAMES	3	1	0	18	0	0	3	4	1	0	3	1	1	0	0	7	1	2	0	0	8	53
MERSEY	1	0	0	2	0	0	0	0	0	1	1	5	0	0	0	0	0	2	0	0	3	16
LANCASHIRE	2	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	11	14
MANCHESTER	3	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7
S. THAMES	1	1	0	6	1	3	3	0	0	1	0	29	0	0	3	3	1	0	0	0	9	61
ARMY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WESSEX	1	0	0	0	0	0	1	0	0	0	0	0	0	2	1	0	0	0	1	0	2	8
S. WESTERN	3	1	0	0	0	1	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	7
LEWISHAM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
WALES	5	3	0	1	1	1	3	0	0	2	0	2	0	2	0	1	0	0	0	0	0	21
NORTHERN	26	1	0	4	8	0	0	0	0	0	0	0	1	0	0	0	0	2	0	0	7	49
N.W. THAMES	11	2	0	8	26	0	1	1	1	1	15	0	0	21	0	1	0	2	13	0	6	109
** Total **	66	12	0	57	40	8	13	5	2	5	22	42	3	29	33	12	3	14	14	23	59	463

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PLASMA INCIDENT SUMMARY

KEY

HBS	Hepatitis.
GF	Glandular Fever.
AIDS	Positive AIDS symptoms (inc. past donations).
HIV	Anti-HIV positive (incl. past donations).
HRA	High risk for AIDS.
VD	Venereal Disease.
HZ	Herpes Zoster.
RB	Rubella.
MP	Mumps.
ML	Measles.
T/M	Tropical Donor - Malaria.
SP	Specific Plasma sent to EPL as Non-Specific.
RTC	RTC request return of pack.
C	Cancer.
S	Failed on sterility test.
UF	Unspecified infection.
Doc	Incorrect documentation.
NT	Not Anti-HIV and/or HBS and/or VDRL tested.
NS	Plasma processed under Non-Sterile conditions at RTC.
DAM	Damaged Packs.
Misc	Misc.

Please refer to current SOP on categories of plasma problems (QCCU23) for fuller explanations of the definitions of each problem.

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