Notes on NBA Virally Inactivated FFP Group: Watford 7-11-97

Present:	L. Williamson (Cambridge	Gael Williams (Cardiff)
	C. Prowse (Edinburgh)	Jim Knipe (Tooting)
	T. Wallington (Bristol)	Terry Male (Leeds)
Apologies:	M. Ashford (Newcastle)	A. Robinson (Watford)
	I. Wilcox	

Points made to Agenda Numbered Headings (Attached)

1. Review of decisions at NBA

- The NBA VI-FFP group has been meeting since May planning for move to Octaplas
- in view of recent SEAC/MSBT concerns on nv CJD it has been decided that NBA will cancel Octaplas contract (A. Robinson has done this verbally and in writing) and proceed on the MB option (no plasma had been sent to Vienna)
- the **attached** draft letter has been prepared for circulation to haematologists
- presumption is that Octapharma will get a licence in due course (?January) and will market Octaplas thereafter (however it is a frozen product and the supply cold chain may be problematic)
- lack of guidelines on VI-FFP has been a concern with Trusts/haematologists
- on nv CJD LW(as SACBC chair) and P. Flanagan (as SACTTI chair) with Brian McClelland prepared the paper (on possible universal leucodepletion as an incremental safety step) for SEAC and MSBT (see SACTTI Newsletter #6 and yesterdays DoH press release).

2. Assessment of Demand

- The attached spreadsheets summarise the results (response rate only 35%) of the NBA questionnaire to haematologists. The last page shows 29.35% as the best estimate of "market" for a pooled VI-FFP (possibly higher for a single unit product)
- provisional estimates for Scotland and Wales are around 20% (~2,000 uFFP in Wales)
- absolute figures for Scotland are 25,000 FFP and 12,500 cryo
- proportion in England, of cryo, is lower:
  In SE Zone 120,000 FFP + 30,000 cryo (latter includes some exports e.g. to Wales)
  ? total cryo use in NBA ~38,000

NBA will plan for 30% of FFP **and 100% of cryoprecipitate.**

3. Clinical Guidelines for VIP

- General consensus that neonates and clotting deficiencies for whom there is not concentrate available are priority groups for VI-FFP
- TTP probably more appropriately given cryosupernatant (or Octaplas)
- coumarin-reversal now recommended to be given PCC
- in line with Prof. Franklin letter to LW, LW will progress these to a draft for agreement with BCSH and BSH (Prof. Burnet) for publication in Transfusion Medicine (?12th December deadline for March issue, or February deadline for June issue - latter seems more likely).

4. Position in SNBTS, NI and Wales

- SNBTS progressing MB option, slightly interrupted by problem with 0.5CPD packs, centred on Edinburgh. Progressing validation based on protocol agreed with LW. Will do "zero time only" validation on NPBI CPD top-and-bottom packs week beginning 17th November. Alongside this making case for funding to Scottish Office (see above for market survey). Two machines in place in Edinburgh
- Wales - Dr Williams agreed will join in with NBA. Baxter have promised 2 machines for Cardiff
- N. Ireland - talking to Baxter independently.

5. Operational Aspects

5A Non-Baxter

- Grifols have franchised Springe technology and may be offering contract processing in Barcelona (TM and A. Slopecki will view 15 / 16 December, when visiting to audit fractionation and blood bag facilities)
- Springe are not offering contract processing, but franchising may be an option (SNBTS have an option on this and CVP report on 1992 site visit available)
- Macopharma are developing bag with MB dry pellet in transfer line that dissolves during plasma transfer of plasma and does not require dark storage. May also be developing a light box. Unclear if bags and boxes will be interchangeable between Macopharma and Baxter systems.

5B Report from Denmark

- Reports from previous visit by NBA group to Aarhas on file
- Jim Knipe and Michell Ashford visited Copenhagen (Dr Sorenson) last week:
  - Copenhagen collect 100,000 donations per year, 15,000 being processed to FFP (not all are to MB as yet)
  - started processing with 10 light boxes 3 or 4 weeks ago

- precool plasma to 20° on cooling boxes to ensure temperature does not rise above 30° on illumination (average 4 or 5° temperature rise) - unclear on reasons for 20° (?4°) lower and 30° upper limits
- hard spin plasma (?4,000 rpm for 15 min) and this type of plasma does not cause blockage of leucocyte filter (see Aarhas report). (Tooting planning to shift to 'dry' rather than 'wet' buffy coat and are assessing T-sol platelet additive solution)
- packs from four local collection centres in Copenhagen arrive throughout the day so phasing of supply during day not problematic and 8 hour limit to frozen final product not seen as a problem (Tooting write donation time on plasma pack)
- leucofiltration under gravity in sets of 10 (one processor) takes 4 or 5 minutes
- after filtration great care taken to remove air prior to illumination, although reasons for this not entirely clear
- do not make pedipacks of plasma and do not vacuum-pack product (?Tooting do)
- current double sided label on flap protects pack (actual pack has no label on faces) and has virus disclaimer on one side and blank base label on other. The latter needs amendment to meet UK base label requirements and Baxter have promised this for December
- in Copenhagen 1 person processes (on 10 machines) 10 packs in first hour and 10 packs per 40 minutes thereafter (5 hours gives 70 packs). Manual recording of processing by writing pack number on list attached to machine and on pack base label
- currently light box is calibrated every ?40 runs by doing run with light meter in place of pack (recorded as J/cm^2 or % of required dose). Also monitor temperature by thermocouple at start/finish on pack surface. Copenhagen have not had a failure but unclear what they would do with packs processed between "pass run" and "fail run" - presumably reject - this needs link between pack and particular machine
- Baxter are developing machine with interlock (to prevent opening during processing) and ability to punch label at start and end of illumination period - ?for December along with UK base label. Also working on management PC that may e.g. not allow processing of pack older than certain time from donation, allow barcode scanning, log processing and allow downloading to "Pulse" (or Progesa)
- Copenhagen probably putting 9 month shelf-life on product. No QA data provided on day, but J Knipe promised this by Sorenson
- labelling of secondary derivatives (cryo, cryosuper, pedipack) discussed in terms of "not in pack which was processed" but agreed this was no different e.g. from e.g. pedipacks of irradiated blood for which systems exist

- also discussed and agreed that if VI-FFP (formally "Fresh frozen plasma (methylene blue treated)") does not meet current red book guidelines, may need separate specification
- while CE certification and no requirement to license MB-FFP established, Terry Male will establish CE position on light box with Baxter
- CVP to ask Baxter to send LW copy of CE submission file or permission to copy her the one he has
- processing centres using this technology will need to amend Specials licence of permissible products to include MB-FFP and dialogue with MCLA or GMP aspects of this
- bags have ? 2 year useable shelf-life
- whenever asked time to availability of planned 16 unit light box from Baxter seems to be 12 months away
- COSTINGS need to include additional LABOUR ELEMENT (? ONE STAFF MEMBER PER SITE INITIALLY).

5C Meeting with Baxter

- TM met up with Dean Pollen and Sarah Thelwall of Baxter and drafted attached evaluation protocol. This is planned as three-phased (i) technical "look-see" (ii) validation (iii) routine (?1 month at estimated 30% of FFP production - ? should products from this be issued). Plan to run this, to include dialogue with MCA on GMP and customers on acceptability (e.g. different bag, green colour), from January in Newcastle and N. London (? also 2 machines in component evaluation unit at Brentwood). Each of these to get 6 machines (with interlock) and 2 light meters (? UK label packs)
- SNBTS should put in place similar programme
- Baxter have commissioned further 50 light boxes (?including 2 promised to Cardiff)
- NBA estimate 30% of FFP will require about 60 boxes (? in all processing sites).

5D IT aspects

- See above, but TM to consider further.

5E Quality aspects

- See above, but TM to consider further.

5F Business aspects

- Provisional marginal planning cost of £25 agreed on roughly current assuming ≤£20 per bag, ≤£2 for SCD wafer, ≤£3 for labour etc., £300 (+ inflation) service charge per light box per year but no capital cost for latter

- joint purchase of SNBTS/NBA/Welsh bag requirement may assist (TM in contact with D. Noonan and M. Tunstall) (TM given quotes received by SNBTS from D. Pollen).

6. Tentative Timetable

- Cryoprecipitate evaluation: Cambridge and Edinburgh: November - December (but 12m for full stability date)
- operational evaluation: Newcastle, London and ?Edinburgh: January - March
- routine availability: ?April 1998
- possible increase use from initial ≤30% thereafter
- modified BCSH guideline publication - ?March or June 1998
- business planning - cost now for commencement in new financial year

7. MB Cryoprecipitate project

- See items 4 and 7. Evaluation commenced in Cambridge and from 17/11/97 in Edinburgh
- Edinburgh may evaluate Erythrosol packs (0.5CPD) once current bag problem sorted (?January 1998)

8. Any other business

- Ideally FFP restocking for MB should coincide with that for PCR testing
- CVP has sent LW draft guidance for clinical uses drafted by Dr A. Todd for comment (attached).

9. Next meeting

Provisional 2pm at BPL on Wednesday 3rd December (CVP to confirm his, or deputy, availability).

Dr CV Prowse
Director, NSL
10 November 1997