JOINT MEETING OF THE STANDING ADVISORY COMMITTEES ON BLOOD COMPONENTS AND TRANSFUSION TRANSMITTED INFECTIONS

WEST END DONOR CENTRE, LONDON
22 NOVEMBER 2000, 10.30 AM

These notes summarise the key issues raised in complex and wide-ranging discussions on a variety of topics. As a result some of the nuances of individual comments may have been lost.

00.1 1.1 **PRESENT**

Dr L Love (Joint Chair)	**LL**	Dr R Eglin	**RE**
Dr L Williamson (Joint Chair)	**LW**	Dr R Warwick	**RW**
Mr M Bruce (Secretary)	**MB**	Dr P Hewitt	**PH**
Dr M Turner	**MT**	Dr R Cardigan	**RC**
Prof D Anstee	**DA**	Dr S Maclennan	**SM**
Dr P Minor	**PMi**	Mr N Beckman	**NB**
Dr J Barbara	**JB**	Dr V James	**VJ**
Dr J Seghatchian	**JS**	Dr K Soldan	**KS**
Prof JP Allain	**PA**	Dr B Dow	**BD**
Mr R Bedford	**RB**	Mr G Geddis	**GG**
Mrs M Ashford	**MA**	Dr D Wenham	**DW**
Dr E Boxall	**EB**	Dr W Murphy	**WM**
Dr J Kurtz	**JK**	Dr G Schild	**GS**
Dr T Snape	**TS**	Mr G Rowe	**GR**
Dr B McClelland	**BMcC**	Prof IM Franklin	**IMF**
Dr T Wallington	**TW**	Dr F Boulton	**FB**
Dr P Mortimer	**PMo**	Mr Carl McDonald	**CMcD**

00.1 1.2 **APOLOGIES**

Apologies were received from:

Prof M Contreras	Dr M McClelland
Mr P Garwood	Dr CV Prowse
Dr H Hambley	Dr A Robinson
Dr C Hodson	Dr R Tedder

00.1 2. **vCJD ISSUES**

00.1 2.1 Liz Love briefly set the aim of the session into context, i.e:

To determine, in the light of recent data concerning transfusion in sheep, whether any further action could/should be taken to improve transfusion safety with regard to vCJD.

00.1 2.2 **MARC TURNER, 10.35 - 11.05 Paper 1a**

MT summarised the current position, ie:

- Phillips Report 27 October 2000, two key features were:
  - take reasonably practicable precautions
  - act with openness and respect for the public
- Reviewed the Lancet sheep BSE transmission article (2000, 356: 999-1000). This represented preliminary data but provided "proof of principle".
- Donor Selection

- reviewed actions taken within UK
- reviewed actions taken/being considered in other countries regarding deferral of UK residents/visitors to the UK

- Donor Screening Assays
  - In development, to be covered by D Anstee (paper App 1b, tabled)

- Blood Component Manipulation Strategies
  - Inactivation
  - Leucodepletion
  - Washing
  - Removal by filtration

- Prophylactic Agents
  - Working with the Institute of Animal Health in Edinburgh regarding the effect of drugs, eg pentosan

00.1 2.3 **DAVE ANSTEE, 11.05 - 11.30 Paper 1b**

2.3.1 DA summarised the position with regard to developing a test for vCJD. This was detailed in paper app 1b, tabled at the meeting. A key question posed by DA was "How will we know when the assay is sensitive enough? Perhaps we shouldn't hold out until we have a highly sensitive assay - maybe we should go with what we have!" Shades of 1st generation anti-HCV here!

2.3.2 DA considered that these "first generation" tests were at a stage where the development of a suitable amplification step could make them useable.

2.3.3 LW asked if we have a transparent pathway to support decision making for the introduction of such an approach.

2.3.4 J Barbara asked for clarity with regard to where responsibility lies for proposing, agreeing, approving and implementing precautionary measures:
- DoH?
- UKBTS and its Chief Executives?
- Professional SACs and JELC?

00.1 2.4 **BRIAN McCLELLAND, 11.35 - 12.05 Paper 1c**

2.4.1 BMcC proposed that there must be a carefully thought out process to support decision making and set out a framework which did this. The key features are set out below.

2.4.2 The characteristics of a decision making process are:
- make good decisions.
- ensure the decisions are defensible in the future, even if history proves them incorrect.
- contribute to improving public health.
- provide a defence for actions taken.

2.4.3 Clarify the Boundaries

- UKBTS - it is our responsibility to:
  - consider <u>all</u> the evidence.
  - carefully consider <u>all</u> options.
  - maintain scrupulous records.
  - use explicit criteria to validate decisions.
  - learn from history, eg HGH CJD transmission enquiry report.
  - do things that make our products safer.

- Clinical Practice

- The UKBTS is not responsible for the standards of clinical practice but is in a position to influence practice to reduce risks, eg to promote increased use of autologous blood.

2.4.4 Illustrative Criteria

Changes that bring maximum benefit; feasibility; consequential risk of the change; effect of action taken on public's attitude; acceptability to clinicians; economic aspects; effect of the action taken on our relationship with the "healthcare industry"; selection of more highly specified donors; use non-UK donors; use alternative production approaches.

Identify groups of patients at greatest risk. (There is an MSBT precedent for this re the provision of more highly specified components for neonatal use). Genetic screening may help identify codon 129 MET homozygotes etc.

2.4.5 V James endorsed the logic of this approach and emphasised that the assembled group had a responsibility to consider measures which would reduce risks across the entire transfusion chain and advise the JELC/ Blood Service Chief Executives accordingly.

2.4.6 LL commented that it would be useful to have a document setting out BMcC's proposed model. BMcC agreed to provide this for circulation. **BMcC**

00.1 2.5 **LORNA WILLIAMSON, 12.05 - 12.25 Paper 2a, b**

2.5.1 LW described the NBS Safer Plasma in Components (SPIC) project.

2.5.2 LW described the risks associated with transfusion of plasma components, ie:

- Residual viral risks
  - HIV - 1 in > 5 million
  - HCV - 1 in 1.6 million post NAT
  - HBV - 1 in 50 k - 200 k
  - new viruses?

- Non-lipid enveloped viruses
  - Hepatitis A and Parvo B19, both rare (J Barbara stated he could recollect 4 HAV cases from single components in his "working lifetime").

- TRALI
  - successive SHOT reports show this to be a serious problem that needs to be addressed.
  - would the use of a pooled component (eg Solvent Detergent treated) help?

- TSE using animal data
  - there is infectivity in plasma
  - infectivity only when animals are symptomatic
  - IV route 5-7 times less infectious than IC

2.5.3 WHY ARE THE NBS FOCUSING ON PLASMA?

- In 1997, MSBT advised the UKBTS that they should make virus inactivated plasma components available.
- SDFFP has been available commercially (from non-UK donors) since 1998.
- MBT FFP, NBS deferred introduction until after Y2k, presently evaluating. SNBTS/NIBTS have introduced and comply with the MSBT position (low demand).

2.5.4 T Snape advised that MSBT have revisited and reaffirmed their decision of 1997 but have not pushed NBS harder to implement because they understood and

accepted the significant "project pressure" under which NBS were operating. (Leucodepletion, NAT etc).

2.5.5 Last February (2000), there was a "special" MSBT meeting which concluded there was a need to undertake a risk assessment (cf the DNV assessment re leucodepletion and plasma import) on the safety of plasma for direct clinical use.

2.5.6 NBS are exploring the demand for MBT FFP and via the SPIC Project have been collecting risk assessment information in anticipation of a request for this from DoH. Despite requests for guidance from LW, DoH had only recently set up a meeting.

2.5.7 LW and SPIC representatives met with DoH last week. They were advised that the DCMO wants to decide on the use of UK FFP at the January MSBT. As a consequence, UK BTS will need to accelerate their information gathering exercise.

2.5.8 LW suggested, and others agreed, this was a working illustration of the lack of clarity on where responsibilities lie, in the blood safety decision making process.

2.5.9 LW advised that DoH will decide whether to move away from UK plasma. The NBS and DoH teams meet again on 27 November 2000.

00.1 2.6 In drawing the "information" system to a close, LL asked for suggestions on what SACTTI should be doing about vCJD and by what process this should be taken forward.

00.1 2.7 **GENERAL DISCUSSION**

2.7.1 *IM Franklin...* Give appropriate, well considered advice, eg he didn't think plasma importation was important because very few patients get plasma only. Most recipients of plasma also receive other components, almost all of which also contain plasma.

2.7.2 *JP Allain.* AFS are considering importation of plasma to France - but cannot source enough on the world market. Availability is a prime consideration.

2.7.3 *T Snape.* The reason that outsourcing FFP is on the DoH agenda is because it is feasible.

2.7.4 *B McClelland.* Counselled caution. Plasma importation for direct clinical use could be a classic case of doing something that achieves nothing. More informed discussion with colleagues in sister organisations might be surprisingly fruitful, eg could the Finnish Red Cross supply red cells for IUT?

2.7.5 *J Kurtz.* Re TRALI. Previously when NBS Birmingham used only male donors for FFP production, did not see cases of TRALI. Following a change in policy, ie plasma for FFP no longer from male donors only, they now see a number of cases.

Re Psoralen, to MT. Does Psoralen have an effect on the vCJD agent? MT, many compounds being examined that have some efficacy in scrapie in cell free systems. Early days!

2.7.6 *P Mortimer.* On at least two occasions at the meeting, had heard speakers say that decisions on further actions would be up to the DoH. However, in PM's view this was wrong. The body of knowledge and experience lay with the UK Blood Services who should not leave difficult decisions to be taken by DoH. UKBTS should take the lead.

2.7.7 *V James* agreed with PM's comments but felt we (UKBTS) should start by discouraging unnecessary transfusions and promoting the use of autologous

transfusion (salvage).

2.7.8 *D Anstee* emphasised the importance of not assuming that the distribution of PRP^{c} in blood is equivalent to the distribution of PRP^{sc} in infectious material. Agreed wholeheartedly with BMcC's approach, eg importation of cellular components for children born since 1996. Feels the public would understand and support this - and satisfied the two key principles in the Phillips Report described by MT.

2.7.9 *T Wallington.* Feels that the DoH are being pressurised by the media to take action on plasma, eg from the media's perspective - we have the "proof of principle" from sheep transmission, other countries are banning donors who visited UK - what are DoH doing about the situation in UK?

2.7.10 *R Bedford.* We have developed a very sophisticated system to demonstrate the safety of UK blood supplies. Agreed we should divert some of that energy to influencing usage. Feels there will be a huge resource requirement to enable us to effectively manage the vCJD problem.

2.7.11 *IM Franklin.* Agrees with potential scale of the vCJD problem and that there is a need for further action - but feels that in considering clinical plasma only at this time the Government is in danger of revisiting the errors made with regard to BSE. "FFP is beef on the bone"! Paul Brown has stated that "we are doing as much as we can" - IMF strongly disagrees.

2.7.12 *K Soldan.* Feels that with regard to testing initiatives, we might use early assays to help elucidate whether currently defined risk factors carry any real risk, ie by testing samples from donors who are being excluded on the grounds of potential CJD risk, eg HGH; brain surgery etc.

2.7.13 *L Williamson* felt we should avoid thinking too conservatively because there is a danger that we begin to believe our own PR – which is to send a reassuring message. Given that that is the message we have been sending, how then do we convince clinicians and politicians there is a potential risk that they need to act to reduce.

2.7.14 *V James.* The messages she was receiving were that testing was a long way off, that theoretical risk was becoming less so and more real. We should change our professional advice, ie remove the word "theoretical" when referring to vCJD risk.

2.7.15 *D Anstee.* Agreed and felt that if we were honest with the public and took a decision to import components for children born since 1996, on the basis that we are playing ultra cautious and the risk to the population is unknown but already very low, the action would enjoy widespread support.

2.7.16 *JP Allain.* We should acknowledge that countries who have banned UK residents/visitors from donating blood have done so because they believe plasma carries a risk. On that basis the introduction of non-UK SD treated plasma for clinical use removes a residual risk.

2.7.17 *BMcC* reasoned that if we invested the resource needed to fund JPA's proposal in reducing inappropriate use we might achieve a far greater risk reduction.

2.7.18 *L Love.* In seeking to draw the discussion to a conclusion, LL proposed a further 1 day workshop on vCJD with a clear objective of identifying the advice we should be giving (to Government, clinicians and the public) as the UKBTS experts.

2.7.19 *T Snape.* Seems that UKBTS staff have to wear two hats - one as a producer and one as a provider of specialist advice to users. Whilst there is an important balance to be struck, the UKBTS should consider producing a clear guidance note on vCJD.

2.7.20 *T Wallington.* Advised that at yesterday's NBS Board meeting, potential actions re vCJD were considered that will make leucodepletion "seem like a picnic".

2.7.21 *P Hewitt.* Emphasised the need for clarity and agreement on who is setting the "blood safety" agenda.

2.7.22 *IM Franklin.* Offered the view that although the 4 UKBTS "Territories" seek to move forward in a co-ordinated way, each national service was independent and, in theory, could choose to go alone. Changes which may be impractical in England might work well in Scotland..

2.7.23 Today's meeting and the NBS Board agenda of this week indicate that the NBS and DoH have a greater awareness of the threat offered by vCJD.

2.7.24 *B McClelland.* The Red Book structure represents most of the framework required to progress discussions such as were taking place today. We should use this opportunity to fix the governance of the blood supply.

2.7.25 *L Love.* The discussion has been useful but there remain many questions to be answered - not least of which was what are the next steps.

2.7.26 *V James.* The four Territory Chief Executives have asked each SAC to produce a workplan for the next 12 months. For SACTTI/SACBC, the way ahead for vCJD would be part of that process.

2.7.27 *B McClelland.* Thinks it unlikely that the Government will allow different approaches in the four territories.

2.7.28 *P Hewitt.* From her experience with the on-going Hepatitis C litigation, PH advised we needed to be aware of the public perception of changes we make to improve blood safety (and the timing of such changes).

2.7.29 *R Warwick.* Reminded the Group of the vCJD mother whose infant developed vCJD and suggested that children of vCJD mothers (parents) may be at higher risk of contracting the disease.

SUMMATION

The following key points were distilled from a very wide ranging discussion:

- **we need to take reasonably practicable precautions**
- **we need to be open and honest with the public**
- **the sheep transfusion transmission study article (Lancet 2000; 356; 999-1000) provided proof of principle that BSE can be transmitted by blood transfusion**
- **donor screening assays are at a stage where development of an appropriate amplification step may allow them to be used**
- **such assays should be trialled on sheep involved in the BSE T.T.I Study**
- **we should not hold out for absolute assay sensitivity prior to introduction**
- **we need clear definition of the decision making process and where responsibilities lie**
- **there should be a clear framework to support and aid the decision making process**
- **there was a clear view that we need to take further precautionary measures**
- **there was agreement that these measures should impact not only on component procurement and production, but also on clinical use. In**

this latter case it was agreed that the UKBTS should be seeking to influence clinical practice

- **there was strong support to explore the feasibility of importing cellular components for children born since 1996**
- **taking reasonable precautions where they can be achieved should be a guiding principle**

With regard to moving the agenda forward, LL proposed that she set up a further workshop to build on the progress made at this meeting. This was agreed. LL to progress. **LL**

00.1 3. **HTLV Paper 3a,b,c,d**

Papers Appended 3a, b, c, d were reviewed for information.

IM Franklin expressed concern that a decision to introduceanti-HTLV screening shouldnot be based only on the use of mini-pools.

J Barbara indicated the options should include testing each donor once only.

00.1 4. **HCV NAT TESTING FOR CELLULAR RELEASE Papers 4a,b**

00.1

4.1 LL explained the NBS wish to have an agreed contingency plan which would allow the release of cellular components, on concession, when HCV NAT results were not available due to technical problems with the assay or the need to release short shelf life components, eg platelets for IUT, before results were available.

00.1 4.2 This provoked a lengthy discussion, the key points of which are set out below.

4.2.1 *J Barbara* expressed a view that components should not be released unless mandatory markers are negative (turn around time $2^1/_2$ hrs). With regard to failed HCV NAT, JB felt we should use a HCV antigen assay. He agreed that a valid option would be to test samples in advance.

4.2.2 *M Ashford* confirmed that the NBS need a fast turn around time for short shelf life components and that this time limit is not always achieved for NAT. Buffy Coats are being issued as leucocyte (granulocyte) components without an HCV NAT result. MA agreed to provide data. **MA**

4.2.3 *JP Allain* expressed a view that the HCV antigen assay has limitations. In support of this he referred to 4 samples from 3 donors tested the previous week. These were HCV RNA positive; anti-HCV negative; HCV antigen negative.

J Barbara corrected the data: 2 of 3 donors tested were HCV core antigen positive.

4.2.4 *IM Franklin* questioned whether concessionary release was appropriate for the business of this meeting.

4.2.5 *M Bruce* reminded the meeting that Section 1, Chapter 5 para 10 gives clear guidance on the rules to be observed for concessionary release.

4.2.6 *J Kurtz* referred to the technical problems currently being experienced with the NBS HCV NAT implementation (for cellular release) i.e. the false positive rate is running at around 5%. He also advised that 2/3 HCV NAT positive, antibody negative donors detected by NBS were antigen positive.

4.2.7 *R Bedford* felt it was important to reflect on the 5-7 hour cycle for HCV NAT as this was distinct from the $2^1/_2$ hour cycle for mandatory serological markers. As a consequence, for some components on some occasions, it will be necessary to

consider concessionary release or even non release.

4.2.8 *JP Allain* wondered how the "courts" would view concessionary release.

4.2.9 *IM Franklin* proposed that any concessionary release algorithms covering HCV NAT should include actions to be taken if the HCV NAT result is subsequently found to be positive.

4.2.10 *T Snape* felt there was a need to clearly define the process by which HCV NAT concessions might progress.

4.2.11 *B McClelland* had a concern with the general principle – in his view, if it was generally not possible to issue granulocytes with an HCV NAT result then we should change the specification and label the component accordingly.

4.2.12 *L Williamson* felt we should discontinue production of granulocytes from pooled buffy coats as there is no evidence of efficacy for this component.

4.2.13 *R Warwick* drew an analogy between untested granulocytes and tissues and advised that where an untested tissue could save a life it would be used.

4.2.14 *IM Franklin* asked if it would be permissible to pre-test the donor where problems in the turn around time for test results was likely to be problematic.

4.2.15 *T Wallington* expressed a view that the position regarding granulocytes needed to be resolved and supported the suggestion made by IMF.

4.2.16 *M Bruce* advised the group that SACBC previously had discussed these matters in the context of GCSF stimulated donors and had produced a draft specification.

MB asked if the Red Book granulocytes specification should be changed to reflect the discussions ie:

- concessionary release can be allowed
- if not fully tested before release, should be labelled accordingly
- mandatory serological markers should be available
- define donor specification (e.g. x previous donations, last tested and found negative for microbiological markers y days ago

4.2.17 *L Williamson* advised that the NBS have screened a panel of HPAIa negative platelet donors. The aim was to have components on the shelf at all times to be used in IUT. Whist these donors are highly selected and tested there may be occasions when it would be necessary to transfuse before HCV NAT results would be available. In such instances it would be useful to have an agreed pre-donation time limit where microbiology results could be considered as acceptable and linked to the donation.

It was agreed that SACTTI would consider and define the maximum interval between removal and testing of sample and donation. LL

4.2.18 *B McClelland* accepted the principle of this but was concerned that a firm time limit might be included in the Red Book.

4.2.19 *P Hewitt* confirmed that with regard to concessionary release, provided that the decision was based on sound judgement and was in the patient's best interests then the approach was justified.

4.2.20 There was a proposal to discontinue the production of granulocytes from pooled Buffy Coats.

4.2.21 *G Rowe* advised the Welsh Blood Service regularly receive requests for this component and provide them on the basis that they were being used to try and treat the patient where other treatments were not effective. On this basis the

component should continue to be provided.

This view was supported by P Hewitt.

4.2.22 *M Bruce* reminded the group that granulocytes from pooled Buffy Coats were no longer specified in the Red Book.

4.2.23 *R Warwick* proposed that clinicians should be left to decide whether or not they want to use pooled Buffy Coats.

4.2.24 *J Barbara* re-emphasised his view that in the event of HCV NAT technical problems delaying the availability of results, all reasonable alternatives should be explored (e.g. HCV antigen) before progressing to concessionary release. JB supported the earlier proposal from B McClelland that if test results are incomplete, this should be stated on the label (this requirement is set out in Chapter 5.14), and agreed the granulocyte specification should be changed.

4.2.25 It was agreed that SACTTI should produce a revised Red Book section to cover HCV NAT. **LL**

00.1 4.3 **SUMMATION**

The following key points were distilled from the discussion:

- **the judicious use of a concessionary release process is entirely valid**
- **where mandatory test results are incomplete prior to issue, details should be printed on the component label (as already required by the Red Book).**
- **all reasonable alternatives should be explored prior to authorising concessionary release**
- **a maximum time between drawing and testing a sample and taking the donation will be defined by SACTTI** **LL**
- **relevant component specifications will be revised by SACBC** **LW**

00.1 4.4 Regarding the use of "previously" tested donors for recovered platelet production, preliminary analysis by M Bruce showed the following general trends:

- most blood services do not follow the "previously tested and found negative in the past 24 months" rule i.e. selection is on the basis of a previous donor history
- in Wales over last 2 years 15% of all buffy coat pools contained platelets from at least one new donor. (Almost 1/3 of platelets were from new donors)
- In Northern Ireland they routinely prepare platelets from new donors.
- In England and Scotland the vast majority of all platelets are produced from know donors. Converting this to 100% would be difficult (e.g. rescheduling University Sessions etc) but achievable.

4.4.3 *K Soldan* noted that pools may contain a mix of 1-4 new/regular donors and that regular donors may be simply those with a previous record and possibly never tested for HCV NAT or may comply with the "24 month" rule. KS said she could rework the residual risk calculations (Appendix 4b) to take account of these differences. **KS**

4.4.4 *J Barbara* wondered whether, in view of differing operational practices, it may prove necessary to calculate residual risk in each National Service.

00.1 5. **BACTERIAL CONTAMINATION OF PLATELETS Papers 5a,b,c,d and 2a**

00.1 5.1 **K SOLDAN. REVIEW OF NBS DATA**

00.1 5.1.1 KS reviewed the NBS data contained in Appendix 5a (an updated version was tabled at the meeting) and emphasised the imbalance in the transmission of

bacterial infections with platelets (ie higher).

00.1 5.1.2 KS indicated there were 2 more 5 day old apheresis platelets to be added to Appendix 5a. 1 x Staph aureus; 1 x Staph epidermidis – one derived from donor arm, neither was fatal.

00.1 5.1.3 *S McLennan* enquired whether there had been any change in incidence since the introduction of leucodepletion.. KS responded that there were insufficient data to draw firm conclusions. However, she emphasised that reports continued to be received (post leucodepletion) and added that reporting systems seemed to have improved.

00.1 5.1.4 *P Mortimer* – had reflected on the bacterial transmission data presented by KS and estimated that if the UKBTS introduced NAT testing for bacterial RNA, the change would have five times more impact than HCV NAT testing.

00.1 5.1.5 *F Boulton* – regularly bled donors can have a dimpling effect at the venepuncture site which can be difficult to clean.

00.1 5.1.6 *J Kurtz* – well known that ineffective venepuncture site preparation can be problematic. Introducing an effective process would provide a simple solution to the problem.

00.1 5.2 **CARL McDONALD – PREVENTION OF BACTERIAL CONTAMINATION BY IMPROVED VENEPUNCTURE SITE PREPARATION; DIVERSION OF THE FIRST X MLS OF BLOOD; TESTING FOR BACTERIA.**

5.2.1 CMcD presented the data set out in appendices 5bi; 5bii; 5c; 5d which prompted a fairly focused discussion and consensus that each of the measures analysed would reduce the risk of bacterial transmission and should be considered for implementation.

5.2.2 *JP Allain* – what is the distribution of contamination across the shelf life of platelets? CMcD from FDA data, 50% of reported reactions occur in platelets aged 5 days (or more). Platelets aged 0-3 days are 95%-97% free of causing a noticeable adverse effect on transfusion. Testing from day 3 is logical (up to that point few adverse events, gives enough time for any bacteria present to expand sufficiently to ensure their presence in test sample).

5.2.3 *J Kurtz* – in Hong Kong they test on day 2 and have results from day 3.

5.2.4 *V James* – how does Bactalert compare with NAT for bacterial RNA on days 0-1 and 3? Why don't we just go ahead and propose the acceptance of CMcD's recommendations to JELC?

5.2.5 It was reported that the bacterial RNA assay developed by J Rider in Bristol did not have an amplification step but was suitable for day 3 testing.

5.2.6 *B McClelland* asked if CMcD had any data from routine use of the proposed arm cleaning procedure. CMcD felt there was enough data to support the introduction of the proposed arm cleaning procedure and urged that this be progressed.

5.2.7 *F Boulton* asked if the diversion of the first x mls of the donation could be used to provide the laboratory samples. This was confirmed.

5.2.8 *L Williamson* supported the proposals but felt we would be unlikely to gain JELC support for introducing all three changes simultaneously. LW suggested that we should attempt to estimate how many of the bacterial transmissions reported by K Soldan could have been prevented by these three interventions – individually and in various combinations. **KS**

00.1 5.3 **LORNA WILLIAMSON – INACTIVATION OF INFECTIOUS AGENTS IN**

COMPONENTS, 15.15-15.25

5.3.1 LW summarised the position regarding virus inactivation of components and focused on the use of Psoralen 5-59 + UVA light for platelets.

5.3.2 LW offered her opinion that these processes would be with us in the near future and suggested the group should consider what impact the introduction of VI processes might have on the decision to introduce or the benefits of other bacterial risk reduction measures.

5.3.3 *T Wallington* suggested that steps be taken to ensure that SHOT could deal with these "new" pharmacological aspects of blood.

5.3.4 *IM Franklin* felt that the issue raised by TW would be covered by post market surveillance. T Snape supported this view.

5.3.5 *JP Allain* asked if S59 treated plasma would be "made available" in line with MSBT recommendations, ie offer clinicians S59 treated and untreated FFP. It was confirmed that would be the intention if UKBTS decided to adopt S59 technology.

5.3.6 *P Hewitt* – from the information presented there was evidence that action(s) could be taken that would reduce bacterial transmissions and, therefore, patient morbidity. Consequently, implementation of these interventions need to be given serious consideration (by JELC and UK Blood Services).

A further comment (unattributed) was that AFS (France) have a two stage arm cleaning process with 30 seconds drying between each application.

It was suggested we might consider specifying the outcome of an effective venepuncture site cleaning procedure.

5.3.7 *B McClelland* restated his concern that we needed an effective process to prioritise the numerous, very important issues that had been discussed in the course of the day.

5.3.8 **It was agreed that SACTTI/SACBC would use the available evidence to make the case for the introduction of the proposed arm cleaning procedure, diversion of the first x mls of donation and bacterial testing (of platelets – this latter, possibly lowest in priority ranking).**

SACTTI will produce the first draft to be agreed with SACBC prior to submission to JELC. **LL**

5.3.9 *P Hewitt* advised that NICE have a framework document that may be helpful in setting out these proposals. It was agreed this would be pursued. **LL**

00.1 6. **LEUCODEPLETION ISSUES Papers 6a,b**

00.1 6.1 **LORNA WILLIAMSON: INTRODUCTION, 15.40-15.45**

LW set out the background to the implementation of universal component leucodepletion and the significant progress made including the development of a proficiency scheme for wbc counting of leucodepleted red cell and platelet components.

00.1 6.2 **NEIL BECKMAN: NBS RESULTS FROM FIRST YEAR, 15.45-15.55**

6.2.1 NB reviewed the NBS experience of leucodepletion over the past year, highlighting the problems associated with particular filters, potential problems with particular batches of filters and the value of using SPC to help analyse and manage performance.

6.2.2 The issue of a dual population of total Hb in red cells in additive solution (buffy coat removed and non) was noted and will be taken forward by SACBC. **LW**

00.1 6.3 **CANADIAN CONSENSUS CONFERENCE ON CMV**

L Williamson tabled the consensus statement from the Canadian Consensus Conference on CMV.

00.1 7. **CLOSE OF MEETING**

LL/LW thanked everyone for their contribution and drew the meeting to a close at 16.10.