APPROVED 13/11/2014

Joint UKBTS Professional Advisory Committee

Minutes of the 58th meeting held at the
Association of Anaesthetists, 21 Portland Place, London,
on Thursday 17th July 2014

Meeting commenced at: 10:50 am

Present

Dr Susan Barnes	**(SB)**	-	Standing Advisory Committee on Care and Selection of Donors
Mr Andrew Broderick	**(AB)**	-	Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)
Dr Akila Chandrasekar	**(AC)**	-	Standing Advisory Committee on Tissues and Cellular Therapy Products
Dr Rebecca Cardigan	**(RC)**	-	Standing Advisory Committee on Blood Components
Mr David Carter	**(DC)**	-	Medicines & Healthcare products Regulatory Agency
Dr Stephen Field	**(SF)**	-	Medical Director, Welsh Blood Service
Dr Stephen Inglis	**(SI)**	-	Director, National Institute for Biological Standards and Control
Mrs Joan Jones	**(JJ)**	-	Representing the Quality Managers of the 4 UK Blood Services
Dr Alan Kitchen	**(AK)**	-	Standing Advisory Committee on Transfusion Transmitted Infections
Dr Sheila MacLennan	**(SM)**	-	Professional Director of JPAC **(Chair)**
Miss Caroline Smith	**(CJS)**	-	JPAC Manager (Minute taker)
Dr Amy Thomas	**(AT)**	-	Human Tissue Authority (HTA)
Prof Marc Turner	**(MT)**	-	Medical Director, Scottish National Blood Transfusion Service
Dr Lorna Williamson	**(LW)**	-	Medical Director, NHS Blood and Transplant

SM welcomed Dr Amy Thomas, the new representative from the Human Tissue Authority (HTA), and Dr Akila Chandrasekar, the new Chair of the SAC on Tissues and Cellular Therapy Products, to the meeting.

ACTION

1. Apologies

Mrs Linda Lodge	**(LL)**	-	Standing Advisory Committee on Information Technology
Dr Kieran Morris	**(KM)**	-	Medical Director, Northern Ireland Blood Transfusion Service
Dr William Murphy	**(WM)**	-	National Medical Director, Irish Blood Transfusion Service
Prof James Neuberger	**(JN)**	-	Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Dr Nay Win	**(NW)**	-	Standing Advisory Committee on Immunohaematology
Prof Maria Zambon	**(MZ)**	-	Director, Centre for Infections, Health Protection Agency (HPA)

2. Minutes of the last meeting held on 20 March 2014 – JPAC 14-30

The minutes were approved as a true record of the meeting with the following amendments:

ACTION

- Item 3.5, page 3, 3rd para, change "endorsed" to "reviewed".
- Item 6.1, page 6, 2nd para. Amend to read "JPAC approved …….. on the new website. SaBTO have requested that the UKBTS develop a framework for evaluating new/changes to PI systems for platelets as was developed for the assessment of prion filters. This needs to be added to both the SACBC and SACTTI workplans."

3. Matters arising not on the agenda (Review of actions list) JPAC 14-31

3.1 **JPAC Decision Making Framework – JPAC 13-23 – item 3.1**

SM had asked AK to put the HTLV paper through the framework for this meeting and also asked SAC Chairs to look out for any appropriate items which could also be put through the process.

AK has submitted JPAC 14-33 as an example which is on the agenda today. This is work in progress with the SACs.

3.2 **Eurocet 128 – JPAC 13-46 – item 3.2**

AC, the new Chair of SACTCTP, is taking this forward and is in the process of setting up a group, but still needs some representation from Wales. AC will liaise with SF regarding a representative and report back to JPAC. AC

3.3 **Complementary Therapy – JPAC 14-06 – item 4.3**

This was discussed at the last SACTCTP meeting and AC will submit a paper to the next JPAC Executive Working Group (EWG) meeting on 1 October.

Post Meeting Note: JPAC EWG 14-60 - Proposal to amend the 'Complementary Therapy' entry in all four Tissue and Cell Donor Selection Guidelines, was submitted to the JPAC EWG meeting on 1 October 2014.

3.4 **Monoclonal gammopathy of Uncertain Significance (MGUS) – JPAC 14-12 – item 5.3**

JPAC approved the recommendation to bring all 4 Tissues and Cells DSGs into line with the Whole Blood DSG by including monoclonal gammopathy of uncertain significance (MGUS) as an example of a clonal disorder under the entry for Haematological Disease. A change notification will be issued.

Post Meeting Note: Change Notification 30 2014 – Haematological Disease was issued on 31 July 2014.

3.5 **Male-sex-with-male - Tissue and Cell Donor Guideline Changes – JPAC 14-13-item 5.4**

SB informed JPAC that they will discuss how to change the wording of the homosexual/bisexual entries at their next SACCSD meeting in August. SB

This also needs to be brought to the attention of the DH as their Blood Safety leaflet still uses homosexual/bisexual wording. SB will contact the relevant people at DH after this has been discussed at SACCSD. SB

3.6 **Look back and Trace back – JPAC 14-20 – item 13.1.**

SM has sent a revised draft to DC for the MHRA and is waiting a response. DC

ACTION

3.7 **Alliance of Blood Operators: Overview of Risk-Based Decision Making (RBDM) from Donor to Recipient – PowerPoint presentation – item 13.3**

LW has submitted the names she has been sent and informed JPAC that the deadline for the consultation has been extended until end of July 2014.

4. Standing Advisory Committee on Transfusion Transmitted Infections

4.1 **Options for HTLV Screening within the UK Blood Services (version 1) – JPAC 14-32**

This is an updated version of JPAC 13-75 presented to JPAC in November 2013, with the major addition being Table 3 HTLV Screening Options, which compares potential options for screening.

SM congratulated SACTTI on this work.

There was considerable discussion and points noted were:

- There is no screening requirement in the EU Directive.
- Leucodepletion appears to be effective in reducing the risk of HTLV transmission through blood components.
- There have been no known transmissions in the UK since commencement of leucodepletion.
- There is no information on the risk without testing - It was noted that a lot of countries don't test for HTLV and we should seek further information from them on haemovigilance data. **Action:** AK. AK
- One option considered was of testing new donors only and although it was noted that there have been seroconversions, there have been only a small number
- There are differences between the UK Blood Services in their current HTLV screening approaches, with both pooled and individual donation screening being performed. In the case of individual donation screening there has been a significant increase in the level of non-specific reactivity, leading to an increase in confirmatory testing and donor notifications
- Screening would need to continue for non-leucodepleted products e.g. granulocytes, and donations from donors with defined HTLV risk.

A paper should go to SaBTO, but it will need to include costings and cost effectiveness calculations and therefore this will be discussed at the Joint NHSBT/ DH Analytical Steering Group to progress this.

Action: LW and AK AK & LW

4.2 **Options for HTLV screening within the UK Blood Services – JPAC Decision Making Framework – JPAC 14-33**

AK had submitted JPAC 14-33 as a first attempt at putting an issue through the JPAC decision making framework which is still draft. As most of the information was in the original HTLV paper it was relatively easy to complete the framework. SM stated that the aim of the framework is to capture the potential implications.

ACTION

It was felt that assessing the level of risk using the bandings provided in the framework for this exercise was not very useful and actual numbers of potential infections should be used instead for this assessment.

4.3 **Borrelia bergdorferi (Lyme disease) Risk Assessment (version 2) – JPAC 14-34**

SACTTI have reviewed the JPAC risk assessment on Borrelia bergdorferi (Lyme disease) and AK highlighted the changes for JPAC.

It was noted that globally there is no evidence of transmission by transfusion.

JPAC endorsed the recommendation that no specific measures are needed for *B.bergdorferi* infection in potential blood donors in view of the lack of evidence of transfusion-transmitted infection.

However, it was noted that infection risk is increasing in some areas of the UK and it would be useful to consider a study looking at seroprevalence with a view to trying to understand potential for transfusion transmission. MT agreed to consider this. MT
Action: MT

4.4 **Chikungunya disease in the Caribbean (version 1) – JPAC 14-35**

AK went through this paper, for information only, which provides a brief update of the spread of Chikungunya across the Caribbean and into the US, and considers the implications to the UK Blood Services in relation to WNV screening when Chikungunya spreads into the continental US.

AK informed JPAC that there are currently no suitable licensed donation screening assays for Chikungunya virus.

The situation in respect of Chikungunya and any implications to the UK Blood Services will be monitored AK

4.5 **West Nile Virus (WNV) JPAC Position Statement (2014) – JPAC 14-36**

The WNV position statement has been updated to include figures from 2013.

AK was asked to amend the statement with regard to numbers per year and then send to CJS to go on the JPAC website.

Post Meeting Note: The updated Position Statement on WNV has been posted on the JPAC website.

5. Standing Advisory Committee on Blood Components

5.1 **Proposed new 'concessionary release' limits for blood components – JPAC 14-37**

SACBC have previously defined 'Discard limits' for a number of components. These were approved by JPAC in 2010 (JPAC 10-74) and adopted into routine practice in the UK in 2011.

The purpose of the current paper (JPAC 14-37) is to recommend the extension of discard limits to other components and quality monitoring parameters as detailed.

SACBC now considers the term concessionary release limits as being more

ACTION

appropriate than discard limits and has therefore now used this throughout this paper.

It was noted that the EU Directive and BSQR, with the exception of leucocyte depletion, do not specify the percentage of components that must meet levels cited for QC testing. Consideration should be also given to raising this issue in response to the draft 18th edition of the Council of Europe "Guide to the preparation, use and quality assurance of blood components".

RC commented that SACBC intend to further discuss whether component specifications need revising, so that hospitals have a clearer idea of the minimum/maximum levels that will be in the majority of components rather than 75%.

DC will take this back to his inspector colleagues for any comments and feedback to SM asap. **Action**: DC — DC

JPAC endorsed the concessionary release limits outlines in table 1 in principle and are awaiting feedback from MHRA. Once this has been received it was agreed that these should be communicated via a single change notification. **Action**: RC — RC

5.2 **Concessionary release limits for leucocyte depletion – JPAC 14-38**

RC went through this paper for JPAC. SACBC recommends that the concessionary release limit for LD is set at >5x 10^6 leucocytes per component and that this is clarified in section 7.1 of the Red Book. This is not a change to guidance but a clarification.

SM asked RC to amend the paper to add how many counts are between 1 and 5x 10^6. The paper will then be submitted to the next Blood Consultative Committee meeting for discussion. **Action**: RC & SM

Post Meeting Note: This paper was updated with the comments from JPAC and submitted to the Blood Consultative Committee (MHRA) meeting on 2 October.

5.3 **Methylene blue-treated plasma – Position Statement – JPAC 14-39**

RC went through this paper for JPAC. This is a review of JPAC 12-98 which was submitted to JPAC in March 2012. Updated information incorporating additional SHOT data from 2012 and 2013 has been added.

RC highlighted table 1b "Reactions subdivided by severity and type", on page 5, as the analysis is slightly different to that presented in 2012.

JPAC asked RC to strengthen the discussion of potential differences between the patient groups receiving different types of FFP in the Summary and Conclusions. — RC

RC was also asked to look at a comparison of reactions to platelets for different patient populations by comparing SHOT data for neonates and adults. — RC

Once these are incorporated the Position Statement can be posted on the JPAC website.

6. Standing Advisory Committee on Care And Selection Of Donors

6.1 **Evaluation of the rewrite of the donor selection guidelines - 'reversing the paradigm' – JPAC 14-40**

ACTION

SB went through this paper for JPAC. The aim of the evaluation is to compare the new version of the DSG with the old DSG to determine whether the same outcome would be achieved in terms of accepting the donor, and specifically, that removal of the current approach would not result in harm to either the donor or the blood supply.

SB asked JPAC to approve this work and for the Medical Directors to give approval for their staff to help with the evaluation. SACCSD will provide a training document for all the Services, similar to the current DSG training documentation. SB

The evaluation was approved by JPAC and the assistance of staff was approved by the Medical Directors who will take this back to their Blood Services to progress. SB MDs

6.2 **Aspirin and Platelet Donation – JPAC 14-41**

This is a paper by Orieji Illoh, of the US Food and Drug Administration, which was presented to the EDQM 14th European Committee on Quality Assurance in Blood Transfusion Services GTS meeting in March. Deferral for aspirin and related drugs will be reduced to 2 days from 5 in the next Council of Europe Guide,18th Edition.

After discussion it was agreed that this needs reviewing by both coagulation and platelet experts. RC will send SB contact details of the relevant people at Cambridge.

Post Meeting Note: JPAC EWG 14-54 - Deferral for aspirin and related drugs for platelet donors, was submitted to the JPAC EWG on 1 October 2014.

6.3 **Hepatitis of Unknown Origin – JPAC 14-42**

The topic 'Hepatitis of Unknown Origin' needs clarification to bring it into line with the other entries for Hepatitis. This will allow acceptance between 12 and 24 months from recovery for the affected individual.

JPAC approved this recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 44 2014 – Hepatitis of Unknown Cause is with the Medical Directors for approval.

6.4 **Latent Tuberculosis – JPAC 14-43**

Following the publication of NICE guidance on Tuberculosis SACCSD have been asked to give clearer information in the Donor Selection Guidelines about Latent Tuberculosis.

JPAC approved this recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 45 2014 –Tuberculosis is with the Medical Directors for approval.

6.5 **Mental Health Problems – resubmission – JPAC 14-44**

A recommendation had previously been submitted and accepted by JPAC in November 2013. It has been noted that there is a second line anti-psychotic medication, Clozapine, for which a common (>=to1% and <= to 10%) side-effect is leucopenia/neutropenia.

Following discussion at SACCSD it was agreed to add the text regarding donors on medication such as Clozapine, and are under close monitoring, into the 'Additional Information'.

ACTION

JPAC approved this recommendation. It was noted that there is a double-negative in the suggested sentence and SB agreed to amend this, following which a change notification will be issued.

Post Meeting Note: Change Notification No 46 2014 – Mental Health Problems has been amended as suggested and is with the Medical Directors for approval.

6.6 **Respiratory Disease – Bronchiectasis – JPAC 14-45**

SACCSD recommends that for clarity Bronchiectasis is added to the obligatory deferrals under Respiratory Disease.

JPAC approved this recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 47 2014 – Respiratory Disease is with the Medical Directors for approval.

LW left the meeting at 13:45.

6.7 **Retinal Vein Thrombosis – JPAC 14-46**

The paper "Retinal vein thrombosis is a marker of immediate or incipient arteriopathy" (BMJ article) was presented at a Journal club in Colindale.

The evidence in the paper supports withdrawing all donors who report retinal vein occlusion.

This submission has been reviewed by the SACCSD who recommends that:

1) Risk of a condition is not a reason for deferral - we accept Diabetes and Hypertension both increase the risk of IHD.

2) We do not exclude donors at high risk of malignancy or with premalignant conditions.

3) Deferral for an episode of Retinal Vein Thrombosis seems unwarranted.

SACCSD also recommends adding:

1) Retinal Vein Thrombosis to the Topic Thrombosis (see attached) and adding link to Thrombosis in Eye Disease "See If Relevant"

2) Place term Retinal Vein Thrombosis in index linked to the topic Thrombosis

JPAC approved these recommendations and a change notification will be issued.

Post Meeting Note: Change Notification No 48 2014 –Thrombosis is with the Medical Directors for approval.

6.8 **Reversible Cerebral Vasoconstriction Syndrome (RCVS) – JPAC 14-47**

The SACCSD recommends that Reversible Cerebral Vasoconstriction Syndrome be added to the index to take to the Migraine topic.

JPAC approved this recommendation.

6.9 **Blood donor selection to minimise risk of transfusion transmissible infectious agents entering the blood supply – Position Statement – JPAC 14-48**

ACTION

This paper has been sent to JPAC for information. The only amendment is on page 2 where a paragraph has been added concerning the SaBTO review in 2011.

The updated Position Statement will be posted on the JPAC website

Post Meeting Note: The updated Position Statement has been posted on the JPAC website.

7. Revisions to the Blood Directives – JPAC 14-49

DC had previously been informed that there would be no revision to the Blood Directives until 2014. Now that the elections have taken place this may be back on the agenda, although DC has not had any information about timescales.

JPAC 14-49 is what was submitted to the Commission in 2012 by the UK (JPAC and MHRA), which at that time was not taken further.

DC asked JPAC if the suggested changes are still relevant, whether new evidence is available and whether there are any further items to add.

One suggested addition is the removal of the additive and anticoagulant formula from labels under Annex 3. **Action**: SM

AC asked whether we could ask that serum for dry eyes be added as a blood component. SM thought this had previously been discussed at the Commission and will look at previous records.

Post Meeting Note: This was discussed in the Competent Authorities Meeting in April 2013 when it was commented that "changes could be considered during a future revision of the legislation".

AC will send suggested wording and evidence to DC. **Action:** AC

SF would like further clarification about endoscopy and this will be discussed at the forthcoming meeting of the SACCSD in August. AC has a risk assessment paper for deceased tissue donors, prepared by Dr Phil Yates, and will forward this to SF and SB.

The SACCSD will review the current list in JPAC 14-49 and suggest any further topics if required.

Post Meeting Note: The updated table of proposed amendments to the EU Directives was sent to David Carter (MHRA) on 27 October for submission to the next Competent Authorities meeting.

8. JPAC Workplans

8.1 **JPAC Workplan 2013/2014 – Final Outcomes – JPAC 14-50**

Following the annual SAC reviews the JPAC workplan for 2013-14 had been updated and submitted to the UK Forum meeting on 6 June. This paper had been submitted to JPAC for information and SM congratulated the SACs on all the work that has been done.

8.2 **JPAC Workplan 2014/2015 – JPAC 14-51**

ACTION

Following the annual SAC reviews the JPAC workplan for 2014-15 had been submitted to the UK Forum meeting on 6 June. This paper had been submitted to JPAC for information.

9. SaBTO update

AB gave a verbal report from the last SaBTO meeting in April.

The working group on Hepatitis E have now met and they are finalising their workplan and outputs. It is expected that they will report in April 2015.

Next year SaBTO plan to review the microbiology guidelines for organs, tissues and cells.

They are also planning further discussions on:

- platelet recommendations (reporting in December 2014)
- Club 96
- HTLV testing
- Sub-Saharan Africa recommendations

10. Blood Component Labelling – JPAC 14-52

JPAC 14-52 is a summary of the JPAC work and actions to date.

SM will be submitting a paper to the UK Forum meeting in September in order to get a steer from the UKF on how they want this taking forward and next steps. SM

It was agreed that the Blood Consultative Committee should be kept updated. SM

11. UK BTS Forum

11.1. SM reported back from the last UK BTS Forum meeting which took place on 6 June 2014.

- Workplans - The UK Forum acknowledge the considerable amount of work undertaken by JPAC and its SACs.

- Appointment of a deputy director for JPAC - This was approved and a job description has gone out for expressions of interest. The closing date is 15 August 2014.

- SAC on Clinical Transfusion Medicine (SACCTM) - Amended Terms of Reference for the SAC were approved and it was agreed that for this vacancy the advert should go to the Medical Directors of the 4 UK Blood Services, JPAC, the UK National Blood Transfusion Committees and the BCSH Transfusion Task Force. The closing date is 31 July 2014.

12. Any Other Business

12.1 **West Nile Virus (WNV)**

SM informed JPAC that there is a consultation on a change to the Directive

ACTION

regarding WNV to reflect the potential for testing. There have been discussions within the EBA which the Medical Directors have been involved with to remove the term “individual“ to NAT testing.

JPAC agreed with this comment.

12.2 **Pancreatic islet cells**

MT raised the issue of pancreatic islet cells from MSM.

The recent JPAC guidance on MSM deferral criteria relating to tissues included islet cells for the first time and MT asked that these be added to the SACTCTP remit because they are a product we supply.

The HTA classify islets as tissues, but they are managed as organs and this sometimes leads to conflict with the transplant surgeons.

AB informed JPAC that SaBTO have agreed to look at the microbiological guidelines because of this type of issue.

AC will contact Sharon Zahra at SNBTS and ask her to provide a paper on current issues relating to islet being classified as tissues, but managed as organs, for discussion at the next SACTCTP meeting. AC

13. Date & venue for future JPAC meetings

2014

- Thursday 13 November - The Association of Anaesthetists, London

2015

- Thursday 12 March - The Association of Anaesthetists, London
- Thursday 18 June - The Association of Anaesthetists, London
- Thursday 12 November - The Association of Anaesthetists, London

Meeting closed at: 14:35