APPROVED 22/06/2017

Joint UKBTS Professional Advisory Committee

Minutes of the 66th meeting held in the Boardroom at the West End Donor Centre, 26 Margaret Street, London, W1W 8NB on Thursday 09 March 2017

Meeting commenced at: 11:00

Present

Dr Neil Almond	**(NA)**	-	National Institute for Biological Standards and Control *(also deputising for Dr Christian Schneider)*
Dr Stuart Blackmore	**(SB)**	-	Standing Advisory Committee on Care and Selection of Donors
Dr Rebecca Cardigan	**(RC)**	-	Standing Advisory Committee on Blood Components **(Minute taker)**
Dr Akila Chandrasekar	**(AC)**	-	Standing Advisory Committee on Tissues and Cellular Therapy Products
Dr Stephen Field	**(SF)**	-	Medical Director, Welsh Blood Service
Dr Alan Kitchen	**(AK)**	-	Standing Advisory Committee on Transfusion Transmitted Infections
Mrs Angela Macauley	**(AM)**	-	Quality Manager, Northern Ireland Blood Transfusion Service representing the Quality Managers of the 4 UK Blood Services
Dr Sheila MacLennan	**(SM)**	-	Professional Director of JPAC **(Chair)**
Dr Gary Mallinson	**(GMal)**	-	Scientific Lead Safety Policy (JPAC/SaBTO)
Dr Gail Miflin	**(GM)**	-	Medical Director, NHS Blood and Transplant
Dr Kieran Morris	**(KM)**	-	Medical Director, Northern Ireland Blood Transfusion Service
Mr David Olszowka	**(DA)**	-	Medicines and Healthcare Products Regulatory Agency
Dr Megan Rowley	**(MR)**	-	Standing Advisory Committee on Clinical Transfusion Medicine
Dr Shirley Stagg	**(SS)**	-	Human Tissue Authority (HTA)
Dr Nay Win	**(NW)**	-	Standing Advisory Committee on Immunohaematology

Observer

Dr Helen New	**(HN)**	-	Member of SACBC

SM welcomed Mr David Olszowka (Senior Regulatory Advisor Inspection, Enforcement & Standards Division at the MHRA) to his first JPAC meeting and Dr Helen New who was attending this meeting as an observer before taking over the Chair of the SAC on Blood Components in April.

ACTION

1. Apologies

Prof John Forsythe	**(JF)**	-	Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Prof Ian Hann	**(IH)**	-	Interim National Medical Director, Irish Blood Transfusion Service
Mrs Linda Lodge	**(LL)**	-	Standing Advisory Committee on Information Technology
Dr Christian Schneider	**(CS)**	-	Director, National Institute for Biological

ACTION

			Standards and Control
Miss Caroline Smith	**(CJS)**	-	JPAC Manager
Prof Marc Turner	**(MT)**	-	Medical Director, Scottish National Blood Transfusion Service
Prof Maria Zambon	**(MZ)**	-	Director, Centre for Infections, Public Health England (PHE)

2. Minutes of the last meeting held on 10 November 2016 - JPAC 17-02

The minutes were approved as a true record of the meeting.

3. Matters arising not on the agenda (Review of actions list) JPAC 17-03

3.1 Perfusion of organs – item 3.1

RC had discussed this issue with Prof John Forsythe and it was hoped that a member of his team would be able to give a presentation at the SACBC in January. Unfortunately, due to a lack of availability, this didn't happen and has been carried over to the SACBC meeting in May. **RC**

3.2 Validation of Plasma and Platelet Quality Following Pathogen Inactivation – JPAC 16-79 – item 4.4

AK is progressing this for plasma. RC, SM and AK to discuss platelets further outside of meeting to decide on best way forward. **AK, SM & RC**

3.3 Use of male donors for red cells for Intrauterine and Neonatal Exchange transfusions as a TRALI risk-reduction measure – JPAC 16-80 – item 4.5

Complete - text has been updated in the 9th Edition of the Red Book.

3.4 Clarify eligibility of female donors who have had IVF treatment with frozen eggs or frozen embryos – WB DSG – JPAC 16-83 – item 5.2

See item 5.4

3.5 Surgery entry in the Bone Marrow and Peripheral Blood Stem Cell, Cord Blood and Living Tissue Donor DSGs – JPAC 16-92 – item 6.2

Waiting for SaBTO review.

3.6 Draft Change Notification with regard to Tropical Virus Risk (Zika Virus) – Deceased Tissues Donor Selection Guidelines – to allow risk assessment of valuable products – JPAC 16-93
Draft Change Notification with regard to Tropical Virus Risk (Zika Virus) – Cord Blood Donor Selection Guidelines – JPAC 16-94
Draft Change Notification with regard to Tropical Virus Risk (Zika Virus) – Tissue Donor Selection Guidelines for Live Tissue Donors and Bone Marrow and PBSC Donor Selection Guidelines – JPAC 16-95 – item 6.3

These changes require the additional availability of screening tests for Chikungunya and Dengue virus, which are still being validated within NHSBT. However, requests for Zika screening can be made and will be reviewed on a case by case basis. AC/AK will bring back to JPAC when this is complete **AK & AC**

3.7 Update to Chapter 9 of Red Book Guidelines: removal of requirement for an anti-HBs level of >100 mIU/ml in anti-HBc reactive tissue or stem cell

ACTION

donations which are HBsAg and ID HBV DNA negative – JPAC 16-108 – item 7.5

Complete and the text has been updated for the 9th Edition of the Red Book.

3.8 Zika Virus – update – item 11

GMal has circulated the final version of the ABO framework to JPAC for information.

4. Standing Advisory Committee on Transfusion Transmitted Infections

4.1 Position Statement: Arrangements in place for monitoring threats to the UK blood supply from new/emerging infectious agents – JPAC 17-04

JPAC approved this updated position statement, which will be posted in the Document Library on the JPAC website.

Post Meeting Note: Updated Position Statement posted on the JPAC website on 13 April 2017.

4.2 Position Statement: The estimated risk that a donation entering the blood supply is a potentially infectious window period donation: risks specific for HBV, HCV and HIV in the UK, 2013 – 2015 – JPAC 17-05

JPAC approved this updated position statement, subject to correction of HIV confidence limits, which will then be posted in the Document Library on the JPAC website.

Post Meeting Note: Updated Position Statement posted on the JPAC website on 13 April 2017.

4.3 The estimated risk that a donation entering the blood supply is a potentially infectious window period donation: risks specific for HBV, HCV and HIV in the UK, 2013-2015 – JPAC 17-06

It was questioned whether there are differences in risk between countries. It is considered not appropriate to look at differences between UKBTS as the numbers are too small to be statistically robust, although it was noted that the Epidemiology Unit produces an annual report that details data by country.

AK to correct error in confidence limits to HIV data.

Post Meeting Note: Amendments received and have also been made to the above Position Statement.

4.4 Extending the annually calculated residual risk figures to include all of the infectious agents for which screening is currently mandatory, i.e. now including HTLV, syphilis and HEV – JPAC 17-07

Agreed that this would be desirable but that the limitations of the available data need to be made clear. As a first step JPAC would like to review when this information has been added. **AK**

4.5 Position Statement : Chikungunya Virus – version 7 – JPAC 17-08

JPAC approved this updated position statement, which will be posted in the Document Library on the JPAC website.

Post Meeting Note: Updated Position Statement posted on the JPAC website on 13

ACTION

April 2017.

4.6 Risk Assessment: Chikungunya Virus – version 7 – JPAC 17-09

JPAC approved this updated risk assessment, which reflects the current position.

4.7 Use of plasma from first time donors – JPAC 17-10

This paper was accepted subject to the opinion of MT who was not present.

Post meeting note – MT has approved this change.

This will require change to Red Book in Component Specifications. It was agreed that this change will NOT apply to neonatal or infants, although a previous amendment (JPAC CN 4-2007) which allows the use of plasma from first time donors if it has been pathogen inactivated still applies.

A change notification will be issued for Chapter 7 of the Red Book.

Post Meeting Note: Change Notification No 10 2017 – Amendment to Chapter 7, Sections 7.3, 7.15, 7.17 and 7.18 issued 10 April 2017.

4.8 Estimated risk of a Zika infected blood component being transfused to a 'risk' recipient - updated 20 February 2017 – JPAC 17-11

Update on residual risk figures provided to JPAC previously. The actual number of cases reported by Public Health England (PHE) are very similar to those estimated previously using this model.

GMal has produced a similar document for tissues – he will update. **GMal**

AK to update Zika Position Statement with the headline figures.

Post Meeting note: Updated position statement submitted to the JPAC meeting on 22 June 2017

4.9 Decreasing the malaria deferral period before a malarial antibody test result can be considered valid and be used to release donations from malaria risk donors – JPAC 17-12

Proposal to reduce deferral before a malarial antibody test can be considered valid from 6 to 4 months. The paper was accepted by JPAC subject to swapping a) and b) in the "Discretionary" section.

SB to draft a change notification, but this would need to go to the SACCSD in the first instance.

SACTTI parasitology sub-group to consider wider implications. BSQR for asymptomatic travellers is 6 months unless tested, but doesn't specify at what point the test should be done. SACTTI to consider what the minimum deferral can safely be reduced to for asymptomatic travellers if donors are tested.

Post Meeting Note: Change Notification No 15 2017 – Malaria is currently going through the Change Notification process.

4.10 Risk Assessment: Leishmania – version 4 – JPAC 17-13

JPAC approved this updated risk assessment, which reflects the current position.

4.11 Risk Assessment: Toxoplasmosis – version 5 – JPAC 17-14

ACTION

Updated to include more information on tissues. Accepted with correction to terminology of heart valves being acellular – AC to provide wording to AK. Changes probably not required to tissue selection guidelines. **AK & AC**

4.12 Risk Assessment: Babesia – version 4 – JPAC 17-15

JPAC approved this updated risk assessment, particularly with reference to the situation in the USA. There are no significant changes to the UK position.

5. Standing Advisory Committee on Care and Selection of Donors

5.1 Use of monoclonal antibodies (biologics) and donor eligibility – Whole Blood and Components Donor Selection Guidelines [Auto-Immune Disease and Osteopenia] – JPAC 17-16

JPAC approved this change to the WB DSG, but asked SB to add examples of names of monoclonal antibodies. With this addition, a change notification will be issued.

Post Meeting Note: Change Notification No 11 2017 – Autoimmune Disease and Osteopenia is currently going through the Change Notification process.

5.2 Inclusion of "Optic Neuritis" in the Eye Disease Topic of the Whole Blood and Components Donor Selection Guidelines – JPAC 17-17

JPAC approved this change to the WB DSG and a change notification will be issued.

Post Meeting Note: Change Notification No 12 2017 – Eye Disease is currently going through the Change Notification process.

5.3 Clarification of eligibility of donors that have had radiation therapy for in situ carcinoma of the breast in the Whole Blood and Components Donor Selection Guidelines – JPAC 17-18

JPAC approved this change for the WB DSG and a change notification will be issued.

Post Meeting Note: Change Notification No 13 2017 – Radiation Therapy is currently going through the Change Notification process.

AC will also take to the SACTCTP for discussion.

Post Meeting Note: Paper submitted to the JPAC meeting on 22 June 2017.

5.4 Clarification of eligibility of donors that have had autologous fresh and/or frozen egg and autologous fresh and/or frozen embryo transfers as part of IVF treatment in the Whole Blood and Components Donor Selection Guidelines – JPAC 17-19

This is a revised paper following comments from a previous JPAC meeting. JPAC approved the change and SB will draft a change notification which will be issued.

Further work would be required as to whether the requirement in c) can be removed for other autologous tissues as opposed to gametes.

Post Meeting Note: Change Notification No 14 2017 – Tissue and Organ Recipients is currently going through the Change Notification process.

ACTION

5.5 Malaria Updates – Travax / GDRI Comparison into line with that of TRAVAX/Fit for Travel – JPAC 17-20

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

Post Meeting Note: Change Notification No 16 2017 – Malaria, GDRI, is currently going through the Change Notification process.

6. Standing Advisory Committee on Blood Components

6.1 Review of current and proposed new concessionary release limits for blood components – JPAC 17-21

JPAC accepted the proposed new concessionary release limits in the paper. RC to amend in 9th edition of the Red Book rather than issue a change notification. Agreed that SACBC should add an annual review of these data to their work plan, as they already do for LD data. There was discussion in relation to what procedures each UKBTS has in place to link results outside of CR to possible donor health issues. Agreed that this was not for JPAC to decide, but RC to take back to SACBC so operational representatives from each UKBTS can consider. **RC**

6.2 Remanufacture of CDP red cell units – JPAC 17-22

This was approved by JPAC and the text will be updated in the 9th Edition of the Red Book. **RC**

6.3 Approval of a new component code for manually washed red cells stored in additive solution – JPAC 17-23

This was approved by JPAC. Noted that SACBC will add review of the process for approval of new component codes to next year's work plan.

6.4 Effect of irradiation on platelet function – JPAC 17-24

JPAC noted this paper. RC to provide paper to those in NHSBT who requested SACBC review this topic. RC to also provide paper to group revising BCSH guidelines on irradiation as literature review may be useful to them. The wider issue of whether irradiation of platelets is necessary at all given the introduction of LD was discussed. Also noted that PI would obviate the need for irradiation and if UKBTS were to implement such systems then this would no longer be an issue. Agreed that the question of whether platelets need to be irradiated per se would need to be considered by SaBTO. Chair of NBTC is raising this with SaBTO. **RC**

6.5 Deviations from the specified storage temperature and interruption of agitation of platelets - practical considerations – JPAC 17-25

Agreed that this paper should be posted on the JPAC website with the following amendment: information from UKBTS in relation to likely maximal periods of non-agitation that occur prior to issue is available on request rather than provided as a matter of course.

Post Meeting Note: Paper posted in "General Documents" the "Document Library" on the JPAC website on 12-04-17.

ACTION

6.6 Change to pH specification for Platelets for Neonatal Use, Leucocyte Depleted – JPAC 17-26

This was approved by JPAC and the text will be updated in the 9th Edition of the Red Book. **RC**

6.7 Rejuvenated red cells – Trial Component Specification – JPAC 17-27

Paper noted. JPAC agreed to review final version offline. Depending on level of comments received, may be necessary to convene a teleconference to discuss.

Post meeting Note: Paper submitted to the JPAC meeting on 22 June 2017

7. Standing Advisory Committee on Tissues and Cellular Therapy Products

7.1 Malaria entry – all four Tissue and Cell Donor Selection Guidelines – JPAC 17-28

Accepted. Agreed to change blood (see above) and tissues guidelines together.

Post Meeting Note: Change Notification No 17 2017 – Malaria, is currently going through the Change Notification process.

7.2 Change to the definition for Surgery which applies to the Tissue Donor Selection Guidelines for Live Tissue Donors, Cord Blood Donors and Bone Marrow & Peripheral Blood Stem Cell Donors – JPAC 17-29

Accepted, subject to amending to align rest of info in line with blood selection guidelines. **AC**

8. Standing Advisory Committee on Immuno-haematology

8.1 NIBSC: WHO Reference reagent to standardise haemagglutination testing of Anti-A and Anti-B in serum and plasma – JPAC 17-49

New standard available from NIBSC. Need to update the Red Book and the text for the 9th Edition.

Post Meeting Note: It was agreed that a direct link would be provided in the Red Book to the NIBSC table on their website.

9. UK BTS Forum

9.1 Report back from the UK Forum meeting on 09 December 2016 – JPAC 17-30

SM to discuss annual appraisal of SAC members with SAC chairs.

Post Meeting Note: Discussed at the JPAC EWG meeting on 10 May 2017.

10. SaBTO – JPAC 17-31

Report from GMal noted.

ACTION

11. Future of the Red Book – JPAC 17-32

Agreed to move to electronic only, subject to agreement by UK Forum.

Post Meeting Note: Move to electronic only agreed by UK Forum with pdf version to be made available for 2017/8 to support transition to online version only.

12. EU Directive Evaluation

- **Evaluation of the EU Legislation on Blood, Tissues and Cells & High level questions of the evaluation process (Sheila MacLennan) – JPAC 17-33**
- **DG Sante Road Map – JPAC 17-34**
- **Blood Directive Amendments – January 2017 – JPAC 17-35**

Papers noted.

13. Draft JPAC Work Plan 2016/2017 – JPAC 17-36

Noted. SM to add colour coding as to whether completed or not and send to UKF.

Post Meeting Note: Work plan submitted to the UK Forum meeting on 24 March 2017, where it was approved.

Telecons have been arranged with SAC Chairs in May to develop next year's plans. Agreed that following year would be helpful to have review with chairs earlier in year (probably January) to enable work plans to be finalised for the start of the financial year.

14. Draft JPAC Constitution – JPAC 17-37

Noted. SM still working on liability section.

Post Meeting Note – Approved by UK Forum. Will be posted on the JPAC website.

15. Tissues and Cells Change Notification Process

Trialled new process with pre-announced publication date as requested. Will keep under review.

16. Any Other Business

16.1 Draft minutes from the 13th CD-P-TS meeting, 3rd to 4th November 2016 – JPAC 17-38

Noted.

16.2 Ingestion of substances prior to donation

AC asked if there needs to be a separate entry in tissue donor guidelines regarding ingestion of substances e.g. poisons prior to donation? JPAC agreed. AC to take to the SACTCTP and draft a change notification for JPAC. This will be brought to the JPAC meeting in November. **AC**

16.3 AK and CJS reviewing horizon scanning documentation to ensure it is up-to-date

ACTION

17. Date & venue for future JPAC meetings

- Thursday 22 June - Boardroom, West End Donor Centre, London
- Thursday 09 November - Boardroom, West End Donor Centre, London

2018

- Thursday 08 March - Boardroom, West End Donor Centre, London
- Thursday 28 June - Boardroom, West End Donor Centre, London
- Thursday 08 November - Boardroom, West End Donor Centre, London

The meeting closed at: 15.40