

# Joint UKBTS Professional Advisory Committee

## Minutes of the 71<sup>st</sup> meeting held in the Portex Room at the Association of Anaesthetists, 21 Portland Place, London, W1B 1PY on Thursday 08 November 2018

Meeting commenced at: 11:00

### Present

Dr Neil Almond	<b>(NA)</b>	- National Institute for Biological Standards and Control ( <i>also deputising for Dr Christian Schneider</i> )
Dr Janet Birchall	<b>(JB)</b>	- Medical Director, Welsh Blood Service
Dr Rebecca Cardigan	<b>(RC)</b>	- Deputy Professional Director of JPAC
Dr Akila Chandrasekar	<b>(AC)</b>	- Standing Advisory Committee on Tissues and Cellular Therapy Products
Dr Stephen Field	<b>(SF)</b>	- Medical Director, Irish Blood Transfusion Service
Dr Lisa Jarvis	<b>(LJ)</b>	- Standing Advisory Committee on Transfusion Transmitted Infections
Mrs Angela Macauley	<b>(AM)</b>	- Quality Manager, Northern Ireland Blood Transfusion Service representing the Quality Managers of the 4 UK Blood Services
Dr Sheila MacLennan	<b>(SM)</b>	- Professional Director of JPAC
Dr Gary Mallinson	<b>(GMal)</b>	- Scientific Lead Safety Policy (JPAC/SaBTO)
Dr Edwin Massey	<b>(EM)</b>	- Standing Advisory Committee on Immuno-haematology
Dr Gail Mifflin	<b>(GM)</b>	- Medical Director, NHS Blood and Transplant
Dr Kieran Morris	<b>(KM)</b>	- Medical Director, Northern Ireland Blood Transfusion Service
Dr Helen New	<b>(HN)</b>	- Standing Advisory Committee on Blood Components
Dr Megan Rowley	<b>(MR)</b>	- Standing Advisory Committee on Clinical Transfusion Medicine
Miss Caroline Smith	<b>(CJS)</b>	- JPAC Manager ( <b>Minute taker</b> )
Dr Amy Thomas	<b>(AT)</b>	- Human Tissue Authority (HTA)
Dr Angus Wells	<b>(AW)</b>	- Standing Advisory Committee on Care and Selection of Donors

SM welcomed Dr Amy Thomas back to JPAC. AT had been a representative of the HTA on JPAC previously.

### ACTION

#### 1. Apologies

Prof John Forsythe	<b>(JF)</b>	- Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Mrs Linda Lodge	<b>(LL)</b>	- Standing Advisory Committee on Information Technology
Mr David Olszowka	<b>(DA)</b>	- Medicines and Healthcare products Regulatory Agency
Dr Christian Schneider	<b>(CS)</b>	- Director, National Institute for Biological Standards and Control

ACTION

- 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 28 June - JPAC 18-79**

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

**3. Matters arising not on the agenda (review of the actions list) JPAC 18-80****3.1 Normothermic regional perfusion in transplantation – JPAC 18-20 – item 3.3**

MG is progressing this and it is hoped to have the first meeting before the end of the year.

MR

**3.2 Herpes Ocular – Deceased Tissue Donor Selection Guidelines – JPAC 18-44**

SACTCTP are referring this to Ocular Tissue Advisory Group (OTAG).

*Post Meeting Note: This has been referred.*

**3.3 Transgender Individuals – JPAC 18-57 – item 5.5**

The European Steering Committee on Blood Transfusion (CD-P-TS) is going to discuss gender issues, with regard to transfusion, at its meeting at the end of November. They may set up a working group. SM will feed-back to the next JPAC meeting.

*Post Meeting Note: CD-P-TS are not going to set up a working group.*

**3.4 Human Parvovirus B19 (B19V) Risk Assessment – version 2 – JPAC 18-58 – item 6.1**

LJ reported that Australia had performed risk modelling and as the risk is primarily from community infection rather than transfusion they have decided to not implement testing.

*Post Meeting Note: With regard to looking at B19 in pregnant women with SCD discussion with Sara Trompeter, NHSBT indicated that this would not be a suitable group to study. Individuals with a haemolytic disorder may become significantly unwell with parvovirus if haemolytic rate is high e.g. Hb70g/l and reticulocytes 8-10; if Hb drops perilously low occasionally this can be fatal. However most women with SCD are being transfused through their pregnancy and are therefore not reliant on their own red cell production (maximum of 30% host cells involved in erythropoiesis). LJ has had discussions with Sara Trompeter to determine if there are any studies/data collection that could assist in gaining knowledge regarding B19 in risk groups and will take to SACTTI.*

RC will send LJ a presentation given on this topic from *Héma-Québec*.

RC

**3.5 UK Blood Services Blood Component Leucocyte Depletion Results: 2017 Review – JPAC 18-63 – item 7.2**

HN had gone back to SACBC to ask if there is a suitable alternative forum who could take this on. After discussion it was agreed that there wasn't another forum and that SACBC should keep this under review. JPAC will only be informed if there is a particular issue.

**3.6 Concessionary Release Limits: Review of current and proposed limits – JPAC 18-65 – item 7.3**

Chapter 6 of the new Red Book has been updated and the new limits will also appear in the next edition of the Handbook of Transfusion Medicine.

**4. Standing Advisory Committee on Transfusion Transmitted Infections**

**4.1 Risk Assessment – Crimean-Congo Haemorrhagic Fever Virus – version 5 – JPAC 18-81**

JPAC approved this risk assessment and endorsed the recommendation no specific measures are needed for CCHF infection in potential donors in view of the low probability of infection acquisition in travellers visiting endemic countries. SACTTI will keep CCHF epidemiology and cases under observation through the Horizon Scanning process. JPAC also approved maintaining a review period of 3 years.

**Kieran Morris and Angela Macauley arrived 11:15**

**4.2 Risk Assessment - Lymphocytic Choriomeningitis Virus (LCMV) – version 5 – JPAC 18-82**

JPAC approved this updated risk assessment and the recommendation to keep the situation with respect to LCMV under long-term review, to archive the risk assessment and revise only when new information becomes available.

**4.3 Risk Assessment - Human Parvovirus (HPTV) – version 5 (previously known as Human Parvovirus 4 or PARV 4) – JPAC 18-83**

JPAC approved this updated risk assessment and the endorse recommendation to keep the situation with respect to PARV4 under long-term review and to archive the risk assessment and revise only when new information becomes available through horizon scanning process.

**4.4 Risk Assessment – Variant CJD (vCJD) – version 5 – JPAC 18-84**

JPAC approved this updated risk assessment and endorsed the recommendation for a one-year review to capture DoH risk assessment changes. Following this the risk assessment will only be revised when new information becomes available.

JPAC noted that in the “Comments”, first sentence on page 8, it should say “screening”. LJ will amend the paper. SF commented that the last clinical case was heterozygous, and it is important to note that.

*Post Meeting Note: Paper has been amended.*

GMal will notify JPAC when the DoH risk assessment is published.

**GMal**

**4.5 SACTTI Risk Assessments – JPAC 18-104**

JPAC endorsed a three-year review period for the Babesia and Leishmania risk assessments and the recommendation that SACTTI is able to determine review periods for risk assessments.

**4.6 Position Statement – Dengue Virus; November 2018 – JPAC 18-85**

**ACTION**

JPAC approved this updated position statement once the new cases have been added. The position statement will then be posted on the JPAC website.

*Post Meeting Note: This updated Position Statement was posted in the Document Library on the JPAC website on 20 November 2018.*

**4.7 Position Statement – Ebola Virus (EBOV); November 2018 – JPAC 18-86**

JPAC asked LJ to amend the last paragraph under “Management of EVD”. The wording is confusing as there is no test and this is hypothetical.

Another sentence should be added with ACTP guidance for tissues.

LJ informed JPAC that SACTTI is about to do an Ebola Virus risk assessment.

LJ will amend the position statement and send to CJS for recirculation to JPAC for approval.

Once the updated version has been approved it will be posted on the JPAC website.

*Post Meeting Note: Updated Position Statement emailed to JPAC for comment on 29 November 2018. This was approved and posted on the JPAC Website.*

**4.8 Position Statement – West Nile Virus (WNV); November 2018 – JPAC 18-87**

LJ will update this revised position statement with the most recent figures. The position statement will then be posted on the JPAC website.

*Post Meeting Note: This updated Position Statement was posted in the Document Library on the JPAC website on 20 November 2018.*

**4.9 Position Statement – Variant CJD (vCJD); November 2018 – JPAC 18-88**

LJ will review this position statement again taking into account JPACs comments on the risk assessment (JPAC 18-84). The position statement will then be posted on the JPAC website.

*Post Meeting Note: This updated Position Statement was posted in the Document Library on the JPAC website on 20 November 2018.*

**4.10 Sexual transmission of tropical viruses (Zika, Chikungunya, Dengue, West Nile) – JPAC 18-89**

It was noted by JPAC that this refers to arboviruses and they asked that the paper be amended. With this change JPAC endorsed the proposal that there should be no change to the current donor selection guidelines.

*Post Meeting Note: This paper has been amended and sent to the JPAC Office.*

**4.11 A road map for UK Blood Services to manage a hepatitis A outbreak – JPAC 18-90**

It was agreed that this paper should be sent to all the UK Public Health Services and the Republic of Ireland, informing them that this has been reviewed by JPAC and asking for their comments and whether or not it is appropriate for this to be posted on the JPAC website. These comments will be brought back to the next JPAC meeting.

SM

**4.12 Human T-Lymphotropic Virus (HTLV) screening in UK Blood Services – JPAC 18-91**

ACTION

SACTTI reviewed the current situation with regard to infection surveillance and efficacy of leucodepletion following the decision to change to testing only new donors and those of non-leucodepleted components for HTLV. The recommendation in this paper is that this policy is retained. JPAC noted that some UK Blood Services are still undertaking universal testing.

## 5. **Standing Advisory Committee on Care and Selection of Donors**

### Whole Blood Donor Selection Guidelines

#### 5.1 **Former sexual partners of individuals with HTLV – JPAC 18-106**

Following the implementation of the SaBTO donor selection review in 2017, it has come to our attention that a donor may return to donation three months after their last sexual contact with an individual with HTLV infection but may not be tested for HTLV. This is because “anti-HTLV screening is only required for blood donations from previously untested donors and for blood donations destined for use to prepare non-leucodepleted products” (Table 9.1, Guidelines for the Blood Transfusion Services).

Blood services will need to ensure health screening includes questions to identify at risk donors and that there is an option for discretionary HTLV testing. Otherwise, donors who report sexual contact with an affected individual must be deferred.

SM will send this paper to Prof Dave Roberts, Associate Medical Director Blood Donation, NHS Blood and Transplant so that operational management of this change can be considered.

*Post Meeting Note: SM has sent this information to Prof Roberts.*

JPAC approved the rewording of this entry and a change notification will be issued.

AW

#### 5.2 **Hepatitis C – JPAC 18-107**

Following implementation of the SaBTO changes in 2017, SACCSD received advice that individuals should be monitored for at least six months following treatment before cure could be assumed. This has been incorporated into the revised guidance.

JPAC approved the reworded entry and a change notification will be issued.

AW

Following approval, an equivalent change notification for the ‘Hepatitis C – N.I’ entry will be prepared.

AW

AC will review the tissues and cells entries and bring back to the next JPAC meeting in March 2019.

*Post Meeting Note: Paper from SACTCTP regarding tissues and cells submitted to the JPAC Meeting on 14 March 2019.*

#### 5.3 **Malignancy – JPAC 18-108**

JPAC asked for clarification of the first sentence of the fifth paragraph on page 4 with regard to “(Breslow thickness of 0 and no regression)”

With this clarification JPAC endorsed the recommended changes to the following entries and a change notification will be issued.

AW

ACTION

- Basal Cell Carcinoma (section a)
- Carcinoma in Situ (section c)
- Melanoma in Situ (section d)
- High risk of cancer due to family history or genetic (section e)
- Minor change to the entry for Cervical Carcinoma in Situ to ensure consistency with Malignancy entry.

**5.4 Repeat HLA/HNA antibody testing after pregnancy – JPAC 18-109**

NHSBT had requested that guidance is added to the Whole Blood and Components DSG to remind users to consider repeat white cell antibody testing for donors who return to donation after pregnancy.

JPAC approved this reworded entry and a change notification will be issued. SM will also bring this to the attention of the Quality Managers and Prof Dave Roberts, Associate Medical Director Blood Donation, NHS Blood and Transplant.

AW, &amp; SM

Geographical Disease Risk Index**5.5 Cape Verde – JPAC 18-110**

JPAC approved the recommendation to reclassify Cape Verde as a Malaria 'B risk' country and the addition of a Previous Malaria Risk category. A change notification will be issued.

AW

**5.6 Tropical Virus Risks – JPAC 18-111**

JPAC approved the recommendation to add various new tropical virus risks to the following countries and a change notification will be issued.

AW

- Costa Rica (Chikungunya)
- Fiji (Dengue)
- Kiribati (Dengue)
- New Caledonia (Dengue)
- Tonga (Dengue)
- Vanuatu (Dengue)
- Wall and Futana (Dengue)

**5.7 Pre- and Post- Exposure (PrEP/PEP) for HIV – JPAC 18-112**

JPAC approved the proposed new entry and the revised blood safety entries in the Whole Blood and Components Donor Selection Guidelines. A change notification will be issued.

AW

AC will take to the next SACTCTP meeting.

*Post Meeting Note: AC submitted a paper to the JPAC EWG on 06 February 2019. As this had already been approved for blood it was agreed that the paper did not need to come back to JPAC for approval and that a Change Notification will be issued.*

**6. Dr Gary Mallinson – Scientific Lead – Safety Policy (JPAC/SaBTO)****6.1 SaBTO update – JPAC 18-92**

GMal gave an update from the last SaBTO meeting on 27 September. It was also noted that Emily Coelho is now the DHSC contact for the SaBTO secretariat.

ACTION

6.2 **Estimate of risk of transmission of Zika Virus to pregnant women from tissue/eye donation from asymptomatic travellers to Zika affected areas – JPAC 18-93**

JPAC endorsed the proposal that the risk assessment is not updated in future unless there is a significant risk in ZIKV cases in the UK.

6.3 **A review of UK blood services patient safety related decisions since 2009 – JPAC 18-94**

GMal had submitted this paper to provide a brief summary of key safety related issued since 2009 by SaBTO, JPAC and TPSG.

JPAC noted that immunological risks/benefits were not taken into account and most of the decisions related to infectious risk. The estimation of risk tolerability showed that following implementation of mitigating steps the resultant risk was found to be 'tolerable'.

JPAC thanked GMal for this very interesting paper. Some suggestions were made as to other risks that might be similarly reviewed e.g. TRALI, transfusion delays. It was noted that different approaches had been made to assess risk at different times but in future if the same (ABO) risk assessment framework is to be used then we will become more consistent. LJ suggested that it would be useful to include a risk estimate at the time of implementing mitigation.

LJ will take the paper to SACTTI for comment and return to GMal to bring back to JPAC.

LJ &amp; GMal

7. **Standing Advisory Committee on Blood Components**

7.1 **Request for updates to Red Book Chapter 7 regarding irradiated components – JPAC 18-95**

JPAC approved the recommendation to update Chapter 7, but asked HN to amend the wording in Request 3

HN

"Red cells washed and stored in saline must be transfused with 24 hours of irradiation or production."

**Steve Field left at 14:25**

7.2 **Guidance for validation of novel plasticisers and additive solutions in blood bags – JPAC 18-96**  
**&**  
**Chapter 8: Evaluation of novel blood components, production processes and blood packs: generic protocols – JPAC 18-97**

SM thanked SACBC for this excellent piece of work which summarised the issues with regard to plasticisers in blood bags. JPAC approved the recommendations in the paper and that Chapter 8 of the Red Book should be updated with specific advice for the validation of blood bag systems that contain novel plasticisers.

SM will forward this paper to DO to send to GAPP – Joint Action "Facilitating the Authorisation of Preparation Processes for blood, tissues and cells".

*Post Meeting Note: Following the meeting HN and SM decided that SACBC would remove specific mention of Chromium 51 in the Chapter 8 revisions given that it is no longer available - the information only came out shortly before the JPAC meeting. HN will send the updated version to CJS for circulation to JPAC.*

HN

SM has sent the paper to DO to send to GAPP.

- 7.3 **Risk assessment of the effect of the Familial Pseudohyperkalaemia genetic variant on red cell unit supernatant potassium – options for screening and management of donors – JPAC 18-98**  
 &  
**Appendix 1 – ABO Risk Assessment Familial Pseudohyperkalaemia genetic variant on red cell unit supernatant potassium – Options for screening and management of donors – JPAC 18-99**  
 &  
**Proposed entry for the Whole Blood and Component Donor Selection Guidelines – JPAC 18-113**

Amy Thomas left at 14:44

Janet Birchall and Kieran Morris left at 15:05

There was considerable discussion on this paper. As some of the Medical Directors and others had to leave the meeting no decision on further action was able to be made, but there will be further discussions following the meeting.

KM and JB agreed to send comments to HN.

*Post Meeting Note: Comments were received.*

Lisa Jarvis left at 15:11  
 Gail Miflin left at 15:12  
 Edwin Massey left at 15:15  
 Neil Almond left at 15:17  
 Akila Chandrasekar left at 15:17  
 Angus Wells left at 15:19

## 8. **Standing Advisory Committee on Clinical Transfusion Medicine**

### 8.1 **Proposal to change the composition and remit of the SAC on Clinical Transfusion Medicine – JPAC 18-105**

JPAC approved the principle of reconvening a SAC CTM group that meets periodically to update and maintain the Handbook of Transfusion Medicine and manage any other relevant issues not covered by other existing groups.

Membership to include:

- Clinical Transfusion Medicine Consultants representing the 4 UK Blood Services
- Clinical Transfusion Medicine Consultants, Clinical Scientists and Haematologists with expertise in different areas of clinical and laboratory transfusion practice

MR

## 9. **Medicines and Healthcare products Regulatory Agency (MHRA)**

### 9.1 **GAPP – Joint Action “Facilitating the Authorisation of Preparation Processes for blood, tissues and cells” - JPAC 18-101**

David Olszowka had submitted this paper to JPAC for information.

### 9.2 **Notes from the meeting of the Competent Authorities on Blood and Blood Components 10<sup>th</sup> and 11<sup>th</sup> October 2018 – JPAC 18-102**



**ACTION**

David Olszowka had submitted this paper to JPAC for information and no action is required.

10. **UK Forum**

10.1 **Report back from the meeting held on 28 September 2018 meeting – JPAC 18-103**

SM feedback from the last UK Forum meeting regarding items submitted by JPAC.

11. **Infected Blood Inquiry - update**

11.1 SM had attended day 3 of the Preliminary Hearings on Wednesday 26 September 2018 representing NHSBT.

Transcripts from all three days are available on their website

<https://www.infectedbloodinquiry.org.uk/news/preliminary-hearings-now-complete>

and you can watch the videos of both the commemoration that opened the Inquiry and all the statements made via their YouTube Channel.

<https://www.youtube.com/channel/UCmFkDoDeSsnYVZtNgo3150g>

Following a request from NHSBT CJS had sent copies of all the papers submitted to Penrose to the NHSBT solicitors Weightmans LLP. All the actions received by the JPAC Office so far are complete.

Both SM and CJS will continue to join the regular NHSBT Inquiry telecons.

12. **Any Other Business**

No other business was discussed.

13. **Date & venue for future JPAC meetings**

**2019**

- Thursday 14 March - Scottish National Blood Transfusion Service, Edinburgh
- Thursday 27 June - The Association of Anaesthetists, London
- Thursday 07 November - The Association of Anaesthetists, London

**The meeting closed at: 15:30**