APPROVED 12/03/2020

# Joint UKBTS Professional Advisory Committee

## Minutes of the 74th meeting held in the Mandela Room at The Wesley Euston Hotel, 81-103 Euston Street, Kings Cross, London, NW1 2EZ Thursday 07 November 2019

**Meeting commenced at: 11:00**

**Present**

| | | | |
|---|---|---|---|
| Dr Janet Birchall | **(JB)** | - | Medical Director, Welsh Blood Service |
| Dr Stephen Field | **(SF)** | - | Medical Director, Irish Blood Transfusion Service |
| Dr Lisa Jarvis | **(LJ)** | - | Standing Advisory Committee on Transfusion Transmitted Infections |
| Dr Richard Lomas | **(RL)** | - | Deputising for Dr Akila Chandrasekar, Standing Advisory Committee on Tissues and Cellular Therapy Products |
| 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 Edwin Massey | **(EM)** | - | Standing Advisory Committee on Immuno-haematology |
| Dr Gail Miflin | **(GM)** | - | Medical Director, NHS Blood and Transplant |
| Dr Helen New | **(HN)** | - | Standing Advisory Committee on Blood Components |
| Mr David Olszowka | **(DA)** | - | Medicines and Healthcare products Regulatory Agency |
| Miss Caroline Smith | **(CJS)** | - | JPAC Manager **(Minute taker)** |
| Dr Stephen Thomas | **(ST)** | - | Deputy Professional Director of JPAC |
| Dr Anna Vossenkaemper | **(AV)** | - | Human Tissue Authority (HTA) |
| Dr Angus Wells | **(AW)** | - | Standing Advisory Committee on Care and Selection of Donors Deputising for Prof Marc Turner, Medical Director, Scottish National Blood Transfusion Service |

SM welcomed Dr Stephen Thomas to his first JPAC meeting since his appointment as Deputy Chair of JPAC in July and thanked Dr Rebecca Cardigan for all her hard work and support as Deputy Chair since 2014

**ACTION**

**1. Apologies**

| | | | |
|---|---|---|---|
| Dr Neil Almond | **(NA)** | - | National Institute for Biological Standards and Control |
| Dr Akila Chandrasekar | **(AC)** | - | Standing Advisory Committee on Tissues and Cellular Therapy Products |
| Prof John Forsythe | **(JF)** | - | Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant |
| Mrs Linda Lodge | **(LL)** | - | Standing Advisory Committee on Information Technology |

**ACTION**

| | | | |
|---|---|---|---|
| Dr Megan Rowley | **(MR)** | - | Standing Advisory Committee on Clinical Transfusion Medicine |
| Dr Christian Schneider | **(CS)** | - | Director, National Institute for Biological Standards and Control |
| 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 27 June - JPAC 19-67**

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

**3. Matters arising not on the agenda (review of the actions list) JPAC 19-68**

**3.1 Proposal to change the composition and remit of the SAC on Clinical Transfusion Medicine – JPAC 18-105 – item 3.3**

MR is in the process of setting up this group. **MR**

**3.2 Borrelia Burgdorferi (Lyme Disease) Risk Assessment - version 4 – JPAC 19-38 – item 4.1**

SM asked AW to review the recommendations for this infection in the Donor Selection Guidelines to get a common procedure for recall after receipt of post-donation information for the services. **AW**

**3.3 Advanced Therapy Medicinal Products (ATMPs) Red Book Entry – JPAC 19-45 – item 4.2**

It was noted by JPAC that this paper is correct as of today, but that this may change following Brexit. JPAC endorsed the document for inclusion as an Appendix in the Red Book. **SM & CJS**

**3.4 Assessing Malarial Residency - Proposed change to the Geographical Disease Risk Index – JPAC 19-48 – item 6.3**

CJS will have talks with Target about redrafting the page on the website. This format could also be used for Change Notifications.

*Post Meeting Note: Discussed with Target and now awaiting list of countries affected from AW*

AW is working on a rewrite for Malaria, which will be completed by the end of the year. **AW**

**3.5 Inclusion of specification for red cells collected by apheresis technology in the current edition of the Guidelines for the Blood Transfusion Services in the UK (Red Book) – JPAC 19-51 – item 7.5**

JPAC approved this paper and the proposed change to Chapter 7 of the Red Book current edition and a change notification will be issued. **CJS**

**3.6 Fresh Frozen Plasma, Leucocyte Depleted Factor VIII specification – JPAC 19-57 – item 7.2**

**ACTION**

JPAC noted the amount of work which had gone into this paper by Simon Procter. The revision of the Fresh Frozen Plasma, Leucocyte Depleted specification was approved, and a change notification will be issued for the Red Book. **CJS**

**EM joined the meeting at 11:06**

## 4. Standing Advisory Committee on Transfusion Transmitted Infections

### 4.1 Dengue Virus Risk Assessment - version 8 - JPAC 19-69

It was noted that some locally acquired cases have been identified in Europe (Spain and France), but all have been localised and outbreaks have not occurred.
JPAC approved the updated risk assessment and to maintain the current Donor Selection guidelines for Dengue Virus.

LJ will update the risk assessment with the information received at this meeting regarding a new Dengue vaccine and send the updated version to CJS.

*Post Meeting Note: Updated Risk Assessment received 08 November 2019.*

### 4.2 Position Statement: Dengue Virus; September 2019 – JPAC 19-70

JPAC approved this position statement which has been updated with the currently available figures for cases of Dengue virus imported into the UK and the EU. The situation in respect of Dengue virus and risk of transmission has not changed, infections continue to be reported from affected countries.

The updated position statement will be posted in the "Document Library" on the JPAC website.

*Post Meeting Note: Update Position Statement posted on the JPAC website on 12 November 2019.*

### 4.3 Hepatitis A Virus (HAV) Risk Assessment – version 2 – JPAC 19-71

JPAC approved the risk assessment and endorsed the recommendation that no there should be no changes to blood donor selection or screening, inactivation or recipient assessment/monitoring. The recommended review period of 3 years was also approved.

### 4.4 A road map for UK Blood Services to manage a hepatitis A outbreak – JPAC 19-72

This road map is based on the actions taken by SNBTS during the 2017 outbreak and identifies options for action in the event of a large HAV outbreak that might have implications for donors and blood donation. Comments were received from PHE and HPS.

JPAC approved the road map for the UK Blood Services, which will be posted in the "General Document" area in the "Document Library" on the JPAC website.

CJS will format the paper for the website.

*Post Meeting Note: Posted on the JPAC website on 12 November 2019.*

### 4.5 Zika Virus Risk Assessment – version 4 – JPAC 19-73

**ACTION**

JPAC approved this risk assessment, which has been updated with the latest scientific information, and a review period of 2 years. A minor typo was noted on page 2. LJ will amend the paper and send to CJS.

*Post Meeting Note: Updated Risk Assessment received 08 November 2019.*

**4.6 Position Statement: Zika Virus; September 2019 – JPAC 19-74**

JPAC approved this position statement which has been updated with the latest scientific information. The updated position statement will be posted in the "Document Library" on the JPAC website.

*Post Meeting Note: Posted on the JPAC website on 14 November 2019.*

**4.7 Toxoplasmosis Risk Assessment – version 6 – JPAC 19-75**

JPAC noted there has been no overall change in the risk of available options, approved this updated risk assessment and a review period of 3 years.

**4.8 Position Statement: West Nile Virus; November 2019 – JPAC 19-76**

JPAC approved this position statement which has been updated with the currently available information on West Nile Virus.

In 2018 WNV Donor Selection Guidance was applied to donors had visited the Alpes-Maritimes region in France, and in 2019 this guidance was modified to include the adjacent Var region. The WNV guideline was also applied to Cyprus in 2019.

The updated position statement will be posted in the "Document Library" on the JPAC website.

*Post Meeting Note: Posted on the JPAC website on 14 November 2019.*

A single case had been reported in both Germany and Slovakia in 2019. LJ informed JPAC that there are now 4 confirmed cases in Germany but that they have not implemented NAT. UK may have to put measures in place next year if Germany does introduce NAT.

**4.9 Position Statement: Variant CJD (vCJD); November 2019 – JPAC 19-77**

JPAC approved this position statement which has been updated to reflect the SaBTO recommendation of September 2019, that some specific risk reduction measures, requiring the use of imported plasma and apheresis platelets for individuals born on or after 1 January 1996 and/or with TTP, be withdrawn.

It was noted that the link to the relevant www.gov.uk/ area, on page 6, had now changed. GMal will send LJ the new link. With this amendment the updated position statement will be posted in the "Document Library" on the JPAC website.

*Post Meeting Note: Posted on the JPAC website on 14 November 2019.*

**4.10 Risk assessment of deferral period for donors with *T.cruzi* risk – JPAC 19-78**

SACTTI has reviewed the scientific literature and *T.cruzi* assay performance and concluded that the deferral period for *T.cruzi* (prior to testing) could be harmonised to that used for malaria i.e. 4-months. This paper had also been to the SACTTI Parasite Sub-Committee. **AW & RL**

**ACTION**

JPAC approved the recommendation that the deferral period for *T.cruzi* can be reduced from 6-months to 4-months for blood, tissues and cells. Change Notifications will be issued for the Whole Blood and the Tissues and Cells DSGs.

**4.11 Residual risk of undetected infection among deceased tissue, living surgical bone and cord bloods, NHSBT 2013 – 2017 – JPAC 19-79**

JPAC approved the residual risk estimates for deceased tissue, living surgical bone and cord blood.

SACTCTP and Katy Davidson aim to publish the data prior to publication on the JPAC website. AC will let the JPAC Office know when and how this should be published on the website - either the paper itself, or a link to the site of the published paper. **AC**

## 5. Standing Advisory Committee on Tissues and Cellular Therapy Products

**5.1 Tamoxifen entries in the Tissue and Cells Donor Selection Guidelines – JPAC 19-80**

SACTCTP had noted a discrepancy between the "Malignancy" and Tamoxifen" entries in the Tissues and Cells Donor Selection Guidelines.

JPAC approved the changes to the entries. A change notification will be issued. **RL/CJS**

**5.2 Infection – Acute, Tamiflu & Relenza entries in the Deceased Tissue Donor Selection Guidelines – JPAC 19-81**

JPAC approved the changes to the entries in the Deceased Tissue Donor Selection Guidelines. A change notification will be issued. **RL/CJS**

**5.3 Pre-retrieval body cooling for Deceased Tissue Donors - Proposed amendment to the Red Book section 21.2 – JPAC 19-82**

JPAC approved the proposal to reword section 21.2. This will appear in the 9th Edition of the Red Book. **RL**

## 6. Standing Advisory Committee on Care and Selection of Donors

**6.1 Clopidogrel New Entry – Whole Blood and Components Donor Selection Guidelines - JPAC 19-83**

JPAC approved this new entry to the Whole Blood and Components Donor Selection Guidelines. A change notification will be issued. **AW**

**6.2 Cervical Carcinoma in situ – Whole Blood and Components Donor Selection Guidelines – JPAC 19-84**

JPAC approved this revised entry for the Whole Blood and Components Donor Selection Guidelines. This reflects changes to screening pathways and terminology. A change notification will be issued. **AW**

**6.3 Haemochromatosis entry – Whole Blood and Components Donor Selection Guidelines – JPAC 19-85**

This entry has been reviewed by SACCSD following the publication of new BSH guideline for management of Genetic Haemochromatosis (GH), more GH patients

**ACTION**

are being advised to donate blood rather than be offered venesection in a hospital clinic.

JPAC approved this revised entry for the Whole Blood and Components Donor Selection Guidelines. A change notification will be issued. **AW**

**6.4 Latent TB – Whole Blood and Components Donor Selection Guidelines – JPAC 19-86**

JPAC approved SACCSDs recommendation that:

- Donors with latent TB can be accepted unless undergoing treatment.
- Donors on treatment for latent TB can donate 7 days after completing anti-TB therapy

**AW**

A change notification will be issued.

**6.5 Tropical Virus entry – Whole Blood and Components Donor Selection Guidelines – JPAC 19-87**

PHE and NaTHNaC have reviewed and updated WHO/CDC Zika travel and sexual transmission advice (revising down sexual transmission risk of male to female to 3 months from 6 months). Further to this SACTTI has reviewed the current guidance in the WBDSG and have recommend this change is implemented.

**AW**

JPAC approved this revised entry and a change notification will be issued.

**6.6 Valproate – new entry – Whole Blood and Components Donor Selection Guidelines – JPAC 19-88**

JPAC approved the proposed new entry for Sodium Valproate and the revisions to the entries for “Mental Health Problems” and “Migraine”. Change Notifications will be issued. **AW**

SM noted that this would be relevant for stem cells and asked RL to take this to SACTCTP to review with regard to tissues and cells. **RL**

**6.7 Viral Haemorrhagic Fever – Whole Blood and Components Donor Selection Guidelines – JPAC 19-89**

JPAC had approved the Ebola risk assessment at the last meeting on 27 June. The risk assessment recommended that a donor’s who have had sexual contact with an individual who has recovered from Ebola Virus Disease should be permanently deferred.

JPAC approved the revised entry for Viral Haemorrhagic Fever and a change notification will be issued. **AW**

SACCSD would welcome further opinion as to the necessity to introduce a new donor question for this new sexual risk deferral, given the length of current questionnaires and the low likelihood of identifying implicated donors. SACTTI are getting expert advice which LJ will collate and send to AW. In the opinion of JPAC members the risk would be very low.

## 7. Standing Advisory Committee on Blood Components

**7.1 Position Statement: Granulocyte Therapy; November 2019 – JPAC 19-90**

**ACTION**

The main changes to the document recognise the lack of provision of a GCSF/steroid stimulated granulocyte component in UK, and an update on the national registry.

JPAC approved the updated Position Statement, which will be posted in the Document Library on the JPAC website.

*Post Meeting Note: Posted on the JPAC website on 14 November 2019.*

**7.2 Change to Red Book Pooled Granulocytes Yield Specification – version 1 – JPAC 19-91**

JPAC endorsed the proposed changes to, and the revised text to be incorporated into, the Red Book by Change Notification or inclusion in 9th edition:

1. Red Book granulocyte yield specification to be revised to 95% or more >5x$10^9$/unit per month.
2. Production processes should be reviewed if any component has <3.8x$10^9$/unit.

**7.3 Update on di-(ethylhexyl) phthalate (DEHP) for JPAC – JPAC 19-92**

This paper has been submitted to JPAC for information. SM thanked HN for bring this to JPAC and asked her to keep us updated of any developments.

RL noted that this may affect the serum eyedrops service as DEHP is present in the current packaging. He will discuss with the manufacturers. **RL**

**7.4 Product codes for red cells for RESTORE clinical trial – JPAC 19-93**

It was noted that these codes have been agreed by SACIT for this purpose. JPAC agreed that no further approvals (from a SACBC/JPAC point of view) are necessary to use the codes.

SACBC asked whether there is a need for JPAC to develop a paper for how to manage blood components that in future may be produced as IMP's rather than under the BSQR. This would be analogous to the considerations previously with respect to where ATMPs sit in relation to the Red Book (JPAC 19-45). It was agreed that no additional entries to the Red Book are required at the present time but that we can consider this in the future if this situation arises.

**8. Dr Gary Mallinson – Scientific Lead – Safety Policy (JPAC/SaBTO)**

**8.1 SaBTO Review – JPAC 19-94**

GMal went through his SaBTO update for JPAC. The main items were:

- SaBTO recommendations to stop importation of plasma and provision of apheresis platelets for individuals born after 1995 as specific risk reduction measures for variant Creutzfeldt-Jakob disease
- SaBTO accepted the current hepatitis E recommendations and will review again in 2 years' time.
- Working Group has been established to investigate the risk of transmission of HBV from donors with occult HBV
- Working Groups has been set up to look at the SaBTO patient consent guidelines
- Virology Review group looking at risk to organ recipients from HHV-8 and seasonal influenza

**ACTION**

The next SaBTO meeting is on 31 January 2020.

**9. Europe**

**9.1 Notes from Conference on the evaluation of the EU legislation on blood, tissues and cells, Brussels 28 October 2019 – JPAC 19-95**

SM went through her personal notes from this conference, which had been submitted to JPAC for information.

**9.2 European Medicines Agency - CHMP position statement on CJD and plasma-derived and urine-derived medicinal products – submission of UK comments – JPAC 19-96**

These collated UK comments were submitted on 30 October 2019 by SM on behalf of the UK Forum.

**10. UK Forum**

**10.1 Feedback from the UK Forum meetings on 06 September 2019 – JPAC 19-97**

SM went through the update for the group.

**11. JPAC Extraordinary Telecon to discuss the SaBTO recommendations regarding import of FFP for people born after 1 January 1996**

**11.1 Minutes of the meeting held on 08 October 2019 – JPAC 19-98**

The minutes had been circulated again for information.

**12. Infected Blood Inquiry - update**

**12.1** JPAC currently have no outstanding actions and we are awaiting instructions for next steps, if any.

**13. Horizon Scanning Process – verbal update**

**13.1** LJ, CJS and Alan Kitchen had met to go through the whole process and update the various documents. The timetable for the next steps is as follows:

January 2020 → SACTTI

February 2020 → JPAC EWG

March 2020 → JPAC

?April 2020 → SaBTO – This will be our annual submission

**14. Any Other Business**

**14.1 ABO risk based decision-making framework.**

JPAC formally adopted the use of this framework.

**ACTION**

GMal informed JPAC that there have been some revisions to the original framework and that he had been asked by GM to run a small workshop which will look at these changes. It is hoped that the workshop will take place before the next JPAC meeting in March 2020. JPAC members would be invited and GMal thought that a number of clinicians would also find this useful. He asked JPAC members to send him the names of anyone who they thought would benefit from attending this workshop. **ALL**

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

**2020**

- Thursday 12 March - West End Donor Centre, London
- Thursday 25 June - West End Donor Centre, London
- Thursday 05 November - West End Donor Centre **NOT** available Venue to be confirmed

  *Post Meeting Note: This meeting will be held at the Scottish National Blood Transfusion Service*

**The meeting closed at: 14:00**