

Joint UKBTS Professional Advisory Committee

**Minutes of the 75th meeting held in the Boardroom
at the NHSBT West End Donor Centre, 26 Margaret Street,
London, W1W 8NB
Thursday 12 March 2020 – 11:00 to 15:00**

Meeting commenced at: 11:05

Present

Dr Neil Almond	(NA)	- National Institute for Biological Standards and Control
Dr Janet Birchall	(JB)	- Medical Director, Welsh Blood Service
Dr Akila Chandrasekar	(AC)	- Standing Advisory Committee on Tissues and Cellular Therapy Products
Dr Bernard Fox	(BF)	- National Institute for Biological Standards and Control – <i>Deputising for Dr Edwin Massey for the Standing Advisory Committee on Immuno-haematology</i>
Dr Lisa Jarvis	(LJ)	- 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 Helen New	(HN)	- Standing Advisory Committee on Blood Components
Mr David Olszowka	(DA)	- Medicines and Healthcare products Regulatory Agency
Dr Stephen Thomas	(ST)	- Deputy Professional Director of JPAC
Prof Marc Turner	(MT)	- Medical Director, Scottish National Blood Transfusion Service
Dr Anna Vossenkaemper	(AV)	- Human Tissue Authority (HTA)

Dialling in

Mrs Linda Lodge	(LL)	- Standing Advisory Committee on Information Technology – <i>For SACIT section only</i>
Dr Angus Wells	(AW)	- Standing Advisory Committee on Care and Selection of Donors
Miss Caroline Smith	(CJS)	- JPAC Manager (Minute taker)

SM welcomed Bernard Fox to JPAC deputising for EM Chair of SACIH.

1. Apologies

Dr Stephen Field	(SF)	- Medical Director, Irish Blood Transfusion Service
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ACTION

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Prof John Forsythe	(JF)	- Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Dr Edwin Massey	(EM)	- Standing Advisory Committee on Immuno-haematology
Dr Gail Mifflin	(GM)	- Medical Director, NHS Blood and Transplant
Dr Megan Rowley	(MR)	- Standing Advisory Committee on Clinical Transfusion Medicine
Dr Christian Schneider	(CS)	- Director, National Institute for Biological Standards and Control
Prof Maria Zambon	(MZ)	- Director, Centre for Infections, Public Health England (PHE)

2. **Minutes of the last meeting held on 07 November - JPAC 20-02**

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

3. **Matters arising not on the agenda (review of the actions list) JPAC 20-03**

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

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 3.2**

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 3.3**

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. In progress.

SM & CJS

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

AW is working on a rewrite for Malaria. This is a large piece of work. In progress.

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 3.5**

JPAC approved this paper and the proposed change to Chapter 7 of the Red Book.

Post Meeting Note: Draft Change Notification 34 2020 in progress.

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

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.

ACTION

Post Meeting Note: Change Notification No 25 issued 05 May 2020.

- N.B. Due to the COVID-19 outbreak, and the issue of several emergency change notifications, routine non urgent changes have been delayed. To date 21 Emergency changes have been made.**
- 3.7 Risk assessment of deferral period for donors with *T.cruzi* risk – JPAC 19-78 – item 4.10**
- Change Notifications will be issued for the Whole Blood and the Tissues and Cells DSGs. In progress.
- AC informed JPAC that this was reviewed at the last SACTCTP meeting and concluded that a change notification for the Tissue & Cells Guidelines is not required
- 3.8 Residual risk of undetected infection among deceased tissue, living surgical bone and cord bloods, NHSBT 2013 – 2017 – JPAC 19-79 – item 4.11**
- 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. In progress. AC
- 3.9 Tamoxifen entries in the Tissue and Cells Donor Selection Guidelines – JPAC 19-80 – item 5.1**
- A change notification will be issued. In progress. RL & CJS
- 3.10 Infection – Acute, Tamiflu & Relenza entries in the Deceased Tissue Donor Selection Guidelines – JPAC 19-81 – item 5.2**
- A change notification will be issued. In progress. RL & CJS
- 3.11 Pre-retrieval body cooling for Deceased Tissue Donors - Proposed amendment to the Red Book section 21.2 – JPAC 19-82 – item 5.3**
- JPAC approved the proposal to reword section 21.2. This will appear in the 9th Edition of the Red Book. In progress. RL
- 3.12 Clopidogrel New Entry – Whole Blood and Components Donor Selection Guidelines - JPAC 19-83 – item 6.1**
- A change notification will be issued. In progress. AW
- 3.13 Cervical Carcinoma in situ – Whole Blood and Components Donor Selection Guidelines – JPAC 19-84 - item 6.2**
- A change notification will be issued. In progress. AW
- 3.14 Haemochromatosis entry – Whole Blood and Components Donor Selection Guidelines – JPAC 19-85 – item 6.3**
- A change notification will be issued. In progress. AW
- 3.15 Latent TB – Whole Blood and Components Donor Selection Guidelines – JPAC 19-86 – item 6.4**
- A change notification will be issued. In progress. AW

ACTION

- 3.16 **Tropical Virus entry – Whole Blood and Components Donor Selection Guidelines – JPAC 19-87 - item 6.5** AW
- JPAC approved this revised entry and a change notification will be issued. In progress.
- 3.17 **Valproate – new entry – Whole Blood and Components Donor Selection Guidelines – JPAC 19-88 – item 6.6** AW
- Change Notifications will be issued. In progress for Whole Blood and Components Donor Selections Guidelines.
- AC informed JPAC that as this is relevant to stem cells their committee are discussing the issue and it is due to be reviewed at the next SACTCTP meeting. AC
- 3.18 **Viral Haemorrhagic Fever – Whole Blood and Components Donor Selection Guidelines – JPAC 19-89 – item 6.7**
- On agenda.
- 3.19 **Update on di-(ethylhexyl) phthalate (DEHP) for JPAC – JPAC 19-92 – item 7.3**
- AC informed JPAC that the response from Meise is that currently, DEHP is only present in the vent bag part of the dispensing system. This serves to collect the air displaced from the vials when they are filled, and we also use it to collect the serum that is used for micro sampling. However, none of the serum that is sent out to patients comes in contact with the vent bag.
- Meise have an alternative plasticizer available (TOTM) which they have fully qualified and could switch to if necessary.
- 3.20 **ABO risk based decision-making framework – item 14.1**
- GMal had 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.
- The workshop had not yet been organised as a result of an increased SaBTO workload following the resignation of Tim Ellis as SaBTO secretary in December. The workshop will be organised for later this year once the disruption from COVID-19 had resolved. GMal
4. **Standing Advisory Committee on Blood Components**
- 4.1 **Leucocyte-depleted Red Cell and Plasma – update on the feasibility study and changes to the provisional component specification – JPAC 20-04**
- In October 2018 the Royal London hospital launched a 2-year study to assess the feasibility of delivering Leucocyte-depleted Red Cell and Plasma (LD-RCP) component in pre-hospital setting to trauma patients who are bleeding.
- SACBC recommended a two-step process to ease the wastage of this component in the feasibility study and to ensure this is not an issue in the long term if the component subsequently becomes used more widely for trauma patients.
- JPAC approved the use and a change to the specification will be made.
- Post Meeting Note: Change Notification No 32 issued 08 June 2020.*

NB It was agreed that paper JPAC 20-07 should be discussed next.

4.2 Leucocyte-depleted Whole Blood – in vitro assessment of plasma, red cell and platelet function and proposed provisional specification – JPAC 20-07

This paper summarised the results of red cell function and plasma quality for LD-WB (described previously in JPAC 18-21), which together with the new data on platelet function will assist with assigning a provisional specification for this component prior to clinical evaluation.

Following discussion, it was agreed that reference to “trauma” should be removed. With this amendment JPAC approved this provisional specification for Whole Blood, Leucocyte Depleted (LD-WB) – for clinical studies.

Post Meeting Note: Draft Change Notification 35 2020 in progress.

4.3 Proposed change to haematocrit specification compliance of Red Cells in Additive Solution (AS) [2020] – JPAC 20-05

JPAC approved the change to the specification for Red Cells in Additive Solution: the haematocrit specification compliance target will increase from 75% or more to 90% or more.

Post Meeting Note: Draft Change Notification 35 2020 in progress.

4.4 Off label use of platelet additive solutions in the manufacture of resuspended platelets (90% PAS: 10% plasma) – JPAC 20-06

JPAC approved the recommendation that the UK and Republic of Ireland Blood Services continue with their current practices, justified by local actions taken in line with the risk and impact assessment and the proposed wording in this paper be added to Chapter 6.1 of the Red Book.

HN

4.5 Red Book updates for new neonatal plasma components from UK plasma – JPAC 20-08

Following SaBTO’s recommendation regarding UK plasma SACBC have submitted proposed specifications for Fresh Frozen Plasma for Neonates and Infants, leucocyte depleted, and Cryoprecipitate for Neonates and Infants, leucocyte depleted for inclusion in the Red Book.

JPAC approved the proposed additional specifications.

Post Meeting Note: Change Notification No 23 and No 24 issued 04 May 2020.

4.6 Rationalising wording of specifications for intrauterine and neonatal/infant components – JPAC 20-09

JPAC approved the proposals in paper JPAC 20-09 to rationalise the wording to the relevant specifications in the Red Book.

HN

5. Standing Advisory Committee on Transfusion Transmitted Infections

5.1 Babesia risk assessment, version 5 – JPAC 20-10

JPAC approved the updated risk assessment and no change to the current deferral policy recommendation.

ACTION**5.2 Leishmania risk assessment, version 5 – JPAC 20-11**

JPAC approved the updated risk assessment. There is no overall change in risk or available options. A 3-year review period was also approved.

5.3 Tick-borne encephalitis virus, version 2 – JPAC 20-12

JPAC approved the risk assessment and endorsed the recommendation that there should be no change to the current situation. SACTTI will maintain a watching brief. 2 year review period was also approved.

5.4 Variant CJD (vCJD) risk assessment, version 6 – JPAC 20-13

JPAC approved the updated risk assessment and a 5 year review period.

5.5 Position Statement – Ebola virus (EBOV) – JPAC 20-14

JPAC approved the updated risk assessment which will be posted on the JPAC website. LJ will update the Position Statement with the latest figures and then send to CJS for posting.

Post Meeting Note: Posted on JPAC website on 17 March 2020.

5.6. Horizon Scanning Process – Annual Review 2019 – JPAC 20-15(a)

LJ submitted 4 papers to provide JPAC with an oversight of the SACTTI/JPAC Horizon scanning process.

5.6.1 Horizon Scanning Annual Report 2019 – Excel spreadsheet – JPAC 20-15(b)

JPAC 20-15(b) documents, actions/decisions made through the Horizon Scanning Process in 2019. It was agreed that this report should be submitted to SaBTO in May 2020.

LJ

5.6.2 Horizon Scanning Process Management Description – JPAC 20-15(c)

It was agreed that this a “JPAC” document and therefore the appropriate headings and descriptions will be added. The final version will then be posted in the Document Library on the JPAC website. It was also agreed that the document should also be reviewed annually using the same process as risk assessment review.

LJ & CJS

The previous version of this MPD contained an algorithm documenting the process and including stakeholders. It was agreed that this algorithm was useful and illustrated how different groups interact, but it is out of date. GMal agreed to revise.

GMal

5.6.3 Horizon Scanning risk assessment tool – JPAC 20-15(d)

This document was provided for information and outlines the process undertaken during the risk assessment.

5.7 Update of the Coronavirus Position Statement

LJ is in the process of updating the position statement to take account of recent events.

Post Meeting Note: Updated version submitted to JPAC meeting on 25 June 2020.

6. Standing Advisory Committee on Tissues and Cellular Therapy Products

ACTION

- 6.1 **Infection: Acute – Living Tissue and Cell Donor Selection Guidelines – JPAC 20-16**
- JPAC approved the proposal and a Change Notification will be issued. AC & CJS
- 6.2 **Infection: Chronic – Living Tissue, Cord Blood, Bone Marrow and also Deceased Tissue Donor Selection Guidelines as stated – JPAC 20-17**
- JPAC approved the proposals and a Change Notification will be issued. AC & CJS
- 6.3 **Systemic Lupus Erythematosus Living and Deceased Tissue Donor Selection Guidelines – JPAC 20-18**
- JPAC approved this new entry and a Change Notification will be issued. AC & CJS
- 6.4 **Proposal to stop importation of serum for the preparation of allogeneic serum eye drops for individuals born after 1995 as a risk reduction measure for variant Creutzfeldt-Jakob disease – JPAC 20-19**
- GMal went through this paper for JPAC.
- JPAC approved the proposal to stop importation of serum for provision of allogeneic serum eye drops to individuals post after 1995 as a risk reduction measure for vCJD and use serum from UK donors.
7. **Standing Advisory Committee on Information Technology**
- LL joined the telecon.
- 7.1 **Publication of the UK Component Portfolio and Mapping Tables – JPAC 20-20**
- LL informed JPAC that SACIT had formed a Short Life Working Group (SLWG) to map the UK CODABAR system components codes to the ISBT128 component codes. This work is now nearly complete.
- Next steps:
- The SACIT SLWG have mapped the remaining codes and are now reviewing before sign off.
 - The final agreed version will then be submitted to the SACBC meeting in May.
 - Following approval at SACBC the final version will be posted on the JPAC website.
- LL
- LL wanted to thank all the members of the SLWG who had done a tremendous amount of work on this project. SM and JPAC also added their thanks to LL and the group for this excellent piece of work.
- After discussion it was also agreed that a similar exercise for tissues maybe advantageous.
- LL left the telecon.
8. **Standing Advisory Committee on Care and Selection of Donors**
- 8.1 **Viral Haemorrhagic Fever – Whole Blood and Components Donor Selection Guidelines – JPAC 20-21**

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

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

9.1 **SaBTO update from the meeting on 31 January 2020 – JPAC 20-22**

GMal went through his SaBTO update for JPAC. The main items from the January meeting were:

- **Occult Hepatitis B working group**
The group intends to complete its work within one year and conduct a wider stakeholder consultation before recommendations are made.
- **Transfusion Consent working group**
- **Risk Tolerability Working Group**
- **FAIR (For the Assessment of Individualised Risk)**
The FAIR group is a UK forum funded collaboration between PHE and the University of Nottingham.
- **HEV**

The provisional date of the next SaBTO meeting is Tuesday 19 May 2020.

10. **UK Forum**

10.1 **Feedback from the UK Forum meeting on 13 December 2019**

SM gave a verbal report from this meeting.

11. **Europe**

11.1 **CD-P-TS meeting report from 13-14 November 2019 – JPAC 20-23**

SM had submitted this paper for information. Production of the Guide is going forward.

11.2 **Transpose**

SM informed JPAC that Transpose is an EU funded project looking at safety of donors/the risk to donors for each donor selection criteria.

11.3 **Tissues and Cells**

AC will report back on the European Tissues and Cells guide at the next JPAC meeting in June.

AC

12. **Draft JPAC Work Plans**

12.1 **Draft JPAC Work Plan April 2019 to March 2020 – JPAC 2024(a)**

SM asked the SAC Chairs to review their sections and send any comments/ amendments to CJS.

ALL

12.2. **Draft JPAC Work Plan April 2020 to March 2021 – JPAC 2024(b)**

ACTION

SM asked the SAC Chairs to review their sections and send any comments/amendments to CJS.

ALL

13. Coronavirus - update

13.1 JPAC have issued a number of Change Notifications since the outbreak of COVID-19. All updated JPAC on relevant recent issues in their areas.

14. Infected Blood Inquiry - update

14.1 JPAC currently have no outstanding actions and we are awaiting instructions for next steps, if any. SM and CJS are still joining the monthly IBI telecons.

SM noted that she had attended one of the Expert Witness hearings at the Inquiry and all the reports are available on the IBI website.

15. Any Other Business

None.

16. Date & venue for future JPAC meetings

2020

- Thursday 25 June - Telecon
- Thursday 05 November - Scottish National Blood Transfusion Service, Edinburgh

2021

- Thursday 11 March - TBC
- Thursday 01 July - TBC
- Thursday 04 November - TBC

The meeting closed at: 14:56