

Joint UKBTS Professional Advisory Committee

Minutes of the 73rd meeting held in the Portex Room At the Association of Anaesthetists, 21 Portland Place, London, W1B 1PY on Thursday 27 June 2019

Meeting commenced at: 11:04

Present

Dr Stuart Blackmore	(SB)	- Deputising for Dr Janet Birchall, Medical Director, Welsh Blood Service
Dr Akila Chandrasekar	(AC)	- Standing Advisory Committee on Tissues and Cellular Therapy Products
Dr Stephen Field	(SF)	- Medical Director, Irish Blood Transfusion Service
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	(GMaI)	- Scientific Lead Safety Policy (JPAC/SaBTO)
Dr Edwin Massey	(EM)	- Standing Advisory Committee on Immuno-haematology and Deputising for Dr Gail Mifflin, 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
Dr Megan Rowley	(MR)	- Standing Advisory Committee on Clinical Transfusion Medicine and Deputising for Prof Marc Turner, Medical Director, Scottish National Blood Transfusion Service
Miss Caroline Smith	(CJS)	- JPAC Manager (Minute taker)
Dr Anna Vossenkaemper	(AV)	- Human Tissue Authority (HTA)
Dr Angus Wells	(AW)	- Standing Advisory Committee on Care and Selection of Donors – Dialled in

SM welcomed Dr Anna Vossenkaemper to her first JPAC meeting. Anna has taken over from Dr Amy Thomas as the representative on JPAC for the HTA. SM also welcomed back Dr Stuart Blackmore, who is deputising for Dr Janet Birchall, Medical Director of the WBS, at this meeting and informed the group that EM is deputising for GM for NHSBT and MR is deputising for MT for SNBTS.

ACTION

1. Apologies

Dr Neil Almond	(NA)	- National Institute for Biological Standards and Control
Dr Janet Birchall	(JB)	- Medical Director, Welsh Blood Service
Dr Rebecca Cardigan	(RC)	- Deputy Professional Director of JPAC

ACTION

Prof John Forsythe	(JF)	- Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Mrs Linda Lodge	(LL)	- Standing Advisory Committee on Information Technology
Dr Gail Mifflin	(GM)	- Medical Director, NHS Blood and Transplant
Dr Kieran Morris	(KM)	- Medical Director, Northern Ireland Blood Transfusion Service
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 14 March - JPAC 19-36

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

3. Matters arising not on the agenda (review of the actions list) JPAC 19-37

3.1 Risk Assessment – Variant CJD (vCJD) – version 5 – JPAC 18-84 – item 3.3

This risk assessment has still not been published. It was agreed that this should be taken off the actions list and that GMal will keep JPAC informed

3.2 A review of UK blood services patient safety related decisions since 2009 – JPAC 18-94 – item 3.4

GMal informed the committee that this had been rolled into the SaBTO risk tolerability review and therefore there was no further action required by JPAC.

3.3 Proposal to change the composition and remit of the SAC on Clinical Transfusion Medicine – JPAC 18-105 – item 3.7

MR and CJS are in the process of setting up this group.

MR & CJS

3.4 Trial component specifications – JPAC 19-07a and JPAC 19-07b – item 4.3

SM had sent the paper to the GAPP working party for information and RC had put the table into Chapter 8.

3.5 A road map for the UK Blood Services to manage a hepatitis A outbreak – item 6.

LJ is still waiting for comments from WBS and NIBTS. SM will chase this up and LJ will bring the final version to the next JPAC meeting in November.

SM & LJ

3.6 Infected blood Inquiry papers

This had been discussed at JPAC EWG and it was agreed that all final SAC minutes and papers submitted to JPAC should be archived.

4. Standing Advisory Committee on Transfusion Transmitted Infections

4.1

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

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

AW

SM asked AW to review the recommendations for this infection in the Donor Selection Guidelines.

4.2 Ebola Virus Risk Assessment- version 1 – JPAC 19-39

SM thanked SACCTI for this very good paper. SF will pass on JPACs thanks to the author Dr Niamh O'Flaherty.

JPAC approved the recommendation that there should be a change to the donor selection guidelines. Potential donors who have had sexual contact with EVD survivors should be deferred indefinitely (currently 6 months) as this is the route of transmission with the longest interval after recovery. This is already the guidance for tissues and cells due to the persistence of the virus in privileged sites, however with the existence of asymptomatic infections and persistence of the virus long-term in semen it is recommended that this deferral is also extended to blood donors.

SM asked AW to take this to SACCSO for review and produce a change notification.

AW

4.3 Usutu Virus Risk Assessment – version 2 – JPAC 19-40

JPAC endorsed the recommendation that no specific measures are needed for USUV infection in potential blood donors in view of the lack of evidence of transfusion-transmitted infection and few reports of human infection associated with clinical symptoms.

Situation to be kept under review through SACCTI Horizon Scanning process.

4.4 Chikungunya Virus Position Statement – JPAC 19-41

JPAC approved this updated Position Statement for publication on the JPAC website.

Post Meeting Note: This updated position statement was posted in the Document Library on the JPAC website on 02 July 2019.

4.5 Emerging Infections Position Statement – JPAC 19-42

JPAC approved this updated Position Statement for publication on the JPAC website.

Post Meeting Note: This updated position statement was posted in the Document Library on the JPAC website on 02 July 2019.

4.6 Guidance for addition and removal of an infectious disease risk entry – version 2 – JPAC 19-43

JPAC asked that information about the ABO risk assessment be added. With this addition the position statement will be posted in the document library on the JPAC website.

Post Meeting Note: This updated position statement was posted in the Document Library on the JPAC website on 02 July 2019.

ACTION**4.7 Position Statement: The estimated residual risk that a donation made in the infectious window period is not detected on testing: risks specific for HBV, HCV and HIV in the UK, 2016-2018 – JPAC 19-44**

It was agreed that an explanation with regard to the increase in HBV residual risk should be added for clarity. SM asked LJ to discuss this further with Katy Davison. After this addition CJS will circulate the paper to JPAC for approval and then publication on the website.

Post Meeting Note: An updated version of this paper was recirculated to JPAC, approved and posted on the JPAC website in the Document Library.

5. Standing Advisory Committee on Tissues and Cellular Therapy Products**5.1 Advanced Therapy Medicinal Products (ATMPs) Red Book Entry – JPAC 19-45**

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

CJS will circulate the updated version of the paper, received yesterday, to JPAC members.

Post Meeting Note: JPAC 19-45 updated was circulated to JPAC on 02 July 2019.

6. Standing Advisory Committee on Care and Selection of Donors**6.1 USA - removal of Zika Virus risk – JPAC 19-46**

The number of cases of Zika transmission in the USA fell in 2017. There were no cases of local transmission in 2018 and to date none have been reported in 2019. Therefore, JPAC approved the removal of Zika Virus in Florida from the USA entry. A Change Notification will be issued.

Post Meeting Note: Change Notification No 25 issued and live on the JPAC website on 12 September 2019

6.2 Oman - new Dengue Virus risk – JPAC 19-47

Horizon scanning has identified a new Tropical Virus risk of Dengue in Oman. Cases reported in 2018 have been within the Muscat Governate (region).

Therefore, JPAC approved the addition of Dengue Virus in the Muscat and surrounding region to the Tropical Virus Risk for Oman. A Change Notification will be issued.

Post Meeting Note: Change Notification No 24 issued and live on the JPAC website on 12 September 2019

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

Following a pilot study, it is proposed to change the structure of the malaria sections in the GDRI.

- AW will send information on the study to AC for SACTCTP members to circulate to their staff to trial and she will feed back to AW. AW will update JPAC on progress in November. **ACTION AW & AC**
- CJS will have talks with Target about redrafting the page on the website. This format could also be used for Change Notifications. **CJS**
- 6.4 Palpitations and Arrhythmias – JPAC 19-49**
- JPAC approved the addition of a separate entry for “Palpitations” and the updating of the Arrhythmia entry. Change Notifications will be issued.
- Post Meeting Note: Change Notification No 27 issued and live on the JPAC website on 12 September 2019*
- 6.5 Familial Pseudohyperkalaemia – JPAC 19-50**
- At the last JPAC meeting in March it was agreed that donations from donors already identified with the FP variant will be excluded from the blood supply of red cells for large volume neonatal and infant transfusions and a new entry had been prepared.
- JPAC approved the addition of a new Entry “Familial Pseudohyperkalaemia” to the Whole Blood DSG and a Change Notification will be issued.
- Post Meeting Note: Change Notification No 26 issued and live on the JPAC website on 12 September 2019*
- 7. Standing Advisory Committee on Blood Components**
- 7.1 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**
- JPAC approved this paper and the proposed change to Chapter 7 of the Red Book. **SM & CJS**
- 7.2 Fresh Frozen Plasma, Leucocyte Depleted Factor VIII specification – JPAC 19-57**
- JPAC noted the amount of work which had gone into this paper by Simon Procter. Fresh Frozen Plasma, Leucocyte Depleted Factor VIII was approved as a new specification and would be added to Chapter 9 of the Red Book. **SM & CJS**
- A Change Notification will be issued. **HN**
- 7.3 X-ray irradiation of blood components – JPAC 19-58**
- JPAC noted the small differences in this study compared to previous studies using x-ray irradiation, although the components studied remained within specification.. HN informed the committee that full validation reports were available on request.
- JPAC endorsed this paper.
- 8. Dr Gary Mallinson – Scientific Lead – Safety Policy (JPAC/SaBTO)**
- 8.1 SaBTO Review – JPAC 19-52**
- GMal went through this update for JPAC. The main items were:

- Paediatric components working group
- Risk tolerability working group

The next SaBTO meeting is on 27 September in London.

9. **UK Forum**

9.1 **Feedback from the UK Forum meetings on 15 March and 14 June 2019 – JPAC 19-53**

and

European Medicines Agency – CHMP position statement on CJD and plasma-derived and urine-derived medicinal products – JPAC 19-53a

SM went through the update for the group, reporting on:

- Infected Blood Inquiry
- Deputy Chair of JPAC
- 20th edition of the Council of Europe Blood Guide

The UK Forum had asked SM to co-ordinate a response from the UK Blood Services, through JPAC, to the European Medicines Agency CHMP position statement on CJD and plasma-derived and urine-derived medicinal products (JPAC 19-53a - attached). The deadline for comments is **October 2019**.

SM asked SAC Chairs to circulate JPAC 19-53a to their members and we will collate comments for the UK Forum.

Post Meeting Note: Joint response from the UK Blood Services (NHS Blood and Transplant, Scottish National Blood Transfusion Service, Welsh Blood Service and Northern Ireland blood Transfusion Service) to the European Medicines Agency CHMP position statement on Creutzfeldt-Jakob disease and plasma-derived and urine-derived medicinal products, Revision 3 (EMA/CHMP/BWP/303353/2010 Rev 3) submitted on 30 October 2019.

10. **Joint Action “Facilitating the Authorisation of Preparation Processes for blood, tissues and cells (GAPP)” – JPAC 19-59**

- 10.1 DO went through his update for JPAC. SM noted that Chapter 8 of the Red Book has been very useful in this project.

11. **Infected Blood Inquiry - update**

- 11.1 SM & CJS updated the committee on recent requests and actions by JPAC in regard to the Inquiry. JPAC currently have no outstanding actions and we are awaiting instructions for next steps, if any.

12. **Deputy Chair of JPAC – Verbal update**

- 12.1 3 applications have been received for this post. Interviews will take place in July.

13. **Any Other Business**

- 13.1 LJ asked CJS to remove “Draft” from the SACTTI minutes.

Post Meeting Note: "Draft" has been removed from the minutes in the JPAC archive.

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

2019

- Thursday 07 November - The Association of Anaesthetists, London

2020

- Thursday 12 March - West End Donor Centre, London
- Thursday 25 June - West End Donor Centre, London
- Thursday 05 November - Venue tbc

The meeting closed at: 14:35