

Joint UKBTS Professional Advisory Committee

Minutes of the 78th JPAC Meeting Zoom meeting held on Thursday 11 March 2021 – 10:00 to 12:30

Meeting commenced at: 10:00

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 Stephen Field	(SF)	- Medical Director, Irish Blood Transfusion Service
Dr Jayne Hughes	(JH)	- Acting Chair of the Standing Advisory Committee on Care and Selection of Donors
Dr Lisa Jarvis	(LJ)	- Standing Advisory Committee on Transfusion Transmitted Infections
Mrs Linda Lodge	(LL)	- Standing Advisory Committee on Information Technology
Mrs Angela Macauley	(AM)	- Quality Manager, Northern Ireland Blood Transfusion Service representing the Quality Managers of the 4 UK Blood Services <i>and Deputising for Medical Director</i>
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 and <i>Deputising for Dr Gail Mifflin</i>
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 <i>Deputising for Prof Marc Turner</i>
Dr Amy Shackell	(AS)	- Human Tissue Authority (HTA)
Miss Caroline Smith	(CJS)	- JPAC Manager (Minute taker)
Dr Stephen Thomas	(ST)	- Deputy Professional Director of JPAC
Prof Marc Turner	(MT)	- Medical Director, Scottish National Blood Transfusion Service
Dr Angus Wells	(AW)	- Standing Advisory Committee on Care and Selection of Donors

GM had asked Dr David Hicks, Interim Medical Director Transfusion NHSBT, to attend this JPAC meeting as an observer but unfortunately he has now had to give his apologies.

SM welcomed Angus Wells back to JPAC. Angus will be presenting item 6.5 Changes required to donor selection guidelines for implementation of the FAIR study.

1.

Apologies

ACTION

ACTION

Prof John Forsythe	(JF)	- Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Dr Gail Mifflin	(GM)	- Medical Director, NHS Blood and Transplant
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 05 November 2020 - JPAC 21-02**

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

3. **Matters arising not on the agenda (review of the actions list)
JPAC 21-03**

3.1 **Borrelia Burgdorferi (Lyme Disease) Risk Assessment - version 4 – JPAC 19-38 – item 3.1**

There is no specific entry in the DSG for *Borrelia Burgdorferi*. Therefore, a way forward was proposed by SACSD, that the information could be added to a new appendix in the DSG. which specifies recall information for a range of infections. SACSD have drafted a document based on existing NHSBT procedures for management of post-donation information which has been circulated to SACTTI. However, although the information pertaining to *Borrelia Burgdorferi* has been approved by SACTTI, SACTTI did not feel that they could approve the document as a whole without a significant review process as it had not been produced by SACCTI in the first instance.

Action: JH, AW and LJ to discuss how to take this forward.

JH, AW &
LJ

3.2 **Advanced Therapy Medicinal Products (ATMPs) Red Book Entry – JPAC 19-45 – item 3.2**

It was agreed that this item should be removed from the agenda.

3.3 **Assessing Malarial Residency - Proposed change to the Geographical Disease Risk Index – JPAC 19-48 – item 3.3**

SACSD is working on a rewrite for Malaria in the GDRI. This is a large piece of work. In progress.

JH & AW

3.4 **Horizon Scanning Process Management Description – JPAC 20-15(c) – item 3.11**

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 will bring to the next JPAC meeting in July. It was also noted that this would be of interest to SaBTO.

GMal

3.5 **UK Component Code Standardisation – JPAC 20-45 – item 3.12**

LL will put together a process for updating the document and bring this back to JPAC.

LL

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

4.1 **Chikungunya Virus Risk Assessment – version 9 – JPAC 21-04**

JPAC endorsed the recommendation to continue travel-associated deferral for donors who have visited CHIKV affected areas within the previous 28 days. Note that CHKV outbreaks in Europe are likely to occur more frequently.

4.2 **SARS-CoV-2/COVID-19 Risk Assessment – version 2 – JPAC 21-05**

JPAC endorsed the recommendation to maintain donor deferral period for SARS-CoV-2 infection at 28 days, but requested that this risk assessment be reviewed with regard to the terminology used, aligning it with the position statement.

LJ will make the changes suggested and this document will be recirculated to JPAC for approval.

Post Meeting Note: JPAC 21-05 Amended was circulated to JPAC on 15-03-2021.

4.3 **SARS-CoV-2/COVID-19 Position Statement and the safety of substances of human origin (SoHO) – January 2021 – JPAC 21-06**

JPAC approved the SACTTI recommendation that we retain the 7day deferral period after vaccination.

This updated version will be posted in the Document Library on the JPAC website.

Post Meeting Note: Posted on the website on 23-03-2021.

4.4 **Update to Chapter 9 (sections 9.5 – 9.9) of the Red Book: Recommended standards for the reduction of bacterial contamination of blood components – JPAC 21-07**

AM raised concerns over the wording of section 9.7.1: Key elements of an E M programme and asked if this applies to all environments. LJ will discuss this further with the lead author for SACTTI, Carl McDonald.

Once this has been clarified JPAC approved its addition to the 9th Edition of the Red Book. LJ

CJS will send LJ Word versions of the SACTTI chapters currently in pre-publish.

Post Meeting Note: Word versions of chapters 9 and 10 sent to LJ 16 March 2021.

4.5 **SACTTI Horizon Scanning Annual Report 2020 – JPAC 21-08a and 21-08b**

SM thanked LJ and SACTTI for this large piece of work and asked GMal to send this report to the next SaBTO on behalf of JPAC.

Post Meeting Note: This was submitted to the SaBTO meeting on 29 March 2021.

Link to the minutes which have been published. The JPAC report is item 13.

<https://app.box.com/s/m6or0zdsph90u6kg3r9/file/814539439945>

5. **Plasma for Fractionation**

ACTION

SM informed JPAC that it has been agreed that the UK can fractionate plasma for production of immunoglobulins and therefore JPAC has put together a small working group to look at what is required.

5.1 SACBC: Draft Red Book Chapter 7 specification for Plasma for Fractionation – JPAC 21-09

HN went through this paper for JPAC.

After discussion it was agreed that this is a good start and work in progress which is not ready to be posted anywhere at this time.

It was questioned whether there is a requirement for red cell antibody screening of this plasma (re Table 12.1 in the Red Book). There was a further question on testing for anti-A and –B.

Post Meeting Note 1: It is noted that neither of these appear in either the EU Pharmacopoeia Monograph or the previous Red Book chapter on plasma for fractionation.

Post Meeting Note 2: Following discussion after the meeting, a 'Provisional Specification' will be proposed in order to allow time for further information to be obtained to specify shelf-life. Action HN.

HN

5.2 SACCSO: Changes to the Whole Blood and Components Donor Selection Guidelines and the Red Book to support plasma collection – JPAC 21-10

JH went through this paper for JPAC. SACCSO has put together a small sub-group to look at donor care and safety.

SM thanked JH for this very good piece of work and noted that the increase in maximum components (plasma and/or platelets) donation frequency from 24 to 26 donations per annum makes managing this limit easier operationally.

The SACCSO sub-group are now looking at donor selection.

Change notifications will be issued.

Post Meeting Note: Change Notifications Nos 15 and 18 went live on 06 July 2021.

5.3 SACCTI: Red Book Chapter 9.3 Specific Screening Targets update – JPAC 21-11

LJ went through this paper for JPAC.

NA asked about the availability of reference materials. NA and ST will discuss

NA & ST

JPAC approved this change in the Red Book and a change notification will be issued.

LJ

5.4 SACIT: Plasma for Fractionation Considerations – JPAC 21-12

LL went through her paper to consider the changes suggested and discuss the options.

SACIT have suggested that they write the changes in such a way that it leaves the decision regarding the data transport method up to the individual service and supplier. For example the data items relevant to the component for fractionation may be conveyed by label, electronic file or RFID or a mixture there of.

It was noted by JPAC that there are a lot of unknowns here as different suppliers and different blood services will have their own requirements. It was agreed that it would be preferable to work towards commonality if possible and that changes to chapter 23 will need to incorporate minimum requirements.

LL will progress this for JPAC.

LL

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

JH presented items 6.1 to 6.4.

6.1 **Geographical Disease Risk Index: Malaria Review – version 1 – JPAC 21-13**

JPAC approved the changes and that change notifications should be issued.

Post Meeting Note: Change Notification No 10 issued on 19 May 2021.

6.2 **Coronavirus Infection entry - Whole Blood and Components Donor Selection Guidelines – JPAC 21-14**

JPAC approved reducing the time travellers who require to quarantine from a 14-day deferral to a 10-day deferral, in line with the current UK Government quarantine rules. A change notification will be issued.

Post Meeting Note: Change Notification No 6 issued on 19 May 2021.

6.3 **Diabetes Mellitus entry - Whole Blood and Components Donor Selection Guidelines- JPAC 21-15**

JPAC approved the addition of information on impact of donation on interpretation of HbA1c (glycated haemoglobin) levels in donors with diabetes and a change notification will be issued.

Post Meeting Note: Change Notification No 7 issued on 19 May 2021.

6.4 **Hypercholesterolaemia entry – Whole Blood and Components Donor Selection Guidelines – JPAC 21-16**

SM thanked Dr Jill Clarkson and JH for their work on this. JPAC approved the proposed changes and a change notification will be issued.

Post Meeting Note: Change Notification No 8 issued on 19 May 2021.

6.5 **Whole Blood and Components Donor Selection Guideline changes required for implementation of the FAIR study – JPAC 21-17**

This item was presented by AW.

The main change is in the Blood Safety Leaflet and these changes were approved. Minor changes to other entries were also approved.

The go-live date for the FAIR changes is planned for June but it is recognised that Services will need to put training in place prior to that, therefore change notifications will need to be distributed early.

SF left the meeting 11:59.

A question was raised about the FAIR recommendation on partners who are on anti-retroviral therapy. This has not yet been discussed at SACTTI and it was unclear

	<u>ACTION</u>
<p>whether it had been discussed at SaBTO. It was agreed this would not be taken forward in June with the other changes but will be further discussed at SaBTO and SACTTI and changes can be made with those required when FAIR 2 has been approved.</p>	<p>LJ & GMa</p>
<p>MR asked if FAIR changes should be mentioned in consent for transfusion documentation which is currently being revised. She will discuss with the SaBTO lead on consent.</p>	<p>MR</p>
<p>7. Standing Advisory Committee on Blood Components</p>	
<p>7.1 <u>Extension of Post-thaw Shelf Life of Cryoprecipitate – JPAC 21-18</u></p> <p>This is a provisional component and the main benefit is to reduce waste. JPAC were asked to note that this does not apply to neonatal specification cryoprecipitate as SACBC have not assessed single units.</p> <p>JPAC approved the provisional component specification to allow units to be stored refrigerated following thawing for up to 120 hours so that the logistical benefits can be further assessed in the hospital setting in a small number of sites and a change notification will be issued.</p>	<p>HN</p>
<p>7.2 <u>Validation of Dried Plasma Components - Requirements for the UK Standing Advisory Committee on Blood Components – Confidential – JPAC 21-19</u></p> <p>HN went through this paper. JPAC were happy with the paper in principle, but would await feedback from the MHRA and manufacturers.</p>	<p>HN</p>
<p>7.3 <u>Reactivation of Red Book Annex 5 Contingency Components – JPAC 21-20</u></p> <p>SM thanked Belinda Pelle who had produced this very good piece of work on behalf of SACBC.</p> <p>JPAC approved the recommendation to include additional guidance notes in Annex 5 and a change notification will be issued.</p>	<p>HN</p>
<p>7.4 <u>Proposed revised Red Book Chapter 6, section 6.2, Concessionary Release definition – JPAC 21-21</u></p> <p>JPAC approved this revision to Chapter 6 and the chapter will be updated in Edition 9 of the Red Book.</p>	<p>HN</p>
<p>7.5 <u>Revisions to JPAC General Document on FFP storage temperature deviations whilst in the frozen state – JPAC 21-22</u></p> <p>JPAC approved this updated version of this paper which will be posted in the Document Library on the JPAC website.</p> <p><i>Post Meeting Note: Posted on the JPAC website on 23-03-2021</i></p>	
<p>7.6 <u>Granulocyte Therapy Position Statement – JPAC 21-23</u></p> <p>JPAC approved this updated version of this position statement which will be posted in the Document Library on the JPAC website.</p> <p><i>Post Meeting Note: Posted on the JPAC website on 23-03-2021</i></p>	

ACTION

8. **Standing Advisory Committee on Tissues and Cellular Therapy Products**

8.1 **Arrhythmias entry in the Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines JPAC 21-24**

JPAC approved these changes to the Arrhythmias entry in these donor selection guidelines and a change notification will be issued.

AC

9. **SaBTO**

9.1 **SaBTO report for JPAC – JPAC 21-25**

GMal presented a brief report as there hasn't been a SaBTO meeting since the last JPAC meeting in November. The next meeting of SaBTO is on Monday 29th March 2021.

10. **UK Forum**

10.1 **Feedback from the UK Forum meetings held on 04 December 2020 and 05 March 2021 – JPAC 21-26**

SM went through this feedback paper for JPAC.

Infected Blood Inquiry: MT informed JPAC that JPAC and the UK Forum may receive separate rule 9 letters. (Rule 9 letters are to individuals or organisations asking them to provide relevant material they hold to the Inquiry for analysis.)

11. **European Union**

11.1 **Consultation on changes to the Blood and Tissues Directives**

DO informed JPAC that the MHRA, as a regulator, have been given approval by the Cabinet Office to partake in this consultation as has the HTA. CJS was asked to circulate the links to the consultation to JPAC members.
SM is co-ordinating a response from the UK Blood Services.

Post Meeting Note: Links circulated on 19-03-2021.

12. **Any Other Business**

12.1 **Suggested JPAC meeting dates in 2022**

- Thursday 24 March (*Easter is in mid-April*)
- Thursday 14 July
- Thursday 17 November

SM asked JPAC to note these dates and inform CJS if there are clashes with any other major meetings/conferences etc.

Post Meeting Note: These dates are now confirmed for 2022.

12.2 **Quality Manager representative on JPAC**

ACTION

AM informed JPAC that this will be her last JPAC meeting representing the Quality Managers of the 4 UK Blood Services. Mr Peter Richardson, from the Welsh Blood Service, is taking over and will attend the next JPAC meeting in July. SM thanked AM for her contribution to JPAC over several years.

12.3 Duration of JPAC meetings

It was agreed that future Zoom JPAC meetings will start at 10:00 and finish at 13:00.

12.4 GAPP Project

AC asked if the MHRA were still leading on a work package on the GAPP project. DO informed JPAC that they had completed the first part, but the second part has been taken over by the French.

MR left at 12:55.

13. Date & venue for future JPAC meetings

2021

- Thursday 01 July - Zoom meeting
- Thursday 04 November - Zoom meeting

The meeting closed at: 13:05