Joint UKBTS Professional Advisory Committee

Minutes of the 79th JPAC Meeting
Zoom meeting held on
Thursday 01 July 2021 – 10:00 to 13:00

Meeting commenced at: 10:02

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
Mr Ryan Evans	**(RE)**	-	Standing Advisory Committee on Blood Components - *Deputising for Dr Helen New*
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 *Deputising for the NIBTS Medical Director and Mr Peter Richardson the JPAC Quality Managers Representative 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
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*
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
Dr Angus Wells	**(AW)**	-	Standing Advisory Committee on Care and Selection of Donors

SM welcomed Mr Ryan Evans to this meeting who is deputising for HN Chair of SACBC. It was also noted that MR was deputising for MT and AM is deputising for both JM and Mr Peter Richardson, the new Quality Manager representative on JPAC.

ACTION

1. Apologies

Prof John Forsythe	**(JF)**	-	Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant

ACTION

Mrs Linda Lodge	**(LL)**	-	Standing Advisory Committee on Information Technology
Dr Joanne Murdock	**(JM)**	-	Medical Director, Northern Ireland Blood Transfusion Service
Dr Helen New	**(HN)**	-	Standing Advisory Committee on Blood Components
Mr Peter Richardson	**(PR)**	-	Quality Manager, Welsh Blood 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 11 March 2021 - JPAC 21-29

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

3. Matters arising not on the agenda (review of the actions list) JPAC 21-30

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

AW informed the group that they were going to take the current guidance used by NHSBT to the SACCSD meeting in the Autumn with regard to using this in the Whole Blood and Components Donor Selection Guidelines. This would then come to the next JPAC meeting in November. **AW**

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

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

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

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 is currently working on an update and will discuss further with SM and LJ before circulating to JPAC. **GMal**

SF had to leave the meeting at 10:10.

3.4 UK Component Code Standardisation – JPAC 20-45 – item 3.5

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

ACTION

3.5 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 – item 4.4

AM had raised concerns at NIBTS over the wording of section 9.7.1: Key elements of an E M programme and asked if this applies to all environments.

NIBTS have confirmed that they are now happy with the new wording provided by SACTTI.

3.6 SACTTI: Red Book Chapter 9.3 Specific Screening Targets update - JPAC 21-11 – item 5.3

This has been completed

AC joined the meeting 10:15.

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

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**

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

SaBTO have asked us to look at this to see how feasible it is. AW is looking at it from a donor selection point of view. This is now on the SACCSD work plan and will be discussed at their autumn meeting. **AW**

With regard to consent MR has completed this action and prepared some reactive comments.

3.9 Extension of Post-thaw Shelf Life of Cryoprecipitate – JPAC 21-18 – item 7.1

Post Meeting Note: Change Notification No 43 2021 Cryoprecipitate Pooled, Leucocyte Depleted, Extended Shelf-life Post-thaw – Provisional Components is with the Medical Directors for approval.

3.10 Validation of Dried Plasma Components - Requirements for the UK Standing Advisory Committee on Blood Components – Confidential – JPAC 21-19 – item 7.2

RE informed JPAC that they are still waiting on feedback. SM will discuss actions with HN. **HN & SM**

3.11 Reactivation of Red Book Annex 5 Contingency Components – JPAC 21-20 – item 7.3

Post Meeting Note: Change Notification No 44 2021 Annex 5 is with the Medical Directors for approval.

3.12 Proposed revised Red Book Chapter 6, section 6.2, Concessionary Release definition – JPAC 21-21 – item 7.4

JPAC approved this revision to Chapter 6 and the chapter will be updated in Edition 9 of the Red Book. **HN**

ACTION

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

This change will be put through with the tissues and cells changes agreed at this meeting.
Post Meeting Note: Change Notification No

4. Standing Advisory Committee on Transfusion Transmitted Infections

4.1 Chikungunya Virus Position Statement, May 2021 – JPAC 21-31

The position statement has been updated with the currently available information on chikungunya cases in Europe, and the current worldwide situation in respect of reported cases/outbreaks. There are no changes to the recommendations.

JPAC approved this updated Position Statement which will be posted on the JPAC website.

Post Meeting Note: Updated Position Statement posted on the JPAC website on 07 July 2021.

4.2 Ebola Virus Risk Assessment: Version 2 – JPAC 21-32

With updated links JPAC approved this risk assessment and that no further action was required by JPAC at this time.

4.3 Ebola Virus Position Statement: May 2021 – JPAC 21-33

SACTTI has updated this position statement in line with the Ebola risk assessment. The guidance has been updated to include recommendation of a permanent deferral of sexual contacts of those who have been diagnosed with an Ebola Virus infection. It was noted that his has already been translated into the Donor Selection Guidelines.

JPAC approved the Position Statement with the amendment to bring the wording in line with the risk assessment and that the updated version should be posted on the JPAC Website.

Post Meeting Note: Updated Position Statement posted on the JPAC website on 07 July 2021.

LJ informed JPAC that there had been a short outbreak of Ebola Virus Disease in Guinea between February and June 2021. AW will prepare a change notification to update the GDRI.

Post Meeting Note: Change Notification No 32 was issued on 10 August and the changes were live on the JPAC website on 31 August 2021.

4.4 Usutu Virus (USUV) Risk Assessment: Version 3 – JPAC 21-34

JPAC approved this updated risk assessment with a 2-year review date.

SACTTI asked JPAC to consider the inclusion of a specific Donor Selection Guideline entry for USUV together with inclusion as a risk criterion in the Geographical Disease Risk Index. The deferral to mirror that for other transmissible viruses e.g. WNV, Dengue etc.

ACTION

SM asked AW to discuss this at the next SACCSD meeting in the autumn and LJ to put together a list of countries where USUV is present. **AW & LJ**

LJ will also ask the EDI Monitoring Group whether any other countries are deferring for USUV. **LJ**

4.5 Yellow Fever: SACTTI Review: Version 2 May 2021 – JPAC 21-35

LJ went through this SACTTI review of Yellow Fever for the group.

There is no specific entry in the Donor Selection Guidelines for Yellow Fever. At present Yellow Fever in the A-Z index links to the "Acute Infection" entry.

AW had submitted papers JPAC 21-43 Dengue Virus and JPAC 21-58 regarding a possible new format for GDRI entries and SACCSD are currently in the process of rewriting the malaria entries. He suggested that they could add Yellow Fever to this work. **AW**

With regard to JPAC 21-58, JPAC were in favour of SACCSD taking this forward and including Yellow Fever in that process. **AW**

5. Standing Advisory Committee on Blood Components

5.1 Update on transfusion administration set wording for the Red Book – JPAC 21-36

Ryan Evans went through this paper for the group. It was noted that the UK is moving away from CE marking and that it will be replaced by a new UK system from 01 July 2023.

NA will contact colleagues within MHRA Devices and ask them to supply a form of words to use.

Post Meeting Note: Information received from MHRA Devices:

1) *They have provided a link to this page on the Gov.uk website https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk*

2) *The comment by Devices colleagues is that the onus for UKCA marking is on the manufacturer to register their device. However, the risk to the Blood Services will be if companies decide not to do this for key pieces of equipment in current use. It should also be noted that different rules apply to NI. This is something that SACBC will need to monitor on the next 2 years before the current rules come fully into force.*

EM will circulate the information to BSH. **EM**

It was agreed that the wording will be changed as requested and this will be reviewed if / when appropriate. **RE**

5.2 Risk of up-classification of blood bags for whole blood collection – JPAC 21-37

JPAC endorsed the recommendation that whole blood collection systems should remain classified as class IIb Medical Devices. SM asked RE to inform JPAC if there are further developments – we should be prepared to respond to consultations as and when they occur. **RE**

ACTION

Post Meeting Note: DO - I am advised by device colleagues that the reclassification is an EU problem that the UK have limited (i.e. zero) scope to influence but that UK regs won't be changing so it limits the problem for us for now. This is very recent so nothing else to report at this stage.

5.3 Component code approval process and managing variations in label text – JPAC 21-38

RE went through this paper for the group.

JPAC approved the proposed changes to the wording of the guidance documents as highlighted in the paper and the updated version will be posted on the JPAC website.

5.4 Chapter 7 Red Book: Draft Plasma for fractionation, leucocyte depleted – JPAC 21-56

ST went through this paper for the group.

As UK plasma may now be used for fractionation to manufacture immunoglobulins for use in the UK the Red Book needs to include a component specification and a section on evaluation.

It was noted that in this specification that leucocyte count per litre was used and it should be single unit equivalent. Other changes to some wording were suggested. ST responded to a query as to why there are different cooling criteria for apheresis and recovered plasma – this aligns with the pharmacopeia.

EM asked if members understood the modelling assumptions that support leucodepletion at collection in addition to the effective leucodepletion processes which occur at a later stage in manufacture of pooled blood products?

ST will make the changes and then we can incorporate into Chapter 7 of the Red Book. **ST**

5.5 Chapter 8 Red Book: Evaluation of plasma for fractionation for the manufacture of immunoglobulin – JPAC 21-57

ST went through this paper for the group. There are a couple of updates discovered after circulation of the paper. Following making these changes this will be incorporated into Chapter 8 of the Red Book. **ST**

6. Standing Advisory Committee on Care and Selection of Donors

6.1 Removal of convalescent plasma recipient derogation – Whole Blood and Components Donor Selection Guidelines: Coronavirus Infection, Clinical Trials & Transfusion – JPAC 21-39

SaBTO have withdrawn the temporary derogation to allow individuals who have received SARS-CoV-2 convalescent plasma to donate convalescent plasma themselves. The derogation is not required as the UK blood services are not collecting CP at this time.

JPAC approved the removal of the derogation from the Donor Selection Guidelines. A change notification will be issued. **AW & CJS**

ACTION

Post Meeting Note: Change Notification No 38 has been prepared but further changes are required and the revised CN will be presented at the next JPAC meeting on 04/11/2021. If approved, this change will be implemented before the end of the year.

6.2 Kidney and Bladder Disease – Whole Blood and Components Donor Selection Guidelines – JPAC 21-40

JPAC approved these changes to improve the information in the Whole Blood and Components DSG entry for Kidney and Bladder Disease and the A-Z Index.

SM requested that the spelling of 'catheterization' be changed to 'catheterisation'. This was agreed and will be included in the change.

A change notification will be issued. **AW & CJS**

Post Meeting Note: Spina bifida has also been included in the change. Change Notification No 39 in progress.

6.3 Non-Contagious Diseases – Contact with – Whole Blood and Components Donor Selection Guidelines – JPAC 21-41

JPAC approved this revision of the Non-Contagious Diseases entry to ensure appropriate deferral of individuals being monitored for any potential zoonotic infection and a change notification will be issued. **AW & CJS**

Post Meeting Note: Change Notification No 41 in progress

6.4 Trying to Conceive – Whole Blood and Components Donor Selection Guidelines – JPAC 21-42

This had initially been identified by SACTCTP (see item 7.6). JPAC endorsed the recommendation to also make the relevant changes to the Whole Blood and Components Donor Selection Guidelines. A change notification will be issued. **AW & CJS**

Post Meeting Note: Change Notification No 42 in progress.

6.5 New Dengue risks to include within the Geographical Disease Risk Index – JPAC 21-43

10 Countries have been identified that require a Dengue Virus risk to be added to their listing in the Geographical Disease Risk Index.

JPAC approved these additions and a change notification will be issued.

Post Meeting Note: Change Notification No 33 issued on 10 August and the changes were live on the JPAC website on 31 August 2021.

7. Standing Advisory Committee on Tissues and Cellular Therapy Products

7.1 Acne & Teratogenic medications in Tissue and Stem Cell donors – all Tissue and Cell Donor Selection Guidelines – JPAC 21-44 and JPAC 21-44B

SM wanted to congratulated Dr Sharon Zahra on this very thorough paper. JPAC endorsed the proposal for implementation as a change notification. AC will draft the change and send to CJS.

ACTION

Post Meeting Note: Change Notification No 19 issued on 04 August and live on the JPAC website on 12 August 2021.

7.2 Coronavirus Infection entry in the BM & PBSC Donor Selection Guidelines – JPAC 21-45

It was noted that the UK Government guidance had been changed to a 10-day quarantine period since this topic was last updated and that the DSGs still have a 14-day deferral.

SM asked AW to refer this back to SACCSD & LJ to look at the current ECDC guidance. **AW & LJ**

With the proviso that the deferral period above has been reviewed and agreed, JPAC endorsed the recommendation to change the deferral period for donors with confirmed or suspected coronavirus infection and contact with confirmed or suspected infection. Refinement of the definitions for 'confirmed infection,' and 'recovery from coronavirus symptoms' (to include 'long COVID'). Guidance relating to travel related quarantine added and additional information section updated.

Post Meeting Note: Change Notification No 21 issued on 04 August and live on the JPAC website on 12 August 2021.

Post Meeting Note: AW is preparing a Change Notification for the WBDSG

7.3 Coronavirus Infection entries in the Deceased, Living and Cord Blood Donor Selection Guidelines – JPAC 21-46

JPAC also endorsed these changes with the same proviso as above.

Post Meeting Note: Change Notification No 22 issued on 04 August and live on the JPAC website on 12 August 2021.

7.4 Coronavirus Vaccination entries in the Deceased and Living Donor Selection Guidelines – JPAC 21-47

This entry currently includes a precautionary 7-day post vaccination deferral for all donors, in the Tissue and Cell DSGs. It is proposed that this is not necessary for tissue donors, where the health of the donor is not a factor.

It was noted that the wording in the change states that the vaccines have been "licensed" in the UK, but that it should be "authorised". DO will send AC the appropriate wording to be used in the notification.

Post Meeting Note: Suggested wording - Currently the COVID-19 vaccines used in the UK are either Temporarily Authorised under Regulation 174 of the Human Medicines Regulations 2012 or will have a Conditional Marketing Authorisation.

With this amendment JPAC approved this change and a change notification will be issued.

Post Meeting Note: Change Notification No 23 issued on 04 August and live on the JPAC website on 12 August 2021.

7.5 Immune Thrombocytopenia, Immunoglobulin Therapy and Transfusion entries in the Living Tissue Donor Selection Guidelines – JPAC 21-48

ACTION

JPAC approved the change to permit donation from donors who have received intravenous Immunoglobulin after 1st January 1999, if the reason for treatment is not a contraindication. A change notification will be issued.

Post Meeting Note: Change Notification No 25 issued on 04 August and live on the JPAC website on 12 August 2021.

7.6 Infertility entries in the Deceased, Living and Cord Blood Donor Selection Guidelines – JPAC 21-49

JPAC endorsed the SACTCTP recommendation that the deferral of donors who have received a donated egg or embryo since 1980 is not required in alignment with the SaBTO guidance: section 12.23.4 of the SaBTO Microbiological Safety Guidelines: "…There is no evidence that donated human eggs can transmit CJD." A change notification will be issued.

Post Meeting Note: Change Notification No 27 issued on 04 August and live on the JPAC website on 12 August 2021.

8. SaBTO

8.1 SaBTO report for JPAC – JPAC 21-50

GMal went through his report for the group.

With regard to the SaBTO Occult Hepatitis B Infection (OBI) review it was noted that it is likely that changes will be required to Chapter 9 of the Red Book. LJ is part of the group looking at this and will take forward any changes required in Red Book through SACTTI. **LJ**

9. UK Forum

9.1 Feedback from the UK Forum meeting held on 18 June 2021 – verbal report

The UK Forum had congratulated JPAC and its SACs for all their hard work over the last year.

10. European Union

10.1 Consultation on changes to the Blood and Tissues Directives

We fed back to the EU and this consultation is now closed. Information on the current status of the revision process can be found here: https://ec.europa.eu/health/blood_tissues_organs/policy/revision_en

11. Any Other Business

11.1 Yellow Fever – Geographical Disease Risk Index JPAC 21-58

Already discussed under item 4.5.

11.2 National Institute for Biological Standards and Control

ACTION

NA informed JPAC that Dr Christian Schneider, Director of the National Institute for Biological Standards and Control, is leaving the agency in the next two weeks and that an Interim Director has been appointed.

12. Date & venue for future JPAC meetings

2021

- Thursday 04 November - Zoom meeting

2022

- Thursday 24 March - Zoom meeting
- Thursday 14 July - Zoom meeting
- Thursday 17 November - Zoom meeting

The meeting closed at: 12:50