Joint UKBTS Professional Advisory Committee

Minutes of the 82nd JPAC Meeting
Teams meeting held on
Thursday 14th July 2022 – 10:00 to 13:00

Meeting commenced at: 10.00

Present

Dr Janet Birchall	**(JB)**	Medical Director, Welsh Blood Service
Dr Helen New	**(HN)**	Standing Advisory Committee on Blood Components
Dr Lisa Jarvis	**(LJ)**	Standing Advisory Committee on Transfusion Transmitted Infections
Ms Anna Witham	**(AnnW)**	Note Taker
Dr Peter Richardson	**(PR)**	Quality Manager, Welsh Blood Service
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 Megan Rowley	**(MR)**	Standing Advisory Committee on Clinical Transfusion Medicine and Interim Medical Director of SNBTS
Dr Amy Shackell	**(AS)**	Human Tissue Authority (HTA)
Dr Stephen Thomas	**(ST)**	Professional Director of JPAC, **Chair**
Dr Jayne Hughes	**(JH)**	Standing Advisory Committee on Care and Selection of Donors – *Deputising for Dr Angus Wells*
Dr Richard Lomas	**(RL)**	Standing Advisory Committee on Tissues and Cellular Therapy Products – *Deputising for Dr Akila Chandrasekar*
Dr Neil Almond	**(NA)**	National Institute for Biological Standards and Control
Dr Tor Hervig	**(TH)**	Medical Director for IBTS
Dr David Olszowka	**(DO)**	Medicine and Healthcare products Regulatory Agency
Dr Vicky Chalker	**(VC)**	NHS Blood and Transplant

ACTION

1. Apologies

Dr Angus Wells	**(AW)**	- Standing Advisory Committee on Care and Selection of Donors
Dr Akila Chandrasekar	**(AC)**	- Standing Advisory Committee on Tissues and Cellular Therapy Products
Prof Maria Zambon	(MZ)	- Director, Centre for Infections, Public Health England (PHE)

ST welcomed Jayne Hughes deputising for Dr Angus Wells and Richard Lomas deputising for Dr Akila Chandrasekar

2. Minutes of the last meeting held on 24 March 2022 - JPAC 22-30

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

ACTION

3. Matters arising not on the agenda (review of the actions list) - JPAC 22-31

3.1 It was mentioned that a discussion had taken place at the previous meeting around the role of JPAC setting guidance for the collection of plasma for the manufacture of pharmaceuticals Historically, there had been a Standing Advisory Committee on Plasma Fractionation but it was felt reinstating this might not be necessary although a task-and-finish group could be convened with representation from across the SACs, to ensure all areas were covered with minimal overlap.

3.2 **Horizon Scanning Process Management Description – JPAC 20-15(c)** **GMal**

Remains open with GMal.

3.3 **Proposed revised Red Book Chapter 6, section 6.2, Concessionary Release definition – JPAC 21-21**

This will be completed in the next release. Closed

3.4 **SACIT: Plasma for Fractionation Considerations – JPAC 21-12**

ST to take forward recruitment of a new Chair of SACIT. **ST**

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

Closed.

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

Closed.

3.7 **Zika Risk Assessment – version 5 – JPAC 21-81**

In progress. AW to check the entry. **AW**

3.8 **Relaxation of travel criteria for plasmapheresis donors – for Information – JPAC 22-14**

In progress, to be discussed at the next SACTTI meeting. **LJ**

3.9 **Pregnancy – JPAC 22-15**

AW

In progress.

3.10 **Update on Donors with HIV positive partners – JPAC 22-17**

ST to discuss with Lisa Jarvis, James Neuberger and Medical Directors. **ST**

3.11 **Validation of Dried Plasma Components – JPAC 22-22**

The website posting of the document approved by JPAC is still awaiting the final go-ahead from RC pending conclusion of commercial discussions with manufacturers. **HN/RC**

EM joined the meeting at 10:18

ACTION

4. Standing Advisory Committee on Tissues and Cellular Therapy Products

4.1 West Nile Virus (WNV) Testing for BM/PBSC Donors – JAPC 22-32

This paper has been reviewed and agreed at SACTTI.

JPAC approved. A non-urgent Change Notification will be issued.

AC to forward the final Change Notification to AnnW to proceed. **AC/AnnW**

4.2 Coronavirus Infection – JPAC 22-33

'Contact with contagious diseases' caused concern previously with regard to the link to the 'infectious disease' entry. This disconnect has now been resolved.

JPAC approved. A non-urgent Change Notification will be issued.

AC to forward the final Change Notification to AnnW to proceed. **AC/AnnW**

4.3 Contact with infectious disease – JPAC 22-34

This paper is to align with the Whole Blood entry.

It was confirmed that COVID-19 is classed as an upper respiratory infection.

JPAC approved. A non-urgent Change Notification will be issued.

AC/AnnW

AC to forward the final Change Notification to AnnW to proceed.

4.4 Red Book – Chapter 19 – JPAC 22-35a,

This is a general review and update which was previously completed and approved by JPAC but not implemented for Chapters 19, 20 and 21 therefore, due to the time lapsed another review has been undertaken.

Changes are not highlighted on the papers as this is considered a re-write.

Chapter 22 will be brought back to a later JPAC meeting after further review.

It was agreed that these are ready for publication.

4.5 Red Book – Chapter 20 – JPAC 22-36

As above

4.6 Red Book – Chapter 21 – JPAC 22-37

As above

4.7 ATMP Signposting Annex – JPAC 22-38

ACTION

It was decided that an annexe to the Red Book would be the best way to signpost references to ATMPs.

Comments had been received from MHRA and HTA, which were discussed and will be taken into account in a further revision

5. Standing Advisory Committee on Care and Selection of Donors

5.1 Coronavirus Infection – JPAC 22-39

Eighteen Change Notifications have been issued since the beginning of the pandemic; more permanent guidance is now required. The guidance has been changed significantly, focusing on confirmed cases/tested positive and also covering Long Covid.

This paper has been circulated to SACTTI.

JPAC approved. A non-urgent but high priority Change Notification will be issued.

AW to forward the final Change Notification to AnnW to proceed. **AW/AnnW**

5.2 Hepatitis of unknown cause – JPAC 22-40

This paper has been updated in line with the recent change to the Hepatitis B guidance.

JPAC approved. A non-urgent but high priority Change Notification will be issued. **AW/AnnW**

AW to forward the final Change Notification to AnnW to proceed.

5.3 Thrombosis and Thrombophilia – JPAC 22-41

The current title for guidance is 'Thrombosis' and the content is fairly sparse therefore this is an update to include additional information for session staff and clarification around early pregnancy loss.

JPAC approved. A non-urgent Change Notification will be issued.

AW/AnnW

AW to forward the final Change Notification to AnnW to proceed.

PR left the meeting at 11.11

5.4 Immunosuppression – JPAC 22-42

This paper was presented for discussion due to the complexity of the topic. In the discussion it was noted that previously guidelines had aimed to mention diseases and not treatments, however in this case there were too many diseases for this approach to be used. **ST**

It was noted that the use of algorithms might be considered to fall under medical device regulation and it would be worthwhile discussing with the MHRA Borderline section. ST to take this forward.

Further work is required on this paper, JPAC agreed that they would like to see this paper again if there is significant change, to be monitored by EWG in the interim.

ACTION

6. Standing Advisory Committee on Transfusion Transmitted Infection

6.1 Borrelia burgdorferi (Lyme disease) risk assessment v5 - JPAC 22-43

There has been no evidence of transmission through blood or tissues, therefore SACTTI to maintain review every three years.

The bacteria strains differ in Europe and the USA. A vaccine was developed but went out of use due to poor sales, however there is some interest in the development of a new vaccine.

Recommending no change and no need for testing, to review again in three years.

Chronic Lyme Disease was queried, LJ agreed to raise this at the next EID Monitor group meeting. **LJ**

JPAC approved. LJ to forward the final to AnnW to upload to the JPAC website. **LJ/AnnW**

6.2 Human herpesvirus 8 (HHV8) - Risk Assessment - JPAC 22-44

This paper was due at the end of the year however SACTTI has moved this forward due to organ donation queries.

There is no evidence of transfusion transmission with no detectable DNA present. However there has been evidence through organ donation. Given that a proportion of organ donors will also be tissue donors the question was raised as to whether all tissues should be tested. SACTTI recommended that this was not needed due to no evidence of transmission.

The risk of HHV8 transmission through haemopoietic stem cell transplant was queried and LJ will check this with her colleagues and update. **LJ**

SACTTI to provide SACTCTP with guidance.

A discussion around the possibility of publishing Risk Assessments onto the JPAC website took place, it was suggested that they be listed and made available on request.

JPAC approved this update.

LJ to forward the final version to AnnW for publication on the JPAC website. **LJ/AnnW**

6.3 Position Statement: Chikungunya Virus; May 2022 - JPAC 22-45

This paper has updated the global situation, where the majority of cases are in India and Brazil. In Europe there have been no local cases just imported.

JPAC approved this update.

LJ to forward the final version to AnnW for publication on the JPAC website. **LJ/AnnW**

Post Meeting Note: This has been uploaded to the JPAC website.

6.4 Position Statement – Ebola Virus (EBOV); May 2022 - JPAC 22-46

ACTION

No major changes within this paper, it has been updated with the most recent outbreaks in Guinea and DRC and a permanent deferral of sexual contact with positive cases.

JPAC approved this update.

LJ to forward the final version to AnnW for publication on the JPAC website.

LJ/AnnW

Post Meeting Note: This has been uploaded to the JPAC website.

6.5 Chapter 9 & 10 Summary of Updates - JPAC 22-47a, b, c

Previously approved by JPAC, minor changes have been added.

These have gone out for gap analysis and comments received.

With a suggested small wording change to 22-47a, JPAC approved.

LJ

LJ to circulate the final versions without tracked changes.

7. Standing Advisory Committee on Blood Components

7.1 Red Cells and Plasma (RC&P), Leucocyte Depleted; provisional specification amendments – JPAC 22-48

This paper is a minor update including an Annex 3 minor wording change.

JPAC approved this update.

HN to forward the final version to AnnW and a Change Notification will be issued. **HN/AnnW**

7.2 EBA position paper: Recommendations for validation of non-DEHP blood components – JPAC 22-49

This paper had been circulated widely before this final version was issued and feedback received from many stakeholders.

Additional gap analysis by SACBC is expected to return few additional comments and if SACBC feel that there are any changes needed to the Red Book, this will be raised with JPAC.

MHRA is content with the approach and the Devices section will provide feedback directly, regarding UKCA and UKNI marking and will also consider whether there is any issue with the movement of blood or components between GB and NI. **HN**

PR re-joined the meeting at 12:25

7.3 Risk assessment of considering all pooled platelets as HT negative – JPAC 22-50

This paper was presented on behalf of SACBC and SACIH, revisited from 2018.

This paper isn't a recommendation for change but for JPAC review.

An in-depth discussion took place regarding this paper, it was agreed that the evidence was not yet sufficient to propose any changes to guidance. It was noted that international practice differed (in general being less risk averse) and further intelligence was being gathered. It was agreed that further discussion could take place offline, prior to possible presentation at a future JPAC meeting. **HN**

ACTION

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EM left the meeting at 13:09

8. SaBTO

GMal provided an update on the SaBTO risk tolerability group meeting earlier in July. The group agreed that the NICE framework on cost effectiveness was the most suitable framework for SaBTO work. NICE has cost modifiers which allow the boundaries of cost effectiveness to be raised in certain circumstances. The group will work with DHSC analysts and external experts in Health Economics to establish how additional risk factors concerning the safety of transfusion and transplantation might be applied as risk modifiers to cost effectiveness boundaries. A paper will go to the next SaBTO meeting.

10. UK Forum

Feedback from UK Forum meeting held on 17 June 2022, report included within the papers.

The position of JPAC Manager has been offered, not expected to be in post by the next JPAC meeting but hopefully by October 2022.

11. European Union

The new EU SoHO regulations have now been published for comment.

It is expected that work will now move quickly within the EBA EU Directives Working Group. ST is a member of this group and will keep JPAC updated.

ST is currently working on a UK Plasma for Fractionation paper and is hoping to get this in the public domain within the next few months.

RL advised of a new EU project called Egalite, which is scheduled to run for around 30 months, the link to website is: https://www.egalite-europe.eu/

12. JPAC Work Plan 2022

This document is tabled for information.

ST will discuss updates offline with relevant chairs.

13. Any Other Business

None raised.

14. Date & Venue for future JPAC Meetings

2022

- Thursday 17 November - Teams Meeting

ACTION

2023

- Thursday 09 March - Teams Meeting
- Thursday 29 June - Teams Meeting
- Thursday 02 November - Teams Meeting

The meeting closed at: 13:18