

Joint UKBTS Professional Advisory Committee

**Minutes of the 69th meeting held in the Boardroom
at the West End Donor Centre, 26 Margaret Street, London, W1W 8NB
on Thursday 08 March 2018**

Meeting commenced at: 11:00

Present

Dr Neil Almond	(NA)	- National Institute for Biological Standards and Control (<i>also deputising for Dr Christian Schneider</i>)
Dr Janet Birchall	(JB)	- Medical Director, Welsh Blood Service
Dr Rebecca Cardigan	(RC)	- Deputy Professional Director of JPAC
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 Linda Lodge	(LL)	- Standing Advisory Committee on Information Technology
Dr Sheila MacLennan	(SM)	- Professional Director of JPAC
Dr Gary Mallinson	(GMal)	- Scientific Lead Safety Policy (JPAC/SaBTO)
Dr Gail Miflin	(GM)	- 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
Miss Caroline Smith	(CJS)	- JPAC Manager (Minute taker)
Dr Shirley Stagg	(SS)	- Human Tissue Authority (HTA)
Prof Marc Turner	(MT)	- Medical Director, Scottish National Blood Transfusion Service
Dr Angus Wells	(AW)	- Standing Advisory Committee on Care and Selection of Donors
Dr Nay Win	(NW)	- Standing Advisory Committee on Immunohaematology

SM welcomed Dr Janet Birchall to her first JPAC meeting as Medical Director of the Welsh Blood Service and Dr Angus Wells to his first meeting as Chair of the SAC on Care and Selection of Donors.

NW is retiring and stepping down as Chair of the SACIH. SM thanked Nay for all his hard work for JPAC since he was appointed as Chair of SACIH in July 2008.

SM also officially welcomed LJ to JPAC as SM didn't attend the last meeting.

ACTION

1.

Apologies

Prof John Forsythe	(JF)	- Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Mrs Angela Macauley	(AM)	- Quality Manager, Northern Ireland Blood Transfusion Service representing the Quality Managers of the 4 UK Blood Services
Dr Kieran Morris	(KM)	- Medical Director, Northern Ireland Blood

ACTION

Transfusion Service
 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 09 November 2017 - JPAC 18-02**

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

3. **Matters arising not on the agenda (review of the actions list) JPAC 18-03**

3.1 **Thyroid Disease entry in the Whole Blood and Components Donor Selection Guidelines – JPAC 17-54 – item 3.1.**

This will be discussed further at the next SAC Tissues and Cellular Therapy Products Meeting on 25 April 2018.

Post Meeting Note: Submitted to JPAC meeting on 28 June 2018.

3.2 **Supernatant free haemoglobin (SNHb) as product release criterion for frozen and recovered red cells – JPAC 17-60 – item 3.3**

This information does appear in the draft text for the 9th Edition of the Red Book.

3.3 **Rejuvenate trial specification update following phase 1 validation – JPAC 17-86**

HN confirmed that Gout isn't included in the exclusion criteria.

3.4 **HIV pre and post-exposure prophylaxis (PrEP): Discussion paper – JPAC 17-96 – item 5.10**

SACCS and SACTCP were asked to consider whether their donor health questionnaires would cover PrEP with regard to taking medication, or whether it should be specifically identified.

AC confirmed that PrEP is covered in the questionnaires for tissues and cells.

AW will put it on the next agenda for SACCS for review. They will also look at the Blood Safety Leaflet.

AW

SF informed JPAC that it does appear on the Irish donor health questionnaire.

SACTTI will also consider if the use of the alternative testing route for re-entry of donors who have non-confirmable reactive in the HIV screening assay (algorithm only used in NHSBT) needs to be re-evaluated in the light of PrEP. LJ will discuss with Dr Pat Hewitt and bring back to the next JPAC meeting in June.

LJ

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

4.1 **Central Nervous System Disease in all the Tissue and Cells Donor Selection Guidelines – JPAC 18-04**

JPAC endorsed the recommendation to include a history of CNS disease of unknown origin and clinically isolated syndrome and a further amendment to allow

ACTION

for individual risk assessment in cases where the underlying cause of the disease has not been established. A change notification will be issued.

Post Meeting Note: Change Notification No 04 2018 issued 10 April 2018.

4.2 G6PD Deficiency in the Cord Blood and the Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines – JPAC 18-05

JPAC endorsed the recommendation to update this entry and a change notification will be issued.

Post Meeting Note: Change Notification No 05 2018 issued 10 April 2018.

4.3 Glycogen Storage Disease in the Cord Blood and the Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines – JPAC 18-06

JPAC endorsed this new entry for both sets of guidelines and a change notification will be issued.

Post Meeting Note: Change Notification No 06 2018 issued 10 April 2018.

4.4 Haemodilution Algorithm – JPAC 18-07

(Appendix 1 – Haemodilution JPAC 18-07a and Appendix 2 – FDA-CoE Haemodilution JPAC 18-07b)

JPAC approved the proposal to change the JPAC haemodilution calculation algorithm in line with international practice, to take into account blood volume and plasma volume. This is an improvement to get a more accurate measure.

JPAC endorsed the recommendation to change Appendix 3 in the Deceased Tissue Donor Selection Guidelines and a change notification will be issued.

Post Meeting Note: Change Notification No 07 2018 has been approved by the Medical Director and is in progress.

AC/CJS

4.5 Haemoglobin Disorders in the Cord Blood and the Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines – JPAC 18-08

The current wording in these entries is confused and not clear. SACTCTP recommends updating the entries to improve clarity of the information provided. JPAC endorsed this recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 08 2018 issued 10 April 2018.

4.6 Hepatitis A in all the Tissue and Cells Donor Selection Guidelines – JPAC 18-09

Following an outbreak in Scotland the immunisation section has been updated to reflect guidance from Public Health England\Scotland. JPAC endorsed this recommendation and a Change Notification will be issued.

Post Meeting Note: Change Notification No 09 2018 issued 10 April 2018.

4.7 Hepatitis E in all the Tissue and Cells Donor Selection Guidelines – JPAC 18-10

JPAC endorsed this recommendation to update this entry to reflect the introduction of hepatitis E testing in cell and tissues donors following SaBTO recommendations. The sections on sexual partners and person sharing home have also been removed.

ACTION

A change notification will be issued.

Post Meeting Note: Change Notification No 10 2018 issued 10 April 2018.

4.8 Pregnancy in the Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines – JPAC 18-11

JPAC noted that G-CSF is not recommended for use in nursing women. The recommendation was endorsed and a change notification will be issued.

Post Meeting Note: Change Notification No 11 2018 issued 10 April 2018.

4.9 Prison entry in the Deceased Tissue Donor Selection Guidelines – JPAC 18-12

JPAC endorsed the recommendation that discretionary acceptance of donors who had been released from prison more than 3 months ago be allowed, subject to individual risk assessment. A change notification will be issued.

Post Meeting Note: Change Notification No 12 2018 issued 10 April 2018.

4.10 Tissue and Organ Recipient entry in the Deceased Tissue Donor Selection Guidelines – JPAC 18-13

AC wants to bring this in line with the entry in the Whole Blood and Component Donor Selection Guidelines. JPAC endorsed this recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 13 2018 issued 10 April 2018.

4.11 Transfusion in the Deceased Tissue Donor Selection Guidelines – JPAC 18-14

JPAC requested that, as we moved to non UK plasma in 1999, we should use a cut-off date of 01 January 1999 and include the reason why in the additional information section.

With that change JPAC endorsed the recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 14 2018 issued 10 April 2018.

4.12 Viral Haemorrhagic Fever in all the Tissue and Cells Donor Selection Guidelines – JPAC 18-15

There is an update to this guidance on the topic of viral haemorrhagic fevers discussed and approved by SaBTO in September 2017. JPAC were requested to consider the changes necessary to update the donor selection guidelines for tissues and cells.

The use of the term “country” or “area” was discussed. It was agreed that the term “area” would be used.

AC had also included changes to the information in the Geographical Disease Risk Index (GDRI) for Guinea, Liberia and Sierra Leone regarding the Ebola outbreak and time limits.

JPAC endorsed the recommended changes to the Tissues and Cells Donor Selection Guidelines and the GDRI and change notifications will be issued.

Post Meeting Note: Change Notification Nos 15 2018 issued 10 April 2018.

ACTION

Change Notification 16 2018 (GDRI) issued on 12 April 2018 and live on the JPAC website on 10 May 2018.

AW will discuss further with SACCSO if any changes are required for whole blood and components donor selection guidelines.

AW

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

5.1 **Chikungunya Virus Position Statement – JPAC 18-16**

JPAC approved the updated position statement which will be posted on the JPAC website.

Post Meeting Note: Updated Position Statement posted in the Document Library on the JPAC website on 27 March 2018.

5.2 **Emerging Infections Position Statement – JPAC 18-17**

CJS to remove the reference to NIBSC from position statement. With this change JPAC approved the updated position statement which will be posted on the JPAC website.

Post Meeting Note: Updated Position Statement posted in the Document Library on the JPAC website on 27 March 2018.

5.3 **Estimated frequency of HBV, HCV and HIV entering the blood supply – JPAC 18-18**

JPAC approved the updated position statement which will be posted on the JPAC website and endorsed the use of the current parameters for the 2015-2017 residual risk estimates.

Post Meeting Note: Updated Position Statement posted in the Document Library on the JPAC website on 27 March 2018.

5.4 **Geographical Disease Risk Index – addition and removal of specific country risk – JPAC 18-19**

JPAC asked LW to amend the paper with regard to the end date of an outbreak. With that change the paper would be recirculated to JPAC as JPAC 18-19 Amended.

JPAC agreed that this would become a JPAC position paper, which would then be posted in the Document Library on the JPAC website. CJS will format the paper using the JPAC Position Statement template.

Post Meeting Note: JPAC 18-19 has been amended and the new Position Statement posted in the Document Library on the JPAC website on 27 March 2018.

6. **Standing Advisory Committee on Blood Components**

6.1 **Normothermic regional perfusion in transplantation – JPAC 18-20**

(NHS Blood and Transplant Organ Donation and Transplantation Directorate: Proposal for blood utilisation for donor organ retrieval, ex situ machine perfusion and preservation technologies – JPAC 18-20a)

Megan Rowley presented this paper on behalf of SACBC.

ACTION

SM informed JPAC that this had also been discussed at the last MHRA Blood Consultative Committee meeting in February.

JPAC asked SACBC to set up a working group lead by MR to look at the issues. The membership should include representation from SACBC, MHRA, HTA and NHSBT ODT National Retrieval Group.

MR

SM will inform Prof John Forsythe, Associate Medical Director of Organ Donation & Transplantation. John is also a corresponding member of JPAC.

Post Meeting Note: SM has informed Prof John Forsythe.

6.2 Red Cells and Plasma, Leucocyte Depleted – Trial Component Specification (whole blood that is leucocyte and platelet depleted) – JPAC 18-21

HN went through this paper for the group.

JPAC agreed that a reduction of the shelf-life from 28 to 14 days was appropriate, but asked that further information on quality monitoring be added to the paper and the specification.

With this amendment JPAC approved the specification for publication in the Trial Specifications area on the JPAC website.

Post Meeting Note: This went live on the JPAC website on 14 June 2018.

7. Standing Advisory Committee on Care and Selection of Donors

7.1 Hepatitis E in the Whole Blood and Components Donor Selection Guidelines – JPAC 18-22

Following the implementation of universal HEV testing changes have been made to the whole blood and components donor selection guidelines. This was approved by JPAC and a change notification will be issued.

Post Meeting Note: Change Notification No 17 2018 was issued and live on the JPAC website on 10 May 2018.

8. Standing Advisory Committee on Information Technology

8.1 Label Specification for Blood Components in the United Kingdom – JPAC 18-23

LL went through this updated specification for the group and the following actions were agreed.

- On the example labels within the specification:
 - Use “Rh” not “RH”
 - Use “Rh D Negative” or “Rh D Positive” – keeping the “D”
 - Don’t use all capitals in the component name etc.
- Post updated version of the specification on the JPAC website
- Inform suppliers of the changes

Post Meeting Note: Version 2.8 has been posted on the JPAC website and an email has been sent to the suppliers.

ACTION**9. Standing Advisory Committee on Immuno-Haematology****9.1 Pooled platelets prepared in platelet additive solution (PAS) and high titre (HT) haemolysin testing – JPAC 18-38**

NW went through this paper for the group.

After considerable discussion it was agreed that the risk of haemolysis is likely to be reduced, but the numbers tested are too small to be certain. In addition, we do not have data on the titres of individual donations, just numbers of donations which are above the cut-off level, which would be needed in order to calculate the risk of a pool remaining HT positive.

It was noted that SNBTS only pool HT negative donations. If this is not possible due to the test results not being available at the time of pooling one other suggestion was that the final pool could be tested.

More international information would be helpful.

GM left the meeting at 14:25

JPAC did not endorse the paper and will not be making any recommendations at this time.

SF and AC left the meeting 14:32**10. JPAC Work Plans****10.1. Draft JPAC Work Plan March 2017 to April 2018 – JPAC 18-24**

JPAC approved the work plan with a few minor amendments.

Post Meeting Note: The work plan was submitted to the UK Forum meeting on 23 March 2018 where it was approved.

10.2 Draft JPAC Work Plan March 2018 to April 2019 – JPAC 18-25

JPAC approved the work plan with a few minor amendments.

Post Meeting Note: The work plan was submitted to the UK Forum meeting on 23 March 2018 where it was approved.

11. JPAC Constitution**11.1 JPAC Constitution – update March 2018 – JPAC 18-26**

JPAC approved the changes to the constitution which will be submitted to the next UK Forum meeting and then, if approved, posted on the JPAC website.

Post Meeting Note: Updated JPAC Constitution was approved at the UK Forum meeting on 23 March and posted on the JPAC website.

12. UK Forum**12.1. Report back from the meeting held on 08 December 2017 – JPAC 18-27**

ACTION

SM reported back from the meeting. Items of note for JPAC were:

- Prion Working Group – closure of the group
- SaBTO recommendations – thanked JPAC for work done
- JPAC Constitution – removal of clause regarding term of office for Professional Director of JPAC

The UK Forum members had had a tour of the SNBTS new Jack Copland Centre and were also given a presentation from the architect.

13. **SaBTO**

13.1 **SaBTO update – JPAC 18-28**

The last SaBTO meeting was held on 17 January. GMal went through his report for JPAC. The main item was the review of the provision of non-UK sourced FFP and cryoprecipitate for individuals born after 1995 or with thrombotic thrombocytopenia purpura (TTP) and provision of apheresis platelets to individuals born post 1995.

14. **JPAC Malaria Working Group**

14.1 **Review of donor selection guidelines using the ABO risk based decision making framework – JPAC 18-29**

It was agreed at the last JPAC meeting that a small working group would be set up to do a formal risk assessment on whether we can reduce the donor deferral period for donors visiting malaria areas from 6 to 4 months.

The first meeting of the JPAC Malaria Working Group will take place at the West End Donor Centre, London, on Monday 19 March. Subsequent meetings will be held by telecon. It is hoped that a report will be ready for the June JPAC meeting.

Membership of the group:

- Sheila MacLennan (**Chair**) – *Chair of JPAC*
- Rebecca Cardigan – *Deputy Chair JPAC*
- Peter Chiodini – *Parasitology Expert (Hospital for Tropical Diseases, London)*
- Akila Chandrasekar – *Chair SAC on Tissues and Cellular Therapy Products*
- Gareth Humphreys – *Head of Insight, Strategy and Innovation NHSBT*
- Lisa Jarvis – *Chair SAC on Transfusion Transmitted Infection*
- Gary Mallinson – *Scientific Lead Safety Policy (JPAC/SaBTO)*
- Claire Reynolds – *Scientist (Epidemiology) NHSBT*
- Angus Wells – *Chair SAC on Care and Selection of Donors*

15. **Benchmarking – JPAC 18-30 – not received**

15.1 Due to time constraints GMal was not able to produce a paper for this meeting. The paper is in the final stages of preparation and GMal will circulate to SAC Chairs in the next few weeks and bring to the next JPAC meeting in June.

GMal

16. **Any Other Business**

ACTION**16.1 Apheresis Granulocytes**

It was noted that NHSBT no longer provide apheresis granulocytes as part of its portfolio and the 3 other UK Blood Services don't provide this service either.

It was agreed therefore that the apheresis granulocyte specification should be removed from the Red Book

SACBC will take this forward.

HN

16.2 Percy Oliver Award

SM asked for nominations for the award. This year it is in the lay category.

Post Meeting Note: The deadline was 25th May and no nominations were received.

16.3 Suggested JPAC meeting dates in 2019

- Thursday 14 March - Boardroom, West End Donor Centre, London
- Thursday 27 June - Edinburgh
- Thursday 07 November - Venue to be confirmed

The above dates were approved by JPAC and, at the request of SNBTS, it was agreed that the June 2019 meeting will be held at their new Centre in Edinburgh.

16.4 Handbook of Transfusion Medicine

Due to financial constraints it was agreed that the next version of the Handbook of Transfusion Medicine would be online only.

16.5 Joint action on Authorisation of preparation processes in blood, tissues and cells

DO thanked JPAC for their assistance in sending the UK response to Europe. The first meeting with the Member States will take place in Rome in June 2018.

17. Date & venue for future JPAC meetings**2018**

- Thursday 28 June - Boardroom, West End Donor Centre, London
- Thursday 08 November - Boardroom, West End Donor Centre, London

The meeting closed at: 15:10