

Joint UKBTS Professional Advisory Committee

**Minutes of the 72nd meeting held
Scottish National Blood Transfusion Service, The Jack Copland Centre,
52 Research Avenue North, Heriot-Watt Research Park, EDINBURGH, EH14 4BE
on Thursday 14 March 2019**

Meeting commenced at: 11:01

Present

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
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	(GMal)	-	Scientific Lead Safety Policy (JPAC/SaBTO)
Dr Edwin Massey	(EM)	-	Standing Advisory Committee on Immuno-haematology
Dr Gail Mifflin	(GM)	-	Medical Director, NHS Blood and Transplant
Dr Kieran Morris	(KM)	-	Medical Director, Northern Ireland Blood Transfusion Service
Dr Helen New	(HN)	-	Standing Advisory Committee on Blood Components
Mr David Olszowka	(DA)	-	Medicines and Healthcare products Regulatory Agency – <i>Dialled into the meeting</i>
Dr Megan Rowley	(MR)	-	Standing Advisory Committee on Clinical Transfusion Medicine
Miss Caroline Smith	(CJS)	-	JPAC Manager (Minute taker)
Prof Marc Turner	(MT)	-	Medical Director, Scottish National Blood Transfusion Service
Dr Angus Wells	(AW)	-	Standing Advisory Committee on Care and Selection of Donors

SM thanked SNBTS for hosting this JPAC meeting.

ACTION

1.

Apologies

Dr Neil Almond	(NA)	-	National Institute for Biological Standards and Control <i>(also deputising for Dr Christian Schneider)</i>
Prof John Forsythe	(JF)	-	Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Dr Christian Schneider	(CS)	-	Director, National Institute for Biological Standards and Control

ACTION

Dr Amy Thomas (AT) - Human Tissue Authority (HTA)
 Prof Maria Zambon (MZ) - Director, Centre for Infections, Public Health England (PHE)

2. **Minutes of the last meeting held on 08 November - JPAC 19-02**

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

1. Item 5.7. 1st paragraph should say "JPAC approved the proposed new entry....."
2. Item 6.3. 3rd paragraph should say "LJ suggested that it would be useful to include a risk estimate at the time of implementing mitigation".

3. **Matters arising not on the agenda (review of the actions list) JPAC 19-03**

3.1 **Normothermic regional perfusion in transplantation – JPAC 18-20 – item 3.1**

MR is progressing this through SACBC and therefore this action is closed to JPAC.

3.2 **Human Parvovirus B19 (B19V) Risk Assessment – version 2 – JPAC 18-58 – item 3.4**

RC will send LJ the presentation given on this topic from *Héma-Québec*.

Post Meeting Note: Received.

3.3 **Risk Assessment – Variant CJD (vCJD) – version 5 – JPAC 18-84 – item 4.4**

GMal informed the group that this is due to be published in Spring 2019. He will keep JPAC informed.

GMal

3.4 **A review of UK blood services patient safety related decisions since 2009 – JPAC 18-94 – item 6.3**

Some comments have been received from SACTTI – GMal to consider what amendments are required.

GMal

3.5 **Request for updates to Red Book Chapter 7 regarding irradiated components – JPAC 18-95 – item 7.1**

JPAC approved the recommendation to update Chapter 7, but asked HN to amend the wording in Request 3. "Red cells washed and stored in saline must be transfused with 24 hours of irradiation or production." HB will send the updated Chapter to CJS.

Post Meeting Note: Received.

3.6 **Guidance for validation of novel plasticisers and additive solutions in blood bags – JPAC 18-96 & Chapter 8: Evaluation of novel blood components, production processes and blood packs: generic protocols – JPAC 18-97 – item 7.2**

Following the last JPAC meeting HN and SM decided that SACBC would remove specific mention of Chromium 51 in the Chapter 8 revisions, given that it is no longer available - the information only came out shortly before the JPAC meeting. HN will send the updated version to CJS for circulation to JPAC.

ACTION

Post Meeting Note: Paper recirculated to JPAC 16 May 2019.

3.7 **Proposal to change the composition and remit of the SAC on Clinical Transfusion Medicine – JPAC 18-105 – item 8.1**

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

MR & CJS

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

4.1 **Pool size for blood components – JPAC 19-04**

This proposes a change to Chapter 6 which has already been received. JPAC agreed this will appear in the new edition of the Red Book.

4.2 **Validation of Plasma and Platelet Pathogen Inactivation – JPAC 19-05**

SM informed JPAC that this topic is included in the GAPP Working Party 7 and that they would be very interested in seeing this paper.

JPAC approved the publication of this paper on the JPAC website

Post Meeting Note: Paper posted on the JPAC website 16 May 2019.

JPAC also requested the removal of the two papers concerning Prion Removal Filters from the Document Library on the JPAC website, as they were no longer relevant.

Post Meeting Note: These papers were removed on 19 March 2019.

The order of the agenda was not followed for the next 2 items.

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

After discussion JPAC approved a change in terminology from “trial component specification” to “provisional component”. The title of Appendix 3 of the Red Book on-line will be changed to reflect this.

It was agreed that this paper, including the examples, would be posted in the Document Library on the JPAC website under general documents.

Post Meeting Note: The title of Appendix 3 on the website has been changed to Provisional Component Specifications and the paper JPAC 19-07a posted in the Document Library.

It was also noted that the paper would be of interest to the GAPP Working Party 5. SM will send to an appropriate person.

SM

RC will put the Table into chapter 8.

RC/HN

4.4 **Risk assessment of the effect of the Familial Pseudohyperkalaemia genetic variant on red cell unit supernatant potassium – options for screening and management of donors – Confidential – JPAC 19-06a & Appendix 1 - Familial Pseudohyperkalaemia ABO risk based framework – JPAC 19-06b**

GM arrived at 11:39.

ACTION

After a lengthy discussion JPAC approved the first recommendation that donations from donors already identified with the FP variant (either through clinical cases or studies where they can be approached in keeping with the studies' ethical approval) should be removed from the blood supply for red cells for large volume neonatal and infant transfusions (including intrauterine and neonatal exchange transfusions). JPAC requested that the wording of the recommendation should be amended so that it applies to all red cells of fetal/neonatal/infant specification (in order to avoid use for intrauterine and large volume neonatal and infant transfusions).

This will need a new entry in the DSG.

Post Meeting Note: DSG entry submitted to the JPAC meeting on 27 June 2019.

Further investigation should be done before considering screening for FP donors or recommending additional restrictions on the use of these donations, and this is planned. A key consideration for prospective screening would be analysis of cost-effectiveness.

It was suggested that SHOT should be informed of FP being a possible cause of hyperkalaemia.

Post Meeting Note: SM sent this information to Dr Shruthi Narayan, Chair of SHOT, and it was discussed at their SHOT Steering Group/WEG meeting in March 2019.

It was noted that the risk is already mitigated for infant cardiac surgery in many hospitals by washing or ultrafiltering red cells prior cardiopulmonary bypass, and by checking potassium in the bypass circuit prior to attaching to the patient as recommended by BSH neonatal transfusion guidelines.

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

5.1 **Chikungunya Risk Assessment – version 8 – JPAC 19-08**

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

5.2 **Human herpesvirus-8 (HHV-8) Risk Assessment – version 5 – JPAC 19-09**

JPAC approved this updated risk assessment. There has been no significant change in risk since the last review.

5.3 **Derogations for UK blood microbiology screening in the event of disruption to supply of test kits during EU-exit – version 5 – JPAC 19-10**

SM thanked LJ for putting this all together in such a short time. It was noted that throughout the paper the DoH was mentioned. This should be changed to DHSC (Department of Health and Social Care). CJS will update the document and save as JPAC 19-10 amended.

The route to get any derogations would be through the DHSC and MHRA.

Post Meeting Note: JPAC 19-10 has been updated. Copies of JPAC 19-10 have been sent to SM and LJ.

LL noted that we would need a lead time to make these changes to IT systems.

5.4 **Parameter review for estimated risks UK 2016 to 2018 – JPAC 19-11**

ACTION

There have been no changes to the values for the infectious window periods used in the risk estimates. The definition of seroconversion remains at 1 year to reflect more recently acquired infections.

JPAC endorsed the use of the current parameters for the 2016-2018 residual risk estimates.

6. **A road map for the UK Blood Services to manage a hepatitis A outbreak**

It had been agreed, at the last JPAC meeting, that this paper should be sent to all the UK Public Health Services and the Republic of Ireland, informing them that this has been reviewed by JPAC and asking for their comments and whether or not it is appropriate for this to be posted on the JPAC website.

SM has sent the documentation to 3 of the Public Health Services (England, Scotland and Wales), but so far no responses have been received.

We have no contact name for Northern Ireland and KM will email SM & CJS the name of an appropriate person.

SM will keep JPAC updated.

KM

SM

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

7.1 **Complementary Therapy entries – All Tissue and Cell DSGs – JPAC 19-12**

The NHSBT Cord Blood Bank have requested that further information be added to this entry to further define the term 'commercial premises' with respect to acupuncture.

JPAC endorsed this recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 17 2019 in progress.

7.2 **Eye Disease entry – Deceased Tissue DSGs – JPAC 19-13**

This entry has been updated to provide additional information on ocular infections and trauma, add a link to the "Herpes – ocular" entry and merge the "Inflammatory Eye Disease" entry into this "Eye Disease" entry. It is also proposed that the "Inflammatory Eye Disease" entry is deleted, if this proposal is accepted.

JPAC endorsed this recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 18 2019 in progress.

7.3 **Hepatitis C entry - All Tissue and Cell DSGs – JPAC 19-14**

It is proposed to change the deferral period from 12 months to 6 months for situations where the donor/donor family reports that their current or former HCV positive partner has been successfully treated for hepatitis C infection and has been free of therapy.

JPAC endorsed this recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 19 2019 in progress.

7.4 **Inflammatory Bowel Disease entry - All Tissue and Cell DSGs – JPAC 19-15**

ACTION

The discretionary section has been updated to accept donors without evidence of systemic/significant infection.

JPAC endorsed this recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 20 2019 in progress.

**7.5 Malignancy entry – Deceased Tissue DSGs – JPAC 19-16a
To accompany paper JPAC 19-16a – Grading of selected central nervous system tumours, Table 4.1 (WHO 2016 classification) – JPAC 19-16b**

JPAC 19-16a - JPAC endorsed the changes in this paper, but asked AC to amend the wording on page 4 with regard to MGUS, check the copyright for the WHO table and to put the primary reference in the paper.

With these amendments a change notification will be issued.

Post Meeting Note: Change Notification No 21 2019 in progress.

7.6 Malignancy entry – Living Tissue and Cell DSGs – JPAC 19-17

A change proposal to the Whole Blood DSGs 'Malignancy' entry was approved by JPAC at its meeting in November 2018. This has been reviewed to evaluate if the agreed changes should also be considered for the Living Tissue and Cell DSGs.

JPAC endorsed this recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 22 2019 in progress.

7.7 STD entries – All Tissue and Cell DSGs – JPAC 19-18

It is proposed that the current 12-month deferral period for infected individuals and sexual partners of infected individuals be reduced to 3 months. For gonorrhoea, there is a proviso that a test of cure has been performed. This proposal is based on advice from SACTTI.

JPAC endorsed this recommendation and a change notification will be issued.

KM noted that this could not apply to Northern Ireland for Live tissue guidelines, however he will manage this under deviation as happens currently.

Post Meeting Note: Change Notification No 23 2019 in progress.

8. JPAC Work Plans

8.1 JPAC Work Plan April 2018 to March 2019 – Final – JPAC 19-19

JPAC approved the submission of this final work plan to the UK Forum meeting on 15 March 2019.

8.2 Draft JPAC Work Plan April 2019 to March 2020 – Final – JPAC 19-20

JPAC approved the submission of this draft work plan to the UK Forum meeting on 15 March 2019.

9. Infected Blood Inquiry - update

ACTION

- 9.1 SM and GM gave a verbal update on the progress so far of the Inquiry.

It was noted that there may be different arrangements between SACs on archive of SAC papers. SM and CJS to discuss and develop a policy.

SM & CJS

10. **Deputy Chair of JPAC – JPAC 19-21**

- 10.1 SM had tabled this paper for information. After discussion it was agreed that the wording of the second to last paragraph could be clarified with regard to who can apply for this post. SM to revise job description before circulating for expressions of interest.

Post Meeting Note: Job description updated, and advert circulated on 15 May with a closing date of 14 June 2019.

11. **UK Forum**

11.1 **Feedback from the UK Forum meeting on 14 December 2018 – JPAC 19-22**

- Individual risk assessment for 'high risk' donor - Su Brailsford presented plan for an NHSBT-led research project with other UK services support.
- Update on Brexit from Emergency Planning lead - JPAC was asked to produce a paper on potential derogations to testing (done by SACTTI and presented to this meeting).
- Infected Blood Inquiry – SM had reported on the request we have had for the JPAC archive.
- JPAC website – extension of contract
- Approval of some change notifications by the JPAC Executive Work Group.

12. **Definition of guideline changes that may be managed by the JPAC Executive Working Group – JPAC 19-23**

At the last UK Forum meeting there was a discussion about whether all proposed changes to guidelines should be presented to JPAC or whether some may be able to be approved by EWG. At the EWG meeting we agreed that five of the changes proposed for Tissues guidelines may be considered for EWG approval. Reasons for this included:

- Changes to wording only to increase clarity without any substantial change in selection criteria
- Changes to tissue guidelines to introduce a change agreed previously by JPAC for whole blood selection guidelines
- Addition of new entry for tissues guidelines agreed previously by JPAC for whole blood
- Deletion of entry(ies) in DSG that is/are duplicated in other entries

JPAC endorsed the recommendation that such changes could be agreed by the EWG and not submitted to JPAC, with the caveat that all should be subject to Medical Director approval prior to implementation as is the case with Change Notifications approved by JPAC.

13. **JPAC Website**

13.1 **Extension of the contract with Target – JPAC 19-24**

JPAC endorsed the recommendation to extend the contract with Target Information Systems and that this should be procured, on JPAC's behalf, by National Services Scotland who did the original procurement for the website.

14. GAPP – Joint Action “Facilitating the Authorisation of Preparation Processes for blood, tissues and cells – JPAC 19-25

- 14.1 DO went through this paper which he had submitted to JPAC to provide information on what GAPP was and the aims of the joint action.

It was noted that the starting and end dates are 01 May 2018 and 30 April 2021. 16 EU Member States and 1 non-EU Member State are involved. There are 26 Partners and 14 collaborating partners.

15. Dr Gary Mallinson – Scientific Lead – Safety Policy (JPAC/SaBTO)

15.1 SaBTO update – JPAC 19-32

GMal gave an update from the last SaBTO meeting on 17 January 2019, where the following were discussed:

- Update on Facilitating the authorisation of preparation process for blood, tissues and cells (GAPP):
- Virology Review Group
- Paediatric components working group
- HEV Screening

SM had received an email from Prof James Neuberger (Chair of SaBTO) with regard to SaBTO being kept abreast of new and emerging infections so that they can ensure their guidance is timely and appropriate.

It was agreed that the dedicated SaBTO mailbox (mbSaBTO@dhsc.gov.uk) should be added to the JPAC change notification distribution list. SaBTO will collate the information received and use this to inform members.

Post Meeting Note: The dedicated SaBTO mailbox email address has been added to the distribution list for JPAC change notifications.

16. Any Other Business

16.1 Letter to Dr Sarah Morley – role of JPAC – JPAC 19-33

Submitted by SM for information.

16.2 Letter from and to The Acupuncture Society – JPAC 19-34

SM had submitted this letter for information.

Post Meeting Note – A response has been received and circulated to JPAC.

16.3 SACBC and SACIT Joint Working Group

LL informed JPAC that a SACBC and SACIT Joint Working Group have been working on mapping component codes and a document should be tabled at the next meeting.

16.4 Proposed JPAC meeting dates in 2020

- *Thursday 12 March* - *Venue tbc*
- *Thursday 25 June* - *Venue tbc – Possibly SNBTS*
- *Thursday 05 November* - *Venue tbc*

17. Date & venue for future JPAC meetings

2019

- *Thursday 27 June* - *The Association of Anaesthetists, London*
- *Thursday 07 November* - *The Association of Anaesthetists, London*

The meeting closed at: 14.55