

Joint UKBTS Professional Advisory Committee

Minutes of the 61st meeting held at the
Association of Anaesthetists, 21 Portland Place, London,
on Thursday 18 June 2015

Meeting commenced at: 11:00 am

Present

Dr Susan Barnes	(SB)	-	Standing Advisory Committee on Care and Selection of Donors
Dr Rebecca Cardigan	(RC)	-	Standing Advisory Committee on Blood Components
Mr David Carter	(DC)	-	Medicines & Healthcare products Regulatory Agency
Dr Akila Chandrasekar	(AC)	-	Standing Advisory Committee on Tissues and Cellular Therapy Products
Dr Stephen Field	(SF)	-	Medical Director, Welsh Blood Service
Dr Alan Kitchen	(AK)	-	Standing Advisory Committee on Transfusion Transmitted Infections
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 Kieran Morris	(KM)	-	Medical Director, Northern Ireland Blood Transfusion Service
Dr William Murphy	(WM)	-	National Medical Director, Irish Blood Transfusion Service
Dr Megan Rowley	(MR)	-	Standing Advisory Committee on Clinical Transfusion Medicine
Miss Caroline Smith	(CJS)	-	JPAC Manager (Minute taker)
Dr Nay Win	(NW)	-	Standing Advisory Committee on Immunohaematology

ACTION

1. Apologies

Dr Stephen Inglis	(SI)	-	Director, National Institute for Biological Standards and Control
Mrs Linda Lodge	(LL)	-	Standing Advisory Committee on Information Technology
Prof James Neuberger	(JN)	-	Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Dr Amy Thomas	(AT)	-	Human Tissue Authority (HTA)
Mrs Joanne Tossell	(JT)	-	Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)
Prof Marc Turner	(MT)	-	Medical Director, Scottish National Blood Transfusion Service
Dr Lorna Williamson	(LW)	-	Medical Director, NHS Blood and Transplant
Prof Maria Zambon	(MZ)	-	Director, Centre for Infections, Public Health England (PHE)

2. Minutes of the last meeting held on 12 March 2015 – JPAC 15-41

The minutes were approved as a true record of the meeting, with one minor typo correction.

3. Matters arising not on the agenda (Review of actions list) JPAC 15-42

3.1 **Male-sex-with-male - Tissues and Cells Donor Guideline Changes – JPAC 14-13 item 3.1**

JPAC felt that the current wording in the TDSGs should be kept and that this item should now be dropped from the Actions List.

3.2 **Proposed new ‘concessionary release’ limits for blood components – JPAC 14-37 – item 3.5**

SM and RC are due to have further discussions with DC.

Post Meeting Note: Change Notification No 21 2015 – Leucocyte depletion of blood components – Concessionary release and Change Notification No 22 2015 – Concessionary Release Limits for Selected Components is in pre-publish on the JPAC website.

3.3 **Patient Assessment Form – item 3.5**

At the November 2014 JPAC meeting AC stated that there is a question about “have you ever been to prison?” on the patient assessment form. Should this be taken off and the guidelines changed? It was agreed that this should be discussed at SACTCTP and brought back to JPAC.

This had been discussed at the last two SACTCTP meetings and the decision was made not to recommend a change. JPAC endorsed this decision. Item closed

3.4 **Whole Blood and Components Donor Selection Guidelines re-write validation – item 4.7**

SB informed JPAC that approx 150 doctors/nurses are to help with the validation. A draft questionnaire and scenarios has already gone to the 4 Blood Services and the progress will be discussed at the next SACCS D meeting on 6 August. SB will keep JPAC updated.

SB

3.5 **Amendment to Chapter 9 of the 8th edition of the Guidelines for the Blood Transfusion Services in the United Kingdom (Red Book) – JPAC 15-10 – item 5.1**

JPAC had approved the recommendation to remove this section for the Red Book and an appropriate Change Notification will be issued. Draft Change Notification. CJS

Post Meeting Note: Change Notification No 23 2015 – Removal of section 9.4.2 and figure 9.6 in Chapter 9 change has been made and is in pre-publish on the JPAC website .

3.6 **Simian Foamy Virus risk assessment, version 3 – JPAC 15-15 – item 5.6**

The risk assessment has been updated.

3.7 **Proposal to remove the Endoscopy entry from the Live Tissue, Cord Blood (CB) and Allogeneic Bone Marrow (BM) and Peripheral Blood Stem Cells (PBSC) Donor Selection Guidelines – JPAC 15-20 – item 6.1**

Work in progress

AC

ACTION

3.8 **Proposal to create Northern Ireland specific entries for the Homosexual and Bisexual Individuals, Tissues Safety and Sex Change entries in the Live Tissue Donor Selection Guidelines – JPAC 15-21 – item 6.2**

Work in progress. *Post Meeting Note: Change Notification No 17 2015 – Homosexual and Bisexual Individuals and Sex Change was issued on 3 August 2015.*

3.9 **Interruption of platelet agitation and handling of apheresis platelets, version 2.11 – JPAC 15-35 – item 7.1**

More work is being done by SACBC. JPAC approved the recommendations in JPAC 15-35. Platelet specifications will be modified and Change Notifications will be issued.

Post Meeting Note: Change Notification No 18 2015 – Interruptions to agitation and testing of Platelets, Pooled, Buffy Coat Derived, Leucocyte Depleted and Platelets, Apheresis, Leucocyte Depleted changes have been made and are in pre-publish on the JPAC website .

It was also agreed that further work will be done on the review of literature on interruption of agitation of PI platelets, and information gathered on handling of platelets in hospitals.

RC

3.10 **Position Statement - Methylene Blue-Treated Plasma – JPAC 15-36 – item 7.2**

Work in progress.

RC

3.11 **Specific gravity of blood components – JPAC 15-38 – item 7.4**

Work in progress.

Post Meeting Note: Change Notification No 20 2015 – Specific gravity of blood components changes have been made and are in pre-publish on the JPAC website.

3.12 **Summary of Recent Validation of Buffy Coat Platelets in Plasma and Additive and Proposed changes to specification for this component, version 3 – JPAC 15-39 – item 7.5**

Work in progress.

Post Meeting Note: Change Notification No 19 2015 – Platelets in Additive Solution and Plasma, Leucocyte Depleted changes have been made and are in pre-publish on the JPAC website.

3.13 **An update on the SaBTO work plan, including the status of publications and reports – JPAC 15-24 – item 9.1**

Still awaiting draft paper on HEV for circulation to JPAC.

LW

3.14 **Acupuncture – item 11.6**

SB is still awaiting data from PHE.

SB

4.

Standing Advisory Committee on Transfusion Transmitted Infections

4.1 **Position Statement: Ebola Virus – JPAC 15-43**

ACTION

SACTTI had been asked to produce a position statement outlining the situation in respect of Ebola virus, and transmission routes. In addition, consideration was given to the use of Ebola convalescent in the treatment of Ebola virus disease.

JPAC approved the addition of Ebola to the JPAC Position Statements and a copy will be posted in the Document Library on the JPAC website.

Post Meeting Note: The JPAC Position Statement on Ebola has been posted in the Document Library on the JPAC website.

There was a question about whether to include Democratic Republic of Congo in the list of affected countries. SB will check and add this to the GDRI if relevant.

SB

4.2 **The Changing Epidemiology of Arthropod-Borne Viral Infections, with Particular Focus on Dengue and Chikungunya and the Impact on the Safety of Blood Products – JPAC 15-44**

This paper was discussed along with paper JPAC 15-45. See 5.1 below.

5. **Standing Advisory Committee on Care And Selection Of Donors**

5.1 **Tropical Virus Risk – JPAC 15-45**

SM thanked AK and SB for these two excellent papers. There was considerable discussion about whether to implement a 'tropics-wide' generic donor deferral as proposed in JPAC 15-44, however this was not agreed at the present time. SACTTI was asked to initiate work to determine the seroprevalence of arthropod-borne infections in UK travellers to provide data to inform future policy.

The following recommendations were approved:

1. West Nile Virus DSG entry

- Continue with separate WNV entry and not include WNV in the new 'Tropical Disease Risk' category, as it is not solely tropical in its distribution.
- Change 'It is less than four months.' to 'It is less than six months.' in 'Obligatory' (a) and (b) to align deferral with Chik V and Dengue guidelines.
- Change four months to six months and remove 'if a validated NAT for WNV is to be undertaken on the donation component(s) accept' from 'Discretionary' (1) and (2). Although the requirement to test is being removed the Services can still choose to test if they prefer.
- A Change Notification will be issued.

SB

2. Tropical Viruses

- It was agreed to include a new entry 'Tropical Viruses' in the DSG with Chik V and Dengue leading to this consolidated entry. This will have the advantage that other viruses with the same deferral criteria can be easily added if required.

SB

3. Dengue

- Add specific entry for Dengue Virus/Dengue Fever to the Donor Selection Guidelines
- Add new Position Statement on Dengue
- SB will review countries which will require Dengue deferral

SB

AK

SB

	<u>ACTION</u>
<ul style="list-style-type: none"> • Add Dengue to GDRI preliminary pages • Amend country topic pages to include Tropical Risk area if affected by Chik V or Dengue • Remove Chik V risk category from country topic pages 	SB SB SB
4. <u>UK Forum</u>	
SM will update the UK Forum at their meeting tomorrow (19 June).	
The DSG and GDRI changes for Tropical Risk, Dengue and Chik V will be brought back to JPAC in November for final approval.	SB
The risk to non-blood products needs to be clarified. AC will formally request AK to investigate this.	AC
5.2 <u>Chronic Fatigue Syndrome (CFS) / Myalgic Encephalomyelitis (ME) – addition of Systemic Exertion Intolerance Disease (SEID) to the Index of the Donor Selection Guidelines – JPAC 15-46</u>	
JPAC approved the recommendation to add 'Systemic Exertion Intolerance Disease' to the Index of the Donor Selection Guidelines. A Change Notification will be issued.	
<i>Post Meeting Note: Change Notification No 26 2015 – Chronic Fatigue Syndrome and SEID was issued on 29 September 2015.</i>	
AC will review the wording to see if it is also applicable to the Tissues and Cells DSGs.	AC
5.3 <u>Amendments to the Donor Selection Guidelines regarding Hydroxychloroquine treatment for Alopecia and Autoimmune Disease – JPAC 15-47</u>	
JPAC approved the recommended amendments to the guidelines on Alopecia and Autoimmune Disease. A Change Notification will be issued.	
<i>Post Meeting Note: Change Notification No 25 2015 – Alopecia and Autoimmune Disease was issued on 29 September 2015.</i>	
5.4 <u>Recommendations for changes to deferral criteria for whole blood and component donors with a past history of malignant disease – JPAC 15-48</u>	
SM thanked SB for this excellent paper. Although the recommendations are in line with the Council of Europe Guidelines it would require a change to the EU Directive.	
SB informed JPAC that having a blanket deferral was causing upset to donors who have been told they are clear of cancer by their physician, but they are then told by us that they still cannot donate.	
DC is going to ask for amendments to the Directive to be an agenda item for the next Competent Authorities meeting in November.	DC
AC plans to produce a similar paper for Tissue donors.	AC
5.5 <u>Addition of text and malarial maps for Brazil, China, Mexico, Peru and South Africa to the Geographical Disease Risk Index – JPAC 15-49</u>	
JPAC approved the addition of these maps and text to the GDRI. A Change Notification will be issued.	

Post Meeting Note: Change Notification No 28 2015 – Malaria was issued on 29 September 2015.

5.6 **Preliminaries for Malaria in the Geographical Disease Risk Index (GDRI) – JPAC 15-50**

JPAC approved the addition of this text for clarity. A Change Notification will be issued.

Post Meeting Note: Change Notification No 27 2015 – Malaria preliminaries in the GDRI was issued on 29 September 2015.

5.7 **Annual comparison of the Geographical Disease Risk Index (GDRI) with Travax – JPAC 15-51**

SM thanked SB and Liz Cawkill for this huge amount of work and JPAC approved the recommended GDRI amendments.

Post Meeting Note: Change Notification No 28 – Malaria changes to the GDRI was issued on 29 September 2015.

6.

Standing Advisory Committee on Tissues and Cellular Therapy Products
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6.1 **Eurocet 128 – Implementation of the single European code for tissue and cellular therapeutic products – JPAC 15-52**

and

Eurocet 128 – Essential information for Tissue Establishments on the implementation of the single European code for tissues and cells – to accompany the above paper – JPAC 15-52a

AC updated JPAC on the status of this project which requires that all Tissue and Cell Therapy products in the EU are labelled with a single European code.

Currently there is no standardisation of coding for Tissues between the UK Blood Services – the new European code will be an additional code to the current coding systems. Harmonisation of the codes is currently underway, due to be completed by end of 2015 and it is recommended that in future new codes will be assigned by SACIT as for blood components.

It was noted there will be resource implications for both blood services and hospitals. MR commented that traceability in the hospital setting was important for tissues as well as blood.

SM will present a paper to the UK Forum in September (AC to provide information).

Post Meeting Note: Paper was submitted to the UK Forum on 1 September 2015

6.2 **Proposal to amend the ‘Age’ entry in the Deceased Tissue Donor Selection Guidelines – JPAC 15-53**

JPAC approved the recommendation to amend the ‘Age’ entry in the Deceased Tissue Donor Selection Guidelines to state that cardiovascular tissue donated for the preparation of pulmonary patch allografts can be donated from donors aged up to 70.

As there is an impending national shortage of pulmonary patch allografts a Change Notification will be issued as soon as possible.

Post Meeting Note: Change Notification No 16 Age (Deceased Tissue Donor Selection Guidelines) has been issued (8 July 2015) and the changes are live on the JPAC website.

7.

Standing Advisory Committee on Blood Components

- 7.1 **Deviations from 4 °C temperature storage for red cells: effect on viability and bacterial growth – JPAC 15-54**
- RC went through this paper for the group. JPAC approved the recommended changes in this paper as follows:
1. Change Notification to the Red Book to allow deviation during transit to 10⁰C on one occasion only RC
 2. Change to Chapter 8 of Red Book to include assessment of temperature deviations to validation of novel red cell components RC
 3. SM to write to the BCSH Transfusion Task Force asking them to consider amending the 30 minute rule – noted that if this is agreed then the Handbook of Transfusion Medicine should also be amended SM
 4. Encourage publication of the bacteriology studies reported in the paper
 5. Noted that a small amount of confirmatory work on the bacteriology studies is planned.
- 7.2 **JPAC Decision Making Framework: to extend the time that blood can be out of controlled temperature storage from 30 to 60 minutes – JPAC 15-55**
- SM thanked RC for putting this work through the risk assessment framework.
- 7.3 **Framework for evaluating pathogen inactivation of blood components - scope of work – JPAC 15-56**
- JPAC were happy with the approach to this task that SACBC/SACTTI are proposing. Initially the focus will be on platelets, with frameworks for red cells and plasma developed later.
- It was agreed that the framework would not include cost-effectiveness as this would be for individual blood services to consider as part of contractual processes for purchasing PI systems.
- With respect to independent review of toxicology data, it was suggested that RC ask for a meeting with the MHRA devices section to discuss the process such devices are subjected to in terms of review of data. JPAC can then consider whether UK Blood Services would have any additional requirements to this. RC
- 7.4 **Pathogen inactivation of platelets – JPAC 15-57**
- JPAC endorsed the recommendations in this paper. SACBC will feed this information back to the manufacturer. RC
8.

SaBTO

- 8.1 **Update on the work plan, including the status of publications and reports – JPAC 15-58**

JT could not attend this meeting and had submitted this paper for information.

9. MHRA

9.1 **Report from the Blood Competent Authorities Meeting held in Brussels on 24 April 2015 – version 1 – JPAC 15-59**

SM thanked DC for submitting his notes from this meeting.

It was noted that discussion of amendments to the Blood Directives was again not on the agenda for this meeting.

10. JPAC Work Plans

10.1 **JPAC work plan 2014 to 2015 – Final – JPAC 15-60**

JPAC congratulated the SACs for all the work they've done.

10.2 **JPAC work plan 2015 to 2016 – Draft – JPAC 15-61**

The proposed work plan was approved.

11. UK BTS Forum

11.1 SM reported back from the meeting on 20 March 2015.

Blood Component Labelling - The UK Forum agreed that the specification developed by the Group could be shared with suppliers.

12. Human T-cell Lymphotropic Virus (HTLV) - update

SM is leading a Working Group to propose recommendations for SaBTO in September.

There will be consultation with JPAC, the UK Forum and individual Blood Services prior to presentation at SaBTO.

Post Meeting Note: Draft 12 of this paper went to JPAC and the UK Forum for comment on 12 August. Final paper was submitted to SaBTO on 21 August for their meeting on 1 September. The paper was updated in October (JPAC 15-92) and has been circulated with the November meetings papers for information.

13. Horizon Scanning - update

SM/AK will bring a paper on microbiological risk assessment scoring to JPAC in November.

SM & AK

14. Blood Component Labelling - update

SM informed JPAC that this is still work in progress – see item 11.1.

15. Any Other Business

ACTION

15.1 As a result of the Penrose Inquiry LW has put together a document looking at how NHSBT are going to mitigate any issues and suggested JPAC do something similar.

SM and RC will look at this for JPAC.

SM & RC

15.2 **Mrs Joan Jones, Quality Manager, WBS**

JPAC wished to congratulate Joan, who had been the Quality Managers' representative on this committee until late last year, on her recent MBE for services to blood transfusion.

16.

Date & venue for future JPAC meetings

2015

- Thursday 12 November - The Association of Anaesthetists, London

2016

- Thursday 10 March - The Association of Anaesthetists, London
- Thursday 23 June - The Association of Anaesthetists, London
- Thursday 10 November - The Association of Anaesthetists, London

Meeting closed at: 15:20