

## Joint UKBTS Professional Advisory Committee

### Minutes of the 62<sup>nd</sup> meeting held at the Association of Anaesthetists, 21 Portland Place, London, on Thursday 12 November 2015

Meeting commenced at: 11.00

#### Present

Dr Susan Barnes	<b>(SB)</b>	-	Standing Advisory Committee on Care and Selection of Donors
Dr Rebecca Cardigan	<b>(RC)</b>	-	Standing Advisory Committee on Blood Components
Mr David Carter	<b>(DC)</b>	-	Medicines & Healthcare products Regulatory Agency
Dr Akila Chandrasekar	<b>(AC)</b>	-	Standing Advisory Committee on Tissues and Cellular Therapy Products
Dr Stephen Field	<b>(SF)</b>	-	Medical Director, Welsh Blood Service
Dr Stephen Inglis	<b>(SI)</b>	-	Director, National Institute for Biological Standards and Control
Dr Alan Kitchen	<b>(AK)</b>	-	Standing Advisory Committee on Transfusion Transmitted Infections
Mrs Linda Lodge	<b>(LL)</b>	-	Standing Advisory Committee on Information Technology
Mrs Angela Macauley	<b>(AM)</b>	-	Quality Manager, Northern Ireland Blood Transfusion Service representing the Quality Managers of the 4 UK Blood Services
Dr Sheila MacLennan	<b>(SM)</b>	-	Professional Director of JPAC <b>(Chair)</b>
Dr Kieran Morris	<b>(KM)</b>	-	Medical Director, Northern Ireland Blood Transfusion Service
Dr William Murphy	<b>(WM)</b>	-	National Medical Director, Irish Blood Transfusion Service
Miss Caroline Smith	<b>(CJS)</b>	-	JPAC Manager (Minute taker)
Dr Shirley Stagg	<b>(SS)</b>	-	Human Tissue Authority (HTA)
Mrs Joanne Tossell	<b>(JT)</b>	-	Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)
Prof Marc Turner	<b>(MT)</b>	-	Medical Director, Scottish National Blood Transfusion Service
Dr Lorna Williamson	<b>(LW)</b>	-	Medical Director, NHS Blood and Transplant
Dr Nay Win	<b>(NW)</b>	-	Standing Advisory Committee on Immunohaematology

This was Dr Sue Barnes last meeting as Chair of the JPAC SAC on Care and Selection of Donors. SM thanked SB for all her hard work over the last over the last 7 years. The Committee has been very proactive during this time and undertaken a huge amount of work for JPAC.

It was also Dr Shirley Staggs first JPAC meeting. SS is representing the Human Tissue Authority while Dr Amy Thomas is on maternity leave.

- |    |                      |   |               |
|----|----------------------|---|---------------|
| 1. | <b>Apologies</b>     |   | <b>ACTION</b> |
|    | Prof James Neuberger | <b>(JN)</b> - Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant |               |
|    | Dr Megan Rowley      | <b>(MR)</b> - Standing Advisory Committee on Clinical Transfusion Medicine                          |               |
|    | Prof Maria Zambon    | <b>(MZ)</b> - Director, Centre for Infections, Public Health England (PHE)                          |               |

**ACTION****2. Minutes of the last meeting held on 18 June 2015 – JPAC 15-65**

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

SF and KM arrived at 11:10

**3. Matters arising not on the agenda (Review of actions list) JPAC 15-66****3.1 Whole Blood and Components Donor Selection Guidelines re-write validation – item 3.4**

SB updated JPAC on the progress of the re-write validation. The questionnaires have been printed and are ready to be sent to the 4 UK Countries and it is hoped that the completed questionnaires will be returned by the end of December with the results available for the next JPAC meeting in March 2016. If it is decided to go ahead with the re-write then the next step will be to put together a forward plan.

SB

**3.2 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 3.7**

In progress.

AC

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

As this is now on the SAC Blood Components work plan, where it will be monitored, it was decided to remove this item from the JPAC actions list. The 2012 position statement will stay on the website until the new information has been published.

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

LW agree to send the paper “Implementation of the supply of Hepatitis E Virus (HEV) testing components”, which was present to the NHSBT Board on 26 November 2016, to CJS for circulation to JPAC for information.

*Post Meeting Note: The above paper was circulated to JPAC on 13 November 2016.*

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

Completed – see item 5.

**3.6 Recommendations for changes to deferral criteria for whole blood and component donors with a past history of malignant disease – JPAC 15-48 item 5.4**

It was noted that there continues to be discussion about possible change to the EU Directive, but no decisions have been made as yet. This recommendation will be revisited when appropriate and could be taken off the actions list.

AC plans to produce a similar paper for Tissue donors.

AC

**3.7 Deviations from 4oC– item 7.1**

SM has written to the BCSH Transfusion Task Force. They would not however be able to include the recommendations on the 30 minute rule into revised guidelines without reference to published data.

**ACTION**

It was agreed that the next step is publication of the bacterial work following which this paper could be posted on the JPAC website.

SM we will keep this on the agenda and keep JPAC updated.

**SM**

**3.8 Framework for evaluating pathogen inactivation of blood components - scope of work – JPAC 15-56 – item 7.3**

RC and AK need to progress. RC will put this on the SAC Blood Components work plan.

*Post Meeting Note: On SACBC and SACTTI work plans*

**3.9 Pathogen inactivation of platelets – JPAC 15-57 – item 7.4**

JPAC had endorsed the recommendation in this paper at the June meeting. RC has fed the relevant information back to the manufacturer. Action Complete

**3.10 Any Other Business – item 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**

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

**4.1 JPAC Position Statement on Chikungunga Virus – JPAC 15-67**

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

*Post Meeting Note: This updated position statement was posted in the Document Library on the JPAC website on 30 November 2015.*

**4.2 JPAC Position Statement on Dengue Virus – JPAC 15-68**

JPAC approved this new Position Statement on Dengue Virus and this will be posted on the JPAC website with some minor amendments.

*Post Meeting Note: Following the requested amendments this position statement was posted in the Document Library on the JPAC website on 30 November 2015.*

**4.3 JPAC Position Statement on West Nile Virus – JPAC 15-69**

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

*Post Meeting Note: This updated position statement was posted in the Document Library on the JPAC website on 30 November 2015.*

SS arrived 11:25

**4.4 SACTTI Risk Assessment on Crimean-Congo Haemorrhagic Fever Virus (CCHF) version 4 – JPAC 15-70**

JPAC approved this updated risk assessment and agreed that the formal review date could be changed from 2 to 3 years.

**ACTION**

*Post Meeting Note: The JPAC Risk Assessment master list has been updated with the 3 year review date.*

**4.5 SACTTI Risk Assessment on Lymphocytic Choriomeningitis Virus (LCMV) version 4 – JPAC 15-71**

JPAC approved this updated risk assessment and agreed that the formal review date could be changed from 2 to 3 years.

*Post Meeting Note: The JPAC Risk Assessment master list has been updated with the 3 year review date.*

**4.6 SACTTI Risk Assessment on Human Parvovirus B19 (Parv4) version 4 – JPAC 15-72**

JPAC approved this updated risk assessment and agreed that the formal review date could be changed from 2 to 3 years.

SM thanked all the SACTTI members for all their work in reviewing these risk assessments.

*Post Meeting Note: The JPAC Risk Assessment master list has been updated with the 3 year review date.*

**4.7 Modifications to Chapter 9 of the 8<sup>th</sup> Edition of the UK Transfusion Guidelines regarding anti-HTLV, HEV and WNV – JPAC 15-73**

JPAC approved the changes to Chapter 9 which include HEV, the recent changes in HTLV screening and the change in reinstatement rules for WNV and a change notification will be issued.

*Post Meeting Note: Draft Change Notification No. 12 2016 – Modifications to Chapter 9 of the Red Book (regarding HTLV, HEV and WNV) has been approved by the Medical Directors and is in pre-publish on the website.*

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

**5.1 Acupuncture - A review of the impact of the acupuncture deferral policy on deferral of NHSBT blood donors – JPAC 15-74**

This topic was reviewed again, and a survey undertaken, because the British Acupuncture Council (BACc) are now on the Professional Standards Voluntary Register.

LW will have another meeting with the BACc.

**LW & SM**

**5.2 JPAC website [transfusionguidelines.org.uk](http://transfusionguidelines.org.uk) – DSG and GDRI app and international usage – JPAC 15-75**

SB presented this paper to JPAC. It was agreed that SM will discuss this further with Aaron Powell, Chief Digital Officer at NHSBT, and ask the UK Forum if they would like JPAC to put together a business case to take this forward.

*Post Meeting Note: This was discussed at the UK Forum on 11 December, where the idea was commended. However, it was felt that there needed to greater understanding of the Government policy, safety, cost and practicalities of the proposal and therefore additional work is required. SM to liaise with IT in NHSBT & possibly NISG. IT will support.*

**SM**

**Review of the shelf life of fresh frozen plasma components following thawing – JPAC 15-89**

This item was discussed at this point of the agenda as LW is leaving the meeting at lunch time. See item 6.3 for the minute of the discussion.

**LW left the meeting at 13:30**

**5.3 JPAC Position Statement on Calcium Abnormalities and Apheresis Donation – JPAC 15-76**

JPAC approved this position statement. An annual review will be carried out by the SAC CSD and the position statement will be posted in the Document Library on the JPAC website.

*Post Meeting Note: This new position statement was posted in the Document Library on the JPAC website on 20 November 2015.*

***Changes to the Donor Selection Guidelines*****5.4 Glycogen Storage Disease (GSD) – New topic – JPAC 15-77**

JPAC approved the recommendation to add a new topic “Glycogen storage disease” and permit potential donors with type 0, type V and maybe types XI, XII and XIII GSD to donate if there are no other contraindications. A change notification will be issued and the paper posted as a supporting paper in the Document Library on the JPAC website.

*Post Meeting Note: Change Notification No. 01 2016 – Glycogen Storage Disease was issued on 18 January, is now live on the JPAC website and the supporting paper posted in the Document Library.*

**5.5 Hepatitis A – update of topic – JPAC 15-78**

SACTTI have recommended that this topic be updated to reduce the obligatory deferral from 12 to 6 months and add a discretion to accept on full recovery. This change applies to the whole blood donor selection guidelines only. JPAC approved this recommendation and a change notification will be issued.

*Post Meeting Note: Change Notification No. 02 2016 – Hepatitis A was issued on 18 January and is now live on the JPAC website.*

**5.6 Hepatitis E – update of topic – JPAC 15-79**

SACTTI have recommended that this topic be updated to reduce the obligatory deferral from 12 to 6 months and add a discretion to accept on full recovery. This change applies to the whole blood donor selection guidelines only. JPAC approved this recommendation and a change notification will be issued.

*Post Meeting Note: Change Notification No. 03 2016 – Hepatitis E was issued on 18 January and is now live on the JPAC website.*

**5.7 Immunizations – table to be added – JPAC 15-80**

SACCSD recommends adding a table of immunization as an appendix to **all** the donor selection guideline entries on immunizations. This table will be reviewed annually. JPAC approved the recommendation for this addition to **all** the DSGs and a change notification will be issued.

**ACTION**

*Post Meeting Note: Change Notification No. 04 2016 – Immunization Tables was issued on 18 January and is now live on the JPAC website.*

**5.8 Memorial Tattoos – amendment to Body Piercing topic – JPAC 15-81**

The use of ashes of cremated loved ones in memorial tattoos had been brought to the attention of SACCSO. After review it was decided that no additional deferral was required, but that memorial tattoos will be added to the Body Piercing topic. JPAC approved this recommendation and a change notification will be issued.

*Post Meeting Note: Change Notification No. 05 2016 – Body Piercing was issued on 18 January and is now live on the JPAC website.*

**5.9 Prion Associated Disease – request to clarify topic – JPAC 15-82**

SACCSO need to make a slight amendment to the Prion Associated Disease topic following the revision of the Position Statement on Creutzfeldt-Jakob Disease by the UK Blood Services Prion Working Group.

JPAC approved this amendment and, as this was for clarification and not a change in guidance, a change notification was not required.

*Post Meeting Note: This clarification was made on 18 January and is now live on the JPAC website.*

**5.10 Renal Disease – update to the Kidney and Bladder Disease topic with regard to acute glomerulonephritis – JPAC 15-83**

JPAC approved the recommendation to amend this topic as per JPAC 15-83 and a change notification will be issued.

SM had taken this paper to the CoE and the deferral for glomerulonephritis will be changed from 5 years to 12 months in the 19<sup>th</sup> Edition of the Guide.

*Post Meeting Note: Change Notification No. 06 2016 – Kidney and Bladder Disease was issued on 18 January is now live on the JPAC website.*

**5.11 Tropical Virus Guidance for all Donors Selections Guidelines except Cord Blood – JPAC 15-84**

JPAC approved the new entry for “Tropical Virus” in the DSGs with Chik V and Dengue leading to this consolidated entry and the edition of a specific entry for Dengue Virus/Dengue Fever in the DSG index.

Two change notifications will be issued. One for the Cord Blood DSG only and another to cover all the other DSGs.

*Post Meeting Note: Change Notifications No. 07 2016 – Tropical Virus Guidance, Cord Blood DSG only and No 08 2016 – Tropical Virus Guidance, all other DSGs were issued on 18 January and are now live on the JPAC website.*

**5.12 West Nile Virus - Amendment to the guidance in all the Donor Selection Guidelines – JPAC 15-85**

JPAC approved this recommendation to amend the West Nile Virus entry in all the DSGs and a change notification will be issued, with the addition of another discretionary clause to allow re-entry before 6 months if a donor is tested.

*Post Meeting Note: Change Notification No. 09 2016 – West Nile Virus was issued*

**ACTION**

on 18 January and is now live on the JPAC website.

***Changes to the Geographical Disease Risk Index (GDRI)***

**5.13 New Edition of the Geographical Disease Risk Index (GDRI) – JPAC 15-86**

SB has reviewed the GDRI with regard to countries which will require Dengue deferral and any additional countries requiring Chik V or Viral Haemorrhagic Fever deferrals. Dengue has been added to the GDRI preliminary pages and country topics pages include Tropical Risk area if affected by Chik V and/or Dengue. Chik V has been removed as a risk category from country topic pages. Changes to the way pages are accessed from the index to countries regions or cities have been made, which will make the GDRI quicker to use.

SM and JPAC thanked SB for this huge amount of work.

JPAC approved the new edition of the GDRI and a change notification will be issued.

*Post Meeting Note: Change Notification No. 10 2016 – GDRI New Edition was issued on 18 January and is now live on the JPAC website.*

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

**6.1 Washed red cells – Proposed changes to current specification – JPAC 15-87**

RC went through this paper for JPAC and the following actions were agreed:

- amend the specification to include guidance on irradiation as per section 11 of JPAC 15-87
- a Hct range of 0.50 to 0.70 should be included in the specification
- sampling technique of quality monitoring of washed red cells should be reviewed
- BCSH Transfusion Task Force should be notified of these changes, as they may wish to consider revising their guidance on irradiation
- SACBC should highlight lack of guidance on irradiation of washed red cells when commenting on the next edition of the CoE guide.

RC

**6.2 Terminology for pathogen reduction/inactivation – JPAC 15-88**

JPAC approved this recommendation. It was agreed that the current specifications do not require change, but in future specifications the terms pathogen inactivation will refer to the process and pathogen-reduced to the final component.

**6.3 Review of the shelf life of fresh frozen plasma components following thawing – JPAC 15-89**

*This item was actually discussed earlier in the meeting after item 5.2.*

SM thanked RC and SACBC for this very comprehensive paper. It was noted that this paper concerns information on thawed plasma and a paper on liquid plasma will be submitted to the next JPAC meeting in March 2016.

RC

After a long discussion JPAC endorsed the following recommendations:

- 1) The shelf-life of thawed MB FFP should remain the same (i.e. 24 hours)

**ACTION**

- 2) The shelf life of thawed standard FFP be extended to 5 days to permit usage according to BCSH guidelines; however the specification should include the statement that FFP should be used as soon as possible. RC
- 3) It was agreed that indications for extended post-thaw life FFP should be set by BCSH and SM and RC will discuss next steps with the Chair of the BCSH FFP writing group.
- 4) Sourcing further data on FFP wastage and effect of this change on both wastage and speed at which plasma can be provided should be discussed with the Blood Stocks Management Scheme. RC
- 5) It was noted that it will be important for UKBTS to provide data on the component and advice on limiting bacterial contamination risk to users.
- 6) SHOT will need to be notified of this change so that they can consider whether reports of adverse events to plasma should include information on how long plasma had been stored for once thawed.

*Post Meeting Note: BCSH drafting group has now written an addendum, this as been to the Transfusion Task Force and is now out for review. SM has sent Paula Bolton-Maggs (SHOT) the JPAC paper and BCSH addendum.*

**6.4 Data Provided by Cerus in relation to Pathogen Inactivation of platelets – JPAC 15-98**

This paper was circulated to JPAC for information and was noted.

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

**7.1 Proposal to set standards for post-mortem retrieval and processing times for ocular tissue – JPAC 15-90**

This paper contains a proposal that time limits for the post-mortem retrieval and post-retrieval processing time for ocular tissue be added to the Red Book Guidelines. The recommendation in JPAC 15-90 is that the maximum time from death to enucleation should be confirmed as 24 hours and that the enucleation to processing time also should not exceed 24 hours. These standards should be considered as separate standards; i.e., a death to enucleation time less than 24 hours does not mean that the enucleation to processing time can be increased beyond 24 hours.

This proposal had been approved at the SAC on Tissues and Cellular Therapy Products meeting on 10 September and AC will also be taking the proposal to the OTAG ( Ocular Tissue Advisory Group) meeting in January. A change notification will be issued after that meeting.

**AC**  
**AC**

**8. SaBTO**

**8.1 SaBTO update including reports from the SaBTO Extraordinary meeting on 7 July 2015 and the SaBTO meeting on 1 September 2015 – JPAC 15-91**

JT went through this paper for JPAC.

ABO, Hepatitis E and the Donor Survey (MSM criteria) will be on SaBTO work plan next year.



**ACTION****Sub-Saharan Africa**

SF asked JT if Sub-Saharan Africa is still on the SaBTO work plan or whether they think it should be discussed at JPAC? SM will take this to the next UK Forum meeting in December.

*Post Meeting Note: (1) This was discussed at the UK Forum meeting on 11 December. It was noted that this topic no longer seems to be on SABTO work plan. SM seeking UKF guidance on way forward; Recognises that JPAC may have role to play but expressed concern about JPAC expertise and resource in this area. UKF acknowledged topic as an important area for further work and agreed that JPAC would consider the scope of work and expertise required for possible inclusion and prioritisation in the next JPAC work plan.*

*Post Meeting Note: (2) This was discussed at the SaBTO meeting on 13 January 2016. SaBTO will be reviewing the donor referral policy for MSM and Also agreed to include other deferrals for disease transmitted by other routes, e.g. tattooing, IVDU and sub-Saharan Africa. JPAC maybe be asked for our input.*

**8.2 Options for Human T-Lymphotropic Virus (HTLV) screening within the UK Blood Services (updated October 2015) – tabled for information – JPAC 15-92**

This is an updated version of the document which had been circulated to JPAC in August, provided to JPAC for information.

**9. UK BTS Forum**

**9.1 Report from the meeting held on 11 September 2015 – JPAC 15-93**

SM went through this report for the group and updated JPAC on the following:

- HTLV screening outcome
- Blood component labelling
- Eurocet
- Proposals for new Safety Coordinator/Scientist role

**10. Horizon Scanning – update JPAC 15-94**

AK went through this paper for JPAC. It was noted that it is still in draft and needs to be used and tested. JPAC were asked to feed any comments back to AK and he will bring the next version back to JPAC in March 2016.

**AK**

**11. Any Other Business**

**11.1 Position Statement on Creutzfeldt-Jakob Disease – produced by the UK Blood Services Prion Working Group – JPAC 15-95**

JPAC endorsed this updated position statement and it will be posted on the JPAC website.

*Post Meeting Note: This updated position statement was posted in the Document Library on the JPAC website on 19 November 2015.*

**11.2 Safety Framework**

SM informed JPAC that the ABO framework is now finalised and there is a tool on

**ACTION**

the ABO website, but as LW is going to give a presentation to the JPAC EWG in January it will not be discussed further at JPAC until the March 2016 meeting.

**11.3 Suggested JPAC meeting dates in 2017**

JPAC approved the suggested JPAC meeting dates for 2017.

- o Thursday 09 March
- o Thursday 22 June
- o Thursday 09 November

**11.4 Middle East Respiratory Syndrome Coronavirus (MERS-CoV)**

SB asked if the temporary MERS-CoV deferral should now be removed. AK will consult SACTTI and confirm with SB as soon as possible so she can change the new GDRI if necessary.

*Post Meeting Note: This has been covered in the new edition of the GDRI – see item 15.3. Change Notification No. 10 2016 – GDRI New Edition was issued on 18 January and will go live on the JPAC website on 16 February 2016.*

**12. Date & venue for future JPAC meetings****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: 15:10**