

## Joint UKBTS Professional Advisory Committee

Minutes of the 59<sup>th</sup> meeting held at the  
Association of Anaesthetists, 21 Portland Place, London,  
on Thursday 13<sup>th</sup> November 2014

Meeting commenced at: 11:07 am

### Present

Dr Susan Barnes	<b>(SB)</b>	- Standing Advisory Committee on Care and Selection of Donors
Mr Andrew Broderick	<b>(AB)</b>	- Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)
Dr Rebecca Cardigan	<b>(RC)</b>	- Standing Advisory Committee on Blood Components
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
Mrs Joan Jones	<b>(JJ)</b>	- Representing the Quality Managers of the 4 UK Blood Services
Dr Alan Kitchen	<b>(AK)</b>	- Standing Advisory Committee on Transfusion Transmitted Infections
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
Miss Caroline Smith	<b>(CJS)</b>	- JPAC Manager (Minute taker)
Dr Nay Win	<b>(NW)</b>	- Standing Advisory Committee on Immunohaematology

### ACTION

1. Apologies

Mr David Carter	<b>(DC)</b>	- Medicines & Healthcare products Regulatory Agency
Mrs Linda Lodge	<b>(LL)</b>	- Standing Advisory Committee on Information Technology
Dr William Murphy	<b>(WM)</b>	- National Medical Director, Irish Blood Transfusion Service
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
Dr Amy Thomas	<b>(AT)</b>	- Human Tissue Authority (HTA)
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
Prof Maria Zambon	<b>(MZ)</b>	- Director, Centre for Infections, Health Protection Agency (HPA)

2. Minutes of the last meeting held on 17 July 2014 – JPAC 14-59

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

ACTION

3. Matters arising not on the agenda (Review of actions list) JPAC 14-60
- 3.1 **Male-sex-with-male - Tissue and Cell Donor Guideline Changes – JPAC 14-13-item 3.5**
- At the request of JPAC SACCSD had discussed how to change the wording of the homosexual/bisexual entries at their meeting in August. SB informed JPAC that Dr Su Brailsford is going to contact the members of the working group on MSM from the 'gay' community, on behalf of SACCSD, but in general the committee felt that, as this was terminology currently used by Stonewall (lesbian, gay and bisexual charity) etc. it was appropriate.
- SB will bring a follow-up paper to the next JPAC meeting in March 2015. SB
- 3.2 **Look back and Trace back – JPAC 14-20 – item 3.6.**
- No response has yet been received from the MHRA about the revised text. SM to contact David Carter.
- SI reported that a new cross MHRA group had been established for blood and related products, co-chaired by Tony Hubbard (NIBSC) and Kevin Page (Inspection, Enforcement and Standards). This would not change functional responsibilities within the Agency but would provide a forum for ensuring that agency wide expertise and knowledge could be brought to bear on issues requiring attention, and also a focal point for interaction with external organisations.
- Post Meeting Note: DC has discussed the revised text for Look Back and Trace Back with the inspectorate and can confirm that this text is acceptable to the MHRA. The definitions have been posted in the Document Library on the JPAC website.*
- 3.3 **Options for HTLV Screening within the UK Blood Services (version 1) – JPAC 14-32 – item 4.1**
- SM informed JPAC that the Analytical Steering Group is currently looking at the cost effectiveness. This will be removed from the actions list and come back to JPAC when all the relevant information has been received.
- 3.4 **Borrelia burgdorferi (Lyme disease) Risk Assessment (version 2) – JPAC 14-34 – item 4.3**
- At the last JPAC meeting it was noted that infection risk is increasing in some areas of the UK and it would be useful to consider a study looking at seroprevalence with a view to trying to understand potential for transfusion transmission. MT agreed to consider this. As MT could not attend this meeting this will be carried over to the next JPAC meeting in March 2015. MT
- 3.5 **Proposed new 'concessionary release' limits for blood components – JPAC 14-37 – item 5.1**
- SM is still awaiting feedback from the MHRA. To be carried forward to next meeting. SM
- 3.6 **Methylene blue-treated plasma – Position Statement – JPAC 14-39 – item 5.3**
- At the last JPAC meeting RC was asked to look at a comparison of reactions to platelets of different patient populations by comparing SHOT data for neonates and adults. RC is awaiting some further information from SHOT. When this is received the paper will be updated and submitted to the JPAC meeting in March 2015. RC

ACTION3.7 **Evaluation of the rewrite of the donor selection guidelines - 'reversing the paradigm' – JPAC 14-40 – item 6.1**

SB informed JPAC that SACCSO have started to work with nurse volunteers comparing the new version of the DSG with the old DSG to determine whether the same outcome would be achieved. As this piece of work will take some time this item will be taken off the actions list and SB will report back to JPAC when this work has been completed.

3.8 **Pancreatic islet cells – item 12.2**

At the JPAC meeting July MT has asked that islet cells be added to the remit of SACTCTP as they are a product we supply. This was discussed at the last SACTCTP meeting on 7 October and AC informed JPAC that it was agreed that SACTCTP will consider impact on islets when discussing changes to DSG entries. Sharon Zahra (SNBTS) attended the meeting as observer and has been invited to join the committee.

4. 

Standing Advisory Committee on Transfusion Transmitted Infections
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4.1 **JPAC Position Statement on Chikungunya Virus – JPAC 14-61**

This updated position statement was approved by JPAC and will be posted on the website.

*Post Meeting Note: Posted in the Document Library on the JPAC website December 2014.*

4.2 **JPAC Position Statement on Emerging Infections – JPAC 14-62**

This updated position statement was approved by JPAC and will be posted on the website.

*Post Meeting Note: Posted in the Document Library on the JPAC website December 2014.*

4.3 **Chikungunya Virus Risk Assessment – version 5 – JPAC 14-63**

SACTTI have reviewed the JPAC risk assessment on Chikungunya Virus and AK highlighted the changes and the options for JPAC. JPAC agreed that it was not in a position to choose between these options at present and more information was required.

SACTTI had noted the inconsistencies of how some arthropod-borne viral infections (West Nile Virus, Chikungunya Virus and Dengue) are dealt with in the Donor Selection Guidelines. This will be reviewed by SACTTI and a paper will be submitted to the next JPAC meeting in March 2015.

AK

5. 

Standing Advisory Committee on Care And Selection Of Donors
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5.1 **Deferral for aspirin and related drugs for platelet donors - JPAC 14-64**

Deferral for aspirin and related drugs will be reduced to 2 days from 5 in the next Council of Europe 'Guide to the preparation, use and quality assurance of blood components', 18<sup>th</sup> edition.

ACTION

SACCCSD recommends a reduction in deferral for aspirin and aspirin based medications for platelet donors from 5 days to 2 days. JPAC had previously asked SACCCSD to seek opinions on the recommendation from specialists in the area.

JPAC 14-64 contains background information and the opinions of several experts.

SB confirmed that the deferral will state "2 clear aspirin free days".

JPAC approved this paper and its submission to the next UK Forum meeting on 12 December for their endorsement.

*Post Meeting Note: This paper was submitted to the UK Forum meeting on 12 December.*

#### 5.2 **Clarification to the Asthma guidance – JPAC 14-65**

DSG guidance for Asthma re 'Steroid therapy' is not identical to that in the topic 'Steroid Therapy' and staff may not follow the 'See if Relevant' link. JPAC 14-65 contains proposed clarifications to both the 'Asthma' and 'Steroid Therapy' topics.

This was approved by JPAC and a change notification will be issued.

*Post Meeting Note. Change Notification No 2 2015 – Asthma was issued on 2 February. Source files were available for training purposes from 17 February and the change will go live on the JPAC website on 17 March 2015.*

#### 5.3 **Clarification to the Kidney and Bladder Disease guidance for Interstitial Cystitis – JPAC 14-66**

SACCCSD have been asked to clarify how long a donor should be deferred for if they have taken Elmiron™ (Pentostan) as it has an anticoagulant effect. SACCCSD feel that a deferral of 7 days from last dose, in line with other anticoagulants, would be appropriate.

This was approved by JPAC and a change notification will be issued.

*Post Meeting Note. Change Notification No 3 2015 – Kidney and Bladder Disease was issued on 2 February. Source files were available for training purposes from 17 February and the change will go live on the JPAC website on 17 March 2015.*

#### 5.4 **Exposure to risk of acquiring a transfusion-transmissible infection (Endoscopy) – JPAC 14-67**

A history of exposure to risk of acquiring a transfusion-transmitted infection is listed as a temporary deferral criteria in Annex III of the Commission Directive 2004/33/EC. The Annex goes on to state that potential donors who have had:

- Endoscopic examination using flexible instruments, should be deferred for 6 months, or 4 months provided a NAT test for hepatitis C is negative. This is translated into the Blood Safety and Quality Regulations 2005.

This assumes that all flexible endoscopic examinations have a risk of acquiring a transfusion-transmitted infection. This has never been proved and no other form of endoscopy rigid or flexible has been associated in any way with the acquisition a transfusion-transmitted infection. This has been confirmed by Public Health England.

Most donors are unclear whether they have had an endoscope used during surgery and if so which type of scope was used. This results in the loss of significant numbers of donors.

ACTION

SACCCSD recommends putting in Discretionary” a) If *the endoscopic examination was not of the gastrointestinal tract (e.g. gastroscopy, colonoscopy), or* has been carried out with a rigid endoscope (e.g. colonoscopies and most arthroscopies and proctoscopies), the donor is well and not waiting for further tests or results, accept.

SM will write to the MHRA, on behalf of JPAC, stating that the evidence suggests this is not a risk and asking the MHRA’s opinion on this and how to best take this forward.

*Post Meeting Note: Response from DC as follows: “I have reviewed the BSQR and the wording of Directive 2004/33/EC in relation to the deferral following an endoscopic examination. The requirement for deferral is, unfortunately, very clear and the wording does not provide for the UK to take a flexible approach. Accordingly MHRA cannot agree to any alteration of the guidance which does not reflect the requirement for deferral in all cases.”*

We agreed that the way forward is to ask the Commission to consider a revision of the Directive on this issue and SM/SB will provide a paper for DC to take to the EC.  
**Action:** SM & SB

SM &amp; SB

5.5 **Erivedge™ (Vimsodegib) – addition of information to the Malignancy guidance – JPAC 14-68**

Product information from Roche advises that ‘blood donation should be avoided ‘while taking this drug and for 24 months after the last dose.’ Therefore SACCCSD recommends amending the Malignancy topic as per JPAC 14-68. This was approved by JPAC and a change notification will be issued.

*Post Meeting Note. Change Notification No 4 2015 – Malignancy was issued on 2 February. Source files were available for training purposes from 17 February and the change will go live on the JPAC website on 17 March 2015.*

5.6 **Fibrin glues and sealants – addition of information to the Surgery guidance – JPAC 14-69**

These products are used for haemostasis and to seal suture lines. They nearly all contain product derived from human pooled plasma. Some also contain a bovine derived product. Product information leaflet supplied for Tisseel™ and Evicel™ give warnings regarding these products and CJD, although the blood does not appear to be UK (it is apparently Israeli or US) in origin. SACCCSD felt an addition needed to be made to the Surgery Topic.

After a full discussion JPAC rejected this proposed change.

5.7 **Malarial Risk Maps for the Geographical Disease Risk Index (GDRI) – JPAC 14-70**

Malarial risk maps were provided in hard copy to assist in interpreting the GDRI until 5 years ago when they were removed as they were out of date and no longer reflected the guidance as given in the text.

SACCCSD has been working with Public Health Scotland, who provide the guidance on the internet ‘Fit for Travel’ widely used by GPs and travellers, and in JPAC 14-70 have developed a number of maps for areas that are some of the most difficult for session staff to interpret.

ACTION

JPAC approved the inclusion of malarial risk maps in the GDRI.

*Post Meeting Note:* Change Notification No 6 2015 – Malaria Maps was issued on 2 February. Source files were available for training purposes from 17 February and the change will go live on the JPAC website on 17 March 2015.

6. 

Standing Advisory Committee on Information Technology
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6.1 **Identification of Haemoglobin S negative units in EDI information – JPAC 14-71**

Hospitals have requested that HbS (Haemoglobin S; Sickle) negative units can be identified through the EDI information in the blood component dispatch information file. JPAC 14-71 contains full detail of the proposed amendments.

This was approved by JPAC and a change notification will be issued.

*Post Meeting Note:* Change Notification No 1 2015 – Identification of Haemoglobin S negative units in EDI information was issued on 20 January 2015 and is live on the JPAC website.

7. 

Standing Advisory Committee on Tissues and Cellular Therapy Products
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7.1 **Eurocet 128 - update – JPAC 14-72**

AC informed JPAC that a subgroup of SACTCTP, with SACIT, has been established to oversee and co-ordinate the implementation of Eurocet 128 by the UK Blood Services. The first meeting of the group was held on 16 October 2014 and it was envisaged that the project would take 2 to 2 ½ years to complete.

JPAC 14-72 is the draft minutes and actions from that meeting, as well as a brief background of the project.

It was agreed that this should go to the UK Forum and that they will want to know what resource is required. Therefore we should aim to have a paper ready for the UK Forum meeting in March 2015.

*Post Meeting Note:* Following discussion at the JPAC Executive Working Group meeting in January it was felt that a more realistic time frame would be to aim for the UK Forum meeting in Belfast on 11 September, as this was the next face-to-face meeting after March.

AC/SM

7.2 **Proposal to include ‘Serum’ as a blood component for topical use in the EU Directive – JPAC 14-73**

Serum eyedrops (SE) are used as a treatment for patients suffering from severe dry eyes who do not benefit from conventional pharmaceutical eyedrops or surgical interventions.

SACTCTP request that consideration be given to including a section in the EU Directive covering “blood components for topical use”, and that the use of serum as SE be recognised within this section. This paper has already been forwarded to DC to include this request in the proposed list of changes to the Directive.

SM commented that there will also be a section on topical use preparations in the 19<sup>th</sup> edition of the COE Guide and serum eyedrops will be included in that.

ACTION7.3 **Proposal to amend the 'Communication Difficulties' entry in the Tissues and Cells Donor Selection Guidelines – JPAC 14-74**

This proposal was approved by JPAC with one amendment to “2. Third party interpreters” it should say “**where** there is an exchange”. After this amendment a change notification will be issued.

*Post Meeting Note. Change Notification No 7 2015 – Communication Difficulties was issued on 25 February 2015.*

7.4 **Proposal to amend the 'Complementary Therapy' entry in all four Tissue and Cell Donor Selection Guidelines – JPAC 14-75**

This proposed change reflects changes to the name and scope of the Health and Care Professions Council and adds additional information to bring the entry in line with the corresponding entry in the Whole Blood Donor Selection Guidelines

This was approved by JPAC and a change notification will be issued.

*Post Meeting Note. Change Notification No 8 2015 – Complementary Therapy was issued on 25 February 2015.*

7.5 **Proposal to amend the 'Infertility' entry in the Tissues and Cells Donor Selection Guidelines – JPAC 14-76**

This proposed change to the Tissues DSGs will bring them in line with the Whole Blood and Components DSG.

This was approved by JPAC and a change notification will be issued.

*Post Meeting Note. Change Notification No 9 2015 – Infertility was issued on 25 February 2015.*

7.6 **Endoscopy**

The possibility of removing the topic “Endoscopy” from the Tissues DSGs had been discussed at the last SACTCTP meeting.

SM asked AC to submit a paper, with their proposals, to the next JPAC meeting in March 2015.

*Post Meeting Note: Paper submitted to the JPAC meeting on 12 March 2015.*

8. **Ebola update – JPAC 14-77**

Ebola convalescent plasma - Summary notes of NHSBT procedure for sourcing, collection, processing and issue of Ebola virus convalescent plasma to accompany generic process flow chart and Co-ordination of European stock of Ebola convalescent plasma – protocol.

*Post Meeting Notes: This paper has been updated and was submitted to the UK Forum meeting on 12 December.*

*The European Blood Alliance has approved the protocol for the management of European stocks of plasma.*

SI commented that NIBSC have been asked to develop international standards for

ACTION

Ebola antibody testing and are working with Public Health England (PHE) on developing a NAT standard for Ebola detection.

9. 

UK BTS Forum
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9.1 **Report back from the meeting held on 12 September 2014 – JPAC 14-78**

SM went through JPAC 14-78 for the group.

• **Blood Component Labelling**

Proposals for changes to blood component labelling were discussed as detailed in paper UKF2014-03-03. The principles were agreed to be sound but there was concern about the size and extent of the proposals, as well as implications for hospital blood banks and IT. JPAC scoping work was acknowledged. It was agreed to pause further work pending informal discussions with IT experts in Scotland (MM) and at EBA in October. The topic will be revisited at March 2015 UKF.

JJ informed JPAC that she is going to undertake a survey to find out what we can change on the label that is cost free.

• **Redevelopment of the JPAC Website**

The current NHSBT IT system has been having speed issues with the new website. This was raised by the new Chief Executive, Ian Trenholm, at the UK BTS Forum meeting earlier this month. Therefore we have been asked to work with NHSBT to try and improve things as quickly as possible. We have spoken with Target and there are several changes we can make straight away to help speed things up. These changes may slightly affect the way some of the pages look, but they will **NOT** affect the content. Initial changes were completed and went live on 14 October. 2<sup>nd</sup> stage improvements are being progressed.

10. 

Blood Component Labelling
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10.1 **Blood Component Labelling – Summary of work done by JPAC and proposals for change – JPAC 14-79** *(Paper submitted to the UK Forum on 12 September 2014)*

Submitted for information – see item 9.1.

11. 

Blood Competent Authorities meeting, Brussels on 3-4 November 2014 – JPAC 14-80
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Submitted for information.

12. 

SaBTO update
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It was noted that there hasn't been a SaBTO meeting since the last JPAC meeting in July.

The Science and Technology Committee published their report and SaBTO responded in October. There has since been a request for further details from the Chair of the Science and Technology committee.



ACTION

SM has agreed that JPAC will send an annual report to SaBTO on infectious agents under review by JPAC. SM and AK will work on this.

*Post Meeting Note: Paper submitted to SaBTO for their December meeting.*

**AB summarised the SaBTO Work Plan:**

1. Further review of the platelet apheresis and the move away from 80% following some operational issues
2. Review of study looking at vCJD spleen in Tissue Donor and whether this should continue
3. Club 96 will be reviewed by SaBTO
4. Hep E working group – trying to get a draft report together by January and to SaBTO in Spring.
5. Changes to the Blood Secretariat and committee: AB leaves the secretariat position in January; Mark Noterman is retiring in May and Tina Lee has already retired.

*Post Meeting Note: The new SaBTO secondee will be Jo Tossell, NHSBT Nurse Consultant Transfusion Microbiology.*

6. Sub Saharan donors on work plan.

13. 

JPAC Annual Review Form – JPAC 14-81
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Last year a suggestion had been made to SM that JPAC consider providing a process for feedback on performance of members of SACs in order to inform their annual appraisal or PDPR.

The JPAC Executive Working Group had looked at two examples of forms used, one from Department of Health (for Non-Executive Directors of DH sponsored public bodies) and one from NHSBT (used for doctors who have joint appointments with trusts).

It was envisaged that SM would provide this information for the SAC Chairs, and the Chairs would provide the information for their committee members. It would also need to be suitable for all SAC members - medical, scientific or administration staff.

JPAC 14-81 has been produced following consultation with the SAC membership.

JPAC felt that the categories “very good” and “poor” should be removed. With this change the form was approved for submission to the next UK Forum meeting. The UKF would be asked whether or not completion of this form should be compulsory.

*Post Meeting Note: This form has been updated and was submitted to the UK Forum meeting on 12 December, where it was approved.*

14. 

Any Other Business
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14.1 **West Nile Virus – Commission Directive amendment – JPAC 14-82**

SM had submitted this document for information. This amendment has already been

ACTION

approved by the Commission and will be published in January.

It will be on the agenda for the next EBA Executive meeting at which LW will be present.

14.2 **New Chair of the SAC on Clinical Transfusion Medicine**

Dr Megan Rowley has been appointed as the Chair of the SAC on Clinical Transfusion Medicine.

*Post Meeting Note: In early 2015, Dr Rowley will also take over from Lorna Williamson as Chair of the RCPATH Advisory Committee for Transfusion Medicine.*

14.3 **SAC Chair renewals**

Dr Sue Barnes – SACCSA – SB has agreed to continue for 1 year  
Mrs Linda Lodge – SACIT  
Dr Nay Win – SACIH

14.4 **Patient Assessment Form**

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.

AC

14.5 **Membership**

The SACTCTP has discussed SACTTI representation on their committee with AK and it has been agreed that a representative will attend SACTCTP meetings if there is a specific item they need advice on.

14.6 **Quality Manager Representative on JPAC**

JJ informed JPAC that she is stepping down from the roll of Chair of UK BTS Quality and Regulatory Group. The next Chair of the group is Angela Macauley from the Northern Ireland Blood Transfusion Service. Angela will therefore also represent the QMs on JPAC. JJ has agreed to act as Angela's deputy on JPAC if required.

15. **Date & venue for future JPAC meetings**

2015

- Thursday 12 March - The Association of Anaesthetists, London
- Thursday 18 June - The Association of Anaesthetists, London
- Thursday 12 November - The Association of Anaesthetists, London

Meeting closed at: 15:15