

## Joint UKBTS Professional Advisory Committee

Minutes of the 60<sup>th</sup> meeting held at the  
Association of Anaesthetists, 21 Portland Place, London,  
on Thursday 12<sup>th</sup> March 2015

Meeting commenced at: 11:05 am

### 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 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
Dr Megan Rowley	<b>(MR)</b>	- Standing Advisory Committee on Clinical Transfusion Medicine
Miss Caroline Smith	<b>(CJS)</b>	- JPAC Manager (Minute taker)
Dr Amy Thomas	<b>(AT)</b>	- Human Tissue Authority (HTA)
Mrs Joanne Tossell	<b>(JT)</b>	- Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)
Dr Lorna Williamson	<b>(LW)</b>	- Medical Director, NHS Blood and Transplant

### ACTION

1. Apologies

Dr Stephen Inglis	<b>(SI)</b>	- Director, National Institute for Biological Standards and Control
Prof James Neuberger	<b>(JN)</b>	- Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Prof Marc Turner	<b>(MT)</b>	- Medical Director, Scottish National Blood Transfusion Service
Dr Nay Win	<b>(NW)</b>	- Standing Advisory Committee on Immunohaematology
Prof Maria Zambon	<b>(MZ)</b>	- Director, Centre for Infections, Public Health England (PHE)

SM welcomed Jo Tossell, Megan Rowley and Angela Macauley to their first JPAC meeting. This is also the first meeting that Rebecca Cardigan is attending as the

ACTION

Deputy Chair.

2. **Minutes of the last meeting held on 13 November 2014 – JPAC 15-02**

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

3. **Matters arising not on the agenda (Review of actions list) JPAC 15-03**

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

At the request of JPAC, SACCCSD had discussed how to change the wording of the homosexual/bisexual entries at their meeting last 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 SACCCSD, 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 informed JPAC that they are still awaiting feedback from Public Health England (PHE). SB

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

Further discussions have taken place between SM and DC. A Change Notification will be issued. SM & RC

3.3 **Methylene blue-treated plasma – Position Statement – JPAC 14-39 – item 3.6**

Please see item 7.2 and JPAC 15-36.

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

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.

AK informed the group that further discussion is required by SACTTI and a paper will be submitted to the next JPAC meeting in June 2015.

SM suggested that inclusion of a representative from the SACCCSD might be helpful.

*Post Meeting Note: Paper " The Changing Epidemiology of Arthropod-Borne Viral Infections, with Particular Focus on Dengue and Chikungunya and the Impact on the Safety of Blood Products" was submitted to the JPAC meeting on 18 June 2015.*

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

DC has submitted this to the European Commission for discussion regarding an amendment to the Directive. Action complete.

3.6 **Eurocet 128 - update – JPAC 14-72 – item 7.1**

It was agreed at the last JPAC meeting 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

ACTION

a paper ready for the UK Forum meeting in March 2015.

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.

AC

3.7 **Patient Assessment Form – item 14.4**

At the last 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.

AC updated JPAC on the discussions which took place at the SACTCTP meeting.

“The current Deceased TDSGs contain a requirement that donors cannot donate tissues if they have been incarcerated within the past 12 months. During review of the new PA1 form with ODT, there were discussions around this question as it is not included in other questionnaires. AC supported the proposal to remove this entry from the deceased TDSG to bring this in line with other guidelines. Pat Hewitt explained that the requirement had been introduced some years ago as a precautionary step. Since then, the sensitivity of testing protocols has increased greatly, and she felt this was an outdated requirement that could be removed. It was not an EU Directive requirement. Sharon Zahra (SNBTS) expressed a concern that for deceased donors, the donor could not be questioned directly and felt there was a risk that relatives or friends providing medical and behavioural history may not have accurate information regarding the donor’s behaviour while incarcerated. Following extensive discussion, it was apparent that an agreement on this matter was unlikely at this meeting. It was agreed that AC would prepare a paper summarising the case against retaining the prison deferral, and Sharon Zahra prepare a paper summarising the case for, to be discussed at the next SACTCTP meeting.”

AC informed JPAC that, when received, the paper from SNBTS would be sent to SACTTI for comment.

AC

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

4.1 **Minimum 28 day travel deferral for all overseas travel – JPAC 15-04**

JPAC had asked the SACCSO to produce a document based on the JPAC decision making framework for discussion. SM thanked the SAC for this review.

JPAC approved the recommendation of the SACCSO not to recommend such a deferral and that the situation should be reviewed if the epidemiological situation changes.

4.2 **Clarification to the Central Nervous System (CNS) Disease entry in the Whole Blood and Component Donor Selection Guidelines – JPAC 15-05**

Some collection sessions were accepting Parkinson's disease if not on treatment. SACCSO advised that the CNS entry needed clarifying to say:

**Discretionary**

- e) If taken for a condition other than Parkinson's Disease as long as not having symptoms of hypotension related to dopamine receptor agonist drugs such as rotigotine, bromocriptine, ropinirole and pramipexole, accept

ACTION

JPAC approved this clarification and a Change Notification will be issued.

*Post Meeting Note: Draft Change Notification No 10 2015 – Central Nervous System Disease is with the MDs for approval.*

#### 4.3 **'Communication Difficulties' entry in the Whole Blood and Component Donor Selection Guidelines – JPAC 15-06**

SACCSD proposed that the 'Communication Difficulties' entry in the Whole Blood and Component Donor Selection Guidelines be amended for the following reasons:

1. To clarify that interpreters and translators do need to understand the importance of providing a truthful and accurate interpretation or translation to enable the Blood Establishment to comply with regulatory requirements
2. To clarify that interpreters and translators have a duty of confidentiality
3. To bring the guidance in line with that for Tissue donors

JPAC approved this recommendation and a Change Notification will be issued.

*Post Meeting Note: Draft Change Notification No 11 2015 – Communication Difficulties is with the MDs for approval.*

#### 4.4 **Complementary Therapy entry in the Whole Blood and Component Donor Selection Guidelines –JPAC 15-07**

SACCSD recommended three amendments to the Complementary Therapy entry:

- 1) Add Pharmacists to the list of professions regulated through the Health and Care Professions Council.
- 2) Add Cosmetic Fillers and Faecal Microbiota Transplantation to the Index, leading to Complementary Therapy.
- 3) Add (illegal) injectable tanning drugs to Index leading to the blood safety entry and a slight amendment made.

For clarity it was suggested that Discretionary b) should be changed to say:

“b) For all other therapies (including Faecal Microbiota)”

It was noted that this also applies to all the Tissues and Cells Donor Selection Guidelines as well.

JPAC approved these amendments and a Change Notification will be issued which will cover all the DSGs.

*Post Meeting Note: Draft Change Notification No 12 2015 – Complementary Therapy is with the MDs for approval.*

#### 4.5 **Chikungunya Virus in the Pacific Region – Change to the Geographical Disease Risk Index (GDRI) – JPAC 15-08**

NaTHNaC has reported further outbreaks of Chikungunya Fever, therefore the SACCSD recommends updating the guidance in the GDRI for:

- American Samoa

ACTION

- French Polynesia
- Samoa
- Tonga
- Tokelau

SACCCSD had noted that Taiwan was currently in the GDRI as an area at risk of Chikungunya Fever, which it is not. Therefore SACCCSD recommends that this entry is changed to “no risk”.

JPAC approved these recommendations and a Change Notification will be issued.

*Post Meeting Note: Draft Change Notification No 14 2015 – Chikungunya Virus (GDRI) is with the MDs for approval.*

4.6 **Namibia - Change to the Geographical Disease Risk Index (GDRI) – JPAC 15-09**

SB informed JPAC that they had received complaints about the current guidance on Malarial deferral following travel to Namibia.

SACCCSD recommends that the Namibia entry is changed as follows for malaria and a map added:

Malaria	Yes <i>All year in the area north of Windhoek except the narrow costal strip.</i>
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Malaria Risk Category	B
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JPAC approved this clarification and a Change Notification will be issued.

*Post Meeting Note: Draft Change Notification No 13 2015 – Namibia (GDRI)is with the MDs for approval.*

4.7 **Whole Blood and Components Donor Selection Guidelines re-write validation – verbal update by SB**

At the last SACCCSD meeting the committee spent a lot of time looking at the operational issues around the validation of the topics.

SB informed JPAC that the Statisticians had asked for a minimum of 200 Doctors/Nurses to help with the validation. This was, however, not thought to be achievable due to limited staff numbers.

LL agreed to contact Dr Angus Wells to ascertain numbers of available staff in Scotland.	LL
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LW requested a copy of the scenarios after they have been discussed at the next SACCCSD meeting.	SB
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5. 

Standing Advisory Committee on Transfusion Transmitted Infections
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5.1 **Amendment to Chapter 9 of the 8<sup>th</sup> edition of the Guidelines for the Blood Transfusion Services in the United Kingdom (Red Book) – JPAC 15-10**

ACTION

- Section 9.4.2 of the 8<sup>th</sup> Edition of the Red Book Guidelines is redundant. The handling of screen reactive tissue and stem cell donations is covered in Section 9.2.3.2.
- JPAC approved the recommendation to remove this section from the Red Book and an appropriate Change Notification will be issued. AK
- 5.2 **Babesia risk assessment, version 3 – JPAC 15-11**
- This is an updated risk assessment for Babesia. JPAC noted that there is no overall change in the risk or available options.
- 5.3 **Dengue risk assessment, version 6 – JPAC 15-12**
- SACTTI have updated this risk assessment. Dengue is now spreading into areas that are not malaria endemic, nor covered by other specific deferral rules, for example areas with ongoing transmission of Chikungunya virus. However this recent spread is currently limited and its significance is not yet known. Although the risk is changing, SACTTI recommends no change in the approach to Dengue at this time. JPAC approved this recommendation.
- AK informed JPAC that the review of arthropod-borne infections, which SACTTI are currently undertaking, will be submitted to the next JPAC meeting in June.
- Post Meetin Note: Paper “ The Changing Epidemiology of Arthropod-Borne Viral Infections, with Particular Focus on Dengue and Chikungunya and the Impact on the Safety of Blood Products” was submitted to the JPAC meeting on 18 June 2015.*
- 5.4 **Leishmania risk assessment, version 3 – JPAC 15-13**
- This is an updated risk assessment for Leishmania, containing information on the most recent literature. JPAC noted that there is no overall change in the risk or available options.
- 5.5 **Middle East Respiratory Syndrome Corona Virus (MERS-CoV) risk assessment, version 4 – JPAC 15-14**
- This is an updated risk assessment for MERS-CoV. JPAC noted that there is no overall change in the risk or available options. SACTTI will keep a watching brief as the situation is still unfolding.
- 5.6 **Simian Foamy Virus risk assessment, version 3 – JPAC 15-15**
- This is an updated risk assessment for Simian Foamy Virus (SFV). JPAC noted that there is no overall change in the risk or available options.
- SACTTI requested that SFV should be removed from the list of risk assessments that require regular review and therefore only reviewed if the situation changes.
- This was approved by JPAC and a comment to this effect should appear in the risk assessment. AK
- 5.7 **Toxoplasma risk assessment, version 4 – JPAC 15-16**
- This is an updated risk assessment for Toxoplasma, containing information on the most recent literature. JPAC noted that there is no overall change in the risk or available options.

ACTION

5.8 **The estimated risk that a donation entering the blood supply is a potentially infectious window period donation: risks specific for HBV, HCV and HIV in the UK, 2011-2013 – JPAC 15-17**

JPAC approved this document which will be published on the website.

*Post Meeting Note: The JPAC Position Statement has been updated with these figures and posted on the JPAC website.*

WM expressed the view that, with regard to donations from MSM, calculation of the WP risk may not be a valid surrogate for the real risk. It was noted, however, that there is a bigger data set that feeds into decision making about overall reduction of risk and not only monitoring of the risk of viral positive donations in the WP.

5.9 **Borrelia burgdorferi (Lyme Disease) - Study to determine the seroprevalence of Lyme borreliosis (LB) within the Scottish blood donor population – JPAC 15-18**

As MT could not attend this meeting AK went through this paper for JPAC.

This was last discussed at the JPAC meeting on 17 July, where it was noted that infection risk is increasing in some areas of the UK.

SNBTS have carried out a study to determine the seroprevalence of Lyme borreliosis (LB) within the Scottish blood donor population. JPAC 15-18 is an explanatory note for JPAC.

SACTTI are keeping this under review.

5.10 **Cost implications of HTLV blood screening options – JPAC 15-19 Amended**

The UK Blood Services started screening in 2002 after instruction by the then MSBTO (now SaBTO). As this decision was made by MSBTO SaBTO need to review and decide if change is needed.

After a long discussion it was agreed that SM and AK will undertake to put together a small working group to review the SACTTI options paper on future screening and the cost-effectiveness paper from the Analytical Steering Group and make recommendations for the SaBTO meeting on 15 September 2015 with draft to JPAC at the next meeting.

SM will update the UK Forum at their meeting on 20 March.

SM

6. 

Standing Advisory Committee on Tissues and Cellular Therapy Products
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6.1 **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**

***Paper JPAC 15-21: A proposal to remove Endoscopy as a deferral criteria for tissue donors, version 1, 2008 accompanies JPAC 15-20 for information***

JPAC noted that Endoscopy is not an exclusion criterion specified in the EU Tissues and Cells Directive and that the Human Tissue Authority (HTA) have no objection to the proposed change as this is not a regulatory requirement.

ACTION

- JPAC endorsed the removal of the endoscopy entry from the Live Tissue, Cord Blood and Allogeneic Bone Marrow and Peripheral Blood Stem Cells Donor Selection Guidelines.
- After discussion it was agreed that the paper needed amending to include prions, after which a Change Notification will be issued. AC
- 6.2 **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**
- This proposal is 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 that are consistent with the corresponding entries in the Whole Blood Donor Selection Guidelines. This will also involve changing the current entries in the Live Tissue Donor Selection Guidelines to cross reference the Northern Ireland specific entries.
- JPAC approved this recommendation and a Change Notification will be issued. AC
7. 

Standing Advisory Committee on Blood Components
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- 7.1 **Interruption of platelet agitation and handling of apheresis platelets, version 2.11 – JPAC 15-35**
- RC went through this paper for JPAC. RC wanted to extend special thanks to Dr Stephen Thomas for pulling all this information together on behalf of SACBC.
- JPAC approved the recommendations in JPAC 15-35. Platelet specifications will be modified and Change Notifications will be issued as follows.
- 1) For all platelet components (including platelets suspended in the current additive solution) - limit any single interruption to agitation to 8 hours with a total length of all interruptions to remain at 24 hours.
  - 2) Temporary splitting of double or triple apheresis platelets at the time of collection.
  - 3) Increase in required percentage of platelets having pH > 6.4 at outdate to 95% from current 75%.
- 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
- 7.2 **Position Statement - Methylene Blue-Treated Plasma – JPAC 15-36**
- SM thanked RC and SACBC for this excellent piece of work updating the Methylene Blue treated plasma Position Paper with further data. The update has concluded that MB-treated plasma is still an acceptable component in the UK.
- It was agreed that this paper merits publication and that when the paper is published a link will be added to the JPAC website. RC



ACTION

7.3 **Position Statement - Shelf life of fresh-frozen plasma following thawing – JPAC 15-37**

For information. On 23 January, following approval at the JPAC Executive Working Group meeting, the previous 2011 paper was removed from the JPAC website and replaced by this summary. This was to avoid copyright issues as the paper had been submitted and accepted as a review article in Vox Sanguinis.

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

The current text in the Red Book only refers to platelets suspended in plasma, but with the imminent introduction of additive solution for suspension of platelets, it is appropriate to consider the addition of a specific entry for this component.

JPAC approved the recommendation to change section 6.3.3. in the Red Book and a Change Notification will be issued.

RC

7.5 **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**

JPAC endorsed the changes to the specification for this component as detailed in JPAC 15-39. A Change Notification will be issued.

RC

8. 

UK BTS Forum
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8.1 **Report back from the meeting held on 12 December 2014 – JPAC 15-23**

RC had joined this telecon on SMs behalf.

9. 

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

JT went through her report for JPAC.

Agenda items for the SaBTO meeting on 14 April are:

- Output from the Hepatitis E Working Group. LW invited comments on a draft paper that she will circulate to JPAC
- Science & Technology Select Committee report
- NHSBT/PHE Donor Survey
- HTLV Testing
- Review of MSBTO microbiology recommendations

LW

10. 

Specification for the future labelling of blood components prepared in the United Kingdom – JPAC 15-25
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It was agreed that this should go to the next UK Forum meeting on 20 March, with the recommendation that the specification can be shared with manufacturers to help assess cost and resource requirements. With a clear understanding that there is no decision as to when this work will proceed. Consultation will take place with

ACTION

procurement to ensure that contact is made in a legitimate fashion.

*Post Meeting Note: SM and LL submitted an updated, more succinct, paper to the UK Forum where they agreed that the specification could be shared with manufacturers to provide information on costs and resources.*

11. 

Any Other Business
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11.1 **Policy on publication of work by JPAC – JPAC 15-26**

RC has produced this policy on behalf of JPAC.

JPAC actively encourages members of its Standing Advisory Committees (SACs) to publish work that has been conducted on behalf of JPAC, where relevant. This will facilitate:

- Independent peer-review
- Professional development of SAC members
- Raising the profile of JPAC and its SAC's

JPAC approved this policy, which should also appear in the JPAC constitution. SM asked the SAC Chairs to disseminate this policy to their committee members.

11.2 **Horizon scanning review – Health Group internal audit – JPAC 15-27**

This paper had been circulated to JPAC for information. LW has put together a task and finish group.

11.3 **ABO risk based decision making project - Dr Lorna Williamson**

This work is coming to a close – the final step will be development of a web-based tool.

11.4 **New MHRA website on .gov**

DC informed JPAC that the MHRA website is now on the .gov site. Please feed back any comments for the MHRA.

11.5 **Penrose Inquiry - Scotland**

The Final Report of the Penrose Inquiry will be published on Wednesday 25 March 2015.

11.6 **Acupuncture**

A survey is underway on loss of donors for reasons of acupuncture – this will help inform a revised risk assessment on the topic following discussion with the British Acupuncture Council (BAcC). A Working Group will be put together for this work.

SM & SB

11.7 **Competent Authorities meeting in April**

JPAC noted that the blood Directives do not appear on the agenda for this meeting.

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12. 

Date & venue for future JPAC meetings
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2015

- Thursday 18 June - The Association of Anaesthetists, London
- 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: 15:40