

## Joint UKBTS Professional Advisory Committee

### Minutes of the 63<sup>rd</sup> meeting held at the Association of Anaesthetists, 21 Portland Place, London, on Thursday 10 March 2016

Meeting commenced at: 11:03

#### Present

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
Dr Sheila MacLennan	<b>(SM)</b>	-	Professional Director of JPAC <b>(Chair)</b>
Dr Gail Mifflin	<b>(GM)</b>	-	Standing Advisory Committee on Care and Selection of Donors
Dr Megan Rowley	<b>(MR)</b>	-	Standing Advisory Committee on Clinical Transfusion Medicine
Miss Caroline Smith	<b>(CJS)</b>	-	JPAC Manager (Minute taker)
Dr Shirley Stagg	<b>(SS)</b>	-	Human Tissue Authority (HTA)
Prof Marc Turner	<b>(MT)</b>	-	Medical Director, Scottish National Blood Transfusion Service

#### Observers

Mr Jonathan Graves	<b>(JG)</b>	-	Department of Health
Dr Gary Mallinson	<b>(GMal)</b>	-	Scientific Lead Safety Policy (JPAC/SaBTO) observing at this meeting.

SM informed JPAC that Dr Stephen Inglis and Dr Christian Schneider (NIBSC) would be joining the meeting at 2:30, so that SI can introduce Christian to JPAC. Christian will become a member of JPAC, as NIBSC Medical Director, when SI retires.

SM welcomed GM to her first JPAC meeting as Chair of the SACCSA and congratulated her on her new job as Medical Director of NHSBT. Therefore GM would be stepping down as the Chair of SACCSA and attending future JPAC meetings in her MD role.

SM also welcomed Jonathan Graves and Gary Mallinson to the meeting. Jonathan works with SaBTO at the DH and GMal, who has been appointed as the Scientific Lead Safety Policy (JPAC/SaBTO), is observing at this meeting as he doesn't start his new role until April. Thereafter he will become a member of JPAC.

#### ACTION

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|-----------|------------------|--|
| <b>1.</b> | <b>Apologies</b> |  |
|-----------|------------------|--|

Dr Stephen Inglis	<b>(SI)</b>	-	Director, National Institute for Biological Standards and Control
Mrs Angela Macauley	<b>(AM)</b>	-	Quality Manager, Northern Ireland Blood Transfu Service representing the Quality Managers of the UK Blood Services

**ACTION**

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
Prof James Neuberger	<b>(JN)</b>	-	Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
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
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)

2. **Minutes of the last meeting held on 12 November 2016 – JPAC 16-02**

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

3. **Matters arising not on the agenda (Review of actions list) JPAC 16-03**

3.1 **Whole Blood and Components Donor Selection Guidelines re-write validation – item 3.1**

GM has now seen the data and this will be discussed at the next SACCS meeting in April and then a decision will be made how to proceed.

**GM**

It was noted that there may be a resource issue if it is decided to rewrite the guidelines entirely. GM will discuss further with SM.

**GM & SM**

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

AC plans to produce a similar paper for Tissue donors.

AC informed JPAC that this would need a change at the European Association of Tissue Banks (EATB) and that she is on that group. It was agreed that this would be taken off the actions list and only brought back to JPAC if there is going to be a change.

3.3 **Deviations from 4oC – item 3.7**

RC had been on a telecon with BCSH where this was discussed. BCSH want to include the JPAC information in their guidance and are planning to add as an appendix, but they cannot do this until they can link with the paper on the JPAC website. RC has asked for an update from bacteriology colleagues as to where the outstanding actions are so that this paper can be posted on the JPAC website.

SM intends to take this paper to the next Blood Consultative Committee (BCC) of the MHRA meeting on 17 March 2016 for information. Mr Chris Elliot and Dr Shubha Allard, from the BCSH, will also be attending this meeting.

*Post meeting note: (1) The outstanding bacteriology work has been completed, the data reviewed and the paper updated to reflect this. The paper has been posted on the JPAC website. (2) This paper was presented at the BCC who noted its contents. BCSH representatives confirmed they were happy to work with JPAC to put the*

**ACTION**

*changes in place.*  
**3.4 Any Other Business – item 3.10**

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 and this will be added to the JPAC work plan.

**SM & RC****LL arrived at 11:15**

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

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

LW and SM had had another meeting with the BAcC, which had been very positive.

SM informed JPAC that there is going to be a SaBTO Donor Deferral Review. Acupuncture and tattooing will be included in this review, as well as IVDU and sub-Saharan Africa. SF is on that group and GM has also been invited.

It was agreed that this will come off actions list and that JPAC will see the outcomes in due course.

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

This will not be progressed at this time.

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

- 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 informed JPAC that all these actions had now been completed, change notification issued and the BCSH notified.

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

**MT arrived at 11:25**

JPAC had endorsed the recommendations in JPAC 15-89 at its last meeting in November 2015.

RC informed the group that the BCSH drafting group had now written an addendum, this has been to the Transfusion Task Force and had gone out for review to the sounding board.

A change notification has been drafted and JPAC agreed that this could be issued now rather than waiting for BCSH.

**ACTION**

It was also noted that The Blood Stocks Management Scheme now includes data on wastage of frozen components in their routine collection of data.

*Post Meeting Note: Change Notification No 16 2016 – Fresh Frozen Plasma, Leucocyte Depleted was issued on 29 March 2016 and live on the JPAC website on 31 March 2016.*

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

4.1 **Acne topic – update to the Whole Blood Donor Selection Guidelines – JPAC 16-04**

JPAC approved the amendment to the Acne topic regarding antibiotics, diuretics (such as spironolactone) and a change notification will be issued.

*Post Meeting Note: Change Notification No 18 2016 Acne was issued on 7 June 2016 and will go live on the JPAC website on 5 July 2016.*

4.2 **Disabled donor topic – update to the Whole Blood Donor Selection Guidelines – JPAC 16-05**

Following a recent complaint from a potential donor, who is a wheelchair user, the SACCS D feel it may be helpful if the criteria used to consider whether such persons may donate are clarified.

JPAC approved the clarification to the Disabled Donor topic and a change notification will be issued.

*Post Meeting Note: Change Notification No 19 2016 Disabled Donor was issued on 7 June 2016 and will go live on the JPAC website on 5 July 2016.*

4.3 **High haemoglobin topic – update to the Whole Blood Donor Selection Guidelines – JPAC 16-06**

These changes apply to the Haematological Disease, Polycythaemia and Haemoglobin Estimation topics and would be issued in one change notification.

JPAC approved the recommendations in this paper, but asked for two amendments to page 4 “Discretionary” - (1) that “copper sulphate” should be replaced with “validated method” and (2) “should” should be replaced with “may”.

*Post Meeting Note: Change Notification No 20 2016 High Haemoglobin was issued on 7 June 2016 and will go live on the JPAC website on 5 July 2016.*

4.4 **Immunoglobulin topic – update to the Whole Blood Donor Selection Guidelines – JPAC 16-07**

JPAC approved the clarification to the wording of the Immunoglobulin Therapy and Transfusion topics and a change notification will be issued.

*Post Meeting Note: Change Notification No 21 2016 Immunoglobulin was issued on 7 June 2016 and will go live on the JPAC website on 5 July 2016.*

4.5 **Malaria – Countries that were previously a malaria risk – Geographical Disease Risk Index – JPAC 16-08**

The management of donors who have a history of residency in a country at a time that malaria was present but is now malaria free had been raised at SACCS D.

**ACTION**

JPAC approved the recommendation to add a new category to appropriate entries: *Previous Malaria Risk* and use the information we have since 1993 to assist in this area. It would be up to each Blood Service to decide how they use this information.

A change notification will be issued.

*Post Meeting Note: Change Notification No 22 2016 Malaria was issued on 7 June 2016 and will go live on the JPAC website on 5 July 2016.*

**4.6 Zika Virus – Update to countries affect by Zika - Geographical Disease Risk Index – JPAC 16-43**

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

*Post meeting Note: Change Notification No 17 2016 – Tropical Virus Risk was issued on 29 March 2016 and the changes went live on the JPAC website on 31 March 2016 (Cuba was also included in this change notification).*

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

**5.1 Endoscopy topic – Living Tissue Donor Selection Guidelines – JPAC 16-09**

JPAC approved the removal of this entry from the Living Tissue Donor Selection Guidelines and a change notification will be issued.

*Post Meeting Note: Change Notification No 24 2016 Endoscopy has been approved by the Medical Directors and the changes are currently in pre-publish on the JPAC website.*

**5.2 Fibromyalgia, new topic – Living and Deceased Tissue Donor Selection Guidelines – JPAC 16-10**

This entry had been created following a request from the Eye Banking Subgroup of the Ocular Tissue Advisory Group.

JPAC approved this new entry in both the Living and Deceased Tissue Donor Selection Guidelines and a change notification will be issued.

*Post Meeting Note: Change Notification No 25 2016 Fibromyalgia has been approved by the Medical Directors and the changes are currently in pre-publish on the JPAC website.*

**5.3 Necrotising Fasciitis entry - Deceased Tissue Donor Selection Guidelines – JPAC 16-11**

JPAC approved this new entry in both the Deceased Tissue Donor Selection Guidelines and a change notification will be issued.

*Post Meeting Note: Change Notification No 26 2016 Necrotising Fasciitis has been approved by the Medical Directors and the changes are currently in pre-publish on the JPAC website.*

**5.4 Post mortem retrieval time limits and time from retrieval to processing for ocular tissue – JPAC 16-12**

AC informed JPAC that this change had been approved by the Ocular Tissue Advisory Group (OTAG)

**ACTION**

JPAC approved this change to Section 21.12 of the Red Book and a change notification will be issued.

*Post Meeting Note: Change Notification No 23 2016 Chapter 21 has been approved by the Medical Directors and the changes are currently in pre-publish on the JPAC website.*

**5.5 Osteogenesis Imperfecta topic - Living and Deceased Tissue Donor Selection Guidelines – JPAC 16-13**

JPAC approved this new entry in both the Living and Deceased Tissue Donor Selection Guidelines and a change notification will be issued.

*Post Meeting Note: Change Notification No 27 2016 Osteogenesis imperfecta has been approved by the Medical Directors and the changes are currently in pre-publish on the JPAC website.*

**5.6 Severe Exercise Intolerance Disease (SEID) topic – All Tissue Donor Selection Guidelines – JPAC 16-14**

JPAC approved adding an entry for SEID to all four tissue and cell guidelines linking to the 'Post Viral Fatigue Syndrome' entry and a change notification will be issued.

*Post Meeting Note: Change Notification No 28 2016 Severe Exercise Intolerance Disease has been approved by the Medical Directors and the changes are currently in pre-publish on the JPAC website.*

**5.7 Xenotransplantation topic - All Tissue Donor Selection Guidelines – JPAC 16-15**

JPAC approved amending the entry in the Living and Deceased Tissue, Bone Marrow and Peripheral Blood Stem Cell and Cord Blood Donor Selection Guidelines and a change notification will be issued.

*Post Meeting Note: Change Notification No 29 2016 Xenotransplantation has been approved by the Medical Directors and the changes are currently in pre-publish on the JPAC website.*

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

**6.1 ZIKA Virus – Position Statement – JPAC 16-16**

JPAC asked AK to make some amendments to page 3 with regard to persistence of the virus in semen, after which the position statement will be posted on the JPAC website.

*Post Meeting Note: JPAC 16-16 Amended was circulated to JPAC on 12-04-16 and the JPAC Position Statement on Zika Virus was posted in the Document Library on the JPAC website.*

**6.2 ZIKA Virus – Risk Assessment – version 1 – JPAC 16-17**

AK went through this risk assessment for JPAC. Several changes/additions were suggested and it was therefore agreed that, when these had been completed, the risk assessment would be recirculated to JPAC for approval by email. It was also agreed that this risk assessment should be review annually rather than every two years.

*Post Meeting Note: The updated risk assessment was emailed to members of*

**ACTION**

*JPAC for approval on 17 March 2016 and subsequently approved. JPAC 16-17 Amended was circulated to JPAC on 12-04-16.*

**6.3 ZIKA Virus – Preliminary risk assessment: deferral of donors who are sexual contacts of travellers to Zika affected areas – JPAC 16-45**

After discussion it was agreed that this should be put through the ABO risk assessment format.

JG informed JPAC that the Zika Virus was on the agenda of the next SaBTO meeting in April and that SaBTO would be interested in this paper.

It was agreed that this should go through the ABO risk assessment before SaBTO on 26 April and that SM will speak on this at the meeting itself. Therefore it was agreed that a sub-group should be formed to look at this which will include: SM, Akila Chandrasekar, Alan Kitchen, Gail Mifflin, Gary Mallinson and Jo Tossell.

*Post Meeting Note: The first meeting was held by telecon on 13 April and a face-to-face meeting was held on 18 May.*

**6.4 Human Herpes Virus 8 (HHV-8) – Risk Assessment – version 4 – JPAC 16-18**

JPAC approved this updated risk assessment.

**6.5 Hepatitis E (HEV) Risk Assessment – version 2 – JPAC 16-19**

JPAC approved this updated risk assessment, which reflects the current position, and agreed a 1 year review date.

**6.6 Harmonisation of deferral periods for ‘at risk’ blood donors requiring additional anti-HBc testing – Verbal update**

SACTTI had received a request from SACTCTP to look at the difference in deferral periods, if the optional anti-HBc testing is not performed, for those donors with tattoos, piercing etc., and those who have had endoscopy. Currently endoscopy has a 6/12 deferral whilst tattoos and piercings etc. have a 12/12 deferral.

Although SACTTI agreed that it was unlikely that there was any risk in harmonising the deferral period, without performing anti-HBc testing, to 6/12, they also thought that there was currently a lack of evidence to support this, and it would therefore be sensible to try to generate some supporting data. NTMRL, NHSBT's Microbiology Reference Laboratory, to generate the data required prior to the May SACTTI meeting. The SACTTI decision could then be taken to the June JPAC meeting.

**AK**

SM stated that this work would then need to be fed into the SaBTO review of donors with additional specific risks.

SF asked why the UK Blood Services does not simply apply the actual requirements of the EU Directive, which is deferral for 4/12. This point could also be fed into the SaBTO review.

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

**7.1 Granulocyte Therapy position statement - posted in December sent to JPAC for information only – JPAC 16-20**

This latest version of the Granulocyte Therapy position statement had been circulated for information only.

**ACTION****7.2 Inclusion of '30 minute rule' in component specifications – JPAC 16-21**

RC informed JPAC that BCSH has questioned why guidance on the 30 minute rule is not in the Red Book, since this relates to storage of blood components. SACBC agreed it would be sensible for guidance to be included in the relevant component specifications in the Red Book as well as in the BCSH guidelines, as hospitals frequently refer to the Red Book for information regarding storage of blood components. RC will progress a Change Notification.

RC

SM agreed to take this to the MHRA Blood Consultative Committee meeting on 17 March for information.

*Post Meeting Note: This addition was presented at the BCC meeting in conjunction with JPAC 15-54.*

**7.3 Liquid plasma – JPAC 16-22**

RC thanked the component development team at NHSBT who have done an enormous amount of work on this project.

It was noted that on page 15, first paragraph under "Results", it says EU guidelines. This is incorrect and should be Council of Europe guidelines. It was also agreed that the paper needed some information on microbiology risk. With these amendments JPAC approved the specification, including the 7 day shelf life and that it would be posted on the JPAC website in Annex 3 Trial Components. It is up to the individual Blood Services to decide operationally whether they would like to consider implementation of this component and whether there is any merit in doing further work to investigate whether the shelf-life could be extended to 11 or 14 days.

SACBC intends to publish this work.

*Post meeting note: A3.3 Liquid Plasma, Leucocyte Depleted has been posted in the Trial Components area on the JPAC website.*

**8. JPAC Work Plans****8.1 JPAC Work Plan 2015 to 2016 – JPAC 16-23**

Circulated for information.

**8.2 JPAC Draft Work Plan 2016 to 2017 – JPAC 16-24**

Circulated for information. The UK Forum have requested that, in future, the work plans need to be divided in routine tasks and priorities. SM and CJS will work on the next draft for ratification at the next EWG teleconference.

SM / CJS

*Post Meeting Note: Draft new format submitted to the UK Forum meeting on 17 July 2016.*

**9. JPAC SACs Terms of Reference****9.1. ToRs re-confirmed at the SAC Annual Review meetings – JPAC 16-25**

Circulated to for information. Noted by JPAC

**10. SaBTO**



**10.1 Notes from the SaBTO meeting on 13 January 2016 – JPAC 16-26**

SM went through this paper for JPAC which includes information on:

- HEV
  - *H SCT*
  - *SOT*
- UK Blood Services Donor Survey
- Donor Deferral Review
- Ebola survivors
- Horizon scanning
- Donor Organ Risk Assessment (DORA) Working Group
- Micro safety of organs, tissues and cells guideline review Working Group

The next SaBTO meeting is on Wednesday 26 April and the following items would be included:

- Zika Virus
- An update on HEV
- Donor organ risk assessment

**11. Horizon Scanning****11.1 Draft JPAC Management Process – Preparedness for emerging infections – JPAC 16-27**

This process was approved.

**11.2 Emerging infections Listing: NHSBT/PHE Epidemiology Unit, Nov-Dec 2015 – JPAC 16-28**

Current situation and circulated for information.

**11.3 Assessment of the probability of the exposure of the UK donor population to an infectious agent which may pose a threat to product safety – Blank form – JPAC 16-29**

Circulated for information.

**11.4 Assessment of the probability of the exposure of the UK donor population to an infectious agent which may pose a threat to product safety – Completed for human hepegivirus – JPAC 16-30**

Circulated for information.

**12. UK BTS Forum****12.1 Report from the meeting held on 04 March 2016 – JPAC 16-44**

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

- JPAC work plans
- Horizon scanning
- Acupuncture
- Zika virus
- Reports from EBA working groups (WG on Blood Directives and WG on WNV Directive)

**ACTION****13. Any Other Business****13.1 EU Directive**

LL informed JPAC that the Medical Devices and IVD Directives are being re-written. There may be implications for the Services with regard to the CE marking of software.

**13.2 Competent Authority Meeting 13 and 14 April 2016**

In the absence of David Carter please contact David Churchward, via email, regarding this next meeting.

**12. Date & venue for future JPAC meetings****2016**

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

**2017**

- Thursday 09 March - The Association of Anaesthetists, London
- Thursday 22 June - The Association of Anaesthetists, London
- Thursday 09 November - The Association of Anaesthetists, London

**2:30 pm** - Dr Stephen Inglis and Dr Christian Schneider (NIBSC) joined the meeting.

**Meeting closed at: 14:45**