

Joint UKBTS Professional Advisory Committee

Minutes of the 64th meeting held at the Association of Anaesthetists, 21 Portland Place, London, on Thursday 23 June 2016

Meeting commenced at: 11:02

Present

Dr Rebecca Cardigan	(RC)	-	Standing Advisory Committee on Blood Components
Dr Akila Chandrasekar	(AC)	-	Standing Advisory Committee on Tissues and Cellular Therapy Products
Dr Stephen Field	(SF)	-	Medical Director, Welsh Blood Service
Dr Alan Kitchen	(AK)	-	Standing Advisory Committee on Transfusion Transmitted Infections joined by telecon
Mrs Joan Jones	(JJ)	-	Quality Manager, Deputising for Mrs Angela Macauley
Dr Sheila MacLennan	(SM)	-	Professional Director of JPAC (Chair)
Dr Gary Mallinson	(GMal)	-	Scientific Lead Safety Policy (JPAC/SaBTO)
Dr Gail Miflin	(GM)	-	Medical Director, NHS Blood and Transplant
Dr Megan Rowley	(MR)	-	Standing Advisory Committee on Clinical Transfusion Medicine
Miss Caroline Smith	(CJS)	-	JPAC Manager (Minute taker)
Dr Nay Win	(NW)	-	Standing Advisory Committee on Immunohaematology

SM welcomed JJ to this meeting representing the Quality Managers, GMal to his first meeting as Scientific Lead Safety Policy (JPAC/SaBTO) and GM to her first meeting in her new role as Medical Director, NHS Blood and Transplant.

ACTION

1.

Apologies

Mrs Linda Lodge	(LL)	-	Standing Advisory Committee on Information Technology
Mrs Angela Macauley	(AM)	-	Quality Manager, Northern Ireland Blood Transfu Service representing the Quality Managers of the UK Blood Services
Mr David Carter	(DC)	-	Medicines & Healthcare products Regulatory Agency
Dr Kieran Morris	(KM)	-	Medical Director, Northern Ireland Blood Transfusion Service
Dr William Murphy	(WM)	-	National Medical Director, Irish Blood Transfusion Service
Dr Shirley Stagg	(SS)	-	Human Tissue Authority (HTA)
Dr Christian Schneider	(CS)	-	Director, National Institute for Biological Standards and Control
Prof John Forsythe	(JF)	-	Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant

ACTION

- Prof Marc Turner **(MT)** - Medical Director, Scottish National Blood Transfusion Service
- Prof Maria Zambon **(MZ)** - Director, Centre for Infections, Public Health England (PHE)

2. **Minutes of the last meeting held on 10 March 2016 – JPAC 16-47**

The minutes were approved as a true record of the meeting, with a correction to item 5 which should read "Ocular Tissue Advisory Group".

3. **Matters arising not on the agenda (Review of actions list) JPAC 16-48**

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

GM informed JPAC that the analysis is underway and will be discussed at the next SACCSD meeting in July and then brought to JPAC in November.

GM

3.2 **Any Other Business – item 3.4**

As a result of the Penrose Inquiry LW had 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. Work in progress.

SM & RC

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

4.1 **Extended storage of frozen red cells – JPAC 16-49**

JPAC endorsed the recommendation to change the shelf-life of specification 7.8 Red cells, thawed and washed, leucocyte depleted, in the Red Book guidelines from:

'The storage may be extended to at least 10 years, if the correct storage temperature is guaranteed'

to

'Storage may be extended to 30 years if the correct storage temperature is guaranteed'

JPAC noted that in the UK, unlike other countries, frozen red cells are only used for the provision of blood of rare phenotypes. A change notification will be issued.

Post Meeting Note: Change Notification No 32 Red Cells, Thawed and Washed, Leucocyte Depleted was issued on 23 August 2016.

4.2 **Inclusion of '30 minute rule' in component specifications – JPAC 16-50**

RC went through JPAC 16-50, which is the proposed wording for a change notification. She also thanked the Bacteriology Laboratory staff, who will be publishing their work through peer review, for all their hard work on this project.

JPAC endorsed the recommendation to issue this as a change notification, with one

ACTION

small amendment to the first sentence, and that this paper should be added as an appendix to the main paper on the JPAC website.

It was noted that the impact of this will be monitored by the blood stocks management scheme.

Post Meeting Note: Change Notification No 33 Removal of red cells from a controlled temperature environment was issued on 23 August 2016

4.3 **Upper limit of pH in platelets – JPAC 16-72**

RC informed JPAC that an amendment to the BSQR in relation to platelet pH is now being made to bring it in line with the Council of Europe Guide and EU Directive. It is therefore now appropriate to issue a change notification to the Red Book to remove the upper limit of pH from all platelet components.

JPAC endorsed the recommendation to issue this as a change notification.

Post Meeting Note: Change Notification No 34 Removal of upper limit of pH from Platelet Components was issued on 23 August 2016

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

5.1 **Borrelia bergdorferi (Lyme disease) risk assessment v3 – JPAC 16-51**

JPAC 16-51 is an update of the current risk assessment. Although levels of infection are increasing there is no evidence of transfusion transmission.

JPAC endorsed the recommendation that no specific measures are needed for *B.bergdorferi* infection in potential blood donors in view of the lack of evidence of transfusion-transmitted infection. This will be reviewed again in 3 years.

5.2 **Review of the need for anti-HBs level of >100 mIU/ml in tissue and HSC donors/donations who are HBsAg and HBV DNA (individual donation screen) negative and anti-HBc reactive – JPAC 16-52**

SACTCTP had requested SACTTI to undertake this review.

JPAC endorsed the proposal that there no longer needs to be a requirement for an anti-HBs level of >=100 mIU/ml to allow release of anti-HBc reactive, HbsAg and ID HBV DNA negative tissue and stem cell donations.

AK will reword table 9.2 in the Red Book.

AK

AC will submit a Change Notification to the Tissue Donor Selection Guidelines for the next meeting of JPAC.

AC

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

Changes to the Geographical Disease Risk Index (GDRI)

6.1 **Argentina - Zika virus added – JPAC 16-53**

JPAC approved the recommendation that Zika virus should be added to the entry for Argentina in the GDRI and that a change notification should be issued.

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Post Meeting Note: Change Notification No 41 2016 Tropical Viruses (Zika) was issued on 04 October and live on the JPAC website on 01 November 2016

6.2 Brunei Darussalam (Brunei) - revised Malarial risk – JPAC 16-54

JPAC approved the recommendation that Brunei should now be considered a malarious area and that Brunei should now be known as Brunei Darussalam in the GDRI, but that Brunei should still appear in the Index linking to Brunei Darussalam.

A change notification will be issued.

AK informed JPAC that this change came out of the new horizon scanning process.

Post Meeting Note: Change Notification No 38 2016 Malaria Risk - Brunei Darussalam was issued on 04 October and live on the JPAC website on 01 November 2016

6.3 Lesser Antilles - Tropical Virus Risk – JPAC 16-55

JPAC approved and recommend that the GDRI should be updated so that there is a statement in the entry for the Lesser Antilles directing one to look at the named individual islands for their specific risks.

A change notification will be issued.

Post Meeting Note: Change Notification No 42 2016 Tropical Viruses (Lesser Antilles) was issued on 04 October and live on the JPAC website on 01 November 2016

6.4 Mexico – revised Malarial risk – JPAC 16-56

JPAC approved the recommendations regarding the malaria risk in Mexico and that Mexico's malaria risk category should change from B to C.

A change notification will be issued.

Post Meeting Note: Change Notification No 39 2016 Malaria Risk - Mexico was issued on 04 October and live on the JPAC website on 01 November 2016

6.5 Polynesia and French Polynesia – update to entry – JPAC 16-57

The entry for Polynesia in the GDRI is causing some confusion as it defaults to French Polynesia. JPAC approved the recommendation that the entry should be amended as follows:

Polynesia

Polynesia is made up of over 1000 islands in the Central and Southern Pacific ocean. Please look under the name of the individual islands donors have visited e.g. Tonga, Samoa, Cook Islands, French Polynesia, and Norfolk Islands etc for advice on what travel criteria apply.

A change notification will be issued.

Post Meeting Note: Change Notification No 40 2016 Polynesia entry was issued on 04 October and live on the JPAC website on 01 November 2016.

6.6 Uruguay and Hawaii – Dengue virus risk – JPAC 16-58

ACTION

JPAC approved the recommendation that Dengue should be added as a Tropical Virus Risk in Uruguay and, as there was also an outbreak in Hawaii in 2015, Dengue should also be added to the United States entry for Hawaii.

A change Notification will be issued.

Post Meeting Note: Change Notification No 43 2016 Tropical Viruses – (Dengue – Uruguay) was issued on 04 October and live on the JPAC website on 01 November 2016. Information regarding the USA entry was added to Change Notification No 49 regarding Zika in Florida – issued as an emergency change on 21 September 2016

7 **Standing Advisory Committee on Immunohaematology**

7.1 **Amendment to Chapter 11 - Reagent Manufacture of the Red Book – JPAC 16-59**

JPAC approved the amendment to Chapter 11 of the Red Book and a change notification will be issued.

Post Meeting Note: Draft Change Notification No 50 is progressing through the change process.

7.2 **Amendment to Chapter 17 - Validation and use of new assays for the detection of antibodies to human platelet antigens (HPA) and human neutrophil antigens (HNA) – of the Red Book – JPAC 16-60**

Technological advances in the field of platelet and granulocyte immunology have resulted in the development of new assays for the detection of antibodies to human platelet antigens (HPA) and human neutrophil antigens (HNA). These new assays do not require direct access to HPA typed platelets or HNA typed granulocytes but instead utilise glycoproteins isolated from human cells, soluble recombinant HPA or HNA attached to a solid phase or recombinant cell lines, which express HPA or HNA. Some of these assays are now available on a commercial basis.

JPAC approved the recommendation to amend section 17.4 of the Red Book and a change notification will be issued.

Post Meeting Note: Draft Change Notification No 51 is progressing through the change process.

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

8.1 **Update to the Cardiomyopathy entries in the Deceased and Live Tissue Donor Selection Guidelines – JPAC 16-61**

JPAC approved the recommendation to update the cardiomyopathy entries and a change notification will be issued.

Post Meeting Note: Change Notification No 44 2016 Cardiomyopathy was issued on 10 October 2016.

8.2 **Proposed new entry for Ehlers-Danlos Syndrome entry in the Deceased Tissue Donor Selection Guidelines – JPAC 16-62**

JPAC approved the new entry for Ehlers-Danlos Syndrome in the Deceased Tissue DSG and a change notification will be issued.

ACTION

Post Meeting Note: Change Notification No 45 2016 Ehlers-Danlos Syndrome was issued on 10 October 2016.

8.3 Updated Hepatitis A entry in the Deceased Tissue, Live Tissue, Cord Blood, and Bone Marrow & Peripheral Blood Stem Cell Donor Selection Guidelines – JPAC 16-63

JPAC approved the recommendation to update the Hepatitis A entry and a change notification will be issued.

Post Meeting Note: Change Notification No 46 2016 Hepatitis A was issued on 10 October 2016.

8.4 Update to the Marfan's Syndrome entry in the Deceased Tissue Donor Selection Guidelines – JPAC 16-64

JPAC approved the recommendation to update the Marfan's Syndrome entry with regard to Pancreatic Islets in the Deceased Tissue DSG and a change notification will be issued.

Post Meeting Note: Change Notification No 47 2016 Marfan's Syndrome was issued on 10 October 2016.

8.5 Update to the Transfusion entry in the Deceased Tissue Donors Selection Guidelines – JPAC 16-65

JPAC approved the recommendation to update the Transfusion entry with regard to Pancreatic Islets in the Deceased Tissue DSG and a change notification will be issued.

Post Meeting Note: Change Notification No 48 2016 Transfusion was issued on 10 October 2016.

9. Red Book online survey 2016

9.1 Results of the online survey carried out in March 2016 – JPAC 16-66

JPAC noted the results of the survey. It was agreed that there is still a need for a hard copy of the guidelines at this time, although a reduced number will be produced, but that this would be kept under review as technology moves forward.

CJS informed JPAC that she has now received a word version of the contents of the Red Book taken from the website version. This will be reformatted and the relevant chapters sent out to the SACs for review.

Post Meeting Note: Reformatted chapters sent to SACs on 12 July 2016.

CJS will liaise with the TSO regarding a timetable for this work.

10. UK BTS Forum

10.1 Report back from the UK Forum meeting on 17 June 2016 – JPAC 16-70

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

- MSM deferral in Northern Ireland
- Zika virus

ACTION

- JPAC Work Plan – new format
- EBA Working Group on Blood Directives

11. Draft JPAC Work Plan 2016-2017**11.1 Proposed new format of the JPAC Work Plan – JPAC 16-71**

SM informed JPAC that the UK Forum approved the suggested new format for the JPAC work plan.

CJS will put this year's draft work plan into the new format in the first instance and then telecons will be arranged with each of the SAC chairs, SM, RC and CJS, to review their items.

Post Meeting Note: The draft work plans have been reformatted and telecons with the SAC Chairs were held in early October to work on these plan. The new work plan for 2016/2017 was submitted to the JPAC meeting on 10 November 2016.

12. SaBTO

12.1 GMal informed JPAC that the minutes from the last meeting on 26 April are now available on the SaBTO website. The main items under discussion were:

- Hepatitis E virus - update
- Donor organ risk assessment - update
- Microbiological screening of donor organs - review
- Microbiological safety of human organs, tissues and cells – draft new revision of existing guidance
- Donor selection evidence review
- Zika and other tropical viruses
- Next meeting date: Wednesday 14 September 2016
- Proposed dates for SaBTO meetings in 2017
 - Wednesday 18 January
 - Wednesday 19 April
 - Wednesday 20 September

13. Zika Virus**13.1 ABO framework – update**

GMal gave an update on the progress of the work putting the Zika virus – sexual partners - through this framework.

14. Any Other Business**14.1 JPAC Website - Major power outage at the data centre where the JPAC website is hosted**

SM and CJS briefed JPAC on this incident.

ACTION

Early on Monday 13 June we were informed by Target Information Systems that their system had alerted them that our website was down and that they were awaiting a response to an email sent to NSS at 06.52 on Sunday morning regarding this issue. CJS then notified the 4 UK Blood Services of the situation and that they would not have access to the electronic versions of the blood, tissues and cells donor selection guidelines.

We have now found out that the incident was caused by a major power outage at the NSS Scotland Data Centre and all their sites, including SNBTS, were affected.

Although we believe this incident was a "*Priority One, Critical – system is down no access for any users – three hours resolution*", JPAC received no notification from NSS that our website was unavailable.

CJS has written to NSS expressing our disappointed that there has been no contact to alert us that there was a problem and that, to date 23 June, there has been no response to emails, phone messages etc. We have asked for reassurances that should this happen again we would be notified as a matter of urgency.

We have systems in place to be able to supply users with paper copies of all the donor selection guidelines if needed, but we need to know if the website is unavailable in the first place.

We are awaiting a response to this letter.

14.2 Perfusion of organs

JJ informed JPAC that seems to be some confusion around how to manage organ perfusion with blood in hospitals – this is being increasingly done temporarily prior to transplant. The issue is how to fate the components (to the donor or the recipient?) There may also be some work required to understand and clarify the specification and handling of the component. It is understood that there is a new BCSH guideline in preparation.

GM will discuss with John Forsythe about what is happening. JPAC and particularly SACBC would be happy to assist in development of specifications.

RC

14.3 High titre testing of pool platelets in PAS

JJ asked about the current requirement for HT testing of pooled platelets and whether this is still required for platelets in PAS.

SM has asked NW and SACIH to look at this issue and he will bring a paper to JPAC in November. RC will give NW the details of a useful contact in the Netherlands.

NW

14.4 Chair of the SACCS D

SM informed JPAC that the interview for a new Chair of the SAC on Care and Selection of Donors will take place on 14 July 2016.

15. Date & venue for future JPAC meetings

Please note new venue for future meetings

2016

- Thursday 10 November - Boardroom, West End Donor Centre, London

ACTION

2017

- Thursday 09 March - Boardroom, West End Donor Centre, London
- Thursday 22 June - Boardroom, West End Donor Centre, London
- Thursday 09 November - Boardroom, West End Donor Centre, London

The Committee did not break for lunch and therefore the meeting closed at: 13.15