APPROVED 08/11/2018

Joint UKBTS Professional Advisory Committee

Minutes of the 70th meeting held in the Boardroom at the West End Donor Centre, 26 Margaret Street, London, W1W 8NB on Thursday 28 June 2018

Meeting commenced at: 11:00

Present

Dr Neil Almond	**(NA)**	-	National Institute for Biological Standards and Control *(also deputising for Dr Christian Schneider)*
Dr Janet Birchall	**(JB)**	-	Medical Director, Welsh Blood Service
Dr Rebecca Cardigan	**(RC)**	-	Deputy Professional Director of JPAC
Dr Lisa Jarvis	**(LJ)**	-	Standing Advisory Committee on Transfusion Transmitted Infections
Mrs Linda Lodge	**(LL)**	-	Standing Advisory Committee on Information Technology
Dr Richard Lomas	**(RL)**	-	Standing Advisory Committee on Tissues and Cellular Therapy Products *(Deputising for Dr Akila Chandrasekar)*
Dr Sheila MacLennan	**(SM)**	-	Professional Director of JPAC
Dr Gary Mallinson	**(GMal)**	-	Scientific Lead Safety Policy (JPAC/SaBTO)
Dr Edwin Massey	**(EM)**	-	Standing Advisory Committee on Immuno-haematology
Dr Gail Miflin	**(GM)**	-	Medical Director, NHS Blood and Transplant **(Joined via telecon)**
Dr Kieran Morris	**(KM)**	-	Medical Director, Northern Ireland Blood Transfusion Service
Dr Helen New	**(HN)**	-	Standing Advisory Committee on Blood Components
Mr David Olszowka	**(DA)**	-	Medicines and Healthcare products Regulatory Agency
Dr Megan Rowley	**(MR)**	-	Standing Advisory Committee on Clinical Transfusion Medicine
Miss Caroline Smith	**(CJS)**	-	JPAC Manager **(Minute taker)**
Dr Angus Wells	**(AW)**	-	Standing Advisory Committee on Care and Selection of Donors

SM welcomed Dr Edwin Massey to his first meeting as Chair of the SAC on Immuno-haematology and Dr Richard Lomas who was deputising for Dr Akila Chandrasekar.

SM also informed the group that Dr Shirley Stagg has moved to the MHRA and therefore the HTA will nominate a new representative for JPAC.

ACTION

1. Apologies

Dr Akila Chandrasekar	**(AC)**	-	Standing Advisory Committee on Tissues and Cellular Therapy Products
Dr Stephen Field	**(SF)**	-	Medical Director, Irish Blood Transfusion Service
Prof John Forsythe	**(JF)**	-	Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Mrs Angela Macauley	**(AM)**	-	Quality Manager, Northern Ireland Blood Transfusion Service representing the Quality Managers of the 4 UK Blood Services

ACTION

Dr Christian Schneider	**(CS)**	-	Director, National Institute for Biological Standards and Control
Dr Shirley Stagg	**(SS)**	-	Human Tissue Authority (HTA)
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 08 March - JPAC 18-40

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

3. Matters arising not on the agenda (review of the actions list) JPAC 18-41

3.1 HIV pre and post-exposure prophylaxis (PrEP): Discussion paper – JPAC 17-96 – item 3.4

SACCSD have had an initial discussion about whether to ask specifically about this medication on the donor health check and will discuss further at their next meeting in August and bring to JPAC in November. **AW**

The alternative testing algorithm is only applicable for NHSBT. SACTTI consider that the current guidelines are appropriate and this will only come back to JPAC if the situation changes.

3.2 Viral Haemorrhagic Fever in all the Tissue and Cells Donor Selection Guidelines – JPAC 18-15 – item 4.12.

AW confirmed that no change is needed to the Whole Blood and Components Donor Selection Guidelines.

3.3 Normothermic regional perfusion in transplantation – JPAC 18-20 – item 6.1

Informal discussions have taken place and the first meeting of the group is being organised. **MR**

Kieron Morris arrived 11:10

4. Standing Advisory Committee on Tissues and Cellular Therapy Products

Dr Richard Lomas went through the SACTCTP papers for the group.

4.1 Blind Donor - Deceased Tissue Donor Selection Guidelines – JPAC 18-42

This change was agreed with medical eye bank advisors and at the Ocular Tissue Transplant Standards Group (OTTSG) meeting last November.

JPAC endorsed the recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 23 was issued on 26 September 2018.

4.2 Eye Disease - Deceased Tissue Donor Selection Guidelines – JPAC 18-43

JPAC endorsed the recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 24 was issued on 26 September 2018.

ACTION

4.3 Herpes Ocular - Deceased Tissue Donor Selection Guidelines – JPAC 18-44

This change had been agreed with medical eye bank advisors and at the Ocular Tissue Transplant Standards Group **(OTTSG**) meeting last November.

JPAC had concerns regarding whether misidentification of the affected eye could also apply to other conditions of the eyes, although it was noted that the "Reason for Change" in the proposed Change Notification states "To clarify that even if only one eye is affected, donation of both eyes is contraindicated".

JPAC endorsed the recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 25 was issued on 26 September 2018.

SM will discuss with AC whether the same principle should be applied for other eye conditions. **SM**

4.4 Infection: Acute - Live Tissue Donor Selection Guidelines, Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines and the Cord Blood Donor Selection Guidelines – JPAC 18-45

JPAC endorsed the recommendation to include SaBTO guidance that expert advice be sought for rare and unusual infections for which there is no specific entry, especially infections that can be hard to eradicate. A change notification will be issued.

Post Meeting Note: Change Notification No 26 was issued on 26 September 2018.

4.5 Infection: Acute – Deceased Tissue Donor Selection Guidelines – JPAC 18-46

JPAC endorsed the recommendation to provide guidance that cold sores, genital herpes and common upper respiratory tract infections such as colds and sore throats are not a contraindication to tissue donation and to include SaBTO guidance that expert advice be sought for rare and unusual infections for which there is no specific entry, especially infections that can be hard to eradicate. A change notification will be issued.

Post Meeting Note: Change Notification No 27 was issued on 26 September 2018.

4.6 Infection: Chronic – Tissues and Cells Donor Selection Guidelines – JPAC 18-47

JPAC endorsed the recommendation to add additional guidance for evaluation of unusual infections for which no specific entry exists, as advised by SaBTO Microbiological Safety Guidelines, 2017 and a change notification will be issued.

Post Meeting Note: Change Notification No 28 was issued on 26 September 2018.

4.7 Laser Treatment - Deceased Tissue Donor Selection Guidelines – JPAC 18-48

JPAC endorsed the recommendation to clarify that prior laser refractive surgery is not an absolute contraindication to eye donation. A change notification will be issued.

Post Meeting Note: Change Notification No 29 was issued on 26 September 2018.

4.8 Reyes Syndrome – Deceased Tissue Donor Selection Guidelines – JPAC 18-49

JPAC endorsed the recommendation to add a discretionary acceptance for eyes to the Reyes Syndrome entry and a change notification will be issued.

ACTION

Post Meeting Note: Change Notification No 30 was issued on 26 September 2018.

4.9 Thyroid Disease – Deceased Tissue Donor Selection Guidelines – JPAC 18-50

JPAC endorsed the recommendation to add an additional discretion for "Eyes" to this entry and a change notification will be issued.

Post Meeting Note: Change Notification No 31 was issued on 26 September 2018.

4.10 Transgender Individuals - Tissues and Cells Donor Selection Guidelines – JPAC 18-51

JPAC endorsed the recommendation to change the title of this entry from 'Sex Change' to 'Transgender Individuals' and, in the Deceased and Live TDSGs, to simplify the contents. A change notification will be issued.

KM stated that Northern Ireland will have to have a deviation for this so that JPAC can go ahead and issue to all the UK Countries.

Post Meeting Note: Change Notification No 32 was issued on 26 September 2018.

4.11 Vasculitis – Deceased Tissue Donor Selection Guidelines – JPAC 18-52

JPAC endorsed the recommendation to clarify the management of eye donors with vasculitis and make it consistent with the existing entry on autoimmune diseases. A change notification will be issued.

Post Meeting Note: Change Notification No 33 was issued on 26 September 2018.

5. Standing Advisory Committee on Care and Selection of Donors

Geographical Disease Risk Index (GDRI)

5.1 Dengue – removal of risk in Japan – JPAC 18-53

JPAC endorsed the recommendation to remove the Dengue risk from Japan and a change notification will be issued.

Post Meeting Note: Change Notification No 18 was issued on 20 August for training and live on the JPAC website on 17 September 2018.

5.2 Malaria – United Arab Emirates – JPAC 18-54

JPAC endorsed the recommendation to clarify the information regarding the previous malaria risk in UAE, but asked for a minor change to be made adding the new wording to the second sentence. With this amendment, a change notification will be issued.

Post Meeting Note: Change Notification No 19 was issued on 20 August for training and live on the JPAC website on 17 September 2018.

Whole Blood and Components Donor Selection Guidelines

5.3 Hepatitis A – Immunization – JPAC 18-55

During management of the hepatitis A outbreak in North Lanarkshire in 2017 it became apparent that donors who had received vaccination after possible exposure to HAV could be accepted too soon.

ACTION

JPAC endorsed the recommendation to revise the obligatory deferral period for immunization post known exposure to six months following guidance from Public Health England and a change notification will be issued.

Post Meeting Note: Change Notification No 20 was issued on 20 August for training and live on the JPAC website on 17 September 2018.

5.4 Narcolepsy – JPAC 18-56

This has been reviewed following a request made by a person working for a Narcolepsy charity.

JPAC endorsed the recommendation to update the 'Additional Information' section with more information about the nature of Narcolepsy and a change notification will be issued.

Post Meeting Note: Change Notification No 21 was issued on 20 August for training and live on the JPAC website on 17 September 2018.

5.5 Transgender Individuals – JPAC 18-57

JPAC endorsed the recommendation to change the title of this entry from 'Sex Change' to 'Transgender Individuals'. A change notification will be issued.

KM informed JPAC that this would have the same implications for Northern Ireland as the changes to the Tissues and Cells DSGs discussed in item 4.10.

SM informed JPAC that the European Steering Committee on Blood Transfusion (CD-P-TS) is going to discuss gender issues with regard to transfusion at its November meeting and they may set up a working group. SM will feed-back from the November meeting. **SM**

Post Meeting Note: Change Notification No 22 was issued on 20 August for training and live on the JPAC website on 17 September 2018.

6. Standing Advisory Committee on Transfusion Transmitted Infections

6.1 Human Parvovirus B19 (B19V) Risk Assessment – version 2 – JPAC 18-58

SM noted that in section 2.c there is no mention of other pathogen inactivation techniques. LJ will add a comment.

Post Meeting Note: Section 2c updated and JPAC 18-58 Amended recirculated to JPAC for information.

JPAC endorsed the previous recommendation that no specific action is required at the present time as there is lack of evidence of harm and the operational considerations of introducing selective screening would be considerable.

GM thought that Australia were also considering this issue and LJ will discuss with the EID Monitor group. She is also aware of work at Guys Hospital on transfusion in pregnancy in patients with SCD and LJ will liaise with Sara Trompeter about this. **LJ** **LJ**

6.2 Zika Virus Risk Assessment – version 3 – JPAC 18-59

LJ went through this risk assessment for JPAC. There is no new evidence to support any changes to the current donor selection guidelines for Zika. JPAC endorsed the

ACTION

risk assessment and the proposal to extend the review period from one year to two years.

GMal

GMal informed JPAC that he was asked to produce a risk assessment for tissues for SaBTO which he will submit this to the next JPAC meeting in November.

6.3 Zika Virus Position Statement – June 2018 – JPAC 18-60

It was noted that there was an error on page 4 - the virus deferral period for malaria should be 4 months and not 6 months. With this change JPAC endorsed this updated position statement, which will be posted on the JPAC website.

Post Meeting Note: The updated Position Statement was posted on the JPAC website on 04 July 2018.

6.4 SACTTI comment on SaBTO updated EBOLA guidance – JPAC 18-61

Following discussion of item 5.7 (Position Statement: Ebola), at the JPAC meeting on 9 November, the Chair of JPAC sent the Chair of SACTTI the SaBTO paper and asked her to raise the deferral period of blood donation at SACTTI.

This was discussed at the SACTTI meeting on 16 May 2018 and it was agreed that at present, blood donors who have been in an EVD-affected area where there was evidence of person to person transmission of EBOV infection at the time the person was in the area, or who have had contact with individuals with confirmed Ebola infection, should not be deferred permanently but should be deferred for 6/12. However, if a suitable Ebola Ab screening assay were to become available screening at 6/12 could be undertaken, but not as a selection criterion.

This was endorsed by JPAC.

6.5 The estimated residual risk that a donation made in the infectious window period is not detected on testing: risks specific for HBV, HCV and HIV in the UK, 2015-2017 - Position Statement – JPAC 18-62

JPAC endorsed the updated position statement for publication on the JPAC website and the use of the current parameters for 2015-2017.

Post Meeting Note: The updated Position Statement was posted on the JPAC website on 04 July 2018.

7. Standing Advisory Committee on Blood Components

7.1 Proposed process map for JPAC website for non-novel Component Code requests – JPAC 18-63

SM thanked SACBC for this very good piece of work. HN especially wanted to thank Belinda Pelle for all her hard work.

JPAC endorsed the recommendation to post the process flow diagram on the JPAC website.

Post Meeting Note: Posted in the Document Library on the JPAC website July 2018.

7.2 UK Blood Services Blood Component Leucocyte Depletion Results: 2017 Review *(Note embedded Excel spreadsheet on page 4: Combined UK Blood Services LD data)* **– JPAC 18-64**

ACTION

HN went through this paper for the group. A long discussion took place as to whether this comes under the remit of JPAC or whether it is an operational issue for the Blood Services.

It was also noted that, in the past, this collated data had been used by SaBTO e.g. the CMV risk assessment.

SM asked HN to take this back to SACBC and ask if there is a suitable alternative forum who could take this on. If not, it was agreed that SACBC would continue with this work. **HN**

7.3 **Concessionary Release Limits: Review of current and proposed limits** *(Note embedded Excel spreadsheet on page 2: UK Quality Monitoring Group component review data)* **– JPAC 18-65**

HN went through this paper for the group.

JPAC endorsed the new limits and the change to Chapter 6 of the Red Book as set out on pages 14 and 15 of this paper. HN will update the text of draft chapter 6 for the 9th Edition of the Red Book. **HN**

MR also felt that information on concessionary release limits should also be made available in the next edition of the Handbook of Transfusion Medicine. **MR**

8. UK Forum

8.1 **Report back from the meeting held on 23 March and verbal report from 22 June 2018 meeting – JPAC 18-66**

SM reported back from last 2 UK Forum meetings where the JPAC constitution amendments were approved along with the JPAC workplans. The UK Forum wanted to congratulate JPAC and its SACs on all their hard work.

9. Europe

9.1 **Council of Europe Meeting GTS Meeting – Edinburgh 17th to 20th April 2018**

The meeting held in Edinburgh was very successful. The venue proved to be ideal and the delegates especially enjoyed the tour of the new SNBTS Centre.

9.2 **EU Directive Focus Group – Brussels 23rd May 2018 (Study supporting the evaluation of the EU Blood and Tissues and Cells Legislation) – JPAC 18-67**

SM has been invited to participate in a Focus Group by the company commissioned by the European Commission to conduct a study on the EU Directive evaluation (ICF) in her capacity as CD-P-TS Chair.

The outcome will be to define whether the Directives have done a good job and if any changes are required. The next phase is for the evidence to be submitted to the Commission to review.

JPAC noted there are parliamentary elections in the EU next year which may impact on this work.

9.3 **GAPP Meeting – Rome 7th and 8th June 2018 (European Commission's Joint Action – Facilitating the Authorisation of Preparation Process for blood tissues and cells)**

ACTION

DO reported that work on the Joint Action "Facilitating the Authorisation of Preparation Processes for blood, tissues and cells (GAPP)" had started. This is a three-year project initiated by the National Institute of Health in Italy. The key objective of the Joint Action is to facilitate the development of a common and optimal approach to assess and authorise preparation processes in blood and tissues establishments for novel components.

The Joint Action is made up of 10 work packages. Just under half of them are housekeeping activities. The other work packages cover developing guidance, assessing quality, safety and clinical data, knowledge sharing and developing training courses. It is about what decisions are made and how, and visibility of decisions, rather like JPAC.

MHRA together with its collaborating partners (JPAC and NHSBT) will be helping with work package 6, a technical Annex 1 on authorization changes in donation, procurement and collection, processing, preservation, storage and distribution (including labelling and package inserts). There will be two subgroups for the work package, one on defining the critical characteristics for each category of blood component, tissue or cell type and one on providing guidance on the assessment of validations to prove achievement of the critical characteristics for each category of SoHO. MHRA will lead for blood. To a large extent Chapter 8: Evaluation of novel blood components, production processes and blood packs: generic protocols of Guidelines for blood transfusion Services should hopefully be very useful.

Both MHRA and JPAC attended the kick-off meeting for the Joint Action which was held at the offices of The National Institute of Health in Rome, on the 7th and 8th of June where each work package leader gave a presentation on their part of the work to be conducted. The next technical meeting is scheduled for September 2018.

9.4 CoE Guide to the preparation, use and quality assurance of blood components 20th Edition – JPAC 18-68

SM updated JPAC on the work that is ongoing to prepare the next edition. This will take three years instead of the usual two, as the chapters are going to incorporate both Standards and Principles i.e. the previous distinct sections will be merged.

Public consultation will take place May – September 2019 and SAC Chairs will receive their relevant sections for review as soon as the draft is circulated.

10. JPAC Website

10.1 Website email alerts

CJS informed JPAC that 954 people had now registered to receive email alerts of changes/updates to the website.

10.2 Possible new section in the Red Book – Appendix 4 Redundant Components

The suggestion to create a new area in the Red Book for redundant components had been raised at the recent JPAC EWG meeting. JPAC approved this new area and asked CJS to look into the possibility of adding a 'watermark' to the pages of this section stating that these products are redundant and that this would also be a useful addition to the trial components pages.

Post Meeting Note: Target have confirmed that adding a 'watermark' to these pages is possible and they are taking this forward.

ACTION

11. SaBTO

SaBTO Report – JPAC 18-69

GMal went through his report for JPAC. The last SaBTO meeting was held on 18th April and there were two substantive agenda items:

- Update on progress of the Paediatric Components Working Group
- Proposed changes to the donor selection criteria for sperm and egg donors by the HFEA.

Laura Carruthers has left the SaBTO secretariat and has been replaced by Emily Coelho. Donna McInnes remains the primary contact for the SaBTO secretariat at the DHSC.

12. Summary of risk assessments carried out by the Malaria Deferral Working Group and final recommendation – JPAC 18-70

The Malaria Deferral WG considered that the increase in number of BAME donations that would result from a reduction in the malaria deferral period for travel would be minor and would not out-weigh the reduction in patient safety. Therefore, the group recommends that the deferral period remains at 4 months. This was endorsed by JPAC.

13. ABO Risk-Based Decision-Making Framework for Blood Safety – JPAC 18-71

GMal went through this document which had been amended following the Malaria Deferral Working Group meeting on 19 March.

Janet Birchall and Kieran Morris left the meeting.

14. Any Other Business

14.1 Review of UK Blood Services patient safety related decisions since 2009 - JPAC 18-77

GMal went through his draft paper for the group. This is very much a work in progress and GMal asked JPAC members to email him any thoughts/comments and he will bring the final document back to JPAC in November. **GMal**

Lisa Jarvis and Linda Lodge left the meeting.

14.2 Filton MHRA Inspection

An issue regarding HTLV testing was raised at this inspection. As this concerned SACTTI and LJ had left the meeting, DO agreed to write to SM about this. **DO**

15. Date & venue for future JPAC meetings

2018

- Thursday 08 November - The Association of Anaesthetists, London
  (Post Meeting Note - new venue)

ACTION

2019

- Thursday 14 March - Scottish National Blood Transfusion Service, Edinburgh *(Post Meeting Note - change of venue)*
- Thursday 27 June - The Association of Anaesthetists, London
- Thursday 07 November - The Association of Anaesthetists, London

The meeting closed at: 15:14

APPROVED 08/11/2018

Joint UKBTS Professional Advisory Committee

Minutes of the 70th meeting held in the Boardroom at the West End Donor Centre, 26 Margaret Street, London, W1W 8NB on Thursday 28 June 2018

Meeting commenced at: 11:00

Present

Dr Neil Almond	**(NA)**	-	National Institute for Biological Standards and Control *(also deputising for Dr Christian Schneider)*
Dr Janet Birchall	**(JB)**	-	Medical Director, Welsh Blood Service
Dr Rebecca Cardigan	**(RC)**	-	Deputy Professional Director of JPAC
Dr Lisa Jarvis	**(LJ)**	-	Standing Advisory Committee on Transfusion Transmitted Infections
Mrs Linda Lodge	**(LL)**	-	Standing Advisory Committee on Information Technology
Dr Richard Lomas	**(RL)**	-	Standing Advisory Committee on Tissues and Cellular Therapy Products *(Deputising for Dr Akila Chandrasekar)*
Dr Sheila MacLennan	**(SM)**	-	Professional Director of JPAC
Dr Gary Mallinson	**(GMal)**	-	Scientific Lead Safety Policy (JPAC/SaBTO)
Dr Edwin Massey	**(EM)**	-	Standing Advisory Committee on Immuno-haematology
Dr Gail Miflin	**(GM)**	-	Medical Director, NHS Blood and Transplant **(Joined via telecon)**
Dr Kieran Morris	**(KM)**	-	Medical Director, Northern Ireland Blood Transfusion Service
Dr Helen New	**(HN)**	-	Standing Advisory Committee on Blood Components
Mr David Olszowka	**(DA)**	-	Medicines and Healthcare products Regulatory Agency
Dr Megan Rowley	**(MR)**	-	Standing Advisory Committee on Clinical Transfusion Medicine
Miss Caroline Smith	**(CJS)**	-	JPAC Manager **(Minute taker)**
Dr Angus Wells	**(AW)**	-	Standing Advisory Committee on Care and Selection of Donors

SM welcomed Dr Edwin Massey to his first meeting as Chair of the SAC on Immuno-haematology and Dr Richard Lomas who was deputising for Dr Akila Chandrasekar.

SM also informed the group that Dr Shirley Stagg has moved to the MHRA and therefore the HTA will nominate a new representative for JPAC.

ACTION

1. Apologies

Dr Akila Chandrasekar	**(AC)**	-	Standing Advisory Committee on Tissues and Cellular Therapy Products
Dr Stephen Field	**(SF)**	-	Medical Director, Irish Blood Transfusion Service
Prof John Forsythe	**(JF)**	-	Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Mrs Angela Macauley	**(AM)**	-	Quality Manager, Northern Ireland Blood Transfusion Service representing the Quality Managers of the 4 UK Blood Services

ACTION

Dr Christian Schneider	**(CS)**	-	Director, National Institute for Biological Standards and Control
Dr Shirley Stagg	**(SS)**	-	Human Tissue Authority (HTA)
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 08 March - JPAC 18-40

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

3. Matters arising not on the agenda (review of the actions list) JPAC 18-41

3.1 HIV pre and post-exposure prophylaxis (PrEP): Discussion paper – JPAC 17-96 – item 3.4

SACCSD have had an initial discussion about whether to ask specifically about this medication on the donor health check and will discuss further at their next meeting in August and bring to JPAC in November. **AW**

The alternative testing algorithm is only applicable for NHSBT. SACTTI consider that the current guidelines are appropriate and this will only come back to JPAC if the situation changes.

3.2 Viral Haemorrhagic Fever in all the Tissue and Cells Donor Selection Guidelines – JPAC 18-15 – item 4.12.

AW confirmed that no change is needed to the Whole Blood and Components Donor Selection Guidelines.

3.3 Normothermic regional perfusion in transplantation – JPAC 18-20 – item 6.1

Informal discussions have taken place and the first meeting of the group is being organised. **MR**

Kieron Morris arrived 11:10

4. Standing Advisory Committee on Tissues and Cellular Therapy Products

Dr Richard Lomas went through the SACTCTP papers for the group.

4.1 Blind Donor - Deceased Tissue Donor Selection Guidelines – JPAC 18-42

This change was agreed with medical eye bank advisors and at the Ocular Tissue Transplant Standards Group (OTTSG) meeting last November.

JPAC endorsed the recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 23 was issued on 26 September 2018.

4.2 Eye Disease - Deceased Tissue Donor Selection Guidelines – JPAC 18-43

JPAC endorsed the recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 24 was issued on 26 September 2018.

ACTION

4.3 Herpes Ocular - Deceased Tissue Donor Selection Guidelines – JPAC 18-44

This change had been agreed with medical eye bank advisors and at the Ocular Tissue Transplant Standards Group **(OTTSG**) meeting last November.

JPAC had concerns regarding whether misidentification of the affected eye could also apply to other conditions of the eyes, although it was noted that the "Reason for Change" in the proposed Change Notification states "To clarify that even if only one eye is affected, donation of both eyes is contraindicated".

JPAC endorsed the recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 25 was issued on 26 September 2018.

SM will discuss with AC whether the same principle should be applied for other eye conditions. **SM**

4.4 Infection: Acute - Live Tissue Donor Selection Guidelines, Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines and the Cord Blood Donor Selection Guidelines – JPAC 18-45

JPAC endorsed the recommendation to include SaBTO guidance that expert advice be sought for rare and unusual infections for which there is no specific entry, especially infections that can be hard to eradicate. A change notification will be issued.

Post Meeting Note: Change Notification No 26 was issued on 26 September 2018.

4.5 Infection: Acute – Deceased Tissue Donor Selection Guidelines – JPAC 18-46

JPAC endorsed the recommendation to provide guidance that cold sores, genital herpes and common upper respiratory tract infections such as colds and sore throats are not a contraindication to tissue donation and to include SaBTO guidance that expert advice be sought for rare and unusual infections for which there is no specific entry, especially infections that can be hard to eradicate. A change notification will be issued.

Post Meeting Note: Change Notification No 27 was issued on 26 September 2018.

4.6 Infection: Chronic – Tissues and Cells Donor Selection Guidelines – JPAC 18-47

JPAC endorsed the recommendation to add additional guidance for evaluation of unusual infections for which no specific entry exists, as advised by SaBTO Microbiological Safety Guidelines, 2017 and a change notification will be issued.

Post Meeting Note: Change Notification No 28 was issued on 26 September 2018.

4.7 Laser Treatment - Deceased Tissue Donor Selection Guidelines – JPAC 18-48

JPAC endorsed the recommendation to clarify that prior laser refractive surgery is not an absolute contraindication to eye donation. A change notification will be issued.

Post Meeting Note: Change Notification No 29 was issued on 26 September 2018.

4.8 Reyes Syndrome – Deceased Tissue Donor Selection Guidelines – JPAC 18-49

JPAC endorsed the recommendation to add a discretionary acceptance for eyes to the Reyes Syndrome entry and a change notification will be issued.

ACTION

Post Meeting Note: Change Notification No 30 was issued on 26 September 2018.

4.9 Thyroid Disease – Deceased Tissue Donor Selection Guidelines – JPAC 18-50

JPAC endorsed the recommendation to add an additional discretion for "Eyes" to this entry and a change notification will be issued.

Post Meeting Note: Change Notification No 31 was issued on 26 September 2018.

4.10 Transgender Individuals - Tissues and Cells Donor Selection Guidelines – JPAC 18-51

JPAC endorsed the recommendation to change the title of this entry from 'Sex Change' to 'Transgender Individuals' and, in the Deceased and Live TDSGs, to simplify the contents. A change notification will be issued.

KM stated that Northern Ireland will have to have a deviation for this so that JPAC can go ahead and issue to all the UK Countries.

Post Meeting Note: Change Notification No 32 was issued on 26 September 2018.

4.11 Vasculitis – Deceased Tissue Donor Selection Guidelines – JPAC 18-52

JPAC endorsed the recommendation to clarify the management of eye donors with vasculitis and make it consistent with the existing entry on autoimmune diseases. A change notification will be issued.

Post Meeting Note: Change Notification No 33 was issued on 26 September 2018.

5. Standing Advisory Committee on Care and Selection of Donors

Geographical Disease Risk Index (GDRI)

5.1 Dengue – removal of risk in Japan – JPAC 18-53

JPAC endorsed the recommendation to remove the Dengue risk from Japan and a change notification will be issued.

Post Meeting Note: Change Notification No 18 was issued on 20 August for training and live on the JPAC website on 17 September 2018.

5.2 Malaria – United Arab Emirates – JPAC 18-54

JPAC endorsed the recommendation to clarify the information regarding the previous malaria risk in UAE, but asked for a minor change to be made adding the new wording to the second sentence. With this amendment, a change notification will be issued.

Post Meeting Note: Change Notification No 19 was issued on 20 August for training and live on the JPAC website on 17 September 2018.

Whole Blood and Components Donor Selection Guidelines

5.3 Hepatitis A – Immunization – JPAC 18-55

During management of the hepatitis A outbreak in North Lanarkshire in 2017 it became apparent that donors who had received vaccination after possible exposure to HAV could be accepted too soon.

ACTION

JPAC endorsed the recommendation to revise the obligatory deferral period for immunization post known exposure to six months following guidance from Public Health England and a change notification will be issued.

Post Meeting Note: Change Notification No 20 was issued on 20 August for training and live on the JPAC website on 17 September 2018.

5.4 Narcolepsy – JPAC 18-56

This has been reviewed following a request made by a person working for a Narcolepsy charity.

JPAC endorsed the recommendation to update the 'Additional Information' section with more information about the nature of Narcolepsy and a change notification will be issued.

Post Meeting Note: Change Notification No 21 was issued on 20 August for training and live on the JPAC website on 17 September 2018.

5.5 Transgender Individuals – JPAC 18-57

JPAC endorsed the recommendation to change the title of this entry from 'Sex Change' to 'Transgender Individuals'. A change notification will be issued.

KM informed JPAC that this would have the same implications for Northern Ireland as the changes to the Tissues and Cells DSGs discussed in item 4.10.

SM informed JPAC that the European Steering Committee on Blood Transfusion (CD-P-TS) is going to discuss gender issues with regard to transfusion at its November meeting and they may set up a working group. SM will feed-back from the November meeting. **SM**

Post Meeting Note: Change Notification No 22 was issued on 20 August for training and live on the JPAC website on 17 September 2018.

6. Standing Advisory Committee on Transfusion Transmitted Infections

6.1 Human Parvovirus B19 (B19V) Risk Assessment – version 2 – JPAC 18-58

SM noted that in section 2.c there is no mention of other pathogen inactivation techniques. LJ will add a comment.

Post Meeting Note: Section 2c updated and JPAC 18-58 Amended recirculated to JPAC for information.

JPAC endorsed the previous recommendation that no specific action is required at the present time as there is lack of evidence of harm and the operational considerations of introducing selective screening would be considerable.

GM thought that Australia were also considering this issue and LJ will discuss with the EID Monitor group. She is also aware of work at Guys Hospital on transfusion in pregnancy in patients with SCD and LJ will liaise with Sara Trompeter about this. **LJ** **LJ**

6.2 Zika Virus Risk Assessment – version 3 – JPAC 18-59

LJ went through this risk assessment for JPAC. There is no new evidence to support any changes to the current donor selection guidelines for Zika. JPAC endorsed the

ACTION

risk assessment and the proposal to extend the review period from one year to two years.

GMal

GMal informed JPAC that he was asked to produce a risk assessment for tissues for SaBTO which he will submit this to the next JPAC meeting in November.

6.3 Zika Virus Position Statement – June 2018 – JPAC 18-60

It was noted that there was an error on page 4 - the virus deferral period for malaria should be 4 months and not 6 months. With this change JPAC endorsed this updated position statement, which will be posted on the JPAC website.

Post Meeting Note: The updated Position Statement was posted on the JPAC website on 04 July 2018.

6.4 SACTTI comment on SaBTO updated EBOLA guidance – JPAC 18-61

Following discussion of item 5.7 (Position Statement: Ebola), at the JPAC meeting on 9 November, the Chair of JPAC sent the Chair of SACTTI the SaBTO paper and asked her to raise the deferral period of blood donation at SACTTI.

This was discussed at the SACTTI meeting on 16 May 2018 and it was agreed that at present, blood donors who have been in an EVD-affected area where there was evidence of person to person transmission of EBOV infection at the time the person was in the area, or who have had contact with individuals with confirmed Ebola infection, should not be deferred permanently but should be deferred for 6/12. However, if a suitable Ebola Ab screening assay were to become available screening at 6/12 could be undertaken, but not as a selection criterion.

This was endorsed by JPAC.

6.5 The estimated residual risk that a donation made in the infectious window period is not detected on testing: risks specific for HBV, HCV and HIV in the UK, 2015-2017 - Position Statement – JPAC 18-62

JPAC endorsed the updated position statement for publication on the JPAC website and the use of the current parameters for 2015-2017.

Post Meeting Note: The updated Position Statement was posted on the JPAC website on 04 July 2018.

7. Standing Advisory Committee on Blood Components

7.1 Proposed process map for JPAC website for non-novel Component Code requests – JPAC 18-63

SM thanked SACBC for this very good piece of work. HN especially wanted to thank Belinda Pelle for all her hard work.

JPAC endorsed the recommendation to post the process flow diagram on the JPAC website.

Post Meeting Note: Posted in the Document Library on the JPAC website July 2018.

7.2 UK Blood Services Blood Component Leucocyte Depletion Results: 2017 Review *(Note embedded Excel spreadsheet on page 4: Combined UK Blood Services LD data)* **– JPAC 18-64**

ACTION

HN went through this paper for the group. A long discussion took place as to whether this comes under the remit of JPAC or whether it is an operational issue for the Blood Services.

It was also noted that, in the past, this collated data had been used by SaBTO e.g. the CMV risk assessment.

SM asked HN to take this back to SACBC and ask if there is a suitable alternative forum who could take this on. If not, it was agreed that SACBC would continue with this work. **HN**

7.3 **Concessionary Release Limits: Review of current and proposed limits** *(Note embedded Excel spreadsheet on page 2: UK Quality Monitoring Group component review data)* **– JPAC 18-65**

HN went through this paper for the group.

JPAC endorsed the new limits and the change to Chapter 6 of the Red Book as set out on pages 14 and 15 of this paper. HN will update the text of draft chapter 6 for the 9th Edition of the Red Book. **HN**

MR also felt that information on concessionary release limits should also be made available in the next edition of the Handbook of Transfusion Medicine. **MR**

8. UK Forum

8.1 **Report back from the meeting held on 23 March and verbal report from 22 June 2018 meeting – JPAC 18-66**

SM reported back from last 2 UK Forum meetings where the JPAC constitution amendments were approved along with the JPAC workplans. The UK Forum wanted to congratulate JPAC and its SACs on all their hard work.

9. Europe

9.1 **Council of Europe Meeting GTS Meeting – Edinburgh 17th to 20th April 2018**

The meeting held in Edinburgh was very successful. The venue proved to be ideal and the delegates especially enjoyed the tour of the new SNBTS Centre.

9.2 **EU Directive Focus Group – Brussels 23rd May 2018 (Study supporting the evaluation of the EU Blood and Tissues and Cells Legislation) – JPAC 18-67**

SM has been invited to participate in a Focus Group by the company commissioned by the European Commission to conduct a study on the EU Directive evaluation (ICF) in her capacity as CD-P-TS Chair.

The outcome will be to define whether the Directives have done a good job and if any changes are required. The next phase is for the evidence to be submitted to the Commission to review.

JPAC noted there are parliamentary elections in the EU next year which may impact on this work.

9.3 **GAPP Meeting – Rome 7th and 8th June 2018 (European Commission's Joint Action – Facilitating the Authorisation of Preparation Process for blood tissues and cells)**

ACTION

DO reported that work on the Joint Action "Facilitating the Authorisation of Preparation Processes for blood, tissues and cells (GAPP)" had started. This is a three-year project initiated by the National Institute of Health in Italy. The key objective of the Joint Action is to facilitate the development of a common and optimal approach to assess and authorise preparation processes in blood and tissues establishments for novel components.

The Joint Action is made up of 10 work packages. Just under half of them are housekeeping activities. The other work packages cover developing guidance, assessing quality, safety and clinical data, knowledge sharing and developing training courses. It is about what decisions are made and how, and visibility of decisions, rather like JPAC.

MHRA together with its collaborating partners (JPAC and NHSBT) will be helping with work package 6, a technical Annex 1 on authorization changes in donation, procurement and collection, processing, preservation, storage and distribution (including labelling and package inserts). There will be two subgroups for the work package, one on defining the critical characteristics for each category of blood component, tissue or cell type and one on providing guidance on the assessment of validations to prove achievement of the critical characteristics for each category of SoHO. MHRA will lead for blood. To a large extent Chapter 8: Evaluation of novel blood components, production processes and blood packs: generic protocols of Guidelines for blood transfusion Services should hopefully be very useful.

Both MHRA and JPAC attended the kick-off meeting for the Joint Action which was held at the offices of The National Institute of Health in Rome, on the 7th and 8th of June where each work package leader gave a presentation on their part of the work to be conducted. The next technical meeting is scheduled for September 2018.

9.4 CoE Guide to the preparation, use and quality assurance of blood components 20th Edition – JPAC 18-68

SM updated JPAC on the work that is ongoing to prepare the next edition. This will take three years instead of the usual two, as the chapters are going to incorporate both Standards and Principles i.e. the previous distinct sections will be merged.

Public consultation will take place May – September 2019 and SAC Chairs will receive their relevant sections for review as soon as the draft is circulated.

10. JPAC Website

10.1 Website email alerts

CJS informed JPAC that 954 people had now registered to receive email alerts of changes/updates to the website.

10.2 Possible new section in the Red Book – Appendix 4 Redundant Components

The suggestion to create a new area in the Red Book for redundant components had been raised at the recent JPAC EWG meeting. JPAC approved this new area and asked CJS to look into the possibility of adding a 'watermark' to the pages of this section stating that these products are redundant and that this would also be a useful addition to the trial components pages.

Post Meeting Note: Target have confirmed that adding a 'watermark' to these pages is possible and they are taking this forward.

ACTION

11. SaBTO

SaBTO Report – JPAC 18-69

GMal went through his report for JPAC. The last SaBTO meeting was held on 18th April and there were two substantive agenda items:

- Update on progress of the Paediatric Components Working Group
- Proposed changes to the donor selection criteria for sperm and egg donors by the HFEA.

Laura Carruthers has left the SaBTO secretariat and has been replaced by Emily Coelho. Donna McInnes remains the primary contact for the SaBTO secretariat at the DHSC.

12. Summary of risk assessments carried out by the Malaria Deferral Working Group and final recommendation – JPAC 18-70

The Malaria Deferral WG considered that the increase in number of BAME donations that would result from a reduction in the malaria deferral period for travel would be minor and would not out-weigh the reduction in patient safety. Therefore, the group recommends that the deferral period remains at 4 months. This was endorsed by JPAC.

13. ABO Risk-Based Decision-Making Framework for Blood Safety – JPAC 18-71

GMal went through this document which had been amended following the Malaria Deferral Working Group meeting on 19 March.

Janet Birchall and Kieran Morris left the meeting.

14. Any Other Business

14.1 Review of UK Blood Services patient safety related decisions since 2009 - JPAC 18-77

GMal went through his draft paper for the group. This is very much a work in progress and GMal asked JPAC members to email him any thoughts/comments and he will bring the final document back to JPAC in November. **GMal**

Lisa Jarvis and Linda Lodge left the meeting.

14.2 Filton MHRA Inspection

An issue regarding HTLV testing was raised at this inspection. As this concerned SACTTI and LJ had left the meeting, DO agreed to write to SM about this. **DO**

15. Date & venue for future JPAC meetings

2018

- Thursday 08 November - The Association of Anaesthetists, London
  (Post Meeting Note - new venue)

ACTION

2019

- Thursday 14 March - Scottish National Blood Transfusion Service, Edinburgh *(Post Meeting Note - change of venue)*
- Thursday 27 June - The Association of Anaesthetists, London
- Thursday 07 November - The Association of Anaesthetists, London

The meeting closed at: 15:14