### Joint UKBTS Professional Advisory Committee

#### Minutes of the 77<sup>th</sup> JPAC Meeting Zoom meeting held on Thursday 05 November 2020 – 10:00 to 12:30

#### Meeting commenced at: 10:03

#### Present

Dr Neil Almond	(NA)	-	National Institute for Biological Standards and Control	
Dr Janet Birchall	(JB)	-	Medical Director, Welsh Blood Service	
Dr Akila Chandrasekar	(AC)	-	Standing Advisory Committee on Tissues and Cellular Therapy Products	
Dr Stephen Field	(SF)	-	Medical Director, Irish Blood Transfusion Service	
Dr Jayne Hughes	(JH)	-	Acting Chair of the Standing Advisory Committee on Care and Selection of Donors	
Dr Lisa Jarvis	(LJ)	-	Standing Advisory Committee on Transfusion Transmitted Infections	
Mrs Angela Macauley	(AM)	-	Quality Manager, Northern Ireland Blood Transfusion Service representing the Quality Managers of the 4 UK Blood Services and Deputising for Dr John Simpson	
Dr Sheila MacLennan	(SM)	-	Professional Director of JPAC (Chair)	
Dr Gary Mallinson	(GMal)	-	Scientific Lead Safety Policy (JPAC/SaBTO)	
Dr Edwin Massey	(EM)	-	Standing Advisory Committee on Immuno-haematology and Deputising for Dr Gail Miflin	
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 and <i>Deputising for Prof Marc Turner</i>	
Dr Amy Shackell	(AS)	-	Human Tissue Authority (HTA)	
Miss Caroline Smith	(CJS)	-	JPAC Manager (Minute taker)	
Dr Stephen Thomas	(ST)	-	Deputy Professional Director of JPAC	

SM welcomed Dr Jayne Hughes to her first JPAC meeting as the Acting Chair of the SACCSD.

# Apologies Action Prof John Forsythe (JF) - Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant Mrs Linda Lodge (LL) - Standing Advisory Committee on Information Technology Dr Gail Miflin (GM) - Medical Director, NHS Blood and Transplant

#### APPROVED 11/03/2021

#### ACTION

JH

JH

Dr Christian Schneider	(CS)	-	Director, National Institute for Biological Standards and Control
Dr John Simpson	(JS)	-	Interim Medical Director, Northern Ireland Blood Transfusion Service
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 25 June 2020 - JPAC 20-51

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

3. Matters arising not on the agenda (review of the actions list) JPAC 20-52

#### 3.1 <u>Borrelia Burgdorferi (Lyme Disease) Risk Assessment - version</u> 4 – JPAC 19-38 – item 3.2

SM Had asked AW to review the recommendations for this infection in the Donor Selection Guidelines to get a common procedure for recall after receipt of postdonation information for the services. In progress.

#### 3.2 <u>Advanced Therapy Medicinal Products (ATMPs) Red Book Entry</u> – JPAC 19-45 – item 3.3

It was noted by JPAC that this paper is correct as of today, but that this may change following Brexit. JPAC endorsed the document for inclusion as an Appendix in the Red Book. In progress.

#### 3.3 <u>Assessing Malarial Residency - Proposed change to the Geographical Disease</u> <u>Risk Index</u> – JPAC 19-48 – item 3.4

SACCSD is working on a rewrite for Malaria in the GDRI. This is a large piece of work. In progress.

#### 3.4 <u>Residual risk of undetected infection among deceased tissue, living surgical</u> <u>bone and cord bloods, NHSBT 2013 – 2017</u> – JPAC 19-79 item 3.6

SACTCTP and Katy Davidson aim to publish the data prior to publication on the JPAC website.

<u>Post Meeting Note:</u> Paper has been rejected by Vox Sang and therefore it will now be submitted to a different journal for publication. AC will keep JPAC informed.

#### 3.5 <u>Pre-retrieval body cooling for Deceased Tissue Donors - Proposed</u> <u>amendment to the Red Book section 21.2</u> – JPAC 19-82 – item 3.9

JPAC had approved the proposal to reword section 21.2. and that it would appear in the 9<sup>th</sup> Edition of the Red Book. Further discussion is taking place at SACTCTP following which a change notification may be issued.

<u>Post Meeting Note</u>: Change Notification No 03 2021 was issued on 12 January 2021.

#### 3.6 Change Notifications from this actions list

The following change notifications have been to the Medical Directors for approval and will be issued after the Coronavirus Infection and Clinical Trials changes, approved at this meeting, have been issued.

- Clopidogrel New Entry Whole Blood and Components Donor Selection Guidelines - JPAC 19-83 – item 3.10
- **Cervical Carcinoma in situ** Whole Blood and Components Donor Selection Guidelines JPAC 19-84 item 3.11
- **Haemochromatosis entry** Whole Blood and Components Donor Selection Guidelines – JPAC 19-85 – item 3.12
- Latent TB Whole Blood and Components Donor Selection Guidelines JPAC 19-86 item 3.13
- **Tropical Virus entry** Whole Blood and Components Donor Selection Guidelines JPAC 19-87 item 3.14
- Valproate new entry Whole Blood and Components Donor Selection Guidelines – JPAC 19-88 – item 3.15

<u>Post Meeting Note</u> Change Notifications Nos 51 to 59 were issued on 19 January 2021

#### 3.7 ABO risk based decision-making framework workshop – item 3.16

The workshop will be organised once the disruption from COVID-19 had resolved.

<u>Post Meeting Note</u>: GMal will bring this back to JPAC as soon as more information is available. This will be removed from the JPAC actions list.

#### 3.8 <u>Proposed change to haematocrit specification compliance of Red Cells in</u> <u>Additive Solution (AS) [2020]</u> – JPAC 20-05 – item 3.18

Post Meeting Note: This will now appear in the 9<sup>th</sup> Edition of the Red Book

3.9 Off label use of platelet additive solutions in the manufacture of resuspended platelets (90% PAS: 10% plasma) – JPAC 20-06 – item 3.19

This will appear in the 9<sup>th</sup> Edition of the Red Book

# 3.10 <u>Horizon Scanning Annual Report 2019</u> – *Excel spreadsheet* – JPAC 20-15(b) – item 3.20

GMal has submitted this report to SaBTO.

# 3.11 <u>Horizon Scanning Process Management Description</u> – JPAC 20-15(c) – item 3.21

CJS will resend the MPD to LJ for a final review before posting in the Document Library of the JPAC website.

Post Meeting Note: MPD resent to LJ 09-11-2020

The previous version of this MPD contained an algorithm documenting the process and including stakeholders. It was agreed that this algorithm was useful and illustrated how different groups interact, but it is out of date. GMal agreed to revise.

GMal

LL

#### 3.12 UK Component Code Standardisation – JPAC 20-45 – item 7.1

LL will put together a process for updating the document and bring this back to JPAC.

#### 4. Standing Advisory Committee on Transfusion Transmitted Infections

#### 4.1 <u>Position Statement: SARS-CoV-2</u> – JPAC 20-53

JPAC approved this updated position which will be posted on the JPAC website.

<u>Post Meeting Note</u>: This updated Position Statement was posted on the JPAC website on 10 November 2020.

#### 4.2 <u>Position Statement: Dengue Virus</u> – JPAC 20-54

LJ will update with November's cases. With this amendment JPAC approved updated position statement which will be posted on the JPAC website.

<u>Post Meeting Note</u>: This updated Position Statement was posted on the JPAC website on 10 November 2020.

#### 4.3 Position Statement: West Nile Virus – JPAC 20-55

JPAC approved this updated position which will be posted on the JPAC website.

<u>Post Meeting Note</u>: This updated Position Statement was posted on the JPAC website on 10 November 2020.

NA informed JPAC that the WHO have now established the first international standard for WNV RNA.

#### 4.4 <u>Position Statement: vCJD</u> – JPAC 20-56

JPAC approved this updated position which will be posted on the JPAC website.

<u>Post Meeting Note</u>: This updated Position Statement was posted on the JPAC website on 10 November 2020.

#### EM joined at 10:27

#### 4.5 <u>Position Statement: Zika Virus</u> – JPAC 20-57

JPAC approved this updated position which will be posted on the JPAC website.

<u>Post Meeting Note</u>: This updated Position Statement was posted on the JPAC website on 10 November 2020.

# 4.6 <u>Position Statement: The estimated residual risk that a donation made in the infectious window period is not detected on testing: risk specific for HBV, HCV and HIV in the UK, 2017-2019</u> – JPAC 20-58

JPAC approved this updated position which will be posted on the JPAC website.

<u>Post Meeting Note</u>: This updated Position Statement was posted on the JPAC website on 10 November 2020.

#### 5. Standing Advisory Committee on Care and Selection of Donors

#### 5.1 <u>Animal Bite (Non-Human) and Rabies topics – Whole Blood Donor Selection</u> <u>Guidelines</u> – JPAC 20-59

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

Post Meeting Note Change Notification No 69 was issued on 19 January 2021.

#### 5.2 <u>Coronavirus Infection topic – Whole Blood and Components Donor Selection</u> <u>Guidelines</u> – JPAC 20-60

It was noted that there was a formatting issue with this paper and that "Additional Information" relates to all the sections and not just no. 4.

The definition of "Fatigue" was discussed at length and it was decided that the recovery fatigue criteria should be updated to "Do not have continuing fatigue which affects daily activities".

With these changes this was approved by JPAC and a change notification will be issued.

<u>Post Meeting Note</u>: JPAC 20-60 Amended received 06-11-2020. Change Notification No 64 2020 – Coronavirus Infection changes were live on the JPAC website on 26 November 2020.

**<u>NB</u>** Although this change was not classed as an "Emergency Change" it is fairly urgent and it was agreed that a 2-week, rather than 4-week, period for training would be more appropriate.

#### 5.3 <u>Clinical Trials topic - Whole Blood and Components Donor Selection</u> <u>Guidelines</u> – JPAC 20-67

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

AC will take to SACTCTP to review for tissues and cells.

**NB** Although this change was not classed as an "Emergency Change" it is fairly urgent and it was agreed that a 2-week, rather than 4-week, period for training would be more appropriate.

<u>Post Meeting Note</u>: Change Notification No 65 2020 - Clinical Trials changes were live on the JPAC website on 26 November 2020.

#### 5.4 <u>Annual Review of the Drug Index – Whole Blood and Components Donor</u> <u>Selection Guidelines</u> – JPAC 20-61

After discussion it was agreed that the sentence in the introductory section, starting "For all drugs listed ......last dose taken", should be revised.

With this amendment this update was approved by JPAC and a change notification will be issued.

<u>Post Meeting Note</u>: JPAC 20-61 Amended received on 06 November 2020 and Change Notification No 70 was issued on 19 January 2021.

#### 5.5 <u>New Tropical Virus Risk entries – Geographical Disease Risk Index</u> – JPAC 20-62

This was approved by JPAC and a change notification will be issued. <u>Post Meeting Note</u> Change Notification No 68 was issued on 19 January 2021.

#### 5.6 <u>Post-donation management of Blood Donors with nerve injury related to</u> <u>donation</u> – JPAC 20-63

This paper was approved by JPAC.

Actions:

- It was agreed that each Blood Service should decide how to distribute this within their own organisation.
- The paper would be posted in the General Documents section on the JPAC Website.

<u>Post Meeting Note</u>: This paper was posted on the JPAC website on 26 November 2020. An email was sent to the Medical Directors, and a pdf of the paper, for onward distribution as they see fit.

#### 6. Standing Advisory Committee on Blood Components

#### 6.1 <u>Request for three updates to the Guidelines for the Transfusion Services in</u> the UK (9<sup>th</sup> edition), Section &.30 and 7.30.2, dealing with the recommended requirement to irradiate never frozen liquid plasma – JPAC 20-64

After discussion JPAC agreed that the abbreviation 'LP' should be removed from the specification. MR informed JPAC that the BCSH guidelines referred to have been updated.

With these amendments JPAC approved this paper and the changes will be made in the 9<sup>th</sup> Edition of the Red Book.

#### 6.2 <u>Annual review of UK Blood Services' specification and concessionary release</u> <u>limit compliance for blood components in 2019 (version 2)</u> – JPAC 20-65

After some discussion JPAC approved this paper and the change will be made in the 9<sup>th</sup> Edition of the Red Book.

#### 6.3 <u>Convalescent Plasma Specification</u> – JPAC 20-66

SM apologised for the late circulation of this paper and thank all those involved for their input enabling the quick submission to JPAC and especially SACBC.

Following discussion JPAC approved this specification which will be added to Annex 3: Provisional Components section of the Red Book on the JPAC website and change notifications will be issued.

<u>Post Meeting Note</u>: Change Notifications Nos 66 and No 67 (Neonates and Infants) were issued on 17 November 2020

#### 7. SaBTO

#### 7.1 SaBTO report for the meetings held on 06 & 13 October 2020 – JPAC 20-68

GMal went through this paper. The main items covered in this paper were:

- Occult Hepatitis B Infection Working Group
- HEV update
- Patient consent for blood transfusion
- FAIR (For the Assessment of Individual Risk) report

#### 8. SHOT Report 2019

#### 8.1 <u>Summary of the Annual SHOT Report 2019</u> – JPAC 20-69

SM informed JPAC that SHOT have asked stakeholders to endorse their report and recommendations. JPAC had no objections to endorsing this report.

#### 9. UK Forum

#### 9.1 <u>Feedback from the UK Forum meetings on 26 June & 18 September 2020</u> JPAC 20-70

SM went through this report for the Committee.

#### <sup>10.</sup> European Union

#### 10.1 <u>Revision of the EU Legislation on Blood, Tissues and</u> Cells – JPAC 20-75

EU are revising the EU Directive and SM has been asked to join the reconvened European Blood Alliance Working Group. SF will also be on this group.

DO informed JPAC that he has arranged a meeting with DHSE and MHRA to discuss this and he will report back to the next JPAC meeting in March 2021.

DO also informed JPAC that there have been some amendments made to the BSQR due to Brexit. These will be sent to CJS for circulation to JPAC.

Post Meeting Note: Received and sent to JPAC 05 November 2020.

AS also informed JPAC that SOHO guidelines have also been updated and she will forward the link for JPAC.

Post Meeting Note: Received and sent to JPAC 03 March 2021.

#### 11. Council of Europe

#### 11.1 <u>Keeping up with Reality and Quality: A Challenge for European Blood</u> Establishments – Webinars held 27 - 29 October 2020 – JPAC 20-76

This had been circulated for information. All the presentations are now available on the EDQM website.

#### 12. Any Other Business

#### 12.1 Handbook of Transfusion Medicine

JB raised with the issue of the Handbook of Transfusion Medicine. As it is on the JPAC web site, it is considered by many users to provide the latest information. For clarity "2014 Edition" will be added under the photo on the website.

#### 13. Date & venue for future JPAC meetings

2021

- Thursday 11 March Zoom meeting
- Thursday 01 July Zoom/Face-to-face meeting venue tbc
- Thursday 04 November Zoom meeting

The meeting closed at: 12:46