Joint UKBTS Professional Advisory Committee

Minutes of the 76th JPAC Meeting Zoom meeting held on Thursday 25 June 2020 – 10:00 to 12:30

Meeting commenced at: 10:05

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 Lisa Jarvis	(LJ)	-	Standing Advisory Committee on Transfusion Transmitted Infections
Mrs Linda Lodge	(LL)	-	Standing Advisory Committee on Information Technology
Mrs Angela Macauley	(AM)	-	Quality Manager, Northern Ireland Blood Transfusion Service representing the Quality Managers of the 4 UK Blood Services
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
Dr Gail Miflin	(GM)	-	Medical Director, NHS Blood and Transplant
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
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
Prof Marc Turner	(MT)	-	Medical Director, Scottish National Blood Transfusion Service
Dr Angus Wells	(AW)	-	Standing Advisory Committee on Care and Selection of Donors

SM welcomed Dr Amy Shackell, from HTA, to her first JPAC meeting.

ACTION

1. Apologies

Prof John Forsythe	(JF)	-	Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Dr Christian Schneider	(CS)	-	Director, National Institute for Biological Standards and Control
Prof Maria Zambon	(MZ)	-	Director, Centre for Infections, Public Health England (PHE)

2. Minutes of the last meeting held on 12 March 2020 - JPAC 20-32

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

3. Matters arising not on the agenda (review of the actions list) JPAC 20-33

Before the group went through the actions from the last meeting CJS explained the current situation with regard to the JPAC Change Notification process during the COVID-19 pandemic, as this affects many of the items on the list.

Background:

For routine changes to the donor selection guidelines (DSG) JPAC was asked by the Services to allow at least 4 weeks from issue of offline browser files/PDF files, for training purposes, for the whole blood and components DSG and 2 to 3 weeks for the tissue and cell DSGs. To generate the PDFs etc. for training the changes all have to be made in pre-publish, and each guideline given a new release number, ready for the appropriate "go live" date.

When we have to make an emergency change it has to be made as soon as possible. If routine changes are sitting in pre-publish, because of way the system is currently designed, they would all go live with the emergency change and there could be confusion with the release numbering.

To date, since the COVID-19 outbreak, 21 emergency changes have been made to the guidelines and therefore we have had to delay making any routine changes.

CJS has asked the project team at Target to investigate ways of improving the system and also discussed the issue with Peter Senior at NHSBT for a quality point of view.

This work will have a cost implication, but we have the money in the JPAC budget for this improvement. JPAC approved taking this forward.

In the meantime, CJS asked if AC would ask the SACTCTP if, during the COVID-19 pandemic, they would accept a 1 week training period for their most important changes. If this was agreed, then the important changes could be made.

<u>Post Meeting Note</u>: AC has confirmed that the SACTCTP has agreed to a 1 week training period for the delayed change notifications. All the SACTCTP changes have now gone through.

3.1 <u>Proposal to change the composition and remit of the SAC on Clinical Transfusion Medicine</u> – JPAC 18-105 – item 3.1

MR is in the process of setting up this group and will bring the information back to JPAC when the group has been formed. JPAC agreed to take this off the "Actions List".

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

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

AW

3.3 Advanced Therapy Medicinal Products (ATMPs) Red Book Entry – 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.

SM & CJS

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

AW

AW is working on a rewrite for Malaria. This is a large piece of work. In progress.

3.5 <u>Inclusion of specification for red cells collected by apheresis technology in the current edition of the Guidelines for the Blood Transfusion Services in the UK (Red Book) – JPAC 19-51 – item 3.5</u>

JPAC approved this paper and the proposed change to Chapter 7 of the Red Book.

Post Meeting Note: Draft Change Notification 34 2020 in progress.

3.6 Residual risk of undetected infection among deceased tissue, living surgical bone and cord bloods, NHSBT 2013 – 2017 – JPAC 19-79 item 4.11

SACTCTP and Katy Davidson aim to publish the data prior to publication on the JPAC website. AC will let the JPAC Office know when and how this should be published on the website - either the paper itself, or a link to the site of the published paper. AC is awaiting comments from Su Brailsford.

AC

3.7 <u>Tamoxifen entries in the Tissue and Cells Donor Selection Guidelines</u> – JPAC 19-80 – item 3.9

A change notification will be issued.

<u>Post Meeting Note</u>: Change Notification No 42 issued 07 October 2020 live on the website 14 October 2020.

3.8 <u>Infection – Acute, Tamiflu & Relenza entries in the Deceased Tissue Donor</u> Selection Guidelines – JPAC 19-81 – item 3.10

Change notifications will be issued.

<u>Post Meeting Note</u>: Change Notifications Nos 39 and 40 were issued on 15 July 2020.

3.9 <u>Pre-retrieval body cooling for Deceased Tissue Donors - Proposed</u> amendment to the Red Book section 21.2 – JPAC 19-82 – item 3.11

JPAC approved the proposal to reword section 21.2. This will appear in the 9th Edition of the Red Book. In progress.

AC

3.10 Clopidogrel New Entry – Whole Blood and Components Donor Selection Guidelines - JPAC 19-83 – item 3.12

AW

A change notification will be issued. In progress.

3.11 <u>Cervical Carcinoma in situ – Whole Blood and Components Donor Selection</u> Guidelines – JPAC 19-84 - item 3.13

AW

A change notification will be issued. In progress.

ACTION 3.12 Haemochromatosis entry - Whole Blood and Components Donor Selection Guidelines - JPAC 19-85 - item 3.14 **AW** A change notification will be issued. In progress. 3.13 Latent TB - Whole Blood and Components Donor Selection Guidelines -JPAC 19-86 - item 3.15 AW A change notification will be issued. In progress. 3.14 Tropical Virus entry - Whole Blood and Components Donor Selection Guidelines - JPAC 19-87 - item 3.16 JPAC approved this revised entry and a change notification will be issued. In AW progress. 3.15 Valproate – new entry – Whole Blood and Components Donor Selection Guidelines - JPAC 19-88 - item 3.17 Change Notifications will be issued. In progress for Whole Blood and Components **AW** Donor Selections Guidelines. 3.16 ABO risk based decision-making framework workshop - item 3.20 The workshop will be organised for later this year once the disruption from COVID-**GMal** 19 had resolved. 3.17 Leucocyte-depleted Whole Blood - in vitro assessment of plasma, red cell and platelet function and proposed provisional specification - JPAC 20-07 - item 4.2 Post Meeting Note: Change Notification No 35 going through the Change Notification process 3.18 Proposed change to haematocrit specification compliance of Red Cells in Additive Solution (AS) [2020] - JPAC 20-05 - item 4.3 Post Meeting Note: Change Notification No 34 going through the Change Notification process 3.19 Off label use of platelet additive solutions in the manufacture of resuspended platelets (90% PAS: 10% plasma) - JPAC 20-06 - item 4.4 HN In progress 3.20 Horizon Scanning Annual Report 2019 - Excel spreadsheet - JPAC 20-15(b) item 5.6.1. JPAC 20-15(b) documents, actions/decisions made through the Horizon Scanning SM & GMal Process in 2019. It was agreed that this report should be submitted to the next SaBTO meeting as the May 2020 meeting had been cancelled. Horizon Scanning Process Management Description - JPAC 20-15(c) - item 3.21 5.6.2 It was agreed that this a "JPAC" document and therefore the appropriate headings LJ and descriptions will be added. The final version will then be posted in the Document Library on the JPAC website. It was also agreed that the document should also be reviewed annually using the same process as risk assessment

review.

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

3.22 European Tissue and Cells guide.

AC updated JPAC on the progress of this guide. The 4th edition of EDQM "Guide to the Quality and Safety of Tissues and Cells for Human Application" was published in 2019. The opening meeting to commence the work on 5th edition was held in Strasbourg in Jan 2020. AC was elected to co-chair the working group at this meeting. The second meeting scheduled in June had to be cancelled due to travel restrictions due to current pandemic. To progress the work, series of web meetings are taking place in 2020, to be followed up with face to face meeting in 2021 to go through second revision of the draft. The 5th edition of the guide is due to be published in 2022.

Gail Miflin joined the meeting.

4. Standing Advisory Committee on Transfusion Transmitted Infections

4.1 Position Statement: SARS-CoV-2 – JPAC 20-34

JPAC noted that there is still no evidence that the virus can be transfusion transmitted, but that this is difficult to identify in a pandemic situation. This is a new infection and there is still a lot we don't know about it.

This position statement has been updated with the current deferrals and also to clarify the Blood Services' position. Noting it is the JPAC position of what we do now.

JPAC asked that "and cord blood donors" be added to the "Living tissue donors" section at the top of page 6. With this amendment JPAC approved the updated Position Statement and that it should be reviewed in 3 months or earlier, when more information on the degree and significance of any RNA viraemia may be available.

The paper will be submitted to the UK Forum for broader discussion, after which it will be posted on the JPAC website.

Post Meeting Note:

- Amended paper was submitted to the UK Forum on 26 June 2020.
- Updated version of the position statement posted on the JPAC website on 30
 June 2020

4.2 <u>Guidance for changes to Donor Selection Guidelines for COVID-19</u> <u>convalescent plasma donors: malaria</u> – JPAC 20-35

LJ went through this paper for JPAC.

Following discussion DO confirmed that the MHRA would be happy for this product to be issued under clinical concession.

JPAC endorsed this paper noting that this guidance is only for the specific request for plasmapheresis donors for COVID-19 and does NOT change the SACTTI Parasite sub-committee advice for standard blood donations.

As this only affected NHSBT SM will send this paper to the NHSBT TPSG group for their information.

Post Meeting Note: This paper has been sent to NHSBT TPSG.

4.3 <u>Position Statement: Chikungunya Virus; June 2020</u> – JPAC 20-36

The Position Statement has been updated with the latest number of imported cases in the UK and also the number of cases in Europe.

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

<u>Post Meeting Note</u>: Updated position statement posted on the JPAC website on 30 June 2020.

5. Standing Advisory Committee on Tissues and Cellular Therapy Products

5.1 <u>Animal Bite Entry - All Tissue and Cell Donor Selection Guidelines</u> – JPAC 20-

JPAC approved this updated entry and a change notification will be issued as soon as possible.

Post Meeting Note: Change Notification No 36 issued on 15 July 2020.

5.2 Rabies Entry - All Tissue and Cell Donor Selection Guidelines - JPAC 20-38

JPAC approved this updated entry and a change notification will be issued.

Post Meeting Note: Change Notification No 37 issued on 15 July 2020.

5.3 <u>South American Trypanosomiasis Risk Entry - All Tissue and Cell Donor</u> Selection Guidelines – JPAC 20-39

JPAC approved this updated entry and a change notification will be issued.

<u>Post Meeting Note</u>: Change Notification No 44 issued 07 October 2020 live on the JPAC website 14 October 2020.

5.4 <u>Transfusion Entry - Living Tissue, Cord Blood and Bone Marrow and</u> Peripheral Blood Stem Cell Donor Selection Guidelines – JPAC 20-40

JPAC approved this updated entry and a change notification will be issued.

<u>Post Meeting Note</u>: Change Notification No 45 issued 07 October 2020 live on the JPAC website 14 October 2020.

6. Standing Advisory Committee on Blood Components

6.1 Options for component shortages in extremis – JPAC 20-41

HN went through this paper which is for noting by JPAC and has already been reviewed by SACBC.

The paper provides the wider context to JPAC 20-42 which recommends a temporary specification for a reduced dose of apheresis platelets to be used as contingency.

In March 2020 NHSBT initiated a piece of work to prioritise component development support for the current COVID-19 pandemic. At that time initial data emerging from Italy suggested that COVID19 patients themselves in the main did not require transfusion, and that decreases in donor numbers was being compensated by decreased demand for red cells. However, the course of the pandemic and its effect on blood supply was uncertain.

JPAC noted the paper.

6.2 Reduced dose Apheresis Platelets Component specification as a contingency – JPAC 20-42

As part of contingency planning for platelet shortages during the COVID-19 pandemic, the splitting of apheresis donations into reduced doses was identified as a potentially rapid method of increasing supply - in particular, splitting double donations (DD) into three rather than two doses (i.e. split equally between the 2 Terumo bags of the donation, and a further Fresenius bag, each DD giving three ½ doses) or splitting all adult doses in half (each to two ½ doses).

JPAC approved the posting of this specification in Annex 5 "Blood Components for Contingency Use" of the Red Book on the JPAC website and a change notification will be issued.

It was noted that it would be up to each Blood Service to decide if they were going to implement this change.

Post Meeting Note: Change Notification No 47 issued on 15 September 2020.

6.3 X-ray irradiation of blood components – JPAC 20-43

In June 2019 JPAC reviewed updated information on x-irradiation of components (JPAC 19-58). The content of this has been turned into a position statement to post on the JPAC website, in part to enable the revised BCSH guidelines on irradiation to reference this material.

JPAC approved this position statement which will be posted in the Document Library on the JPAC website once the JPAC position statement formatting has been applied.

<u>Post Meeting Note</u>: This Position Statement was posted on the JPAC website on 21 July 2020.

6.4 <u>Deviations from the specified storage temperature and interruption of</u> agitation of platelets - practical considerations – JPAC 20-44

ST presented this paper.

This is an updated version of General Information 09 which is in the Document Library on the JPAC website.

Since the paper was endorsed in 2017 there have been occasions since where clearer guidance would have helped to enable pragmatic application of guidance and avoid the waste of clinically-acceptable blood components. The literature has been re-examined and minor revisions made to the attached guidance document. The guidance will now refer to periods of non-agitation of up to 11 hours, instead of eight hours, this period was studied in the key paper on which the guidance was based. The specifications for platelet handling will still specify three periods of eight hours but the guidance will now add reassurance that short, unplanned over-runs will not necessarily lead to discard of valuable blood components.

JPAC approved this updated version which will be posted in the Document Library on the JPAC website.

<u>Post Meeting Note</u>: This Position Statement was posted on the JPAC website on 30 June 2020.

7. Standing Advisory Committee on Information Technology

7.1 <u>UK Component Code Standardisation</u> – JPAC 20-45

LL went through this paper and firstly thanked both SACBC and SACIT members for all their hard work on this paper.

A joint working group between SACBC and SACIT has reviewed current 'Codabar' component codes in use within the UK. The aim was to identify suitable ISBT codes to map the currently used Codabar against. The proposed codes have been approved by SACIT and SACBC.

JPAC approved posting this information on the JPAC website as a reference document.

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

LL

8. Dr Gary Mallinson – Scientific Lead – Safety Policy (JPAC/SaBTO)

8.1 SaBTO update - JPAC 20-46

GMal went through his SaBTO update for JPAC.

The routine Spring meeting had been cancelled but an extraordinary telecon was held on 28 April. This meeting considered urgent safety related measures around collection of plasma from individuals recovering from SARS-CoV2 infection (Convalescent Plasma, CP). The recommendations have been accepted by health minsters in England and Scotland.

The update also includes information on the progress of SaBTO's various working groups during this COVID-19 pandemic.

It is hoped that SaBTO's work plan will be discussed at their September meeting.

9. UK Forum

9.1 Feedback from the UK Forum meeting on 13 March 2020

The JPAC workplans had been shared with the UK Forum following our last JPAC meeting and will be discussed at the meeting on 26 June (tomorrow). Because of COVID-19 some of the timelines will need to be updated.

Infected Blood Inquiry

- Hearings likely to be postponed over summer
- Two years to process current data / documents
- Ethics report now available
- Some questions about setting up of lookback

- Delay in introduction of HCV testing will be looked at
- Prison population
- vCJD seen to be well considered and no concerns

10. Any Other Business

10.1. Medical Director Irish Blood Transfusion Service

SF informed JPAC that he will be 70 next year and hoping to retire. Advert for his post as Medical Director of the Irish Blood Transfusion Service will be circulated in early 2021.

10.2 JPAC Website

CJS informed JPAC that PDF versions of chapters, and individual pages, of the Guidelines for the Blood Transfusion Services in the UK and the Handbook of Transfusion Medicine are now available. The PDF icon appears at the top right-hand corner of each page. This is a welcome improvement to the website.

10.3 Zoom Account

CJS informed JPAC that yesterday we had confirmation that we can have our own Zoom (Professional) account. This will also be available for the SACs and working parties to use. When CJS has read all the information etc. she will contact the SAC Chairs.

Post Meeting Note: Information sent to SAC Chairs on 30 June 2020.

11. Date & venue for future JPAC meetings

2020

• Thursday 05 November - Zoom meeting

2021

Thursday 11 March - Zoom meeting

Thursday 01 July - Face-to-face meeting – venue tbc

Thursday 04 November - Zoom meeting

Following the success of this meeting it was agreed that we would trial holding one face-to-face and two virtual meeting per year.

The meeting closed at: 12.21