Joint UKBTS Professional Advisory Committee

Minutes of the 81st JPAC Meeting Teams meeting held on Thursday 24 March 2022 – 10:00 to 13:00

Meeting commenced at: 10:05

Present

| Dr Janet Birchall | (JB) - | Medical Director, Welsh Blood Service |
|---------------------|----------|--|
| Dr Helen New | (HN) - | Standing Advisory Committee on Blood Components |
| Dr Lisa Jarvis | (LJ) - | Standing Advisory Committee on Transfusion Transmitted Infections |
| Ms Anna Witham | (AnnW) - | - Note Taker |
| 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 Megan Rowley | (MR) - | Standing Advisory Committee on Clinical Transfusion Medicine and Interim Medical Director SNBTS, |
| Dr Stephen Thomas | (ST) - | Deputy Professional Director of JPAC |
| Dr Angus Wells | (AW) - | Standing Advisory Committee on Care and Selection of Donors |
| Dr Farrukh Shah | (FS) | Associate Medical Director of Transfusion NHS Blood & Transplant - Deputising for Gail Miflin |
| David Olszowka | (DO) - | Medicine and Healthcare products Regulatory Agency |
| Dr Tor Hervig | (TAH) - | Medical Director, IBTS |
| Peter Richardson | (PR) - | - QM WBS, representing The Quality Managers' Group |
| Dr Rebecca Cardigan | (RC) - | - Guest for Item 7 |

ACTION

1. Apologies

Dr Neil Almond - National Institute for Biological Standards and Control

Dr Gail Miflin - Medical Director, NHS Blood and Transplant

Mrs Linda Lodge - Standing Advisory Committee on Information Technology

Prof Maria Zambon - Director, Centre for Infections, UKHSA

2. Minutes of the last meeting held on 04 November 2021 - JPAC 22-02

SM welcomed:

Dr Farrukh Shah - Deputising for Gail Miflin.

Peter Richardson - The Quality Group

Dr Tor Hervig - The new Medical Director for IBTS

Dr Stephen Thomas into his new role as Director of JPAC from 1 April.

With an addition of 'Donor Selection' as a title to the final paragraph on page 7, the minutes were approved as a true record of the meeting.

3. Matters arising not on the agenda (review of the actions list) - JPAC 22-03

3.1 <u>Arrhythmias entry in the Bone Marrow and Peripheral Blood Stem Cell Donor</u> Selection Guidelines JPAC 21-24

AC

A change notification will be issued.

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

AW

In progress.

3.3 <u>Horizon Scanning Process Management Description</u> – JPAC 20-15(c)

GMal

This item referred to a flowchart of Horizon Scanning Algorithm for Infectious Threats that depicted flow of information between JPAC and external organisations and which was removed from the Horizon Scanning Position Statement as it was out of date. GMal and colleagues have decided that rather than updating this complex flowchart, a descriptive section will instead be incorporated into the SaBTO induction material. He will present at the next JPAC Meeting on 14th July 2022 for information.

3.4 <u>Validation of Dried Plasma Components - Requirements for the UK Standing</u>
<u>Advisory Committee on Blood Components - Confidential</u> - JPAC 21-19

On agenda

3.5 <u>Proposed revised Red Book Chapter 6, section 6.2, Concessionary Release</u> <u>definition</u> – JPAC 21-21

HN

ST

In progress.

3.6 SACIT: Plasma for Fractionation Considerations – JPAC 21-12

. ST

LL has resigned as SACIT Chair, there has been difficulty in finding a new chair. ST to take this forward.

3.7 <u>Update on transfusion administration set wording for the Red Book</u> – JPAC 21-36

Closed

EM circulated as requested. This is now complete.

3.8 Chapter 7 Red Book: Draft Plasma for fractionation, leucocyte depleted – JPAC 21-56

Closed

Complete and posted in Chapter 7 on the JPAC website.

3.9 <u>Chapter 8 Red Book: Evaluation of plasma for fractionation for the manufacture of immunoglobulin</u> – JPAC 21-57

HN

On agenda.

ACTION Leucocyte-depleted Whole Blood (LD-WB) - revision of shelf-life specification 3.10 and approval of its use outside the pre-hospitals setting, as part of the randomised control trial - JPAC 21-63 Closed Closed. Change Notification No. 11-2022 issued. 3.11 **Inflammatory Bowel Disease** AW In progress. 3.12 Post donation information – JPAC 21-75 AW In progress. 3.13 Addition of Yellow Fever to the GDRI - JPAC 21-76 AW In progress. 3.14 Addition of implanted devices to the Indwelling Shunts and Stents entry -AW **JPAC 21-79** In progress. **Donors with HIV positive partners - VERBAL UPDATE** AW 3.15 On agenda. 3.16 Zika Risk Assessment - version 5 - JPAC 21-81 AW AW to complete. Anna can you check this with Angus, I can't remember what it was about Closed 3.17 Blood component labelling specification - JPAC 21-88 Complete. Uploaded to the JPAC Website. 4. Standing Advisory Committee on Transfusion Transmitted Infection Dengue Position Statement (September 2021) - JPAC 22-04 4.1 The main changes in this Position Statement are update of imported case numbers in UK and Europe. Most imported cases are ex. Thailand and India **JPAC** Manager Approved. It was agreed that this will be posted on the JPAC website. 4.2 Tick-borne encephalitis virus risk assessment, version 3 - JPAC 22-05 Significant referencing has been updated within this Risk Assessment. Updates include 2 UK cases reported, from probable infections in the New Forest. There is a general spread of cases in Europe, presumably associated with the spread of ticks due to climate warming. Cases have been identified in The Netherlands and France. A typo was identified on the summary sheet, page 1 section 6, delete first 'no'. LJ Approved. To be reviewed in 2 years. 4.3 SARS-CoV-2/COVID-19 Position Statement and the safety of substances of

human origin (SoHO) - February 2022 - JPAC 22-06

Position Statement has been updated to align with changes, approved at JPAC November 2021 and this meeting, to SACTCTP and SACCSD donor selection guidelines. Changes are largely regarding deferral times relating to recall, vaccination and illness deferrals with a new section on deceased donors. A further request from SACCSD and SACTCTP regarding removal of contact deferrals is currently being considered by SACTTI and will be included in new version of the donor selection guidelines if approved. It was noted that it is difficult to keep the Position Statement up to date.

LJ

GMal

AC

After discussion, approved by JPAC. This will be posted on the JPAC website.

4.4 **SACTTI Horizon Scanning - JPAC 22-07**

Annual Report 2021

On an annual basis LJ compiles this report providing a selection of actions taken from the Horizon Scanning process (all emerging reports for which action is required and a selection of other **@Mats** for JPAC oversight): this report will be submitted to SaBTO.

An external audit for Horizon Scanning has been undertaken. The report overall was very positive with one recommendation; an annual review of the sources for the Horizon Scanning process. This has been prepared for 2021 and is also included in JPAC 22-07. GMal indicated that he would recommend both JPAC 22-07 in its entirety is taken to SaBTO.

5. Standing Advisory Committee on Tissues and Cellular Therapy Products

5.1 Diabetes Mellitus entry in the BM&PBSC DSGs - JPAC 22-08

This entry has been reviewed and updated, specifically for Bone Marrow and doesn't affect other tissue Donor Selection Guidelines.

Approved. A change notification will be issued.

AC

5.2 Animal Bite entry - CB DSGs - JPAC 22-09

This entry has been reviewed by SACTTI and includes an increased deferral from 12 to 24 months.

Approved. A change notification will be issued.

5.3 Clopidogrel - BM&PBSC DSGs - JPAC 22-10

> Approved. A change notification will be issued. AC

5.4 Coronavirus Infection Entry – All Tissue and Cell DSGs – JPAC 22-11

This entry has been updated several times since 2020. There is currently a 14-day deferral for Bone Marrow, proposed to be reduced to 7 days.

AC advised of an all-time low of cornea stock therefore requested that this be managed as an urgent Change Notification.

A wording change was suggested to the Deceased Donors section from 'providing the donor remains well' to 'if had no Covid 19 symptoms.'

AC

AW suggested that from a blood perspective, it is becoming increasingly difficult to apply the rules now for 'contact' and that his preference is to remove 'contact' from the guidelines. This could also apply to Tissue DSGs.

It was agreed that AC will forward the current Change Notification to LJ for circulation to SACTTI followed by an updated version at a later date to remove 'contact' when the issue has been discussed and agreed.

AC/LJ/JPA C Manager

Approved. An urgent change notification will be issued.

5.5 Malaria entry in the Cord Blood DSGs - JPAC 22-12

Approved. A change notification will be issued.

AC

5.6 <u>Immunosuppression entry – Deceased Tissue DSGs</u> – JPAC 22-13

This paper has previously been submitted to JPAC, at that time the HTA wanted to review it. AS from HTA confirmed they are now happy with the entry.

AC

Approved. A change notification will be issued.

6. Standing Advisory Committee on Care and Selection of Donors

6.1 Relaxation of travel criteria for plasmapheresis donors – for Information – JPAC 22-14

AW is aiming to make it easier for plasmapheresis donors to donate by applying criteria in the BSQR that can be relaxed if the donation is for plasmapheresis only, AW proposes to discuss with SACTTI to place into the Donor Selection Guidelines at a later date.

It was agreed that this is a good move forward, although concerns were raised in terms of operational challenges.

AW/LJ

AW to take this forward with SACTTI.

6.2 Pregnancy – JPAC 22-15

AW advised that guidance currently defers donors with an early pregnancy loss, before 12 weeks. It is SACCSD's proposal to put a structure in place to allow these donors to be accepted.

AW

After discussion AW agreed to amend the paper and forward it to DO for review.

6.3 Sleep Apnoea - JPAC 22-16

This is a change to the Donor Selection Guidelines; the current entry is quite restrictive therefore SACCSD are proposing that donors whose symptoms are well controlled be allowed to donate.

Approved. A Change Notification will be issued.

AW

6.4 Update on Donors with HIV positive partners - JPAC 22-17

SACCSD have been tasked with creating operational guidance on accepting donors whose partners are currently receiving treatment for HIV. It is SACCSD's proposal to pause this recommendation and reconsider the matter in a couple of years.

SaBTO had endorsed the FAIR recommendation. SaBTO recognise there is very low risk of transmission but there is in fact a 'risk' and accepted this is a difficult thing to operationalise.

SACTTI have concerns and it was the general consensus that 'watchful waiting' would be beneficial.

GMal suggested that SaBTO would welcome a letter of position from JPAC.

SM

Due to the difficulty in operationalising this, it was agreed that JPAC would advise SaBTO via letter of this discussion. SM agreed to take this forward.

6.5 **Surgery – JPAC 22-18**

AW

Approved. A Change Notification will be issued.

6.6 Addiction and Drug Abuse - JPAC 22-19

This is a simple change around medication to support donor abstinence.

AW

Approved. A Change Notification will be issued.

6.7 Platelet Count - JPAC 22-20

Approved. A Change Notification will be issued.

AW

6.8 <u>DSG changes to HBV</u> – JPAC 22-21

AW advised that this paper is to support the OBI project, and simplify the guidelines to take out any further testing. The proposal for donors with previous or active HBV is to take samples only.

AW

Approved. A Change Notification will be issued.

7. Standing Advisory Committee on Blood Components

7.1 Validation of Dried Plasma Components – JPAC 22-22

HN explained that this paper was originally presented a year ago, and it has been updated to clarify the regulatory aspects. The paper includes minor amendments throughout the paper. RC explained that a regulatory work package is included in her proposed programme of work.

After discussion it was agreed that this document will be posted on the JPAC website for transparency.

HN/JPAC Manager

7.2 Revised 9th Edition Red Book Chapter 8 for JPAC Website - JPAC 22-23

HN explained that the majority of the changes within this paper have already been agreed at JPAC, HN advised that any wording in red are new changes.

After discussion it was agreed that this revised chapter was approved. It will be circulated to national Quality Managers, in advance of publication on the website in approximately one month

AW

8. UK Forum

Feedback from UK Forum meeting held on 24th March 2022

SM reported to the UK Forum that CJS will not be returning to her role as JPAC Manager, the UK Forum chair has written to CJS to thank her for her work.

SM submitted workplans, UK Forum are very happy with the Work Plans and grateful for all JPAC's hard work.

10. SaBTO

SaBTO Report for JPAC 22-24

GMal provided an update on the work of SaBTO and its working groups. SaBTO plans to establish a lookback group to produce general principles and guidance for lookback investigations. Members noted that the Infected Blood Inquiry were aware of the group. A report by the HEV working group on the HEV testing strategy is being finalised for the next meeting.

11. European Union

SM has been informed that the revision of the EU Directives has been delayed, possibly until May.

12. JPAC Work Plans

JPAC Work Plan 2020-2021 JPAC Work Plan 2021-2022

These documents are tabled for information.

13. Any Other Business

No other business to discuss.

14. Date & Venue for future JPAC Meetings

2022

Thursday 14 July - Teams meeting
 Thursday 17 November - Teams meeting

The meeting closed at: 12:57