approved 06.11.23

Meeting details

Subject	**85th JPAC meeting**
Date	Thursday 22 June 2023
Time	10:00 to 13:00
Location	Microsoft Teams

Retrospective comments and subsequent amendments to the minutes are indicated in yellow.

Attendees

Allameddine Allameddine	**AA**	Medical Director, NIBTS	
Akila Chandrasekar	**AC**	Chair, SACTCTP	
Ryan Evans	**RE**	Chair, SACBC	
Lisa Jarvis	**LJ**	Chair, SACTTI	
Lorna McLintock	**LM**	Medical Director, SNBTS	
Gary Mallinson	**GMa**	Scientific Lead Safety Policy, JPAC/SaBTO	
Edwin Massey	**EM**	Medical Director, WBS	
Gail Miflin	**GMi**	Chief Medical Officer, NHSBT	
Peter Rae	**PRa**	Scientific Publishing Manager, JPAC	(Minutes)
Peter Richardson	**PRi**	Chair, UK Quality Managers	
Megan Rowley	**MR**	Chair, SACCTM	
Amy Shackell	**AS**	Regulation Manager, HTA	
Stephen Thomas	**ST**	Professional Director, JPAC	(Chair)
Angus Wells	**AWe**	Chair, SACCSD	
Anna Witham	**AWi**	Administrator, JPAC	

Apologies

Neil Almond	**NA**	MHRA South Mimms
Tor Hervig	**TH**	Medical Director, IBTS
David Olszowka	**DO**	Regulatory Governance Lead, MHRA
Nicole Thornton	**NT**	Chair, SACIH

Agenda items

1 Welcome

ST welcomed Allameddine Allameddine to his first JPAC meeting since taking up the post of Medical Director for NIBTS. Members briefly introduced themselves.

2 Previous meeting minutes

The minutes of the previous JPAC meeting held on 16 March 2023 (**JPAC 23-29**) were approved.

3 Actions list

A number of actions were closed prior to the meeting as indicated on the actions list (**JPAC 23-30**) under the 'Closed' status. The remaining open actions were discussed.

Review of open actions:

3.1 Pregnancy – JPAC 22-15

For discussion by SACCSD in July 2023, for submission to JPAC in November 2023.

3.2 Validation of Dried Plasma Components – JPAC 22-22

Can now be published on JPAC website under General Documents. **[PR]**

3.3 EBA position paper: recommendations for non-DEHP component validation- JPAC 22-49

SACBC has performed gap analysis. Individual comparisons between the Red Book and the EBA position paper will be carried out as each non-DEHP component validation is performed, with subsequent recommendations for Chapter 8 updates submitted to JPAC as/when required. This work is now on the SACBC workplan. Action closed.

3.4 Residual risk for HEV

For discussion by SACTTI in September 2023. **[LJ]**

3.5 Washed red cells (2015 paper) to be revisited

To be discussed by SACBC in September 2023. **[RE]**

3.6 Receive closure report for Reduced Dose PLT approval (expected 14.06.23)

Report not yet received. RE to chase. **[RE]**

3.7 Meeting of JPAC/SACTTI/SaBTO to discuss long-term horizon scanning process

Meeting to be arranged. Likely Autumn 2023. **[ST]**

3.8 Appointment of Chair of SACIT

On hold pending outcome of current JPAC Ways of Working review. **[ST]**

3.9 Re JPAC workplan item 38 (donor adverse incident reporting) – further discussion suggested to avoid duplication of work with SHOT benchmarking of adverse event rates

ST to provide update at next JPAC meeting on 16 November 2023. **[ST]**

4 SACCSD

4.1 Clinical supervision at donor sessions (JPAC 23-31)

Wording within the revised Chapter 4 of the Red Book has been amended to clarify that health care professionals other than doctors and nurses are suitable to perform clinical supervision of donor sessions, provided that they meet the required proficiencies as stated.

It was suggested that an additional amendment be made to reflect that ensuring appropriate staffing levels were the responsibility of the blood service, rather than an individual consultant on session, and that a clearer definition of 'health care professional' may be required. These suggestions will be taken back to SACCSD for discussion and appropriate changes made. **[AWe]**

Approved for publication pending these minor changes. **PR** to liaise with **AWe**. **[PR]**

4.2 Transgender and non-binary donors (JPAC 23-32)

The latest version of this paper has been circulated to stakeholders, including donor experience representatives, for feedback on language and wording. It was also noted that clarification on cross sex hormone therapy was still required. It is planned that the principles document will be published on the website, perhaps as a Position Statement or in the Document Library.

Once stakeholder feedback is received, revisions will be submitted to JPAC for approval. **[AWe]**

4.3 Relaxation of travel criteria for plasmapheresis donors (JPAC 23-33)

It was noted that Viral Haemorrhagic Fever (VHF) is not included in these proposed new WB-DSG entries because VHF is not listed in either BSQR or the Council of Europe guidelines. It will be made clear in the published entries that for risks not listed in these entries, the existing guidance for whole blood and component donors within the WB-DSG will apply.

Approved for publication. **PR** to liaise with **AWe**. **[PR]**

4.4 Immunosuppression (JPAC 23-34)

Regular review of the table of vaccines in the WB-DSG will be added to the SACCSD workplan to ensure ongoing alignment with the Green Book (Immunisation against infectious disease, UKSHA).

Approved for publication. **PR** to liaise with **AWe**. **[PR]**

Updates to the Green Book are included in the **Vaccine Update** newsletter, available from UKSHA at **www.gov.uk/government/collections/vaccine-update**. There is an option to sign up for email delivery.

5 SACTCTP

5.1 Change in timing of mandatory testing for autologous stem cell donors

Following a query about the timing of mandatory testing for allogenic and autologous bone marrow and peripheral blood stem cell donors, HTA sought legal advice regarding the interpretation of the existing guidance within the European Union Tissues and Cells Directive (EUTCD). The accepted interpretation is now that samples must be taken at the time of donation for autologous donors.

A survey of European Competent Authorities showed no uniform practice in timing of mandatory testing for autologous donors across Europe, likely as a result of the ambiguous wording of the current EUTCD.

The change in interpretation of the EUTCD will not be reflected in upcoming updates to Red Book chapter 22 and the new annexe 7, with the caveat that guidance is still under review by HTA.

Current NHSBT practice is to take samples 30 days prior to donation and at the time of donation for both allogeneic and autologous donors so the change in interpretation causes no operational difficulties in NHSBT.

SNBTS discontinued time of donation testing for autologous donors following a risk assessment in 2018 that showed no positive results were obtained on samples at the time of donation from donors who had a negative result on the sample taken 30 days prior to donation, and so is currently not carrying out testing in line with the new interpretation. However, until there is further clarity following the HTA review, in line with annexe 7, it is understood that this practice will be maintained.

The updated Red Book chapter/annexe approved for publication. **PR** to liaise with **AC**. **[PR]**

6 SACBC

6.1 Assessment of 42 day shelf life for Red Cells in Additive Solution, LD (JPAC 23-35)

The recommendation from SACBC is to incorporate validation of 42 shelf life for routine red cells into the upcoming validation of DEHP-free blood bags. However, given that the DEHP sunset date may move from 2025 to 2030, it may not be justifiable to delay further work on extending red cell shelf until DEHP-free validation begins.

It was noted that further modelling of the effect of 42 day shelf life on blood stocks management is still required to fully understand the benefits of extending red cell shelf life before further recommendations are made.

To be submitted for discussion at UK Forum meeting in September or December 2023. **[ST]**

6.2 Review of UK Protocol for Normothermic Regional Perfusion (NRP)

The need for a reference to the current UK NRP protocol in the red cell specifications given in the Red Book will be discussed by SACBC in September 2023. **[RE]**

7 SACIH

7.1 Discontinuation of T antigen testing and anti-T titration

At the meeting held on 03 May 2023, EWG was informed that T antigen testing was to be withdrawn by NHSBT due to the only available test kit having been discontinued by the manufacturer.

However, following a meeting with paediatric nephrologists in Newcastle, it was noted that the test remains useful for the acute management of haemolytic uraemic syndrome in young children. T antigen testing will therefore remain available until February 2024, with a validated extended reagent shelf life, while SACIH undertakes an EBA survey to assess similar testing in other countries.

Beyond this date it is expected that either an inhouse test will need to be developed and provided within the UK or, if an EBA test provider can be identified, that testing will be outsourced.

To be submitted to JPAC for further discussion once the EBA survey is complete. **[NT]**

8 SACTTI

8.1 SARS-CoV-2 – revised Risk Assessment and Position Statement (JPAC 23-36 and JPAC 23-37)

The SARS-CoV-2 risk assessment has been reviewed. Given a lack of evidence of recipient or donor risk, with no reported transfusion transmitted SARS-CoV-2 infections through blood, tissue or cell donations, SACTTI have proposed the recommendation for the testing of asymptomatic stem cell donors by respiratory swab be removed from the existing Position Statement.

It was noted that removal of this recommendation for testing from the existing BM-DSG entry will contradict the current NICE guidelines. These were issued in July 2022 and while an update to the NICE guidelines is expected, the timeline for publication is unclear. It was agreed that it was reasonable to deviate from the NICE guidelines given that the removal of asymptomatic testing is well-evidenced. If there is a discrepancy with the revised NICE guidelines, SACTTI's proposal will be reviewed to examine the rationale with supporting evidence.

Updated Position Statement approved for publication. **PRa** to liaise with **LJ**. **[PRa]**

The proposed changes will be taken to SACTCTP to allow BM-DSG updates to be discussed. **[AC]**

9 SaBTO

There has been a SaBTO meeting since the summary report (**JPAC 23-38**) was submitted so an additional verbal update was provided.

9.1 HEV working group

The working group's final report was submitted to SaBTO and its recommendations agreed. These will now be sent to DHSC Ministers for noting. The working group determined there were no cost-effective measures to reduce HEV transmission risk so no changes to HEV testing would be supported by SaBTO at the current time.

9.2 Lookback working group

Two workstreams are currently ongoing, one looking at the ethics of lookback and another looking at the storage and availability of samples for lookback.

9.3 Risk Tolerability working group

It has been suggested that a new working group be constituted to focus on making the Alliance of Blood Operators Risk-Based Decision-Making Framework the basis of any work relating to risk tolerability in the future. This safety framework may be useful when looking at cost effectiveness.

9.4 Virology working group

Ines Ushiro-Lumb will chair the working group now the previous chair has stood down. The workplan is still being reviewed but it is likely to include a review of CMV later in the year.

10 JPAC Office

10.1 Ways of Working review

Katie Begg has already had a number of meetings with SAC chairs, SAC members and other JPAC stakeholders. Attendees were invited to contribute to the review if they have not yet been approached.

10.2 Website refresh project

A business analyst and a user researcher have been conducting stakeholder interviews and again, if not already involved, attendees were invited to contribute.

11 Any other business

Lisa Jarvis will be stepping down as Chair of SACTTI after the next JPAC meeting in November 2023. Expressions of interest for the position are being sought, with interviews planned for September.

Nicole Thornton has now replaced Edwin Massey as Chair of SACIH.

Anna Witham will shortly be going on maternity leave, with best wishes from JPAC.

Stephen Thomas will be on annual leave between 03 July 2023 and 04 August 2023 with Gary Mallinson deputing while he is away. The JPAC Office remains open.

12 Papers for noting

There were no objections or corrections to the papers included in the agenda for noting.