Meeting details

Subject	**JPAC Board Meeting**
Date	Thursday 14 March 2024
Time	10:00 to 13:00
Location	Microsoft Teams

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

Attendees

Allameddine Allameddine	**AA**	Medical Director, NIBTS	
Neil Almond	**NA**	MHRA South Mimms	
Akila Chandrasekar	**AC**	Chair, SACTCTP	
Jill Clarkson	**JC**	Member, SACCSD	(Observer)
Laura Green	**LG**	Deputising for Chair, SACBC	
Heli Harvala	**HH**	Chair, SACTTI	
Evelyn McLennan	**EMc**	Chair, UK Quality Managers Group	
Lorna McLintock	**LM**	Medical Director, SNBTS	
Gary Mallinson	**GMa**	Scientific Lead for Safety Policy, JPAC/SaBTO	
Edwin Massey	**EMa**	Medical Director, WBS	
Gail Miflin	**GMi**	Chief Medical Officer, NHSBT	
David Olszowka	**DO**	Regulatory Governance Lead, MHRA	
Peter Rae	**PRa**	Scientific Publishing Manager, JPAC	(Minutes)
Megan Rowley	**MR**	Clinical Transfusion Medicine Specialist	
Amy Shackell	**AS**	Regulation Manager, HTA	
Stephen Thomas	**ST**	Professional Director, JPAC	(Chair)
Angus Wells	**AWe**	Chair, SACCSD	

Apologies

Ryan Evans	**RE**	Chair, SACBC	
Tor Hervig	**TH**	Medical Director, IBTS	
Shruthi Narayan	**SN**	Medical Director, SHOT	(Observer)
Peter Richardson	**PRi**	Chair, UK Quality Managers Group	
Nicole Thornton	**NT**	Chair, SACIH	
Anna Witham	**AWi**	Administrator, JPAC	

Agenda items

1. Welcome

ST welcomed Evelyn McLennan to the meeting as the new Chair of the UK Quality Managers Group. Peter Richardson was thanked for his contribution to JPAC.

Laura Green, deputising for Ryan Evans and to present item 6.1, and Jill Clarkson, an observing member of SACCSD, were also welcomed.

Apologies given as noted.

2. Minutes of the previous meeting

The minutes of the previous JPAC Board meeting held on 11 November 2023 (**JPAC 24-02**) were approved for publication on the website. **PRa**

3. Review of open actions

Actions that were closed since the last meeting were marked with the 'Closed' status on the actions list (**JPAC 24-03**) for information, to be archived on the 'Closed' tab following the meeting.

The following open actions were discussed:

- **Appointment of Chair of SACIT** (from JPAC 16.03.23, item 8)

  A meeting of a temporary group was held on 21 February 2024, comprising previous members of SACIT and other interested parties, to discuss the remit of a restarted SACIT. Christie Ash (NHSBT) and David Mason-Hawes (Velindre University NHS Trust) have kindly agreed to co-chair this temporary group to allow the remit, required expertise and workplan of SACIT to be agreed. Action closed.

- **Clinical supervision at donor sessions** (from JPAC 22.06.23, item 4.1)

  Relevant stakeholders have been engaged by SACCSD for review and comment on the proposal for recommendations on clinical supervision at donor sessions. Submission of the proposal is expected at the next EWG meeting on 24 April 2024. **AWe**

- **Travel criteria for plasmapheresis donors** (from JPAC 22.06.23, item 4.3)

  CN 08-2024 (previously CN 31-2023) is in progress. Publication planned for April 2024. **PRa**

- **Immunosuppression** (from JPAC 22.06.23, item 4.4)

  CN 07-2024 (previously CN 30-2023) is in progress. Publication planned for April 2024. **PRa**

- **42 day red cell validation** (from JPAC 22.06.23, item 6.1)

  The decision not to proceed with validation was noted at the UK Forum meeting held on 01 March 2024. Action closed.

- **T antigen testing** (from JPAC 22.06.23, item 7.1)

  Paper to be submitted to the next EWG meeting on 24 April 2024. Notification will be given to the Medical Directors of the four UK Services before any cessation of testing. **NT**

- **Lymphocyte proliferation studies** (from JPAC 06.11.23, item 4.1)

  Ongoing work.

- **Transgender and Non-Binary Donors – changes to WB-DSG and RB** (from JPAC 06.11.23, item 5.1)

  After consideration of Services' preferred timeframes for publication and minor clarifications having been made to approved text, changes are planned to be issued in April 2024. **PRa**

- **HAV and B19 – changes to WB-DSG** (from JPAC 06.11.23, item 5.2)

  CN 06-2024 (previously CN 41-2023) is in progress. Publication planned for April 2024. **PRa**

- **Acupuncture – discuss authority for changes with DHSC and MHRA** (from JPAC 06.11.23, item 5.3)

  On agenda for discussion (see 7.4).

- **Appointment of interim Chair of SACTCTP** (from JPAC 06.11.23, item 8.1)

  On hold pending the outcome of the current review of SACTCTP (see 8.2).

4. SACTCTP

4.1. Cerebrovascular Disease & CNS Disease – new/updated entries in BM-DSG (JPAC 24-04)

This change will have some bearing on the ongoing discussions around cerebral amyloid angiopathy (CAA) because potential donors who have had a previous cerebral haemorrhage will be now deferred, although the change in guidance will not address concerns regarding

those who are fit and well at the time of donation but then go on to develop a cerebral haemorrhage in the future.

It was noted that whilst this change may have a slight negative impact on the donor base, it was agreed by SACTCTP that the change is required in the interests of donor protection.

Approved for publication. CN to be prepared. **PRa**

5. SACCSD

5.1. Bleeding Disorders – updated entry in Whole Blood DSG (JPAC 24-05)

Clarifications to the entry, including additional information on specific coagulation factor deficiencies and revised guidelines for Affected Individuals and Carriers including discretionary guidance on Type 1 vWD and carrier states, were approved for publication.
CN to be prepared. **PRa**

The proposal also included the removal of deferral for contacts of individuals with bleeding disorders (i.e. family members, carers and sexual partners). Whilst there was broad agreement that this change is appropriate in principle, the original rationale for deferring contacts was unclear at the time of discussion. Therefore, it was agreed that a clear understanding of the governance route for approval was required before a decision on this change could be made.

If contacts of individuals with bleeding disorders were originally deferred as a risk reduction measure for HIV and Hepatitis C, it was on the basis of potential viral transmission through blood-derived coagulation factor concentrates or from high-risk sexual partners (i.e. those with confirmed HIV or Hepatitis C infection). SACCSD considers that the significantly reduced risk of viral transmission when using modern factor concentrates no longer necessitates a restriction on those in contact with treated individuals and, under current guidelines, donors with high-risk sexual partners would still be deferred. In this case, it was agreed a short paper could be written to accompany the proposal, detailing this rationale, and could be submitted to the JPAC Board for approval.

If contacts of individuals with bleeding disorders were originally deferred as a risk reduction measure for vCJD, further discussions would need to be had with SaBTO as part of its current work on reviewing donor deferral criteria and other risk reduction measures to prevent CJD transmission. In this case, if SaBTO recommends that deferral of contacts, as a precautionary measure for vCJD, can be removed, the JPAC Board would then review their recommendation as part of the approval process for this proposal.

To allow the correct approval pathway to be identified for this change, previous Change Notifications and historic meeting documentation will be reviewed. **JC/AWe**

5.2. Upper age limit for donors – updated entry in Whole Blood DSG (JPAC 24-06)

Proposal to increase the upper age limit from 70 to 72 for returning donors (i.e. those who have previously given a full donation but have not donated in the last 24 months). There is no change proposed for the upper age limit for new donors (66) or the requirement to give a full donation every two years to be considered a regular donor. Regular donors are currently often accepted over the age of 70, according to individual Blood Service policies, at the discretion of its responsible Medical Director (in compliance with BSQR).

Haemovigilance data (SHOT, 2020-2022) show that there are a lower number of systemic (vasovagal) reactions in donors over the age of 70 compared with younger donors, although there is a slightly higher rate of local complications such as rebleeding and bruising. However, as the data do not allow a comparison between the relative risk of returning donors at age 70 compared to age 72, there is potential that there may be increased risk to older returning donors if the upper age limit is increased. It was noted that the local complications observed in older donors are not likely to progress to wider complications, and many local complications can be mitigated with correct arm care at donation. It was also suggested that increasing the upper age limit for returning donors brings negligible risk as many of the returning donors would have been regular donors (and likely donated beyond the age of 72) had they not had an unintended break in their donation career.

Approval for the change in upper age limit was given on the agreement that its implementation will be accompanied by monitoring of reported adverse events to identify any changes in the risk profile of older returning donors. This will be done for 12-24 months, in collaboration with SHOT, with SACCSD initially reporting back to the JPAC Board in 6-12 months. This data may also help to identify if further changes to the upper age limit for whole blood or plasma donors are possible in the future. **AWe**

Approved for publication. CN to be prepared. **PRa**

5.3. Cardiovascular Disease – updated entries in Whole Blood DSG (JPAC 24-07)

Clarification of current guidance based on user feedback and cardiology literature review.

The proposal introduces differential deferral criteria for Left Bundle Branch Block (LBBB) and Right Bundle Branch Block (RBBB), both subject to deferral in the current entry. Reflecting that RBBB can be a normal physiological variant, SACCSD agreed that donors with RBBB should now be accepted provided they have no other underlying cardiac or pulmonary disease. Donors with LBBB will continue to be deferred.

With reference to the discussion about the upper age limit for returning donors, it was noted that the incidence of LBBB and RBBB increases with age and may be difficult to distinguish in primary care. SACCSD is not proposing routine screening of donors for LBBB/RBBB but intends that this change will allow potential donors who have an incidental finding of RBBB (e.g. through health screening) to be consistently and appropriately accepted for donation.

Whilst the proposed changes are consistent with BSQR, the general statement “This is a requirement of the Blood and Safety Quality Regulation 2005” is planned to be removed from

the 'Information' section of the 'Arrythmias' entry, to be consistent with other recent changes in the WB-DSG. However, it was agreed that information about the relevant part of BSQR should be included in the 'Additional Information' section for assurance. **AWe**

Approved for publication. CN to be prepared. **PRa**

6. SACBC

6.1. SWiFT trial – clinical indications of Leucocyte-depleted Whole Blood (JPAC 24-08)

The SWiFT trial was previously discussed at the JPAC meeting held on 04 November 2021 (**JPAC 21-63**). Within the trial, Leucocyte-depleted Whole Blood (LD-WB) is used for pre-hospital treatment of traumatic major haemorrhage. It was agreed that an extension of the use of LD-WB, primarily to reduce wastage, could be sought if the safety data of the first 200 patients (100 in the LD-WB arm) indicated no safety concerns.

LG presented a review of this safety data, which has been assessed by the trial's Data Monitoring Committee (DMC). The DMC identified no safety concerns with the use of LD-WB, although no comparisons were made with control arm participants as this was not prespecified in the protocol. It was also noted that there is a lack of clinical evidence from other trials since the SWiFT trial began in December 2022.

The potential clinical indications for LD-WB were considered by attendees, although it is understood that JPAC does not have a remit to produce clinical advice and clinical indications are not given in the Red Book. Beyond trauma patients transfused in the trial, it was discussed that LD-WB may not be suitable for use in all bleeding patients due to the different clinical responses required for specific haemorrhage types (e.g. obstetric, gastrointestinal, paediatric, etc). However, as a clinical decision beyond JPAC's scope, it would be for individual hospitals to decide on specific use cases for LD-WB if approved for use outside of the trial indication.

The logistical considerations for the use of LD-WB were also discussed. These include whether Blood Establishments would have capacity to produce sufficient quantities if use of LD-WB becomes widespread, and the complexity of the changes required in hospitals to receive, issue and use LD-WB appropriately alongside other components.

While adverse events in patients transfused with LD-WB outside of the trial indication would be monitored through the SHOT haemovigilance scheme, as with those within the trial, the current lack of clinical evidence relating to safety remains a concern for the JPAC Board.

Given the outstanding questions regarding evidence, logistics and indications, the JPAC Board did not approve the use of LD-WB outside the trial at this time. **LG** was invited to revise and resubmit the proposal for discussion at the next JPAC Board meeting on 20 June 2024. **LG**

7. SaBTO

A summary report of SaBTO's activities was provided (**JPAC 24-08**) and a verbal update from the SaBTO meeting held on 11 March 2024 was given.

7.1. CJD Review group

A number of recommendations for donor deferral criteria are being considered by SaBTO, including the removal of deferral for previously transfused individuals (vCJD) and those who have received corneal or scleral grafts (CJD). These recommendations will be finalised prior to submission for ministerial approval. MHRA has noted that the Plasma for Medicines (PFM) risk assessments previously carried out by the Commission on Human Medicines is conditional on there being no changes to the current donor deferral criteria. DHSC will coordinate with relevant health administrations to ensure this point is considered if the CJD Review group's recommendations are approved for implementation.

It has also been noted that there is potential risk of transfusion-related acute lung injury (TRALI) if male donors alloimmunised through transfusion enter the blood supply and this will require further consideration by JPAC as work progresses.

7.2. Cerebral amyloid angiopathy

SaBTO has prepared an internal position paper on CAA.

The MRC Prion Unit has arranged a workshop on iatrogenic amyloid-beta transmission and CAA for 17 April 2024, to be attended by expert clinicians, regulators and research funders. Subsequent to this meeting, SaBTO will consider what additional work is required.

7.3. Vein-to-vein traceability

It is currently unclear if SaBTO's remit extends to vein-to-vein traceability but the Terms of Reference for a working group are being drafted. If agreed, the working group would likely focus on identifying recipient risk from not having adequate systems of traceability in place.

7.4. Acupuncture

Joint meetings of representatives from DHSC, MHRA and JPAC have been held to discuss the donor deferral criteria for acupuncture, with a view to allow acupuncture recipients to donate if practitioners are either registered with the Professional Standards Agency (PSA) or hold a local authority license for their premises.

The proposal is currently being finalised, to be discussed by DHSC, MHRA and JPAC at a meeting on 28 March 2024, before being submitted to DHSC for consideration.

7.5. Hepatitis E

The SaBTO Hepatitis E report is nearing completion.

7.6. FAIR

It was noted that there are several items arising from the ongoing work of the 'For the Assessment of Individualised Risk' (FAIR) steering group (e.g. polyamory, partners of individuals with undetectable HIV viral load, sex-workers) which will come to JPAC for consideration in due course.

8. JPAC Office

8.1. Terms of Reference document (JPAC 24-11)

Attendees were asked to provide feedback on the draft Terms of Reference document within the next two weeks, with a view to publication on the website thereafter. The accompanying draft Ways of Working document will be circulated to attendees shortly for similar review. **PRa**

8.2. Review of SACTCTP

A draft report has now been written and will be submitted to the Medical Directors ahead of a feedback meeting to be held on 22 March 2024.

9. European regulations

9.1. EDQM Blood Guide (JPAC 24-12)

Great Britain follows the 20th edition of the Blood Guide whereas Northern Ireland (which aligns with ROI under the Windsor Framework) follows the current (i.e. 21st) edition. Following a commission from DHSC to SaBTO to perform a gap analysis between the 20th and 21st editions, JPAC was asked to review alignment of the Red Book with each version.

The Good Practice Guidelines (GPGs) within the 21st edition of the Blood Guide have been reviewed, with feedback provided to DHSC, but a gap analysis of the full text of the Guide is still required. **ST**

MHRA has advised that although the GPGs alone are legally binding in the UK, it considers that the entire Guide must be taken into account to achieve full compliance with the GPGs.

10. Other activities

10.1. Horizon scanning meeting (JPAC 24-13)

Minutes of the EWG horizon scanning meeting held on 18 January 2024 were provided, and attendees invited to submit feedback, comments or amendments.

Horizon scanning meetings will be scheduled annually. **PRa**

10.2. Malaria meetings (JPAC 24-14)

A summary of the malaria meetings held on 12 December 2023 and 06 January 2024 was provided for information.

Relevant actions arising from these meetings are to be added to the JPAC workplan. **PRa**

10.3. Restarting SACIT

Minutes of the SACIT restart meeting held on 21 February 2024 were provided for information.

A follow-up meeting with Christie Ash and David Mason-Hawes is scheduled for 11 April 2024. **ST**

11. Any other business

11.1. Rescheduling JPAC Board meeting in June 2024

The JPAC Board meeting originally planned for 20 June 2024 now clashes with a meeting of UK Forum and needs to be rescheduled.

JPAC Office will liaise with attendees to find a suitable alternative date and time. **PRa**

11.2. Peer-review publication

It was noted that the work relating to risk profiles of donors of different ages (item 5.2) may be appropriate for academic publication. **AWe**