Meeting details

Subject	**JPAC Board meeting**
Date	Thursday 14 November 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	
Lian Wea Chia	**LWC**	Member, SACCSD	(Observer)
Clare Denison	**CD**	Deputy Director, JPAC	
Ryan Evans	**RE**	Chair, SACBC	
Dora Foukaneli	**DF**	Clinical Transfusion Medicine Specialist, JPAC	
Richard Lomas	**RL**	Chair, SACT	
Lorna McLintock	**LM**	Medical Director, SNBTS	
Gary Mallinson	**GMa**	Scientific Lead for Safety Policy, JPAC/SaBTO	
Edwin Massey	**EM**	Medical Director, WBS	
Gail Miflin	**GMi**	Chief Medical Officer, NHBST	
David Olszowka	**DO**	Regulatory Governance Lead, MHRA	
Peter Rae	**PR**	Scientific Publishing Manager, JPAC	(Minutes)
Amy Shackell	**AS**	Regulation Manager, HTA	
Stephen Thomas	**ST**	Professional Director, JPAC	(Chair)
Nicole Thornton	**NT**	Chair, SACIH	
Ines Ushiro-Lumb	**IUL**	Chair, SACTTI	
Angus Wells	**AWe**	Chair, SACCSD	
Anna Witham	**AWi**	Administrator, JPAC	

Apologies

Kenny Douglas	**KD**	Chair, SACCTP	
Andrew Godfrey	**AG**	Medical Director, IBTS	(Observer)
Shruthi Narayan	**SN**	Medical Director, SHOT	(Observer)

Agenda items — Action

1. Welcome and apologies

ST welcomed Clare Denison, Dora Foukaneli and Ines Ushiro-Lumb to their first JPAC Board meeting since taking up their respective roles within JPAC.

Apologies from **EM** and **GMi** that they would be unable to attend from the start of the meeting and would join as soon as possible. The points at which they joined are subsequently indicated.

Other apologies received as noted.

2. Previous meeting minutes

The minutes of the JPAC Board meeting (JPAC 24-56) held on 20 June 2024 were approved for publication on the website. **PR**

3. Review of open actions

Actions that were closed since the last meeting were marked with the 'Closed' status on the list (JPAC 24-57) for information, to be archived on the 'Closed' tab following the meeting.

Open actions were discussed:

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

  On agenda for discussion (see 9.1). Action closed.

- **Bleeding disorders** (from JPAC Board 14.03.24, item 5.1)

  To be progressed by SACCSD. **AWe**

- **Cerebrovascular Disease and ICH (WB-DSG)** (from JPAC Board 20.06.24, item 5.1)

  To be progressed by SACCSD. **AWe**

4. SACBC

4.1. Cryodepleted Plasma Recovered for Plasma for Medicine (CDPrPfM) (JPAC 24-62)

NHSBT has identified cryoprecipitate-depleted plasma as a potential source of plasma for medicines but there is currently no relevant specification in the British or European

Pharmacopoeia, or the Red Book. Following the completion and review of an NHSBT validation study to assess its quality, SACBC has produced a new specification for CDPrPfM for inclusion in the Red Book.

Study data informed on manufacturing times and component quality but shelf-life, which was not included in the study, requires further work. A shelf-life of 36 months, the currently accepted standard for other plasma components, has been proposed until this work has been completed. In addition, validation of the proposed maximum period of 24 hours from thawing of intermediate cryoprecipitate to refreezing of CDPrPfM will be carried out in a subsequent study.

It is understood that although the new specification will provide UK Blood Services with consistent guidance for the collection of CDPrPfM, it will not guarantee its acceptance by fractionators. This is likely to be subject to assessment by individual fractionators.

Approved for publication by JPAC Board. **PR**

5. SACTTI

5.1. Position Statement on Mpox – August 2024 (JPAC 24-63)

Revised to reflect recent clade I outbreak in West Africa, with additional information on clades I and II, and a map of affected countries.

No additional measures are recommended for UK Blood Services.

This paper was approved for publication by EWG on 27 September 2024. It was included in the main agenda for this meeting for particular noting due to interest in the recent outbreak.

No action was required by JPAC Board.

5.2. Position Statement on Residual Risk for HBV, HCV and HIV, 2021-2023 (JPAC 24-64)

Overall, residual risk estimates for HBV, HCV and HIV in 2021-2023 are similar to those in the previously calculated period (2020-2022). Residual risk remains highest for HBV but within the confidence interval of the previous estimate. There were no HCV seroconversions detected during 2021-2023 but as HCV risk is unlikely to be zero it has been reported as less than 0.01 per million donations tested.

This paper was approved for publication by EWG on 18 October 2024. It was included in the main agenda for this meeting to highlight that there has been no significant change in estimated risk from the previous three-year period, and to note that it includes the first 2.5 years of data collected under the FAIR (For the Assessment of Individualised Risk) donor selection policy.

No action was required by JPAC Board.

Note: **EM** joined the meeting.

6. SaBTO

A summary report (JPAC 24-65) was submitted, with the following items verbally discussed:

6.1. CJD Review Group

The CJD Review Group has recommended that existing risk reduction measures for vCJD risk should be lifted. These include the deferral of blood and apheresis donors who have received a blood component transfusion in the UK or worldwide, been treated with UK plasma-derived intravenous immunoglobulin, or have undergone plasma exchange since 01 January 1980.

However, given ongoing concerns over the potential risk of amyloid-beta (Aβ) pathologies, the group has recommended that the deferrals themselves are retained but with a change of rationale, i.e. they would now serve as risk reduction measures for transmission of Aβ rather than for vCJD.

There is currently an item on the SACIH workplan to consider the increased risk of transfusion-related acute lung injury (TRALI) if the recommendation to remove previous transfusion as a deferral criterion is implemented. As it now seems likely that the deferral will remain in place, this item will be changed to a watching brief with the understanding that TRALI will need to be considered if removal of the deferral is proposed in the future. **NT**

A change in rationale, even if deferrals remain in place, may have an impact on the approval by MHRA of the use of UK plasma for fractionation. Approval was granted subject to there being no changes made to donor selection criteria relating to vCJD risk. As the vCJD/Aβ recommendations are further refined, SaBTO and DHSC will coordinate with MHRA to ensure this is considered before a decision is made.

The change in rationale will also require amendments to the current blood component specifications in the Red Book, and blood component labels, which reference vCJD risk. This will be added to the SACBC workplan (and noted for future consideration by SACIT once reconvened). **RE**

A new SaBTO working group is being convened to continue discussions. This will also include a review of previous recommendations relating to tissues and cells made by SaBTO's predecessor, the Advisory Committee on the Microbiological Safety of Blood, Tissues and Organs (MSBTO).

6.2. Health economics

A new group is being established to develop a generic economic model for assessing the cost of blood safety measures. The model would aim to describe a consistent method for appraising the value of measures to protect safety, taking into account contextual issues such as the impact on patients' quality-adjusted life years (QALYs) and social wellbeing. It would avoid making recommendations on cost boundaries, deferring cost-effectiveness decisions to

Ministers, but would aim to provide guidance on how to adequately justify why certain proposals fall outside current boundaries. The Alliance of Blood Operators (ABO) Risk-Based Decision-Making Framework (RBDMF) will be a key consideration in the model.

A group meeting is planned for later this month, ahead of proposals being made to SaBTO.

Note: **GMi** joined the meeting.

6.3. Improvements in patient safety

SaBTO is considering how it can support various initiatives, both nationally and internationally, working to enhance blood safety. This includes clarification of the various regulatory bodies that need to be involved. A workshop of relevant stakeholders is being planned for 2025.

6.4. Consent working group

Following the Infected Blood Inquiry (IBI) report, a working group is being established to review SaBTO's previous work on consent (2020). This group will assess whether the previous recommendations are still relevant and/or require updating and consider the work of other bodies that may make similar recommendations.

6.5. Ebola risk assessment

Following the last review of the Ebola risk assessment (JPAC 24-48), there was general consensus within SACTTI that the same time-limited deferrals that are in place for blood donors who have had contact with an affected individual could be safely applied to tissue and bone marrow donors. However, as the current permanent deferral arose from previous SaBTO recommendations, it was agreed that such a change would need to be discussed by SaBTO. It will be included on the agenda for the SaBTO meeting on 02 December 2024.

7. European regulatory activities

7.1. EDQM Blood Guide, 22nd edition

The 22nd edition of the EDQM Blood Guide was adopted at the European Committee on Blood Transfusion (CD-P-TS) meeting on 04-05 November 2024. A recent gap analysis has been carried out by JPAC to ensure alignment between this edition of the Guide and the Red Book.

Drafting of the 23rd edition of the Blood Guide has now started, with a publication date of 2026. The 23rd edition will therefore be the edition that will be a technical annexe to the EU SoHO Regulation, applicable from 07 August 2027, alongside the 6th edition of the EDQM Tissues and Cells Guide produced by the European Committee on Organ Transplantation (CD-P-TO), due for publication in 2025.

Clarification is required regarding which edition of the Blood Guide is currently used for MHRA inspections in the UK, i.e. the 20th edition, as stated in BSQR; the 21st edition, as the current

version; or the 22nd edition, now adopted ahead of publication. JPAC has prepared a draft Position Statement (JPAC 24-80) to confirm its practical use of the 'current' edition, despite the 20th edition being required by BSQR, due to the 20th edition having been superseded and no longer publicly available. The Position Statement was approved by EWG on 16 October 2024 but a decision on its publication will await further clarification on the position of MHRA. A meeting with appropriate DHSC colleagues will be arranged to discuss this further. **DO**

7.2. Commission from DHSC

The EU SoHO Regulation entered into force on 06 August 2024. It will apply from 07 August 2027, following a three-year transition period.

DHSC has commissioned SaBTO to assess the requirements for any future UK legislation by comparing current UK legislation with the SoHO Regulation. Assessments of the EDQM Guides (as technical annexes to the Regulation) are also required but will be carried out at a later date, as the editions of the Guides that will form the annexes are not yet available for review.

It was noted that while the SoHO Regulation does not apply to GB following its exit from the EU, NI is subject to most EU regulations and directives in order to align with ROI through the Windsor Framework. This will need to be considered in the assessment.

JPAC and SaBTO are convening a working group to carry out the assessment. JPAC already carries out regular gap analyses between the Red Book and revised editions of the EDQM Guides, but the working group will require appropriate input for regulatory analysis.

8. JPAC Office

8.1. Website project

Development of the new JPAC website is due to begin on 19 November 2024.

Development will start with an initial discovery phase (user research, content review and design strategy), followed by design and build phases, then content migration and testing.

The maintenance and hosting contract with the current provider is due to expire in October 2025. The provisional target date for public release of the new website is September 2025.

8.2. Update on SACIT

Work to reconvene the Standing Advisory Committee on Information Technology (SACIT) continues. The previous interim co-chair, Christie Ash, has now left NHSBT. Marian Zelman (NHSBT) will now work with the other interim co-chair, David Mason-Hawes (Velindre University NHS Trust), to continue scoping work, including refinement of SACIT's Terms of Reference and required membership.

A review meeting with the interim co-chairs is to be arranged to discuss progress. **AWi**

9. SACCSD

9.1. Clinical supervision at blood donation sessions

The Red Book provides guidelines for the staffing and supervision of donation sessions. SACCSD was previously asked to consider whether healthcare practitioners (HCPs) other than nurses or doctors could provide clinical supervision at blood donation sessions.

SACCSD made an initial recommendation (JPAC 23-06) which proposed a framework by which the suitability of other professional groups could be assessed. This recommendation was refined (JPAC 23-31) and approved by JPAC Board on 22 June 2023. However, following stakeholder feedback prior to their planned publication on 04 September 2023, the proposed amendments to the Red Book were subsequently withdrawn.

The recommendation has now been further revised (JPAC 24-59). The proposed amendments incorporate the stakeholder feedback, taking into account operational considerations required for their implementation. While it is understood that registered nurses remain the most likely staff group to provide clinical supervision at donor sessions, it has been clarified that Blood Services are able to consider other HCPs provided they have a suitable policy in place that describes any practical skills, training and experience required to perform the role. Such a policy would only be required if HCPs other than registered nurses are used to provide clinical supervision at donation sessions.

To avoid duplicated effort across the Blood Services, it was agreed that SACCSD will produce a template policy document that can be used or adapted by each Service if they choose to use HCPs other than registered nurses for clinical supervision. **AWe**

It was noted that the change from 'consultant' to 'physician', added since the last proposal, might introduce additional risk. For example, a junior doctor (a 'physician' but who may not be suitably qualified) may inadvertently be considered appropriate to provide clinical supervision at a donation session. 'Physician' was chosen to align with wording in Council of Europe guidelines, but further revision of the terminology will be considered to remove ambiguity while remaining appropriate to all UK Blood Services. **AWe**

Approved by JPAC Board, subject to this revision. Once amended, the proposed text will be circulated to attendees for final review before publication. **PR**

9.2. Transfusion (post-IBI update) (JPAC 24-60)

The IBI recommended that anyone who has received a transfusion prior to 1996 should be tested for Hepatitis C. Donors who have received a transfusion since 01 January 1980 are currently deferred from further donation and therefore will not be tested through routine donation screening. This paper proposes an update to the 'Transfusion' entry in the WB-DSG to include guidance for staff to prompt previously transfused donors to seek a Hepatitis C test. It does not propose that these tests are provided by the UK Blood Services but that donors are advised to discuss testing with their GP or another clinical service.

Local donor selection guidelines in SNBTS already includes this guidance, added following a similar recommendation made by the Penrose Inquiry (2015) and updated since the IBI recommendation. The text of this proposed update is based on the SNBTS text and aims to standardise guidance across the UK Blood Services.

Approved for publication by JPAC Board. **PR**

9.3. Donation frequency (whole blood) (JPAC 24-61)

UK Forum requested that JPAC assess whether UK Blood Services could safely implement changes to donation frequency of two months for men (assigned male at birth, AMAB) and three months for women (assigned female at birth, AFAB) when a blood supply shortage is anticipated.

SACCSD convened a working group to consider this and respond. It has proposed that the suggested donation frequencies could be adopted during periods of increased demand without a significant impact on donor quality of life, provided a package of measures is put in place to identify donors on an increased donation frequency who are at risk of iron deficiency and other symptomatic effects. These include:

- A quantitative haemoglobin (Hb) assessment on the day of donation, which would be available at the donor's next attendance
- The deferral of any donors whose Hb had dropped significantly (20 g/L) since their last donation
- The exclusion of donors with recent low Hb deferrals, i.e. two within the last two years
- Specific donor information and consent material which includes clear communication of the increased risk of iron deficiency and other symptomatic effects
- Further risk assessment (including consideration of tests to assess iron stores) if an increased donation frequency is expected to last for more than six months

The use of 'must' and 'should' in the draft Position Statement has been considered. 'Must' has been used to prioritise those aspects which SACCSD deems essential for donor safety. 'Should' has been used where (risk-assessed) concessions could be made, if necessitated by operational requirements, with a less significant impact on donor safety. In line with JPAC's remit, these recommendations primarily consider the risk to donor safety (of an increased donation frequency) rather than the risk to patient safety (of a blood shortage). However, it was appreciated that the balance of donor and patient risk would need to be considered if Blood Services chose to implement the recommendations.

It was noted that maintaining a two-tiered donor population (i.e. those on normal schedule and those on an increased schedule) and the associated mitigation measures during times of blood shortage would be difficult. However, while it might be more straightforward to apply uniform increased donation frequencies to the whole donor population, this goes beyond the request from UK Forum, would require significant operational change, and is not being considered at this time.

There was concern about the passive nature of the proposed package of mitigation measures, given the requirement for measurement of iron stores only if a blood shortage lasts longer

than six months. However, SACCSD has taken a pragmatic approach to its recommendations, taking into account what is operationally feasible. A more proactive approach to donor monitoring is not currently possible as full blood counts, ferritin testing and other measures of iron stores are not available for use at donation sessions within any of the UK Blood Services.

A question remains as to how much of an impact increased frequencies would have on blood supply during a shortage. It could also carry significant risk due to future donor deferrals caused by the increased frequency, mitigated to some degree by the measures proposed, but which could persist even after the shortage has resolved. While this goes beyond the original question to assess the impact of increased donation frequencies on donor safety, which has been answered, it will require further discussion.

While it is understood that implementation would be extremely challenging, there was broad agreement with the scope of the Position Statement, recognising the value of having such an option, one of many, available to Blood Services during a blood shortage.

It was suggested that point 10 of the draft Position Statement, relating to the future development of individualised donation frequencies, was beyond its scope and should be removed. An amended title of 'Position Statement on whole blood donation frequency in response to blood shortages' was also suggested for clarity. **AWe**

Approved by JPAC Board, pending these amendments. Once amended, the draft Position Statement will be circulated to attendees for final review before publication. **PR**

10. Any other business

10.1. CE-marking of NIBSC standards

MHRA South Mimms will cease supply of CE-marked NIBSC reference materials by May 2025, at which point they will be removed from the product catalogue. Equivalent non-CE-marked NIBSC materials will be available. These materials are not regulated under the current Medical Devices Regulations because they are not used to assess the performance of diagnostic assays, and therefore do not require alternative (e.g. UKCA) marking.

MHRA South Mimms will issue a formal notification by the end of November 2024. JPAC Office will circulate this to JPAC Board to ensure it is cascaded to relevant stakeholders within the UK Blood Services and to provide a point of contact for any feedback to MHRA South Mimms. **PR**

11. Papers for noting

There were no objections to the papers included for noting.

12. Dates of future meetings

EWG Tuesday 21 January 2025

EWG Wednesday 19 February 2025

JPAC Thursday 20 March 2025

EWG Wednesday 23 April 2025

EWG Wednesday 21 May 2025

JPAC Thursday 19 June 2025

EWG Wednesday 23 July 2025

EWG Wednesday 15 October 2025

JPAC Thursday 13 November 2025