Meeting details

Subject JPAC Board

Date Thursday 20 March 2025

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	Modical Director NIPTS	
		Medical Director, NIBTS	
Neil Almond	NA	MHRA South Mimms Laboratories	
Clare Denison	CD	Deputy Director, JPAC	
Kenny Douglas	KD	Chair, SACCTP	
Ryan Evans	RE	Chair, SACBC	
Dora Foukaneli	DF	Clinical Transfusion Medicine Specialist, JPAC	
Andrew Godfrey	AG	Medical Director, IBTS	(Observer)
Jayne Hughes	JH	Deputy Chair, SACCSD	
Richard Lomas	RL	Chair, SACT	
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	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	
Marian Zelman	MZ	Interim co-chair, SACIT	

Apologies

Evelyn McLennan	ЕМс	Chair, UK Quality Managers Group	
David Mason-Hawes	DMH	Interim co-chair, SACIT	
Shruthi Narayan	SN	Medical Director, SHOT	(Observer)
Angus Wells	AWe	Chair, SACCSD	
Anna Witham	AWi	Administrator, JPAC	

Agenda items Action

1. Welcome and apologies

ST welcomed attendees.

JH attended to represent SACCSD, deputising for **AWe**.

MZ attended as interim co-chair of SACIT.

Apologies received as noted.

2. Minutes of the previous meeting (JPAC 25-02)

Approved for publication, pending minor corrections.

PF

3. Review of open actions (JPAC 25-03)

• Bleeding Disorders - removal of deferral of contacts (JPAC Board 14.03.24, item 5.1)

SACCSD is progressing this work.

• CNS Disease – clarification of guidance regarding medication (JPAC Board 20.06.24, item 5.1)

SACCSD is progressing this work.

• Clarification of EDQM Blood Guide edition used for MHRA inspections (JPAC Board 14.11.24, item 7.1)

DHSC has confirmed that MHRA is currently inspecting against the 21st edition. Action closed.

DHSC is currently in the process of approving the use by MHRA of the 22nd edition of the Blood Guide. This edition was adopted by the European Committee on Blood Transfusion (CD-P-TS) in November 2024 and its publication is imminent.

4. JPAC workplan (JPAC 24-04)

The workplan will be reviewed at the upcoming annual SAC review meetings to clarify the anticipated completion date of existing work items and to add any additional items not already included. It was suggested that work items be segregated into those planned for completion in the coming year and those with longer timescales (i.e. two to three years) or dependencies external to JPAC.

A revised workplan will be prepared for the JPAC Board meeting on 19 June 2025.

ST

5. Outcomes of the JPAC Ways of Working review

5.1. Updated Terms of Reference and Ways of Working documents (JPAC 25-06 and 25-07)

Both documents were approved by the EWG at the meeting held on 19 February 2025. Given the schedule of upcoming meetings, they were presented at the UK Forum meeting on 07 March 2025 before being submitted for approval by the JPAC Board.

Approved by the JPAC Board with minor amendments suggested. The Terms of Reference will be published on the website and the Ways of Working document held by the JPAC Office for internal use.

PR

5.2. Ensuring adequate resourcing of JPAC activities (JPAC 25-08)

Role Definitions have been written for SAC Chairs and members to inform candidates and line managers of the expected time commitment and to enable resource planning within individual Blood Services.

In response to the Infected Blood Inquiry, a funding bid has been made through NHS England for an additional scientific post within JPAC to provide support for SAC activities and further funding for the UK Blood Services to support the additional duties required of each SAC Chair. The outcome of this funding bid is awaited.

5.3. Position Statement on the relationship between JPAC and SaBTO (JPAC 25-09)

The Position Statement was presented at the joint meeting of the JPAC and SaBTO secretariats held on 18 March 2025 and was well received. The SaBTO secretariat intends to include it in its induction pack for new members once published on the JPAC website. The final version will be shared with Claire Vittery (SaBTO secretariat) for review and approval.

GMa

Approved for publication by the JPAC Board, pending approval from SaBTO.

PR

5.4. Appointment of lay member(s) to the JPAC Board

In collaboration with the NHSBT Patient and Public Advisory Group (PPAG), the JPAC Office held an introductory session to give prospective lay members an overview of JPAC and an opportunity to ask questions. Following this session, interested individuals were invited to submit a formal application.

These applications have now been received, reflecting a variety of patient and public involvement and engagement experiences, and will be reviewed before offers of membership are made. It is hoped that the appointed lay member(s) will attend the JPAC Board meeting on 19 June 2025.

5.5. Annual survey to Quality Assurance departments of the UK Blood Services

A survey has been sent to the four UK Blood Services to assess which Change Notifications issued in 2024 have been implemented and any Service-specific changes that were required. It also invited feedback on the current Change Notification process. The deadline for the survey is 31 March 2025.

5.6. Summary workplan for the JPAC website (JPAC 25-13)

The Ways of Working review recommended the distribution of an annual workplan summary to stakeholders. While the JPAC Office maintains an email distribution list for circulating Change Notifications to the UK Blood Services, it is felt that a summary workplan published on the website would be more accessible and could be more regularly updated.

6. Standing Advisory Committee on Blood Components (SACBC)

6.1. Red Cells and Plasma, LD (JPAC 25-10)

The British Society for Haematology (BSH) recommends the early transfusion of red cells and plasma (1:1 ratio) in major traumatic bleeding. Two options to support this in the pre-hospital setting are Whole Blood, Leucocyte Depleted (LD-WB) and Red Cells and Plasma, Leucocyte Depleted (LD-RCP).

A working group was established to consider the implementation of both components. It recommended a number of changes to support the interim use of LD-RCP, as the implementation of LD-WB was anticipated to take much longer due to manufacturing and logistical challenges.

While the JPAC Board broadly agreed with the proposal, it needs to be assured that it is appropriate to expand the use of LD-RCP from the treatment of traumatic haemorrhage to include all major haemorrhage patients. It was noted that there may be certain situations (e.g. obstetric haemorrhage) in which specific clinical considerations, or alternative components, might be required. Although the provision of particular components is left to the discretion of individual Blood Services, it is important that their inclusion in the Red Book aligns with current clinical guidelines. This will be discussed this with the relevant BSH guideline writing group and feedback provided to the JPAC Board.

DF

PR

The proposal was approved by the JPAC Board in principle, with minor amendments suggested. Once BSH has been consulted, and provided no concerns are raised, publication will proceed. If further discussion is required, the proposal will be resubmitted to the JPAC Board at a future meeting.

6.2. **Update on recent activities**

The validation of DEHP-free blood bags is ongoing. SACBC is planning to review data from the Phase 0 studies of two manufacturers' blood bags at its next meeting.

7. Standing Advisory Committee on Care and Selection of Donors (SACCSD)

7.1. **Acupuncture (JPAC 25-11)**

A provisional WB-DSG entry for 'Acupuncture' has been prepared, following discussions to refine the current donor selection criteria for acupuncture recipients. JPAC, SaBTO and MHRA have jointly recommended that guidance should be updated to allow the acceptance of recipients of acupuncture performed by non-NHS practitioners registered with an accredited body or performed in a licensed commercial setting. This reflects the low risk of blood-borne viral transmission associated with acupuncture under these conditions. A new Position Statement has also been prepared.

Specific considerations for implementation in each of the four UK nations have required further discussions between DHSC and the devolved administrations, and approval of the proposed changes in each nation. Approval has already been given in England and Scotland, with decisions on approval in Wales and Northern Ireland expected shortly. Although it was suggested that the new guidance could be implemented immediately in those nations that have given approval, the JPAC Board agreed that waiting until approval has been given by all four nations would ensure alignment across the UK and avoid the complexities associated with issuing nation-specific guidance.

The changes were approved by the JPAC Board in principle, understanding that finalisation of the wording will await the outcome of the discussions between DHSC and the devolved administrations.

7.2. Update on recent activities

SACCSD has prepared substantial revisions to the current 'Malaria' entry in the WB-DSG and the 'Tropical Virus' risks in the GDRI, which will be shared with SACTTI for review and comment.

In collaboration with SHOT, a number of new donor haemovigilance documents are being written which, once approved by the EWG and the JPAC Board, will be published on the JPAC website.

Work is ongoing to standardise donor consent and the assessment of donor adverse events across the UK Blood Services.

8. Updates on recent SAC activities

8.1. Standing Advisory Committee on Cellular Therapy Products (SACCTP)

SACCTP has held its first meeting since the separation of the previous SAC on Tissues and Cellular Therapy Products (SACTCTP) into two committees.

SACCTP is considering the implementation of a set of guidelines for related allogeneic bone marrow and peripheral blood stem cell donors. There are currently no national guidelines and the existing BM-DSG is intended for the selection of unrelated allogeneic donors only.

A consultation of relevant stakeholders is needed to assess the appetite for related donor guidelines before a decision is made on their implementation, due to the significant workload this will entail.

8.2. Standing Advisory Committee on Immunohaematology (SACIH)

Jennifier Laird has been appointed as Deputy Chair. She will also act as the SACIH liaison to the newly formed UK Red Cell Immunohaematology working group.

The committee's main focus for the coming year will be updating the Red Book chapters for which it is responsible, particularly those detailing donation (<u>chapter 12</u>) and patient (<u>chapter 13</u>) phenotyping.

8.3. Standing Advisory Committee on Information Technology (SACIT)

A provisional committee has recently held several meetings to define the Terms of Reference and required membership of a reconvened SACIT, as well as identify key work items.

It has been agreed that SACIT should prioritise formalisation of the current component code allocation process and the updating of relevant Red Book chapters. The committee will also consider how it can support UK Blood Services to implement the full-face labelling specification previously issued in 2021.

8.4. Standing Advisory Committee on Tissues (SACT)

The SACT workplan was discussed at its last meeting. Key work items are a gap analysis between the Red Book and the current edition of the EDQM Tissues and Cells Guide, and a full review of the TD-DSG and TL-DSG to identify entries in need of updating or removal.

Victoria Carroll (Clinical Support Nurse Manager, NHSBT) has been invited to join SACT to provide representation for guideline users. Existing members Kyle Bennett and Sharon Zahra have offered to provide secretariat support for the committee.

8.5. Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI)

The risk assessment for 'H5N1 pandemic influenza' has been retitled 'H5N1 zoonotic infection' to reflect its current non-pandemic status. The risk assessments for *Borrelia burgdorferi* (Lyme Disease) and Usutu Virus are being reviewed and will be submitted for approval by SACTTI at its next meeting.

<u>Chapter 9.3</u> of the Red Book is currently being updated to reflect the upcoming withdrawal of CE-marked NIBSC working standards in May 2025. While alternative NIBSC reagents will be available without a conformity mark, it is understood that Blood Services in the UK and ROI require such reagents to have a conformity mark, either CE (ROI, as an EU member) or UKCA (UK, as it transitions from CE marking follow its exit from the EU).

9. SaBTO

A summary report on SaBTO's activities to February 2025 was provided (JPAC 25-12). SaBTO met on 05 March 2025 and a joint meeting between the JPAC and SaBTO secretariats was held on 18 March 2025 to discuss areas of common interest.

In September 2024, the CJD review group brought preliminary recommendations to SaBTO that the deferral of blood and apheresis donors who have, or may 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 1st January 1980 should be lifted for vCJD risk. However, due to ongoing concern over the potential transmission risk of amyloid-beta from blood transfusion, the group also recommended that this deferral should remain in place while a new working group investigates the transmission risk of amyloid-beta pathologies.

A SaBTO working group is also expected to be convened to review pathogen inactivation of platelets but is awaiting the revision of the relevant Cochrane review paper.

Note EM, GMi and MZ left the meeting.

10. European regulatory activities

10.1. UK legislation and EU SoHO Regulation

The gap analysis between UK legislation and the SoHO Regulation continues. The relevant regulators are expected to report back by the end of March 2025 as part of the first phase of the analysis.

Novel areas of the SoHO regulation, such as breast milk and intestinal microbiota, are expected to require additional consideration in the next phase of the analysis.

10.2. EBA / ECDC / EDQM

JPAC, on behalf of the UK Blood Services, has recently provided feedback to the EBA for the consultation on the new ECDC *Guidelines on the prevention of donor-derived transmission of HIV through substances of human origin*.

Writing groups have been convened for the 23rd edition of the EDQM Blood Guide and the 6th edition of the EDQM Cells and Tissues Guide. Once published these editions will become technical annexes to the SoHO Regulation.

11. Website project

The third phase of user research has now been completed, with feedback obtained on proposed changes to the website's navigation and design. The next stage of the project, an initial build of the new website content management system, is underway.

The new website is planned to launch in September 2025.

12. Papers for noting

There were no objections to the papers included for noting (JPAC 25-13 to 25-28).

13. Dates of future meetings

EWG Wednesday 23 April 2025

EWG Wednesday 21 May 2025 **JPAC Board** Thursday 19 June 2025

EWG Wednesday 23 July 2025

EWG Wednesday 15 October 2025 **JPAC Board** Thursday 13 November 2025