Meeting details

Subject	**JPAC Board Meeting**
Date	Thursday 20 June 2024
Time	14:00 to 17:00
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	
Ryan Evans	**RE**	Chair, SACBC	
Heli Harvala	**HH**	Chair, SACTTI	
Tor Hervig	**TH**	Medical Director, IBTS	
Richard Lomas	**RL**	Chair, SACT	
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	
Peter Rae	**PR**	Scientific Publishing Manager, JPAC	(Minutes)
Megan Rowley	**MR**	Clinical Transfusion Medicine Specialist	
Stephen Thomas	**ST**	Professional Director, JPAC	(Chair)
Nicole Thornton	**NT**	Chair, SACIH	
Angus Wells	**AWe**	Chair, SACCSD	

Apologies

Shruthi Narayan	**SN**	Medical Director, SHOT	(Observer)
David Olszowka	**DO**	Regulatory Governance Lead, MHRA	
Amy Shackell	**AS**	Regulation Manager, HTA	
Anna Witham	**AWi**	Administrator, JPAC	

Agenda items

1. Welcome and apologies

ST welcomed Richard Lomas to his first JPAC Board meeting as the newly appointed Chair of the Standing Advisory Committee on Tissues (SACT).

This would be Tor Hervig's final JPAC Board meeting as Medical Director of IBTS prior to his retirement. He was thanked for his contribution to JPAC during his tenure and best wishes given for his retirement. The incoming Medical Director of IBTS, Andrew Godfrey, will be welcomed at the next JPAC Board meeting in November.

Apologies received as noted.

2. Previous meeting minutes

The draft minutes of the previous JPAC Board meeting (**JPAC 24-28**) held on 14 March 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 24-29**) 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)

  Additional feedback on the proposal is to be sought from stakeholders prior to submission to EWG (September/October) and JPAC Board (November) meetings for discussion. **AWe**

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

  RE confirmed Michelle Ray is working with NHSBT Component Development Laboratory (CDL) to progress this work.

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

  Following the separation of the current SAC into two separate groups as recommended by the recent review of SACTCTP, chairs for the nascent SACs on Tissues (SACT) and Cellular Therapy Products (SACCTP) have been sought. As noted above, **RL** has been appointed as the Chair of SACT and will take over relevant responsibilities from **AC**. Recruitment of a Chair of SACCTP is ongoing, with interviews scheduled for 11 July 2024.

- **Bleeding Disorders (clarifications to WB-DSG entry)** (from JPAC Board 14.03.24, item 5.1)

  CN 20-2024 has been prepared and is awaiting an agreed publication date. **PR/AWe**

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

  To be discussed by SACCSD at its next meeting. **AWe**

- **Upper age limit for returning donors** (from JPAC Board 14.03.24, item 5.2)

  CN 22-2024 has been prepared and is awaiting an agreed publication date. **PR/AWe**

- **Cardiovascular Disease – updated entries in the WB-DSG** (from JPAC Board 14.03.24, item 5.3)

  CN 21-2024 has been prepared and is awaiting an agreed publication date. **PR/AWe**

4. Infected Blood Inquiry (IBI)

The final IBI report was published on 20 May 2024.

The report's recommendations were initially discussed by EWG at its scheduled meeting on the day of publication. Although there was insufficient time to review the report in its entirety at that time, initial indications were that the report contained no recommendations relating specifically to JPAC or its output that required immediate action.

An extraordinary meeting of the UK Forum was also held on 03 June 2024 to discuss the IBI report where it was similarly agreed that there were no immediate actions for UK Forum to take in response to the report's recommendations.

It was noted that JPAC has proactively reviewed and revised its governance processes, and that the new Terms of Reference and Ways of Working documents on the agenda for approval at this meeting were timely. By clarifying its ways of working with clear documentation, JPAC will continue to provide assurance as to the safeguards in place for robust decision making.

Following the publication of a statutory inquiry report, the UK Government is obligated to make a response to the inquiry within a specific timeframe. In this instance, due to the announcement of the upcoming general election, the timeframe for response is unclear. The governance surrounding the response is better understood, however, with the Cabinet Office having delegated responsibility to DHSC. A group has been established within DHSC to coordinate the Government's response to the inquiry, with each of the UK Blood Services having input through named representatives.

From an England perspective, the response from NHSBT will focus on blood transfusion safety through its current Transfusion Transformation strategy. A government oversight group has been established in Scotland with representation from SNBTS and the Scottish National Blood Transfusion Committee (SNBTC), with its first meeting scheduled for next week. WBS and NIBTS

have both started mapping processes to formulate their responses to the inquiry. Information will be shared between the UK Blood Services through the established governance structure of UK Forum, with nothing specifically required of JPAC at present.

A key theme of the IBI report is the importance of patient engagement during decision making and this will be addressed by JPAC in due course through the appointment of lay representation on the JPAC Board, as outlined in its Ways of Working. From a practical point of view, it was noted that routes to patient engagement can be unclear at times, that work is required to identify opportunities and support for engagement, and that JPAC should proactively promote the inclusion of patient representation wherever possible and appropriate.

It was suggested that accessible summaries of JPAC guidelines or its Position Statements, which are primarily aimed at healthcare professionals and may not be readily comprehensible to lay readers, could be created to improve patient understanding and encourage engagement. In addition, as the established governance around transfusion safety may be unclear to a public audience at times, a lay summary explaining the roles, responsibilities and interactions between key groups such as JPAC, SaBTO, SHOT and MHRA might be beneficial.

There are two IT-related recommendations within the IBI report (national traceability, IT for patient safety) which might be appropriately within the scope of the restarted SACIT. As these are UK-wide considerations, input from all four Blood Services through SACIT, as well as contributions from representatives within the clinical community, would be most effective.

While not directly associated with the recommendations of the IBI report, MHRA South Mimms are having discussions around the reference materials for microbiological testing as they relate to the reassurance of patient safety sought by the inquiry. It has been previously noted that the current wording of 'or equivalent' with regards to the requirements for working standards in Chapter 9 of the Red Book may be considered ambiguous (i.e. subsequent batch number of same NIBSC standard vs. comparable standard available from an alternative manufacturer). This was discussed by SACTTI in 2023 and it was decided that no change to wording was required at that time. However, given that the procurement of materials is expected to become an increasing challenge in several areas, clarification of guidance for laboratories seeking equivalents would be welcomed. SACTTI will discuss this at its next meeting. **HH**

5. SACCSD

5.1. Cerebrovascular Disease and Benign Intracranial Hypertension – updated entries in WB-DSG

It was noted that the Obligatory guidance relating to medication was confusing. This is existing text, unchanged in this proposal, which was first introduced in 2014. As approaches to medication have since developed, and this guidance may no longer be required as written, it will be discussed by SACCSD for a future amendment. **AWe**

Approved for publication. **PR/AWe**

5.2. Platelet Disorders – updated entries in WB-DSG

Approved for publication. **PR/AWe**

5.3. Revised Severity Grading of Donor Adverse Events – updated chapter in the Red Book

The changes to the grading system may result in an increase in the reporting of events to SHOT, although it is likely this will reflect a small number of relatively minor complications (e.g. arm pain). Overall, the benefits of adopting a more robust grading system are expected to outweigh the negative impact of increased reports.

Approved for publication. **PR/AWe**

6. SaBTO

A summary report (**JPAC 24-33**) was submitted, with the following items verbally discussed:

6.1. CJD Review Group

The recommendations of the CJD Review Group were discussed at the SaBTO meeting on 03 June 2024. Its most significant recommendation is the removal of the deferral for donation of recipients of blood transfusions since 1980 as the risk of vCJD transmission is now considered to be very small. However, it has been decided to withdraw the recommendations until the group has further discussed A(β) amyloid pathology, to prevent the removal of donor deferral criteria for vCJD/CJD transmission risk resulting in an unintended increased risk of A(β) amyloid transmission. A position paper has been developed and will be refined before the next SaBTO meeting in September.

6.2. Infected Blood Inquiry

SaBTO is holding a meeting on 24 June 2024 to discuss the recommendations of the IBI report. Items for discussion include a review of SaBTO's ways of working, donor to recipient traceability, donor lookback, the speed of decision making, cost effectiveness, stakeholder engagement and patient safety networks.

7. European regulatory activity

7.1. EU Regulation on Substances of Human Origin (SoHO)

The final publication of the new SoHO Regulation in the Official Journal of the European Union is imminently expected. Once published, there will be a three-year implementation period during which existing Directives and national regulatory laws will continue to apply. The SoHO Regulation will not apply in GB but will apply in NI, which is obliged to align with ROI/Europe through the Windsor Framework. The approach of the UK Government to alignment with the SoHO Regulation (i.e. revisions to BSQR) is currently unclear but continues to be discussed.

7.2. 22nd edition of the EDQM Blood Guide

EDQM is currently undertaking stakeholder consultation on the draft text of the 22nd edition of the Blood Guide. JPAC is coordinating the response of UK Blood Services and has asked SAC

Chairs and other relevant stakeholders to review and comment on the proposed changes, with a focus on the impact of adopting the 22nd edition. The deadline for the EDQM consultation is 30 June 2024.

Both the EDQM Blood Guide and the Tissues and Cells Guide will become technical annexes to the new SoHO Regulation. Due to the two-year revision cycle, a further (23rd) edition of the Blood Guide will be produced before the end of the implementation period of the SoHO Regulation. This will introduce further complexity to the current discrepancy between different versions of the Blood Guide which are legally mandated to be followed by GB (20th edition, now obsolete) and NI ('current' edition). Discussions have been held with DHSC regarding this discrepancy but revision of BSQR to include reference to the 'current' edition for GB does not appear to be achievable at present.

8. JPAC Office

8.1. Revised Terms of Reference and new Ways of Working documents

Both documents (**JPAC 24-35**, **JPAC 24-36**) were approved and will be submitted to the UK Forum meeting on 21 June 2024 for ratification ahead of publication. **PR**

8.2. Meeting dates for 2025

The proposed schedule for EWG and JPAC Board meetings in 2025 was approved. **PR**

EWG	Wednesday 22 January 2025		
EWG	Wednesday 19 February 2025	**JPAC**	Thursday 19 March 2025
EWG	Wednesday 23 April 2025		
EWG	Wednesday 21 May 2025	**JPAC**	Thursday 18 June 2025
EWG	Wednesday 23 July 2025		
EWG	Wednesday 15 October 2025	**JPAC**	Thursday 13 November 2025

8.3. Website refresh

JPAC Office is currently working with SHOT and SRI to produce new websites for all three organisations. The development of the SHOT and SRI websites by an external supplier is progressing well with go-live planned for November 2024. The procurement process for the JPAC website has now started with an NHSBT Commercial Lead having been assigned. Discussions are currently ongoing regarding the most appropriate route to market and business requirements are being finalised for use in the invitation to tender.

8.4. Upcoming appointments

Expressions of interest are being sought for the Chair of SACCTP and will be sought for the Deputy Director of JPAC, with interviews scheduled for 11 July 2024. **ST**

The recruitment of a Clinical Transfusion Medicine Specialist was unsuccessful prior to the publication of the IBI report. The Role Definition will now be reviewed, and expressions of interest once again sought from interested candidates. **MR** has kindly agreed to remain on EWG and JPAC Board as CTM Specialist until September 2024 while this appointment is made. **ST**

9. Any other business

There were no additional items for discussion.

10. Paper for noting

There were no objections to the papers included for noting.