approved 22.06.23

Meeting details

Subject	**84th JPAC meeting**
Date	Thursday 16 March 2023
Time	10:00 to 13:00
Location	Microsoft Teams

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

Attendees

Neil Almond	**NA**	MHRA South Mimms	
Akila Chandrasekar	**AC**	Chair, SACTCTP	
Ryan Evans	**RE**	Chair, SACBC	
Tor Hervig	**TH**	Medical Director, IBTS	
Lisa Jarvis	**LJ**	Chair, SACTTI	
Jennifer Laird	**JL**	Deputising for Medical Director, SNBTS	
Angela Macauley	**AM**	UK Quality Managers	
Gary Mallinson	**GMa**	Scientific Lead Safety Policy, JPAC/SaBTO	
Edwin Massey	**EM**	Chair, SACIH	
Gail Miflin	**GMi**	Chief Medical Officer, NHSBT	
David Olszowka	**DO**	Regulatory Governance Lead, MHRA	
Peter Rae	**PRa**	Scientific Publishing Manager, JPAC	(Minutes)
Amy Shackell	**AS**	Regulation Manager, HTA	
Stephen Thomas	**ST**	Professional Director, JPAC	(Chair)
Angus Wells	**AWe**	Chair, SACCSD	
Anna Witham	**AWi**	Administrator, JPAC	

Apologies

Janet Birchall	**JB**	Medical Director, WBS
Lorna McLintock	**LM**	Medical Director, SNBTS
Peter Richardson	**PRi**	Chair, UK Quality Managers
Megan Rowley	**MR**	Chair, SACCTM

Meeting commenced at **09:58**

Agenda items

1 Welcome

ST congratulated Edwin Massey on his upcoming appointment as Medical Director of the Welsh Blood Service. Janet Birchall was thanked for her contribution to JPAC during her time as Medical Director of WBS, with best wishes for her retirement.

ST also welcomed Jennifer Laird deputising for Lorna McLintock, and Angela Macauley kindly representing NIBTS in the absence of an appointed Medical Director.

2 Previous meeting minutes

The minutes of the previous JPAC meeting held on 17 November 2022 (**JPAC 23-02**) were approved.

It was noted that the minutes of individual SAC meetings will not be routinely presented at future EWG or JPAC meetings but will be available from the JPAC Office on request.

3 Actions list

A number of actions were closed prior to the meeting as indicated on the actions list (**JPAC 23-09**) under the 'Closed' status. The remaining open actions were discussed.

Review of open actions:

 # 5.4: Immunosuppression (JPAC 22-42)

For discussion by SACCSD in April/May, for submission to JPAC in June 2023. **[AWe]**

 # 6.1: Relaxation of travel criteria for plasmapheresis donors (JPAC 22-14)

For discussion by SACCSD in April/May, for submission to JPAC in June 2023. **[AWe]**

Regarding guidelines for plasma donors, it was previously discussed that a short-life working group might be convened rather than re-establishing the previous SAC on Plasma for Fractionation (SACPFF) but this was on hold until a plasma fractionator was appointed. This appointment is now expected within the next few months, and given that there is scope within BSQR and the CoE guidelines to relax other plasmapheresis donor selection criteria, this meeting can now be planned. **[ST]**

 # 6.2: Pregnancy (JPAC 22-15)

For discussion by SACCSD in April/May, for submission to JPAC in June 2023. **[AWe]**

 # 7.1: Validation of dried plasma components (JPAC 22-22)

Tendering process ongoing. Not yet ready for publication.

 # 7.1: Red cells and plasma, LD; provisional specification amendments (JPAC 22-48)

Previously approved at JPAC meeting held on 14 July 2022. Draft CN in progress. **[PRa]**

 # 7.2: EBA position paper: recommendations for non-DEHP component validation (JPAC 22-49)

SACBC to perform gap analysis to identify if changes to Red Book are required. **[RE]**

 # 8.1: Reconvening SACIT

Verbal update to be given in the meeting (see section **8 SACIT**). Action closed.

 # 8.3: Residual risk for HEV

To be discussed by SACTTI on 17 May 2023. **[LJ]**
Action list amended to clarify that HEV may be added to existing PS on residual risk for HBV, HCV and HIV rather than a separate document being produced.

 # 8.7: Washed red cells (2015 paper) to be revisited

To be discussed by SACBC on 19 April 2023. **[RE]**

 # 8.8: 42 day red cells – impact-effort analysis

To be discussed by SACBC on 19 April 2023. **[RE]**

 # 1.1: Receive final version technical report for Reduced Dose PLT validation

Technical validation data received. Item closed.

 # 1.2: Receive closure report for Reduced Dose PLT approval

This is expected after 14 June 2023 when the current approval period ends. It was noted that the reduced dose platelet component has not yet been required.

4 SACTCTP

4.1 Malaria – revised entry in Deceased Tissue, Living Tissue and Bone Marrow DSGs (JPAC 23-03)

Change request approved. **PRa** to liaise with **AC** to prepare Change Notification (CN). **[PRa]**

4.2 Proposed changes following recommendations of FAIR III report, as CN 17-23 (JPAC 23-04)

Changes approved in principle, to be held pending instruction to publish. **[PRa]**

5 SACCSD

5.1 Transgender and non-binary donors – principles for donor selection

The accompanying paper (**JPAC 23-05**) was withdrawn from the agenda prior to the meeting but a verbal update was provided. Work is ongoing by SACCSD to clarify the guidance for transgender and non-binary donors across the UK Blood Services to ensure all individuals are treated in an appropriate and respectful manner during donor sessions, while optimising blood supply and maintaining donor and patient safety. The limitations of the computer systems in use by the different Services, inconsistencies in the advice given by various advocacy groups and some negative public responses to gender neutral donor questions in Scotland were all highlighted as challenges in achieving a single, acceptable solution for all Services. As a result, further amendments to the paper have now been suggested which necessitate further discussion by SACCSD before re-submission to JPAC.

The paper will be resubmitted for the next JPAC meeting to be held on 22 June 2023. **[AWe]**

It was suggested that engagement with relevant network groups within each Blood Service (e.g. LGBT+ Network within NHSBT) might be helpful to ensure the use of appropriate language.

Once approved, the paper will inform the changes required to be made to the WB-DSG and Red Book chapters, and may also be published as a PS on the JPAC website.

5.2 Clinical supervision at sessions – SACCSD recommendations March 2023 (JPAC 23-06)

SACCSD have considered the requirements for clinical supervision on session and prepared this paper which includes the recommendation that donor sessions be supervised by a registered nurse, and a framework for Blood Services to assess the suitability of other healthcare professionals based on the Standards of Proficiency for Registered Nurses published by the Nursing and Midwifery Council.

It was discussed that the preference for a registered nurse as stated in the paper may be a subjective recommendation and that by using this phrasing the use of, for example, suitably capable paramedics, operating department practitioners or other healthcare professional registered with the Health and Care Professions Council (HCPC) is not adequately endorsed. It was suggested that a nurse could be given as an example of a suitable session supervisor or described as the established choice of supervisor, rather than being stated as the preferred choice.

It was also noted that while BSQR is prescriptive regarding interactions with a single donor (i.e. a qualified healthcare professional who is a doctor, nurse or donor carer) this paper seeks to address the clinical supervision of the donor session as a whole, which is not as clearly defined within BSQR.

Following these discussions, the paper will be reviewed again by SACCSD, with a planned submission for the next JPAC meeting to be held on 22 June 2023. **[AWe]**

6 SACTTI

6.1 Horizon Scanning Report 2022 (JPAC 23-07)

Report presented to provide JPAC with oversight of the current horizon scanning process.

It was noted that a significant number of Emerging Infectious Agent Reports (EIAR) are required to be reviewed each month as part of the horizon scanning process although experience allows some to be quickly scanned for relevance and discarded. Regular feedback is also given to NHSBT/UKHSA to ensure only the most relevant reports are sent to SACTTI for review.

Although a degree of longer-term horizon scanning is carried out as part of the current process, the value of formalising a more defined two-tier process (e.g. 10-year horizon in additional to the current one to three year review process) was discussed. Longer-term horizon scanning may also be helpful with regards to development of reference materials and anticipating changes in assay requirements as a result of changes in disease distribution over time.

It was suggested that the SaBTO Virology Review Group could be engaged to take a strategic view of a more long-term horizon scanning process, possibly to produce a position paper for the UK Blood Services and a mechanism by which risks could be identified and reviewed. Expertise could also be sought from agencies such as UKHSA or the Advisory Committee on Dangerous Pathogens. A separate meeting of relevant members of JPAC, SACTTI and SaBTO was suggested to further discuss this option. **[ST]**

7 SACIH

Due to **EM**'s appointment as Medical Director of WBS, he will have to step down as Chair of SACIH.

An invitation for expressions of interest for the position was distributed to colleagues across the four UK Blood Services on 15 March 2023, with interviews planned for mid-late April.

8 SACIT

A reconvened SACIT, led by Ian Millar, met on 28 February 2023. **RE** gave a verbal update:

- Due to the retirement of several key individuals since its last meeting, there are knowledge gaps within SACIT that will need to be addressed.
- Regarding ways of working, SACIT discussed representation from other SACs, noting a good connection with SACBC due to joint processes for new component codes
- The need to update Red Book chapters 23 to 27 was discussed, particularly given that the ongoing full face labelling project will impact all of these chapters.
- It was suggested that it would be beneficial for a representative of SACIT to sit on the Plasma for Medicines Working Group, as there will be considerations around the format and transfer of data once an appointed plasma fractionator's specifications are available.

In addition to the existing connection to SACBC, it was noted that representatives from SACTCTP and SACIH should be invited to sit on SACIT once fully re-established.

The Terms of Reference for SACIT need to be reviewed and updated. Once this is done, the process to recruit and appoint a Chair will begin. **[ST]**

9 SaBTO

9.1 SaBTO summary report

Report (**JPAC 23-08**) presented to summarise the SaBTO meeting held on 7 December 2022 and the recent activities of the various SaBTO working groups.

A regular joint meeting of SaBTO and JPAC Chairs and Secretariat is being arranged, to be held quarterly, to allow the exchange of workplans and for SaBTO to brief JPAC on upcoming agenda items that may be of common interest. This meeting will have a flexible agenda with an open invitation for SAC Chairs to attend if/when relevant.

10 JPAC Office

Two amendments were proposed to the process of approval and publication (**JPAC 23-11**):

1. The introduction of a delegated approval process

This involves delegating the right to approve to different levels of the JPAC structure (i.e. the Director, EWG and JPAC) depending on the type and size of the intended change, rather than each change request (CR) needing to be discussed and approved in a linear, multi-stage process.

A framework for the delegated approval process, including examples of the types of CRs that are appropriate for each approval level and the process by which urgent CRs are processed, will be included in the JPAC Publication Policy to ensure consistency. **[PRa]**

2. The removal of Medical Director approval for final CNs

Currently the Medical Directors are asked to approve the final CN document that will be circulated to relevant stakeholders to indicate the upcoming changes. As this approval relates specifically to the CN document (i.e. formatting and presentation) rather than approval of the change itself, it is an unnecessary step in the process. Medical Directors will still have oversight of all CRs through the delegated approval process and from the pre-publish email which is circulated (approx. one month) prior to any changes being enacted.

Both proposed amendments were approved.

11 AOB

Work plan item 38 – benchmarking of adverse event rate

AC has now discussed this with Dr Shruthi Narayan (SHOT).

There are four streams for unrelated stem cells donors in the UK (British Bone Marrow Registry, DKMS, Welsh Bone Marrow Donor Registry and Anthony Nolan) who have a joint meeting. All unrelated donors are initially followed up two, 14 and 30 days after donation, and then at longer term intervals of one, three, five, seven and 10 years.

Serious (Product) Events and Adverse Reactions (SPEAR) reports are published annually by the World Marrow Donor Association. The 2020 report is available now, the 2021 report is yet to be published and the 2022 report is due to be written.

It was suggested that further discussion would be useful, both to avoid duplication of work in this space and, particularly given the planned review of JPAC, to better define JPAC's role in producing stem cells guidelines for the whole of the UK. **[ST]**

Strategic review of JPAC

The Infected Blood Inquiry (IBI) report is expected to have an impact on JPAC when it is published later this year. For this reason, the previously proposed large external review of JPAC is now planned to be smaller and focus on ways of working, the constitution of the SACs, and the current and future output of JPAC. An external communications consultant is being engaged to seek feedback from JPAC members and stakeholders and prepare a report, with recommendations to be taken to UK Forum if the need for changes to the constitution or scope of JPAC are identified.

Website

The contract with the current commercial website provider is ending in July 2024 and it is recognised that the website requires modernisation. Both internal (NHSBT) and external (commercial) provision is being considered. Discovery work is being done with Serious Hazards of Transfusion (SHOT) and Systematic Review Initiative (SRI) on the feasibility of a joint website solution. The requirements for the new JPAC website are being considered, with input sought from JPAC members and other relevant stakeholders so that an updated website specification can be written.

12 Papers for noting

There were no objections or corrections to any of the papers included on the agenda for noting.

Meeting concluded at **12:10**