Approved 16/03/23

Meeting details

Subject	**JPAC Meeting**
Date	Thursday 17 November 2022
Time	10:00 to 13:00
Location	Microsoft Teams

A recording of the meeting was made with the agreement of all attendees. The recording will be kept temporarily to allow minutes of the meeting to be written and be deleted once minutes are approved.

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

Attendees

Dr Neil Almond	**NA**	MHRA (NIBSC)	
Dr Janet Birchall	**JB**	Medical Director, WBS	
Dr Akila Chandrasekar	**AC**	Chair, SACTCTP	
Dr Lisa Jarvis	**LJ**	Chair, SACTTI	
Dr Lorna McLintock	**LM**	Medical Director, SNBTS	
Dr Gary Mallinson	**GMa**	Scientific Lead Safety Policy, JPAC/SaBTO	
Dr Edwin Massey	**EM**	Chair, SACIH	
Dr Gail Miflin	**GMi**	Chief Medical Officer, NHSBT	
Dr Helen New	**HN**	Deputising for Chair, SACBC	
Dr David Olszowka	**DO**	Regulatory Governance Lead, MHRA	
Dr Peter Rae	**PRa**	Scientific Publishing Manager, JPAC	(Minutes)
Dr Peter Richardson	**PRi**	UKQM	
Dr Megan Rowley	**MR**	Chair, SACCTM	
Dr Amy Shackell	**AS**	Regulation Manager, HTA	
Dr Stephen Thomas	**ST**	Professional Director, JPAC	(Chair)
Dr Angus Wells	**AWe**	Chair, SACCSD	
Ms Anna Witham	**AWi**	Administrator, JPAC	

Apologies

Mr Ryan Evans	**RE**	Chair, SACBC (Helen New deputising)
Dr Tor Hervig	**TH**	Medical Director, IBTS

Meeting commenced at **09:59**

Agenda items

1 Introductions

Lorna McLintock was welcomed as the new Medical Director for SNBTS.

Peter Rae was welcomed as the new Scientific Publishing Manager for JPAC.

2 Draft minutes of the last meeting held on 14 July 2022

Minor typographical error noted in section 7.2 (now amended). The draft minutes were approved.

3 Matters arising and actions list

Action – SACIT: Plasma for fractionation considerations (JPAC 21-12)

To be addressed by assembling a short-life working group rather than re-establishing the previous SAC on Plasma for Fractionation (SACPFF) but will require input from SACIT. Ian Millar (SACIT) has included it on the agenda for the SACIT meeting on Tuesday 6 Dec 2022.

An additional item was added to the actions list regarding the reconvened SACIT: including the appointment of a new Chair, and a review of its 2022-2023 work plan and Red Book updates. **[ST]**

Action – Zika Risk Assessment v5 (JPAC 21-81)

A revised DSG entry will be discussed at the next SACCSD meeting with a planned submission to JPAC at the next meeting on Thursday 16 March 2023.

Action 6.1 – Relaxation of travel criteria for plasmapheresis donors (JPAC 22-14)

Previously passed to SACTTI for review. Planned for submission to JPAC for Thursday 16 March 2023.

Action 6.2 – Pregnancy (JPAC 22-15)

DO, on behalf of MHRA, has agreed to look at proposal. **AWe** to prepare updated briefing paper and forward proposal to **DO**. Planned for submission to JPAC for Thursday 16 March 2023. **[AWe]**

Action 6.4 – Update on donors with HIV positive partners (JPAC 22-17)

Item closed as these issues will be addressed with the implementation of FAIR IV.

Action 7.1 – Validation of dried plasma components (JPAC 22-22)

Tendering process still ongoing so not yet ready for publication.

Action 3.2 – Horizon Scanning Management Process Description (MPD) (JPAC 20-15c)

The flow chart for horizon scanning information dissemination has now been withdrawn from the Horizon Scanning MPD and the SaBTO induction package. **GM** has prepared organograms illustrating the relationships between the Blood Services, the Government, the devolved administrations and the various committees in terms of horizon scanning, for inclusion in the SaBTO Induction Pack. Item closed.

Action 5.4 – Immunosuppression (JPAC 22-42)

Planned for submission to JPAC for Thursday 16 March 2023.

Action 6.2 – Risk Assessment, HHV8 (JPAC 22-44)

Action amended (RAs are not published on the website) and item closed as RA has been approved.

Action 7.1 – Red cells and Plasma (RC&P), LD, provisional specification amendments (JPAC 22-48)

Draft CN in progress.

Action 7.2 – EBA position paper: Recommendation for validation of non-DEHP blood components (JPAC 22-49)

A detailed gap analysis will be discussed at the next SACBC meeting.

Action – Position Statement: Coronavirus Vaccination

It was noted that this PS was discussed at a previous EWG meeting, to be finalised and submitted to JPAC, but does not appear on the action list for either EWG or JPAC. Added to JPAC action list as a SACCSD item and **PRa** to ascertain status of PS. **[PRa]**

A draft version of this PS was submitted at the EWG meeting on Wednesday 15 June 2022 but was not finalised until after the JPAC meeting on Thursday 14 July 2022. It was mistakenly omitted from the agenda for the JPAC meeting on Thursday 17 November. The final version of the PS will be circulated to attendees for information. **[PRa]**

4 Standing Advisory Committee on Transfusion Transmitted Infection

4.1 Position Statement – The estimated residual risk that a donation made in the infectious window period is not detected on testing: risks specific to HBV, HCV and HIV in the UK, 2019-2021

The risk continues to be low. The risk for HIV and HCV has remained the same and has reduced for HBV since the last PS. This PS includes six months of data following the implementation of FAIR I and shows no increase in risk as a result.

HEV residual risk was previously discussed by SACTTI in 2016 with the decision made not to include it in the PS. A different model would be needed (one-year data rather than three-year data) due to fluctuations in HEV risk and because a significant proportion of HEV infections are food-borne. A risk estimate for missed HEV infections could therefore be prepared but it is unclear how relevant it would

be to TTI risk. However, it was noted here that publishing HEV residual risk data in some format would be useful as there is currently no publicly available statement on HEV risk that can be used to provide information to doctors and patients. The current patient information leaflet is due to be reviewed in July 2023 and would benefit from being reviewed by SACTTI and, if possible, the inclusion of appropriate risk data. **MR** to discuss with **LJ**. Residual risk for HEV to be discussed at the next SACTTI meeting in January 2023. **[MR/LJ]**

Concern was raised that the HBV residual risk estimated in this PS does not include occult HBV infection (OBI) which would be important for fully informed patient consent. SACTTI had previously discussed calculating OBI risk and found that the risk was minimal once anti-HBc screening was considered. The PS summary sheet does state that OBI is not included in the risk calculations but this disclaimer, as well as clarification around OBI and window periods, will be added to the PS. **[LJ]**

PS approved pending minor amendments. **PRa** to liaise with **LJ** to progress publication. **[PRa]**

Papers for noting

SACTTI papers (agenda item 14) approved for publication without further comments.
PRa to liaise with **LJ** to progress publication. **[PRa]**

5 Standing Advisory Committee on Blood Components

5.1 2015 paper updating specification for "Red cells, washed, leucocyte depleted"

This paper was provided as background for the proposed changes below. It was noted that a number of interesting points in this paper could be taken back to SACBC for discussion. **[HN]**

5.2 Washed Red Cells – proposed changes to the current specification

Minor updates proposed to chapter 7.7 of the Red Book:

1. Remove references to 'saline' because it is not available from blood pack suppliers and is not currently used in blood components produced by the UK Blood Services
2. Change the recommendation for the use of an automated closed washing system to the use of a manual closed washing system due to improved component quality
3. Increase the shelf-life of washed red cells produced in sterile closed systems from 24 hours to 14 days if stored in SAGM at a core temperature of 4 ± 2 °C. If alternative solutions are subsequently used, shelf-life would need to be defined through validation.

Changes approved for publication. **PRa** to liaise with **RE** to progress publication. **[PRa]**

Red cell stock issues – recent Amber Alert

Contingency products (including 42 day red cells) are detailed in Annex 5 of the Red Book. It was suggested that universally increasing red cell shelf-life (rather than simply as a short-term measure) might be advantageous given the stock shortages experienced recently are likely to occur more frequently. It was noted that when the contingency components were first proposed, the available data did not give sufficient reassurance to recommend routine use. However, several years have now passed and this data could be revisited. A global change to component shelf life would be a large

piece of work given the technical and clinical validation required (with additional work likely if non-DEHP blood bags are classed as Class III medical devices). An initial impact-effort analysis by SACBC would be useful to assess the benefits of such a change against the work involved. **[RE]**

6 Standing Advisory Committee on Tissues and Cellular Therapy Products

These CNs were previously presented at the JPAC meeting on Thursday 14 July 2022. There have been additional discussions since that meeting and while unanimous agreement has not been reached regarding the final recommendations, a majority view was taken to achieve a satisfactory consensus.

6.1 Change Notification no. 51-2022: Coronavirus Infection

CN51 approved for publication. **PRa** to liaise with **AC** to progress publication. **[PRa]**

6.2 Change Notification no. 52-2022: Infectious Diseases, Contact with

CN52 approved for publication. **PRa** to liaise with **AC** to progress publication. **[PRa]**

7 Standing Advisory Committee on Care and Selection of Donors

7.1 Change Notification no. 61-2022: New WNV risk in France

Updated to include new WNV risk area in the South of France.
CN61 approved for publication. **PRa** to liaise with **AWe** to progress publication. **[PRa]**

It was noted that given the spread of mosquitos as a result of climate change, the geographical regions that require deferral are likely to increase/change and this may impact the sufficiency of the blood supply. Additional measures may eventually become necessary (e.g. selective testing for viral infections such as Dengue, 28 day blanket deferral for donors who have travelled outside the UK).

Papers for noting

Regarding agenda item 15.3 (Donor Weight DSG entry, JPAC 22-74), it was clarified that drugs for obesity treatment, even those purchased privately, require a prescription. It was also explained that a previous study showed blood volume calculation can help to assess the risk of fainting in young female donors, although this related to those below the age of 20. SACCSD intends to look at how this guidance might be adapted to a wider age range (perhaps up to 30 years).

Regarding agenda item 15.1 (Dental Treatment DSG entry, JPAC 22-72), it was clarified that the entry makes a distinction between human (deferred) and animal and non-biological (non-deferred) sources of implant material because there are human-sourced dental products licensed for use in the UK.

SACCSD papers for noting (agenda item 15) approved for publication.
PRa to liaise with **AWe** to progress publication. **[PRa]**

8 Work plan 2022-2023

Item 1 – Whole blood packs – possible Class III medical devices

From the recent CD-P-TS meeting, it seems very likely that blood packs will be classes as Class III medical devices in the future, due to the presence of citrate. If so, significant validation will be required.

Item 2 – Washed red cells – review and update specification to reflect current practice

As discussed, proposed changes to specification approved. Item closed.

Item 3 – Review CoE guide proposal to use glucose for quality monitoring of platelets in PAS

Ongoing workplan item for SACBC. UK Blood Services to undertake a review of the ability to implement platelet quality monitoring by glucose across the UK.

Item 4 – Extension of post-thaw shelf-life of cryoprecipitate

Work by NHSBT Component Development Laboratory. On hold due to technical issues.

Item 6 – Implementation of anti-HBc screening in the UK Blood Services

Updates have been made to Red Book. Item closed.

Item 7 – Donor selection criteria for transgender and non-binary donors

Ongoing work by SACCSD. Rescoped to March 2023

Item 8 – Immunosuppression and Autoimmune Disease entries in the Donor Selection Guidelines

As discussed, planned for submission to JPAC for Thursday 16 March 2023.

Item 10 – Pregnancy

As discussed, planned for submission to JPAC for Thursday 16 March 2023.

It was discussed whether the update to pregnancy guidance should be delayed until upcoming changes to the EU directive are approved. The timescale for this is unclear (but likely to be a year or more) so it was decided that the pregnancy entry should be updated now.

Item 11 – Thrombosis and bleeding disorder entries

CN 57-2022 (Thrombosis) has been issued. More work required on bleeding disorder entry.

Item 13 – Document criteria for inclusion of female plasma donors for fractionation(/convalescent)

While donors will not be screened for HLA or HNA antibodies in the same way as for platelet donations, it is unclear whether donors who are already known to have HLA or HNA antibodies can be accepted into a plasma donation programme. The same concern exists for known high titres of ABO and other

red cell antibodies. Item kept on the workplan as a watching brief as much of this will be driven by the requirements of the fractionators.

Item 14 – Universal blood components

Ongoing work by SACBC. No specific submission to JPAC expected (March 2023 date removed from work plan) unless further updates or additional data warrant resubmission.

Item 15 – Review of '30 minute rule' for FFP

Ongoing work by SACBC.

Item 15 – Serum eye drops blood component specification

Ongoing work by SACBC and SACTCTP.

Item 17 – Perfusion of organs SACCTM/SACBC collaboration

Ongoing work by SACBC and SACCTM.

Item 18 – Consider the FAIR III study recommendations for T&C-DSGs

This work is of significant political interest and gives rise to a number of operational implications.

Planned for discussion at SACTCTP in January 2023, the recommendations are currently on the list to go before the Health Minister for approval in England and are seemingly ready to be approved by the Scottish Government (if not already).

While the current position of waiting until all administrations have approved the recommendations is reasonable, it is possible that devolved administrations may choose to implement changes at different times, given that the timeline for ministerial approval is unclear, which would result in different donor criteria in different countries of the UK. Due to the operational challenges this would present, it was suggested that this possibility be discussed at the next UK Forum meeting. **[ST]**

Item 19 – Individual risk assessments for 'High risk donor'

Item currently paused, awaiting the outcome of the FAIR IV study.

Wording of the work plan needs to be amended to reflect the wider nature of the FAIR IV working group beyond NHSBT and including SACTTI representation. **AW** to provide **PRa** with text. **[AW]**

Item 20 – Donor adverse incident reporting

Dr Shruthi Narayan (SHOT) is leading the implementation of this across the four nations. Likely not before end of March 2023. Updates will be discussed at subsequent SACCSD meetings.

Item 22 - Review autologous donation guidance within RB and WBDSG

Awaiting publication of BSH guidelines then work can be re-scoped.

Item 24 – Occult HBV

HBV DSG entry was updated earlier in the year to reflect OBI. Following feedback, wording is to be updated taking into account experience of testing in England and Scotland to date. Planned for submission to next JPAC meeting on Thursday 16 March 2023.

Item 25 – Acute Infection

Minor change to DSG entry. Due to workload, to be re-scoped to latter part of 2023.

Item 28 – Provision of HLA matched RBC for renal transplant

SACIH item currently paused as work largely dependent on external agencies.

Work has been taken on by David Roberts (NHSBT). **GMi** to ask Dave Roberts to contact **EM**. **[GMi]**

Item 29 – New format GDRI

Item will require rescoping after Malaria DSG entries are updated (workplan item 41).

Item 30 – Arrythmia and Cardiovascular Disease entries

Clarifications required in response to user feedback. Planned for submission to JPAC for March or June 2023, depending on workload.

Item 32 – Review any reports of discrepancies between CofE Cell and Tissue Guide and JPAC Guidelines

Discrepancies will be addressed at SACTCTP if/when identified rather than committing resources to a full gap analysis. Ongoing for 2023.

Item 33 – Keep a watching brief on the update of the EU Cell and Tissue Directives

Ongoing work item for all SACs.

Item 34 – Clarification of VHF deferral for stem cell donors

SACTCTP queries to be addressed at next SACTTI meeting.

Item 35 – Latent TB

Item closed.

Item 36 – Clarification of DSG for animal bite for cord blood donors

Item closed.

Item 37 – Guidance on risk of transmitting malaria – bone marrow/stem cell donors and live tissue donors with risk < 4 months

AC preparing proposal for next SACTCTP meeting in January 2023.

Item 38 – Benchmarking of adverse event rate

To be combined with item 20. **AC** to discuss with Dr Shruthi Narayan (SHOT) and rescope. **[AC]**

Item 39 – Donor selection criteria that could change post BSQR

Long-term work item – ongoing.

Item 40 – Finalise/decide Red Book chapter 22

On agenda for SACTCTP meeting in January 2023.

Item 41 – Update Malaria entry in TC-DSG

On agenda for SACTCTP meeting in January 2023.

Item 42 – Review Monkeypox entry

On agenda for SACTCTP meeting in January 2023.

Item 43 – Standardisation and resilience for the implementation of ffDNA RHD screening

Planned for submission to JPAC for Thursday 16 March 2023.

Item 44 – Review testing for T crypt-antigen and related antigens

Planned for submission to JPAC for Thursday 16 March 2023.

9 SaBTO feedback

The Risk Tolerability WG aims to determine a framework for how risk tolerability can be used in decision making. DHSC would like SaBTO to use the principles of the UK Government Green Book (i.e. cost/QALY as the measure of cost effectiveness) as the future basis of risk-based decisions. SaBTO members have expressed concerns about this approach and wish to reach a compromise in which special cases that justify extra spending might be defined.

Prof Richard Fordham, newly appointed SaBTO health economist, is carrying forward this work. Proposal and remit planned for submission to next SaBTO meeting in December 2022.

It was suggested that a formal process for change implementation agreed between the main stakeholders (i.e. DHSC, JPAC, SaBTO, UKF) could help to avoid previously experienced issues such as delays in ministerial approval, significant periods between stakeholder approvals, approval of different changes in different nations, etc.

Such a policy may be difficult to achieve given a lack of JPAC/SaBTO control over Civil Service processes, but it can be taken back to SaBTO for discussion. **[GMa]**

10 UK Forum feedback

Business continuity plans were discussed at last UKF meeting, including alert levels for blood stocks, communication, and the alignment of terminology and trigger point between Blood Services.

For the next UKF meeting, **ST** will put forward a proposal for the terms of reference for a planned external review of JPAC.

11 European activities

A regulation to rescind the current EU directives on blood and components, and on tissue and cells, was proposed at the recent CD-P-TS meeting of the Council of Europe. The process will likely take six to nine months. The existing directive on organs will not be affected. It is likely that the existing directives will become technical annexes to the new regulation. As the current directives are transposed into UK law, a DHSC working party will work with MHRA, HTA and HFEA to understand what the UK position will be if these directives cease to exist.

The EBA working party has been reviewing the text of the regulation and has sent suggested amendments to EBA member organisations to be discussed with their competent bodies. JPAC will collate the responses from the four UK Blood Services and forward these to DHSC. The Northern Ireland position is unclear because of complications surrounding the NI Protocol.

Regarding vCJD and deferral policies, there was a desire amongst CD-P-TS members to accept UK plasma but until the European Medicines Agency position changes there is little appetite to progress this. A technical report is expected from ECDC due later this year.

12 Any other business

Update on current state of the Red Book – 9th edition

The updated Red Book is planned to be online-only with rolling updates when required. A number of recently updated chapters (9, 10, 19-21, annex 6) are finalised and ready to be published. Several other chapters (4, 5, 11-18) are awaiting final review by relevant SAC members and may be published alongside the finalised chapters, depending on timescales. Of the remaining chapters, some are being updated but are unlikely to be ready imminently, and some do not require updates at this time.

It was noted that care must be taken at this time to ensure mismatches are not introduced between related chapters if one chapter is published while another is awaiting approval. Checking for such discrepancies will also form an important part of the future rolling update process to ensure consistency across the Red Book.

13 Dates of future JPAC meetings

Thursday 16 March 2023
Thursday 22 June 2023
Thursday 16 November 2023

Meeting concluded at **12:39**