APPROVED 24/03/2022

JPAC EWG 22-04

Joint UKBTS Professional Advisory Committee

Minutes of the 80th JPAC Meeting
Zoom meeting held on
Thursday 4 November 2021 – 10:00 to 13:00

Meeting commenced at: 10.03

Present

Dr Neil Almond	**(NA)**	-	National Institute for Biological Standards and Control
Dr Janet Birchall	**(JB)**	-	Medical Director, Welsh Blood Service
Dr Su Brailsford	(SB)	-	Consultant in Public Health NHSBT, representing Dr Gail Miflin
Dr Jill Clarkson	**(JC)**	-	NHS Blood and Transplant - Observer
Mr Ryan Evans	**(RE)**	-	Standing Advisory Committee on Blood Components - *Deputising for Dr Helen New*
Dr Stephen Field	**(SF)**	-	Medical Director, Irish Blood Transfusion Service
Dr Laura Green	(LG)	-	Consultant NHSBT – for item 5.1
Dr Lisa Jarvis	**(LJ)**	-	Standing Advisory Committee on Transfusion Transmitted Infections
Ms Martina Leonard	(ML)	-	Note Taker
Mrs Angela Macauley	**(AM)**		Quality Manager, Northern Ireland Blood Transfusion Service *Deputising for the NIBTS Medical Director and Mr Peter Richardson, JPAC Quality Managers Representative of the 4 UK Blood Services*
Dr Sheila MacLennan	**(SM)**	-	Professional Director of JPAC **(Chair)**
Dr Gary Mallinson	**(GMal)**	-	Scientific Lead Safety Policy (JPAC/SaBTO)
Dr Edwin Massey	**(EM)**	-	Standing Advisory Committee on Immuno-haematology
Mrs Shirley Stagg	**(DA)**	-	Medicines and Healthcare products Regulatory Agency
Dr Megan Rowley	**(MR)**	-	Standing Advisory Committee on Clinical Transfusion Medicine and *Deputising for Prof Marc Turner*
Dr Amy Shackell	**(AS)**	-	Human Tissue Authority (HTA)
Dr Stephen Thomas	**(ST)**	-	Deputy Professional Director of JPAC
Dr Angus Wells	**(AW)**	-	Standing Advisory Committee on Care and Selection of Donors

ACTION

1. Apologies

Dr Akila Chandrasekar	Chair SACTCTP
Prof John Forsythe (JF)	Associate Medical Director – Organ Donation and Transplantation, NHSBT
Mrs Linda Lodge (LL)	Standing Advisory Committee on Information Technology

ACTION

Dr Gail Miflin (GM)	Medical Director, NHS Blood and Transplant
Dr Helen New (HN)	Standing Advisory Committee on Blood Components
Mr Peter Richardson (PR)	Quality Manager, Welsh Blood Service
Miss Caroline Smith (CJS)	JPAC Manager
Prof Marc Turner (MT)	Medical Director, Scottish National Blood Transfusion Service
Dr Joanne Murdock (JM)	Medical Director, Northern Ireland Blood Transfusion Service
Prof Maria Zambon (MZ)	Director, Centre for Infections, UKHSA

2. Minutes of the last meeting held on 01 July 2021 - JPAC 21-61

The minutes were approved as a true record of the meeting.

3. Matters arising not on the agenda (review of the actions list) - JPAC 21-62

3.1 Borrelia Burgdorferi (Lyme Disease) Risk Assessment - version 4 – JPAC 19-38 – item 3.1

AW

On agenda.

3.2 Assessing Malarial Residency - Proposed change to the Geographical Disease Risk Index – JPAC 19-48 – item 3.3

A meeting has been arranged with LJ and the Chair of the SACTTI Parasites subgroup. Plan to report to JPAC in March or June 22. **AW**

3.3 Horizon Scanning Process Management Description – JPAC 20-15(c) – item 3.4

Still in progress. **GMal**

3.10 Validation of Dried Plasma Components - Requirements for the UK Standing Advisory Committee on Blood Components – Confidential – JPAC 21-19 – item 7.2

Awaiting return of HN - no further update. **HN & SM**

3.11 Reactivation of Red Book Annex 5 Contingency Components – JPAC 21-20 – item 7.3

Post Meeting Note: Change Notification No 44 2021 Annex 5 is with the Medical Directors for approval.

In progress

3.12 Proposed revised Red Book Chapter 6, section 6.2, Concessionary Release definition – JPAC 21-21 – item 7.4

In progress.

4.4 Usutu Virus (USUV) Risk Assessment: Version 3 – JPAC 21-34

ACTION

LJ has asked the EID Monitor group whether any country has specific guidelines for this and none have. It was agreed that no further action be taken. Action closed. **Closed**

4.5 **Yellow Fever: SACTTI Review: Version 2 May 2021 – JPAC 21-35**

On Agenda **AW**

5.4 **SACIT: Plasma for Fractionation Considerations – JPAC 21-12**

LL

No further update..

5.1 **Update on transfusion administration set wording for the Red Book – JPAC 21-36** **Closed**

EM will circulate the information to BSH.

5.4 **Chapter 7 Red Book: Draft Plasma for fractionation, leucocyte depleted – JPAC 21-56**

In progress **ST**

5.5 **Chapter 8 Red Book: Evaluation of plasma for fractionation for the manufacture of immunoglobulin – JPAC 21-57**

Added section clearer. This paper has now been further updated as JPAC 21-64, on the agenda for this meeting.

4. Standing Advisory Committee on Blood Components

4.1 **Leucocyte-depleted Whole Blood (LD-WB) – revision of shelf-life specification and approval of its use outside the pre-hospitals setting, as part of the randomised control trial – JPAC 21-63**

LG discussed the aims of the paper; extending the current shelf-life of LD-WB from 14-day to 21-days and extending the clinical indications for LD-WB component to allow it to be used in hospitals who are taking part in the trial for the treatment of non-trauma major haemorrhage to reduce wastage. The latter change would only happen if the safety data of the first 200 patients shows no concerns.

Change-1
'The component may be stored for a maximum of 14 days at a core temperature of 4 ±2°C.'

To:
'The component may be stored for a maximum of 21 days at a core temperature of 4 ±2°C.'

Change-2
'Whole Blood, Leucocyte Depleted (LD) - for clinical studies is intended for the treatment of major haemorrhage only, and currently only as part of clinical studies, initially in the pre-hospital situation, with transfusion of a maximum of 4 units (or weight-related equivalent for children) prior to switching to standard component therapy.'

To:
'Whole Blood, Leucocyte Depleted (LD) - for clinical studies is intended for the treatment of major haemorrhage only, and currently only as part of clinical studies, initially in the pre-hospital situation, ***and later to other non-trial patients who are***

ACTION

bleeding in hospitals which supply the participating Air Ambulances, if there are no safety concerns from the initial recruitment, *with transfusion of a maximum of 4 units (or weight-related equivalent for children) prior to switching to standard component therapy.'*

Discussed and approved. A change notification will be issued to extend the shelf life.

4.2 **Guidance for validation of plasma for the manufacture of immunoglobulins – Phase 0 requirements - JPAC 21-64**

This was approved and the new sectionwill be incorporated into the 9th Edition of Chapter 8 of the Red Book. **RE (HN)**

4.3 **Update of provisional component specifications for Convalescent Plasma for COVID 19 - JPAC 21-65**

There was a question as to whether the name of the component i.e. 'convalescent plasma' is still valid as a major requirement is that it is collected from donors who have been vaccinated against COVID-19. SM agreed to investigate. With the exception of this query, the specification was approved and a change notification will be issued. **SM**

Post-meeting note: The donors will have both been infected with COVID-19 and had subsequent vaccination therefore the name is appropriate.

5. Standing Advisory Committee on Tissues and Cellular Therapy Products

5.1 **Cervical Dysplasia, Cervical Carcinoma in situ, Cervical Cone Biopsy and Laser Treatment entries in all Tissue and Cell DSGs – JPAC 21-66**

Approved. A change notification will be issued.

5.2 **Immunosuppression entry – Deceased and Living Tissue DSGs – JPAC 21-67**

AS to discuss further with colleagues and report back regarding changes. **AS**

5.3 **Infertility entry for live tissue, deceased tissue, cord blood and HSC – JPAC 21-68**

Additional sentence added for clarification. Approved. A change notification will be issued.

5.4 **Psoriasis – all Tissue and Cell DSGs – JPAC 21-69**

Obligatory referral added. Approved. A change notification will be added.

5.5 **Update the Disease of Unknown Aetiology entry in all Tissue and Cell DGSs and create an Idiopathic Pulmonary Fibrosis entry in the Deceased Tissue – JPAC 21-70**

Clarification to encourage people to think about such disorders, additional information added. Approved. A change notification will be issued.

6. Standing Advisory Committee on Immunohematology

6.1 **Introduction of new tests for immunoglobulin A (IgA) deficiency and for antibodies against IgA – JPAC 21-71**

ACTION

EM presented this paper, the contents of which were noted.

7. Standing Advisory Committee on Care and Selection of Donors

7.1 Narcolepsy – JPAC 21-72

Modify the entry – defer for 7 days after taking medication. Approved. A change notification will be issued.

7.2 Conn's Syndrome – JPAC 21-73

Additional entry. Approved. A change notification will be issued.

7.3 Ehlers Danlos Syndrome – JPAC 21-74

Eligibility regarding joint dislocation. Approved. A change notification will be issued.

7.4 Post donation information – JPAC 21-75

It was agreed that this would be a useful addition to the DSG. The document was approved with a few minor changes suggested. It will be added to the DSG as an Annex. **AW / CJS**

7.5 Addition of Yellow Fever to the GDRI – JPAC 21-76

6 month deferral – same deferral period as other tropical viruses. Approved. A change notification will be issued.

7.6 Further changes to the Coronavirus entry in the WBDSG – JPAC 21-77

Entry change relating to testing after travel and confirmation of a negative result. Approved. A change notification will be issued.

7.7 Inflammatory Bowel Disease – JPAC 21-78

Change regarding medication, if no longer taking any medication and are well, can donate. Approved. A change notification will be issued.

7.8 Addition of implanted devices to the Indwelling Shunts and Stents entry – JPAC 21-79

Accepted. A change notification will be issued.

7.9 Donors with HIV positive partners – VERBAL UPDATE

AW

Work still being carried out on this, will have a recommendation by next meeting.

8. Standing Advisory Committee on Transfusion Transmitted Infections

8.1 Dengue Virus Risk Assessment - version 9 – JPAC 21-80

Risk assessment updated, no changes to DSG. Review in two years.

8.2 Zika Risk Assessment – version 5 – JPAC 21-81

Risk assessment updated. It is proposed that the sexual contact question could now be removed. AW to feedback to SACCSD for discussion and feedback at next meeting. **AW**

8.3 SARS-CoV-2/COVID-19 Position Statement and the safety of substances of human origin (SoHO) – September 2021 – JPAC 21-82

ACTION

Approved. A change notification will be issued.

8.4 **Position Statement: West Nile Virus (September 2021) – JPAC 21-83**

No major changes, figures updated. Approved. A change notification will be issued.

8.5 **Position Statement - Variant CJD (vCJD); September 2021 – JPAC 21-84**

Updated with information on manufacture of plasma derivatives form UK plasma. Accepted. A change notification will be issued.

8.6 **Position Statement: Zika Virus; September 2021 – JPAC 21-85**

Approved. A change notification will be issued.

8.7 **Risk assessment - Crimean-Congo haemorrhagic fever virus (CCHF) v6 – JPAC 21-86**

Note additional cases (Spain) include risk assessment – risk in UK low. Approved. Review in two years. A change notification will be issued.

8.8 **Position Statement: The estimated residual risk that a donation made in the infectious window period is not detected on testing: risks specific for HBV, HCV and HIV in the UK, 2018-2020 – JPAC 21-87**

No change to parameters – all three risks less than 1 in 1 million. Approved. Post on JPAC/UKHSA sites. A change notification will be issued.

9. Standing Advisory Committee on Information Technology

Blood component labelling specification – JPAC 21-88

Labelling specification to be posted on website. Approved. A change notification will be issued.

SACIT – SM informed JPAC that LL has now left the role as SACIT Chair and a replacement has not yet been identified. It was agreed to organise a special meeting with SACTII members and SACBC to discuss the role of SACIT. Interaction very helpful between groups and the number of experts is diminishing. Need to keep the profile and expertise up, really important to maintain and continue relationships. SM to arrange a meeting. **SM**

10. UK Forum

Feedback from UK Forum meeting held on 18 June 2021- JPAC 21-89

SM had informed the UK Forum that a Position Paper on COVID vaccines and blood transfusion has been posted on the website.

11. SHOT 2020 Report

SHOT Report 202 – JPAC 21-90

A summary of the recent SHOT report was tabled for information.

12. SaBTO

SaBTO Report for JPAC 21-91

Since the last report SaBTO have met on the 11/08/21 and 28/10/21.

ACTION

Occult hepatitis B Infection Working Group - the OBI working group presented its report with the following key recommendations:

- Introduction of an anti-HBc testing strategy once on all donors, subsequently only on new donors or lapsed donors. There would be a review after 12 months of implementation with additional data:

- All anti-HBc reactive donations should undergo confirmatory and further testing, including anti-HBs and HBV DNA by ID NAT.

- Lookback investigations should be conducted on previous donations of current donors who are anti-HBc positive, going back for a minimum period of 3 years. Group 4 donors are considered safe to continue to donate. Group 1 & 2 should be prioritised for lookback investigation

SaBTO accepted all the recommendations in the report, the recommendations will now go to UK health ministers for decision.

Following the OBI working group's consideration of lookback protocols, SaBTO have agreed to establish a working group to consider wider aspects of recipient lookbacks such as medico-legal and ethical issues, together with assessment of both the potential benefits *and* the potential harms, associated with lookback

HEV working group
This group has now met twice in September and October. The group is developing an options appraisal for cost benefit analysis. Two options currently being examined are: enhanced screening of platelet donors, particularly ID-NAT on apheresis donors and; improving the sensitivity of NAT screening by reducing mini-pool size.

Virology review sub-committee
The HHV-8 workstream recommendation to introduce universal testing of all deceased organ donors was accepted by SaBTO. It was acknowledged that the test requires further development, SaBTO asked for a further update before implementation. Two further workstreams on WNV and TBEV are being convened.

Pathogen Inactivation of platelets
The SaBTO 2014 report on pathogen inactivation of platelets was briefly reviewed at the August meeting to see if the recommendations were still relevant or if PI of other components needed consideration. SaBTO thought that recommendations in the report were still applicable but asked virologists on the committee to look in more detail at certain aspects for the October meeting. Discussion at the Oct meeting included a cost appraisal commissioned for Cerus which indicated that PI for platelets would be cost effective. This appraisal was criticised by virologist on assumptions and emphasis around new and emerging infections and costs for bacteria screening. SaBTO agreed to a more detailed reappraisal of this and the 2014 report with bacteriology and health economic input to be conducted for the next SaBTO meeting.

It was agreed to review documentation on donor selection criteria and microbiological safety guidelines. It was agreed to seek further legal guidance regarding donor deferral for acupuncture.

13. **European Union**

SM provided an update.

Evaluation of Directives pushed back to early next year – unlikely to be any changes for at least 18 months to 2 years.

GAPP Project – EU project how to revaluate manufacturing – contributed Chapter 8 of Red Book.

ACTION

Launch of new processes in January 2022.

SM to forward email regarding algorithms to RE and SS. **SM**

13. JPAC Work Plans

JPAC Work Plan 2020-2021
JPAC Work Plan 2021-2022

These documents are still in draft but were tabled for information.

14. Any Other Business

14.1 Neil Almond - Impact of the IVDR on NIBSC supplying reference materials noted in the Red Book and how NHSBT labs can assist.

Need for manufacturers to gather information and users to document performance of materials and suitability of purpose. Question of how to get the information, feedback is valuable, also an endorsement of materials would be helpful not just from Blood Services but across all services. EQA schemes could capture information which would be marked as an additional activity.

LJ, JB, DR and SF put themselves forward as contacts for NA.

15. Date & Venue for future JPAC Meetings

2022

- Thursday 24 March - Zoom meeting
- Thursday 14 July - Zoom meeting
- Thursday 17 November - Zoom meeting

The meeting closed at: 12:49