APPROVED 08/03/2018

Joint UKBTS Professional Advisory Committee

Minutes of the 68th meeting held in the Boardroom at the West End Donor Centre, 26 Margaret Street, London, W1W 8NB on Thursday 09 November 2017

Meeting commenced at: 11:05

Present

Dr Neil Almond	**(NA)**	-	National Institute for Biological Standards and Control *(also deputising for Dr Christian Schneider)*
Dr Rebecca Cardigan	**(RC)**	-	Deputy Professional Director of JPAC **(Chaired the meeting)**
Dr Akila Chandrasekar	**(AC)**	-	Standing Advisory Committee on Tissues and Cellular Therapy Products
Dr Stephen Field	**(SF)**	-	Medical Director, Irish Blood Transfusion Service
Dr Lisa Jarvis	**(LJ)**	-	Standing Advisory Committee on Transfusion Transmitted Infections
Mrs Angela Macauley	**(AM)**	-	Quality Manager, Northern Ireland Blood Transfusion Service representing the Quality Managers of the 4 UK Blood Services
Dr Gary Mallinson	**(GMal)**	-	Scientific Lead Safety Policy (JPAC/SaBTO)
Dr Gail Miflin	**(GM)**	-	Medical Director, NHS Blood and Transplant
Dr Helen New	**(HN)**	-	Standing Advisory Committee on Blood Components
Mr David Olszowka	**(DA)**	-	Medicines and Healthcare Products Regulatory Agency
Miss Caroline Smith	**(CJS)**	-	JPAC Manager **(Minute taker)**
Dr Shirley Stagg	**(SS)**	-	Human Tissue Authority (HTA)
Dr Nay Win	**(NW)**	-	Standing Advisory Committee on Immunohaematology
Miss Anna Witham	**(AW)**	-	JPAC Administrator

ACTION

1. Apologies

Prof John Forsythe	**(JF)**	-	Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Mrs Linda Lodge	**(LL)**	-	Standing Advisory Committee on Information Technology
Dr Sheila MacLennan	**(SM)**	-	Professional Director of JPAC
Dr Kieran Morris	**(KM)**	-	Medical Director, Northern Ireland Blood Transfusion Service
Dr Megan Rowley	**(MR)**	-	Standing Advisory Committee on Clinical Transfusion Medicine
Dr Christian Schneider	**(CS)**	-	Director, National Institute for Biological Standards and Control
Prof Marc Turner	**(MT)**	-	Medical Director, Scottish National Blood Transfusion Service
Prof Maria Zambon	**(MZ)**	-	Director, Centre for Infections, Public Health England (PHE)

ACTION

2. Minutes of the last meeting held on 22 June 2017 - JPAC 17-83

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

3. Matters arising not on the agenda (review of the actions list) JPAC 17-84

3.1 Thyroid Disease entry in the Whole Blood and Components Donor Selection Guidelines – JPAC 17-54 – item 4.4

AC will check whether this also applies to the TDSGs so that one notification can be issued to cover all the guidelines. It will be discussed at the next SACTCTP meeting in January. **AC**

3.2 Use of transfusion administration sets in conjunction with blood components and removal of statement regarding microaggregate filter (screen) pore size – JPAC 17-59 – item 6.4

SM had taken this paper to the meeting of the Council of Europe (7 & 8 November 2017) where it was accepted and the next edition of the CoE guide will be amended accordingly.

HN has also amended the SACBC chapter for the new 9th Edition of the Red Book and it will also appear in the BSH administration guidelines.

3.3 Supernatant free haemoglobin (SNHb) as product release criterion for frozen and recovered red cells – JPAC 17-60 – item 6.5

JPAC noted that this is an improvement in quality and a tighter specification. HN will check that it is in the text for the 9th Edition of the Red Book. **HN**

3.4 Chapter 10 of the Red Book - Investigation of suspected transfusion-transmitted infection – JPAC 17-66 – item 7.6

CJS and AW will check that all chapters received are the most up-to-date.

Post Meeting Note: Red Book Chapters check list is up-to-date, with reminders sent to SAC Chairs for any further updates/chapters.

3.5 6th Edition of the Handbook of Transfusion Medicine – JPAC 17-71 – item 9.1

JPAC requested that the wording of question 6 in the survey should be modified to include the possibility that if hard copies are produced they may have to be purchased by users. **MR**

4. Standing Advisory Committee on Blood Components

4.1 Position Statement on Granulocyte Therapy – JPAC 17-85

The November 2015 position statement on Granulocyte Therapy has been revised to take into account the publication of The Resolving Infection in Neutropenia with Granulocytes (RING) study (Price et al, 2015), and the ongoing UK prospective registry of outcomes following granulocyte transfusion, the 'PROspective GRanulocyte usage and outcomEs Survey (ProGRES) (Morton et al, 2017)'.

JPAC approved the updated position statement which will be posted on the website.

ACTION

Post Meeting Note: Updated Position Statement posted on the JPAC website.

4.2 Rejuvenate trial specification update following phase 1 validation – JPAC 17-86

HN went through this paper for the group.

Overall findings of the study are satisfactory. SACBC had reviewed and approved the data at their meeting on 16 October and also a plan for further validation work (Phase 1b).

The paper recommended that the trial component specification is amended to reduce the potassium specification to 3.5 mmol/l. JPAC suggested that the trial group review the need to reduce the potassium specification, so as not to cause any issues for the ongoing trial by it being too tight a specification.

JPAC approved the recommendations in the paper that:

1) the additional data from the planned phase 1b study does not need to be viewed by SACBC/JPAC provided that:

   a) the final validation report is signed off by NHSBT internal QA processes
   b) the hypoxanthine data are as expected, within the levels considered low risk by external toxicology experts.

AC asked whether patients with gout had been considered. HN agreed to look at the exclusion criteria and feedback to AC. **HN**

5. Standing Advisory Committee on Transfusion Transmitted Infections

5.1 Risk Assessment: Hepatitis A virus – JPAC 17-87

JPAC approved this new risk assessment and endorsed the recommendation that there should be no changes to blood donor selection or screening, inactivation or recipient assessment/monitoring.

JPAC also agreed that the UK Blood Services should consider evaluation of HAV NAT assays for listing on KEG (England and Wales)/MTEG (Scotland and Northern Ireland) approved assay lists to allow use of assays in an outbreak situation.

Action: GM will take this to KEG (Kit Evaluation Group) and LJ to MTEG (Microbiology Test Evaluation Group)

Post Meeting Note: LJ has sent this to MTEG and it is on the agenda for their next meeting. GM has sent this to the KEG.

5.2 Risk Assessment: Tick-borne encephalitis virus – JPAC 17-88

JPAC approved this new risk assessment and endorsed the recommendation that there should be no change to the current situation and that no specific measures are needed in view of the lack of evidence of TBEV presence in the UK. A review period of 2 years was agreed.

5.3 Risk Assessment: Toxoplasmosis – JPAC 17-89

JPAC approved this updated risk assessment, which will be reviewed again in 2 years' time.

ACTION

5.4 Risk Assessment: Usutu virus – JPAC 17-90

This is a new risk assessment. Usutu virus risk had been identified through the SACTTI/JPAC horizon scanning process which identified that a risk assessment should be prepared.

USUV is not endemic in the UK and no epizootic outbreaks have been reported. There are currently no reports of any imported cases of USUV. Infectious blood donations are not expected to enter the UK blood supply.

JPAC approved this new risk assessment and endorsed the recommendation that no specific measures are needed for Usutu virus infection in potential donors in view of the lack of evidence of transfusion-transmitted infection. SACTTI will keep Usutu Virus under observation through the Horizon Scanning process. A review period of 2 years was agreed.

RC summarised a presentation she had recently seen from Hans Zaaijer on the current situation with Usutu virus in the Netherlands, which has resulted in the death of approximately 0.5 million blackbirds in the past 3 years. RC to forward to GM and LJ.

Post Meeting Note: RC has sent the relevant information to GM and LJ.

5.5 Risk Assessment: Human herpesvirus-8 - v4 – JPAC 17-91

The HHV-8 risk assessment currently has a 2-year review period (last reviewed January 2016). At the September 2017 SACTTI meeting it was agreed that the review period for this risk assessment could be increased to three years. HHV-8 is a well-known and characterised agent and over the last two years of monthly horizon scanning meetings no issues/additional data pertaining to HHV-8 have been identified. JPAC approved this recommendation.

5.6 Position Statement : Dengue virus – JPAC 17-92

JPAC approved this position statement which has been updated with the currently available figures for cases of Dengue virus imported into the UK. The situation in respect of Dengue virus and risk of transmission has not changed, infections continue to be reported from affected countries but no major outbreaks have been reported in the last year. The position statement will be posted in the Document Library on the JPAC website.

Post Meeting Note: Updated Position Statement posted on the JPAC website on 21 November 2017.

5.7 Position Statement: Ebola – JPAC 17-93

This position statement has been updated with the currently available information on Ebola.

JPAC approved the updated Position Statement which will be posted in the Document Library on the JPAC website.

It was noted that at the recent SaBTO meeting a proposal to change the deferral period from 6 months to permanent for Tissue donations was accepted. AC will discuss a change to the Tissue DSGs at the next SACTCTP meeting and bring back to JPAC in March. **AC**

There was also a question about whether the deferral period for blood donation should be reconsidered in the light of new evidence. SACTTI will be asked to

ACTION

discuss this.

Post Meeting Notes: Updated Position Statement posted on the JPAC website on 21 November 2017.

SM has forwarded the SaBTO paper to LJ and asked her to raise the deferral period for blood donation at SACTTI. **LJ**

5.8 Position Statement: West Nile virus – JPAC 17-94

The position statement has been updated with the currently available information on WNV across the USA and Europe. The situation in respect of WNV virus and risk of transmission has not changed.

JPAC approved this updated Position Statement which will be posted in the Document Library on the JPAC website.

Post Meeting Note: Updated Position Statement posted on the JPAC website on 21 November 2017.

DO agreed to circulate the notes from the last EU Competent Authorities meeting to JPAC, which discussed pool testing for NAT.

Post Meeting Note: JPAC 17-112 - Notes from the Competent Authorities Meeting for Blood and Blood Components: 22 & 23 June 2017 - circulated to JPAC 22 November 2017.

5.9 Residual Risk estimates: Blood (HBV, HCV, HIV): 2014-2016 – JPAC 17-95

JPAC noted that there are no changes to the values for the infectious window periods used in the risk assessment and the data presented. An updated position statement will be submitted to the next JPAC meeting in March 2018. **LJ**

5.10 HIV pre and post-exposure prophylaxis (PrEP): Discussion paper – JPAC 17-96

SACTTI wanted to formulise their discussions into a paper for JPAC. This paper reviews the information available regarding PrEP, considering any impact its use might have in UK blood donors and donations.

SACCSD and SACTCP were asked to consider whether their donor health questionnaires would cover PrEP with regard to taking medication, or whether it should be specifically identified. To also consider improvement in donor information to ensure compliance with the questionnaire. **AC & Chair of SACCSD**

SACTTI will also consider if the use of the alternative testing route for re-entry of donors who have non-confirmable reactive in the HIV screening assay (algorithm only used in NHSBT) needs to be re-evaluated in the light of PrEP. **LJ**

Post Meeting Note: As this algorithm is only used by NHSBT it has been decided to take this off the JPAC actions list.

5.11 Update to Chapter 9 of Red Book Guidelines: clarification that the algorithms depicted are guidelines and may be modified to be Blood Service specific – JPAC 17-97

JPAC approved this updated chapter which will appear in the new 9th Edition of the Red Book.

ACTION

5.12 The UK estimates of residual risk: definitions and scope, 2014 to 2016 – JPAC 17-98

This paper was submitted to provide JPAC with the rationale as to why residual risks should not be estimated for HTLV, syphilis and HEV. JPAC noted the contents of the paper.

5.13 Pathogen Inactivation: Minimum required levels of effectiveness for PI applied to blood and components to support UK Blood Services in the procurement of PI systems – JPAC 17-99

RC thanked SACTTI for this paper, which had evolved from a SaBTO recommendation.

JPAC requested that a comment be added below Table 1, stating that the blood is no longer infectious.

RC will work on combining this paper with the SACBC paper on PI and produce an overall summary which will be sent to PI Manufacturers for comment.

Next steps:

- Send the paper to PI Manufacturers for comment in the first instance.
- Then post on the JPAC website for information.

JPAC will only see this paper again if it is significantly different.

Post Meeting Note: Added the next year's work plan.

5.14 Deferral period for donors with malaria risk – JPAC 17-111

Information in this paper has been approved by Prof Peter Chiodini, Chair of the SACTTI Working Party on Parasitology and Blood Safety.

JPAC requires further information on the risk of reducing the deferral period from 4 months.

GMal suggested setting up a small working group may be the best way to take this forward. He will discuss this further with SM agreeing the set-up and time scales. **GMal**

It was noted that this is only for asymptomatic donors.

6. Standing Advisory Committee on Tissues and Cellular Therapy Products

6.1 Toxoplasma in Living and Deceased Tissue Donor Selection Guidelines – JPAC 17-100

JPAC approved this change and a change notification will be issued.

Post Meeting Note: Change Notification No 02 2018 was issued on 24 January 2018

ACTION

6.2 Poisoning – All Tissue and Cell Donor Selection Guidelines – JPAC 17-110

JPAC approved the recommendation for a new entry to be added to all the Tissues and Cells the donor selection guidelines and a change notification will be issued.

Post Meeting Note: Change Notification No 01 2018 was issued on 24 January 2018

7. Standing Advisory Committee on Immuno-Haematology

7.1 Pooled platelets prepared in platelet additive solution (PAS) and high titre (HT) haemolysin testing

NW gave an update on the current situation and it was agreed the paper will come back to JPAC EWG in January. **NW**

8. Minutes of the JPAC Extraordinary Telecon – SaBTO Changes – JPAC 17-102

Circulated for information.

9. JPAC Standing Advisory Committees Terms of Reference – JPAC 17-103

The ToRs were discussed with the individual SAC Chairs at their SAC Annual Review meetings. All the ToRs were felt to still be relevant and no changes were made.

10. SaBTO

10.1 SaBTO update – JPAC 17-104

GMal went through his report for JPAC.

The SaBTO Microbiological safety guidelines are going to ministers to note.

Membership - Richard Tedder and Charles Newstead are standing down from SaBTO. Andrea Harris (NHSBT) has been appointed as the nurse representative replacing Catherine Howell.

Donor selection working group recommendations – following advice from their lawyers the Ministers did not approve the SaBTO decision regarding acupuncture.

The changes to the donor selection criteria approved by Department of Health ministers and the Scottish & Welsh devolved administrations will be implemented on the 27th November in Scotland & Wales and on the 28th November in England.

NI would not be changing the selection criteria relating to sexual behaviours but this will be reviewed next year.

10.2 Risk Assessments – outline presentation by Gary Mallinson

GMal gave a presentation on assessing the risk tolerability for transmission of blood-borne infections by the UK blood services. The assessment will be made by reviewing historical decisions. The aim will be produce a review paper which will help develop a consistent approach to current and future risk decisions. It was not always easy to compare historical decisions as different approaches were used to

ACTION

assess available data. For the review it was agreed that risk tolerability should be assessed, where possible, as the frequency per million donations and that the actual risk of a donation transmitting an infection to a recipient should be used rather than the number of reported transfusion related events. The review will be prepared for the next JPAC meeting. **GMal**

11. EU Directive evaluation stakeholder event 20 September 2017, Brussels

11.1 Evaluation of the Blood, Tissues and Cells Legislation, Stakeholder Event, September 20th 2017 – PowerPoint presentation (PDF) – JPAC 17-05 and JPAC 17-106

SM submitted the UK Blood Services' response to this evaluation on 30 August and attended the Stakeholder Event in Brussels on 20 September 2017

The timetable for taking this forward is as follows:

- All submissions will be published Jan 2018
- April 2018 – draft report will be received from contractor, finalised June 2018
- DG SANTE will consider report and produce final report Dec 2018
- If agree that changes need to be made then how to go about this will be considered after this

The files from the event have been uploaded in the event page http://btcl.icfeurope.eu/event/stakeholder-event-20-september-2017-brussels/60 .

12. Any Other Business

12.1 Tissues chapters in the Red Book

Check all the references that will appear in the new version of the Red Book.

Post Meeting Note: References and website links will be checked in all the chapters before they go live on the site.

13 Date & venue for future JPAC meetings

2018

- Thursday 08 March - Boardroom, West End Donor Centre, London
- Thursday 28 June - Boardroom, West End Donor Centre, London
- Thursday 08 November - Boardroom, West End Donor Centre, London

The meeting closed at: 15:01