

Joint UKBTS Professional Advisory Committee

Minutes of the 56th meeting held at the
Association of Anaesthetists, 21 Portland Place, London,
on Thursday 14th November 2013

Meeting commenced at: 11:07

Present

Mr Andrew Broderick	(AB)	- Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)
Dr Rebecca Cardigan	(RC)	- Standing Advisory Committee on Blood Components
Mr David Carter	(DC)	- Medicines & Healthcare products Regulatory Agency
Dr Stephen Field	(SF)	- Medical Director, Welsh Blood Service
Prof Ian Franklin	(IMF)	- National Medical Director, Irish Blood Transfusion Service
Dr Victoria Gauden	(VG)	- Human Tissue Authority (HTA)
Dr Stephen Inglis	(SI)	- Director, National Institute for Biological Standards and Control
Dr Jane Liston	(JL)	- Standing Advisory Committee on Care and Selection of Donors <i>(Deputising for Dr Sue Barnes)</i>
Dr Alan Kitchen	(AK)	- Representing the Standing Advisory Committee on Transfusion Transmitted Infections
Dr Sheila MacLennan	(SM)	- Professional Director of JPAC (Chair)
Dr Derek Norfolk	(DN)	- Standing Advisory Committee on Clinical Transfusion Medicine
Miss Caroline Smith	(CJS)	- JPAC Manager (Minute taker)
Prof Marc Turner	(MT)	- Medical Director, Scottish National Blood Transfusion Service
Dr Phil Yates	(PY)	- Standing Advisory Committee on Tissues and Cellular Therapy Products

Guests

Mrs Mary Morgan	(MM)	- Director, Scottish National Blood Transfusion Service/Chair of the UK BTS Forum (Observer)
Mr Darren Elvidge	(DE)	- JPAC Website Manager (to demonstrate the JPAC website)

The Chair welcomed Alan Kitchen, representing SACTTI, and Darren Elvidge, invited to demonstrate the new JPAC website, to the meeting.

The Chair informed the group that this would be Victoria Gauden's last meeting and Dr Julia Jenkins would be taking over her role as HTA representative after Christmas. This was also Prof Ian Franklin's last meeting. Ian has been a member of JPAC since 1997 representing SNBTS and, for the last 3 years, the IBTS. Dr Willie Murphy will be rejoining JPAC as the IBTS representative in the New Year.

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|----|------------------|-------------|--|
| 1. | Apologies | | <u>ACTION</u> |
| | Dr Susan Barnes | (SB) | - Standing Advisory Committee on Care and Selection of Donors |
| | Mrs Joan Jones | (JJ) | - Representing the Quality Managers of the 4 UK Blood Services |
| | Mrs Linda Lodge | (LL) | - Standing Advisory Committee on Information Technology |
| | Dr Kieran Morris | (KM) | - Medical Director, Northern Ireland Blood |

ACTION

- Transfusion Service
- Prof James Neuberger **(JN)** - Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
- Dr Lorna Williamson **(LW)** - Medical Director, NHS Blood and Transplant
- Dr Nay Win **(NW)** - Standing Advisory Committee on Immunohaematology
- Prof Maria Zambon **(MZ)** - Director, Centre for Infections, Health Protection Agency (HPA)
2. Minutes of the last meeting held on 4 July 2013 – JPAC 13-59
- The minutes were approved as a true record of the meeting.
3. Matters arising not on the agenda (Review of actions list) JPAC 13-60
- 3.1 **Chapter 13: Donation testing (red cell immunohaematology) 13.11.3 Additional Phenotyping – JPAC 12-70 – item 3.3**
- Unfortunately NW was not able to attend this meeting. Work in progress. **NW**
- 3.2 **JPAC Decision Making Framework – JPAC 13-23 – item 3.9**
- The framework is being discussed at the JPAC Executive Working Group meetings, where it was noted that it was not appropriate for the work of SACIT. SM has asked the SAC Chairs to work through the current version for a couple of topics. The results of these trials will be discussed at the JPAC meeting on 20 March 2014. **SM/CJS**
- 3.3 **Anti Parkinson's disease drugs/Dopamine-receptor agonists and Restless legs syndrome – JPAC 13-39 – item 4.1**
- JPAC endorsed the changes to the Whole Blood Donor Selection Guidelines, as per JPAC 13-39, amending the entries for Central Nervous System Disease and Accept. A change notification will be issued. **JL**
- 3.4 **Correction of the Whole Blood Donor Selection Guideline entries for Chiari Syndrome and Malformation - JPAC 13-40 – item 4.2**
- Post Meeting Note: Change Notification No 22 2013 – Surgery was issued on 17 December 2013.*
- 3.5 **Eurocet 128 – JPAC 13-46 – item 6.1**
- PY informed JPAC that, as requested, he is in the process of setting up a small working group to take this forward. PY will bring a paper back to the next JPAC meeting in March. **PY**
- Prof Ian Franklin arrived at 11:10**
- 3.6 **Shelf-life (when frozen) of FFP, cryoprecipitate, cryodepleted plasma and MB-treated FFP – JPAC 13-47 – item 7.1**
- A Change Notification is in the process of being issued.

3.7 **Extra-corporeal volume tables in the 'red book' 8th edition – item 13.1**

A Change Notification is in the process of being issued.

4. **Standing Advisory Committee on Care And Selection Of Donors**

4.1 **Draft re-writing of Whole Blood and Components Donor Selection Guideline entries – JPAC 13-61**

Mrs Mary Morgan (MM) arrived at 11:22

SM welcomed MM to the meeting, who was attending as an observer.

JL went through this paper for the group and wanted to thank Lynne Chiplin and her colleagues in the WBS for all their hard work on this project.

SM also thanked JL on behalf of JPAC who thought this was a very worthwhile project.

JPAC noted that this was a significant piece of work and that agreement to adopt the new guideline style was needed from all four UK Blood Services.

The following actions were approved:

- SACCSO will produce 20 scenarios for these 10 entries with 'Gold standard' outcomes
- Each service will validate the new DSG entries with appropriate staff
- Outcomes to be tabled at the following JPAC meeting
- Should this validation be acceptable, Change Notifications will be agreed for these entries and they can be used on a day to day basis for a period of 6-9 months. This will allow time to ensure there are no problems encountered with the new entries and to allow the rewriting of a complete new edition of the DSG.

Action: JL will take this forward on behalf of SACCSO

JL

4.2 **Alitretinoin – JPAC 13-62**

JPAC approved the recommendations to:

- 1) Amend the Skin disease DSG entry and the Dermatitis entry.
- 2) Remove d) under obligatory for Skin Disease as it runs counter to e) and causes a lot of confusion.

Post Meeting Note: Change Notification No 20 2013 – Alitretinoin was issued on 17 December 2013.

4.3 **Mental health problems – JPAC 13-63**

Persons with chronic mental health conditions other than anxiety, depression or bipolar disorder, who are still on treatment, are not currently accepted for donation. The medication for these mental health problems is no different than that used for other chronic mental health conditions.

JPAC approved the recommendation to change the wording in the Mental Health Problems topic as per JPAC 13-63. The change will ensure that all donors with

mental health conditions can donate blood if they are well enough to do so and have the mental capacity to give full informed consent.

Action: A Change Notification will be issued

Post Meeting Note: We have been advised to withdraw Change Notification 19 2013, Mental Health Problems, from publication with release 20 of the Whole Blood and Components Donor Selection Guidelines. This is pending further consideration of information received since the draft change notification was approved by the Medical Directors. We hope to issue an amended change notification after the SAC on Care and Selection of Donors has reviewed this new information.

JL

4.4 **South American Trypanosomiasis – JPAC 13-64**

The wording of the “Additional Information” for this topic has caused unnecessary deferrals due to the differing interpretations of the wording “living in poor conditions” in the guidance.

JPAC approved the recommendation to amend the wording as follows:

Additional Information

Infection with *T. cruzi* is very common in many parts of South or Central America and is often symptomless. It can be passed from an infected mother to her unborn baby and by transfusion. The insect that passes the infection on is only common in rural areas and the greater time that an individual has spent living in *housing conditions with thatched roofs or mud lined walls which harbour the insect vector*, the greater their risk of becoming infected. Testing is available and should be performed if there is a possibility of infection. Waiting six months from the last time of exposure allows time for the antibodies that are tested for to develop.

Camping or trekking in the jungle in South or Central America (including Southern Mexico) is not considered of high enough risk to merit exclusion.

Action: A Change Notification will be issued

Post Meeting Note: Change Notification No 21 2013 – South American Trypanosomiasis was issued on 17 December 2013.

4.5 **Carcinoma in Situ – JPAC 13-65**

JPAC approved the recommendation to change the current DSG entry for Malignancy to allow a wider range of carcinomas in situ to be accepted once cured and to clarify the position regarding premalignant conditions.

Action: A Change Notification will be issued

Post Meeting Note: Change Notification No 18 2013 – Malignancy (Tamoxifen and Carcinoma in Situ) was issued on 17 December 2013.

4.6 **Tamoxifen or Raloxifene for breast cancer prevention – JPAC 13-66**

JPAC approved the recommendation that the Malignancy entry is amended to add a further discretion:

e) Potential donors with a high risk of cancer due to family history or following genetic tests, even if had or having prophylactic surgery or on prophylactic medication (e.g. Tamoxifen), accept.

See if Relevant

Surgery

Action: This change will be included in the Change Notification above for Malignancy.

Post Meeting Note: Change Notification No 18 2013 – Malignancy (Tamoxifen and Carcinoma in Situ) was issued on 17 December 2013.

5.

Standing Advisory Committee on Tissues and Cellular Therapy Products
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5.1 **Acute Nephritis Entry in all the Tissues and Cells Donor Selection Guidelines – JPAC 13-67**

PY informed JPAC that the SACTCTP have been reviewing all their guidelines and will be bringing any changes to JPAC in batches.

JPAC approved the change of deferral for this topic to 1 year in the Tissues and Cells DSGs to bring them in line with the entry for blood donors.

Action: A Change Notification will be issued

Post Meeting Note: Change Notification No 10 2014 Kidney Disease has been issued and the changes will go live on the JPAC website on 31 March 2014.

5.2 **Body Piercing Entry in the Bone Marrow & PBSC Donor Selection Guidelines and the Cord Blood Donor Selection Guidelines – JPAC 13-68**

JPAC noted that this change was only to the Bone Marrow and PBSC DSG and the Cord Blood DSG.

The reason for this change was to allow a risk assessment to be performed when the donor is the best match for the recipient.

JPAC approved the recommendation to add a discretionary after “If less than 4 months after last piercing” which says:

Discretionary - If the donor does not comply with the above discuss with the designated medical officer who will decide if the donor may be accepted following a documented risk assessment and discussion with the transplant centre. In this scenario a negative NAT for HBV, HCV and HIV is mandatory as an extra safety check.

Action: A Change Notification will be issued

Post Meeting Note: Change Notification No 4 2014 Body Piercing has been issued and the changes will go live on the JPAC website on 31 March 2014.

5.3 **Complementary Therapy Entry in the Bone Marrow & PBSC Donor Selection Guidelines and the Cord Blood Donor Selection Guidelines – JPAC 13-69**

JPAC noted, as with item 5.2. above, that this change was also only to the Bone Marrow and PBSC DSG and the Cord Blood DSG and the reason for this change was to allow a risk assessment to be performed when the donor is the best match for the recipient.

JPAC approved the recommendation to add a further item under “Discretionary”:

3. If the donor does not comply with any of the above discuss with the designated medical officer who will decide if the donor may be accepted

following a documented risk assessment and discussion with the transplant centre. In this scenario a negative NAT for HBV, HCV and HIV is mandatory as an extra safety check.

Action: A Change Notification will be issued

PY

5.4 **Hepatitis B Entry in the Bone Marrow & PBSC Donor Selection Guidelines and the Cord Blood Donor Selection Guidelines – JPAC 13-70**

JPAC noted that this change was also only to the Bone Marrow and PBSC DSG and the Cord Blood DSG.

The reason for change was to remove the requirement for anti-HBs levels to be >100 iu/l for acceptance of stem cell donations from donors who are anti-HBc-positive provided the HBV DNA result is negative.

Action: A Change Notification will be issued

Post Meeting Note: Change Notification No 7 2014 Hepatitis B has been issued and the changes will go live on the JPAC website on 31 March 2014.

5.5 **Infection – Acute Entry in the Cord Blood Donor Selection Guidelines – JPAC 13-71**

This change is to the Cord Blood DSG only and will align the guidance with that for Bone Marrow and PBSC DSG.

Current guidance states “must not donate if infection occurred during this pregnancy”. As a consequence there are a lot of deferrals for maternal UTIs and minor infections or infections in early pregnancy.

JPAC approved the wording in JPAC 13-71 with one amendment. In “Additional Information”, second sentence, replace the word “better” the word “resolved”.

Action: A Change Notification will be issued

Post Meeting Note: Change Notification No 9 2014 Infection Acute has been issued and the changes will go live on the JPAC website on 31 March 2014.

5.6 **Sarcoidosis Entry in all the Tissues and Cells Donor Selection Guidelines – JPAC 13-72**

This change applies to all the Tissues and Cells DSGs.

JPAC approved the wording in JPAC 13-72 which will bring the TDSGs in line with the entry for whole blood donors.

Action: A Change Notification will be issued

Post Meeting Note: Change Notification No 13 2014 Sarcoidosis has been issued and the changes will go live on the JPAC website on 31 March 2014.

5.7 **Steroids Entry in the Cord Blood Donor Selection Guidelines – JPAC 13-73**

PY went through this paper for the Group. JPAC had some concerns about taking cord blood from neonates with lung problems and asked PY to take this back to SACTCTP.

PY

5.8 **Weight Entry in the Bone Marrow & PBSC Donor Selection Guidelines – JPAC 13-74**

JPAC noted that this change was only to the Bone Marrow and PBSC DSG.

SACTCTP recommended adding a statement under the Discretionary section which says "Potential PBSC donors with a BMI between 35 and 40 should be carefully assessed for other risk factors for cardiovascular disease before they are accepted as suitable."

Reason for this change is to align the guidelines with Anthony Nolan, DKMS (*Delete Blood Cancer [New York, USA]*), NMDP (*National Marrow Donor Program [Minnesota, USA]*), Canadian current guidance and WMDA (*The World Marrow Donor Association*) draft guidance. NMDP is the world's largest listing of potential stem cell donors.

JPAC approved the wording in JPAC 13-74.

Action: A Change Notification will be issued

Post Meeting Note: Change Notification No 16 2014 Weight has been issued and the changes will go live on the JPAC website on 31 March 2014.

6. Standing Advisory Committee on Transfusion Transmitted Infections

6.1 SACTTI HTLV discussion paper: Review of HTLV testing within the UK Blood Services 2013 – JPAC 13-75

AK went through this paper for the Group.

The paper reviews the current situation within the 4 UK Blood Services, taking into account results of 11 years of testing and outlines 4 options for HTLV testing of UK blood donations. These options are:

- 1) Minipool HTLV test all donations in pools of up to 48 donations (current/previous system)
- 2) Individual HTLV test on selected (previously untested) donors
- 3) Individual HTLV test all donations
- 4) Withdraw HTLV test

It was noted that HTLV testing was introduced following an MSBT instruction in 2001 and therefore any decision to change would need to be endorsed by SaBTO.

After a long discussion SM asked AK to put this through the draft JPAC decision making framework and bring it back to the next JPAC meeting in March.

AK

6.2 SACTTI position paper: Duration of blood donation archive sample storage – JPAC 13-76

In 2003 SACTTI produced a position paper for JPAC with the recommendation that each Blood Service should maintain a donation archive to allow the appropriate investigation of haemovigilance incidents.

JPAC 13-76 reviews the current situation and concludes that the 2003 recommendation remains appropriate.

JPAC noted the contents of JPAC 13-76 and it was agreed that SM should submit the paper to the UK Forum for information.

Post Meeting Note: This paper was submitted to the UK BTS Forum Meeting on 6 December for information.

6.3 **Human Partetra Virus (HPTV) risk assessment – version 3 (previously known as Human Parvovirus PARV 4) – JPAC 13-77**

AK went through this risk assessment for the Group.

JPAC Endorsed the recommendation to keep the situation with respect to PARV4 under review and to revise the risk assessment as/when new information becomes available.

7. **SaBTO update – JPAC 13-78**

AB went through this paper for JPAC, which was an update following the SaBTO meeting of the full committee on 17 September 2013.

- SaBTO Tissues and Cells: MSM Donor Selection review was published on the SABTO website on 17 October.

PY informed JPAC that there will be over 20 changes per tissues and cells guideline following this review. SM asked that the changes should be submitted to JPAC for approval.

PY

- A short term working group has been established by SaBTO to consider the effectiveness and cost effectiveness of pathogen inactivation of platelets. The group plan to report to SaBTO in December 2013.

8. **Acupuncture donor deferral criteria – JPAC 13-79**

At the last JPAC meeting on 4 July, donor deferral criteria for acupuncture was discussed following the British Acupuncture Council's accreditation under the new DH voluntary registration scheme. JPAC considered that the position had not changed, and that statutory registration still afforded the best overall guarantee that blood donated by individuals who have been treated with acupuncture is safe.

SM and LW met with Nick Pahl, the CEO of the British Acupuncture Council (BAcC), the BAcC secretary, Christine Braithwaite and another officer from the Professional Standards Authority who manage the voluntary accreditation. We learnt that their code of practice requires single use needles and other hygiene steps and is likely to be safe. At present however there is no data to support that. We proposed a study to establish the incidence of HBV markers after different forms of piercing and are discussing that with the Epidemiology Team.

After a lengthy discussion it was agreed that this should be discussed at the next UK Forum meeting in December.

Post Meeting Note: This was discussed at the UK BTS Forum meeting on 6 December 2013

9. **UK BTS Forum**

9.1. **Report back from the UK BTS Forum meeting on 13 September 2013 – JPAC 13-80**

SM went through this paper for the group.

With regard to Middle East respiratory syndrome coronavirus (MERS-CoV), it was agreed that JPAC no longer needs to receive the 2 weekly updates, but SM asked

SACTTI to continue to monitor the situation and inform JPAC if there are any changes.

Action: **AK**

It was noted that, apart from France, no country has taken any measures with respect to blood donors and the current outbreak and that WHO does not advise special screening at points of entry with regard to this event, nor does it currently recommend the application of any travel or trade restrictions.

10. **Blood Component Labelling – update – JPAC 13-81**

This update was noted.

11. **Any Other Business**

David Carter gave a verbal report from the Competent Authorities on Blood and Blood Components meeting held in Brussels in early November.

He informed JPAC that there will be no amendment to the Blood Directive until 2015 at the earliest.

There were presentations on:

- WNV
- Dengue
- Malaria
- New European rapid alert system for blood issues
- Survey on voluntary unpaid donations
- Hepatitis E – The Commission were very interested in NHSBT study on Hepatitis E and would like feedback on the report
- Upper age limit for donation - a presentation was given on the upper age limit for donation by Finland, which noted fewer adverse events in older donors. Romania won't accept a donor over 55.

Good Practice Guideline – a final version is to be published in December this year and included in the 18th Edition of CoE guide which will be published in 2015, but the Commission wanted to know how it worked in practice before that date.

Risk behaviours – A CoE group will continue to review epidemiological data.

Overview of the blood market survey doesn't seem to be of the quality expected and the Competent Authority has been asked to review their countries data.

12. **JPAC website transfusionguidelines.org.uk**

12.1 **Redevelopment of the JPAC website – update – JPAC 13-84**

JPAC noted the paper.

12.2 **Demonstration of the new website**

DE demonstrated the new website for the group.

13. **Date & venue for future JPAC meetings**

ACTION

2014

- Thursday 20 March – The Association of Anaesthetists, London **New date!**
- Thursday 17 July – The Association of Anaesthetists, London
- Thursday 13 November – The Association of Anaesthetists, London

Meeting closed at : 14:45