JPAC 10-65

Joint UKBTS / NIBSC Professional Advisory Committee [1]
Summary Sheet

1. Paper for the JPAC meeting on:	11 November 2010
2. Date submitted:	28 October 2010
3. Title (including version no.):	Reinstatement of 'non-specific' reactive tissue donors v1
4. Author(s):	H Gillan & P Yates
5. Brief summary:	Around 4% of cadaveric tissue donations are discarded due to a reactive virology marker which can be shown on subsequent confirmatory testing to be negative and therefore a 'false reaction'. The SAC-T are seeking a mechanism to allow the reinstatement of these 'non-specific reactive' donors. There are two possible ways a) sending samples for confirmatory testing by a reference laboratory on all repeat reactive donors and reinstating if the donor is confirmed to be negative (ie a non-specific reactive') b) by using an alternative testing algorithm similar in principle to parallel testing. We propose to initially perform single assay serology testing but then to re-test any 'initial reactive' assay using an alternative manufacturer's assay of equal or better sensitivity. This would then differentiate 'non-specific reactives' which could be reinstated from 'probable infections' which would go on to full confirmatory testing.
6. Action requiredby JPAC: (What do you want JPAC to do in response to this paper?) e.g. • endorse a specific recommendation • advise where there is a choice of possible actions • advise on priorities within the work plan • provide a steer on policy	To endorse the principle of reinstating tissue donors and to recommend which of the two mechanisms should be used to achieve this.
7. Any other relevant information:	This paper was sent to SACTTI for consideration prior to the JPAC meeting in November – please see attached summary report from SACTTI. These proposals were also submitted to SaBTO as part of the consultation process for revision of the document 'Guidance on the microbiological safety of human organs, tissues and cells used in transplantation'. Although not yet issued the revised final draft now allows for alternative assay testing to be performed.

The overall specificity of the serology assays with deceased donor post-mortem samples is lower than the specificity with living donor samples. A study (see attached paper) of 1659 deceased donor samples by the English Blood Service has shown that 5.6% of deceased donor samples are repeat reactive for any one or more of the mandatory screening tests. When confirmatory testing is performed only 13% of these repeat reactive samples can be shown to be positive and over 75% being shown to be negative (when there is sufficient sample for a conclusive result). There are significant differences between blood, tissue and organ donors and the question of risk 'v' benefit must always be taken into account. • For blood there is a surplus of product, the donor can return to donate again, there is little time to perform confirmatory testing and no cost benefit to reinstating an individual donation. • For organs there is a scarcity of donors/donations, no time to perform conventional confirmatory testing and a massive cost benefit in reinstating a donor to obtain a number of organs. This is achieved by the use of 'parallel testing' to detect the 'non-specific reactive' donors who can then be reinstated. • For tissues there are few cadaveric donors and some tissues are in short supply, the tissues can be held in quarantine for months until the results of confirmatory testing are available, and there would be a very large cost-benefit to reinstating an individual 'non-specific reactive' donor with a large number of tissues.	

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1. Paper for the JPAC meeting on:	11 November 2010
2. Date submitted:	22 October 2010
3. Title (including version no.):	Reinstatement of "non-specific" reactive tissue donors v1
4. Author(s):	Pat Hewitt
5. Brief summary:	SACTissues submitted this paper to the July 2010 JPAC meeting. The SACTissues submission requested that JPAC endorse the principle of reinstating tissue donors whose sample has given a reaction in an initial microbiology screening assay, but which reaction is deemed to be "false/ non-specific reactivity", and to recommend which of the two mechanisms should be used to achieve this. JPAC members asked SACTTI to review the paper, and this has now been done. SACTTI agrees that tissue donors can be "reinstated" if, after an initial reactive screening test result is obtained in any of the microbiological tests performed, a second screening assay of equal, or better, sensitivity records negative results. Alternatively, if a sample is repeatedly reactive in the initial screening assay but determined

	negative for evidenc of the infection in question on further testing in a recognised reference laboratory, then the donor may be reinstated and tissue products issued for clinical use. SACTTI expressed no preference for one of the two alternatives as both mechanisms will achieve the same end: if subsequent tests confirm lack of infection then they give assurance that intitial reactivity in the screening assay is due to non-specific reactivity and that any tissue products may be safely issued for clinical use.
6. Action required by JPAC: (What do you want JPAC to do in response to this paper?) e.g. • endorse a specific recommendation • advise where there is a choice of possible actions • advise on priorities within the work plan • provide a steer on policy	Note SACTTI's view and agree that the choice of mechanism used for reinstatement of donors is primarily an operational issue.
7. Any other relevant information:	

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