Joint UKBTS / NIBSC Professional Advisory Committee (1) Summary Sheet

1.	Paper for the JPAC meeting on:	9 th July 2009
2.	Date submitted:	01 July 2009
3.	Title (including version no.):	Pandemic H1N1V influenza mitigating actions v1
4.	Author(s):	Patricia Hewitt for SACTTI
5.	Brief summary:	SACTTI has been sent a number of questions from SNBTS and from SAC CSD about possible mitigating factors to maintain a sufficient supply of blood in the face of an H1N1V influenza pandemic. These questions were discussed at the SACTTI meeting on 11 June 2009.
6.	Action required by JPAC: (What do you want JPAC to do in response to this paper?) e.g.	1. Endorse the advice given by SACTTI.
	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	
7.	7. Any other relevant information:	

(¹) Joint United Kingdom Blood Transfusion Services and National Institute for Biological Standards and Control Professional Advisory Committee

SACTTI Report for JPAC: Pandemic H1N1V influenza mitigating actions: June 2009

SACTTI has been asked to address a number of questions posed by SNBTS and by SAC CSD covering mitigating actions which might be taken to ensure an adequate supply of blood components to meet clincial needs in the face of an H1N1V influenza pandemic. SACTTI considered these questions at its meeting on 11 June 2009.

The questions and responses are listed in this paper.

1. Deferral of donors for 2 weeks following recovery from flu.

This is an EU/ BSQR guideline: deferral for 2 weeks following a febrile illness. SACTTI considered that, during a flu pandemic, the majority of donors who report a recent febrile illness will have suffered from the (pandemic) flu strain. Although viraemia is unlikely in association with H1N1 flu, it may occur. If so, it would occur at the onset of symptoms and would be unlikely to occur after 5 days of symptoms. Viral shedding (eg from the respiratory tract) is also unlikely to occur before the onset of symptoms, but may persist more than 5 days after the onset of symptoms. Although the virus could be non-infectious at this stage, it should be borne in mind that viral shedding from the respiratory tract could expose contacts to the possibility of infection. Viral shedding is unlikely to persist once symptoms have ceased.

From a risk-benefit view point, during a pandemic there would probably be little risk of accepting donors who have suffered a recent flu-like illness, provided that they are completely asymptomatic and have fully recovered from flu. They must also have discontinued any anti-viral treatment.

2. Use of first-time donors for apheresis without any "pre-testing".

Currently, in both UK and Eire, apheresis donations are taken from donors who have been previously tested for mandatory markers. Use of previously untested donors for apheresis donations would necessitate a balance of risk : the risk of lack of platelets to treat patients with clinical bleeding versus the small additional risk of blood-borne virus infection transmission from first-time untested donors. Currently, red cell preparations are prepared and issued from previously untested donors, and such red cell donations may be transfused to the same patient population as apheresis platelets. Recipients are therefore already exposed to the risk of receiving components from previously untested donors, and the additional risk would be dependent on the number of relevant components transfused. An apheresis donor who donated without any pre-testing, but transmitted infection from a first-time donation, would infect a maximum of three recipients. It is assumed that the donor would have sero-converted by the time of the next donation, so there is no further risk from that donor. SACTTI is unaware of any recent data in SHOT of transfusion-transmitted infection from a first-time donated within the window period of infection.

3. Accept donors 4 months after a piercing event.

This is permitted in the BSQR, and there is no reason why it should not be applied, with the additional safeguard of anti-HBc testing to detect a recent (HBsAg negative) HBV infection.

4. Accept donors within 4 months of a piercing event.

There is an EU/ BSQR guideline to defer donors within 4 months of a piercing event. SACTTI is carrying out a review of the risk associated with piercing. Indications from NHSBT data relating to anti-HBc testing for donors who have had a piercing between 6 months and 12 months before donation are that there is no measurable virological risk over the background risk expected in the donor population. That being so, there is no evidence from the testing data that deferral of donors who have undergone piercing is reducing the risk of blood-borne infection over background risk. SACTTI has not completed its review of this subject, but the indications are that in the face of a flu pandemic and blood shortages, acceptance of donors who have had recent skin piercing could be relaxed with little evidence that blood safety would be affected. Further analysis of NHSBT testing data may help in this assessment, but the complete SACTTI review of piercing will not be complete before the next SACTTI meeting in October 2009.

5. Use of non-accredited donors for neonatal/ IUT transfusions.

It is believed that this was an MSBTO recommendation, and the basis for the recommendation has not been seen by SACTTI. The same comments apply as for 3. above.

6. Issue components without specific testing required in the Red Book.

There are already clinical concession routes in place which allow, for example, issue of leucodepleted blood components in place of CMV-tested components.

Questions from SAC CSD (N.B. these questions were not put in writing, so the discussion may not accurately reflect the SAC CSD concern):

1. Reduce the deferral period after a visit to a malaria endemic area to 4 months.

This is already allowed under the EU Directive. It could be adopted during a flu pandemic but the forthcoming NHSBT travel survey may give a good indication of the likely gain of donors if such a change was to be implemented, and therefore the utility of making such a change. Expert advice is that there is little data to distinguish between a 4 month deferral and a 6 month deferral, but most cases of Falciparum malaria will have presented by 6 months, and as this is the main concern in the UK, there is logic in keeping a 6 month deferral under normal circumstances. A change to 4 months could be considered in a pandemic situation, but SACTTI recommends reviewing travel data before deciding whether a change should be made.

2. Reduce the period of deferral after a visit to an area with ongoing WNV activit and/or reduce the WNV season.

SACTTI has already recommended to JPAC that the WNV section of donor selection guidelines in the EU Directive is inappropriate and that specific mention of WNV should be removed, so that travel to a WNV-affected area should be dealt with like all other travel to areas of the world affected by outbreaks of "emerging infections" or disease outbreaks. This has been taken forward by MHRA. Meanwhile, SACTTI believes that the results of the travel survey to be conducted by NHSBT may give valuable information about the current loss of donors through travel to North America, and the possible potential gain in donors if there was to be a change in the deferral period after travel to North America. It is not possible to recommend a shortening in the "WNV season" (currently May to end November) in view of the wide geographic and climatic variation across North America, where there may be snow on the ground in October in one area, while mosquitoes are still active in other areas. Any more detailed attempt at defining the risk area would require changing instructions and changing areas over the months September to November, which is likely to be impossible to implement within collection sites. In 2008, mosquito activity and cases of WNV continued well into October.

SACTTI advice to JPAC: pandemic H1N1V flu Peh/sacttipanflu06.09