

CIRCULAR INFORMATIVA

Nº 05/GDG/09
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Assunto: Alerta urgente vírus West Nile e critérios de selecção de dadores de órgãos, tecidos, células e sangue

Para: Conhecimento a todos os estabelecimentos que colham, preservem ou apliquem órgãos, tecidos, células e sangue

De: Subdirectora-Geral, Dr.^a Margarida Amil

A Autoridade para os Serviços de Sangue e da Transplantação (ASST) recebeu da Comissão Europeia uma actualização relativamente à notificação de casos de infecção pelo **West Nile Virus (WNV)** na Europa.

Lembramos que nesta matéria, se mantêm em vigor os seguintes diplomas:

- a. Circular Normativa n.º 8, de 31.10.2008;
- b. Circular Normativa n.º 10, de 20.11.2008;
- c. Circular Normativa 007/CN-IPS/04 do Instituto Português do Sangue, IP.

A Subdirectora-Geral,



(Margarida Amil)



WNV surveillance and prevention of transfusion transmission in Italy

Communication to DG SANCO 11th August 2009

- **Concerning the local WNV epidemic outbreak occurred in 2008**, we retrospectively estimated the risk of blood donations from viremic asymptomatic donors entering the blood stock.
Applying the statistical model published by Biggerstaff & Petersen¹, based on the incidence of human neuroinvasive cases and their overall length, the average risk of blood donation by viremic asymptomatic donors was estimated at **2.2/10,000 donations**.
We also applied an internally generated statistical model² starting from seroprevalence in blood donors (according to a study carried out on 8,000 blood donors from the area of Ferrara in 2008-2009, seroprevalence was 0.77%). With this model the average estimated risk of blood donations by viremic asymptomatic donors was **3.6/10,000 donations**. Hence, the overall average dimension of the risk in Summer-Autumn 2008 estimated by the Biggerstaff-Petersen model was confirmed starting from seroprevalence in blood donors.
As previously reported³, WNV NAT testing on blood donations in at risk areas was started end September and discontinued beginning of December, 2008. No NAT positive donors were detected, most probably because the probability to detect viremic asymptomatic donors is very significantly related to the peak of activity of vector insects, which in Italy occurs in midsummer.
- **Concerning the prevention of the transmission of WNV infection by transfusion in 2009**, epidemiological surveillance in the at risk areas (provincial districts of Ferrara, Rovigo and Mantua) has been started since late Spring, by entomological and wild bird surveillance. Surveillance on horses is now less helpful, as most horses have been vaccinated. Active surveillance of human neuroinvasive WNV has been restarted in the regions of Emilia Romagna (Ferrara), Veneto (Rovigo) and Lombardy (Mantua).
For the prevention of the transmission of WNV infection by transfusion it was decided to adopt the same criteria adopted in 2008, i.e. temporary introduction of NAT testing in the pertinent at risk area and 28 day deferral of blood donors having been for at least one night in the same area, immediately after the notification of the first human neuroinvasive WNV case. As previously reported³, the introduction of NAT testing is justified by the fact that discontinuing blood donations in any Italian northern area - especially in the middle of Summer - would cause critical regional shortages in the blood supply and possibly significant national shortages, as several northern blood centres critically supply some southern regions year round. Furthermore, it was decided to experimentally introduce WNV NAT testing on all blood donations from donors resident in the provincial districts of Ferrara, Rovigo and Mantua and to serologically test a significant number of them, in the period 1st Aug – 30th Oct. This decision was taken considering the 2008 estimates of the risk of collecting blood and blood components from viremic asymptomatic donors, the first

¹ Biggerstaff BJ, Petersen RL. *Estimated risk of transmission of West Nile Virus through blood transfusion in the US, 2002*. *Transfusion*. 2003 Aug;43(8):1007-17

² Pupella S, Panetta V, Grazzini G. Italian National Blood Centre and Biostatistics Unit, Research Foundation "Fatebenefratelli" – Rome, Italy.

³ Grazzini G, Liumbruno GM, Pupella S, et Al. *West Nile virus in Italy: a further threat to blood safety, a further challenge to the blood system*. *Blood Transfus*. 2008 Oct;6(4):235-7.

results of entomological surveillance, and in order to obtain as much information as possible about this year's circulation of the virus in blood donors in at risk areas, in order to enhance decision making ability for next year(s).

Following the introduction of NAT testing, it was also decided to consider the first WNV NAT positivity in an asymptomatic blood donor as a trigger to implement the 28 day deferral provision related to the involved provincial district, independent from the occurrence/notification of human neuroinvasive WND cases.

All the above decisions were shared by the regional public health and blood authorities of Emilia Romagna, Veneto and Lombardy, the National Blood Centre and the Department of Prevention of the Ministry of Labour, Health and Social Policies.

- On 4th August the first WNV NAT positive blood donation from an asymptomatic donor resident in the area of Mantua was detected by the Blood Centre of Mantua.

Following the confirmation and official notification of the above positivity, on 7th August the Italian National Blood Centre indicated a 28 day deferral for all donors having been for at least one night in the provincial district of Mantua. Provision to be applied nationwide.

Update as of 10th September 2009

- During the month of August the regional public health authorities of Emilia Romagna communicated to the National Blood Centre that the results of entomological surveillance indicated a significant degree of positivity of WNV PCR tests carried out on mosquito captures, and a significantly high overall concentration of mosquitoes in several monitored areas of the region.
- On 31st August the second WNV NAT positive blood donation from an asymptomatic blood donor was notified from the Blood Centre of Rovigo, and 3 cases of human neuroinvasive WND were notified interesting respectively two patients resident in the provincial district of Ferrara and one patient resident in the provincial district of Mantua.
- On 1st September 1 case of human neuroinvasive WND in a patient resident in the city of Modena was notified; Modena is located in the Emilia Romagna region, neighboring the provincial districts of Ferrara and Mantua.
- Blood donations were not discontinued in the provincial area of Modena as WNV NAT testing was immediately implemented. WNV NAT testing was implemented also on blood donations from donors resident in the neighboring provincial districts of Bologna and Reggio Emilia.
- On 3rd September 1 case of human neuroinvasive WND in a patient resident in the provincial district of Rovigo was notified.
- On 5th September WNV NAT positivity was detected in a solid organ donor resident in the provincial district of Reggio Emilia [information from the Italian National Transplant Centre].
- On 7th September 1 more case of human neuroinvasive WND was notified in a patient resident in the provincial district of Ferrara.
- On 9th September 2 additional cases of human neuroinvasive WND were notified respectively in a patient resident in the provincial district of Ferrara and in a patient resident in the provincial district of Bologna.
- Blood donations were not discontinued in any of the above provincial districts because they were covered by WNV NAT testing.

- On 31st August the National Blood Centre indicated the application (nationwide) of 28 day deferral of blood donors having been for at least one night in the provincial districts of Rovigo and Ferrara (the same indication about Mantua had already been issued on 7th August).
- On 1st September the National Blood Centre indicated the application (nationwide) of 28 day deferral of blood donors having been for at least one night in the provincial district of Modena.
- On 10th September the National Blood Centre has indicated the application (nationwide) of 28 day deferral of blood donors having been for at least one night in the provincial districts of Bologna and Reggio Emilia.
- Adequate preventive measures for the prevention of WNV transmission were applied to cord blood and haematopoietic stem cell donations as well.

A summary of the above information and a geographical reference map are reported at page 4.

Giuliano Grazzini, MD
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September, 10th, 2009

SUMMARY
as of 10th September 2009

Provincial Districts	WNV NAT testing of blood donations in place	WNV NAT positive blood (b) / organ (o) donors	Notified cases of human neuroinvasive WND	Provisions to be applied nationwide (blood system)
Ferrara	Since 1 st Aug	0	4	28 day deferral of blood donors having been for at least one night in these provincial districts
Rovigo		1 (b)	1	
Mantua		1 (b)	1	
Modena	Since 1 st – 3 rd Sept	0	1	
Bologna		0	1	
Reggio Emilia		1 (o)	0	

Geographical reference

