

HPA Press Statement

18 January 2007

4th case of variant CJD infection associated with blood transfusion

A new case of variant-Creutzfeldt-Jakob disease (vCJD) associated with a blood transfusion has recently been diagnosed.

This latest patient has been diagnosed with vCJD about nine years after receiving a blood transfusion from a donor who later went on to develop vCJD. A transfusion from the same blood donor was also associated with one of the previously identified cases. The patient is still alive and is under specialist care.

This fourth case of vCJD infection associated with blood transfusion increases the concern about the risk of vCJD transmission between humans via blood transfusion. All four cases relate to the transfusion of blood components: no cases have been reported relating to treatment with plasma products.

The patient is one of a small number (less than 30) of living individuals who are known to have received a blood transfusion in the UK from a donor who later developed vCJD. All these individuals have previously been informed of their potential exposure to vCJD and asked to take certain precautions to reduce the chance of passing on vCJD to other people via healthcare procedures, such as surgery.

The Health Protection Agency has been in contact with doctors caring for the other patients who have been exposed to blood transfusions from donors who later developed vCJD. This is to ensure that they are informed of this new development and provide access to the latest information and specialist advice about their risk due to blood transfusion.

Professor Peter Borriello, Director of the HPA's Centre for Infections said, "This new case of vCJD infection increases our concern about the risk to the small group of people who had blood transfusions from donors who unknowingly at the time of donation must have had vCJD infection. However, this new case does not change our understanding of the risk for other people in any specific way. It does however reinforce the importance of the precautions that have already been taken to reduce the risk of transmission of vCJD infection by blood."

Dr Angela Robinson, Medical Director of NHS Blood and Transplant said, "Blood transfusions are often given to save or prolong the life of patients who are very ill and the benefit of receiving a transfusion when needed must always be balanced against any possible risk. Nonetheless, our primary concern is the safety of our patients through maintaining the quality of blood used for medical treatment. Since 1997, the NBS has introduced a range of precautionary measures against the risk of vCJD."

vCJD is a rare disease, and less than 2% of the vCJD cases reported to date in the UK have been associated with blood transfusion.

Notes to Editors:

1. To date, there have been 66 people identified in the UK who have received vCJD implicated blood transfusions. The transfusions received by these 66 individuals were donated by eighteen different donors who were diagnosed with vCJD after their blood donation. Of these 66 people, 40 have died of illnesses other than vCJD, including one patient who was found to have evidence of vCJD in parts of their body after their death. Including the new (4th) case, 3 of these people who have received vCJD implicated blood transfusions have developed symptoms of vCJD. There are 23 people who have received vCJD implicated blood transfusions who are alive and have not been diagnosed with vCJD.
2. The identification of cases of variant-CJD associated with blood transfusion has depended on the Transfusion Medicine Epidemiology Review, a collaborative study between the National Blood Services, the National CJD Surveillance Unit and the Office of National Statistics. For further information about this study see Hewitt *et al* Creutzfeldt-Jakob disease and blood transfusion: results of the UK Transfusion Epidemiology Review study. *Vox Sanguinis* 2006 91:221-230.
3. 'Blood Transfusion' means transfusion with labile blood components (e.g. red cells, platelets, fresh frozen plasma). This latest case (and the previous three referred to) relate to transfusion of blood components and not treatment with plasma products (i.e. products that are manufactured from plasma). To date, no case of vCJD has been associated with treatment with plasma-products (e.g. clotting factors used to treat individuals with bleeding disorders such as haemophilia).
4. This fourth case has been classified by the National CJD Surveillance Unit (www.cjd.ed.ac.uk) as a 'probable' case of vCJD. Of the 158 vCJD cases that have died (data to 5 Jan 2007), all 112 that have undergone post-mortem (46 have not) have been 'confirmed' by neuropathological examination (examination of brain tissue).
5. The first clinical case of vCJD associated with transfusion was identified in December 2003. A case of vCJD 'infection' associated with transfusion was identified a few months later. The patient had no symptoms but evidence of infection (abnormal prion proteins) was identified in a post mortem

investigation. The individual died from causes unrelated to vCJD.

6. Following the first case of vCJD associated with a blood transfusion in 2003, the Department of Health asked all recipients of blood transfusions not to donate blood as a precautionary measure to protect the blood supply from vCJD.
7. Patients who are informed that they are considered to be 'at risk' of vCJD for public health purposes are asked to take the following precautions to reduce the chance of passing on vCJD to other people:
 - Not to donate blood, tissues or organs and
 - To inform their healthcare providers of their 'at-risk' status so that special procedures may be arranged for certain instruments used in their healthcare (NB. Their GPs are also asked to do this.)
8. A range of measures have been put in place by the Department of Health to minimise the possible risk of vCJD being passed through blood:
 - Since 1997 all cases of vCJD that are reported to the National CJD Surveillance Unit and diagnosed as having 'probable' vCJD, result in a search of the UK Blood Services blood donor records. If the patient has donated blood, any unused parts of that blood are immediately removed from stock. The fate of all used components of blood from the donor is traced, and surviving recipients informed of their risk.
 - In July 1998, the Department of Health announced that plasma for the manufacture of blood products, such as clotting factors, would be obtained from non-UK sources.
 - Since October 1999, white blood cells (which may carry the greatest risk of transmitting vCJD) have been removed from all blood used for transfusion.
 - In August 2002 the Department of Health announced that fresh frozen plasma for treating babies and young children born after 1 January 1996 would be obtained from the USA, extended to all children under 16 years of age (Summer 2005).
 - In December 2002, the Department of Health completed its purchase of the largest remaining independent US plasma collector, Life Resources Incorporated. This secures long-term supplies of non-UK blood plasma for the benefit of NHS patients.
 - Since April 2004, blood donations have not been accepted from people who have themselves received a blood transfusion in the UK since 1980. This has been extended to include apheresis donors and donors who are unsure if they had previously had a blood transfusion (August 2004).
 - Since late 2005, blood donations have not been accepted from donors whose blood was transfused to patients who later developed vCJD.
 - The UK Blood Services continue to promote the appropriate use of blood and tissues and alternatives throughout the NHS.
9. The likelihood of a person who may be infected with vCJD going on to develop symptoms of the disease is uncertain, and may depend on individual susceptibility. It is possible that infected individuals may never develop symptoms.
10. For further information contact the HPA press office on 0208 327 7098/7097/6055
11. Specialist care for vCJD is available from The NHS National Prion Clinic, based at The Hospital for Neurology and Neurosurgery, Queen Square, London <http://www.nationalprionclinic.org/>
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13. For further information about vCJD go to:
 - http://www.hpa.org.uk/infections/topics_az/cjd/menu.htm
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医薬品 研究報告 調査報告書

識別番号・報告回数		報告日	第一報入手日	新医薬品等の区分	総合機構処理欄
一般的名称	輸血	研究報告の 公表状況	http://www.hpa.org.uk/hpa/news/articles/press_releases/2007/070118_vCJD.htm	公表国	
販売名(企業名)	—			英国	
研究報告の概要 771	<p>英国において輸血に関連する変異型クロイツフェルト・ヤコブ病 (vCJD) の新規症例 (4 例目) が診断された。この患者は、後に vCJD を発症したドナーからの輸血を受けて、約 9 年後に vCJD と診断された。同じドナーからの輸血は、以前に判明した 3 症例のうちの 1 例とも関連があった。患者は生存しており、専門医ケアを受けている。</p> <p>この 4 例目の輸血関連 vCJD 感染症例により、輸血を介したヒト-ヒト間での vCJD 伝播のリスクについての懸念が増大している。4 症例はすべて血液成分輸血に関連している。血漿製剤投与と関連する症例は報告されていない。英国健康保護局 (HPA) の Centre for Infections の Director である Peter Borriello 教授は「この vCJD 感染症例は、供血時に vCJD 感染をしていたドナーからの輸血を受けた、少数の人々へのリスクに関する懸念を増大させる。血液から vCJD が伝播されるリスクを減じるためには、既に講じられている予防措置が重要である。」としている。vCJD は稀な疾患であり、今までに英国で報告された vCJD 症例の 2% 未満が輸血と関連づけられている。</p> <p>エディターの注記 「輸血」とは、血液成分 (例えば、赤血球、血小板、新鮮凍結血漿) の輸注を意味する。これまで報告されている 4 例は血液成分の輸血と関連し、血漿分画製剤 (すなわち、血漿から製造される製品) の投与とは関連しない。現在まで、血漿分画製剤 (例えば、血友病のような出血性疾患を有する患者を治療するために用いられる凝固因子) の投与に関連づけられた vCJD 症例は 1 例もない。</p>				<p>使用上の注意記載状況・ その他参考事項等</p> <p>重要な基本的注意 現在までに本剤の投与により変異型クロイツフェルト・ヤコブ病 (vCJD) 等が伝播したとの報告はない。しかしながら、製造工程において異常プリオンを低減し得るとの報告があるものの、理論的な vCJD 等の伝播のリスクを完全には排除できないので、投与の際には患者への説明を十分行い、治療上の必要性を十分検討の上投与すること。</p>
	報告企業の意見	今後の対応			
英国における輸血による 4 例目の vCJD 症例の報告である。現時点まで血漿分画製剤からの vCJD 伝播の報告はない。また、異常プリオン蛋白については、血漿分画製剤の製造工程で除去できるとの考え方がある。	今後とも vCJD に関する安全性情報等に留意していく。				

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The patient is one of a small number (less than 30) of living individuals who are known to have received a blood transfusion in the UK from a donor who later developed vCJD. All these individuals have previously been informed of their potential exposure to vCJD and asked to take certain precautions to reduce the chance of passing on vCJD to other people via healthcare procedures, such as surgery.

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医薬品 研究報告 調査報告書

<p>識別番号・報告回数</p>			<p>報告日</p>	<p>第一報入手日 2007. 1. 22</p>	<p>新医薬品等の区分 該当なし</p>	<p>機構処理欄</p>
<p>一般的名称</p>	<p>(製造承認書に記載なし)</p>		<p>研究報告の公表状況</p> <p>L. Sawyer, R. Mababangloob, N. Patel, J. Kinsey, A. Sampson-Johannes, D. Hanson. American Society of Hematology Annual Meeting</p>		<p>公表国</p>	
<p>販売名(企業名)</p>	<p>合成血「日赤」(日本赤十字社) 照射合成血「日赤」(日本赤十字社) 合成血-LR「日赤」(日本赤十字社) 照射合成血-LR「日赤」(日本赤十字社)</p>				<p>米国</p>	
<p>研究報告の概要 777</p>	<p>○赤血球中の病原体のS-303およびグルタチオンを用いた改良処理法による不活化 背景:S-303 (アクリジン化合物) 0.2mMおよびグルタチオン(GSH) 2.0mMを用いた赤血球(RBC)の処理により、ウイルス、細菌、寄生虫を含む様々な病原体および混入白血球を不活化することが示されている。PhaseIII臨床試験中、S-303処理RBCの表面に結合した残存アクリジンに特異的な抗体が数名の被験者に検出され、免疫原性を低減するために改良S-303処理法が開発された。改良された工程ではS-303 0.2mMおよびGSH 20mMを用いる。ここでは改良S-303処理法を用い、RBC中の細菌およびウイルス不活化の有効性を評価するためにデザインした現行試験から得られたデータを報告する。 方法:AS-3保存液中に白血球除去したRBC約280 mL(ヘマトクリット約60%)を調製した。RBCに約6logs/mLの病原体を添加し、処理を施していない病原体添加コントロールを分取した。これに、GSHを加えてよく攪拌した。室温で5~10分間インキュベートした後、サンプルを取り出し、残存生菌を検出する分析を行った。コントロール溶液は、調製直後に力価を測定し、その後病原体添加3時間後に再度力価測定した。試験には輸血に関連するグラム陽性菌およびグラム陰性菌、マイナス鎖RNAウイルスとして Vesicular stomatitisウイルス、非エンベロープDNAウイルスとしてAdenovirus 5を用いた。また、HIVおよびウシウイルス性下痢ウイルス(HCVのモデル)の不活化を評価した。各微生物について反復実験を実施し、得られた結果を観察された不活化レベルの平均±標準偏差(SD)で示した。不活化はlog reductionで表した。 結果:グラム陽性菌およびグラム陰性菌、エンベロープ、非エンベロープウイルスのいずれも改良S-303処理により十分に不活化された。 結論:当該改良S-303処理は、RBC中の細菌およびウイルス病原体を効果的に不活化する。</p>					<p>使用上の注意記載状況・ その他参考事項等</p> <p>合成血「日赤」 照射合成血「日赤」 合成血-LR「日赤」 照射合成血-LR「日赤」</p> <p>血液を介するウイルス、 細菌、原虫等の感染 vCJD等の伝播のリスク</p>
<p>報告企業の意見</p>			<p>今後の対応</p>			
<p>S-303およびグルタチオンを用いた改良処理法によって赤血球製剤中の細菌およびウイルス病原体が効果的に不活化されたとの報告である。</p>			<p>日本赤十字社では、輸血情報リーフレット等により、細菌感染やウイルス感染について医療機関へ情報提供し注意喚起している。また、「血液製剤等に係る適及調査ガイドライン」(平成17年3月10日付薬食発第0310009号)における「本ガイドライン対象以外の病原体の取扱い。細菌」に準じ細菌感染が疑われる場合の対応を医療機関に周知する。 今後も細菌やウイルスを不活化する方策について情報の収集に努める。</p>			

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Abstracts Not Selected for Presentation

Inactivation of Pathogens in Red Blood Cells by a Modified Treatment Process Utilizing S-303 and Glutathione.

L. Sawyer^{1,*}, R. Mababangloob^{1,*}, N. Patel^{1,*}, J. Kinsey^{1,*},
A. Sampson-Johannes^{1,*} and D. Hanson^{1,*}

(Intr. by Laurence Corash)¹ Development, Cerus Corporation, Concord, CA, USA.

Abstract

Background: Treatment of red blood cells (RBC) with 0.2 mM S-303 (an acridine compound) and 2.0 mM glutathione (GSH) has previously been shown to inactivate a variety of pathogens, including viruses, bacteria, protozoan parasites and contaminating leukocytes. During Phase III clinical trials antibodies to S-303-treated RBC were detected in a few trial participants. These antibodies were later determined to be specific to residual acridine bound to the RBC surface. As a result of these antibodies, a modification of the S-303 treatment process has been developed to reduce the potential immunogenicity of S-303-treated RBC. This modified process utilizes 0.2 mM S-303 and 20 mM GSH. In this abstract we report data from an ongoing series of studies designed to evaluate the efficacy of bacterial and viral inactivation in RBC using the modified S-303 treatment process.

Methods: Leukoreduced RBC units of approximately 280 mL with a hematocrit of approximately 60% were prepared in AS-3 storage medium. RBC units were inoculated with approximately 6 logs/mL of organism when possible, and an aliquot was removed to serve as the untreated, input control. GSH in a solution of 2 equivalents NaOH was added to the inoculated units to a final concentration of 20 mM and mixed well. Following a 5 to 10-minute room temperature incubation, S-303 was added to a final concentration of 0.2 mM and the units were again mixed well and incubated at 20 to 25 °C for three hours. After incubation, samples were removed and assayed to detect residual viable organisms. Control preparations were titered immediately after preparation and again after the 3-hour incubation. Bacterial titers were determined by colony formation on agar plates and viral titers were determined by plaque formation in MT-2 cells (HIV), BT cells (BVDV), vero E6 cells (VSV) and A549 cells (Adenovirus). Bacteria were chosen to represent Gram positive and Gram negative organisms of relevance to transfusion. Vesicular stomatitis virus (VSV) was used as a representative negative sense RNA virus, and Adenovirus 5 as a representative non-enveloped DNA virus. HIV and bovine viral diarrhea virus (BVDV, model for HCV) inactivation was evaluated because of their relevance to blood transfusion. Replicate experiments were performed for each organism and the results are expressed as the mean and standard deviation (SD) of the observed inactivation levels. Inactivation is expressed as log reduction.

Results: See table below. Both Gram positive and Gram negative bacteria were effectively inactivated by treatment with the modified S-303 process. This process also resulted in effective inactivation of both the enveloped and non-enveloped viruses tested.

Conclusion: The modified S-303 process effectively inactivates bacterial and viral pathogens in RBC.

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Organism	Log Reduction ^a (Mean ±SD)
Staphylococcus aureus	≥6.9 ±0.4
Staphylococcus epidermidis	≥7.0 ±0.1
Yersinia enterocolitica	4.1 ±0.8
Escherichia coli	6.1 ±0.7
Serratia marcescens	4.0 ±0.4
HIV	>5.8 ±0.2
BVDV	>4.4 ±0.2
Vesicular stomatitis virus (VSV)	4.2 ±0.1
Adenovirus 5	≥8.0 ±0.3

Footnotes

^a Corresponding author

Disclosures: Cerus Corporation Employee.; Cerus Corporation Stock Options.

医薬品 研究報告 調査報告書

<p>識別番号・報告回数</p>			<p>報告日</p>	<p>第一報入手日 2006. 11. 20</p>	<p>新医薬品等の区分 該当なし</p>	<p>機構処理欄</p>
<p>一般的名称</p>	<p>(製造承認書に記載なし)</p>		<p>研究報告の公表状況</p>	<p>ProMED 20061118-3303, 2006 Nov 18. 情報源:Daily Yomiuri Online, 2006 Nov 18.</p>	<p>公表国</p>	
<p>販売名(企業名)</p>	<p>合成血「日赤」(日本赤十字社) 照射合成血「日赤」(日本赤十字社) 合成血-LR「日赤」(日本赤十字社) 照射合成血-LR「日赤」(日本赤十字社)</p>				<p>日本</p>	
<p>研究報告の概要</p>	<p>○フィリピンでイヌにかまれた京都の男性が狂犬病で死亡 2006年11月17日、京都府の保健所は、京都市の60歳代の男性がフィリピンで犬にかまれ、帰国後に狂犬病を発症して死亡したと発表した。 厚労省によると、日本人が国内で狂犬病を発症したのは36年ぶりである。 厚労省によると、男性はフィリピン滞在中の8月末に野良犬にかまれ、11月1日に帰国した。9日に風邪のような症状で京都市内の病院を受診した。その後、幻覚症状、水や風を怖がるなど狂犬病特有の症状を発症した。国立感染症研究所が調べたところ、男性の唾液から狂犬病ウイルスが検出された。</p>					<p>使用上の注意記載状況・ その他参考事項等</p>
						<p>合成血「日赤」 照射合成血「日赤」 合成血-LR「日赤」 照射合成血-LR「日赤」 血液を介するウイルス、 細菌、原虫等の感染 vCJD等の伝播のリスク</p>
<p>報告企業の意見</p>			<p>今後の対応</p>			
<p>京都市の60歳代の男性がフィリピンで犬にかまれ、帰国後に狂犬病を発症して死亡したとの報告である。</p>			<p>日本赤十字社では、輸血感染症対策として問診時に海外渡航歴の有無を確認し、帰国後4週間は献血不適としている。また、動物に嘔まれた場合は3ヶ月間供血不可としている。今後も引き続き、新興・再興感染症の発生状況等に関する情報の収集に努める。</p>			

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From: Akira Goto <dolphin@mail.ne.jp>

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A Kyoto resident in his 60's died of rabies on his return to Japan after a stray dog bit his hand in the Philippines, the Public Health and Welfare Bureau in Kyoto announced on Fri 17 Nov 2006. The man, who fell into a coma before his death, was the first Japanese to be diagnosed with the virus in 36 years, the Health, Labor and Welfare Ministry said.

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According to the ministry, the man was bitten by the dog at the end of August [2006] and returned to Japan on 1 Nov 2006. He visited a doctor in Kyoto on 9 Nov 2006 with cold [flu-like?] symptoms before developing characteristic signs of rabies such as hallucinations and a fear of water and wind.

The National Institute of Infectious Diseases diagnosed the man with rabies after testing his saliva.

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Akira Goto

<dolphin@mail.ne.jp>

[Akira Goto has provided the following additional information translated from a press release in Japanese from the Ministry of Health, Labour and Welfare (<<http://www.mhlw.go.jp/houdou/2006/11/h1116-2.html>>). "The 1970 human case was also an imported case from Nepal; the most recent domestic human and canine rabies cases in Japan were reported in 1954 and 1956, respectively."

PromED-mail greatly appreciates Akira Goto's initiative in providing this information. - Mod.CP]

{see also:

2002

Rabies, imported dogs - Japan: alert [20021229.6150](#)

.....cp/pg/dk

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