医薬品　研究報告 調査報告書

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研究報告の概要

フランスで８例目の変異型クロイツフェルト・ヤコブ病（vCJD）患者が確認され、10年間に10回の供血をしていたことがわかった。保健当局は「患者は、まだ存命中の若年者（氏名、年齢、性別は未公表）で、1993年から2003年の間に数回にわたって供血を行なっていた」と発表した。
供血された血漿は、フランスのLFB社で血漿分画製剤88バッチに使用され、流通中の16のバッチを回収したが、残りはすでに使用または廃棄されていた。しかしながら保健当局は血漿分画製剤を介してvCJDが感染する証拠はないと強調した。
フランスで８例目のvCJD患者であるが、初の供血していた例であり、他の７人は供血していなかった。
イギリスの２人のvCJDのケースは、輸血を介して伝播する可能性が増したことを示したが、血漿分画製剤による伝播の危険性は明確になっていないと保健当局は述べている。

使用上の注意記載状況・その他参考事項等

報告企業の意見	今後の対応
現時点まで異常プリオン蛋白を含む可能性のある原料血漿由来の血漿分画製剤からのvCJD伝播の報告はない。また、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。	今後ともプリオン蛋白除去等の安全対策に関する情報収集に努めていく。

Simian Foamy Virus (continued from page 5)

Canadians Invoke Precautionary Principal. As the FDA panel deliberated, the Canadian government issued a statement announcing that new research has shown that simian foamy virus can be transmitted through blood from one non-human primate. This creates "an emerging issue related to safety and adequacy of Canada's blood supply," the Canadian Government said in a statement from the Public Health Officer (10/21/04).

> **The agency has completed an assessment of the risk of simian foamy virus to the blood supply and advised Health Canada that although there are no known risks, "it would be prudent to take action to ensure that simian foamy virus does not enter the blood system."**

According to the statement, "Health Canada is considering action to reduce the potential for entry of simian foamy virus in the blood supply. This could include precautionary measures to screen for people who may be at risk of having simian foamy virus. Options include asking those who work closely with non-human primates to not give blood, or screening them out in the interview process before a donation."

> **"Once the new scientific information has been fully analyzed by the Public Health Agency and by Health Canada, and that the impact of potential risk mitigation measures on the safety of the blood supply have been fully evaluated, Health Canada will make a decision on any necessary precautionary measures," the Canadian government said.**

The Canadian Public Health Agency reminded people who work with animals to follow occupational safety precautions to minimize their risk of exposure to simian foamy virus. Occupations that have "some risk" of infection include people who work in zoos, public or private biomedical research institutions and animal sanctuaries, the agency said.

Based on current available information, pet owners of monkeys are not at risk of exposure to simian foamy virus because the New World monkeys usually kept as pets are not known to transmit the virus, the Canadian government said. "However, if pet owners are bitten or scratched, they should follow standard first aid precautions. As with other animals, other infections are possible. Signs of infection, or if the animal is ill, should prompt medical consultation."

There is no diagnostic test for human simian foamy virus infection, but since no illness has been associated with infection, there is no need for exposed people to be tested, the Canadian Public Health Agency said. The agency said "it will continue to examine this public health issue as new information becomes available and will continue further research in this area."

Additional information on Simian Foamy Virus is available on the Canadian Government Web site at: www.news.gc.ca/cfmx/CCP/view/en/index.cfm?articleid=103939 ♦

France's Eighth vCJD Victim Was Blood Donor, Health Authorities Announce

An individual who donated blood 10 ten times in a 10-year period has been identified as France's eighth known sufferer of variant Creutzfeldt-Jakob disease (vCJD), health officials announced yesterday. According to media reports, French authorities are working to identify the 10 recipients of the donors' blood and contact their doctors who will inform them in coming days that they may have been exposed to the disease, said Jean-Francois Riffaud, MD, of France's national blood service. The physicians will also tell them about precautions they should take to avoid exposing other people should they be infected with vCJD.

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French Blood Donor has vCJD (continued from page 6)

A ministry spokesman said the patient was "a young person who is still alive." The person's name, age and gender have been withheld. The individual gave blood "several times between 1993 and 2003," the health ministry said in a statement.

Plasma from the donations was used by a French company, LFB, to make 88 batches of derivatives, enough for several thousand people. LFB has identified 16 batches that remained in circulation and re-called them. The rest were either used or were destroyed. The French health authorities emphasized, however, that there is no proof that vCJD can be transmitted through plasma derivatives.

This is France's eighth case of vCJD but the first blood donor. None of the other seven people known to be infected with vCJD in France were blood donors.

The case of two people in Britain with vCJD pointed to an "increased risk" of contracting the disease through blood transfusion, although the risk of infection through blood derivatives remained unclear, pending the outcome of research, the French health department said. (Sources: Agence France Presse, Associated Press,10/21/04) ♦

North Americans Addressing vCJD Risk from UK Plasma

In a recent and highly precautionary measure, the UK Health Protection Agency began informing the recipients of certain plasma products, prepared from UK plasma, that they may face a slightly increased risk of developing variant Creutzfeldt-Jakob Disease (vCJD), the human form of mad cow disease.

The action follows the discovery that vCJD may have been transmitted through blood transfusions in two recipients. The UK Health Protection Agency previously had examined cases of patients diagnosed with vCJD and found that several of the vCJD patients had been blood donors between 1980 and 2001.

Plasma from these donations was manufactured by two companies – Bio-Products Laboratory (BPL) and Protein Fractionation Centre – into blood derivatives. The UK Health Protection Agency now is notifying patients in the UK who have been infused with plasma products derived from UK plasma about their potential risk for vCJD.

The US National Hemophilia Association now is seeking to learn if any US hemophilia patients used factor XI manufactured by BPL.

According to a National Hemophilia Foundation *Medical Advisory* (#401, 9/27/04), neither of the two companies were licensed by the US Food and Drug Administration to distribute products in the United States. But UK plasma products, particularly factor XI, may have been brought into the US for use in clinical trials or for compassionate or personal use, NHF said.

NHF is seeking to learn whether any US clinical studies used UK plasma products. The association has asked anyone who suspects they may have used a UK plasma product between 1998 and 2001 or anyone who lived or visited the UK during 1980 to 2001 and used UK plasma products during that time to contact their hemophilia treatment center.

According to NHF, the last year the potentially infected product was produced was 1998, but the risk extends to the 2001 expiration date for these products. UK plasma products manufactured after 1998 did not use plasma collected from UK donors.

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一般的名称	－		研究報告の公表状況	CDR Weekly 14(39), 2004.9.23	公表国 英国	
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研究報告の概要	使用上の注意記載状況・その他参考事項等
CJD伝播管理の専門家委員会(CJDIP)は、汚染された血漿由来製剤による変異型クロイツフェルト・ヤコブ病(vCJD)のリスク管理に関する勧告を発表した。現在まで英国で9人の供血者がvCJDを発病したことが知られており、これら供血者より23件の血漿供与が行われた。その血漿は第Ⅷ因子、第Ⅸ因子、アンチトロンビン、静注用免疫グロブリン、アルブミン、筋注用ヒト免疫グロブリンおよび抗Dグロブリンの製造に用いられたが、これまでのところ受血者にvCJDが伝染したとの記録はない。2004年7月に2例目の輸血によるvCJD感染疑い例が確認され、血液による感染の懸念が大きくなっている。供血後vCJD発病者由来の血漿由来製剤受血者の一部については、他者にリスクをもたらす可能性があることから公衆衛生予防措置(血液や臓器、組織などを供与しないこと、外科手術、歯科治療が必要な場合は医師に知らせることなど)が必要と勧告した。 また、公衆衛生予防措置を要する可能性に応じ、汚染された血漿由来製剤のバッチを「高、中、低」に分類すると共に、vCJDリスクを有する患者(出血性疾患、原発性免疫不全などの血漿由来製剤による治療を定期的に受ける人)には、講じる必要のある予防措置を通知する。なお、筋注用免疫グロブリン(Rh陰性の妊娠女性に投与される抗Dグロブリン、A型肝炎予防のための人免疫グロブリンなど)を投与されたことのある人々はリスクがないと考えられ、措置を講じる必要がないとしている。	

報告企業の意見	今後の対応
異常プリオン蛋白を含む可能性のある原料血漿由来の製剤からのvCJD伝播の報告はないが、供血後にvCJDを発症した人由来の製剤投与を受けた人の一部については血液等の提供をしないようにする等を勧告している。 なお、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。	今後もvCJDに関連する情報収集に努めていく。

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Variant Creutzfeldt-Jakob disease and plasma products: implementation of public health precautions in the UK

The CJD Incidents Panel (CJDIP), an expert committee set up to advise on the management of "incidents" of potential transmission of CJD between patients, has issued recommendations on the management of variant Creutzfeldt-Jakob disease (vCJD) risk from implicated plasma products.

To date, nine UK plasma donors are known to have developed vCJD. Collectively, they made 23 plasma donations. The donated plasma was used to manufacture factor VIII, factor IX, antithrombin, intravenous immunoglobulin G, albumin, intramuscular human normal immunoglobulin, and anti-D.

The potential risk of vCJD infection following treatment with any implicated plasma products, on top of the risk from dietary exposure to the BSE agent, is very uncertain. So far, there are no recorded instances of vCJD being spread through surgery, nor have there been any cases among recipients of plasma products sourced from individuals who later developed vCJD. In December 2003, the death of a person from vCJD some years after receiving a blood transfusion from a donor who themselves died of vCJD, was announced. In July 2004 a second probable case of transfusion-associated vCJD infection was identified. These two events have increased concern about the potential infectivity of blood and plasma products

Public health precautions against vCJD
The CJDIP now recommends that certain special public health precautions need to be taken for some recipients of UK sourced plasma products that were manufactured using donations from individuals who subsequently developed vCJD. This is in order to reduce any possible risk of iatrogenic transmission of vCJD (*ie*, disease or infection acquired via a healthcare setting).

The CJDIP has used a vCJD blood risk assessment <http://www.dnv.com/consulting/news_consulting/RiskofInfectionfromvariantCJDinBlood.asp> together with information on how the particular batches of plasma products were manufactured, to assess the potential levels of infection that patients were exposed to.

The CJDIP advises certain special public health precautions need to be taken for recipients of UK sourced plasma products who have been exposed to a 1% or greater potential additional risk of vCJD infection as these patients could pose a risk to others in defined circumstances. These "at risk" patients are asked:

- not to donate blood, organs or tissues, and
- to inform their clinician if they need medical, surgical or dental treatment, so that infection control precautions can be taken <http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/> to reduce any possible risk of spreading vCJD, and to consider informing their family, in case the patient needs emergency surgery in the future.

The CJDIP has categorised each batch of implicated plasma products according to the likelihood that special public health precautions need to be taken as follows:

- **High:** the amount of potential infectivity in product batches was high enough to warrant special public health precautions following the administration of a very small dose. These batches should be traced, the recipients advised of their exposure and asked to take special public health precautions.

- **Medium:** substantial quantities of the material in question would need to have been administered to warrant special public health precautions. Efforts should be made to trace these batches and assess the additional risk to individual recipients to determine if special precautions should be taken.

- **Low:** the potential additional risk to recipients is considered negligible. These batches do not need to be traced and the individual recipients do not need to be informed.

This categorisation is based on very cautious assumptions, and the uncertainties underlying the assessment of 'risk' are great. The CJDIP guidance is to limit any possible iatrogenic human-to-human transmission ofvCJD. It should **NOT** be interpreted as an estimate of an individual patient's additional risk of developing vCJD, which is uncertain, and likely to be very low.

Informing patients

The patients who may be affected include some patients with bleeding disorders, primary immunodeficiency (PID), and with other conditions, who may include, for example, patients with secondary immunodeficiencies, certain neurological and autoimmune conditions, plasma exchange recipients, patients with severe burns, and those with some other conditions requiring critical care.

Patients who are 'at-risk' of vCJD for public health purposes are being contacted by their doctors and informed of the precautions they will need to take.

The **MAIN MESSAGES** for patients are:

1. ALL people treated regularly with plasma products , *eg,* patients with bleeding disorders or primary immunodeficiency (PID) are being contacted by the specialist doctor responsible for their care.

2. Hospitals will trace other people who received implicated plasma products , *eg,* for emergency treatment of severe burns) and arrange to have their exposure assessed. Individuals will be contacted **ONLY IF THEIR EXPOSURE IS IDENTIFIED AND WARRANTS FURTHER ACTION.** The process of traceback and assessment may take a number of weeks, and, where treatment took place a number of years ago, it may not be possible to find out who received the implicated plasma products.

3. People who have received intramuscular immunoglobulins (eg anti-D for Rhesus negative pregnant women; human normal immunoglobulin for travel prophylaxis for hepatitis A) are **NOT** considered to be 'at-risk' and no action is needed.

Sources for Additional information

The Health Protection Agency's (HPA) CJD section at the Communicable Disease Surveillance Centre (Colindale) is co-ordinating the patient notification in England, Wales, and Northern Ireland. The Scottish Centre for Infection and Environmental Health (SCIEH) is co-ordinating this notification in Scotland. Background information about vCJD with useful links is available from their websites:

HPA: <http://www.hpa.org.uk/infections/topics_az/cjd/menu.htm>.

SCIEH: <http://www.show.scot.nhs.uk/scieh>.