別紙様式第 2−1
No. 21

医薬品
医薬部外品　研究報告 調査報告書
化粧品

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	機構処理欄
				2005.3.3	該当なし	

一般的名称	解凍人赤血球濃厚液	研究報告の公表状況		公表国
販売名(企業名)	解凍赤血球濃厚液「日赤」(日本赤十字社) 照射解凍赤血球濃厚液「日赤」(日本赤十字社)		Reuters. 2005 Mar 3.	モロッコ

研究報告の概要

モロッコ政府は、おそらく北アフリカ諸国で初めてvCJDによって人が死亡したと考えられると発表した。モロッコの保健省の発表では、患者は61歳男性、定期的にヨーロッパを訪問していたが、どこの国かは明かされていない。患者はカサブランカ病院で死亡した。政府高官は「まだ検体を調べている途中なので、100%確実とは言えないが、vCJDが原因で死亡した可能性が高い」と語った。モロッコ人約200万人がヨーロッパに住んでおり、モロッコはヨーロッパ産の食料を多く輸入している。モロッコでは、ヨーロッパの狂牛病に対応して2000年に家畜類の輸入禁止を実施したが、昨年10月に解除した。

報告企業の意見	今後の対応
モロッコでvCJDに感染した疑いのある患者が死亡したとの報告である。	今後も引き続き、プリオン病に関する新たな知見及び情報の収集に努める。

使用上の注意記載状況・その他参考事項等

解凍赤血球濃厚液「日赤」

照射解凍赤血球濃厚液「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

15

Morocco Suspects It Has First Human Mad Cow Death

REUTERS

RABAT (Reuters) - Morocco said Thursday it believes a man died of the human form of mad cow disease, suspected to be the first case of its kind in the North African country.

The 61-year-old was a regular visitor to Europe, the health ministry said in a statement, without saying which country. He died Wednesday in a Casablanca hospital.

"We are not 100 percent sure as we are still carrying out checks through samples, but it's highly possible he died of Creutzfeldt-Jakob Disease (vCJD)," a senior ministry official told Reuters.

Some two million Moroccan expatriates live in Europe, and Morocco is a main importer of European-origin food products.

It lifted in October last year a ban on imports of livestock, which was imposed in November 2000 in response to the food scare linked to mad cow disease in Europe.

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	厚生労働省処理欄
一般的名称	－		研究報告の公表状況	http://www.dh.gov.uk/PublicationsAndStatistics/PressReleases/PressReleasesNotices/fs/en?CONTENT_ID=4086160&chk=9/Ni4w	公表国 英国	
販売名（企業名）	－					

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
血液組織微生物学的安全性諮問委員会（MSBT）からのアドバイスに従い、血液を介した変異型クロイツフェルト・ヤコブ病（vCJD）伝播のリスクを低減させる為のさらなる措置が発表となった。 2003年12月の血液を介したヒトからヒトへのvCJD伝播可能性例の初めての報告により、「1980年以降に英国内で輸血を受けた人」は、2004年4月5日以降、献血ができなくなると措置がとられた。さらに、今回、1980年以降に輸血を受けた2グループ、「以前に輸血を受けたかどうか定かでない献血者」、「以前に輸血を受けたことのある血漿成分提供者」が追加され、この規制は2004年8月2日より実施される。 血液を介したvCJDのヒトからヒトへの伝播の可能性のある2例目の症例が英国国立CJDサーベイランス部により確定された。この患者は、後にvCJDを発症した献血者からの血液を用いた輸血を1999年に受け、vCJDとは関連のない原因で死亡したが、死後剖検により脾臓からvCJD病原体が発見された。	

報告企業の意見	今後の対応
本報告は、vCJD多発国である英国での措置であるが、当社の特殊免疫グロブリンの原料血漿原産国である米国の動向に留意していきたい。 なお、国内では問診により輸血歴のある人は献血者から既に除外されている。	今後もvCJDの発生状況、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。

Update on precautions to protect blood supply

Published: Thursday 22 July 2004
Reference number: 2004/0270

Following advice from the Committee on the Microbiological Safety of Blood and Tissue (MSBT) further measures to reduce the risk of transmission of variant Creutzfeldt Jakob Disease (vCJD) via blood transfusion were announced today.

Following the first resport of a possible transmission of vCJD from person to person via blood in December 2003 it was recommended that recipients of blood transfusions since January 1980 be excluded from donating blood in the future. This precautionary measure was implemented from April 5th this year.

Today two further groups who have received transfusions since January 1980 will be added to those excluded from giving blood in the future. They are:

donors who are unsure if they have previously had a blood transfusion; and

apheresis donors who have previously had a blood transfusion. Apheresis donors are a small pool of committed donors who make frequent attendances to centres to donate blood, where machine processing removes only certain blood components, and the rest is returned to the donor.

When actions were taken in April 2004 neither of these groups were excluded until any potential impact on the blood supply became clearer. However, it has become apparent that the impact on blood supplies is small and MSBT has therefore recommended that these additional groups can be excluded. These new exclusions will take effect from 2nd August 2004.

In a separate development, a second case of possible transmission of vCJD from person to person via blood tranfusion has now been confirmed by the National CJD Surveillance Unit. A patient in the UK received a blood transfusion in 1999 from a donor who later went on to develop vCJD. The patient died of causes unrelated to vCJD but a post mortem revealed the presence of the vCJD agent in the patient's spleen.

After the first person to person transmission of vCJD was indentified it was expected that further cases may follow. This second case is of particular scientific interest as the patient had a different genetic type to that so far found in patients who have developed vCJD. A detailed account of the case will be appearing in The Lancet medical journal shortly.

Precautions already in place to protect the blood supply include:

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 National Blood Service blood donor records. If the patient has given blood, subsequently any stocks of that blood are immediately destroyed.

Since 1998, plasma derivatives, such as clotting factors, have been prepared from plasma imported from the USA.

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 we announced that fresh frozen plasma for treating babies and young children born after 1st January 1996 would be obtained from the USA.

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.

The Secretary of State for Health John Reid said:

"We are continuing to follow a highly precautionary approach. Although people may have concerns about the implications of this announcement, I would emphasise again that the exclusion crieteria are being tightened because of a small but unquantifiable risk. People should continue to have a blood transfusion when it is really necessary. Any slight risk associated with receiving blood must be balanced against the significant risk of not receiving that blood when it is most needed.

"People who can, should continue to give blood. Blood donation is a safe procedure and people should continue to donate blood regularly. We place great value on those who already donate and would welcome new donors."

For media enquiries ONLY please contact the Department of Health press office on the numbers provided:

Contact Press Office
Phone **Press Officers**
020 7210 5649/5656/5282.