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 2006年12月25日	新医薬品等の区分	厚生労働省処理欄

一般的名称	①②③人血清アルブミン ④乾燥濃縮人血液凝固第Ⅷ因子 ⑤乾燥濃縮人血液凝固第Ⅸ因子	研究報告の公表状況	AABB WEEKLY REPORT 2006; 12(44): 4-5	公表国 アメリカ
販売名 (企業名)	①献血アルブミン-Wf（ベネシス） ②献血アルブミン(5%)-Wf（ベネシス） ③アルブミン-Wf（ベネシス） ④コンコエイトーHT（ベネシス） ⑤クリスマシンーM（ベネシス）			

研究報告の概要

伝達性海綿状脳症（TSE）諮問委員会が2006年12月15日に公開で開催され、ヒト血漿由来抗血友病因子製剤におけるvCJDの感染リスクについて討議した。この諮問委員会では以下の2つのトピックを取り上げた。
1)ヒト血漿由来抗血友病因子製剤（FVIII）におけるvCJDへの曝露についてのFDAのリスク評価についての検討及びコミュニケーション手段
2)血漿由来FVIII製造におけるTSEクリアランスのレベル
このリスク評価に対して諮問委員会は、報告が強制でないことから過小報告をFDAは如何に説明しようと考えているのか、及び最終製品が4 logのリダクションを有しているとの仮定をするのにFDAはどんな具体的なエビデンスを用いたかについて懸念を表明した。委員会はまた、感染性病原体のクリアランスを決定するためのステップとしてスパイク実験を用いることに支持を表明した。
提示されたリスク伝達の計画について長い議論が交され、委員会の考えは理に適ったものであるが、改善の余地があるとの結論に至った。委員会は型通り全てに適合する哲学はありえないことに合意した。
ミニマムTSE病原体リダクション・ファクターの有効性についてのFDAからの助言求めに応じて、PPTAの病原体安全対策委員会の議長が製造工程で除去されたプリオンのレベルについてのデータを示したが、値は企業によって3.9から>9.05 logまでの範囲があった。このプレゼンテーションには、検体調製の方法論からlogリダクションが工程全体で如何に決定されたかまでの話題について質問が殺到し、最終的に外因性物質を用いた実験は血漿由来第VIII因子製剤の安全性を保証する一手段であるとの多数決での決定に至った。しかし諮問委員会は、FDAに対して何が適切なlogリダクション・ファクターかについての勧告をすることができなかった。

報告企業の意見	今後の対応
2006年12月15日開催の米国伝達性海綿状脳症委員会（TSEAC）会合において、抗血友病因子製剤のvCJDの感染リスクについての検討結果についての報告である。(BENE2006-025の結果の報告) これまで血漿分画製剤によってvCJD、スクレイピー及びCWDを含むプリオン病が伝播したとの報告はない。しかしながら、万一vCJD感染者の血漿が本剤の原料に混入した場合には、製造工程においてプリオンを低減し得るとの報告があるものの、製剤から伝播する可能性を完全には否定し得ない。そのため、弊社の血漿分画製剤の製造工程におけるTSE感染性低減に関する検証実験を加速し、自社データを早期に取得し、工程評価を行い、必要に応じて工程改善を実施する予定である。	本報告は本剤の安全性に影響を与えないと考えるので、特段の措置はとらない。

使用上の注意記載状況・その他参考事項等

代表として献血アルブミン-Wfの記載を示す。
2. 重要な基本的注意
(1)略
1)略
2)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。

In an effort to underscore the overall value of the proposed trial, Daniel Freilich, MD, CRD, MC, the lead investigator in the proposed Navy trial, pointed out that traumatic hemorrhagic shock is a significant public health problem that currently sees an estimated 50 percent mortality rate. "The current treatment is unsatisfactory," he said, noting that preclinical data show a strong prospect for patient benefit.

When questioned by some committee members on the homogeneity of the trial design, Freilich pointed out that although socioeconomic and other demographic data are not readily available, trauma patients whose transport to a hospital is less than approximately 15 minutes would not be included in the trial, which would help to avoid disproportionate emphasis on certain populations. Supporters of the study also say that another way to ensure equitable distribution of risk would be to go beyond the urban setting and include rural trauma centers in the trial. Nonetheless, some critics have said that the proposed trial design is unethical and that FDA's previously cited reasons for blocking the study remain valid.

In reviewing the trial design for FDA, Laurence Landow, MD, FRCPC, medical officer in the Division of Hematology in FDA's Office of Blood Research and Review, reiterated the agency's concerns about safety and dosing. FDA is concerned that the number of severe adverse events observed in HBOC clinical trials with animals could be even higher in the critically ill trauma patient population. The agency also believes that minimal evidence has been provided to support the safety of the default HBOC infusion rate.

One of the major roadblocks BioPure has faced is the lack of Phase II data that would support a Phase III trial. The multicenter, randomized Phase II trial involved individuals undergoing nonemergency orthopedic surgery. Of the 353 patients who received HBOC 201, 10 patients died and 21 suffered heart complications whereas six people from the control group died and five experienced heart problems. The Phase II trial did not include trauma patients, the population that would be evaluated according to the design of the proposed Phase III trial. The committee discussed the possibility that BioPure could plan a smaller Phase II trial that more closely resembles the intended use of the product rather than have FDA approve the Phase III clinical trial sought by the Navy.

If FDA agrees with BPAC's recommendations, it would mark the fourth time since June 2005 that the agency has blocked Hemopure trials from taking place.

TSE Advisory Committee Convenes to Discuss Plasma-derived Factor VIII Safety

The Transmissible Spongiform Encephalopathies (TSE) Advisory Committee held an open public meeting Dec. 15, 2006, in Silver Spring, Md., to discuss the potential risk of variant Creutzfeldt-Jakob disease (vCJD) in human plasma-derived antihemophilic factor products. The advisory committee had two topics for discussion: 1) review of FDA's risk assessment for potential exposure to vCJD in human plasma-derived antihemophilic (FVIII) products and communications materials; and 2) the levels of TSE clearance in the manufacture of plasma-derived FVIII.

FDA presented a risk assessment to the TSE Advisory Committee to seek its advice on key message points in both the risk assessment itself and appropriate ways to communicate this information to physicians, patients and the general public.

In response to the risk assessment — which found that the potential to transmit vCJD from plasma-derived FVIII products used by some patients with hemophilia A and von Willebrand disease is highly uncertain, but appears likely to be very low — the advisory committee voiced concerns about how the FDA was going to account for underreporting since reporting is not mandatory and what objective evidence FDA used in making its assumption that there is a four-log reduction in the final product. The committee also expressed its support for the use of spiking experiments as a step in the right direction for determining the clearance of the infectious agent.

A lengthy discussion was held on the proposed risk communication plan, with the committee concluding that the concept was sound but that there was some room for improvement. The advisory committee agreed that there cannot be a "one size fits all" philosophy. The key points for a physician would be different from those for a patient. For example, the message to physicians should be that infected patients need to receive the same standard of care as noninfected patients, not be treated differently as when HIV was first an issue during the 1980s. For patients, there should be a focus on the positive aspects of the therapy, i.e., the benefits of taking the product.

The committee also addressed the safety and efficacy of plasma-derived FVIII products. In response to an FDA request for advice on the efficacy of a minimum TSE agent reduction factor — which has been demonstrated in laboratory-based experimental models to enhance vCJD safety of the products — the chair of the Plasma Protein Therapeutics Association (PPTA) Pathogen Safety Steering Committee presented data on the level of the prion removed by the manufacturing process, a value that ranged from 3.9 to >9.05 logs, depending on the company. The presentations prompted questions on subjects ranging from the methodology of preparing the samples to how the log reduction was determined for the overall process, ultimately leading to a nonunanimous decision that, based on the scientific evidence, exogenous studies are a means of assuring the safety of plasma-derived FVIII products. However, the advisory committee was unable to make a recommendation to FDA for what would be an appropriate log reduction factor.

AABB Bulletin

New *AABB Weekly Report* to Launch in January

AABB Weekly Report will be replaced in January by a new e-newsletter that will bring more timely information about the latest developments affecting the transfusion medicine and cellular therapies fields to all AABB members as part of their membership dues.

Brief articles highlighting what has occurred in the field during the previous week will be included in the soon-to-be launched publication. The articles — on topics ranging from regulatory issues to standards and accreditation — will link to more detailed content on the Web. Links to new government Web resources also will be included in this e-newsletter. Periodic news flashes will be distributed if there is urgent news to communicate to members.

News reported by the mainstream media will continue to appear daily in *AABB SmartBrief*, which launched in October. Available to both members and nonmembers free of charge, *AABB SmartBrief* summarizes the day's most important news — selected from a wide range of media sources — providing links to the original articles for those who want to learn more about a particular topic. The content is organized into categories — science and health, government developments and emerging

別紙様式第2-1

No. 20

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	機構処理欄
				2007. 1. 24	該当なし	

一般的名称	人血清アルブミン	研究報告の公表状況	ABC News Letter. 2006 Dec 15; 5.	公表国
販売名(企業名)	赤十字アルブミン20(日本赤十字社) 赤十字アルブミン25(日本赤十字社)			米国

研究報告の概要

○FDAの専門家委員会が血漿分画製剤におけるvCJDリスクについて討議

血漿由来の第Ⅷ因子製剤(pdFVIII)による患者への変異型クロイツフェルト・ヤコブ病の病原因子伝播のリスクは、極めて低いと見られる。生物製剤評価調査センター(CBER)のSteven Anderson博士は、「しかし、リスクはゼロではない」と伝達性海綿状脳症(TSE)諮問委員会で話している。CBERは、2005年10月31日の委員会で提示されたコンピュータモデルと仮説に基づいたリスク分析案の概要を示した。入力された情報は、英国におけるvCJDの推定発生率、渡航歴による供血延期の効果、動物モデルでの血液中の感染性の強さ、伝播の効率性、製造工程における除去、患者によるFVIIIの使用量を含んでいる。Anderson博士は、リスク分析には不確定な要素が含まれていると強調した。このモデルでは、現在米国で実施されている供血延期方針の有効性は85～99%と見積もられている。重要度解析では、リスクを決定する主要な要素は、製造工程におけるvCJD感染因子の低減である。

他にも幾つかの研究が報告され、委員会では、「これらの研究は見当違いという訳ではなく、他に方法がない以上継続する必要がある。しかし、血液との関連は未知である」と結論づけた。こうした懸念にもかかわらず、TSE減少を決定する根拠となる外部スパイク物質の研究を行うかどうかの採決は、免疫アッセイだけではなくバイオアッセイを行うという条件で可決された。

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報告企業の意見	今後の対応
FDAの専門家会議が第Ⅷ因子製剤のvCJDのリスクについて討議したとの報告である。	これまでの疫学研究等では、ヒトにおいて、血漿分画製剤を介してvCJDが伝播するという証拠はない。異常プリオンがアルブン製剤の製造工程で効果的に除去されるとの報告もあるが、輸血によりvCJDに感染する可能性が示唆されたことから、今後も情報の収集に努める。尚、日本赤十字社は、vCJDの血液を介する感染防止の目的から、献血時に過去の海外渡航歴(旅行及び居住)を確認し、英国を含む欧州36ヶ国に一定期間滞在したドナーを無期限に献血延期としている。また、英国滞在歴を有するvCJD患者が国内で発生したことから、平成17年6月1日より1980年～1996年に1日以上の英国滞在歴のある方からの献血を制限している。

使用上の注意記載状況・その他参考事項等

赤十字アルブミン20
赤十字アルブミン25

血液を原料とすることに由来する感染症伝播等

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Scottish Decision to Use Chagas' Test Frustrates Some Donors

The National Blood Transfusion Service for England and Wales has chosen to perform Chagas' testing on donors at risk for Chagas'. But the Scottish National Blood Transfusion Service (SNBTS) has decided it is too expensive to perform testing for the estimated 200 people at risk for the disease and too complicated to obtain testing results for people who have been tested in Wales and England by the National Blood Transfusion Service.

The different UK policies have frustrated at least one long-time donor. In an interview with *The Scotsman* (12/12/06), Michael Turnbull, whose mother is from Brazil, said he was allowed to donate blood in England after being tested, but has been barred from giving blood in Scotland. Mr. Turnbull, who has type O-negative blood, says he feels so strongly about donating that he plans to give blood when visiting his daughter in Bedford, England.

Jack Gillon, MD, a consultant with the SNBTS, told *The Scotsman*: "We have relatively few donors in this category now, and on the whole the resources issue is a real one. Setting up a test with all the safeguards and quality assurance you need is quite risk intensive... We are not in a position where we can take that lightly, but we have to use the resources we have got to the best of our ability." ♦
The blood transfusion services in England, Wales and Scotland currently defer donors who were born in South America or Central America (including Southern Mexico) or whose mothers were born in these regions; who were transfused in South America, Central America (including Mexico); or who lived and/or worked in rural subsistence farming communities in these countries for a continuous period of four weeks or more.

For situations other than transfusion, blood services may accept a donor if it has been at least six months from the date of the last exposure, and a validated test for *T. cruzi* antibody is negative.

FDA Expert Panel Addresses Risk of vCJD in Plasma Products

The risk of transmission of the variant Creutzfeldt-Jakob disease (vCJD) agent to recipients of plasma derived Factor VIII (pdFVIII) manufactured in the US most likely is extremely small. "But the risk may not be zero," Steven Anderson, PhD, from the Center for Biologics Evaluation and Research's (CBER) Office of Biostatistics and Epidemiology told the Transmissible Spongiform Encephalopathies Advisory Committee at its meeting today.

CBER staff briefed the panel on a draft risk assessment based on a computer model and assumptions that had been presented to the committee on October 31, 2005. The inputs included prevalence estimates of vCJD in the UK, the efficiency of donor deferrals for travel, the quantity of infectivity in blood based on animal models, the efficiency of transmission, clearance during manufacturing, and FVIII usage by the patient population.

Dr. Anderson emphasized that the risk assessment contained significant uncertainty. For instance, the prevalence estimates varied from 1 in 1.8 million for UK epidemiologic studies that predicted 70 cases of vCJD between 2002 and 2080, to 237 per million derived from tonsil/appendix tissue surveillance (3 positives in 12,674 samples tested). The model assumes that the efficacy of the currently applied donor

(continued on page 6)

Risk of vCJD in Plasma Products (continued from page 5)

Deferral policies in the US is 85-99 percent. According to an importance analysis, the major factor determining risk is the log reduction of vCJD agent achieved by the manufacturing process.

> **"It is important to avoid complacency and retain a sense of proportion on this particular issue."**
>
> ***– Mark Skinner***

Dorothy Scott, MD, from OBRR's Division of Hematology, reported that a preliminary review of clearance studies performed by the plasma industry indicated that all products in the US market achieve a clearance of at least 4-6 logs in spiking experiments. Dr. Anderson estimated that the individual vCJD risk for a severe Hemophilia A patient is 1 in 1.3 million if the lower prevalence estimate is considered and 1 in 15,000 if the highest prevalence estimate is used. The estimated risk for that same population is 1 vCJD infection in 3,077 years for the lower prevalence, and 1 vCJD infection in 35 years for the highest prevalence.

Mark Skinner, president of the World Federation of Hemophilia welcomed that FDA analysis. But he emphasized that "it is important to avoid complacency and retain a sense of proportion to this particular issue." His advice was to maintain timely communication with openness and transparency, acknowledgement of areas of uncertainty and avoidance of patient stigmatization with consequent denial of access to care. Stigmatization was also the theme of Jan Hamilton from the Hemophilia Federation of America and Val Bias, from the National Hemophilia Foundation.

The Committee of Ten Thousand (COTT), represented by Richard Colvin, MD, PhD also welcomed the assessment but was skeptical of some of the assumptions. COTT President Cori Dubin pleaded for a compensation system for injured recipients. Dave Cavenaugh, also from COTT, raised substantial doubts about surveillance for bovine spongiform encephalopathy in the US, was very critical of the Department of Agriculture, and said he still believes that vCJD is a clear and present danger for recipients of plasma derived clotting factors.

In the second part of the TSEAC meeting, Thomas R. Kreil, PhD, chair of the Plasma Protein Therapeutics Association Pathogen Safety Steering Committee presented the current status of TSE clearance studies being performed by the industry. His presentation generated substantial discussion about the nature of the spiking materials used in the studies and the measurement of clearance based on immunological methods.

The committee concluded that "these studies are not irrelevant and should be continued because there is nothing else available. However, the relationship with blood is unknown." Despite these concerns, when asked specifically whether studies with exogenous spiking materials could be the basis for the determination of a TSE reduction factor, the committee voted yes (10-0 with two abstentions), provided that the assessment is based on bioassays, not just immunological assays.

FDA has prepared a wealth of resources communicating the results of the risk assessment to the patient community, physicians, and the population in general. The draft risk assessment and the draft communication materials are posted on the FDA Web site at www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4271b1-index.htm ♦

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No. 21

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	機構処理欄
				2007. 2. 26	該当なし	

一般的名称	乾燥濃縮人血液凝固第Ⅷ因子	研究報告の公表状況	ABC News Letter. 2007 Feb 9; 7.	公表国
販売名(企業名)	クロスエイトM250(日本赤十字社) クロスエイトM500(日本赤十字社) クロスエイトM1000(日本赤十字社)			英国

研究報告の概要

○輸血がvCJD二次的感染拡大を引き起こすことはなさそうである
将来のvCJDによる死亡率は、供血に関する公衆衛生上の施策によって予想されていたよりも遙かに低くなるだろうと英国の研究者が報告した。Royal Society Journal Interface誌オンライン版によると、ロンドン衛生・熱帯病教室と全国CJDサーベイランスユニットは、2080年までの輸血によるvCJDの死亡例は50例と予測した。感染牛の摂食によるvCJD感染が排除されたため、現在では輸血による伝播が最も可能性が高いと研究者は話している。
この研究では、数学モデルを使用して輸血によるvCJDの感染拡大が発生した場合のシナリオを試算し、公衆衛生上の施策の影響も分析した。vCJD感染リスクに対応して、英国では1980年以降輸血歴のある人からの供血禁止、白血球の除去、血漿分画製剤製造のための血漿輸入など様々な方策を実施してきた。研究者は、「こういった安全対策がない場合、感染例は2080年までに900例になるが、生物学的には起こりそうもない。楽観的な想定では、公衆衛生上の施策によって感染は250例まで減少し、さらに生物学的可能性のあるシナリオが検討の対象となる。この研究は、大規模で持続的な感染拡大という事態は、可能性はあるが起こりそうもなく、公衆衛生上の施策が効果的であるという考えを支持するものである」と記している。
研究者によると、若い人が供血し60代以上の老人に輸血されることが多いため、vCJDは若い人から老人へと伝播するが、受血者は高齢で供血することは少なく、感染伝播したとしてもvCJDが供血システムに戻ることはないと考えられる。このことは、政府による他の施策と合わせて、輸血によるvCJDの死亡症例数を減少させる。一つ不明な点は、外科手術用器具を介しての危険性である。これには「年齢による防御効果」がなく、汚染防止の対策もリスクを完全に排除できない。しかし、汚染された手術器具への暴露後のvCJD発症の証拠はない。

報告企業の意見	今後の対応
供血に関する公衆衛生上の施策によってvCJDによる死亡率は予想されていたよりも遙かに低くなると考えられ、英国における2080年までの輸血によるvCJDの死亡例は50例と予測されるとの報告である。	これまでの疫学研究等では、ヒトにおいて、血漿分画製剤を介してvCJDが伝播するという証拠はない。異常プリオンが本製剤の製造工程で効果的に除去されるとの報告もあるが、輸血によりvCJDに感染する可能性が示唆されたことから、今後も情報の収集に努める。尚、日本赤十字社は、vCJDの血液を介する感染防止の目的から、献血時に過去の海外渡航歴(旅行及び居住)を確認し、英国を含む欧州36ヶ国に一定期間滞在したドナーを無期限に献血延期としている。また、英国滞在歴を有するvCJD患者が国内で発生したことから、平成17年6月1日より1980年～1996年に1日以上の英国滞在歴のある方からの献血を制限している。

使用上の注意記載状況・その他参考事項等

クロスエイトM250
クロスエイトM500
クロスエイトM1000

血液を原料とすることに由来する感染症伝播等
vCJD等の伝播のリスク

Australian Red Cross to Screen Platelets for Bacterial Contamination (continued from page 6)

A Red Cross spokesman called implementing bacterial detection a "vitally important measure" that demands immediate attention. "To assist governments in their decision making when they meet at the end of March, the ARCBS Board has decided to absorb the one-off capital costs in 2006-07 in the interests of the enhanced safety of the Australian community," she said. "This will be achieved without any diminution in our capacity to meet the ongoing demand for blood."

"When new technologies are available to make it better and are recommended by the experts in that area, then really it's incumbent upon government to ensure we continue to get the safest possible [blood] supply."

– Australian Medical Association President Mukesh Haikerwal, MD

Under the new plan, the Red Cross would screen 100 percent of platelets by April next year. Current laws require only 5 percent to be checked. If left to the scheduled budgetary processes, the Red Cross believes full screening will not be possible until 2009, placing more Australians at risk.

Australian Medical Association President Mukesh Haikerwal, MD told *The Age* that health politicians needed to act quickly on the advice of their blood experts. "A very important part of our surgical and medical care is our ability to provide blood products that are safe and disease free," he said. "When new technologies are available to make it better and are recommended by the experts in that area, then really it's incumbent upon government to ensure we continue to get the safest possible supply." ♦

Blood Transfusion Unlikely to Create Secondary vCJD Epidemic

The future death toll from vCJD is likely to be far lower than originally anticipated because public health interventions have dramatically reduced the number of infections that could have been transmitted by blood transfusion, British researchers reported this week. In a paper published online in the *Royal Society Journal Interface*, investigators at the London School of Hygiene & Tropical Medicine and the National CJD Surveillance Unit, predicted just 50 deaths from transfusion-transmitted vCJD by 2080.

A large scale epidemic of vCJD via blood transfusion running into thousands of cases is unlikely to occur, and public health interventions, such as a ban on donation by transfusion recipients, were timely and effective in limiting the scale of the epidemic, the researchers said.

According to the latest UK Department of Health statistics, there have been 112 vCJD deaths in the UK in which the diagnosis has been pathologically confirmed through post mortem examination of brain tissue. Since the primary method of contracting vCJD – eating infected meat – has been effectively eliminated, blood transfusions now are considered to be the most likely way of transmission, the researchers said.

In 2004, a study of 13,000 appendix and tonsil samples suggested that thousands of people might unknowingly be harboring vCJD. The discovery of three individuals suspected to have contracted variant Creutzfeldt-Jakob disease (vCJD) through blood transfusions heightened concerns that a secondary epidemic via human-to-human transmission could occur in the UK.

Since that time, however, only four people have been shown to have contracted vCJD through blood transfusions. They were among a group of 66 who received blood transfusions from donors who went on to develop the disease.

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On Believing in Prions

"It's not very politically correct if you don't believe in prions. It means that you won't get any grant money.

– *Yale University neuropathologist Laura Manuelidis, MD, in a recent interview with* Nature *on the controversy over her contention that a virus causes neurological conditions such as Creutzfeldt-Jakob disease in humans and scrapie in animals, rather than an infectious protein, or 'prion,' as most researchers believe.*

Transfusion-Transmitted vCJD Epidemic Unlikely (continued from page 7)

The researchers used mathematical models to explore scenarios in which a new vCJD epidemic, carried by infected blood, might develop. They also assessed the impact of public health interventions that have been implemented on its spread.

To address the risk of vCJD infection, the British government and the National Blood Service put in place a number of measures to protect transfusion recipients from contracting vCJD, the researchers pointed out. These include prohibiting anyone who has received a blood transfusion since 1980 from donating blood. In addition, since 1999, white blood cells – which are the most likely to carry the infection – have been removed from blood used for transfusions. Blood derivatives now only manufactured using plasma from the US.

Without these blood safety measures, the researchers wrote, "the size of the epidemic (up until 2080) was bounded above by 900 cases, with self-sustaining epidemics also possible; but the scenarios under which such epidemics could arise were found to be biologically implausible." They continued: "Under optimistic assumptions, public health interventions reduced the upper bound to 250 and further still when only biologically plausible scenarios were considered. Our results support the belief that scenarios leading to large or self-sustaining epidemics are possible but unlikely, and that public health interventions were effective."

According to the researchers, young people – those in their 20s, 30s and 40s – are most likely to donate blood, but people aged 60 and over are most likely to need transfusions. This means it is possible for vCJD to be transferred from a young donor to an old recipient, they said. But, because of their age, these recipients would not go back to donate blood so even if they were infected through transfusion, the disease would not be passed back into the blood donor system. This fact, along with other interventions put in place by the government, limits the number likely to die from vCJD contracted through blood transfusions, they said.

"Patients requiring blood transfusions do really need them, often because they are in a life-threatening situation, so we hope this study will reassure people of the remote risk of contracting this disease," Azra Ghani, MD, an epidemiologist who worked on the study, said in an interview with BBC News.

But she added: "One uncertainty is around the dangers linked to surgical instruments, because there you would not have the 'age protection' factor, and we know that contamination protection measures do not remove the risk. "However there has been no evidence of a case of vCJD developing after exposure to contaminated instruments," she pointed out. (Sources: *Medical Laboratory World*, 2/7/07; BBC News, 2/7/07)

Citation: Clarke P *et al.* Is there the potential for an epidemic of variant Creutzfeldt-Jakob disease via blood transfusion in the UK? J R Soc Interface FirstCite Early Online Publishing, 1742-5689. ♦