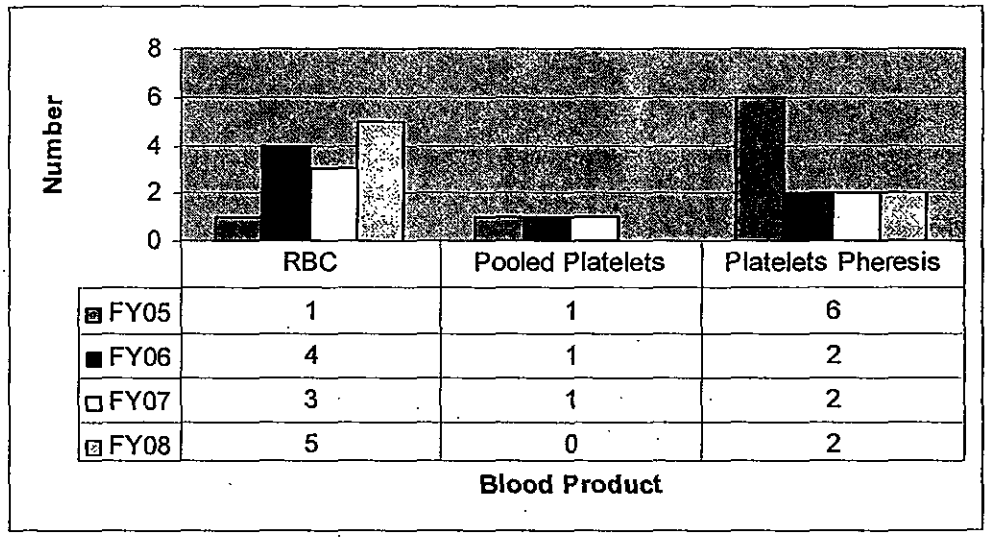
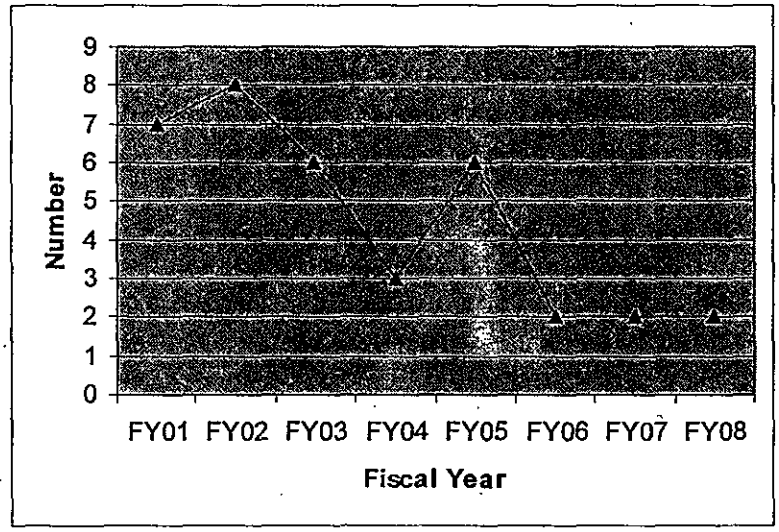
**Figure 4: Microbial Infection by Implicated Blood Product, FY2005 through FY2008**




Red Blood Cells microorganisms: *S. marcescens (1), E. coli (1), Y. enterocolitica (1), B. microti (9), B. MO1(1)*
Pooled Platelets microorganisms: *S. aureus (1), E. coli (1), Streptococcus dysgalactiae (1)*
Platelets Pheresis microorganisms: *S. aureus (4), S. marcescens (1), S. lugdunensis (1), S. epidermidis (2), E. limosum (1), E. coli (1), M. morganii (1), K. oxytoca (1)*

**Figure 5: Bacterial Infection by Apheresis Platelets, FY2001 through FY2008**




## E. Transfusion Not Ruled Out as Cause of Fatality

In these reported fatalities, the reporting facilities were unable to identify a specific complication of transfusion as the cause of death. Often, these patients had multiple co-morbidities, and after review of the investigation documentation, our medical reviewers could neither confirm nor rule out the transfusion as the cause of the fatality (Table 5). We did not include these reported fatalities in the analysis in Sections II.A through II.D (transfusion-related fatalities), above.

Combining the transfusion related fatalities with those that our medical officers could not rule out, there was a decrease in total reported fatalities from 63 in FY2007 to 55 in FY2008.

## F. Not Transfusion Related

After reviewing the initial fatality reports and the investigation documentation, we categorized a number of reported fatalities as "Not Transfusion Related." Our medical reviewers concluded that, while there was a temporal relationship between transfusion and subsequent death of the recipient, there was no evidence to support a causal relationship (Table 5). Thus, we did not include these reported fatalities in the analysis in Sections II.A through II.D (transfusion-related fatalities), above.

**Table 5: Fatalities Not Related to Transfusion or Transfusion Not Ruled Out, FY2005 through FY2008**

| | FY05 | FY06 | FY07 | FY08 |
|---|---|---|---|---|
| Not Transfusion Related | 21 | 8 | 13 | 18 |
| Not Ruled Out | 14 | 10 | 11 | 8 |
| Totals | 35 | 18 | 24 | 26 |

## G. Post-Donation Fatalities

There was a small decrease in FY2008 in the number of reported fatalities following Source Plasma donation, and one fatality following donation of Apheresis Red Blood Cells (Table 6). In all of these cases, our medical reviewers concluded that, while there was a temporal link between the donations and the fatalities, there was no evidence to support a causal relationship between the donations and subsequent death of the donors.

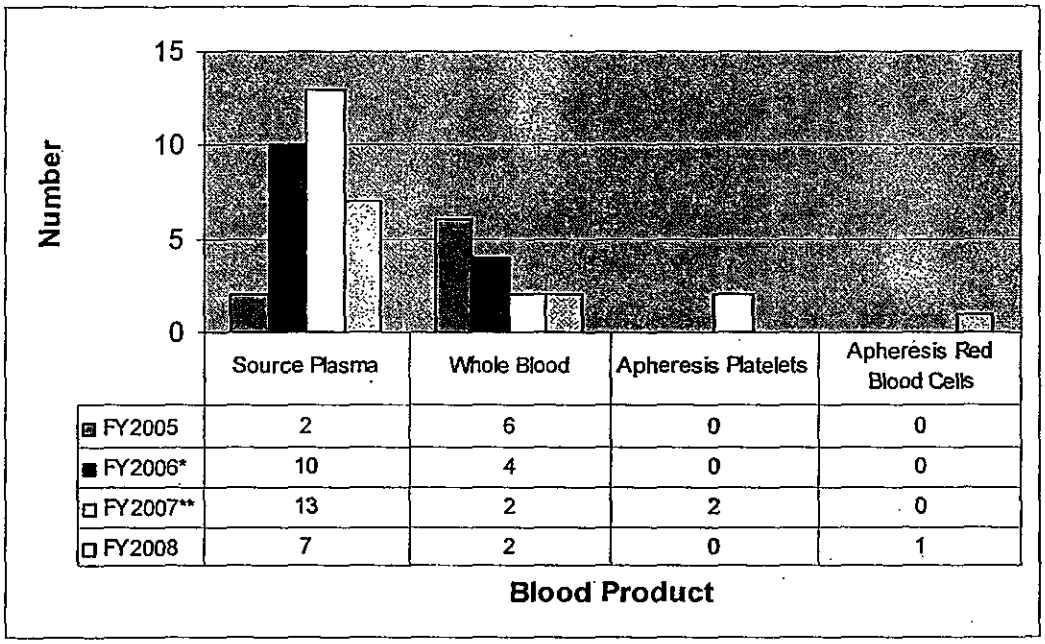
In FY2008, we received reports of two fatalities following Whole Blood donation collected by manual methods. In both cases, our medical reviewers found no evidence to support a causal relationship between the donation and subsequent death of the donor.

**Table 6: Post-Donation Fatality Reports by Donated Product, FY2005 through FY2008**

| Donated Product | FY05 | FY06 | FY07 | FY08 |
|---|---|---|---|---|
| Source Plasma | 2 | 10 | 13 | 7 |
| Whole Blood | 6 | 4* | 2** | 2 |
| Apheresis Platelets | 0 | 0 | 2 | 0 |
| Apheresis Red Blood Cells | 0 | 0 | 0 | 1 |
| Total | 8 | 14 | 17 | 10 |

*Includes 2 autologous donations
**Autologous donations

**Figure 6: Post-Donation Fatality Reports, FY2005 through FY2008**




*Includes 2 autologous Whole Blood donations
**Both Whole Blood donations in FY07 were autologous

別紙様式第2-1

No. 27

# 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 |
|---|---|---|---|---|---|---|
| | | | | 2009. 4. 15 | 該当なし | |

| 一般的名称 | 人赤血球濃厚液 | 研究報告の公表状況 | OIE - World Organisation for Animal Health. Available from: http://www.oie.int/eng/info/en_esbmonde.htm. | 公表国 OIE |
|---|---|---|---|---|
| 販売名(企業名) | 赤血球濃厚液-LR「日赤」(日本赤十字社)<br>照射赤血球濃厚液-LR「日赤」(日本赤十字社) | | | |

**研究報告の概要**

○世界(英国を除く)の畜牛におけるウシ海綿状脳症(BSE)症例の報告数
1989年から2008年までに、世界各国から国際獣疫事務局(OIE)に報告されたウシ海綿状脳症の報告数である。2008年にBSE症例が報告されたのはカナダ(4頭)、フランス(8頭)、ドイツ(2頭)、アイルランド(23頭)、イタリア(1頭)、日本(1頭)、オランダ(1頭)、ポーランド(5頭)、ポルトガル(18頭)、スペイン(25頭)である。

| 報告企業の意見 | 今後の対応 |
|---|---|
| 1989年から2008年までに、世界各国(英国を除く)から国際獣疫事務局(OIE)に報告されたウシ海綿状脳症の報告数である。 | 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、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1980～96年に1日以上の英国滞在歴のある人の献血を制限している。今後もCJD等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**

赤血球濃厚液-LR「日赤」
照射赤血球濃厚液-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

undefined

* Number of cases in the United Kingdom
* Number of reported cases worldwide (excluding the United Kingdom) * Cases in imported animals only
* Annual incidence rate

# Number of reported cases of bovine spongiform encephalopathy (BSE) in farmed cattle worldwide*(excluding the United Kingdom)

| Country/Year | 1989 | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Austria | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 2 | 1 | 0 |
| Belgium | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 6 | 3 | 9 | 46 | 38 | 15 | 11 | 2 | 2 | 0 | 0 |
| Canada | 0 | 0 | 0 | 0 | 1(b) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2(a) | 1 | 1 | 5 | 3 | 4 |
| Czech Republic | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 4 | 7 | 8 | 3 | 2 | 0 |
| Denmark | 0 | 0 | 0 | 1(b) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 6 | 3 | 2 | 1 | 1 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1(a) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| France | 0 | 0 | 5 | 0 | 1 | 4 | 3 | 12 | 6 | 18 | 31(a) | 161(d) | 274(e) | 239(f) | 137(g) | 54(h) | 31 | 8 | 9 | 8 |
| Germany | 0 | 0 | 0 | 1(b) | 0 | 3(b) | 0 | 0 | 2(b) | 0 | 0 | 7 | 125 | 106 | 54 | 65 | 32 | 16 | 4 | 2 |
| Greece | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Ireland | 15(a) | 14(a) | 17(a) | 18(a) | 16 | 19(a) | 16(a) | 73 | 80 | 83 | 91 | 149(d) | 246(e) | 333(f) | 183(g) | 126(h) | 69(i) | 41(j) | 25(k) | 23(l) |
| Israel | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| Italy | 0 | 0 | 0 | 0 | 0 | 2(b) | 0 | 0 | 0 | 0 | 0 | 0 | 48 | 38(a) | 29 | 7 | 8 | 7 | 2 | 1 |
| Japan | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3(e) | 2 | 4(g) | 5 | 7 | 10 | 3 | 1 |
| Liechtenstein | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2(a) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Luxembourg | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 2 | 2 | 20 | 24 | 19 | 6 | 3 | 2 | 2 | 1 |
| Poland | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4(f) | 5 | 11 | 19 | 10 | 9 | 5 |
| Portugal | 0 | 1(b) | 1(b) | 1(b) | 3(b) | 12 | 15 | 31 | 30 | 127 | 159 | 149(a) | 110 | 86 | 133 | 92(a) | 46 | 33 | 14 | 18 |
| Slovakia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 6 | 2 | 7 | 3 | 0 | 1 | 0(i) |
| Slovenia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 2(a) | 1 | 1 | 1 | 0 |
| Spain | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 82 | 127 | 167 | 137 | 98 | 68 | 36 | 25 |
| Sweden | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0(i) |
| Switzerland | 0 | 2 | 8 | 15 | 29 | 64 | 68 | 45 | 38 | 14 | 50 | 33(d) | 42 | 24 | 21(g) | 3 | 3(i) | 5 | 0 | 0 |
| United Kingdom | see particular table | | | | | | | | | | | | | | | | | | | |
| United States of America | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 |

* Cases are shown by year of confirmation.
... Not available

(a) **Canada:** 1 case diagnosed in Canada in May 2003 + 1 case diagnosed in the United States of America in December 2003 and confirmed as having been imported from Canada.
**Finland:** date of confirmation of the case: 7 December 2001.
**France:** includes 1 imported case (confirmed on 13 August 1999).
**Ireland:** includes imported cases: 5 in 1989, 1 in 1990, 2 in 1991 and 1992, 1 in 1994 and 1995.
**Italy:** includes 2 imported cases.
**Liechtenstein :** date of the last confirmation of a case: 30 September 1998.
**Portugal:** includes 1 imported case.
**Slovenia:** includes 1 imported case.

(b) Imported case(s).

(c) **Ireland** - Data as of 31 March 2009. Cases detected by the active surveillance programme = 4.

**Luxembourg** - Data as of 28 February 2009.

(d) **France year 2000** - Clinical cases = 101. Cases detected within the framework of the research programme launched on 8 June 2000 = 60.
**Ireland year 2000** - Clinical cases = 138. Cases identified by active surveillance of at risk cattle populations = 7. Cases identified by examination of depopulated BSE positive herds, birth cohorts and progeny animals = 4.
**Switzerland year 2000** - Clinical cases = 17. Cases detected within the framework of the investigation programme = 16.

(e) **France year 2001** - Clinical cases = 91. Cases detected at rendering (bovines at risk) = 100 (out of 139,500 bovines tested). Cases detected as result of routine screening at the abattoir = 83 (out of 2,373,000 bovines tested).
**Ireland year 2001** - Clinical cases = 123. Cases identified by systematic active surveillance of all adult bovines = 119. Cases identified by examination of depopulated BSE positive herds, birth cohorts and progeny animals = 4.
**Japan year 2001** - Clinical cases = 1. Cases detected as result of screening at the abattoir = 2.

(f) **France year 2002** - Clinical cases = 41. Cases detected at rendering (bovines at risk) = 124 (out of 274,143 bovines tested). Cases detected as result of systematic screening at the abattoir = 74 (out of 2,915,103 bovines tested). The active BSE surveillance programmes implemented in France in 2002 led to routine examination of cattle aged over 24 months, which were slaughtered for consumption purposes, were euthanised or died due to other reasons.
**Ireland year 2002** - Clinical cases = 108. Cases detected by the active surveillance programme = 221. Cases identified by examination of depopulated BSE positive herds, birth cohorts and progeny animals = 4.
**Poland year 2002** - Clinical cases = 1. Cases detected as result of routine screening at the abattoir (cattle over 30 months) = 3.

(g) **France year 2003** - Clinical cases = 13. Cases detected at rendering (bovines at risk) = 87. Cases detected as result of systematic screening at the abattoir = 37.
**Japan year 2003** - The 9th case was a bullock aged 21 months.
**Ireland year 2003** - Clinical cases = 41. Cases detected by the active surveillance programme = 140.
**Switzerland year 2003** - Clinical cases: 8. Cases detected within the framework of the official surveillance programme: 11. Cases detected through voluntary testing following routine slaughter: 2.

(h) **France year 2004** - Clinical cases = 8: Cases detected at rendering (bovines at risk) = 29. Cases detected as result of systematic screening at the abattoir = 17.
**Ireland year 2004** - Clinical cases = 31. Cases detected by the active surveillance programme = 94. Cases identified by examination of depopulated BSE positive herds, birth cohorts and progeny animals = 1.

(i) **Ireland year 2005** - Cases detected by the passive surveillance programme = 13. Cases detected by the active surveillance programme = 56.
**Switzerland year 2005** - Cases detected by the passive surveillance programme = 1. Cases detected within the framework of the official surveillance programme: 1. Cases detected through voluntary testing following routine slaughter = 1.

(j) **Ireland year 2006** - Cases detected by the passive surveillance programme = 5. Cases detected by the active surveillance programme = 36.

(k) **Ireland year 2007** - Cases detected by the passive surveillance programme = 5. Cases detected by the active surveillance programme = 20.

(l) **Ireland year 2008**- Cases detected by the passive surveillance programme = 3. Cases detected by the active surveillance programme = 20.
**Slovakia** - Data as of 30 June 2008.
**Sweden** - Data as of 30 June 2008.

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*Last update : 07-Avr-2009 (fr)*

# 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 |
|---|---|---|---|---|---|---|
| | | | | 2009. 4. 15 | 該当なし | |

| 一般的名称 | 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) | 赤血球濃厚液-LR「日赤」(日本赤十字社)<br>照射赤血球濃厚液-LR「日赤」(日本赤十字社) | | OIE - World Organisation for Animal Health. Available from: http://www.oie.int/eng/info/en_esbru.htm. | OIE |

**研究報告の概要**

○英国の畜牛におけるウシ海綿状脳症(BSE)症例の報告数
1987年以前から2008年までに、英国から国際獣疫事務局(OIE)に報告されたウシ海綿状脳症の報告数である。2008年にはグレートブリテン島で33頭、北アイルランドで4頭の計37頭が報告された。

| 報告企業の意見 | 今後の対応 |
|---|---|
| 1987年以前から2008年までに、英国から国際獣疫事務局(OIE)に報告されたウシ海綿状脳症の報告数である。 | 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、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1980～96年に1日以上の英国滞在歴のある人の献血を制限している。今後もCJD等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**

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照射赤血球濃厚液-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