time of the last visit, death, seroconversion, or receipt of an additional transfusion that was either HHV-8–seropositive or had equivocal results (more than 2 months after transfusion). Transfusions that were repeatedly HHV-8–seronegative were allowed throughout follow-up and did not lead to censoring of data.

LABORATORY PROCEDURES

Specimens were transported daily from Mulago Hospital to the Centers for Disease Control and Prevention (CDC) laboratory at the Uganda Virus Research Institute in Entebbe. The recipient's pretransfusion plasma was tested for antibodies against HIV, and reactivity was confirmed by polymerase-chain-reaction assay for recipients who were 24 months of age or younger.

Testing for HHV-8 antibody was performed at the CDC in Atlanta. Three serologic assays were used: two peptide enzyme immunoassays based on epitopes in the open reading frames 65 and K8.1[22,23] and an immunofluorescence assay based on lytic HHV-8 antigens.[24] The immunofluorescence assay was performed as described previously,[24] except that plasma was diluted to 1:40 for screening and 1:80 for confirmation. Specimens that showed reactivity in two or more tests (with the immunofluorescence assays performed at two different dilutions counted as separate tests) were categorized as positive. Results were categorized as equivocal when more than one of the individual assays showed equivocal reactivity or when the test results were conflicting or incomplete because of depletion of the specimen. For all recipients, the pretransfusion specimen and the linked specimen from the blood donor were tested for antibodies against HHV-8. For recipients who were HHV-8–seronegative before transfusion, the last two follow-up specimens were tested, and if either was positive, all follow-up specimens were tested. The laboratory staff was unaware of the recipient–donor linkages.

For the purpose of analysis, patients who had received a transfusion of any HHV-8–seropositive blood products were categorized as exposed, regardless of the serologic status of additional units. Patients who had received transfusions of HHV-8–seronegative blood alone were categorized as unexposed. Patients who had received blood with equivocal serologic status or a combination of seronegative blood and blood with equivocal serologic status were excluded from the analysis.

STATISTICAL ANALYSIS

The data were double-entered with the use of Epi Info software (version 6.04) and analyzed with the use of Stata software (version 8.0) and SAS software. The primary data analysis evaluated whether the risk of HHV-8 seroconversion was higher among recipients of HHV-8–seropositive blood than among those who received seronegative blood. To allow sufficient time for HHV-8 antibodies to develop in the event of an infection and for any passive HHV-8 antibodies from the donor to be cleared, seroconversion was defined as two or more consecutive HHV-8–seropositive results obtained at least 25 days after transfusion. The date of seroconversion was defined as the midpoint between the last seronegative and the first seropositive visit.

For each recipient, we analyzed the variables of sex, number of children in the household, HIV status, hemoglobin concentration, admission diagnosis, number of transfusions, volume and component (whole blood, packed cells, or plasma) of blood transfused, and duration of blood storage, according to the recipient's exposure status and risk of seroconversion. Continuous variables with a normal distribution were analyzed by Student's t-test, and those with a non-normal distribution were analyzed by the Wilcoxon rank-sum test. Categorical variables were analyzed by Fisher's exact test.

Using survival analysis, we compared the risk of HHV-8 seroconversion over time in the exposed and unexposed groups. We calculated the excess risk of seroconversion as the difference between the Kaplan–Meier survival functions for time to seroconversion in exposed and unexposed recipients, both for the full follow-up period and for the 3-to-10-week period after transfusion that is most likely to be associated with transfusion-transmitted infection. We used Greenwood's formula (SAS software) to calculate the variance of the excess risk as the sum of the variance of the Kaplan–Meier estimates. Confidence intervals were calculated by using a normal approximation. We evaluated recipients' age, the number of blood units transfused, and the duration of blood storage for confounding and an interaction with exposure status. All comparisons were two-sided, and a P value of less than 0.05 was considered to indicate statistical significance.

The study was approved by the Uganda National Council for Science and Technology and

the institutional review board of the CDC and the Uganda Virus Research Institute. Written informed consent was obtained from all adults and from the parents of children less than 18 years old.

RESULTS

STUDY POPULATION

A total of 6533 patients had pretransfusion specimens and were evaluated for enrollment (Fig. 1). Of these, 72.3% were not enrolled because they did not receive a transfusion, were too ill, declined participation, lived too far away, died, or were discharged before enrollment. The remaining 1811 recipients were enrolled and followed for an average of 4.6 months. The seroprevalence of HHV-8 among the 1761 linked blood donations was 36.2%. The seroprevalence of HHV-8 was 14.5% overall among the enrolled patients before transfusion and increased with age; the seroprevalence was 11.4% among those 2 years of age, 14.9% among those 5 years of age, 21.2% among those 10 years of age, 27.8% among those 20 years of age, and 32.4% among those 30 years of age or older.

Of the 1811 transfusion recipients who were enrolled, 820 were excluded from seroconversion analysis: 266 were seropositive for HHV-8 before transfusion, 17 had equivocal serologic results before transfusion, 101 had received blood from unlinked donors, 362 had insufficient follow-up, 62 had an additional transfusion with a positive or equivocal HHV-8 test result 8 days to 2 months after the first transfusion, and 12 had other reasons for exclusion (Fig. 1). The characteristics of the 991 recipients included in the seroconversion analysis are summarized in Table 1. The recipients tended to be young (median age, 1.5 years; interquartile range, 0.1 to 4.6), and most had received one transfusion (range, one to eight). The majority (79.2%) had received packed red cells, 14.6% had received whole blood, 0.2% had received plasma, and 6.0% had received units of undetermined type. On the average, a recipient had 7 follow-up visits (range, 3 to 12) and was observed for 144 days (Table 1).

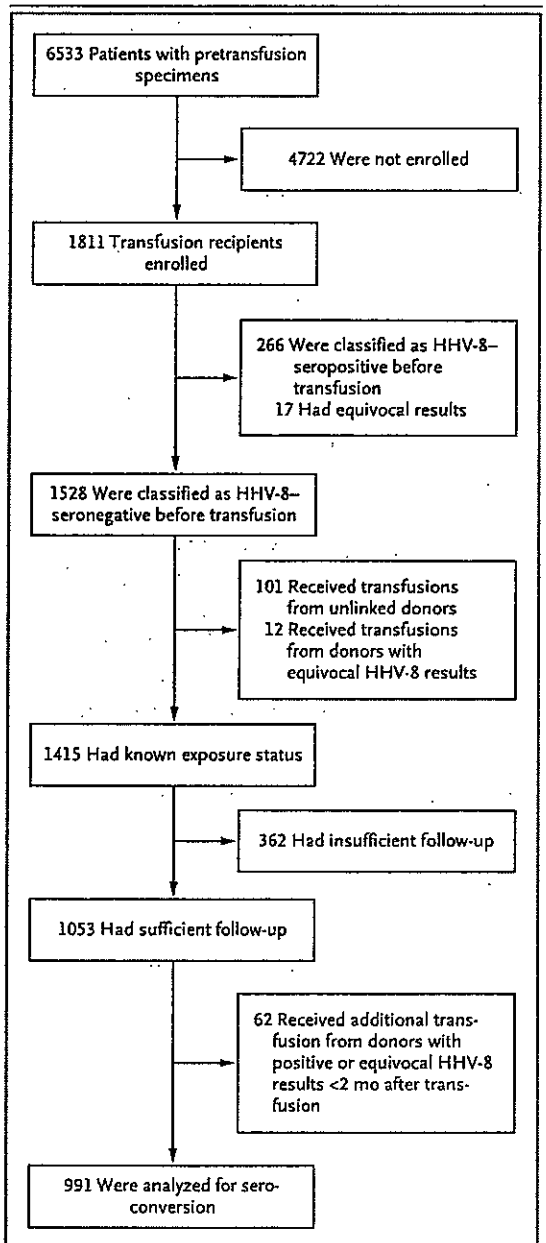


Figure 1. Enrollment and Outcomes.

HHV-8 SEROCONVERSION

Of the 991 patients included in the analysis, 425 (42.9%) received HHV-8–seropositive units and 566 (57.1%) received only HHV-8–seronegative units. Forty-one recipients (4.1%) met the case definition for HHV-8 seroconversion. The excess risk of seroconversion after transfusion with HHV-8–seropositive blood during the 24-week follow-up period was 2.8% (Table 2), suggesting that an estimated 12 of the 425 patients who received HHV-8–seropositive blood were infected by transfusion. The seroconversion risks for various periods after transfusion are presented in Table 2. At week 3, there was no significant difference in risk between exposed recipients and unexposed recipients; however, by week 10, the excess risk of

Table 1. Characteristics of the Study Patients According to Whether They Were Exposed to HHV-8–Seropositive Blood during Transfusion.*

Characteristic	All Patients (N=991)	Exposed Patients (N=425)	Unexposed Patients (N=566)	Odds Ratio†	P Value
Female sex — no. (%)	515 (52.0)	234 (55.1)	281 (49.6)	1.24	0.09
Median age — yr	1.5	1.6	1.5	—	0.14
Age ≥2 yr — no. (%)	400 (40.4)	188 (44.2)	212 (37.5)	1.32	0.03
HIV-infected — no./total no. (%)	76/758 (10.0)	28/319 (8.8)	48/439 (10.9)	0.78	0.33
Reason for transfusion — no./total no. (%)					
Malaria	828/988 (83.8)	344/423 (81.3)	484/565 (85.7)	0.73	0.07
Obstetrical or gynecologic procedure	46/988 (4.7)	19/423 (4.5)	27/565 (4.8)	0.94	0.83
Sickle cell anemia	48/988 (4.9)	21/423 (5.0)	27/565 (4.8)	1.04	0.89
Hemorrhage	20/988 (2.0)	11/423 (2.6)	9/565 (1.6)	1.65	0.27
Cancer	4/988 (0.4)	1/423 (0.2)	3/565 (0.5)	0.44	0.47
Unknown	42/988 (4.3)	27/423 (6.4)	15/565 (2.7)	2.50	0.004
Median duration of blood storage — days	5.0	5.0	5.0	—	0.73
Median observation time — days	144	144	144	—	0.92
Mean no. of follow-up visits	7.3	7.1	7.3	—	0.17
Mean no. of transfusions per recipient	1.3	1.4	1.2	—	0.001

* Patients who had received a transfusion of any HHV-8–seropositive blood products were categorized as exposed, regardless of the serologic status of additional units. Patients who had received transfusions of HHV-8–seronegative blood alone were categorized as unexposed.
† Odds ratios are for seroconversion in the exposed patients as compared with the unexposed patients.

Table 2. Kaplan–Meier Estimates of Cumulative Risk of HHV-8 Seroconversion after Blood Transfusion.*

Observation Period	Study Population		Patients with Seroconversion		Risk of Seroconversion		Excess Risk (95% CI)†	P Value
	Exposed Patients	Unexposed Patients	Exposed Patients	Unexposed Patients	Exposed Patients	Unexposed Patients		
	number				*percent*			
Wk 1–3	425	566	4	7	0.9	1.2	−0.3 (−1.6 to 1.0)	0.69
Wk 1–10	425	566	18	11	4.2	1.9	2.3 (0.1 to 4.6)	0.04
Wk 1–24	425	566	24	17	5.9	3.1	2.8 (0.1 to 5.5)	<0.05
Wk 3–10	421	559	14	4	3.4	0.7	2.7 (0.8 to 4.6)	0.005
Blood storage‡								
≤4 days	156	—	9	—	5.9	—	4.2 (0.1 to 8.3)	<0.05
>4 days	240	—	4	—	1.7	—		

* Patients who had received a transfusion of any HHV-8–seropositive blood products were categorized as exposed, regardless of the serologic status of additional units. Patients who had received transfusions of HHV-8–seronegative blood alone were categorized as unexposed.
† Confidence intervals (CIs) that do not cross zero indicate statistical significance.
‡ For the analysis of the effect of the duration of blood storage, the total number of exposed recipients was reduced to 396, because recipients who had multiple storage records or conflicting or missing data were not included.

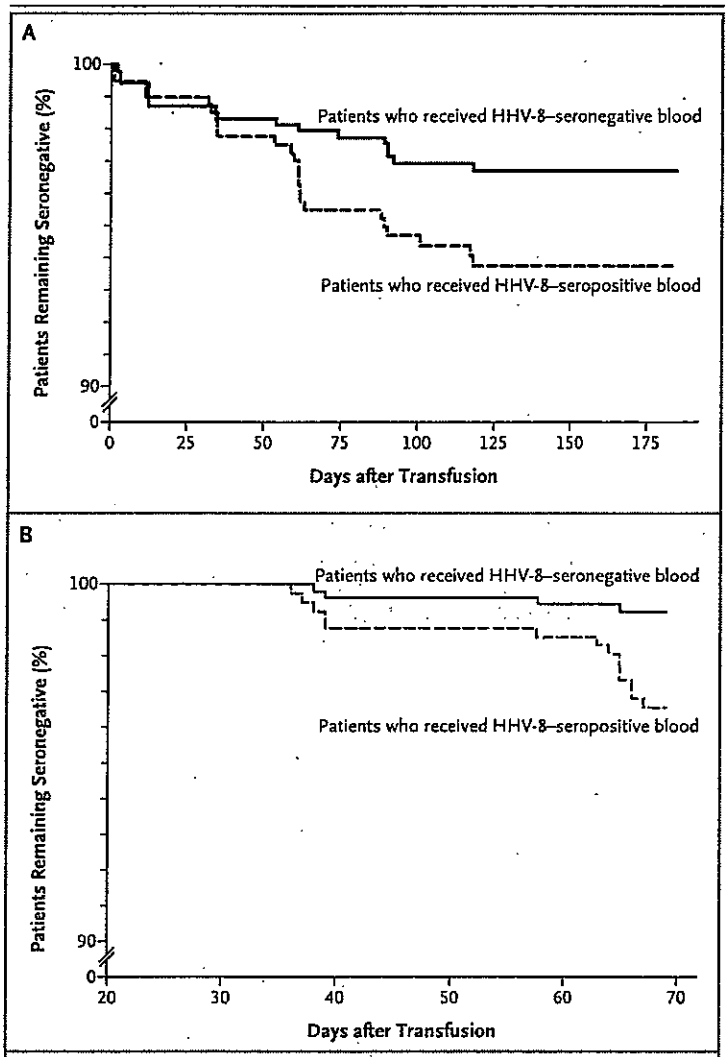


Figure 2. Kaplan–Meier Analysis of the Percentage of Transfusion Recipients Who Remained Seronegative for the Entire 6-Month Follow-up Period (Panel A) and from Week 3 to 10 after Transfusion (Panel B), According to Whether They Were Exposed to HHV-8–Seronegative or HHV-8–Seropositive Blood.

Patients who had received a transfusion of any HHV-8–seropositive blood products were categorized as exposed, regardless of the serologic status of additional units. Patients who had received transfusions of HHV-8–seronegative blood alone were categorized as unexposed. During the entire 6-month follow-up period, there were 24 seroconversions among exposed recipients, as compared with 17 among unexposed recipients ($P<0.05$) (Panel A). During the first 3 to 10 weeks after transfusion, there were 14 seroconversions among exposed recipients, as compared with 4 among unexposed recipients ($P=0.005$) (Panel B).

seroconversion for exposed recipients rose to 2.3% ($P=0.04$). The excess risk among exposed recipients was 2.8% ($P<0.05$) through week 24 and 2.7% for the period from week 3 to week 10 ($P=0.005$) (Table 2 and Fig. 2). Figure 3A shows the time to seroconversion after transfusion for the 41 recipients with conversion and highlights the proportionately greater number of seroconversions among exposed recipients 3 to 10 weeks after transfusion. Figure 3B shows the numbers of exposed and unexposed transfusion recipients according to age group.

The relation between the duration of blood storage and seroconversion was also evaluated for the recipients of HHV-8–seropositive blood. An excess risk of 4.2% was observed among patients who received blood stored for up to 4 days, as compared with those who received blood stored for more than 4 days (Table 2). The risk of seroconversion was not associated with the number of HHV-8–seropositive units transfused, the volume of blood transfused, the type of blood component, the sex or HIV status of the recipient, or the number of children in the recipient's household.

All 41 recipients with seroconversion had been found to be seronegative for HHV-8 when examined on visits before seroconversion. Reversion to seronegative status was not observed, although one patient had equivocal reactivity at the last follow-up visit after having had four visits with seropositive results. Seroconversion did not occur in 12 patients who received seropositive units from donations linked to persons with seroconversion (split donations); however, on follow-up visits, some of them had seroreactivity on one test or were seropositive at one visit and therefore did not meet the criteria for seropositivity or seroconversion.

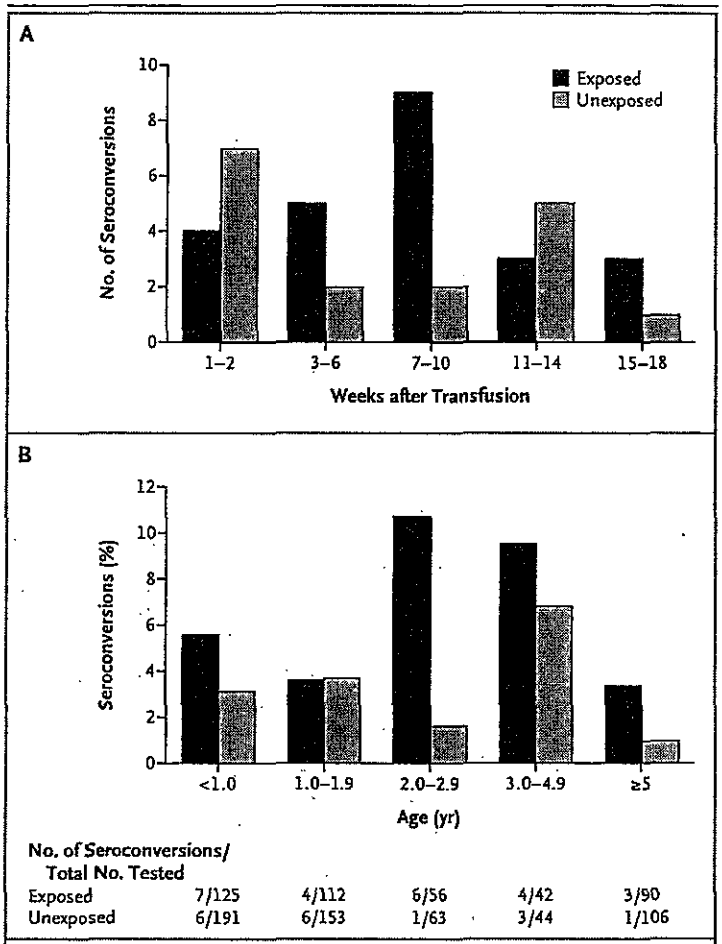
DISCUSSION

We conducted a prospective cohort study assessing the risk of transfusion-associated HHV-8 infection in a large population of linked blood donors and transfusion recipients. Patients who received HHV-8–seropositive blood were significantly more likely to become infected than were recipients of seronegative blood. The increased risk associated with receiving HHV-8–seropositive blood was most striking among recipients in whom seroconversion occurred 3 to 10 weeks after transfusion, an interval that is similar to the timing of the immune response for other transfusion-transmitted herpesviruses.[25] The risk of seroconversion was also higher among recipients of seropositive units that had been stored with shorter storage times than among recipients of blood that had been stored for more than 4 days

(excess risk, 4.2%), as has been found with other herpesviruses.[25] Together, these results provide compelling evidence of the transmission of HHV-8 by blood transfusion.

Previous studies have not detected transfusion-associated HHV-8 infection,[6-8,26] probably because of small samples, low seroprevalence of HHV-8 in the donor pool, low[27-29] or intermittent[30] viremia among antibody-positive donors, and deferral of donors at risk for infectious diseases. The design and setting of our study — with a large study population, high seroprevalence of HHV-8 in the community, short duration of blood storage before transfusion, and absence of leukocyte reduction — optimized our ability to detect transfusion-associated transmission of HHV-8 even in the context of a high rate of incident infection, especially in our young study population, who had early and relatively rapid acquisition of HHV-8 (with a seroprevalence of 15% by the age of 5 years).

To account for the fact that HHV-8 serologic assays are not standardized, we used stringent criteria for seropositivity and seroconversion, which provided greater specificity but probably lowered our testing sensitivity and estimates of risk. In this setting, we estimated that 2.8 infections occurred for every 100 seronegative recipients of HHV-8–seropositive blood. A retrospective, cross-sectional study of children with sickle cell disease in the same hospital[20,31] estimated a similar risk of infection. The Nakasero Blood Bank released 52,512 blood units for use in 2001. By extrapolating the findings of our study (and adjusting the seroprevalence of HHV-8 in the patient population to 21% according to age), we estimated that these transfusions may have resulted in approximately 300 HHV-8 infections in 2001.



No. of Seroconversions/ Total No. Tested					
Exposed	7/125	4/112	6/56	4/42	3/90
Unexposed	6/191	6/153	1/63	3/44	1/106

Figure 3. Seroconversion among Patients Who Received HHV-8–Seronegative Blood and Those Who Received HHV-8–Seropositive Blood, According to the Interval between Transfusion and Seroconversion (Panel A) and the Recipient's Age (Panel B).

Patients who had received a transfusion of any HHV-8–seropositive blood products were categorized as exposed, regardless of the serologic status of additional units. Patients who had received transfusions of HHV-8–seronegative blood alone were categorized as unexposed. In Panel A, from 3 to 10 weeks after transfusion, seroconversion was proportionately more common among exposed recipients than among unexposed recipients.

The policy implications of our findings warrant careful consideration. High-throughput serologic assays suitable for blood-bank screening do not yet exist for HHV-8. Nucleic acid testing would not be effective, since most seropositive blood donors tested to date have had very low or undetectable HHV-8 viral loads. Having enough blood available for transfusion is an ongoing public health challenge throughout sub-Saharan Africa; availability would be jeopardized by efforts to eliminate donations from HHV-8–positive donors in high-prevalence areas. Further studies are needed to determine whether leukocyte reduction, longer storage time, or other techniques could reduce the risk of transmission of HHV-8. However, the cost and logistics of leukocyte reduction would probably be substantial barriers in most African countries, and longer storage times might increase the risk of bacterial infection and other adverse events.[32]

The relevance of our findings with respect to the U.S. blood supply may be different from that in Uganda, since the seroprevalence of HHV-8 among blood donors in the United States is low (3.5%).[5] Most blood products in the United States are leukocyte reduced, but the efficacy of this tech-

nique for reducing the risk of HHV-8 infection has not been evaluated. The risk of transfusion-associated Kaposi's sarcoma would be highest among HIV-infected and other immunocompromised recipients. Selective screening of blood products for immunocompromised populations may be warranted if this approach is found to be effective.

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No potential conflict of interest relevant to this article was reported.

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Department of Health and Human Services.

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別紙様式第2-1

No. 1

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
			2006. 9. 16	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	中日新聞. 2006 Sep 4.	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)			日本

研究報告の概要

○日本人でHIV2型の感染初確認 西アフリカで輸血

エイズウイルス(HIV)のうち、世界で感染が広がっている主流のHIV1型とは遺伝子タイプが異なる2型に日本人が感染したことを、厚生労働省のエイズ研究班が確認したことが9月3日分かった。国内滞在中の外国籍の感染者は過去に報告があるが、日本人感染者の確認は初めてである。厚労省は、医療機関や保健所などが実施している検査で2型の感染を見逃さないよう、検査の徹底を求める通知を出した。

HIV2型の感染が確認されたのは、過去に西アフリカで輸血を受けた経験がある男性である。同省は「滞在していた地域では2型が流行しており、現地での輸血が感染原因とみられる」としている。

男性は気管支ぜんそくの症状で国内の医療機関に入院した。治療を受け回復し、既に退院している。入院時の1次検査でHIV感染の疑いが分かり、確認検査で2型と分かった。エイズ研究班を通じ8月に厚労省に情報提供された。

日本での2型の感染確認はこれまで、検査のため来日した韓国籍の男性や、定住者のアフリカ出身の男性ら計3例の報告がある。

厚労省によると、保健所や医療機関で実施されているHIVの1次検査では、1型、2型を問わず感染の疑いを判別する。その後に実施される確認検査では、1型と2型を別々に調べる必要がある。同省は「通常は両方とも調べており緊急対応が必要な状況ではないが、感染がまれな2型の検査が抜け落ちると見逃す恐れがあり、検査の徹底が必要」として、都道府県などに通知を出し、管内の保健所や医療機関に対し注意喚起するよう求めた。

報告企業の意見	今後の対応
HIV2型に西アフリカで輸血を受けたことがある日本人が感染したことが初めて確認されたとの報告である。	日本赤十字社では、輸血感染症防止のため国内外を問わず輸血歴のあるドナーを無期限に献血延期としている。また、国内のHIV感染、AIDS発生の動向について、引き続き情報の収集に努めるとともに、次期NAT試薬についても評価する。

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

47

5

別紙1

MedDRA/J Ver.8.0.1

日本人でHIV2型の感染初確認

西アフリカで輸血

エイズウイルス(HIV)のうち、世界で感染が広がっている主流のHIV1型とは遺伝子タイプが異なる2型に日本人が感染したことを、厚生労働省のエイズ研究班が確認したことが3日、分かった。

同省によると、国内滞在中の外国籍の感染者は過去に報告があるが、日本人感染者の確認は初めて。

厚労省は、医療機関や保健所などが実施している検査で2型の感染を見逃さないよう、検査の徹底を求める通知を出した。

同省によると、HIV2型の感染が確認されたのは、過去に西アフリカで輸血を受けた経験がある男性。同省は「滞在していた地域では2型が流行しており、現地での輸血が感染原因とみられる」としている。

男性は気管支ぜんそくの症状で国内の医療機関に入院。治療を受け回復し、既に退院している。入院時の1次検査でHIV感染の疑いが分かり、確認検査で2型と分かった。エイズ研究班を通じ8月に厚労省に情報提供された。

日本での2型の感染確認はこれまで、検査のため来日した韓国籍の男性や、定住者のアフリカ出身の男性ら計3例の報告がある。

厚労省によると、保健所や医療機関で実施されているHIVの1次検査では、1型、2型を問わず感染の疑いを判別。その後に実施される確認検査では、1型と2型を別々に調べる必要がある。

同省は「通常は両方とも調べており緊急対応が必要な状況ではないが、感染がまれな2型の検査が抜け落ちると見逃す恐れがあり、検査の徹底が必要」として、都道府県などに通知を出し、管内の保健所や医療機関に対し注意喚起するよう求めた。

◇徹底検査に尽きる　吉倉広・元国立感染症研究所所長の話

さまざまな国とこれだけ人の行き来がある中で、エイズウイルス(HIV)2型への日本人の感染は当然予想されたものというべきで、保健所や医療機関の検査で見落とさないようにすることに尽きる。2型の今後の広がりを把握するため、HIV感染の監視制度の在り方についても、コストの点を考慮しながら検討を進めていく必要があるだろう。

＜エイズウイルス(HIV)2型＞　世界的に感染の主流となっている1型に対し、遺伝子のタイプが異なり、感染力が比較的弱いとされる。主に西アフリカ地域で流行。フランスやインドなどでも報告例がある。感染しても潜伏期間が長く、症状の進行も遅いとされている。