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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
既往歴の質問は，血液ドナーの感染リスクを判断するために供血前インタビュー時に実施される。この調査はこれらの質問事項の効果を評価する目的で行われた。2000 年から 2001 年にかけて一時的に除外されたドナーのうち，それ以前の 2 年間に供血未経験，除外されたことのあるドナーの 22.08%が 2000 年から 2003 年にかけて再度供血に訪れていた。以前 2 年間に供血未経験，或いは除外されたことのあるドナーと初回供血者を比較した場合，また過去に供血したことがある者と反復供血者を比較した場合，感染症リスクがあったため一時的に除外されたことのある再来供血者であっても，ウイルスマーカーの罹患率に変化は見られなかった。 この調査結果より，ウイルス感染リスクがあったため 2000 年から 2001 年にかけて一時的に除外された供血者で再来した者は初回供血者又は反復供血者と比較してもリスクに変化は見られないことが確認された。	BYL-2005-0192

報告企業の意見	今後の対応
この調査結果から，供血において事前に確認できない場合もリスクの増大は示唆されないと考えられる。	現時点で新たな安全対策上の措置を講じる必要はないと考える。引き続き関連情報の収集に努める。

Prevalence of selected viral infections among temporarily deferred donors who returned to donate blood: American Red Cross blood donor study

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BACKGROUND: Health history questions are introduced into the predonation interview to identify blood donors believed to pose a higher risk of infectious diseases to recipients. This study assesses the current impact of some of those questions.

STUDY DESIGN AND METHODS: Donor deferral and donation data were extracted from a research database of the American Red Cross. The prevalence of hepatitis B surface antigen or antibodies to human immunodeficiency virus, hepatitis C virus, or human T-lymphotropic virus was obtained for different groups of donors who were temporarily deferred in 2000 through 2001 and later returned to donate blood in 2000 through 2003. The results were compared with either first-time or repeat donors in 2000 through 2003, while controlling for differences in sex, age, and year of donation.

RESULTS: Of donors temporarily deferred in 2000 through 2001 who had had no donation or deferral during the previous 2 years, only 22.08 percent subsequently returned to donate blood in 2000 through 2003. Donations from returning donors who had been deferred for potential infectious disease risk did not show a higher prevalence for any of the viral markers when those with no donation or deferral during the previous two years were compared with first-time donations, and those with prior donation were compared with repeat donations.

CONCLUSION: Blood donors temporarily deferred in 2000 through 2001 for potential risk of viral infection who later returned to donate blood did not appear to pose a higher risk compared to first-time or repeat donors. The effectiveness of some of the currently used deferral questions in reducing viral risks warrants further study.

The safety of blood collected for transfusion is ensured through appropriate procedures for donor recruitment and testing of donated blood units.[1] Safe donors are encouraged to donate their blood, whereas at-risk donors are encouraged to self-defer from blood donation. At blood collection sites, presenting donors are informed of known or newly identified risks of blood-borne infections to help their decision making regarding donation. Presenting donors are further interviewed for history of potential exposure to transmissible diseases that are caused by blood-borne infections such as human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human T-lymphotropic virus (HTLV). Donors who are believed to be at an increased risk for those infections are deferred from making a donation. All donors who pass the health history and physical findings screens are given an opportunity to have their blood donations not used for transfusion via a confidential exclusion process (known as confidential unit exclusion or CUE).[2] At the American Red Cross (ARC), donors with repeatedly reactive tests are currently deferred from making further donations regardless of the corresponding confirmatory test results; ARC does not employ routine reentry at this time.

ABBREVIATIONS: ARC = American Red Cross; BBPR = blood-borne pathogen risk; DS = donor safety; GBS = general blood safety; RR(s) = risk ratio(s).

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During the blood donor interview, donors are screened through medical examination and a questionnaire for health history. The examination and questions are related to either the safety of donors or their potential risk of exposure to infectious diseases.[3] For example, date of last donation, date of birth, hemoglobin (Hb) level, blood pressure, pulse, and weight are mainly for the safety of blood donors; histories of close contact with someone having or potentially at higher risk for HIV, hepatitis, or other blood-borne, sexually transmitted, or certain endemic infections are clearly for safety of the blood recipients. There are additional questions that could be related to blood safety broadly but not related to specific infections. Donors in the first category are deferred from donating blood because the donation process may harm their health. Donors in the latter two categories are deferred from donating blood to prevent blood recipients from exposure to potentially higher risk of infectious diseases. Such donors may be harboring an infectious agent and potentially be able to transmit that agent to recipients through the donated blood. Deferral could be indefinite or temporary, according to the cause for deferral. Indefinitely deferred donors should not return to donate their blood any longer, whereas temporarily deferred donors can return to donate after expiration of the deferral period. For blood-borne infections for which no testing is available, blood donor interview and subsequent deferral are believed to represent important safeguards against transfusion transmission of such infections. Even for blood-borne infections for which there is routine testing, donor interview and deferral are considered extra layers of assurance.

The expanding list of health history questions related to potential exposure to blood-borne infections has had a significant impact on the blood collection process. Not only have such questions resulted in a large number of blood donors being deferred each year by blood centers in the United States, but also many of the temporarily deferred donors do not return to donate blood anymore.[3-8] Few studies have been conducted to evaluate the interview process or the majority of the screening questions, other than the question related to exposure to bovine spongiform encephalopathy.[9-17] With the changing epidemiology of blood-borne infections among blood donors and the improved testing methods for donated blood, an assessment of the current impact of such an interview process and the screening questions has become more relevant. This study assesses the risks of infectious diseases among donors who were deferred for various reasons and later returned to donate blood through analysis of donor deferral data in the ARCNET Data Center of ARC. Donations from donors who had been temporarily deferred were compared against first-time or repeat donations from donors who had not been deferred for prevalence of infectious disease markers.

MATERIALS AND METHODS

Blood donors who presented to ARC Blood Services between January 1, 2000, and December 31, 2001, and were temporarily deferred from donating their blood were included in this study. The records of these donors were then followed up for their returning donations. Data for these deferred donors were merged with donation records for the period between 2000 and 2003 in the ARCNET database, and any donations that a deferred donor may have made after their deferral were identified through an identification number that is unique to an individual donor.

The ARCNET Data Center maintains data of blood donors and donations as well as donor deferrals, excluding name or other information that would allow identification of individual donors, for all blood services regions of the ARC since 1995.[18] The data include deferral codes, records of previous deferrals and donations, and both screening and confirmatory testing results of donated blood units for hepatitis B surface antigen (HBsAg); antibodies to HIV (anti-HIV), HCV (anti-HCV), and HTLV (anti-HTLV); and other markers.

Owing to the small number of deferrals for many questions or deferral codes, for the purpose of this study, the donor interview questions and health assessment codes that result in temporary deferral are classified into several categories according to certain similarities in the reason for deferral (Table 1). Findings from inspection of arms may result in two types of deferral: deferral code M6 for skin infection or deferral code 12 for intravenous or intramuscular drug use, which is an indefinite deferral and was not included in this study. Question 17, "In the past 12 months, have you traveled outside of the U.S. except Canada, Australia, New Zealand, Japan, or Western Europe, including the British Isles," relates to risk of exposure for malaria. Question 1, "Are you in good health today," and Question 33, "Do you have a medical condition not referred to in any question above which requires regular follow-up by a health-care professional," were grouped into "other deferrals" because they could be related to either donor safety (DS) or blood safety.

The deferred donors were further classified into three groups according to their prior donation or deferral history before the index deferral in 2000 through 2001: those who did not make any successful donation and had not been deferred during the 730 days before their index deferral (Group 1); those who had made one or more successful donations during the 730 days before the index deferral (Group 2); and those who had been deferred once or more during the 730 days before the index deferral (Group 3). If a deferred donor had made one or more donations and had had one or more deferrals during the 730 days before the index deferral, the donor was classified into Group 2 or Group 3 according to the dona-

TABLE 1. Categorization of deferral questions or codes

Category	Deferral questions or codes
DS	Date of last donation (D1) Date of birth (D2) Hb level (M1) Blood pressure (M3) Pulse (M4) "Do you have lung disease, other than asthma" (Question 11) "Are you a female who, in the past 6 weeks, has been pregnant or is now pregnant" (Question 29)
GBS	Temperature (M2) Findings from inspection of arms (M6) "Do you have an infection now, or are you taking antibiotics now" (question 2) "In the past 12 months, have you had injections for exposure to rabies or have you received any experimental vaccine" (Question 20) "In the past 3 years, have you taken Soriatane or in the past 4 weeks, taken Accutane, finasteride (Proscar or Propecia), or any experimental drug" (Question 30) "In the past 4 weeks, have you had any vaccination" (Question 31)
BBPR	"In the past 12 months, have you been in close contact with anyone having yellow jaundice or hepatitis, or have you received hepatitis B globulin (HBIG)" (Question 5) "In the past 12 months, have you received a blood transfusion or an organ or tissue transplant" (Question 18) "In the past 12 months, have you had a tattoo, ear/body piercing, acupuncture, accidental needlestick, come into contact with someone else's blood, or taken (snorted) cocaine or any other street drug through your nose" (Question 19) "In the past 12 months, have you had or been treated for syphilis or gonorrhea or tested positive for syphilis" (Question 21) "In the past 12 months, have you had sex, even once, with anyone who has ever used a needle for illegal or no-prescription drugs" (Question 22) "In the past 12 months, have you had sex, even once, with anyone who has taken money or drugs in exchange for sex since 1977" (Question 23) "In the past 12 months, have you given money or drugs to anyone to have sex with you" (Question 24) "In the past 12 months, have you had sex, even once, with anyone who has taken clotting factor concentrates" (Question 25) "In the past 12 months, have you had sex, even once, with anyone who has had AIDS or tested positive for the AIDS virus" (Question 26) "Are you a female, who, in the past 12 months, has had sex with a male who has had sex, even once, with another male since 1977" (Question 27)
Malaria exposure risk (Q17)	"In the past 12 months, have you traveled outside of the U.S. except Canada, Australia, New Zealand, Japan, or Western Europe, including the British Isles" (Question 17)
Other deferrals (other)	"Are you in good health today" (Question 1) "Do you have a medical condition not referred to in any question above which requires regular follow-up by a health-care professional" (Question 33)

tion or deferral that was immediately before the index deferral.

The patterns of returning donation were determined for these three groups of deferred donors. Donors who returned to make a nonvoluntary donation, such as autologous or therapeutic donations, were not counted as returning donors. Further, testing results of infectious disease markers for donations made by returning donors were compared with testing results for donations made to ARC Blood Services in 2000 through 2003 by all first-time or repeat volunteer donors who had not been deferred in 2000 through 2001. During the period covered by this study, all donations were tested as described previously for anti-HIV, anti-HCV, anti-HTLV, and HBsAg.[18] During this period, nucleic acid testing (NAT) was also performed on blood donations for detecting HIV RNA and HCV RNA.[19,20] NAT results, however, were not included in this study because the increased sensitivity of NAT over serologic tests mostly detects infections during the window periods before seroconversion while this study aims to use testing results on subsequent returning donations from deferred donors to reflect the risks at their time of deferral. To define the prevalence of infectious disease markers, the number of donations and the number of serologically confirmed positive donations were determined. Statistical analyses were carried out by computer software (SAS, SAS Institute, Inc., Cary, NC).[21] Comparisons were performed with chi-square test or Mantel-Haenszel chi-square test if data were stratified. Analysis of prevalence among different groups was performed with Poisson regression with SAS.[22] During the analysis, sex and age of donors and year of donations, as well as deferral categories, were included in the model. All reported p values are two-sided. A p value of less than 0.05 or a confidence interval (CI) of a risk ratio (RR) that does not include 1 indicates that a difference is considered to be significant.

RESULTS

Profile of temporarily deferred donors in 2000 through 2001

During the 2-year period between 2000 and 2001, a total of 1,229,268 donors were temporarily deferred for the reasons outlined above. The first deferral during the 2-year period was designated as the index deferral. Among those deferred, 42.46 percent had not made any successful donation and had not been deferred during the 730 days before the index deferral (Group 1), 55.69 percent had made at least one successful donation during the 730 days before the index deferral (Group 2), and 1.85 percent had been deferred at least once during the 730 days before the index deferral (Group 3). Table 2 shows the composition of temporarily deferred donors in 2000 through 2001 by sex and deferral category. For all three groups, women accounted for the majority of the deferrals, largely because of deferral for low Hb levels (part of the DS category). Women also contributed more deferrals attributed to other reasons with the exception of malaria risk (Q17). Within Group 1, the deferral category for blood-borne pathogen risk (BBPR) accounted for 10.5 percent of total temporarily deferred donors and malaria risk (Q17) accounted for 7.5 percent. Within the BBPR category, Question 19 (tattoo, ear and/or body piercing, acupuncture, accidental needlestick, blood contact, or drug snorting) accounted for 7.6 percent of all temporarily deferred donors. For Groups 2 and 3, relatively more deferred donors were accounted for by the DS category whereas other deferral categories contributed less. For example, the BBPR category accounted for only 3.1 percent in Group 2 and 4.1 percent in Group 3. The attribution to Question 19 was 2.1 and 2.7 percent, respectively.

Return of temporarily deferred donors

Table 3 shows the proportions of donors temporarily deferred in 2000 through 2001 who subsequently returned to donate blood between 2000 and 2003 after their index deferral, according to prior donation or deferral history (Group 1, 2, or 3) and by deferral category of the index deferral. Deferred donors who returned to make nonvoluntary donations, such as autologous or therapeutic donations, were excluded from both the numerators and the denominators for the calculation of return rates. Overall, 48.8 percent of temporarily deferred donors subsequently returned to donate blood, with 22.6 percent for those in Group 1, 68.9 percent for those in Group 2, and 46.0 percent for those in Group 3. Donors deferred for

TABLE 2. Composition (%) of a temporarily deferred donor population, 2000 through 2001* (n = 1,229,268)

	Group 1			Group 2			Group 3			Total		
Deferral category	Men	Women	Total	Men	Women	Total	Men	Women	Total	Men	Women	Total
DS	7.7	52.8	60.5	11.9	65.3	77.2	10.2	68.0	78.2	10.1	60.0	70.1
GBS	6.2	8.4	14.6	5.0	5.8	10.8	2.8	6.6	9.4	5.5	6.9	12.4
BBP risk†	4.6	5.9	10.5	1.3	1.8	3.1	1.3	2.8	4.1	2.7	3.6	6.3
Q19	3.5	4.1	7.6	0.8	1.3	2.1	0.8	1.9	2.7	2.0	2.5	4.4
Malaria risk	3.7	3.8	7.5	2.2	2.0	4.3	1.6	2.6	4.1	2.9	2.8	5.7
Other deferrals	2.8	4.0	6.8	2.3	2.4	4.6	1.4	2.7	4.1	2.5	3.1	5.5
Total	25.1	74.9	100.0	22.7	77.3	100.0	17.3	82.7	100.0	23.6	76.4	100.0

* By donation or deferral history during the 730 days before the index deferral: Group 1—no prior donation or deferral; Group 2—with prior donation; Group 3—with prior deferral.
† Including deferrals for Question 19 (Q19).

TABLE 3. Return rate of temporarily deferred donors with different history of prior donation or deferral*

Deferral	Group 1			Group 2			Group 3			Total		
category	Total	Returned	Percent	Total	Returned	Percent	Total	Returned	Percent	Total	Returned	Percent
DS	315,937	71,096	22.5	528,464	370,991	70.2	17,752	8,269	46.6	862,153	450,356	52.2
GBS	76,301	21,943	28.8	74,115	53,216	71.8	2,146	1,077	50.2	152,562	76,236	50.0
BBP risk†	54,926	9,259	16.9	21,113	9,185	43.5	941	303	32.2	76,980	18,747	24.4
Q19	39,416	7,109	18.0	14,392	6,036	41.9	617	183	29.7	54,425	13,328	24.5
Malaria risk	39,365	8,950	22.7	29,204	17,764	60.8	936	417	44.6	69,505	27,131	39.0
Other deferrals	35,428	6,890	19.4	31,705	20,675	65.2	935	386	41.3	68,068	27,951	41.1
Total	521,957	118,138	22.6	684,601	471,831	68.9	22,710	10,452	46.0	1,229,268	600,421	48.8

* By donation or deferral history during the 730 days before the temporary deferral: Group 1—no prior donation or deferral; Group 2—with prior donation; Group 3—with prior deferral.
† Including deferrals for Question 19 (Q19).

BBPR had the lowest return rate (24.4%), especially among those in Group 1 (16.9%). More than 70 percent of those in Group 2 who were deferred for DS subsequently returned to donate blood following their deferral. Even for donors in Group 2 who were deferred for BBPR, 43.5 percent returned to donate blood again after their deferral. The results indicate that, although return rates varied by deferral category, donors who had had prior donation, regardless of reasons for their deferral, showed higher return rates.

Sex and age compositions of temporarily deferred donors who subsequently returned to donate blood were compared with those who did not return to donate. For Groups 2 and 3, there were more older donors among those who returned. For example, among deferred donors in Group 2 who did not return, men and women of younger than 20 years accounted for 13.5 and 16.5 percent, respectively, whereas among returned donors, only 3.1 and 6.5 percent were men and women of the same age. Similarly, among deferred donors in Group 3 who did not return, 13.9 and 16.2 percent were men and women of younger than 20 years, compared to 3.1 and 5.0 percent among returned donors.

Prevalence of infectious disease markers among returned donors

The prevalences of confirmed positive tests for anti-HCV, anti-HIV, HBsAg, and anti-HTLV and for any one of the four markers (any marker) were determined for donors who were temporarily deferred in 2000 through 2001 and subsequently returned to donate in 2000 through 2003, by prior donation or deferral history before the index deferral. Overall, Group 1 had the highest prevalence among the three groups, whereas Group 2 had the lowest prevalence.

The prevalence results among returned donors were further analyzed by deferral categories, controlling for sex, age, and year of donation. Donations from Group 1 or Group 2 were compared with first-time or repeat donations, respectively. Table 4 shows the results of returning donations by Group 1, in comparison with first-time donations to the ARC Blood Services in 2000 through 2003 that were made by volunteer donors who had not been deferred in 2000 through 2001. Donors deferred for DS, general blood safety (GBS), malaria exposure risk (Q17), or other reasons had lower prevalence of anti-HCV, with a ratio of prevalence or RR and their confidential intervals (CIs) of 0.36 (CI, 0.28-0.45), 0.47 (CI, 0.33-0.68), 0.17 (CI, 0.07-0.41), or 0.56 (CI, 0.32-0.98), respectively, and lower prevalence of any marker, with an RR of 0.43 (CI, 0.35-0.52), 0.49 (CI, 0.36-0.68), 0.44 (CI, 0.28-0.71), or 0.54 (CI, 0.33-0.90), respectively. RR and CI can not be calculated for comparisons where one group had no marker positive.

Table 5 shows the comparison of Group 2 with repeat donations to the ARC Blood Services in 2000 through 2003 that were made by volunteer donors who had not been deferred in 2000 through 2001. Donors deferred for DS had a lower prevalence of anti-HCV with an RR of 0.27 (CI, 0.13-0.57), but a higher prevalence of anti-HIV with an RR of 3.63 (CI, 1.88-7.03). The differences for other deferral categories were not significant. RR and CI cannot be calculated for comparisons where one group had no marker positive.

TABLE 4. Prevalence (per 100,000) of viral markers among temporarily deferred and subsequently returned donors with no prior donation and/or deferral history (Group 1) in comparison with first-time donors

	Anti-HCV		Anti-HIV		HBsAg		Anti-HTLV		Any Marker	
Deferral category	Positive	Rate	Positive	Rate	Positive	Rate	Positive	Rate	Positive	Rate
DS	69	97.1	3	4.2	28	39.4	8	11.3	107	150.5
GBS	28	127.6	2	9.1	8	36.5	1	4.6	39	177.7
BBPR	13	140.4	1	10.8	10	108.0	1	10.8	24	259.2
Q19	9	126.6	1	14.1	5	70.3	1	14.1	15	211.0
Malaria risk (Q17)	5	55.9	0	0.0	10	111.7	2	22.3	17	189.9
Other deferrals (other)	12	174.2	0	0.0	2	29.0	1	14.5	15	217.8
First-time donations* (FT)	15,080	287.7	596	11.4	3,894	74.3	571	10.9	19,942	380.5
Comparison†										
DS vs. FT	0.36 (0.28-0.45)		0.51 (0.16-1.58)		0.72 (0.49-1.04)		0.63 (0.31-1.28)		0.43 (0.35-0.52)	
GBS vs. FT	0.47 (0.33-0.68)		0.89 (0.22-3.57)		0.52 (0.26-1.05)		0.39 (0.05-2.74)		0.49 (0.36-0.68)	
BBPR vs. FT	0.61 (0.35-1.04)		1.05 (0.15-7.48)		1.56 (0.84-2.89)		1.01 (0.14-7.16)		0.81 (0.54-1.21)	
Q19 vs. FT	0.62 (0.32-1.19)		1.39 (0.20-9.87)		1.01 (0.42-2.42)		1.51 (0.21-10.71)		0.72 (0.43-1.19)	
Q17 vs. FT	0.17 (0.07-0.41)		NA‡		1.51 (0.81-2.81)		1.56 (0.39-6.25)		0.44 (0.28-0.71)	
Other vs. FT	0.56 (0.32-0.98)		NA‡		0.41 (0.10-1.64)		1.02 (0.14-7.26)		0.54 (0.33-0.90)	

* Donations made by volunteer donors excluding those that had been deferred and subsequently returned to donate and are included in groups 1, 2, and 3.
† Data are reported RR (CI).
‡ NA = not available.

TABLE 5. Prevalence (per 100,000) of viral markers among temporarily deferred and subsequently returned donors with prior donation history (Group 2) in comparison with repeat donors

	Anti-HCV		Anti-HIV		HBsAg		Anti-HTLV		Any marker	
Deferral category	Positive	Rate	Positive	Rate	Positive	Rate	Positive	Rate	Positive	Rate
DS	7	1.9	10	2.7	5	1.3	1	0.3	23	6.2
GBS	3	5.6	2	3.8	1	1.9	0	0.0	6	11.3
BBPR	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Q19	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Malaria risk (Q17)	2	11.3	0	0.0	0	0.0	0	0.0	2	11.3
Other deferrals (other)	0	0.0	0	0.0	1	4.8	0	0.0	1	4.8
Repeat donations* (RP)	1109	6.3	221	1.3	374	2.1	47	0.3	1742	9.9
Comparison†										
DS vs. RP	0.27 (0.13-0.57)		3.63 (1.88-7.03)		1.21 (0.50-2.96)		0.45 (0.06-3.31)		0.67 (0.45-1.02)	
GBS vs. RP	0.76 (0.25-2.37)		3.03 (0.75-12.24)		1.36 (0.19-9.71)		NA‡		1.09 (0.49-2.44)	
BBPR vs. RP	NA‡		NA‡		NA‡		NA‡		NA‡	
Q19 vs. RP	NA‡		NA‡		NA‡		NA‡		NA‡	
Q17 vs. RP	1.82 (0.45-7.30)		NA‡		NA‡		NA‡		1.27 (0.32-5.06)	
Other vs. RP	NA‡		NA‡		3.66 (0.51-26.14)		NA‡		0.51 (0.07-3.60)	

* Donations made by volunteer donors excluding those that had been deferred and subsequently returned to donate and are included in Groups 1, 2, and 3.
† Data are reported as RR (CI).
‡ NA = not available.

DISCUSSION

Schreiber and coworkers[23] reported that approximately half of first-time donors donate only once. This study demonstrated that donors who were temporarily deferred in 2000 through 2001, with no donation or deferral in the previous 2 years, had a low return rate of 22.6 percent. Clearly, deferral discouraged donors to return, consistent with earlier reports.[3,6,8] The results indicate that temporary deferrals that are included in this study led to a loss of many donors.

Among those temporarily deferred donors with no donation or deferral in the previous 2 years, 14.6 percent (76,292) were deferred for GBS questions, 10.5 percent (54,923) for potential exposure to blood-borne infections (BBPR), and 7.5 percent (39,364) for potential exposure to malaria infections (Q17). Of those donors, 28.8, 16.9, and 22.7 percent subsequently returned to donate again. Among temporarily deferred donors with prior donation history, the three deferral categories accounted for 10.8 percent (74,112), 3.1 percent (21,113), and 4.3 percent (29,203), respectively. Of those donors, 71.8, 43.5, and 60.8 percent subsequently returned to donate again. At their return donation, donors deferred for reasons of the three categories in the above-stated two groups did not show an increased prevalence of viral markers, anti-HIV, HBsAg, anti-HCV, or anti-HTLV, compared to first-time or repeat donors without such deferral. Even donors deferred for BBPR who returned did not show a higher risk of the viral infections under study. In addition, Q17 (travel outside of the United States, for malaria infection risk) does not appear to have any merit of serving as a possible surrogate for potentially increased exposure to blood-borne or sexually transmitted infections while traveling abroad although this study is unable to assess the effectiveness of this question in reduction of malaria risk for which it was introduced. To explore whether the lower prevalence of anti-HCV in Group 1, compared to first-time donors, was caused by the inclusion of limited number of donors who had no donation or deferral during the 2 years before the index deferral but had donated before the 2-year period, deferred donors in Group 1 were matched against the entire ARCNET database, which has donation records since 1995, to remove those who had any prior record in the database. Deferred donors who had no record in the database before their index deferral (102,638/118,138 or 87%) were compared, at their returning donation, with first-time donors. The DS, GBS, and malaria exposure risk categories nevertheless had lower prevalence of anti-HCV than first-time donors, with RRs of 0.45 (CI, 0.35-0.57), 0.58 (CI, 0.40-0.84), or 0.22 (CI, 0.09-0.52), respectively. The differences between the remaining deferral categories and first-time donors were not significant. It is possible that returned donors in Group 1 might be underrepresented by test seekers compared to first-time blood donors.

Among the specific reasons of deferral for BBPR, Question 19, namely, "In the past 12 months, have you had a tattoo, ear/body piercing, acupuncture, accidental needlestick, come into contact with someone else's blood, or taken (snorted) cocaine or any other street drug through your nose," caused 4.4 percent (54,425) of all of the temporary deferrals included in this study. Several studies have assessed the effectiveness and impact of this deferral question or part of the question. For example, de Nishioka and colleagues[15] reported that non-professional tattoos and number of tattoos should be assessed as potential deferral criteria in screening blood

donors. In a study by Haley and Fischer,[24] having a commercially applied tattoo was strongly associated with HCV seropositivity. A study by the Rhode Island Blood Center of 454 donations made by people who had tattoos less than 1 year ago with aseptic technique procedures, however, showed only four reactive donations for hepatitis B core antibody, less than the mean overall reactive rate for the center.[25] Results from this study do not show an increased risk of viral infections by HIV, HBV, HCV, or HTLV among donors who were deferred for Question 19 and subsequently returned to donate blood. The prevalence (per 100,000) among those with no prior donation or deferral history was 126.6 for anti-HCV, 14.1 for anti-HIV, 70.3 for HBsAg, 14.1 for anti-HTLV, or 211.0 for any marker, compared to 287.7, 11.4, 74.3, 10.9, or 380.5 for first-time volunteer donors. None of the 6036 donors who were deferred for Question 19 and had had a prior donation were positive for any of the viral markers, compared to a prevalence (per 100,000) of 6.3, 1.3, 2.1, 0.3, or 9.9 for those markers among repeat volunteer donors. Comparison through Poisson distribution showed that the differences were not significant ($p > 0.05$ for all comparisons).

Nevertheless, caution needs to be exercised in extrapolating data from this study to the entire population of temporarily deferred donors for the deferral reasons included in this study. There could be selection bias between returned donors and those who did not return to donate. Although the analysis was performed on voluntary donations, by prior donation or deferral history, and differences in sex, age, year of donation, and deferral category were taken into account during data analysis, other possible differences may exist between those who returned and those who did not. For example, returned donors may be more committed to donate and may be more likely at lower risk of exposure to infectious diseases. A study found that HIV seroconverting donors may delay their return.[26] In contrast, there could be donors who returned to donate to obtain test results and thus may be at higher risk of exposure to infectious diseases.[27] Neither of such bias could be excluded based on data available from this study. Should test seeking bias exist, namely, more donors deferred for possible exposure to blood-borne infections subsequently returned to donate blood to seek tests, the results from this study would have potentially overestimated the prevalence of viral markers among deferred donors. In other words, the true risk of these infections among those who were deferred for BBPR at the time of their deferral could be lower than what has been observed from this study, which would suggest that these deferral questions were not effective. If returned donors were overrepresented by those who were at lower risk and were more committed to donate, however, the true risk of these infections among those who were deferred for BBPR would be higher than what has been observed from this study. In other words, temporary deferral of donors who reported potential risk of exposure to blood-borne infections could have put off those donors from return and thus has reduced the risk of the blood collected.

It is possible that some of the deferred donors returned after an extended period following their deferral so that testing results at returning donations may not accurately reflect their status at the time of deferral because of positive-to-negative seroconversion or possible fluctuation. Nevertheless, the four viral markers under this study, anti-HIV, anti-HCV, HBsAg, and anti-HTLV, generally persist in most of chronically infected individuals. Therefore, the status of these viral markers at the time of their returning donation should reflect their status at the time of deferral reasonably well although such a reflection is not expected to be precise.

In summary, donors temporarily deferred for potential risk of infectious diseases who returned did not show a higher prevalence for the infectious disease markers under study. The results indicate that temporarily deferred donors who return are no more risky than any other donors. Either the questions have no value for reducing the risk of HIV, HBV, HCV, and HTLV infection or those with actual infection do not return, at least over a 2- to 3-year period. An investigation is under way to recruit deferred donors either at the site of deferral or shortly after deferral to collect their blood for further assessment of their infectious disease risks. It is not expected that the investigation will be able to recruit most of the deferred donors and thus there will be selection bias. It is conceivable, however, that deferred donors who consent to the investigation will not completely overlap with deferred donors who return to donate blood. Therefore, the result from the investigation, in combination with results from this analysis of returned donors, should shed more light on the effectiveness of the current donor selection and deferral process as well as specific deferral questions.

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医薬品 研究報告 調査報告書

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研究報告の概要

（**問題点**：西ナイルウイルスに感染したカラスの脳組織及び脳脊髄液の曝露により結膜経由での人への感染が確認された。）

2003 年に地域的に行われた WNV 鳥類調査活動の一環で、動物管理局員 1 名が病気や死亡した corvids をアルバータ州サフィールドの Canadian Forces Base で回収した。彼は保護服を着用していたが、マスクまたは防護面は着けていなかった。傷ついたカラス 1 羽を殺す間に、その局員はもがく鳥の水平管入り口付近をたたいたため、頭蓋骨が割れ、脳組織および脳脊髄液が彼の頭、顔、首および右肩にかかった。その鳥の体液および脳内物質が彼の目に入ったが、口には入らなかった。暴露した部分には、傷口の開いた損傷は無かったと思われた。同僚が直ちに可視物質をふき取り、彼は 2～3 時間後にシャワーを浴びた。

死亡したカラスは、解析のためにアルバータ州政府の魚類野生動物室へ送られ、VecTest 試験法（Medical Analysis Systems, Inc., Camarillo, CA, USA）による検査が行われ、WNV 抗原陽性であることが明らかになった。

暴露から 7 日後、本動物管理局員は体調不調となり、受診した。症状には、頭痛、眩暈、スパイク熱、および汗があった。

EDTA を伴う全血サンプルおよび血清サンプルを採取し、同時にエンテロウイルス感染の可能性を除外するためにウイルス培養用咽頭スワブも採取した。

血漿中の WNV RNA が検出された。血漿サンプルと同時に採った血清サンプルは、2 種類のキット（Panbio, Windsor, Queensland, Australia および Focus Technologies, Cypress, CA, USA）で行われた酵素免疫測定法において、免疫グロブリン M（IgM）抗体陰性であった。暴露から 14 日後、回復期の血清サンプルから WNV に対する IgM 抗体が両キットによる検査で認められた。血漿サンプルはウイルス RNA 陰性であった。咽頭スワブはエンテロウイルス陰性であった。

蚊に刺されたか、他の経皮ルートでの感染の可能性を除外できないが、暴露の性質と症状発症までの時間から、感染が結膜への暴露後に起こったことが強く示唆される。

報告企業の意見	今後の対応
別紙のとおり	現時点においては、特段の対応は不要と考えるが、今後とも関連情報の収集に努め、本剤の安全性の確保を図っていきたい。

使用上の注意記載状況・その他参考事項等

記載なし

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appear to have subsequently acquired methicillin resistance through horizontal transfer of *SCCmec* type IV. The *spa* type of the Italian isolate comprises 7 nucleotide repeats, indicated by XJ4AKAOM in the alphabetical code. This repeat sequence differs from that of the classical SWP clone, indicated by XKAKAOMQ (8), by only 1 bp in the second repeat and loss of the last Q repeat. In spite of these differences, the *spa* type is in substantial agreement with the MLST result and indicates that the Italian isolate is either a descendent or a local variant of the SWP clone. The most common clone of CA-MRSA described in Europe is ST80, *spa* type 44. CA-MRSA belonging to ST80 tend to be more antimicrobial drug resistant than isolates belonging to other clones (4). Resistance to fusidic acid, typical of ST80, has been proposed as a marker for CA-MRSA in Europe (10). In light of our finding, we cannot rely on resistance to fusidic acid to screen for PVL-producing CA-MRSA in our country.

To our knowledge, this is the first report from Italy of necrotizing pneumonia caused by PVL-positive CA-MRSA. The presentation was typically that of a severe pneumonia that occurred in a previously healthy, young adult with no risk factors for MRSA acquisition, as described in other cases (11). This is also the first report of a SWP clone isolate in southern Europe; if the strain is circulating in Italy or is occasionally imported from the SWP area, whether our patient acquired it through contact with a foreign contact remains unknown.

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West Nile Virus Infection and Conjunctival Exposure

To the Editor: Corvids (crows, blue jays, magpies, and their relatives) are particularly susceptible to West Nile virus (WNV) (1). Birds are useful indicators of the spread of WNV (1), and Canada has implemented WNV surveillance strategies that use these species as sentinels.

Direct acquisition of WNV through percutaneous injuries has been reported in 2 laboratory circumstances, involving a blue jay and a mouse (2). We describe a conjunctival exposure to WNV that occurred in the field and probably resulted in infection in the exposed person.

As part of the local WNV bird surveillance activities in 2003, an animal control officer collected sick and dead corvids at the Canadian Forces Base, Suffield, Alberta. He had a protective suit on, but he wore no mask or face shield. While killing an injured crow (*Corvus brachyrhynchos*), the officer struck the struggling bird on a nearby horizontal pipe gate, which resulted in fracture of the skull, causing brain tis-

sue and cerebrospinal fluid to spray onto his head, face, neck, and right shoulder. Body fluids and brain material of the bird entered his eyes, but not his mouth; he had no known open lesions on the exposed area. His coworkers immediately wiped off visible material, and a few hours later he showered.

The dead crow was sent for analysis to the Fish and Wildlife Division, Government of Alberta, where laboratory tests using the VecTest assay (Medical Analysis Systems, Inc., Camarillo, CA, USA), indicated that the crow was positive for WNV antigen. This test has been validated for detecting viral antigen in oropharyngeal and cloacal swabs in crows (3).

Seven days after exposure, the animal control officer became unwell and sought medical assistance. His symptoms included headaches, dizziness, spiking fevers, and sweats; on examination, mild otitis was noted, but he did not display meningismus or other neurologic signs. A whole blood sample with EDTA and a serum sample were collected, together with a throat swab for viral culture to exclude a possible enteroviral infection, as part of a standardized provincial protocol for investigating suspected WNV infections in Alberta. Betahistine dihydrochloride was prescribed for the dizziness and a cephalosporin for otitis. A cerebrospinal fluid sample was not collected, since his clinical signs did not suggest neurologic involvement.

At the Provincial Laboratory, WNV RNA was detected in the plasma by nucleic acid sequence-based amplification, with primers described by Lanciotti and Kerst (4), which was confirmed by the Artus RealArt RT-PCR assay (artus biotech USA Inc, San Francisco, CA, USA) in a Roche LightCycler. The serum sample, collected at the same time as the plasma sample, was negative for immunoglobulin M (IgM) antibody by enzyme immunoassay using 2 kits (Panbio, Windsor, Queensland, Australia; and Focus Technologies, Cypress, CA, USA). Fourteen days after exposure, a convalescent-phase serum sample showed IgM antibody to WNV in both kits; the plasma sample was negative for viral RNA. Hemagglutination inhibition assay on the acute- and convalescent-phase serum samples, collected 7 days apart, showed rising titers, from <1:10 on the acute-phase serum, to 1:40 for dengue virus (serotypes 1–4), 1:40 for St. Louis encephalitis virus, and 1:80 for WNV on the convalescent-phase serum. Preliminary data from our laboratory indicate that in ≈40% of cases of acute West Nile fever, the acute-phase plasma sample shows viral RNA before IgM antibody develops, after which viral RNA is no longer detectable (J. Fox, unpub. data). Two weeks after culture was initiated for virus isolation, the throat swab was negative for enteroviruses.

The patient's severe fever, sweats, headaches, anorexia, fatigue, and diminished concentration and memory continued. His symptoms peaked 2 weeks after the initial exposure. Three months later, his symptoms of fatigue, dizziness, headaches, and poor memory were severe enough to prevent him from returning to fulltime work. Eight months after exposure, he continues to have fatigue and headaches.

We believe this is the first reported case of apparent conjunctival transmission of WNV in an occupational setting. As the officer spent considerable time outdoors in areas where WNV transmission was relatively high in 2003 and repeatedly handled infected birds, we cannot eliminate the possibility of a mosquito bite or other percutaneous route of transmission. However, the nature of the exposure and the time to symptom development strongly suggest that infection occurred after conjunctival exposure. Persons who dispatch sick wildlife are encouraged to use appropriate, humane methods and should take precautions against exposure to tissues and body fluids.

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