Benefits of a blood donation archive repository: international survey of donor repository procedures and Scottish experiences

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BACKGROUND: The use of a donation sample archive has been in place within the Scottish National Blood Transfusion Service for almost 35 years but the advent of human immunodeficiency virus donor testing led to this archive being kept for an indefinite period. This article describes the uses made of our archive repository.

STUDY DESIGN AND METHODS: Records of various potential transfusion transmission episodes were accessed and examined to assess the age of the archives investigated and the outcome of the investigations. Other uses of the archive repository were also investigated by reviewing the records of retrievals. The use of the archive to aid the interpretation of hepatitis C virus–indeterminate results was also conducted. Finally a global survey was performed to ascertain the temperature and length of storage used by various transfusion services.

RESULTS: A 3-year archive would have allowed for the investigation of 45 percent of cases (including all hepatitis B virus cases), while a 10-year archive would have allowed for 90 percent of cases. Only 34 percent of cases were shown to be transfusion-transmitted. Of 16 donors with c22-indeterminate bands on recombinant immunoblot assay, 2 (12%) could have been classified as confirmed-positive on the basis of their archive samples. A considerable proportion (41%) of the most recent requests for retrieval from the archive have been associated with the need to perform new mandatory tests for tissue donations at issue. Samples older than 3 years accounted for 25 percent of all samples retrieved. The global survey showed a variety of conditions in terms of both length and temperature of storage.

CONCLUSION: The use of a donation archive has been shown to be extremely useful in the investigation of potential transfusion-transmitted infections with most (66%) having no evidence of transfusion transmission. Although 90 percent of our cases could have been fully investigated with only a 10-year archive, perhaps the future retention period of hospital records should be considered when determining the length of storage of current donation archive samples.

Scotland has a population of approximately 5 million and the Scottish National Blood Transfusion Service (SNBTS) is responsible for all its blood transfusion services, including tissue services. Between 250,000 and 350,000 blood donations and 1,500 to 2,000 tissue donations are collected each year. The retention and storage of donation samples were introduced by the SNBTS in the early 1970s. This frozen serum (approx. 0.5-2.0 mL) archive was introduced to assist the investigation of reported cases of posttransfusion hepatitis around the time of the implementation of routine donor hepatitis B surface antigen testing. These posttransfusion hepatitis cases usually involved donations given in the previous 6 months, and therefore after 1 year of storage, samples were destroyed.

The advent of routine human immunodeficiency virus (HIV) donor screening in 1985 led SNBTS to retain these donation samples indefinitely, so that a complete archive, originally stored locally by five regional centers, has been kept since that time. Donation nucleic acid testing (NAT), initially for hepatitis C virus (HCV), was developed in SNBTS during 1998 based on the use of an extra third sample—a plasma preparation tube (PPT; Becton Dickinson, San Jose, CA). After sampling for NAT, this tube is retained as our archive sample. The donation archive has now reached a considerable size (7 million) stored on approximately 200 pallets (1.2 × 1 m) occupy-

ABBREVIATIONS: PPT(s) = plasma preparation tube(s); SNBTS = Scottish National Blood Transfusion Service; TTI(s) = transfusion-transmitted infection(s).

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ing an area of 250 m^3 with an associated maintenance cost that is now considerable (UK£60.000 p.a.) and is accumulative.

Recent EU legislation (EU Directive 2002/98/EC), now encompassed in UK law as the Blood Safety and Quality Regulations 2005, states that "Each blood establishment maintain data needed for full traceability of blood and blood components for not less than 30 years." More recent proposed guidance from the UK Royal College of Pathologists and Institute of Biomedical Science recommend that archived blood donation samples be stored for at least 3 years, preferably longer if practicable, to facilitate "lookback" exercises.

This article reviews the uses made of the current SNBTS donation archive that now spans 20 years, with regard to the relative age of the specimens according to the investigation. In addition a review of other blood services throughout the world was conducted to ascertain whether retaining a donation archive was normal practice and if so the length of storage.

MATERIALS AND METHODS

Sample archive

The original sample archive from the Glasgow Center was an aliquot of serum (usually approx. 0.5-2.0 mL) kept in a capped polytube at –20°C. Each tube was labeled with the corresponding donation number, and medical laboratory assistants would check that the serum tube matched the polytube before decanting residual serum and cap the tube. Red cell antibody quality checks were performed on a small percentage of samples to ensure correct procedures had been followed.

Since 1998 all centers within the SNBTS have utilized the actual tube used for NAT testing, a PPT, as the archive tube. This involves no aliquot procedure. This tube is stored in a central location at –20°C.

Sample retrieval

Sample retrieval is generally restricted. Requests are made from SNBTS donor consultants to retrieve archive samples. These requests are batched so that visits to the cold storage unit are usually carried out on a monthly basis. Retrieval, however, may be deemed more urgent to aid an investigation of transfusion-transmitted infection (TTI) or other adverse transfusion event, for example, transfusion-related lung injury (TRALI). On retrieval of any sample from the archive, a blank or empty tube is placed in the corresponding space in the rack showing the date of retrieval. This procedure should identify situations where the same donation is involved in separate cases. Since 2000, a formal policy has been in place to restrict access to the donation archive for approved indications (such as TTI and TRALI investigations, lookback investigations on donors with confirmed microbiologic markers, and in some cases to screen "at issue" materials with new mandatory tests). Other requests would require approval by the National Medical Director (IMF).

Review of Glasgow center's use of their archive

The Glasgow center (SNBTS West) has consistently accounted for between 45 and 50 percent of the blood supply for SNBTS. Records of reported TTI investigations were reviewed for the period 1993 through 2002 (10-year period) to determine the age of the associated archive samples that had to be retrieved to conduct a serologic investigation. In each situation, the ages of the archive samples were determined by the time of reported transfusion of the implicated units. Additional situations arose where subsequent donations from the implicated donors were also retrieved to aid in the investigations. The conclusion of the investigation, that is, definite TTI or alternatively not proven TTI, was determined for each investigation and correlated to the microbiologic specificity.

Review of the use of the SNBTS national archive

In 1998, centralization occurred of all SNBTS archival donation sample material with the transfer of all materials to one site. A system was devised to request the retrieval of archives and the documentation of these requests was electronically stored in a database. The records for the period January 2000 to August 2005 were available for review.

HCV serologic lookback on indeterminate samples

Twenty-five regular donors, who exhibited second-generation HCV enzyme-linked immunosorbent assay (ELISA; Ortho, Raritan, NJ; Murex, Temple Hill, Dartmouth, UK; or United Biomedical, Inc., Hauppauge, NY) repeat reactivity together with recombinant immunoblot–(RIBA-2, Chiron Corp., Emeryville, CA) indeterminate reactivity for either c100 or c22, were selected to retrieve their earliest (previously HCV untested) archive sample for testing by RIBA-2. This exercise was performed in 1992, shortly after the introduction of HCV donor screening in the UK. Where the earliest archive sample was shown to be RIBA-2–negative, then the next subsequent donation was also retrieved and tested.

Questionnaire to other blood services

Individuals in various blood services were sent an electronic questionnaire on donation archives. Questions asked included the number of donations collected during

the calendar year 2003 and whether they retained a sample. If samples were kept, additional questions probed the type of specimen, volume, storage temperature, and duration. Further questions tried to assess the use of these archives.

RESULTS

Use of the archive for TTI investigations

The number of TTIs reported to the Glasgow center during the 10-year period from 1993 to the end of 2002 were examined (Fig. 1). A total of 31 reported cases were investigated. Thirteen (42%) used archive samples that were less than 1 year from the time of donation. The use of the current 3 years' recommended storage of the UK Royal College of Pathologists and Institute of Biomedical Science would have allowed an investigation of only one additional case; that is, 45 percent of cases would have archive samples available. A 10-year archive would have allowed the investigation of 28 (90%) cases whereas the remaining cases involved transfusions that reportedly occurred over 10 years (13, 14, and 16 years) previously.

Focusing on reported cases of possible transfusion-transmitted hepatitis B virus (HBV), HIV, or HCV infections during this period showed a total of 26 cases (Table 1). Suspected HCV infections accounted for the vast majority with 19 (73%) cases, HBV infections accounted for 6 (23%), and there was only 1 reported possible HIV infection.

The ages of the archive donations that were required in these investigations showed that HBV infections were reported within 2 years of transfusion; HIV, 9 years after transfusion (only one case), and HCV, up to 17 years after transfusion. Seventeen (89%) of the 19 HCV cases were reported within 10 years of transfusion.

The outcome of the serologic investigations on testing the archive samples demonstrated only 9 (34%) cases of definite TTI of the 26 reported cases. No case of HIV TTI was confirmed in this period, whereas 2 (33%) cases of HBV were confirmed as transfusion-transmitted as were 7 (37%) cases of HCV (all the latter before the introduction of anti-HCV donor testing).

Use of the archive for scientific research

An exercise performed in 1992 utilizing archive samples demonstrated the persistence of HCV-specific antibodies or alternatively the evolution of HCV seroconversion or loss of reactivity for specific HCV antibodies over time (Table 2). Of the 25 donors selected, 16 showed HCV c22-indeterminate reactivity, and the remainder (9) showed HCV c100-indeterminate reactivity. The earliest archive samples from 4 donors were negative, suggesting possible HCV seroconversion. Two donors were shown to have previous donations (both 7 years previously) that were considered to be RIBA-2–positive, that is, sufficient to be confirmed HCV-positive. Both index samples were reactive by all second-generation HCV ELISAs unlike the majority of the samples exhibiting RIBA-2–indeterminate reactivity. All other samples showed identical indeterminate results although most gave slightly stronger activities.

The SNBTS donation archive has been kept at –20°C since 1985. During 2002 a lookback study was performed on newly recognized human T-lymphotropic virus (HTLV)-positive donors to ascertain whether recipient

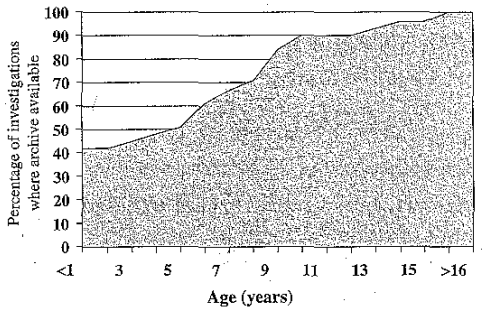

Fig. 1. Value of an archive in TTI investigations in SNBTS West in period 1993 to 2002. Age (years) of archive samples involved in TTI investigations. (The repository was established in 1986.) (▩) Archives available.

TABLE 1. Age of archive and conclusion of TTI investigations for Glasgow center (SNBTS West) over the period 1992 through 2002

	Reported TTI (n = 26)					
	HBV (n = 6)		HIV (n = 1)		HCV (n = 19)	
Age of archive* (years)	Not-TTI	TTI	Not-TTI	TTI	Not-TTI	TTI
<1	4	1			1	
1	1				1	
2					1	
3					2	
4					1	1
5					1	
6					2	
7					2	
8					1	
9			1		2	
10					1	1
12						
14					1	
16						
17					1	
Total	4	2	1		12	7

* Age of archive refers to the length of storage of the archive before its access to conduct a TTI investigation.

TABLE 2. Use of archive samples to determine the significance of an HCV RIBA-2–indeterminate result

	Index sample results							
			HCV ELISA (second-generation)			Archive results		
Donor	Index date	RIBA-2	Ortho	Murex	UBI	Archive date	RIBA-2	Conclusion
2	23.02.92	C22 1+	Positive	Negative	Negative	03.03.85	Negative	Seroconversion
5	03.02.92	C22 2+	Positive	Negative	Negative	25.08.86	C22 3+	Seroconversion
						10.02.85	Negative	
18	26.11.91	C100 1+	Positive	Positive	Negative	02.10.89	C100 1+	Seroconversion
						16.11.87	Negative	
25	30.12.91	C100 3+	Positive	Negative	Negative	10.01.90	C100 3+	Seroconversion
						18.07.84	Negative	
4	04.12.91	C22 1+	Positive	Positive	Positive	03.12.84	Positive	Seroreversion
14	17.02.92	C22 4+	Positive	Positive	Positive	18.09.85	Positive	Seroreversion
1	17.09.91	C22 1+	Positive	Negative	Negative	05.08.84	C22 1+	
3	10.12.91	C22 1+	Positive	Negative	Positive	1987	C22 1+	
6	12.01.92	C22 2+	Positive	Positive	Positive	29.06.88	C22 4+	
7	23.12.92	C22 2+	Negative	Negative	Positive	16.07.84	C22 3+	
8	16.12.91	C22 2+	Positive	Negative	Negative	30.03.87	C22 3+	
9	19.01.92	C22 2+	Positive	Positive	Positive	23.01.91	C22 3+	
10	09.03.92	C22 3+	Positive	Negative	Negative	05.10.87	C22 3+	
11	05.01.92	C22 3+	Positive	Negative	Negative	02.06.85	C22 4+	
12	02.10.91	C22 3+	Positive	Negative	Negative	25.04.89	C22 3+	
13	05.01.92	C22 3+	Positive	Negative	Negative	03.06.90	C22 4+	
15	12.11.91	C22 4+	Positive	Positive	Positive	22.05.84	C22 4+	
16	27.11.91	C22 4+	Positive	Positive	Negative	13.11.85	C22 4+	
17	16.01.92	C100 1+	Positive	Negative	Negative	10.09.87	C100 2+	
19	14.10.91	C100 1+	Positive	Negative	Negative	06.05.87	C100 2+	
20	23.12.91	C100 2+	Positive	Negative	Negative	05.09.84	C100 3+	
21	24.11.91	C100 2+	Positive	Negative	Negative	02.03.86	C100 1+	
22	12.02.92	C100 2+	Positive	Negative	Negative	02.07.87	C100 2+	
23	06.04.92	C100 2+	Positive	Negative	Positive	05.02.91	C100 4+	
24	28.10.91	C100 2+	Positive	Negative	Negative	28.10.88	C100 2+	

TABLE 3. Showing number of requests (and samples) according to specificity and year of retrieval (January 2000 to August 2005)

Year	HBV	HCV	A/HBc	HIV	TRALI	Malaria	Tissues	Other
2000	2 (96)	4 (6)	7 (14)		1 (1)		1 (201)	HAV* 1, Q-fever 1 (20), TPHA 1 (2)
2001	4 (12)	2 (7)	4 (29)		2 (8)			HTLV 2 (3)
2002	5 (8)	11 (166)	2 (6)	6 (15)	4 (29)		3 (373)	HTLV 5 (14), TPHA 1 (2)
2003	4 (11)	8 (30)	10 (11)		7 (21)	3 (9)		Parvo 1 (10), *Trypanosoma cruzi* 2 (3)
2004	5 (7)	6 (18)	1 (1)	1 (2)	6 (38)	4 (6)		TPHA (1)
2005	1 (1)	4 (9)	12 (85)	2 (2)	1 (3)	3 (3)		Bacteria 1 (2)
Total	21 (135)	35 (236)	36 (146)	9 (19)	21 (100)	10 (18)	4 (574)	
Number of archive visits for samples >3 years old	3	32	11	3	0	1	0	HTLV 2

* HAV = hepatitis A virus.

counseling and testing were necessary. The earliest archive sample was retrieved from each donor. If this sample was found to be negative, then all intermediate donations would be retrieved to determine when seroconversion occurred. This would determine the number of recipients that would then need to be traced and counseled (i.e., all positive donations plus the immediate preceding negative donation). During this exercise 20 archive samples (including samples from 16 and 17 years previously) were retrieved, and all were shown to give identical serologic results as their index samples. Similarly various lookback studies conducted with our archive have demonstrated that HCV, HIV RNA, HBV DNA, and antibodies to HCV, HIV, and HBV can survive storage for at least 15 years at –20°C.

Review of the use of the centralized archive

Reviewing the use of the national archive from January 2000 to August 2005, there were a total of 150 requests for retrieval of 1293 samples that were batched and dealt with by 39 visits to the off-site archive (Table 3). The SNBTS tissue directorate requested 574 (44%) of all samples retrieved—mostly for malaria antibody and/or anti-HTLV

testing of banked frozen materials that had not required those tests on collection but required them as mandatory tests for issue.

Samples older than 3 years accounted for 25 percent of all samples retrieved, involving 32 HCV, 3 HIV, 3 HBV, 2 HTLV, 1 malaria, and 11 anti-hepatitis B core antigen (HBc) investigations. The high number of HCV investigations in 2002 to 2003 were related to announcements of considerable compensations for those infected with HCV via transfusion. The three HIV investigations were related to regular donors who were found to have seroconverted for HIV since their previous donation (over 3 years previously).

The majority of the 35 HCV, 9 HIV, and 21 HBV investigations were related to lookback investigations from notified infected recipients. The 7 HTLV investigations were associated with donor lookback after the introduction of anti-HTLV testing. Similarly the 36 anti-HBc investigations involved either donor lookback on recently introduced selective anti-HBc donor screening reactive samples or were associated with mandatory testing of banked tissue materials. TRALI accounted for 21 visits to the archive with the vast majority of the 100 related samples being less than 1 month old.

Other visits for retrieval were to complete investigations of either donor seroconversion or implication in reported transfusion-associated illnesses, for example, Q fever, parvovirus, bacterial contamination, hepatitis A virus, and syphilis.

Survey of blood services

The global survey of the use of a donation archive is shown in Table 4. The survey was conducted in early 2004 and at that time several countries (Portugal, Canada, United States, South Africa, and some Swedish hospitals) did not have a donation archive. Surprisingly of those services, only the European and South African blood services considered a donation archive would indeed be useful. Those blood services that possessed a donation archive all utilized it for the investigation of TTI cases and lookback studies, while some considered it useful for TRALI investigations.

The length of storage varied considerably from a few weeks (Umea, Sweden) to indefinite (Scotland, Ireland). The length of storage was related to the available space in some organizations (Wales; N. Ireland; Switzerland; Denmark; and Ostergotland, Sweden), whereas most services followed government regulations that dictated the length of storage. Where investigations are carried out on TTI cases involving donations beyond the time span held within the donation archive, then a search is carried out for subsequent donations from the implicated donors. Invariably this results in an incomplete investigation due to donors who have never returned and who do not respond to letters, probably as they have changed their home address. Nevertheless, an investigation should still be carried out on those samples available to attempt to identify the source of infection. With an extensive donation archive, investigations on all implicated samples should be feasible. A limited series of tests may be necessary when only small volumes are retained.

The actual sample stored varied across the world. There seems to be a general trend for countries either introducing donation archives (e.g., parts of Australian blood service) or alternatively increasing the length of storage (e.g., Japan were storing samples for 10 years but after recent legislation they must store for 30 years). Many used serum or plasma being the residue of microbiology or blood grouping donation samples. More recently, Scotland, Ireland, and France have used PPTs for nucleic acid testing and these tubes have been used as the archive sample. This latter tube allows the storage of at least 1 mL of plasma, whereas the use of other sources of material tended to provide smaller samples.

The temperature of storage varies from 4°C (Umea, Sweden) to −195°C (France). Denmark uses −80°C whereas Lund, Sweden, uses −70°C. Wales and Finland both use −40°C storage. All other services use either −30°C (six services), −25°C (Belgium), or −20°C (seven services).

DISCUSSION

The SNBTS donation archive has proven essential in the investigation of reported cases of possible TTI since the 1970s.[1] The Glasgow center's experiences over the 10-year period from 1993 to 2002 have shown that in the majority (approx. two-thirds) of these cases, transfusion would appear to have been eliminated as the cause of infection. In such circumstances, subsequent samples from any implicated donor should also be tested to exclude the possibility of the implicated donation being in the earliest period of seroconversion.[2] In the situation where an implicated donation harbors an agent, genotyping (and in some cases sequencing) of this and the patient's sample should be considered to conclusively prove transfusion transmission.

It is pertinent to note that in some of the unresolved reported cases of possible HBV TTI, the hospitals concerned subsequently identified health-care workers that probably were the sources of HBV infections. The relatively greater proportion of reported possible HCV TTI cases actually increased in 2002 and 2003 with resultant increase in retrievals for that marker (Table 3). This, however, was partly due to media publicity over potential financial support for those individuals who obtained their HCV infection shortly before implementation of HCV donor screening. This clearly demonstrated the need for hospitals to maintain an accurate record of the fate of blood donations together with maintaining patients' records beyond 15 years. Without the donation archive

TABLE 4. Global survey of donation archive use by various blood services (conducted in 2004)

Country	Number of donations	Archive	Sample	Volume (mL)	Temperature (°C)	Time	Determined by	Access <10	Access 10-100	TTI	TRALI	Look-back	If no, useful?
Scotland	250,000	Yes	PPT	2	–20	Indefinite	Government		Yes	Yes	Yes	Yes	
England	2,352000	Yes	Serum/plasma	0.5-1	–20	3 years	Recommend		Yes	Yes	Yes	Yes	
Wales	116,500	Yes	Plasma	1 + 0.8	–40	Indefinite/ 1.5 years	Freezer space		Yes	Yes		Yes	
N. Ireland	73,713	Yes	Plasma, PPT	0.81 + 2	–30	11 years+	Freezer space	Yes		Yes	Yes	Yes	
Dublin, Ireland	103,000	Yes	Serum, PPT	0.96	–20	Indefinite	Regulations		Yes	Yes		Yes	
Cork, Ireland	42,700	Yes	Plasma, serum	0.96	–30	Indefinite			Yes			Yes	
Germany		Yes	Plasma	1-2	–30	3 years	Regulations		Yes	Yes		Yes	
Netherlands	950,000	Yes	Plasma EDTA	0.8	–20	3 years	Regulations		Yes	Yes	Yes	Yes	
France	2,347,000	Yes	PPT	1	–195	5 years	Regulations	Yes		Yes		Yes	
Luxembourg	27,000	Yes	Serum	0.9	–30	20 years	General rules	Yes				Yes	
Belgium	204,000	Yes	Serum/plasma	0.85	–25	10 years	Regulations	Yes				Yes	
Switzerland	423,000	Yes	Serum/plasma	0.9	–30	5 years	Freezer space	Yes		Yes		Yes	
Austria	200,000	Yes	Plasma	2-3	–20	2 years	Regulations	Yes		Yes	Yes	Yes	
Portugal	230,000	No										Yes	
Norway	190,000	Yes	Plasma	1	–20	2 years	Regulations	Yes				Yes	
Denmark	370,000	Yes	Plasma	0.3	–80	2 years	Freezer space	Yes		Yes		Yes	
Finland	300,700	Yes	Plasma	0.5	–40	5 years	Organization	Yes		Yes		Yes	
Solna, Sweden	43,000	No										Yes	
Ostergotland, Sweden	29,000	Yes	Serum	0.4	–20	8 months	Freezer space		Yes				
Huddinge, Sweden	41,000	No										No	
Lund, Sweden	69,900	Yes	Plasma	<0.5	–70	5 years	Local rules	Yes				Yes	
Umea, Sweden	14,234	Yes	EDTA, segment	2-10	4	2 weeks-2 months	Regulations	Yes		Yes		Yes	
HaemaQuebec, Canada	250,000	No										No	
Canada	840,000	No										No	
United States Blood Systems	950,000	No											
South Africa	540,000	No										Yes	
New Zealand	180,000	Yes	PPT	2	–30	5 years	Regulations			Yes	Yes	Yes	
Australia	1,074,000	Part*	Plasma	0.3	–25	5 years	Freezer space		Yes	Yes		Yes	Yes
Japan	5,473,000	Yes	Serum	2.5-3	–30	10 years	Government		Yes	Yes	Yes	Yes	

* 20 percent currently archived, but plan to have a national archive.

(and good hospital records) it would theoretically be possible for any HCV-positive individual to claim they received blood and be awarded ex gratia UK government payments. Therefore, the cost savings involved by demonstrating that transfusion was not the source of these infections should adequately fund the maintenance of the donation archive.

Other uses of the donation archive include investigation of TRALI episodes (to determine the presence of HLA and/or white blood cell antibodies) and lookback on previous donations when regular donors are found to possess a microbiologic marker. In the latter instance, we have demonstrated that in the infancy of HCV donor testing, a RIBA-indeterminate result was generally shown to be consistent over several years. In a few instances apparent seroconversion occurred, and in 2 (8%) of 25 cases a confirmed anti-HCV–positive result was obtainable on an earlier sample. The value of the donation archive has also been demonstrated in the UK national HCV lookback exercise whereby earlier samples from confirmed HCV-positive donors were investigated so that only HCV-positive donations needed to be traced.[3,4]

Our review of the use of the centralized donation archive revealed that the main reason for retrieval was for extra tests (anti-HTLV, anti-HBc, or malaria antibody) on tissue donation samples to allow release. If tissue sample retrieval and TRALI samples are excluded, then 328 of 619 (53%) samples retrieved had been stored for at least 3 years. We recognize that the period of 2002 and 2003 involved many reports and resultant investigations of possible HCV TTI. In our most recent year, however, 2005, 67 percent of samples retrieved had been stored for at least 3 years. This particular year (2005) was unusual though because a limited selective donor anti-HBc screening was introduced that involved donor lookback on all anti-HBc–reactive samples.

The temperature of storage is obviously important. In our survey one blood service used 4°C storage for up to 2 months. Obviously this type of storage is not recommended for long-term storage as it has been demonstrated that HCV RNA will lose one half-log following storage at 4°C for 1 week.[5] Our archive at –20°C has shown to preserve HTLV, HCV, HIV, and HBV antibodies; HCV and HIV RNA; and HBV DNA after considerable lengths of time (>15 years). Indeed even multiple freeze-thaw cycles appears to have little effect on HBV DNA.[6]

Other blood services also utilize donation sample archives and have found them invaluable in the investigation of potential cases of transfusion-transmitted infection.[7,8] Although the United States Blood Services currently do not retain a routine donation sample archive, several scientific repositories of different kinds and purposes have been utilized since the 1970s.[9] These American repositories have been a productive source of scientific knowledge in transfusion medicine. The main American repositories have been the Transfusion-Transmitted Virus Study (TTVS) and more recently the Retrovirus Epidemiology Donor Study (REDS) Allogeneic Donor and Recipient (RADAR) study. The TTVS samples helped demonstrate the potential use of surrogate non-A, non-B hepatitis tests before the availability of specific HCV assays.[10,11]

The RADAR organized by American blood services attempts to archive linked donations to recipient samples (both baseline and follow-up) so that new emerging blood-borne virus disease tests can be readily evaluated.[12,13] Although our donation archive gives a full library of donor samples, we unfortunately are presently unable to collect baseline and necessary follow-up samples from recipients. Instead in the UK, we must rely on clinicians observing recipients with blood-borne infection and reporting these events to our local transfusion services for investigation and also to the Serious Hazards of Transfusion (SHOT) reporting system.[14]

The donation archive should be respected. It is not a source of material for endless scientific studies. The donor samples that have been retained are with the donor's knowledge so that investigations can be conducted on any *adverse* reaction that involves these donations. Therefore, the donation archive is strictly controlled so that access is only approved under certain specific conditions. The number of occasions where access is granted is determined by the number of TTI reported cases and the duration of the archive but our global survey suggested that approximately 15 to 40 (mean, 25) instances of access may be the norm for services collecting around 250,000 donations per annum (i.e., 1 retrieval event per 10,000 donations).

The length of time that the donation archive should be held remains unanswered. Some emerging diseases (e.g., variant Creutzfeldt-Jakob disease) have extremely long incubation periods, so it could be argued that "indefinite" is the correct period to store donation archives. If European hospital records are now to be retained for a minimum of 30 years, perhaps it would be better to identify the current period of retention of hospital records and use that as the minimum period. Although our repository grows larger, the cost of storage incrementally increases. Our current ability to investigate all actual donations (and often subsequent donations from donors) implicated in reported cases from donations transfused now up to 20 years ago still presently outweighs these increased costs, both from scientific and from legal or financial compensation standpoints. Alternatively, a 10-year archive appears to be sufficient for approximately 90 percent of our necessary investigations.

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