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Donor Deferral Pattern in a Hospital-Based Transfustion Center

MOHAMMAD H. QARI, FRCPA
Department of Hematology,
Faculty of Medicine, King Abdulaziz University,
Jeddah, Saudi Arabia

ABSTRACT. The exclusion of high risk-donors by selection is one of the most crucial steps to improve the overall safety of the blood supply and the donor eligibility. This is currently achieved through the donor questionnaire, medical assessment, complete blood count, and the serological testing for the blood borne pathogens, namely: syphilis, hepatitis B & C, and HIV infection. This study was undertaken in a donation center of tertiary card teaching hospital to assess the common causes of donor deferral and the pattern of change i the disease markers that can lead to donor exclusion over the course of time. A total of 32,775 potential non-remunerated blood donors encountered at the donor center of King Abdulaziz University were enrolled in this study over the years 1997 through 2002. The data was collected and analyzed for the distribution of the donor exclusion causes. Among all the encountered donors 12.07% were deferred, the causes of rejection were donor interview (7.03%), CBC (0.96%), and positive Serology (4.08%). Hepatitis B & C are the two most prevalent infections among blood donors. The number of donors excluded on the basis of the donor interview exceeded those who were excluded after the serological testing, underlining the importance and the efficiency of the interview in ensuring both the donor eligibility and the safety of the blood supply.

Keywords. Blood donor deferral, Voluntary donor, Transfusion transmitted infections, Donor interview, Temporary deferral, and Permanent deferral.

Correspondence & reprint requests to: Dr. Mohammad H. Qari
P.O. Box 80215, Jeddah 1589, Saudi Arabia
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Introduction

Infection in blood donors can be transmitted to blood product recipients. Strategies to reduce the risk to recipients has involved public education programs, administration of questionnaires pertaining to HIV rick factors, the use of a confidential self-exclusion option that allows the donor to indicate in a confidential manner that their blood should not be used for transfusion, and direct questioning about risk behavior. These strategies have been found to eliminate some high risk[1-3] and some infected units[4].

Despite the small risk of infection from donated blood, there is strong public pressure to ensure that all measures to reduce the risk of transfusion-transmitted infection are used. A potential role for improved risk factor detection through pre-donation screening would be to reduce the risks from as yet unknown blood borne disease if these disease were associated with other known rick groups. Explicit direct questions instead of indirect references to high-risk behaviors for HIV/AIDS have been shown to increase self-deferral rates in donors at least two-fold[5, 6].

While there have been notable decreases in the HIV-positive donations lately[7, 8], some donors who are aware of their high-risk behavior continue to donate without self deferral [1, 4, 9-12].

It has been estimated that the standard donor health assessment questionnaire may miss as many as 10% of donors who engage in high-risk behaviors[9]. Studies using various computerized questionnaire methods have found increased reporting of perceived socially undesirable behaviors compared to face-to-face interviews in high-risks groups[13, 14].

At the level of donor testing, various infectious agents that can be transmitted by human blood products to recipients are screened. Agents of major importance are the Human Immunodeficiency Virus Type I and II (HIV-1/2), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human T-Lymphotropic Viruses Type I and II (HTLV-I/II). Agents of minor importance are Cytomegalovirus (CMV), Human Parvo-B19 Virus (HPV-B19), Hepatitis A Virus (HAVE) and possibly Hepatitis G (HGV) and Human Herpes Virus Type 6 (HHV-6). Also various species of Gram-negative *e.g.,* Yersinia Enterocolotica and Gram-positive bacteria can grow in human blood products stored a 4˚C or at room temperature (platelet concentrates). Furthermore, parasites such as Plasmid (Malaria) and Trypanosoma Cruzi (Sagas Disease) can be transmitted by blood products especially in areas where these agents are endemic. At present, considerable concern exist about the possible transmission to the patients of infectious prions by (pooled) blood products causing Creutzfeldt-Jakob Disease (CJD) or new variant of CJD. However, proin infections are as yet not reported to be transmitted by transfusion of blood products[15]. Various methods are applied to improve the safety of the blood supply. The corner stone is (still) the testing of all blood donations for the above-mentioned infectious agents of major importance. Some intracellular viruses *e.g.,* CMV, HTLV-I/II, HHV-6) and possibly proin[16] can be removed from the blood prod-

ucts by leukocytes depletion with filters. Also, the inactivation of viruses by physical and/or chemical methods in plasma derivatives is an important step forward to guarantee the safety of these preparations. The exclusion of high-risk donors by selection is one of the most crucial steps to improve the overall safety of the blood supply. It should be stressed that high donor risk is equivalent to a high incidence rate of acute viral infections in donors, which can be transmitted by transfusion of blood products. In the window period of such acute infections current screening tests are not able to detect the infectious agents. Therefore, the major aim of donor selection is to prevent this window infection risk[15].

Serologic testing is now performed on all acceptable donors in Canada. In the past, window-period infections have been a concern; however, the use of highly sensitive nucleic acid amplification technology (NAT) has now reduced this risk of a transfusion-transmitted infection due to a window-period donation to an estimated on per million donations or fewer in the USA[17,18].

This work was undertaken to assess the common causes of donor deferral in a donation center of a tertiary cared teaching hospital and assess the pattern of change in the disease markers that can lead to donor exclusion over the course of time.

Materials and Methods

A total of 32,775 potential blood donors encountered at the donor center of King Abdulaziz University were enrolled in this study over the years, 1997 through 2002. The purpose of their donation included voluntary or directed donation for a relative or a friend. The donors reporting to the donor center are met and interviewed by a clerk. The questionnaire filled is the standard donor questionnaire as approved by the American Association of Blood Banking (AABB), containing a set of direct questions in both languages, Arabic and English. The anticipated answers are either “yes” or “no”. Upon, completion of the interview the donor weight and blood pressure were taken with other vital signs, followed by the medical check-up by the attending physician. The donor complete blood count (CBC) was performed if all the previous steps are passed successfully. This is followed by the actual donation process if the donor is satisfying all the previous criteria, including an apparently normal (CBC). The total amount collected in the blood bag is 435 mls of whole blood; subsequently, this was sent to the blood bank were the following serological tests were performed from the blood left over in the I.V. line segments of the bag itself. Rapid plasma reagent (RPR), Hepatitis B surface Antigen (HBsAG) Hepatitis C virus antibodies (HCV) and P_{24} antigen and anti-body combined test for HIV, after separating the serum from the aliquot blood in the line segment. The serological tests reagents used for donor blood screening are identified under therapeutic goods code of the USA, and are obtained from Abbott Corporation, USA. The actual testing is carried out on the AXXYM equipment also purchased from Abbott, USA. The controls are carried out routinely in accordance with the regulations of the AABB. These include positive and negative controls performed repeatedly at every shift in the blood bank, their results are checked for validity

and appropriate documentation is carried out. Any failure in the control results necessitates the abortion of the testing process until the corrective measures are taken. It is also noteworthy that the blood bank is subscribed the external quality assurance program of the College of American Pathologist.

The positivity in any serological test result is excluding the unit and informing the donor center in writing to defer the donor permanently from future donations and advice him of the positive results through the attending physician in the donor center to seek medical advice.

The data gathered include numerical results that are tabulated and further illustrated using the graphics for comparison purposes.

Results

The total number of potential donors encountered in the donation center was 32,775 blood donors including voluntary donors and directed donors for relative or a friend, during the years 1999 through 2002. The male:female ratio was 4:1.

In total, 3,934 donors(12.07%) were excluded from donation due to the above-mentioned causes altogether.

The donors who were excluded on the basis of the donor questionnaire were 2,302 (7.03%) of all the interviewed donors.

The rest of interviewed donors had their CBC checked resulting in further exclusion of 314 donors (0.96%) of all the encountered donor. The serological tests namely RPR, HbsAg, HCV, and HIV antigen and antibody tests resulted in excluding 1,338 blood donors (4.08%) of the total number of donors. The distribution of the main causes of donor exclusion is displayed in Table 1.

The cause of donor exclusion at donor interview and the CBC results are detailed in numbers and percentages in Table 2. The serological test performed for the enrolled blood donors who are eligible for donation at the interview and CBC levels were RPR; HBsAg; HCV antibodies; and combined Ag/Ab test for the detection of HIV antigen and antibodies. Table 3 illustrates the results of the above-mentioned serological test during the years 1997 through 2002.

Discussion

While the risk of blood borne infection to blood products recipients has been dramatically reduced due to the application of stringent donor selection criteria, and the use of new diagnostic technologies, this study suggest that it may be possible to further improve the blood donor screening process.

TABLE 1. The total numbers of potential and deferred donors.

Cause of Exclusion	No.	% Among All Donors	% Among Deferred Donors
Excluded at the interview	2,281	7.03	58.23
Excluded due to abnormal CBC result	314	0.96	7.94
Excluded due to a positive serology	1,338	4.08	33.83
Total	3,933	12.07	100.00

TABLE 2. Detailed causes of deferral at the interview.

Causes	No.	%
High Blood Pressure	678	26.13
Low Blood Pressure	856	32.99
Abnormal CBC	304	12.10
Jaundice, Hepatitis	155	5.97
Previous Admission	151	5.82
Donation < 3 months	74	2.85
Malaria or Travel to Endemic Areas	57	2.19
Low Weight	98	3.78
Menses	16	0.62
Lactating Mother	2	0.08
Previous Deferral	46	1.77
Small Vein	14	0.54
Bleeding History	30	1.16
Vaccinations	40	1.54
Medication	12	0.46
Age	52	2.00
Pregnancy in the last 6 months	0	0
Sexual Misconduct History	0	0
Transfusion History	0	0

TABLE 3. Numbers and percentages of deferred donors on the basis of serological testing in the years of 1997 and 2002.

Year	Total	RPR	RPR %	Hbs AG	Hbs AG %	HCV	HCV %	HIV I, II	HIV I, II %
1997	3,478	5	0.14%	90	2.58%	73	2.09%	1	0.03%
1998	4,190	2	0.04%	147	3.50%	86	2.05%	1	0.02%
1999	4,649	3	0.06%	139	2,92%	74	1.59%	2	0.04%
2000	4,984	8	0.16%	136	2.72%	78	1.56%	14	0.28%
2001	5,974	19	0.31%	134	2.24%	62	1.03%	5	0.08%
2002	6,905	78	1.12%	111	1.60%	61	0.88%	9	0.13%
Total	30,180	115	1.83%	757	15.56%	434	9.20%	32	0.58%

In addition to completing a comprehensive questionnaire, U.S. donors today are advised that every unit of allongeneically donated blood is tested for evidence that the donor might be infected with syphilis, hepatitis B (HBV), hepatitis C (HCV), HTLV-I/II, HIV 1/2. These tests reflect the scientific data regarding endemicity of disease as well as the public policy issues of the extent measure to be used to ensure flood safety. In other countries, where epidemiology of disease such as the hepatitides and HIV differ, the nature and exact testing to be performed should and does differ. The selection of which tests to be performed and the exact testing required depends on a combination of scientific and government decisions. In the USA, tests applied to donate blood must generally receive FDA evaluation and approval or acceptance. No claims for added safety can be made using tests that have not received FDA approval[1].

In this study, it was noticed that the overall percentage of potential donors who deferred was 12.07% of all encountered donors, this is close to the figures observed elsewhere; ranging between 14.4 - 20.0%, in various blood transfusions center, *e.g.*, Iran, Pakistan, and Singapore[19-21].

The number of donors excluded on the basis of the donor interview exceeded those who were excluded after the serological testing, underlining the importance and the efficiency of the donor questionnaire in ensuring both the donor eligibility and the safety of the blood supply.

The donor questionnaire remains an area of improvement in modern blood banking, particularly with respect to detection of potential donors with high risk of serious blood borne infections like AIDs, and hepatitis; nevertheless, some of the direct questions regarding the sexual contact and drug abuse receive a negative answer invariably by all donors in this study, an issue that should be considered if the social stigma of the sexual misconduct can pose a threat to the safety of the blood supply. A possible approach is to implement self-administered questionnaire with confidential self-exclusion of the concerned donor.

The common causes of donor disqualification are illustrated in Fig. 1., where it is obvious that blood pressure changes is invariably the most common, followed by anemia, and history of jaundice or hepatitis.

Donor testing was performed on all the blood units collected from the donors who qualify at the interview and whom their CBC was normal, together about one-third of the total interviewed donors were disqualified on the basis of a positive test result.

In the order of frequency the most common infection diagnosed among the blood donors was Hepatitis B (667 cases), followed by Hepatitis C (434 cases); both infections are on the decline as shown in Fig. 2. Perhaps the variation in the prevalence rate of blood borne infection is related to more than one factor; including the improvement in the education and socioeconomic state of the donors, the awareness of the public on the

importance of voluntary donation versus the donation to a relative or a friend, as common in the past. The efficiency of the stringent donor questionnaire in detecting donors with potential risk of infections.

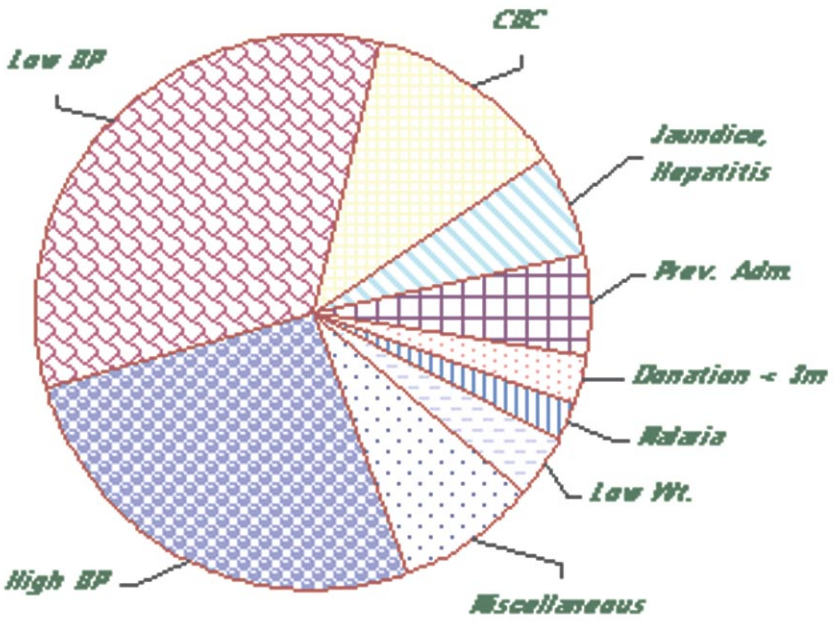


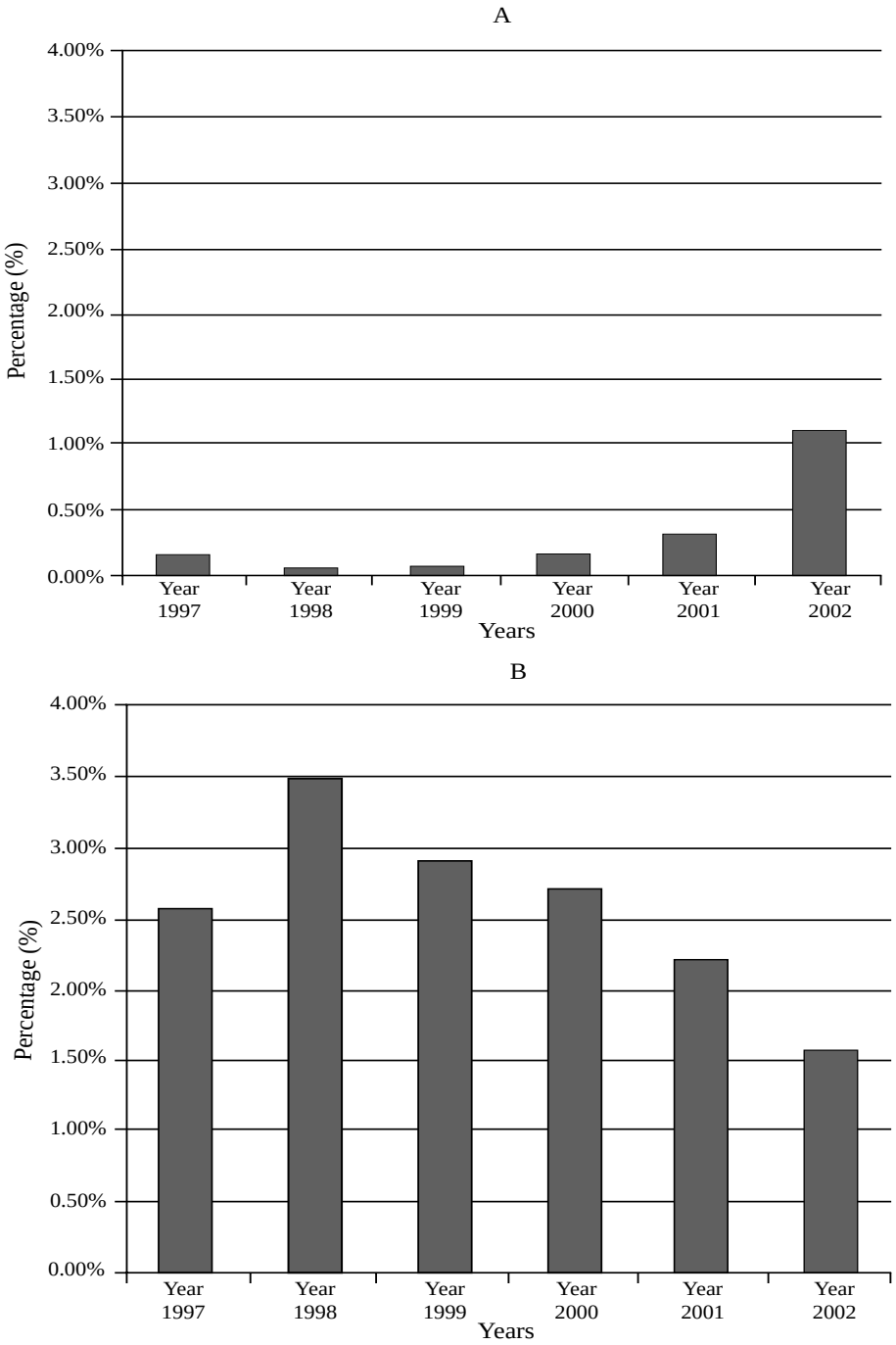
Fig. 1. Distribution of the common causes of deferring blood donors at the interview.

The test done for detection of syphilis is RPR. It is a very sensitive test carrying in account the proportion of false positive results.

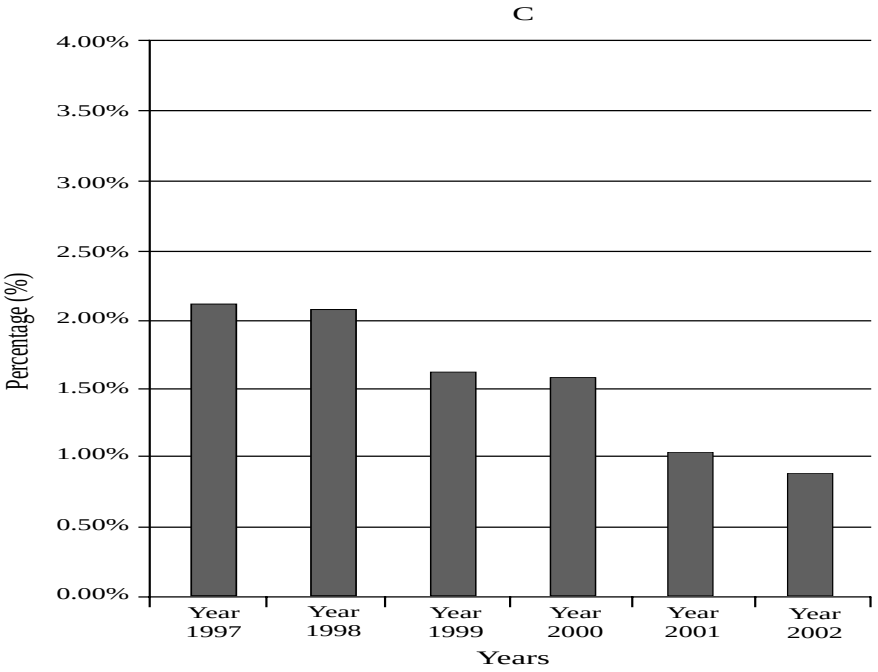
The relatively small number of cases of HIV infection (32 cases) among the blood donor population probably reflects that this viral infection is not as common as it it thought to be in the studied population (Fig. 2).

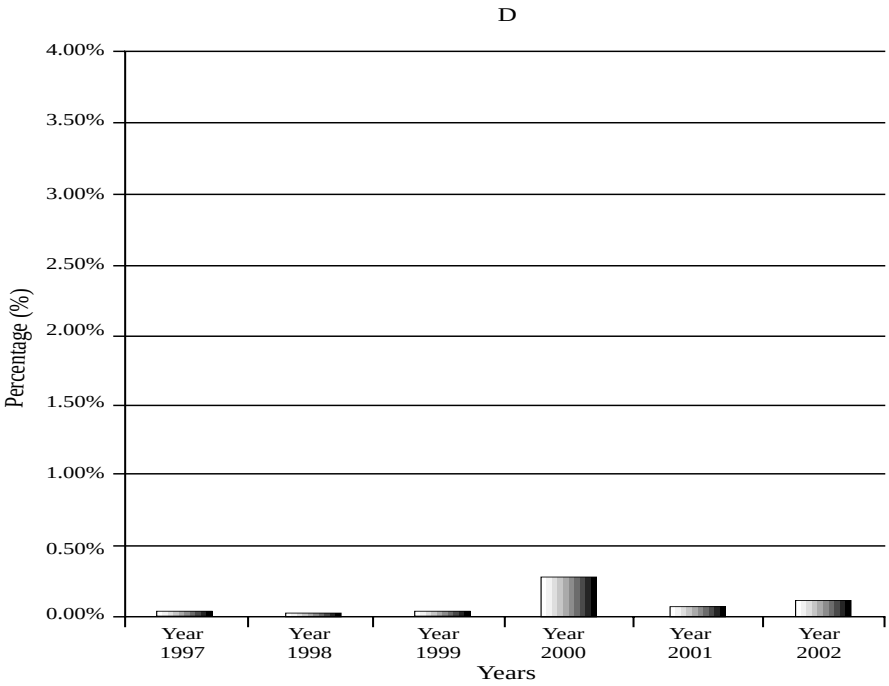
In conclusion, the importance of the donor questionnaire cannot be over emphasized, along with application of sensitive, accurate, and state of the art serological testing reagents, that are conforming to the AABB standard to ensure safety of the blood supply.

The coming years will witness the introduction of nucleic acid testing to cover of the window phase, when the donor harbors the virus but the antibodies are not yet detectable, a time gap that remains a potential threat to the safety of blood supply as well as the threat of pathogens that are difficult to diagnose like variant Creutzeldt Jakob Disease or pathogens that are not yet identified.



Figs. 2A & 2B. Serology screening results over the years, 1997 - 2002.
A = RPR; B = Hbs Ag.





Figs. 2C & 2D. Serology screening results over the years, 1997 - 2002.
C = HCV; D = HIV I II.

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نموذج إخضاع المتبرع بالدم في مركز نقل الدم التابع للمستشفى الجامعي

محمد حسن قاري
قسم أمراض الدم ، كلية الطب ، جامعة الملك عبد العزيز
جـــدة – المملكة العربية السعودية

المستخلص. الخلفيه: يعتبر أسلوب الانتقاء من أهم الوسائل للتعرف على المتبرعين ذوي الخطورة العالية الذين يجب الاستغناء عنهم للحفاظ على سلامة المتبرعين وسلامة مخزون الدم بصفة عامة. ويتم ذلك حاليا عبر استمارة التبرع والفحص الطبي واختبار الدم الشامل والاختبارات السيرولوجية لكل من الزهري والتهاب الكبد بنوعية ب و ج وكذلك مرض نقص المناعة المكتسبة. ولاستقصاء الأسباب الشائعة للاستغناء عن المتبرعين ومدى التغير في دلائل الأمراض عبر السنوات الماضية في مركز التبرع بالدم التابع للمستشفى يقدم رعاية طبية من الدرجة الثالثة. تمت دراسة عدد ٣٢٧٧٥ متبرعا متطوعا (بدون أجر) استقبلوا للتبرع بالدم في مركز التبرع بالدم التابع لمستشفى جامعة الملك عبدالعزيز خلال ست سنوات من الفتره ١٩٩٧ – ٢٠٠٢ ميلادية وتم جمع المعلومات وتحليلها لمعرفة الأسباب الشائعة المؤدية لعدم أخذ الدم من المتبرع ، تم الاستغناء عن (12.07%) من المتبرعين المتقدمين (7.03%) منهم تم الاستغناء عنهم عقب تعبئة استمارة الاستبيان ، و (0.96%) عقب إجراء فحص الدم الشامل ، و (4.08%) عقب إجراء اختبارات السيرولوجي التي أظهرت أن التهاب الكبد هو الأكثر شيوعا بين المتقدمين للتبرع بالدم بالنوعين ب وج. يتضح أن عدد اللذين تم الاستغناء عنهم عقب المقابلة وتعبئة استمارة الاستبيان الخا صة با لتبرع يزيد عن عدد الذين تم رفض تبرعهم نتيجة لوجود نتائج إيجابّية لاختبارات السيرولوجي. مما يؤكد على أهمية وكفاءه المقابلة الأولية وتعبئة استمارة الاستبيان الخا صة با لتبرع في الحصول على دم آمن لتخرينه وانتقاء متبرعين سليمي البنيه الصحيه .