

Impact of new AABB guidelines on hepatitis B and C testing among Saudi blood donors

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Introduction

Transfusion medicine services and blood banks worldwide experience mismatches between local supply and demand for blood products, which has increased significantly over the years. This necessitates the mobilisation and recruitment of blood donors to maintain sufficient blood supplies. In addition, the cost of running a transfusion medicine service (TMS) has increased, owing to regulatory pressure, quality improvement initiatives and scientific progress in understanding transfusion-transmitted diseases. At the same time, hospitals and laboratories are under fiscal pressure to reduce costs. The American Association of Blood Banks (AABB) revises and updates its guidelines and standards to cope with these changes.¹

King Abdulaziz Medical City (KAMC) is a tertiary level National Guard medical complex in Riyadh, Saudi Arabia. Before July 1995, as required by the old AABB guidelines,² 58.4% of its volunteer blood donors were deferred from donating blood. Of these deferrals, 28% were due to high levels of alanine aminotransferase (ALT).³ In July 1995, the institution adopted the new AABB guidelines for transfusion-transmitted diseases testing,¹ which now does not recommend ALT testing as part of the screening protocol.

The aim of this study is to compare the advantages and disadvantages of implementing the new versus old AABB guidelines for hepatitis B (HBV) and hepatitis C (HCV) screening of blood donors.

Materials and methods

Since introduction of the new AABB guidelines,¹ all potential

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ABSTRACT

This study aims to compare the advantages and disadvantages of implementing the new American Association of Blood Banks (AABB) guidelines for hepatitis B and C against its old criteria for screening blood donors. Between July 1995 and December 2002, 63,368 consecutive blood donors were screened for hepatitis B and C according to the new guidelines. Cost and prevalence were analysed and compared with those found using the old AABB guidelines prior to July 1995. The overall percentage rate of deferred donors showed a significantly decrease to 19.3% in 2002, compared to 58.4% before July 1995 ($P < 0.001$). The new prevalence of hepatitis B and C among Saudi blood donors was found to be 1.7% and 0.6%, respectively, compared to 4% and 1.4%, respectively, under the old AABB guidelines. This resulted in a significant increase in the number and yield of blood units, and a decrease in the prevalence of hepatitis B and C was observed among screened donors. Using the new AABB guidelines, the estimated direct cost of donor screening for hepatitis B and C decreased significantly from \$42.8 per donor to \$29.2 per donor ($P < 0.001$).

KEY WORDS: Blood donors.
Hepatitis B.
Hepatitis C.
Alanine aminotransferase.

blood donors were screened at the blood donor centre from July 1995 and until end of December 2002. Donors were asked specific questions about their general health and high-risk activity prior to screening. As a precaution, those who self-reported high-risk sexual or other high-risk behaviour were deferred from blood donation.

All blood donations were screened routinely for hepatitis surface antigen (HbsAg) and anti-HCV (Abbott Laboratories, Abbott Park, IL, USA), in addition to other tests recommended in the AABB guidelines. The manufacturer's instructions were followed in all procedures.

Reagent costs were based on the business-contracting concept of guaranteed price per reportable result (GPPRR; a type of reagent lease which includes all capital and running costs). Labour costs were calculated on the average of the hourly paid rate for a full-time equivalent (FTE) medical technologist. The estimation of total direct cost of the laboratory test was calculated using the model of Garber and Carey.⁴ In this analysis, reagents, supplies and labour were included.

Statistical analyses were performed using web-based χ^2 calculator software (Schnoodles.com/cgi-bin/web_chi.cgi).

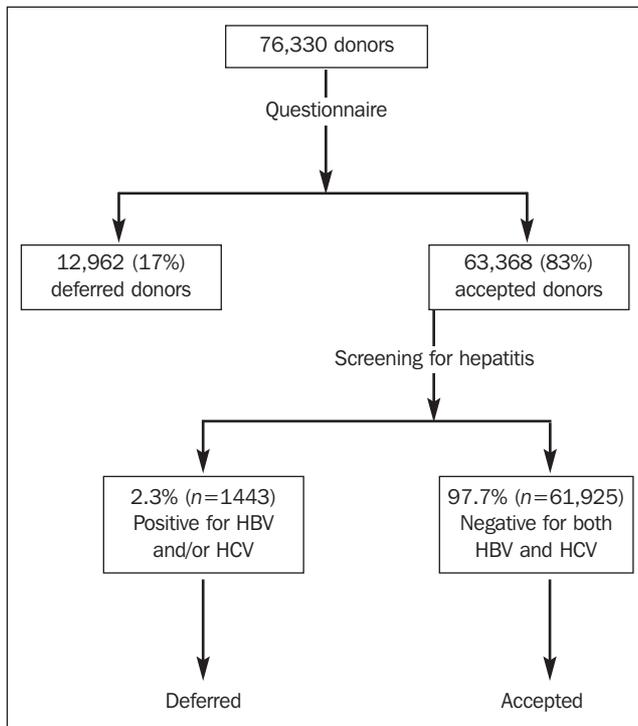


Fig. 1. Screening of blood donors for hepatitis B and C following the new AABB criteria between July 1995 and December 2002.

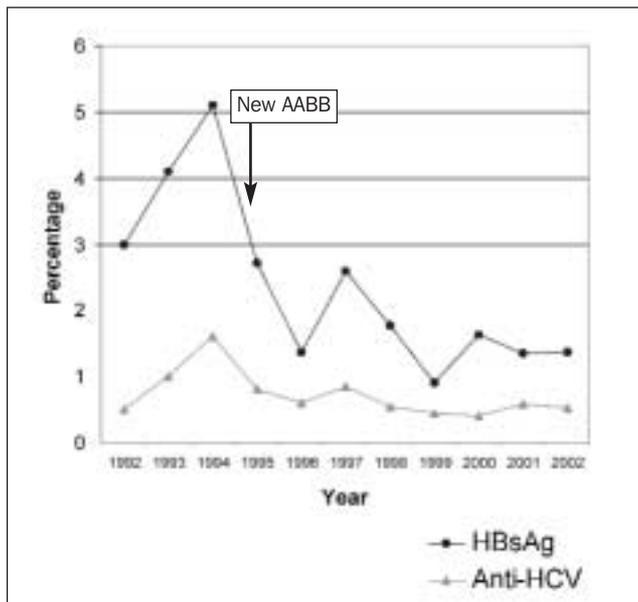


Fig. 2. Frequency of positive rate for HBsAg and anti-HCV among Saudi blood donors over the past 10 years.

Results

Figure 1 shows a flow chart of donors screened following the new AABB guidelines for HBV and HCV testing over the period between July 1995 and December 2002. Those volunteers tested positive for viral hepatitis were advised to visit their family practitioner for further investigation.

Figure 2 shows the frequency of HBsAg and anti-HCV positivity among Saudi blood donors over the past 10 years at KAMC. Table 1 summarises the number of screened

Table 1. Summary of blood donors and the prevalence of hepatitis B and C before and after the introduction of new AABB guidelines.

	Jan 1992 –Jan 1995	July 1995 –Dec 2002
Donors (prior to questionnaire)	15,006	76,330
Deferred donors (prior to hepatitis testing)	3832 (25%)	12,962 (17%)
Deferred donors (with high ALT level)	4161 (28%)	N/A
Screened donors	7013 (47%)	63,368 (83%)
Positive HBsAg donors	284 (4%)	1073 (1.7%)
Positive anti-HCV donors	72 (1.4%)	370 (0.6%)
Overall deferred donors	8349 (58.4%)	14,405 (19.3%)
Estimated direct cost per donor (\$)	42.8	29.2

donors, the overall number of deferred donors and the prevalence of HBV and HCV before and after July 1995. The estimated direct cost of HBV and HCV testing per donor sample is also summarized.

Discussion

Very high prevalence rates (up to 28%) of elevated blood ALT levels (>38 U/L) have been reported among blood donors in Saudi Arabia,^{3,5} which contrasts with only 2.3% in Western populations.^{6,7} Consequently, any donor with high ALT levels was automatically deferred from blood donation under the old AABB guidelines.² Subsequently, however, only 11% of those with high ALT levels were found to be positive for HBV or HCV by serological means.³ In addition, using ALT levels as a screen for viral hepatitis lacks the sensitivity to predict all infectious units of blood. This was one of the reasons why the AABB deleted ALT testing from its new guidelines.¹

Since implementation of the new guidelines in July 1995, the overall percentage of rejected donors at KAMC has decreased significantly ($P < 0.001$). This could be explained by arguing that the implementation of the new AABB screening criteria, which omitted testing of blood donors for ALT level, simply removed this criterion for donor rejection, thereby reducing overall donor rejection rates.

In a previous study,³ the present group concluded that, in addition to viral hepatitis, the causes for high ALT levels in blood donors are diverse and may include fatty liver, physical exercise,^{8,9} and high body mass index (BMI).¹⁰ This is particularly relevant as the vast majority of KAMC blood donors are military recruits. Other causes of elevated ALT include undiagnosed metabolic liver disease, alcohol intake and drug-induced hepatitis.¹¹ These may also have contributed to the prevalence of high ALT levels among KAMC donors, but this remains to be investigated.

It is unlikely that undiagnosed or preclinical acute hepatitis B and/or C contributed significantly to elevated ALT in KAMC blood donors because screening actively eliminated these factors, as did referral of volunteers with risk factors or symptoms. Furthermore, other investigators have reported the role of different factors and multiple or

other viral infections in producing high ALT levels in blood donors.¹²

The significant ($P < 0.001$) decline in the prevalence of hepatitis B and C in KAMC donors (4% to 1.7% and 1.4% to 0.6%, respectively) during the study period was lower than those reported previously by other investigators¹³⁻¹⁵ from different regions of the country. Some of these investigators¹³ have also reported a decline in the prevalence of hepatitis B among their blood donors.

However, the prevalence data presented here are higher than those reported in Western countries, particularly the USA.¹⁶ These findings may also support previous observation that increased ALT levels in Saudi donors probably has non-infectious causes.³

The decline in the rate of positive hepatitis markers may partly be a benefit from the improved pre-donation questionnaire applied by AABB standards. The greater decline in prevalence of hepatitis B compared to that of hepatitis C may be attributed to the implementation of an immunisation programme in Saudi Arabia in 1989.^{13,17}

The estimated total direct screening cost also decreased significantly ($P < 0.001$) to \$29.2 per donor compared to \$42.8 using the old AABB guidelines. This may have been due, in part, to improvements in immunoassay technology, reduction in reagent costs and the elimination of manual ALT testing.

In conclusion, the results presented here show that fewer donors were deferred under the new AABB guidelines. Moreover, the prevalence of HbsAg and anti-HCV positivity among KAMC blood donors decreased. Overall, implementation of the new AABB guidelines has resulted in an increased yield of safe blood units at reduced cost. □

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