Blood transfusion practices in India: results of a national survey

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Background: Blood transfusion may lead to serious clinical consequences for the recipient, if the transfused blood is not safe. To assess the functioning of the blood banks in India, a nation-wide, questionnaire-based study was conducted between November 1995 and November 1996 under the auspices of the Indian Association for Study of the Liver. Methods: Of 604 blood banks in 31 states and union territories to whom the questionnaires were sent, responses were obtained from 78 (13%) blood banks in 17 (54.8%) states, providing information on 275,000 donors. Results: A majority (58%) of donors in these blood banks were replacement donors, followed by voluntary (39.3%) donors. About 87% of the respondent blood banks screen blood for hepatitis B, 95% for HIV, 94% for syphilis, 67% for malaria, and only 6% for hepatitis C. Marked heterogeneity in the test methods was observed with only 13% using ELISA kits for HBsAg. Only 21% of the blood banks prepare blood-derived components. Feedback to the blood banks on the occurrence of transfusion-associated hepatitis is given on less than 40% of occasions. Conclusions: Testing for transfusion-transmitted infections is unsatisfactory and poorly regulated in India. Reporting of adverse events after transfusion is poor and no stringent donor deferral system exists. [Indian J Gastroenterol 2000;19:64-67]

Key words: Blood banking

Blood transfusion can be a source of infection to the recipient. The important and largely preventable infections transmitted by blood include viruses like the human immunodeficiency virus (HIV), hepatitis B (HBV), C (HCV) and delta (HDV) viruses, human T-cell lymphotropic viruses (HTLV 1 and 2), cytomegalovirus (CMV) and Epstein-Barr virus (EBV); bacterial infections like syphilis; and protozoal infections like malaria, toxoplasmosis and trypansosomiasis.

To ensure high standards of safety in transfusion products, the World Health Organization (WHO) launched the Global Blood Safety Initiative (GBSI) in 1990.1

In India, the infections for which effective screening of blood and blood products is currently mandatory are: HIV, HBV, syphilis and malaria.2 However, it is not known whether such screening is practised at district, zonal or regional supervising centers or blood banks.3

To investigate this vital issue, a questionnaire-based ‘National Transfusion Survey’ was conducted under the auspices of the Indian Association for Study of the Liver to obtain information on the blood banking practices in the country.

Methods
Addresses of all the registered and unregistered blood banks were obtained from the Indian Red Cross and National AIDS Control Organization (NACO). A questionnaire was sent to six hundred and four blood banks whose addresses were available. It was specified that strict confidentiality would be maintained regarding the identity of the blood bank and its personnel. Information was sought on the following issues:

a) The total period for which the blood bank had been operational as in January 1996.
b) The organization managing the blood bank (government/private/voluntary organization).
c) The number of blood donors reporting to the blood bank every year and whether voluntary, replacement, professional or autologous.
d) Infections for which donor blood was screened and the procedure/test kits employed for the same. Information was specifically sought for HBV, HCV and HIV infections, syphilis and malaria, and the use of surrogate markers like alanine aminotransferase and antibody to core antigen of HBV (anti-HBc), and the type and generation of testing kits used for these studies.
e) Specialized screening practices for HBV DNA or HCV RNA or both.
f) Method employed for disposing off infected blood/blood products.
g) Post-screening information to donors testing positive for HBV/HCV/HIV.
h) Feedback from clinicians regarding occurrence of transfusion-associated hepatitis (TAH) and the number of cases notified to the bank in the last one year.
i) Information regarding blood component preparation undertaken by the bank and the results of screening for
hepatitis and HIV viruses from pooled samples (if any).

j) Problems faced by blood banks in screening donors.

k) Rejection of donors, if any, in the last one year and the reasons for the same.

l) The number of voluntary donation camps organized in the last one year.

m) Suggestions for improvement of blood banking system in the country.

Blood banks which did not respond to the first request in the specified 8 weeks were sent a second request. The collected information was tabulated on a provincial basis and analyzed. The national data was then pooled.

**Statistical analysis**

Statistical analysis was done using the $\chi^2$ test. Values of $p<0.05$ were considered statistically significant.

**Results**

Of the 604 blood banks from 31 provinces to which the questionnaire was sent, only 78 (12.8%) from 17 (54.8%) provinces responded. The statewise response rate was: Andhra Pradesh (4), Arunachal Pradesh (1), Bihar (4), Delhi (8), Goa (1), Gujarat (8), Himachal Pradesh (2), Karnataka (2), Kerala (8), Madhya Pradesh (3), Maharashtra (12), Meghalaya (1), Mizoram (1), Punjab (2), Tamil Nadu (5), Uttar Pradesh (7) and West Bengal (9). These blood banks had been operational for periods ranging from 3 months to 50 years.

Majority of blood banks (51; 65%) were managed by the central or the state governments. Voluntary/autonomous organization(s) managed 15 (19%) blood banks and private organizations accounted for another 12 (16%). The donor profile was nearly similar all over the country. Information was available on 275,000 donors: about 55% (159,000) of donations were from replacement donors and 39% (107,000) from voluntary donations. Only 31% (8,525) of donations were from recognized professional donors and a meager 0.1% (275) from autologous donors. Sixty one (78.2%) blood banks reportedly refused blood donors in the past one year, for reasons such as inappropriate age, anemia, history of hepatitis, low body weight, identification of donor being an intravenous drug user, or a professional donor.

Donor blood was being tested for HBV, syphilis, malaria, ALT, anti-HBC and HIV in 68, 73, 52, 7, 11 and 74 blood banks, respectively; testing for HCV was being carried out in only 5 blood banks.

For detection of HBV, only 13 (16.7%) respondent centers were using ELISA, 7 (9%) reverse passive hemagglutination (RPHA), 12 (15.4%) latex agglutination, whereas 36 (46.2%) did not specify the method used. Only one blood bank performed HBV DNA testing.

Forty seven (60.3%) blood banks reported that they followed the practice of informing donors if they tested positive for HBV or HCV markers. Clinicians informed the blood banks of TAH cases on only four out of 10 occasions. Only two blood banks had been informed of 20 or more such cases in the last one year by their clinical departments.

Only 16 (20.5%) respondent blood banks were engaged in preparation of blood-derived products. All of them claimed to test the final product for hepatitis and HIV viruses. Forty three (56.4%) blood banks reported difficulty in screening donor blood effectively. Most commonly, this was due to constraints of funds, space, kits and trained personnel. Forty four (55.1%) blood banks organized voluntary donation camps in the year November 1995 to October 1996. The number of camps ranged from less than 10 (19 respondents) to more than 50 (6 respondents) per year.

The common methods reported for disposing off infected blood/blood products ranged from no treatment to disposal in septic tanks or ground burial or incineration with or without pre-treatment with chemical agents (e.g., bleaching powder).

There was no significant difference in the positivity for HIV between the voluntary (0.77%) and professional donors (0.71%), whereas HBsAg (1.6% vs. 2.03%; $p<0.0001$) and syphilis markers (0.49% vs. 0.55%; $p<0.05$) were less common among voluntary donors.

Data from the blood banks from four tertiary referral centers in the country were compared with the Indian Red Cross, to assess the prevalence of hepatitis B and C infection in voluntary and replacement donors (Table 1). There was a wide variation in HBV prevalence, ranging from 0.98% to 4.5% despite the use of ELISA kits by all these centers. Hepatitis C tests were done mainly in Delhi, with anti-HCV positivity ranging from 1.7% to 2.4%.

**Discussion**

This survey represents blood banking practices in 17 of 31 provinces in India. However, the number of participating blood banks was rather low (13%). This reflects the indifference and probably lack of transparency in
the functioning of these services.

It is noteworthy that, even today, the proportion of voluntary donors is quite low (39.3%). In 1985, when the Indian Council of Medical Research (ICMR) published its survey results, the proportion of replacement and voluntary donors was 44% and 34%, respectively. This could be a reflection of the lack of awareness amongst the general public about voluntary blood donation. Many replacement donors are actually professional donors. Indeed, in Japan, a mere change in practice from paid donations (1963-64) to voluntary donations (1968-72) decreased the incidence of TAH from 51% to 16%. It is therefore important that replacement donations should be discouraged and voluntary donations encouraged.

The main reasons for rejection of donors by the blood banks included inappropriate age, anemia, low body weight or history of hepatitis. None of the blood banks rejected a donor on the basis of being a high-risk donor. There are clear guidelines regarding a “non-eligible donor”. A person may be excluded for 6 to 24 months if there is a history of blood transfusion, acupuncture, tattooing, ear piercing, past donations for recipients who went on to develop TAH, or if he is a household contact of patients with hepatitis.

Only 20.5% of the respondent blood banks prepare blood products. This perpetuates the practice of transfusing whole blood when packed cells or plasma would suffice. It is well known that a part of the blood pool deficit that we face can be overcome by greater use of blood-derived products. Also, by separation of leukocytes (which harbor viruses like CMV and HTLV) the risk of transfusion-transmitted infection can be decreased.

In most developed countries, the incidence of TAH due to hepatitis B is less than 0.5%. A study done by the National Institute of Health, USA showed that the frequency of TAH was dependent on the technique used for screening of blood for HBsAg (4.8% with gel diffusion, 3.7% with counter immunoelectrophoresis, and 0.6% with radioimmunoassay).

The 1985 ICMR report stated that about 17% of the blood banks in India tested donor blood for HBsAg. This number has increased to 87% as per the current survey but the techniques used by various blood banks were variable. Only 13 of 78 (16.7%) respondent banks that tested donor blood for HBsAg used enzyme immunoassay (EIA). Thirty six respondents did not mention the technique used by them. Seven respondents mentioned the use of RPHA, which is much less sensitive than EIA. The Japanese Red Cross uses the particle agglutination technique (which is 10 times less sensitive than EIA or RIA) but also tests for anti-HBc (using hemagglutination inhibition), thus preventing transmission of HBV through blood transfusion.

Donor screening for anti-HBc was specifically asked for in the questionnaire, both because of its value in acting as a surrogate marker (along with ALT) for HCV and non-B, non-C hepatitis viruses as well as the concern for transmission of HBV through HBsAg-negative blood. Only 14% of blood banks were practising it. In areas of intermediate to high seroprevalence of HBsAg (for India, the average HBsAg positivity is 4.7%), it is worthwhile to evaluate the use of anti-HBc screening. Seven to ten percent of HBsAg negative, anti-HBe positive blood units may have presence of HBV DNA. In areas of low HBsAg seroprevalence, testing for anti-HBc is not as important, though in the US, this was made mandatory in 1986-87.

A study from the US, conducted on healthy volunteers (with normal ALT and negative HBsAg and anti-HBc), showed HBV DNA positivity rate of 1.7%. However, none of the recipients developed TAH. Therefore, the amount of virus required for a positive test may not be sufficient to cause infection. No such data are available from India though a small study from Delhi showed HBV DNA positivity in HBsAg negative donors to the tune of 5% by DNA probe hybridization assay, whereas the average HBV DNA positivity in HBsAg negative voluntary donors is about 9%.

Though 16 blood banks manufacturing blood products (especially plasma) claimed to test the final product for hepatitis and HIV viruses, this issue needs to be addressed further. Multiply transfused patients (hemophiliacs, thalassemics, hemodialysis patients) require these products time and again. Numerous studies have shown high prevalence of HBV- and HDV-related markers in these patients: HBsAg 2%-10%, anti-HBs up to 75%, anti-HDv up to 13%. Since specific clotting factors and cryoprecipitates are derived from pooled plasma, the screening of individual units of donated blood for both HBsAg and high titer anti-HBC is mandatory. A number of studies found HBsAg positivity in 17% and anti-HDv positivity in 33% of immunoglobulin batches, which are also derived from pooled plasma.

Around the world, more than 75% of TAH is caused by HCV. The incidence of HCV-related TAH in the US and Japan in 1970 was 7.12% and 45%, respectively. With the use of specific assays for HCV, in 1994-95, the incidence in the US was reduced to <1% and in Japan to nearly zero. While first-generation anti-HCV assays decreased the incidence of TAH by 80%, the second-generation assays decreased it by more than 90%. Hepatitis C detection in donor blood by tests like IgM antibody to HCV core protein may abrogate the transmission of HCV completely.

Only 6.4% of respondent blood banks tested donor blood for HCV. This rate suggests a need for drastic improvement, possibly through legislation. This is important since no vaccine is currently available against
Table 2: Transfusion-associated hepatitis in India

<table>
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<th>Center (Ref)</th>
<th>Total</th>
<th>HBV*</th>
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<td>33%</td>
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<tr>
<td>GBPI* (21)</td>
<td>7.7%</td>
<td>21.4%</td>
<td>31.4%</td>
</tr>
</tbody>
</table>

AIIMS: All India Institute of Medical Sciences, New Delhi. SGPGI: Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow. GBPI: G B Pant Hospital, New Delhi.

*% of total TAH. **25% of patients were anti-HCV positive by EIA-2. *Study with small sample size (n=41) of multiply transfused cardiac patients. **Dual infection (HBV and HCV) encountered in 7.2% of patients.

HCV infection, which can become chronic in 80%-85% of affected individuals. A properly evaluated third-generation assay for anti-HCV should be used for this purpose. The Japanese Red Cross uses a unique gelatin particle agglutination test, with a sensitivity of nearly 100%, for the detection of HCV.

The limited data on TAH available from our country are shown in Table 2. As the present survey reflects, very few blood banks are informed of TAH cases by clinicians. If this is done, the archival sample of the donated blood could be retested by a confirmatory test, and if positive, the donor should be excluded from the donation chain.

In summary, these are the first comprehensive data, based on a 'National Transfusion Survey', indicating the blood banking practices in the country with specific emphasis on TAH. It highlights the shortcomings of the current approaches, both in policy design and program implementation. This information can be of help in improving transfusion services in India. Mandatory use of third-generation EIA for HCV testing needs to be enforced. Need for anti-HBc testing should also be assessed further. The study highlights the need to centralize and reorganize our blood banking services. The issues of quality assurance, judicious preparation and use of blood components, donor awareness programs, donor deferral system and recipient surveillance after transfusion should be urgently addressed by the health care authorities.

References


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