

SAFETY OF BLOOD AND BLOOD COMPONENTS: ANALYSIS OF SEROPREVALENCE AND TRENDS OF HIV, HBV AND HCV

***Mangwana S.¹, Arya D.¹ and Yadav P.²**

¹*Department of Blood Transfusion Services, Sri Balaji Action Medical Institute, New Delhi.110063*

²*Department of Hospital Administration, Sri Balaji Action Medical Institute, New Delhi.110063*

**Author for Correspondence*

ABSTRACT

Blood transfusion service (BTS) is an integral and indispensable part of the healthcare system. TTI is still a major concern to all stakeholders i.e. patients, physicians and policy makers to have a risk-free blood supply. Analysis of seroprevalence and trends of infectious markers of HIV, HBV and HCV among voluntary and replacement donors population at a tertiary care centre was done to assess the safe blood supply. A data-based study covering 7 years period (2007 – 2013) was conducted. A total of 46,758 units of blood were collected from voluntary and replacement donors. All the donors were screened for hepatitis B Virus (HBV), Human immunodeficiency virus (HIV) and Hepatitis C virus (HCV).

Out of 46758 healthy adult donors screened, 45271 (96.82%) were males and 1487 (3.18%) females (Male: Female Ratio-30.44:1). Voluntary donors were significantly low [896 (1.92%)] as compared to replacement donors [45862 (98.08%)]. Total prevalence for HIV, HBV and HCV was 2.11 % with predominance of male donors (98.17%) and only 1.83 % female donors. Amongst all sero-reactive donors, proportion of voluntary donors was significantly low (0.3%) as compared to replacement donors (99.7%). All the voluntary donors were males and sero-reactive for HBV. The overall prevalence for HIV, HBV and HCV were 0.29%, 1.30% and 0.52% respectively. HIV seropositivity showed decreasing trends from 0.41% to 0.22%. Prevalence of HBV rose significantly in initial years from 0.90% to 3% in 2009 but 2010 onwards, it showed decreasing trend from 1.11% (2010) to 0.71%(2013). Seropositivity for HCV increased significantly from 0.34% to 0.59% in 2008 but afterwards, HCV remained almost constant to 0.57% .High number of replacement donors reflects lack of awareness in general population, misconception and fears for blood donation and lack of health education. There is need to have multidimensional strategies to improve health sector especially fragmented BTS with awareness and emphasis on voluntary donations, adequate infrastructure and trained manpower, strict donor selection criteria and inclusion of improved technologies like NAT for detecting infectious markers to ensure safer blood supply.

Keywords: *Transfusion Transmitted Infections, TTI, Seroprevalence, Blood Donors, Human Immunodeficiency Virus, HIV, HBV, HCV*

INTRODUCTION

Blood is an intrinsic requirement for health care and well organized Blood Transfusion Service (BTS) is a vital component of any health care delivery system. The annual requirement of blood for the country was estimated by National AIDS Control Organization (NACO) at 80 Lac units of blood in 2012-13(Annual Report, NACO, 2012-13). An integrated strategy for Blood Safety is essential for elimination of Transfusion Transmitted Infections (TTI) and for provision of safe and adequate blood transfusion services to the people, which are possible through collection of blood only from voluntary, non-remunerated blood donors, and screening for all transfusion transmitted infections.

Preventing the transmission of infectious diseases through blood transfusion in developing countries is difficult given that the resources required are not always available, even when policies and strategies are in place (Fernandes, 2010). The strategies that have been used to reduce Transfusion Transmitted Infection (TTI) include improving donors' selection, testing the donated blood for specific antibodies for

Research Article

infectious agents, reducing exposure to allogenic blood by use of autologous transfusion and changing transfusion guidelines to use blood more conservatively. Despite these extremely effective strategies, transmission of diseases still occurs, primarily because of the inability of the test to detect the disease in the pre-seroconversion or “window” phase of their infection, immunologically variant viruses, non-seroconverting chronic or immuno-silent carriers and laboratory testing errors (Fernandes, 2010). TTI is still a major concern to all stakeholders i.e. patients, physicians and policy makers to have a risk-free blood supply.

According to Joint United Nations Programme on HIV/AIDS (UNAIDS) Global report 2013; an estimated 35.3 (32.2–38.8) million people worldwide were living with HIV in 2012. There is a 33% decline in the number of new infections from 3.4 (3.1–3.7) million in 2001 to 2.3 (1.9–2.7) million. Estimated people in India living with HIV are 21 million (17–26 million), third highest in the world, with 0.1 % of young people aged 15 to 25 years are living with HIV. (UNAIDS, 2013). The adult HIV prevalence, both in men and women at national level in India has also shown decline from 0.41% in 2001 to 0.27% in 2011. Declining trend has sustained in majority of states but few states in north, north west and north east have shown rising trends (Annual Report, NACO, 2012-13). Nearly 119,000 cases of all causes of viral hepatitis were reported in India in 2012. HBV and HCV together are estimated to have led to 500 million chronically infected persons and one million deaths annually. India is having 3.7% HBV Seroprevalence, considered to have as intermediate level of endemicity (NCDC letter, 2014).

Human immunodeficiency virus (HIV), Hepatitis B virus (HBV) and hepatitis C virus (HCV) are the three most important agents responsible for transfusion transmitted infections (TTIs). The past several decades have witnessed great advances in techniques of detecting these TTIs. With the advent of nucleic acid amplification technique (NAT), western countries have decreased the risk of TTIs to a major extent (Pahuja, 2007). Despite this dramatic progress, India has to go a long way to achieve a “zero risk” blood supply.

This study presents data on the prevalence rate of infectious markers of HIV, HBV and HCV in our donor population and trends in 7 years (2007 – 2013), among voluntary and replacement donors in the blood transfusion service in a tertiary care Centre.

MATERIALS AND METHODS

A data-based study covering the period between 2007 and 2013 at the blood transfusion service in a tertiary care Centre was conducted. A total of 46,758 units of blood were collected from donors (voluntary and replacement) from January 2007 to December 2013. All the blood donors were selected in accordance with rules laid down in Drugs and Cosmetic Act, Ministry of Health and Family Welfare, Govt. of India. Care was taken to eliminate professional donors by taking history and conducting clinical examination.

All the donors were screened for Human immunodeficiency virus (HIV), hepatitis B virus (HBV) and Hepatitis C virus (HCV). HIV was screened by fourth-generation ELISA kit using P24 antigen and antibodies to HIV 1 and HIV 2 by Genscreen Ultra HIV Ag-Ab (Bio-Rad) with sensitivity of 100% and specificity of 99.95%. Hepatitis B Virus was screened for Hepatitis B surface antigen (HBsAg) using third-generation ELISA kits (Monolisa HBsAg Ultra; Bio-Rad) with sensitivity of 100% and specificity of 99.94%. Till July 2011, HCV was screened using third-generation ELISA kits (Monolisa Anti -HCV plus, version 2; Bio-Rad) with sensitivity of 100% and specificity of 99.8%. After July 2011, HCV was screened using fourth-generation ELISA Kits (Monolisa HCV Ag-Ab Ultra; Bio-Rad) based on detection of Capsid antigen and antibodies associated with an infection by Hepatitis C virus. Sensitivity of the kit is 100% with 99.83% specificity. All the reactive samples were repeated in duplicate. Repeat reactive sera were labeled as ELISA positive cases (seroreactive).

The statistical analysis was done using Chi square test for trends in proportions when proportions are very small.

Research Article

RESULTS AND DISCUSSION

Results

A total of 46758 apparently healthy adult donors were screened during 7 years period from January 2007 to December 2013. Among them, 45271 (96.82%) were males and 1487 (3.18%) were females (Male: Female Ratio -30.44:1). In the evaluation of data, we found that 45862 were replacement donations (98.08%) while only 896 (1.92%) were voluntary donations. On statistical analysis, proportion of voluntary donor was found to be significantly low (p value < 0.001) (Table 1).

Table 1: Total blood collection and sex distribution of donors

Year	Total Donors	Voluntary No. (%)	Replacement (%)	No.	Males No. (%)	Females No. (%)
2007	4100	84 (2.05)	4016 (97.95)		3952 (96.39)	148 (3.61)
2008	6469	74 (1.14)	6395 (98.86)		6226 (96.24)	243 (3.76)
2009	5278	93 (1.76)	5185 (98.24)		5095 (96.53)	183 (3.47)
2010	7490	142 (1.90)	7348 (98.10)		7266 (97.01)	224 (2.99)
2011	7092	155 (2.19)	6937 (97.81)		6796 (95.83)	296 (4.17)
2012	8012	184 (2.30)	7828 (97.70)		7800 (97.35)	212 (2.65)
2013	8317	164 (1.97)	8153 (98.03)		8136 (97.82)	181 (1.78)
Total	46758	896 (1.92)*	45862 (98.08)		45271 (96.82)*	1487 (3.18)

Note- *p value <0.001 (Highly Significant)

Total prevalence for HIV, HBV and HCV during 7 years period was 2.11% (986) with predominance of male donors (968; 98.17%) as compared to female donors (18; 1.83%) which is statistically significant (p value < 0.001). Amongst all sero-reactive donors, proportion of voluntary donors were significantly low (0.3%; 3) as compared to replacement donors (99.7%; 983). All the voluntary donors were males and seroreactive for HBV.

Table 2: TTI Prevalence in Voluntary and Replacement Donors

Year	Total Donation	Total Seroprevalence No. (%)	HIV			HBsAg			HCV		
			Total	Vol. No. (%)	Replac. No. (%)	Total	Vol. No. (%)	Replac. No. (%)	Total	Vol. No. (%)	Replac. No. (%)
2007	4100	68(1.66)	17(0.41)	0	17(0.41)	37(0.9)	0	37(0.9)	14(0.34)	0	14(0.34)
2008	6469	199(3.08)	35(0.54)	0	35(0.54)	126(1.95)	0	126(1.95)	38(0.59)	0	38(0.59)
2009	5278	214(4.05)	18(0.34)	0	18(0.34)	170(3)*	1(0.59)	170(3)	27(0.51)	0	27(0.51)
2010	7490	141(1.88)	18(0.24)	0	18(0.24)	83(1.11)	1(1.2)	82(98.80)	40(0.53)	0	40(0.53)
2011	7092	130(1.83)	16(0.23)	0	16(0.23)	74(1.04)	1(1.35)	73(98.65)	40(0.56)	0	40(0.56)
2012	8012	109(1.36)	14(0.17)	0	14(0.17)	57(0.71)	0	57(0.71)	38(0.47)	0	38(0.47)
2013	8317	124(1.49)	18(0.22)*	0	18(0.22)	59(0.71)*	0	59(0.71)	47(0.57)	0	47(0.57)
Total	46758	986(2.11)	136(0.29)	0	136(100)	606(1.30)	3(0.50)	603(99.50)	244(0.52)	0	244(100)

Research Article

Note- *-p value <0.001 (Highly Significant)

The overall prevalence for HIV, HBV and HCV were 0.29%, 1.30% and 0.52% respectively. Among HIV, all seroreactive donors were replacement donors with 136 males (96.32%) and 5 females (3.68%) (p value < 0.0001). Among HBV, out of 606 seroreactive donors, only 3 (0.50%) were voluntary donors with majority (99.5%; 603) as replacement donors (p<0.001). Amongst replacement donors, numbers of female donors were significantly low (1.65%; 10) as compared to male donors (98.35%; 593) (p value <0.001). Amongst HCV, all 244 seroreactive donors were replacement donors with 241 (98.77%) male donors and only 3 (1.23%) female donors (p < 0.001) (Table 2). The Trends in Seroprevalence of HIV, HBV and HCV over the 7 years period are shown in Figure 1. Seropositivity of HIV has decreased from 0.41% to 0.22% (p < 0.05). Prevalence of HBV rose significantly in initial year from 0.90% in 2007 to 3% in 2009 (p<0.001) but from 2010 onwards, it showed decreasing trend from 1.11% (2010) to 0.71% in 2013 which is constant for the last 2 years.

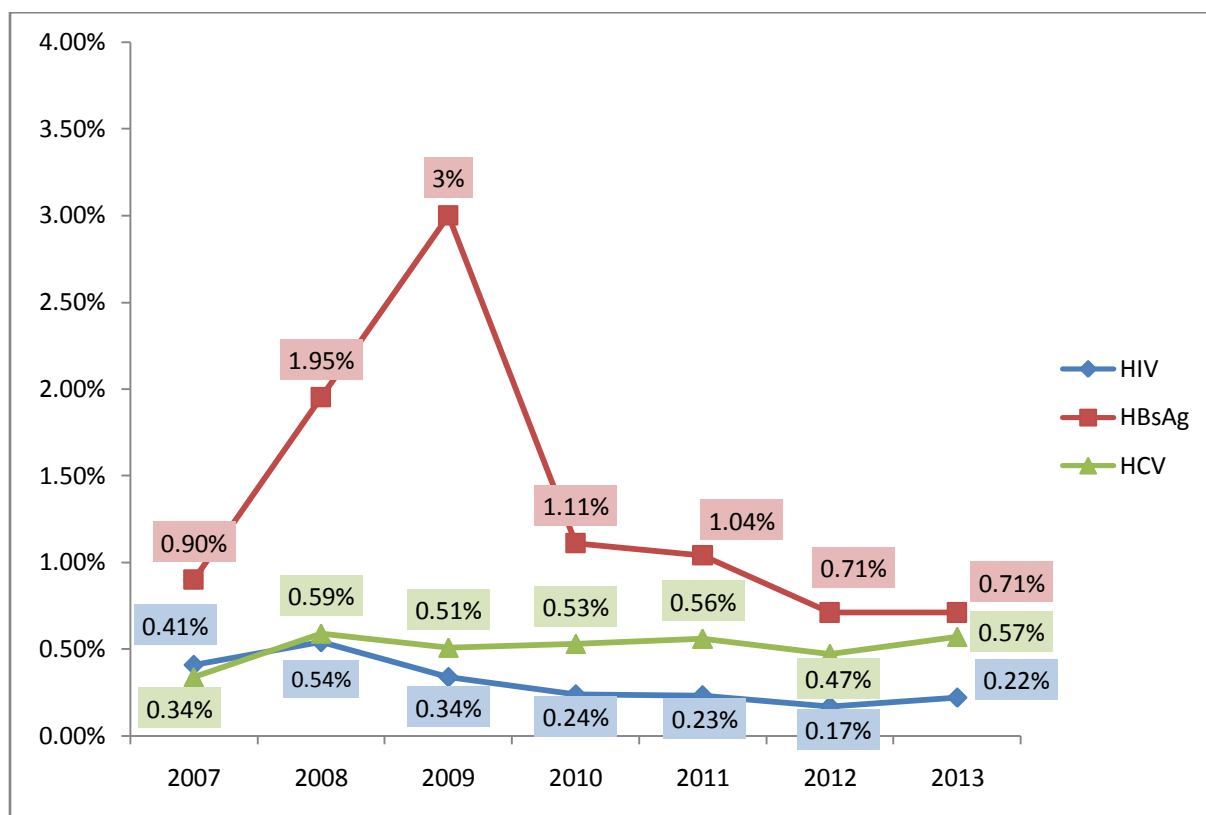


Figure 1: Prevalence and Trends of HIV, HBV and HCV

The seropositivity for HCV increased significantly from 0.34% in 2007 to 0.59% in 2008 (p<0.05) but after 2008, HCV is showing irregular trend and almost same to 0.57% in 2013.

Discussion

Blood Transfusion is an integral part of healthcare system. Safety of blood transfusion is ensured by careful selection of donors and performance of mandatory screening tests for TTIs.

Replacement donors constitute the largest group of blood donors in India (Makroo, 1996). Our study has shown predominance of replacement donors (98.08%) similar to studies by Singh *et al.*, (2005), Kakkar *et al.*, (2004) and Pahuja *et al.*, (2007) where 82.4%, 94.7% and 99.48% respectively donors were replacement donors. Size of Voluntary donors (1.92%) was very small in this study; finding as observed by Pallavi *et al.*, (2011) and Arora *et al.*, (2010). High number of replacement donors reflects lack of

Research Article

awareness in general population, misconception and fears for blood donation and lack of health education. Despite efforts by government and non government organizations to increase public awareness, voluntary blood donation is still not the norm in India. Females constituted a smaller section of the study (3.18%). This could be due to the fact that Indian women in child bearing age group have high incidence of anemia and hence are deferred; finding also observed by Mangwana (2013) where 50.58 % females were deferred with 68.01% of women were deferred due to low hemoglobin. World over the risk of TTI using voluntary donated blood is much less than that associated with replacement donation (Singh *et al.*, 2004; Makroo *et al.*, 1996; Sabharwal *et al.*, 2008). Very often replacement donations are made under stress where the donor may conceal his/her past medical history. The safety of the blood supply is compromised, as the country depends heavily on replacement donors, and the escalating costs of medical care make the desired result still more difficult to obtain (Pahuja, 2007).

With every unit of blood, there is 1% chance of transfusion associated problems including TTI (Arora, 2010). Despite mandatory screening of TTIs, Blood transfusion carries the risk of transmitting certain transfusion transmissible infections like HIV, HBV and HCV which can be due to window period. However, by use of nucleic acid amplification tests, early detection can reduce transmission of TTIs. In the present study, HIV seropositivity was 0.29%, comparable to HIV Seropositivity in other studies which ranged from 0.249% to 0.56% (Makroo, 2011; Singh, 2005; Pahuja, 2007; Pallavi, 2011; Deshpande, 2012). No voluntary donor was found to be seropositive for HIV; similar to findings by Arora *et al.*, (2010). In our study, we found decreasing trend of HIV seropositivity from 0.41% to 0.22%. Adult HIV prevalence at national level has also shown steady decline from 0.41% in 2001 to 0.27% in 2011. NACO supported blood banks in India have also shown decline in HIV seroreactivity from 1.2% to 0.2% from 2007 to 2012 (Annual Report, NACO, 2012-13).

Overall HBV Seropositivity in the present study was 1.30% which was comparable with other studies as 1.27% (Pallavi, 2011), 1.41% (Bhawani, 2010) and 0.66% (Gupta, 2004) while it was lower than some other studies where it was found to be 2.23% (Pahuja, 2007), 2.68% (Deshpande, 2012), 3.2% (Kulkarni, 2012) and 2.68% (Vishwanath, 2014). Voluntary donor had very small proportion of HBV seropositivity (0.5%) with 100% male predominance. WHO has grouped South Asia including India as countries with intermediate endemicity (2-7% prevalence) with India having over 40 million HBV carriers which accounts for 10-15% of the entire pool of HBV carriers of the world. (Anand, 2013). Rise of HBV seroprevalence in initial years from 0.90% (in 2007) to 3% (in 2009) may be due to concealment of medical history by replacement donors coming to donate blood under family pressure but stringent donor selection with strict selection criteria has reduced HBV prevalence remarkably to 0.71% by 2013. Prevention strategies include primary prevention of new cases i.e. post exposure prophylaxis and vaccines. WHO recommends the use of hepatitis B vaccine; the mainstay of hepatitis B prevention, to all infants after birth. Hepatitis B Vaccination is 95% effective in preventing infection and its major consequences (WHO| Hepatitis, 2014). Additionally, implementation of blood safety strategies including screening of all donated blood and blood components with improved technologies can prevent HBV transmission.

Seroprevalence of HCV in our study was 0.52% which was in agreement with studies in North India (Gupta, 2014; Pahuja, 2007; Acharya, 2013) while low prevalence is found in studies from southern and western states of India (Pallavi, 2011; Kulkarni, 2012; Vishwanath, 2014; Fernandes, 2010). HCV seroprevalence in Indian studies on blood donors ranged from 0.06% to 1.09%. Difference in seropositivity could be attributed to the use of different generation of ELISA test kits having different sensitivities and specificities, education level and health awareness of population. 350,000 to 500,000 people die each year from Hepatitis C related liver diseases (WHO| Hepatitis, 2014) and currently there is no vaccine for Hepatitis C so screening of blood and blood component with sensitive tests before transfusion is important in preventing Hepatitis C transmission.

Availability of safe blood is major concern in transfusion services. This can be achieved by thorough screening of blood donors, promotion of voluntary donations and inclusion of improved technology like

Research Article

Nucleic Acid Amplification (NAT) test which reduces window period and early detection of seroreactivity.

Conclusion

High number of replacement, male donors in our study reflects lack of awareness in general population, misconception and fears for blood donation and lack of health education. To achieve the objectives of National Blood Policy to provide safe and adequate quantity of blood and blood components, there is need to have multidimensional strategies to improve health sector especially fragmented Blood Transfusion Services with awareness and emphasis on voluntary donations, adequate infrastructure and trained manpower, strict donor selection criteria. Available latest technologies like NAT should be incorporated in Blood Transfusion Services for early detection of infectious markers to ensure safer blood supply with promotion of effective and efficient clinical use of blood and blood components through education and training.

REFERENCES

- Acharya S, Kumar R and Kudesia S (2013).** Safety of Blood and components obtained from voluntary and Replacement Donors: a comparative analysis. *IOSR Journal of Nursing and health Sciences* **1**(6) 5-8.
- Anand AC and Puri P (2013).** Indian Guidelines and Protocols: Hepatitis B In: Gastroenterology. Available: www.apiindia.org/medicine_update_2013/chap53.pdf [Accessed 08 July 2014] 242-245.
- Annual Report (2012-13).** NACO, Department of AIDS Control Ministry of Health and Family Welfare. Available: http://www.naco.gov.in/upload/Publication/Annual%20Report/Annual%20report%202012-13_English.pdf [Accessed 07 July 2014].
- Arora D, Arora B and Khetarpal A (2010).** Seroprevalence of HIV, HBV, HCV and syphilis in blood donors in Southern Haryana. *Indian Journal of Pathology and Microbiology* **53** 308–309.
- Bhawani Y, Rao PR and Sudhakar V (2010).** Seroprevalence of Transfusion Transmissible Infections among Blood Donors in a tertiary care hospital of Andhra Pradesh. *Biology and Medicine* **2**(4) 45-48.
- Deshpande RH and Wadde SK (2012).** Seroprevalence of HCV in Blood donors Status of Blood Donors Seropositivity of HCV in Marathwada, India. *Journal of Pharmaceuticals and Biomedical Sciences* **23**(22)1-4.
- Fernandes H, D'souza PF and D'souza PM (2010).** Prevalence of Transfusion Transmitted Infections in Voluntary and Replacement Donors. *Indian Journal of Hematology and Blood Transfusion* **26**(3)89-91.
- Government of India (1989).** Drugs and Cosmetic Act 1940 *The Gazette of India New Delhi*.
- Gupta N, Kumar V and Kaur A (2004).** Seroprevalence of HIV, HBV, HCV and syphilis in voluntary blood donors. *Indian journal of Medical Science* **58** 255-257.
- Kakkar N, Kaur R and Dhanoo J (2004).** Voluntary donors—need for a second look. *Indian Journal of Pathology and Microbiology* **47** 381–383.
- Kulkarni N (2012).** Analysis of the Seroprevalence of HIV, HBsAg, HCV and syphilitic infections detected in the pretransfusion blood: A short report. *International Journal of Blood Transfusion and Immunohematology* **2** 1-3.
- Makroo RN, Chowdhry M, Bhatia A and Rasamma NL (2011).** Prevalence of HIV among blood donors in a tertiary care centre of North India. *Indian journal of Medical Research* **131** 950-953.
- Makroo RN, Salil P, Vashist RP and Lal S (1996).** Trends of HIV infection in blood donors of Delhi. *Indian Journal of Pathology and Microbiology* **39** 139-42.
- Mangwana S (2013).** Analysis of blood donor deferral pattern: Scenario in a Tertiary Health Care Hospital in India. *Asian Journal of Transfusion Science* **7**(3) 160-161.
- National Blood Policy, (2003).** Available <http://upsacs.nic.in/bs%20doc/bs%20National%20Blood%20Policy.pdf> [Accessed 29 July 2014].
- NCDC letter (2014).** Available http://ncdc.gov.in/writereaddata/linkimages/NewsLtr0103_20146480274026.pdf [Accessed 07 July 2014]

Research Article

Pahuja S, Sharma M, Baitha B and Jain M (2007). Prevalence and trends of markers of Hepatitis C Virus, Hepatitis B Virus and Human Immunodeficiency Virus in Delhi Blood Donors: A Hospital based Study. *Japanese journal of infectious diseases* **60** 389-391.

Pallavi P, Ganesh CK, Jayashree K and Manjunath GV (2011). Seroprevalence and Trends in Transfusion Transmitted Infections among Blood Donors in a University Hospital Blood Bank: A 5 Year Study. *Indian Journal of Hematology and Blood Transfusion* **27**(1) 1–6.

Sabharwal ER and Langer S (2008). Prevalence and trends of Seroprevalence of HIV and syphilis in blood donors of Delhi. *Indian Journal of Practicing Doctor* **5**(3) 5-8.

Singh B, Kataria SP and Gupta R (2004). Infectious markers in blood donors of East Delhi: prevalence and trends. *Indian Journal of Pathology and Microbiology* **47** 477-479.

Singh B, Verma M, Kotru M, Verma K and Batra M (2005). Prevalence of HIV and VDRL Seropositivity in blood donors of Delhi. *Indian journal of Medical Research* **122** 234-236.

UNAIDS Report on Global AIDS Epidemic 2013. Available: http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/unaids_global_report_2013_en.pdf [Accessed 14 July 2014].

Vishwanath H, Gadwalkar SR, Venugopal K and Sunil KN (2014). Seroprevalence of Transfusion Transmissible Infections among Healthy Blood Donors in and around Bellary, Karnataka State, India *International Journal of Basic and Applied Medical Sciences* **4**(1) 108-111.

WHO| Hepatitis B Media Centre Fact Sheet N^o 204 (2014). Available: <http://www.who.int/mediacentre/factsheets/fs204/en/> [Accessed 07 July 2014].

WHO| Hepatitis C Media Centre Fact Sheet N^o 164 (2014). Available: <http://www.who.int/mediacentre/factsheets/fs164/en/> [Accessed 07 July 2014].