ORIGINAL ARTICLE

# HEPATITIS B, C AND HIV EXPOSURE ON NAT AND CLIA BLOOD EXAMINATION METHODS AT REGIONAL BLOOD CENTRE ABBOTTABAD

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**Background:** Blood transfusion is a lifesaving method in clinical emergencies. Despite various preventive measures, the spread of Hepatitis B, C and HIV remains a big issue in Pakistan. This study was done to describe transfusion transmitted diseases using NAT and CLIA techniques, on exposure to these viruses. **Method:** This study was conducted from 1st April to 25th August 2022. A descriptive study was done along with univariate analysis. The data was obtained from the regional blood centre in Abbottabad and it consists of reactive and non-reactive cases of NAT and CLIA in the sample size of 6233 donors. Data was collected from donors, and selected according to predefined criteria. **Result:** In 6233 samples, 53 were reactive for either Hepatitis B, C or HIV. Forty-seven were reactive with both CLIA and NAT. 6 were reactive with NAT only and 6107 were non-reactive. **Conclusion:** NAT yield detected in this study is 0.096%. (1:1039 donations). It implies that NAT should be the preferred method for screening in blood banks.

**Keywords:** Transfusion Transmitted Infection; NAT; CLIA

**Citation:** Irshad R, Farooq U, Shah T, Gul A, Badshah A. Hepatitis B, C and HIV exposure on NAT and CLIA blood examination methods at regional blood centre Abbottabad. J Ayub Med Coll Abbottabad 2023;35(2):285–7.

**DOI:** 10.55519/JAMC-02-11600

## INTRODUCTION

Blood donation is a very important and lifesaving intervention in the field of medical science but transfusion transmitted infections (TTI) remain a serious health issues across the globe. Various preventive strategies have been devised to minimize the risk of transmitting this disease through blood donation but screening for these infection agents remains a major challenge for blood banks in developing countries where resources are limited.

Pakistan has a population of 220 million and the annual blood collection is estimated to be 3 million with predominant reliance on replacement donation (85%) and about 10–15% of donations are voluntary and nonremunerated.[1]

The prevalence of HBV and HCV in the general. The population is 2.5% and 6.2% respectively.[2,3]

The national blood policy and strategic framework (2014–2020) is the national policy for safe blood transfusion. The section "Cluster: 3, core Business" underlines the importance of TTI screening and ensuring 100% screening of TTI on donated blood as well as ensuring proper resource allocation for adequate and sustainable supply of validated screening assay and required accessories.[4]

In order to recruit and retain safe blood donors, it is important to understand infectious markers in the general population, thus identifying low-risk donor population, along with an effective donor education, motivation and recruitment strategy. Confidence of all the stakeholders in the results of TTIs in a Blood bank is of critical importance. In Pakistan, blood screening is done by serological tests for hep B surface antigens and antibodies to HIV and HCV. However, some blood banks still use ICT method to detect these viruses. The screened seronegative donations done by ELISA or CLIA are still at the risk of TTIs because these serological markers may not appear in the blood until up to 03 months after the infection, leaving a "window period in which the risk of transmission of these diseases increases.[5]

The need arises for a more sensitive screening test to reduce this risk. With the implementation of NAT this risk has been reduced considerably in Western countries in the last 2–3 decades. NAT is a highly sensitive technique which is specific for viral nucleic acid. It is based on the amplification of the targeted region of viral RNA or DNA and detects them earlier than the other screening method thus narrowing their window period.[6]

The blood samples can be pooled together in a batch of 6 or 8 before testing to screen a large number of donations with a few tests mini-pool, NAT (MPNAT) or it can be run on every individual sample (IDNAT). It has been debated in various studies whether the pooling of samples results in decreased

sensitivity of detection as the volume of the individual sample gets lesser in the pool. Therefore, the greater the number of samples in the pool, the lesser the sensitivity of the detection of the test. Furthermore, the replication rate of HBV is very low, with a mean doubling time of 2.6 days and the viral load is very low during the window phase.[7]

The introduction of NAT for screening pooled or individual donations has led to improved blood safety. The size of MPNAT is considered critical for the identification of infected donors, during the presero-conversion phase of infection. The very small size of the pool helps greater reduction in the serological window phase.[8] The risk of viral infection is lower today than ever before due to improvements in donor screening and testing practices. NAT has lowered the risk even further in a few centres where this has been adopted. However, this additional benefit comes at an additional cost to the healthcare system.[9] Major barrier to implementing routine NAT testing in Pakistan is its high cost and lack of technical expertise in most of the blood centres. Regional blood centres (RBC), Abbottabad is one of the few centres in Pakistan which use this technology. RBC Abbottabad is a project, funded by the German government under the title, safe blood transfusion program (SBTP) along with the health department of Pakistan. Four centres were developed in KPK, Peshawar, Swat, D I Khan and Abbottabad. These centres were connected with existing hospital blood banks. These centres are provided with state-of-the-art equipment and technical support to establish an internationally recommended blood transfusion system in the province. A study conducted here from 1st April 22 to 25 Aug 22 tested 6233 donors on CLIA as well as on NAT.

## MATERIAL AND METHODS

RBC Abbottabad collected 6233 blood donations from 1st April to 25 August 22. The donors undergo strict pre-donation counselling, donor questionnaire and medical examination. This study is a retrospective study, which is presented descriptively.

## RESULTS

The blood collected was screened using NAT and CLIA methods. The chemiluminescence method (CLIA) is done by (Atellica, SIEMENS) and is used as the main serological screening test for HBV, HCV, HIV and syphilis. Malaria was checked by ICT method. All these samples were tested by NAT using (Procleix panther system). The NAT test was added as a supplementary test along with routine serology. Data was analyzed by using the SPSS version 21.
The results of blood screening done by NAT and CLIA methods from April to August are presented in table-1.

From April 22 to Aug 22 a total of 6233 samples are tested. Out of these 6233 samples, 47 were reactive by CLIA including 28 for HBV, 16 for HCV and 3 for HIV. ALL Samples were then tested by NAT out of 6233 samples 39 were reactive, 26 for HBV, 11 for HCV and 02 for HIV. There were 06 HBV, HCV and HIV infection cases that were not detected by serology but reactive by NAT. out of these 6 cases, 4 were HBV cases and 2 were HCV cases. No HIV window cases were detected by NAT testing as shown in Figure 1. Thus, the HBV and HCV NAT yield was 0.096% (1: 1039 donations).

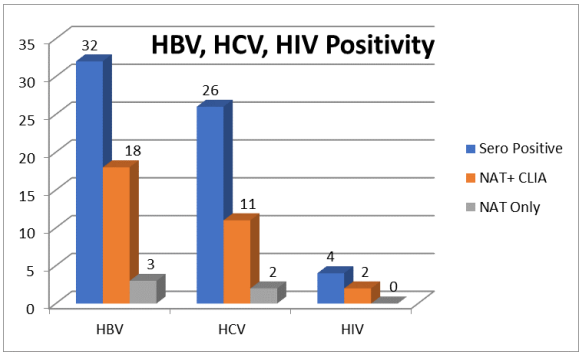


**Figure-1: HBV, HCV and HIV Positivity**

**Table-1: Month wise screening of blood donors**

| Month | Donation/Month | CLIA & NAT Reactive | NAT Reactive | Non Reactive |
|---|---|---|---|---|
| April | 581 | 2 | 0 | 579 |
| May | 1329 | 12 | 2 | 1315 |
| June | 1453 | 1 | 1 | 1451 |
| July | 1334 | 15 | 3 | 1316 |
| August | 1536 | 17 | 0 | 1519 |

## DISCUSSION

A safe, blood transfusion service is an essential component of a good and efficient health care service. It is the responsibility of the state to ensure safe blood by improving services like providing modern facilities and techniques, establishing infrastructure, and providing workforce and policies.

NAT testing is more sensitive than conventional tests. While the conventional methods depend on antibodies to produce a positive result NAT is based on the presence of viral genetic material in the

body and it happens before the body begins producing antibodies in response to the virus, thus giving it an opportunity to detect the disease at early stage TTI testing is based on serological testing in Pakistan. But even after the implementation of more sensitive and new techniques in serology, a considerable risk remains of the residual infection.[10] As we see in our study,53 cases were found positive for TTIs out of 6233. But out of these 53 cases, 47 were positive on CLIA but 6 cases were missed by this technique and were picked by NAT, giving NAT a yield of 0.096% (1:1039 donations). This yield is much higher than in studies done in Europe and USA where the reported prevalence is found to be 1: 6000000 for HCV-RNA and 1:1.8 million for HIV-RNA.[11]

Another large study in USA screened 66 million donations by NAT over 10-year period beginning in 1999 and identified additional 32 HIV cases (NAT yield for HIV 1:2 million) and another 244 HCV cases (NAT yield for HCV 1:270000).[12] Whereas in developing countries NAT yield was found as high as 1:2800 for HBV and 1:3100 for HCV.[13] Most populations with limited resources have a high prevalence rate of TTIs and they are expected to have more occult carriers and consequently have a greater number of window period donations. Thus, NAT screening is expected to identify more yield cases in these populations as compared to the developed world and thus will be more cost-effective. [14] Thus, NAT is found to be a highly sensitive advanced technique which reduces the period of HBV to 10–34 days, HCV to 1.34 days and HIV to 2.93 days.[15] But its drawbacks are, it is highly technically demanding, it has a high cost, and needs dedicated infrastructure, equipment, consumables and technical expertise so NAT testing should be started in any facility while considering all these issues.

## CONCLUSION

NAT yield detected in this study is 0.096%. (1:1039 donations). It implies that NAT should be the preferred method for screening in blood banks.

Its Implementation will improve Blood safety and will result into the detection of the infection during the window period. Reduction in the window period will reduce the treatment cost and burden on healthcare

## AUTHORS' CONTRIBUTION

RI: Literature search, Conceptualization of study design, data collection, data analysis, data interpretation, write-up, proof reading. UF: Data analysis, data interpretation and proof reading. TS, AG, AB: Data collection and data analysis.

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| *Submitted: December 10, 2022* | *Revised: February 12, 2023* | *Accepted: March 14, 2023* |
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