Introduction:

Blood transfusion is considered one of the most important therapies in modern-day medical science and most of the time it serves as a lifesaving drug. It is estimated that approximately 1-3% of any population group needs a blood transfusion every year for various reasons. But this drug works as a double-edged sword because of its inherent risks and benefits. The biggest threat is the transmission of transfusion transmissible infections (TTI) like HIV, Hepatitis B, and Hepatitis C to the patients being transfused. Transmission of these infections can occur even after completion of all mandatory tests with currently available tests methods like Rapid Card Test, ELISA, and Chemiluminescence technology because all these techniques are indirect and based on the detection of a sufficient amount of antibodies produced by the host immune system in response to the virus which takes about 3-12 weeks to detect with 99.9% accuracy. This period from infection to appearance of detectable antibody of virus is called *window period*. Blood collected from donors during this window period can transmit the infections to the transfused patient because in this period donors remain absolutely healthy and tests results are negative even in the presence of the virus. Therefore to have a safe transfusion practice with zero risk of TTI, a new method is required to detect these viruses even in the window period.

Problem Magnitude:

According to *The Joint United Nations Programme on HIV and AIDS (UNAIDS)* facts sheet published on 1st December 2016, World Aids Day, globally 36.1 million people are living with HIV with 2.1 million new infection and 1.1 million death from AIDS related illness per year. The total number of people living with HIV (PLHIV) in India is estimated at 21.17 lakhs in 2015according to the technical report "*India HIV Estimations 2015"* published by NACO. Among the states/UTs, Manipur has shown the highest estimated adult HIV prevalence, followed by Mizoram, Nagaland, Andhra Pradesh & Telangana, Karnataka, Gujarat and Goa. Assam is still considered as a low prevalent state but in this report, a rising trend in total number of HIV cases has been observed in comparison to the previous years which is a matter of real concern. At the end of 2015, the total number of people living with HIV in Assam is 12,090 with annual addition of 928 new cases and 229 deathdue to HIV related illness.

Over two billion people worldwide are infected with HBV, which is the leading cause

of liver disease. Of these, more than 350 million are chronically infected, with a higher risk for liver cancer and liver cirrhosis. In addition, worldwide 170 million people are infected with HCV.

What is NAT?

Nucleic Acid Amplification Test, NAT is the most advanced, Polymerase Chain Reaction (PRC) based, highly sensitive test technology introduced in 1999 in Australia and USA initially for direct detection of RNA of HIV and HCV. Later on Japan for the first time, performed routine HBV NAT in addition to HCV and HIV-1 NAT screening and observed a significant reduction in transmission of this virus as well. The principle is the extraction of viral nucleic acid from donor plasma followed by use of a nucleic acid amplification test to amplify and detect viral genetic sequences. With NAT, the window period is shortened considerably, for detection of HIV it is reduced from 20.3 to 5.6 days, for HCV it is reduced from 58.3 days to 4.9 days and for HBV from 53.3 days to 35.4 days making the blood transfusion much safer if combined with serological 3rd and 4th generation ELISA. There are two types of NAT methods-Mini Pool NAT or MP-NAT and Individual Donor NAT or ID- NAT. In MP-NAT, a pool of 6-16 samples are pooled together and tested to identify any reactive sample. If the pool shows any positive results, the next step is to identify that particular unit by retesting the individual samples. In this whole process, it takes approximately 24-48 hours. This method is cost effective but time consuming and all the units in the test pool need to be quarantined till the reactive unit is identified by individual testing in the second test. Another disadvantage is that in the pooling process, samples get diluted and false negative result may be reported if viral load is very low in the initial period of infection.

In ID-NAT, same principle of nucleic acid extraction is applied to test individual donor samples with better sensitivity. It has the advantage of detecting the infected donor unit at the end of first test only and detection rate is also more as the individual samples are tested separately without any dilution. Slightly higher cost per test is the only demerit.

Global and National scenario:

Most of the developed countries like Australia, Indonesia, Hong Kong, Korea, Malaysia, New Zealand, Singapore, Thailand, Japan, Europe, Middle East, Africa, France, Germany, Israel, Italy, Spain, Switzerland, UK, America, Brazil, Caribbean, Canada and many other European countries have already switched over to NAAT

and reports from these countries have documented the benefit of this technology in reducing the transfusion associated infections. In India also more than 20 Transfusion centers are currently providing NAAT tested blood and blood products. They are mostly from corporate and private sectors in urban areas. But in June 2016, for the first time in any government sector in India, Govt. of Orissa took the revolutionary step by launching the NAAT technology after the Orissa High Court issued a mandamus for blood testing through NAAT. It was after a boy of only 17 months of Baramba region in the district of Cuttack was afflicted with AIDS after receiving transfusion on operation table in 2011 and Orissa High Court had imposed cash punishment on the State Government holding the blood supplied by the Municipal Corporation Blood Bank as infected with HIV in window period.

Benefits of NAT:

Till now nationally and internationally, many studies have been conducted to find out the implication of NAT testing in blood transfusion service. The larger studies carried out in India have already proven that NAT can detect approximately 1 infected(HIV, HBV and or HCV) blood out of 2000 units which are tested negative by other currently adopted methods. The detection rate is higher for HIV than the other two infections. Now a days, as most of Blood Banks prepare at least 3 components from one donated unit, so one infected donor can infect 3 different patients. It has been observed that the frequently transfused patients like Thalassemia cases, patientsundergoing dialysis and cancer patients are the common victims of these infections. With the annual collection of approximately 90 million units in our country, the infected units will be approximately 9000 units and if at least 3 components are prepared the number of infected units will be 27000 units, which can be prevented by NAT.

Summery:

Blood and blood components are not completely safe in terms of transmissible infections until it is NAT tested. Although it cannot eliminate the risk of infection, it has significantly reduced the transmission rate. Therefore many developed countries have made itsuse mandatory for screening of donated blood. But in India with a population burden of more than 130 million and with lots of economic constrain, it is still not possible to make it compulsory.Implementation of NAT is

definitely a challenging task for any government or private organizations as it needs proper planning, trained manpower and huge amount of investment. Butat the same time, it is worth remembering that we live in a country with high prevalence of HIV and Hepatitis B where majority blood units are collected from family replacement donations and processed with doubtful quality control. Therefore, implementation of NAT system initially at least in the selected large sized blood banks collecting more than 20,000 units per annum, would definitely provide a reliable layer of safety in blood transfusion service. Other smaller centers can get their samples tested in the parent blood banks where this NAT system is available.

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