Article published online: 2022-06-10

Adaptation of a Public–Private Partnership Model for the Implementation of Minipool Nucleic Acid Testing for Screening Routine Blood Donations and Assay Evaluation

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J Lab Physicians 2022;14:317–323.

Abstract

Background Nucleic acid amplification testing (NAT) for the screening of blood donations is known to improve blood safety. The decision to initiate NAT requires careful deliberation of infrastructure, skilled manpower, and financial resources. This report outlines the initiative of the Government of Odisha to implement NAT screening in government blood banks in the state of Odisha, India, through public–private partnership (PPP) and evaluates the incremental yield of minipool NAT screening over serology testing of blood donations.

Methods Blood donations collected between June 2016 and September 2018 were initially screened for HBV (HBsAg), HCV (anti-HCV), and HIV (anti-HIV-1 and HIV-2) by ELISA, and syphilis and malaria. Sero-nonreactive donations were further screened in pools of six by Roche cobas TaqScreen MPX test version 2.0 (MPX2) NAT.

Results On screening 3,39,472 blood donations, 1.34% seroreactive donations were detected. In all, 847 NAT-reactive donations (0.26%): 693 HBV, 58 HCV, and 96 HIV were detected. The NAT yields were 1:386 overall, 1:472 for HBV, 1:5642 for HCV, and 1:3409 for HIV.

Conclusion NAT testing using the highly sensitive MPX2 assay leads to incremental detection of TTIs over serology. Implementation of NAT along with serological testing in blood centers all over India will be an important step towards providing safe blood. Our study not only highlights the benefits of minipool NAT testing but also presents a scalable PPP model that can serve as a template for application across other states.

Keywords
- nucleic acid amplification technology
- minipool
- transfusion-transmitted infection
- blood donation
- public–private partnership model
- NAT yield

published online
June 10, 2022

DOI https://doi.org/10.1055/s-0042-1748825.
ISSN 0974-2727.

Thieme Medical and Scientific Publishers Pvt. Ltd., A-12, 2nd Floor, Sector 2, Noida-201301 UP, India

Introduction

India is able to collect only 9 million units against an annual demand of 12 million units, that is, 1.2 crore units for transfusion per year[1] and a high prevalence of potential transfusion-transmitted infections (TTIs) across different states.[2] The National AIDS Control Organization (NACO), and National Blood Transfusion Council (NBTC) of India's assessment shows seropositivity of TTI among blood donors to be the highest for HBV (0.87%), followed by HCV (0.34%), syphilis (0.17%), HIV (0.14%), and malaria (0.06%); nonetheless, a huge variation exists among different states.[2] In India, all blood donations are mandatorily screened for human immunodeficiency virus 1/2 (HIV 1/2), hepatitis B virus (HBV), hepatitis C virus (HCV), and syphilis by serology as well as for malaria in accordance with the Drugs and Cosmetics Act, 1940.[3] Nucleic acid amplification testing (NAT) added to standard screening can potentially enhance the sensitivity of screening. It can thus reduce the risk for TTIs, especially in a country of high prevalence such as India.[4] There are several instances when serological assays fail to detect an infection while the NAT test can detect the presence of viral genome in the donated blood. Such a sample that is sero-nonreactive but NAT reactive is called a "NAT yield.[5]

The decision to initialize screening by NAT requires considerations of availability of infrastructure, skilled manpower, and the cost involved in procuring consumables and equipment.[6] The challenges seem even more onerous when contemplating widespread implementation with an aim to benefit a large number of patients with limited resources at their disposal. This report outlines the initiative of the government of Odisha to furnish NAT screening in the government-run blood banks through the adoption of the public–private partnership (PPP) model.

Implementation of NAT through PPP Model

Recognizing the benefit that NAT tested blood brings to the patients, Odisha became the first state in India, to have implemented nucleic acid testing (NAT) at the state level. This project aimed to provide the people of Odisha access to safer blood by implementing sophisticated screening methods in government-run blood banks. The project was operationalized by the government of Odisha under the public–private partnership (PPP) with Roche Diagnostics India Pvt. Ltd. To provide equal access to NAT-tested blood for all patients, irrespective of their socioeconomic status, the government has subsidized 100% of the additional cost of NAT testing to the patients, thereby providing quality medical care to the people of Odisha.

The objective of this study was to evaluate the incremental yield of minipool nucleic acid testing compared with serology testing using a highly sensitive NAT, the cobas TaqScreen MPX test, version 2.0 (MPX2) for blood screening to validate the installation of NAT PCR system.

Materials and Methods

Adaptation of NAT Testing through PPP

Once it was decided by the Department of Health and Family Welfare of the Government of Odisha to adopt NAT screening for transfusion-transmitted infections besides serological screening tests, the government formed a technical resource group of experts from various functions to give recommendations on the implementation of NAT screening. The group recommended the implementation of automated NAT testing and the adoption of the PPP model due to considerations of human resource requirement, expertise building, investment, and convenience in running day-to-day operations. The project was implemented through a hub and spoke model to maximize access and laboratory efficiency and minimize expenditure. It has been executed in a phased manner.

In the currently ongoing phase 1, NAT PCR laboratories were established in four blood banks while testing was extended to two satellite blood banks. The private partner provided expertise for infrastructure development, setting up the laboratory in four blood banks, and training NAT laboratory associates. State Blood Transfusion Council (SBTC) was the nodal body that supervised and monitored the six sites through a Nodal Officer. Gradually, the blood banks became well versed with the SOP prepared by SBTC for NAT testing and reporting.

The samples from the satellite blood banks were sent to the respective associated blood banks and were conveyed the NAT results within 24 hours of sample collection by the NAT laboratory associate. The blood components which were NAT were released for the issue to patients who were NAT nonreactive. NAT testing was smoothly implemented through the PPP model in the six centers of the state. It was decided to expand the scope of the project to the entire state of Odisha if the pilot proved successful.

Study Design, Study Centers, Methodology, and Inclusion Criteria

This retrospective multi-centric study was conducted over a period of 2 years and 4 months from June 2016 to September 2018 across six government-run blood banks in Odisha that had access to NAT under the government project. The four testing centers were Capital Hospital (CAPITAL), Bhubaneswar; Sri-Rama Chandra Bhanja Medical College and Hospital (SCBMCH), Cuttack; Veer Surendra Sai Institute of Medical Sciences and Research (VIMSAR), Burla; and, Odisha Red Cross Blood Bank, Maharaja Krishna Chandra Gajapati Medical College Hospital (MKCGMCH), Berhampur. In addition, the two satellite blood banks, BMC Hospital, Bhubaneswar whose samples were processed at Capital Hospital, Bhubaneswar and Central Red Cross Blood Bank (CRC), Cuttack whose samples were processed at SCBMCH, Cuttack, were included.

A total of 3,39,472 blood donations collected at the six study sites were included in the study. Overall, 2,11,016 (62.2%) were from voluntary donors, and 1,28,456 (37.8%) from replacement. The highest proportion of voluntary donors was in BMC (98.1%) and the lowest in CRC (51.5%).

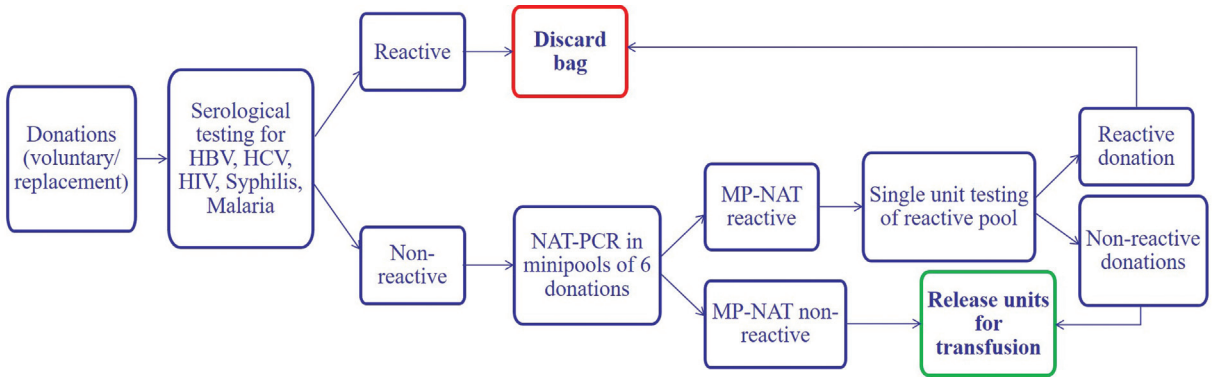

Fig. 1 Screening algorithm for donated blood.

All donations were tested by serology. A total of 3,27,241 sero-nonreactive donations were tested by NAT. As NAT screening was implemented over a period of 1-month at these six sites, not all sero-nonreactive donations collected in the month were tested by NAT, leading to the difference in the number of sero-nonreactive donations and those tested on NAT.

Serological screening of all blood donations collected during this timeframe was performed using the third-generation ELISA kits for HBsAg (by ERBA LISA PICO HBsAg), anti-HCV (by ERBA LISA PICO HCV), anti-HIV 1 + 2 (by ERBA LISA PICO HIV 1 + 2 TRANSASIA Bio-Medicare Pvt. Ltd.) provided by the Government of Odisha to all government blood banks on semi-automated ELISA platforms to maintain the uniformity of screening in all centers. The donations were also screened for syphilis (by Carbogen TULIP Diagnostic Pvt. Ltd.) and malaria (HRP-2, LDH MyTest By Bio-footprints Health care Pvt. Ltd.) by rapid tests. All assays were performed according to the manufacturers' instructions. Along with the quality control of the reagents beforehand, an appropriate negative control was incorporated in all procedures. The donations reactive for any of the above were discarded per the blood bank SOP and the non-reactive donations were further subjected to NAT. There was a marked difference in the window periods of the viruses in both ELISA and NAT tests. The window period through ELISA screening and NAT screening were 21, 8 days for HIV, 42, 16.7 days for HBV and 60, 3.9 days for HCV respectively.[7]

NAT was performed by the Roche cobas TaqScreen MPX Test v2.0 on cobas s 201 System (Roche Molecular Systems, Branchburg, USA). Cobas TaqScreen MPX Test v2.0 is a qualitative multiplex test based on PCR and can detect and discriminate between HBV, HCV, HIV-1 groups M and O and HIV-2, simultaneously. Donor samples were pooled in minipools of six using the Hamilton Microlab STAR pipettor (Hamilton, Reno, NV). NAT was performed following the manufacturer's instructions for the assay and automated platform. A reactive minipool was resolved by testing single units of the six members of the pool to identify the reactive donation and the viral cause of the reaction. The reactive donations were discarded per the Blood Bank SOP, and nonreactive units were released for transfusion in accordance with the planned screening algorithm for donated blood shown in ►**Fig. 1**. The 95% detection limits for MPX2 are shown in ►**Table 1**.

Analytical Sensitivity: Limits of Detection

The limits of detection (LOD) of the cobas TaqScreen MPX Test, v2.0 for HIV-1 Group M RNA, HIV-1 Group O RNA, HIV-2 RNA, HCV RNA, and HBV DNA were determined using the following standards: the WHO Second International Standard for HIV-1 RNA, Second International Standard (NIBSC code 97/650),[8] the WHO International Standard for Hepatitis B virus DNA for Nucleic Acid Amplification Technology (NAT) assays (NIBSC code 97/746),[9] the WHO Second International Standard for Hepatitis C Virus RNA for Genomic Amplification Technology Assays (NIBSC code 96/798),[10] and the Roche Primary Standards for HIV-1 Group O and HIV-2. Additionally, the LOD of the cobas TaqScreen MPX Test, v2.0 for HIV-2 was determined using the HIV-2 RNA International Standard (NIBSC code 08/150).[11] No international standard is currently available for HIV-1 Group O RNA. For the WHO and Roche standards, three independent dilution series of each viral standard were prepared with pooled human plasma collected in EDTA anticoagulant. Each dilution series was tested using three different lots of the cobas TaqScreen MPX Test, v2.0 kits with approximately 20 replicates per lot, for approximately 180 replicates per concentration. For the HIV-2 International Standard, 10 replicates per lot from three independent dilutions and three reagent lots were tested for 90 replicates per concentration. Finally, analysis of the combined data from all replicates tested for each virus was used to estimate the LOD.

Table 1 Detection limits for NAT assays used in the study

Target	95% LOD* of cobas® TaqScreen MPX Test, v2.0
HBV	6 IU/mL
HCV	6.8 IU/mL
HIV-1 Group M	50.3 IU/mL
HIV-1 Group O	18.3 copies/mL
HIV-2	57.4 copies/mL

Abbreviation: LOD, limit of detection.
*The level at which 95% of test results would be expected to be reactive.

As per the Blood Bank Standard Operating Procedures, any donor reactive on a serological or NAT screening assay was informed and counseled about the results of the screening test and asked to follow up with the relevant specialty for confirmation and further management, if any. Donors identified as reactive on serology or NAT were not allowed to donate again. Other healthy donors who were previously seronegative through serology/NAT testing and came back for repeat donation again were not excluded from the study. They were further evaluated with both the screening tests, that is, ELISA followed by NAT testing.

Statistical Analysis

Our study was conducted as a descriptive study showing incremental reactivity with NAT over serology. As no comparison was intended, tests of significance were not applied. Any yield obtained with NAT over and above serology is considered important. All data were entered electronically in Microsoft Excel 2016. Descriptive statistics were used, and no statistical tests were performed. Data variables in the study have been presented as an absolute or relative frequency in the form of percentages.

Results

Serological Testing

The seroreactivity results of 3,39,472 blood donations from six study sites are given in ►**Fig. 2**. A total of 4,551 seroreactive donations were detected (1.34%). Overall, seroreactivity was the highest for HBV (1.07%), followed by HCV (0.10%), HIV (0.09%), malaria (0.05%), and syphilis (0.03%). The proportions of seroreactive donations detected out of total blood donations at the study sites from west to east were 3.08% at MKCGMCH, 1.31% at SCBMCH, and 1.3% at CAPITAL. The seroreactivity at other centers was less than 1%. The highest seroreactivity for HBV and HIV was found at MKCGMCH (2.75% and 0.15%, respectively), while the highest seroreactivity for HCV was found at SCBMCH (0.17%).

Of the total 4,551 seroreactive donations detected at all study sites, 80% were HBV-reactive, 8% HCV-reactive, 7% HIV-reactive, 4% malaria-reactive, and 2% syphilis-reactive. However, out of the total seroreactive donations detected at each study site, 74 to 89% were HBV-reactive, 4 to 14% were HCV-reactive, 5 to 10% were HIV-reactive, with lesser proportions of syphilis and malaria-reactive donations. The VIMSAR site was an exception to this pattern where the proportion of HBV was much lower (44%) and the proportion of malaria and syphilis was higher (22% and 11%, respectively) than other sites.

Molecular Testing

A total of 847 NAT-reactive donations were detected, and the overall NAT yield was 1:386 (0.26%). Although NAT testing was uniformly done in all centers on an automated platform, the NAT reactivity and NAT yield of sero-nonreactive donations varied in all study sites across Odisha, which is depicted in ►**Table 2**. Overall, MKCG MCH (1:158) followed by VIMSAR (1:272) showed a higher NAT yield compared with SCBMCH showing the lowest total NAT yield (1:1089). The HBV NAT yield and HCV NAT yield were the highest for MKCGMCH. However, the HIV NAT yield was the highest for VIMSAR. SCBMCH had the lowest yield for all three viruses: HBV (1:1208), HCV (1:27773), and HIV (1:18515).

NAT-reactivity was the highest for HBV ($n = 695$ amongst 847 donations, 82.5%), followed by HIV ($n = 96$ amongst 847 donations, 11.3%), and HCV ($n = 59$ amongst 847 donations, 6.9%).

NAT-Reactivity Stratified by Voluntary/Replacement Status and Gender

The information on NAT reactivity by voluntary/replacement status and gender is given in ►**Table 3**. The mean age of NAT reactive donors was 32.6 years.

Discussion

Our two and half years of experience with the implementation of NAT screening on a statewide basis demonstrates the

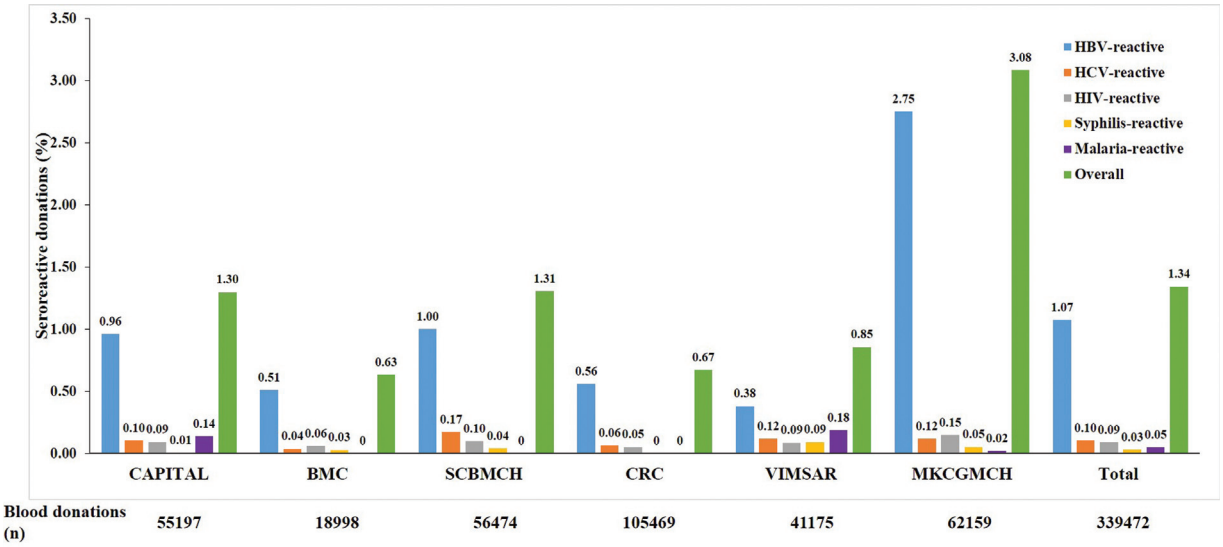

Fig. 2 Seroreactivity (%) at different study sites across Odisha.

Table 2 NAT reactivity and NAT yield of sero-nonreactive donations at study sites across Odisha

Site (No. of donations tested by NAT)	HBV (n)	HCV (n)	HIV (n)	Total NAT reactive donations (n)	HBV yield	HCV yield	HIV yield	Total NAT yield
CAPITAL ($N = 53,663$)	79	10	12	101	1:679	1:5,366	1:4,472	1:531
BMC ($N = 18,758$)	36	7	2	45	1:521	1:2,680	1:9,379	1:417
SCBMCH ($N = 55.546$)	46	2	3	51	1:1,208	1:27,773	1:18,515	1:1,089
CRC ($N = 99,876$)	108	7	12	127	1:925	1:14,268	1:8,323	1:786
VIMSAR ($N = 40,302$)	105	7	36	148	1:384	1:5,757	1:1,120	1:272
MKCGMCH ($N = 59,096$)	319	25	31	375	1:185	1:2,364	1:1,906	1:158
Total ($N = 327,241$)	695	59	96	847	1:472	1:5,642	1:3,409	1:386

Table 3 NAT-reactivity stratification based on voluntary/replacement status and gender

Site	V (*n*) (%)	R (*n*) (%)	V + R (*n*)	V-NAT yields (*n*) (%)	R-NAT yields (*n*) (%)	Total NAT yields (V + R)	M-NAT yields (*n*)	F-NAT yields (*n*)
CAPITAL	39,099 (70.8)	16,098 (29.2)	55,197	72 (71.3)	29 (28.7)	101	94	2
BMC	18,639 (98.1)	359 (1.9)	18,998	45 (100.0)	0 (0)	45	45	0
SCBMCH	30,743 (54.4)	25,731 (45.6)	56,474	24 (51.1)	23 (48.9)	51	42	4
CRC	54,336 (51.5)	51,133 (48.5)	1,05,469	60 (47.2)	67 (52.8)	127	121	6
VIMSAR	30,658 (74.5)	10,517 (25.5)	41,175	–	–	148	144	4
MKCGMCH	37,541 (60.4)	24,618 (39.6)	62,159	191 (51.1)	183 (48.9)	375	370	4
Total	2,11,016 (62.2)	1,28,456 (37.8)	3,39,472	392 (56.5)	302 (43.5)	694	816	20

Note: BMC, Blood Bank, BMC Hospital, Bhubaneswar, Odisha; CAPITAL, Blood Bank, Capital Hospital, Bhubaneswar, Odisha; CRC, Central Red Cross Blood Bank, Cuttack, Odisha; F, Female; M, Male; MKCGMCH, Orissa Red Cross Blood Bank, Maharaja Krishna Chandra Gajapati Medical College Hospital, Berhampur, Odisha; NAT, Nucleic acid amplification testing; R, Replacement; SCBMCH, Srirama Chandra Bhanja Medical College and Hospital (SCBMCH), Cuttack, Odisha; V, Voluntary; VIMSAR, Department of Transfusion Medicine, Veer Surendra Sai Institute of Medical Sciences and Research, Burla, Odisha.

*Because this was a retrospective study, some information could not be collected for VIMSAR center, and some data are missing for other centers too.

success of the PPP model. The data presented here show the ability of NAT-PCR applied in a minipool format to identify infectious units over and above serology. This is one of the largest datasets from a large number of centers published so far, though smaller studies have been published.

NAT implementation in government-run blood banks is a state-of-art project of the Odisha government, operationalized under the PPP model with a private entity. The theoretical advantages of PPP such as improved efficiency with focused strategies and resources, and overcoming challenges of accessibility and affordability have been corroborated by our experience.[12] The detection of a high number of serology-negative NAT reactive donations in our study revealed the significant benefits of NAT testing and validated the decision to implement NAT in the state. It paves the way for a statewide application of NAT. The government in addition, with a view to providing equal access to NAT-tested blood for all patients irrespective of their socioeconomic status, subsidizes 100% of the additional cost of NAT testing to the patients. This has not only served the purpose of providing quality medical care to people of Odisha but has also contributed toward the prevention of transmission of viral infections to recipients of transfusion and saving significant financial resources in the management of the infections.

The National AIDS Control Organization (NACO), under the Ministry of Health & Family Welfare, and National Blood Transfusion Council (NBTC) provided a report on the assessment of blood banks in Odisha from January 2015 to December 2015. HBV had the highest seropositivity (0.87%), followed by HCV (0.34%), and HIV (0.14%).[13] Accordingly, in the present

study, the highest percentage of seropositivity was observed with HBV (1.07%), followed by HCV (0.10%), and HIV (0.09%). Serological screening of all blood donations collected during this timeframe was performed using the third-generation ELISA kits for HBsAg, anti-HCV, anti-HIV from different manufacturers approved and provided by the Government of Odisha to all government blood banks on semi-automated ELISA platforms to maintain the uniformity of screening in all centers. Overall, seroreactivity varied between different parts in different districts of Odisha. In coastal Odisha, Berhampur (MKCGMCH) had the highest seroreactivity (3.08%) and BMC in Bhubaneswar had the lowest seroreactivity (0.63%). Although NAT testing was uniformly done in all centers on an automated platform, the NAT reactivity and NAT yield of sero-nonreactive donations varied in all study sites across Odisha. Similar to serology, the NAT yield was also higher in the sites in the coastal side of Odisha, 1:158 for MKCGMCH, Berhampur followed by 1:272 for VIMSAR, Burla, in the Western Odisha. The lowest NAT yield of 1:1089 was found in SCBMCH. The variation in the serological and NAT reactivity in different sites was may be due to the fact that certain Districts such as Ganjam and Sambalpur having the cities Berhampur and Burla, respectively, have higher seroprevalence of hepatitis and HIV viruses in comparison to the other districts the State of Odisha.

In India, the published NAT yields vary widely. Most studies report a NAT yield of 1:2,000 to 1:3,000.[14–17] The NAT yield in our study is among the highest published in India. The combined NAT yield of the six sites of our study (1:386) was higher in contrast to most of the previous studies in India on NAT yield of 1:2,000 to 1:3,000 but was similar to the NAT yield of 1:384 reported by Chandra et al[14] at a tertiary care government center in Northern India using minipool-NAT-PCR in donations screened serologically by ELISA. The reason might be due to the use of an assay with high sensitivity for HBV, such as the cobas TaqScreen MPX2 Test, leading to a high yield of NAT in minipool format.

There are other assays such as serological assays for the screening of transfusion-transmitted infections such as enzyme-linked immunoassay (ELISA), chemiluminescence assay (CLIA) which are different from NAT testing in the principle of the test. The principle of ELISA is the binding of antibodies to the target antigen and to detect the presence and quantity of antigen binding, whereas the principle of CLIA is in the presence of complementary antigen and antibody, the paratope of the antibody binds with the epitope of the antigen to form an antigen–antibody or immune complex. NAT testing is more sensitive and specific for viral ribonucleic acid. It is based on the amplification of targeted regions of viral ribonucleic acid or deoxyribonucleic acid (DNA) and detects them earlier than the other screening methods, thus narrowing the window period of HIV, HBV, and hepatitis C virus (HCV) infections.[6]

To our knowledge, the NAT yield of MKCGMCH, Berhampur (1:158), is the highest ever reported in a published study from India. This study demonstrates the interdiction of a large number of serology nonreactive by NAT, thus minimizing TTIs. This benefit becomes even more evident when considering the possibility of component separation, wherein every blood unit is split into three components that may be transfused to three separate recipients. Thus, in the present study over a period of 2.5 years, approximately 2,541 (847 NAT yields $\times$ 3) TTIs were prevented. In other words, one TTI was interdicted per 128 transfusions.

The proportion of voluntary donors in the study was 62.2%; however, a lower proportion (56.5%) of NAT reactivity was found in the voluntary donors. This brings forth the importance of continuing to encourage voluntary donations. At the same time, it also points toward the continued need for rigorous screening even in the voluntary donors.

In our study, NAT yield was the highest for HBV at 1:472, followed by HIV at 1:3,409, and HCV at 1:5,642. The highest yield for HBV is expected as the incidence and prevalence of HBV in India are much higher than those of HCV and HIV.[18,19] HBV is the most common viral infection amongst HBV, HCV, and HIV in the general population of India and also the most common infection found in blood banks through serology and NAT.[2,13,15–17,20] Similar situation is observed in Odisha. Hence, the HBV seroreactivity and HBV NAT yield were both high in our study. It has been demonstrated earlier that cobas TaqScreen assays detects HBV infections less than 2.3 IU/mL in concentration.[17,21] It is important in regions with a high prevalence of HBV, where the possibility of window period donations and occult infections with low viral loads is high, that an assay that is very sensitive for the detection and identification of HBV DNA be used.

Interestingly, in this study, the next common yield to HBV was HIV. In general, HIV is found to be the least common NAT yield in most studies from across India reflecting the much lower prevalence of HIV than HCV and HBV in the country.[20,22] The prevalence of HIV in the population aged 15 to 49 years in Odisha is found to be 0.13%. The high NAT yield in our study could possibly be due to the lower effectiveness of the HIV serology screening assay.

The highly sensitive MPX2 NAT assay used on cobas s 201 system offers additional advantages. It is a real-time PCR-based assay that requires low sample volumes for the detection of DNA/RNA. The multiplex and multi-dye technology utilized in this assay allows simultaneous detection and real-time target identification within a single test. The system is completely automated, requires no calibration, uses ready-to-use reagents, avoids cross-contamination by using the enzyme AmpErase, and works with minimal maintenance. The screening algorithm is simple and requires testing of only sero-nonreactive donations. Pooling reduces the number of tests performed and cost and improves specificity. The minipool test has a low limit of detection and has the capacity to detect HBV infections with viral load less than 6 IU/mL, which indicates the acceptable high sensitivity also.

The study had some limitations such as non-collection of viral load and follow-up data for seroconversion. In addition, being a retrospective study, data on some of the variables are missing from some centers. Nonetheless, this is a very large study of approximately 3.4 lac donations that showed the very high NAT yields that could be identified using a highly sensitive NAT assay.

Conclusion

The results of the present study revealed the incremental identification of potentially infectious donations by screening minipooled samples after being found nonreactive by serology assays. The advantages of using an automated molecular screening system were also amply clear. Minipool NAT-PCR could detect HBV, HCV, and HIV infections over and above serology testing. The high HBV yield observed in this study supported the use of a high sensitivity assay to detect HBV. Considering the high prevalence of viral infections, the number of transfusions, and the high proportion of component separation in the country, there is an acute unmet need for NAT testing to prevent TTIs. The PPP model applied in Odisha State can serve as a template for application across other states in India. PPP is a convenient step toward making NAT-testing a norm in the country. Our study not only presents the benefits of minipool NAT PCR testing but also presents a scalable model for the application of NAT throughout blood banks in India.

Authors' Contributions

All the authors contributed to the concept, design, data collection, data analysis, interpretation of data, and critically reviewing the manuscript. All authors approved the final version of the manuscript.

Funding

None.

Conflicts of Interest

None declared. This manuscript has been read and approved by us, the requirements for authorship as stated earlier in this document have been met, and we believe that the manuscript represents original work.

Acknowledgments

We would like to thank Turacoz Healthcare Solutions, Gurugram India (www.turacoz.com) for the manuscript writing support.

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