

Five years of experience with ID-NAT at a tertiary care centre in North India: An interdictory step in preventing the TTIs



Dr Diptiranjana Rout

Dept. of Transfusion Medicine

All India Institute Of Medical Sciences, New Delhi

Introduction

- **TTIs** are a **NIGHTMARE** for the transfusion service providers and other patient care providers.
- Screening for TTIs is a **critical part** of the process of ensuring transfusion safety.



Prevalence of TTI: India

	General population@	Donor population#
HIV	0.36	0.27
HBV	2-4.7	1.4
HCV	< 2	0.37-1.09

@HIV Sentinel Surveillance 2012-13. Online resource: www.naco.gov.in/NACO/Quick_Links/Directory_of_HIV_Data

Anand AC, Puri P. Indian Guidelines and Protocols: Hepatitis B. Online resource:

www.apiindia.org/medicine_update_2013/chap53.pdf

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##Annual NACO Report 2013-14.

#Annual NACO Report, 2014

**Bhatia R. Blood Transfusion Services in developing countries of Southeast Asia, Transfusion Today 2005; 65: 4-5.

#Shah N, Shah JM, Jhaveri P, Patel K et al. Seroprevalence of HBV, HCV, HIV and Syphilis among blood donors at a tertiary care teaching hospital in Western India. GMJ;68(2):35-9



Tests used for TTI

1. Rapid Immunoassay
2. Serology (ELISA, ChLIA)
3. **Nucleic Acid Testing (NAT)**

- NAT detects the direct presence of infectious agent.
- Capable of detecting low levels of viral genomic materials present soon after infection; thus, reducing the window period donations.
- Involves extraction or capture of nucleic acid, amplification, and detection.

Few Definitions

- **NAT Reactive:** Once samples come reactive in NAT is considered NAT reactive, regardless repeat NAT and discriminatory results. (It may or may not be sero reactive).
- **NAT Yield:** Sample comes reactive in NAT and non-reactive in Serological test is considered as NAT Yield.
- **Yield Rate:** No. of Sample tested/No. of NAT yield.
- **RNR:** Repeat non-reactive;
- **DNR:** Discriminatory non-reactive;
- **RR-DNR:** Repeat reactive and discriminatory non-reactive.

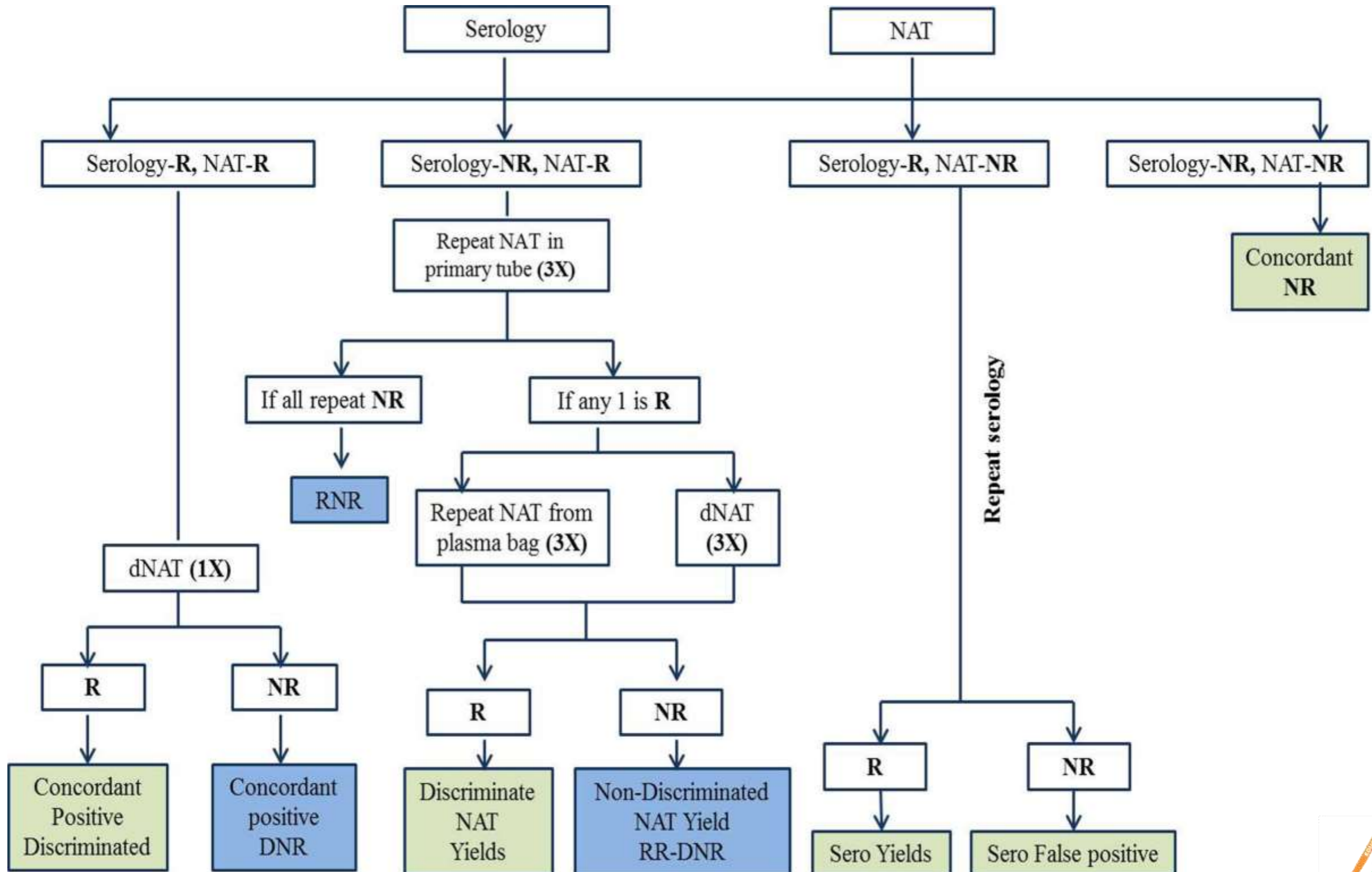


AIIMS Experience

- In 2009, an evaluation study was conducted to assess the feasibility and cost-effectiveness of ID-NAT to improve the blood safety and strengthen the transfusion services.
- Subsequently, since July 2010, ID-NAT technique was routinely implemented at AIIMS, New Delhi for TTI screening of all the donated blood units.



NAT algorithm for ID-NAT



Results

Total donations: 193,167		
Gender	Males	185,308 (95.93%)
	Females	7,859 (4.07%)
Type of donation	Voluntary	32,870 (17.01%)
	Replacement	160,297 (82.99%)
Donor status	First time	185,404 (95.98%)
	Repeat donors	7,763 (4.02%)



Results

Units tested	Initial NAT reactive	dNAT not done	dNAT done for	dNAT reactive units				
				HIV	HCV	HBV	Co-infection	Total (%)
193,167	3,556	61	3,495	193	421	2,060	96	2,770 (79.25)

Multiplex reactive dNAT non-reactive			
RNR	DNR	RR-DNR	Total (%)
456	244	25	725 (20.75)



NAT yield

Virus	Yield	Yield rate
HIV	2	1 in 96,584
HBV	141	1 in 1,370
HCV	72	1 in 2,683
HBV/HCV	13	1 in 14,859
Total	228	1 in 847

Achievements

A total of **684 (228 x 3)** cases of TTIs were interdicted by the use of NAT at our centre.



Concerns with NAT!!!

- We observed 0.14% units that were initial NAT reactive but dNAT non-reactive (False positive).
- This implicates
 - Introduction of policy for quality control.
 - Proficiency testing of the NAT.
- Donor notification
- Nation-wide implementation



NAT is an **ADD-ON** test **NOT** a Replacement

- NAT is **not replacement test** for serology rather it is an **ADD-ON test** to make our blood supply safer.
- Though there are incidences of HBsAg positive and NAT negative cases, one must not forget the high percentage of **NAT yield** cases especially in countries with medium to high HBV prevalence.



Conclusion

- Despite advancement TTI screening technologies, zero-risk blood and/or blood product(s) is still an elusive goal.
- The residual risk of breakthrough transmissions remains.

There should not be any compromise in patient safety.



Thank you

