4. Mandatory Nucleic Acid Test (Nat) - Polity

The Supreme Court has decided to look into whether blood banks should compulsorily conduct the Nucleic Acid Test (NAT) for identification of diseases

1. Background of the Case

1. A Bench of the Supreme Court of India comprising Justices Surya Kant, Joymalya Bagchi, and Vipul M. Pancholi examined a petition seeking wider adoption of Nucleic Acid Testing (NAT) in blood banks.
2. The Court questioned the cost-effectiveness and feasibility of implementing NAT nationwide when the commonly used Enzyme-Linked Immunosorbent Assay (ELISA) is already widely deployed.
3. The Court directed the petitioner to provide detailed data regarding-
    1. States where NAT is currently being used.
    2. Number of hospitals and blood banks implementing NAT screening.
    3. Financial implications for State governments if NAT is made mandatory.

2. Right to Safe Blood and Article 21

1. The petitioner NGO argued that safe blood transfusion is part of the Right to Life under Article 21 of the Constitution of India.
2. Article 21 guarantees protection of life and personal liberty, which has been interpreted by courts to include the right to health and access to safe medical treatment.
3. Therefore, ensuring screened and infection-free blood transfusion is considered a component of the State's constitutional responsibility.

3. Nucleic Acid Testing (NAT)

A. Definition

1. Nucleic Acid Testing (NAT) is a molecular diagnostic technique that detects the genetic material (DNA or RNA) of pathogens directly in biological samples such as blood.
2. NAT can identify infections such as-
    1. Human Immunodeficiency Virus (HIV)
    2. Hepatitis B virus (HBV)
    3. Hepatitis C virus (HCV)

B. Key Feature

1. NAT can detect infections during the "window period", which is the early stage when the virus is present but the immune system has not yet produced detectable antibodies.

4. Working Principle of NAT

A. Direct Detection of Genetic Material

1. NAT identifies viral DNA or RNA directly, rather than detecting the immune response produced by the body.

B. Importance of Early Detection

1. This allows identification of infections days or weeks earlier than antibody-based tests, reducing the risk of transfusion-transmitted infections.

C. Working Mechanism of NAT

1. Sample Collection
    1. Blood or another biological sample is collected from the donor.
2. Nucleic Acid Extraction

    1. Viral genetic material (DNA/RNA) is isolated from the sample using laboratory procedures.
3. Amplification
    1. The extracted nucleic acids are multiplied using Polymerase Chain Reaction (PCR) or similar molecular techniques.
    2. Amplification allows detection even when the virus is present in very small quantities.
4. Detection
    1. Specific molecular probes identify the pathogen's genetic sequences.
5. Result Interpretation
    1. If viral nucleic acids are detected, the test confirms active infection.

5. NAT vs ELISA Test

1. Detection Method
    1. NAT detects viral DNA/RNA.
    2. ELISA detects antibodies or antigens.
2. Window Period
    1. NAT has a shorter window period.
    2. ELISA has a longer window period.
3. Accuracy
    1. NAT has higher sensitivity and specificity.
    2. ELISA has moderate sensitivity and specificity.
4. Cost
    1. NAT is expensive.
    2. ELISA is relatively cheaper.
5. Usage in India
    1. NAT has limited adoption.
    2. ELISA is widely used.
6. ELISA remains the standard screening method in most Indian blood banks because of its lower cost.

6. Advantages of Nucleic Acid Testing

A. Enhanced Blood Transfusion Safety

1. NAT reduces the risk of transfusion-transmitted infections (TTIs).
2. It screens donated blood for viruses before transfusion.
3. Example- Screening blood units for HIV, Hepatitis B, and Hepatitis C.

B. Protection for High-Risk Patients

1. NAT is particularly important for patients requiring frequent blood transfusions.
2. Example- Patients with thalassemia often undergo repeated transfusions and face a higher risk of infection.

C. Strengthening Disease Surveillance

1. NAT can help identify emerging viral infections in blood screening programmes.
2. Example- Early detection of new infection trends during public health surveillance.

D. High Sensitivity and Accuracy

1. Because NAT directly identifies pathogens, it provides higher sensitivity and specificity compared to antibody-based tests.

2. Example- Early detection of Hepatitis C infections that may remain undetected in antibody tests during the early stage.

7. Limitations of Nucleic Acid Testing

A. Requirement of Skilled Personnel

1. NAT involves advanced molecular techniques such as PCR.
2. Laboratories require highly trained technicians and molecular biologists.

B. Limited Availability in Rural Areas

1. Most NAT-enabled laboratories are concentrated in urban tertiary hospitals and large diagnostic centres.
2. Many district-level blood banks still rely on ELISA due to infrastructure limitations.

C. Operational and Maintenance Challenges

1. NAT equipment requires-
    1. Controlled laboratory environments
    2. Regular calibration
    3. Strict quality control procedures.
2. Technical errors may compromise the reliability of results.

D. High Cost of Implementation

1. NAT requires expensive-
    1. Laboratory equipment
    2. Reagents
    3. Maintenance systems.
2. Many government blood banks in developing regions may find it financially challenging to adopt NAT.

8. Public Health Significance

A. Improved Blood Safety

1. Adoption of NAT can significantly reduce transfusion-transmitted infections.

B. Strengthening Healthcare Systems

1. It encourages the development of advanced molecular diagnostic infrastructure.

C. Policy and Legal Implications

1. The Supreme Court case raises the issue of whether advanced diagnostic technologies should be mandated as part of the right to safe healthcare.

Source- https-//www.livelaw.in/top-stories/pil-in-supreme-court-seeks-compulsory-nat-testing-in-all-blood-banks-across-india-524591