Policy Brief

Health Technology Assessment of Point of Care test kit for Hemophilia A and Von Willebrand Disease screening

ICMR-National Institute of Research in Reproductive and Child Health, Mumbai
A Regional Resource Hub for Health Technology Assessment in India (HTAIn)

Recommendations:

- Availability of highly effective Point of Care test Kit for Hemophilia A and Von Willebrand Disease developed by ICMR NIIH, would improve access to screening of bleeding disorders and early detection.
- It is cheaper than standard of care which needs extensive investigations that are currently available in only limited facilities in India
- This kit should be made available across all levels of public health care system
- There is a need to formulate standard treatment workflow for diagnosis of patients using the POC test kit and referral following detection for Hemophilia A and Von Willebrand Disease.

Key Findings:

- The cost per case tested and cost per case detected using the POC for diagnosis of Hemophilia A/VWD is lower than Standard of care test.
- The total cost saving in both the scenarios of POC test kit as compared to the SOC test is more than INR 42 crores (100% coverage).
- In the current cohort, the POC test kits is able to additionally diagnosis more than 70,000 cases of Hemophilia A and 10,000 cases of VWD which would have been missed using the current standard of care regimen.

Background

- Globally, 1 in 1000 individuals is affected by bleeding disorders, with Hemophilia A (HA) and Von Willebrand Disease (VWD) being the most common hereditary types (1).
- Hemophilia A prevalence: ~1 in 5000 males, 1 in 10,000 overall. India estimates 1,40,000 Hemophilia cases, but only 27,000 are registered with Hemophilia Federation of India (HFI) (2).
- Von Willebrand Disease (VWD) affects ~1% of the general population; in India, this translates to ~1 crore cases *(3)*.
- There are only a few comprehensive diagnostics facilities in our country. Even coagulation screening facilities are unavailable in many district hospitals and medical colleges. Many labs do not have facilities to diagnose VWD, and patients are often misdiagnosed with Hemophilia A *(5)*.

PICO	Description of the components
Population	Cohort of individuals of 0-40 years of age presenting to public health facilities with symptoms suggestive of Hemophilia A (HA) and Von Willebrand disease (VWD). **Cohort size: 2,85,945**
Intervention	HA and VWD screening with Point of care (POC) test kit at all levels of healthcare facilities. **Scenario 1:** Testing everyone directly with POC test kit **Scenario 2:** Initial screening using CBC, PT/aPTT and if aPTT prolonged or abnormal followed by POC test kit
Comparator	Standard of Care (SOC): Initial screening with CBC, PT/aPTT (at primary, secondary and tertiary level) and if aPTT prolonged/abnormal, confirmatory factor assay for HA and immunoturbidimetry for VWD at centre of excellence facility
Outcome	1. Cost per case tested 2. Cost per case detected 3. Number of cases detected 4. Additional number of cases detected 5. Budget Impact Assessment

Cost per case tested and detected of **POC lower than SOC**

Cost per case tested:
POC test:
- Scenario 1: **INR 582**
- Scenario 2: **INR 605**

SOC test:
- Comparator: **INR 2086**

Cost per case detected:
POC test:
- Scenario 1: **INR 977**
- Scenario 2: **INR 1107**

SOC test:
- Comparator: **INR 7461**

World's first POC for Hemophilia A/VWD -Innovation from ICMR NIIH

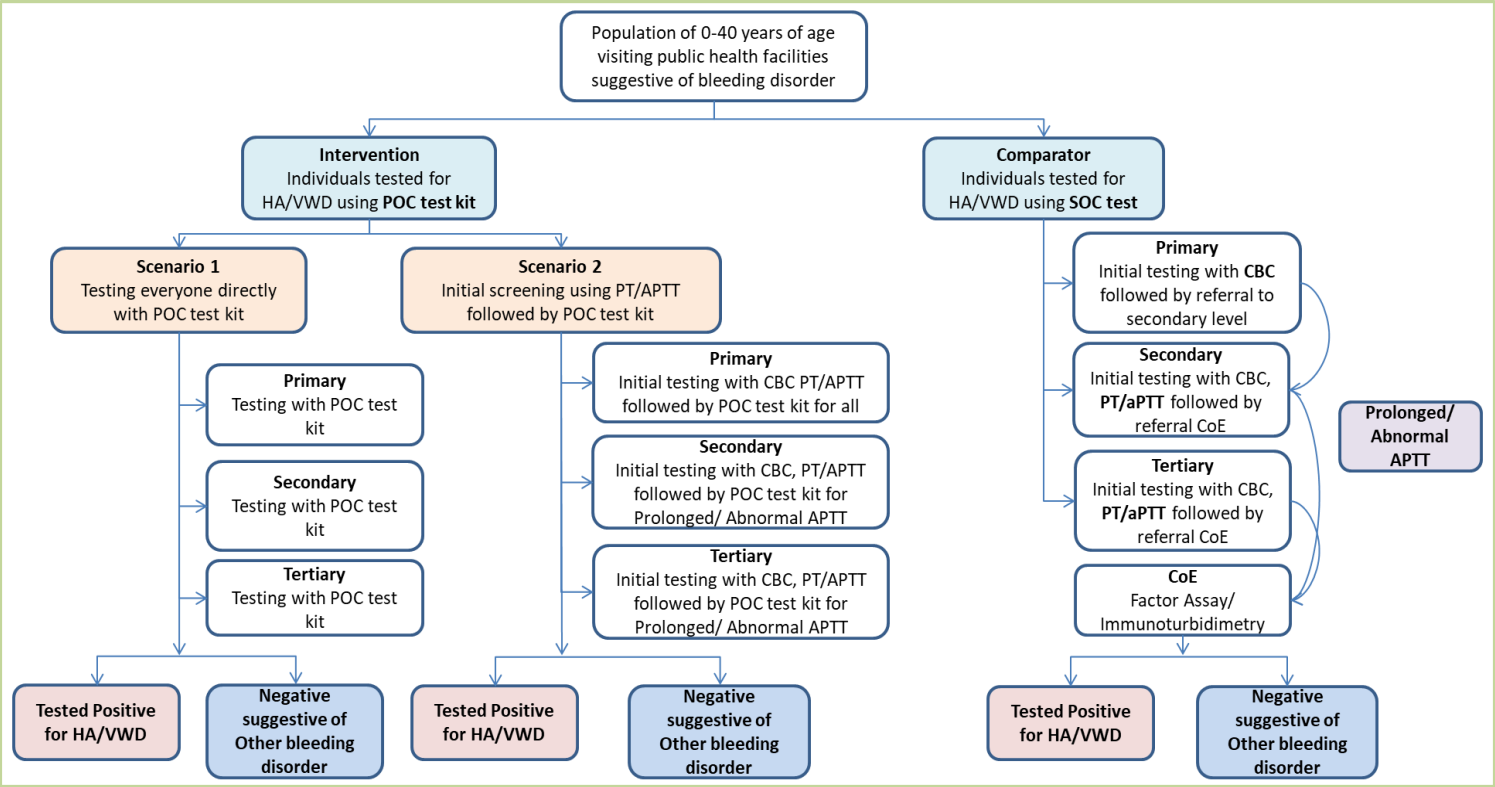
Portable and Feasible to use at all levels of public health facilities

Sensitivity: 98.12%
Specificity: 98.27%

Manufactured by Bhat Biotech it is priced at: INR 250 for HA and INR 200 for VWD

POC test kit could additionally diagnose around **70,000 cases** of Hemophilia A and **10,000 cases** of VWD among those with symptoms of bleeding disorder

Decision tree for testing Hemophilia A and VWD using POC and SOC



Budget Impact Analysis:

- **The total cost saving in both the scenarios of POC test kit as compared to the SOC test is more than INR 42 crores at** 100% coverage, **INR 33 crores** at 80% coverage and **INR 21 crores** at 50% coverage.
- The total health system cost for testing Hemophilia A and von Willebrand disease for the POC is much lower than the SOC test, thus **reducing the health system cost** approximately by **3 times**.

Conclusion:

- The POC test kits are critical in improving the access to diagnosis for patients of Hemophilia A and Von Willebrand diseases.
- The POC test kit will substantially reduce the cost and time for diagnosis and ensure early treatment initiation for Hemophilia A and VWD patients thus implying reduced out-of-pocket expenditure, early diagnosis, improved management and better quality of life.
- Early detection of additional cases of Hemophilia A and VWD cases due to POC kits will require proper guidelines and facilities for appropriate treatment and management within the health system.
- The overall societal cost incurred due to a missed or incorrect diagnosis of Hemophilia A and VWD cases with existing standard of care leading to complication, disability and mortality could potentially reduce.

References

1) *Skinner MW. WFH: closing the global gap--achieving optimal care. Haemophilia. 2012 July;18 Suppl 4.*
2) *Berntorp E, Shapiro AD. Modern haemophilia care. Lancet. 2012 Apr 14;379(9824):1447-56.*
3) *Srivastava A, Santagostino E, Dougall A, Kitchen S, Sutherland M, Pipe SW, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia. 2020 Aug 3;26:1-158.*
4) *Zahid H. Speciality Medical Dialogues. 2019 [cited 2023 Aug 31]. Indian Scientists develop first cost effective rapid test for common bleeding disorders.*
5) *Phadke S. Hemophilia care in India: a review and experience from a tertiary care centre in uttar pradesh. Indian J Hematol Blood Transfus. 2011 September;27(3).*
6) *Ministry of Health and Family Welfare (India). Report of the Technical Group on Population Projections for India and States 2011-2036.*
7) *National Statistical Office (India). Key Indicators of Social Consumption in India: Health. New Delhi: Ministry of Statistics and Programme Implementation; 2019.*
8) *Post-Graduate Institute of Medical Education and Research, National Health System Cost Database India. https://www.healtheconomics.pgisph.in/costing_web/*
9) *IndiaMart, Market Price. https://buyer.indiamart.com/*