Policy Brief

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HTA In

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

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Recommendations

- The Point of Care test Kit for Hemophilia A and Von Willebrand Disease can be considered suitable qualitative diagnosis of individuals presenting with bleeding symptoms. Once the patients are diagnosed, quantitative assessment of the cases in terms of severity and requirement of factors during prophylaxis treatment will require factor assays.
- The POC test kits should be made available at all levels of care (primary, secondary and tertiary) in public health facilities for improving access and detecting additional cases.
- This kit should be made available across all levels of public health care system

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.
- 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).
- Von Willebrand Disease (VWD) affects ~1% of the general population; in India, this translates to ~1 crore cases.
- 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.

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

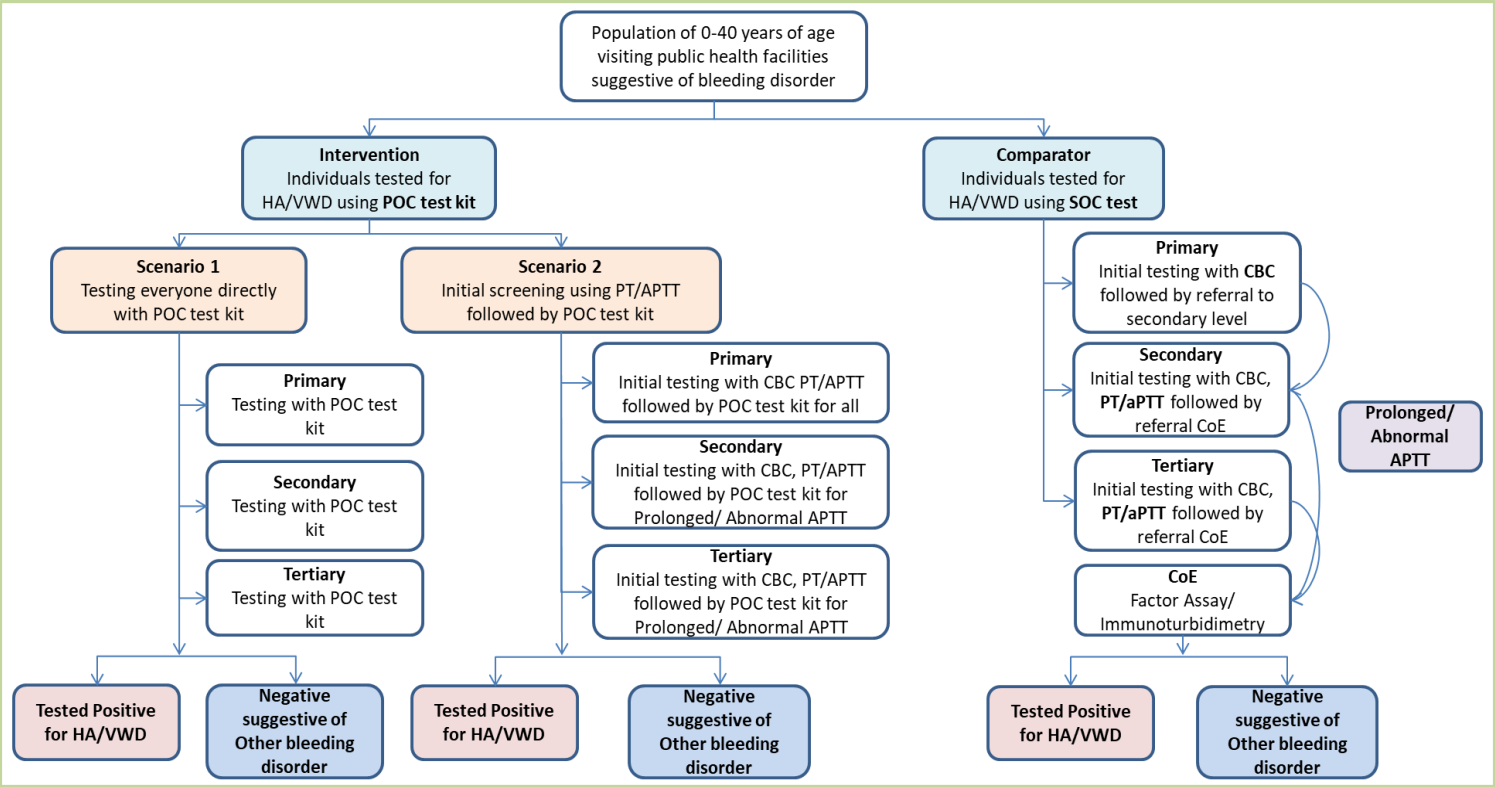
Portable and Feasible to use at all levels of public health facilities

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

- Cost per case tested: The cost per case tested and cost per case detected using the POC for diagnosis of Hemophilia A/VWD is lower than the SOC test.
- Cost saving: The total cost saving in both scenarios of the POC test kit as compared to the SOC test is more than INR 42 crores (100% coverage).
- Additional cases diagnosed: In the current cohort, the POC test kit is able to additionally diagnose 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.
- 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 and additional cases of Hemophilia A and VWD cases due to POC kits will require the availability of improved treatment and management facilities within the health system.
- The overall societal cost incurred due to a missed or incorrect diagnosis of Hemophilia A and VWD cases leading to complication, disability and mortality will be reduced.