

Recommendations:

- Truenat-based HPV screening is cost-effective under current price assumptions when screening coverage remains below 40%, therefore, adoption of this intervention is suitable in low-coverage screening settings.
- As coverage increases beyond this level, Truenat is no longer cost-effective at the prevailing unit cost, beyond this point a price reduction of 28.4% is recommended to maintain its cost-effectiveness even in higher-coverage screening settings.
- Truenat® HPV-HR Plus is cost effective at current coverage levels, and that any point-of-care HPV test with comparable diagnostic performance and a per-test cost is likely to be cost-effective under the same programme conditions and scenarios in which Truenat was found to be cost-effective.

Key Findings

- Cervical cancer screening using Truenat HPV HR Plus compared with VIA is cost saving and cost effective.
- As coverage increases beyond 40 percent, Truenat is no longer cost-effective at the prevailing unit cost, beyond this point a price reduction of 28.4% is recommended to maintain its cost-effectiveness even in higher-coverage screening settings.

Background

- Cervical cancer ranks as the 8th most common cancer worldwide, disproportionately impacting women in low- and middle-income countries.
- In India, cervical cancer is the second most common cancer and remains a leading cause of mortality among women.
- Although the WHO recommends high-performance HPV DNA testing, large-scale adoption in India is hindered by high costs and the intensive infrastructure required for traditional laboratory-based tests.
- Current screening in low-resource settings often relies on Visual Inspection with Acetic Acid (VIA), which, while accessible, lacks the diagnostic precision of DNA-based testing. In this context, point-of-care (POC) HPV DNA tests are a viable option.
- TrueNat® HPV-HR Plus, a portable indigenous molecular test. It can detect about 8 high risk HPV variants, yields results within 60 minutes, demands minimal infrastructure. It serves as a critical bridge between the infrastructure requirements of high-quality diagnostics and the practical constraints of rural and community health settings.
- This Health Technology Assessment (HTA) evaluates the cost-effectiveness of Truenat HPV HR Plus compared to VIA among women aged 30-65 in India to inform national screening strategies.

PICO	Description of the components of PICO
Population 	• Women aged > 30 (30-65 years)
Intervention 	• Truenat® HPV-HR Plus by Molbio® Diagnostics Limited
Comparator 	• Visual Inspection with Acetic Acid (VIA)
Outcome 	• Number of cases averted • Number of deaths averted • Life years gained • ICER per QALY gained, INB
Perspective	• Health System
Time Horizon	• Lifetime
Discount Rate	• 3%
Willingness to Pay Threshold	• 1 Gross domestic product (GDP) per capita

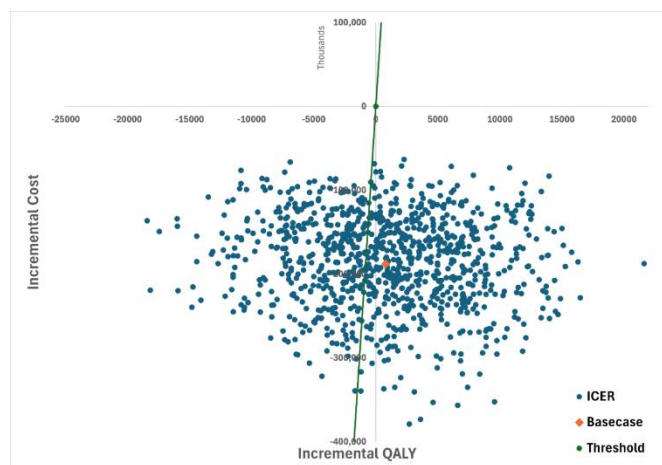


Results:

- In the base-case scenario, Truenat HPV HR Plus emerged as a dominant strategy, meaning it is both more effective and less expensive than the current standard of care.
- Compared with VIA, Truenat is the dominant strategy, being both less costly and more clinically effective.
- The Incremental Cost-Effectiveness Ratio (ICER) was estimated at -₹2,27,311 per QALY, placing it in the south-east quadrant of the cost-effectiveness plane.
- A positive Incremental Net Benefit (INB) of ₹366 million confirms that Truenat is the economically preferred strategy at India's current WTP threshold.

Uncertainty analysis:

- Probability Sensitivity Analysis (PSA) confirms that Truenat is consistently cost-saving, with nearly all simulations showing lower costs and 60.3% falling below the willingness-to-pay threshold.
- The model results are most sensitive to utility values, particularly utility of CIN2, HPV and healthy state, indicating that quality of life assumptions are a key driver of cost effectiveness
- Among transition probabilities, progression from CIN3 to Stage I, CIN2 to CIN3, and healthy to background mortality show moderate influence. Changes in these parameters consistently shift the ICER but to a lesser extent than utilities.
- However, ICER remained within threshold level across of these ranges, indicating Truenat remained cost



Conclusion:

- Truenat HPV HR Plus is cost-effective compared to VIA for women aged 30-65 years at current low screening coverage levels in India, with PSA and scenario analyses supporting the base case results.
- At higher screening coverage, VIA may become more cost-effective as the additional benefits of Truenat may not justify its higher costs.
- Point-of-care (POC) HPV tests are a viable option for cervical cancer screening in low-resource settings with low screening coverage, which reflects the current scenario in India. These tests are likely to remain cost-effective even as screening coverage increases, provided that test prices decrease through economies of scale or negotiated procurement.

References

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