

# Purpose and options for Integrating the GIFT device into Sexually Transmitted Infections management algorithms: Results from a two-round modified Delphi process

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## Background

Sexually transmitted infections (STIs) and bacterial vaginosis (BV) are often asymptomatic in women but cause genital inflammation which increases HIV risk

Our team through a multi-centre clinical study is developing a Genital InFLammation Test (GIFT) device. This test is a novel, point-of-care device for detecting genital inflammation caused by STIs and/or bacterial vaginosis (BV) in women.

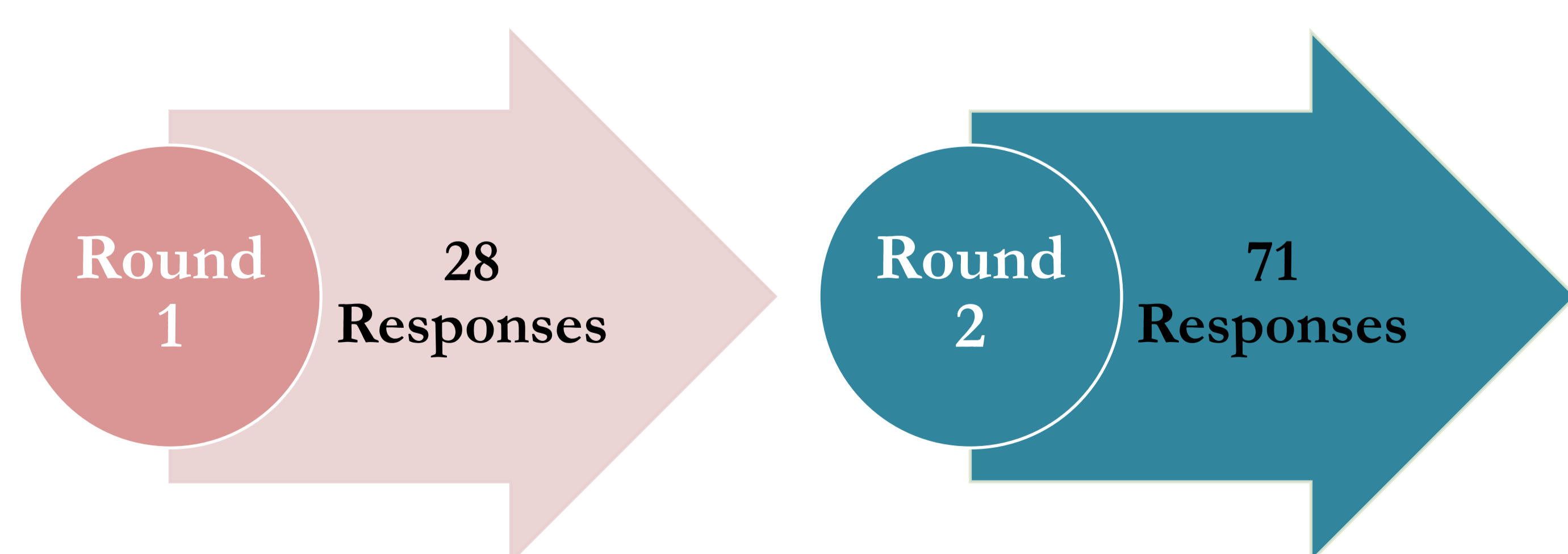
We used a modified Delphi to explore the main purpose of GIFT and potential integration points within WHO STI guideline pathways. The survey focused on low- and middle-income contexts.

## Methods

We employed a modified Delphi technique in two rounds. We developed the questionnaire for both rounds and the Delphi and was administered as an online survey. Round one included open ended in-depth questions and round two sought to build upon consensus and findings from the round one.

Both rounds collected and aggregated informed opinions of expert participants in the field of STI management. Health service providers, programmers, researchers and policy makers were recruited as respondents. The survey was designed with input from the project's International Advisory Board.

Themes from the round one survey was used to inform items presented in the round two survey to build consensus on. Responses on the survey items were on a 5-point Likert scale from strongly agree to strongly disagree. Consensus was reached if  $\geq 70\%$  of the participants selected strongly agree or agree.



## Results

We received a total of 28 responses in round one and 71 responses in round two. For gender, we had a good distribution with 58% females and 42% males. Majority of the participants were aged between 25 and 54 years with only 12% above age 55.

Analysis of results from both rounds showed that the GIFT device was more suitable for use as a screening tool rather than as a diagnostic tool. Attributes of the GIFT device prioritised for integration into STI management pathways include high sensitivity and specificity, affordability and ease of use. Potential barriers in its implementation and use include lack of provider awareness, high cost and stock-outs.

### Attributes prioritized for GIFT roll out

<b>Stakeholder awareness / Training</b>	There is need to engage stakeholder and train service providers so that they are able to offer services using the GIFT device
<b>Accuracy of the GIFT data</b>	High sensitivity and specificity: Strong evidence of high specificity and high sensitivity of the GIFT device is needed for it to be incorporated into STI guidelines
<b>Cost / affordability</b>	The device costs may be more than the drug costs, so it may become irrelevant. Health care workers may prefer to just treat rather than test first it could be important to put it at a free cost
<b>Ease of use / Self-administration</b>	Provide for over the counter use and to ensure self collection is possible
<b>Storage</b>	Should be stable at room temperature and not requiring special storage conditions
<b>Availability</b>	The device should be readily available for use for consistency, avoiding periods of stock outs

## Conclusion

While the GIFT device promises to be a valuable point of care screening tool for detecting genital inflammation in asymptomatic women, strong evidence of high specificity and sensitivity is needed for it to be incorporated into STI management guidelines. Costs and affordability of the device is key for its use and there is need to sensitize and train healthcare providers and patients on its use.

The test would be of greatest value in resource-constrained settings where diagnostic resources are lacking.

Stakeholder consultations will facilitate its roll out and sustained use within healthcare systems.



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