







Assessment of the Pregnancy Test Market in India

The Indian Ministry of Health and Family Welfare supports the use of pregnancy tests in family planning services. The government procures the pregnancy tests, which are widely available in public clinics for free and in the private sector at a range of prices.

The SHOPS Plus project conducted a market shaping assessment of pregnancy tests in India, which shows that the Ministry of Health and Family Welfare supports the use of pregnancy tests. The ministry actively procures the tests, and they are widely available in public clinics free of charge and in the private sector at a range of prices. Affordability is not a problem in public clinics, but could not be fully evaluated in the private sector without population–based analysis. Awareness of pregnancy tests is not an apparent problem. Product design and quality did not emerge as stakeholder concerns in this assessment but need to be fully evaluated under separate methods.

Opportunities for improvement largely relate to clinical practice and provider training in the use of pregnancy tests, as well as the World Health Organization (WHO) pregnancy checklist. Given the limited and varied reliance on both the tests and the checklist in clinics, there may be options for decreasing provider reliance on the "first five days" criterion and increasing same-day start of contraception through increasing provider familiarity and confidence in using them. Another recommendation is to consider developing a new brief on guidance for combined use of the pregnancy tests and checklist, along with the importance of same-day initiation for United States Agency for International Development (USAID) missions and implementing partners. A third recommendation is to develop outreach and communication programs for women using home tests to motivate them to access family planning services.

Background

Screening for pregnancy is often an important step in supporting the immediate start of a contraceptive method when a woman seeks family planning services. Pregnancy status can be determined by conducting a pregnancy test or patient history using the pregnancy checklist. The checklist was developed by WHO and comprises six questions about medical history. Answering "yes" to at least one of the questions allows the provider to be reasonably sure that the patient is not pregnant. If pregnancy cannot be ruled out, the patient may be asked to come back during her next menses.

Ensuring same-day provision of family planning methods is an important way to ensure reliable access to contraception for women and protect them from unplanned pregnancy. Studies suggest that making pregnancy tests more widely available can increase the same-day start of contraception for women seeking family planning services and reduce the current delay and denial by providers. Family planning 2020's goal includes an emphasis on country-level efforts related to increasing access to quality family planning information, services, and products. Pregnancy tests can play an important role in these efforts.

Key family planning indicators in India

Family Planning 2020 Indicator	Percent
Contraceptive prevalence rate, modern methods (all women)	39%
Contraceptive prevalence rate, modern methods (married women)	52%
Demand satisfied (married women)	72%

Source: 2016 Family Planning 2020 Progress Report

In India, almost 39 percent of women use modern contraception (table).

The purpose of this market assessment was to collect and analyze country-level market data for pregnancy tests and their use in family planning services to evaluate whether interventions are needed to increase availability and access to low-cost, quality pregnancy tests.

Methods

Several methods were used to collect the information for this assessment in India, including secondary research, email inquiries, stakeholder interviews, and field visits. Between June and August 2016, a consultant based in the country conducted in-depth interviews and site visits with public and private sector providers, government staff, retailers, and other stakeholders in the Lucknow region. The assessment team also researched national guidelines for the use of pregnancy tests in the delivery of family planning and related health services, the inclusion of pregnancy tests on essential commodity lists, and procurement practices.

Interviews focused on provider clinical practices, availability and costs of pregnancy tests, and procurement practices. The assessment team collected data on the manufacturers, types, and costs of pregnancy tests that were available in various outlets. Outlet types included public and private clinics, private sector pharmacies, and clinics run by social marketing organizations. Incountry data collection was limited to Lucknow and surrounding areas.

Following data collection, the SHOPS Plus team analyzed the findings, using the market shaping framework presented in the USAID Center for Accelerating Innovation and Impact Healthy Markets for Global Health (figure). This process involved identifying possible market weaknesses using the criteria of affordability, availability, assured quality, appropriate design, and awareness. The team assessed provider perceptions of the quality of pregnancy tests, but objective quality standards will be completed through a separate process led by FHI 360.

The five A's of market health



Source: USAID Center for Accelerating Innovation and Impact (2014)

To increase access to and availability of quality, lowercost pregnancy tests, the team identified potential interventions to address market shortcomings.

Findings

The following sections outline findings for the Lucknow region in India from interviews conducted with stakeholders.



Family planning policy

The Indian government supports the use of the WHO pregnancy checklist to rule out pregnancy

as outlined in reference materials on individual contraceptive methods. A reference manual on oral contraceptive pills (Government of India 2016a) states that pregnancy should be ruled out using the WHO checklist, which is included as an annex in the document. According to the checklist, if pregnancy cannot be ruled out, the client should wait until her next period or be issued a pregnancy test. The same guidance is provided in the reference manual for injectable contraceptives. Regarding intrauterine contraceptive devices, the reference manual for Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) doctors notes that these providers should rule out pregnancy based on the client's assessment (Government of India 2014). It does not reference the specific questions in the WHO checklist, but gives general guidance on what should be included in contraceptive, menstrual, obstetric, reproductive/sexual, and medical history. It also does not mention using pregnancy tests to determine pregnancy prior to insertion.



Provider use of the checklist and pregnancy tests

Public providers interviewed in Lucknow indicated that they often do not use the WHO pregnancy

checklist or a negative pregnancy test result to initiate contraception. On average, one in four reported knowing about the pregnancy checklist. The "first five days" criterion was described as common practice: providers require that clients visit a clinic within the first five days of their menstrual bleeding in order to initiate a contraceptive method during the clinic visit. Providers estimated that 55 percent of clients visited a family planning clinic during menses and were provided contraception at the same visit.

Similarly, private providers reported using the "first five days" criterion despite the availability of pregnancy tests. Clients who go to clinics outside of the first five days of menstruation are advised to return during the next menstrual bleeding. All doctors indicated they would not be comfortable with same-day initiation of contraception past the first five days of menstruation. Their reasoning was that if the client goes to the clinic between conception and the next menses due date, the pregnancy test may not display a positive result due to its sensitivity 10 days after implantation.

A physical copy of the pregnancy checklist was not typically used by private providers. However, some providers reported using the questions based on their knowledge of the checklist. Pregnancy tests were used mainly to rule out or confirm pregnancy in women presenting with delayed or scanty menses, as well as in lactating mothers and clients with injectable contraceptive-induced amenorrhea. The majority of providers who were interviewed estimated that between 50 and 98 percent of women with delayed menses perform a pregnancy test at home before going to a clinic. All providers indicated that in some cases, they themselves repeat a test.

Public procurement

The government of India is currently procuring pregnancy tests. Each state sends the Ministry of Health

and Family Welfare its annual requirement, which provides the basis for forecasting and procurement. The Central Medical Services Society procures the tests through a centralized tender, storage, and inventory of medicines and essential health commodities for national programs. The Central Medical Services Society sends pregnancy tests to a logistics management cell for family planning commodities at Lucknow. The chief medical officers of each of the 75 districts are responsible for sending their requirements to the 18 regional warehouses across Uttar Pradesh, which forward the requirements to the logistics management cell. At regular intervals, the logistics management cell dispatches commodities to the regional warehouses, which then forward them to the Central Medical Stores Department of each district. The chief medical officer then authorizes supply of the commodities to the various public health sector facilities in the district. Quality specifications currently do not exist.



Availability

This research indicated that pregnancy tests were universally available in both public clinics and across private sector

facilities and retailers. The assessment identified 19 brands and 14 manufacturers. While not all brands might be available at the same time, stockouts were uncommon. In the public sector, pregnancy tests were also made available to Accredited Social Health Activist frontline community health workers. However, those workers are not supposed to initiate contraception, rather they are expected to refer women to doctors at facilities.

While consumer research was not conducted, providers and retailers indicated that women were generally comfortable buying and using the pregnancy tests from retail outlets, even before visiting a health facility or interacting with a field worker. Doctors reported that nearly all women have used the pregnancy test correctly.

Number of pregnancy test brands, types, and manufacturers

Brands identified	Dipstick	Cassette	Midstream	Manufacturers identified
19	0	19	0	14



Pricing and costs

Pregnancy tests in public clinics are available free of charge. This assessment found a range of prices

in the private sector. In retail pharmacies, products ranged in price from \$0.45 to \$0.96 with retail margins between 69 and 81 percent. Prices were slightly higher at private providers. Pregnancy tests cost between \$0.75 and \$1.49, which is similar to prices for the emergency contraceptive pill. The cost of a family planning consultation at a private provider (\$2.99 and \$4.48) is much higher than purchasing a pregnancy test at a retail pharmacy. This difference may in part explain why clients routinely purchase from pharmacies and perform the test at home. Given the range of prices available in the private sector and that the tests are widely available for free in the public sector, this assessment found no evidence that affordability is a barrier to use.



Product design and quality

The only type of product found to be available in the Lucknow region was

the cassette format, and there was no evidence of provider or client concerns with its design or usability.

Similarly, while an objective evaluation of the quality of pregnancy tests was not included in the research, interviews did not indicate procurer, provider, or client concerns with test quality. Most providers across both the public and private sectors indicated that they felt that pregnancy tests were reliable.

Costs of pregnancy tests and family planning consultations

Pregnancy test at public clinic	Pregnancy test at retail pharmacy	Pregnancy test at private provider	Family planning consultation at private provider	Other product for comparison (emergency contraceptive pill)
Free	\$0.45-0.96	\$0.75—1.49	\$2.99—4.48	\$0.75—1.49

Recommendations

Address clinical practice through policy modification and updated provider training on same-day family planning initiation. Partner with professional associations and teaching organizations to better understand and influence provider practice. Doing so requires understanding current provider protocols and training programs, then pursuing support for changes from the Ministry of Health and Family Welfare and medical institutions. This course of action could require alterations in medical school curricula. The challenges would be that provider training is deeply established, changing clinical practice is a long process, and there may be provider resistance.

Consider developing a new brief, which would provide guidance on combined use of the pregnancy checklist and pregnancy tests, along with the importance of same-day initiation, for dissemination to USAID missions and implementing partners. This document could resemble the High Impact Practices briefs, and could leverage both WHO and USAID resources and influence. It would require consensus on recommended practice.

Develop outreach and communication programs targeted at women purchasing and using home pregnancy tests to motivate them to access family planning services. Given the wide use of home tests, an intervention could be focused on generating demand for family planning services and contraception as a result of purchases made in the private sector. An example of this approach would be to link the purchase of pregnancy tests to information about family planning services (for example, advertise family planning services through pharmacies). This approach would require funding for communication, such as a mass media campaign, and the design of a targeting mechanism. It might be best pursued through existing programs in family planning and maternal, newborn, and child health. The communications campaign strategy should also include youthfriendly programs.



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