Crossing Over the Thin Blue Line: Increasing Access to Pregnancy Tests

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Ruling out pregnancy

“She can start _____ immediately if it is reasonably certain that she is not pregnant.”

WHO “Selected Practice Recommendations for Contraceptive Use,” 2nd Ed. 2004
An ongoing medical barrier

- Non-menstruating women are routinely denied family planning services
- Nearly half of new family planning clients are not menstruating when they visit the clinic

Few non-menstruating clients are actually pregnant

According to WHO, no known harm occurs to either a pregnant woman or a fetus from exposure to hormonal family planning methods*

*In case of the IUD, it is very important to rule out pregnancy because inserting an IUD in a woman who is already pregnant may result in septic miscarriage, which is a serious complication.
Partial Solution: The Pregnancy Checklist

- Research demonstrates that the checklist is effective at ruling out pregnancy
- Included in the Global Handbook for Family Planning and in the WHO Decision-Making tool
- Instances when the checklist cannot exclude pregnancy
- Some providers don’t like/trust the checklist

How to be Reasonably Sure a Client is Not Pregnant

Ask the client questions 1–6. As soon as the client answers YES to any question, stop, and follow the instructions.

1. Did you have a baby less than 6 months ago or are you fully or nearly fully breastfeeding, and have you had no menstrual period since then? **YES**
2. Have you abstained from sexual intercourse since your last menstrual period or delivery? **YES**
3. Have you had a baby in the last 4 weeks? **YES**
4. Did your last menstrual period start within the past 7 days (or within the past 12 days if you are planning to use an IUD)? **YES**
5. Have you had a miscarriage or abortion in the past 7 days (or within the past 12 days if you are planning to use an IUD)? **YES**
6. Have you been using a reliable contraceptive method consistently and correctly? **YES**

If the client answered NO to all of the questions, pregnancy cannot be ruled out. The client should avoid/methods or use a pregnancy test.

If the client answered YES to at least one of the questions and she is free of signs or symptoms of pregnancy, provide client with desired method.
Pregnancy tests available for purchase for ≤ US$0.10
Research in Zambia (FHI 360)

% New, Non-Menstruating Clients Denied Effective Method

Research in Madagascar and Nepal

Distribution by community health workers: Number of new users of hormonal contraceptives increased by 24 percent in an average month compared to control group.

In press in *Contraception*

Distribution by community health volunteers: Facilitated referrals for FP, ANC and safe abortion services.
Additional potential benefits

- FP demand generation
- Social marketing
- Tool for improving continuation of progestin-only methods
- Contribute to decrease in gestational age for clients seeking ANC and abortion services
Innovation Fund project

Partnership between FHI 360 and Marie Stopes International

- Country-level data collection and analysis
- Stakeholder engagement
- Development of clinical guidance for healthcare providers and advocacy tool for global stakeholders

Pregnancy tests for FP added to the NURTHs Caucus list in 2012 as one of priority underutilized technologies
Data Collection in Kenya, Malawi and Mali

- Data collected in public and private sector facilities and pharmacies/drug shops
- Standardized questionnaire; tailored for each sector
- Convenience sample used with sites both in the capital city and in semi-urban and rural areas surrounding the capital
- Information collected on availability and price as well as basic information about quality
- Interviews with national stakeholders—Ministry of Health and regulatory personnel

For the purposes of this assessment, “Public Sector” is defined as facilities and programs run by the government. “Private Sector” is defined as facilities run by national and international non-governmental organizations (NGOs), faith-based organizations, social marketing groups including social franchises, and privately owned, for-profit clinics.
### Preliminary Results: Sample Size

<table>
<thead>
<tr>
<th>Facility Type</th>
<th>Mali (n=13)</th>
<th>Malawi (n=9)</th>
<th>Kenya (n=45)</th>
<th>Total (n=67)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private</td>
<td>3</td>
<td>4</td>
<td>21</td>
<td>28</td>
</tr>
<tr>
<td>Public</td>
<td>4</td>
<td>2</td>
<td>17</td>
<td>23</td>
</tr>
<tr>
<td>Pharmacy / Drug shop</td>
<td>6</td>
<td>3</td>
<td>7</td>
<td>16</td>
</tr>
</tbody>
</table>

All results presented today are preliminary; data collection is ongoing.
Availability of Pregnancy Tests

- **Mali (n=13)**: Typically & day of survey
- **Malawi (n=9)**: Typically, but not day of survey
- **Kenya (n=45)**: Not Available

The chart shows the availability of pregnancy tests in three countries with different percentages.
Price of pregnancy tests in US dollars by facility type

<table>
<thead>
<tr>
<th>Mean price US$ [range] (n)</th>
<th>Mali (n=11)</th>
<th>Malawi (n=8)</th>
<th>Kenya (n=42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private</td>
<td>2.57 [1.71-3.43] (n=3)</td>
<td>0.85 [0.36-1.24] (n=4)</td>
<td>1.41 [0-5.70] (n=20)</td>
</tr>
<tr>
<td>Public</td>
<td>1.43 [0-2.57] (n=3)</td>
<td>0.00 [0-0] (n=1)</td>
<td>0.60 [0-4.75] (n=15)</td>
</tr>
<tr>
<td>Pharmacy / Drug shop</td>
<td>2.14 [1.20-2.57] (n=5)</td>
<td>0.59 [0.36-0.80] (n=3)</td>
<td>0.81 [0.47-1.90] (n=7)</td>
</tr>
<tr>
<td>Mean across sectors</td>
<td>2.06 [0-3.42]</td>
<td>0.65 [0-1.24]</td>
<td>1.02 [0-5.70]</td>
</tr>
</tbody>
</table>

Reflects the “least expensive” pregnancy test available at each facility
Reported access to pregnancy test by client type (public & private facilities only)

- Mali (n=7)
- Malawi (n=5)
- Kenya (n=36)

Categories:
- Any client
- ANC clients
- FP clients
Q: Are pregnancy tests procured for family planning programs specifically?
A: No.
Q: Which programs are they procured for?
A: They go for antenatal care to confirm pregnancy.”

-From interview with MOH official, Kenya
# Quality of Pregnancy Tests

<table>
<thead>
<tr>
<th>Quality measure (%)</th>
<th>Mali (n=10)</th>
<th>Malawi (n=8)</th>
<th>Kenya (n=38)</th>
<th>Total (n=56)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valid date (not expired)</td>
<td>100</td>
<td>100</td>
<td>87</td>
<td>91</td>
</tr>
<tr>
<td>Written instructions in correct language</td>
<td>70</td>
<td>100</td>
<td>97</td>
<td>93</td>
</tr>
<tr>
<td>Illustrated instructions</td>
<td>100</td>
<td>100</td>
<td>97</td>
<td>98</td>
</tr>
<tr>
<td>CE mark appears</td>
<td>60</td>
<td>88</td>
<td>63</td>
<td>66</td>
</tr>
<tr>
<td>ISO 13485 appears*</td>
<td>8</td>
<td>11</td>
<td>7</td>
<td>7</td>
</tr>
</tbody>
</table>

*ISO 13485 appears on 5 tests total: Mali (n=1), Malawi (n=1), Kenya (n=3)*
Awareness, availability and use of Pregnancy Checklist (public & private facilities only)

- Mali (n=7)
- Malawi (n=6)
- Kenya (n=38)

- Ever heard of
- Providers typically use
- Copy at facility
[To rule out pregnancy,] providers typically would find out if the woman had menses or not. Because the Checklist is there, but how many have been trained?...How many have been caught up with? *Typically* it will be a menses history.”

-Interview with MOH official, Kenya
Ruling out Pregnancy in Non-Menstruating Women (public and private facilities only)

<table>
<thead>
<tr>
<th>Approach (%)</th>
<th>Mali (n=7)</th>
<th>Malawi (n=6)</th>
<th>Kenya (n=38)</th>
<th>Total (n=51)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine pregnancy test</td>
<td>71</td>
<td>67</td>
<td>95</td>
<td>88</td>
</tr>
<tr>
<td>Pregnancy checklist</td>
<td>100</td>
<td>17</td>
<td>37</td>
<td>43</td>
</tr>
<tr>
<td>Women purchase pregnancy test off-site</td>
<td>29</td>
<td>17</td>
<td>50</td>
<td>43</td>
</tr>
<tr>
<td>Physical examination</td>
<td>0</td>
<td>0</td>
<td>37</td>
<td>27</td>
</tr>
<tr>
<td>Patient history</td>
<td>0</td>
<td>17</td>
<td>32</td>
<td>25</td>
</tr>
</tbody>
</table>

Other approaches include: given FP same day if postpartum and is breastfeeding (n=8), FP given same day (n=6), client asked to return when menses return or baby older for postpartum women not having normal cycles (n=5), clients asked to return when menstruating/when menses return (n=3)
Interviews with regulatory personnel

**Kenya**

**Registration & Import**
- Registration of pregnancy tests is overseen by the Kenya Medical Laboratory Technicians and Technologist Board (KMLTTB)
- Currently an import license issued by KMLTTB - only requirement for importation

**Quality**
- There are concerns over the number and quality of unregistered pregnancy tests in the market and the challenges around surveillance. Wil inform part of KMLTTB’s future strategic plan

**Procurement**
- There is procurement by the MOH, but with the devolution of budgets, each county procures individually and not necessarily through KEMSA which makes tracking and monitoring of products a challenge

**Malawi**

**Registration & Import**
- There is currently no regulatory process for pregnancy tests in Malawi
- Pregnancy tests don’t have to be registered prior to import; anyone can import pregnancy tests
- Pregnancy tests are subject to tax

**Quality**
- There are currently no formal surveillance activities or quality initiatives for pregnancy tests; however the pharmacy board is looking to establish process

**Procurement**
- Currently, NGOs, private outlets and the MOH are procuring pregnancy tests through the Central Medical stores
We cannot give you the data of how many false positives. There is quite a bit that goes on. This is really an area of concern for us....

KMLTTB needs to be supported so we can also [undertake] post marketing surveillance....we need to be very vigilant.”

-Interview with Kenya Medical Laboratory Technicians and Technologist Board (KMLTTB) official, Kenya
What’s next?
Innovation Fund project

• Country-level data collection and analysis (ongoing)
• Stakeholder engagement
• Development of clinical guidance for healthcare providers and advocacy tools for global stakeholders
Development of Clinical Guidance

Recommendations: Providers should be equipped with and trained in use of both pregnancy checklist and pregnancy tests

• Use checklist first. If pregnancy cannot be ruled out, follow up with pregnancy test.
  • Exception 1: If menses are late, skip checklist & confirm pregnancy with pregnancy test
  • Exception 2: Do not use a pregnancy test between two normal menses
National Essential Medicines Lists

Findings from the International Consortium for Emergency Contraception’s Innovation Fund project:

- Pregnancy tests are not in the EML in Kenya, Malawi or Mali
- The only countries in SSA, Asia and Latin America that reference pregnancy tests in their EMLs are:
  - SSA: Cape Verde, Cote d’Ivoire, DRC, Madagascar, Namibia, Rwanda
  - Latin America and Caribbean: Guyana & Trinidad and Tobago
  - East Asia & Pacific: Papua New Guinea
Thank you!

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Questions for consideration

• Who is buying pregnancy tests and for what programs?
• What price are procurers paying and for what volumes?
• What is driving the large mark-up for end-user prices?
• What percentage of non-menstruating women seeking FP do not receive services when pregnancy tests aren’t free?
• Does availability of pregnancy tests impact which methods are offered to clients?
• How can we best estimate use volumes for FP clinics?
• Is international normative guidance from WHO needed to prioritize procurement and/or to have pregnancy tests added to national EMLs?