



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

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## An ongoing medical barrier

- Non-menstruating women are routinely denied family planning services
- May be a particular issue with access to implants

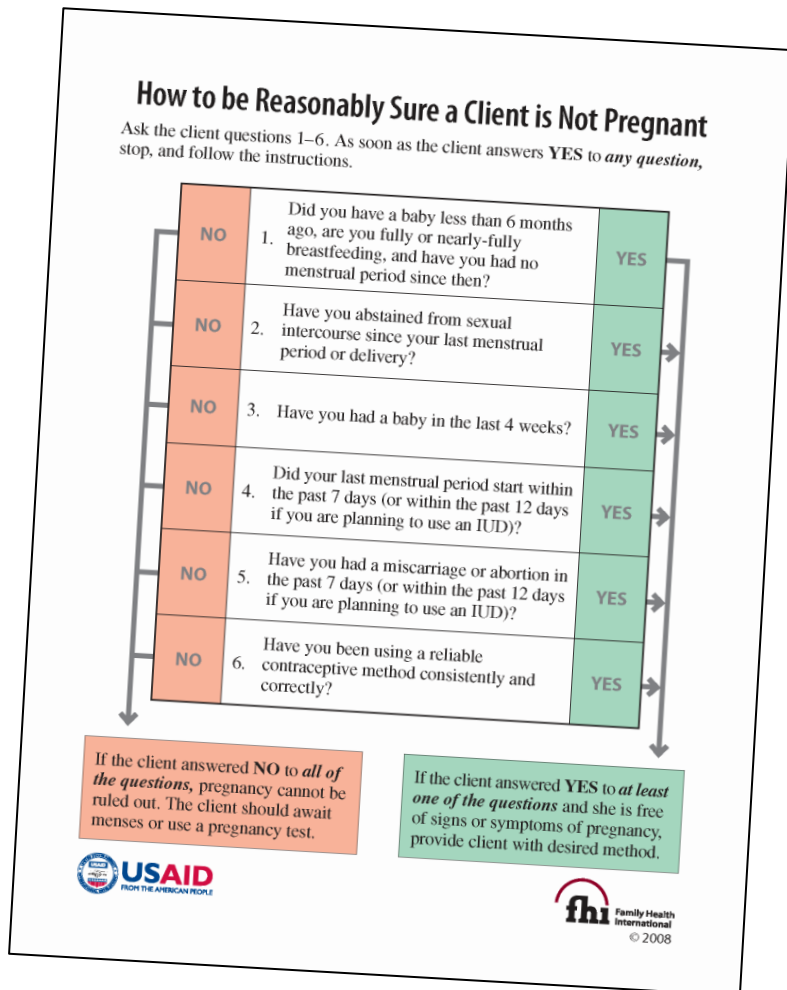
- Nearly half of new family planning clients are not menstruating when they visit the clinic

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



Pregnancy tests available  
for purchase for  $\leq$  US\$0.10

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# Innovation Fund project

Partnership between FHI 360 and Marie Stopes International

Pregnancy tests for FP added to the NURTHs Caucus list in 2012 as one of priority underutilized technologies

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

## 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

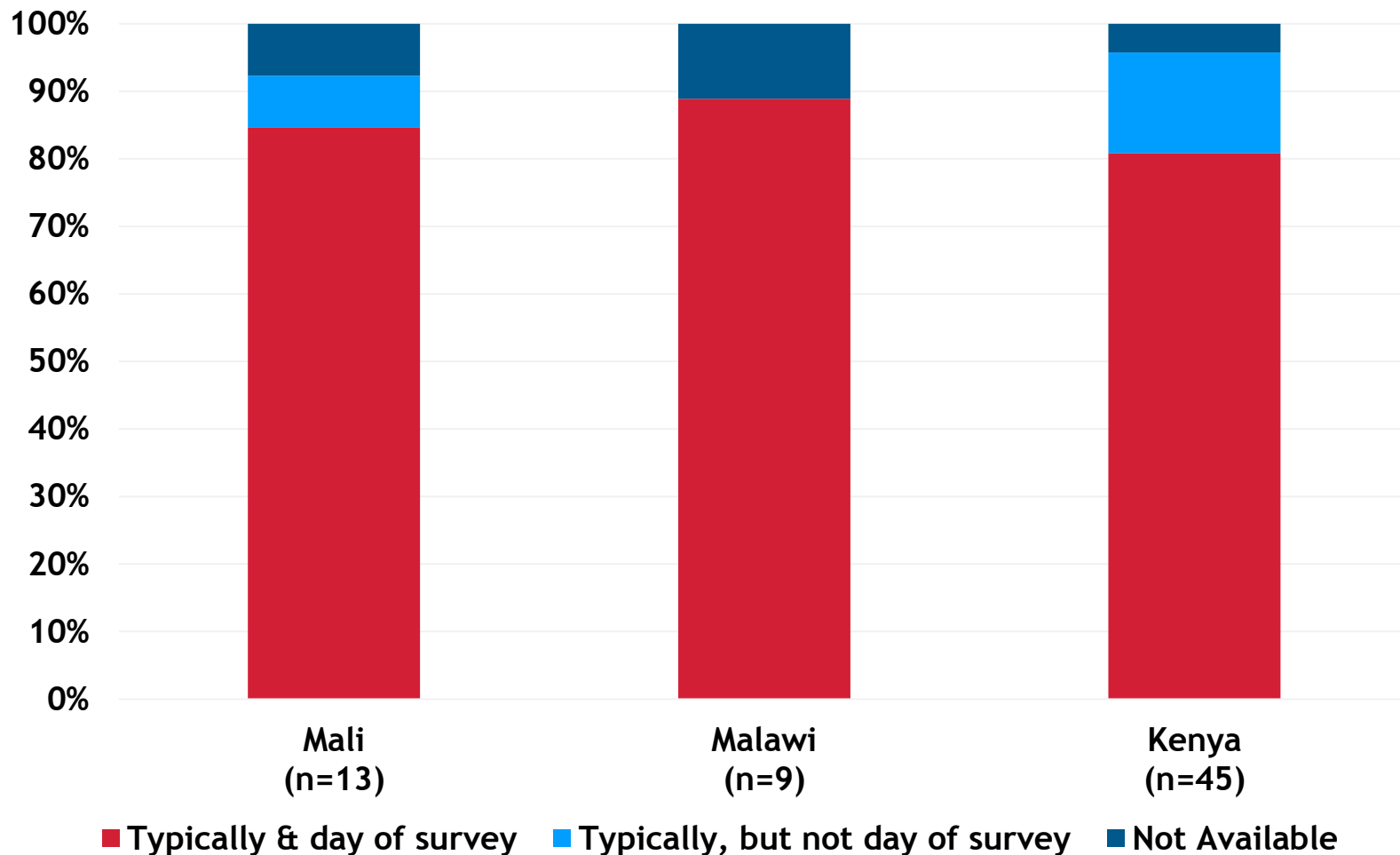
For the purposes of this assessment, “Public Sector” is defined as facilities and programs run by the government. “Private Sector” is defined as facilities run by national and international non-governmental organizations (NGOs), faith-based organizations, social marketing groups including social franchises,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

## Preliminary Results: Sample Size

Facility Type	Mali (n=13)	Malawi (n=9)	Kenya (n=45)	Total (n=67)
Private	3	4	21	28
Public	4	2	17	23
Pharmacy / Drug shop	6	3	7	16

**All results presented today are preliminary; data collection is ongoing**

## Availability of Pregnancy Tests





## Price of pregnancy tests in US dollars by facility type

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

Reflects the “least expensive” pregnancy test available at each facility

## Quality of Pregnancy Tests

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

*\*ISO 13485 appears on 5 tests total: Mali (n=1), Malawi (n=1), Kenya (n=3)*



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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

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## 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

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## 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

## Additional reflections—Impact of Innovation Fund



- Project has helped initiate important discussions with partner organizations and donors
- Sharing learnings across Innovation Fund projects
- Project addresses all four of strategic pillars of Coalition

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# Thank you!

## Project team

- Tracey Brett
- Mohamed Patrice Diallo
- Mahamadou Haddau
- Elena Lebetkin
- Mario Mame
- Mary Mittochi
- John Mwaiseghe
- Kate Rademacher
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- John Stanback