



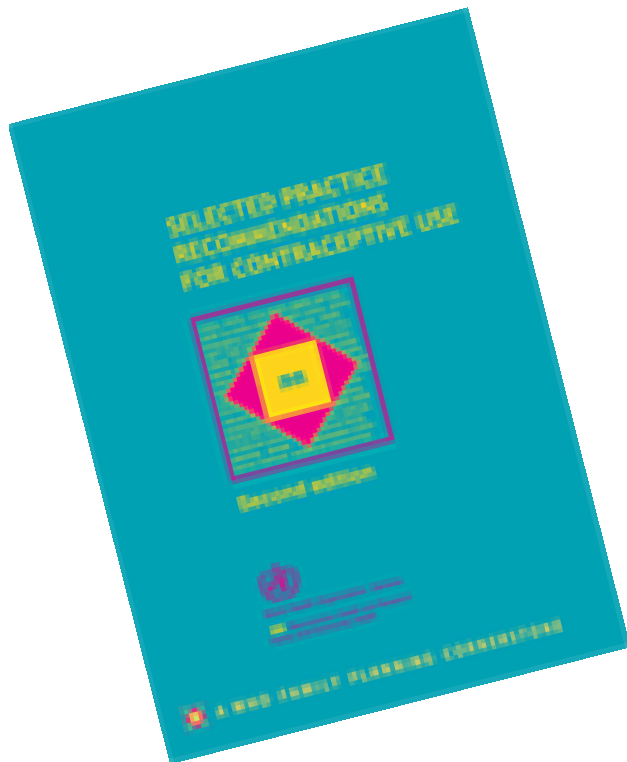
Crossing Over the Thin Blue Line: Increasing Access to Pregnancy Tests

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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

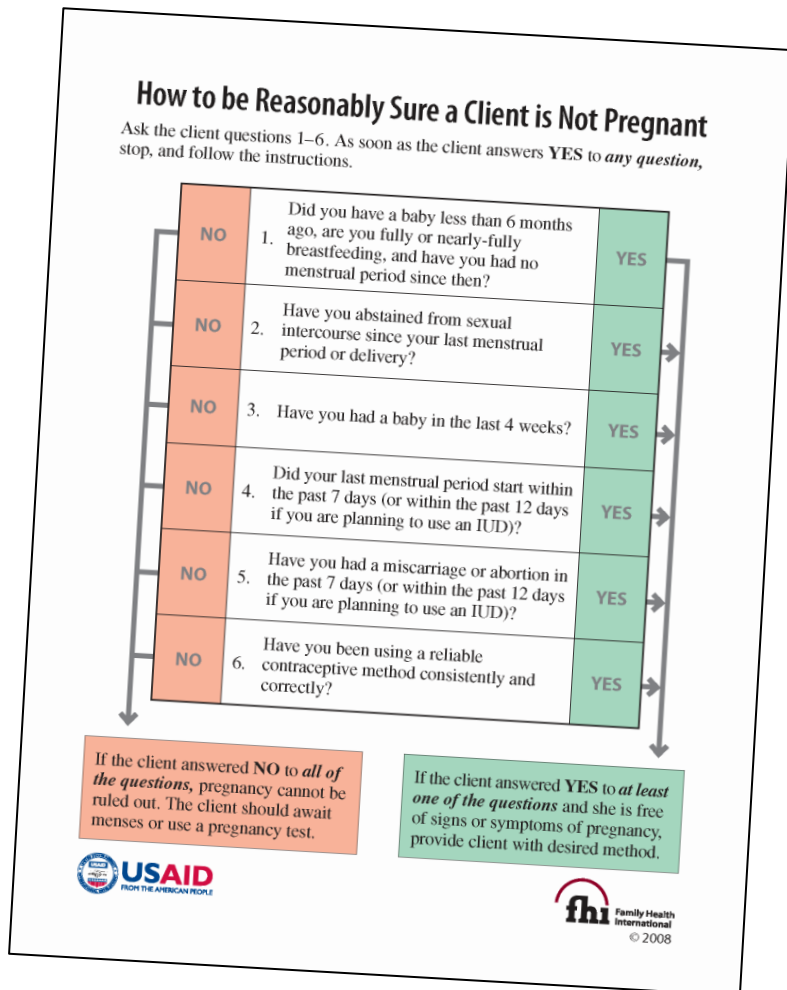
- Nearly half of new family planning clients are not menstruating when they visit the clinic

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



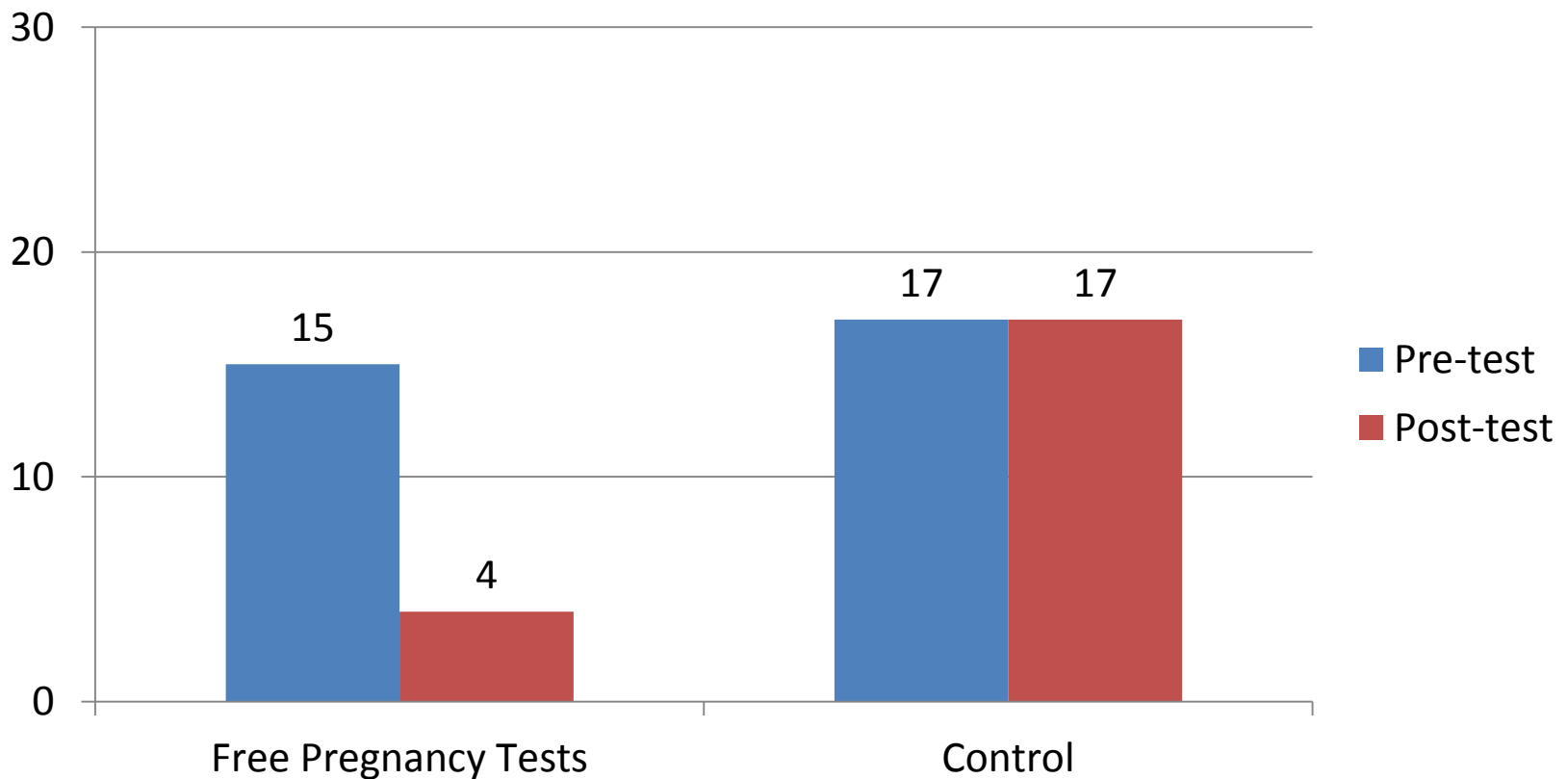
- Research demonstrates that the checklist is effective at ruling out pregnancy
- Included in the *Global Handbook for Family Planning* and in the *WHO Decision-Making tool*
- Instances when the checklist cannot exclude pregnancy
- Some providers don't like/trust the checklist



Pregnancy tests available
for purchase for \leq 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*

USAID
FROM THE AMERICAN PEOPLE

Pregnancy Tests Increase Contraceptive Clients among Health Workers: Evidence from a Randomized Controlled Trial in Madagascar

Health workers face when they provide hormonal contraceptives to a randomized controlled trial in Madagascar found that offering pregnancy tests to health workers for free increases their number of new contraceptive clients.



A community health worker explains the various methods of family planning to an interested woman.

Key Findings

- The intervention increased the number of new hormonal contraceptive clients supplied by CHWs by 24 percent per month.
- There was no effect on the number of family planning counseling sessions conducted by the CHWs.
- CHWs do not use the pregnancy checklist as intended.
- CHWs likely used the pregnancy tests as substitutes for the checklist.

SHOPS
Strengthening Health Outcomes through the Private Sector

GHSP GLOBAL HEALTH: SCIENCE
Dedicated to what works in global health

Early pregnancy detection by trained female community health volunteers in Nepal: Impact on reproductive health outcomes

Kathryn Andersen, Anuja Sirin, et al.

Trained female community health volunteers leading to counseling and appropriate abortion care.

ABSTRACT
Background: Female community health workers (FCHVs) in early pregnancy detection using urine pregnancy tests (UPTs) for the detection of unintended, safe abortion, or family planning services. **Methods:** Between July 2008 and June 2009, FCHVs in Nepal provided counseling and referral to women on their number of clients served and the type of service received. **Results:** Of the FCHVs with follow-up data, 80% provided UPTs to their clients. FCHVs provided 24% more UPTs than other contraceptive services, and 24% more referrals for appropriate reproductive health services such as FCHVs are a promising channel for early identification of pregnancy status. **Conclusions:** Providing FCHVs with the skills and support to provide UPTs is a promising service availability and a viable option for record keeping.

BACKGROUND
Timely identification of pregnancy is important to initiate antenatal care (ANC) among women with unintended pregnancies and to seek abortion services when women with unwanted pregnancies. Although gestational age is a safe procedure, the medical risk is greater in advanced gestational ages.¹ In addition, early identification of pregnancy is important so that women have access to abortion services before they exceed the allowed gestational limit.

Lack of timely identification of pregnancy status can cause delays in seeking ANC or abortion. For example, a study of women in South Africa found that women who were pregnant for 5 months gestation before feeling they were pregnant typically had more difficulties in identifying pregnancy status and seeking care.² In addition, early identification of pregnancy status can cause delays in seeking ANC or abortion. For example, a study of women in South Africa found that women who were pregnant for 5 months gestation before feeling they were pregnant typically had more difficulties in identifying pregnancy status and seeking care.² In addition, early identification of pregnancy status can cause delays in seeking ANC or abortion. For example, a study of women in South Africa found that women who were pregnant for 5 months gestation before feeling they were pregnant typically had more difficulties in identifying pregnancy status and seeking care.²

South Africa showed that women who used urine pregnancy tests (UPTs) presented for ANC services 3.6 weeks earlier, and abortion clients 1.4 weeks earlier, than women who did not use UPTs.³ Another study

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

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 global 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

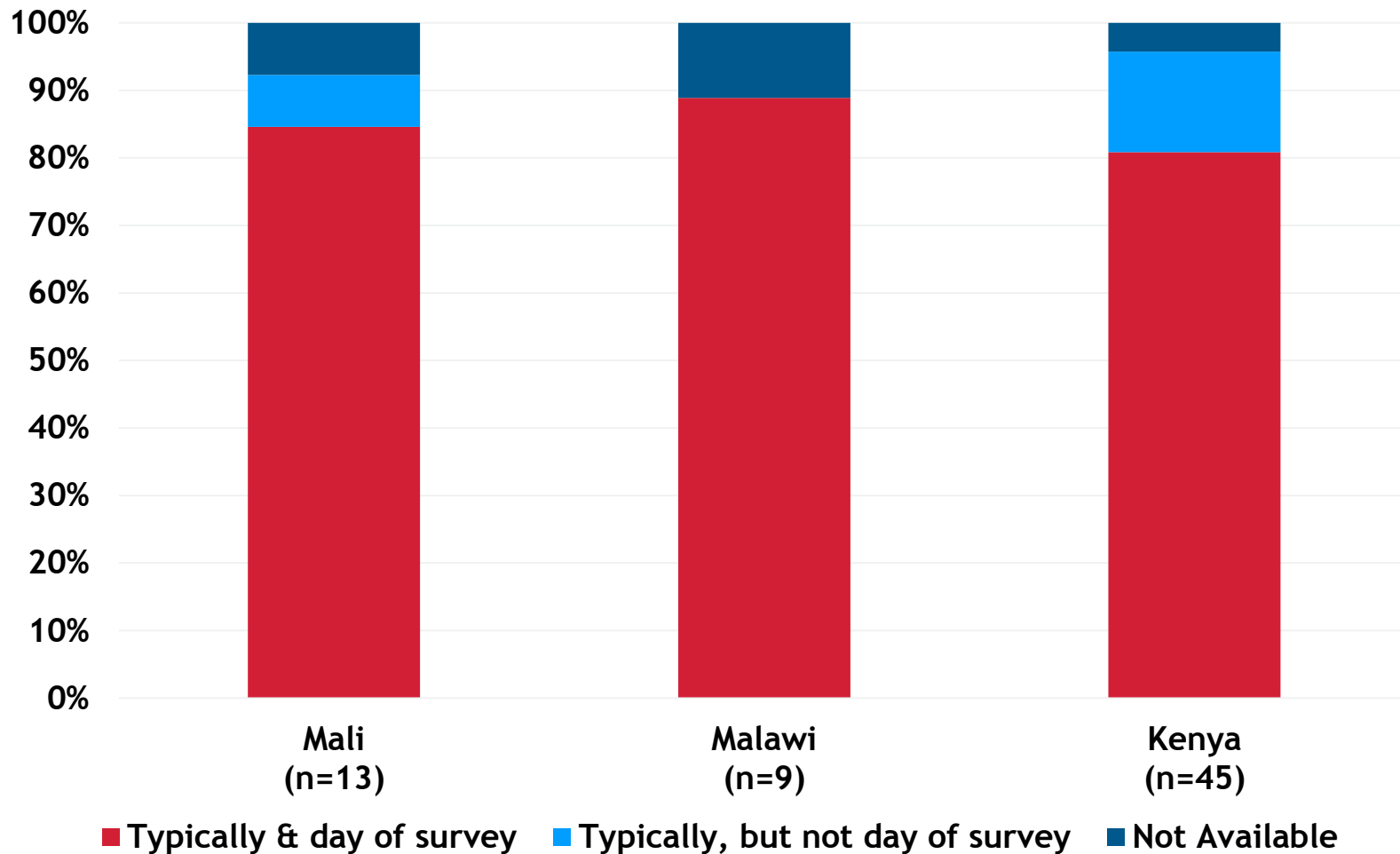
For the purposes of this assessment, “Public Sector” is defined as facilities and programs run by the government. “Private Sector” is defined as facilities run by national and international non-governmental organizations (NGOs), faith-based organizations, social marketing groups including social franchises,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

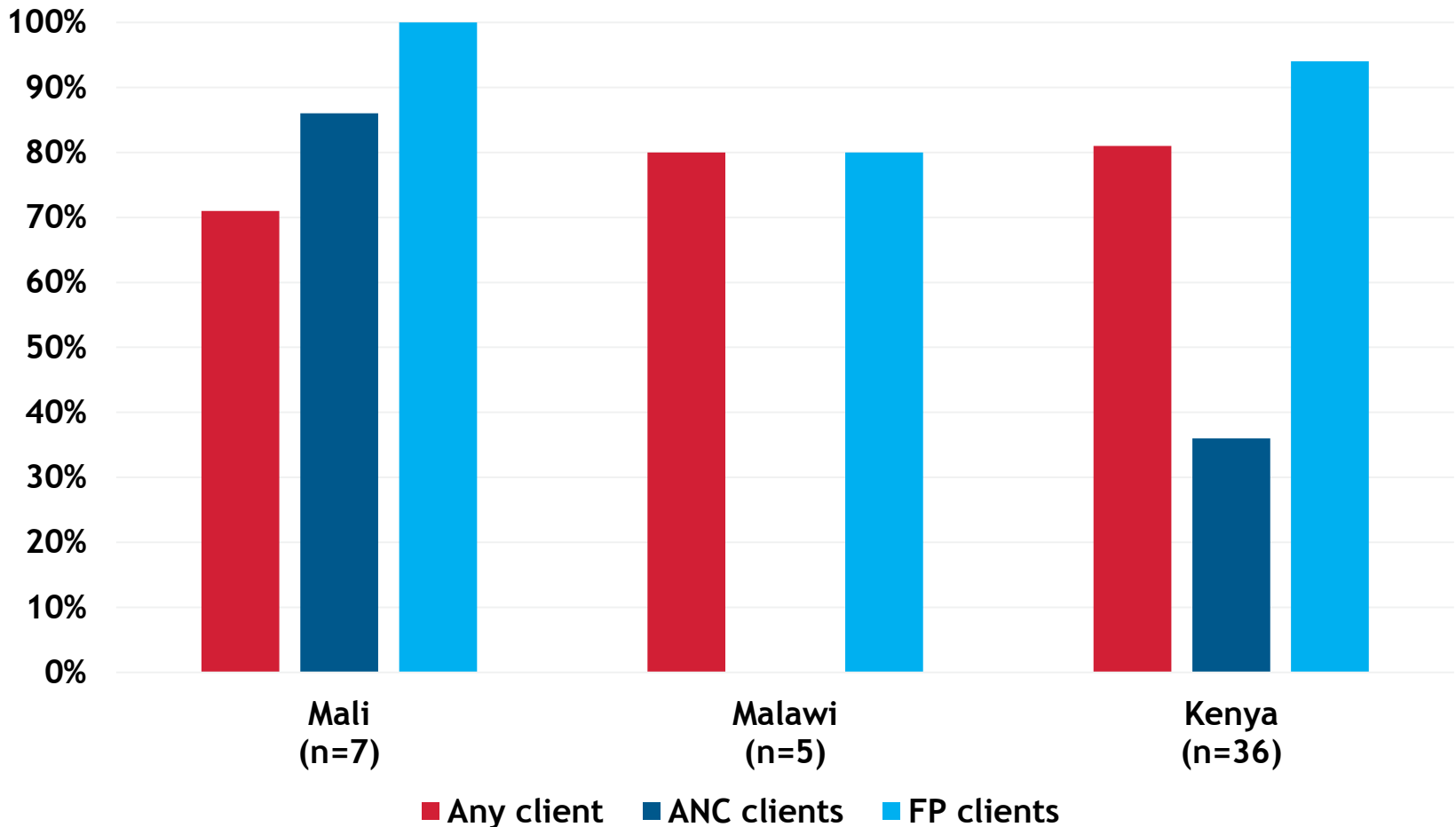


Price of pregnancy tests in US dollars by facility type

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

Reported access to pregnancy test by client type (public & private facilities only)





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.”

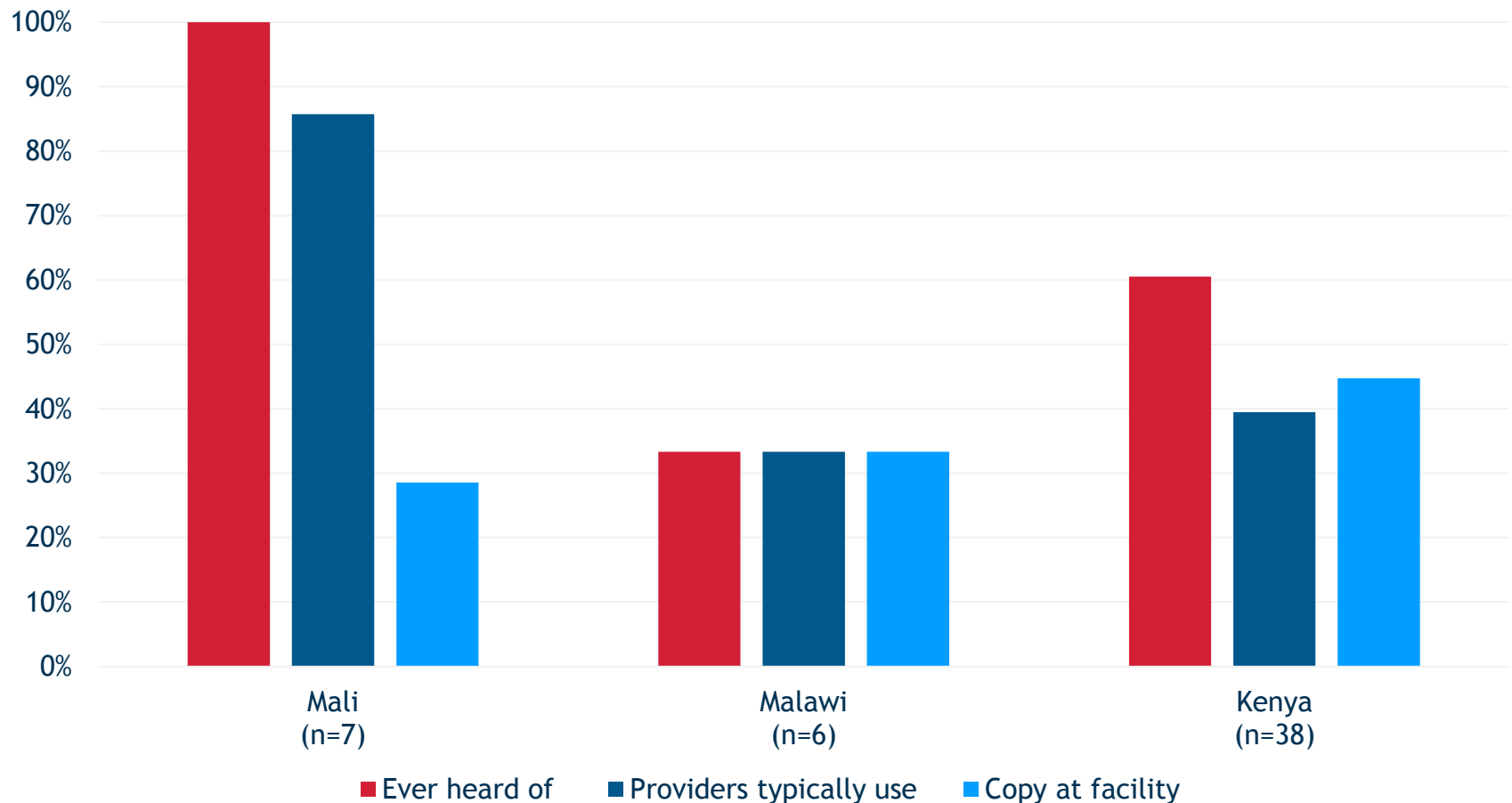
-From interview with MOH official, Kenya

Quality of Pregnancy Tests

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)*

Awareness, availability and use of Pregnancy Checklist (public & private facilities only)





[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)

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

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 test in the market and the challenges around surveillance. Will 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!

Project team

- Tracey Brett
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- Mary Mittochi
- John Mwaiseghe
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- John Stanback

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?