

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

FHI 360 & Marie Stopes International
Innovation Fund Project—Reproductive Health Supplies Coalition
January 14, 2016

Background & Rationale

Dr. John Stanback

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
- May be a particular issue with access to LARCs

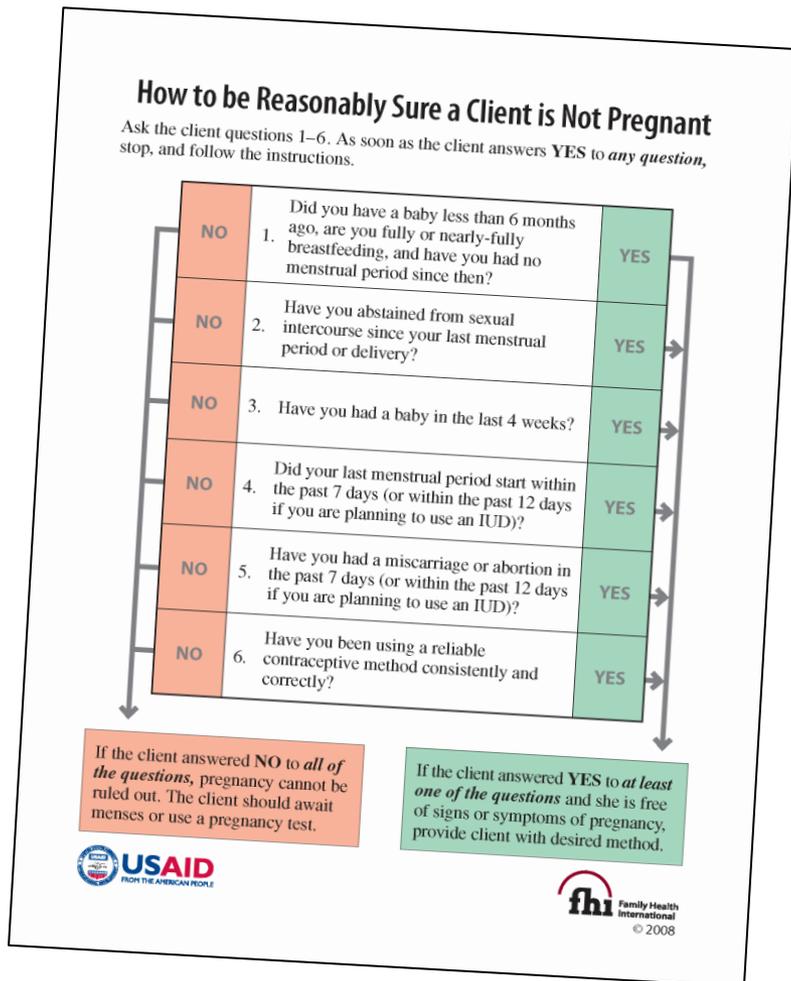
- Nearly half of new family planning clients are not menstruating when they visit the clinic

Few non-menstruating clients are actually pregnant

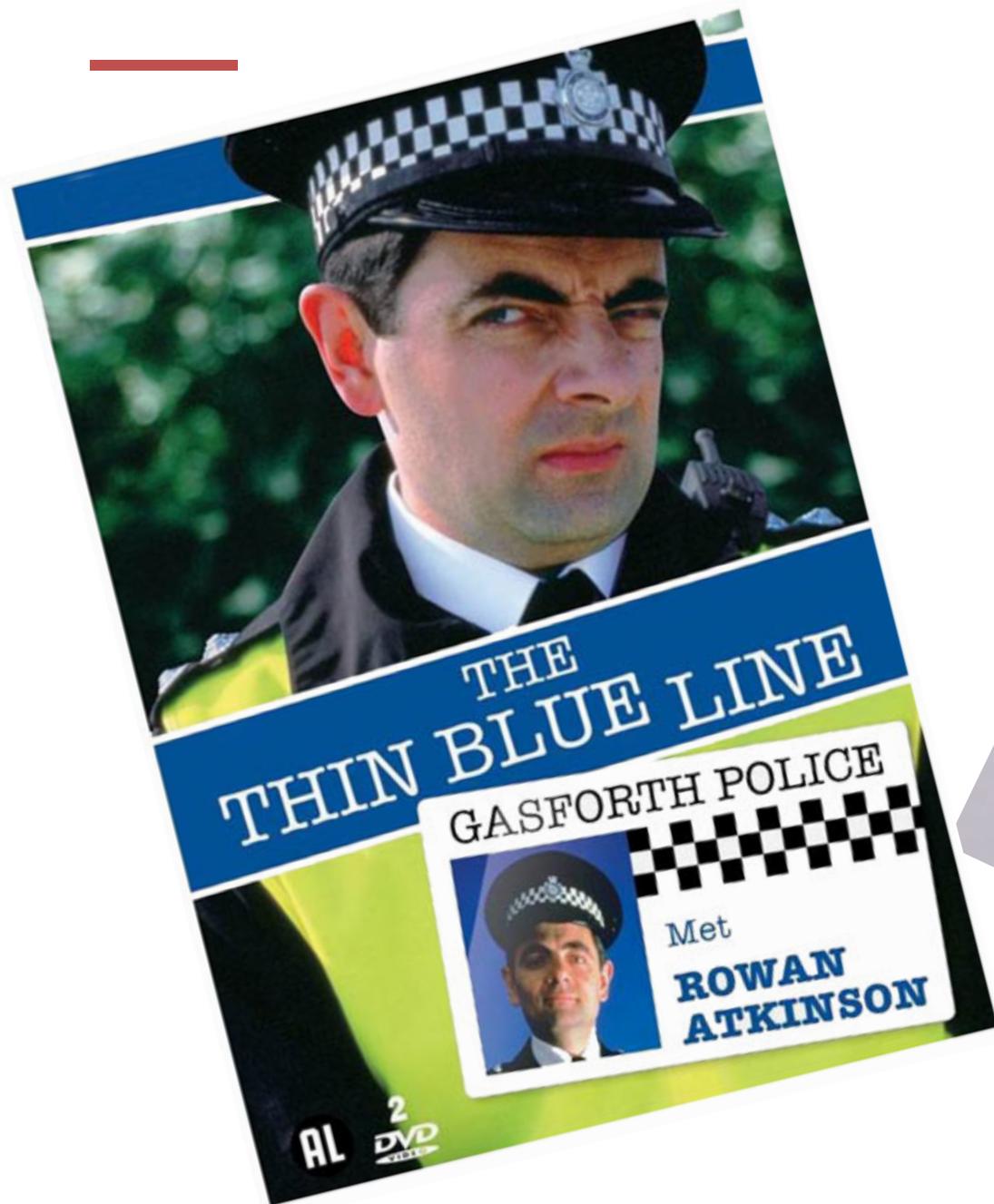
According to WHO, no known harm occurs to either a pregnant woman or a fetus from exposure to hormonal family planning methods*

*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



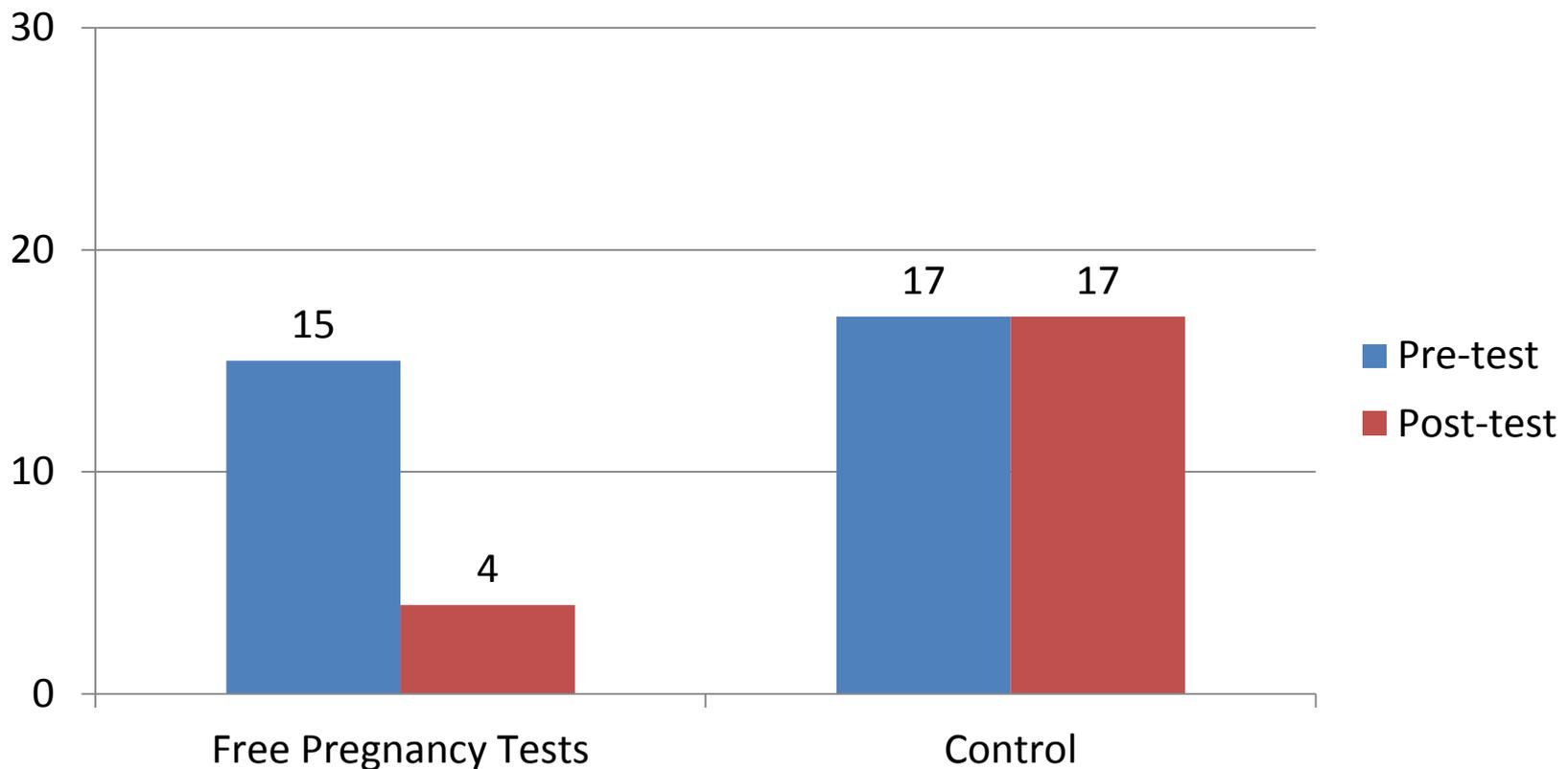
- Research demonstrates that the checklist is effective at ruling out pregnancy
- Included in the *Global Handbook for Family Planning* and in the *WHO Decision-Making tool*
- Instances when the checklist cannot exclude pregnancy
- Some providers don't like/trust the checklist



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

Research in Zambia (FHI 360)

% New, Non-Menstruating Clients Denied Effective Method



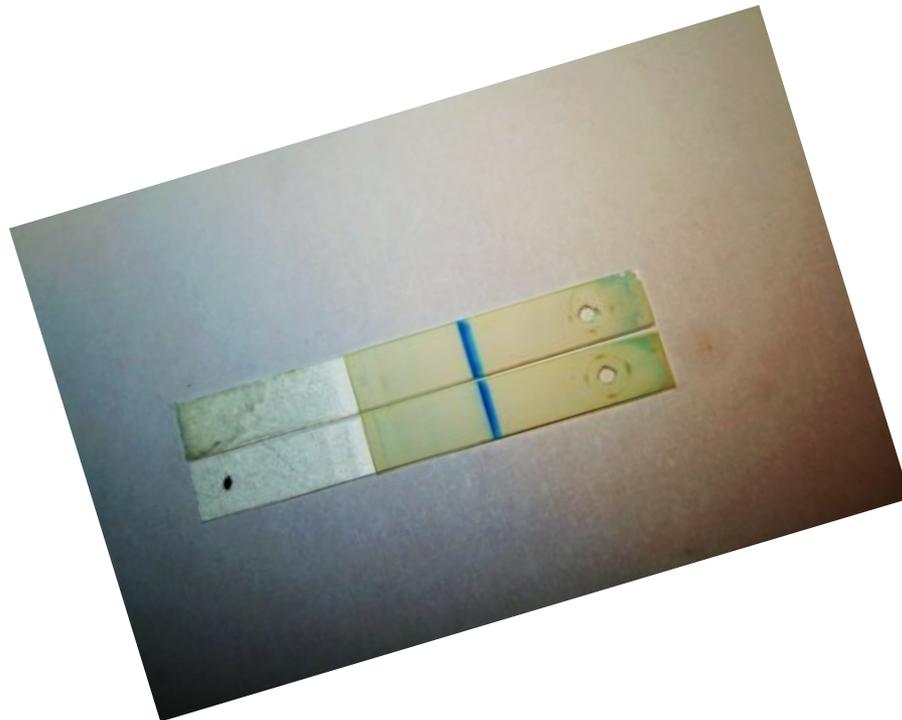
Additional potential benefits

- 🥤 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



When should a pregnancy test be used?

- E.g., for women presenting between menses?
- Misuse is common
- Official guidance can be confusing, contradictory



Proposed Clinical Guidance: When to use the Checklist vs. Pregnancy Test

	Hormonal Methods	Intrauterine Devices (IUDs)
Amenorrhea	<p>Take history using pregnancy checklist.</p> <ul style="list-style-type: none"> • If pregnancy ruled out, provide method. • If pregnancy not ruled out, use pregnancy test if available. • If the test is negative (or not available), provide the method, but schedule a follow-up pregnancy test in 3-4 weeks. 	<p>Take history using pregnancy checklist.</p> <ul style="list-style-type: none"> • If pregnancy ruled out, provide method. • If pregnancy not ruled out, a pregnancy test should be used. If negative, advise woman to use a barrier method or abstain for 3-4 weeks, then repeat pregnancy test. • If the test is still negative, provide an IUD.
Between Menses	<p>Do not use pregnancy test (it is too early for it to be effective).</p> <p>Take history using pregnancy checklist.</p> <ul style="list-style-type: none"> • If pregnancy ruled out, provide method. • If pregnancy not ruled out, do not provide implant, but “Quick Start” (explained below) is acceptable for pills and injectables (pregnancy assessment recommended if next menses are delayed). 	<p>Do not use pregnancy test (it is too early for it to be effective).</p> <p>Take history using pregnancy checklist.</p> <ul style="list-style-type: none"> • If pregnancy ruled out, provide method. • If pregnancy not ruled out, do not provide IUD. Advise woman to use barrier method or abstain and return for IUD insertion within 12 days of onset of next menses.
Missed Period	<p>History not necessary; use pregnancy test.</p> <ul style="list-style-type: none"> • If using highly sensitive pregnancy test (e.g., 25 mIU/ml) and it is negative, provide desired method. • If using test with lower sensitivity (e.g., 50 mIU/ml) and it is negative, wait and reassess at least 10 days after expected date of menses. If test is still negative, provide desired method. 	



Impact of Free Pregnancy Test Kits on Contraceptive Distribution: Evidence from an Experiment in Madagascar

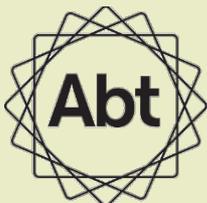
Alison Comfort, Ph.D.

(co-authors Slavea Chankova, Randall Juras, Natasha Hsi, Lauren Peterson, and Payal Hathi)

Abt Associates

Reproductive Health Supplies Coalition - Webinar

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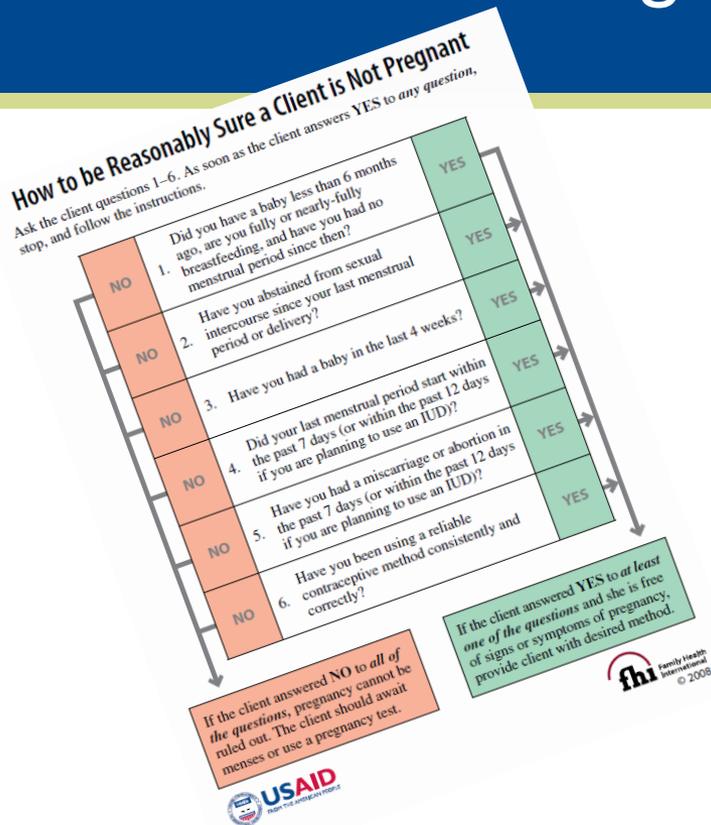
O'Hanlon Health Consulting

Background

Contraceptive provision by CHWs

- There remains significant unmet demand for contraceptives in sub-Saharan Africa (SSA)
- Contraceptive provision has been shifted to community health workers (CHWs) to improve access, particularly in remote and rural areas
- CHWs are trained to provide oral and injectable contraceptives
 - Most popular forms of contraceptives in SSA
 - Sell hormonal contraceptives at a small profit

Barrier to selling hormonal contraceptives



- WHO recommends that health workers confirm that a woman is not pregnant before offering hormonal contraceptives
- CHW have been trained to rule out pregnancy using a pregnancy checklist

- Challenges with checklist:
 - Some women categorized as “could be pregnant” but are not
 - CHW may not trust the woman’s responses
- CHWs used checklist but only 46% viewed it as reliable

Intervention

- Provide CHWs pregnancy test kits to distribute for free
- Benefits of pregnancy tests:
 - Easy to administer
 - False positive are highly unlikely
 - Increasingly affordable
- Intervention could increase contraceptive distribution by:
 - Improving access: CHWs use test as complement to checklist
 - Generating interest in FP: Women want to know pregnancy status, resulting in FP counseling



(Cypress Diagnostics hCG Dipstrip)

Research question



- Does providing CHWs with pregnancy test kits increase the number of new hormonal contraceptives clients per CHW?
- Outcome of interest
 - Number of new hormonal contraceptive clients per CHW

Study Methodology

Study participants



(CHW showing examples of FP methods)

- All CHWs supported by the Santénet2 project and trained in selling oral and injectable contraceptives
- Study participants = 622 CHWs

Regions



Study design: randomized experiment

Treatment group

Given free pregnancy test kits
+
Training on how to use them

272 CHWs

Control group

No free pregnancy test kits
+
No training on kits

263 CHWs

Baseline: characteristics of CHWs

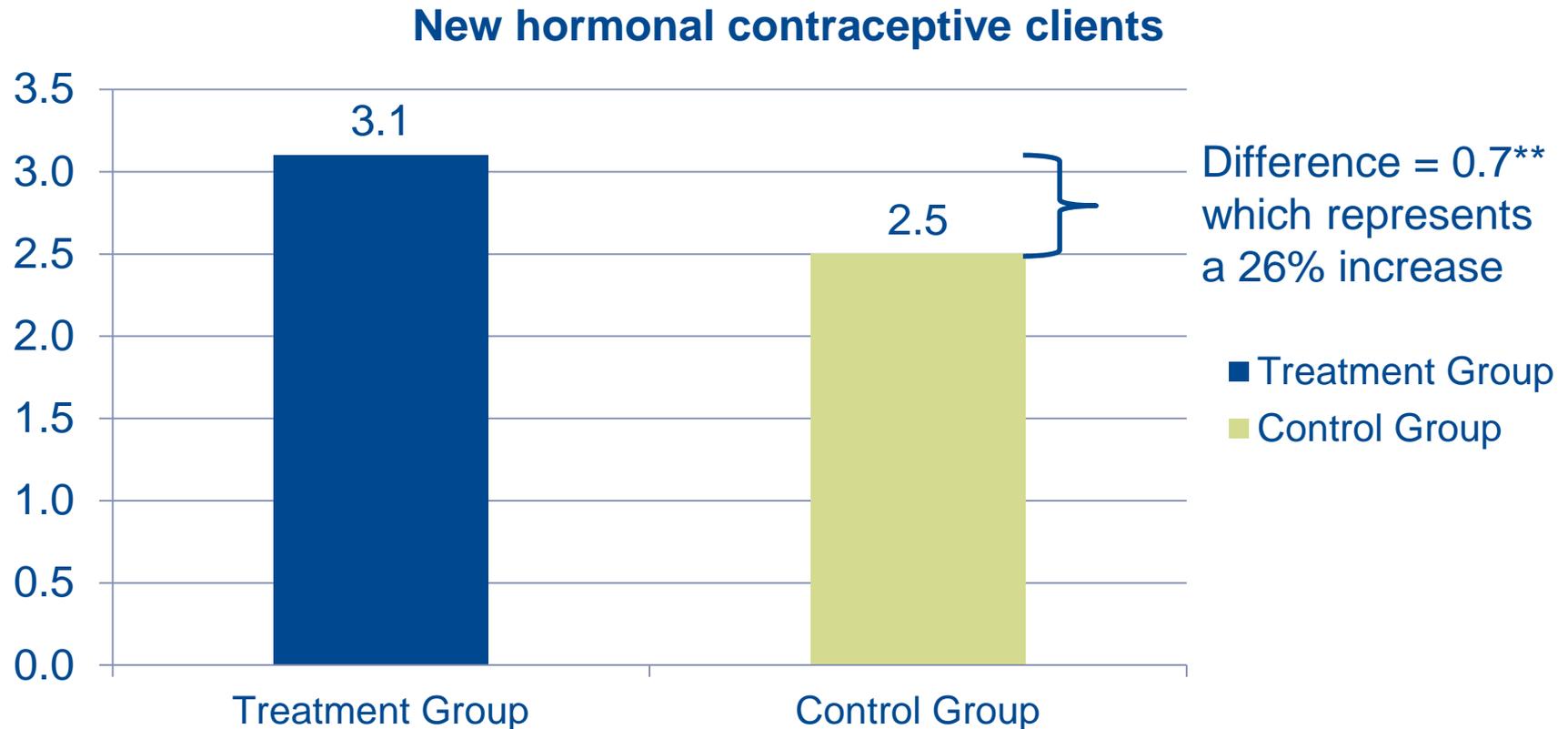
- Most CHWs are women
- 5th grade level of education
- Live 2 hours from nearest health center
- Have 39 FP clients



(CHW speaking with client)

Results and Policy Implications

26% increase in number of new hormonal contraceptive clients per CHW per month



** indicates that the difference is statistically significant at the 95% level ($p < 0.05$)

Policy implications

- Intervention is an effective approach to increase distribution of contraceptives in countries like Madagascar
- Pregnancy tests should be included as a low cost addition to community-based distribution programs
- Based on the results of our study, Ministry of Health in Madagascar decided to scale-up distribution of free pregnancy test kits

Full study available in *Contraception* (2016)



Contraception

Contraception 93 (2016) 44–51

Original research article

Providing free pregnancy test kits to community health workers increases distribution of contraceptives: results from an impact evaluation in Madagascar[☆]

Alison B. Comfort^{a,*}, Slavea Chankova^b, Randall Juras^a, C. Natasha Hsi^{b,1},
Lauren A. Peterson^b, Payal Hathi^{a,2}

^aAbt Associates, 55 Wheeler Street, Cambridge, MA 02138, United States

^bAbt Associates, 4550 Montgomery Avenue, Bethesda, MD 20814, United States

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Abstract

Objectives: To improve access to contraceptives in remote and rural areas, sub-Saharan African countries are allowing community health workers (CHWs) to distribute hormonal contraceptives. Before offering hormonal contraceptives, CHWs must determine pregnancy status but often lack a reliable way to do so. No studies have evaluated the impact of providing CHWs with urine pregnancy test kits. We assessed the impact of giving CHWs free pregnancy test kits on the number of new clients purchasing hormonal contraceptives from CHWs.

Study design: We implemented a randomized experiment in Eastern Madagascar among CHWs who sell injectable and oral hormonal contraceptives. A total of 622 CHWs were stratified by region and randomly assigned at the individual level. Treatment-group CHWs were given free pregnancy tests to distribute (n analyzed=272) and control-group CHWs did not receive the tests (n analyzed=263). We estimated an ordinary least-squares regression model, with the monthly number of new hormonal contraceptive clients per CHW as our primary outcome.

Results: We find that providing CHWs with free pregnancy test kits increases the number of new hormonal contraceptive clients. Treatment-group CHWs provide hormonal contraceptives to 3.1 new clients per month, compared to 2.5 in the control group. This difference of 0.7 clients per month (95% confidence interval 0.13–1.18; $p=.014$) represents a 26% increase.

Conclusions: Giving CHWs free pregnancy tests is an effective way to increase distribution of hormonal contraceptives. As pregnancy tests become increasingly affordable for health-care systems in developing countries, community-based distribution programs should consider including the tests as a low-cost addition to CHWs' services.

Implications: No study has evaluated the impact of giving CHWs free urine pregnancy test kits for distribution to improve provision of hormonal contraceptives. Giving CHWs free pregnancy test kits significantly increases the number of clients to whom they sell hormonal contraceptives. Community-based distribution programs should consider including these tests among CHWs' services.

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Keywords: Pregnancy tests; Community health workers; Hormonal contraceptives; Sub-Saharan Africa; Family planning

Scale-up of intervention

Scale-up of intervention

- Pregnancy test kits were added to the essential medicines list in Madagascar
- Created a Technical Working Group with key stakeholders
- USAID procured pregnancy test kits
 - Total of 700,000 procured
 - In our sample, CHWs distributed 7 tests/month
- Being distributed by social marketing organization (PSI)
- MIKOLO project, 5-year USAID project, is leading the scale-up
 - Training CHWs to incorporate these tests in their work

Training of CHWs to provide pregnancy tests

- MIKOLO trained a total of 3,146 CHWs as of August 2015
- Integrate training on pregnancy tests kits into refresher training on FP
- CHWs are trained to use the test as a complement to checklist
- Collecting monitoring data on number of new FP users and antenatal care referrals

Preliminary results from scale-up

- New contraceptive clients was 6,500 once pregnancy tests were available, compared to 4,500 in previous months (45% increase)
- Anecdotal evidence that CHWs like using the tests because it facilitates their work
- Challenges:
 - Some CHWs have incorporated use of test more rapidly/easily than others
 - Lack access to supplies such as gloves and sterile cups
 - Waste management (e.g. cups, gloves, tests)



Thank you



For additional comments:
Alison_Comfort@abtassoc.com

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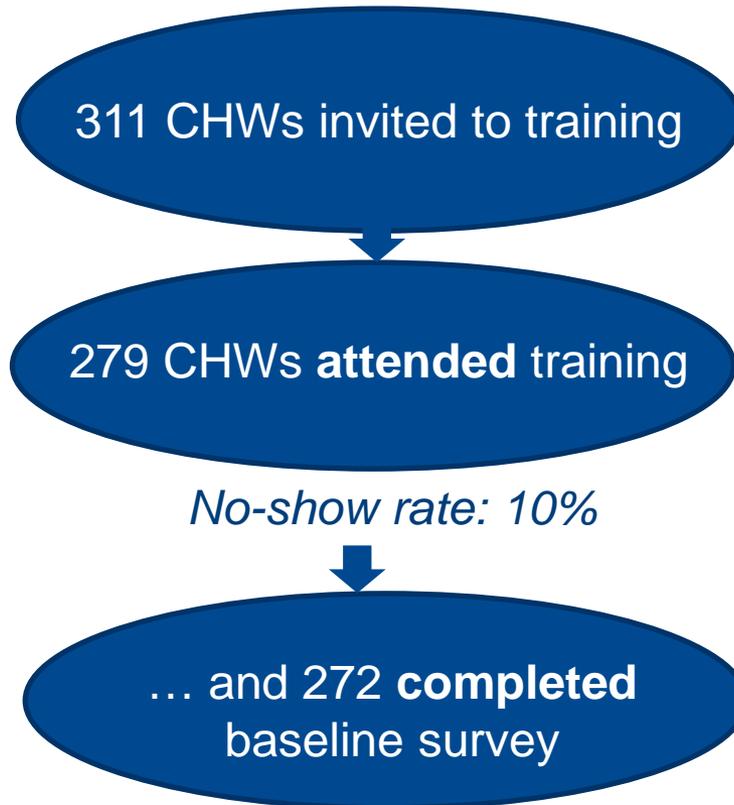
Extra slides



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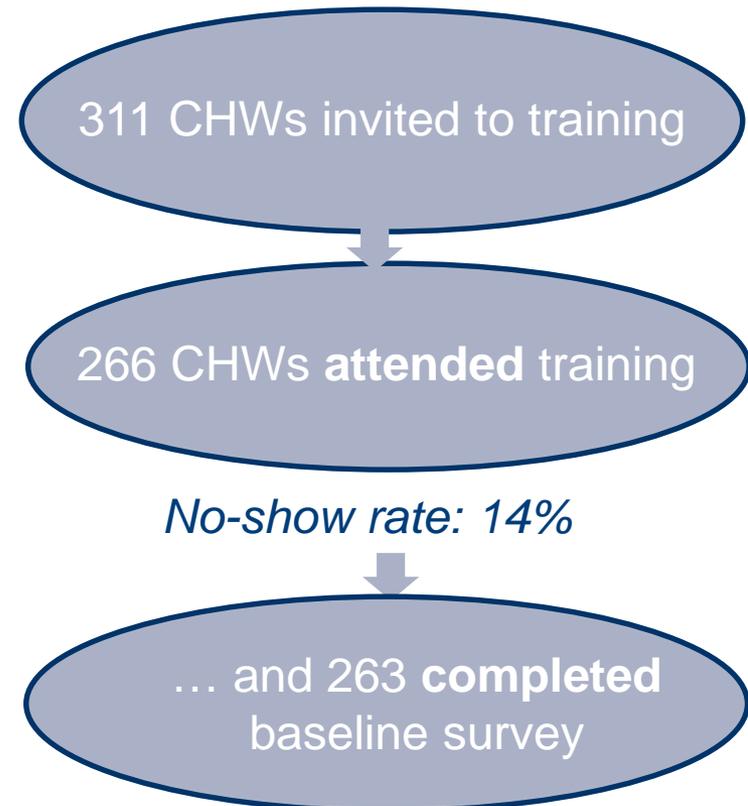
Number of study participants

Treatment group



...and not complete baseline data: 13%

Control group



...and not complete baseline data: 15%

Analytical approach

Using an ordinary least squares regression model with month fixed effects, we estimated:

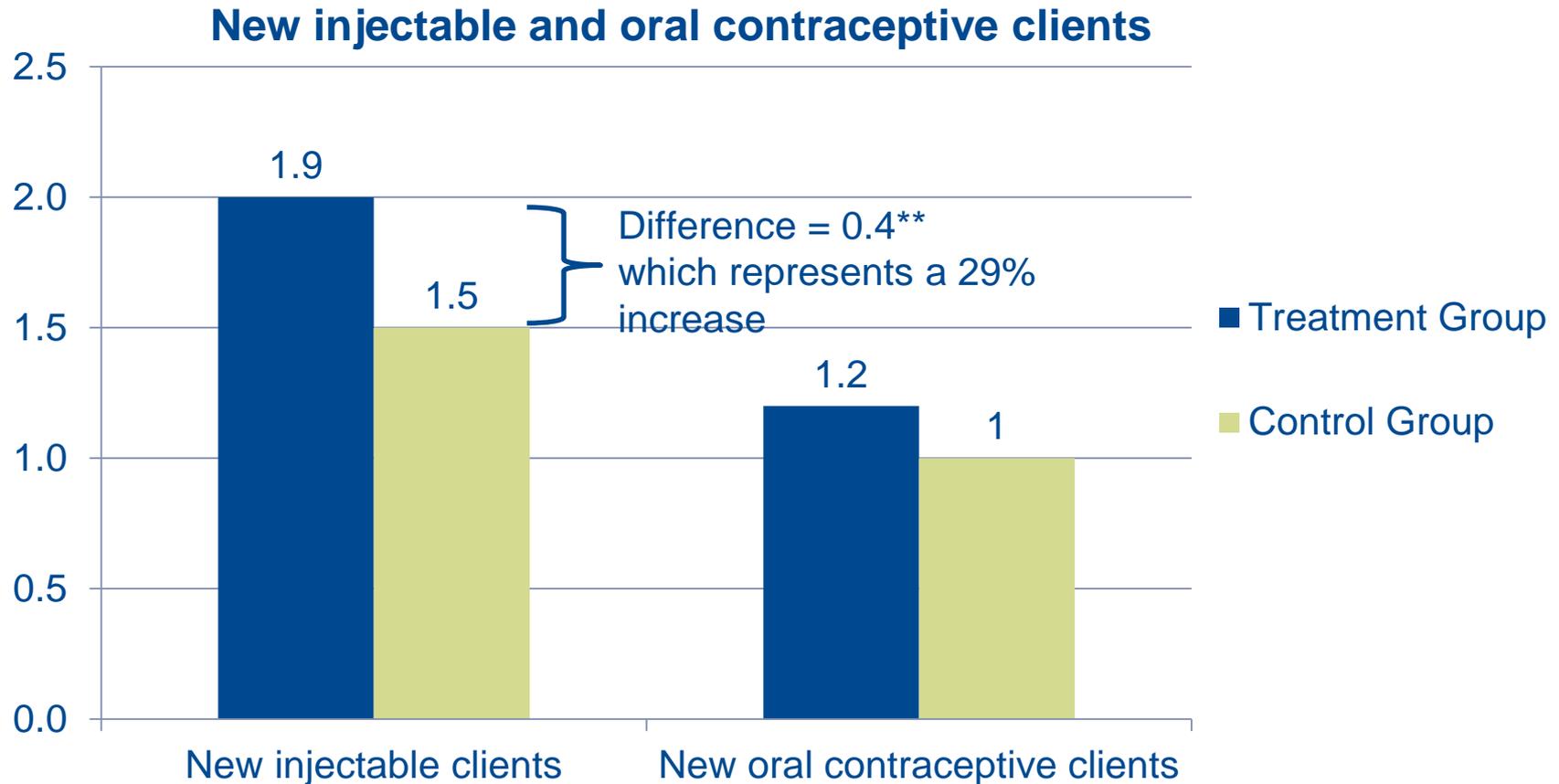
$$y_{idt} = \alpha + \beta \text{Treatment}_i + \gamma X_i + \tau_t + \delta_d + \varepsilon_{idt}$$

for CHW i in district d at time t .

Variables	Definitions
y	Number of new hormonal contraceptive clients
$Treatment$	Dummy variable for whether CHW given free pregnancy test kits
X	Vector of CHWs' baseline characteristics
τ	Month fixed effect
δ	District fixed effect
ε	Random error

We cluster the standard errors at the CHW level.

29% increase in number of new injectable clients per CHW per month



** indicates that the difference is statistically significant at the 95% level ($p < 0.05$)
Any inconsistencies are due to rounding.

Limitations of the study

- Unable to distinguish the underlying mechanism
- Used self-monitoring data
 - Non-response: 38% of total reports not submitted
 - However, results are robust when including non-response weights to weight up to experimental sample

Hypothesized chain of causality

CHWs are offered pregnancy test kits to distribute for free + training on how to use these kits

CHWs use tests to check whether women who want contraceptives are pregnant

Women who want to check whether they are pregnant approach CHWs for the tests

CHWs provide free tests and use this opportunity to also **provide FP counseling**

Some women who are not pregnant decide to take up contraceptives

Women with negative pregnancy test results become **new contraceptive clients of CHWs**

1. CHWs use test kits (instead of pregnancy checklist) for all new clients who want contraceptives

or

2. CHWs use test kits only for women whom the checklist categorizes as "could be pregnant"

Intervention and evaluation timeline

2013

Follow-up: study data collection

Mar

Apr

May

Jun

Jul

Aug

Sept

Oct

Nov

CHWs invited to trainings
(baseline data collection and pregnancy test distribution)

Trainings held
Baseline survey

CHWs distribute pregnancy tests and submit monthly monitoring forms
(4 months after training for each CHW)

Trainings

Treatment group

1. Invited to the training
 - Filled baseline data survey
 - Trained on reporting forms

2. Trained on pregnancy test kits

3. Given pregnancy test kits to distribute for free
 - 50 kits per CHW

Control group

1. Invited to the training
 - Filled baseline data survey
 - Trained on reporting forms

Baseline: CHWs' contraceptive clients

	Total clients purchasing FP from CHWs
Injectables	24.0
Oral contraceptives	13.7
Condoms/spermicides	0.5
Standard days methods/cycle beads	0.9
All contraceptives	39.2

Innovation Fund Project: Kenya, Malawi and Mali

Kate H. Rademacher

Project Goal:

- Better understand the current availability and affordability of pregnancy tests in three countries
- First systematic analysis that has been conducted in this area to date of which we are aware
- Work will guide future assessments, scale-up and advocacy work
- Aligns with RHSC four strategic pillars

Project team

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

Data Collection in Kenya, Malawi and Mali

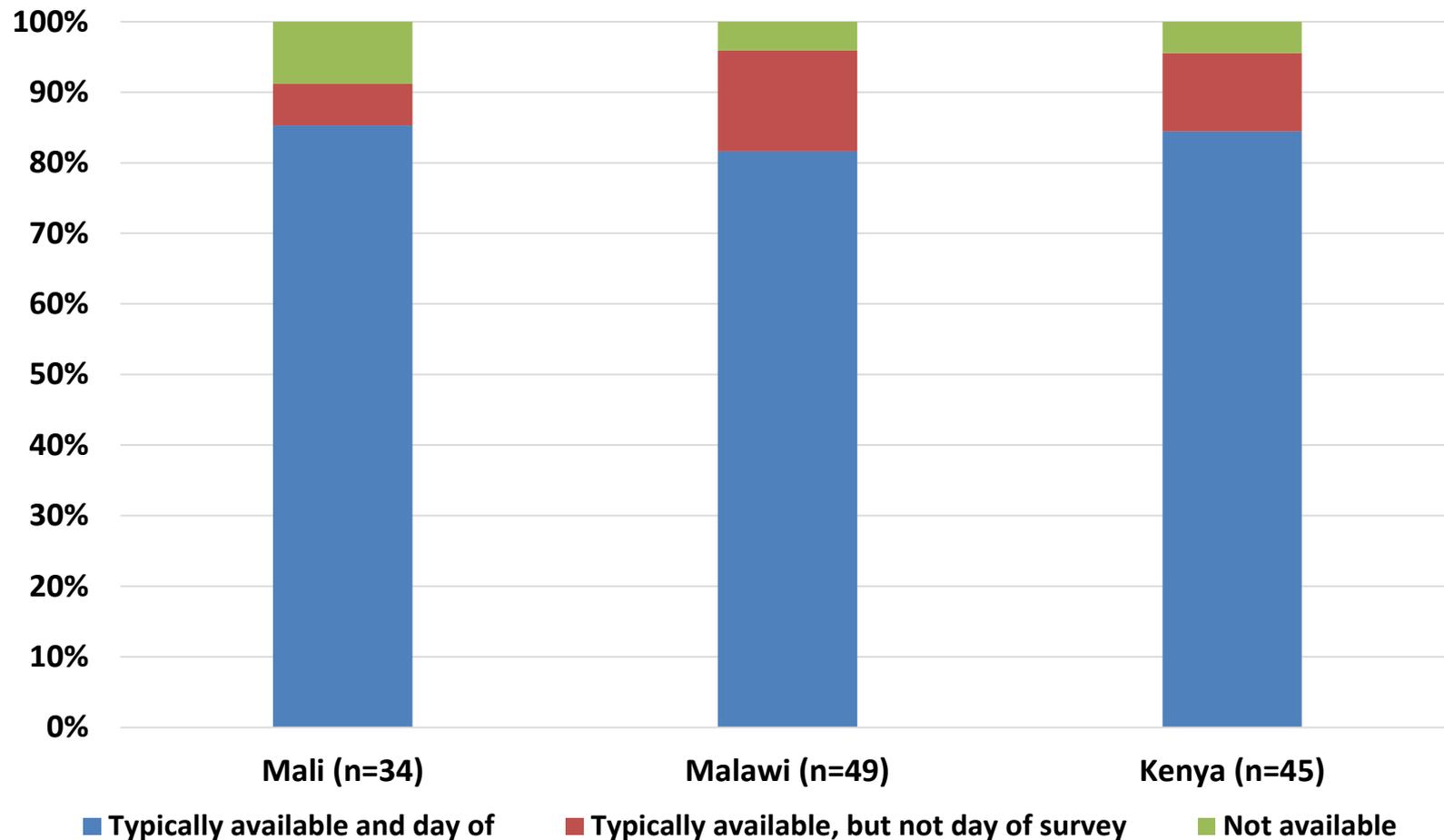
- Data collected in public and private sector facilities and pharmacies/drug shops
- Standardized questionnaire; tailored for each sector
- Convenience sample used with sites both in the capital city and in semi-urban and rural areas surrounding the capital
- Information collected on availability and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

Sample Size

Facility Type	Mali (n=34)	Malawi (n=49)	Kenya (n=45)	Total (n=128)
Private	15	27	21	63
Public	12	11	17	40
Pharmacy / Drug shop	7	11	7	25

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.

Availability of Pregnancy Tests

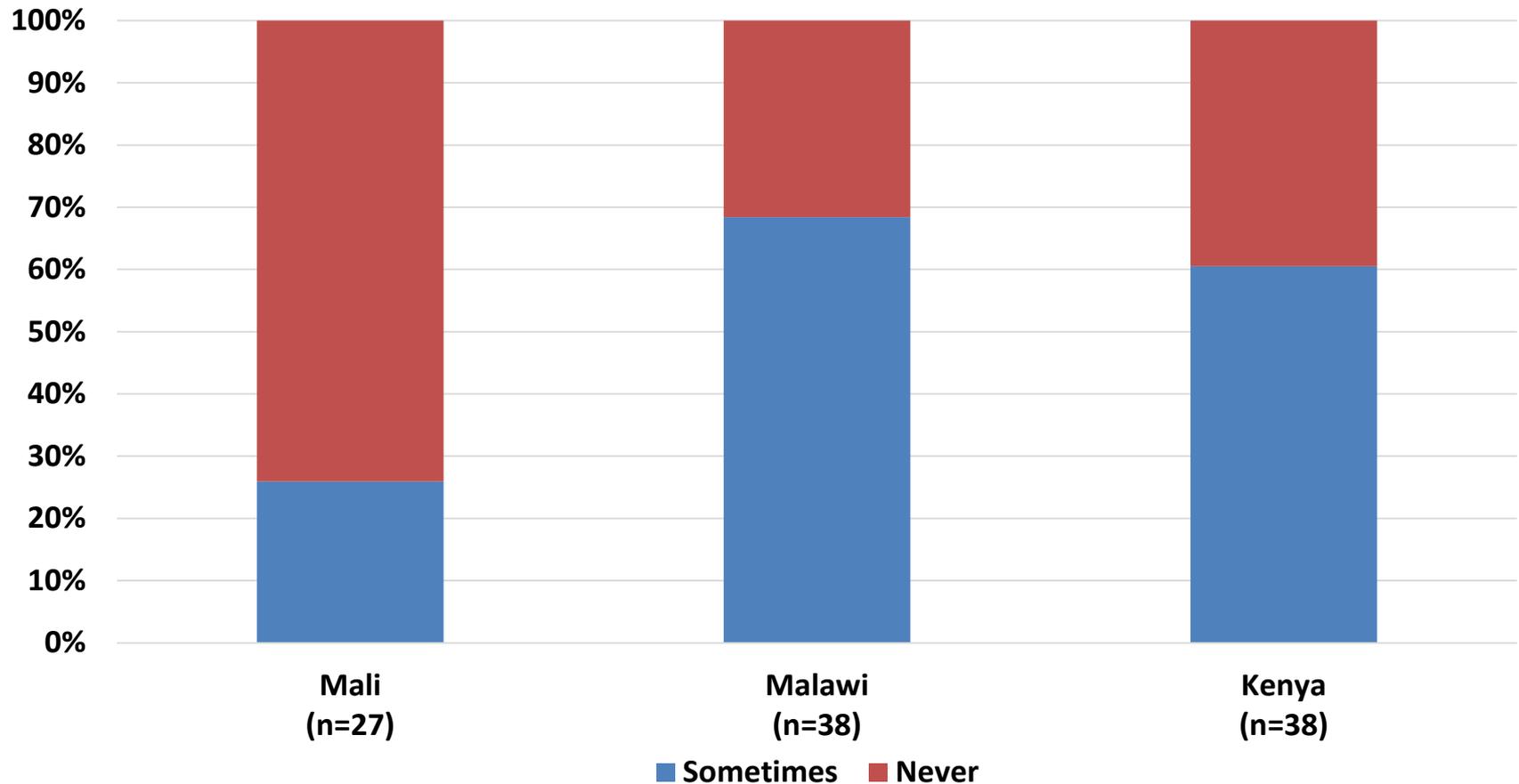


Pregnancy tests available at day of survey

% facilities with test	Mali (n=29)	Malawi (n=40)	Kenya (n=38)	Total (n=107)
“Dip strip” urine test	97	95	100	97
Midstream urine test	7	5	5	6
Rapid blood test	0	5	0	2
Other	0	3	3	2

Note: 21 facilities were not administered this question due to either (1) not typically having urine pregnancy tests available, or (2) not having any in stock at the day of the survey. Facilities could have multiple different types of tests in stock.

Are Women Ever Sent Away to Buy Tests? (Public & private facilities only)



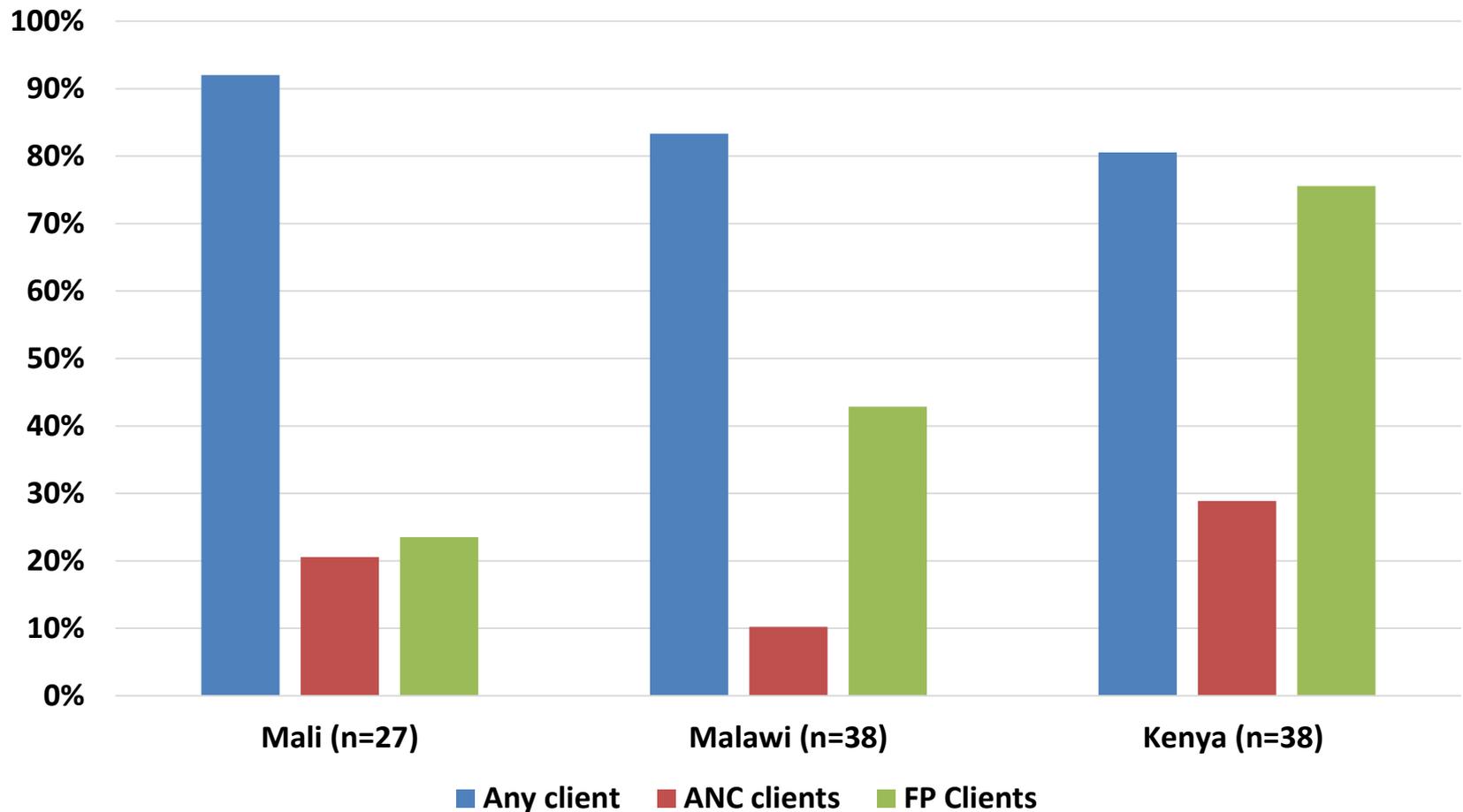
Results from following question: “If there are either occasional stock-outs of pregnancy tests or if pregnancy tests are never available at this facility, are women ever instructed to purchase pregnancy tests elsewhere?”

Price of 'least expensive' pregnancy test available in US dollars by facility type

		Mali (n=30)	Malawi (n=39)	Kenya (n=42)
Private	mean* [range], US\$	1.99 [0.41-3.28]	0.95 [0.35-1.77]	1.94 [0.98-5.87]
	sample size	n=14	n=19	n=20
	<i>No charge for test</i>	<i>(n=1)</i>	<i>(n=2)</i>	<i>(n=5)</i>
Public	mean* [range], US\$	1.72 [0.82-2.46]	0.35 [0.35-0.35]	1.86 [0.98-4.89]
	sample size	n=10	n=9	n=15
	<i>no charge for test</i>	<i>(n=1)</i>	<i>(n=8)</i>	<i>(n=10)</i>
Pharmacy / Drug shop	mean* [range], US\$	2.12 [1.15-2.46]	0.66 [0.35-0.88]	0.84 [0.49-1.96]
	sample size	n=6	n=11	n=7
	<i>no charge for test</i>	<i>(n=0)</i>	<i>(n=0)</i>	<i>(n=0)</i>

*Mean calculated among facilities that reported charging for the test. 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?

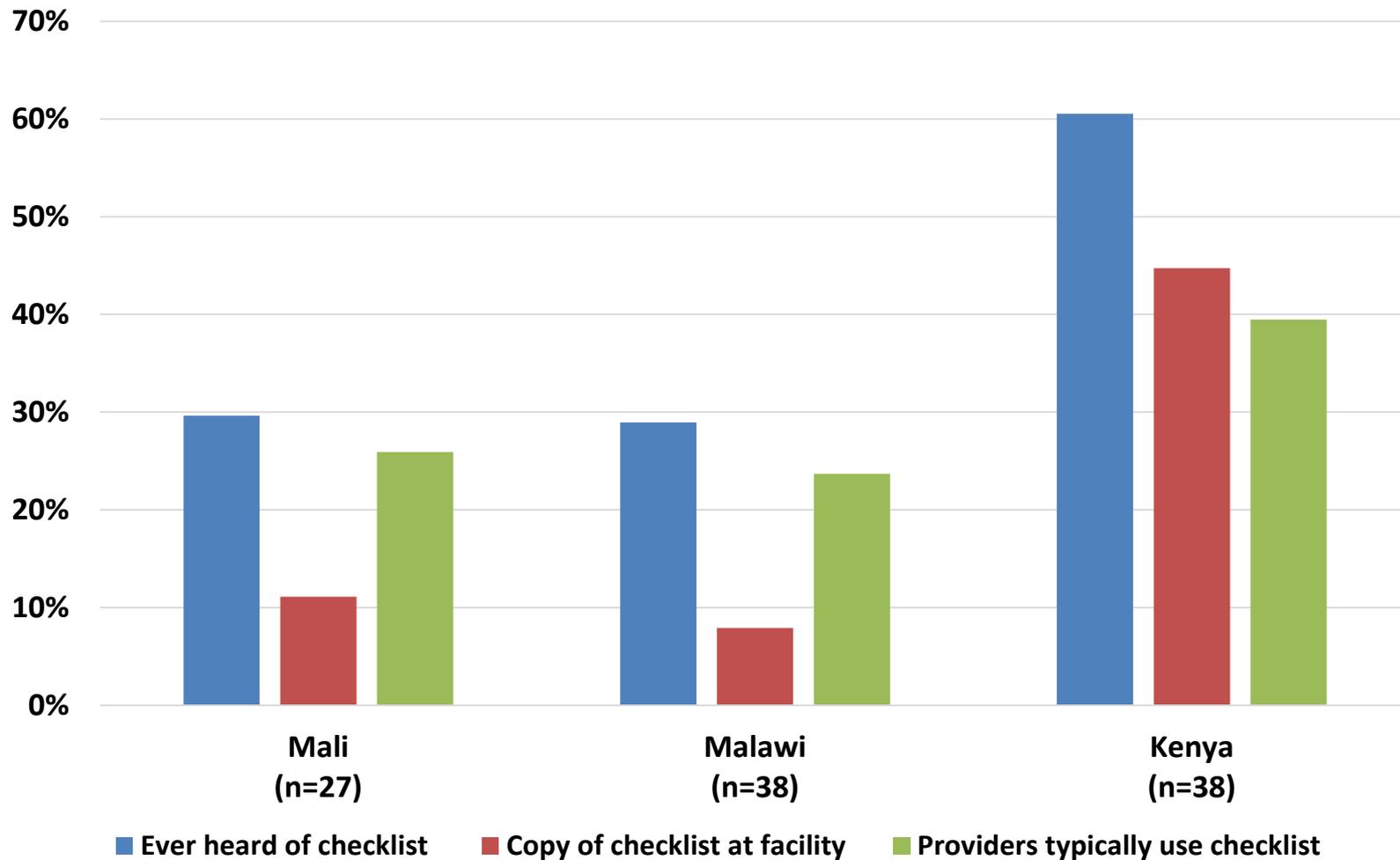
A: No.

Q: Which programs are they procured for?

A: They go for antenatal care to confirm pregnancy.”

-From interview with MOH official, Kenya

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

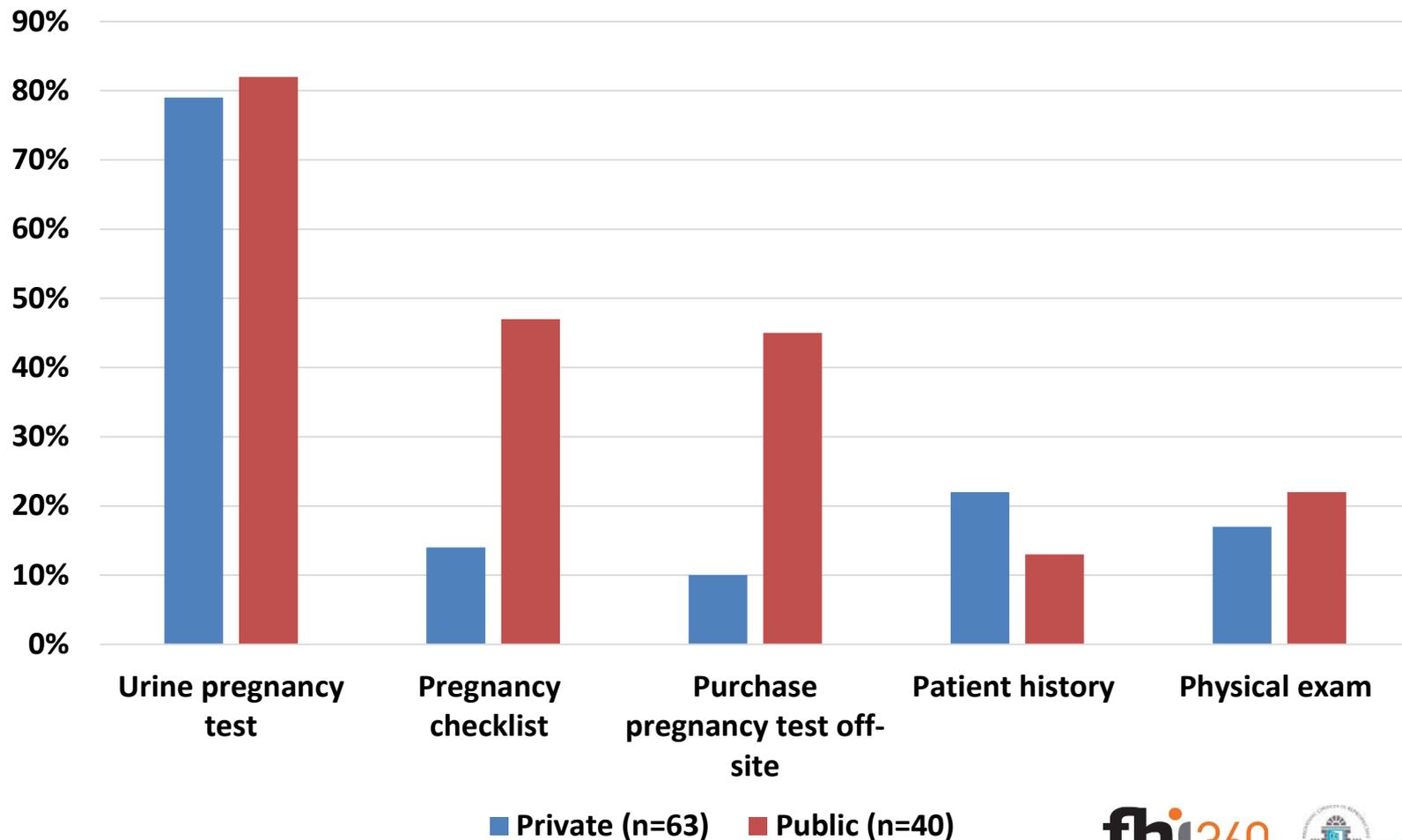




[To rule out pregnancy,] providers typically would find out if the woman had menses or not. Because the Checklist is there, but how many have been trained?...How many have been caught up with? *Typically* it will be a menses history.”

-Interview with MOH official, Kenya

Ruling out Pregnancy in Non-Menstruating Women (public vs. private facilities)



Key Take-aways: Availability & Affordability

- Availability of pregnancy tests in facilities/pharmacies does not seem to be a key area of concern, although in Malawi and Kenya more than half of women are sometimes sent away to another site to purchase pregnancy tests
- Across the three countries, **average price to consumers was 4-21 times** the procurement price and the **range was 4-59 times** the procurement price (assuming a procurement price of US \$0.10). High mark-ups observed across public, private and pharmacies
- Availability and use of Pregnancy Checklist low, particularly in Malawi and Mali

Quality & Supply Chain Considerations

Tracey Brett

Methodology

- Interviews with MOH and National Regulatory personnel in Kenya, Malawi and Mali
- Review of pregnancy test samples from the field
- Discussions with FP global procurers and supply chain stakeholders
- Review of available information on international pregnancy test quality standards.

International Quality Standards

CE MARKING: EUROPE

- Pregnancy tests are classified as **in vitro diagnostic medical devices** (IVD) subject to the European Directive 98/79/EC (IVDD).
- CE marking applies to a **specific product or product family** from the same manufacturer; therefore even if the manufacturer can show previous compliance this does not mean all products manufactured are 'CE' compliant.
- The importer is responsible for ensuring compliance and is often considered the "manufacturer" if marketing under its trademark/own label.
- A 'Notified Body'—an independent organization that has been accredited to assess whether a product meets certain standards— should verify the design of the pregnancy test. Also, their compliance number should appear after the CE mark symbol on the product.

USFDA 510 (K) Clearance: US

- Pregnancy tests are US FDA regulated as Class II devices (moderate risk) and require 510(k) clearance prior to marketing.
- 510 K clearance applies to a **specific product or product family** from the same manufacturer
- FDA staff review a number of performance factors during 510(k) review – including *precision, cut-off performance, linearity, interference, accuracy, and stability*.
- FDA also evaluates inserts & box labelling
- FDA conducts pre- and post-market reviews of pregnancy test devices
- FDA report from July 2013 in US market indicates pregnancy test devices are accurate, with few false positive and/or false negative results generally reported
- No symbol displayed on product

Innovation Fund Project: Quality of Pregnancy Tests

Quality measure (%)	Mali (n=28)	Malawi (n=37)	Kenya (n=38)	Total (n=103)
Valid date (not expired)	93	91	87	91
Written instructions in correct language	43	97	97	82
Illustrated instructions	100	100	97	99
CE mark appears	43	92	63	68

Quality and Procurement challenges

- Concerns about fake or suspect CE-marked products entering markets.
- A number of samples collected through the Innovation Fund project didn't have any evidence of international quality assurance or they had misleading quality marks.
- Limited regulatory approval/oversight at national level.
- Limited information and visibility for procurers on the supply side: vetting of potential suppliers, suppliers' prior performance, methods to verify quality including pre- or post-shipment testing & lack of standardized specifications (labelling, packaging, materials used)
- International procurement is split across a number of buyers – relatively 'low volume and low value' which often translates into no dedicated resourcing for quality assurance, limited sharing of information and pooling of resources.



We cannot give you the data of how many [inaccurate results]. 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

Source of supply of pregnancy tests

Country	Facility type	Source of supply known	Sources of supply
Mali	Public (n=10)	90%	<ul style="list-style-type: none"> Local NGO through social marketing/social franchising Local pharmacy chains Local wholesaler
	Private (n=13)	77%	<ul style="list-style-type: none"> Local NGO through social marketing/social franchising Local pharmacy chains
Malawi	Public (n=9)	100%	<ul style="list-style-type: none"> MOH district hospital MOH medical stores Clinic network
	Private (n=27)	78%	<ul style="list-style-type: none"> Local NGO through social marketing/social franchising Local pharmacy chains Local wholesaler
Kenya	Public (n=15)	93%	<ul style="list-style-type: none"> Local wholesaler MOH medical stores
	Private (n=19)	68%	<ul style="list-style-type: none"> Central hospital International NGO Local NGO affiliate Local wholesaler Local pharmacy chain

National Essential Medicines Lists (EMLs)

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

Question for discussion: Should pregnancy tests be included in WHO and/or national EML's? Would their inclusion lead to an increased demand for pregnancy tests for FP and maternal health programs, and in turn, increase focus on quality and supply chain issues?

*Information about Madagascar EML provided by SHOPS project

Key Take-aways – Quality and Procurement

Our assessment indicates that there is:

- Lack of knowledge/confusion amongst *consumers, providers, importers, distributors, pharmacists* and even in some cases *regulatory personnel* on internationally recognized quality standards for pregnancy tests (including what existing standards mean and how they can be used to ensure that only quality pregnancy tests enter national markets)
- Lack of publically available protocol for pre- and post-shipment testing of batches
- Lack of strategy, focus and harmonization around pregnancy test procurement.

Question for discussion:

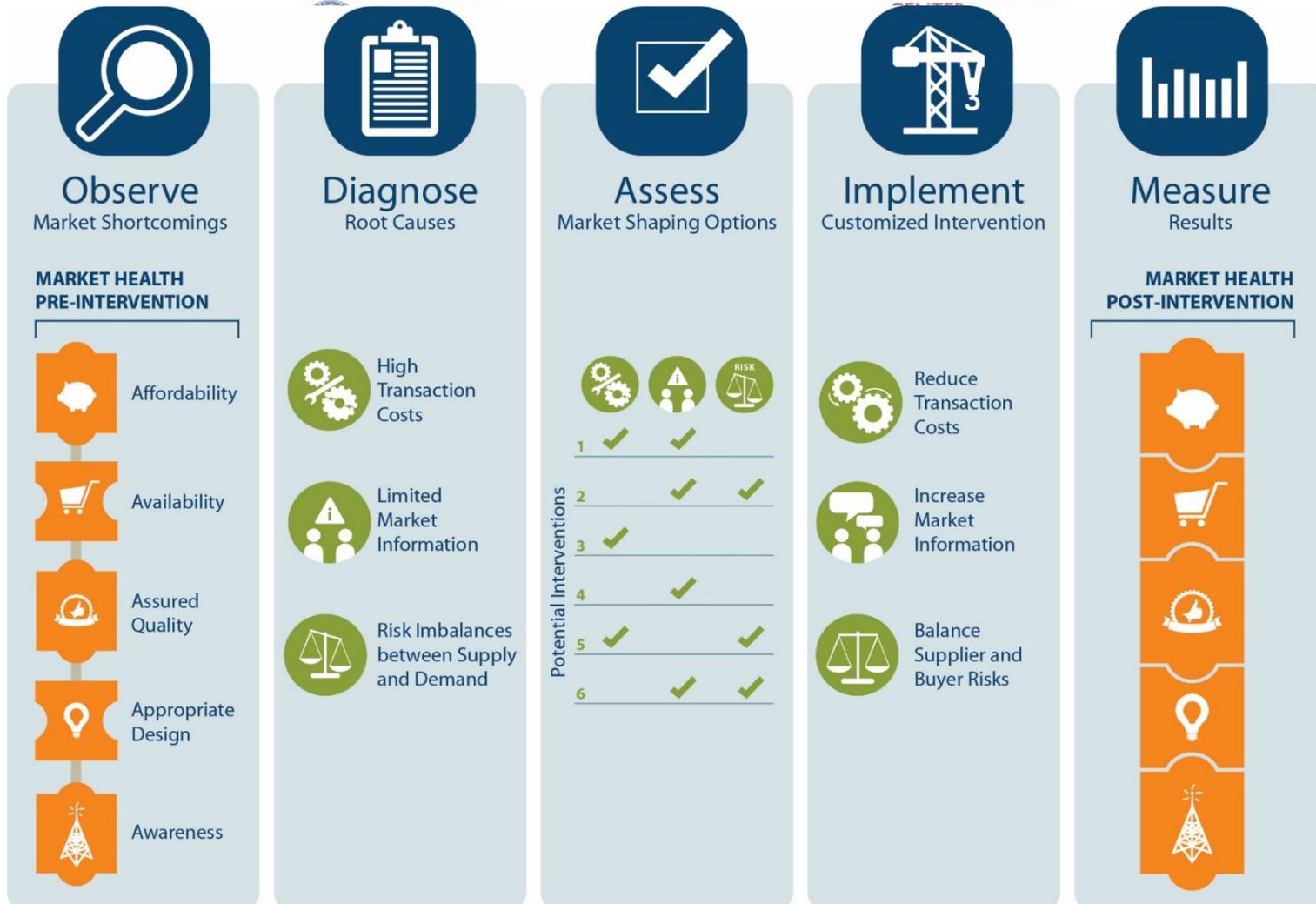
- Would a more coordinated approach among donors and implementing agencies help address challenges around pricing, quality and availability?

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Applying the *Market Shaping Primer* to the Pregnancy Test Market

January 2016

Market Shaping Primer framework can guide analysis of the pregnancy test market



High markups and inconsistent availability appear to be key market shortcomings

Market Factor	Status	Notes
Affordability 	WEAK	
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Availability 	WEAK	
<hr style="border-top: 1px dashed black;"/>		
Assured Quality 	MIXED	
Appropriate Design 	STRONG	
Awareness 	STRONG	

Initial analysis suggests market shaping may be able to address root causes



Diagnose Root Causes



High
Transaction
Costs



Limited
Market
Information



Risk Imbalances
between Supply
and Demand

- Fragmented demand due to fractured procurement by NGOs, national governments, donors, and for-profit actors
- Possible inefficient ordering for different health areas: family planning and ANC orders not consolidated

- Little knowledge of how availability of pregnancy tests can affect access to FP or have other health benefits
- Potential procurers perceive pregnancy tests as expensive
- Unclear provider or end-user demand, including by market sector and across health areas

- Current, uncoordinated demand for pregnancy tests from all sources likely represents small commercial opportunity for manufacturers

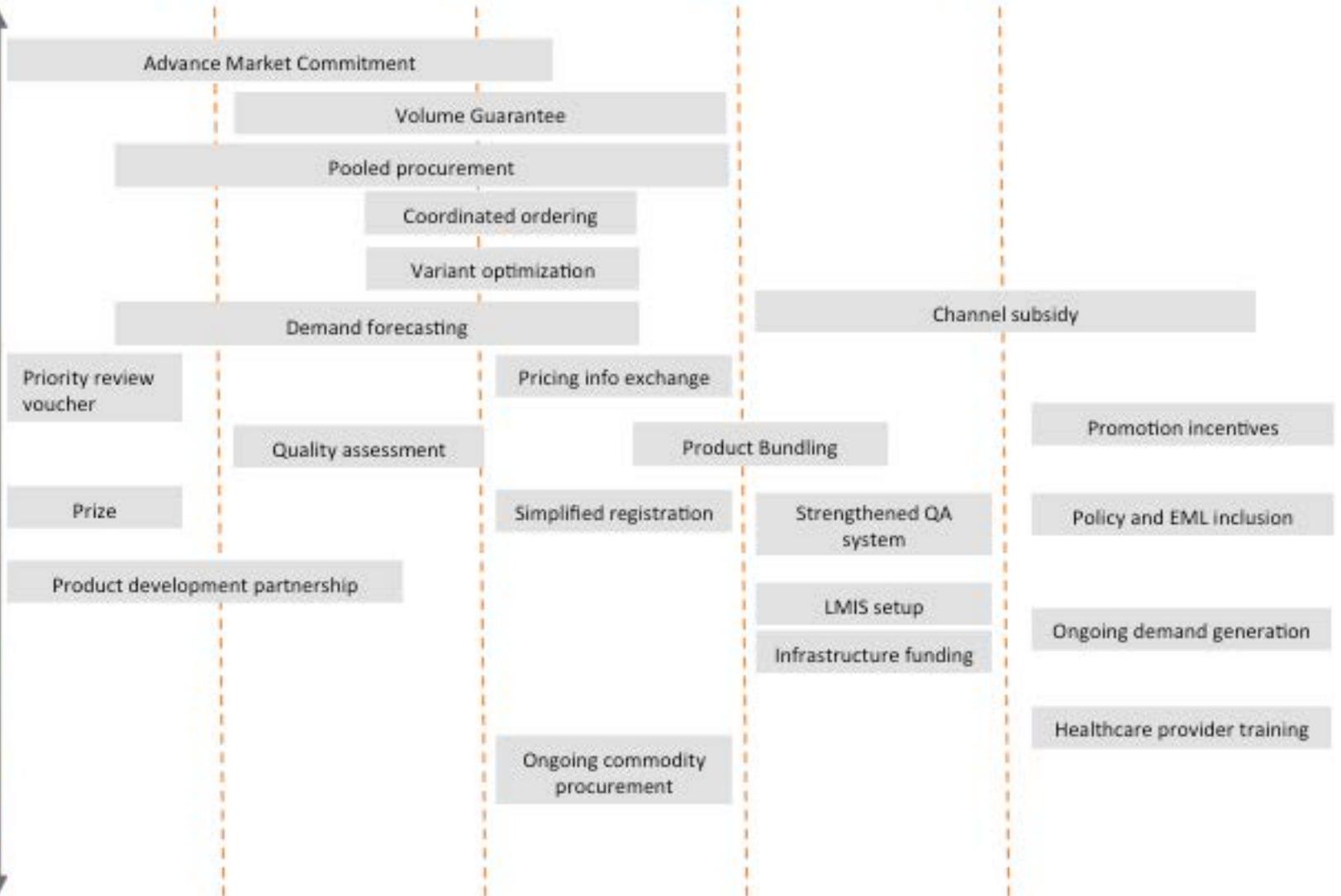
Consider market shaping options to address root causes in preg test market



RESEARCH & DEVELOPMENT → MANUFACTURING → PROCUREMENT → DISTRIBUTION → SERVICE DELIVERY/ USER ADOPTION

Market Shaping Interventions

Global Health Programmatic Interventions



Preg test market shaping: Potential to generate significant health impact, but need more data/analysis

Market Shortcomings



High price to end-users

- Cost of \$0.06-0.10 (ex-factory)
- Average markups of 4x-21x in pharmacies/clinics, and high even in public sector
- MOHs perceive tests to be expensive despite price drops



Uncertain availability

- Tests often not procured for FP programs
- Few countries include pregnancy testing in routine FP services
- Conflicting data on clinic-level availability

Root Causes



Fractured procurement

- Inefficient ordering for FP and ANC programs
- Uncoordinated orders across procurers (donors, NGOs, MOHs, for-profit sector)



Low awareness of potential health impact

- Growing evidence that pregnancy test availability improves access to modern FP, especially LARCs
- Only ~1% of non-menstruating FP clients pregnant, but many unable to prove status
- Potential to encourage earlier access to ANC

Intervention Options

- **Create/consolidate demand forecasts** and share with suppliers
- **Coordinate or pool procurement** of pregnancy tests
 - Across health areas
 - Across procurers
- **Bundle pregnancy test kits with FP methods** for streamlined pricing and distribution
- Conduct **market and programmatic research on critical assumptions** to validate country-specific findings that pregnancy tests can increase FP access and possibly enable earlier ANC

Nearly half of new FP clients are not menstruating at clinic visit, and an estimated **17% of these women are denied FP services¹**

Zambia study showed FP clinics with pregnancy tests **4x less likely to deny a woman FP services**; Madagascar project showed pregnancy tests **increased hormonal contraceptive access by >20% per month²**