Pregnancy Test Market: Exploring potential impact and conducting country-level analyses

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of the
REPRODUCTIVE HEALTH SUPPLIES COALITION
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Agenda

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- **Background**
- Estimating potential impact
- Conducting country-level market analyses

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Non-menstruating women face risk of being denied FP (and ANC) services

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- Non-menstruating women can be denied family planning services
  - *WHO Decision-Making Tool for Family Planning Clients and Providers* states that providers can start a woman on contraception if "reasonably certain she is not pregnant"
  - *Tool* notes that "If in (any) doubt, use pregnancy checklist…or perform pregnancy test."
- Inability to rule out pregnancy can be a barrier to accessing *all* FP methods
- Women who are denied will either:
  - Face a delay in accessing FP;
  - Experience an unintended pregnancy; or
  - Continue to experience unmet FP need
- Women suspecting pregnancy can be prevented from accessing earlier ANC services

1) How large is the problem of same-day service (FP or ANC) denials due to inability to rule out pregnancy?

2) What pregnancy test interventions, if any, can address this problem?

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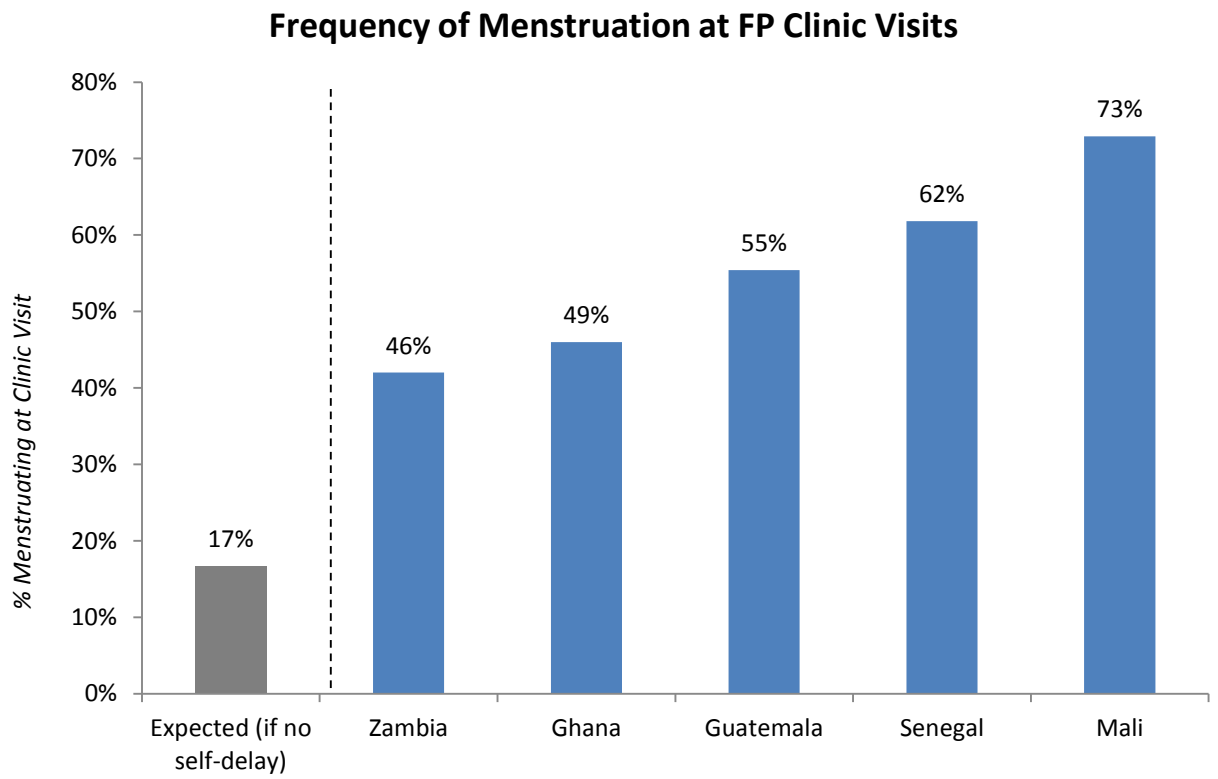
Many women currently "self-delay" to time their FP clinic visits around menses

- Many women currently "self-delay" to time their FP clinic visit during menstruation
  - If women were NOT self-delaying, the percentage of women menstruating on the day of FP clinic visit should be ~17% or 5/30 days in a month

- Increased FP access for non-menstruating women from greater use of both pregnancy tests and Pregnancy Checklist might help address this practice of self-delay



Sources: http://www.ghspjournal.org/content/1/3/382/T1.expansion.html; http://onlinelibrary.wiley.com/doi/10.1111/j.1728-4465.2005.00073.x/pdf ; note estimate for ~17% menstruation rate without self-delay assumes menstruation occurs about 5 days in a 30-day month

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Joint CII, FHI 360 and RHSC Webinar and Idea Incubator kicked off ongoing consultative process

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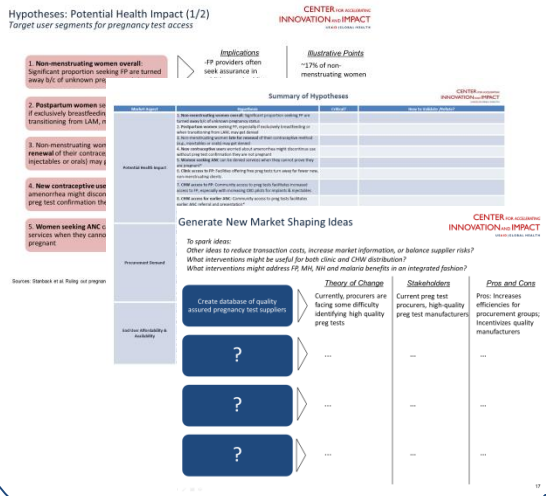
Webinar and Idea Incubator posed hypotheses and started exploratory discussions…



…that engaged donors, researchers, service delivery partners, suppliers, and other stakeholders…

Reproductive Health Supplies Coalition
fhi360
Bill & Melinda Gates Foundation
Abt Associates
William Davidson Institute at the University of Michigan
msh
Jhpiego
Clinton Health Access Initiative
World Health Organization
IPPF
PREGNA International Ltd.
HELM
Bayer
Gynuity
UNFPA
unicef
psi
Marie Stopes International

…who have posed key questions and offered important input

- *Can the observed health impact from pregnancy test access be cost-effectively scaled and replicated?*
- Estimate potential impact with data and/or modeling
- Consider country-specific markets and explore market shaping intervention ideas
- Develop guidance to streamline the procurement process for high quality pregnancy tests
- Continue reaching out to organizations with aligned activities, projects and/or funding

RHSC MDAWG Pregnancy Test Workstream an ongoing forum to consult with diverse set of stakeholders

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Research shows potential for health impact through increased pregnancy test access

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Evidence has shown that **free access to pregnancy tests** can generate the following types of **health impact**:

- **~70% reduction in denial rates** in FP clinics in Zambia when woman is not menstruating (from 15% to 4%)[1]
- >20% increase in access to **hormonal contraceptives** in Madagascar when pregnancy tests distributed by CHWs[2]
  - Ongoing scale up via CHW distribution in Madagascar (led by MSH) can provide additional data
- However, impact can vary and FP impact results from Ghana study were **inconclusive**
- **Reduction in gestational age** at first ANC presentation in South Africa by ~3 weeks[3]
  - Potential maternal and child health benefits from earlier ANC initiation, including earlier access to **malaria IPTp**

[1] Zambia results from FHI360 study and published in *Global Health Science and Practice*
[2] Madagascar results from SHOPS/Abt research and published in *Contraception*
[3] A woman being sent from any clinic to obtain a pregnancy test at a private pharmacy and return with the results increased gestational age at presentation by 2.8 weeks among ANC clients, South Africa study (*BMC* article)

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Initial impact model estimated the number of additional FP users if free pregnancy tests were available in clinics

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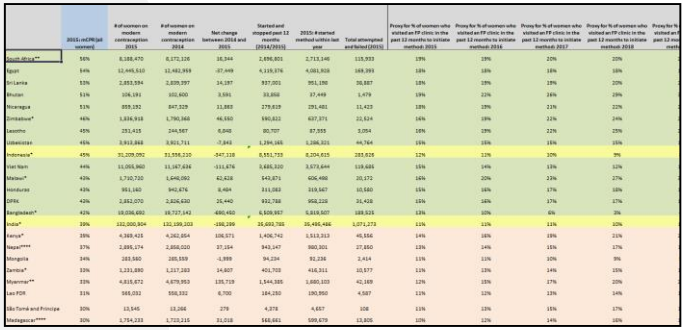
- USAID CII in collaboration with FHI360 developed preliminary model of aggregated impact of free pregnancy tests in clinics for all FP2020 countries

- Outputs include:
  - # of same-day FP denials averted per year
  - # of additional FP users per year

- Sources based on desk review of available data, including DHS, mCPR, peer-reviewed journal articles, and Track20 data

- Key caveat: Very limited country-specific data so relies heavily on FHI 360 Zambia study to estimate increases in FP uptake due to pregnancy tests

- Other considerations to build a more conservative model:
  - More conservative because it does *not* include impact of distribution of pregnancy tests through CHWs
  - More conservative because it does *not* include decrease in number of women self-delaying FP visits due to lack of menses
  - More conservative because it does *not* include health impact of pregnancy tests on ANC access



Planned literature review can seek to identify additional, country-specific data to further refine this impact model

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Impact model estimates substantial number of new FP users for countries selected for market analysis

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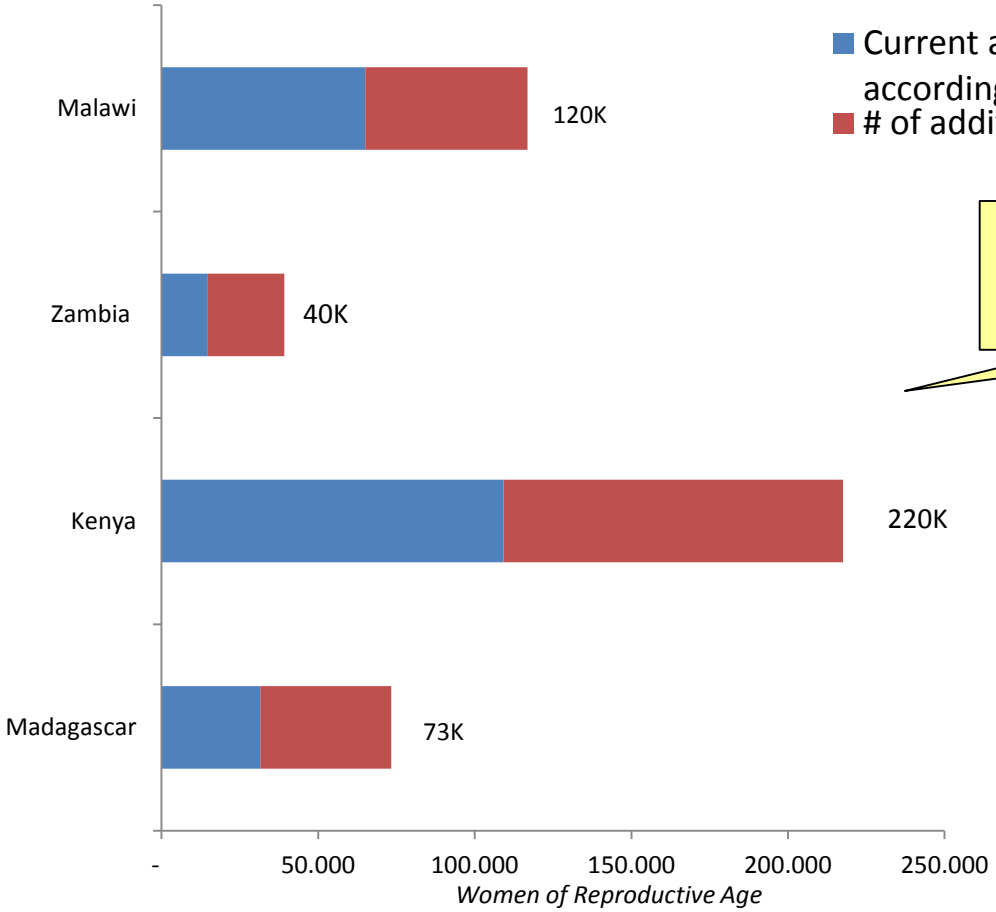
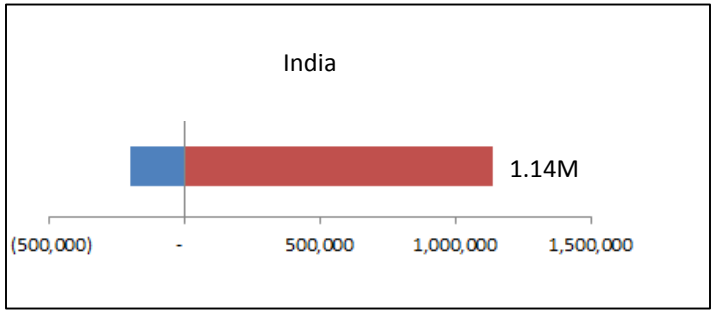
Forecasted Total New FP Users with Free Pregnancy Tests in 2020: Market Analysis Countries



Note that many assumptions use Zambia study findings; planned literature review can seek to identify additional, country-specific data to further refine this impact model



Note: Countries were selected for market analysis based on sites of pregnancy test research and scale-up, USAID mission interest, and feasibility of conducting market research, among other factors

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Extrapolating Zambia experience to all FP2020 countries would mean ~5M same-day denials averted and ~3M new FP users per year

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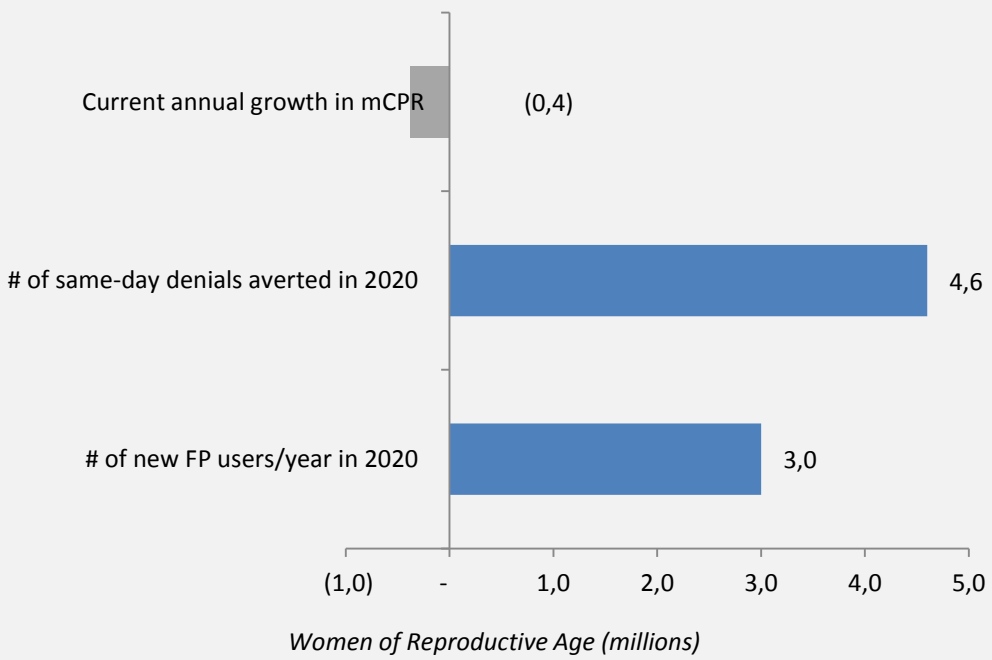

Considerations:

- Additional refinements to the model could consider range of impact scenarios, especially with new data from the planned literature review
- With limited country-specific data, questions remain on how to better estimate individual country impact, especially data on:
  - Frequency of FP denial
  - Reasons for FP denial and whether these are related to inability to rule out menses

Indicates potential scale of the broader opportunity– although not all countries will see impact similar to Zambia's, as evidenced by the inconclusive results observed in the Ghana study

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Extrapolating Zambia experience: how model estimates relate to FP2020 goals

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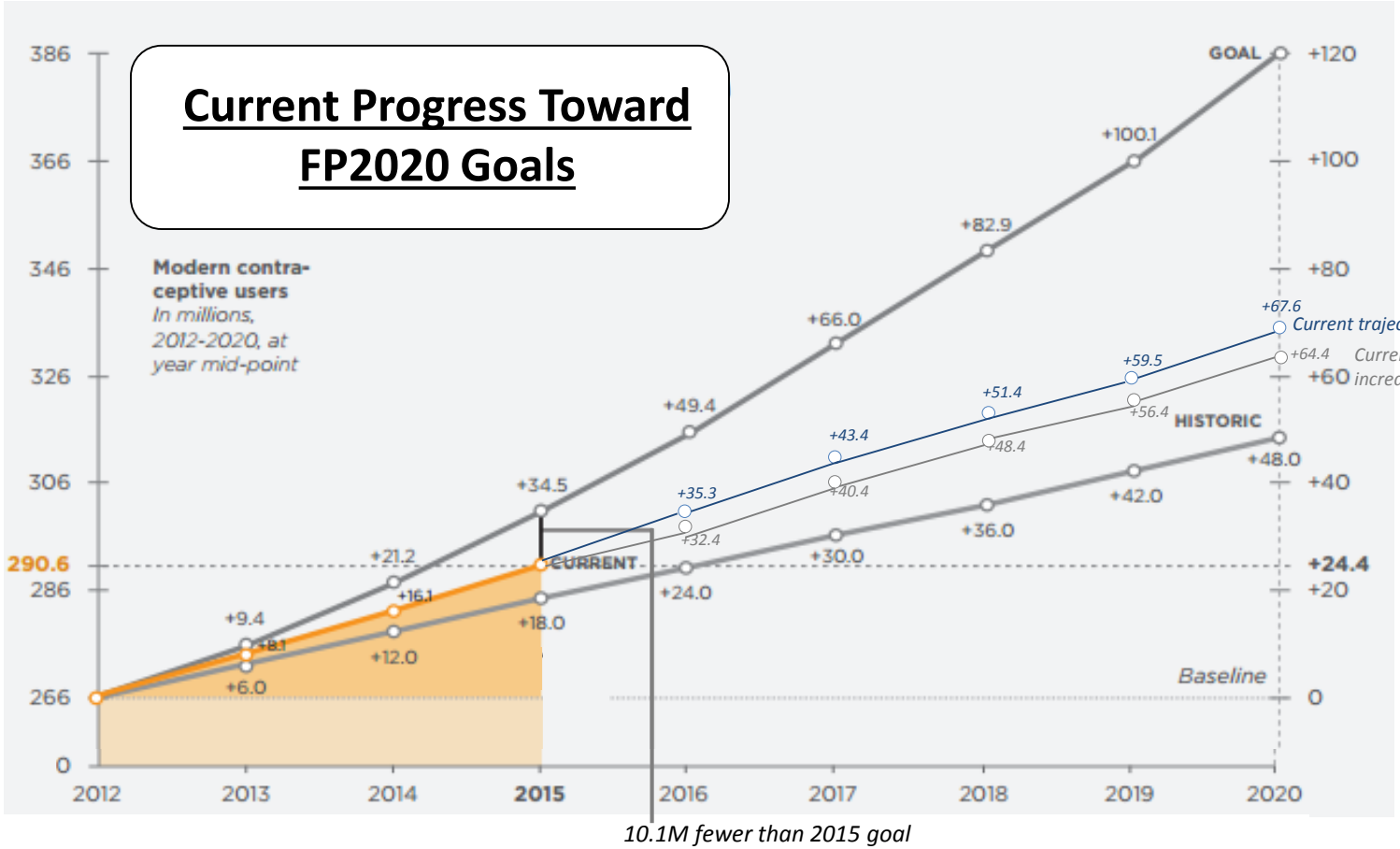

10.1M fewer than 2015 goal

- Historic trajectory of adding only 6M new users/year
- **14M-17M new users/year needed** for FP2020 goal

Impact model estimates availability of free pregnancy tests would make a noticeable, but far from sufficient, impact in accelerating progress

Source: http://progress.familyplanning2020.org/resources

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- Background
- Estimating potential impact
- **Conducting country-level market analyses**

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Country-level market analyses studied market shortcomings and possible market shaping interventions

Conduct in-country market research:

USAID CII and PRH project through SHOPS Plus in collaboration with Abt Associates

Key questions to answer:

- What barriers related to the availability and use of PTs may cause FP clients to drop out?
- What variations in market conditions can be observed between countries?
- What market-shaping and programmatic interventions might reduce barriers?

Scope:

- PT prices, availability and perceived quality in the public and private sectors
- Government policy vs. PT use and procurement
- Service delivery practices

Geography and timeframe:

- Five countries: India, Kenya, Madagascar, Malawi, Zambia
- Assessments conducted June–September 2016

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Focus was on the *Observe*, *Diagnose* and *Assess* steps of the Market Shaping Primer framework

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Market analysis drew on range of qualitative, country-level data sources

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- Interviews with service providers, distributors, wholesalers, retailers
- IMS and public records, on-site observation of PT brands, types, and prices
- Consultations with public officials, manufacturers, procurers (not in table)

Country	Number of site visits				
	Public clinics	Private clinics	Distributors Wholesalers	Retailers	Total
India	13	23	2	8	46
Kenya	3	14	3	7	27
Madagascar	2	7	6	11	26
Malawi	13	24	5	18	60
Zambia	13	7	5	22	47
Total	**44**	**75**	**21**	**66**	**206**

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Overview of findings from country-level market analysis

Indications that vibrant private sector market exists for pregnancy tests (PTs)

- Market shortcomings do not appear to be upstream
- Wide product variety, availability, and range of prices

Mixed availability in the public sector

- With different root causes

Policy and programmatic issues emerged across all countries

- Low and variable awareness and adherence to clinical protocols
- PT use (self and clinic) not directly leading to FP method initiation

Possible interventions will span a continuum and vary by country

- Market shaping and programmatic

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Large range of pregnancy test costs to end-users

Country	GNI Per Capita 2015	PT Cost at Public Clinic USD	PT Cost at Retail Pharmacy USD (range)	PT Cost at Private Sector Provider USD	FP Consultation Cost at Private Sector Provider USD	Contraceptive Product Cost (ECP) USD
India	6,020	Free	0.45–0.96	0.75 –1.49	2.99–4.48	0.75–1.49
Kenya	3,060	0.99–1.40	0.29–4.17	0.97–1.94	0.99–3.00[2]	0.99–1.48
Madagascar	1,400	PTs not available	0.33–3.45	0.49–0.99	0.99–1.66	0.33–3.25
Malawi	1,140	PTs not available	0.28–1.80	0.69 –2.08	0.14–1.39	0.69–2.08
Zambia	3,660	Free	0.10–4.50[1]	Included	2.00–6.50	0.15

1. Excludes midstream digital test found in two outlets, at a maximum price of $12.40
2. Typically includes FP method and service.

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Market shortcomings around availability and awareness arose across the 5 countries

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	Overall	India	Kenya	Madagascar	Malawi	Zambia
Affordability	+ public + private	+ public + private	- public + private	+ public + private	+ public + private	+ public + private
Availability	- /+ public	++ public	- / + public	- public	- public	- /+ public
	++ private	PTs are widely available across private sector, including pharmacies and clinics				
Awareness*	- / +	Practice is to initiate FP method during menses.	Mixed awareness of WHO checklist and variations in practice.	No MOH policy to support public procurement of PTs	Some variation in practice for non-menstruating clients.	General familiarity with checklist and use of PTs.
Assured Quality	++	Minimal to no provider-reported quality issues for PTs. (No actual product quality testing.)				
Appropriate Design	++	Wide variety of PT types and brands generally available. Ease of use is reported for providers and clients.				

14

* On this summary, awareness encompasses issues on the programmatic spectrum of service delivery & user adoption. Addressed in subsequent slides.

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India: a robust PT market but clinical practice may delay access to contraception

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Main client drop-off point

- Non-menstruating clients asked to return during menses

Market strengths

- PT public procurement fully in place & ongoing
- PTs widely available in both sectors at various prices

Bottleneck/shortcoming	Root cause
Providers do not use WHO checklist to initiate FP	➢ Cultural norms, provider training, risk aversion
Providers use PTs only for clients with delayed menses	➢ Disconnect between PT use & access to FP services
High home use results in lost opportunity to reach potential FP users	

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Zambia: Policies and procurement in place, but signs of execution challenges

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Main client drop-off point

- FP clients must buy a PT in the private sector when they are not available at the public clinic, incurring delays and added costs

Market strengths

- MOH policy supports PT use for FP
- National PT procurement system
- PTs widely available in private sector

Bottleneck/shortcoming	Root cause
PT stockouts at public clinics	➢ Ineffective or deprioritized ordering ➢ Insufficient supply chain visibility, weak ordering process, logistics issues
Demand for PTs in public clinics exceeds supply	➢ Insufficient funding
Commercial PTs may not be affordable to some clients	➢ Commercial built-in margins drive up PT prices

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Next steps to consider: addressing impact questions and developing intervention ideas

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How to address pending impact questions?

- Conduct comprehensive **literature review** to uncover more data or proxies on FP denial rates, reasons, and use of pregnancy tests
- Continue **collaboration** with aligned activities, such as scale-up in Madagascar, Fpwatch data collection, or CHW cost-effectiveness modelling
- **Refine impact model** with additional data uncovered from literature review
- Consider **new research opportunities** to generate country-specific data in order to prioritize countries for analyzing potential interventions

How to further develop market shaping and other intervention ideas?

- Further develop and analyze **initial intervention ideas** generated by market analysis and stakeholder discussions
  - Build on market analyses and consultations
  - Engage country stakeholders
  - Consider critical behavior change or other programmatic interventions
- Assess **prioritization of countries**, incorporating any new data uncovered by literature review to estimate potential impact
- Consider how to incorporate new procurement and **quality guidance**
- Consider how to field test and apply new **clinical guidance**

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Appendix

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Appendix: Assumptions Table

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Variable	Assumption	Source	Notes
# WRA	Varies by country and by year	World Bank Health Nutrition and Population Statistics	
% of women who visited an FP clinic in the past 12 months to initiate method (starting or restarting)	Country –specific proxies with built-in yearly increase	DHS; 2004 FHI360 Egypt study; FP2020 Track20	**[% of women who started on current FP method in the last 12 months]** derived from DHS discontinuation rates (took average discontinuation of 33% for all countries with the exception of India and Indonesia for which used 27%) added to country-specific annual mCPR growth rates from Track20 + **[% of women seeking FP in the last 12 months who were denied same day and did not get a method within a year]** derived from Egypt findings: "% of women turned away for any reason" from Egypt 2004 study who did not obtain a method within 1 month of denial/"Egypt 2005 mCPR" from DHS = 4.35%/56.5% = 7.7% in order to approximate *conservative* denial rate + **[Yearly increase/decrease in % of women who visited an FP clinic in the past 12 months to initiate method]** using country-specific mCPR annual growth rates from Track20
% of women not menstruating during FP visit	44%	Stanback J, Vance G, Asare G, Kasonde P, Kafulubiti B, Chen M, et al. Does free pregnancy testing reduce service denial in family planning clinics? A cluster-randomized experiment in Zambia and Ghana. Glob Health Sci Pract. 2013;1(3):382-388.	Many women currently "self-delay" to await menses before presenting at a FP clinic. If women were not self-delaying, the percentage of menstruating to non-menstruating women would be about 1/6, or 17%, assuming that a woman bleeds about 5/30 days per month. The percentage menstruating in Zambia was between 40%-50%. Model is conservative in that it does not take into account decrease in self-delays once it is known that pregnancy tests are widely available for free in clinics
% of non-menstruating women denied FP due to lack of menses	15%	Ibid	
% of non-menstruating women for whom denial is averted by availability of free pregnancy tests	73%	Ibid	
% of women denied that successfully obtain FP method on 2nd try within 1 year (used to derive # of new FP users per year)	35%	2004 FHI360 Egypt Study	Proxy for this variable is calculated as follows: % of women who were denied FP due to lack of menses that obtained an FP method on their 2nd try within one month (70%), reduced by 50% to reflect unique circumstances in Egypt (higher GDP, second highest mCPR)