



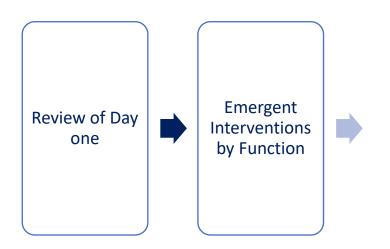
Family Planning Health India Market Description

FHM Engage India Workplan Annexure

June 17th, 2023 Delhi, India

Day I





Market Systems Frameworks

What is market development?

MDA is **NOT** about...

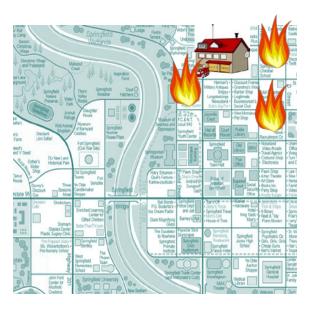
Dealing with symptoms...



MDA is NOT about...

Dealing with symptoms...

... More efficiently



MDA IS about...

Addressing the underlying causes of the problem



Why apply a Market Development Approach?

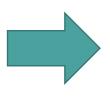
Analyzing a market through the lens of Market Systems can identify market constraints that inhibit barriers to sustainable use, while ensuring interventions deliver on:

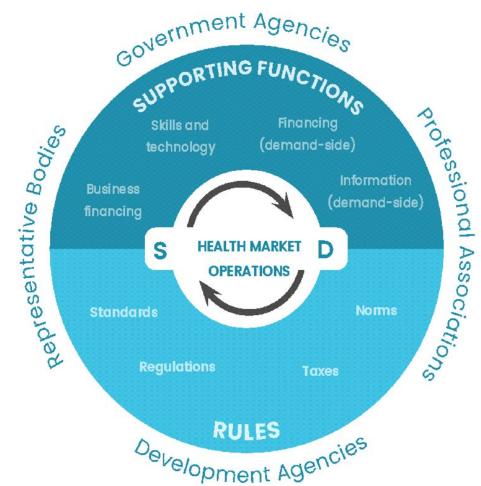
- Access to essential products or services across all sectors;
- Quality assured products and services;
- Equity objectives, supporting affordability through competition and targeted use of subsidy;
- Choice focusing on products & services that meet the needs of individual consumers with a range of needs;



FHM Engage Market Development Approach

An <u>analytical approach</u> that begins with an understanding of current market performance in terms of users as well as market functions and actors

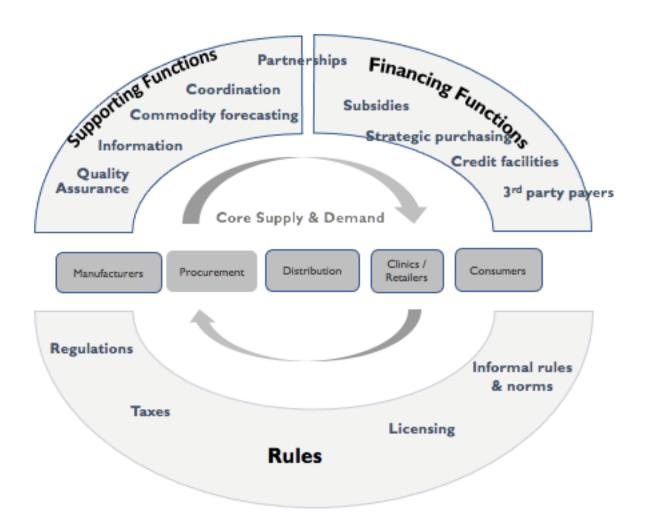




Measured in respect of:

- > Impact
- Sustainability
- > Scale

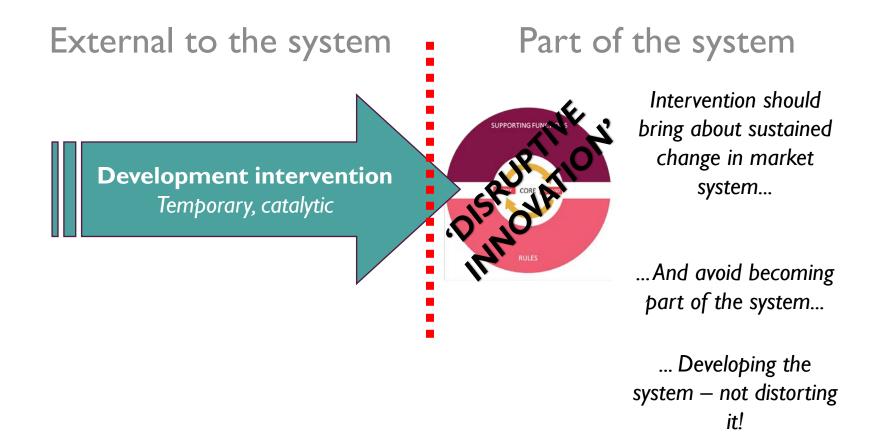
Representing the market as an ecosystem (The 'donut')



- I. Supply & demand functions describe the value chain - from manufacturing to procurement, to distribution and users
- 2. Supporting Functions describe the critical elements required to support a market that reside outside supply & demand. This includes government agencies assuring quality of products & services, and market stewardship functions such as leading and coordinating market actors, forecasting and procurement.
- 3. Financing Functions address issues related to how services and products are paid for including the role of subsidy
- 4. The Rules environment includes regulatory bodies and restrictions on how products are imported, registered, and taxed. Informal rules such as stigma play large role

¹ Barbara O'Hanlon, Ohealth Consulting & Springfield Centre

Role of FHM Engage: external to or embedded in the market system?



Market Facilitation

CHARACTERISTICS OF MARKET DEVELOPMENT

Recognizes the long view is required to support systemic change – markets are slow to evolve

Agnostic and process-driven approach that includes partner organizations

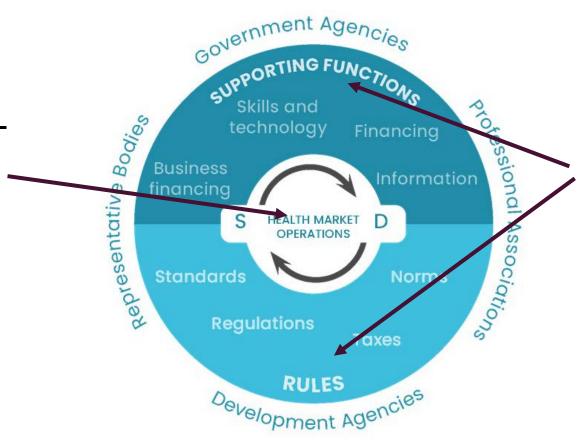
Emphasizes the role in facilitating markets rather than attempting to provide services directly

Ownership by local champions and players, which may be supported by global or regional experts

Active local stakeholders' participation and stewardship

Market System Framework underpins all market analyses

Start with the user - understand who the market is failing



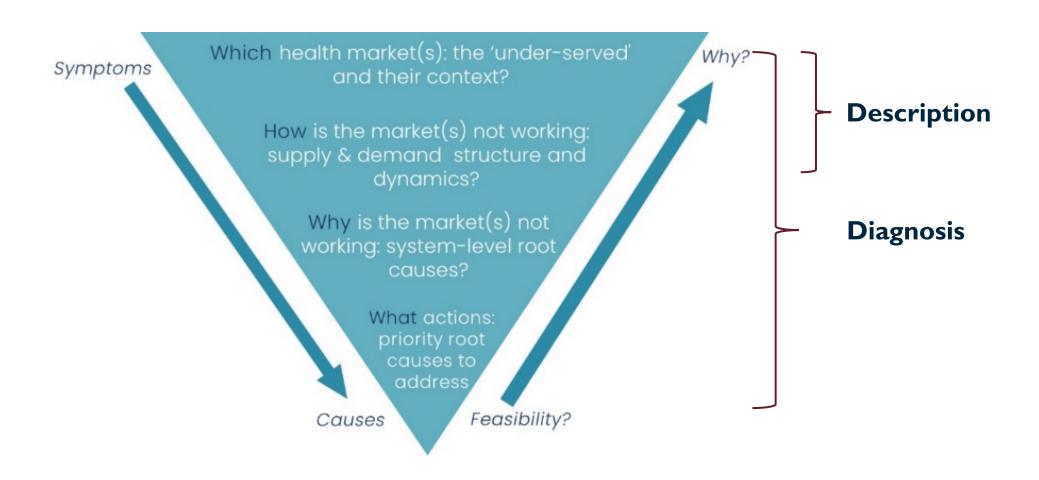
Diagnose how the market is failing to address those user needs

Understand the underlying root causes of those failures

Market description aligns understanding of FP situation, role of pvt sector Identifies potential market challenges and opportunities

May reveal areas for further data gathering and deeper analysis

Description / Diagnostic Process

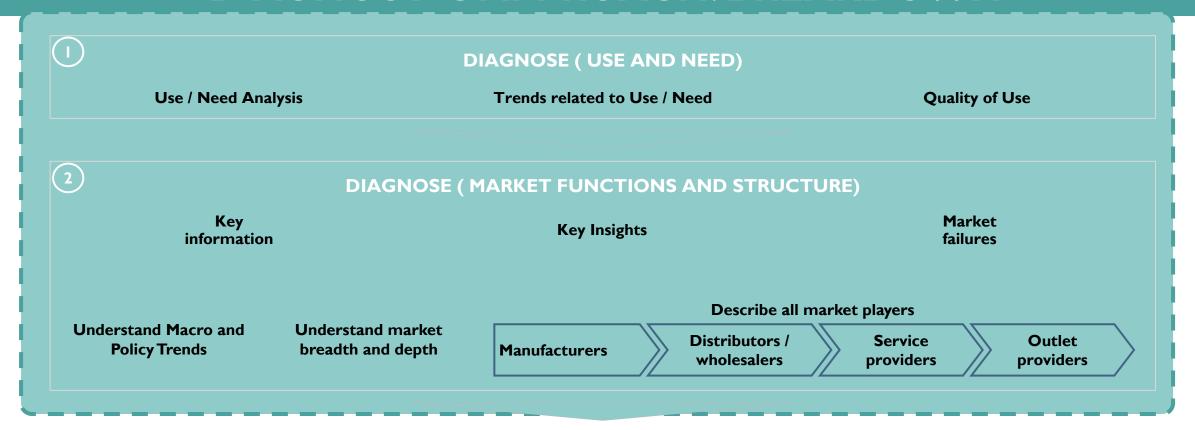


Rapid Market Performance Analysis

AIMS Worksheet: Market system performance analysis for INSERT COUNTRY & MARKET

Market characters			Α	1	М	Observations
Core Market	Supply					
Mar	Demand					
Supporting Functions	Financing	S & D				
		Subsidies				
		Business				
	Info	Supply				
		Demand				
	Skills, Capacity					
	Stewardship					
Rules & Regs	Regulations					
	Tariffs, Taxes					
	Standards					
	Norms	Supply				
		Demand				

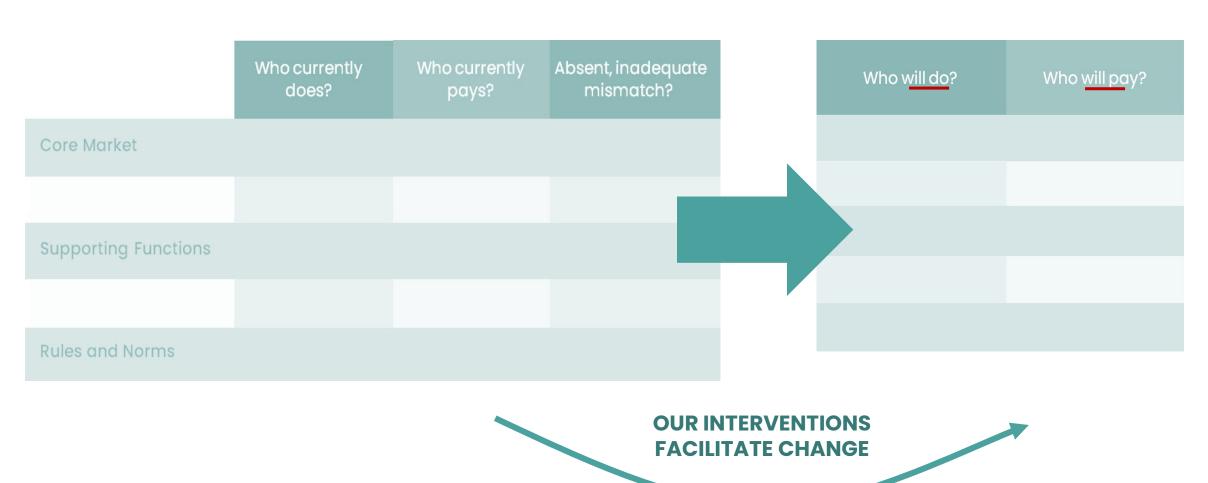
MARKET DESCRIPTION DIAGNOSTIC APPROACH: BREAKDOWN



OESIGN: WHERE AND WITH WHICH PLAYERS DO WE WORK IN THE MARKET?

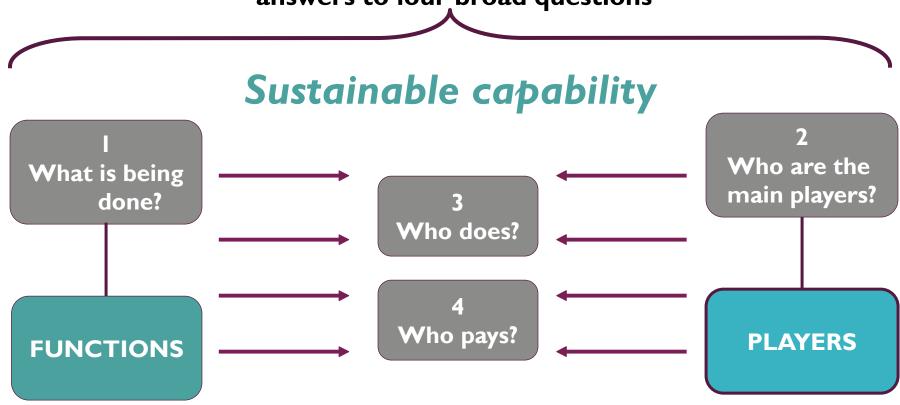
DELIVER & LEARN: HOW DO WE GET THERE?

Develop a Theory/Vision of Change for a 'well' performing market



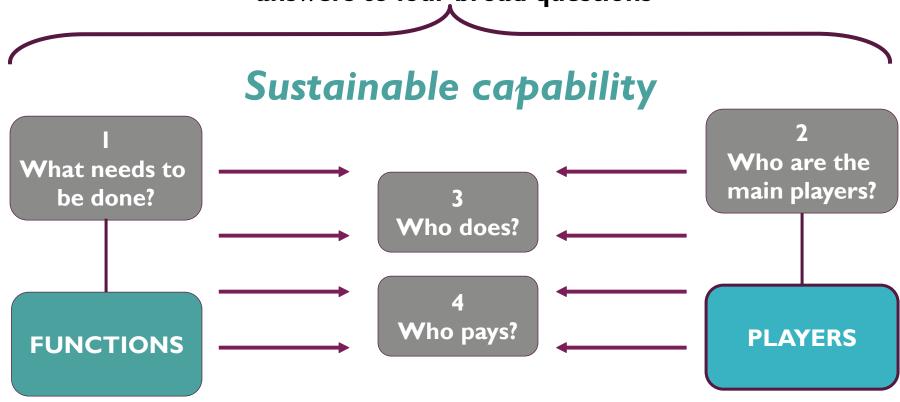
Capability: the central concept in sustainability

In order for markets to operate in a sustainable manner we need answers to four broad questions



Capability: the central concept in sustainability

In order for markets to operate in a sustainable manner we need answers to four broad questions



Feasibility Check

Market player with capacity to deliver change, but lacking in motivation

(Low will, high skill)

SKILL

Market player
possesses both
incentive and
the capacity to deliver
change

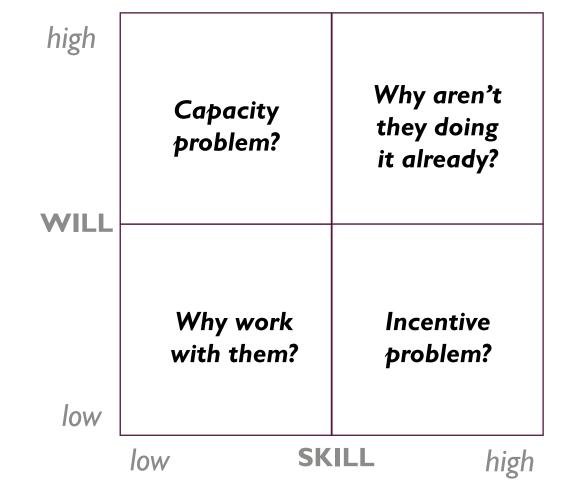
(High will, high skill)

Market player lacks
both incentive and
the capacity to deliver
change

(Low will, high skill)

Market player with strong incentives for change but lacking capacity to deliver this

(High will, low skill)



WILL

17

Strategic Logic Model

List health outcome(s) **IMPACT:** Improved Health Outcomes OUTCOMES: Vision of well performing market Increased access to improved healthcare at affordable costs List market system changes OUTPUTS: Improved performance of mixed health markets List market interventions areas and activities INPUTS: Market Interventions

Market Systems Logic Model and Theory of Change

Improved

Rule Functions

Policy Regulation

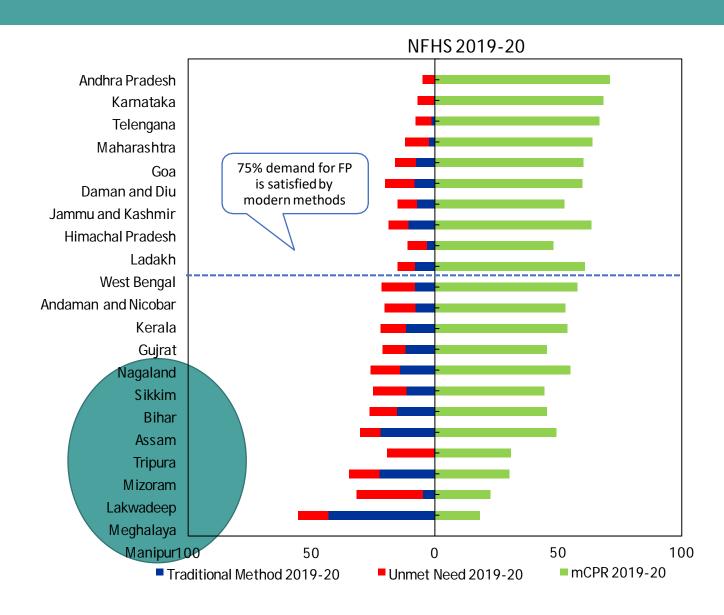
Taxes / Tariffs

Design Approach Diagnostic Approach Theory of Change Who is the **IMPACT:** Improved Health Impact **Market Failing?** Health Outcomes Improved behaviors among target populations (USE / NEED) [Increased correct and consistent Use/Adoption of health products, services and information] Vision of well-How is the **OUTCOMES:** Increased access performing market failing? Improved behaviors among market players for a functioning market system market to improved healthcare/product operations at an affordable cost Improved Core **Increased Support** Functions (Demand and Where do we **Functions** Supply) **OUTPUTS:** Improved work in the performance through market market system? Market 4Ps system changes Intelligence/information/ (across market players) Coordination /Financing Activities to achieve How do we Interventions designed to address the the market system **INPUTS:** above functions get there? changes Market Interventions

USE NEED ANALYSIS

India Use Need Analysis

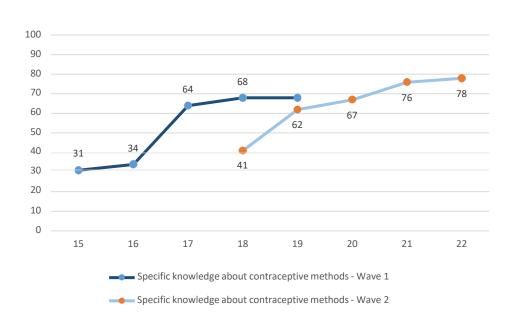
- Teenage pregnancies higher than
 10% in East/Northeast India.
- 2. Favorable shifts to reversible methods.
- 3. In 5 states Urban unmet need is higher than rural.
- 4. Place P for Use/Need Intervention and consumer segments aligned with USAID FHM engage focus.

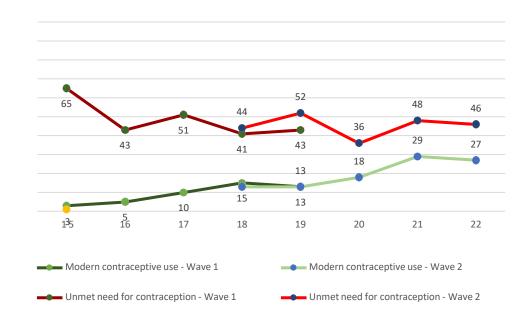


Young People (60% of Pop) needs are unmet

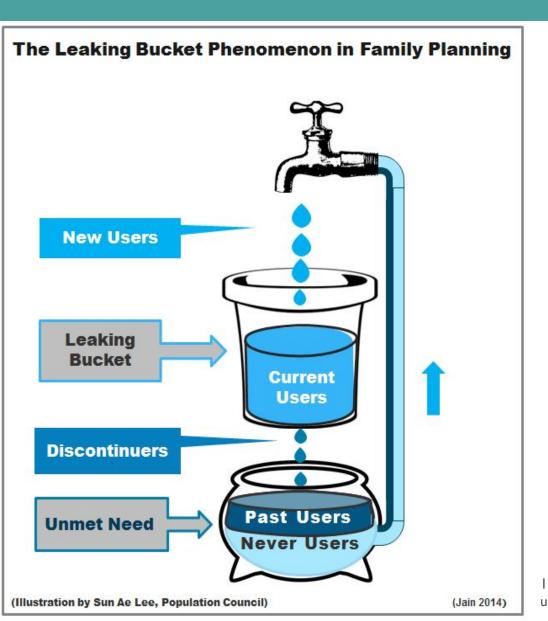
Low contraceptive knowledge, low use of contraception in early years of marriage is linked to high levels of unmet need for contraception. When the young people use contraception they go for reversible contraceptive methods and most get those from private sector.

Knowledge, use of contraceptive methods among older adolescents married, recruited in 2015-16 (%)





Quality of Use: Discontinuty remains High



Awareness/ Acceptance

 >60% CMWs have never used a modern method; OCPs, IUDs and ICs have been used by a very small proportion of CMWs education

Availability /
Access

- Govt. is preferred source for IUD and sterilization.
- 90% of the users prefer pharmacies for purchasing condoms and OCPs;

Affordability

Out of CMWs who discontinued¹ use of IUDs, condoms and OCPs,
 1% mentioned high cost as a reason for discontinuation

Assured Quality

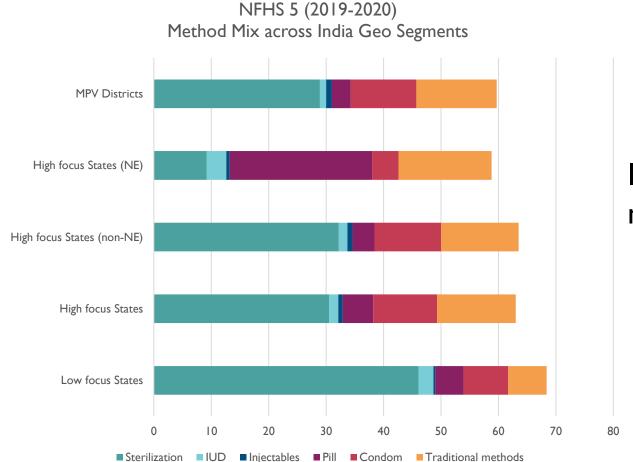
 A very small proportion of users were informed of potential side effects before they adopted modern family planning methods (40% for IUDs, 26% for OCPs and 21% for sterilization)

Appropriate Design

 Out of CMWs who discontinued¹ OCPs, 22% discontinued due to side effects and 3% because the method was inconvenient to use

I. Defined as percent of CMWs who have used the mentioned modern FP product in the past, but are currently not using any modern FP method

Basket of choice, Quality of information and Services Still a gap



In some states, Sterilization is often the first modern method adoption for women in India.

Source: India FP 20230 Vision

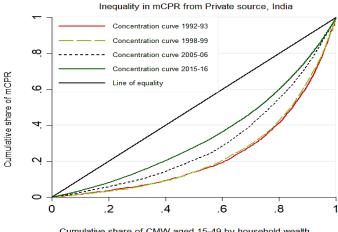
Private sector role important



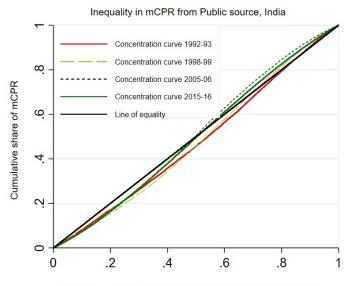
Inequity in mCPR is primarily attributed to user pattern of services in private sector



Expanding private sector may be helpful in reducing economic inequities

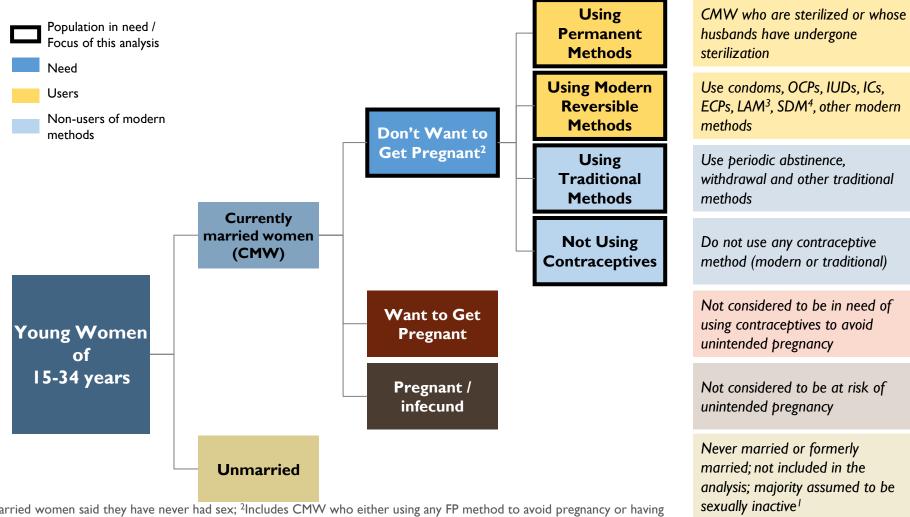






Cumulative share of CMW aged 15-49 by household wealth

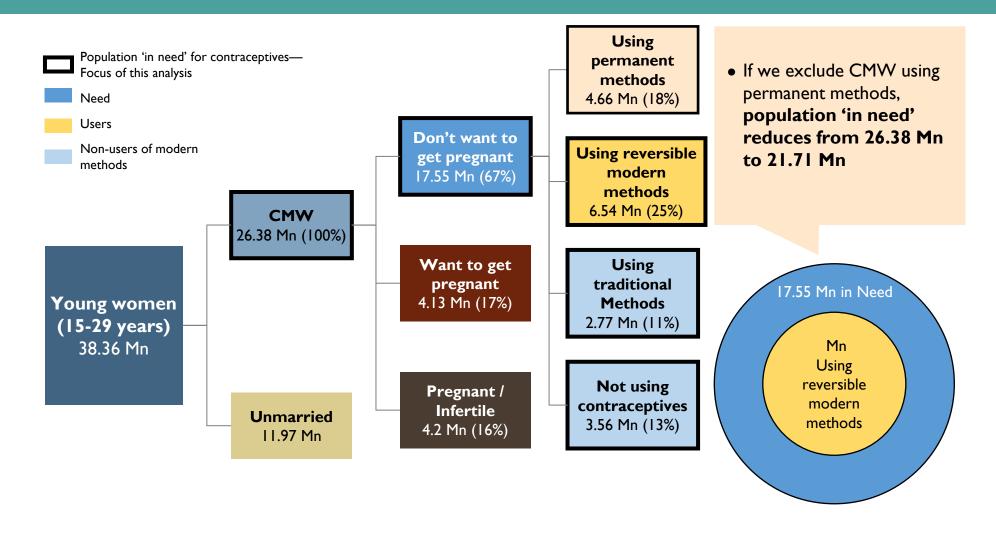
Modern family planning (FP) method Use / Need - Schematic Representation



¹As per NFHS 2019-21, XX% of unmarried women said they have never had sex; ²Includes CMW who either using any FP method to avoid pregnancy or having unmet need for contraception (includes pregnant women whose pregnancy was mistimed or unwanted); ³Standard Day Method, ⁴Lactational Amenorrhea Method

Sources: NFHS 2019-21

Modern FP Use & Need among 15-29 years women—Select USAID focus states*



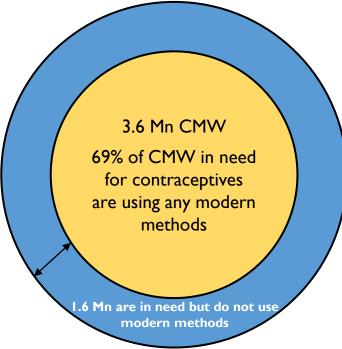
Includes pregnant CMW whose pregnancy was mistimed or unwanted Note: % indicates percent of CMW of 15-34 years

Sources: Based on 2023 female population projections of 15-49 years by RGI; female population of 15-34 years derived using NFHS 2019-21 sample weights

Modern FP^I Use / Need representation among women of 19-29 years (select Indian states)

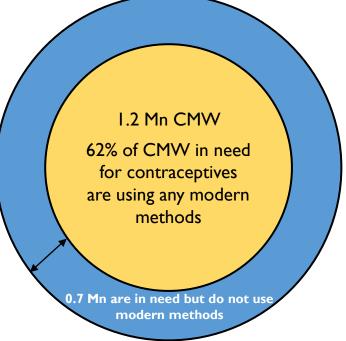
Maharashtra (matured)

5.2 Mn CMW² are in need (don't want to get pregnant)



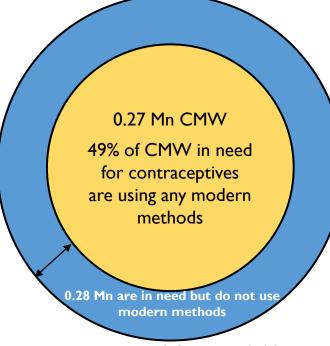
Total number of CMW = 8.3 MnmCP³ = 44% Assam (evolving)

1.9 Mn CMW² are in need (don't want to get pregnant)



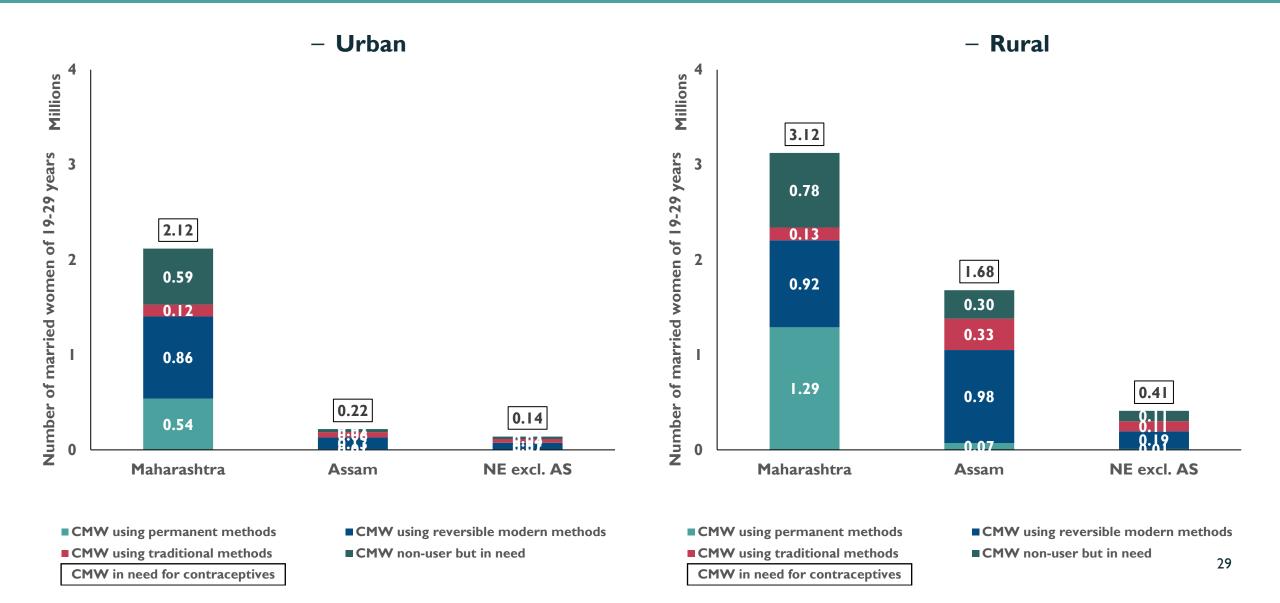
Total number of CMW = 2.7 MnmCP³ = 45% Northeastern states excluding Assam (challenging)

0.55 Mn CMW² are in need (don't want to get pregnant)

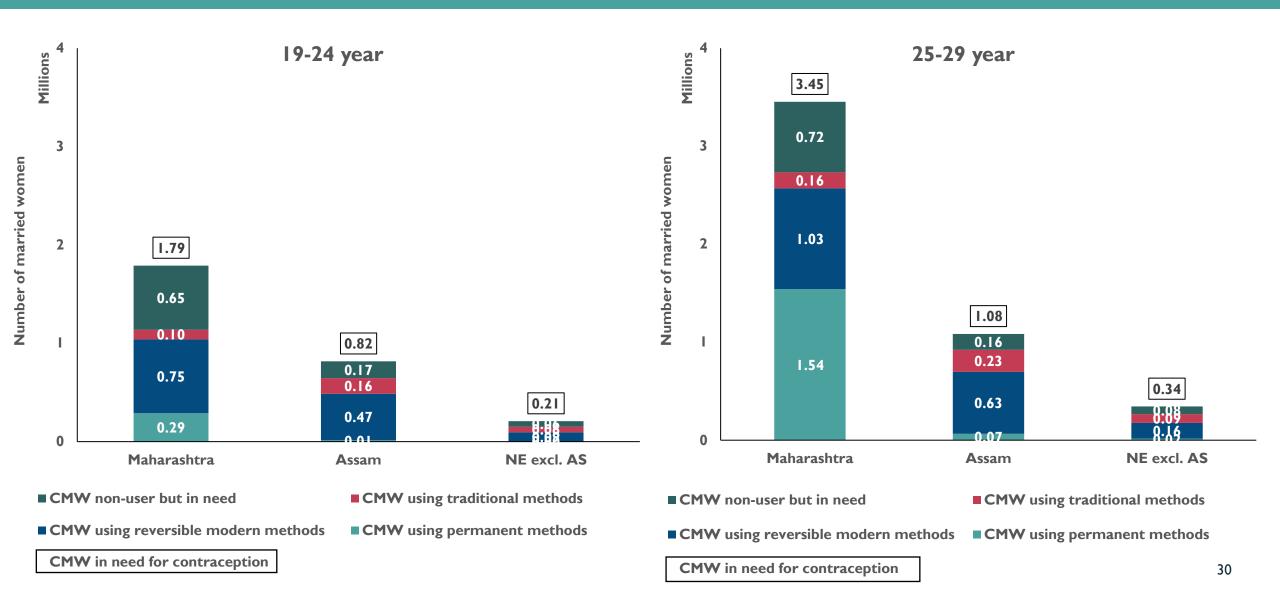


Total number of CMW = 0.82 MnmCP³ = 33%

Number of married women of 19-29 years using (and not using) contraceptives among those who are in need for contraception from urban and rural areas of select Indian states



Number of married women of different age groups using (and not using) contraceptives among those who are in need for contraception from select Indian states



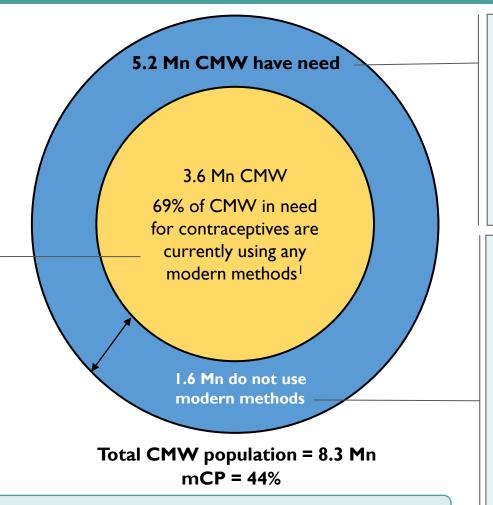


Maharashtra

(Matured)

Modern FP Use / Need – Maharashtra (NFHS 2019-21) among currently married women of 19-29 years

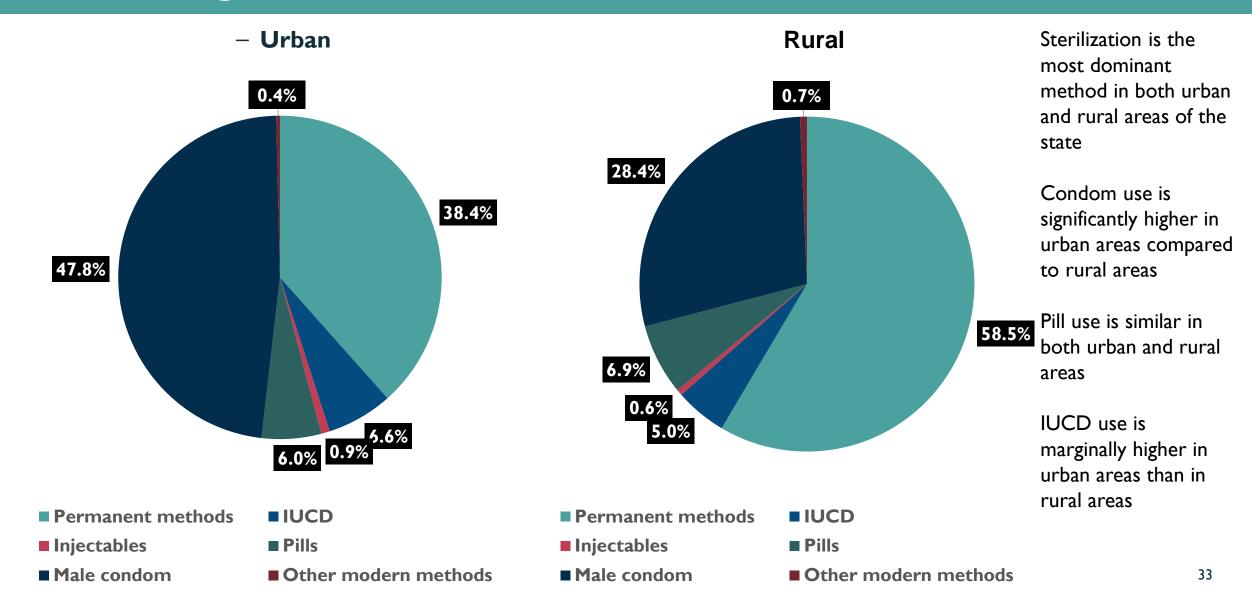
- 3.6 Mn CMW (62% of CMW who are 'in need' for contraceptives) currently use modern methods
 - 51% of modern method users are using permanent methods i.e., female/male sterilization
 - Condoms are the 2nd most used modern method (36% of modern method use)
 - While share of sterilization is high in rural areas (58%), condoms have a higher share in urban areas (38%)



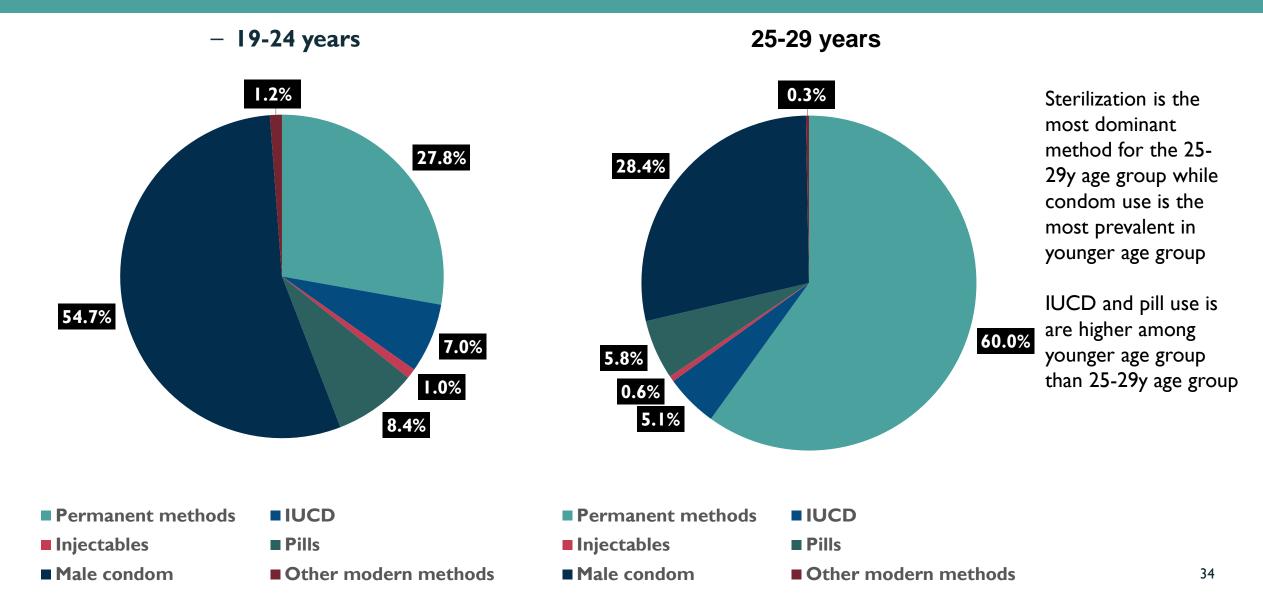
- Out of 8.3 Mn CMW in Maharashtra, 5.2
 Mn are in need for contraception (i.e., the population at risk of unintended pregnancies if not using a contraception)
 - If we exclude permanent method users, this reduces to 3.4 Mn
- Rural Maharashtra accounts for 3.1 Mn (64%) CMW 'in need' for contraceptives
- 1.63 Mn CMW in Maharashtra need contraception but do not use any modern methods
 - 0.26 Mn use traditional methods while
 1.37 Mn do not use any contraception
 - Use / Need gap for modern contraceptives —in terms of number of CMW— is marginally higher in rural areas (0.9 Mn) than in urban areas (0.7 Mn) but the % of the gap to number of women 'in need' is higher in urban areas (34%) than in rural areas (29%)

The market is 'matured' yet 34% CMW in urban and 29% in rural areas are not using any modern methods; less than 16% of non-users of modern methods, who are in need, are using traditional methods

Method-mix of modern contraceptives use among married women of 19-29 living in urban and rural areas of Maharashtra, NFHS 2019-21



Method-mix of modern contraceptives use by age groups of married women of 19-29 living in Maharashtra, NFHS 2019-21

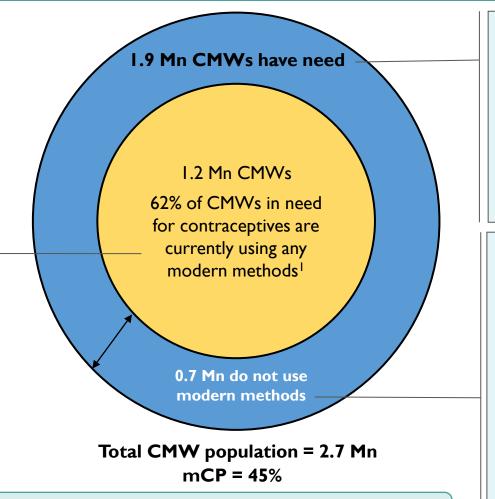


Assam

(Evolving)

Modern FP Use / Need – Assam (NFHS 2019-21) among currently married women of 19-29 years

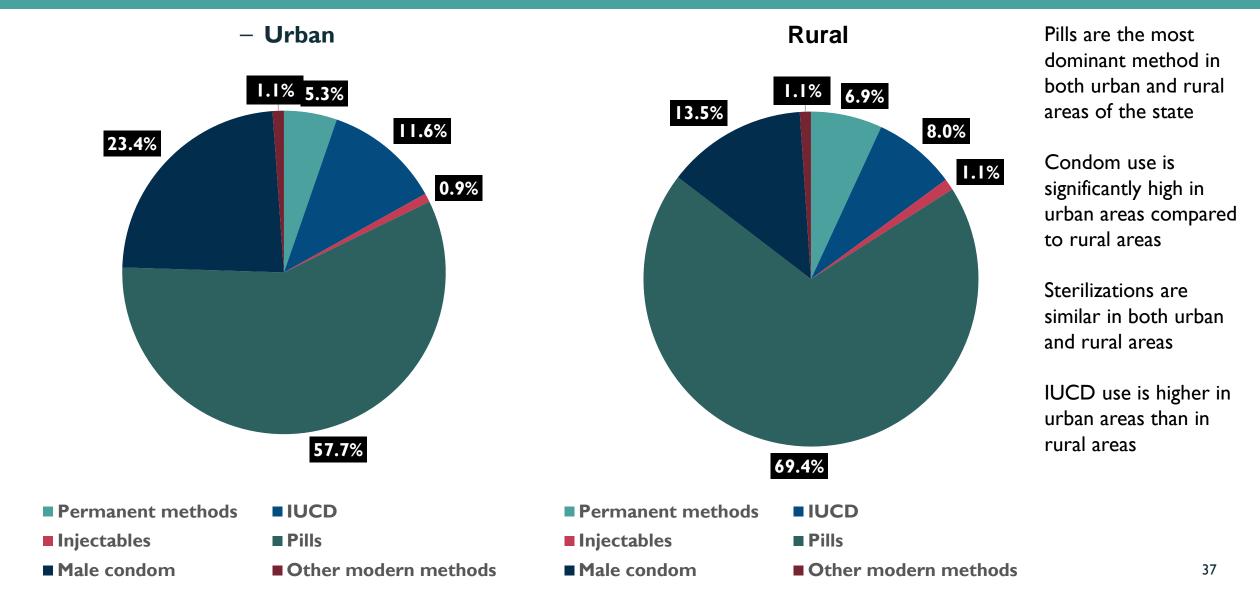
- 1.2 Mn CMW (62% of CMW who are 'in need' for contraceptives) currently use modern methods
 - Pills are the most used modern method (68% of modern method use)
 - Condoms are the 2nd most used modern method (15% of modern method use)
 - 7% of modern method users are using permanent methods i.e., female/male sterilization
 - While share of pills is high in rural areas (69%), condoms have a higher share in urban areas (23%) compared to rural areas (14%)



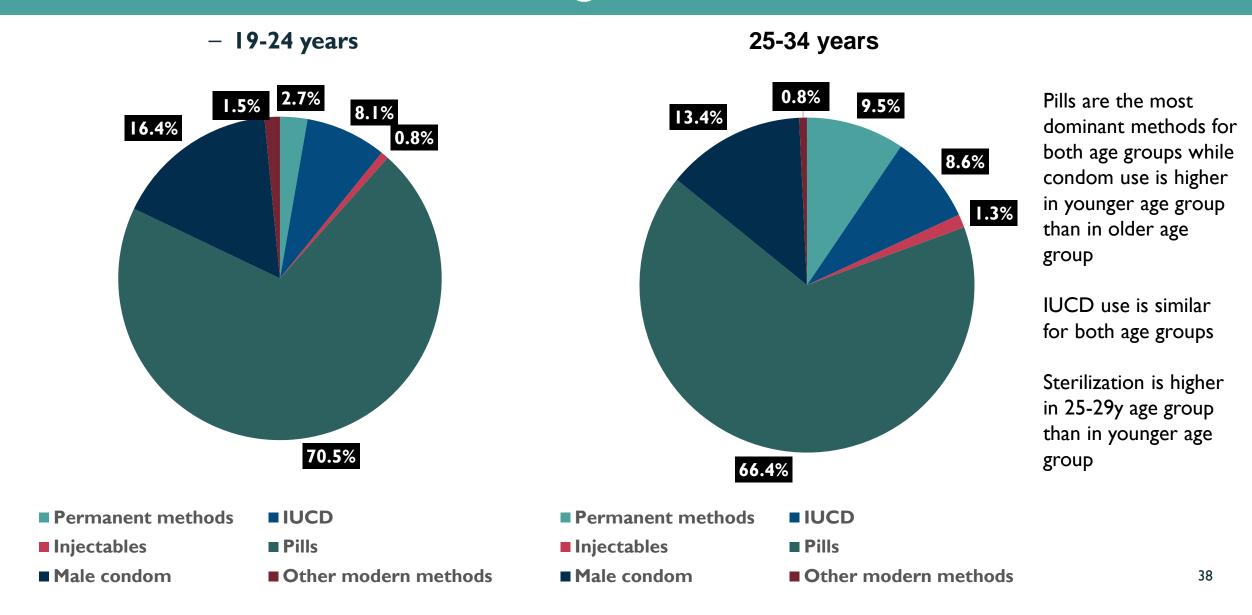
- Out of 2.7 Mn CMW in Assam, I.9 Mn are in need for contraception (i.e., the population at risk of unintended pregnancies if not using a contraception)
 - If we exclude permanent method users, this reduces to 1.9 Mn
- Rural Assam accounts for I.7 Mn (71%) CMW 'in need' for contraceptives
- 0.7 Mn CMW in Assam need contraception but do not use any modern methods
 - 0.4 Mn use traditional methods while 0.3
 Mn do not use any contraception
 - Use / Need gap for modern contraceptives —in terms of number of CMW— is higher in rural areas (0.6 Mn) than in urban areas (0.1 Mn) but the % of the gap to number of women 'in need' is higher in urban areas (40%) than in rural areas (37%)

The market is evolving as 40% CMW in urban and 37% in rural areas are not using any modern methods; 54% of non-users of modern methods, who are in need, are using traditional methods

Method-mix of modern contraceptives use among married women of 19-29 living in urban and rural areas of Assam, NFHS 2019-21



Method-mix of modern contraceptives use by age groups of married women of 19-29 living in Assam, NFHS 2019-21

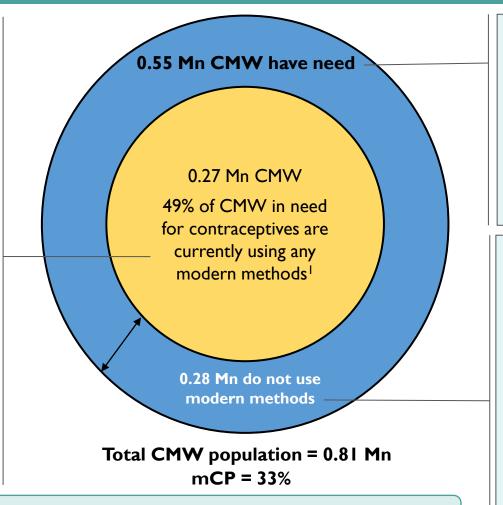


NE states excluding Assam

(Challenging)

Modern FP Use / Need – Northeastern states except Assam (NFHS 2019-21) among currently married women of 19-29 years

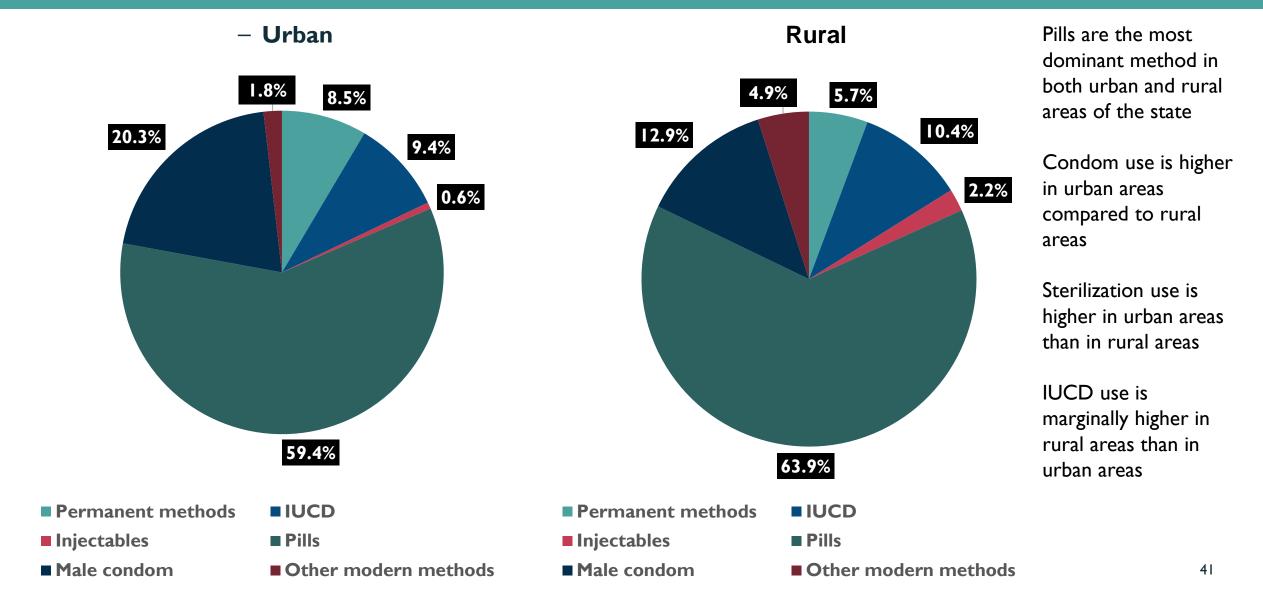
- 0.27 Mn CMW (49% of CMW who are 'in need' for contraceptives) currently use modern methods
 - Pills are the most used modern method (63% of modern method use)
 - Condoms are the 2nd most used modern method (15% of modern method use)
 - 6% of modern method users are using permanent methods i.e., female/male sterilization
 - While share of pills is high in rural areas (64%), condoms have a higher share in urban areas (20%) than in rural areas (13%)



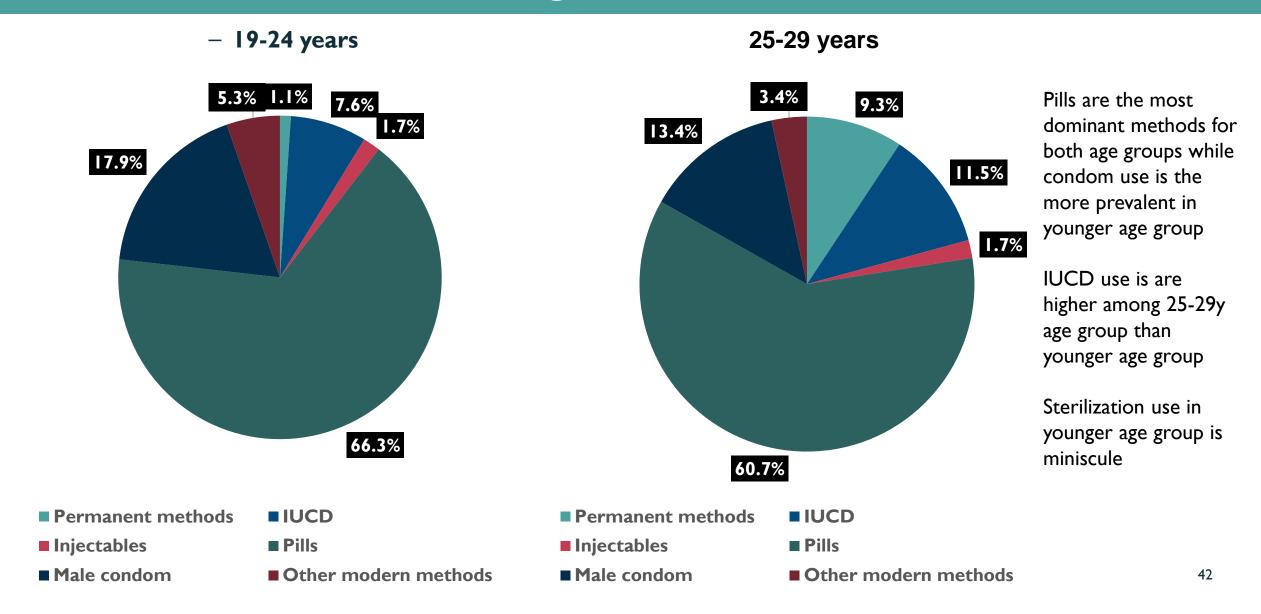
- Out of 0.81 Mn CMW in NE states, 0.55
 Mn are in need for contraceptives (i.e., the population at risk of unintended pregnancies if not using a contraception)
 - If we exclude permanent method users, this reduces to 0.53 Mn
- Rural areas of NE states accounts for 0.41 Mn (67%) CMW 'in need' for contraceptives
- 0.28 Mn CMW in NE states need contraception but do not use any modern methods
 - 0.145 Mn use traditional methods while
 0.135 Mn do not use any contraception
 - Use / Need gap for modern contraceptives —in terms of number of CMW— is much higher in rural areas (0.215 Mn) than in urban areas (0.065 Mn) but the % of the gap to number of women 'in need' is higher in rural areas (52%) than in urban areas (46%)

The market is 'challenging', as 52% CMW in rural and 46% in urban areas are not using any modern methods; 52% of non-users of modern methods are using traditional methods

Method-mix of modern contraceptives use among married women of 19-29 living in urban and rural areas of NE states, NFHS 2019-21



Method-mix of modern contraceptives use by age groups of married women of 19-29 living in NE states, NFHS 2019-21



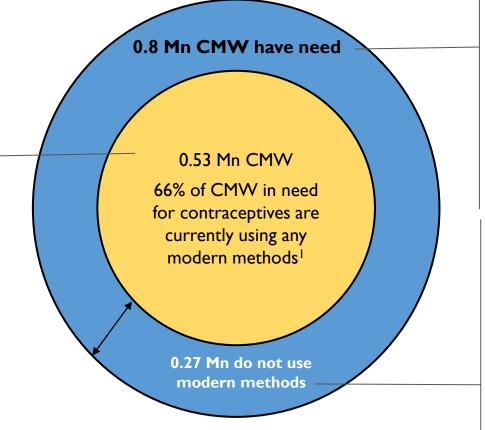


NCT of Delhi

(Predominantly urban)

Modern FP Use / Need – National Capital Territory Delhi (NFHS 2019-21) among currently married women of 19-29 years

- **0.53 Mn CMW** (72% of CMW who are 'in need' for contraceptives) **currently use modern methods**
 - Condom are the most used modern method (64% of modern method use)
 - IUCD is the 2nd most used modern method (17% of modern method use)
 - I 0% of modern method users are using permanent methods i.e., female/male sterilization



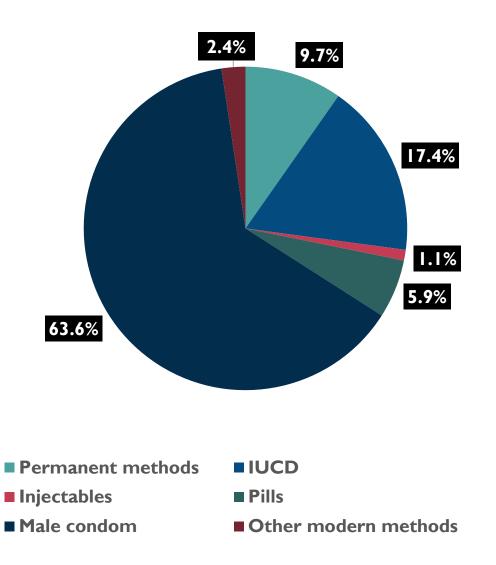
Total CMW population = 1.1 Mn mCP = 48%

The market is somewhat 'matured', as 34% CMW 'in need' are not using any modern methods; 67% of non-users of modern methods are using traditional methods

- Out of I.I Mn CMW in NCT Delhi, 0.8 Mn are in need for contraceptives (i.e., the population at risk of unintended pregnancies if not using a contraception)
 - If we exclude permanent method users, this reduces to 0.75 Mn

- 0.27 Mn CMW in NCT Delhi need contraception but do not use any modern methods
 - 0.18 Mn use traditional methods while
 0.09 Mn do not use any contraception

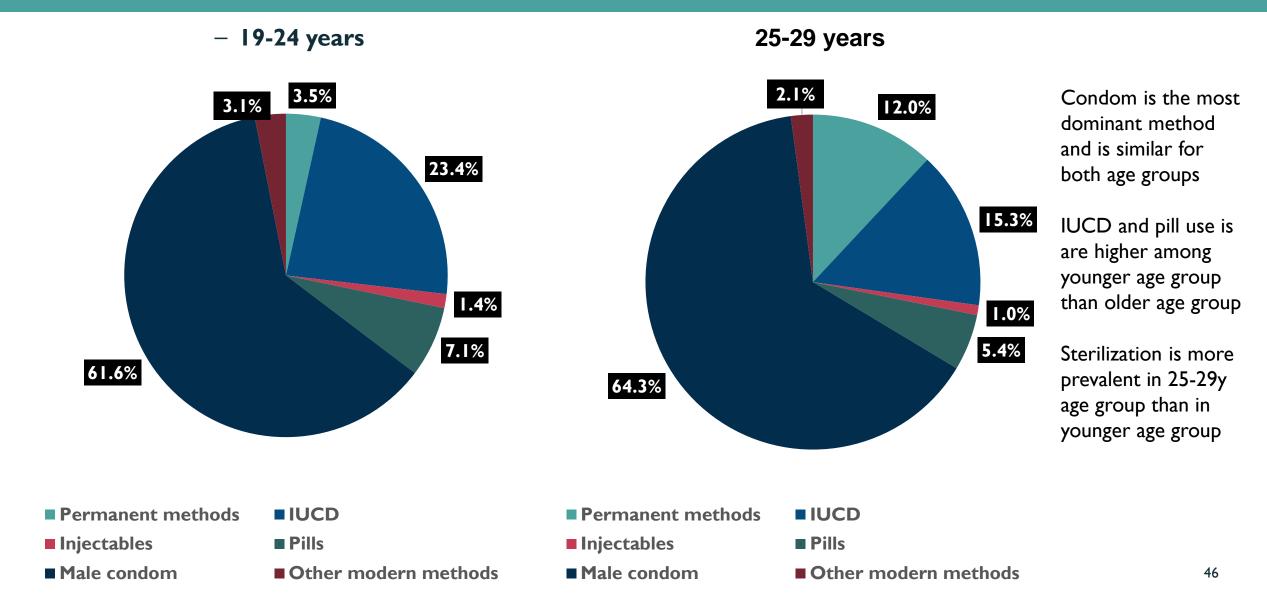
Method-mix of modern contraceptives use among married women of 19-29 living in NCT Delhi, NFHS 2019-21



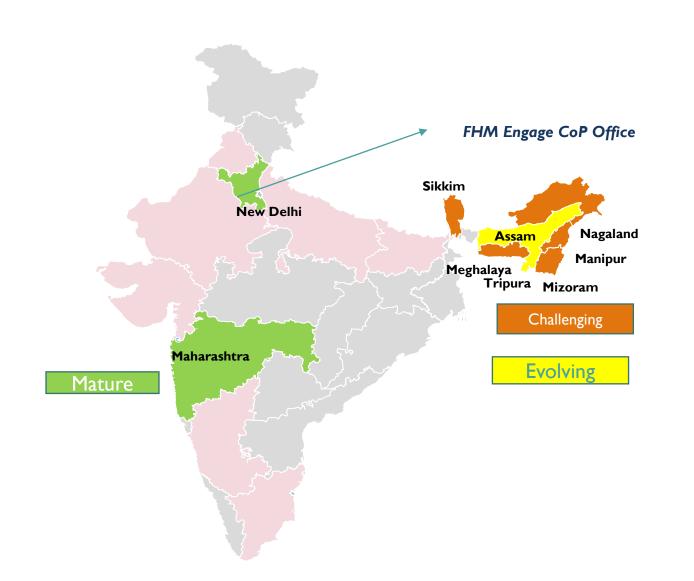
Condom is the most dominant method

The other two prevalent methods are IUCD and sterilizations

Method-mix of modern contraceptives use by age groups of married women of 19-29 living in NCT Delhi, NFHS 2019-21



Summary: Need In Focus states



- 17.5 Mn Currently Married Women (In focus states of Maharashtra, Delhi, Assam, Northeast states) not wanting to get pregnant is the total addressable market.
- This includes 6.5 Mn CMW who use a reversible modern method, and 3.5 Mn CMW who are in need but not using any method.
- There are 11.97 Mn Women who never married or formerly married in the focus

USE/NEED: WHO IS THE MARKET FAILING? Discussions

MACRO TRENDS:POLICY & STEWARDSHIP

Health in India, roles and functions of key Departments at the national level

Union Government

Ministry of Health and Family Welfare

Ministry of AYUSH Ayurveda, Yoga, Naturopathy, Unani, Siddha,

Ayurveda, Yoga, Naturopathy, Unani, Siddha Sowa-Rigpa and Homoeopathy

AYUSH systems of medicine in parallel with western medicine systems. The NHP 2017 also highlights a choice of system of medicine towards pluralistic health system. Utilization of AYUSH practitioners in the provision of primary health care

Department of Health Research

Department of Health and Family Welfare

Indian Council of Medical Research (ICMR) + Specific disease research institutions across the country

Technical support for epidemics and national disaster. Establishment of Network of Research Laboratories for Managing Epidemics and Natural Calamities.

Central government health scheme	National AIDS Control Organisation	Directorate General of Health Services*
		Central bureau of health intelligence National centre for disease control Central health education bureau National council for clinical establishments Regional offices Central drug standard control organization

Professional councils	National Health Mission	Central nealui Service	Statistics
National Medical Commission Dental council of India Indian nursing council Pharmacy council of India Allied health professional council	 Disease control programmes Immunization programme RMNCH Health system support up to district level (infrastructure, eHealth, CHW, HR, etc.) National health system resource centre 		

AIIMS (All 23 Central government health institutions institutions (other than AIIMS) nationwide)* Food Safety and Standards Authority of India# Central medical services society (in charge of national procurement)* National Health Authority

(AB PM-JAY)*

Other Ministries

Ministry of Labour and Employment

Employees' State Insurance Corporation, hospitals under ESIC, ESIC medical college, partnership with NHA for AB PM-JAY. immigration of nurses

Indian Railways

Health Directorate of Railway Board Industrial medicine, Medical treatment of serving and retired railway employees, Hospitals, empaneled facilities

Department of Defence

Armed force medical service Ex-Servicemen Contributory Health Scheme (ECHS)

Ministry of Chemicals & Fertilizers

Department of Pharmaœuticals National Pharmaœutical Pricing Authority

Ministry of Finance Insurance regulation

Insurance regulation Health financing

Ministry of Women and Child Development

Nutrition programmes

Ministry of Jal Shakti

Drinking water and sanitation

Source: Adapted from APO secretariat based on published websites and documents

Major Healthcare Initiatives in India: 2005-2021



Gol focus: Major Private Sector Segments in India's Healthcare Sector

Hospitals **Pharmaceutical Diagnostics** Medical Equipment and **Supplies** Medical Insurance Telemedicine

Government (healthcare centres, district hospitals, general hospitals)

Private (nursing homes, mid-tier & top-tier private hospitals)

Includes manufacturing, extraction, processing, purification & packaging of chemical materials for use as medications for humans or animals

Comprises businesses & laboratories that offer analytical or diagnostic services, including body fluid analysis

Includes establishments primarily manufacturing medical equipment & supplies, e.g. surgical, dental, orthopedic, ophthalmologic, laboratory instruments, etc.

Includes health insurance & medical reimbursement facility, covering an individual's hospitalization expenses incurred due to sickness

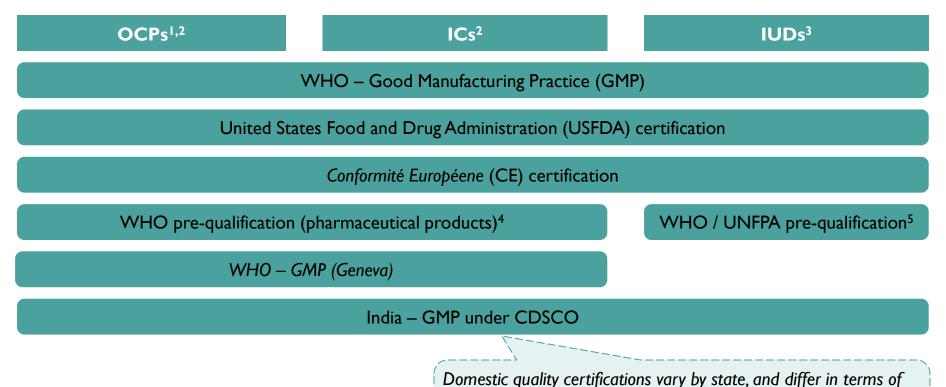
Has enormous potential in meeting the challenges of healthcare delivery to rural & remote areas besides several other applications in education, training & management in the health sector

AatmaNirbhar Bharat Abhiyaan Package for Boosting Domestic Manufacturing of Drugs

Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of medical devices						
Overview	INR 3,420 Crore					
Incentive	5% of incremental sales over base year 2019-20 will be provided on the segments of medical devices identified under the scheme.					
Total financial outlay	INR 121 Crore					
Tenure	FY 2020-2021 to FY 2027-2028					
	Promotion of Medical Devices Parks					
Overview	A one-time grant-in-aid will be provided for creation of common infrastructure facilities in selected medical device parks proposed by a State Government					
Incentive	100 Crore per park					
Total financial outlay	INR 400 Crore					
Tenure	FY 2020-2021 to FY 2024-2025					

Overview	India possesses a complete ecosystem for the development and manufacturing of pharmaceuticals and a robust ecosystem of allied industries. The new PLI scheme will incentivize global and domestic players to engage in high-value production.
Products	Category I
	i. Biopharmaceuticals ii. Complex generic drugs iii. Patented drugs or drugs nearing patent expiry iv. Cell-based or gene therapy products v. Orphan drugs vi. Special empty capsules vii. Complex excipients
	Category 2
	i. APIs/KSMs and/DIs
	Category 3
	i. Repurposed drugs ii. Auto-immune drugs, anti-cancer drugs, antidiabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs, and anti-retroviral drugs iii. In-vitro Diagnostic Devices (IVDs) iv. Phytopharmaceuticals v. Other drugs not manufactured in India vi. Other drugs as approved

FP Quality Assurance and certification

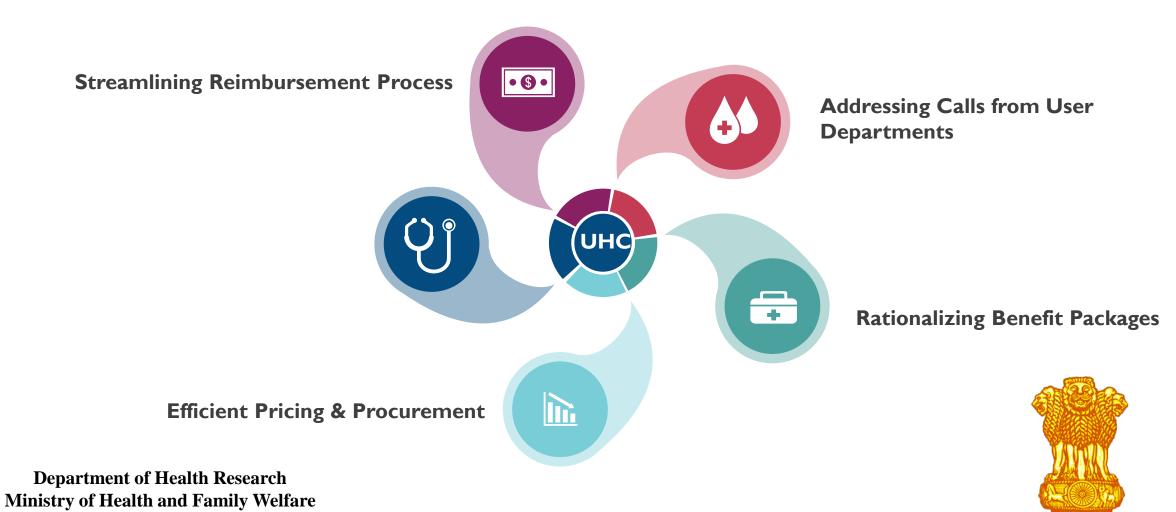


trial requirements for new products, ongoing documentation requirements and compliance requirements for hormonal facilities

¹Most guidelines require OCP manufacturers to have a separate facility for manufacturing of hormonal products, this can be within a plant but there must be a clear, proper separation; ²For OCPs and ICs, most large international procurers require a manufacturer to have WHO-GMP (Geneva) certification, and in some cases WHO-pre qualification; ³For IUDs, most large international procurers require a manufacturer to meet at least two pre-qualifications amongst USFDA, CE, and WHO / UNFPA, mentioned above; ⁴WHO pre-qualification for pharmaceutical products requires a manufacturer to undergo pharma equivalence tests for their hormonal products. These can cost up to USD 2 million, without a guarantee of equivalency approval. For ICs, Pfizer is the only WHO pre-qualified vendor in the world; ⁵Since 2007, WHO and UNFPA have harmonized the pre-qualification process for condoms and IUDs.

Note: The certifications above reflect the common standard for tenders agreed on by most large international procurers

Adoption and use of Global Frameworks for Health Technology Assessments (HTA)



Government of India

सत्यमेव जयते

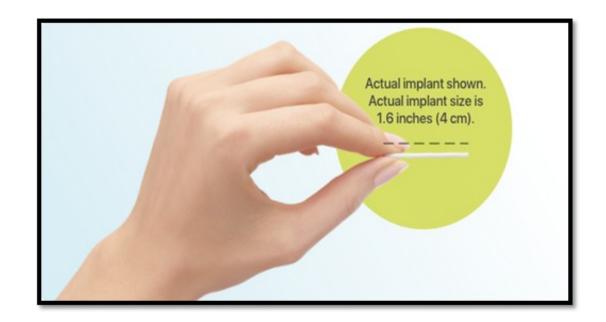
Objectives of HTAIn

- **❖ Maximising Health** − Expanding coverage without compromising the quality of healthcare services.
- * Reducing out of pocket expenditure Achieving reduction in proportion of catastrophic households' expenditures and consequent impoverishment.
- * Reducing Inequality Minimizing disparity on account of gender, poverty, caste, disability, other forms of social exclusion and geographical barriers



Expanding Informed Contraceptive Choice for Indian Women: Will Nexplanon Matter?

- India's National family planning program has two Long-Acting Reversible Contraceptive (LARC) methods: Copper-Intra Uterine Device-380-A and Depot Medroxy Progesterone Acetate (DMPA) three-monthly injections.
- The policy question of whether another LARC (Nexplanon, a subdermal ContraCeptive implant) should be added to this basket is addressed in this brief. Health Technology Assessment (HTA) has been the Chosen approach to explore this question
- Literature review, primary data Collection for Costing and eConomiC evaluation via deCision analytiC modelling was done as a part of HTA.
- The decision analytical model, which is a mathematical model, that simulates reality, showed that an additional Cost of 17,716 INR will be incurred by the Indian government to gain one Quality adjusted life year (QALY) if Nexplanon is added to the Current basket of ContraCeptive ChoiCes in the public health system. This shows that the intervention is very Cost-effective, using the Comparator as the threshold of GDP per Capita.



Illustrative Product registration: multi-step process that may vary depending on desired market entry strategy

If importing

finished product (b)

Regulatory application for all steps need to be made by an Authorized Indian Agent with a Wholesale License¹

- If market entry strategy is to partner with a local entity, then that partner could serve as the **Authorized Indian** Agent and would likely already have a Wholesale License
- If setting up supplier's own Indian entity, then would need to obtain Wholesale License from State **Drug Licensing** Authorities

Permission to Import or Manufacture a New Drug

Authority: CDSCO², "Subsequent New Drugs" division Timeline: ~1-3 months + additional time for local clinical trials if required **Cost**: ~\$2.8-6.7K filling fee + optional ~\$6.7K for presubmission meeting if requested; local clinical trials if required would add cost

- This step may or may not be needed depending on exact interpretation and application of regulations at the time of submission
- Regulator may also consider relaxing or waiving clinical trial req. on a case-by-case basis

If mfg in India

- If partnering with CMO, would need to add drug to their existing ML
- If setting up own mfg site, would need to obtain new ML

Certificate (RC) (IC)

Authority: CDSCO, "Import & Registration" division Timeline: ~5-9 months for RC + ~15-45 days for IC Cost: ~\$15K for RC (~\$10K for registering mfg site, ~\$5K for each drug registered at site) + ~\$140 for IC; if site inspection is required would be \$25K additional cost

(a) needs to be obtained before (b), but applications can be prepared and submitted concurrently

> Manufacturing License (ML) (mfg site + drug)

Registration

Authority: State Drug Licensing Authorities Timeline/cost for additional drug only³: *Timeline*: ~15-20

days *Cost*: ~\$4 **Registration Certificate** and Import License for API/other components (e.g., Uniject)

Import License

Same process as importing finished product **Authority: CDSCO Timeline & cost**: May vary depending on component, could be similar to that for finished product

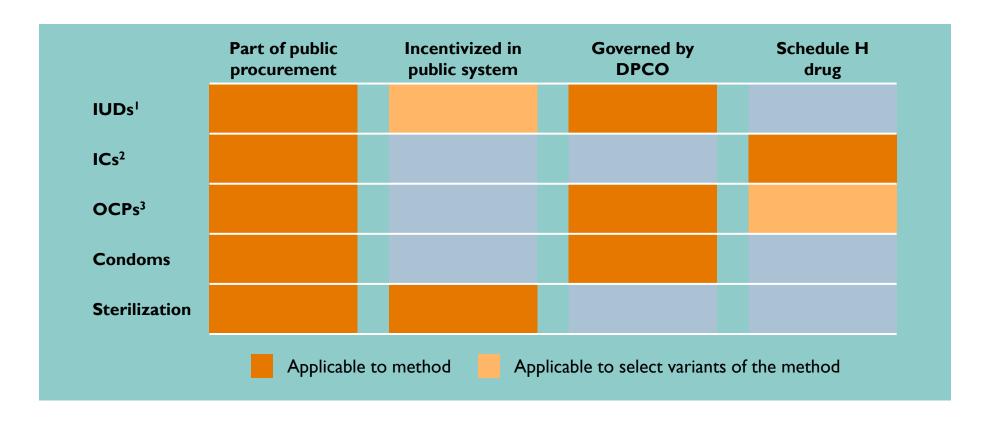
¹ Wholesale License is a generic license for warehousing drugs for sale, it is granted per entity, not per drug, so likely no additional work required to offer DMPA-SC

² Central Drugs Standard Control Organisation under MOHFW is the Central Licensing Authority in India

³ For obtaining new Manufacturing License, estimated timeline is 2-3 months and cost is ~\$1K

Policy and Incentives skewed: Not a level Field for market development

With introduction of ICs into the National Family Planning Programme, all 5 modern contraceptive methods are part of the public procurement system;



¹Insertion of PPIUCDs is incentivized throughout the year in the public system, while IUD insertion is incentivized only during certain months; ²IC has been approved for introduction into the public procurement system; ³Government brands, all subsidized brands, and a few commercial brands of 2nd generation OCPs are Schedule K drugs

Sources: Secondary Research

The state of the policy environment governing digital counseling for family planning

Criteria	Digital Counselling					
Cilleila		Ind	Ken	Nig	Pak	
Digital Counselling					•	
Digital health standards in place	•	•	•		•	
Integrated in FP policies						
Digital counseling in use for FP	•			•	•	
Quality oversight in place	•	•	•		•	
Formal training in place	•	•	•	•	•	







The state of the policy environment governing DTC channels, including e-commerce sites

Criteria	DTC Channels					
Cilleria		Ind	Ken	Nig	Pak	
DTC Marketing allowed	•					
Licensing/registration requirement	•	•	•	•	•	
Quality oversight in place	•	lacktriangle	•	•	•	
Integrated in FP policies	•	•	•	•	•	
Included in supply chain systems	•	•	•		•	
Drug schedule clarifies sales permissions	•	lacktriangle	•	\blacksquare	•	
Formal training in place	•	•	•	•	•	





Market Stewardship: How can we translate intention to action?

Several key macro trends affect the FP market, from government policies and pharma market trends to factors affecting mainly the FP market or specific products

Trends in Govt. spending

• Gol is devolving more financial powers to states

- It is unclear how expenditure will evolve; implementation is stalling as relevant bodies / ministries take a "wait and watch" approach
- Over last 5 years, expenditure on health as % of GDP has increased from 1.3 to 2.1, it has decreased over 2022 RE. Omnibus Capex expenditure on Infra in Urban areas.

Pharma market trends

FP 2030

- Since 2013, many pharma products have been brought under Drug Price Control, including condoms, OCPs, and IUDs
 - Recent amendments to new drug approval process have made the process more stringent, and potentially slower
 - IC roll out stalled by pandemic. Sayana Press and Implants approved for public sector roll outs. DCGI generic DMPA SubQ generic file approvals under progress.

Policy and governance (FP 2030 Commitment)

Developing the country's roadmap/guidance for improved private sector engagement through establishing a national level platform/Leveraging the existing private sector platforms (with participation from all health-related private sector). The platform can play a crucial role in advocacy for improving involvement of the private sector, strengthening inter-sectoral convergence, strengthening a market development approach, expanding social health insurance schemes and building partnerships with pharmaceutical companies to understand the requirements and align them with 'Make in India' campaign.

Opportunities for Market Access

Mixed outlook on DMPA-SC – varied stakeholder enthusiasm for SC value proposition and scale-up prospects in India; key conditions cited for scale up include demand generation, advocacy, domestic suppliers, and pricing comparable to IM.

- 1. 400 K under Volumes Guarantee: PHSI (24 Months)
- 2. Route to Market: Pilots in 5 states
- 3. Smart Social Marketing to short circuit traditional supply chain.

Upbeat outlook on Implanon – Promise of adding choice but domestic production needs Tech transfer for Implanon. Local assembly for dual rods is not feasible.

- I. Assess and Validate Unit Economics for Volumes.
- 2. Organon is interested to co create market investment and business case.

SUMMARY | POLICY TRENDS

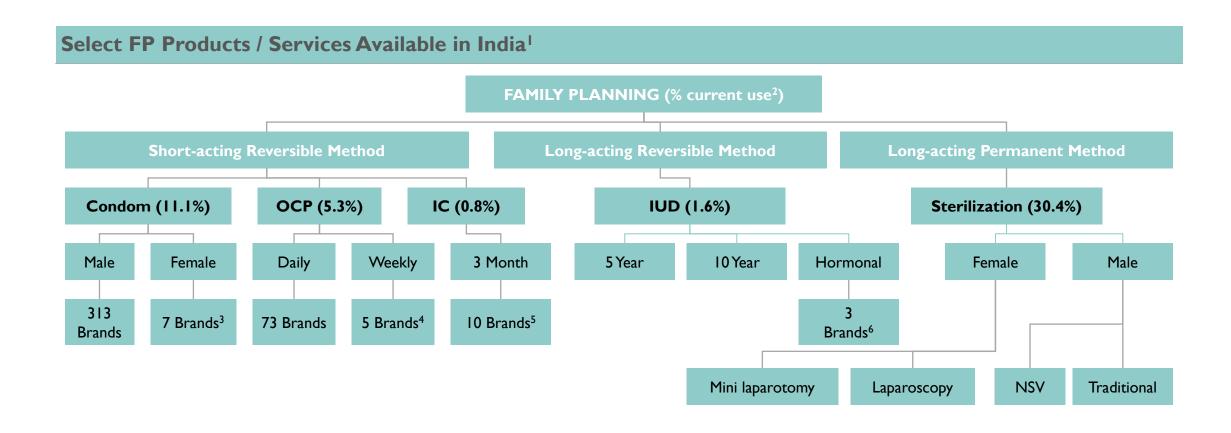
- Market access barriers remain high.
- Inconsistent application and changes in laws makes it unattractive for manufacturers to demonstrate range and innovation in domestic backyard.
- Social Marketing languishing for new guidelines, expansion of choice and delayed procurements.
- Inflationary price escalation across supply chain due to low/no incentives for FP products manufacturing.



STEWARDSHIP: DISCUSSIONS

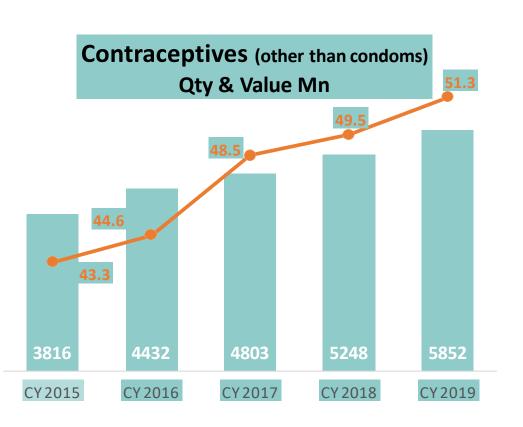
MARKET DESCRIPTION

India Market Breadth & Depth Number of Modern FP Methods/ Brands



Note: ¹Only includes major FP products/services available in India, based on primary and secondary research and may not be exhaustive; ²Percentages in brackets below each product denote the proportion of CMWs of 15-49 years currently using the product (at an all-India level); ³Available female condom brands include Confidom, Velvet, Reddy, V Amour, L'amour, VA WOW Feminine condom and Sutra; ⁴Centchroman (ormeloxifene) is now a part of the National FP Program. Available brands in India are Saheli, Centrn, Ormetect, Novex and Sevista; ⁵Pfizer's Depo-Provera is the market leading brand for ICs. Other major brands include Myone Depot, Petogen, Depo-Kare, Freedom Inject, Pari, Procosteron, Khushi, B Sure, and Noristerat (Net-en); ⁶Hormonal IUD brands present in India are Eloira, Emily, and Mirena IQVIA, 2019

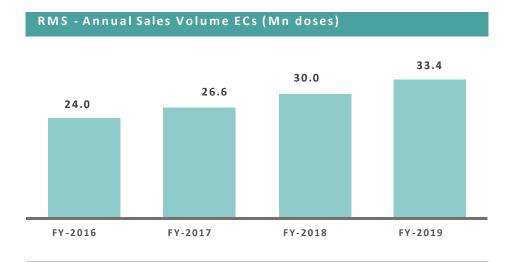
Market Value and Volume 9% Brands drive 75% value



Insights

- The Indian Private contraceptive market constituting around 175 brands is valued at Rs 5852 Mn as at December 2019 and represents around 8.5% of the Gynaecology market. The contraceptives have grown at a CAGR of 11% over the period CY-2015 to CY-2019.
- Ovral-L (Ethinyl Estradiol + Levonorgestrel) is the largest contraceptive brand valued at app. Rs 850 Mn. It holds 75th position amongst all Pharma brands in India.
- Top-15 Contraceptive Brands constitute 75% of the overall Market of 5852
 Mn. Amongst the top-15 brands, we have 11 OCPs, 2 ECs, 1 Injectable and an IUS brand.
- Depo-Provera Injection is the 14th biggest contraceptive brand valued at app. Rs 145 Mn.
- There are a total of 84 brands which constitute less than 1% of the contraceptive market.

EC in India: Market Concentration with 2 brands (Price and Access power key market failure)



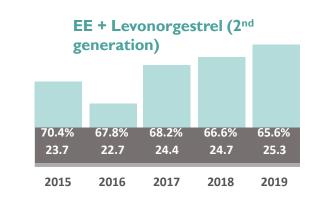
2053.0 2316.0 2736.0 3110.0 EY-2016 EY-2017 EY-2018 EY-2019

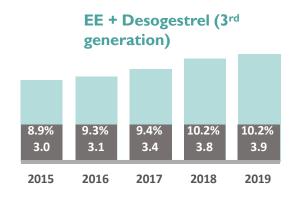
Insights

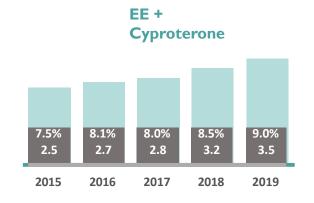
- The private EC market is entirely dominated by 2 brands namely, Unwanted-72 (Mankind Pharma) & I-pill (Piramal Enterprises Ltd).
- Unwanted-72 is the market leader with about 80% Market Share (26.5 Mn doses) while Piramal's i-pill has app. 18% market share (6.0 Mn doses). The 3rd biggest brand sells only about 0.2 Mn doses.

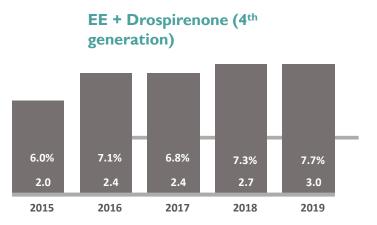
Source: IQVIA RMS ending March 2020.

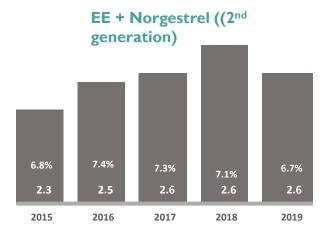
OCP: 3 out of every 4 pills sold is still a 2nd generation COC.

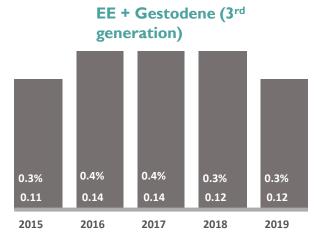




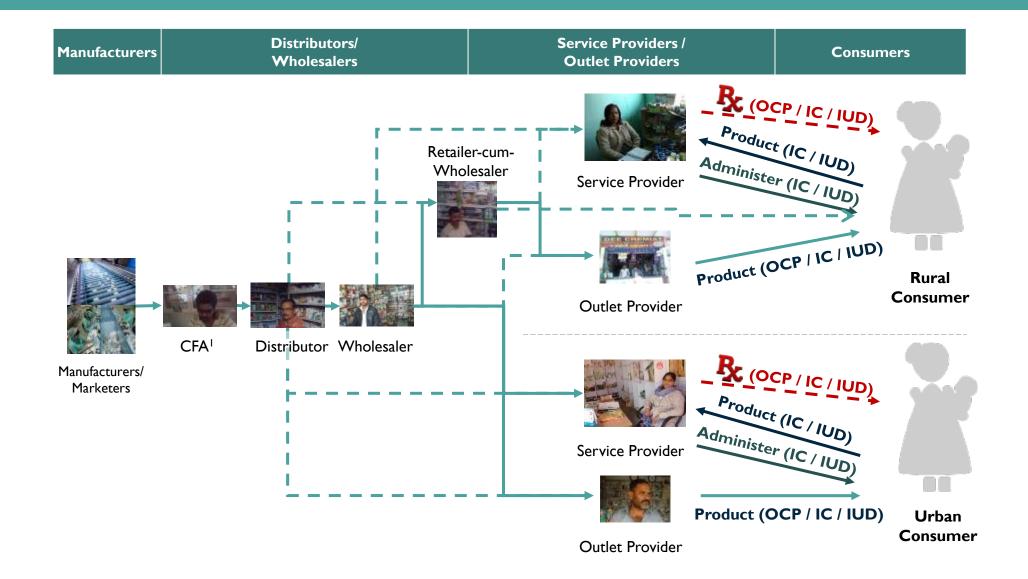




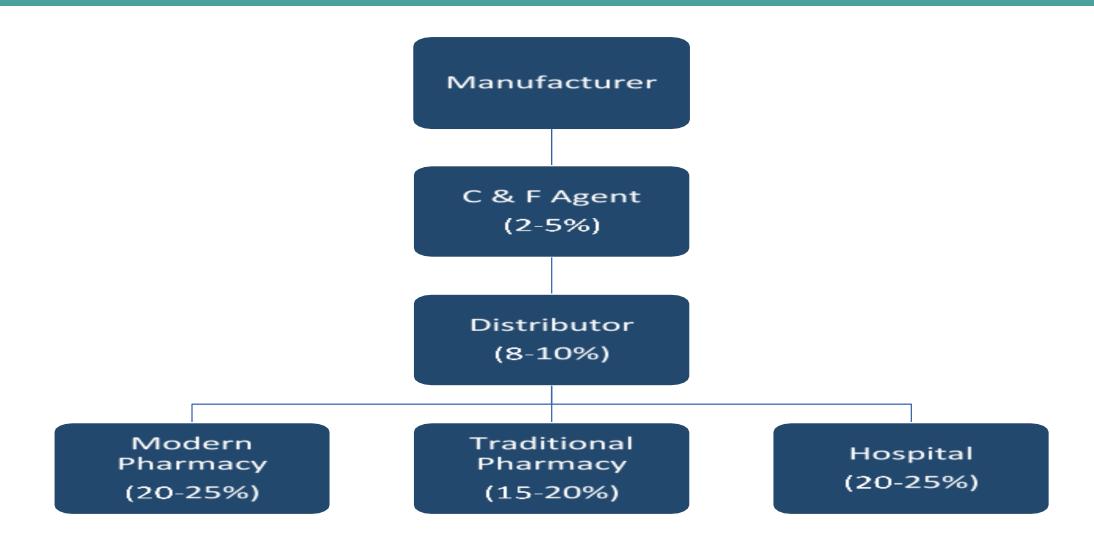




Private Sector Value Chain

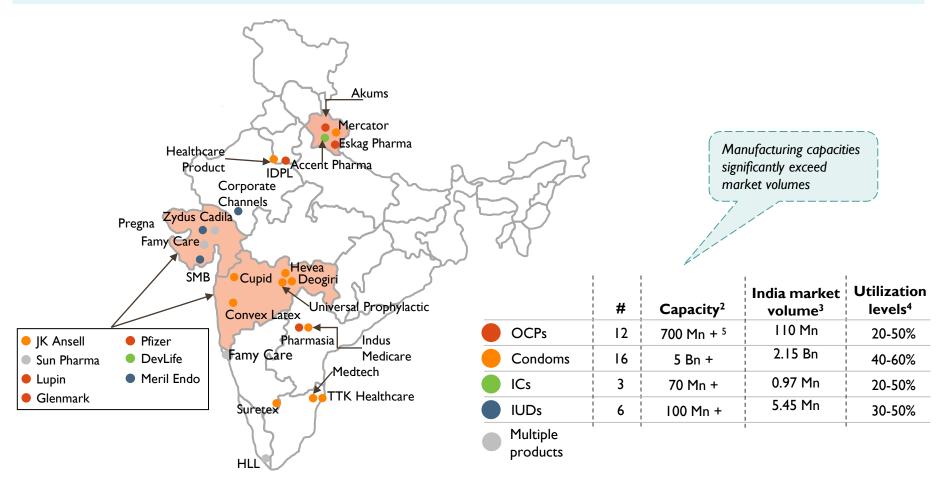


Indicative supply-distribution chain, with the profit margins varying across the C&F agent, distributor and retailers



Manufacturing: Innovative yet underutilized in Domestic back yard

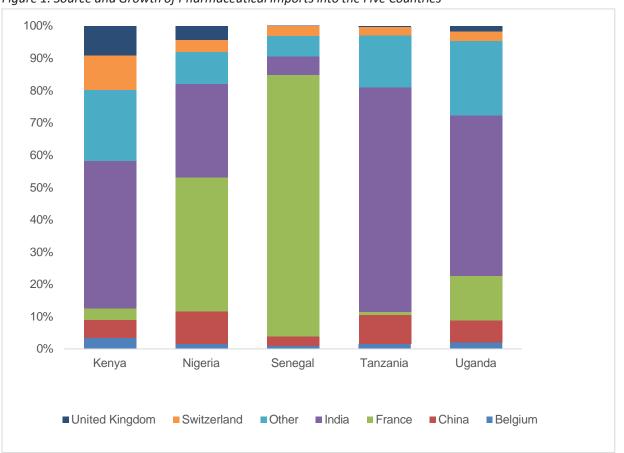
Most manufacturers are concentrated in Gujarat, Maharashtra, and Uttarakhand, and are focused on exports; capacity exceeds domestic demand (and actual production)



¹The number of manufacturers is not exhaustive. By estimates, they cover 60-90% of domestic production; ²Capacity information not available for all manufacturers; ³India market volumes for 2019; ⁴Overall utilization levels; ⁵OCP data is in Mn cycles

India Manufacturing has impact on underserved Global South

Figure 1. Source and Growth of Pharmaceutical Imports into the Five Countries



India is the largest source of pharmaceuticals for the five countries in this study, accounting for 38% of imports in 2017, with France second at 29%, followed by China with 8% of pharmaceutical imports.

All types of Pharmacy: Market size

State Wise Split of Retail market size of Pharmacy & Wellness category					
States	Pharmacy & Wellness Retail Market Size for FY 2020 (USD Billion)	% of Pharmacy & Wellness Retail Market Size - FY 2020	Pharmacy & Wellness Retail Market Size for FY 2025(P) (USD Billion)	% of Pharmacy & Wellness Retail Market Size – FY 2025(P)	CAGR (FY 2020-FY 2025)
Maharashtra	3.4	15%	5.2	14%	9%
Uttar Pradesh	1.6	7%	2.4	7%	8%
Andhra Pradesh	0.9	4%	1.3	4%	8%
Telangana	0.9	4%	1.5	4%	11%
Tamil Nadu	1.8	8%	2.8	8%	9 %
West Bengal	I	4%	1.5	4%	8%
Gujarat	1.4	6%	2.1	6%	8%
Karnataka	1.6	7%	2.6	7%	10%
Rajasthan	0.9	4%	1.4	4%	9 %
Kerala	0.8	3%	1.2	3%	8%
MP	0.7	3%	1.2	3%	11%
Delhi	I	4%	1.5	4%	8%
Haryana	0.9	4%	1.4	4%	9 %
Bihar	0.7	3%	1.4	4%	15%
Punjab	0.6	3%	0.8	2%	6%
Orissa	0.4	2%	0.7	2%	12%
Jharkhand	0.3	1%	0.5	1%	11%
Northeastern States	0.4	2%	0.9	3%	18%
Others	3.7	16%	5.6	16%	9%
TOTAL	23	100%	36	100%	~10%

State-wise presence of key pharmacy retailers, as of March 31, 2021

	State Wise Store Presence (March 31, 2021)					
States	Apollo Pharmacy	MedPlus	Wellness Forever	Emami Frank Ross		
Tamil Nadu	850	447	-	-		
Karnataka	604	514	15	28		
Andhra Pradesh	634	263	-	-		
Telangana	655	435	-	-		
West Bengal	425	183	-	163		
Maharashtra	130	166	193	-		
Orissa	100	73	-	-		
Other States	250	-	15	-		
Total Stores	4,118	2,081	223	191		

KEYTRENDS IN HEALTHCARE RETAIL

- **Gradual transition towards modern formats (offline + online)**: Penetration of modern retail in pharmacy is relatively lower than most other categories except food and grocery. However modern pharmacy retail is estimated to grow at a rate of 25%, growing faster than other categories. Inclination towards modern pharmacy is being witnessed on account of better customer experience, wider product range, value added services and transparent discounts.
- Rapid development of online channel: The e-commerce and omni-channel retail is expected to grow at a CAGR of 44%, with pharmacy e-commerce expected to be one of the fastest growing segments after food and grocery. B&M stores are in position to capitalize on this growth with their digitally-enabled platform linked with the physical stores and warehouses which will allow them to grow at faster pace.
- Emergence of self-diagnostic devices: Manufacturers of health-tech devices that allow users to self-diagnose ailments and monitor health risks have witnessed a surge in sales growth, further buoyed by the impact of the COVID-19 pandemic. Modern pharmacy chains have benefitted from this recent emergence, due to 1) better availability of such products, and 2) suitability of such products, which generally have high brand agnosticism, to selling via private labels.
- Loyalty programs aid customer retention: Established market players such as Apollo and the MedPlus have developed customer loyalty platforms that enable greater customer acquisition and improved customer retention through the utilization of advanced data analytics, the ability to offer discounts and leveraging loyalty driven behavior to up-sell and cross-sell.
- **Ecosystem Play**: Besides dispensing pharmaceutical and FMCG products, modern pharmacies are now building up a complete ecosystem of related services in order to acquire customers. They have augmented their proposition by offering a wide range of value-added services like appointments for doctors, online consultation, health blogs, medicine reminders & refills alerts, tie ups with diagnostic centres.
- Increased focus on private label products to drive higher margins: Private labels in pharma and wellness retailing is expected to grow at 36% CAGR between financial year 2020 and financial year 2025, thereby increasing its share from 8% of the industry in financial year 2020 to 12% by financial year 2025.

Supply Chain Resilience: Key Insights

- Smart warehouses: Eco-friendly warehouses that use energy management systems for better utilization of energy. With the combination of timers, thermostats and gauges for all forms of electricity, gas, heat and water, energy management systems support the best practices of consumption without excessive wastage. Warehouses also use telematics software to help in controlling fuel costs, allowing businesses to use less fuel and slash fuel costs.
- **Green sourcing**: With rising environmental concerns, procurement professionals are sourcing or purchasing of materials and components, which have eco-friendly characteristics, such as reusability, recyclability and nonuse of hazardous/dangerous chemicals.
- **Digitization**: Digitization and automation for environmental sustainability by enhancing resource and information efficiency with the application of Industry 4.0 technologies throughout the product lifecycle. This would reduce menial, repetitive tasks and enable deep visibility into the supply chain where businesses could assess the sustainability practices of their suppliers and vendors.

Doctors: Low Density, Different types & Varied FP service delivery Propensity

OBGYN / Female MBBS	Male MBBS – Hospitals	Male MBBS- GP Clinics	Female AHU	Male AHU / RMP
More than 10 years	More than 10 years	Span various levels of experience	Less than 20 years	Span various levels of experience
Ante-natal, deliveries, gynae complications	Surgery, seasonal ailments	Seasonal ailments, respiratory ailments	Ante-natal, deliveries, gynae complications	Seasonal ailments, stomach ailments
FOGSI, IMA	IMA, Surgeon Associations ³	IMA	NIMA ¹ (Ayurveda & Unani providers only)	NIMA ¹ (Ayurveda & Unani providers only)
	More than 10 years Ante-natal, deliveries, gynae complications	More than 10 years More than 10 years Ante-natal, deliveries, gynae complications MBBS – Hospitals More than 10 years Surgery, seasonal ailments IMA, Surgeon	MBBS – Hospitals MBBS – GP Clinics More than 10 years More than 10 years More than 10 years More than 10 years Span various levels of experience Ante-natal, deliveries, gynae complications Surgery, seasonal ailments, respiratory ailments IMA, Surgeon	MBBS – Hospitals MBBS – GP Clinics AHU More than 10 years More than 10 years Ante-natal, deliveries, gynae complications MBBS – Hospitals MBBS – GP Clinics AHU Span various levels of experience Eass than 20 years Seasonal ailments, respiratory ailments MBBS – GP Clinics AHU Alu MBBS – Hospitals Span various levels of experience Less than 20 years Ante-natal, deliveries, gynae complications MIMA NIMA (Ayurveda & Unani

^{1.} National Integrated Medical Association – Only relevant for Ayurveda and Unani providers

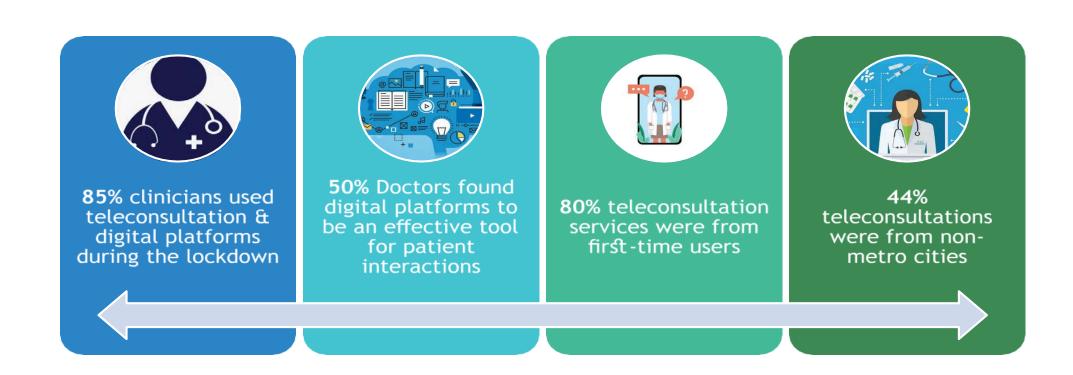
². Examples of family planning programs – DMPA, PEHEL, etc.; Examples of NGOs – PSI, DKT, MSI, etc.

³. Examples of Surgeon Associations - Association of Surgeons of India (ASI), Society of Endoscopic & Laparoscopic Surgeons of India (SELSI)

Private Service Provider Segmentation | Potential Areas of Engagement

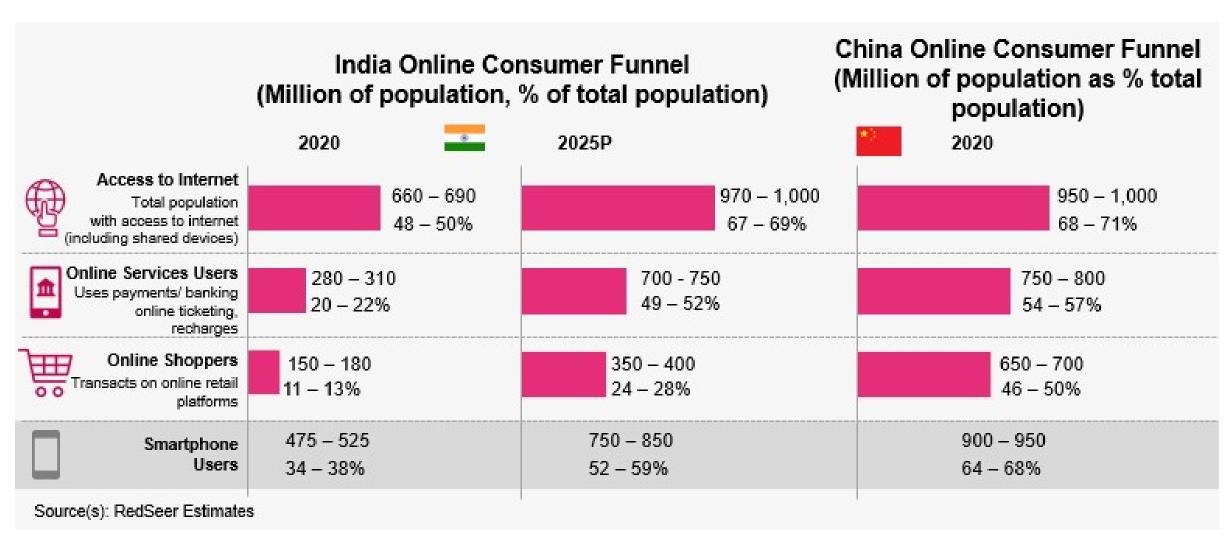
	OBGYN / Female MBBS	Female AHU	Male AHU / RMP
Guidelines	Continue to provide information on new products, and on management of side-effects	Provide guidelines and updated information on family planning, especially on ICs and new generation OCPs, and management of side effects	Provide guidelines on family planning, especially on second generation OCPs
Training		Provide regular trainings , especially for LARCs	Provide training, especially on counselling for family planning
Mobilization	Ensure adequate post adoption user support through online platforms Ensure indemnity/Insurance for performing family planning procedures Drive demand for family planning to their facilities	Drive Demand for family planning to their facilities	Motivate them to offer counselling on family planning to their clients

How India Accessed Healthcare During | March - 31 May 2020: Digital Healthcare Emerged as a Viable Alternative to Traditional Delivery Models



Note: Survey of 800 physicians conducted by BCG across Metros and Tier 1 cities

India Online Trends: Consumer Behaviors



DIGITAL PLAYERS | INDIA FP

PARTNERSHIPS	SERVICES	STAGE OF PURCHASE FUNNEL	LEARNINGS
NIVI AI	AI BASED 1-1 PERSONALIZED CHAT	CONVERT SUSPECTS TO PROSPECTS	COST PER ENGAGEMENT HIGH. CUSTOMIZATION WAS A CHALLENGE GENERIC CONTENT.
JUBI AI	AI BASED 1-1 PERSONALIZED CHAT	CONVERT SUSPECTS TO PROSPECTS	NEW PARTNERSHIP(CURRENTLY ON PAUSE) . VARIED AND ENGAGING FORMATS FOR CONTENT DELIVERY. VERY OPEN TO CUSTOMIZATION.
1 MG.COM	E-COMMERCE	CUSTOMERS [PRODUCT UPTAKE]	NOT INTERESTED IN PURCHASING AND STOCKING LOW VOLUME PRODUCTS.
NETMEDS.COM	E-COMMERCE	CUSTOMERS [PRODUCT UPTAKE]	RECENT PARTNERSHIP. PURCHASES LIMITED QUANTITY BASIS STOCK LEVELS. FREE OPTION FOR DOCTOR COUNSELING AND PRESCRIPTIONS.
DOCTERZ.COM	ONLINE CONSULTATIONS	CUSTOMERS [PRODUCT UPTAKE]	REGISTRATION AND CONSULTATION PROCESS WAS TEDIOUS. DOCTORS DIDN'T ADHERE TO APPOINTMENTS.
HOWL DIGITAL AGENCY	CREATIVE AND MEDIA PLANNING	AWARENESS	MID-SIZED DIGITAL AGENCY LEARNING CURVE IN THE CATEGORY WAS LONG. CONVERSION OF BRIEFS TO CONTENT/CREATIVES WERE POOR.
SOCIAL PANGA DIGITAL AGENCY	CREATIVE AND MEDIA PLANNING	AWARENESS	MID-SIZED DIGITAL AGENCY RECENT PARTNERSHIP. CATEGORY EXPERIENCE LIMITED BUT HAS CREATIVE STRENGTH.

PRACTO: REPORTED 234% INCREASE IN FP PRODUCT AND CONSULTING REVENUE FROM SEXUAL AND REPRODUCTIVE HEALTH CATEGORY IN 2022 DURING PANDEMIC.

INFORMATION FLOW | INDIA DIGITAL LANDSCAPE



DIGITAL USERS

622 million internet users (43% of population): 67% of the urban population i.e., **323 million individuals in urban India** are active internet users (4% growth over the past year) while 31% of the rural population i.e., **299 million individuals in rural India** are active internet users (13% growth over the past year)



DEMOGRAPHIC on the INTERNET

200 Mn+ Screenagers (Born between 1996-2005), In Urban India, the ratio between male to female Internet users is around 57:43 while in Rural India, the ratio between male to female Internet users is 58:42.



INTERNET ACESS and USAGE TRENDS

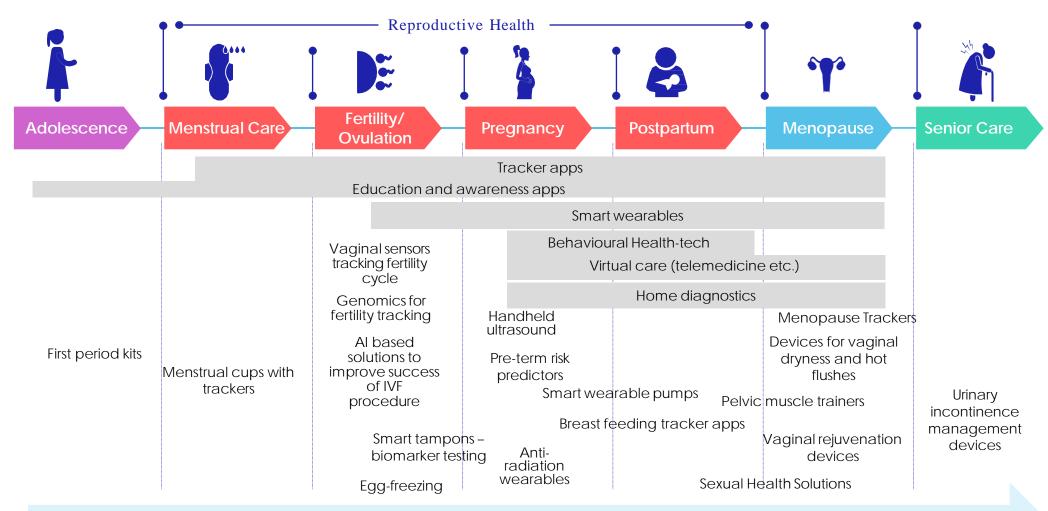
Cell phone remains the most used device for accessing internet with almost 100% of the active internet users opting for cell phones to access internet. 9 out of 10 active internet users access internet every day; On an average, they spend around 107 minutes actively on the internet daily.



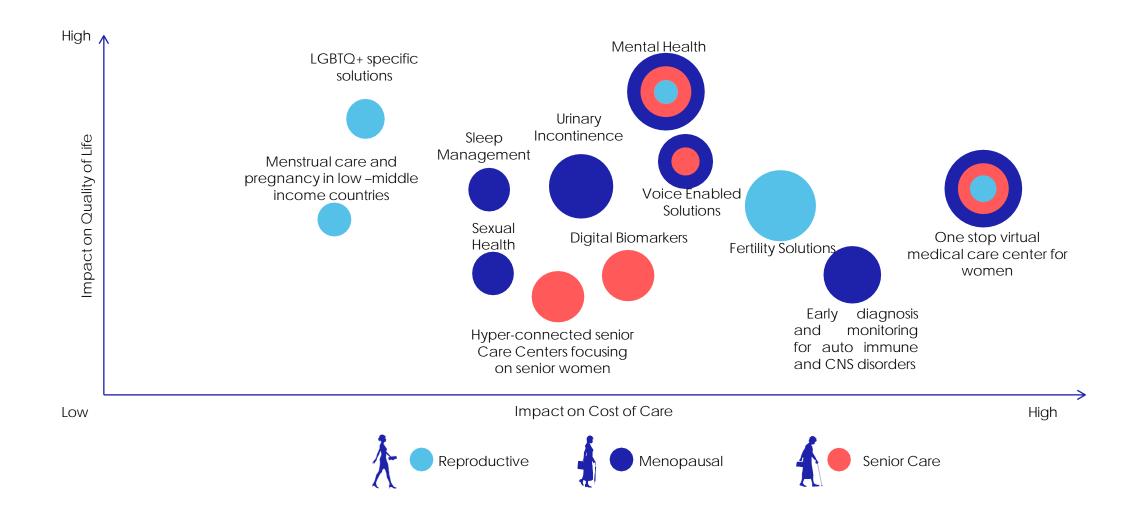
ACTIVITES on the INTERNET

96% of the AIU use internet for entertainment, followed by online communication (text, voice and video chats, emailing, etc.) and social media, 90% and 82% respectively. About 45% of All India Users (AIUs) have done any kind of online transaction (net commerce) and 28% of AIU do online shopping related activities on internet. Consumer health e-commerce sales as a % of retail sales is 1% (Bain and google report, 2017)

Disruptive Change: Digital and Femtech



Femtech: Top 12 Growth Opportunities in 2025



Preliminary insights: The Urgency To Become Mainstream

Accessibility y with respect to cost and outreach programs in developing countries would increase the customer base

Driving adoption and adherence through government policies and insurance or reimbursement agencies

B2B partnering with large public hospitals, healthcare companies, public health entities, and NGOs which have deeper distribution channels for mass screening and awareness campaigns

Personalized revenue models based on the application of Femtech solutions like renting devices for limited period of use

Developing affordable solutions and focusing on least explored aspects of women's health

Summary | Market Players

Manufacturers

- **Development of domestic demand** would be critical to ensure manufacturers' capacity is used to service local demand. (Underutilization is a challenge)
- Additionally, increased demand for innovative products in the domestic market would ensure the capability of players is reflected in the Indian FP market

Distributors/ Wholesalers

 There is potential to engage with distributors / wholesalers for point-of-sale promotions targeted at Outlet Providers

Service Providers

- Continued engagement with OBGYN / Female MBBS providers is critical as they are well
 positioned to offer the entire basket of family planning services
- Engaging with female AHU and male AHU would be critical to cater to rural and low-income consumers; additionally, the high density of AHUs in East makes it important to engage with them

Outlet Providers

- Working with in-hospital outlet providers, and standalone/ adjacent to hospital outlet providers who provide additional services would help ensure availability of a wide portfolio of contraceptive products
- Engagement with standalone outlet providers and outlet providers adjacent to hospital / clinic in urban UP would help to improve access to 3rd and 4th generation OCPs
- Working with outlet providers adjacent to hospital / clinic will help improve access to 3rd and 4th generation OCPs for young consumers

FINANCING

Key Principles of Health Financing Work

- I. Focus on the **sustainable expansion of FP markets**, not on advocacy, policy or capacity development
- 2. Focus on USAID priority PRH countries, learn from USAID graduated countries (e.g., Brazil where mCPR is two lagging states was led by HMOs, third-party insurance and group medical plans, municipalities contracting with large NGOs to deliver FP services).
- 3. Linkage to Health Outcomes (e.g., increase in mCPR)
- 4. Focus on how donor resources for FP can be used better and to support financial sustainability and transition.
- 5. Embedded in Sustainability principles market actors define, and drive embedded in country context while taking global good practices and evidence into account

FHM Engage may produce a toolkit based on global work, evidence so that market facilitators can apply it while doing MDA. Will include a global literature review of know good practices in FP health financing.

Each of the elements of mCPR slow to rapid growth to leveling off has health financing elements.

The mCPR growth trajectory is an important factor in family planning strategic planning and identifying programmatic priorities for investment. Exiting rapid Leveling off Slow growth **Entering** rapid Rapid growth growth growth Higher mCPR Investment in: demand Investment in generation, ensuring mCPR shifting social equity, longnorms, and term establishing sustainability, infrastructure to continued deliver family service planning services improvement, and expanded Investment in reducing barriers to access, ensuring method choice contraceptive availability and high quality services, and sustaining demand generation Lower mCPR fapted from Track20, "The S-Curve: Putting mCPR Growth in Context," available at: http://track20.org/download/pdf/S Curve One Pager.pdf

Following the Key Principles of High Performing Health Financing Systems Contributes to Sustaining FP Outcomes with country financing

Resource mobilization



- How much is being raised for health?
- What are the sources of funding?

Pooling



- What types of and how many pools exist?
- What proportion of the population is included in each pool?

Purchasing



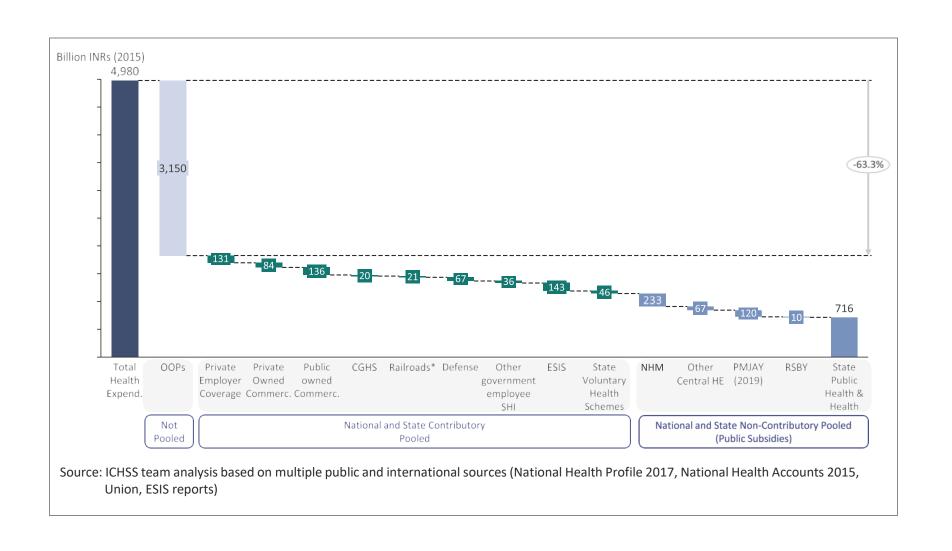
- What services are being purchased and by whom?
- What are the mechanisms for purchasing healthcare?

Donor resources are an important funding source for many priority USAID PRH countries. If donor resources support more pooling and purchasing within a country's political and economic context, the country's ability to move into mCPR leveling off and sustain with its own funds increases.

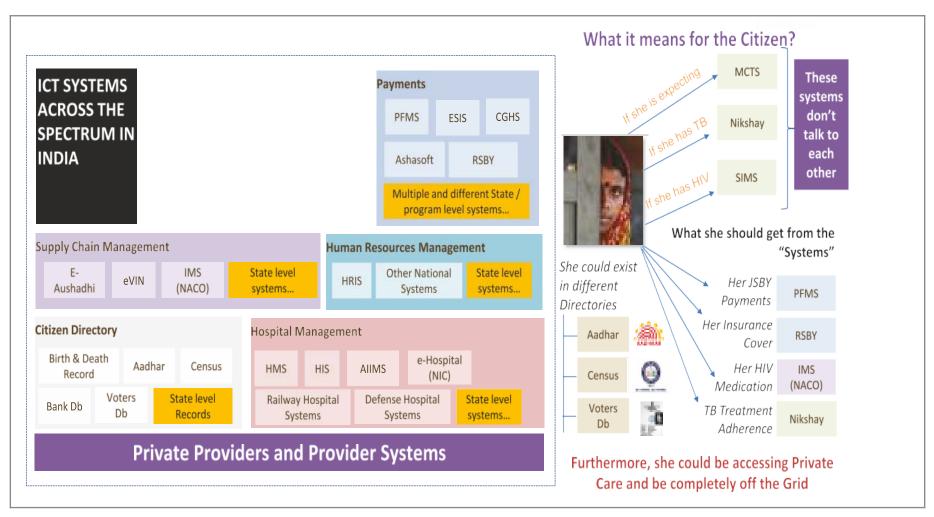
Examples of HF tools/approaches we will look at to build our framework and toolbox

mCPR level, HF level	Types of HF Interventions	Potential Countries/Tracer Countries
Slow Growth (mCPR = <20%) – <i>Interventions</i> : Investment in Demand Generation, establishing infrastructure to deliver FP. Typical Health Financing Landscape : Low fiscal space for health, High donor dependence, limited pre-payment schemes, high out-of-pocket. High health financing fragmentation reducing efficiency, increasing costs of delivery.	 Voucher programs targeting specific groups (e.g. youth). Virtual pooling of donor financing, catalytic financing. Contracting (strategic purchasing) with SMO, SFOs, NGOs with donor funds (performance-based. E.g. activities, outputs) (e.g. Afghanistan) 	DRC Modern Contraceptive Prevalence Rate: 9% Total Fertility Rate: 6.2 children per woman (conflict/post-conflict/fragile state). Very high dono funding. Nigeria Modern Contraceptive Prevalence Rate: 11% Total Fertility Rate: 5.7 children per woman (basic Health Insurance)
Enter rapid growth, rapid growth (mCPR = >20% - < 50 %) Investment in reducing barriers to access, ensuring contraceptive availability and access to services, sustaining demand generation Typical Health Financing Landscape: A mix but some countries with fiscal space, emergent prepayment schemes, beginning or advanced transition from donor financing, linkages to UHC	 Slow growth interventions (previous row) apply. Potential for blended finance (government, donor through programmatic funding approaches for national FP programs). Strategic purchasing of FP through PRH packages. Contracts with accredited private providers. 	INDIA POTENTIAL DEEP DIVE

India has low level and very fragmented risk pooling, with household out-of-pocket funding at 64% of total expenses dominating the overall system financing

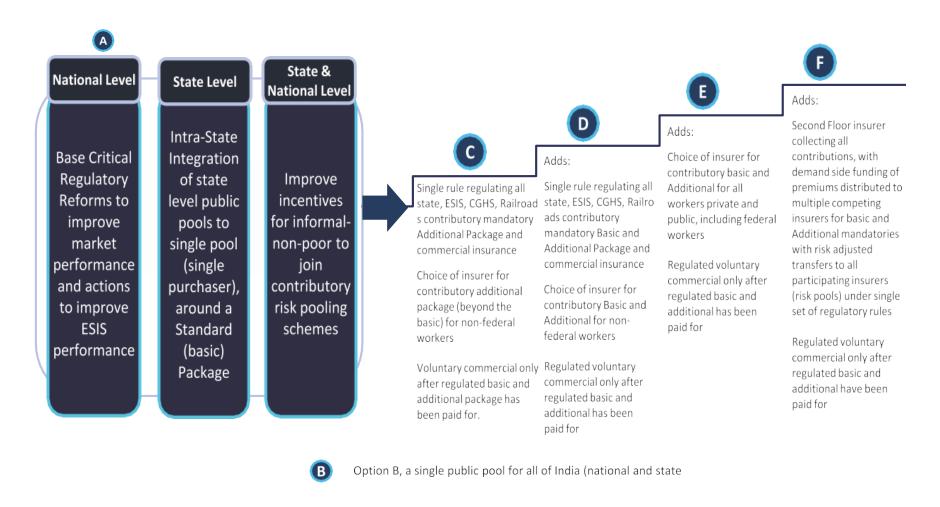


User: Accessing equitable benefits has several frictions



Source: Health Systems Reforms, 2019, NITI, ICHSS Team analysis

Health System for a New India: Building Blocks Reforms: A two-step option and transition approach to improve risk pooling in India



Source: Health Systems Reforms, 2019, NITI, ICHSS Team analysis

Different Output-Based Options to Pay Providers Each creates certain risks and Incentives

	Provider incentive to					
Payment mechanism	Payer	Provider	Increase No of patients	Decrease number of services per payment: Units	Increase Reported Illness Severity	Select healthier patients
Fee for service	All risk borne by payer	No risk borne by Provider	√	X	√	X
Case Mix Adjusted Per Admission (e.g., DRG)	Risk of Number of Cases and Case Severity Classification	Risk of Cos: of Treatment for a giver case	√	√	√	√
Per admission	Risk of number of Admission	Risk of Cos: of treatment for a giver case	√	√	X	√
Per-Diem	Risk of number of days to stay	Risk of cost of services within a given day	✓	√	×	X
Capitation	Amount above ' Stop Loss' ceiling	All risk borne by provider up to a given ceiling (Stop loss)	√	√	N/A	√
Global Budget	No risk borne by payer	All risk borne by provider	X	N/A	N/A	√

Source: Health Systems Reforms, 2019, NITI, ICHSS Team analysis

Strategic Purchasing: Situation in India

Strategic Purchasing – Enablers: India today lacks several enablers for implementing

Monitoring

- Public purchasing organizations perform (in general*) very limited monitoring activity:
 - Mostly limited to audits
 - Limited data collection (if any), and not standardized
 - Limited capacity / capabilities for analysis
 - Limited financial review, beyond line-item accounting
- Private purchasing organizations have more developed but still improvable practices:
 - Mandatory reporting to IRDAI
 - Regular claims review / audit by insurers / TPAs, with focus on fraud prevention

Provider autonomy

- Limited autonomy of Public Providers in:
 - Using funds due to line-item budget
 - Hiring / firing of personnel
 - Pricing of services
- Limited financial planning capabilities at public and (most of) private providers
- reservation of 25% of beds for EWS
 (Economically Weaker Sections) in private hospitals limiting efficient capacity utilization and fostering fraud

ICT / data systems

- Lack of (integrated) ICT infrastructure for providers and payors
- Non existence of standardized data dictionary
- Limitations with existing EMRs (Electronic Medical Records)
- Only basic tools for actuarial function and financial planning
- Automation still limited, been introduced in commercial payors and larger private providers:
 - Core Underwriting
 - User enrollment and management
 - Claims Processing
 - Fraud prevention (triggers)
 - Interface payor-hospitals
 - Other support functions

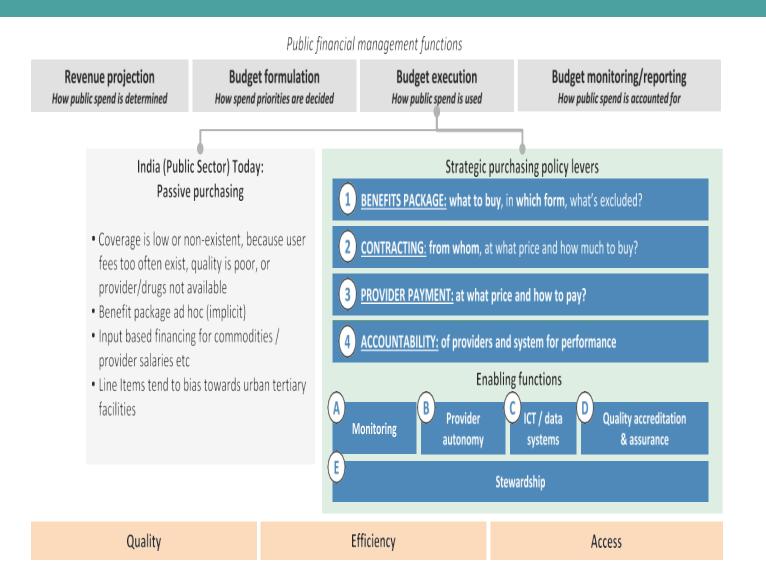
Quality accreditation & assurance

- Clinical Establishment Act setting guidelines but implemented only in 9 states
- Lack of standards / guidelines e.g. treatment protocols, costing guidelines, etc.
- HMIS** is used to collect data in Public facilities
 with concerns on accuracy of data reported
- Private hospitals self-report few quality indicators, not subject to independent validation
- State Quality Assurance Units (SQAU) exist but with limitations:
 - No facility field assessments in 5 states
 - Inactive (no review meetings in last 3 years) in 12 states
 - Not existing in 3 states
- Medical Doctor registration is mandatory but with ambiguity and rules flouting at State level
- NABH / NABL provides guidelines and accreditation to hospitals / laboratories, but with limited utilization (480 facilities in 2017)

^{*} Some examples exist of good monitoring practices, e.g. in Karnataka and Tamil Nadu

^{**} Health Management Information System

Strategic Purchasing: Current policy levers to drive change



- Supply or "benefits package" (the what to buy, in which form, and what to exclude)?
- Factor and product markets or "contracting" (the from whom, at what price to buy, and how much to buy)?
- Prices and incentive regime or "provider payment systems" (at what price and how to pay)?
- Accountability measures to assure funds are spent efficiently and achieve optimal levels of quality.

99

How can blended finance be pivotal for India's healthcare industry?

	Build	Strengthen	Transition
Health status	Minimal public health expenditure, insufficient access to health facilities, and poor health outcomes	Moderate public health expenditure, better health infrastructure but low access, improving health outcomes	Higher public health expenditure with variable access and better health outcomes
Investment attractiveness	Underdeveloped financial sector, lack of investor interest	Financial markets still developing, but private healthcare players have better access to capital	More established financial sector, as well as moderately, developed private sector and investor interest
Approach to blended finance	Development agencies can focus more on building capacity and pipeline for blended finance	Amenable to deploying simpler instruments but likely not ready for complex blended finance tools	Development agencies can deploy complex blended finance tools, gradually helping countries transition to self-reliance

Source: Country Archetypes, Figure 7, Greater than the sum of the parts, Blended Finance Roadmap for Global Health, USAID, CII Investing for Impact

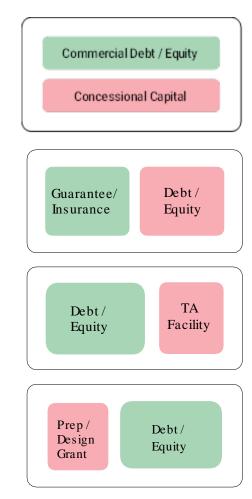
Blended finance archetypes

I. Public or philanthropic funders provide funds at below-market terms within the capital structure to lower the overall cost of capital, or provide an additional layer of protection to private investors (referred to as concessional capital).

II. Public or philanthropic funders provide credit enhancement through guarantees or insurance on below-market terms to private investors (referred to as risk guarantees/insurance).

III. The transaction is associated with a grant-funded technical assistance facility that can be utilized pre- or post-investment to strengthen commercial viability and developmental impact (referred to as technical assistance funds).

IV. Transaction design or preparation is grant-funded (including project preparation or design-stage grants) (referred to as design-stage grants).



DIAGNOSIS (How is the Market Failing?) a) Key Market Constraints 02

INDIA DIAGNOSIS: AIM Analysis

Worksheet: Analyze market system performance for INDIA

Observations

Market characters

Core Market	Supply		x	 Adverse Incentives that skews Method Mix in public sector, Young user centric strategies and approaches at state level have not been tried with intention. 		
Core	Demand			x		 Discontinuty system not addressed, Side effects management requires support. Promotion 'P' has several restrictions. Provider bias high which limits demand.
	80	S & D	X			Limited awareness of and access to insurance / indemnity schemes exacerbates the perceived high risk involved in providing certain FP services Lack of market development capital makes it difficult for manufacturers/ marketers to expand their product portfolio
	Financing	Subsidies		X		Social Marketing guidelines and procurement stuck due to lack of data for decision making
SI	"	Business	x			FP as an category is low priority and there has been no concerted Investment case made for gender lens investing.
Supporting Functions	lnfo	Supply	x			 Complete absence of market intelligence across collection, analysis and use in public sector for Private sector stewardship. Private sector do not want to invest in market creation for FP services and products without trusted information and guidance from MoHFW.
portir	_	Demand			x	Restricted to few INGOs and FP coalition partners who 'interface' between market players and consumers.
Sul	Skills, Capacity X		x	 Platforms are Absent for networking of entrepreneurs whose business models are focused on Womens health. Across market actors' skills available barring Implants delivery in India. Low priority. 		
	Stewardship X			 Absence of <u>segmented approach for youth market</u>, <u>Old paradigm and low urgency expected to shape new consumer segments.</u> <u>Private sector stewardship is product focused and not category wide.</u> Consumer level stewardship is dominantly in <u>Digital information space</u> <u>by women entrepreneurs.</u> However, no conversion from awareness to uptake of services and products for <u>SRH</u> 		
	Regulations		x	 Self care strategy absent, Quality assurance mechanisms need focus, The government's regulatory framework on procurement and product trials makes it difficult for manufacturers and marketers to launch new, improved FP products 		
\egs	Tariffs, Taxes X		x	Price regulation restricts innovation and range introduction in domestic market.		
Rules & Regs	Standards X		x	Set by MoH and Experts lacks self care agenda and 'consumer centered' and insight driven process. Top down.		
- Ru		Supply				Generally, an enabling tailwind across Samaaj (Civil society), Sarkaar (Government) and Bazaar (Markets) for the youth demography. However, intentions don't translate to action across the systems development approach which is Youth Centric, leadership and supported.
	Norms	Demand				

Market Constraints (1/6) | Market Entry Barriers

- The government's regulatory framework on procurement and product trials makes it difficult for manufacturers and marketers to launch new, improved FP products. The key constraints include:
 - Government subsidizes and procures only certain FP products and versions for sale through SMOs
 - Unfavorable public procurement process, with high quotas for public sector undertakings (PSUs)
 - Government has stringent trial requirements for new products
 - Inhibitory regulations on new hormonal products (guided by market activism) who often have a biased view based on one-sided information, delays availability of new FP products
- The regulatory environment disallows private sector providers from providing comprehensive FP services. The key constraints include:
 - Regulatory constraints on provisioning by types of providers
 - Marketing activities restrictions across content and timing
- There are laws that inhibit penetration of different generations of FP hormonal drugs and devices, due to the varying regulations across schedules of drugs & medical devices
 - Formal rules like the classification distortions (Schedule H vs. K) increase complexity

Market Constraints (2/6) | Consumer Access Barriers

- AYUSH / RMPs do not have adequate access to information, infrastructure and guidance towards providing balanced FP services. This is due to the following reasons:
 - Lack of organized platforms / associations for providing guidance and / or information on FP service provisioning
 - Financing challenges to invest in requisite infrastructure for FP service provisioning
 - Limited investment in targeted FP trainings for AYUSH / RMPs
 - Lack of updated information as usual sources (e.g., MRs) do not visit AYUSH / RMPs to promote FP products
- There is no strategic approach to include private OBGYN / MBBS providers and methods other than sterilization. Key manifestations include:
 - NGO client mobilization is geared towards public facilities
 - Demand generation for FP is conducted by outreach workers (e.g. ASHA, NGOs), whose method-based incentives are skewed toward sterilization and / or public sector facilities

Market Constraints (3/6) | Biases

- The government largely focuses its FP efforts on sterilization conducted at public sector facilities and does not steward the market towards balanced FP provisioning across methods. This is due to the following reasons:
 - Lack of evidence regarding significant impact of reversible methods, specifically OCPs, ICs, and IUDs, on mCPR
 - Government finds permanent method/IUDs easier to manage and monitor
- Biases held by private OBGYN/MBBS providers prevent them from providing comprehensive FP services.
 These biases include the following:
 - Some OBGYN / MBBS providers believe certain FP products may not be appropriate for rural consumers or consumers with low education levels
 - Some OBGYN / MBBS providers have biases related to offering IUDs to nulliparous women
 - Gender biases prevent OBGYN / MBBS providers from offering specific services to clients of the opposite gender
 - There is reluctance amongst OBGYN / MBBS providers on task-shifting for ICs

Market Constraints | Public Stewardship (Information Asymmetry)

- Lack of a segmented understanding of consumers inhibits adequate market development for many FP methods and restricts adoption amongst certain consumer segments. Key manifestations include:
 - Government focuses on public sector sterilization as the primary FP mechanism for all consumers
 - Govt. lacks segmented understanding of market and consumers for a balanced method mix and choice
 - Lack of segmented understanding of consumers tends to distort priorities around business models – for reach and access

Market Constraints | Public Stewardship (Information Asymmetry)

- There is an absence of a level playing field in incentives provided to the private sector, especially related to compensation and disbursement of funds. Key manifestations include:
 - Limited awareness of and access to insurance / indemnity schemes exacerbates the perceived high risk involved in providing certain FP services
 - Misunderstood cost benefit analysis for the private sector by the government leading to insufficient government compensation for providers
 - Government processes for claiming compensation are inconvenient (e.g., significant paperwork required to claim subsidy, delays in government reimbursements) limit the number of providers providing certain FP services

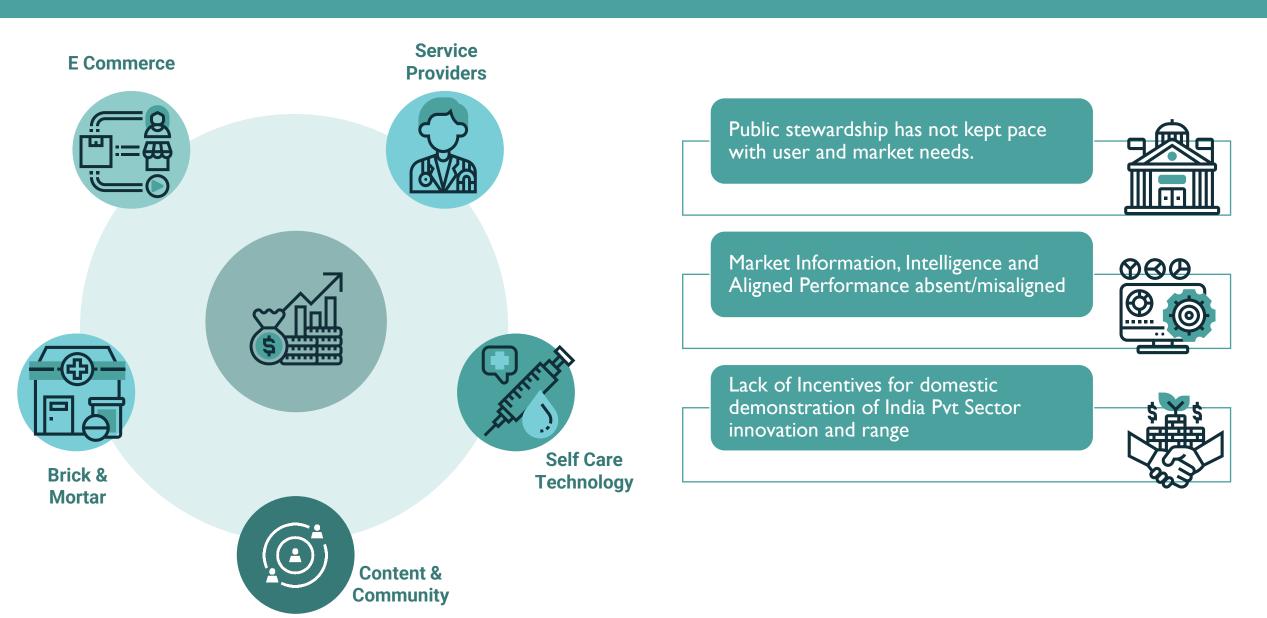
Market Constraints | Lack Of Incentives/Information

- Lack of market development capital makes it difficult for manufacturers/ marketers to expand their product portfolio. This is due to the following reasons:
 - High cost of debt financing and limited internal cash reserves for small manufacturers, constrains brand investment
 - Limited internal cash reserves for SMOs, due to low product margins; and insufficient, and inefficient subsidies
 - Limited returns from utilizing their product development capability and their production capacities for the domestic
 market
 - Brand building for new FP products requires time and resources
 - New products and versions require greater investments due to higher selling prices charged by manufacturers
- Marketers are underinvesting in expanding their geographical footprint, leaving many consumers underserved by the private market. This is due to the following reasons:
 - Limited financial returns from operating in small catchment areas as a result of low turnover of FP products
 - SMOs/Social Sector do not intentionally target hard-to-reach consumers, unless grant funding exists for specific consumer segments

Market Constraints | Lack Of Incentives/Information

- Lack of market development capital makes it difficult for manufacturers/ marketers to expand their product portfolio. This is due to the following reasons:
 - High cost of debt financing and limited internal cash reserves for small manufacturers, constrains brand investment
 - Limited internal cash reserves for SMOs, due to low product margins; and insufficient, and inefficient subsidies
 - Limited returns from utilizing their product development capability and their production capacities for the domestic
 market
 - Brand building for new FP products requires time and resources
 - New products and versions require greater investments due to higher selling prices charged by manufacturers
- Marketers are underinvesting in expanding their geographical footprint, leaving many consumers underserved by the private market. This is due to the following reasons:
 - Limited financial returns from operating in small catchment areas as a result of low turnover of FP products
 - SMOs/Social Sector do not intentionally target hard-to-reach consumers, unless grant funding exists for specific consumer segments

Catalyse India Youth FP Market: Insights from Information



Solution Segmentation: High level Draft

Segment	Public	Private	Private		
Draft Metrics					
 Value and Volume growth. Increased quality of services. Increased private sector participation in FP. Catalytic financing unlocked. 	MoHFW develops a segmented strategic approach in line with FP2030 commitments	Harness the private sector providers to address FP needs among underserved segments. (Private provision for public delivery)	Business models to increase sustainability and grow total domestic market	Capacity building to address 'can-do gap' among FP value chain players	Market entry strategy for innovative (and new) FP products, including business case.
Equity	Young,WRA, 15-24 years				
Choice	Permanent Method (strengthen male Engagement) Long-Acting Reversible Methods Short and the strength of the s		t and Long-Acting Reversible Methods and novel on-demand FP products ntiles High Wealth Quintiles		
Access	Rural		Urban/Peri-urban		

DRAFT THEORY OF CHANGE

Who is the Market Failing?

How is the market failing?

Where do we work in the market? Preliminary Health Impact: Reduced Maternal and Infant Mortality

Support a robust, diversified and sustainable FP market that delivers agency for youth with access and choice to quality assured affordable products and services. The project will emphasize:

- ➤ Youth aged 19-24
- ➤ Youth 25-29
- in urban and peri urban areas, pushing into rural areas
- ➤ Lower middle-income youth (C&D classes)
- I. Domestic Market players have access to Market intelligence and trusted information for investments to introduce new products and create demand for the youth segment.
- 2. Ministry of Health and Family Welfare provides ongoing and consistent stewardship to collect, integrate and utilize data across markets for FP strategy to catalyze Youth markets through enabling policies and guidelines for market participation.
- 3. FHM Engage facilitates the development of a platform that will sustainably act as a Market place for Women's health with a vision to grow the value and volume of social ventures with access to finance, networks and mentorship to succeed.

Improved Core Functions

Refer Consolidated P2U Solutions sheet under Price, Place, Product, Promotion **Increased Support Functions**

Refer Consolidate P2U Solutions sheet under Supporting Functions.

Improved Rule Functions

Refer Consolidated P2U Solutions sheet under Rules and regulations

How do we get there?

Refer consolidated P2U workbook for Use case and draft Solutions sheet

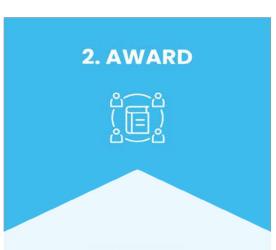
Proposed Strategic Approach

April-September 2023



GET ALIGNED AND ORGANIZED

Complete Market diagnosis and Diligence for strategic partners. Agree on Theory of change and metrics with USAID.



CODIFY AGREEMENTS

Complete sub awarding with roles and responsibilities with all market actors and alliances.

Create the WOHLA partnership.



MAKE IT ACTIONABLE

By September 2023, FHM
Engage will be ready with the
3 years sustainable and
scalable pathways, critical
interdependencies are defined
and Technical assistance plan
for Market actors established



Develop Tools and practice management briefs and SOP: Investment cases, Climate and resilience pathways to scale, Blueprint for Youth Stewardship and private sector participation

SCALE

ANNEXURE

Summarized Cross walk to workplan

Summary of Approach

Goal

Improved Health Impact through reduced maternal and infant Mortality

Outcomes

Increase in adoption of modern contraceptive methods among WRA 19-30 with specific focus on; Youth in Urban India (FHM Engage USAID focus geo in India)

Outputs & Activities

IR 2: Expand access to a range of affordable

IR. I: Improving Market stewardship to bring youth centered approaches for FP			
IR. I.I: Investing in Market Intelligence	IR. 1.2 Strengthen Mkt Development Approaches to sustainable FP	IR. I.3 Improving Coordination of the Private Sector	
IR. I.4 Improving the Policy & Regulatory Environment	IR. I.5Investing in Financing		

•	raceptives for youth
Support expansion of contraceptive choice through investments in OCP and EC brands, and strategic support for LARC	Incubate, accelerate, and sustain digital innovations for improving access to contraceptives.

IR 3: Increase demand for SRH products and services

Strengthen youth voices for a call to action towards FP 2030 with the private sector leading to market system changes

IR I.I: Improving Market stewardship to bring youth centered approaches for FP: Improving Coordination of the Private Sector

What's the problem we're solving: Improved coordination is important to understanding the scope and scale of private sector engagement, in building trust, and identifying opportunities for PPP, and achieving national goals

Constraints

Strategic Priority

Outputs

Activities that lead to desired outputs

- Insufficient understanding ar appreciation of the private sector (role, potential, current impact) by Gol contributes to mistrust and missed opportunities to collaborate
- Insufficient structures for coordination and collaboration inhibit potential PPP
- A fractured private sector doesn't enable needs and perspective to be integrated into Gol strategy, policy and regulatory environment.
- No platforms or coalitions exist to align private sector actors and advocate
- Coordinating bodies that do exist generally focus on specific products

Improved
Commercial
Sector
Coordination and
strategy through
the
establishment of
the Women's
Health and
Livelihood
Alliance (WoHLA)

- I. WoHLA
 established and
 capacity built to
 take a leading role
 on advocacy,
 coordination, and
 facilitation of
 market
 interventions
- 2. Improved stewardship leading to ability to coordinate, collaborate and align key market actors in Youth FP markets

- **Establish WoHLA:** Identify and select organization to establish WoHLA, whose mandate is to provide TA for GoI institutions to improve public-private coordination and facilitate dialogue on policy and program coordination.
- **Identify potential anchor partners for WOHLA**: develop value proposition for shared value partnerships and solicit financial commitments
- Develop **capacity of WOHLA** to be a change agent to identify, attract and leverage investments into Women and AYSRH related issues
- Map Gol and entities to understand roles, responsibilities and identify opportunities to advocate for improved coordination, policies, and identify opportunities of collaboration.
- Landscape investment and partnership opportunity (i.e. workplace programs)
- Launch "WoHLA on Wheels" targeting vulnerable women (i.e tribal women);
- Identify opportunity to support platforms which increase access to capital for women health entrepreneurs for products, services, and Information
- Build capacity and support the development of WoHLA mgt secretariate
- Facilitate discussions to recognize the relevance of Social Marketing that compliments Gol and commercial actors and contributing to sustainable health markets.
- Explore and identify opportunities to invest in digital innovations supporting FP infor and services delivery; data collection, and analysis and contraceptive social marketing.
- Strengthen social franchising
- Extension of the COT model for all States.
- Support decentralization of stewardship/leadership within sub-national state govt platforms, especially within State Health Mission.
- Inform and advocate to GoI and think taks like Niti Aayog on the role, size, and scope, and impact of the commercial sector.
- Advocate for Gol commitment to develop a roadmap for youth interventions across FP 2030, G20 and I20 events,
- Tackle strategic interventions that address prioritized market weaknesses.

Key Partnerships & Roles: FHM (Market Facilitation), WoHLA, entity selected to incubate WoHLA (Coordination); Access Intl (Research, Design and Development), MoH

IR 1.2: Improving Market stewardship to bring youth centered approaches for FP: Investing in Market Intelligence

<u>The problem we're solving:</u>A dearth of market intelligence impedes the ability of the private sector to understand opportunities for product introduction, growth, and areas of investment.

Constraints

Strategic Priority

Outputs

Activities that lead to desired outputs

- Limited access to tools for forecasting, determining historic trends, and quantifying market demand by method and opportunity for their brand.
- Poor market data makes demand forecasting, business planning, and identification of market potential challenging.
- Info asymmetries impact supply chain stakeholders, where demand is being created and clients need customized services.

'Fit for purpose'
market
Intelligence
informs policies,
commercial actor
investments, and
market
intervention
design and
monitoring

I. Gol understands role of private sector to improve coordination, make informed investments in context of all sectors, and design and implement favorable policies

II. Private sector actors make informed investments in the Indian contraceptive Market

- **Develop demand estimates** for national and subregional FP market to illustrate potential volume and value of next generation OCPs, ECs & other
- Collect priority market data across sectors in targeted states. Potential studies include market value and volumes; value chain analysis (from manufacturing to channels); distribution coverage; user demand; and policy.
- Analyze, synthesize, share and disseminate market data, coordinating sharing across organizations to identify market gaps and insights, risks and opportunities
- Use analysis to create category and productspecific action plans to address prioritized market weaknesses, improve supplier diversity and promote overall market health.

Key Partnerships & Roles: FHM (Market Facilitation, Adaptive Learning and Knowledge management), entity selected to incubate WoHLA, Access Intl (Research, Design and Development), Pharmrack, Viatris (Sales and distribution data) MoH; Youth NGO (Youth User and Journey insights)

IR 1.3: Improving Market stewardship to bring youth centered approaches for FP: Invest in Financing

What's the problem we're solving?

- Market actors require access to credit for facility upgradation, working capital for optimizing inventory and incorporating efficiency tools and MIS.
- Women need access to credit to improve health, livelihood, entrepreneurship.

Constraints

Strategic Priority

Outputs

Activities that lead to desired outputs

- Limited access to affordable finance, operating capital, misaligned credit cycles, and un-bankable collateral
- Distortive subsidy disrupts category and inhibits commercial performance
- A lack of blended financing models restricts leveraging Gol and/or donor financing
- Marketers/distributors are underinvesting in expanding their geographical footprint
- Lack of working capital for distributors
- Less than qualified providers (LTQP) don't have access to formal loans or financing Consumers lack access to insurance or third-party payer financing

Expand
sustainable
access to
relevant, fit for
purpose
financing to
reach more
youth by
manufacturers,
distributors,
private providers

I. Establish WoHLA as the platform to curate and facilitate blended financing for private sector

2. Leverage financial instruments to impact system change

- Establish WoHLA to bring finance and programs together; serve as a marketplace for women's health and grow the value and volume of social ventures
- Identify and facilitate access to <u>private</u> funds including (i) commercial loans with loan guarantees and soft loans with loss guarantees, (ii) Corporate financing and CSR, and (iii) returnable grants providing short-term, affordable, and flexible capital (zero interest and zero collateral).
- Identify and facilitate access to <u>public</u> funds including (i) state led strategic purchasing and Service Level Agreements (SLAs) between private providers and public suppliers, (ii) while developing a longterm health financing strategy.
- Explore and pilot creative demand-side mechanisms funded by private sector actors for women's health (i.e. E-vouchers, payback schemes, subscriptions, and livelihood assistance capital for women).
- Explore and pilot supply-side mechanisms such as savings and insurance programs (i.e. Care Insurance pilot & subscription-based models) within community insurance schemes or workplace supported healthcare intervention
- Research, Design and Develop Strategic Purchasing initiatives by Gol

Key Partnerships & Roles: FHM (Market Facilitation), WoHLA (Women targeted financing for health, skills and livelihood, supply chain financing, supply / demand Sub Grants, resource mobilization and partnerships, State Level engagements and implementation of SLAs/IFA), Access Intl (Research, Design and Development of Strategic purchasing)

IR I.: Improving Market stewardship to bring youth centered approaches for FP: Improving the **Policy & Regulatory Environment**

<u>The problem we're solving</u>: Unfavorable policy and regulatory environement creates an uneven playing field, inhibits commercial sector investment in domestic market

Constraints	Strategic Priority	Outputs	Activities that lead to desired outputs
 Private sector actors are reluctant to invest in creating a market for FP services and products without trusted information and clear guidance from MoHFW. A lack of a PPP engagement strategy prevents Gol from optimizing private sector Self-care strategy is absent Poor user and market segmentation inhibits a coordinated approach Price regulations restrict innovation (conflicting regulations across drug schedules and devices). The regulatory environment prevents private sector providers from providing comprehensive FP service 	Invest in policy and regulatory environment	Favorable policy and regulatory environment facilitating commercial sector participation in the FP market	 Reduce policy and regulatory barriers on Abbreviated New Drug Application processes, product importation, registration, or testing requirements through engagement w/ Dept. Of Pharmaceuticals and CDSCO – With NPPA/PMRU, understand feasibility of production linked incentives and licensing for product innovations for manufacturers and permission of promotions Landscaping of ministries (in 1.3) Identify opportunities and outcomes for state level partnerships across schemes focusing on Livelihood, women's health and empowerment Identify advocacy priorities and design interventions to influence policy/regulatory shifts Conduct leg/reg review to identify regulatory bottlenecks Design, develop, and integrate youth led advocacy strategies and interventions at state level Identify, design, implement production linked incentive schemes, PTUAS, GMP upgrade. Integrate Adaptive Learning and Knowledge management into program design

Key Partnerships & Roles: Access Intl (Landscaping and scoping opportunities across Ministries and Departments, Design state level interventions)

FHM (Market Facilitation), WoHLA (State level partnerships across schemes on Livelihood, women's health and empowerment); Youth NGO (Youth lead strategies implementation at state level) Mkt Manufacturers: (Production linked incentives schemes, PTUAS, GMP Upgrade, Generic product, Price reduction or packaging innovations)

IR 2: Expand access to a range of affordable, accessible FP contraceptives for youth

<u>The problem we're solving:</u> Insufficient investment by manufacturers, marketers and support by providers to serving priority populations

Constraints	Strategic Priority	Outputs	Activities that lead to desired outputs
Providers are both an opportunity and barrier to serving priority populations: • Private providers struggle to access information & training • AYUSH / RMPs do not have adequate access to information, infrastructure, and guidance	Support expansion of	I. Support supplier diversity and market health to increase availability/launch of new contraceptive methods (OCP and ECP) for youth	 Develop investment case to manufacturers and marketeers growing the market in targeted priority states Create financing / economic incentives Invest in effective and resilient supply chains through support for planning with manufacturers, distributors, deployme of financing, buffering strategies and encouraging stronger relationships. Identify actions that improve climate resilient delivery models and ESG practices for value chain stakeholders (study)
 Lack of a strategic approach to include private OBGYN / MBBS providers in FP provision Biases held by private OBGYN/MBBS providers Marketers/Wholesalers are underinvesting in expanding their geographical footprint Perceived limited financial returns / opportunity SMOs struggle to target underserved pops 	contraceptive choice through investments in OCP and EC brands, and strategic support for LARC	II. Build local provider capacity to deliver higher generation contraceptives and other hormonal methods	 Identify & invest in aggregator / intermediary models that target provider/ facilities preferred by youth (i.e. pharmarack) Expand innovative and cost-effective provider behavior change / training approaches to include private healthcare providers, including pharmacists and drug shop providers Co-design with youth leaders services and products that meet the needs and preferences of youth Encourage and coordinate product launches / increased availability of next gen contraceptives and other hormonal methods w/ consumer financing mechanisms to remove cost barriers Coordinate to create incentives for: QA, Risk sharing with debt funding, innovation for last mile delivery, Climate Resilience, Serving the poor

<u>Key Partnerships:</u> FHM, (facilitation) Phramarack and other integrators (wholesalers and distributors – expansion and addition of increased range of OCP, ECP)

Manufacturing partners (New product introduction and sales) Provider aggregators org like FPAI/NIMA (Provider capacity Building, Consulting and Prescription (tele medicine and in-clinic) Consultants like FSG (Climate change effects mitigation and design of solutions study)

IR 2.2: Expand access to a range of affordable, accessible FP contraceptives for youth - Digital Solutions

<u>The problem we're solving:</u> Insufficient investment by manufacturers, marketers and support by providers to serving priority populations

Constraints	Strategic Priority	Outputs	Activities that lead to desired outputs
Providers are both an opportunity and barrier to serving priority populations: • Private providers struggle to access information & training • AYUSH / RMPs do not have adequate access to information, infrastructure, and guidance • Lack of a strategic approach to include private OBGYN / MBBS providers in FP provision • Biases held by private OBGYN/MBBS providers Marketers/Wholesalers are underinvesting in expanding their geographical footprint • Perceived limited financial returns / opportunity • SMOs struggle to target underserved pops	Incubate, accelerate, and sustain digital innovations for improving access to contraceptives	Harness the power of digital technology to identify and test scalable solutions, esp. for improved management of side effects, and reach towards youth	 Evaluate (conversion rates, etc.) and identify high potential interventions reaching youth and support start-ups linked to on-line and brick and mortar sites, support consumer oriented digital platforms such as LOVE MATTERS Document use of direct-to-consumer distribution, shifts to self-care, private retailers, multi-month dispensing, last mile solutions and support and scale successful adaptations post-pandemic to increase access to SRH supplies and services. Support consumer oriented digital platforms (i.e. social media platforms) for business viability - to reach youth FemTech supported to provide solutions to improve healthcare for women across several female-specific conditions (i.e. maternal and menstrual health, pelvic and sexual health, fertility, menopause, and contraception, osteoporosis and cardiovascular disease) Engage opportunities for FemTech India type startups to collaborate and partner with healthcare and feminine products enterprises.

Key Partnerships: FHM, (facilitation) Phramarack and other integrators (wholesalers and distributors – expansion and addition of increased range of OCP, ECP)

Manufacturing partners (New product introduction and sales) Provider aggregators org like FPAI/NIMA (Provider capacity Building, Consulting and Prescription (tele medicine and in-clinic) Consultants like FSG (Climate change effects mitigation and design of solutions study)

IR 3: Increase demand for SRH products and services

<u>The problem we're solving:</u> Gaps in demand by youth for modern methods

Lack of positioning for FP fo youth to fulfil aspirations &

Constraints

 Contraceptive knowledge gaps and inequities in information access for youth.

dreams for a better life.

- Youth prefer brands, but brand building is not core component of most distributors' business model.
- Youth do not know the quality, what to expect when they purchase, consume, and use the method. Service points and sales points are not discrete and bias free.
- Discontinuation not addressed. Side effects management requires support. Post adoption side effects management support negligible

Strategic Priority

Strengthen youth

to action towards

FP 2030 with the

leading to market

system changes

private sector

voices for a call

Outputs

Activities that lead to desired outputs

I. Strengthen youth voices for a call to action towards FP 2030 with the private sector

Develop and execute evidence-driven Marketing strategy and campaign

- Collect evidence for and develop SBCC strategy
- Map the user journey across all touchpoints
- Mobilize and include youth and civil society organizations to cocreate supply- and demand strategies and interventions that meet their needs
- Advocate for, identify, and work on youth friendly services and providers
- Develop marketing campaign to improve youth experience around continuous contraception and improve support for consistent use
- In-Person Engagement Strategy to create a supportive social network for uptake of contraceptive methods and increasing awareness
- Support gendered safe spaces: within workplace, women's savings groups, or collectives. In clinic engagement high client load facilities.

Key Partnerships: Digital Online Platforms for information and BCC, supported under WOHLA member companies (Leverage digital technology to generate demand and test scalable solutions), Femtech platform supported through ACCESS Health at policy/regulations (Focus on demedicalising the category and improving self care initiatives) WOHLA (POS Financing distribution for increasing demand with Youth for FP);

THANK YOU

FOR MORE INFORMATION, PLEASE CONTACT:

Dr.Amit Bhanot abhanot@fhm-engage.org







FHM ENGAGE

Healthy Markets for Healthy People