Big challenges in introducing and scaling up new prevention technologies

SAHIVCS Conference, Johannesburg. October 2018

Professor Helen Rees

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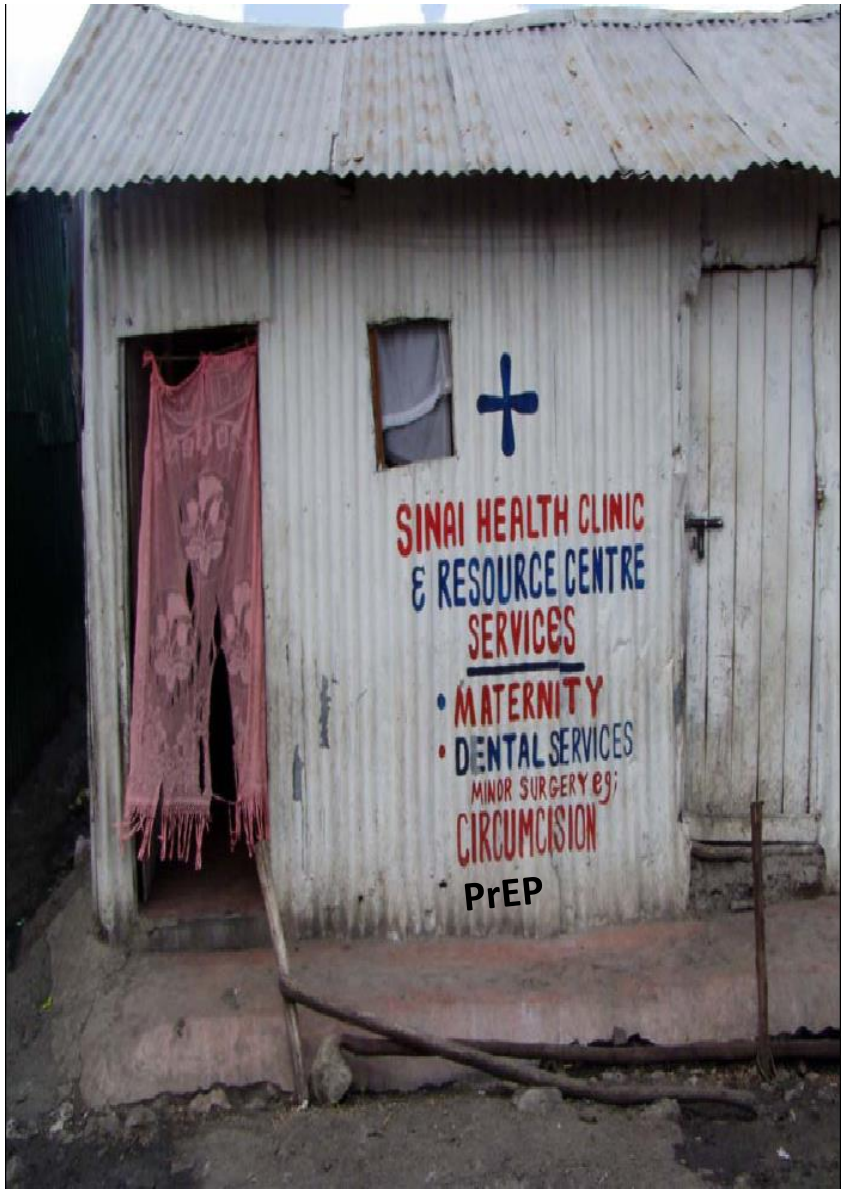
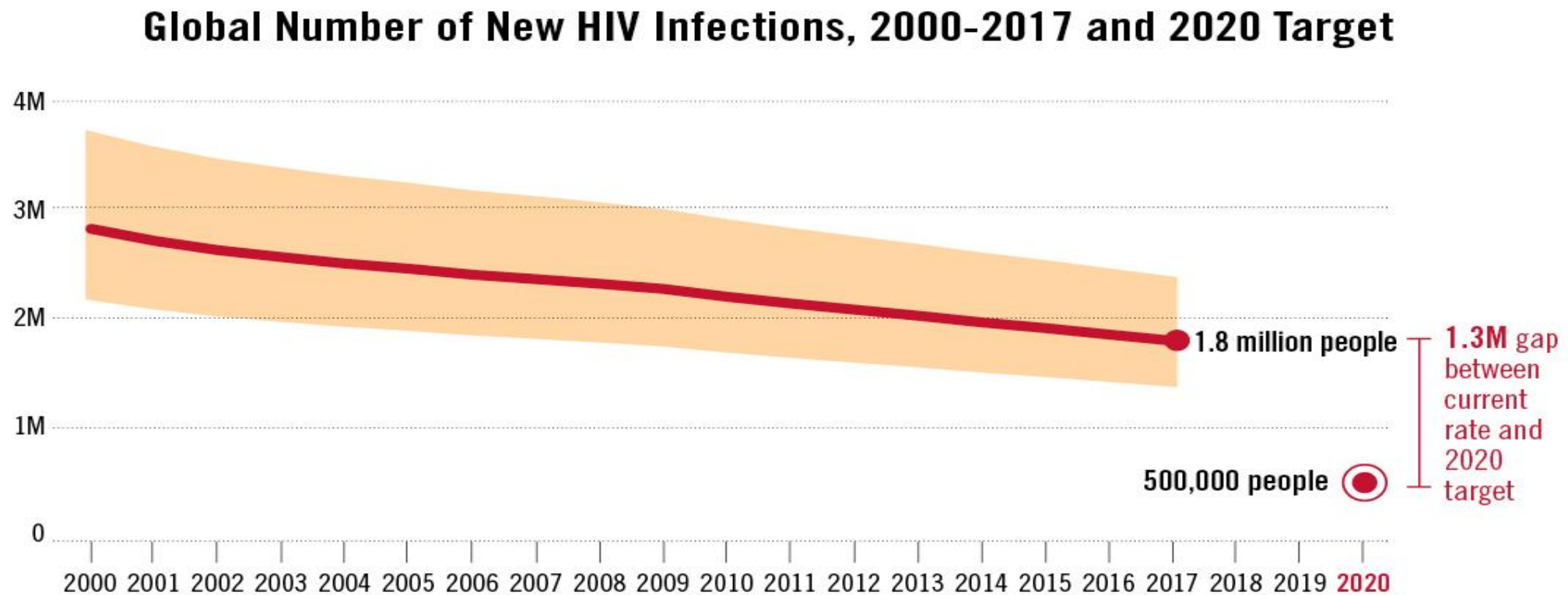
Co-Director African Leadership in Vaccinology Expertise, Wits University
Honorary Fellow, Murray Edwards College, Cambridge University
Honorary Professor, London School of Hygiene and Tropical Medicine



University of the Witwatersrand
WITS RHI

WITS
UNIVERSITY

Why do we need to take this seriously?



Source: UNAIDS. *Miles to Go—Closing gaps, breaking barriers, righting injustices.* July 2018. Accessible at: *www.unaids.org/en/resources/documents/2018/global-aids-update.*

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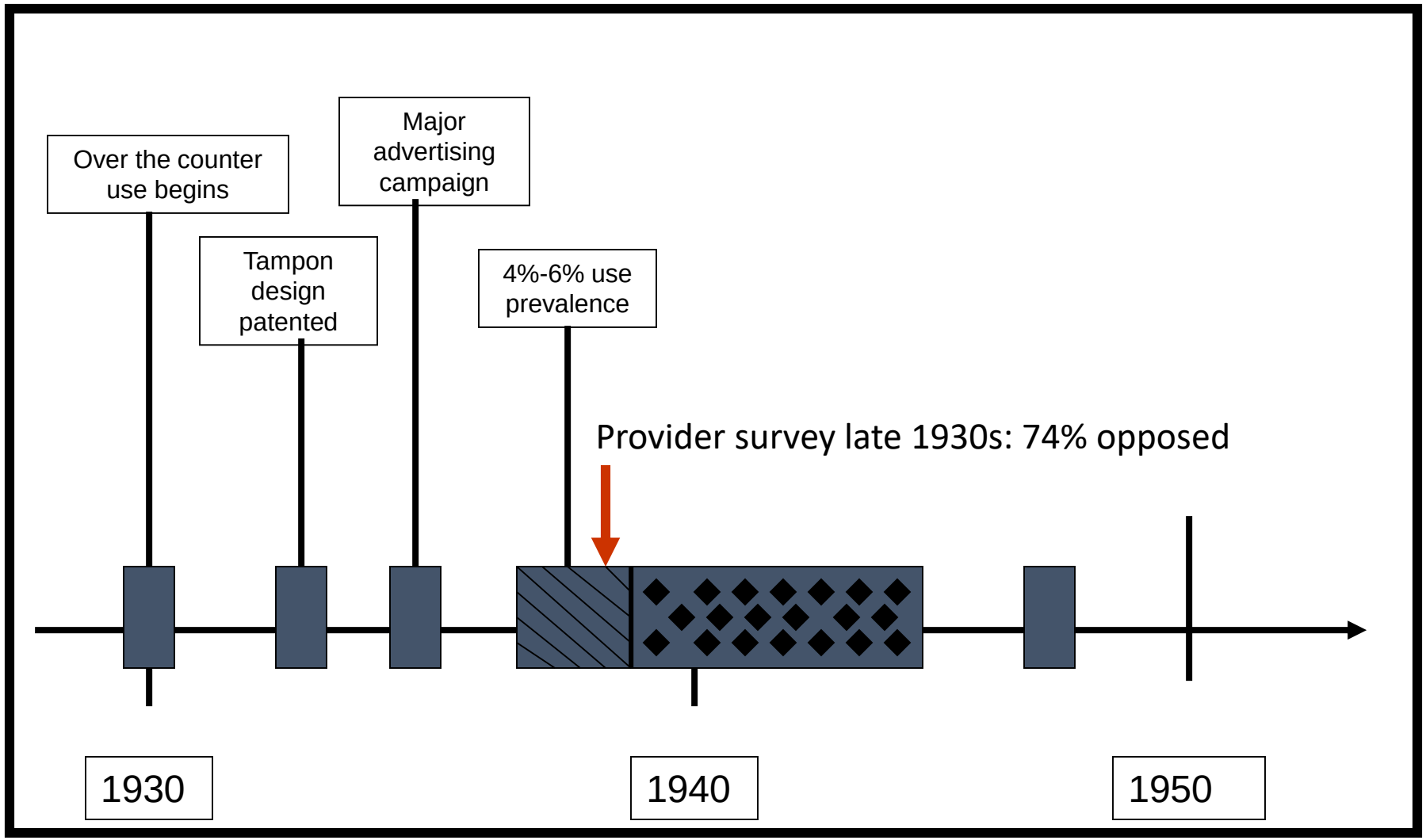
Many a slip twixt cup and lip……..

- Salient lessons from history
- Theoretical model of product intervention
- What have we learnt from introducing technologies in the RH field
- What have we learnt so far from PrEP and MMC
- What's required to take to new technologies to scale

What did we learn from the Tampon?



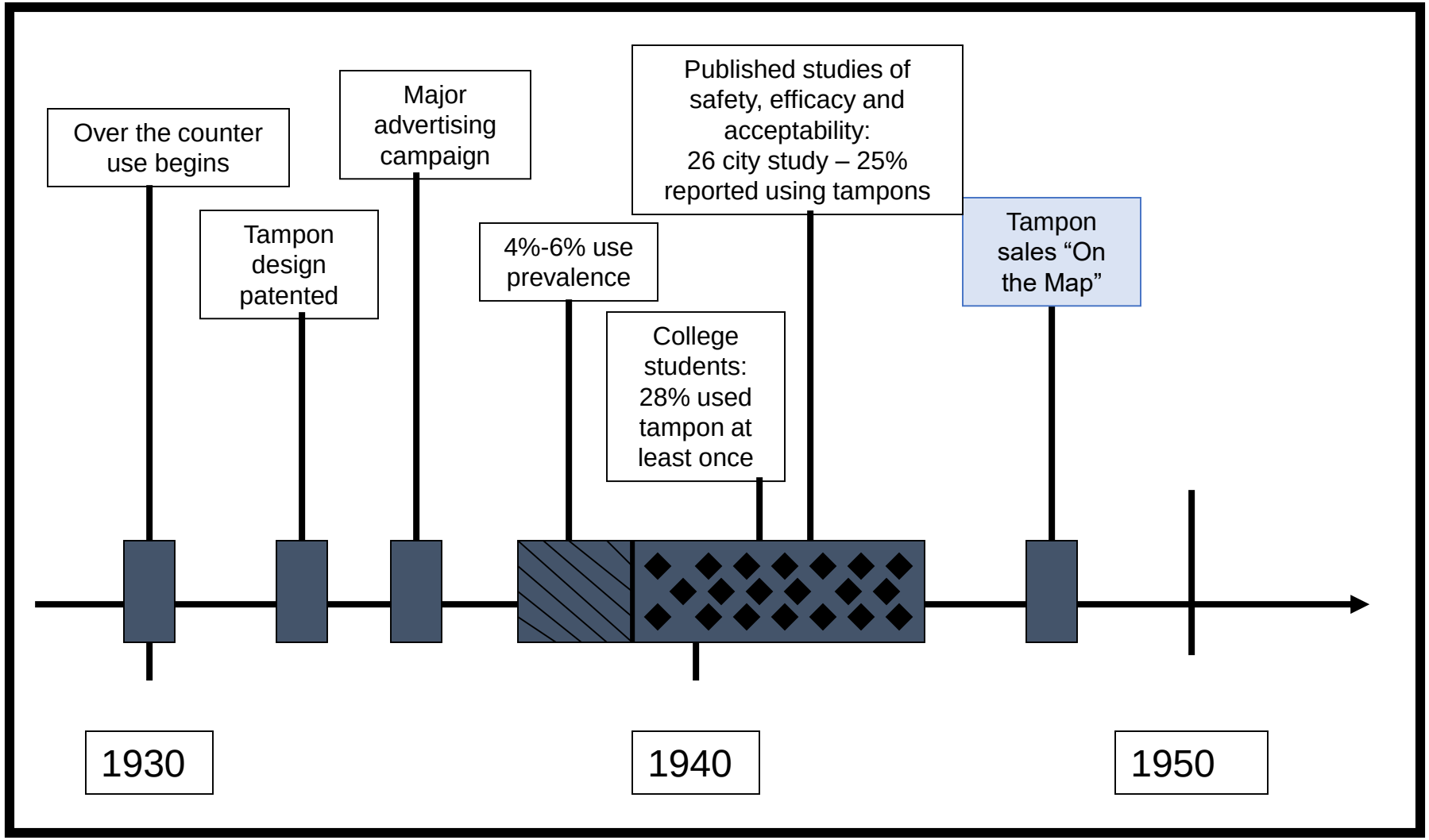
Source: Latka, Journal of Urban Health, 2001

What did we learn from the Tampon?

“ It is our opinion that inefficacy of the method, common sense, and fear would limit the use of this procedure to a relatively small number and that the fad should die of its own weight, were it not for the constant new crop of neophytes in schools and colleges gullible to attractive advertising and sampling.”

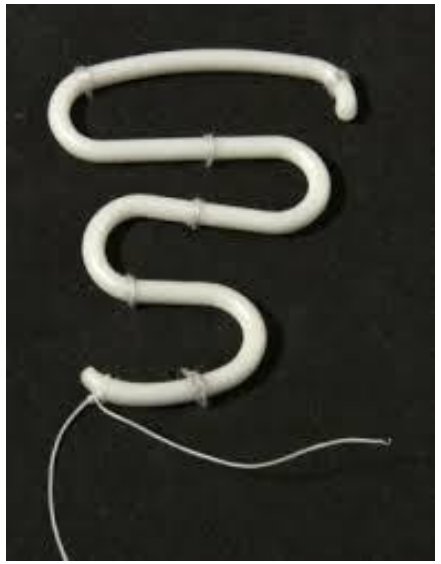
Source: Singleton West J Surg .
Vaginal tampons in menstrual hygiene

What did we learn from the Tampon?



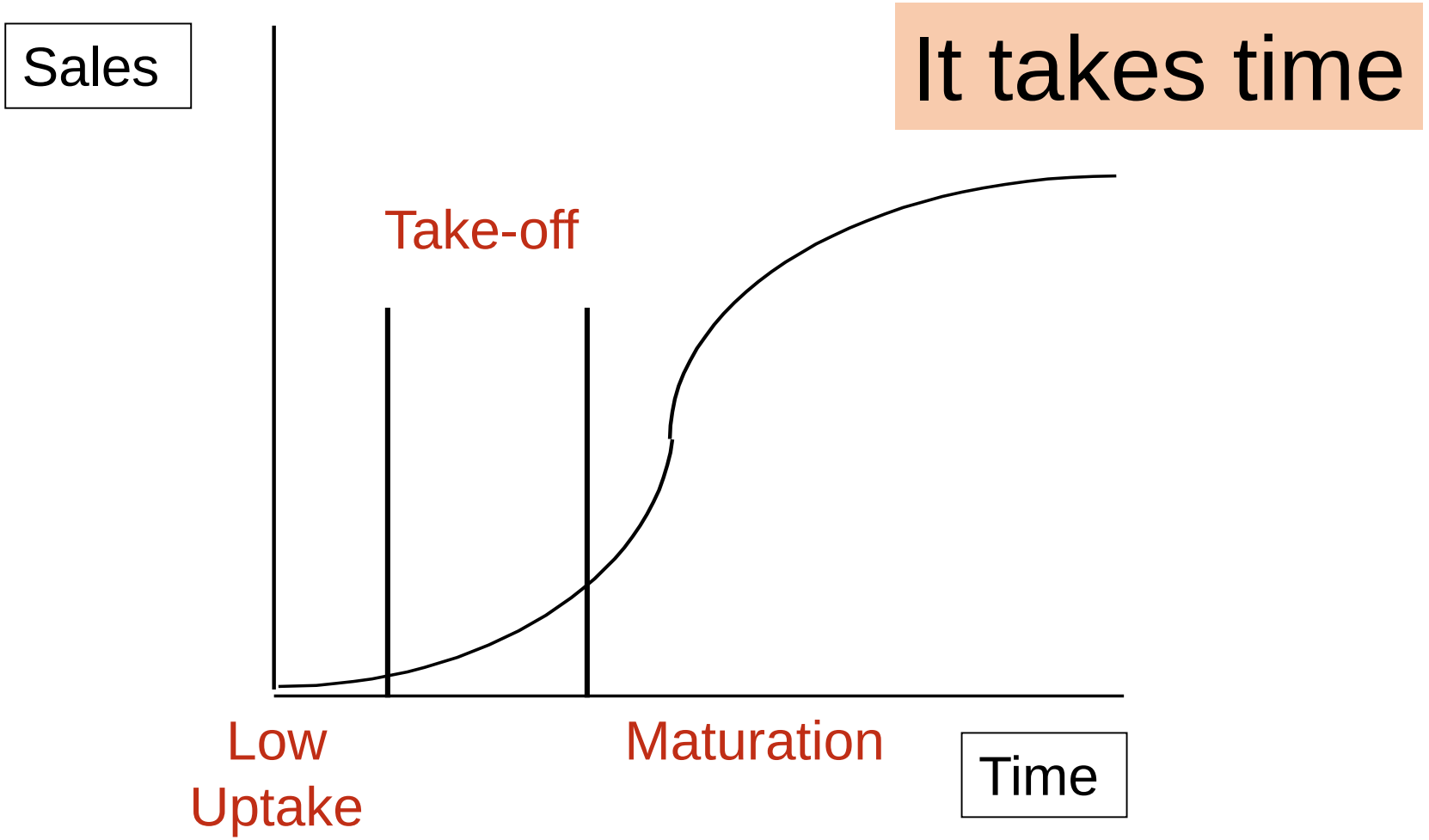
And the failures: The Lippes Loop in India

1960s Lippes Loop IUD introduced into India's Family Planning programme



- "…enthusiastically introduced as the vital missing link in the Indian programme. Within two years of its introduction 1.7 million IUDs were inserted. But the success and optimism were short-lived as inadequate pre-insertion checks, poor follow-up, genuine side effects and grossly exaggerated rumours led to high termination rates and a 7-year slump in annual insertions. The programme has quite simply been pushed through without organizational preparedness to cope with the known side effects." *(Source: Soni 1984)*

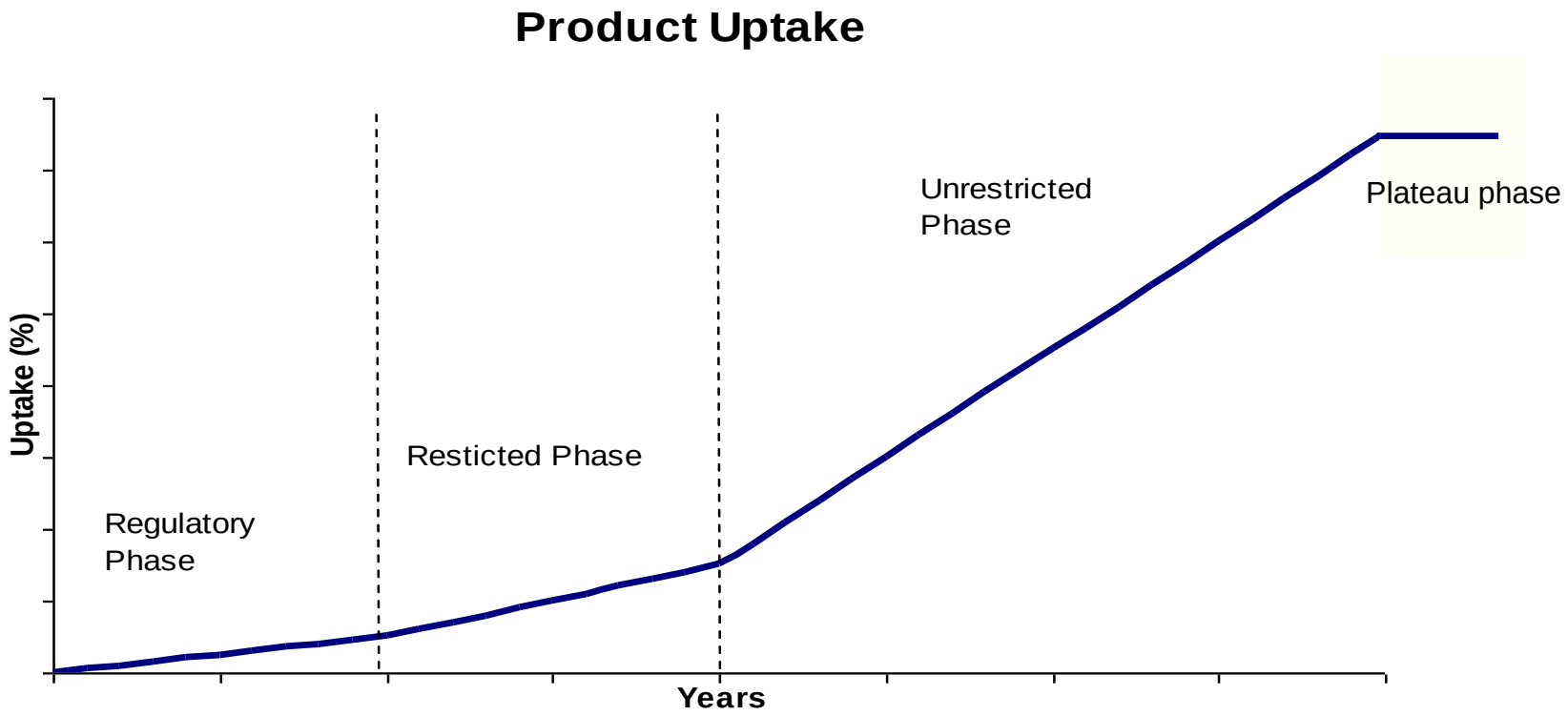
Theoretical Model of Product Introduction from Diffusion and Adoption Literature



Modelling study on public health products: determinants and time to uptake

- Reviewed 11 products in South Africa, Uganda and India
- Assessed time-period until the ‘take-off’ phase
- Assessed likely level of coverage/sales achieved at the different phases
- Evaluated how long will it take for maturation of market

Assumptions built into model: 4 stages of product distribution



Regulatory Phase

Regulatory approval & market autorisation - product provide on a limited scale to trial participants

Restricted Phase

Restricted delivery for 3 years. Product only available on prescription, through public heath facilities

Unrestricted Phase

Delivery not restricted and freely available. To achieve market saturation through chosen supply routes

Lilani Kumaranayake, LSHTM, 2008

Main findings

Products reviewed

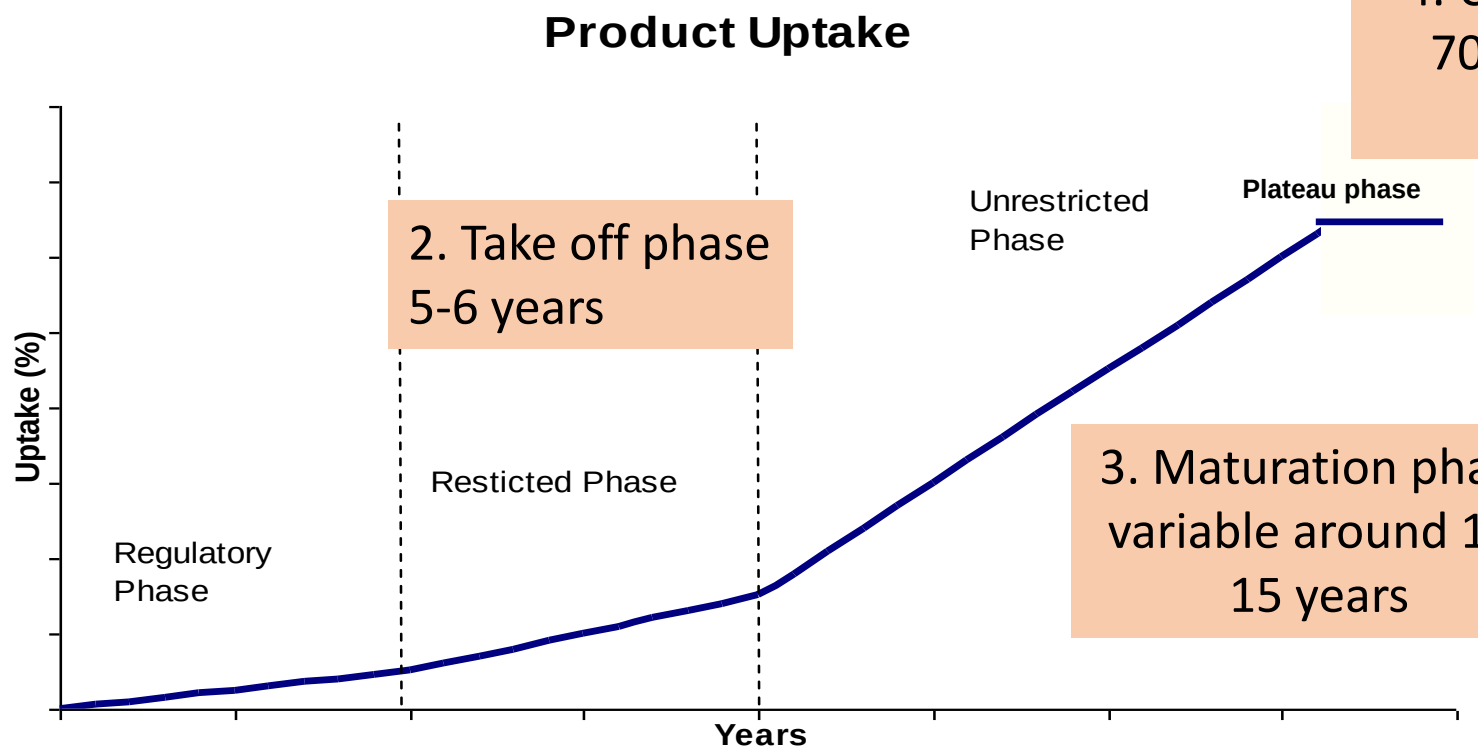
- Female Condoms
- Tampons
- Condoms
- Spermicide, Sponges
- Diaphragm, cervical caps
- Hormone implant and injections
- IUDs and oral contraceptives (including EC)
- Public health products (bednets)
- Surgical sterilisation
- Voluntary counselling and testing
- ARV (prevention of mother-to-child transmission)

- Large variation in uptake by product and setting
- Affected by a large range of factors
  - Type of product
  - Price
  - Distribution Channel (vending machines, OTC, wholesalers, health facility, private sector)
  - Type of provider
  - Marketing and targeting of advertising

Lilani Kumaranayake, LSHTM, 2008

Time frame for the 4 stages of product distribution

1. Gradual take off is the norm



2. Take off phase 5-6 years

3. Maturation phase variable around 10-15 years

4. Upper bound 70% of target market

Regulatory Phase

Regulatory approval & market autorisation - product provide on a limited scale to trial participants

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Lilani Kumaranayake, LSHTM, 2008

Time frame from introduction to uptake: Pharmaceuticals

Public sector

30 years for 50-60% coverage

Private sector

US private sector drugs: 8 years for 60% coverage

Add up to 5-6 years for registration unless ‘fast tracked’ product

Time from introduction to uptake: Vaccines

Hepatitis B Public sector

30 years to developing countries

HPV vaccines

4 years for developed country introduction: Developing countries?

HPV vaccine cost and programme implications of adolescent vaccine are major barriers despite GAVI support for poorest countries

Time frame from introduction to uptake: Anti-retrovirals

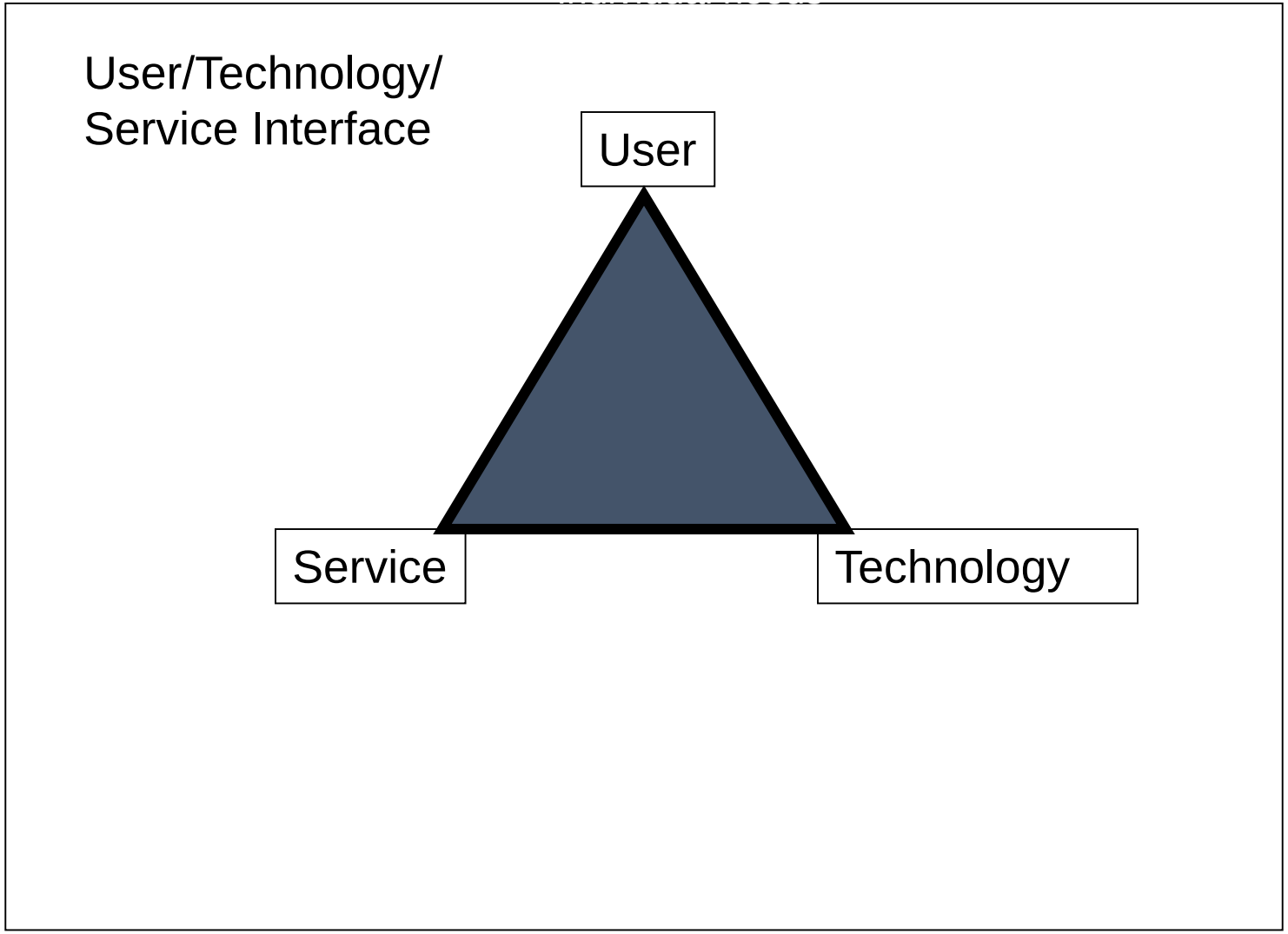
Public sector

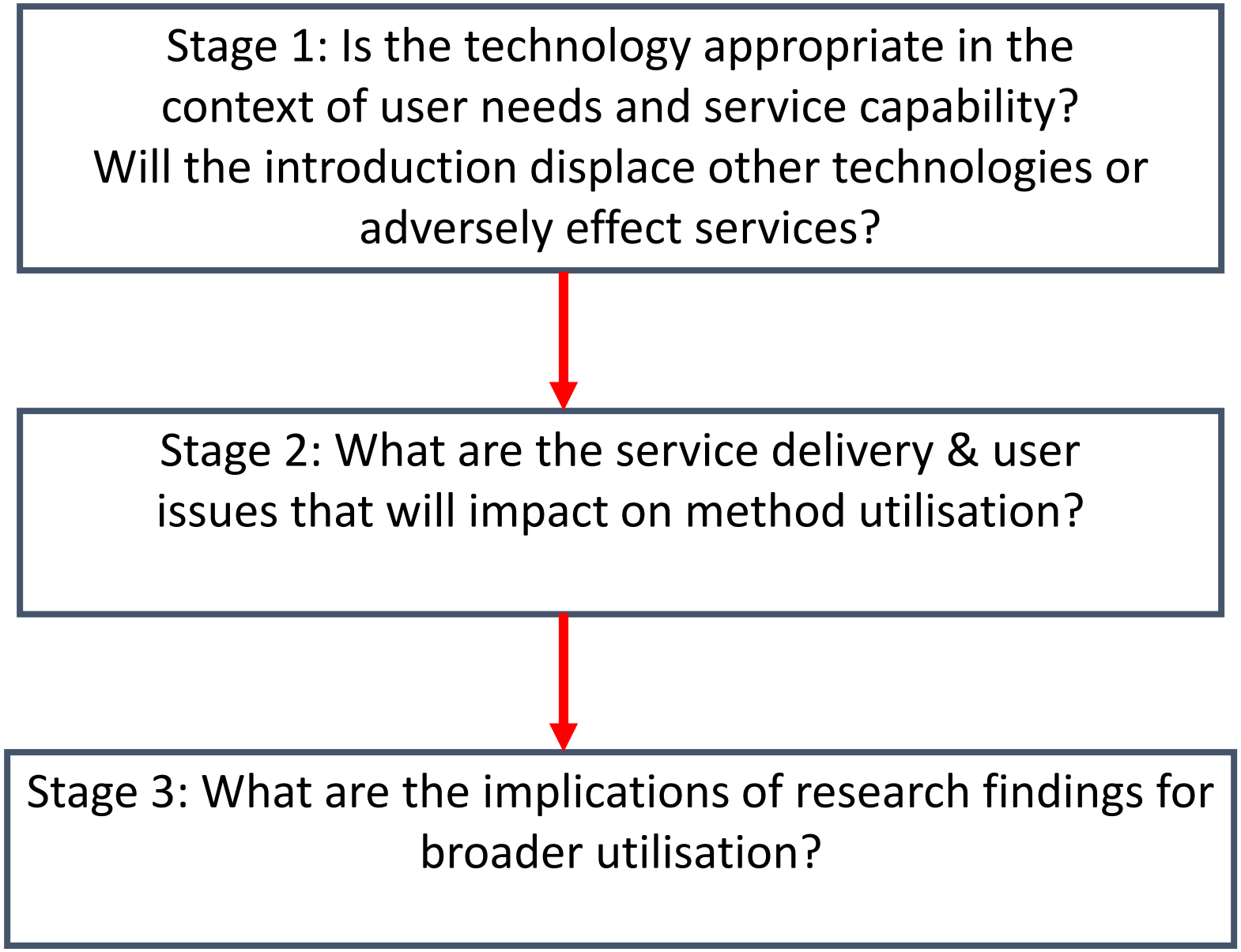
RSA: 4 years from 30,000 on treatment to 1 million on treatment

Donor commitment
Government commitment
Generics
Regulatory fast track
Epidemiology & targets

Understanding successful introduction: Lessons learnt from introduction of three products

WHO's Conceptual Framework for Contraceptive Introduction




Stage 1: Is the technology appropriate in the context of user needs and service capability? Will the introduction displace other technologies or adversely effect services?
Stage 2: What are the service delivery & user issues that will impact on method utilisation?
Stage 3: What are the implications of research findings for broader utilisation?

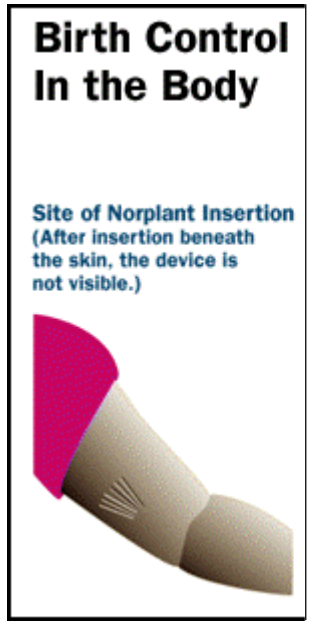
Implants: Norplant

- Norplant (Six rod progestin implant) introduced into Family Planning services in Africa, Asia, US, UK
- 1983: regulatory approvals, national training centres, identification of programme needs, service provider & user feedback
- 1987: Counselling & training, clinic management, scale up planning
- Problems occurred with the technology: Side effects, law suits after botched removals in the US
- Media coverage UK: 101 articles changed from a positive new method to a damaging product over one year *(Entwhistle, Lancet 2000)*
- Wyeth withdrew 6 rod product 2000
- Improved 2 rod product introduced

Implants: Norplant

Introductory approach did not

- Evaluate whether method had a place within the system at outset
- Evaluate service capability to offer method at outset
- Consider whether this method should be restricted to specific settings with trained staff
- Focus sufficiently on other health care services other than national training centres



Implants: South African experience with Implanon

SAMJ CME

GUEST EDITORIAL

Introduction of the contraceptive implant in South Africa: Successes, challenges and the way forward

SAMJ CME

Lessons learnt from the introduction of the contraceptive implant in South Africa

M Pleaner,[1] MEd; C Morroni,[1,2,3,4] MB ChB, DFSRH, DTM&H, MPH, MSc, PhD; J Smit,[5] BPharm, MSc, PhD; N Lince-Deroche,[6] MIA, MPH, PhD; M F Chersich,[1] MB BCh, PhD; S Mullick,[1] MB ChB, MSc, MPH, PhD; D Pillay; M Makua,[7] DLitt et Phil, MTech; H Rees,[1] MB BChir, MA (Cantab), MRCGP, DCH, DRCOG

thods dispensed, 2013/14–2015/16

	2014/15 Number	2014/15 Contraceptive years dispensed	2015/16 Number	2015/16 Contraceptive years dispensed	Change 2014/15 to 2015/16 %
Female			7 005 805	135 029	28.0
IUCD in			15 150	60 600	-61.3
Male co			89 874 751	4 199 373	17.9
Medrox			5 578 228	1 394 557	1.2
Norethis enantha			3 676 445	621 740	-4.1
Oral pill					
Sterilisa					
Sterilisa					
Sub-der inserted					
		5 854 963			

* Sub dermal implants for 2015/16 were reported by only four provinces.

Source: DHIS.

SAMJ CME

Strengthening implant provision and acceptance in South Africa with the 'Any woman, any place, any time' approach: An essential step towards reducing unintended pregnancies

H Rees,[1] MB BChir, MA (Cantab), MRCGP, DCH, DRCOG; Y Pillay,[2] PhD; S Mullick,[1] MB ChB, MSc, MPH, PhD; M F Chersich,[1] MB BCh, PhD

[1] *Wits Reproductive Health and HIV Institute, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa*
[2] *National Department of Health, Pretoria, South Africa*

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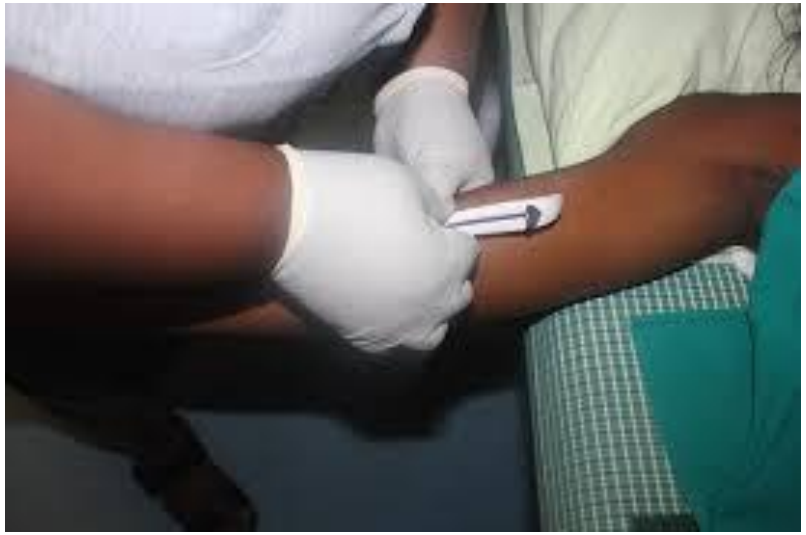
Implants: South African experience with Implanon

Boom or Bust of new product introduction

- Optimistic introduction, initial high uptake
- New methods promoted as far superior to existing ones - downplaying potential side effects
- Focus on technological novelties, not on the method benefits and disadvantages
- Inadequate attention to preparation for introduction



Implants: South African experience with Implanon

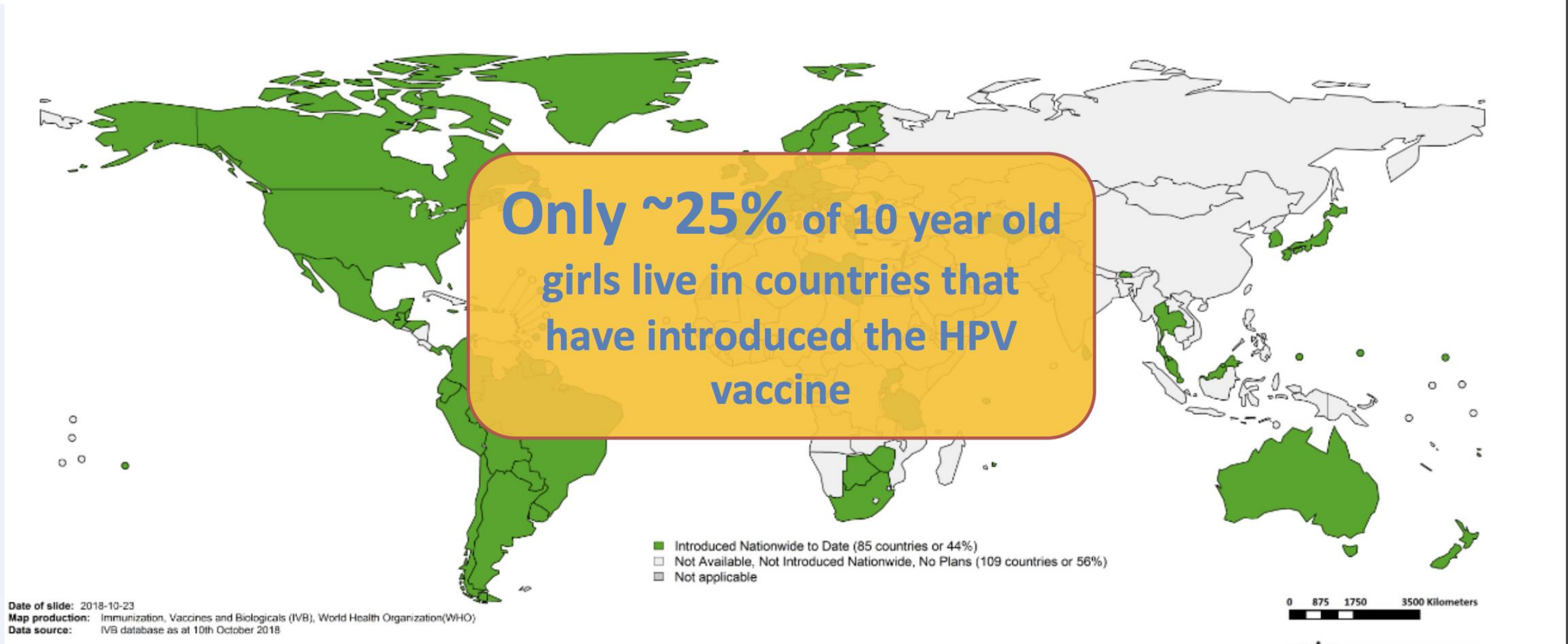
- Insufficient staff training, target driven, rapid national scale up – sites under-prepared
- Poor management of adverse events and negative publicity:
  - HCWs not confident to manage side effects
  - HCWs not confident with insertion and even less so with removal
  - HCW attitudes towards method
  - Rumours influenced Community/Women's perception of the method
  - Media sensationalism
  - Real problems with botched removals

Lessons learnt from implants

- Importance of deciding if the technology is a priority for introduction
- Inadequate evaluation of service capability
- Inadequate preparation of services and HCW training
- HCW bias influences success
- Wrong choice of service outlet contributing to method problems
- Side effects of technology
- Adverse media coverage influencing consumers
- Community perception

85 countries have introduced the HPV vaccine

(as of Oct. 2018)

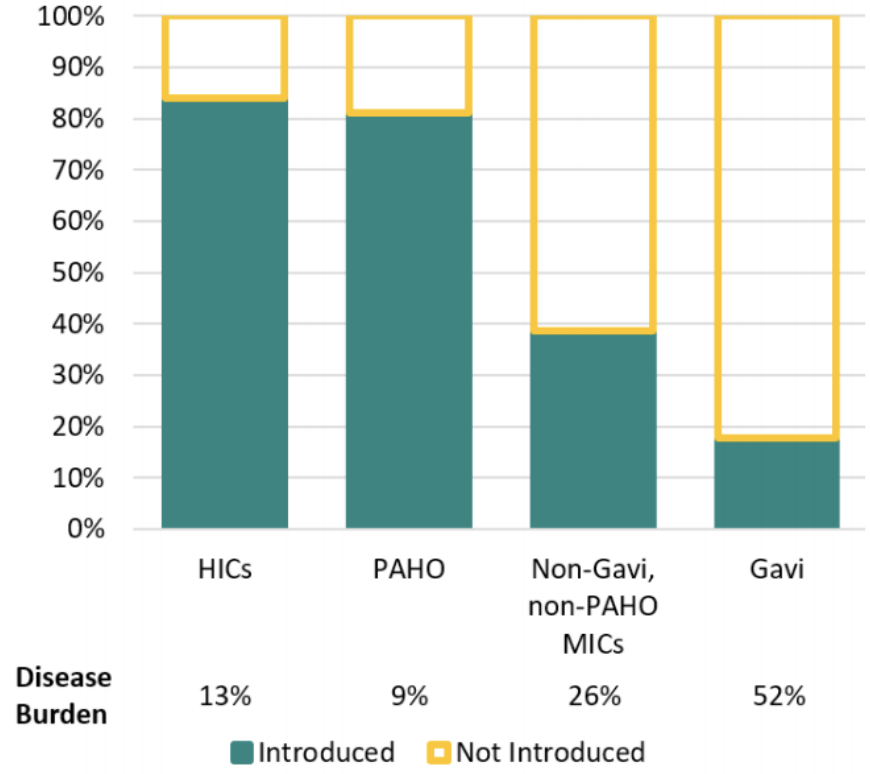


Date of slide: 2018-10-23
Map production: Immunization, Vaccines and Biologicals (IVB), World Health Organization(WHO)
Data source: IVB database as at 10th October 2018

World Health Organization

The countries that need the vaccine most are the last to get it

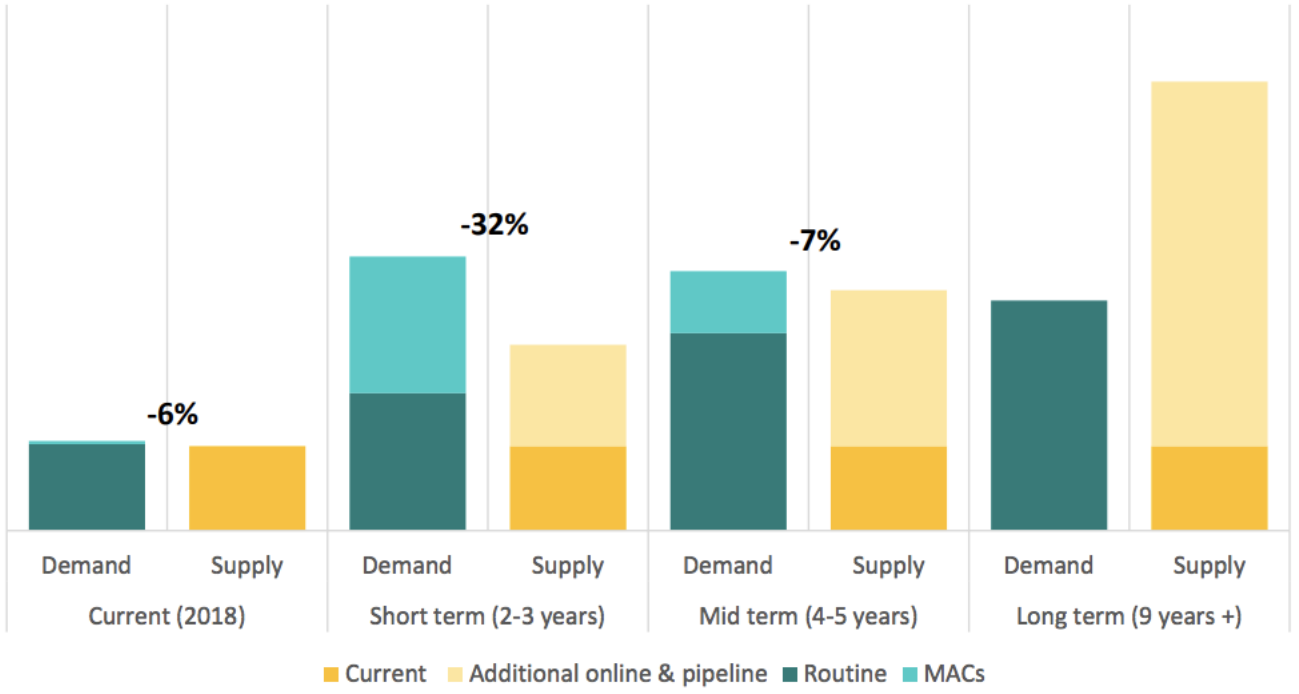
FIG. 1: HPV INTRODUCTION STATUS AND DISEASE BURDEN BY COUNTRY GROUP



GLOBAL MARKET STUDY HPV VACCINES, Sept 2018, WHO

Supply Shortages: Advanced Market shaping is essential for manufacturers and sustainable supplies

FIG. 3: DEMAND-SUPPLY BALANCE OVER TIME[13]



GLOBAL MARKET STUDY HPV VACCINES, Sept 2018, WHO

Massive variability in vaccine pricing across countries, with multi-country purchasing bringing prices

FIG. 4: 2017 PRICE PER DOSE FOR HPV, BY PRODUCT

GLOBAL MARKET STUDY HPV VACCINES, Sept 2018, WHO

HPV vaccines: Costs go down as scale goes up

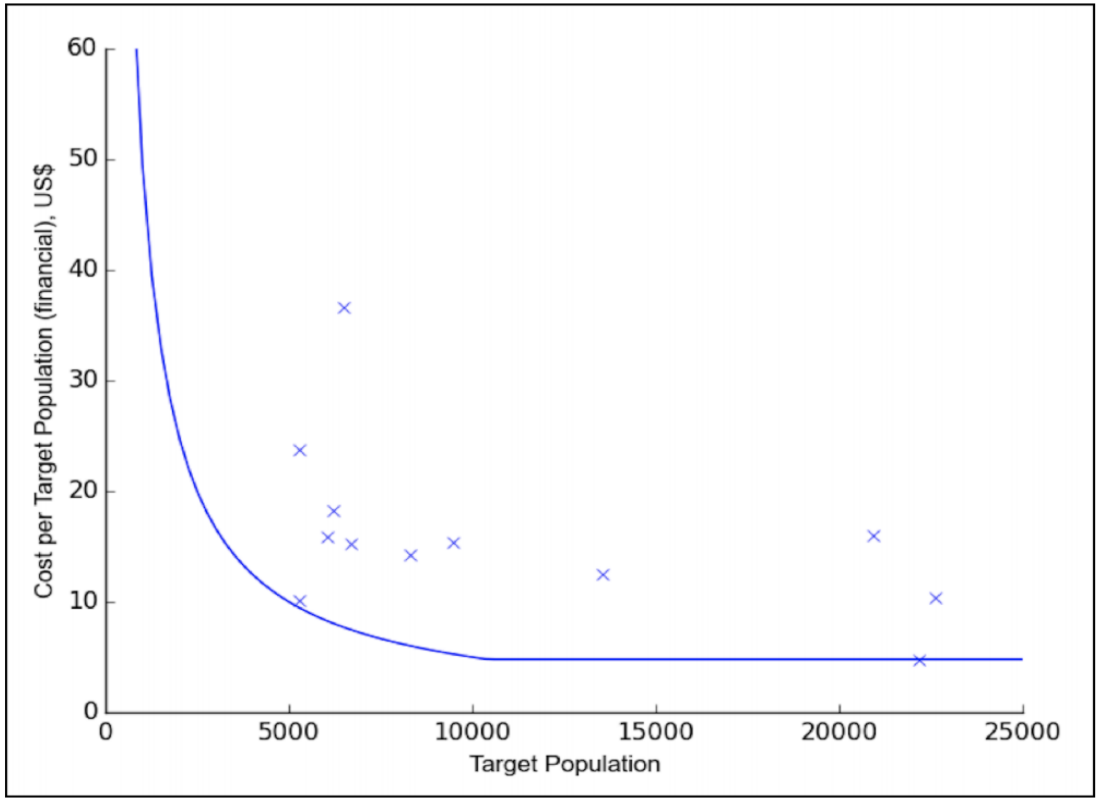
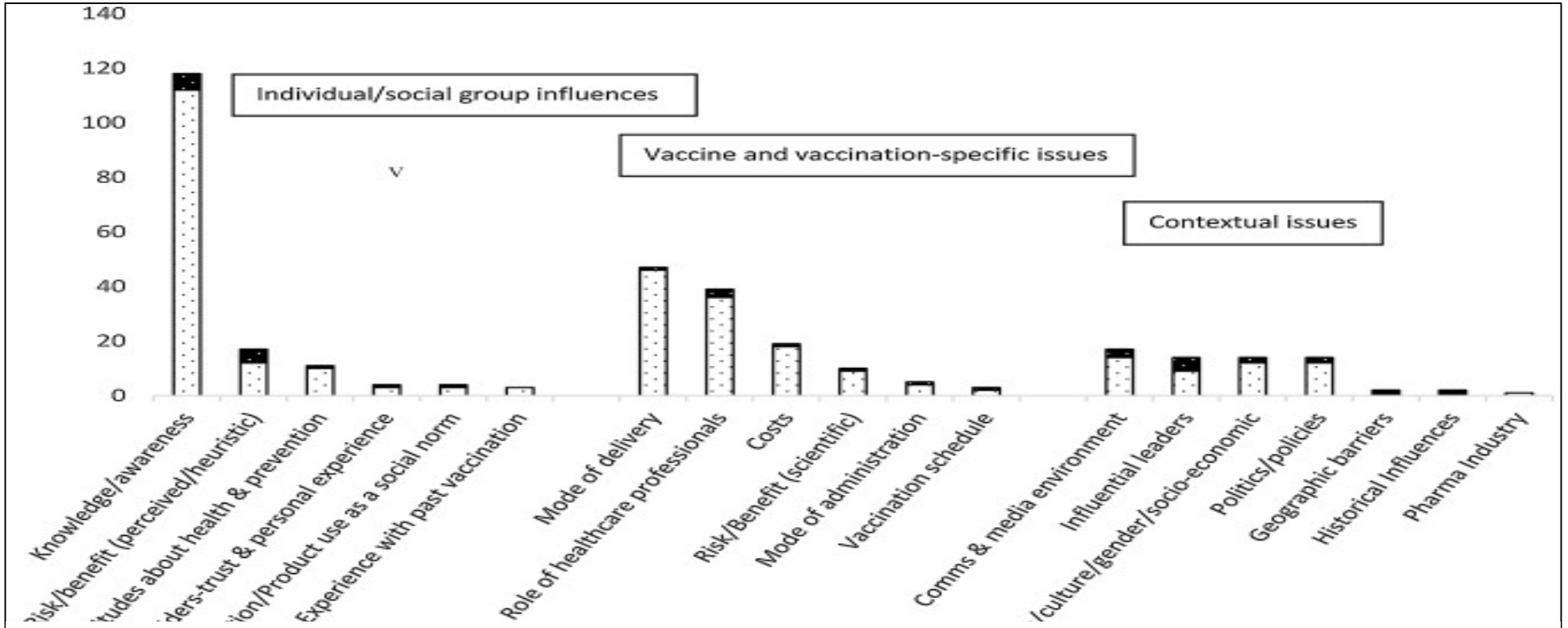


Fig 1. Target population and financial cost per dose in demonstration project countries. US$, United States dollars. Blue curve represents theoretical cost per girl in the target population if countries were to spend exactly the amount provided by the Gavi demonstration project first year grant. The points (denoted by "x") represent the actual financial cost per girl in the target population from Gavi demonstration projects.

Operational costs of HPV vaccine demonstration projects
PLOS ONE | October 10, 2017

Vaccine demand and Vaccine hesitancy



Few existing strategies have been explicitly designed to address vaccine hesitancy and fewer strategies have quantified impact of the intervention

Role of the media to support or condemn technology

The Guardian | Saturday October 8 2005

Schools may offer cervical cancer vaccination to all girls

Sarah Boseley
Health editor

Vaccination against cervical cancer could become as common in schools as jabs against meningitis are now, following the dramatic results of the latest clinical trials. The breakthrough is generally seen as a real victory against one of the commonest cancers and may eliminate it in the UK.

The good news comes as steady but much slower progress is being made against other forms of cancer. Most of the advances are in the treatment of cancer – not in preventing it. In most cancers, the numbers diagnosed continue to rise, even as deaths are falling.

The new vaccine, called Gardasil, gives protection against two strains of the human papilloma virus (HPV) which cause 70% of cervical cancer. But most women who are sexually active become infected with HPV at some time, so girls as young as 10 to 13 will be the target population.

The demise of the smear test, offered to all women every few years from the age of 25, is not imminent. The NHS national screening programme's director, Julietta Patnick, said it could be more than half a century before all sexually active women have been vaccinated as children. By that time, there will probably be an even better vaccine. This one protects against HPV 16 and HPV 18, but not strains responsible for the other 30% of cervical cancers.

Peter Stern of the immunology group at the Paterson Institute for Cancer Research at Manchester's Christie hospital, funded by Cancer Research UK, said it would probably be possible to create a vaccine that would protect against all strains of HPV. "Everything is feasible if you have enough money to pay for it," he said. But a better solution might be to find and attack what the strains have in common.

Kevin Harrington of the Institute of Cancer Research, a clinical oncologist at the Royal Marsden hospital in London, said it was possible the vaccine could stamp out cervical cancer in developed countries. "All the excitement is entirely justified," he said. "Cervical cancer could be eradicated." There are 3,300 cases a year in the UK and 1,300 women die, although screening has reduced the toll enormously. It is a far greater problem in south-east Asia and India, he said. "Often women are presenting at a late stage and they are not curable." As with Aids drugs, it is likely the vaccine will not be affordable where it is most needed.

Other cancers may also succumb to a vaccine against HPV, he said, as the virus also causes penile cancer, anal cancer and cancer of the vulva, and is possibly involved in some head and neck cancers.

John Toy, the medical director of Cancer Research UK, said the breakthrough was "almost a one-off". But he added: "We are beginning to understand the biology of cancer – what it is that differentiates the cancer cell." This has allowed the development of drugs for breast cancer and acute myeloid leukaemia which target cancer cells and avoid the destruction caused by chemotherapy.

Professor Stern said immunology could provide the tools to make still greater advances. "There has been a revitalisation of optimism about being able to harness the immune response to treat cancer," he said. Immunologists hope to teach the immune system to recognise the enemy within – the cancerous cell – and attack it before it causes potentially fatal disease.

Campaigners release balloons, each one representing a woman who has died of cervical cancer

Progress report

Bowel cancer The first national screening programme begins in April, offering hope of early detection. Two biological agents are being assessed for general use in the NHS, and chemotherapy is showing good results alongside surgery.

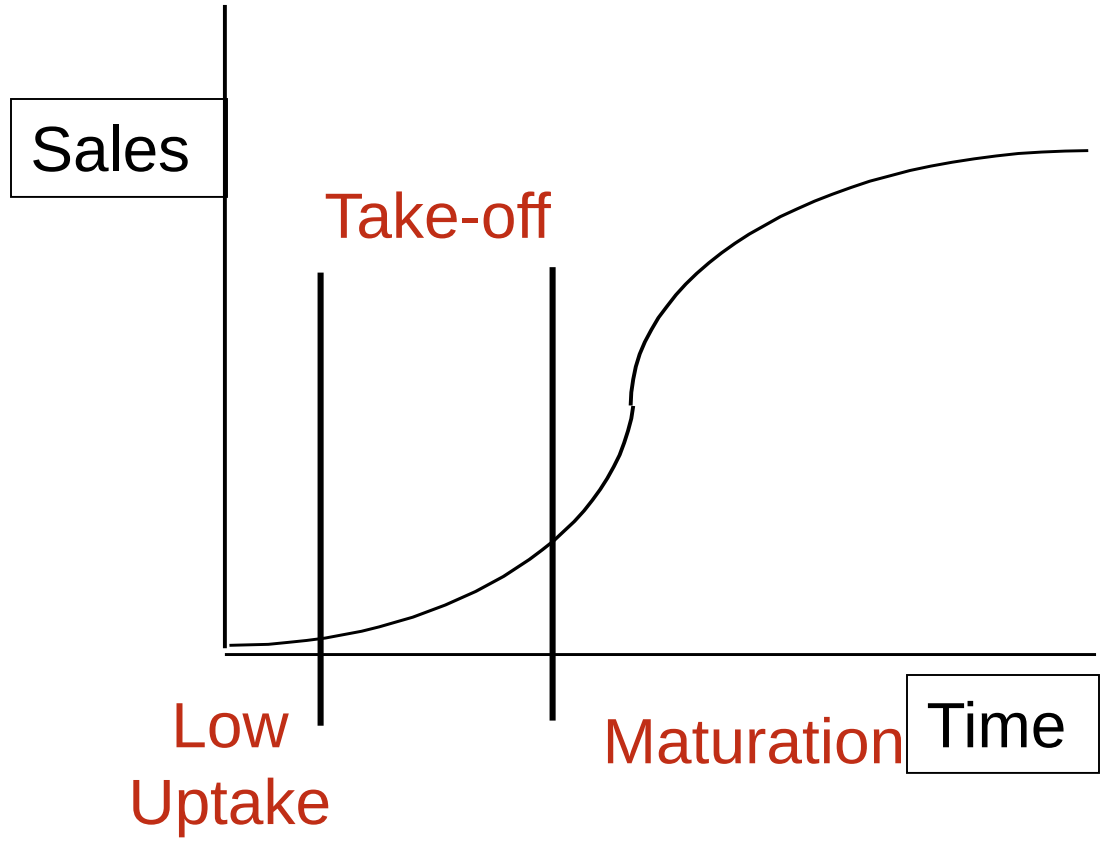
Breast cancer Screening and better drugs have brought down the death rates. New drugs such as Herceptin look set to reduce them still further.

Prostate cancer Hardly off the starting blocks, but various urine tests are in trials.

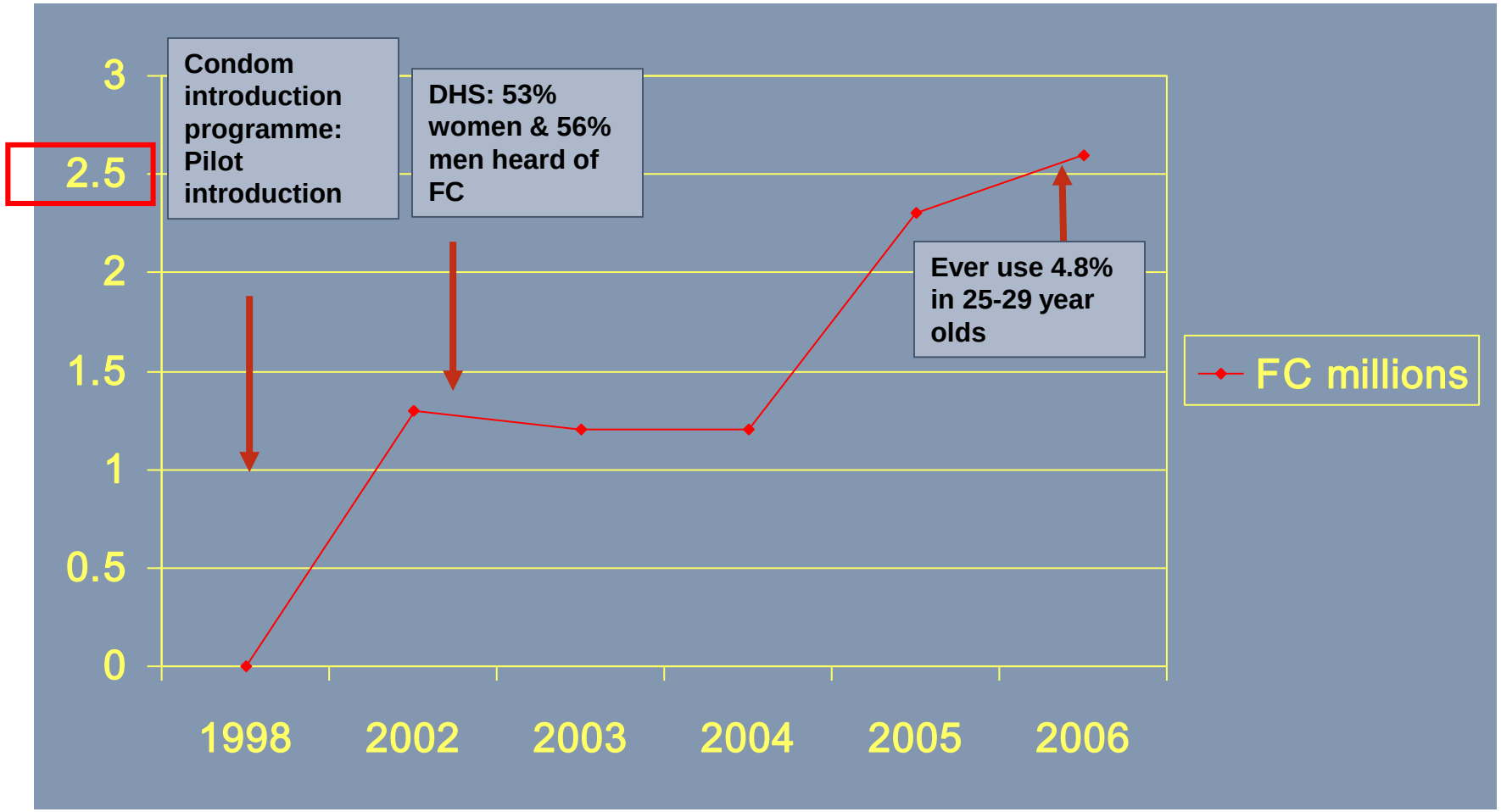
Lung cancer A vaccine against nicotine addiction would prevent 90% of cases and is being investigated. Research into targeted drugs similar to Herceptin is also under way.

SocietyGuardian.co.uk/cancer »

Theoretical Model of Product Introduction: Female Condom

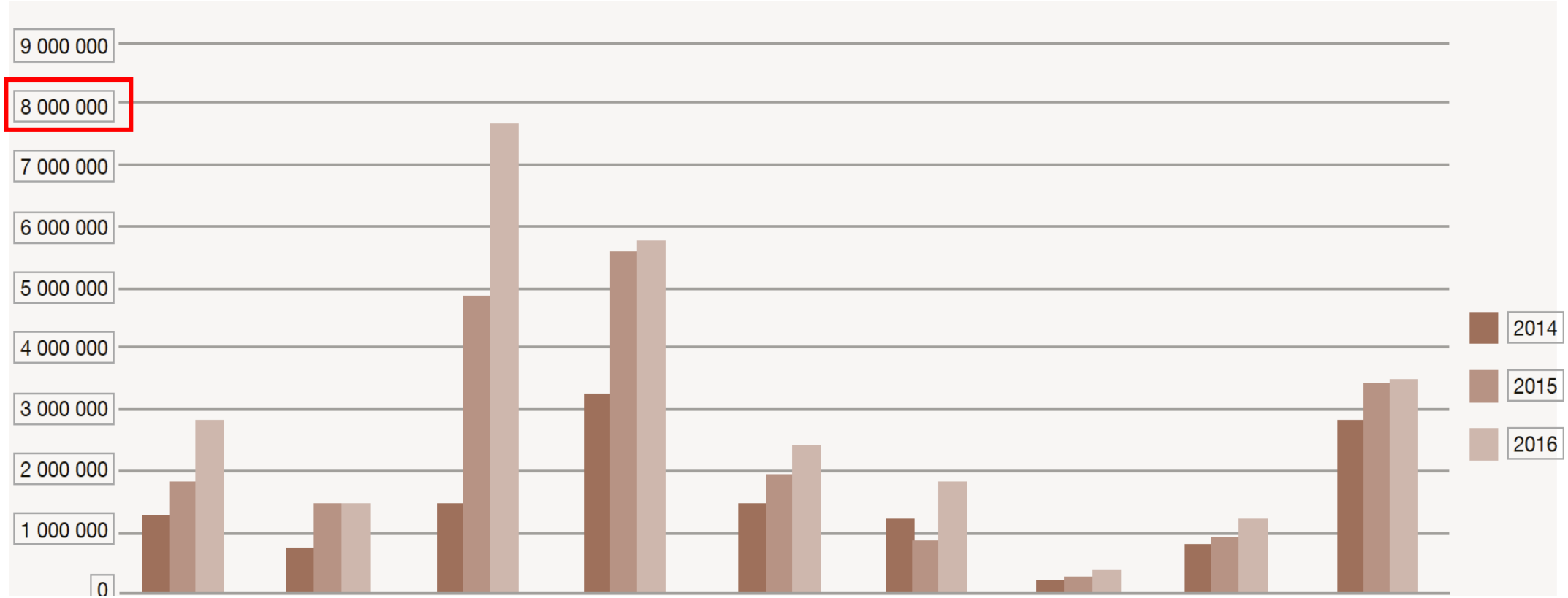


Female condom Distribution: Early low uptake in South Africa



FC programme now well established but uptake remains low

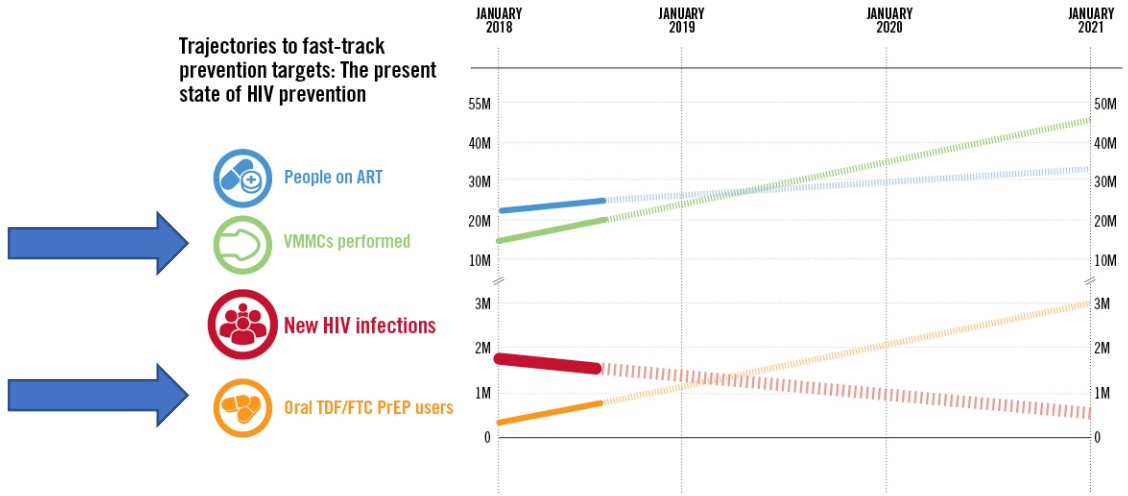
Figure 2: Female condom distribution by province between 2013/2014 and 2015/2016

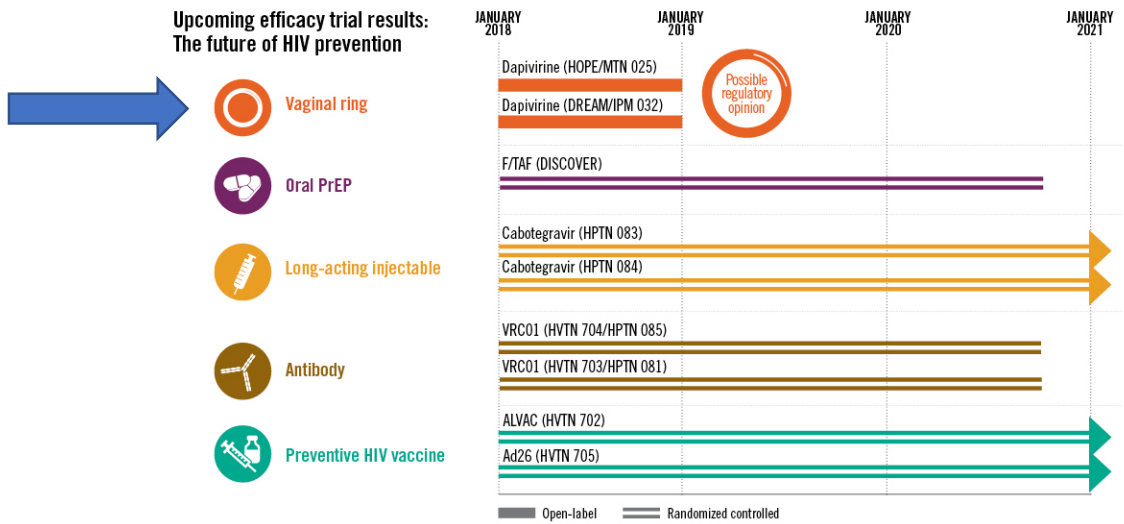


This low level of use has been attributed to limited availability (often due to higher cost compared with MC), lack of male acceptance, and difficulties in use.

One Timeline, Two Stories, One Message: Putting trials and targets together

One problem with HIV prevention agendas is that they either live in an eternal present or in a far-off future. It's *Work with what we've got, which is condoms and VMMC and a little bit of PrEP,* or it's *Nothing can change without an AIDS vaccine.* The future depends on using what's available, better and more widely, without ever losing sight of what's in the pipeline. As the figures below show, in the very same timeframe that the world will miss its critical target for incidence reduction and scale-up of primary prevention, several trials will release results that could change the future. 2020 will be a time of hope and reckoning. But only if the two stories start to be told as one.





Visit *www.avac.org/pxrd* for trial status updates.

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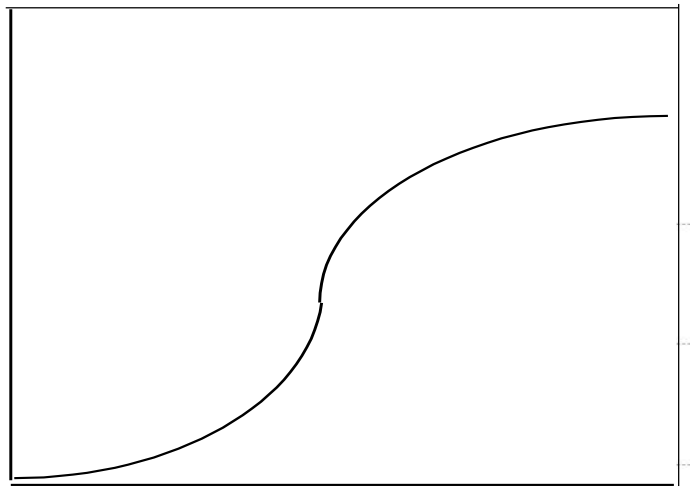
Lessons from VMMC



Source for VMMC figures: UNAIDS. *Miles to Go—Closing gaps, breaking barriers, righting injustices.* July 2018. Accessible at: *www.unaids.org/en/resources/documents/2018/global-aids-update.*

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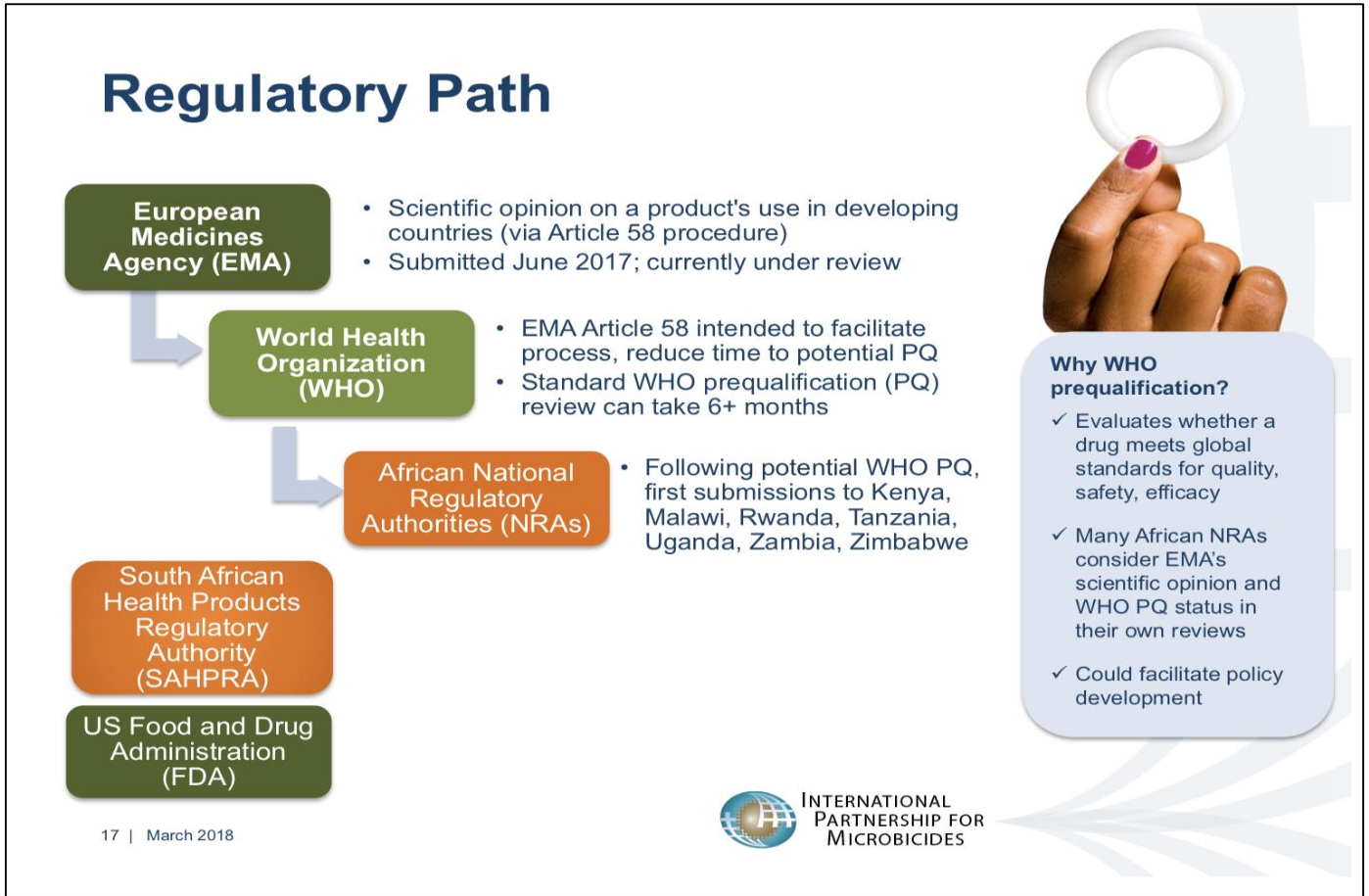
Dapivirine Ring: Regulators and results

ASPIRE Overall Results (Phase 3 study)	31% effective, CI 1-51
Secondary Analysis excluding data form 2 sites (lower retention and adherence)	37% effective, CI 12-56



Target Setting: Anatomy of a target

Resourced

Targets without sufficient resources are empty promises. Set the price tag, raise the resources and don't ask countries to do more with less.

Audacious

The best goals redefine possible. There were 50,000 people in low-income countries on ART in 2003. The 3 by 5 target changed the world.

Achievable

Effective targets reflect evidence and experience. AIDS science is evolving. We can't set a deadline for finding a cure. But we can aim high with research milestones.

Measurable

Quantification is key. Prevention targets need to be tied to impact including incidence and other validated, indirect measures.

Accountable

Setting a target means taking responsibility for mobilizing resources, tracking progress and sharing data.

Political Support

Country-level support is key. Goals that originate in Geneva won't go anywhere without endorsement by leaders in hard-hit countries.

Collective Priority

No one, including scientists, can set targets on their own. Civil society, policy makers and politicians all need to buy in.

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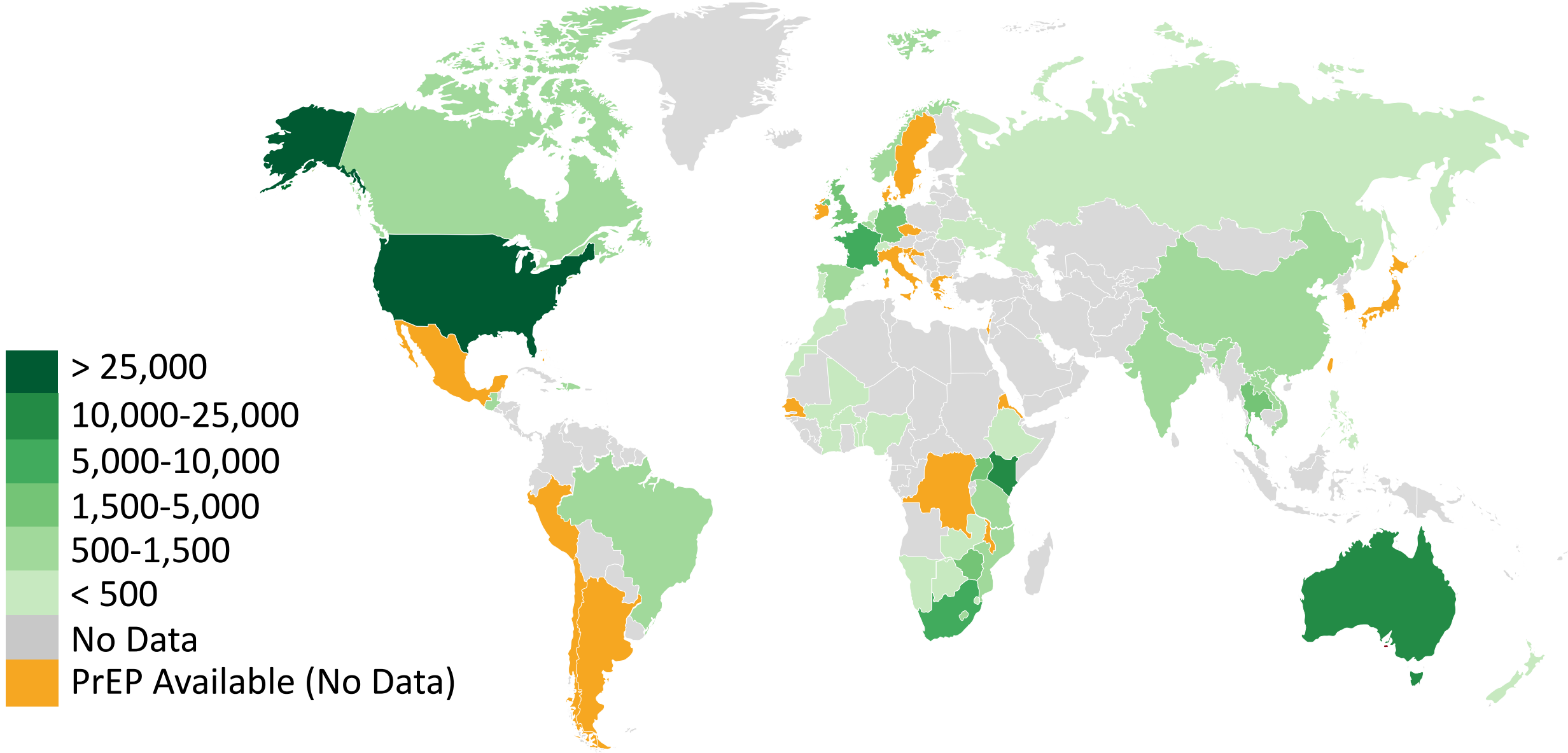
PrEP Initiations by Country (April 2018)



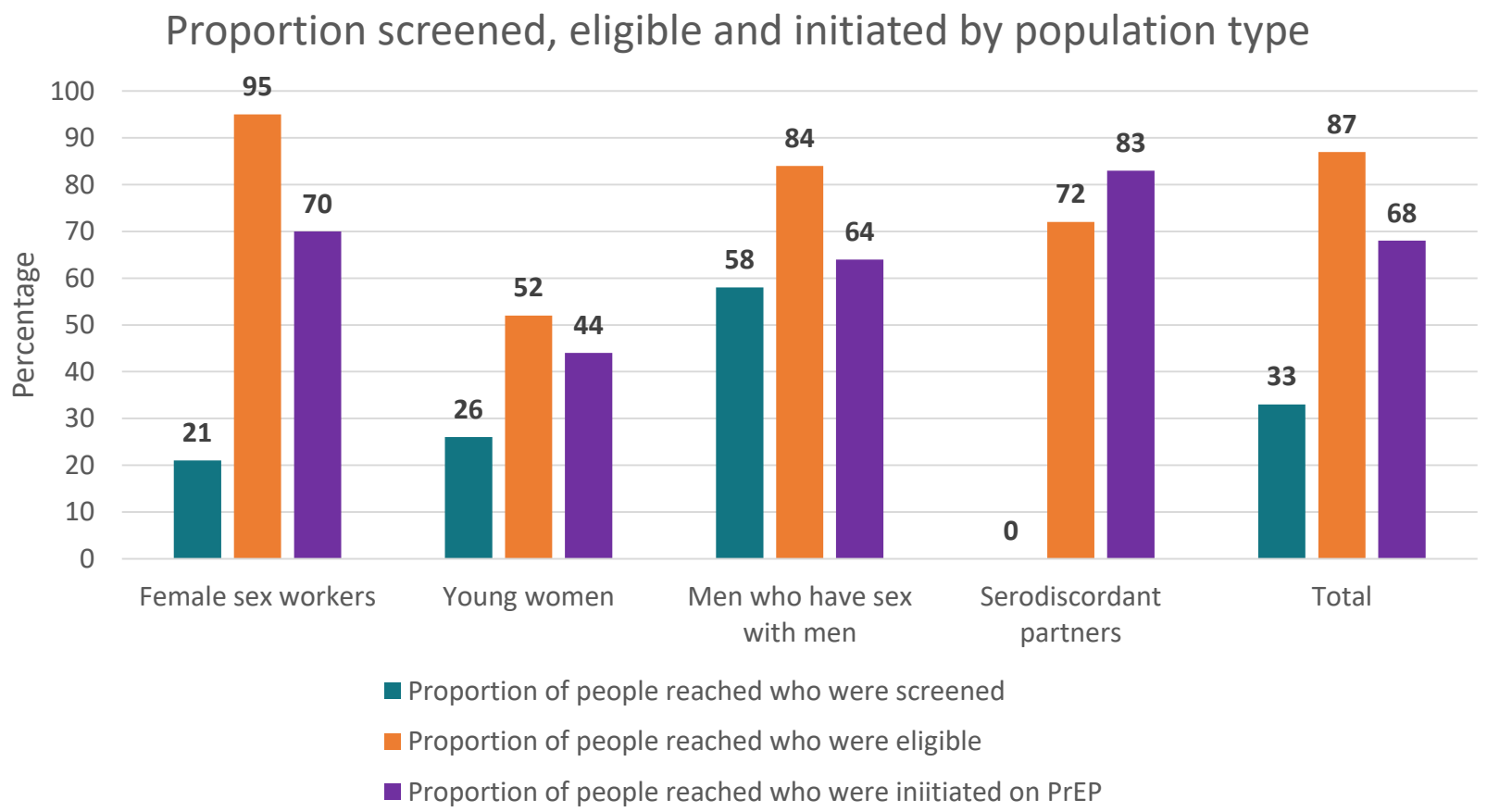
Source: AVAC Global PrEP Initiation Tracker 2018

BMGF PrEP Demonstration Projects: Overview

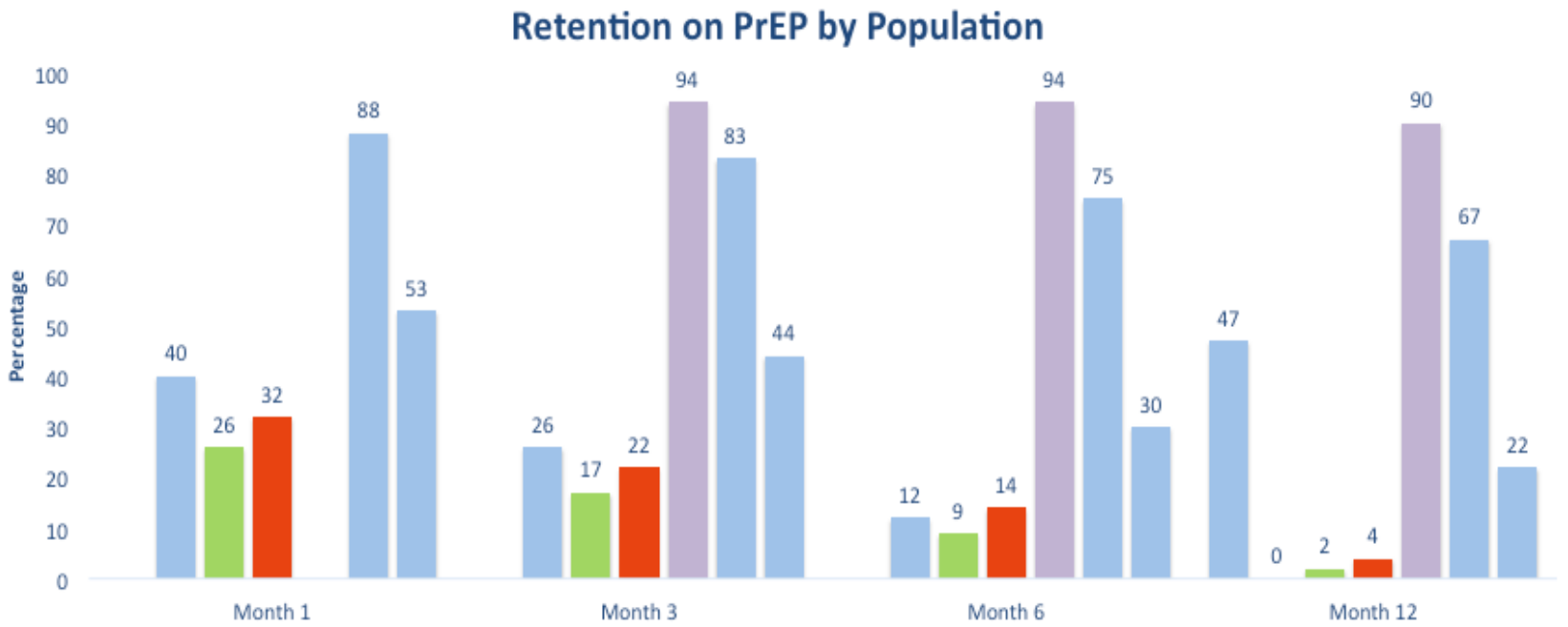
BMGF PrEP Demonstration Projects: Overview

Country	Location	Organization	Study population(s)	Median age	**Number initiated**	PrEP service delivery point(s)
Benin	Cotonou	CHU Québec University D'Abomey-Calavi	FSW	31 years	**256 FSW**	Primary Health Center clinic
India	Kolkata Mysore	University of Manitoba DMSC Ashodaya Samithi	FSW	29 years	**1,325 FSW**	Community based within national program Peer educator delivery Weekly Clinic pick up
Kenya	Nairobi Kisumu Homa Bay	LVCT	FSW YW MSM	Data forthcoming	**Total: 1,585** • **FSW: 528 (33%)** • **MSM: 438 (28%)** • **YW: 619 (39%)**	Private NGO facilities (MSM and FSW) Gov't health center and hospital (YW)
Kenya/ Uganda	Thika Kisumu Kampala Kabwohe	Partners/University of Washington	SDC	30 years	**1,013 Couples** • **HIV-** • **67% female** • **33% male**	HIV care centers; experience with HIV prevention research
Nigeria	Calabar Jos Nnewi	National Agency for the Control of AIDS	SDC	Data forthcoming	**354 Couples** • **HIV-** • **57% female** • **43% male**	HIV clinic (Nnewi) Family Health Output Clinic (Calabar) Decentralized Community PC sites w/ Hub (Jos)
Senegal	Dakar	African AIDS Research Council	FSW	37 years	**273 FSW**	Ministry of Health clinics
South Africa	Johannesburg Pretoria	Wits RHI	FSW	29.8 years	**219 FSW**	SW clinics and mobile sites run by Wits RHI

Proportion screened, eligible and initiated by population type

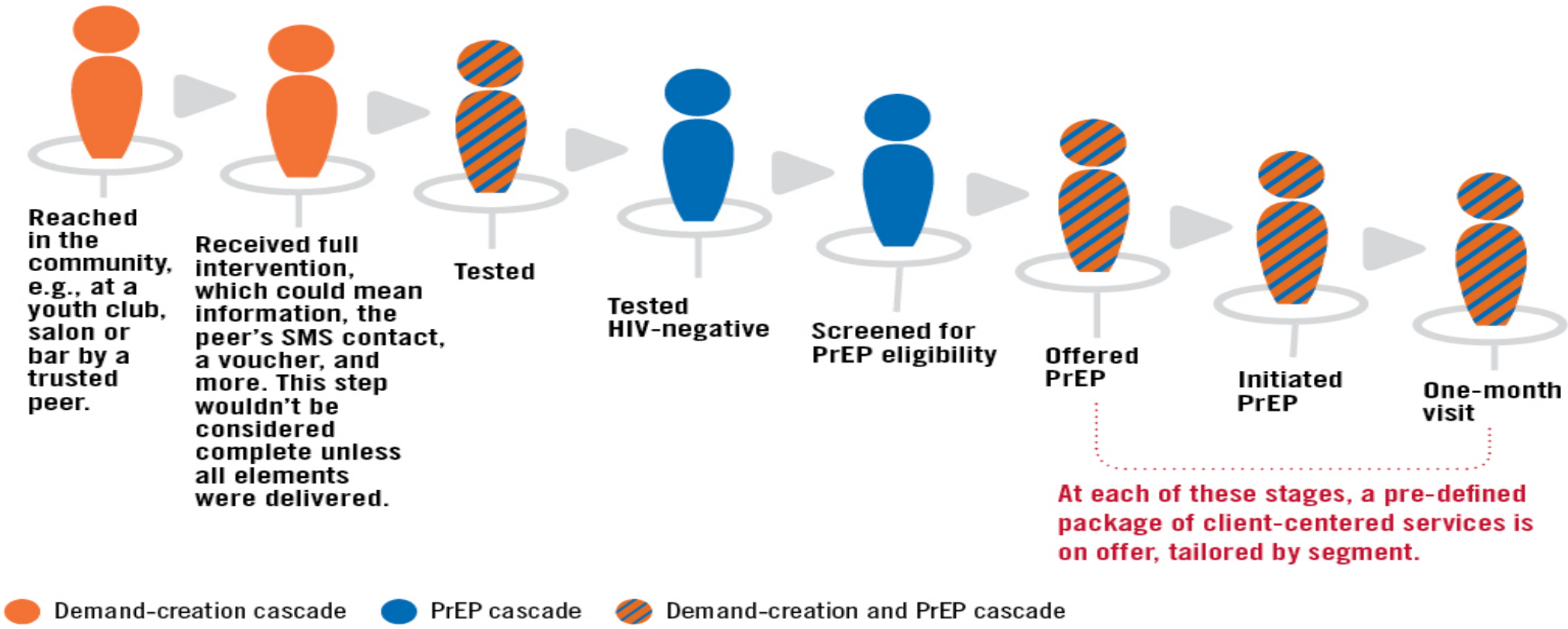


Retention on PrEP by Population



- Among first PrEP demo projects and provided proof of concept
- Demonstrated feasibility of services to initiate clients on PrEP
- Showed that people at risk are interested in PrEP and willing to try it
- Retention of clients on PrEP was a major challenge for most projects
- Few strategies shown to be successful in short project timeframe

Demand creation



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Conclusion

- **Introduction and scale up takes time**: Plan phased iterative introduction and shorten where you can, expect slow take-off
- **Make the public health case**: Epi, Modeling, target populations, human rights, cost effectiveness, impact
- **Prepare health services**: Phase in, train HCWs, scale up, anticipate problems
- **Acceptability**: Identify attributes important for users, HCW, health service impact, policymakers, donors
- **Anticipate possible problems**: Technology, health services, community, users, regulatory
- **Market shaping**: Do ahead of time, set targets, negotiate technology and HS costs, private sector, regulatory
- **Involve key stakeholders early** : users, activists, donors, policymakers, regulators, media
- **Plan for the push back**: Proactive communication and media strategy for users, HCWs, communities, media, leaders
- **Strategic research agenda**
- **Think of unintended consequences** : Risk compensation, health service impact

When we get a new technology, let's introduce it carefully

University of the Witwatersrand
WITS RHI

What we have learnt…….

- **Individual /social group influence**
- Knowledge/awareness
- Risk/Benefit (perceived/real)
- Beliefs/Attitudes about health & prevention
- Health system providers trust & personal experience
- Product use as social norm
- Experience with similar technologies
- Acceptability

Technology specific issues

- Mode of delivery
- Mode of administration
- Ease of delivery (HCW/user)
- Schedule
- Health service trade offs
- Risk of side effects or complications
- Role of healthcare professionals
- Costs
- Risk/benefit (scientific)
- Regulatory requirements

- **Contextual issues**
- Comms & media environment
- Influential leaders
- Religion/culture/gender/SE
- Politics/policies
- Geographic barriers
- Historical influences

- **Market shaping**
- Targets (national/donor)
- Pharma’s commercial interest
- Donor interest
- Geographic/population need
- Manufacturing challenges
- Sustainable funding

Developing Uptake and Impact Scenarios for Modeling Microbicide Introduction

Watts et al, 2008

Three country workshop: Low and high uptake of products by country

Country	Low Uptake	High Uptake
India	**Tampons** Less than 10% penetration in urban market. Some firms completely pulled out of selling	**Sanitary napkins** Since 1997, rapid growth in sales (annual rates of 6%). Estimated coverage 20-25% achieved after 10 years

Watts, Kumaranayake 2007 & 2008

Three country workshop: Low and high uptake of products by country

Country	Low Uptake	High Uptake
India	**Tampons** Less than 10% penetration in urban market. Some firms completely pulled out of selling	**Sanitary napkins** Since 1997, rapid growth in sales (annual rates of 6%). Estimated coverage 20-25% achieved after 10 years
South Africa	**Socially Marketed Condoms** Market penetration is <10%	**Injectable contraceptives** More than 50% coverage achieved within 20 years

Watts, Kumaranayake 2007 & 2008

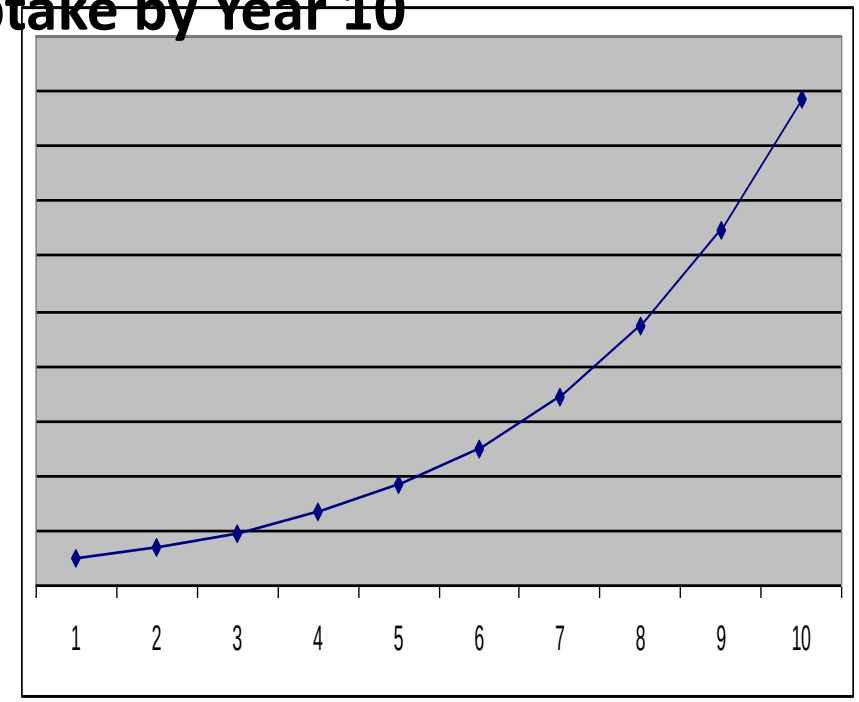
Three country workshop: Low and high uptake of products by country

Country	Low Uptake	High Uptake
India	**Tampons** Less than 10% penetration in urban market. Some firms completely pulled out of selling	**Sanitary napkins** Since 1997, rapid growth in sales (annual rates of 6%). Estimated coverage 20-25% achieved after 10 years
South Africa	**Socially Marketed Condoms** Market penetration is <10%	**Injectable contraceptives** More than 50% coverage achieved within 20 years
Tanzania	**Female condoms** Sales of less than 150,000 after 7 years, with market <10%	**Insecticide Treated Nets** Overall household net use as high as 80% in some towns and 50% in rural areas

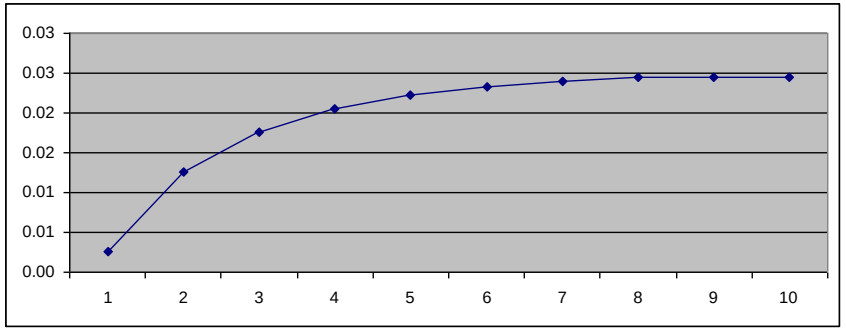
Watts, Kumaranayake 2007 & 2008

Proposed modelling for India

25% uptake by Year 10



3% uptake by Year 10



Modelling allows impact evaluation and setting of targets

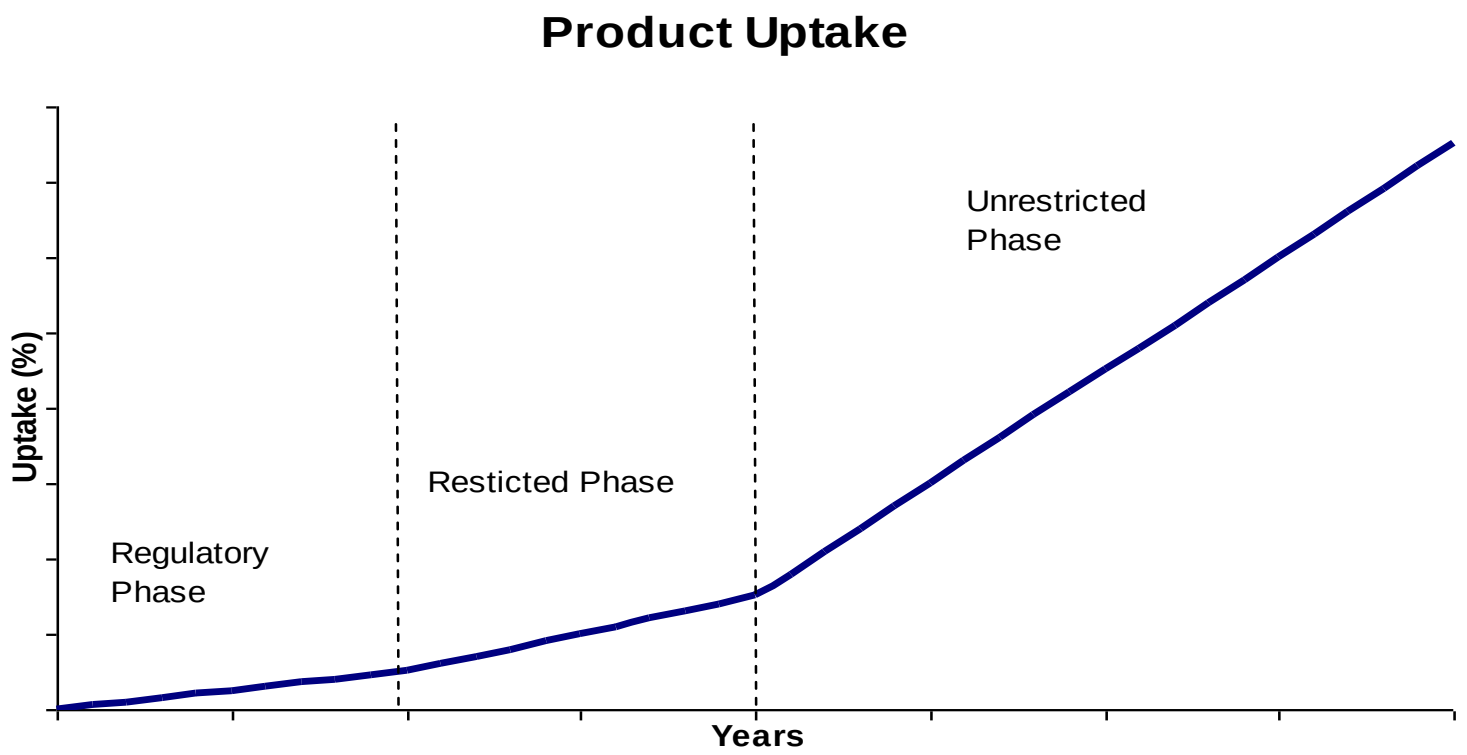
Watts, Kumaranayake 2006

Microbicide impact results, India

- The model projected that in a population of 1.6 million approximately 91,000 HIV infections would occur over 15 years if no microbicide or other new intervention was introduced.

- In the highest impact scenario, the model predicted that 17,390 (range 6,638 – 28,672) HIV infections would be averted over 15 years.

What could we do to speed up technology introduction and uptake?



In summary we will need to..

Get political commitment from policymakers

Phases of Informed-Choice PrEP Counseling

This flow chart emerged from socio-behavioral research, including surveys and in-depth interviews with Kenyan and South African women. The research team set out with the goal of adapting the informed-choice approach used in family planning programs for use in PrEP, a prime example of fields learning from each other. The result is very clinic-centered; AVAC has added the column at the far right to reflect additional elements. However, it is a step towards much-needed exploration of how to make informed choice a reality in HIV prevention today.

Introductory phase

The counselor:

Informs client that PrEP is available, explains what it is and asks if client is interested.

The client:

- Expresses interest in PrEP and proceeds to information phase.
- Is not interested in PrEP and proceeds to standard HIV risk-reduction counseling.

Information phase

The counselor:

- Explores the client's current context of risk and preventive behaviors.
- Educates about what different choices (and combinations) such as PrEP, condoms and ART (leading to viral load suppression for known partners living with HIV) can and cannot do.
- Encourages client questions and asks questions to ensure comprehension.

The client:

- Helps the counselor understand her context of risk and preventive behaviors.

Deliberation and decision-making phase

The counselor:

- Helps client apply information to her individual circumstances.
- Provides information and skills to reduce HIV risk and promote overall sexual health.
- Supports client in her informed decision.

The client:

- Considers information and makes a decision about what method(s) are right for her to use.

Concluding phase

- The client finalizes her decision.
- The counselor welcomes her to return in the future if she would like to try a different approach.

Requirements: An advocacy checklist

- Commodities to support client decisions
- Training and supportive supervision for counselor to assess client risk, provide non-judgmental and supportive space for decision-making
- Staffing levels and compensation that support the time needed for conversation
- Peers to support and enhance choices
- Commitment to revisiting client's choice(s) over time
- Monitoring and evaluation approaches to measure decision quality and informed choice

Adapted from: FHI 360. Guidance for Providing Informed-Choice Counseling on Sexual Health for Women Interested in PrEP: Kenya and South Africa. 2016. Accessible at: *https://bit.ly/2WuhnW.*

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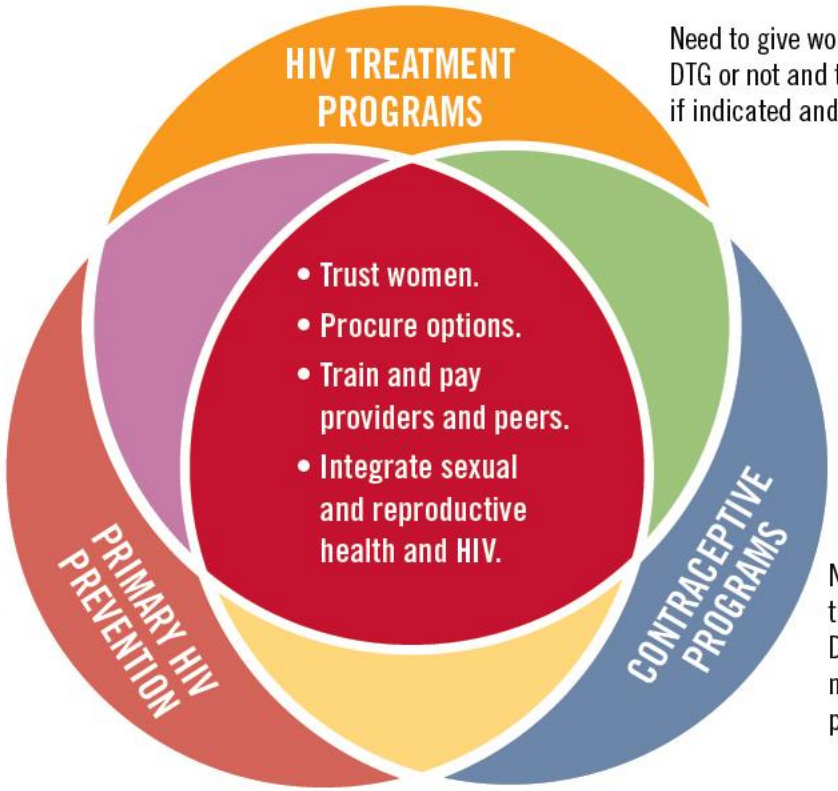
Putting Women* at the Center: Informed choice in 2018 and beyond



Need to give women the choice to use DTG or not and to use contraception if indicated and desired.

Need to support choices across options, with risk reduction—not use of a specific product—as the primary outcome.

Need to give women the choice to use DMPA-IM or –SC or not, and to use HIV prevention as desired.

* This graphic uses issues of primary relevance to cisgendered women and does not reflect diversity within those communities. The principles at the center could be adapted to apply to every category of person affected by HIV, including but not limited to transgender women, gay men and other men who have sex with men, heterosexual men and migrants. We also stand firm in the belief that the needs and issues of cisgendered women must be continually and specifically foregrounded as central to any epidemic response.

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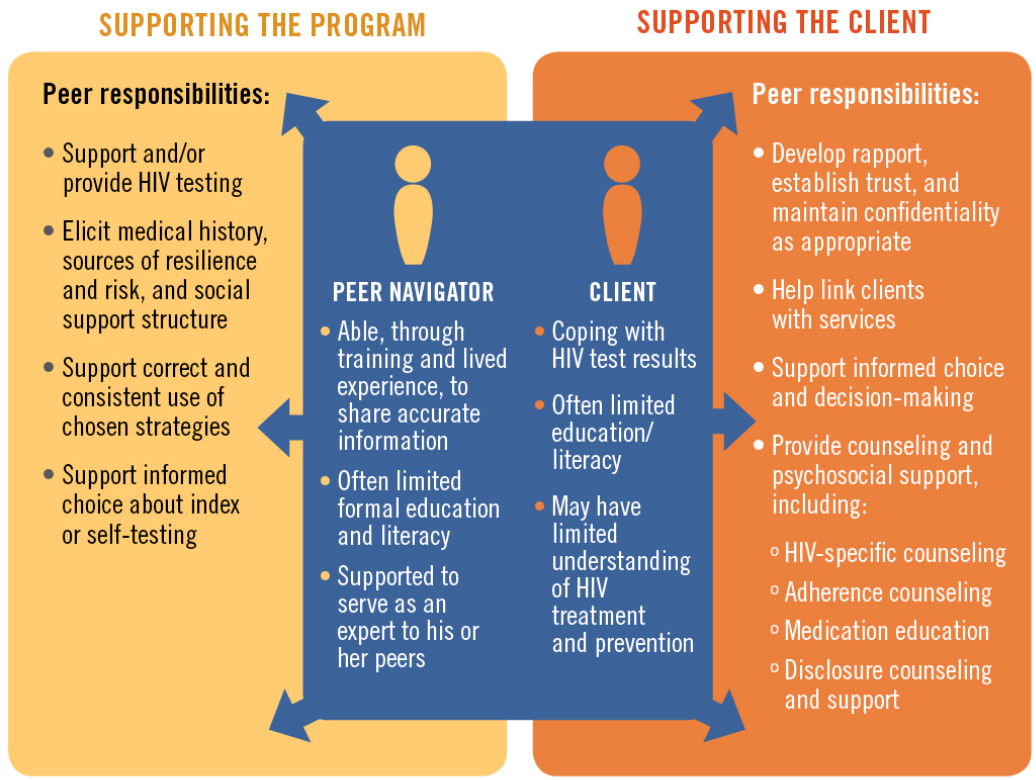
Peers are Primary: Towards a systematic approach to lay cadres

Across treatment and prevention programs, peer navigators, mentor mothers and lay counselors are recognized as essential to good services. Yet many countries don't have clear schemas for quantifying the number of individuals needed, budgeting for their remuneration and defining the roles and responsibilities that lead to impact. Activists are working to ensure clarity by demanding that governments, funders and implementers take steps to:

- Quantify the need and coverage gap for lay workers supporting HIV and other health services;
- Recognize lay cadres in government human-resources-for-health plans;
- Monitor performance in sites and programs with different types of lay workers;
- Provide updates on investments in human resources for health by cadre as part of all PEPFAR Country Operational Plans, AIDS reviews and other annual surveys.

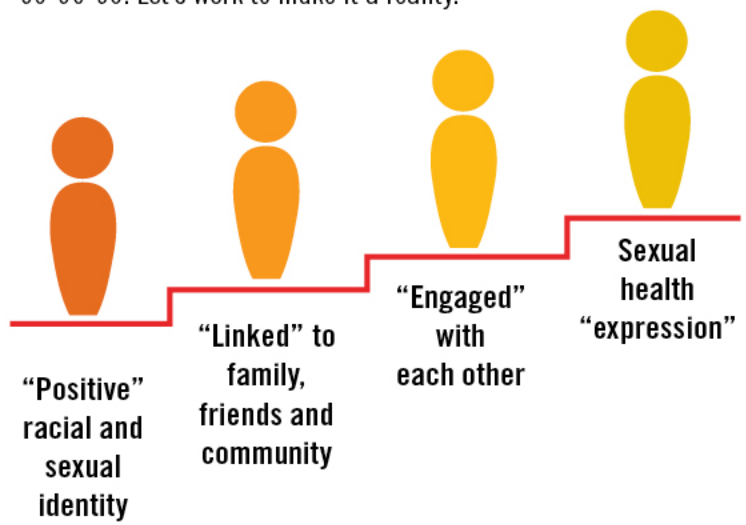
Defining the peer or lay person's roles and responsibilities is essential. The graphic below is one example of what a specific job description could look like.



Graphic adapted from: Karwa et al. *Leveraging peer-based support to facilitate HIV care in Kenya. PLoS Med.* 2017. DOI: 10.1371/journal.pmed.100235.

Public Health is Personal, Pleasurable and Connected

What gets measured gets funded, the adage goes. What would happen if communities demanded measurements of individual and collective health and well-being that have nothing to do with a retrovirus or a specific sex act, and everything to do with human dignity, comfort and safety in one's own skin—a comfort that's hard-fought in racist, sexist, homo– and trans-phobic nations? Imagine a world in which this cascade counted as much as 90-90-90. Let's work to make it a reality.



Credit: David Malebranche, Morehouse School of Medicine, USA, *Making the Treatment Cascade Work in Key and Vulnerable Populations*, AIDS 2018 (Accessible at: *http://programme.aids2018.org/Programme/Session/35*).

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The Future of ARV-Based Prevention and More (October 2018)

The pipeline of non-vaccine HIV prevention products includes oral pills, vaginal rings, vaginal and rectal gels, vaginal films, long-acting injectable antiretrovirals and more. Also pictured are the range of multipurpose prevention technologies in development that aim to reduce the risk of HIV and STIs and/or provide effective contraception for women. (Visit *www.avac.org/hvad* for vaccine and broadly neutralizing antibody pipelines.)

AVAC Report 2018: No Prevention, No End
www.avac.org/report2018

With Thanks

- Charlotte Watts, Anna Foss, Lilani Kumaranayake, Andrew Cox, Fern Terris-Prestholt and Peter Vickerman (LSHTM)
- Sinead Delay-Moretlwe, Mags Beksinska, Catherine MacPhail, RHRU
- The teams from India, Tanzania and RHRU, South Africa who contributed to the modeling workshops
- The researchers and the many women and men who have contributed to the studies used in this presentation
- The donors who supported this research

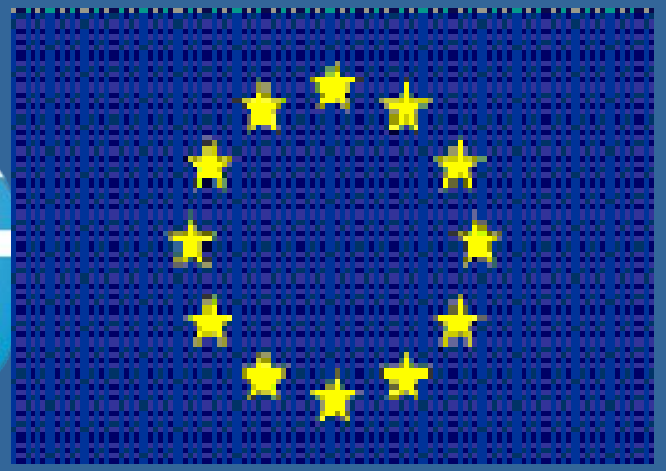
RHRU
Reproductive Health & HIV Research Unit
of the University of the Witwatersrand, South Africa.

Understanding the uptake of public health technologies

- Female Condoms
- Tampons
- Condoms
- Spermicide, Sponges
- Diaphragm, cervical caps
- Hormone implant and injections
- IUDs and oral contraceptives (including emergency contraceptives)
- Public health products (bednets)
- Surgical sterilisation
- Voluntary counselling and testing
- ARV (prevention of mother-to-child transmission)

Watts, Kumaranayake 2007 & 2008

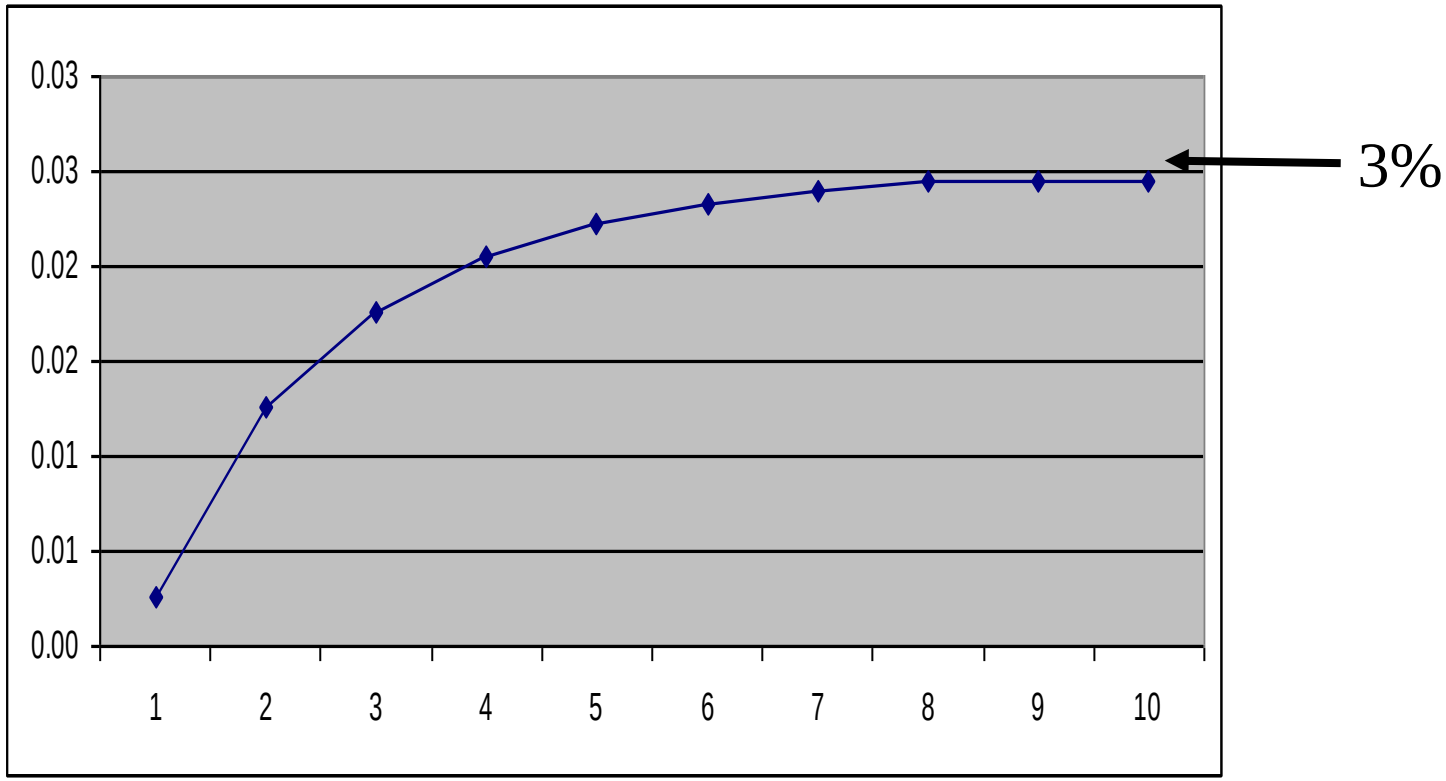
Summary of research by the LSHTM



Identifying optimal strategies for microbicide distribution in India and South Africa: Modeling and cost-effectiveness analyses

Proposed Uptake Modelling for India – Low Uptake (3% by year 10)

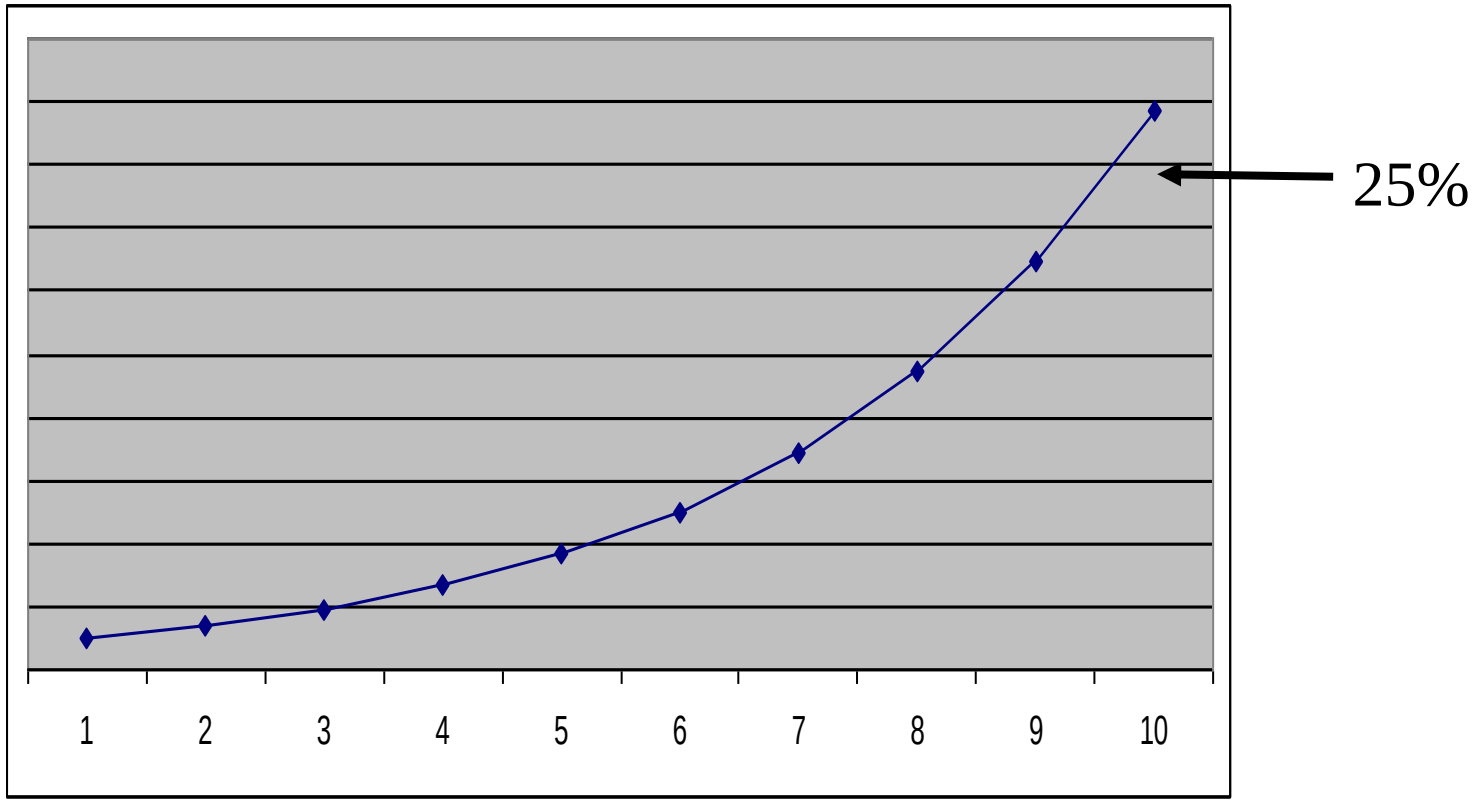
Coverage = 57933Ln(Year) + 12473



Watts, Kumaranayake 2008

Proposed Uptake Modelling for India – High Uptake (25% by year 10)

$$\text{Coverage} = 74940 \exp^{0.3164\ \text{Year}}$$



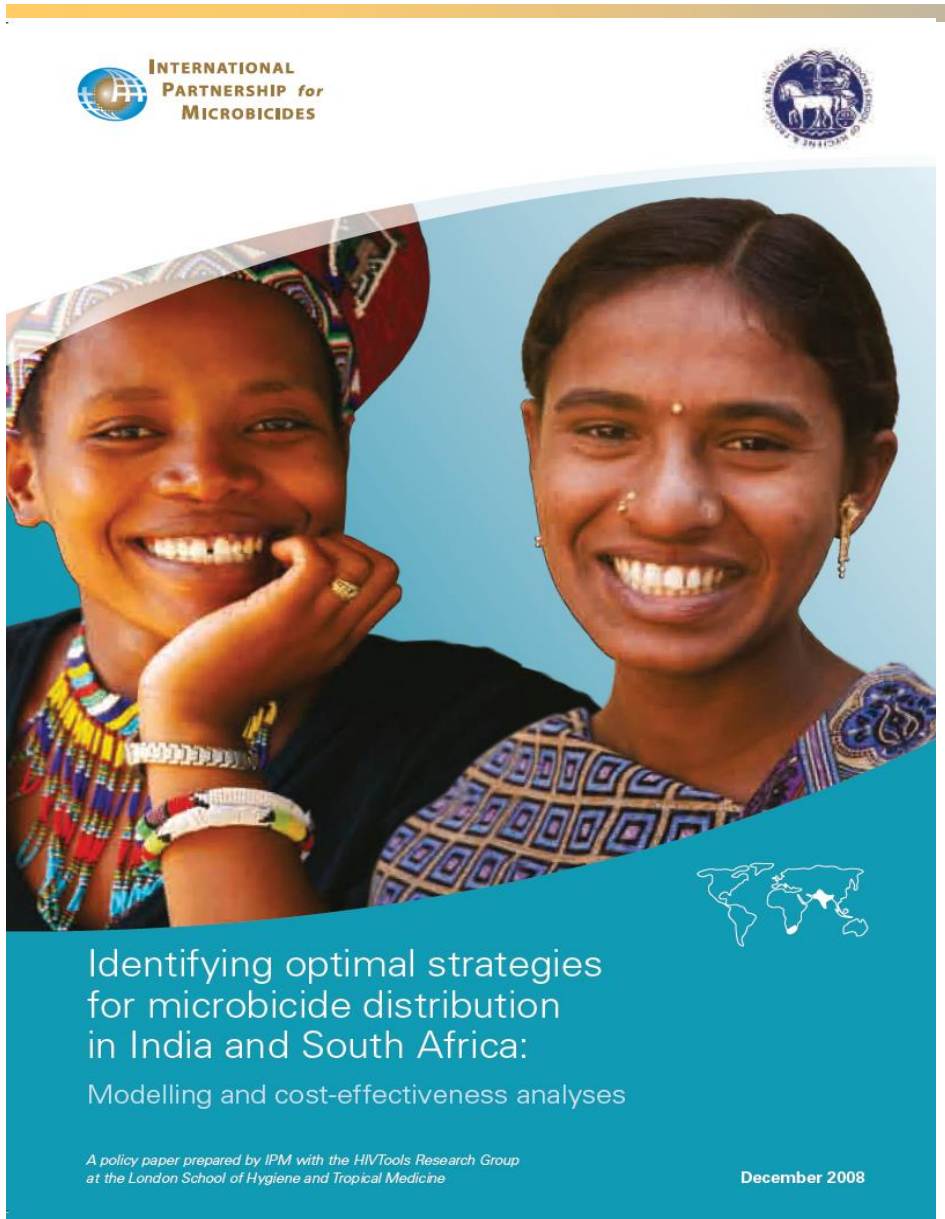
Watts, Kumaranayake 2008

Purpose

This report presents the findings from a study that uses epidemiological modeling and economic analyses to explore the potential impact and cost-effectiveness of different microbicide introduction strategies in Southern India and South Africa.

Policy Brief

www.ipm-microbicides.org/pdfs/english/ipm_publications/2008/IPM_PolicyReport(English).pdf



Guiding questions

A range of important questions must be addressed in order to ensure future product approval and a successful introduction:

- What scale of impact might be achieved if an effective microbicide were added to current preventative measures in a particular setting?
- If supplies or resources are limited, should a product be widely available, or focus on reaching specific, vulnerable groups?
- What is the likely potential public health impact of a product in a specific setting? How does impact vary by introduction strategy used?
- Will these be cost-effective, in comparison to other areas of health investment?

Aims

Estimate the impact of microbicide introduction on the HIV epidemic in two contrasting settings (Southern India and urban South Africa).

Explore how impact is related to:

- Product efficacy and use;
- Microbicide introduction strategy and uptake;
- Speed of approval and potential restrictions on product delivery .

Build on previous cost estimate exercises and cost studies to estimate the total costs of each of the different microbicide introduction strategies in each setting.

Explore which strategy is most cost-effective, and assess whether the delivery scenarios with the highest impact are also the most cost-effective.

Methods

In India and South Africa, country workshops were set up to discuss likely strategies for future product introduction.

Reviews of current evidence about the rate of introduction of new health technologies were used to inform the likely rate of product introduction.

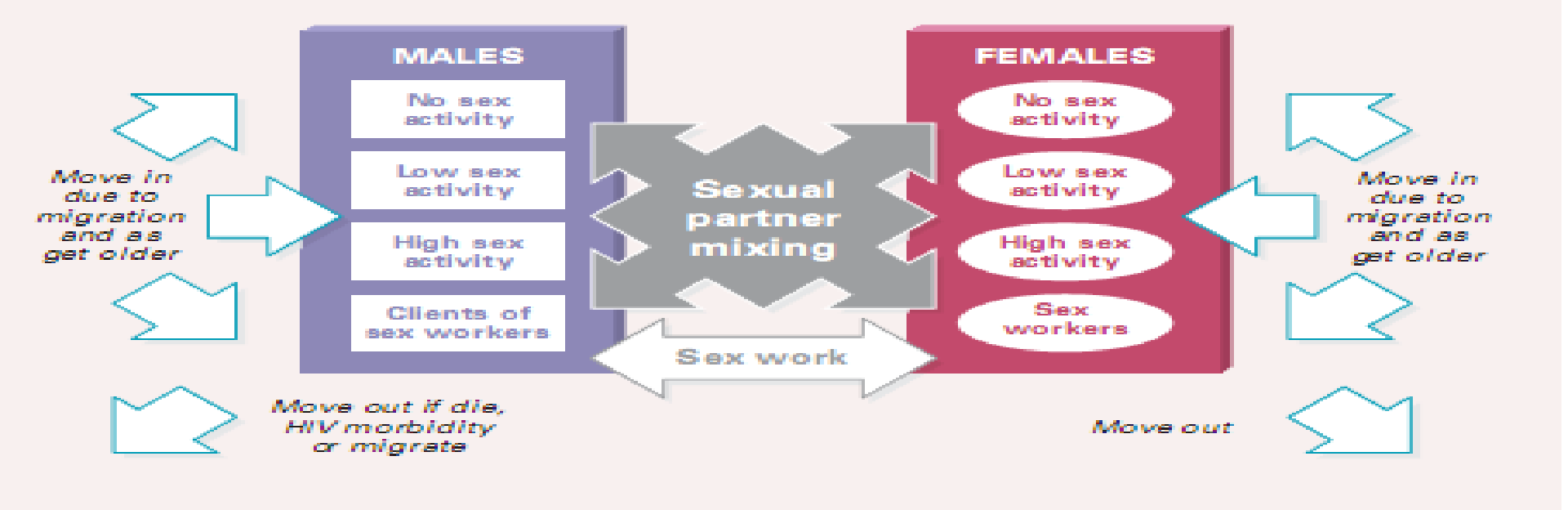
Population-based data from each country were analyzed to produce estimates of the extent to which women accessed different services in each setting.

This was used to develop potential introduction scenarios with low and high uptake assumptions.

120 and 156 different scenario combinations were considered in India and South Africa respectively.

Epidemiological Impact Model

HIV transmission model



- Dynamic deterministic transmission model of HIV & other STI
- Programmed in C++
- Explicitly model HSV-2, syphilis & another STI
- Age structured
- Model uses detailed setting specific & epidemiological input data
- Model projections fit to local epidemiology of HIV

Epidemiological Model

An existing epidemiological model was adapted in order to assess the impact of each of the introduction strategies on HIV transmission, taking into account product uptake.

The modeling had an emphasis including realistic assumptions about the stages and achievable rates of product uptake.

The modeling analysis considered two contrasting settings:

- Mysore District, Karnataka, in Southern India
  - Population at a reproductive age of around 1.6 million;
  - HIV prevalence in the general population is around 1%, as opposed to 26% among FSWs.
- Gauteng Province, South Africa
  - Population of reproductive age of about 5.7 million;
  - HIV epidemic is more generalized, general population HIV prevalence of around 10.8%, with 8.2% of males and 13.3% of females infected;
  - Estimates of the HIV prevalence in FSWs varied considerably, the range of 40 - 67% was used in this analysis.

Scenarios

Based upon the reviews and workshop recommendations, agreements were made about levels for:

- Efficacy of microbicides;
- Consistency of microbicide usage;
- Potential approaches to targeting;
- Likely strategies and timeframes for introduction.

3 x 2 Scenarios for efficacy and usage

Microbicide efficacy and consistency:

(Agreed combinations to be used for the scenarios)

HIV- efficacy per sex act	Percentage of sex acts protected (Consistency)
Low - 35%	Moderate - 50%
Low - 35%	High - 80%
Medium - 60%	Moderate - 50%
Medium - 60%	High - 80%
High - 85%	Moderate - 50%
High - 85%	High - 80%

Introduction Strategy Scenarios

Urban Southern India

1. Population-level distribution to all sexually active women
2. Focused provision to female sex workers (FSWs) through sex worker programmes

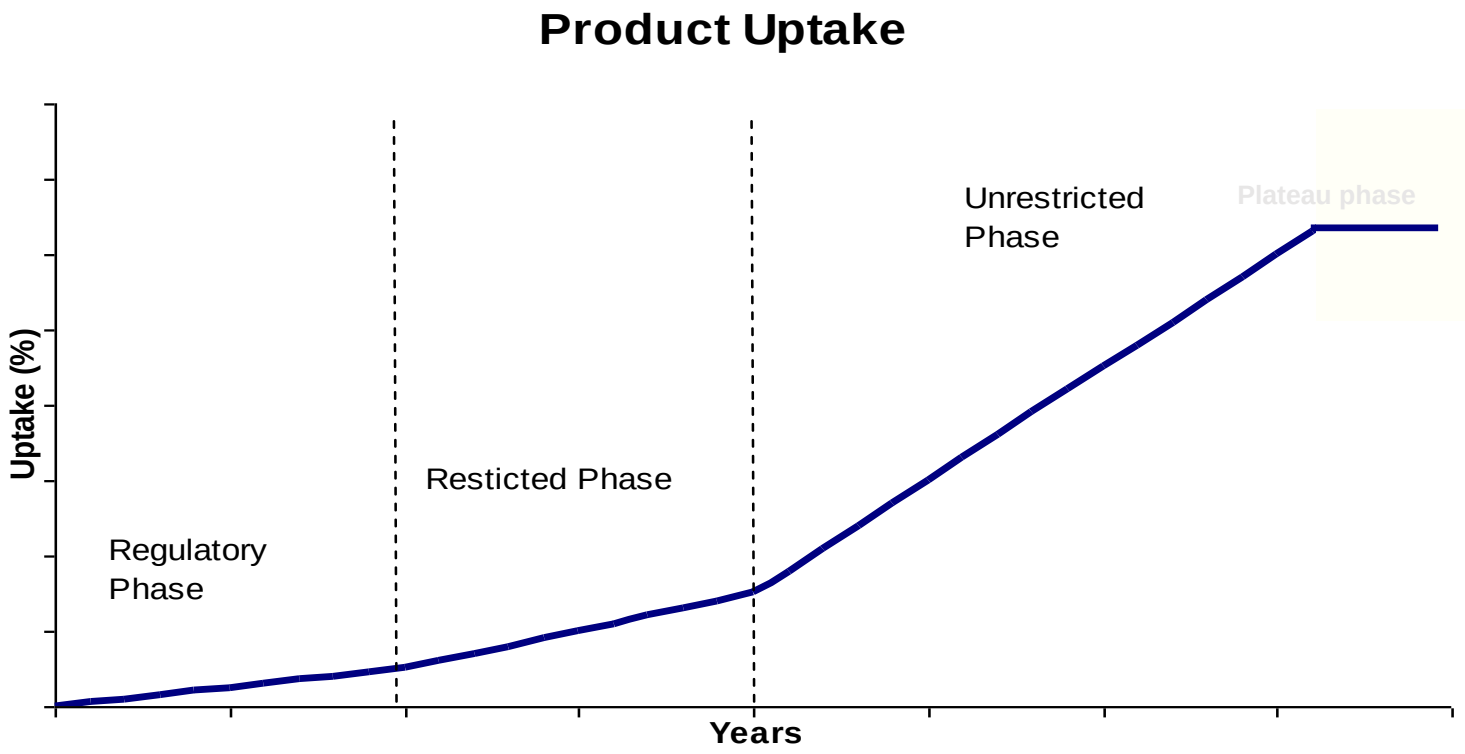
Urban South Africa

1. Population distribution to all sexually active women
2. Population distribution with enhanced provision to youth 3 years post-approval
3. Population distribution with enhanced provision to FSWs through sex worker programmes

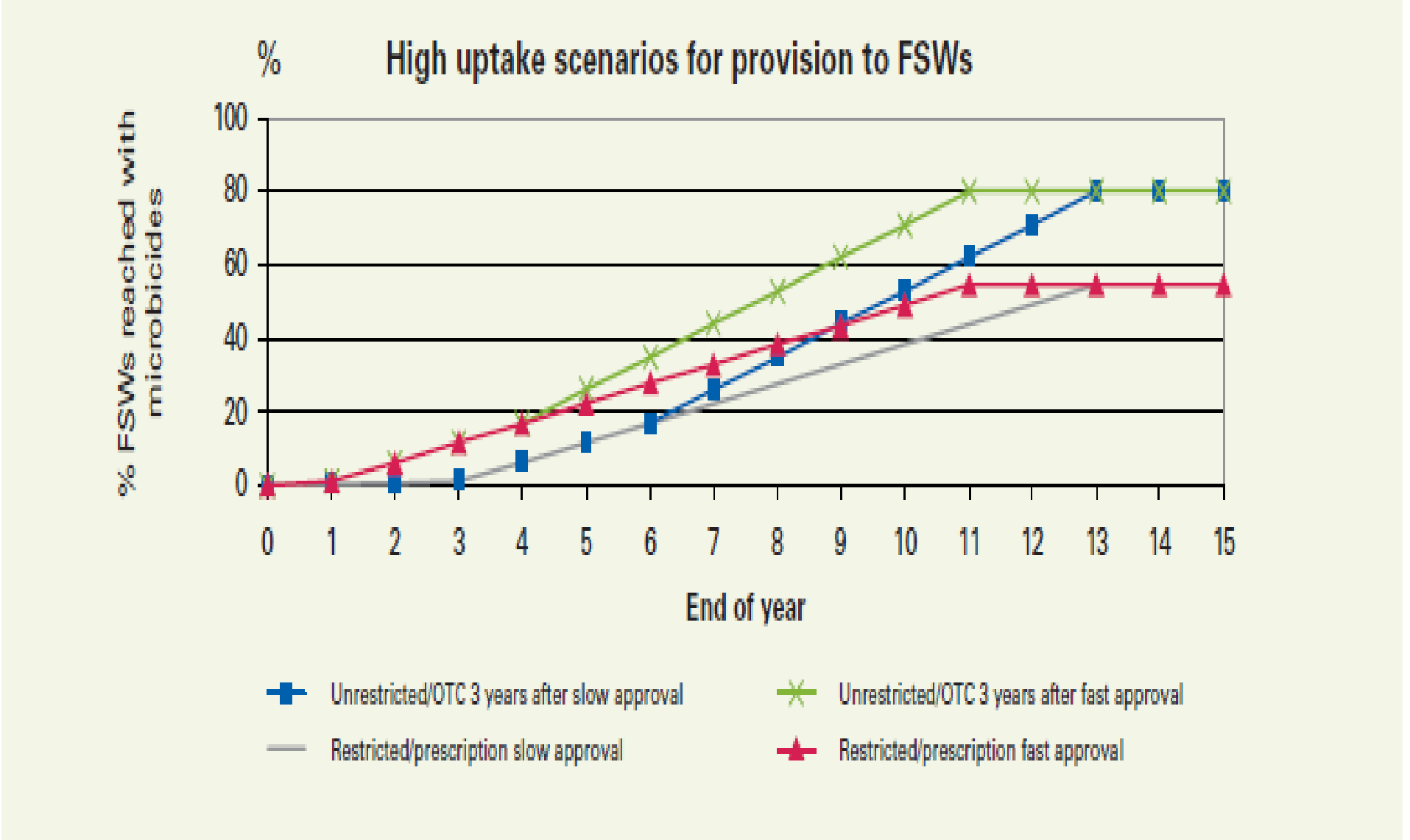
Parameterisation of stages of product introduction in Urban India and South Africa

Stage	India	South Africa
Regulatory approval & market authorisation: product provided on a limited scale to trial participants	Up to 1% of FSWs have access to microbicides Slow – 3 yrs Fast – 1 year	Up to 0.1% of females in general population have access to *microbicides* Slow – 3 yrs Fast – 1 year
Restricted delivery for 3 years: product only available on prescription, through public health facilities	34% of the general population have access to public health facilities 68% of FSWs have access to public health facilities	50% of the general population have access to public health facilities 70% youth (3 yrs post approval) have access to public health facilities 70% FSWs (3 yrs post approval) have access to public health facilities
Potentially unrestricted delivery e.g. supermarkets, shops, social marketing, GPs, pharmacies	Coverage 10 years post approval: Gen population Low – 3% Med – 15% High – 30% FSW: Low – 30% High – 80%	Coverage 10 years post-approval Gen pop / youth Low – 3% Med – 15% High – 30% FSW: Low – 30% High – 80%
Achievable market saturation	Levels of distribution plateau	

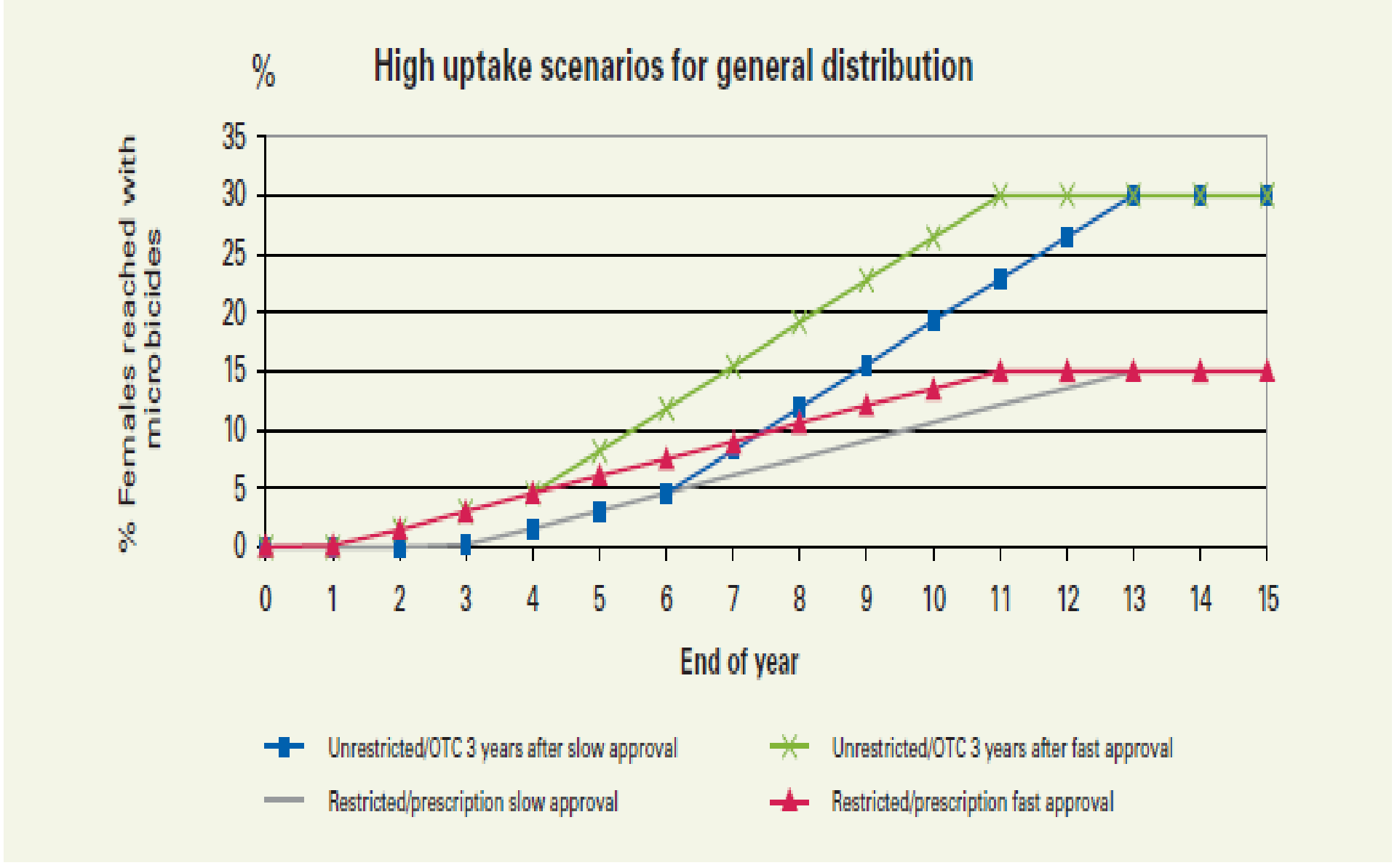
Assumptions built into model: 4 stages of product distribution



Example of high uptake trajectories modeled in India analysis



Example of high uptake trajectories modeled in South Africa analysis



Highest impact scenario, India

- In the India analysis, the highest impact ('top') scenario was :

  - a high efficacy product (85%);
  - With high consistency of usage (80%);
  - That cleared regulatory approval quickly (1 year);
  - and then was distributed with ***focused provision to only FSWs;***
  - with a relatively fast transition from a restricted to an unrestricted microbicide introduction program (3 years post-approval);
  - progressing to a high level of uptake (80% after 10 years post-approval) .

Impact after 15 years, India

- For all of the top ten scenarios the impact in the final year is on average about 2.4 times the average number of HIV infections averted per year over the 15 years of the intervention.

- After 15 years, the best model fit predicts a relative reduction in incidence per susceptible of 49% over all the population and 70% among FSWs alone.

Top 10 impact scenarios in India

Distribution scenario	Infections averted	Infections averted / 100,000 population	Relative percentage of top scenario
FSW Top - all high / fast / good	17,390	1,054	100%
FSW Top, but restricted always	12,560	762	72%
FSW Top, but slow approval	12,095	733	70%
FSW Top, but medium efficacy	12,015	728	69%
FSW Top, but moderate consistency	10,564	641	61%
FSW Top, but restricted always AND slow approval	8,965	544	52%
FSW Top, but restricted always AND medium efficacy	8,701	528	50%
FSW Top, but slow approval AND medium efficacy	8,368	507	48%
FSW Top, but restricted always AND moderate consistency	7,661	464	44%
Gen pop Top - all high / fast / good	7,415	450	43%

Microbicide impact results, SA

- The model projected that almost 2.5 million HIV infections would occur over 15 years if no microbicides or other new interventions introduced.
- In the highest impact scenario 167,223 (143,255 – 193,381) HIV infections would be averted over 15 years, equivalent to 2,930 HIV infections averted per 100,000 people.
- This overall impact reflects what might be expected from a gradual increase in product distribution.

Highest impact scenario, SA

- The highest impact ('top') scenario came from:
  - A high efficacy product (85%);
  - With high consistency of usage (80%);
  - That cleared regulatory approval quickly (1 year);
  - And then distributing microbicides ***to the general population and FSWs;***
  - With a relatively fast transition from a restricted to an unrestricted microbicide introduction program (3 years post-approval);
  - Progressing to a high level of uptake (80% in FSW and 30% in the general population after 10 years post-approval).

Impact after 15 years, SA

- After 15 years, for all of the top ten scenarios, the number of HIV infections averted per 100,000 population is on average about twice as high as the average number of HIV infections averted per year over the 15 year period.

- The most effective scenario reduces the incidence in year 15 per susceptible by 15%.

Top 10 impact scenarios in SA

Distribution scenario	Infections averted	Infections averted / 100,000 population	Relative percentage of top scenario
Gen pop + FSW Top - all high / fast / good	167,223	2,930	100%
Gen pop Top - all high / fast / good	130,444	2,286	78%
Gen pop + FSW Top, but slow approval	124,333	2,179	74%
Gen pop + FSW Top, but medium efficacy	115,392	2,022	69%
Gen pop + FSW Top, but moderate consistency	101,544	1,779	61%
Gen pop + FSW Top, but restricted always	98,110	1,719	59%
Gen pop Top, but slow approval	97,887	1,715	59%
Gen pop Top, but medium efficacy	90,973	1,594	54%
Gen pop + FSW Top, but slow approval AND medium efficacy	86,089	1,508	51%
Gen pop Top, but moderate consistency	80,281	1,407	48%

Impact SA vs. India

- Comparing the highest impact population distribution strategies:
  - In Gauteng, SA, the strategy averts (at least) double the infections, than in Mysore, India (1,102 vs. 493 per 100,000 population);

- But the percentage reduction in HIV incidence was lower:

  - Over the period of 15 years: 6.7% vs. 19%;
  - In year 15: 15% vs. 49% over all the population and 70% among FSWs alone.

- These findings are consistent with modeled projections of the impact of other HIV prevention interventions in different epidemiological settings.

Cost Effectiveness Projections

Aims

- Estimate the costs of introducing microbicides based on the different distribution scenarios considered in each setting.
- Estimate the average cost and cost effectiveness of different distribution scenarios.
- Assess whether the delivery scenarios with highest impact are also the most cost-effective.

Methods

- The analysis:
  - Uses *economic* costs (not financial costs);
  - From a *providers* perspective (not user perspective);
  - Considering *incremental* costs (not full service costs);
  - *Discounting* is used to convert future costs and benefits to their present value.

Outcome measurement

- To consider whether a particular distribution strategy is ‘cost-effective’ or not, it is necessary to compare this with other possible interventions .

- Two outcomes can be used to compare cost-effectiveness among health interventions:
  - HIV infections averted;
  - Disability Adjusted Life Years (DALYs) saved.

Definition of cost effectiveness

- Generic cost-effectiveness cut-offs suggested by World Bank Development Report.

- For middle income countries, (such as India and South Africa, adjusted to 2008) cost-effectiveness cut offs are :

  - in India $1,425 per HIV infection averted;
  - in South Africa of $3,005 per infection averted.

- Interventions achieving a cost of less than these figures being seen to be ‘cost-effective’.

Assumptions about unit costs

Scenario	Price ($)
Daily use	
Medium (Base case)	0.10
Low	0.05
High	1.00
Monthly use	
Low	1.00
High	5.00

Top ten cost-effectiveness scenarios for microbicide distribution in Mysore District, India

Top nine scenarios are identical regarding CE and impact, although order differs

Rank	Distribution focus and attributes	Discounted		Undiscounted	
		HIV infections averted	C-E*	HIV infections averted	C-E
1	FSW, Non-facility, fast approval, high uptake, high efficacy, high consistency	10,696	788	17,.390	585
2	FSW, Facility, fast approval, high uptake, high efficacy, high consistency	7,879	1,048	12,560	790
3	FSW, Non-Facility, fast approval, high uptake, medium efficacy, high consistency	7,408	1,138	12,015	846
4	FSW, Non-Facility, slow approval, high uptake, high efficacy, high consistency	6,984	1,154	12,015	803
5	FSW, Non-Facility, fast approval, high uptake, high efficacy, low consistency	6,520	1,236	10,564	915
6	FSW, Facility, slow approval, high uptake, high efficacy, high consistency	5,313	1,499	8,965	1,067
7	FSW, Facility, fast approval, high uptake, high efficacy, high consistency	5,473	1,509	8,701	1,141
8	FSW, Facility, fast approval, high uptake, medium efficacy, high consistency	4,823	1,656	7,661	1,249
9	FSW, Non-facility, slow approval, high uptake, medium efficacy, high consistency	4,846	1,664	8,368	1,161
10	FSW, Non-Facility, fast approval, high uptake, medium efficacy, low consistency	4,534	1,777	7,327	1,320
Most Cost-effective General Population Strategy					
44	General, Non-facility, fast approval, high uptake, high efficacy, high consistency	4,584	7,959	7,415	6,470

Comparison of impact and cost-effectiveness rankings in Gauteng, South Africa

Scenario	Population and distribution, relative to all best	Impact Ranking (undiscounted)	CE rank (discounted)
124	FSW facility based, low uptake	79	1
148	FSW not facility based, low uptake	58	2
112	FSW facility based, slow reg app & low uptake	92	3
136	FSW not facility based, slow reg app & low uptake	71	4
154	FSW facility based, all best	1	5
130	FSW, restricted	6	6
142	FSW, unrestricted, slow reg app	3	7
118	FSW, restricted, slow reg app	13	8
70	Gen pop, all best	2	9
52	Gen bop, slow reg app	7	10

- The comparison between impact rankings and cost effectiveness rankings highlight the importance of women's risk profiles in the cost-effectiveness .
- Although the top 3 scenarios for cost effectiveness are low in impact, they are the top three when ranked by infections averted per woman reached.
- However, the top 3 impact scenarios do still appear in the top 10 cost-effective scenarios.

Summary

Optimization of Product Introduction

- In all settings, the likely HIV efficacy of a microbicide is a central issue affecting product acceptability and its potential market, although issues of cost, pleasure, accessibility, and contraceptive efficacy are also important.

- Beyond the preventive efficacy of the microbicide and its ease of use by women, distribution strategies and the pace of product introduction and uptake will determine the impact of this potential new prevention technology on the HIV epidemic.

- This analysis helps understanding the interrelationship of the various parameters of product characteristics, access and use, and can inform optimization of product introduction strategies by identifying scenarios where preventive impact and cost effectiveness are achieved.

Conclusions

- From the epidemiological modeling we conclude that microbicides could lead to significant and cost-effective reductions of new HIV infections, and are likely to be an important addition to our current combination prevention portfolio.

- To fully utilize the protective potential of microbicides it will be important to ensure that microbicides are accessible and used by those who are most vulnerable to HIV infection, both in concentrated and generalized epidemics, including sex workers.

Optimal distribution strategies will vary by HIV epidemic setting

- In India, highest impact and cost-effective strategy focuses on provision to sex workers
- In South Africa, most impact and high cost-effectiveness achieved with broad population distribution
- Differences reflect stage of HIV epidemic in each setting
- Illustrate how future distribution approaches will differ in different HIV epidemic settings

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  - University of Manitoba and Centre de Hospitalier affilié universitaire de Quebec, Canada
  - Reproductive Health and HIV research Unit Johannesburg, SA

- Funding:
  - European Union (EC, DG Development)

- Coordination:
  - IPM

- Short three slide summary

Strategies for Microbicide Distribution in India and South Africa

- Potential impact and cost-effectiveness modeling.
- Urban settings:
  - Karnataka, India
    - 1.6M of reproductive age
    - HIV prevalence 1% general population, 26% FSW
  - Gauteng, South Africa
    - 5.7M of reproductive age
    - HIV prevalence 11% general population, 40-67% FSW
- Epidemiologic models parameterized to each setting and fitted to local HIV/STI prevalence data.

Strategies for Microbicide Distribution in India and South Africa

- Scenario with greatest impact in both settings:
  - Product with 85% efficacy;
  - Approved within 1 year of submission;
  - Unrestricted distribution within 4 years.
- Southern India:
  - Targeted distribution to FSW largest impact;
  - Annual HIV incidence reduced by 49% after a 15 year implementation period;
  - All scenarios cost effective with daily use at 10 cents.
- South Africa:
  - Distribution to both general population and FSW largest impact;
  - Annual HIV incidence reduced by 15% after a 15 year implementation period;
  - 40 of 156 scenarios cost effective; most involved distribution to general population and FSW.

Conclusions

- Optimized microbicide implementation strategies could lead to important and cost-effective reductions in new HIV infections.

- Potentially important addition to current HIV prevention portfolio.

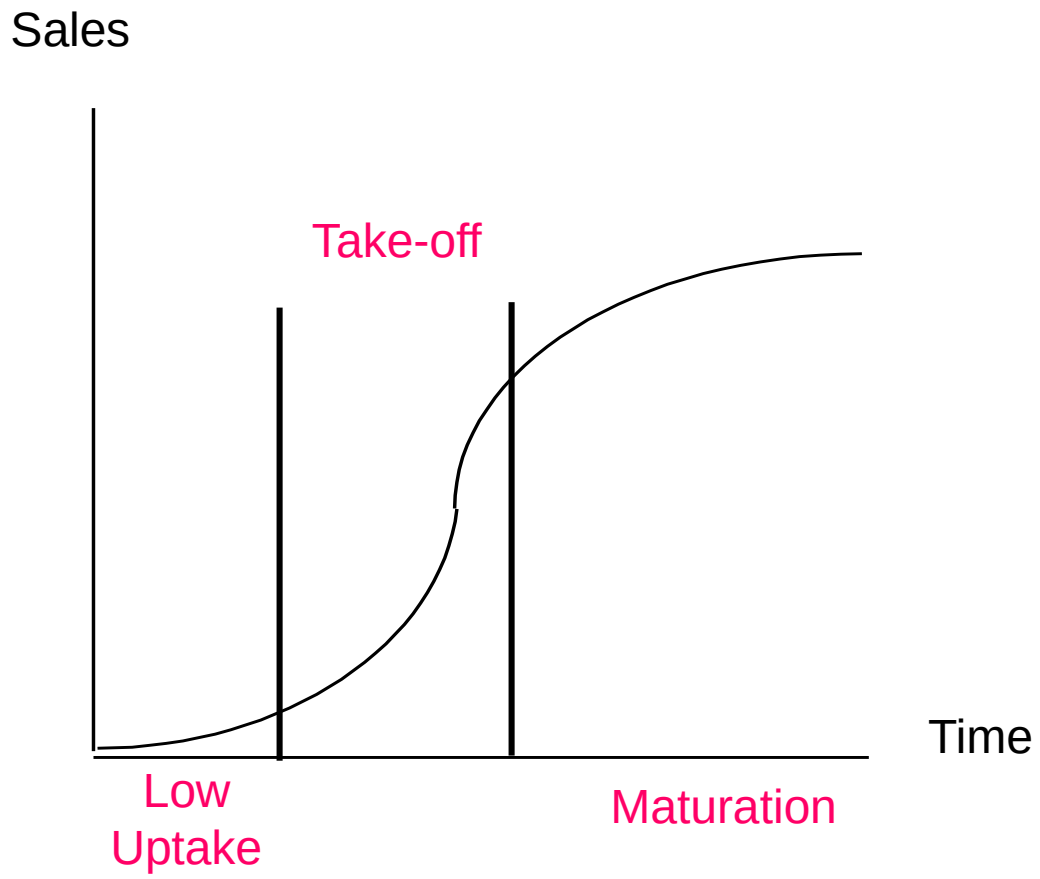
- Combination of factors influence impact:
  - Product efficacy;
  - Consistent product usage;
  - Time to approval;
  - Achieving target uptakes.

Evidence Related to Introduction of New Technologies

Lilani Kumaranayake, Fern Terris-Prestholt; Christine Michaels

London School of Hygiene and Tropical Medicine

Theoretical Model of Product Introduction Diffusion and Adoption Literature



Three Key Issues When Thinking About Uptake

- What is the time-period until the ‘take-off’ phase?
- What is the likely level of coverage/sales achieved at the different phases?
- How long will it take for maturation of market?

Scope of Literature Review

- Female Condoms
- Tampons
- Condoms
- Spermicide, Sponges
- Diaphragm, cervical caps
- Hormone implant and injections
- IUDs and oral contraceptives (including emergency contraceptives)
- Public health products (bednets)
- Surgical sterilisation
- Voluntary counselling and testing
- ARV (prevention of mother-to-child transmission)

Key Lessons Learnt (1)

- Large variation in uptake by product and setting

- Affected by a large range of factors
  - Price
  - Distribution Channel (vending machines, behind the counter, use of wholesalers, marketing and targeting of advertising, ability of staff to be discrete in health facilities

Key Lessons Learnt (2)

- Upper bounds for coverage seem to be about 70%
    - Exceptional case of condom use by married couples in Japan
- Take-off phase
    - Generally takes at least 5-6 years
        - Male condom use in Uganda went from 1%-16% within 5 years
    - Generally gradual uptake
        - Tampon introduction in US had only 25% of women using them after 10 years on the market
- Maturation phase can vary, but likely to be 10-15 years
        - Oral contraceptive use in Thailand increased from 26%-45% of market share over 18 year period

Case Study of Introduction of Female Condom in Zimbabwe

- Similarities between female condom and microbicides
  - both products are female initiated,
  - will be required to be inserted into the vagina prior to sex.
  - both methods require addressing of vaginal taboos and stigma.
  - The first generation of microbicide products being tested are coitally dependent, requiring that, like the female condom, women will need to be regularly provided with supplies.

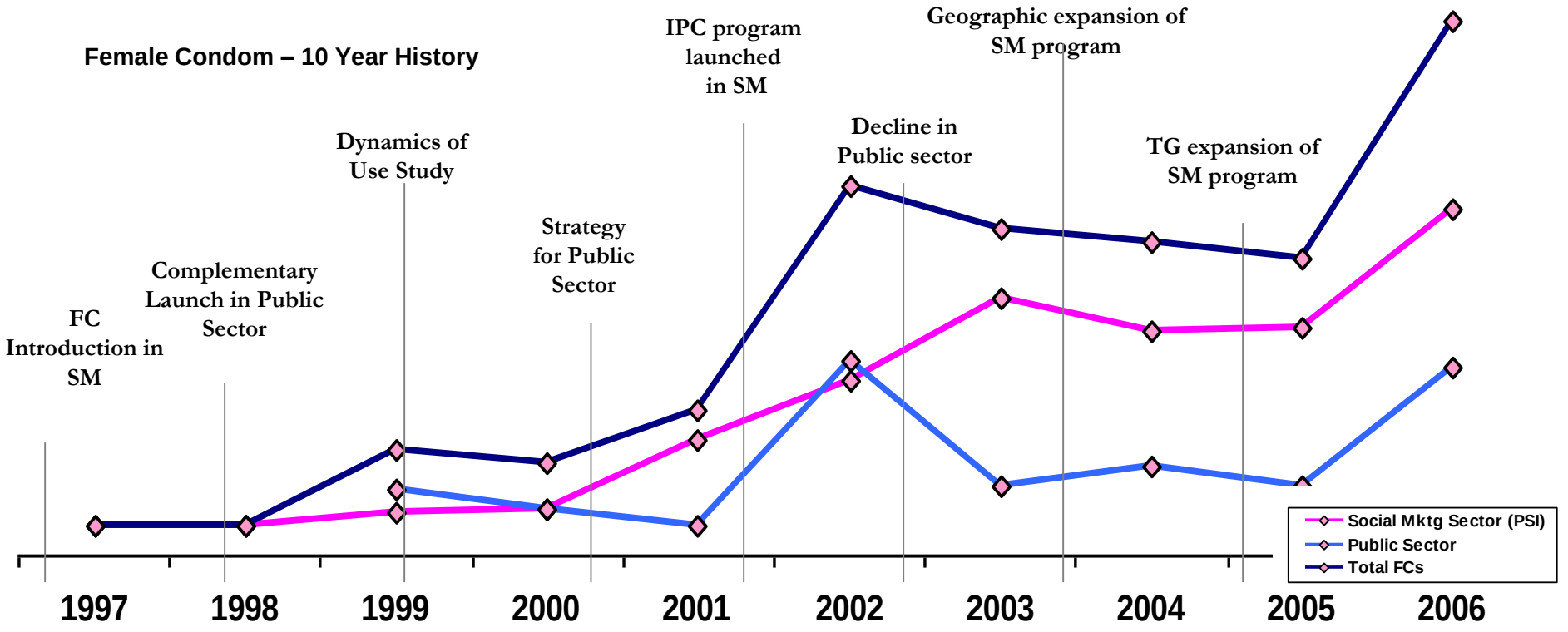
Case Study – Madan et al (2008)

- Madan, Kumaranayake, Philpott, Terris-Prestholt, Wood, Watts (2008), “The Female Condom in Zimbabwe: Learning from Successful Female-Initiated Programmes for Future Microbicide Introduction.” M2008. Abstract 633.
    - The female condom first new HIV prevention technology
    - Scaling up female condom programmes, while successful in some country settings, encountered obstacles in others.
    - Zimbabwe considered one of the most “successful” female condom programmes worldwide,
    - Between 1996 & 2006, total female condom market in Zimbabwe grew from 120,720 in 1997 to over 2.1 million in 2006.

Zimbabwe - phases of product introduction

The evolution of the Social marketing program can be broken down into four distinct phases:

- pre-launch 1994-1997
- product introduction 1997-1999
- early market development 2000-2002
- strategic expansion (2002-onwards).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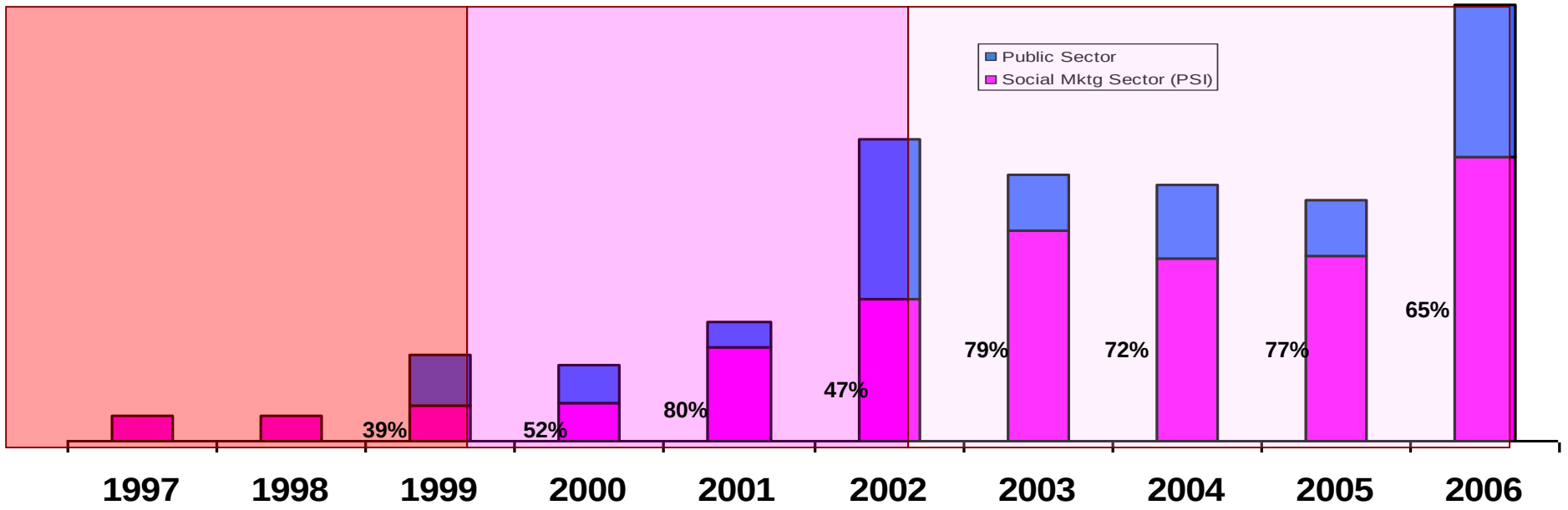
IPC program launched in SM
Decline in Public sector
Geographic expansion of SM program
TG expansion of SM program
Social Mktg Sector (PSI)
Public Sector
Total FCs
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006


Public Sector
Social Mktg Sector (PSI)
39%
52%
80%
47%
79%
72%
77%
65%
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006

Factors Influencing Success (1)

- Complementarity between the public-private sector relationship
  - The female condom was introduced in the social marketing sector
  - This was followed by a complementary launch in the public sector
  - Initial success in social marketing, public sector only had sustained growth from 2006 onwards
  - The two sectors brought different comparative advantages

Factors Influencing Success (2)

- Phased Approach and Planned Expansion of Social Marketing
  - Program was constantly modified based on field experience and research data (e.g. dynamics of use study)
  - Program did not try to target everyone at the same time, but strategically expanded (geographically, distribution channels and target groups)
  - Helped to ensure sustained growth rather than ad hoc distribution seen in the public sector

Factors Influencing Success (3)

- Complementary role of mass media and interpersonal communications (IPC)
  - Innovative use of IPC to promote a niche product
  - Used hair salons to promote, and this helped create sustained users

Factors Influencing Success (4)

- Programme not solely product focused
  - Dedicated resources for female condoms
  - Clear defined role of female condoms in HIV prevention programming moving beyond product focus to get consumer buy-in
  - Product positioned as ‘contraceptive sheath’

Developing Uptake Scenarios for Modelling

Product Delivery and Potential Uptake

- What may be realistic scenarios for how the product might be introduced?
  - Who may be the first key target groups and what distribution channels would be used? How will this likely to be expanded?
  - What would be the likely roles of the public and private sectors?
  - What may be the influence of the characteristics of the products? How quickly could a new product be introduced?
  - What will influence the speed of distribution?
  - How may this differ between providers or between products?

Workshops: how quickly could a microbicide be introduced?

Cited examples of success and weaker introduction

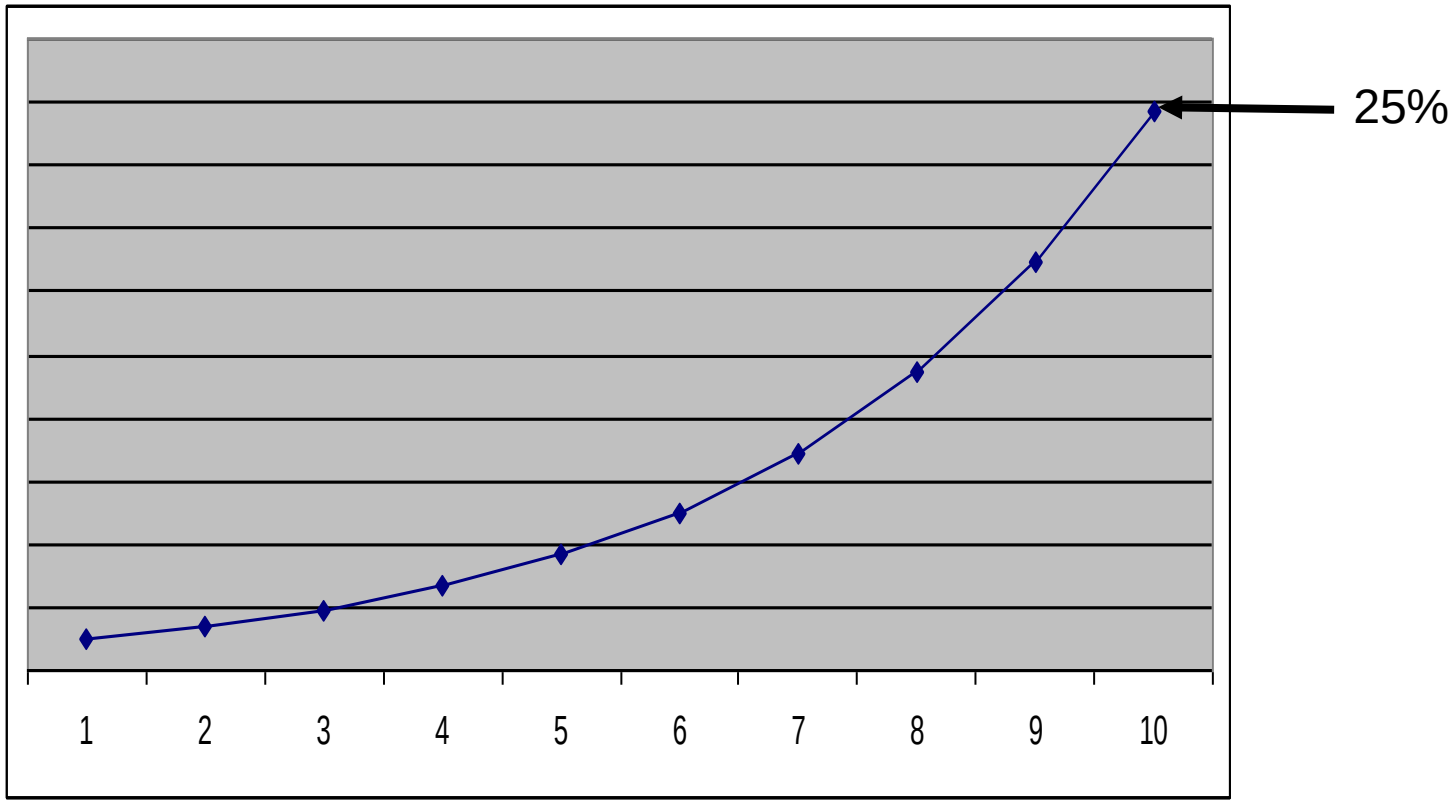
- India
  - Low – tampons and diaphragms
  - High – sanitary napkins
- South Africa
  - Low – condom social marketing, female condom
  - High – injectable contraceptives, mobile phones
- Tanzania
  - Low - contraceptives
  - High - insecticide-treated bed nets

Low and High Uptake Products By Country

Country	Low Uptake	High Uptake
India	**Tampons** Less than 10% penetration in urban market. Some firms completely pulled out of selling	**Sanitary Markets** Since 1997, rapid growth in sales (annual rates of 6%). Estimated coverage 20-25% achieved after 10 years
South Africa	**Socially Marketed Condoms** Market penetration is < 10%	**Injectable contraceptives** More than 50% coverage achieved within 20 years
Tanzania	**Female condoms** Sales of less than 150,000 after 7 years, with market <10%	**Insecticide Treated Nets** Overall household net use as high as 80% in some towns and 50% in rural areas

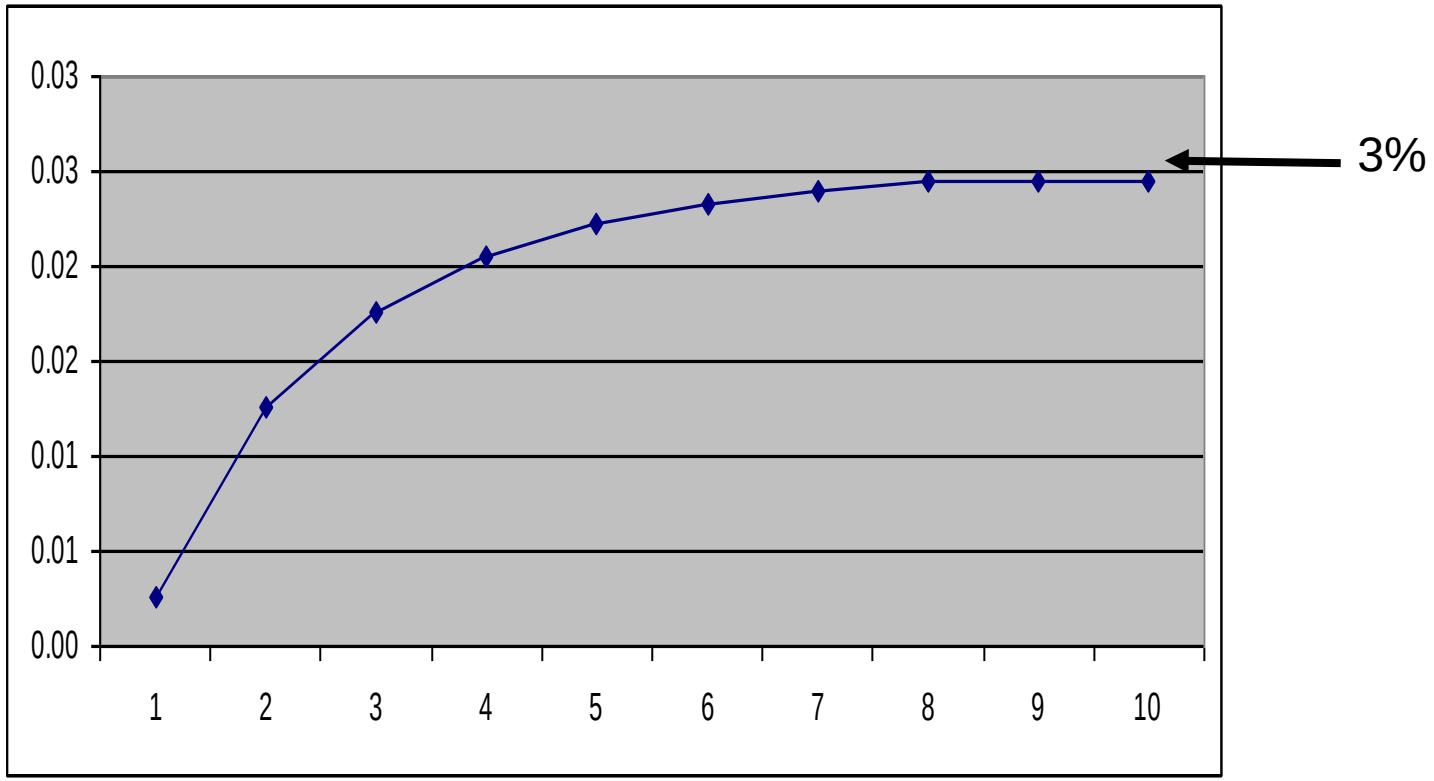
Proposed Uptake Modelling for India – High Uptake (25% by year 10)

Coverage = 74940 $\exp^{0.3164\ Year}$



Proposed Uptake Modelling for India – Low Uptake (3% by year 10)

Coverage = 57933Ln(Year) + 12473



Next Steps

- Feedback about uptake curves
- Integrate into modelling
- Explore curves for South Africa and Tanzania

Why it's useful to look at the Introduction of Female Condom

- Similarities between female condom and early generation microbicides.

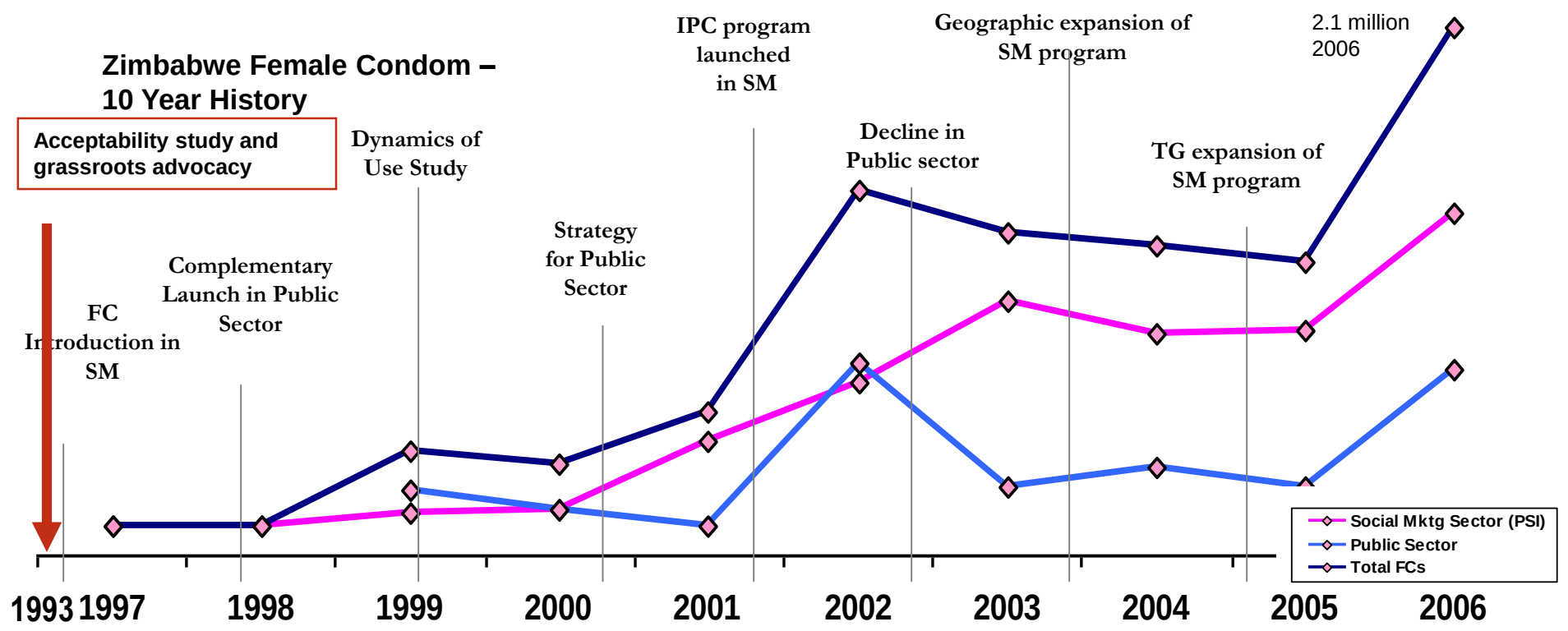
  Both products :

  - are female initiated
  - require to be inserted into the vagina prior to sex
  - require addressing of vaginal practices, taboos and stigma
  - are coitally dependent (first generation microbicides) so like the female condom, women will need to be regularly provided with microbicide supplies

Zimbabwe - phases of product introduction

- The evolution of the public sector & social marketing programme can be broken down into distinct phases:
  - 1993 pilot after which 30,000 women signed advocacy petition
  - pre-launch 1994-1997
  - product introduction 1997-1999
  - early market development 2000-2002
  - strategic expansion (2002-onwards).

Madan, Kumaranayake, M 2008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Total FCs
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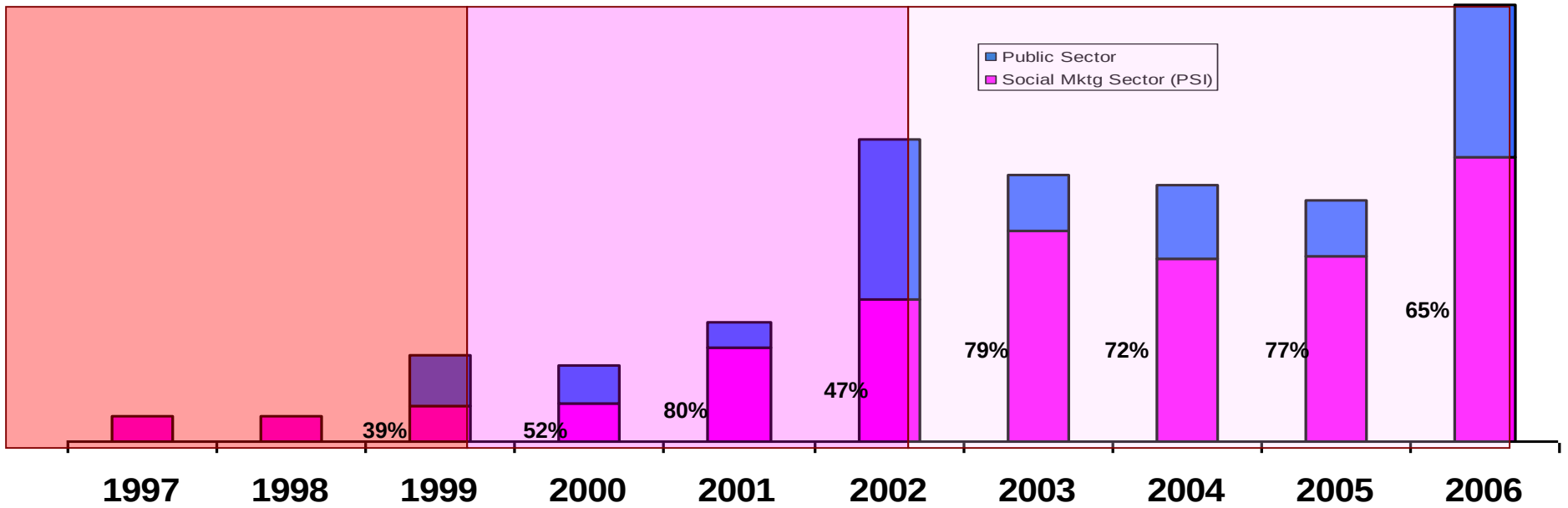
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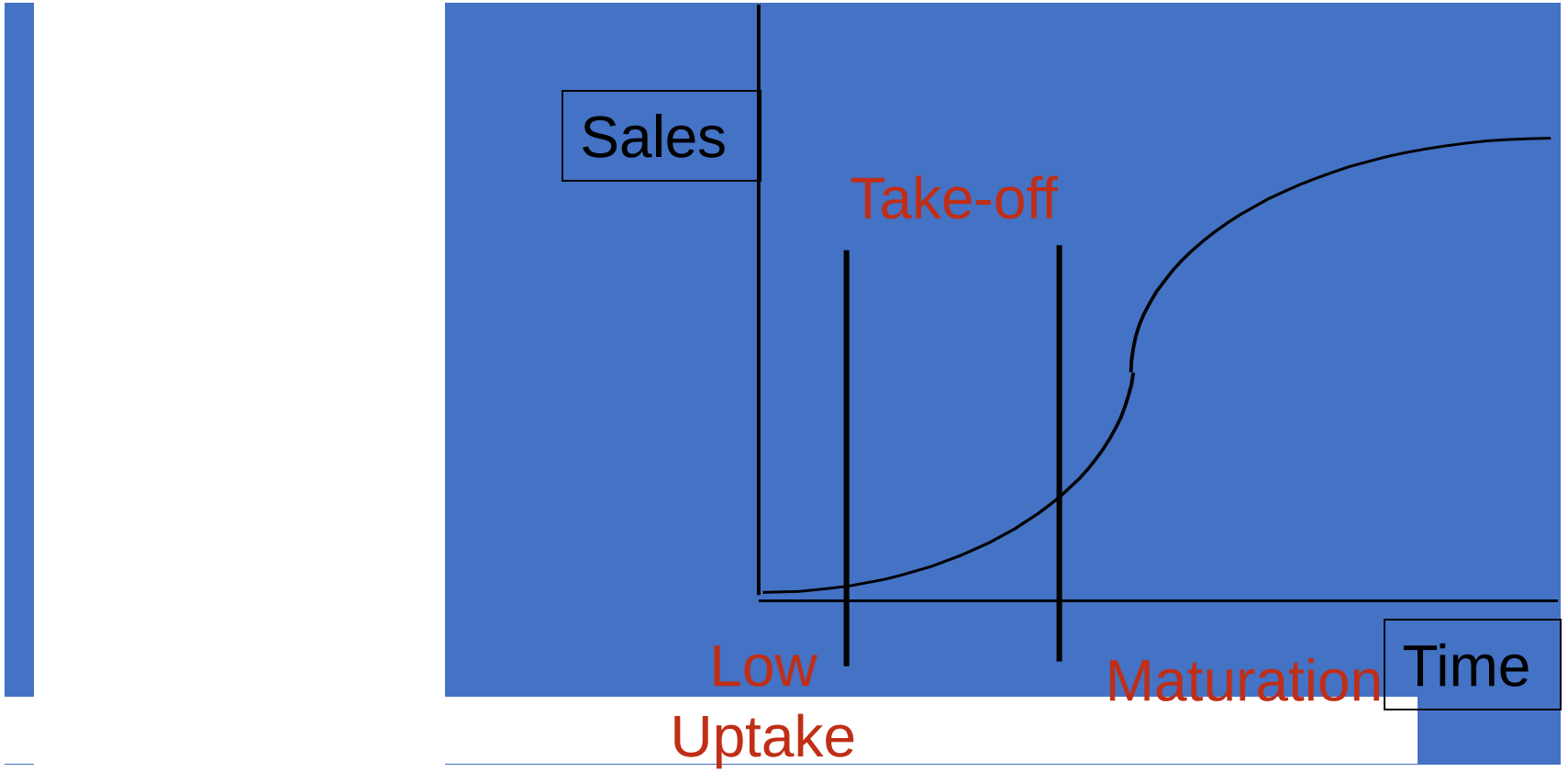
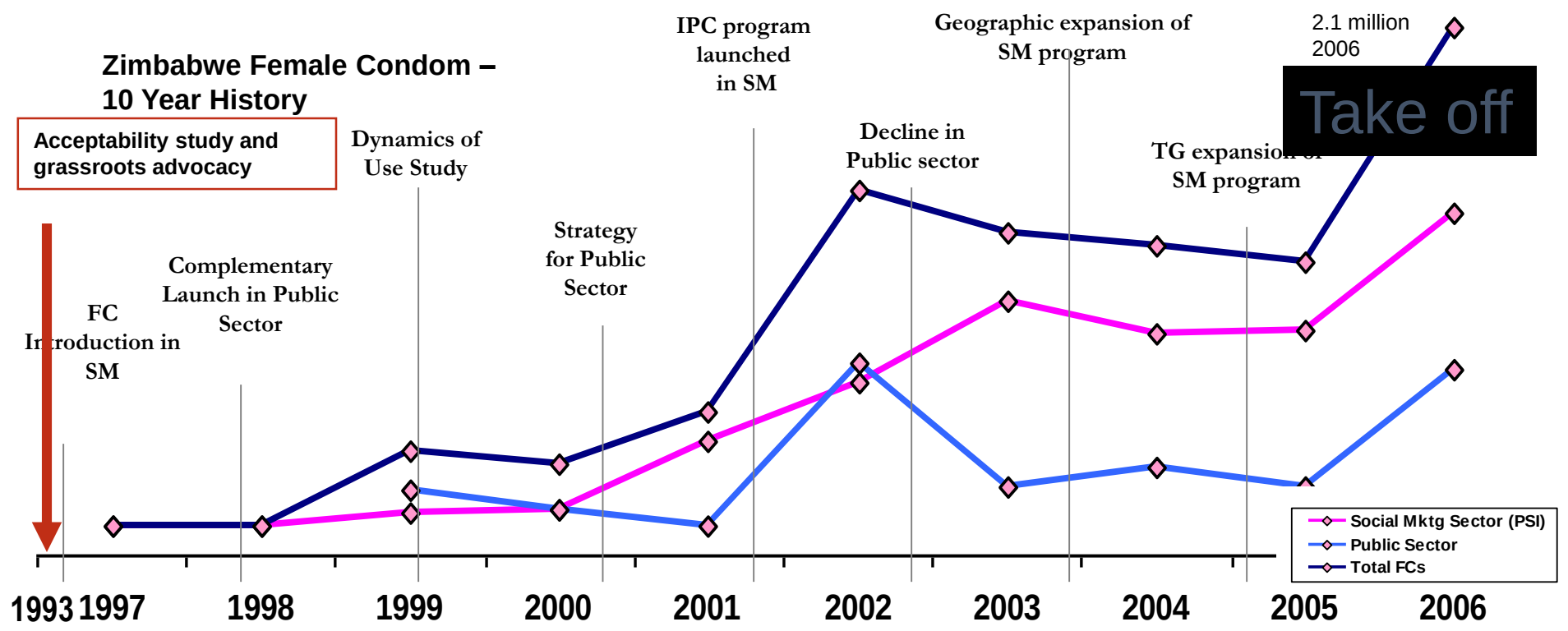
Theoretical Model of Product Introduction



Diffusion and Adoption Literature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Take off
Social Mktg Sector (PSI)
Public Sector
Total FCs
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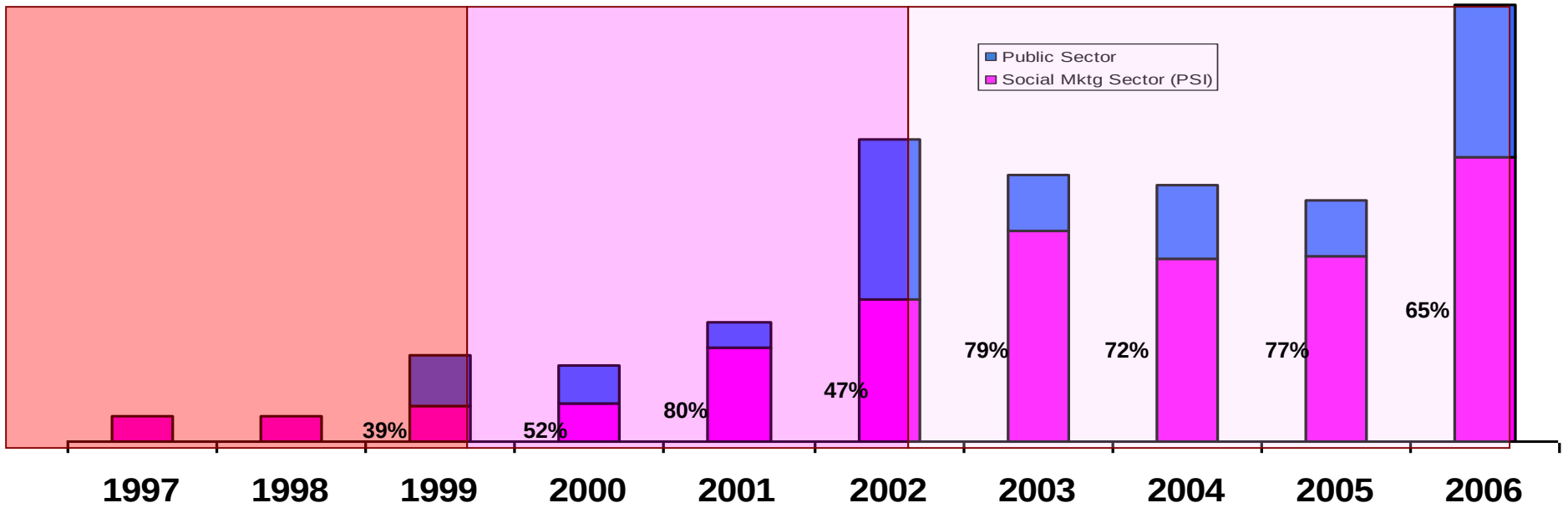
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Indian pilot programme and the positioning of female condom

- 2007: 6 states in general population and 2 states SWs
- Social marketing through peer educators
- Positioning different to other two countries

  ‘Condom Gaps’
  - Sex under pressure ‘No pleasure’
  - For more money
  - Non-availability of Male condom
  - Group sex situation
  - Regular partner/lover
  - Drunken clients
  - Young clients
  - Police
  - Rowdies

One year: 450,000 distributed with slow steady increase i.e. Low Uptake phase

Kavitha Patturi: Hindustan Latex Family Planning Promotion Trust, 2007

Comparisons between three country FC introductions

	South Africa	Zimbabwe	India: Pilot FC2
Public sector	**+++**	**++**	
NGO	**+**	**+**	**++ costs Rs3/**
Social marketing	**+**	**+++**	**+++ end user Rs5/**
General population	**++**	**++**	**++**
Sex worker	**+**	**+**	**+**
Targeted populations e.g., rural, urban, HE students	**+**	**+**	**+**
Unintended pregnancy and STI/HIV prevention	✓	✓	**Sex worker messaging as well**
Pilot: acceptability, HCW and consumer training	**FC1** ✓	**FC1** ✓	**Cheaper FC2** ✓
Take off	✓	✓	

Findings from three countries after pilot phase

- Female controlled technology acceptable to some women and their male partners
- Programmes need to position the product within their own context e.g. Contraceptive and STI/HIV prevention, 'Condom Gap'
- Many women (and male partners) reported liking the FC
- In South Africa (88%) said they were using protection more with availability of FC, and half reported dual method use with hormonal methods

(M.Beksinska 2006)

- In South Africa women more likely to use FC if believe in its efficacy

(J. Smit M2008)

Factors influencing success (1)

- Good situation analysis and pilot studies to guide FC introduction into different sectors
- Programmes do not target everyone at once, but strategically expand (geographically, target groups & distribution channels)
- Pilots demonstrated that different distribution channels can be complementary through public, NGO and private sectors simultaneously
- Programmes must be constantly modified based on pilot studies, field experience and research data *(e.g. Dynamics of use study, Zimbabwe, Pilot study, South Africa and India)*

Factors Influencing Success (2)

- Complementary role of mass media
- Innovative use of Inter Personal Communication helps sustain users
  - South Africa used workplaces & truck stops
  - Zimbabwe used hair salons
  - India used peer educators

Identifying funding for product

Other lessons learnt from pilot introduction studies

- Not all research useful in promoting product: Reuse research, although successful, did not move FC use forward
- Programmes must anticipate and monitor for trade offs e.g. Condom drift with FC being promoted at cost of male condom
- Earlier pilots showed need to improve product and increase acceptability

  e.g. inner ring size, lubrication, insertion problems
- Need to decrease costs
  - Unless FCs are cheaper programmes will not be able to purchase them i.e. governments and/or donors

New Female Condom Research in Response to these Challenges

- New products to improve the design and acceptability
- Non latex & latex products to reduce costs
- WHO and regulatory approvals sought

RHRU & PATH 2007

South Africa's Female Condom Introduction Programme

- 1998 Joint pilot programme of National and Provincial Departments of Health & RHRU
- Reality female condoms introduced into pilot sites in 8 provinces. Sites included:-
  - 19 DoH Family Planning clinics
  - 12 Planned Parenthood managed sites
  - 2 Commercial Sex Worker sites
  - Social marketing programme managed by Society for Family Health

Beksinska, Smit 2007