

Multipurpose Prevention Technologies: HPTN 104

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HPTN
HIV Prevention
Trials Network

ANNUAL MEETING
2022

EVERY MINUTE

Approximately:

- 230 unplanned pregnancies
- 140 abortions
- 3 infected with HIV
- 1 HIV/AIDS-related death

Every 2 minutes

- 1 maternal death

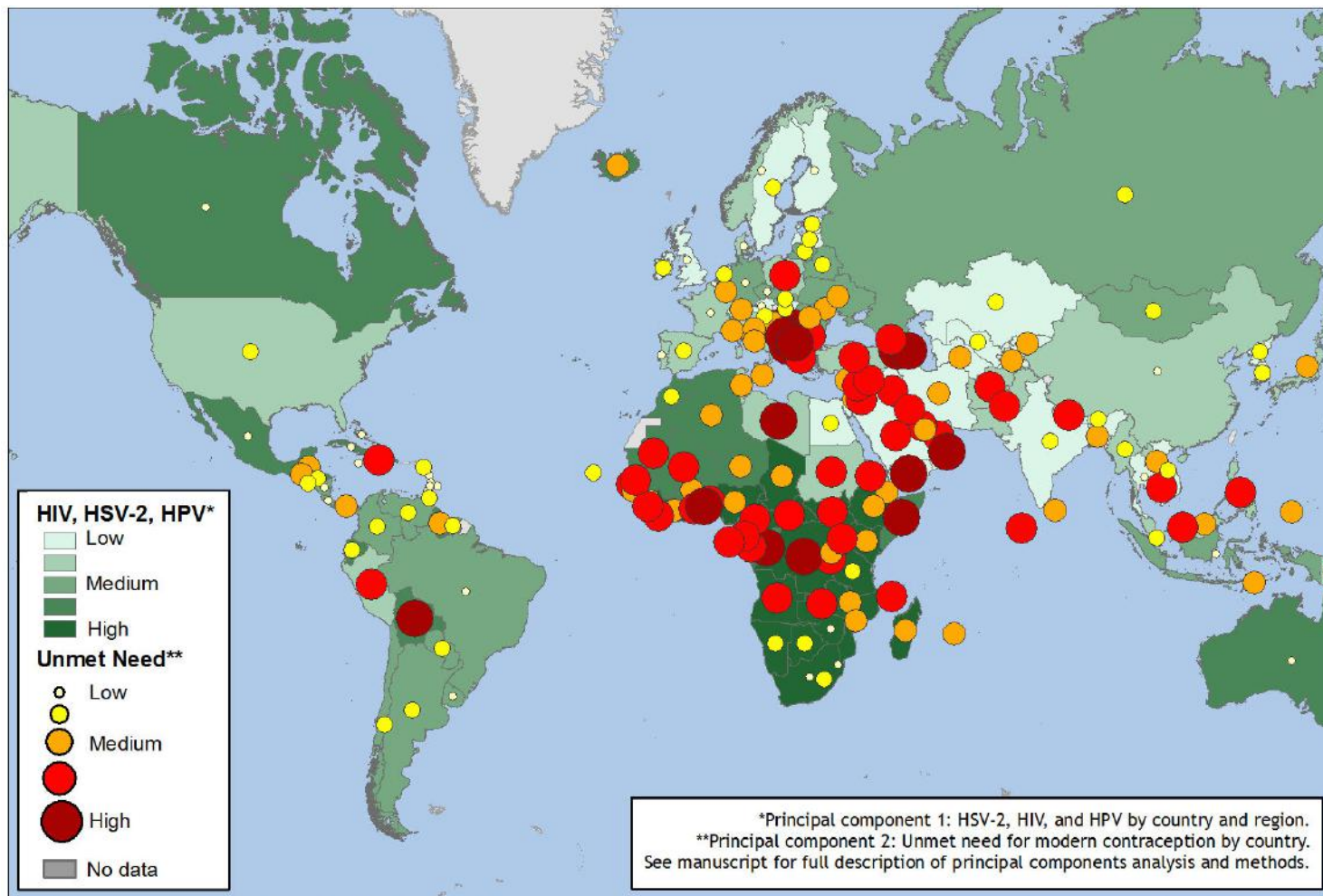


Global Need: Overlapping Risks

1.5 million acquired
HIV in 2020

~40% all pregnancies
are unintended

Over 1 million people
contract a sexually
transmitted infection
every day



Names and boundary representation are not necessarily authoritative

GIS guidance and Principle Component Analysis provided by the GEOCENTER

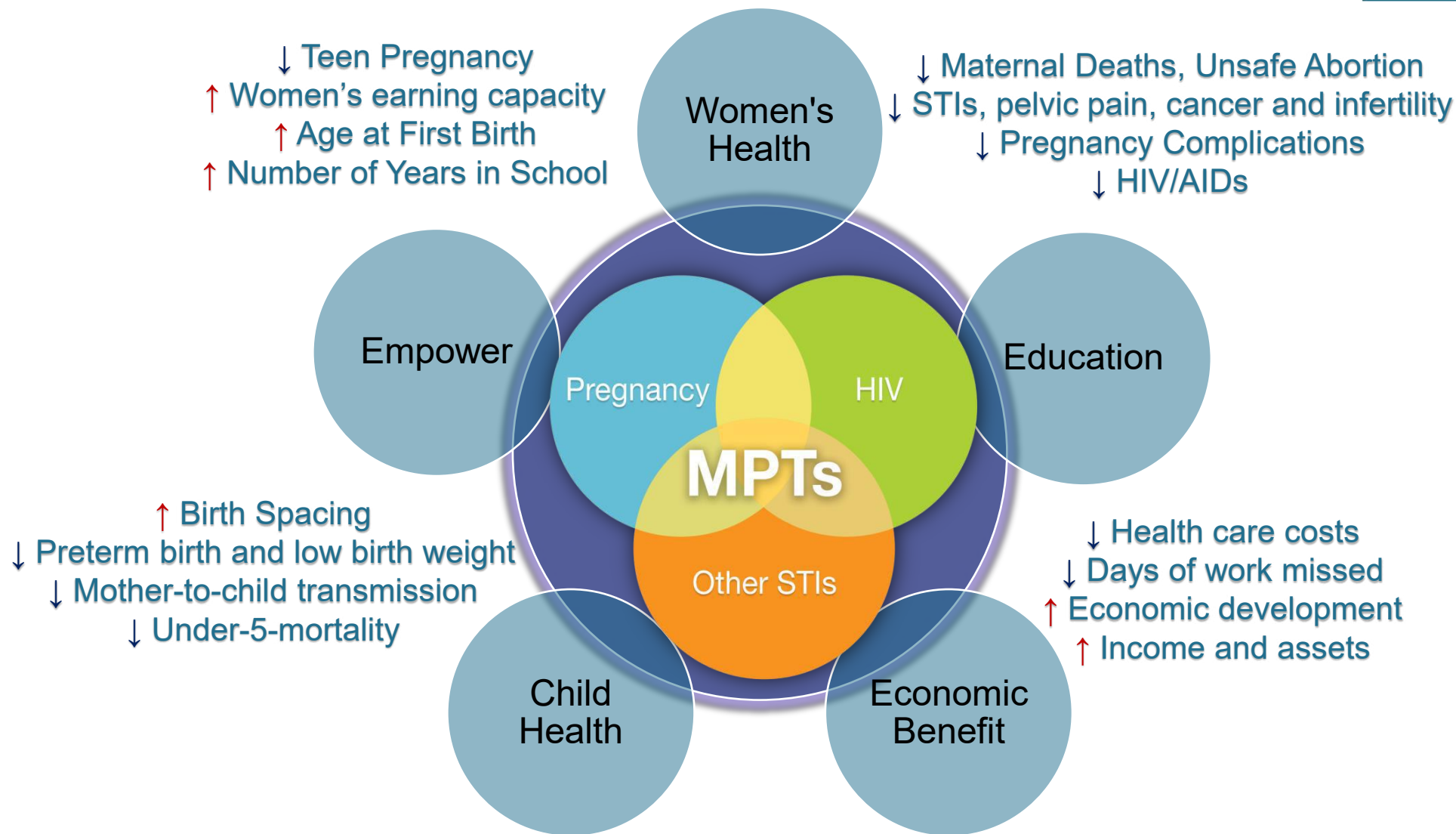
Current HIV/STI Prevention Options have Limited Potential and Do Not Address the Needs of Many Women



Studies Show Women Want MPTs

- 83% of 18-29 year old women (n=835) in an online U.S. Mturk survey were interested in MPTs (Hynes)
- 96% of women (n=225) in TRIO study a product for HIV and pregnancy prevention versus 2 separate products (Minnis)
- 82% of women (n=640) in the Share.Learn.Shape online survey preferred an HIV/STI prevention product with contraception versus disease prevention alone (Friedland)

Multiple Benefits of MPTs



Multiple reasons for wanting an MPT

Discreet

Control

Convenient

Easier to adhere

Greater acceptability



Overcome stigma

Improving sex for partner

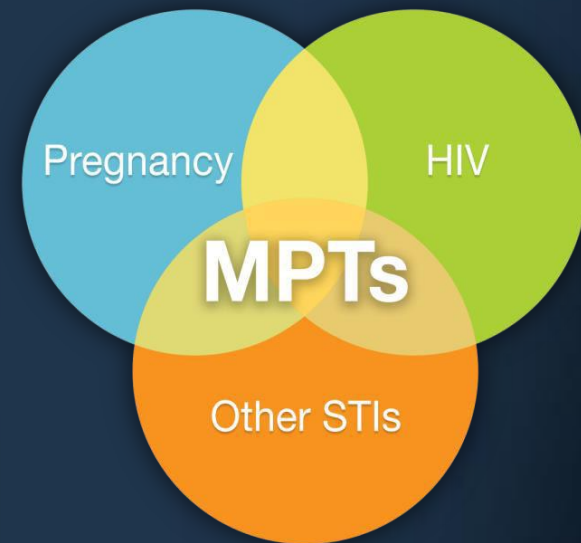
Enhancing sex

Minimize clinic visits

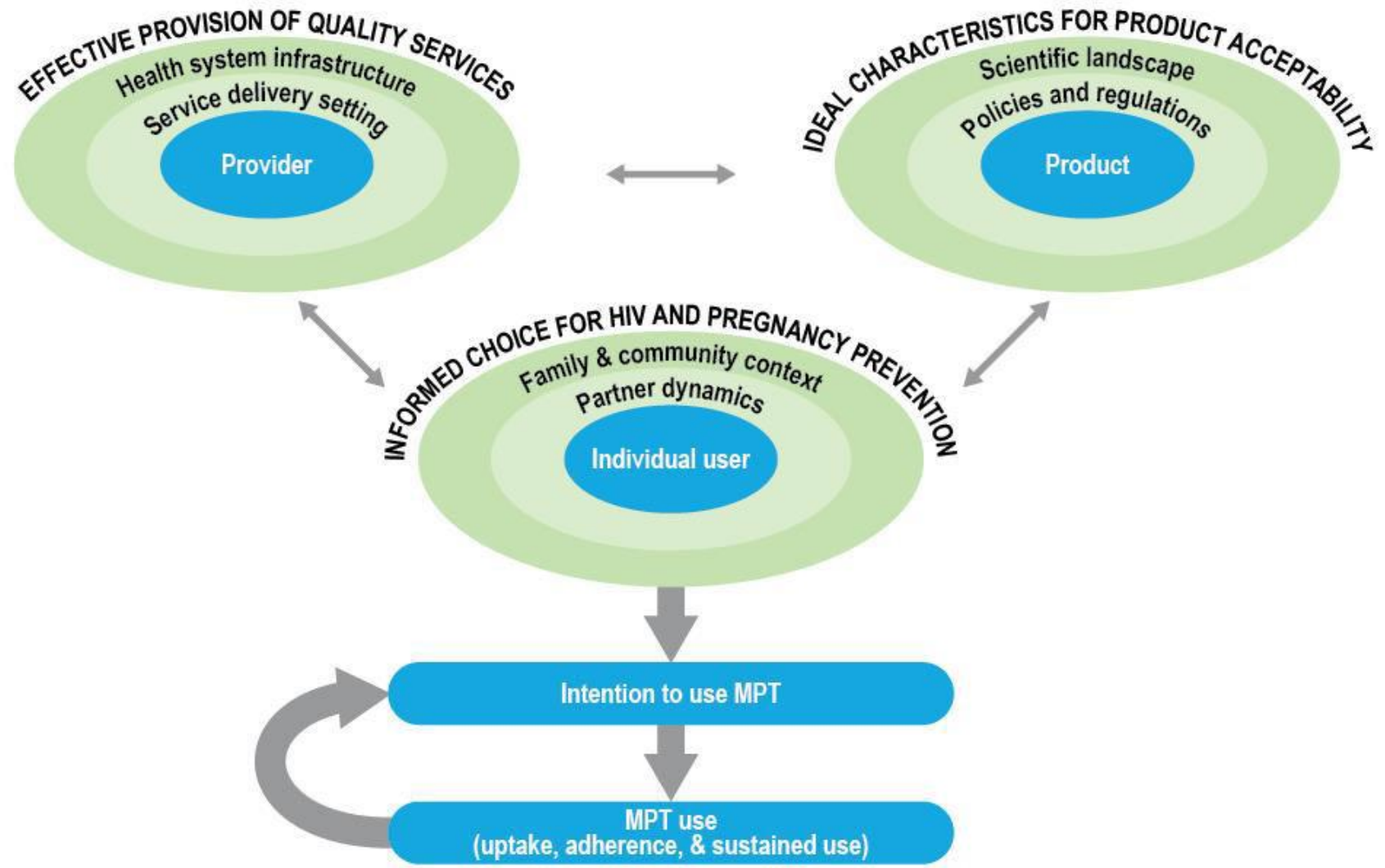
Autonomy

GOAL

To decrease HIV incidence via increasing optimal PrEP use and enhance choice for people of childbearing potential

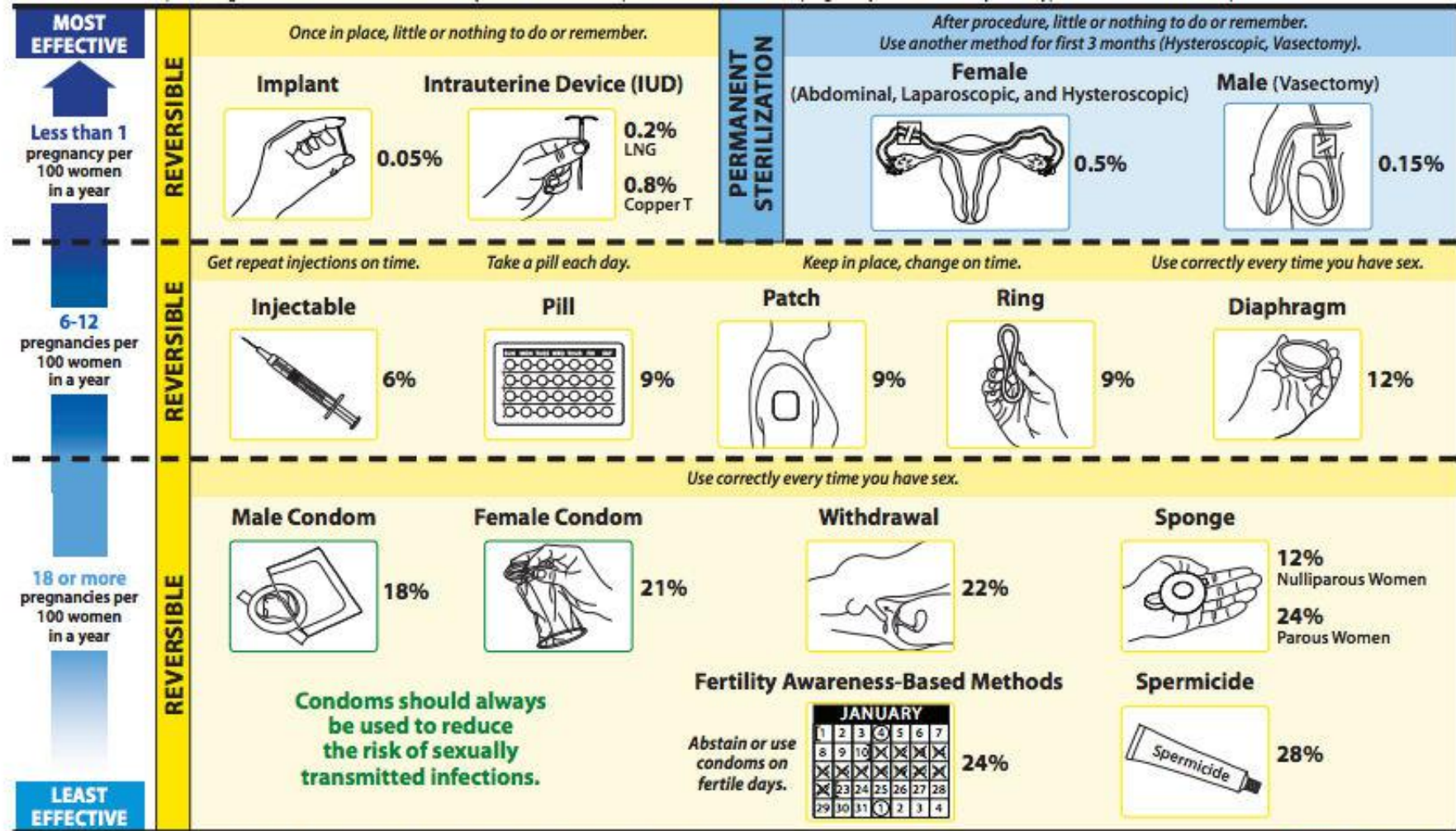


MPT development/ introduction framework



Positioning MPTs within the Current Contraceptive Landscape

- Effectiveness
- Control
- Side Effects
- Secondary Benefits
- Shared Decision-making



Other Methods of Contraception: (1) Lactational Amenorrhea Method (LAM): is a highly effective, temporary method of contraception; and (2) Emergency Contraception: emergency contraceptive pills or a copper IUD after unprotected intercourse substantially reduces risk of pregnancy. Adapted from World Health Organization (WHO) Department of Reproductive Health and Research, Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP), Knowledge for health project. Family planning: a global handbook for providers (2011 update). Baltimore, MD: Geneva, Switzerland: CCP and WHO; 2011; and Trussell J. Contraceptive failure in the United States. Contraception 2011;83:197-404.

MPT Products in Development:

A focus on choice, convenience and control

Provider administered

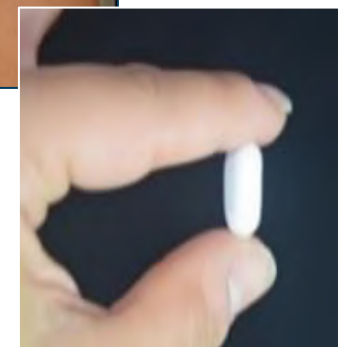
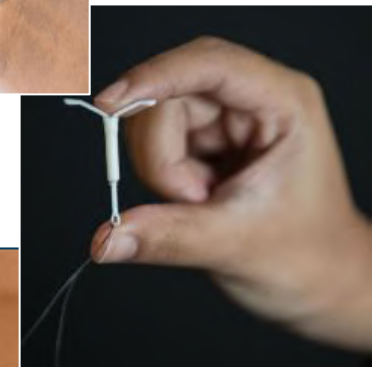
- Implants
- IUDs

User controlled

- Daily oral tablets
- Intravaginal rings
- Patch
- Films, gels, inserts

Characteristics of APIs and Regimens

- Long-acting, short-acting, on demand
- Hormonal/non-hormonal contraceptive
- ARV vs non-ARV
- Systemic (absorbed in blood) vs topical
- Approved vs novel





**Combined Oral
Contraceptive Pills**



Oral PrEP



**Dual Prevention Pill
(contraceptives + PrEP)**

Dual prevention pill (DPP)

Streamlined regulatory pathway: no efficacy trials required, only bioequivalence

WHO/CDC guidelines recommend PrEP and combined oral contraceptives prescribed together

Promise of the DPP

Findings from formative acceptability studies

- Ease of Use
 - Lessen the burden of taking two pills
 - Result in fewer clinic visits for women currently using both PrEP and COCs
- Control
 - Autonomy in preventing HIV and pregnancy
 - Quick return to fertility
- Enhanced protection for unprotected/ condomless sex

I think it's good because the pills will not be too many for you, you would know that you take one (pill) for both unlike taking this one and then you take another one.

Zimbabwe

Like if the male partner tested HIV-positive, he has HIV and wants to sleep with you by force he won't be able to infect you because you are taking the DPP.

South Africa

Potential Challenges of the DPP

Findings from formative acceptability studies

- Product
 - Side effects
 - Daily dosing, difficulty swallowing
- Service provision
 - Judgmental service providers
- Social
 - Male partner approval
 - Parental approval
 - Community misconceptions and stigma

The DPP pill is good, but if we look at it closely when its combined [PrEP and COC] the side effects will be many, they [the side effects] will be dual as well.

Zimbabwe

The last time I went ... looking for PrEP ... they straight up denied giving [it] me and said no.

South Africa

Market Size

- 250,000 to 1.25M women currently using COCs, condoms, or with an unmet need may use the DPP
- Potentially a 2- to 10-fold increase in PrEP usage

Cost-Effectiveness

- Likely to be cost-effective in settings with higher HIV burden and low ART coverage
- More cost-effective than oral PrEP if adherence enhanced
- Likely cost-saving among FSWs, sero-discordant couples



**Will PrEP adherence
be enhanced with
the DPP?**

**Will people prefer to
use and continue
using the DPP
compared to oral
PrEP?**

HPTN 104

Adherence to a dual prevention pill (TDF/FTC + a combined oral contraceptive) versus a two pill regimen

Primary Objective

Compare adherence to the
DPP versus two pill regimen

Secondary Objectives

Preference

Adherence *during Choice*

Persistence *during Choice*

Tolerability, Side Effects

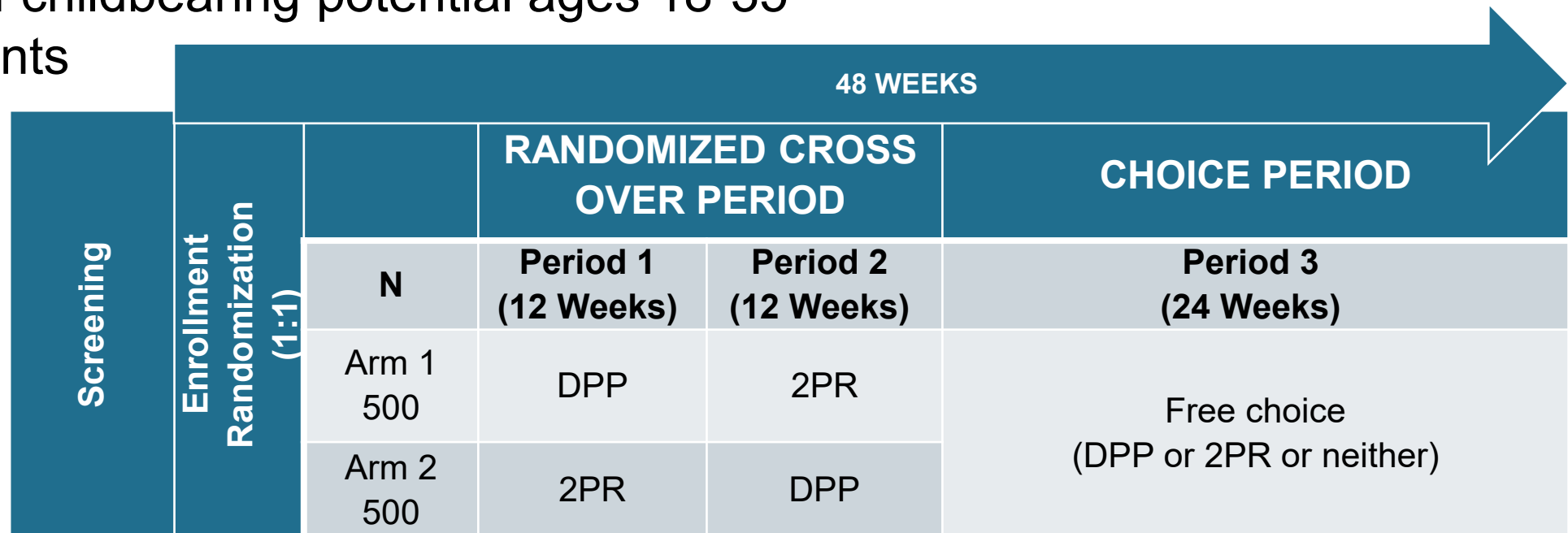
Acceptability

Exploratory Objective

Examine **facilitators and barriers** of DPP adherence, acceptability, and persistence

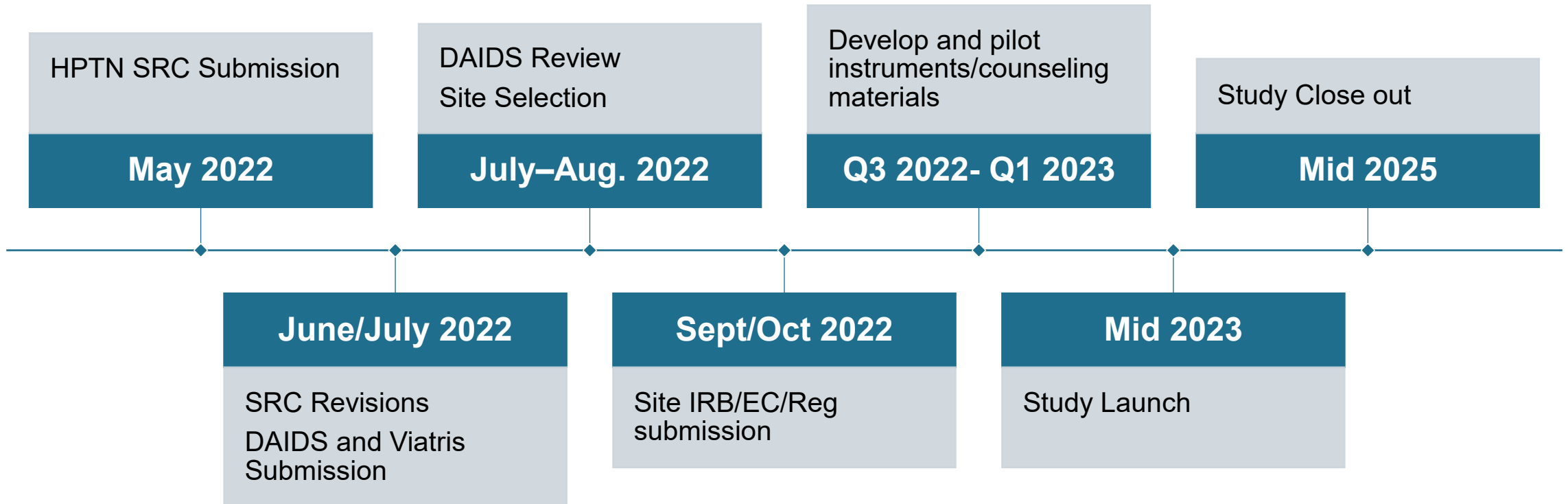
HPTN 104 Overview

- Open-label, multisite, randomized, crossover trial : DPP versus 2 pill regimen (2PR)
- N= 1,000 people of childbearing potential ages 16-35 years old
 - 800 people of childbearing potential ages 18-35
 - 200 adolescents



Qualitative sub-study: In-depth interviews with up to 100 participants

Timeline



Protocol Team



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Thank you

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/HIVptn

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