On the Horizon for Consideration: *Biomedical Advances in HIV Prevention*

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BRIDGING SCIENCE, POLICY AND PUBLIC HEALTH

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NATIONAL ALLIANCE OF STATE & TERRITORIAL AIDS DIRECTORS

Mission

NASTAD strengthens state and territory-based leadership, expertise and advocacy and brings them to bear on reducing the incidence of HIV and viral hepatitis infections and on providing care and support to all who live with HIV/AIDS and viral hepatitis

Vision

NASTAD's vision is a world free of HIV/AIDS and viral hepatitis

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Presentation Overview

- Review of HIV/AIDS Toolkit
- Update on Vaccine Development
- Antiretroviral Medications as Prevention
- Issues for Consideration

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HIV/AIDS Toolkit

Prior to exposure

- Education & Behavior change
- Male circumcision
- Preventive Vaccines
- Pre-exposure prophylaxis (PrEP)
- HSV2 suppression or vaccine

Point of transmission

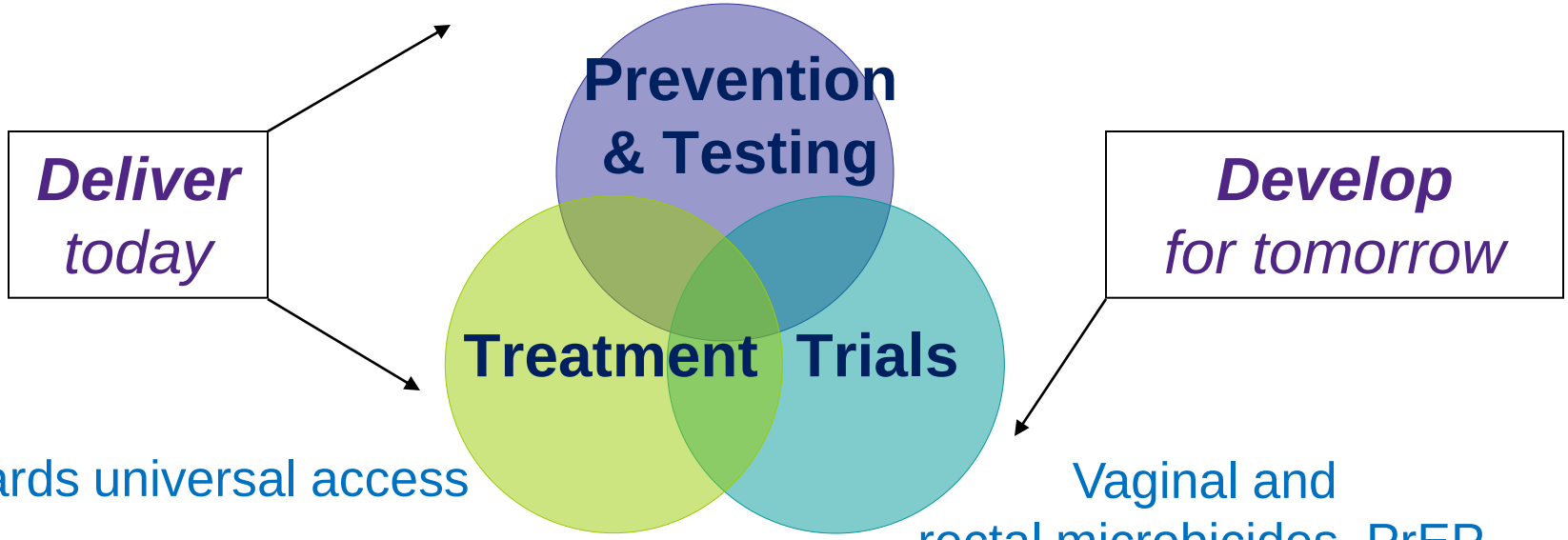
- Male and female condoms
- Antiretroviral therapy (mother-to-child)
- Post exposure prophylaxis (PEP)
- Microbicides
- Diaphragm, cervical barriers & new FCs

After infection

- Antiretroviral therapy
- Care
- Education & Behavioral change
- Therapeutic Vaccines

Comprehensive, Integrated, and Sustained Response

An expanded alphabet soup of prevention:
ABC (M&F), clean needles, male circumcision, VCT



Towards universal access

Vaginal and
rectal microbicides, PrEP,
vaccines, cervical barriers…

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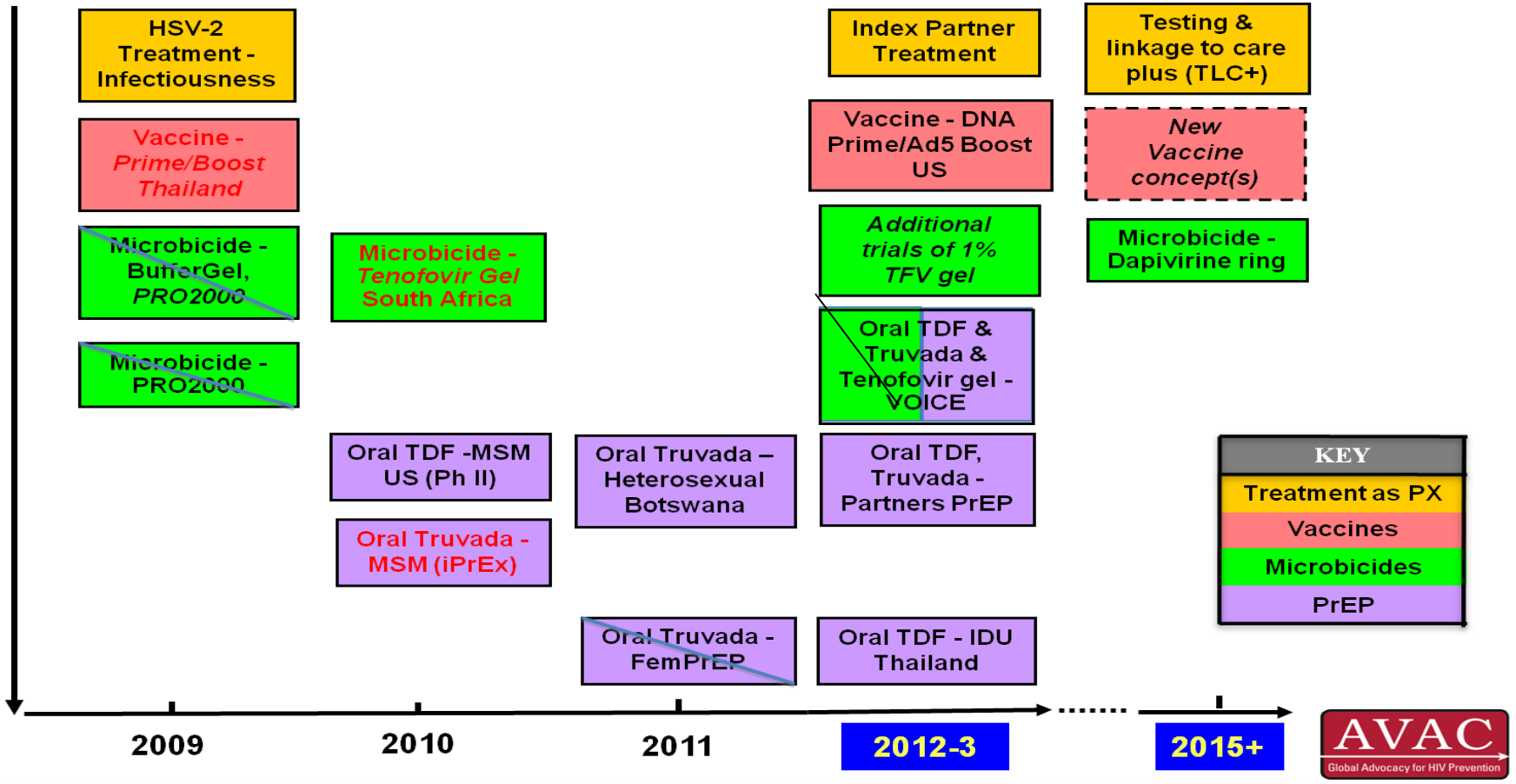
HIV Prevention Research Landscape



AVAC
Global Advocacy for HIV Prevention

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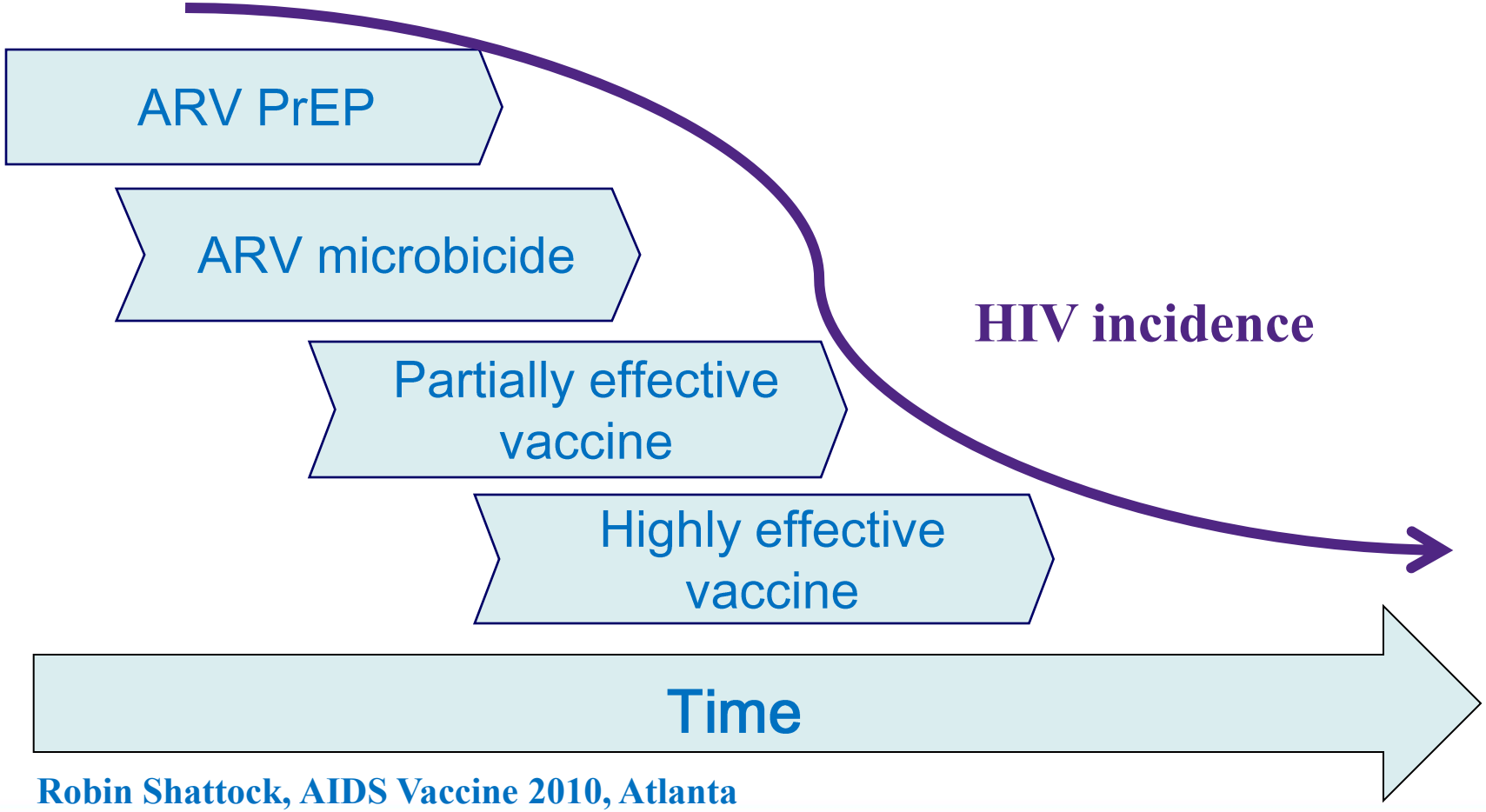
Pathway to reversing the epidemic



Robin Shattock, AIDS Vaccine 2010, Atlanta

Trials Illustrate Key Concepts in HIV Vaccine Development

- We can learn important lessons from products that don't work or have modest efficacy;
- Science usually proceeds in small steps;
- Clinical trials are essential; humans clinical trials don’t lie;
- Clinical, preclinical and basic research are all essential;
- Every study raises new questions;
- Humility; and
- ***An HIV vaccine is possible!***

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Discovery & Development

Virus or Bacteria	Year Discovered	Year Vaccine Licensed	Year Elapsed
Typhoid	1884	1989	105
Haemophilus Influenzae	1889	1981	92
Malaria	1893	None	-
Pertussis	1906	1995	89
Polio	1908	1955	47
Measles	1953	1995	42
Hepatitis B	1965	1981	16
Rotavirus	1973	1998	25
HPV	1974	2007	33
HIV	1983	None	-

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HVTN 505

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ARVs for Prevention

- Studies in animals have reduced risk of infection if ARVs are administered before virus exposure;
- **PMTCT**: ARVs are given to HIV-positive mothers and their infants to help reduce the risk of HIV transmission to the infant;
- **PEP**: Post-exposure prophylaxis is an HIV risk-reduction method in which someone takes a short-course ARV regimen to reduce the risk of HIV infection from a possible exposure;
- **PrEP**: Pre-exposure prophylaxis is the use of ARVs in HIV-negative individuals who maybe at higher risk of infection; and
- Evidence that low viral load in an HIV-positive individual decreases transmission rate to HIV-negative partners.

Post-Exposure prophylaxis (PEP)

- PEP is the short term use of ARV medications to reduce the risk of HIV infection;
- Must be started within 72 hours of exposure;
- Originally used for occupational exposures (e.g., needle sticks, bodily fluid exposures);
- CDC does have guidelines for use in non-occupational exposures (e.g., sexual assaults, high risk sexual behaviors, or injecting drug use);
- Data shows evidence of effectiveness, but it has not yet been definitively proven;

Pre-Exposure Prophylaxis (PrEP)

- PrEP is pre-exposure prophylaxis of ARV medication prior to exposure in the attempt to stop HIV infection;
- PrEP is not yet recommended for use;
- You can still get HIV when taking PrEP;
- PrEP is not a “vaccine” or a “morning-after” pill; and
- PrEP is not for everyone at risk of HIV.

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Global iPrEx Study

- iPrEx designed to determine effectiveness of daily oral Truvada in safely and effectively prevent HIV infection among MSM and Transgendered Women.
- Investigators found that study participants who took the daily dose of oral ARVs experienced an average 44 percent fewer HIV infections than those who received the placebo pill.
- Those who took the drug on 50 percent or more days as measured by pill count, bottle count and self-reporting experienced 50.2 percent fewer infections.
- Those who took the drug on 90 percent or more days had 72.8 percent fewer HIV infections.

Partners PrEP and CDC TDF2

- Partners PrEP was the use of Truvada and Viread in discordant heterosexual couples. It enrolled more than 4,700 couples and had 95 percent retention, and self-reported adherence was 98 percent.
- CDC TDF 2 show the efficacy of oral Truvada was 73 percent overall in heterosexual men and women, similar to the efficacy found in Global iPrEx study among MSM reporting pill use on 90 percent of days.

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FEM-PrEP

- The primary objective of FEM-PrEP was to assess the safety and effectiveness of once-daily Truvada to prevent HIV acquisition, among HIV-negative women, between the ages of 18 and 35, at risk of HIV through sexual intercourse.
- FEM-PrEP was an “event-driven” trial (scheduled to run until a pre-determined number of HIV infections had taken place – not until a specific date.
- FHI announced on April 18, 2011 that the trial was closing as it couldn’t demonstrate efficacy even if it continued.

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HPTN 052

- The HPTN 052 study was designed to evaluate whether immediate versus delayed use of ART by HIV-infected individuals would reduce transmission of HIV to their HIV-uninfected partners and potentially benefit the HIV-infected individual as well.
- The Data Safety Monitoring Board has concluded that initiation of ART by HIV-infected individuals substantially protected their HIV-uninfected sexual partners from acquiring HIV infection, with a 96 percent reduction in risk of HIV transmission.
- Strategies for scaling up knowledge of HIV status and increasing treatment coverage are critical next steps to realizing the public health benefits of this finding.

PrEP Implementation and Guideline Activities

- CDC Interim Guidance (Released January 2011)
- Technical Assistance
- Monitoring and Evaluation
- Implementation Research
- Policy
- Communication
- Stakeholder Engagement
- Public Health Guidelines (Expected in 2012)

*CDC Does not plan to fund PrEP medications or clinical care

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Can we deliver on the promise?

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Issues for Consideration

- Is PrEP feasible? How much will it cost? How many will benefit?
- Are there dosing strategies other than ongoing, once-daily dosing that could be used with oral PrEP drugs to reduce risk?
- Can PrEP strategies be developed for other populations? Adolescents? Pregnant women? Intravenous drug users?
- Can other compounds be developed as PrEP drugs?
- What are the long-term safety consequences of PrEP use?
- What are the rates of drug resistance associated with individuals using PrEP who seroconvert?
- How does this impact future treatment options and HIV testing?

***Keep in mind that only 10 percent of iPrEX data has been analyzed to date.**

NASTAD's PrEP Activities

National PrEP working group, PrEP Fact Sheet, Issues for Consideration, and NASTAD bi-monthly update memo.

CDC Consultation(s)

Benefit Managers and Insurers

Moving forward with PrEP implementation for MSM in the US

Public Health Guidelines

Gilead Community Meetings

Community Education Needs

Safety Issues and Considerations

Fair Pricing Coalition

Pricing of Truvada for PrEP

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