

# Scale-Up of Pre-Exposure Prophylaxis (PrEP)

*Monitoring its implementation and evaluating its impact on incidence and behavior*

HIV Epidemiology and Field Services Program  
NYC Department of Health and Mental Hygiene  
*August 2009*

# PrEP M & E Consultation

- CDC hosted a consultation on monitoring and evaluation of PrEP in August 2008
- Convened expert panel consisting of
  - CDC staff involved in PrEP trials and planning for US rollout
  - Clinicians
  - HMO administrators
  - Academics
  - Public health officials representing state and local health departments

# Expert Panel

Dawn Smith – CDC  
Peter Kilmarx – CDC  
Dale Stratford – CDC  
Tom Chapel – CDC  
John Beltrami -- CDC  
Peter Kerndt – LA County  
Health Dept  
Ted Palen – Colorado  
Permanente Group  
Robert Heimer – Yale  
School of Medicine  
Sandra Huang – SF Dept of  
Public Health  
Paul Aaron – Florida Dept of  
Public Health

Nick Reuter – SAMHSA  
Lucia Torian – NYC Dept of  
Health  
Neil Abernathy – University  
of Washington  
Jerry Gibson – South  
Carolina Dept of Health  
Ann Robins – Texas Dept of  
State Health Services  
Will Wong – Chicago Dept  
of Health  
Cort Lohft – VT Dept of  
Health

# Charge to the Panel: How to Evaluate PrEP?

- Similar to evaluating a vaccine
- Ultimate objective: reduce incidence
  - Examples: MMR, flu, polio, Hepatitis B
- Challenges in this application:
  - Not everybody will get it (unlike MMR, polio, flu, HBV)
  - High risk population denominators do not exist
  - Therefore, incidence rates cannot be computed within risk groups
- Two-arm evaluation needed
  - Within populations known to be receiving PrEP
  - Population-based surveillance statistics – if epidemic is truly driven by these HR groups, effect will be seen

# Basic Assumptions and First Steps of PrEP M & E

- Will need to move fast once concept is proven
- Tasks:
  - Identify target populations – highest incidence groups
  - Identify and get consensus from stakeholders
  - Figure out how many doses needed and \$\$
  - Identify initial implementation sites
    - Clinical management infrastructure
    - Pre-existing data collection systems – adapt, don't create; build onto systems already reporting to DOH and CDC
    - Ability to follow patients over time – stable organization
    - PH sites probably best initial, but others will also implement – therefore, identify data systems they report to
  - Identify variables needed for monitoring
  - Modify existing systems that *already report regularly*

# Some of these first steps require answers that are not yet available

- Which trials showed efficacy? Variables:
  - Target population(s)
  - Administration protocol
  - End points – HIV, STD incidence, behavior  $\Delta\downarrow\uparrow$
  - Length of follow-up period
- Which group(s) did best – MSM, IDU, HET?
- Which drug worked better in what population?
  - Which had the lower adverse event profile?
  - Which had better compliance statistics?
  - Was one drug less costly but equally effective?

# Identifying Local and National Target Populations

- Will depend on:
  - Results of trials (see previous slide)
  - Local incidence data
- Access via public or private sector?
  - Access *will* be preferential, based on demonstrated risk
  - Public sector is already committed to addressing disparities of minority group members in access to care, support services – for this and other reasons, roll out and evaluate PrEP in public sector first?
- Some private providers are already using PrEP (for MSM, discordant couples)
  - More will likely do so based on the trial data
  - Challenge – find data sources to monitor use and measure impact

# Identifying Local Target Populations

- Local implementation
  - Use trial results PLUS your local incidence data; for example, in NYC:
    - Use surveillance data to determine incidence and behavioral risk in the transmission category identified by the first trial(s)
    - Determine variables needed for PrEP M & E
    - Determine data systems that can be adapted for PrEP M & E
  - Balance concept of target population against equitable distribution
    - Patient meets definition of high risk (is everyone “high risk” if in high prevalence pool like NYC?)
    - Equal access within that definition, if willing to comply with protocol?
    - Persons <18 need parental consent?

# Where Can We Access these High Risk Populations?

- In many venues
- But where do we find infrastructure and data collection capacity that can be quickly adapted to monitoring PrEP? Possible sites:
  - Public STD clinics
    - MSM
    - Heterosexuals at risk
  - Needle Exchange and Methadone Programs
  - Public hospital systems and HMOs
  - OB/GYN clinics
  - VA
  - Prisons

# Developing the Monitoring System

Implementation protocol (1)

*Eligibility criteria:*

- Initial screening and assessment: HIV -
- High risk – however defined
- No contraindications
- Willing and able (adolescents?)
- Daily dosing (is DOT needed?)
- Visit, Rx renewal, and repeat HIV testing q3mo
- Intermediate outcomes
  - Tolerance and compliance (self-report and lab)
  - Adverse event surveillance and reporting
  - STD incidence – laboratory, clinical and self-report
  - Behavior

# Developing the Monitoring System

## Implementation Protocol (2)

### *Distribution and F/U:*

- Initial screen, eligibility determination, and Rx
- Visit q3mo
  - Rx renewal
  - Adverse event reporting and labs, e.g., LFTs
  - Repeat HIV Ab/Ag test
  - STD screening
  - Questionnaire
    - Risk behaviors (UAI and UVI)
    - Condom usage
    - Compliance with regimen

# Monitoring PrEP

## Process Variables: Point of Distribution

- Site type (e.g., STD, NEP, Corrections, HMO, VA)
- N enrolled in PrEP at site
  - N in follow-up q 3 mo
  - N discontinuing PrEP
    - HBV, adverse effects
- FTE for PrEP at site – additional work required of:
  - Administrative staff
  - Clinical staff
  - Laboratory staff
  - Data collection and reporting staff

# Monitoring PrEP Implementation

## Independent Variables: Patient and System

- Site of PrEP
- PrEP agent
- Demographic characteristics
- Risk factor at entry
- Ongoing risk (measure q3mo)
  - UAI or UVI
  - Sharing of injection equipment
  - Condom use by partner type
  - Disclosure to partners
  - PrEP-sorting of potential partners
- Self-reported compliance with regimen
  - Adverse events

# Monitoring PrEP Outcomes

## Intermediate outcomes:

- Tolerance and compliance – self-report, pill counts, laboratory measures
- Adverse event surveillance and reporting
- STD incidence
  - Laboratory tests
  - Clinical examination
  - Self-report
- Behavior change – positive or negative
- Ultimate outcome:
  - HIV incidence (i.e., failure)
    - In PrEP users
    - Impact on population

# What Existing Reporting Systems Could Be Used or Modified to Include Variables for M & E of PrEP?

- Examples:
  - HIV Surveillance, including incidence and resistance Surveillance (PrEP use by newly diagnosed)
  - Sexually Transmitted Disease Surveillance (PrEP use by clinic patients, PrEP use by persons with new STD)
  - SAMSHA, needle exchange, and MMTPs (PrEP use, injecting behavior, sexual risk behavior)
  - BRFSS and NHANES (behavior, HIV testing)
  - NHBS – local samples of IDU, MSM and HET (“)
  - HMO and Public Hospital System databases (PrEP use, intercurrent diagnoses, adverse events)
  - Medicaid (PrEP use)
  - Pharmacy chain databases (PrEP prescriptions)
  - VA (PrEP use, behavioral risk, adverse events)

# M & E During First Few Years of PrEP Implementation

- Will likely:
  - Be specific and site-focused
  - Initially follow populations that are officially involved in clinical settings implementing PrEP, both public and private
  - Be similar to an immunization registry
  - Include data to enable case-control analysis
  - Be complemented by HIV case surveillance for community outcomes (HIV incidence). Also consider monitoring surrogate markers:
    - STD surveillance
    - Behavioral surveillance – NHBS, BRFSS, NHANES

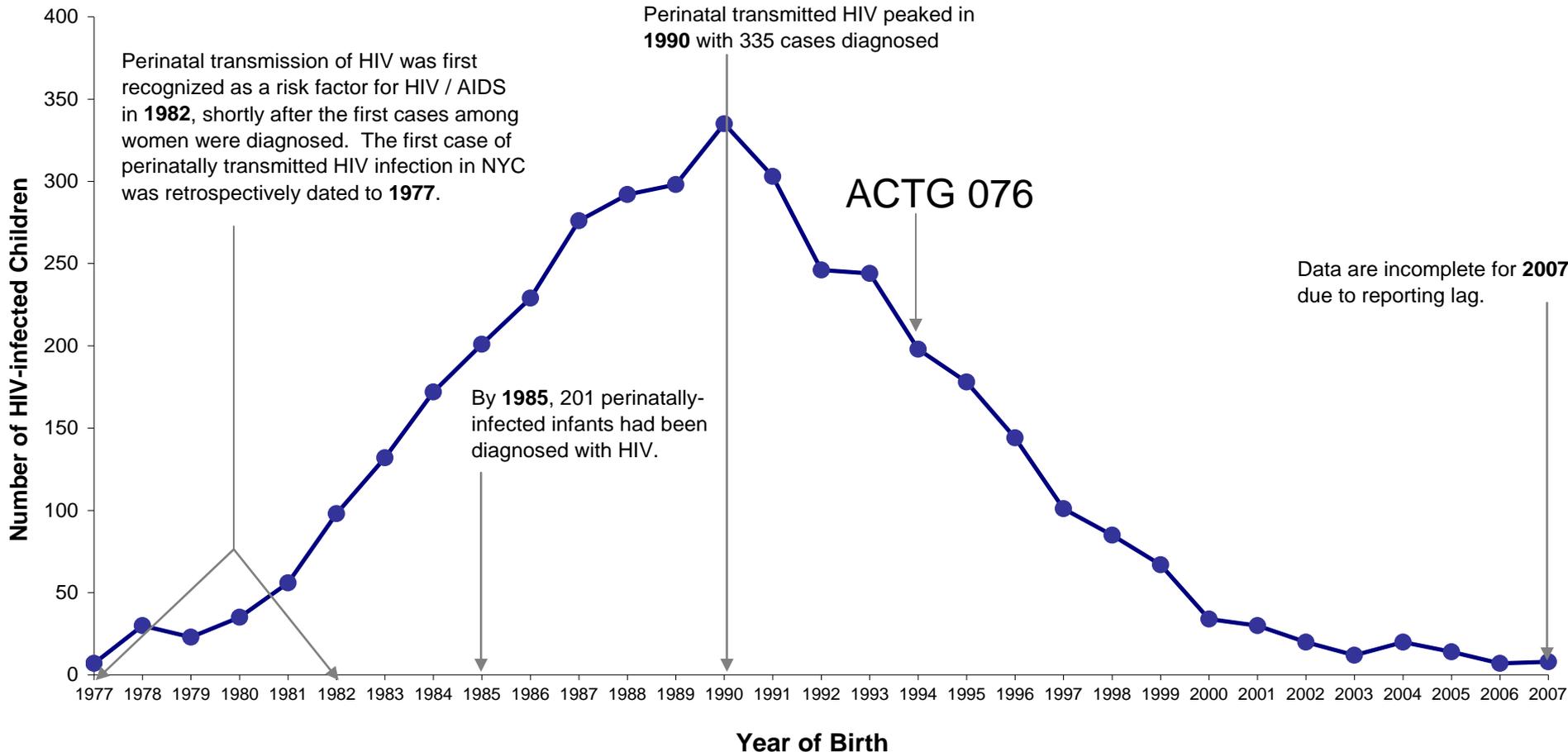
# Data Source for Evaluating Overall Community Impact of PrEP = **HIV Surveillance**

- In New York State, we can modify the New York State Provider Report Form
  - Already asks for ARV History
  - Change to:
    - ARV for treatment (“Rx while you were positive”)
    - ARV for prevention (“Rx while you were negative”)
- Gauge population impact of PrEP
  - Not able to measure incidence rates in HR pops as we do not have denominators for MSM, IDU, high-risk heterosexual
  - But if these groups are driving the epidemic, we should see effect in population rates overall

# **If PrEP is Appropriately Deployed and Works in the Populations that are Driving the HIV Epidemic...**

**This is what we want to see**

# Perinately Infected Babies Born in New York City, 1977-2007



**This graph dramatically demonstrates the single success story of the epidemic. NYC is within reach of eliminating perinatal transmission.**

# Summary

- PrEP rollout requires intensive evaluation – follow population on PrEP using multiple data sources
- Evaluate PrEP at local, state, national level
- Initial site selection probably public sector – but others will administer and we can use many different data sources to follow
- Adapt existing data collection and reporting systems for rapid turnaround of process and outcome data
  - Don't create new forms and a new reporting system – they won't deliver the data in time
- Consider special analyses of seroconverters
- Streamline PrEP M & E for long-term monitoring if PrEP becomes part of standard prevention menu