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?

- 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
Perinatally Infected Babies Born in New York City, 1977-2007

Perinatal transmission of HIV was first recognized as a risk factor for HIV / AIDS in 1982, shortly after the first cases among women were diagnosed. The first case of perinatally transmitted HIV infection in NYC was retrospectively dated to 1977.

By 1985, 201 perinatally-infected infants had been diagnosed with HIV.

Perinatal transmitted HIV peaked in 1990 with 335 cases diagnosed.

Data are incomplete for 2007 due to reporting lag.

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