



PrEP Implementation Planning for the US

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CHAMP Community Teleconference
30 September 2008



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Why start planning before trial results are in?

- There are reasons to be optimistic
- It will take time to plan effectively...
 - An important biomedical intervention program accessible to high-incidence populations
 - Guidance need to use with maximal efficacy and safety
 - Consider the viewpoints, needs, and concerns of many stakeholders



Trials may prove efficacy

- Reasonable to prepare for possible efficacy because:
 - Biologically plausible
 - Concentrated levels in genital tract secretions
 - Works for post-exposure prophylaxis
 - Works in animal models
 - Safe in FHI trial
- Despite imperfect adherence, antimicrobial PrEP works for
 - PMTCT
 - Malaria
 - AIDS OIs

In progress...

PrEP Implementation Planning

- Goals

- To be prepared for
 - Rapid
 - Consensus-based
 - Effective and safe
 - Affordable and accessible
 - PrEP implementation in persons/populations most at risk for acquisition of HIV
- In order to maximize reduction in new HIV infections



PrEP Program Assumptions

- PHS will issue recommendations based on trial results
- All PrEP programs will include:
 - **Screening**
 - HIV negative with ongoing risk of acquisition
 - No contraindication to meds (lab tests)
 - **Visits q 3-6 months**
 - HIV rapid test
 - Assess side effects and adherence
 - Risk reduction counseling
 - Med refill
 - **Periodic assessment of ongoing risk and safety labs**



Potential Features of a PrEP Program

- Opportunity to provide periodic risk reduction counseling and HIV testing
- May work for more than one type of exposure (e.g., IDU who also have sex)
- Can be stopped during low risk periods
- Gender neutral
- Covert use is feasible
- Not dependent on anticipating risk events
- Opportunity to improve links to preventive care



Planning to Prevent Access Disparities

- Plan for effective public sector provision of PrEP
 - High incidence in **African Americans, Hispanics** and **young MSM**
 - Often **Un/underinsured**
 - Same groups have **disparities in treatment access**
 - Rely on **health departments** (STD, FP, community health clinics) for health care



Anticipating Possible Scenarios

- IDU positive results first
 - Moderate efficacy in IDU
 - High efficacy in IDU
- MSM positive results first (interim)
 - Moderate efficacy in MSM
 - High efficacy in MSM
- Positive results in two trials
 - IDU + MSM
 - MSM+HET



Critical questions (so far)

- Once efficacy is proven...
 - Where and by whom can PrEP be delivered?
 - How will PrEP candidates be recruited, selected, and retained in care to maximize incidence reduction?
 - How will access to related services be assured?
 - Who will pay for this?
 - Who will oppose/support this and why?
 - How will it be monitored for safety, efficacy, and cost – at the population level?



Activities Begun for the United States

- CDC has
 - **initiated conversations** with a wide range of stakeholders to
 - raise awareness of PrEP and timeline for trial results
 - develop collaborations and
 - gain input about implementation issues
 - **Assembled a multidisciplinary study group** to work on implementation planning and evaluation questions
 - **Planned surveys** of national stakeholders, program managers, and potential participants about what it would take to implement PrEP effectively
 - **Planned focus groups** with potential users about desired characteristics of a PrEP program
 - **Begun development of tools with partners** to assist in implementation



Planning

- **Reviewing a range of informative literature**
 - Implementation of other biomedical interventions (e.g., family planning)
 - Implementation science
 - Health services research approaches
- **Exploring useful implementation models**
 - Developing a logic model (still a work in progress)
 - Program cost models
 - Diffusion of innovation models



Lessons Learned (so far)

- **Case Study 1 – 076**

- Start planning before trial results in
- Develop and maintain strong relationships with federal partners
- Systematically engage diverse external stakeholders
- Fund external expertise and capacity development
- Systematically monitor implementation, coverage, and impact

- **Case Study 2 – Non-occupational PEP**

- Recommendations necessary but not sufficient
- No implementation support leads to sporadic use

- **Case Study 3 – Routine HIV testing**

- Consensus with diverse stakeholders (including skeptics) speeds uptake
- Identifying funding stream(s) critical
- Important role of external partners
- Create expectation of gradual implementation



Perspectives

- Include multiple perspectives throughout the planning process
 - Potential users
 - Potential providers
 - Program officials
 - Policy makers
 - Communities
 - Media
 - Prevention advocates
 - Researchers
 - Politicians



Conference Calls Planned

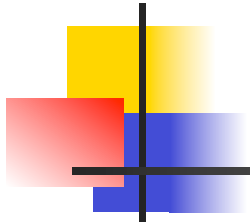
- CBOs and Advocates for Specific Populations
 - IDU
 - African American MSM
 - MSM
 - Women
 - Youth
 - Native Americans



Laying groundwork for implementation

- Conduct implementation research
 - Develop cost-effectiveness and program cost models
 - Assess provider and user requirements
 - Develop and pre-test tools and materials
 - Develop issues management
 - Develop financing strategies
 - Technical expert meetings
 - And more....

Technical Expert Meetings Held



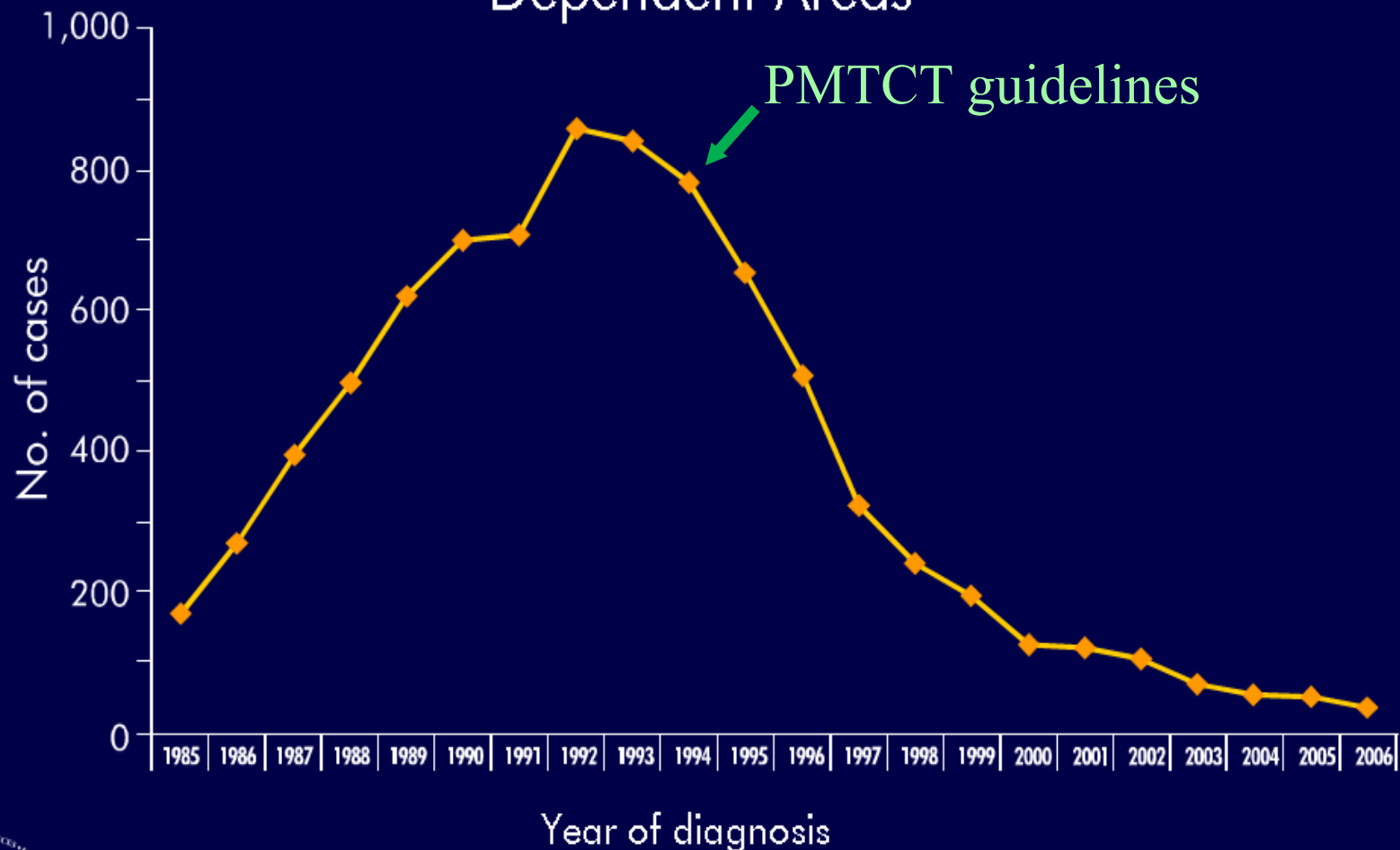
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- Reimbursement and Financing
 - Using Network Science (GSU)
 - M&E Framework
 - Public Health Ethics
- April
 - September
 - September
 - September



Technical Expert Meetings Being Considered

- Brief counseling protocols
- Provider issues
- Discordant couples and conception
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Estimated Number of Perinatally Acquired AIDS Cases by Year of Diagnosis, 1985–2006—United States and Dependent Areas



Note. Data have been adjusted for reporting delays and cases without risk factor information were proportionally redistributed.





More questions?

- Contact Dawn Smith
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- Additional materials available at www.prepwatch.org

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