Implementation Science: Building the Prevention 2.0 Ship as We Sail Her

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Controlling the HIV Epidemic with Antiretrovirals:
Treatment as Prevention and Pre-Exposure Prophylaxis
June 12, 2012
Overview

• Prevention 2.0 within the context of current HIV epidemiology in Western Industrialized Settings

• Implementation Science and Prevention 2.0 – Rationale, Strategies, and Issues

• Prevention 2.0 and Implications for National Public Health Agencies

• Concluding thoughts
Current Challenges to HIV prevention in Western Industrialized Countries

- **Dynamic:** Changing demography, patterns and distribution of risk behavior, disease epidemiology, cultural norms and values
- **Disparities:** Among the worst health inequities observed for sexual and reproductive health
- **Concentration:** Increasing concentration of issues among the socio-economically disadvantaged, minorities, migrants, and those with poor healthcare access
- **Interconnectedness:** Overlapping epidemics or ”syndemics” require a systemic change in our health care delivery system
- **Contexts:** Challenging policy and fiscal environments require increased efficiency, harmonization and minimize duplication
Looking Ahead: Challenging Times for HIV Prevention

• Picture in the United States especially grim:
  – Federal deficit ~$1.3 trillion for FY 2011
  – 5-year freeze on federal discretionary spending
  – Reductions in HIV prevention by health departments
    • ~45,000 state and local public health jobs lost
    • Staff furloughs, hiring freezes, pay cuts
  – Many community organizations closed or struggling

• Similar picture being observed in other Western Industrialized settings, driven by economic downturn

Kaiser Family Foundation; NASTAD; Center on Budget and Policy Priorities

*Total includes HIV and viral hepatitis prevention programs, but majority of funds cut were from HIV
Note: PMTCT, Screening transfusions, Harm reduction, Universal precautions, etc. have not been included – this is focused on reducing sexual transmission.
Combination Prevention
Multiple disciplines and approaches

- Biomedical Interventions
- Structural Interventions
- Community Interventions
- HIV/STI Testing & Linkage to Care
- Individual & Small Group Interventions

Adapted from Coates Lancet; 2008
Prevention with Positives

- HIV testing, linkage to care and prevention services
- Antiretroviral therapy
- Retention in care and adherence
- Partner services
- Risk reduction interventions and condoms
- STD screening and treatment
- Perinatal transmission interventions

Prevention with Negatives

- Condom distribution
- Behavioral risk reduction interventions and condoms
- Pre-exposure prophylaxis (PrEP)
- Microbicides
- STD screening and treatment
- Post-exposure prophylaxis

Not focused on HIV status

- Social mobilization
- Condom availability
- Substance use, mental health, and social support

Not all interventions are supported financially by CDC or other federal agencies.
HIV Prevention 2.0: The imperative for urgent action

• Stable HIV incidence is not acceptable
  • To prevent increasing prevalence, need to decrease new infections more aggressively
  • Too many at risk individuals are not being reached

• Combination prevention now offers hope
  • Always had combination prevention - now targeted combinations
  • Will require new partnerships and strong health care systems
  • Must incorporate context, epidemic phase, target populations, implementation, quality, impact
  • Limited resources are available and we need to prioritize

• Applying the science of implementation to maximize impact, and improve quality
Do we have effective interventions?
Are we implementing these interventions effectively?
Are they being applied targeted and managed appropriately?
Are we scaling these interventions to have impact?
Are we learning from our experiences to improve program and research quality and impact?

WILL OUR PREVENTION 2.0 PROGRAMS AND RESEARCH BE FIT FOR PURPOSE?
We will never be able to leverage the full potential of HIV prevention or treatment if we fail to target appropriately, implement effectively, and bring to scale what we know works.
Overall Strategy for Addressing the Implementation of Prevention 2.0

Expedite the translation of scientific knowledge to implementation of interventions that protect the public, prevent disease and injury, and promote health.

Knowledge

- Data on burden and impact
- Evidence-based interventions

{---------- GAP ----------}

Implementation

Social values & norms → Politics and law

Ethical Principles for Policy Rationales:
- Maximize benefits
- Minimize risk/harm
- Ensure fairness
- Respect liberty

Intervention Choices (examples):
- Information
- Persuasion
- Programs
- Incentives
- Non-coercive “nudges”
- Sanctions/enforcement
MAXIMIZING OPPORTUNITIES FOR PREVENTION 2.0 IMPLEMENTATION

GETTING RESEARCH INTO PRACTICE (GRIP)
1. Evidence
2. Policy Formulation
3. Implementation
4. Evaluation

GETTING RESEARCH OUT OF PRACTICE (GROP)
1. Evidence
2. Development of hypotheses
3. Operational Research and Process Evaluation
4. Outcomes Evaluation
5. Design Intervention
6. Implementation

High Impact Prevention

• CDC’s new strategic approach to HIV prevention, developed in response to the new National HIV/AIDS Strategy

• High Impact Prevention encourages us to model, implement, and evaluate the highest impact biomedical, behavioral, and structural interventions together. Key components:
  • Effectiveness and cost-effectiveness of the intervention
  • Address the social, structural and political contexts
  • Prioritization of populations and interventions
  • Feasibility of full-scale implementation
  • Coverage of targeted populations
  • Interaction, combination and targeting of interventions
  • Implementation Science

Prevention 2.0
Implementing High Impact Prevention

• Enhanced Comprehensive HIV Prevention Planning Project (ECHHP)
  – 12 jurisdictions with 44% of epidemic
  – Planning for maximizing impact

• Expanded Testing Initiative
  – 2.8 million tests conducted in first 3 years
  – 18,000 people newly diagnosed with HIV; 70% African American; 12% Latino
  – Averted an estimated 3,381 HIV infections
  – Achieved a return of $1.97 for every dollar invested

• Health Department FOA
  – $359M annual funding, FY2012-2016 (assuming level funding)
  – Realigns federal resources with burden of epidemic
Four Required Program Components

**HIV Testing**
- HIV testing in healthcare, non health care settings and venues that target undiagnosed HIV infection
- HIV testing of pregnant women
- Ensure linkage to care and prevention services

**Comprehensive HIV Prevention with Positives**
- STD screening and treatment
- Partner services
- Behavioral Interventions for HIV-positive persons
- Retention and re-engagement in care
  - **ART and adherence interventions**

**Condom Distribution**
- Focus on people with HIV and at high risk

**Structural and Policy Initiatives**
- Support efforts to align structures, policies, and regulations with optimal HIV prevention, care, and treatment and create an enabling environment for HIV prevention efforts, **including PrEP**
Program Science

- Program Science is defined as the systematic application of scientific knowledge to improve the design, implementation and evaluation of public health programs.

- Program Science is concerned with three aspects of prevention programs:
  - Strategic planning of programs (who to target, when and for how long);
  - Implementation of interventions to achieve the best outcomes;
  - Program management processes that are necessary for scaling up and optimizing program quality.

What’s different about these approaches?

- Focuses on **packages of interventions**, and the synergies and antagonisms across interventions
- Considers the **combination**, differential uptake and sustainability of interventions
- Includes interventions that modify **social determinants** of morbidity
- **Includes planning**, modeling and research into “required and achievable coverage” or reach of interventions
- Prioritizes evaluation and **operational research** on implementation of interventions
- Considers issues of **resource expansion**, advocacy, and mobilization
Implementation Science
Implications for Prevention 2.0

• We must acknowledge current problems with the science base for programs
  – The “know-do” gap
  – The “knowledge translation” bias
  – The “science – program” gap

• We need SMART Prevention 2.0 initiatives that incorporate a strong implementation science component so that best practices can be identified
  – Critical look the diagnosis-care-treatment cascade to examine opportunities to optimize process and improve outcomes
  – Demonstration projects to examine best practices for seek test treat and retain are important

Clinical Care System
Public Health System

PREVENTION 2.0: URGENT IMPLEMENTATION REALITIES
Clinical Care System Considerations
Addressing the HIV Continuum of Care

• Getting tested for HIV is a critical first step
• Linkage to care and treatment prolongs life and reduces transmission
• ART (viral suppression) significantly reduces transmission by 96%
• Only 28% of HIV infected persons are getting the care they need

www.cdc.gov/vitalsigns
Clinical Care System Considerations
Addressing the HIV Continuum of Care

850,000 with HIV do not have virus under control (72%)

MMWR (60), 2011
Clinical Care System Considerations
Linkage, retention, and effectiveness

• Linkage to care and preventive services
  – Only 69% of persons with HIV attend clinic within 12 months of diagnosis
  – Case management improves linkage by 32% at cost of $1,200 per person
  – Interventions focused on adherence increase likelihood of undetectable viral load by 15%

• Effectiveness depends on coverage during entire cascade from testing to care
  – Transmission reductions can vary from 15% to 44%

Walensky CID 2010, Marks AIDS 2010; Crepaz AIDS 2006
Areas with Laws and Regulations for Reporting CD4 and Viral Load Values
January 2012

Laboratory reporting (laws and regulations)
- Not all values
- All values, specified
- All values, not specified

Puerto Rico
Virgin Islands, U.S.
Clinical Care System Considerations
Diffusion and uptake of TasP and PrEP

• Current prevention efforts may reduce new infections but are unlikely to achieve sustained and widespread reduction in HIV incidence

• New interventions frequently require convincing evidence and considerable time before they are implemented.
  – Eg. male circumcision took approximately 20 years and 3 RCTs showing consistent efficacy yet adoption has been slow
  – PMTCT took years of basic science and field research before RCTs supported the use of ARVs and ART to prevent transmission.

• Real questions remain on how to integrate ARV-based prevention with existing behavioral and biomedical approaches and how best to package these interventions for specific populations (“combination HIV prevention’”)
Public Health Considerations
Prevention 2.0 requires greater integration to maximize health

Leverage the Far Larger Personal Health System to Achieve Population Health Goals
SWOT: POSSIBLE Pros and Cons for Public Health and Prevention 2.0 Implementation?

(+)

- New sources of revenue
- New sources of data for decision-making
- Provide patient-centered holistic care
- Link clinical and community based services for comprehensive prevention, care, and treatment

(−)

- Additional fragmentation in an already fragmented system
- Competitiveness with established for-profit, non-profit, and other public health care providers
- Medical homes and Accountable Care Organizations: downside financial risk (performance-based payment)
### Public Health Considerations

Mismatch at the Local Level where Current Core Business not aligned with “ideal” Core Business for Prevention 2.0

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Source: Georgia Health Policy Center
### Public Health Considerations

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Source: Georgia Health Policy Center
Public Health Considerations
Mismatch at the Local Level where Current Drivers not aligned with “ideal” Drivers for Prevention 2.0

Current Drivers:
- Money
- Safety Net
- Uninsured
- Performance-based budgeting
- Regulation
- Leaders’ philosophies

Ideal Drivers:
- Need
- Evidence-based practices
- State strategy informed by local perspective
- Local culture

Source: Georgia Health Policy Center
Public Health Considerations
Prevention 2.0 and health inequity concerns

- Biomedical interventions are complex and rely on delivery through health systems which are already failing at risk communities.

- New interventions are more likely to be taken up and diffused among those who are already engaged in health care, and have access to new technologies.

- Root cause of inequalities are a complex interaction of social and structural determinants these interventions address only one component.
Prevention 2.0

- Enforce Laws
- Link To or Provide Care
- Diagnose & Investigate
- Monitor & Evaluate
- Develop Policies
- Inform, Educate, Empower

Constraints:
- Fiscal & Budgetary
- Demographic Pressures
- Coverage Expansions
- Cost Control
- Public Opinion Tensions
- Quality Improvement
- Governing Difficulties
Implementation Science
What Does Prevention 2.0 Mean For National PH Agencies?

• Should local health agencies provide direct services?
• Should public health funding be used to pay for services for insured individuals?
  – HIV, STD, TB, and hepatitis screening and treatment
  – Pre-Exposure Prophylaxis (PrEP) for HIV prevention
• How can public health capture reimbursement dollars from payers – public or private?
  – Are there concerns about robbing Peter to pay Paul?
• What new partners should PHAs be seeking out?
• How can we capture data from the health care system?
• What new KSAs do public health practitioners need?
Prevention 2.0

TOWARDS EFFECTIVE IMPLEMENTATION
6 Things on Our Prevention 2.0 To Do List

- Influence decisions
- Educate others
- Strategically plan under uncertainty
- Stay abreast of new information that emerges
- Create new partnerships
- Build capacity: workforce, information technology, and care coordination
Public Health Agencies Can Supports State and Local Partners in Many Ways

• Provide data for action
• Provide technical assistance (strike teams, Epi Aids, etc.) to supplement state/local resources and support critical needs
• Provide tools, resources and training for officials
• Increase and improve public health workforce
• Create opportunities for states/locals to adapt to changing times and address their specific issues
Public Health Agencies Can Supports State and Local Partners in Many Ways

- Improve public health department and health system performance
- Develop and disseminate best practices
- Promote public health accreditation
- Improve basic public health capacity (e.g., in laboratories, surveillance, and epidemiology)
- Provide opportunities for direct state/local input
Summary

• To achieve implementation and best outcomes for Prevention 2.0, Public Health Agencies must
  – Not only gather surveillance data and provide scientific evidence about health impact and effectiveness of interventions,
  – But, should also address the “GAP” and societal acceptance

• National Public Health Agencies need knowledge about
  – Social values and moral claims of stakeholders, particularly of those who may be disproportionately affected (e.g., the poor)
  – Ways to address competing social values and ethical tensions in the “GAP” – framing policy rationales and justifications
Summary

• Major advances in treatment and prevention over the past 30 years, with early signals of impact. Despite this more needs to be done, and a sense of urgency remains

• Now, more than ever, it is possible to change the course of the HIV epidemic, by combining HIV prevention interventions, including ART for treatment and prevention

• Future success will depend on our ability to implement and bring to scale what we know works, for those at risk
  – Knowledge of the epidemiology and ability to choose & target efficacious combinations for synergy against specific risks
  – Robust engagement with affected communities
  – Strong health care delivery systems
  – Ability to enroll, retain and maintain adherence
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