Implementation Science and Cost-Effectiveness Research

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Revitalizing the U.S. Domestic HIV/AIDS Response
New Science and New Approaches to Improve Outcomes and Reduce Costs
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• Implementation Science
  – What is it? What isn’t it?
  – Example: Prevention of mother-to-child HIV transmission (PMTCT) in Africa

• Cost-effectiveness Research
  – What is it? What isn’t it?
  – Example: Clinical and economic impact of a generic first-line ART regimen in the US
Editorial

Welcome to Implementation Science
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Implementation science is the scientific study of methods to promote the integration of research findings and evidence-based interventions into healthcare policy and practice and, hence, to improve the quality and effectiveness of health services and care.
Implementation science research

• Examples of research funded by NIH
  – Implementation of evidence-based cancer early detection in black churches
  – Testing an organizational implementation strategy in children’s mental health
  – Implementation science to increase use of evidence-based pediatric brain injury guidelines

• Examples of global health research funded by WHO and PEPFAR
  – Implementation of a rapid test and same day treatment to prevent congenital syphilis
  – Effectiveness of prevention of mother-to-child HIV transmission programs in Africa (PEARL)
Where is the science in implementation science?

• Different from monitoring and evaluation
  – Similar objectives: to understand what is working well, what is not working well, and why
  – Monitoring and evaluation focuses on measuring services provided
  – Implementation science uses scientific rigor to understand the etiology of gaps between expected results and observed outcomes

Hirschhorn 2007 J Infect Dis
Range of skills

- Decision science and operations research
- Industrial engineering and management science
- Health systems and outcomes research
- Health and behavioral economics
- Epidemiology
- Statistics
- Finance
- Policy analysis
- Anthropology, sociology, and psychology
- Ethics
Range of methods

• Experimental and quasi-experimental studies
  – Cluster-randomized trials
  – Comparisons of intervention “packages”

• State-transition and agent-based simulation models
  – Feasibility and efficiency
  – Cost-effectiveness

• Qualitative methods
  – Focus groups and surveys

• Quality improvement
  – Fidelity assessments
  – Continuous process improvement designs
Dissemination is not implementation
Prevention of mother-to-child HIV transmission (PMTCT) in Africa
Identify the evidence-based intervention
Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomised trial

Laura A Guay, Philippa Musoke, Thomas Fleming, Danstan Bagenda, Melissa Allen, Clemensia Nakabiito, Joseph Sherman, Paul Bakaki, Constance Ducar, Martina Deseyve, Lynda Emel, Mark Mirochnick, Mary Glenn Fowler, Lynne Mofenson, Paolo Miotti, Kevin Dransfield, Dorothy Brav, Francis Mmiro, J Brooks Jackson
Analyze the problem: the implementation “cascade”
Cascade of PMTCT coverage in 4 African countries: PEARL Study

Seropositive deliveries (100%)
Documentation available (92%)
Maternal HIV testing offered (84%)
Maternal HIV testing accepted (80%)
Maternal HIV+ test result received (75%)
Maternal nevirapine dispensed (71%)
Mother adherent to nevirapine (58%)
Infant given nevirapine pre-discharge (54%)
Variability of problems

Zambia

South Africa

Ivory Coast

Cameroon

0% 20% 40% 60% 80% 100%
Variability in outcomes

Zambia

South Africa

Ivory Coast

Cameroon
Design and evaluate the implementation solution
Quality improvement to reduce variability of adherence to PMTCT guidelines

- Health district in South Africa
  - 46% antenatal HIV prevalence in 2006
  - Estimated 33% of women were receiving antiretrovirals during pregnancy

- Participatory quality improvement program
  - Participatory assessment phase
  - Feedback and planning phase
  - Implementation and monitoring phase
Effectiveness of a participatory quality improvement project in South Africa

- HIV testing uptake
- CD4 testing rate
- NVP uptake mothers
- NVP uptake babies
- PCR testing of babies at 6 wks

Doherty 2009 BMC Public Health
Implementation science challenges

- Insufficient coordination between funders of research and funders of delivery – who owns implementation science?
- Requires interdisciplinary collaboration, lack of consensus on scientific approaches
- Different expectations between researchers and implementers about validity and generalizability
  - Researchers want high degree of certainty; implementers want to reduce uncertainty
  - Researchers want broad generalizability; generalizability may not be necessary for implementers
Cost-effective ≠ cost-saving
Cost-effectiveness is about value for money

- Cost-effectiveness analysis is about comparative assessment of worth
- Very, very few health interventions are cost-saving
- Cost-effectiveness is evaluated from the societal perspective
- Cost-effectiveness analysis does not directly address the cost impact on specific budgets
All models are wrong, some models are useful
Cost-effectiveness of PrEP in MSM:

- Cost-effectiveness ratio is more attractive when PrEP is targeted to high-risk MSM:
  - <$100,000/QALY with high incidence (2-3%) vs. >$200,000/QALY with lower incidence (0.8%)  
  - Mixed results for intermediate incidence (1-2%)  
  - Ways to target: younger age, 5+ annual partners, not being tested for HIV annually
- Cost-effectiveness improves dramatically when effectiveness improves or cost of PrEP is lower
- Results less sensitive to resistance, toxicity

Schackman and Eggman 2012 *Curr Opin HIV AIDS*
Cost of PrEP in high-risk MSM

- High-risk MSM, average annual cost for a 20-year program (based on Juusola, 2012)
  - 100% coverage: $4.25 billion cost, $0.5 billion health care savings, $3.75 billion net cost
  - 20% coverage: $850 million cost, $150 million health care savings, $700 million net cost

Clinical and economic impact of a generic first-line ART regimen in the US

Please see: