HIV/AIDS Prevention Research at USAID

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USAID Office of HIV/AIDS

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Summary

USAID’s prevention interests are broad and are reflected in our research and in programmatic investments.

Translating research into effective programs is a core activity for USAID
Overview

• Review USAID Office of HIV/AIDS strategic agenda and research priorities
• Quick review USAID has a long history of promoting biomedical prevention research
• Discuss some of our current work on male circumcision
• Discuss the newly disseminated strategy on microbicide roll out
Priorities for HIV/AIDS Prevention

Dr. Rajiv Shah: David E. Barmes Global Health Lecture

February 15, 2011

- Behavior Change
- Microbicides
- Circumcision
- PMTCT
- PrEP
- Vaccine Research
Strategic Agenda for HIV/AIDS Research Priorities

Three Objectives

• Implementation science and program evaluations focused on integrated, cost-effective, and sustainable HIV/AIDS programming;
• Biomedical prevention research in vaccines and microbicides and;
• Research capacity-building efforts to improve local capacity to conduct and utilize research.
Strategic Agenda for HIV/AIDS Research Priorities

Five-Year Priorities

- Prevention
- Microbicide Introduction
- Capacity Building
Five-Year Priorities: Prevention

• A multi-layered evaluation of Combination Prevention

• A multi-country evaluation of the systematic scale up of medical male circumcision
Five-Year Priorities: Microbicide Introduction

- Implementation research
- Market research
- Epidemiological impact
- Gender research
- More to be added following the implementation meeting in South Africa
Five-Year Priorities: Capacity Building

- Build sustainable research and evaluation capacity at the individual, organizational, and systems levels to strengthen local institutions
- Link research and evaluation programs with strategic information programs
USAID and Biomedical Prevention

- Over 15 years of support to microbicide development and pre-exposure prophylaxis (PrEP) research
- Over 10 years of support to HIV vaccine R&D
- Male Circumcision
  - Sponsored first international meeting on MC (2000)
  - Sponsored the first meeting on OR agenda for MC
  - Sponsored the second international meeting on MC 2005
- Currently implementing a highly ambitious scale up of MC in Swaziland
Keeping Things in Balance

- Biomedical interventions reduce susceptibility and transmission.
- Behavioral and structural interventions address the underlying causes of the epidemic.
- and reduce the barriers between persons at risk and the services they need.
Medical Male Circumcision for HIV/AIDS prevention
Systematic Monitoring of the Male Circumcision Scale-up (SYMMACCS)

- Research to Prevention (R2P) Project - funded by USAID
- Johns Hopkins University/Tulane University (sub)
- Jane T. Bertrand (PI); Dino Rech (co-PI)
- Implemented in collaboration with CDC and OGAC
Background

- Male circumcision reduces HIV transmission by 60% or more.
- Many governments in Eastern and Southern Africa have committed to a scale-up among adolescent and adult males.
- Need to increase efficiency and cost efficiency of MC service delivery – while assuring safety and quality.
High Quality High Volume MC in Orange Farm SA.

Realistic and practical solutions to MC scale up in Africa.

By Dr. Dino Rech
MC’s per week in Orange Farm After Instituting High Quality High Volume
Efficiencies introduced into the surgical process (MC MOVE)

- Surgical technique:
  - Forceps-guided
  - Dorsal slit
  - Sleeve resection
- Haemostasis:
  - Electrocautery
  - Ligating sutures
- Task shifting:
  - Clinical officers or nurses perform MC
- Task sharing:
  - Surgeon performs most complex aspects of operation, others the rest
- Allocation of more than 1 surgical bay per surgeon
- Bundling of tools:
  - Prepacking of supplies, tools
Objectives of SYMMACCS

• To document the pace of scale-up of MC in 4 African countries:
  – Kenya (FHI/Kenya):
  – South Africa (CHAPS):
  – Tanzania (JHPIEGO/Tanzania):
  – Zimbabwe (PSI-Zimbabwe):

• Examples of questions:
  – What % of sites use forceps-guided?
  – What % of sites have more than 1 bay per surgeon?
  – What % of sites bundle supplies, tools?
Objectives of SYMMACCS (2)

• To determine if adoption of these efficiency elements relates to increased productivity
  – And if so, which elements are most important for increased productivity?
• Plan to have preliminary results by September 2011
Reducing Costs for Male Circumcision

• USAID/PEPFAR has reduced the unit cost of MC Kits $22 to $11.
• Pooled procurement and competition among suppliers - PSCM.
• PSCM is now providing technical assistance
  – procurement of MC commodities
  – supply chain system strengthening and
  – waste management
“Neither the elegance of the science, nor the strength of the effect predict the ease of implementation.”

David Stanton  June 2009

USAID Proposal for a Shared Vision and Strategic Plan for Microbicide Introduction
Aims of the strategy

• Provide a broad roadmap
• Not a USAID strategy – a USAID proposal
  • **Focusing on the interval between completion of a trial and the introduction of the product**
  • Undertake initiatives to identify the practical steps to bring a microbicide product to market and maximize its impact
  • Inform future product introduction efforts – beyond tenofovir gel
Assumptions

• Early products will be partially protective
• Early products will require a prescription, at least initially
• Availability will be limited due to facility based distribution and adoption will be slow – based on similar experiences (e.g. FC and MC).
• Regulatory process will be slow without manufacturer and stakeholder resources and interest
• Regulatory process will differ significantly between countries
• Product roll out will be influenced by the number of purposes it has
Assumptions

- Research at the user, clinical, and health systems levels will be essential.
- The first counties to adopt a product are likely to be those where clinical trials took place . . . . maybe.
- Normative agency support will be critical.
- Public sector pricing agreements will be different from the private market price.
- Newer products exiting the pipeline (i.e. rings or PrEP) may alter optimized introduction plans.
USAID will support 7 high-priority strategy elements:

1. Establish an inter-disciplinary microbicide access and introduction working group – in partnership with OGAC
2. Provide support for regulatory, licensure, manufacturing, and financing needs
3. Develop and implement a comprehensive communication and advocacy strategy
4. Design and implement a microbicide readiness assessment tool
USAID will support 7 high-priority strategy elements (2):

5. Adapt and pilot cost modeling for microbicide introduction as an intervention for HIV prevention
6. Adapt and implement a gender analysis tools to assess women’s access to microbicides and the impact of microbicides on reducing women’s vulnerability to HIV infection
7. Develop and implement a social science and operations research agenda for microbicide introduction, demand, and delivery
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<tr>
<th>Strategy Element</th>
<th>Deliverable</th>
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<td>1. Establish an inter-disciplinary microbicide access and introduction working group.</td>
<td>Working group established in the second half of 2011.</td>
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<td>2. Streamline support for regulatory, licensure, manufacturing, and financing needs.</td>
<td>Deliverables defined at June 13 and 14, 2011 South Africa meeting. Deliverables for 2012 determined as part of the 2011 process.</td>
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<td>3. Create comprehensive communication and advocacy tools.</td>
<td>Draft communication and advocacy tools adapted and piloted in two countries by the middle of 2012.</td>
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<td>6. Adapt and implement gender analysis tools to assess women’s access to microbicides and the impact of microbicides on reducing women’s vulnerability to HIV infection.</td>
<td>Gender analysis tool adapted in 2011 and field tested in 2012.</td>
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<td>7. Develop and implement a social science and operations research agenda for microbicide introduction, demand, and delivery.</td>
<td>A global-level generic social science and operations research plan with guidelines for application will be designed in 2011 and tested in two countries in 2012.</td>
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Purpose:

• Identify priority actions to ensure rapid expansion and availability of 1% tenofovir gel following licensure

• Inform normative guidance on use of the gel in high HIV incidence countries and settings
Tenofovir Gel Implementation Planning Meeting
South Africa (June 13- 14)

Outputs: Identify research priorities

1. Issues in Service delivery
2. Prioritising user groups and communities
3. Marketing and information for users
4. Manufacturing, pricing and demand
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