INTRODUCTION OF NON-SURGICAL DEVICES

Tim Farley, Ph.D.
Nyon, Switzerland

Consultant to WHO/HIV Department
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Case Example – Introduction of Student-led Family Planning Services in Nursing Schools

Cynthia Chasekola (Head of Nursing, Zimbabwe)

- To address large unmet need for family planning services among nursing students
- Proposed model of student-led services
- Conducted detailed stakeholder mapping
  - Faculty, hospital staff and management, National Family Planning Council, …
- Involved key stakeholders at all stages of project
- Identified legal, institutional and political changes required to ensure program could expand
- Pilot demonstrated that students were able to run FP service, clinic staffed 24h per day, lowered pregnancy rates and reduced student drop-out rates
Case Example – Introduction of Student-led Family Planning Services in Nursing Schools

Lessons

- Stakeholder engagement critical to ensure support at all stages and eventual adoption of innovation
- Helped identify future leaders to champion the innovation once shown safe, effective and appropriate
- Strategic expansion beyond initial pilot
  - Identified sites, assessed feasibility, adjusted program as necessary to the local setting, ensured clear targets and regular monitoring
- Planning process should begin with the end in mind and anticipate final result of scale-up
- Stakeholder mapping and participation is core to success
- Consultations with regulatory bodies and professional associations at early stage are critical
## Introduction of PrePex Device - Brainstorming on Key Stakeholders

### Ministry of Health
- National AIDS Council
- Director of Clinical Services
- Director of Nursing
- Procurement and supplies teams
- …

### Dept. of Defence

### Regulatory issues
- Regulatory authority
- Professional bodies

### Providers
- Clinicians, nurses

### End-users
- Clients who may be affected by change in services
- Women (mothers and partners)

### Political Support
- Parliamentary committee on HIV/AIDS
- Community leaders
“Beginning with the End in Mind”

Lessons

- Engage stakeholders
  - Strategic mapping of stakeholders, why involved, when involved
  - Prioritize stakeholder involvement
- Identify information needs required to engage different stakeholders

Key Message

- Map out the process that must be engaged in country to ensure successful diffusion of innovation
Planned Initial PrePex Pilot Studies

Renee Ridzon

- Developed standardized
  - model protocol
  - tools
  - definitions of AEs
- based on field studies conducted to generate clinical data to submit for WHO pre-qualification process

Countries planning initial studies *in anticipation of WHO Pre-Qualification*

- Botswana, Kenya, Lesotho, Malawi, Mozambique, Rwanda, South Africa, Swaziland, Tanzania, Uganda, Zambia, Zimbabwe
Core Protocol and Tools

Mary Glenshaw (CDC Botswana), Beverly Cummings (CDC Mozambique)

Goal

- Evaluate SAFETY and ACCEPTABILITY of PrePex™ in routine VMMC clinical settings in Botswana and Mozambique

Objectives

1. Determine training needs of PrePex™ providers
2. Describe client and provider acceptability
3. Describe and assess safety when PrePex™ VMMC performed by nurse providers
4. Describe costs of PrePex™ circumcision (Mozambique only)
Core elements developed, for potential adaptation and use in other countries

Client Inclusion Criteria
Client Exclusion Criteria
Provider Criteria
Research Data Collection Tools
Non-Research Tools
Clinical Data Collection Tools
Provider Assessments: Primary Endpoints & Themes
Discussion

Safety and Acceptability Studies critically important

Studies will be conducted prior to pre-qualified device and recommendation on use of device, so require IRB and other research approvals

Extremely valuable to have model protocol and tools to use

Device procurement and supply issues
Lessons

Many questions will NOT be answered by the model safety and acceptability studies

Map out introduction PROCESS and engage stakeholders

THIS MUST BE adequately resourced !!!!