

# INTRODUCTION OF NON-SURGICAL DEVICES

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**Sigma<sup>3</sup> Services** *Scientific & Statistical Solutions*

# 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 !!!!**

