SUPPLIER SUMMIT

USAID Global Health Supply Chain Program Supplier Summit
February 21-23, 2017
VOLUNTARY MEDICAL MALE CIRCUMCISION KITS

THE JOURNEY SO FAR AND THE PATH AHEAD...
SESSION GOAL

To provide an update of the progress, targets, and future trends in USG VMMC programs and explore ways to improve the performance of suppliers and the services provided by GHSC-PSM.
SESSION TOPIC OVERVIEW

• VMMC: Role in PEPFAR programs
• Overview: USG VMMC program achievements, targets, and future trends
• How GHSC-PSM serves country VMMC programs
• VMMC product issues
• GHSC-PSM demand forecasts
• Discussion: The way forward to achieve excellent service by suppliers and by GHSC-PSM
USAID-SUPPORTED VMMC PROGRAMS
VMMC BACKGROUND

• Oldest and most common surgical procedure in the world.

• Studies in the mid-1980s indicate that circumcised men have a lower prevalence of HIV infection than uncircumcised men.

• Therefore it is recommended that VMMC is included as part of a comprehensive HIV prevention strategy which includes HIV testing and counseling; treatment for sexually transmitted infections (STIs); the promotion of safer sex practices; and the distribution of condoms as well as their correct and consistent use.
Findings published in 2005 from the South Africa Orange Farm Intervention Trial demonstrated at least a 60% reduction in HIV infection among men who were circumcised.

In 2007, WHO issued guidance that “Male circumcision should now be recognized as an efficacious intervention for HIV prevention, and promoting male circumcision should be recognized as an additional, important strategy for the prevention of heterosexually acquired HIV infection in men.”

http://apps.who.int/iris/bitstream/10665/43751/1/9789241595988_eng.pdf

**WHY VMMC?**

- Findings published in 2005 from the South Africa Orange Farm Intervention Trial demonstrated at least a 60% reduction in HIV infection among men who were circumcised.

- In 2007, WHO issued guidance that “Male circumcision should now be recognized as an efficacious intervention for HIV prevention, and promoting male circumcision should be recognized as an additional, important strategy for the prevention of heterosexually acquired HIV infection in men.”
By the end of 2017, achieve a 40 percent reduction in HIV incidence among adolescent girls and young women (aged 15-24) within the highest burden geographic areas of 10 sub-Saharan African countries.

By the end of 2016, PEPFAR will provide 11 million voluntary medical male circumcisions for HIV prevention, cumulatively.

60%  
Percentage by which VMMC reduces men’s risk of sexually acquiring HIV (Loi, 2015).

$16.5 billion  
Potential savings in HIV care & treatment costs if 8 of every 10 men are circumcised through rapid VMMC (Njeuhmeli, 2011).

11.7 million  
The number of VMMC procedures that PEPFAR has supported to reduce the risk of HIV transmission in Eastern and Southern Africa (PEPFAR).
HOW GHSC-PSM SERVES COUNTRY VMMC PROGRAMS
PEPFAR'S VMMC PROGRAM

- 14 focus countries with high HIV prevalence - low MC prevalence
- Most procedures have been USG funded in all 14 focus countries except for South Africa and Kenya
Figure. Annual number of voluntary medical male circumcisions performed for HIV prevention in 14 countries in East and Southern Africa, 2008–2015

Cumulative total: 11 685 591 VMMC through 2015

VMMC PROGRAM SCALE-UP

• Why is continuing to scale up VMMC important?
  – Achieving and maintaining 80% VMMC coverage by 2020 in PEPFAR’s 14 priority countries could avert 3.5 million new HIV infections

• PEPFAR will continue investment in and expansion of VMMC
  – Expanding to under-14-year-olds in high performing countries

• Targets:
  – By 2021, 90% of males aged 10–29 years will have been circumcised in priority settings in sub-Saharan Africa
  – The 90% target translates to 27 million procedures
VMMC AT GHSC-PSM
GHSC-PSM: VMMC STRATEGY

Key Objectives for GHSC-PSM’s Strategy: Improve Forecasting and Planning

- Establish close collaboration across GHSC-PSM teams, implementing partners, and countries
- Set expectations and processes for communication and data requirements
- Provide technical assistance and in-country support for quantification and other supply chain aspects critical to VMMC implementation

Benefits to Suppliers

- Improved communication within GHSC-PSM and with the VMMC implementer’s network leads to more accurate and further reaching forecast information to better advise suppliers on expected shipments and capacity needs
- Information on implementing partner’s progress toward targets, total progress to date, etc., guides future forecasts which can inform all levels of the supply chain
  - E.g., VMMC saturation within a target age group may signal shifts to different types of kits within a country
Strategic Priorities for GHSC-PSM’s VMMC Program

- Long-term IDIQ
- VMI Agreements
- Improved Forecasting
**METHODOLOGY OVERVIEW**

- Procurement forecasts are informed by country supply plans and are augmented with order history, SPSS models, and qualitative/quantitative information from COPs/IPs.
- GHSC-PSM’s VMMC procurement forecast is then used to plan restocking orders and place orders with suppliers to meet demand for the upcoming six- to nine-month period.
GHSC-PSM DEMAND FORECASTS
GLOBAL VMMC KIT FORECAST

UNAIDS Fast-Track target: 27 million between 2016-2021

VMMC 2012-16 target: 20.8 million

Source: UNAIDS, Joint United Nations Programme on HIV/AIDS; VMMC, voluntary medical male circumcision

Current trajectory
Cumulative Progress
Trajectory towards 2021 target
Targets

YEAR
MILLIONS OF VMMCs
0 5 10 15 20 25 30 35 40

Source: UNAIDS, Joint United Nations Programme on HIV/AIDS; VMMC, voluntary medical male circumcision
### Preliminary VMMC Demand Forecast

<table>
<thead>
<tr>
<th>MC Kit Description</th>
<th>2017 Q1</th>
<th>2017 Q2</th>
<th>2017 Q3</th>
<th>2017 Q4</th>
<th>2017 Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MC Kit, Non-Sterile, Reusable Instruments for Forceps-guided Procedure</strong></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1,000</td>
<td>1,000</td>
</tr>
<tr>
<td><strong>MC Kit, Non-Sterile, Reusable, Instruments for Dorsal Slit/Sleeve Resection</strong></td>
<td>260</td>
<td>189,440</td>
<td>1,123</td>
<td>402</td>
<td>191,225</td>
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<tr>
<td><strong>MC Kit, Sterile, Single Use, Forceps-guided Procedure</strong></td>
<td>123,101</td>
<td>358,018</td>
<td>87,446</td>
<td>186,050</td>
<td>754,615</td>
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<tr>
<td><strong>MC Kit, Sterile, Single Use, Additional Instruments for Dorsal Slit/Sleeve Resection</strong></td>
<td>6,000</td>
<td>42,772</td>
<td>33,000</td>
<td>80,000</td>
<td>161,772</td>
</tr>
<tr>
<td><strong>MC Kit, Sterile, Single Use, for All Surgical Procedures</strong></td>
<td>38,478</td>
<td>182,672</td>
<td>35,000</td>
<td>20,000</td>
<td>276,150</td>
</tr>
<tr>
<td><strong>MC Kit, Sterile, Single Use, Essential Consumables</strong></td>
<td>29,000</td>
<td>29,600</td>
<td>42,200</td>
<td>40,200</td>
<td>141,000</td>
</tr>
<tr>
<td><strong>MC Kit, Sterile, Single Use, PrePex Removal</strong></td>
<td>0</td>
<td>0</td>
<td>21,000</td>
<td>0</td>
<td>21,000</td>
</tr>
</tbody>
</table>
GHSC-QA PROJECT MANAGEMENT TEAM

Chryste Best
Deputy Project Director

Aida Cancel, PhD
Associate Director, Regulatory

Katie Cretin, MPH
Associate Director, Business Operations

David Jenkins, PhD
Associate Director, Research

Thomas Layloff, PhD
Senior Technical Advisor

Jeff Tremelling
Associate Director, Laboratory Testing

Steve Hamel
Director

SUPPLIER SUMMIT
USAID Global Health Supply Chain Program Supplier Summit
Establish and implement a comprehensive **Quality Assurance Program** for USAID that:

- Provides global technical leadership regarding quality issues to the international quality assurance community
- Provides technical assistance to host country governments and other stakeholders
- Assures that health commodities purchased on behalf of USAID meet applicable quality standards
- Implements Model Quality Assurance System (MQAS) guidance (WHO Technical Report Series)
- Employs risk management practices to maintain diligence and recognizes that by limiting the risk of accepting products of inadequate quality, increased protection of the client/patient and USAID is ensured.

**GHSC-QA** provides independent Quality Assurance for:

- **Task Order 1-HIV**
- **HIV RTKs (RMI)**
- **Task Order 3-Reproductive Health**
- **Task Order 4-Maternal and Child Health**
Eligibility Requirements

- Voluntary Medical Male Circumcision Technical Working Group (VMMC TWG) determines requirements and technical specifications for each type of kit.
  - Supplier must meet
    - ISO13485:2016; and
    - ISO 11135-1:2007 (for sterile kits)
  - GHSC-QA audit
  - Validation of sterilization cycles for the various kit options

QA and QC Activities

- Frequency of GHSC-QA audits dependent on risk assessment (2 – 4 years)
- Pre-shipment, concurrent, or post-shipment sterility testing dependent on risk assessment, and physical inspection.
- Sterility validation data reviewed and approved by GHSC-QA

REQUIREMENTS FOR VMMC KITS

- MC kit for all surgical procedures, Single use, Sterile
- MC kit, Additional Instruments for Dorsal Slit/Sleeve Resection, Single Use, Sterile
- MC kit, Essential Consumables Pack, Single Use, Sterile
- MC kit, Forceps-guided Procedure, Single Use, Sterile
- MC kit, Reusable Instruments for Dorsal Slit/Sleeve Resection, Non-Sterile
- MC kit, Reusable Instruments for Forceps-guided Procedure, Non-Sterile
- MC1:C25C kit for all surgical procedures, Single Use, Sterile, 1 kit
- PrePex Removal Kit
NAVIGATING GHSC-PSM SYSTEMS
ARTMIS OVERVIEW

BI&A Contractor’s Business Intelligence Tools

Core Management Information System
- Project Order Catalog
- Management Reporting
- Data Integration Business
- Order Management

Chemonics Financial MIS
- Contract Management
- Demand Forecasting and Supply Chain Optimization
- e-Catalog and Ordering

K+N Logistics MIS Portal
- Supplier Portal
- Transportation Management
- Warehouse Management

USAID Users (Washington and Missions)

Chemonics Finance Team
- Project Users (Home Office and Field Office)
- Cooperating Country Ministries of Health (Future State)

K+N Staff, 3PL Agents, Freight Forwarders, & Suppliers
RO PROCESSING/CATALOG

- Catalog product browsing
- Process Requisition Orders (ROs)
- Catalog management

URL: https://pmsso.ghsc-psm.org/webapp/wcs/stores/servlet/en/psmb2bstore
ORDER FULFILLMENT

- Drop Ship Purchase Orders (POs) – Supplier to country
- Replenishment Purchase Orders (IOs) – Supplier to RDC
- Distribution Orders (DOs) – RDC to country
SOURCING AND CONTRACTS MANAGEMENT

Conduct and manage RFxs

Contract management

Supplier onboarding and management
EVALUATION CRITERIA (AQSCIR-P)

- **Assurance of Supply**
  - Production capacity
  - Quantity in stock (when required)
  - Past performance

- **Regulatory**
  - Administrative requirements
  - Registration in country

- **Quality**
  - QA requirements (USFDA, WHO, GHSC-QA)
  - Shelf life
  - Stability studies/climatic zone standards

- **Service**
  - Lead time (stock, fresh production)
  - Customer service
  - Product Identification

- **Cost**
  - Specific/Unique label language
  - Unique Distribution requirements

- **Innovation**
  - Serialization
  - Packaging optimization
  - New/improved products

- **Price**
  - FCA Unit price

Criteria and % Weights are Tailored to the Commodity and/or Product and Specific Sourcing Strategy

BEST VALUE AWARD STRATEGY TO ACHIEVE DESIRED MARKET OUTCOME
GHSC-PSM APPROACH FOR MULTI-VENDOR AWARDS

<table>
<thead>
<tr>
<th>Amount/Scope</th>
<th>AQSCIR-P Evaluation</th>
<th>Multi-Vendor Award Strategy</th>
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</thead>
<tbody>
<tr>
<td>Total Volume to be Awarded</td>
<td>Assurance of Supply</td>
<td>Vendor A</td>
</tr>
<tr>
<td>100K Packs</td>
<td>Vendor B</td>
<td>Vendor B</td>
</tr>
<tr>
<td></td>
<td>Regulatory</td>
<td>Vendor C</td>
</tr>
<tr>
<td></td>
<td>Quality</td>
<td>Vendor D</td>
</tr>
<tr>
<td></td>
<td>Service</td>
<td></td>
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<tr>
<td></td>
<td>Cost</td>
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<tr>
<td></td>
<td>Innovation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Price</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>50K Packs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>25K Packs</td>
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<tr>
<td></td>
<td></td>
<td>15K Packs</td>
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<tr>
<td></td>
<td></td>
<td>10K Packs</td>
</tr>
</tbody>
</table>

To t a l Volume to be Awarded: 100K Packs
# SCORECARD METRICS

<table>
<thead>
<tr>
<th>Category</th>
<th>Weight</th>
<th>Metrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Quality</td>
<td>40%</td>
<td>- Percentage of POs with and out of specification</td>
</tr>
<tr>
<td>Order Fulfillment</td>
<td>30%</td>
<td>- Were the goods supplied in the right quantities?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Were the goods made available on time?</td>
</tr>
<tr>
<td>Invoicing</td>
<td>10%</td>
<td>- Were the goods invoiced correctly?</td>
</tr>
<tr>
<td>Service</td>
<td>10%</td>
<td>- Are the suppliers responsive to communications?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Ease of doing business?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Does the supplier offer after-sales service or in-country support (i.e., lab supplies, vehicles)?</td>
</tr>
<tr>
<td>Innovation</td>
<td>10%</td>
<td>- Is the supplier innovative in its supply chain and/or business processes?</td>
</tr>
</tbody>
</table>
ADOPTION OF GLOBAL STANDARDS FOR IDENTIFICATION AND DATA CAPTURE AND EXCHANGE

Implement global standards for:
- Product and location identification
- Packaging, presentation, and data capture
- Data exchange of orders, shipment status, and delivery notification

Goal is to achieve:
- End-to-end data visibility
- Supply chain efficiency
- Supply chain security

For more information, we suggest you attend the following sessions:
- Implementation of GS1 Global Standards for Product Identification
- Data Exchange with GHSC
Q&A AND DISCUSSION
DISCUSSION

• Supplier feedback
• Current challenges
• How GHSC-PSM can help
• Market feedback
• Emerging innovations
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The USAID Global Health Supply Chain-Procurement and Supply Management project provides commodity procurement and logistics services, strengthens supply chain systems, and promotes commodity security. We support USAID programs and Presidential Initiatives in Africa, Asia, Latin America, and the Caribbean, focusing on HIV/AIDS, malaria, maternal and child health, and reproductive health commodities.