Update on PEPFAR
Headquarter Activities:

- Logistics and Supply Chain Readiness
WHO
USG (OGAC, CDC, DoD, USAID)
UNAIDS
The Clinton Foundation
The Bill & Melinda Gates Foundation
Population Services International (PSI)
Jhpiego
Family Health International (FHI)
EngenderHealth
Marie Stopes International (MSI)
African Comprehensive HIV/AIDS Partnerships (ACHAP) USAID
Communication for Change (C-CHANGE)
USAID Health Policy Initiative (USAID HPI)
Johns Hopkins University Center for Communication Program (JHUCCP)
Rakai Health Science Program (RHSP)
Orange Farm (OR)
University of California San Francisco (UCSF)
Results:

• Detailed specifications for components of three purchasing options for surgical instruments and consumables
  – Reusable (partially) surgical instrument for forceps guided inside an autoclave sterile box plus a kit of consumables
  – Reusable (partially) surgical instrument for dorsal slit and sleeve method inside an autoclave sterile box plus a kit of consumables.
  – Fully disposable surgical instruments and consumables into a kit for forceps guided.

• Three modules for infection prevention, equipment and emergency toolkit.
Recommendations:

The efficiency of services also relies on appropriate material commodities being available for their delivery. It is important to consider:

- the bundling of commodities;
- the forecasting of supply needs;
- procurement;
- distribution

Defined contents for each of three kit procurement options (disposable; reusable FG; reusable DS/SR)

- List of Critical Commodities (>80) (Appendix 5)
Benefits of MC Kit Standardization:

• Cost (as volumes increase)
  – Initial kit price in 2010: $23
  – Current kit price: $14

• Quality
  – The MC kits are stringently tested & quality controlled
  – Manufacturers meeting quality standards can be accessed by any procurement agent
  – Priontex, IDA, MissionPharma

• Reduction in Lead Time
  – Current lead time from manufacturer: 24 weeks
  – Current lead time for SCMS stocks at Regional Distribution Center (RDC): 8 weeks
Number of MC disposable kits supplied through SCMS by country

Total Number of Kits: 762,865

Number of MC disposable Kits

- Botswana: 40,000
- Kenya: 6,800
- Lesotho: 10,000
- Malawi: 34,080
- Mozambique: 72,800
- Rwanda: 10,376
- South Africa: 120,020
- Swaziland: 44,805
- Tanzania: 110,500
- Uganda: 195,395
- Zambia: 14,900
- Zimbabwe: 103,189
MC Kits – Reported Quality Issues

- Broken clamps
- Stiff needle holders
- Unusable gloves
- Un-releasable scalpel blade
- Missing instrumentation

Note: For a claim to be filed with the manufacturer, pictures, lot numbers and ideally the defective kit should be sent back to SCMS
**PFSCM MC Kit Incident Reporting Form**

**Reporter Information:**

<table>
<thead>
<tr>
<th>First Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Name</td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td></td>
</tr>
<tr>
<td>Email</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td></td>
</tr>
</tbody>
</table>

**Clinic/Site Information:**

<table>
<thead>
<tr>
<th>Clinic/Site Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinic/Site Location</td>
<td></td>
</tr>
<tr>
<td>Date of Report</td>
<td></td>
</tr>
<tr>
<td>Surgeons Name</td>
<td></td>
</tr>
</tbody>
</table>

**Product Information:**

<table>
<thead>
<tr>
<th>Batch/Lot No.</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td></td>
</tr>
<tr>
<td>Manufacturer Location</td>
<td></td>
</tr>
<tr>
<td>ASN (if known)</td>
<td></td>
</tr>
<tr>
<td>Number of Kits Affected</td>
<td></td>
</tr>
<tr>
<td>Detailed description of the product condition, event or incident</td>
<td></td>
</tr>
</tbody>
</table>

**Photos Attached (Preferred):**

- Yes ☐
- No ☐

Send your completed form or report contents to your SCMS Field Office Representative or email: [productquality@pfscm.org](mailto:productquality@pfscm.org).
MC Kits – Quality Assurance

- Vendor replaced all damaged or missing items
- "Report Product Quality Concerns to PFSCM at productquality@pfscm.org or call +1-571-227-8600" added to all MC Kits
- Post-market surveillance of kits:
  - Physical inspection of MC Kit contents
  - Sterility testing
- Vendor inspection completed in June 2012 & upcoming in December 2012
- Adding ISO & ASTM standards for each component is being discussed for the next RFQ
<table>
<thead>
<tr>
<th>Current Item</th>
<th>Proposed item</th>
<th>Qty</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combination disposable needle holder and scissor.</td>
<td>Disposable needle holder.</td>
<td>one</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Disposable suture scissors with total length 12-15 cm.</td>
<td>one</td>
<td>Malawi, Tanzania, Zimbabwe</td>
</tr>
<tr>
<td>Disposable circumcision forceps hemostatic cross clamp:</td>
<td>Disposable circumcision forceps hemostatic cross clamp:</td>
<td>one</td>
<td>NO CHANGE</td>
</tr>
<tr>
<td>Mosquito clamp disposable straight (aka mosquito forceps, hemostatic forceps):</td>
<td>Mosquito clamp disposable straight (aka mosquito forceps, hemostatic forceps):</td>
<td>one</td>
<td>NO CHANGE</td>
</tr>
<tr>
<td>Mosquito clamp disposable curved (aka mosquito forceps, hemostatic forceps):</td>
<td>Mosquito clamp disposable curved (aka mosquito forceps, hemostatic forceps):</td>
<td>one</td>
<td>NO CHANGE</td>
</tr>
<tr>
<td>Non-toothed plastic forceps (aka pick-ups, dissection forceps):</td>
<td>Metal disposable tissue forceps one tooth in each side (AKA adson forceps):</td>
<td>one</td>
<td>Malawi, Tanzania, Zimbabwe</td>
</tr>
<tr>
<td>Disposable scalpel and handle (retractable and lockable): blade type 23, total length 11 cm</td>
<td>Disposable scalpel and handle (retractable and lockable): blade type 23, total length 11 cm</td>
<td>one</td>
<td>NO CHANGE</td>
</tr>
<tr>
<td>Consumables</td>
<td>Description</td>
<td>Amount</td>
<td>Location</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>--------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Stable plastic recycle tray to conduct procedure, 3 compartments</td>
<td>Stable plastic recycle tray to conduct procedure, 4 compartments</td>
<td>one</td>
<td>NO CHANGE</td>
</tr>
<tr>
<td>Apron - plastic - disposable. Quality of the trash bag</td>
<td>Apron - plastic - disposable. Quality of the trash bag</td>
<td>two</td>
<td>NO CHANGE</td>
</tr>
<tr>
<td>Gauze, petroleum jelly impregnated. Paranet Gauze 10cm X 10cm (1 ply)</td>
<td>Gauze, petroleum jelly impregnated. Paranet Gauze 10cm X 10cm (1 ply)</td>
<td>one</td>
<td>NO CHANGE</td>
</tr>
<tr>
<td>Gauze swabs, 100x100mm (12 ply)</td>
<td>Gauze swabs, 100x100mm (12 ply)</td>
<td>20</td>
<td>NO CHANGE</td>
</tr>
<tr>
<td>Sterile prep gloves. Examination glove large (pair)</td>
<td>Sterile prep gloves. Examination glove large (pair)</td>
<td>2 pair</td>
<td>Uganda, Tanzania</td>
</tr>
<tr>
<td>Surgical Gloves Powdered [non-powdered] Sterile Pair (size 7)</td>
<td>Surgical Gloves Powdered [non-powdered] Sterile Pair (size 7.5)</td>
<td>2 pairs</td>
<td>Uganda, Zimbabwe</td>
</tr>
<tr>
<td>Gloves Sterile Pair (7.5)</td>
<td>Surgical Gloves Powdered [non-powdered] Sterile Pair (size 8)</td>
<td>1 pair</td>
<td>NO CHANGE</td>
</tr>
<tr>
<td>Glove Sterile Pair (8)</td>
<td>Surgical Gloves Powdered [non-powdered] Sterile Pair (size 8)</td>
<td>1 pair</td>
<td>NO CHANGE</td>
</tr>
<tr>
<td>Item</td>
<td>Details</td>
<td>Quantity</td>
<td>Notes</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>----------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Alcohol swabs</td>
<td>1 1/4&quot; x 2 1/2&quot; (32mm x 64mm)</td>
<td>Two</td>
<td>NO CHANGE</td>
</tr>
<tr>
<td>Disposable O-drape</td>
<td>100cm x 75 cm</td>
<td>one</td>
<td>NO CHANGE</td>
</tr>
<tr>
<td>Needle 21G x 1.5&quot;</td>
<td>[21G or 23G] x 1.5&quot; [1 - 1.5] used to draw</td>
<td>one</td>
<td>Small gauge needle to minimize pain (proposed by consultant)</td>
</tr>
<tr>
<td>Needle 23G x 1.5&quot;</td>
<td>25G [25-27] x 1.5&quot; [1.25 - 1.5]</td>
<td>one</td>
<td>NO CHANGE</td>
</tr>
<tr>
<td>Suture 3/0 braided synthetic (polyglycolic acid suture)</td>
<td>75 cm, on Reverse cutting needle 26mm</td>
<td>two</td>
<td>NO CHANGE. Question re: catgut</td>
</tr>
<tr>
<td>Syringe 10ml</td>
<td></td>
<td>one</td>
<td>NO CHANGE</td>
</tr>
<tr>
<td>Surgical paper tape micropore 12mm, 1-3 meter in length</td>
<td>12mm - 18mm, 3 meter in length</td>
<td>one</td>
<td>NO CHANGE</td>
</tr>
<tr>
<td>Surgical crepe paper to wrap kit 60cm x 60 cm</td>
<td></td>
<td>one</td>
<td>NO CHANGE</td>
</tr>
<tr>
<td>Indicator bag and sterilization.</td>
<td></td>
<td>one</td>
<td>NO CHANGE. shelf life &gt; 3 years.</td>
</tr>
<tr>
<td>INSTRUMENTS</td>
<td>Proposed item</td>
<td>Proposed Qty</td>
<td>Comments</td>
</tr>
<tr>
<td>-------------</td>
<td>---------------</td>
<td>--------------</td>
<td>----------</td>
</tr>
<tr>
<td>Straight Dissecting Scissors. (eg Straight mayo scissors). Total Length: 13-15 cm</td>
<td>one</td>
<td>Zambia, Tanzania</td>
<td></td>
</tr>
<tr>
<td>Toothed tissue forceps. AKA &quot;pick-ups&quot;, &quot;dissection forceps&quot;. Total length 13cm [12-15].</td>
<td>one</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mosquito clamp disposable straight (aka mosquito forceps, hemostatic forceps): Total length 12-14 cm, working surface 30mm [20-30]. Example: Halstead disposable straight mosquito</td>
<td>three</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemostatic Clamps. AKA &quot;Artery Forceps&quot; for Dorsal Slit MC. Total Length 13-15 cm. Working surface 40 mm</td>
<td>two</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Commodities Next Steps

Implementation of Kit Revisions:

– Approval of new specification by PEPFAR MC TWG
– Request for Proposals from manufacturers using new specs (field feedback) will be released - 6 weeks
– Quality testing (components / sterility) - 4 months

• Benefits:
  – Increase diversification with more approved vendors
  – Provide safety stock at the RDC from multiple suppliers

• Creation of standard specs for Diathermy machines, Procedure Tents and Prefab Buildings
Injectable Pharmaceuticals

- Most challenging and high risk required products are sterile injectables (Lidocaine and Bupivacaine)
  - Current global market shortage (USFDA).
  - USG procurement regulations require product be sourced from an SRA-approved manufacturer. Only three currently exist.
  - Registration of drugs differs between countries
  - Current lead times can be as much as 6-9 months.
  - Complicated and costly to maintain quality standards for injectables to prevent contamination and serious adverse reactions.

- PEPFAR goal of achieving 4.7 million VMMC procedures by the end of 2013.
  - 1.2 million vials of Lidocaine 1% / 1 million vials of Bupivacaine 0.5%.
  - Pooling procurement to reduce lead times and cost, increase quality
Health Care Waste Management Toolkit
VMMC Project

HCWM System

- Assessment
- Identification/Segregation
- Quality Management
- Treatment / Disposal
- Storage
- Transport / Transfer
Project Timeframe

1. REQUIREMENTS GATHERING
   - Gather and finalize requirements
   - Review relevant documents
   - Begin to draft preliminary SOPs and tools

2. SOP & JOB AIDS DEVELOPMENT
   - Complete first draft of SOPs, Job Aids and other tools
   - Review and validate draft tools/materials with key stakeholders
   - Finalize SOPs and other tools

3. TRAINING & QM DEVELOPMENT
   - Create comprehensive training program
   - Develop quality management and assessment tools
   - Pilot tools
   - Develop website/platform

4. TOOL FINALIZATION
   - Final SOPs, Job Aids and other requirements
   - Final training program and quality management and assessment tools
   - Final toolkit

Key Activities

Outputs

- List of required tools and responsible persons
Thank You
• Critical MC Commodities:
  – MC Kits (reusable and disposable)
  – RTKs
  – Pharmaceuticals
  – Additional Essential Items (e.g. gauze, gloves)
  – Infection Prevention supplies (e.g. face masks, sharp boxes)
  – Emergency supplies (e.g. airways)
  – Equipment (e.g. lamps, diathermy machines)
  – Temporary infrastructure (e.g. tents)