NEED FOR CERTIFICATION OF HOUSEHOLD WATER TREATMENT PRODUCTS: EXAMPLES FROM HAITI

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³: Centers for Disease Control and Prevention, Atlanta, GA, USA
Background: Global Drinking Water

- 780 million people drink from unimproved water sources (UNICEF/WHO, 2012)
- 1.2 billion more drink contaminated water from improved sources (Onda et al., 2012)
Background

Household Water Treatment (HWT) Products are promoted to:

- Improve microbiological water quality
- Reduce burden of diarrheal disease
Background

- Specific country regulations exist (e.g. US EPA)
- Voluntary Standards Organizations (NSF Int’l)
- WHO International Scheme to Evaluate Household Water Treatment Technologies
  - Launched in 2014
  - Laboratory efficacy targets: Bacteria, Viruses, Protozoan cyst removal
  - Categorizes products as:
    - Highly protective
    - Protective
    - Limited Protection
Haitian Ministry of Health and Population (MSPP), with Tufts University, established a process for certifying HWT products in Haiti.

Two-stage Certification Process:
- Validation stage
- Approval stage

Specific to chemical treatment products
**Validation Stage**

Is the product certified as efficacious for treating drinking water through a recognized international process? (NSF, EPA, other)

- **No**
  - Has the product been shown to reduce organisms of concern to the WHO standards in drinking water in laboratory settings?
    - **No**
      - REJECT
    - **Yes**
      - APPROVAL STAGE

**Approval Stage**

- **Yes**
  - Has a product sample’s composition been verified to be within 20% of stated composition?
    - **No**
      - REJECT
    - **Yes**
      - Would effluent water meet internat’l and local drinking water quality criteria?
        - **Yes**
          - APPROVE
        - **No**
          - REJECT

- **Yes**
  - Is the product packaged appropriately?
    - In Haitian Creole
    - Product contents
    - Directions for HWT use
    - Lot number
    - Manufacture date
    - Expiration date
    - Ability to measure dose

- **No**
  - REJECT
Products

- **SAFI**
  (Clean Water Environmental, LLC)

- **SCI-62®**
  (Chem-a-Co, Inc.)

- **SilverDYNE®**
  (World Health Alliance International, Inc.)

- **Antinfek™ 10H**
  (Dove Biotech Limited)
Methodology

- Reviewed documentation provided by companies
- Verified International Certifications / Registrations (online databases, web search)
  - NSF/ANSI Standard 60
  - EPA Registration under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
- Evidence of Efficacy data
  - Reviewed test results provided by companies
  - Literature Review: Laboratory research that the product meets WHO limited protection target
Methodology

- **Tested Product Composition**
  - within 20% of stated

- **Calculated if drinking water standards for health effects would be met**
  - WHO Guidelines for Drinking Water Quality
  - US EPA and European Union Drinking Water Regulations

- **Reviewed Product Packaging**
  - Ability to measure dose
  - Language
  - Contents listed
  - Directions for HWT (with correct dose)
  - Lot number, mfr date, expiration date
Zinc Sulfate and/or Copper Sulfate solution

Approvals:

Efficacy:

Composition:

Health Effects:

Dosage:

Package:
SCI-62®

Copper Sulfate solution

Approvals:

- NSF / ANSI 60 approval: Yes

“for applications in waters destined for use as drinking water, those waters must receive additional and separate potable water treatment”

Efficacy:

- Copper sulfate: effective algicide & bactericide
- Cu efficacy for HWT in laboratory trials – in contact overnight to 24 hours
- Technical representative advised using chlorine instead of this product to treat drinking water for US hikers

Composition:

- Product had 21% more copper than label

Health Effects:

- Safe Cu levels

Dosage:

- None given for HWT

Package:

- No information
SilverDYNE®

Colloidal Silver solution

Approvals:

Efficacy:

Composition:

Health Effects:

Dosage:

Package:

http://www.ezylife.com/product/silver-dyne
Antinfek™ 10H

Poly(hexamethylene biguanide) Hydrochloride (PHMB)

Approvals:

Efficacy:

Composition:

Health Effects:

Dosage:

Package:
## Results: Summary

<table>
<thead>
<tr>
<th></th>
<th>SAFI</th>
<th>SCI-62®</th>
<th>Silverdyne®</th>
<th>Antinfek™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Int'l Certifications for Drinking Water</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Efficacy: meets WHO target at recommended dose</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Composition Verification (within 20%)</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>-</td>
</tr>
<tr>
<td>Meets Guidelines: Health Effects</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Achievable Dosage</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Complete Labeling</td>
<td>No</td>
<td>No</td>
<td>Almost</td>
<td>No</td>
</tr>
</tbody>
</table>
Conclusions

- Difficult to sort out misleading information, even when it’s in your language
  - Certifications that may not mean anything (e.g. facility registration with FDA)
  - Certifications for a different product by the same company
  - Test results that are:
    - for a different product
    - for a different use
    - at a different dose or contact time
There is a need for:

- **Assessments** of whether commercial HWT options meet WHO performance targets

- **Capacity-building** with developing country regulatory agencies to assist in evaluating HWT products, Considering language, usability, cultural appropriateness
  - Web-searches for certifications/approvals
  - Laboratory procedures and product testing

- **Enforcement** of product regulations from authorities in countries of manufacture
Thank You

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WORLD HEALTH ORGANIZATION EARLY WARNING INDICATORS OF HIV DRUG RESISTANCE IN NAMIBIA

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Assistant Professor
Division of Geographic Medicine and Infectious Diseases
Department of Public Health and Community Medicine
Adults and children estimated to be living with HIV | 2012

- **Eastern Europe & Central Asia**: 1.3 million
  - [1.0 million – 1.7 million]
- **Western & Central Europe**: 860,000
  - [800,000 – 930,000]
- **North America**: 1.3 million
  - [980,000 – 1.9 million]
- **Caribbean**: 250,000
  - [220,000 – 280,000]
- **Latin America**: 1.5 million
  - [1.2 million – 1.9 million]
- **Middle East & North Africa**: 260,000
  - [200,000 – 380,000]
- **Sub-Saharan Africa**: 25.0 million
  - [23.5 million – 26.6 million]
- **East Asia**: 880,000
  - [650,000 – 1.2 million]
- **South & South-East Asia**: 3.9 million
  - [2.9 million – 5.2 million]
- **Middle East & North Africa**: 260,000
  - [200,000 – 380,000]
- **Sub-Saharan Africa**: 25.0 million
  - [23.5 million – 26.6 million]
- **East Asia**: 880,000
  - [650,000 – 1.2 million]
- **South & South-East Asia**: 3.9 million
  - [2.9 million – 5.2 million]
- **Caribbean**: 250,000
  - [220,000 – 280,000]
- **Latin America**: 1.5 million
  - [1.2 million – 1.9 million]

**Total: 35.3 million** [32.2 million – 38.8 million]
Global Scale-Up of ART

Number of people receiving antiretroviral therapy in low- and middle-income countries, by region, 2002–2011

Emergence of HIV Drug Resistance (HIVDR) is Inevitable

- High replication rates
- High mutation rates
- Necessity for lifelong treatment

Emergence of HIV drug resistance (HIVDR)
Public health approach to HIVDR surveillance

- Rapid or uncontrolled emergence and transmission of HIVDR is a widely feared consequence of ART scale-up, which could lead to failure of ART programs and strategies to prevent HIV transmission increasing morbidity, mortality and cost.

- Public Health Approach to scaling up ART works
  - Standardized, population based approaches
  - Inexpensive, generic, fixed dose combinations

- Population-based assessment of HIVDR is critical to:
  - Optimize population-level outcomes
  - Monitor program-wide functioning
  - Strengthen public-health approach to ART delivery
World Health Organization (WHO) HIVDR Strategy

- WHO recommends that countries develop a public health strategy to assess and minimize the emergence and transmission of HIVDR.

- WHO has developed global HIVDR strategy designed to be fully integrated into country’s routine HIV prevention and monitoring activities.

Goal of the WHO HIVDR Surveillance Strategy

- Promote the long-term effectiveness of available regimens, improve quality of care, and optimize program efficiency

- Using simple, low cost and standardized methods
  - Inform population-based selection of first- and second-line ART regimens
  - Support national programs in minimizing the emergence and transmission of HIVDR
WHO HIV Drug Resistance Surveillance and Monitoring Strategy

- Surveillance of Transmitted HIVDR in Recently Infected Populations
- Monitoring of HIVDR Early Warning Indicators
- Surveillance of pre-treatment HIVDR in Populations Initiating ART
- Surveillance of Acquired HIVDR in Populations Receiving First-Line ART
- Surveillance of HIVDR in Children <18 months of Age
HIVDR Surveillance Framework

Early Warning Indicators (EWI):
why and where is HIVDR likely to be emerging?
What happens if you stop this drug?
Stopping drugs with different half lives

- Drug concentration
- Zone of potential replication
- Last Dose
- Day 1
- Day 2
- MONOTHERAPY
- IC_{90}
- IC_{50}

S. Taylor et al. 11th CROI Abs 131
NNRTI Resistance and Treatment Discontinuation

- Virologic failure was associated with repeated drug holidays.
- Repeated drug holidays was the only risk factor for developing a major mutation

*Parienti et al CID 2004:38:1311-6*
Frequency and Duration of Treatment
Interruptions >48hrs over 24 weeks on Self-pay ART in Uganda

Oyugi AIDS 2007

<table>
<thead>
<tr>
<th>Interruptions ≥ 48 hours</th>
<th>199 interruptions</th>
<th>62 people (64%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean # interruptions/person</td>
<td>2.0 ±2.9 (S.D)</td>
<td></td>
</tr>
<tr>
<td>Mean duration (days) for those who have interruptions</td>
<td>11.5 ±9.2 (S.D)</td>
<td></td>
</tr>
</tbody>
</table>

90% of missed doses were during treatment interruptions. Financial difficulty securing ARVs and drug stock-outs largely accounted for interruptions!!
MEMS-Defined 48 Hour Treatment Interruptions Predict Resistance (Uganda)

<table>
<thead>
<tr>
<th>Interruption</th>
<th>Resistant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes &gt;48 hours</td>
<td>8/62 (13%)</td>
</tr>
<tr>
<td>No</td>
<td>0/33 (0%)</td>
</tr>
</tbody>
</table>

P=0.04

• **Steady and reliable access to medications**, in order to avoid treatment interruptions, will be critical to limiting the development of drug resistance in resource-limited settings.
• Focus on supply and distribution

*Oyugi. AIDS 2007*
What do you see?
There is a lion, but it is good at hiding
Drug resistance can “hide”

Like the lion, you may only know it is there by other indicators
Early Warning Indicators (EWIs)

- EWIs assess factors at individual clinics which are known to create situations favourable to the emergence of HIVDR
- EWIs provide clinic specific information
- EWIs provide necessary program context for interpretation of surveys of HIVDR

Bennett DE et al., Antivir Ther 2008
How are ART clinics and the ART program as a whole performing in minimizing population-level HIVDR?

1. Drug stock out
2. Retention in care
3. VL suppression
4. Adherence
5. Dispensing of triple drug regimens
EWI Reporting: Scorecard

- **Red**: Poor performance, below desired level
- **Amber**: Fair performance, progressing toward desired level
- **Green**: Excellent performance, achieving desired level
- **Grey**: Data not available

A “white” score is assigned only for the retention indicator and only in non-UNGASS reporting years.
## WHO HIVDR EWI Package

<table>
<thead>
<tr>
<th>Early Warning Indicator</th>
<th>Target</th>
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</thead>
</table>
| **1. On-time pill pick-up** | • Red: <80%  
• Amber: 80–90%  
• Green: >90% |
| **2. Retention in care * | • Red: <75% retained after 12 months of ART  
• Amber: 75–85% retained after 12 months of ART  
• Green: >85% retained after 12 months of ART |
| **3. Pharmacy stock-outs** | • Red: <100% of a 12-month period with no stock-outs  
• Green: 100% of a 12-month period with no stock-outs |
| **4. Dispensing practices** | • Red: >0% dispensing of mono- or dual therapy  
• Green: 0% dispensing of mono- or dual therapy |
| **5. Viral load suppression at 12 months #** | • Red: <70% viral load suppression after 12 months of ART  
• Amber: 70–85% viral load suppression after 12 months of ART  
• Green: >85% viral load suppression after 12 months of ART |

* Retention in care definition equal to UNGASS #24 and PEPFAR #T1.3.D; #Targets for virological suppression in children <2 years old; Red <60%; Amber 60–70%; Green >70%
## EWI Site - Specific Results: 2014 Adults

<table>
<thead>
<tr>
<th>Region</th>
<th>Site: Main Sites Outreach Sites</th>
<th>EWI 1: On-Time Pill Pick-Up</th>
<th>EWI 2: Retention</th>
<th>EWI 3: Pharmacy Stock-outs</th>
<th>EWI 4: Dispensing Practices</th>
<th>EWI 5: Virological Suppression Viral Load Completion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>185/212 (87%)</td>
<td>41/61 (67%)</td>
<td>12/12 (100%)</td>
<td>0/212 (0%)</td>
<td>11/20 (55%)</td>
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<tr>
<td>Kunene</td>
<td>Khorixas Hospital</td>
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<tr>
<td></td>
<td>Anichab Clinic (5/7) (71%)</td>
<td>½ (50%)</td>
<td>12/12 (100%)</td>
<td>0/7 (0%)</td>
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<tr>
<td></td>
<td>Anker Clinic (5/6) (83%)</td>
<td>1/1 (100%)</td>
<td>12/12 (100%)</td>
<td>0/6 (0%)</td>
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<tr>
<td></td>
<td>Bersig Clinic (18/19) (85%)</td>
<td>1/1 (100%)</td>
<td>12/12 (100%)</td>
<td>0/19 (0%)</td>
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<tr>
<td></td>
<td>Erwee Clinic (3/3) (100%)</td>
<td>-</td>
<td>12/12 (100%)</td>
<td>0/3 (0%)</td>
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<tr>
<td></td>
<td>Fransfontein Clinic (17/17) (100%)</td>
<td>-</td>
<td>12/12 (100%)</td>
<td>0/17 (0%)</td>
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<tr>
<td></td>
<td>Khorixas Hospital (137/160) (86%)</td>
<td>38/57 (67%)</td>
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<td></td>
<td></td>
<td>341/432 (79%)</td>
<td>123/171 (72%)</td>
<td></td>
<td>0/434 (0%)</td>
<td>2/4 (50%)</td>
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<tr>
<td></td>
<td>Opuwo Hospital</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Epupa Clinic (12/13) (92%)</td>
<td>4/4 (100%)</td>
<td>12/12 (100%)</td>
<td>0/13 (0%)</td>
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<tr>
<td></td>
<td>Etoto Clinic (10/13) (77%)</td>
<td>2/2 (100%)</td>
<td>12/12 (100%)</td>
<td>0/13 (0%)</td>
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<tr>
<td></td>
<td>Okangwati Clinic (15/21) (71%)</td>
<td>1/1 (100%)</td>
<td>12/12 (100%)</td>
<td>0/21 (0%)</td>
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<tr>
<td></td>
<td>Opuwo Hospital (154/184) (84%)</td>
<td>86/120 (72%)</td>
<td>12/12 (100%)</td>
<td>0/185 (0%)</td>
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<tr>
<td></td>
<td>Orumana Clinic (14/28) (50%)</td>
<td>4/8 (50%)</td>
<td>12/12 (100%)</td>
<td>0/29 (0%)</td>
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<tr>
<td></td>
<td>Oruvandjei Clinic (14/21) (67%)</td>
<td>3/5 (60%)</td>
<td>12/12 (100%)</td>
<td>0/21 (0%)</td>
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<tr>
<td></td>
<td>Otjimuhaka Clinic (37/41) (90%)</td>
<td>4/4 (100%)</td>
<td>12/12 (100%)</td>
<td>0/41 (0%)</td>
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<tr>
<td></td>
<td>Otjiu Clinic (5/7) (71%)</td>
<td>1/1 (100%)</td>
<td>12/12 (100%)</td>
<td>0/7 (0%)</td>
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<tr>
<td></td>
<td>Otjiokavare Clinic (11/11) (100%)</td>
<td>1/1 (100%)</td>
<td>12/12 (100%)</td>
<td>0/11 (0%)</td>
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<tr>
<td></td>
<td>Otjondeka Clinic (23/28) (82%)</td>
<td>¾ (75%)</td>
<td>12/12 (100%)</td>
<td>0/28 (0%)</td>
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<tr>
<td></td>
<td>Otuani Clinic (15/18) (83%)</td>
<td>6/7 (86%)</td>
<td>12/12 (100%)</td>
<td>0/18 (0%)</td>
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<td></td>
<td>Sesfontein Clinic (31/47) (66%)</td>
<td>8/14 (57%)</td>
<td>12/12 (100%)</td>
<td>0/47 (0%)</td>
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<td></td>
<td></td>
<td>256/324 (79%)</td>
<td>120/160 (75%)</td>
<td></td>
<td>0/326 (0%)</td>
<td>9/11 (82%)</td>
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<td></td>
<td>Outjo Hospital</td>
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<tr>
<td></td>
<td>Kamanjab Clinic (82/118) (69%)</td>
<td>34/43 (79%)</td>
<td>12/12 (100%)</td>
<td>0/119 (0%)</td>
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<tr>
<td></td>
<td>Okaukuejo Clinic (17/20) (85%)</td>
<td>-</td>
<td>12/12 (100%)</td>
<td>0/20 (0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Outjo Hospital (157/186) (84%)</td>
<td>86/117 (74%)</td>
<td>12/12 (100%)</td>
<td>0/187 (0%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## National EWI Summary 2014 (Adults)

<table>
<thead>
<tr>
<th>EWI</th>
<th>EWI Target for all sites (time period)</th>
<th>Number of sites meeting EWI target (% of sites meeting target) N=X ART sites</th>
</tr>
</thead>
</table>
| EWI 1: On-time ARV Drug Pick–up | Green: >90%  
Amber: 80–90%  
Red: <80%  
(1 Jan 2013 - ) | Green 40/194 (21%)  
Amber 58/194 (30%)  
Red 94/194 (48%)  
Grey 2/194 (1%) |
| EWI 2: Retention in care | Green: >85%  
Amber: 75–85%  
Red: <75%  
(1 Jan 2012 – 31 Dec 2012) | Green 66/194 (34%)  
Amber 47/194 (24%)  
Red 58/194 (30%)  
Grey 23/194 (12%) |
| EWI 3: Pharmacy stock-outs | Green: 100%  
Red: <100%  
(1 April 2013 - 31 Mar 2014) | Green 179/194 (92%)  
Red 15/194 (8%)  
Grey 0/194 (0%) |
| EWI 4: ARV dispensing practices | Green: 0%  
Red: >0%  
(1 Jan 2013 - ) | Green 191/194 (98%)  
Red 1/194 (<1%)  
Grey 2/194 (1%) |
| EWI 5: Virological Suppression | Green >85%  
Amber 70-85%  
Red <70%  
(1 Oct 2013-31 March, 2014) | Green 0/47 (0%)  
Amber 3/47 (6%)  
Red 5/47 (11%)  
Grey 39/47 (83%) |
## National EWI Summary 2014 (Paediatrics)

<table>
<thead>
<tr>
<th>EWI</th>
<th>EWI Target for all sites (time period)</th>
<th>Number of sites meeting EWI target (% of sites meeting target) N=X ART sites</th>
</tr>
</thead>
</table>
| EWI 1: On-time ARV Drug Pick-up | Green: >90%  
Amber: 80–90%  
Red: <80%  
(1 Jan 2013 - ) | Green 54/162 (33%)  
Amber 30/162 (18%)  
Red 77/162 (48%)  
Grey 1/162 (<1%) |
| EWI 2: Retention in care | Green: >85%  
Amber: 75–85%  
Red: <75%  
(1 Jan 2012 – 31 Dec 2012) | Green 60/162 (37%)  
Amber 9/162 (6%)  
Red 24/162 (15%)  
Grey 69/162 (42%) |
| EWI 3: Pharmacy stock-outs | Green: 100%  
Red: <100%  
(1 April 2013 - 31 Mar 2014) | Green 142/162 (88%)  
Red 20/162 (12%)  
Grey 0/162 (0%) |
| EWI 4: ARV dispensing practices | Green: 0%  
Red: >0%  
(1 Jan 2013 - ) | Green 160/162 (99%)  
Red 1/162 (<1%)  
Grey 1/162 (<1%) |
| EWI 5: Virological Suppression | Green >85%  
Amber 70-85%  
Red <70%  
(1 Oct 2013-31 March, 2014) | Green 1/47 (2%)  
Amber 3/47 (6%)  
Red 11/47 (23%)  
Grey 32/47 (68%) |
Summary of EWI Results - Namibia (1)

EWI 1: On-time ARV Pick-up & EWI 2: Retention in care

- There may be data capture issues at certain sites and in certain regions affecting adherence/retention data

- Broad range of adherence and retention rates between sites suggest there may be factors at site-level that are influencing population adherence and retention

- Data suggest many patients may not be picking up pills on time and/or disengaging from care within first 12 months of ART and/or many transferring out without informing site
Summary of EWI Results - Namibia (2)

**EWI 3: Pharmacy stock-outs**
- Few stock-outs reported

**EWI 4: ARV dispensing practices**
- Few inappropriate regimens dispensed
EWI 5: Virological Suppression

- Low VL completion rates at many sites
  - Due to data capture?
  - Actual problem with conducting of VL?

- Low VL suppression rates at many sites
  - Due to biased sample?
  - Data capture problem?
  - Actual problem with VL suppression?
Recommended action plan (1)

EWI 1: On-time ARV pick-up & EWI 2: Retention in care

- Investigate data capture at poorly performing sites
- Investigate sites with poor performance to look for site-level factors contributing to poor population-level adherence and retention

- Ongoing operational research:
  - Defaulter Tracing Study
  - Namibia Adherence Retention Project (NARP)
  - Development AID from People to People (DAPP) tracing
  - Management Science for Health (MSH) Mhealth study
Recommended action plan (2)

**EWI 5: Virological Suppression/Completion**

- Investigate why VL completion rate is so low at many sites
  - Are clinicians not doing VL on all eligible patients?
  - Are clinicians selectively doing VL on sickest patients?
  - Are VL results not being returned to the medical record? Entered into electronic medical records?
  - Other reasons?
EWI monitoring Process

Abstract
- data on EWIs

Analyze data
- Site specific
- National

Pinpoint actions
- Site specific
- National

Reduce HIVDR, optimize care

Genotyping surveys are of limited use without ART programme information on which to base public health action.
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