From '3 by 5' to Treatment 2.0: Catalyzing the Next Phase of Treatment, Care & Support

Revolution or Evolution?
The Public Health Approach: From "Treatment 1.0" to "Treatment 2.0"

- Standardized treatment protocol and simplified clinical monitoring
- Optimal use of available human resources
- Involvement of community members and people living with HIV
- Strategies to minimize cost
- Human rights protected and promoted
Achievements and Challenges: The Numbers Speak for Themselves

- People receiving ART:
  2003: 400,000  
  2009: 5,200,000

- People currently eligible for ART: best guess 16,000,000

- People currently receiving ART: best guess 6,000,000

- Treatment gap: 10,000,000

- UNAIDS and WHO Goal: Universal Access by 2015

- Resource Constraints
What is Treatment 2.0?

- Initiative that aims to achieve universal access by 2015: Catalyze the Next Phase of Treatment, Care and Support

- Key objectives
  - Expand access to quality-assured, rights-based testing, counselling, treatment, care and support
  - Improve efficiency & impact of HIV programmes (HIV & non-HIV health outcomes)
  - Shift HIV treatment from emergency to long-term sustainable programming
  - Stimulate innovation in drugs, diagnostics and service delivery

- UNAIDS/WHO launch of Treatment 2.0: June 2010

- Core component of UNAIDS/WHO Strategies, 2011 - 2015
Principles

- Simplified
- Innovative
- Efficient
- Effective & Cost-effective
- Accessible
- Affordable
- Equitable and protective of human rights
Treatment 2.0 Priorities

I – Optimize **drug regimens**

II – Promote diagnostics using **point of care** and other simplified technologies.

III – Reduce **costs**

IV – Adapt **delivery systems**

V – Mobilize **communities**, protect human rights
Co-Coordination

- **UNAIDS Secretariat:**
  - Broad multi-constituency partnership
  - Global advocacy and leadership on HIV/AIDS
  - Strong country presence and coordination role

- **WHO:**
  - Normative guidance on health issues and technical support to countries (drug optimization, simplified diagnostics, adapting service delivery systems)
  - Direct accountability to ministries of health, HIV in the health sector
  - Prequalification, Essential Medicines, Diagnostics
Influence of WHO guidelines on scale-up of ART in resource limited settings

1996 – ART in industrialized settings
The Dawn of HAART (One World, One Hope): potent ART combination becomes available. “Hit Hard, Hit Early Era”

2002/2003 – WHO guidelines
Treatment costs high, ART toxicity is a concern, health systems are weak “Treat those with greatest need”.
(Treat at CD4 < 200) "The 3 by 5 Initiative"

2006 – WHO guidelines
Access improves, Rx costs lower but late diagnosis as a major barrier.
Treat if CD4 < 200, but consider if < 350
"Commitment to Universal Access"

2010 – WHO guidelines
Evidence mounting to treat earlier and with less toxic regimens. Do no harm and equity as key principles.
“Treat at CD4 <350”

"Treatment 2.0"
Radical simplification and optimization of quality treatment to increase ART access
Adding the benefits of treatment in prevention of new infections

Intl AIDS Conference Vancouver
I. Optimize Drug Regimens (1)

- Reduce pill burden/pill size
- Reduce toxicity
- Minimize drug-drug interactions
- Minimize laboratory monitoring needs
- Safe to use in adults, adolescents, children and pregnant women

- Improve API route synthesis
- Improve drug bioavailability
- Dose reduction
- Use of extended release formulations
- Substitution of drug components
- Co-formulation (FDC or co-blister pack and paediatric formulation)
- Use of new strategies (e.g.: induction-maintenance)

- Improved adherence & clinical outcomes (maximize time on effective 1st line therapy)
- Improved convenience (patient and programme levels)
- Reduced costs (direct and indirect)
I. Optimize Drug Regimens (2)

Expand analysis, advocacy and communications to:

- Mobilize innovator, generic and API companies, public/academic/private foundation research organizations to optimize currently available drug regimens and expand research into new drugs and drug regimens for children and adults (ongoing)

- Communicate expectations for drug regimen optimization to Pre-Qualification Programme and Essential Medicines List Expert Committee (1st quarter 2011)

- Communicate expectations to stakeholders for drug regimen optimization towards 2012/13 ART guidelines (2nd quarter 2011)

- Develop 2013 ART Guidelines

- Expedite access to more effective, affordable drugs through AMDS: market transparency (GPRM) and influence through demand forecasting and expanded analysis
II. Point of Care and Other Simplified Diagnostics

- Convene expert consultation to establish consensus on optimal package of existing and foreseeable POC diagnostics and simplified laboratory platforms for HIV diagnosis and treatment monitoring in children and adults.

- Identify bottlenecks to research, development and delivery and agree on a critical path for moving forward (Q2 2011).

- Communicate through policy statements and rapid advice new developments and standards (from Q2 2011).

- Provide normative guidance for simplified HIV diagnosis (including EID) and treatment monitoring (2012/13).

- Expand analytical and communications activities of AMDS to influence research and market dynamics of HIV diagnostics (from Q2 2011).
III. Reduce Costs

- Generic drugs (mostly 1st line): reduce costs of Active Pharmaceutical Ingredients (APIs)
- 2nd and 3rd line (mostly) patented drugs and diagnostics costs: reduce prices by improving price competition and increasing use of TRIPS flexibilities
- Procurement and supply chain costs
- Non-commodity costs: greater frontline service delivery through community systems, simplified monitoring tests, task shifting - non-drug costs account for 60-80% of treatment costs
- Less hospitalization, absenteeism and out-of-pocket expenses through early treatment
IV. Adapt Delivery Systems (1)

- Expand HIV testing and counselling (health sector and community-based)
- Decentralize treatment initiation
- Task-shifting for delivery (primary health centres and community systems)
- Shift away from stand-alone ART services (integration with primary care and other services)
- Strengthen procurement and supply systems
- Impact and cost-effectiveness of community based service delivery
IV. Adapt Delivery Systems (2)

Expand normative guidance to include service delivery

- Create a reference panel of programme managers, community practitioners and other experts on existing decentralized, integrated ART programmes to guide work (Q2 2011)

- Communicate goals and objectives to stakeholders (Q2 2011 and beyond)

- Use key outcomes framework (HIV, non-HIV, cost, equity/human rights protections, HSS and security) to analyze current evidence on decentralized, integrated ART service delivery in a variety of epidemiological contexts (to be completed Q4 2011)

- Identify gaps in evidence and drive research to advance evidence base (Q4 2011 and beyond)

- With partners, implement AMDS early warning indicators for stock outs

- Produce and disseminate global recommendations/guidelines for decentralized, integrated service delivery for adaptation at national level (2013)
V. Mobilize Communities

- Strengthen demand side for treatment through treatment literacy, advocacy, communications
- Community-based testing and counselling
- Involvement in design and delivery of care and treatment programmes
- Design and delivery of enabling/support services, including advocacy on promoting/protecting human rights
Globally

- UNAIDS/WHO & Global Partners: Endorsement of Treatment 2.0, developing Blueprint for release in conjunction with IAS 2011 in Rome outlining timeframes, key activities to 2015 and beyond

- WHO: normative guidance process (towards “Treatment 1.5 guidelines” and “Treatment 2.0 guidelines”), engaging multiple stakeholders
  - Emphasis on Drug Regimens, Diagnostics and Monitoring, Service Delivery

- Expand strategic information through AMDS to influence market transparency and dynamics, link with Prequalification, Essential Medicines and Essential Health Technologies

- Provide technical assistance to countries to implement next phase of scale-up, including support to amend national legislation to make use of TRIPS flexibilities.
Treatment 2.0: Collaboration & Partnership

Country level

- Adapt WHO normative/technical guidance
- Expand access to HIV testing, counselling services
- Expand/optimize tx and simplified diagnostics for adults/paeds
- Reduce co-infections/co-morbidities among PLHIV
- Decrease TB burden among PLHIV
- Reduce costs of programming
- Positive Health, Dignity & Prev for PLHIV
- Collect/report data (intervention coverage, impact)