1. Drug Treatment Regimens:

How and why WHO makes its global recommendations

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2. WHO Drug Treatment Regimens

- Why WHO needed to make recommendations and to set global norms and standards
- How WHO set about doing this
- Consider how successful or not WHO's work has been in ART scale-up so far
- Revised (2008) WHO processes for making recommendations and issuing guidance

3. “Three by Five”

2002 / 2003: GFATM and PEPFAR established and resourced

The target: three million people on treatment by the end of 2005

The goal: universal access to antiretroviral therapy (ART) as a human right to health to all in need

The treatment gap was declared a global health emergency
Sept 22nd, 2003 at UN General Assembly

4. Filling the treatment gap

- WHO entered “emergency mode”
- Defined the extent of the problem
  - end 2002, estimated 300,000 on ART
  - 91% of treatment gap in 34 countries
- Recognised the extent of the challenge
  - New intervention with limited experience
  - Countries most in need had weakest health systems
  - Prevailing view: ART was complex and specialised

5. Delivering on 3 x 5

WHO’s strategy: to catalyse rapid uptake of ART in communities where it is needed now but not widely accessible by adopting a two-pronged approach:
Simplifying and standardizing ART as far as possible without compromising effectiveness so it can be universally scaled up and delivered in resource-constrained settings

Supporting countries to recognise and respond to their HIV/AIDS treatment gap and leveraging the necessary resources to enable ART to be scaled up rapidly in line with 3x5 target

6 Public Health ART Strategy

**Vision:** Universal access to ART

**Elements:**
- One global standard of care for ART
  - One first-line then one second-line regimen (then stop)
  - Sequential use of 3 drug classes
  - Simple recommendations for when to start switch & toxicity substitutions
  - Tiered laboratory support for clinical decision-making
  - Standard population-based HIVDR monitoring and surveillance
  - Pharmacovigilance/toxicity monitoring
- Chronic disease management
- Integrated and decentralised care

**Process:** Evidence-based
  - Simplification
  - Standardisation

7 Harmonised ART

Policy Guidance

(Slide show 4 images of report covers)

8 Audience for guidelines

- Primarily national planners and policy makers engaged in public sector ART and in target-setting
  - What ARVs to make available in public sector first and second-line regimens
  - How to use: the four Ss of clinical management: when to start, substitute, switch and stop
- Care implementers - basic knowledge to use ARVs effectively according to national policy recommendations
- Trainers, M&E experts – to design appropriate tools and materials to support national policy recommendations

9 Slide shows Image of “Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, January 29, 2008"

10 Slide shows 1st and 2nd Line ARVs for Adults

11 When to Start – adults

(Slide shows Table of Recommendations for initiating ART in adults and adolescents based on clinical stage and availability of immunological markers)
12 Slide shows diagram of Failure / When to Switch
13 Slide shows “When to Switch from 1st Line to 2nd Line ARV Regimens for Treatment Failure
14 Slide shows image of article titled “Outcomes from monitoring patients on antiretroviral therapy in resource-limited settings with viral load, CD4 cell count, or clinical observation alone: a computer simulation model”
15 Slide shows “The WHO HIVResNet is a global group of experts, laboratories, and organizations constituted to support HIVDR prevention, surveillance, and monitoring as antiretroviral treatment (ART) is rolled out worldwide.”

16 Universal Access
Slide shows picture of world leaders.
17 Slide shows bard chart of Number of people receiving antiretroviral therapy in low- and middle-income countries, 2002-2007
18 Slide shows bar chart of Progress has been made with children
19 Revised simplified dosing
   (slide shows table image of drugs and amounts)
20 Slide shows chart of Weight-for-Age Boys
21 Revised (2008) WHO process
   • New WHO Guideline review committee
   • Revised WHO guidelines for guidelines
   • Minimum standards for:
     ✓ Reporting
     ✓ Processes
     ✓ Use of evidence
   • Different types of guidance documents recognised to fit different purposes:
     E.g. Emergency, Standard, Full , ‘Books ’ joint guidelines?
22 Quality of evidence – GRADE approach
   Slide shows table results
Strength of a recommendation
Slide shows table of factors and comments

Conclusions
• Developing WHO drug treatment regimens is challenging – but can have great impact

• Balance between
  – being permissive; driving ART agenda forward
  – maintaining relevance to all countries

• Processes updated in WHO (GRADE)
  – Even more rigorous and transparent
  – Costs and feasibility