

## 1 Drug Treatment Regimens:

How and why WHO makes its  
global recommendations

Prof Charles Gilks

Director, Co-ordinator  
Antiretroviral Treatment and Care  
Department of HIV/AIDS  
WHO Geneva.

## 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

(ART) as a

The **goal**: universal access to anti-  
human right to health to all in need

retroviral therapy

The treatment gap was declared a global health emergency  
Sept 22<sup>nd</sup>, 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 1<sup>st</sup> and 2<sup>nd</sup> 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 1<sup>st</sup> Line to 2<sup>nd</sup> 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 bar 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

- 23  Strength of a recommendation  
Slide shows table of factors and comments

- 24  **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