

# Global HCV Access to Care:

## Key priorities

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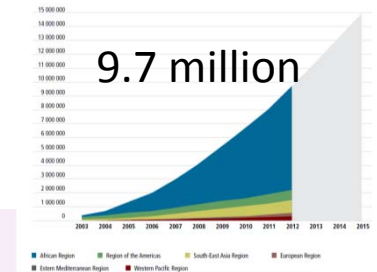
World Health  
Organization

# Shared initial barriers to increasing treatment access: HIV, HCV and HBV

Barrier	HIV	HCV	HBV
Limited data on epidemiological situation	✓	✓	✓
High stigma and discrimination	✓	✓	✓
Lack of political and financial commitment	✓	✓	✓
Complexity of drug regimens, high pill burden Side effects that complicate adherence	✓	✓	
Complexity of screening, treatment and follow-up monitoring	✓	✓	✓
High cost of drugs and tests	✓	✓	✓
Lack of treatment guidelines for LMICs	✓	✓	✓
Highly specialized vertical services	✓	✓	✓
Limited patient and community engagement	✓	✓	✓

Adapted from Y. Lo, 2014

# Some key lessons from ART scale-up



## I. Treatment guidelines

I. Guiding principles of “Public health approach” + “health equity”

## II. Simplification

I. Drug regimens

II. Diagnostics and monitoring

III. Models of service delivery and testing

III. Global funding initiatives

IV. Reduction in drug costs through generic competition

V. Key role of community and engagement of PLHIV

VI. Forecasting for programme planning

VII. Surveillance systems and monitoring tools

VIII. Research and trial networks in LMICs

# Improving access to HCV diagnosis and treatment: What is WHO doing?

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## 1. HCV Treatment and Screening Guidelines

### 1. WHO Essential Medicines list

### 1. WHO Prequalification program

- Diagnostics: HCV rapid diagnostic tests and cross-platform RNA
- Generic medicines



# WHO management guidelines: Distinctive features

Feature	WHO Guideline	Other Guidelines
APPROACH	Public health approach	Individualised treatment
TARGET AUDIENCE	National Programme managers	Treating Clinicians
SETTINGS	Low and middle income countries Generalised/Concentrated	High income countries
CONSOLIDATION	Across ages, populations Across continuum of care Clinical, operational, programmatic	Clinical Separate Adult and paediatric
EVIDENCE-BASED GRADE APPROACH	Quality of evidence Benefits and harms Values and preferences Resource use Feasibility+ Equity	Variable use of evidence- based framework (feasibility, equity, resource use not considered)

**GRADE**

# Guiding Principles

## The “Public health approach” and health equity

### “Public health approach” seeks to:

- **Simplified** and **standardized** approaches to ensure the **widest possible access** to high-quality services at the population level
- Strike a balance between implementing the best-proven standard of care and what is **feasible on a large scale** in resource-limited settings

### Promotion of “health equity and human rights” so that:

- Expanded access is **fair and equitable**
- **Priority** for treatment given to those **most in need**
- In environment **free of stigma and discrimination**

### The WHO public-health approach to antiretroviral treatment against HIV in resource-limited settings

Charles F. Gillis, Siobhan Crowley, René Ekpini, Sandy Gave, Jos Perriens, Yves Souteyrand, Don Sutherland, Marco Vitoria, Teguest Guerra, Kevin De Cock

WHO has proposed a public-health approach to antiretroviral therapy (ART) to enable scaling-up access to treatment for HIV-positive people in developing countries, recognising that the western model of specialist physician management and advanced laboratory monitoring is not feasible in resource-poor settings. In this approach, standardised simplified treatment protocols and decentralised service delivery enable treatment to be delivered to large numbers of HIV-positive adults and children through the public and private sector. Simplified tools and approaches to clinical decision-making, centred on the “four Ss”—when to start drug treatment; substitute for toxicity; switch after treatment failure; and stop—enable lower-level health-care workers to deliver care. Simple limited formularies have driven large-scale production of fixed-dose combinations for first-line treatment for adults and lowered prices, but to ensure access to ART in the poorest countries, the care and drugs should be given free at point of service delivery. Population-based surveillance for acquired and transmitted resistance is needed to address concerns that switching regimens on the basis of clinical criteria for failure alone could lead to widespread emergence of drug-resistant virus strains. The integrated management of adult or childhood illness (IMA)/(MCI) facilitates decentralised implementation that is integrated within existing health systems. Simplified operational guidelines, tools, and training materials enable clinical teams in primary-care and second-level facilities to deliver HIV prevention, HIV care, and ART, and to use a standardised patient-tracking system.

Lancet 2006; 368: 595-10  
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# Simplified drug regimens

## Approach used in HIV

- Limited number of preferred first-line regimens
- Available as fixed-dose combinations (Decrease pill burden/increase adherence)
- Simplified procurement and drug supply



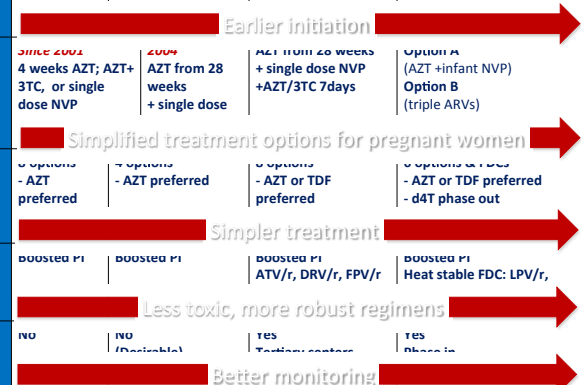
## Relevance to HCV/HBV

- Potential to limit number of preferred regimens
- Alternative regimens for special circumstances
  - Different genotypes
  - Null responder
  - Treatment-experienced

Evolution of WHO ART Guidelines

Vitoria M et al, Curr Opin HIV/AIDS 2013

TOPIC	2002	2003	2006	2010
WHEN TO START	CD4 ≤ 200	CD4 ≤ 200	CD4 ≤ 200 - Consider 350	CD4 ≤ 350 - Irrespective CD4 for TB &
PMTCT	<del>Since 2004</del> 4 weeks AZT; AZT+3TC, or single dose NVP	<del>2004</del> AZT from 28 weeks + single dose	<del>2006</del> AZT from 10 weeks + single dose NVP +AZT/3TC 7days	Option A (AZT +infant NVP) Option B (triple ARVs)
1 <sup>ST</sup> LINE	- AZT preferred	- AZT preferred	- AZT or TDF preferred	- AZT or TDF preferred - d4T phase out
2 <sup>ND</sup> LINE	boosted PI	boosted PI	boosted PI ATV/r, DRV/r, FPV/r	boosted PI Heat stable FDC: LPV/r,
VIRAL LOAD TESTING	NO	NO (Dedicated)	YES Tertiary centers	YES Phase in



# Innovative and **simplified** diagnostics



## Approach used in HIV

- **Innovation in diagnostics**
  - Rapid tests
  - Point-of-care CD4 and VL
  - Dried blood spots (DBS) DNA + RNA
- **Simplified monitoring- clinical**
  - Access to lab tests should not be a barrier to treatment
- **Prequalification** of HIV screening assays

## Relevance to HCV/HBV

- **Evaluate potential innovations in diagnosis and staging:**
  - Qualitative PCR
  - PoC assays + DBS
  - Use of HIV Lab platforms and facilities
- **Evaluate potential for simplified monitoring**
  - Non-invasive assessment of fibrosis
- **Establish Prequalification** system for rapid diagnostic tests and cross-platform RNA ± DBS



# Simplified service delivery and testing models



## Approach used in HIV

- **Decentralization** of services to primary care level supports access and retention in care
- **Integration** of HIV/ART care into TB, MNCH settings and OST services
- **Task shifting** of roles to nurses and other HCW
  - Training programmes and curricula

## Relevance to HCV/HBV

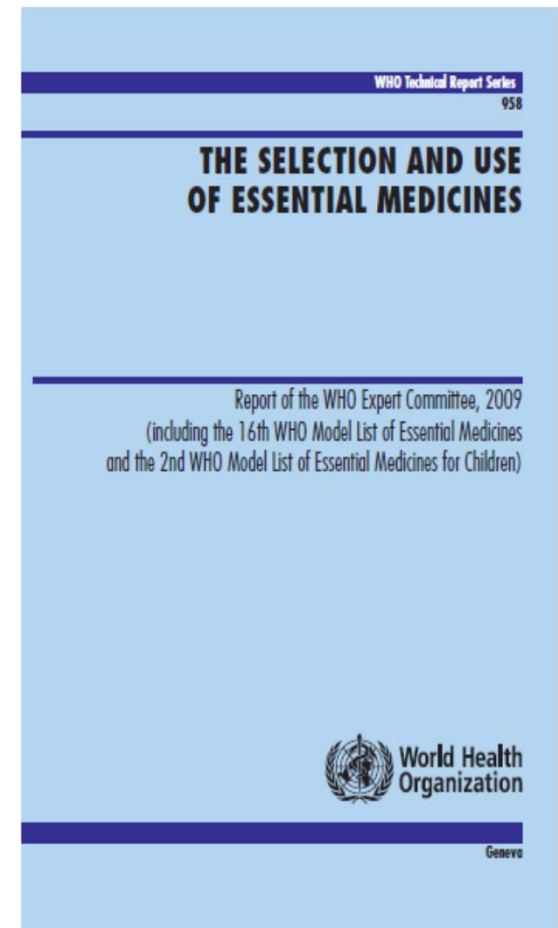
- **Develop, adapt + evaluate** different models of **decentralised** and **integrated** care
  - Prison health services, needle exchange and OST programmes
  - Pilot and demonstration projects in HIV care settings (AmFar and MSF)
- Develop **HCV/HBV treatment training** programmes + curricula



# WHO Essential Medicine List (EML)

## Inclusion of PEG-IFN + Ribavirin

- Revised every two years: 2013: Contains more than 400 medicines
- **Essential medicines are**
  - those that satisfy priority health care needs of the population
  - Selection criteria: Disease prevalence, efficacy and safety, and comparative cost-effectiveness
- Anybody can file application: PEGIFN was included in 2013 based on application filed by MSF
- 156 countries have national list of essential drugs: 81% have been updated in last 5 years

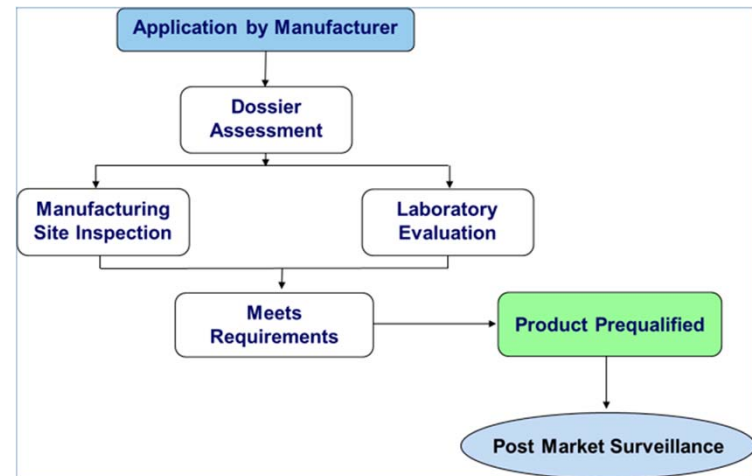


# WHO “Pre-qualification” quality assurance program

**Mission:** make quality priority medicines and diagnostics available for those in need; extends to medicines, vaccines, diagnostics, API and laboratories

Adding products to treat hepatitis (generic DAAs, biosimilars, diagnostics) is possible, **but**

- medicines need to be on EML or in treatment guidelines; requests from disease programmes needed
- an international procurement agency has to require prequalification



	RDT	EIA	Other	Total
HCV	5	10	3	18
HBsAg*	8	6	0	14
HCV molecular	None, but 3/5 HIV molecular tests WHO PQ across 4 platforms, suitable for HCV quantitative RNA			

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# Thank you

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