Modelling for Decision-Making in the Era of ARVs for Prevention

Comment to “Epidemiology and Economics: Modelling the Scenarios for End of AIDS”, by R Granich

TasP Summit

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Carlos F. Cáceres, MD, PhD
Cayetano Heredia University, Lima

UNIDAD DE SALUD, SEXUALIDAD Y DESARROLLO HUMANO
Universidad Peruana Cayetano Heredia
Facultad de Salud Pública y Administración Carlos Vidal Layseca

Key Messages

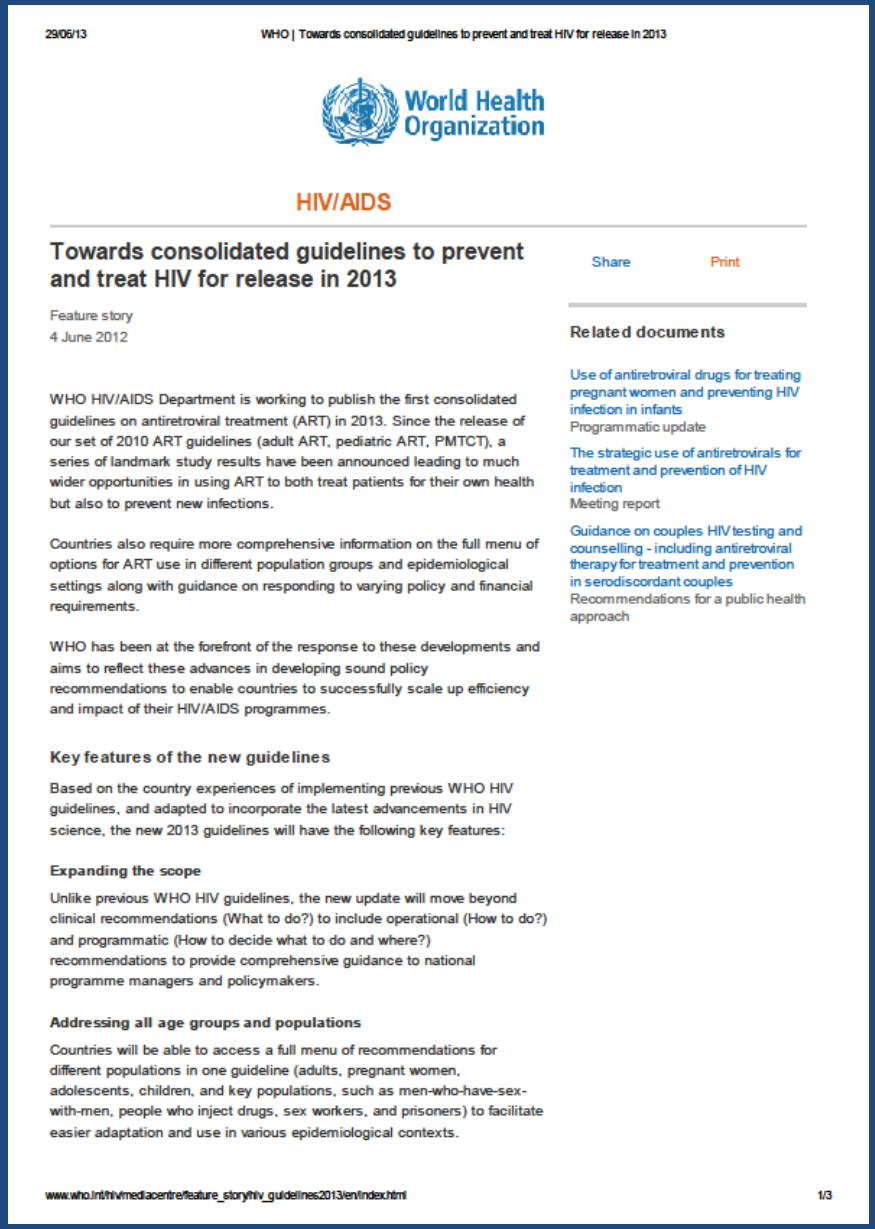
- ARV-based prevention of sexual transmission (mainly preventive effects of treatment and PrEP) represents now a key component of combination prevention.
  - **However, the field is changing quickly – what was 'early treatment for prevention' a few months ago is now 'treatment'.**
- Decisions must be taken about priorities in prevention and care, and modelling can help.
  - **Just remember that modelling is a fantastic tool that depends on our hypotheses and parameters.**
- Evidence to develop our models is more necessary than ever
  - **It must come from several fields and consider scenarios with diverse levels of success.**
  - **Global collaboration to supply such evidence is needed.**

On Modelling in the HIV Field

- Modelling has been broadly used.
- Very useful in retrospective evaluations
  - Check whether observed patterns are consistent with a specific hypothesis
  - Model parameters are better known
- Modelling the future: less straightforward
  - Parameters also less certain
  - e.g. Expectations about VMMC
- Models must consider barriers and less than ideal scenarios/parameters

New Consolidated Guidelines For the use of Antiretroviral Drugs for Treating and Preventing HIV Infection

Launched in IAS 2013,
in Kuala Lumpur, June 2013.



World Health Organization

HIV/AIDS

Towards consolidated guidelines to prevent and treat HIV for release in 2013

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Feature story
4 June 2012

WHO HIV/AIDS Department is working to publish the first consolidated guidelines on antiretroviral treatment (ART) in 2013. Since the release of our set of 2010 ART guidelines (adult ART, pediatric ART, PMTCT), a series of landmark study results have been announced leading to much wider opportunities in using ART to both treat patients for their own health but also to prevent new infections.

Countries also require more comprehensive information on the full menu of options for ART use in different population groups and epidemiological settings along with guidance on responding to varying policy and financial requirements.

WHO has been at the forefront of the response to these developments and aims to reflect these advances in developing sound policy recommendations to enable countries to successfully scale up efficiency and impact of their HIV/AIDS programmes.

Key features of the new guidelines

Based on the country experiences of implementing previous WHO HIV guidelines, and adapted to incorporate the latest advancements in HIV science, the new 2013 guidelines will have the following key features:

Expanding the scope

Unlike previous WHO HIV guidelines, the new update will move beyond clinical recommendations (What to do?) to include operational (How to do?) and programmatic (How to decide what to do and where?) recommendations to provide comprehensive guidance to national programme managers and policymakers.

Addressing all age groups and populations

Countries will be able to access a full menu of recommendations for different populations in one guideline (adults, pregnant women, adolescents, children, and key populations, such as men-who-have-sex-with-men, people who inject drugs, sex workers, and prisoners) to facilitate easier adaptation and use in various epidemiological contexts.

Related documents

Use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants
Programmatic update

The strategic use of antiretrovirals for treatment and prevention of HIV infection
Meeting report

Guidance on couples HIV testing and counselling - including antiretroviral therapy for treatment and prevention in serodiscordant couples
Recommendations for a public health approach

WHO Guidelines – 'early treatment for prevention' is now treatment

- As a priority, ART should be initiated in all individuals with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and individuals with CD4 count ≤350 cells/mm3 (strong recommendation, moderate-quality evidence).

- ART should be initiated in all individuals with HIV with CD4 count >350 cells/mm^3 and ≤ 500 cells/mm3 regardless of WHO clinical stage (strong recommendation, moderate-quality evidence).

- ART should be initiated in all individuals with HIV regardless of WHO clinical stage or CD4 count in the following situations:
  - Individuals with HIV and active TB disease (strong recommendation, low-quality evidence).
  - Individuals coinfected with HIV and HBV with evidence of severe chronic liver disease (strong recommendation, low-quality evidence).
  - Partners with HIV in serodiscordant couples should be offered ART to reduce HIV transmission to uninfected partners (strong recomm., high-quality evid.).

Modelling a Moving Target

- Additional difficulty: 'TasP' is a changing concept; moreover, it is used with different meanings:
  - ARV between 350 and 500 CD4?
    - It is now *treatment* (WHO)
    - Countries still to adopt this guideline
  - ARV over 500 CD4?
    - Completely different discussion (as of now).
    - Strategy to avoid missing newly diagnosed cases?
  - Prevention effects of *any* ARV treatment?
    - Much broader connotation.
  - ARVs for prevention, including in uninfected people?
    - E.g. PrEP → Even more so.

WHO Guidelines: PrEP Demo Projects

In July 2012 WHO released recommendations for Demonstration Projects focused on PrEP.

- "In countries where HIV transmission occurs in serodiscordant couples and additional HIV prevention choices for them are needed, daily oral PrEP (TDF or TDF-FTC) may be considered"
- "In countries where HIV transmission occurs among men and transgender women who have sex with men and additional HIV prevention choices for them are needed, daily oral PrEP (specifically TDF-FTC) may be considered."

  It is currently not possible to provide definitive guidance on how best to deliver daily oral PrEP, for which demonstration project research is needed.

Some Barriers for Achieving Potential Impact of Treatment on Prevention

- Countries to adopt new guidelines
- Considerable ARVT coverage gaps
  - Particularly among KAPs
- Health systems preparedness
- Financing increased costs
- Partner notification issues (for prioritisation)
- Structural components neglected
  - Limited understanding of their operation
- Effectiveness not guaranteed unless targeting, quality and coverage are adequate

Some Barriers for Implementing PrEP

- Health systems limitations
  - Cost and potential competition with treatment
  - Capacity to increase testing and monitor use
- Acceptability issues – still substantial
  - Beneficiaries: Information and adherence
  - Providers: Use of ARVs in uninfected individuals
  - Decision makers: Skepticism about cost & efficiency; errors in PrEP prescription to HIV+ individuals; low adherence and risk compensation

A Network for Multidisciplinary Studies in ARV-Based Prevention (NEMUS)

Seeking the convergence of a number of groups around the world interested in policy, social science, cost/cost-effectiveness, modeling and/or demonstration projects around ARV-based prevention.

1. Discuss opportunities and challenges for implementation of ARV-based prevention, based on existing as well as new evidence generated by individual projects.
2. Foster collaboration in ongoing studies, with a focus on potential comparison of the results of similar studies across countries, and diversification of studies to cover various dimensions/models
3. Develop concepts and resources for collaboration in the design and implementation of potentially useful studies around ARV-based prevention scale-up, including the perspectives of the social sciences, economics, policy, bioethics and other
4. Communicate findings and lessons learned to global stakeholders.

In collaboration with WHO

World Health Organization

Potential Research Questions

- Policy

  Who are the stakeholders? Are they aware? What are their perspectives? What is the focus of disagreement? Is it feasible to seek consensus? What kind of consensus can be reached?

- Health Systems and Cost/Cost-Effectiveness

  Are services prepared to offer ARV-Based prevention? What needs to be implemented and what is the cost? Is the proposed programme anticipated to be cost-effective and sustainable? Can the necessary levels of coverage and adherence be reached? Who should be prioritised?

- Social Science

  How will people react to introduction of new strategies? Is it likely that they will be transformed by users? What will happen to other sexual practices? Is there a possibility of stigmatization of users? Will new strategies have an overall positive impact on communities?

- Bioethics

  Who (and how) should decide the inclusion of each of these measures, if universal access to treatment has not been reached?

NEMUS: Initial Steps

- Inception phase - March-August 2013:
  - Small meetings at CROI, IAS and ASSHH – informal discussions led to expressions of interest about this effort; interest list
- Next phase will consider (in collaboration w/ partners):
  - Facilitation of effective communication/exchanges across researchers, policy makers, activists and others.
  - Contribution to the research agenda
  - Support in dissemination among stakeholders, global and local decision-makers
- Contact: carlos.caceres@upch.pe