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## **INFORMATION BRIEF ON THE *LANCET* ARTICLE:**

### ***'UNIVERSAL VOLUNTARY HIV TESTING WITH IMMEDIATE ANTIRETROVIRAL THERAPY AS A STRATEGY FOR ELIMINATION OF HIV TRANSMISSION: A MATHEMATICAL MODEL'***

In November 2008, an article was published in the renowned medical journal, the *Lancet*. The article was welcomed by HIV activists, healthcare workers, scientists and officials at organizations like UNAIDS and the World Health Organization (WHO) because of the remarkable potential of its results. Based on computer modeling, the authors argued that universal HIV testing, followed by the immediate initiation of ART for those who were HIV-positive, could virtually eliminate HIV transmission in the future and reduce the number of people developing AIDS by 95%. This information brief includes a discussion of:

1. The *Lancet* article itself and TAC's response to the article (from a press statement released in December 2008, available on the TAC website).
2. The responses of various experts to the article, published as letters, also in the *Lancet*.
3. The responses of HIV activists and other health experts to the article, written in a series of emails just after the article was published.

#### **1. THE *LANCET* ARTICLE AND TAC'S RESPONSE**

The article, 'Universal voluntary HIV testing with immediate antiretroviral therapy as a strategy for elimination of HIV transmission: a mathematical model' is co-authored by Reuben Granich, Kevin de Cock and Charlie Gilks. The authors of the article are leading members of World Health Organization (WHO) HIV and TB team, but the study is an independent work that has not been endorsed by the WHO.

The authors argue that current HIV prevention efforts may reduce incidence but are unlikely to eliminate the disease. The article proposes that universal

voluntary testing and the immediate initiation of ART upon determining HIV-positive status will lead to the elimination of HIV. Elimination would mean that the number of secondary infections resulting from the primary infection would be below 1. Elimination would measure HIV incidence as less than 1 new case per 1000 people per year.

The authors use a mathematical model to determine the long-term effects on the epidemic of universal voluntary testing and immediate initiation of ART. The model uses data from South Africa as a test case of a country with a generalized epidemic. The authors use models to explore the effects of various treatment strategies and to measure the potential impact of universal testing and immediate initiation of ART for all those who test HIV-positive. The authors conclude that the dual strategy of universal testing and immediate initiation of ART for all those who test HIV-positive could reduce HIV prevalence to less than 1 per 1000 by 2016.

The authors argue that ART should be used as life saving treatment for HIV-positive people, and *also* as a **public health strategy to prevent new infections**. Because ART reduces the high viral load of an HIV-positive person, it therefore makes it more difficult to transmit the virus to another person.

The authors argue that, for ART to prevent transmission, patients must be initiated onto treatment as early as possible. This means that it is vital that people know their status, and will be achieved by annually testing of all individuals over the age of 15.

The cost analysis of the theoretical strategy shows that the initial cost of implementation will be almost three times greater than the present global strategy of ART treatment. But the article argues that the theoretical strategy will vastly reduce costs in the long term. The costs of the present strategy and the theoretical strategy would both be \$1.7 billion in 2032, after which the authors argue that the cost of the theoretical strategy would decline while cost for the present strategy would continue to increase.

The authors stress that the prevention of transmission through the use of ART should be combined with current methods of prevention including condoms, circumcision, STI treatment and changing sexual behaviors. The authors also stress that there is more research that needs to be done to assess the feasibility of universal testing and immediate treatment. The authors highlight that 'better data is needed for the acceptability and uptake of universal voluntary HIV testing, the infectiousness of people receiving ART, adherence, behavior change after initiating ART, and the rates of emerging resistance'.

### **TAC's Response:**

TAC noted the innovative research conducted by the authors of the article, and welcomed its positive findings. TAC also stated that:

1. Further research must be done to determine long-term effects and feasibility of universal voluntary testing and immediate ART. Important questions arising from the article include:

- What are the impacts of initiating immediate life-long ART for all HIV-positive people, irrespective of disease stage?
- How can methods of ART adherence be improved?
- How viable is annual, universal HIV testing, and how acceptable would it be to populations?
- How feasible is universal ART?
- How can methods of ART adherence be improved?
- How will sexual behavior be influenced?

2. Some of the study's assumptions about the efficacy and potential scale-up of prevention mechanisms are very ambitious.

- Will the already over burdened public health programs in developing countries be able to scale up this quickly and efficiently?

3. The sums necessary to support the strategy are beyond the means of poor countries.

- Will wealthy countries fund these programmes, especially in light of the current global economic situation?

4. Current prevention strategies must not be undermined. TAC's policy on prevention is based on measures which are proven to be effective and are relatively easy to implement. These include the use of condoms and clean needles, ARVs for PEP and PMTCT.

## 2. CRITICAL RESONSES PUBLISHED IN THE LANCET

The *Lancet* recently published a series of letters from experts in response to the original article on universal testing and treatment. This is a summary of the criticisms of the article written by various authors:

i. The authors of the original article made numerous **unrealistic assumptions**. They assume that:

- HIV-positive infected people will reduce their risk behaviour by an average of 40%;
- Second-line regimens are immediately accessible after first-line regimens;
- ART will reduce infectiousness by 99% (D. Wilson)
- There will be a yearly drop out rate of only 1.5%. This is very optimistic.

It will be very hard, if not impossible to universally test everyone due to resource constraints:

- In order for the study to be successful in reality there needs to be strong health systems, adequate human resources and a continuous supply of commodities. These are not available in many sub-Saharan countries.
- Recommendation: 'High yield' – 'high impact' testing by target testing those at most risk in the population rather than attempting to universally test everyone (Y. Assefa & M. Lera).
- Stigma and discrimination have been neglected as a barrier to implementation. Both of these block access to testing and treatment significantly (R. Jurgens et al).

ii. Little is known about the **long-term impact of ART** (M. Cohen, T. Mastro and W. Cates):

- The benefits cited in the study are generalized from the individual to the population.
- Infectivity may be reduced, thereby benefiting the population, but not enough research has been conducted on the risks and benefits of beginning ART with a CD4 count above 350 (H. Jaffe, A. Smith & Hope, T).

iii. There are **methodological flaws** in the study:

- The authors argue that the HIV eradication phase will only be possible if ART begins when the CD4 count is 1150 cells per micro litres - this is impossible because in Africa the average CD4 count immediately after seroconversion is 884 cells per micro litres.
- The model estimates that on average an individual has 8 sexual partners a year. This is very different to a South African survey which suggests that people tend to have far fewer sexual partners a year (A. Ruark et al).
- The model does not take into account HIV transmission between long-term overlapping partners which accounts for a substantial amount of HIV transmission (H. Epstein).
- The study is based on testing once per year. This neglects those in the acute stage of infection (D. Wilson and M. Cohen, T. Mastro and W. Cates). People who are in the acute infection stage cannot be detected by a test. This population may contribute significantly to the spread of HIV. There is therefore a need for more frequent tests and improvements in acute testing (Y. Hen Hsieh & H. Arazoza).

### **3. RESPONSES DISCUSSED IN EMAILS BETWEEN ACTIVISTS AND OTHER HEALTHCARE EXPERTS**

### **Support for the model:**

Although there was no resounding support for annual mandatory universal testing, many correspondents recognised ARVs as an effective treatment approach in localised settings.

Correspondents argued that the underlying premise of the article was more important than the suggested mathematical model, and that aggressive approaches to testing and treatment may present a glimmer of hope in the global AIDS response by offering better treatment to individuals, reducing the spread of HIV and preventing morbidity and mortality attributed to HIV infection.

Some correspondents argued that, although HIV prevention and treatment access is increasing on a global scale, WHO Guidelines are still not being met. Other avenues towards the global AIDS response have been closed. New information that presents the possibility of a solution to HIV epidemic must be seriously considered and researched.

### **Opposition to the model:**

Correspondents argued that the article lacked insight into:

- Ethical issues and practical barriers surrounding universal, mandatory testing.
- The influence of factors that impeded access to HIV services, such as stigma, discrimination and human rights violations.

The debate focused on the **human rights implications** of the implementation of universal mandatory testing, the potential criminalisation of HIV transmission, and the lack of consideration given to the negative outcomes proven to be associated with universal mandatory HIV testing.

Correspondents argued that the article put the benefits of public health ahead of those of the individual patient's, irrespective of associated costs.

Correspondents also argued that huge assumptions were made by the authors surrounding the risks associated with cost, human resources, drug-resistance, adverse events, secure access to testing facilities, adherence and monitoring.

The potential for over-testing, over-treatment, side-effects, resistance and the reduced autonomy of the individual in their choices of care were also identified as issues that were overlooked in the article.

Emphasis was put on the need for clinical trials and a greater assessment of how scaling-up would affect drop-out, treatment failure and death rates if such a model had any hopes of being used in the future.

## **Suggestions**

The majority of correspondents insisted that stigma, discrimination and peoples' rights should be the primary concern of those involved in the prevention and treatment of HIV. The need for innovative prevention options was highlighted because, despite intensive prevention programmes, HIV transmission continues to occur. Though there were suggestions that more effort should be put into interventions that are known to work, 'already-proven' HIV prevention approaches were largely criticised for not addressing what puts people at risk of HIV. The scaling-up of testing and counselling as well as access to ART beyond current efforts was stressed as the most practical solution for the future.

Overall, it was agreed upon that innovative methods must be established to get more people voluntarily tested and into services while protecting rights.

## **Moving forward**

Policy, Communications and Research (PCR) district staff members, in consultations with their district co-ordinators, will hold briefings with district offices to discuss the *Lancet* article and its meaning, as outlined in this document. The PCR district staff member will take notes on the responses of TAC staff members to the article, and will write a report on these to be submitted to district co-ordinators, provincial co-ordinators and the national PCR department by 6 May.

The AIDS and Rights Alliance of Southern Africa (ARASA) and the Open Society Initiative for Southern Africa (OSISA) have organized an activist meeting in Johannesburg from 28 April – 30 April, and representatives from a range of health advocacy groups in Southern Africa will attend. Mark Heywood, Nokhwezi Hoboyi and Rebecca Hodes will represent TAC at this meeting, where the implications of the *Lancet* article will be discussed in detail and a position formulated on behalf of HIV activists and health advocates in Southern Africa.

From 5 – 7 May, HIV activists from Southern Africa will attend a WHO consultation in Geneva, at which the response of international health institutions to the *Lancet* article will be formulated, together will a possible programme of action. The results of this meeting will be communicated to TAC staff.

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