

# **GRAND ROUNDS**

## **HIV Center for Clinical and Behavioral Studies**

**New York State Psychiatric Institute and Columbia University**

### **“Research and Policy: Sometimes the Twain Shall Meet. Examples from the Rakai Health Sciences Program, Uganda”**

**Maria Wawer, Ph.D.**

**March 30, 2006**

---

—

Dr. Maria Wawer, Professor of Clinical Public Health, Mailman School of Public Health, Columbia University, discussed the ways in which research and policy interact and the difficulties of designing effective prevention interventions, using examples from Rakai, Uganda.

There are no easy answers in HIV prevention. It is fraught with complexities, uses a multiplicity of approaches (abstinence, condoms, male and female education), and is highly influenced by politics. It is, therefore, a good paradigm for the problems of translating research into policy and programs. In Rakai, the interaction of policy and research is illustrated in a number of areas: STD control for HIV prevention, the role of medical injections in the spread of HIV, home administered nevirapine for the prevention of mother to child HIV transmission (pMTCT), HIV prevention strategies like ABC, and the use of U.S. informed consent procedures in African research. Columbia University collaborators in the Rakai studies include the Uganda Virus Research Institute/Ministry of Health, CDC, NIH, and several universities: Johns Hopkins, Washington, and Pittsburgh.

Since the mid-1980s, the general assumption has been that STD control will help to decrease HIV transmission. There have been four randomized trials to test this. The first, in Mwanza, Tanzania, provided preliminary data that showed a highly significant impact of STD control. These results were published in 1995, followed by great excitement. However, a Rakai trial that showed no impact was published in 1999 without fanfare. The assumption was that the Rakai data were wrong or were valid only for the Rakai population. Confusion ensued. However, although published data from a third study, in the Masaka district in Uganda, also showed no impact, only the Mwanza study is cited frequently. A fourth study, from Nairobi, Kenya, published in 2004, showed no impact. A fifth study soon to be published also found no impact of STD control on HIV transmission. The implication is that while STD control has benefits it is unclear whether it should be promoted as a method to decrease HIV transmission. A WHO meeting in 2006 will discuss this.

This STD/HIV research history prompts additional questions and discussion points: 1) promising results are more readily accepted than negative ones; 2) researchers were perhaps too polite about questioning the discrepancy between the Mwanza and Rakai results; 3) many people have

a large stake in the relationship between STD control and HIV; and 4) it's difficult to determine how best to use data to inform policy.

Regarding the use of nevirapine to decrease MTCT, there have been some unexpected types of resistance to adoption of this treatment as a worldwide standard. The problem for health service administrators in developing countries is that most women deliver their babies at home, so that neither HIV-positive women nor infants receive medication to prevent MTCT. In Rakai, a system was designed using community health workers (women on motorcycles called Hell's Aunties) to visit pregnant women at home. They offered voluntary HIV counseling and testing and gave HIV-positive women medication in tablets and syrup form (along with a baby syringe to administer the drug). HIV-negative women were given vitamin tablets and non-medicated syrup to avoid stigma. Results were that 92% of pregnant HIV+ women accepted and took their medications, and 100% gave them to their children. MTCT fell by 50%.

Researchers assumed this intervention would be quickly promoted and widely used. But policy makers resisted, fearing women would not come to the clinics for delivery, even though most do not in any case. The strategy has not been widely adopted, but has been used by individual programs. To work effectively, it requires trained pharmacy and clinic staff and an ongoing delivery system. Stigma must be carefully avoided.

Workplace needlesticks and poor hygiene in injection practices were thought to be a leading cause of HIV transmission in Africa (injection practices alone were estimated to be responsible for 30% of transmission and all iatrogenic causes combined for as much as 60-70%). But in Rakai, there was no greater HIV incidence among people who got injections, and a literature review did not indicate an overall greater transmission risk from dirty needles. The most likely interpretation is that injection practices (including transfusions) together with sexual behavior lead to HIV transmission. As stated in U.S. Senate committee hearing testimony, while contaminated needles are clearly a hazard, and there is some transmission via this route in Africa (perhaps under 3% in most settings), the main causes of HIV transmission in Africa are unsafe sex and MTCT.

The implications are that research data can easily be misinterpreted and applied inappropriately in different contexts, that researchers should be assertive and coordinated in reporting findings and caveats, and that politics are always a factor. There is, however, no evidence that the injection issue diluted sexual behavior prevention efforts.

Regarding HIV incidence, data from Rakai indicate that AB behaviors (the abstinence and "be faithful" parts of ABC prevention messages) are declining (that is, risk behavior is increasing). But condom use has increased, and HIV incidence has decreased. Condom use is associated with 75% of this decrease in HIV risk and is considered essential to prevention efforts. HIV deaths are still outpacing new cases, but there is also the possibility of new increases in HIV transmission. Ugandan officials had a measured and reasoned response, holding a meeting in January 2006 and ensuring that there are no longer condom shortages. However, anti-condom campaigns continue, supported with U.S. funding from the political right.

Overall research implications for policy are that research data produce clear results and have a

clear constituency. Researchers must be able to communicate nuanced results clearly, demonstrate how results can be replicated, and advocate for training resources to ensure this. Barriers to the impact of research on policy include poor communication, a lack of belief in the validity of results, competing political interests, old policy habits, and uncontrollable external factors. However, researchers should continue to do rigorous studies, promote timely release of clear data, and seek training in media relations so they can interact effectively with the press and policy makers. They must also remember that change is slow and often complicated.

**Discussion:**

Concerning the impact of President Thabo Mbeki (South Africa) and others who deny HIV science, it is very difficult even in Uganda to counter with an effective response, and generally scientists do not have the time or funding for this. There is a need for advocacy of HIV prevention science.

Practitioners, as well as government officials, can be an important force building consensus and supporting research. Professional consensus is vital prior to establishment of public consensus.

Research also has implications for the public health curriculum.

It's possible that the Mwanza results can be explained by bias or differences between the treatment and control groups.

Data on many different STDs were reviewed, especially those readily treatable. An open STD ulcer is a risk factor at the individual level but not the population level. The importance of viral load overwhelms any bacterial infection effect. If the study were to be redone, researchers would include HSV (herpes virus) suppression.

The issue of circumcision is becoming more important. But there are questions about when and how to begin a study of this, what the implications would be if the results were negative, and how to guard against the inevitable misuse of data.

It is difficult for researchers to spend time doing media and policy outreach. They also do not want to be perceived as hungry for publicity. But there is a clear need for advocacy for prevention research and public discussion of results, including damage control for data misinterpretation, rather than just a press release following a study. Public discussion is also dependent on greater public scientific literacy.

---

**RELATED PUBLICATIONS:**

Gray RH, Wawer MJ, et al, "Relative risks and population attributable fraction of incident HIV associated with symptoms of sexually transmitted diseases and treatable symptomatic sexually transmitted diseases in Rakai District, Uganda. Rakai Project Team." *AIDS*. 1999 Oct 22;13(15):2113-23.

Grosskurth H, et al "Impact of improved treatment of sexually transmitted diseases on HIV

infection in rural Tanzania: randomized controlled trial." *Lancet*, 1995. 346:530-36.

Orroth, KK, et al, "Higher risk behaviour and rates of sexually transmitted diseases in Mwanza compared to Uganda may help explain HIV prevention trial outcomes," *AIDS*. 2003 Dec 5;17(18):2653-60.

STD Treatment to Prevent HIV Infection: Implications of Recent Community-Level Studies, July 1998. [http://www.cdc.gov/nchstp/dstd/Facts\\_Treatment\\_Prevent\\_HIV\\_Infection.htm](http://www.cdc.gov/nchstp/dstd/Facts_Treatment_Prevent_HIV_Infection.htm)

Wawer, MJ. "The Rakai randomized, community-based trial of STD control for AIDS prevention: no effect on HIV incidence despite reductions in STDs [Abstract no. 12473]. Conference Supplement of the 12th World AIDS Conference. Geneva, Switzerland, June 28-July 3, 1998.

Wawer, MJ, et al, "Control of sexually transmitted diseases for AIDS prevention in Uganda: a randomised community trial. Rakai Project Study Group" *Lancet*, 1999. 353(9152):525-35.

Wawer, MJ, U.S. Senate "AIDS Crisis in Africa" hearing testimony:  
[http://72.14.207.104/search?q=cache:PDk-\\_\\_hS74sJ:help.senate.gov/Hearings/2003\\_03\\_27/wawer.pdf+Wawer+Senate+committee+testimony&hl=en&gl=us&ct=clnk&cd=2](http://72.14.207.104/search?q=cache:PDk-__hS74sJ:help.senate.gov/Hearings/2003_03_27/wawer.pdf+Wawer+Senate+committee+testimony&hl=en&gl=us&ct=clnk&cd=2)

White RG, et al, "Can population differences explain the contrasting results of the Mwanza, Rakai, and Masaka HIV/sexually transmitted disease intervention trials?: A modeling study," *Journal of Acquired Immune Deficiency Syndrome*. 2004 Dec 1;37(4):1500-13.

---

NOTE: This HIV Rounds summary is a report based on notes from an oral presentation. It is not a source document for citation. Please contact the presenter(s) and peer reviewed materials for verification of data and further information.

---

**KEYWORDS:** policy, prevention, Uganda, international, STD, abstinence, condoms, education, MTCT, needles, needlestick, community health workers, politics, advocacy, stigma, communication, viral load, circumcision.

**SHORT TITLE:** Research and policy: Rakai, Uganda