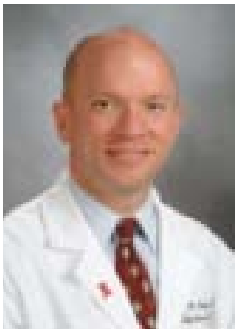

Roy M. Gulick – MD
Professor of medicine - Weill Cornell Medical College
Physician - New York Presbyterian Hospital
Board certifications - Internal Medicine and Infectious Disease

Prof. Roy M. Gulick

Dr. Gulick received his undergraduate degree from Johns Hopkins University in 1982. In his early career, he worked as a Biologist in the Medicinal Chemistry Laboratory at the National Institutes of Health in Bethesda, MD. He went on to earn his MD degree at Columbia University College of Physicians and Surgeons in 1986 and his Master of Public Health degree at Harvard University in 1993, focusing on clinical trial design. After completing his internship and residency in internal medicine at Columbia-Presbyterian Medical Center in 1989, Dr. Gulick held fellowships in infectious diseases at Beth Israel Hospital and Massachusetts General Hospital in Boston from 1989-1991.

Dr. Gulick joined the faculty of the Harvard Medical School in 1991, serving as the Medical Director of the Virology Research Clinic and Instructor of Medicine in the Division of Infectious Diseases at Beth Israel Hospital in Boston. In 1994, he returned to New York City to join the faculty of New York University School of Medicine where he was Director of the HIV Research Clinic at Bellevue Hospital and an attending physician in the Division of Infectious Diseases.

Dr. Gulick joined the faculty of Weill Cornell Medical College as an Assistant Professor of Medicine in 1998. He became Director of the HIV Clinical Trials Unit in 1999, serving through 2008. He was promoted to Associate Professor of Medicine in 2001 and Professor of Medicine in 2007. In 2009, he became the Chief of the Division of Infectious Diseases.

He serves as a Board Member of the International Antiviral Society-USA, and as a member of the Panel on Clinical Practices for Treatment of HIV Infection of the U.S. Department of Health and

Human Services. He previously served as the Chairman of the Antiviral Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) and as Co-Chairman of the Forum for Collaborative HIV Research. He is a member of the American Society of Clinical Investigation (ASCI), the Infectious Diseases Society of America (IDSA), the Infectious Diseases Society of New York (IDSNY), and the International AIDS Society (IAS) and has presented at national and international meetings and published widely.

Stefano Rusconi:
New drugs: what does future hold?

Prof. Gulick:

There are a number of new antiretroviral drugs and formulations in the pipeline. Our greatest needs for new drugs are those that are either more convenient, better tolerated and less toxic, or have activity against drug-resistant viruses.

An investigational integrase inhibitor, cabotegravir can be injected as a nanoformulation every 3 months and attain therapeutic levels. A newer preparation of rilpivirine, formulated as a nanoformulation can be injected every month. These 2 long-acting compounds may allow less frequent, parenteral dosing of suppressive antiretroviral therapy. Newer formulations of current drugs also improve convenience? Under consideration at regulatory agencies are the new co-formulations: abacavir/lamvudine/dolutegravir, atazanavir/cobicistat and darunavir/cobicistat.

An investigational pro-drug of tenofovir, taf, demonstrates virologic activity and a suggestion of less renal and bone toxicity then the current tdf formulation and currently is under investigation in phase 3 studies.

An investigational nnrti, doravirine, demonstrates activity against nnrti-resistant viral strains and is in early clinical studies. An investigational small-molecule cd4 attachment inhibitor, bms-663068, currently shows virologic activity in early clinical trials; with its new mechanism of action, activity against drug-resistant viral strains is expected.

Stefano Rusconi:

What's your opinion about simplification versus de-intensification following virological success?

Prof. Gulick:

Following virologic success, older studies that tried de-intensification (E. G. Going from 3 drugs to 2 drugs) led to viral rebound. More recent studies demonstrate that regimens that are suboptimal for initial therapy can maintain virologic suppression (e.G. Some 2 drug regimens, triple nucleosides). Currently, i would not recommend this strategy unless there is a compelling reason to do it.

Simplification, on the other hand, makes perfect sense since we ask our patients to continue these regimens for life ? I agree with reducing the pill count (perhaps with newer co-formulations), the dosing interval, and the other requirements (fasting, taking with food) as much as possible? The simpler the regimen, the better for long-term virologic success.