A Strategy Symposium
March 24-25, 2009 – Berkeley, California

LINKING BIOPHYSICAL FUNCTIONS TO USER PERCEPTIONS AND ACCEPTABILITY IN PRECLINICAL PRODUCT DEVELOPMENT

MORROW, KM; FAVA, JL; ROSEN, RK; KISER, P; KATZ, D
UNITED STATES
kmorrow@lifespan.org

To be successful, microbicides – or any sexual and reproductive health products - must optimize both biological effectiveness and user acceptability. Biological effectiveness requires both potent active ingredients and functional delivery systems that deliver those ingredients to target sites with requisite kinetics. An acceptable product is one that users trust to be efficacious and whose formulation does not interfere with, or actually may enhance, the experience of sex. Project LINK is developing behavioral tools and novel delivery systems that lead to future product formulations that exhibit optimal drug delivery and optimal acceptability. Project LINK's primary focus is on rationally designing anti-HIV microbicides; however, what we learn about biophysical properties and performance measures that can be perceived by users, and that also predict their decisions to use a product, should apply to any vaginal or rectal product indicated for sexual and reproductive health: whether the indication is prevention of HIV infection, other STIs, or pregnancy - or whether it is designed to medicate or alleviate symptoms (e.g., vaginal dryness). Four primary acceptability dimensions (leakage, application process, impact on sexual pleasure and implications for covert use) are measured by 26 preliminary scales and additional items, all of which provide evidence for users' abilities to perceive "gel behaviors" dictated by formulation biophysical properties and performance. We will discuss these positive results, specifically 1) the development of innovative behavioral scales measuring user perceptions of "gel behavior" and 2) data analyses reflecting the correspondence between these measures and biophysical properties and performance. (Microbicide Innovation Program: R21/R33-MH80591)