



Potential applications

The potential strategic impact on solving societal problems for any project aimed at developing a preventative strategy against HIV/AIDS (microbicides or vaccines) is almost incalculable. HIV/AIDS is a global issue and UNAIDS/WHO estimate that at the end of 2004, 40 million people globally were living with HIV, of which 28.5 million were in Sub-Saharan Africa. In Eastern Europe and Central Asia, a rapid increase in HIV infections resulted in 1.4 million people being affected. In Western Europe, an estimated 610,000 people were living with HIV. Globally, there are 14,000 new HIV infections per day, of which 95% are in developing countries. Approximately 12,000 of these infections are in persons aged 15-49 years, of whom almost 50% are women, and 50% are 15-24 years of age. In S. Africa, 1 in 4 women are infected with HIV by the age of 22. Thus, this disease is wiping out the entire generation on which the economic future of many developing countries is dependent. It has been estimated that a 60% efficacious prophylactic treatment, introduced into 73 low income countries and used by only 20% of women would avert 2.5 million HIV infections over 3 years in women, men and infants.

In some countries, public health programmes have achieved modest results in reducing HIV rates of infection. Although the use of condoms has slowly increased in countries most severely affected by the HIV epidemic, many vulnerable women are unable to ensure that they are used routinely.

The development of new HIV/AIDS vaccines and microbicides has been identified as key areas in FP6. This builds on past high quality research programs on vaccines and therapeutics supported by the EU through FPs 4 and 5. However, while significant progress has been achieved in understanding immune response to HIV-1 antigens and in the development of effective antiretroviral therapy, significant challenges to the development of effective preventative strategies still remain. It is now well accepted that under most circumstances, vaccines delivering non-replicating antigens fail to induce sufficient mucosal responses and immunological memory to provide protection against high viral challenge. In contrast, while it may be technically easier to develop Microbicides that prevent transmission when applied before intercourse, their duration of protection is likely to be short lived and their efficacy will be critically dependent upon user compliance. To date both fields have been slow to work together in the development of products that provide multiple levels of protection.

This network is focused on the premise that microbicides and vaccines that target multiple stages of mucosal transmission will have the best chance of success. Since both target the same processes there is clear overlap between the two fields. The aim of this proposal is to bring together, for the first time, EU scientist working in both microbicide and Vaccine fields to maximize research synergy in development of novel approaches to provide effective protection against HIV-1 transmission. Indeed there are many compelling reasons why the two fields should work together on developing effective strategies to prevent mucosal vaginal or rectal transmission:

(1) Approximately 80% of new HIV infections are now heterosexual, and the main portal of entry is across the vaginal or rectal mucosa. Local immunity at the site of infection is likely to be the most potent form of protection.

(2) Topically applied products are likely to have a high level of acceptance. Importantly, their use would be female initiated. This is an important factor for women who have no means to protect themselves if their partners do not use male condoms or do not allow female condoms to be used.

(3) Effective microbicides are likely to be available before effective vaccine candidates. Thus it is highly likely that in the not too distant future all vaccine efficacy trials will be carried out in an environment where there is widespread use of vaginal microbicides. Thus it will be important to understand the interaction and potential interface of these different prevention technologies. Furthermore, microbicides, if successfully introduced, may provide an established route for vaginal delivery of formulations designed to stimulate and/or activate protective immunity. The future combination of strategies developed in this programme either through cross over of microbicide and vaccine use in common populations or as a result of a deliberate strategy to develop a combined vaccine-microbicide modality has potential to maximize the protective effects of both strategies.

The potential direct impact of this network therefore, is multifaceted and broad in scope. There is a clear and urgent need to network European microbicide and vaccine research to provide a clear and coordinated strategy for the development of new prevention technology against HIV/AIDS. Such an approach has obvious potential for direct health benefits that will translate into social stability and development, scientific benefits by the creation of new knowledge as well as maintaining a strong science base in Europe. It is generally accepted that HIV vaccines and microbicides will have the most significant impact on the growth of this pandemic in both the developing world and within Europe. The potential to derive enormous health benefits, by itself, argues for a strong, integrated approach to the development of HIV-1 prevention strategies.