Preface

More than 30 years after the first cases were reported, the HIV/AIDS pandemic remains a global health priority. Heterosexual transmission of HIV accounts for 70–80 % of infections worldwide, and women are disproportionately affected by this disease, especially in sub-Saharan Africa where they account for approximately 60 % of infections. In developing countries, factors such as low acceptance of condoms, patterns of sexual behavior, social attitude, viral loads in the semen of the HIV-positive partner, local viral subtypes, and coinfection with other sexually transmitted disease mean that exposure to an infected partner is much more likely to result in transmission than in developed countries, with women again the most affected. There are also anatomical and physiological factors that put women at a greater risk of infection than men. In addition, social, legal, and economic disadvantages make women more likely to become HIV infected.

In order to change the course of the HIV pandemic, effective strategies for prevention of HIV transmission are critical. Abstinence, reducing the number of sexual partners and concurrent sexual relationships, and correct, consistent condom use has been found to be effective in reducing the probability of HIV infection. However, these methods have proven to be insufficient to control infection rates. More HIV prevention strategies are required that provide options for those populations who need protection the most. Thus, safe and effective HIV prevention methods, particularly those that are female-controlled, could play a major role in reducing the incidence of HIV-1 transmission.

In recent years, a number of biomedical interventions have shown promise in HIV prevention. These include pre-exposure prophylaxis (PrEP), treatment as prevention, and microbicides. The concept of microbicides as an HIV prevention strategy was first introduced in an article titled ‘HIV Prevention: The Need for Methods Women Can Use’ published in April 1990. Microbicides are topical products that can be applied vaginally or rectally to protect the user from acquiring HIV and, possibly, other STIs.

Early microbicides were nonspecific compounds that worked by either disrupting the viral envelope (e.g., surfactants), electrostatically blocking the virus from interacting with target cells in the vagina (e.g., polyanions), or by maintaining the low pH of the vagina, making it inhospitable to HIV. All of these microbicides were formulated as gels that were intended to be applied vaginally just prior to sex. Clinical trials of these early candidates all failed to demonstrate efficacy, which led to an increased focus on products based on more potent and highly specific antiretroviral compounds. These microbicides are able to be formulated in a wider range of dosage forms, including formulations for daily use and sustained release products for use over a month or more, and can incorporate combinations of active ingredients that may improve their effectiveness further. In 2010, the microbicide field achieved its first proof of concept when a vaginal gel containing 1 % tenofovir was shown to protect women by 39 %.

The development of microbicides is a long and complicated process, with many challenges in product design, in the conduct and design of clinical trials, and in obtaining licensure for a new class of products intended for use almost exclusively in developing countries. This edition of Current Topics in Microbiology and Immunology is entirely dedicated to the field of microbicides. It is intended to cover all the critical areas associated with the development of microbicides, from the selection of appropriate candidate molecules, their formulation, preclinical and clinical testing for safety and efficacy, strategies for product registration and finally, issues associated with product launch, distribution, and access.

The authors were all selected because of their expertise in the development of microbicides. Consequently, much of the information is derived directly from their personal experience over years of product development, and is supplemented with knowledge gained from the experience of colleagues in the field. Since no microbicide product has yet been brought to market, some of the information presented represents what is believed rather than proven to be best practice, but reflects the current state of the art and the techniques, models, procedures, and processes available. However, researchers, developers, advocates, and regulators are together learning more about the transmission process and how to prevent it, determining what will be necessary to get these products to market, and how this can best be achieved.

My hope is that this edition will prove valuable to both workers in the microbicide field and others who are interested in learning more about this promising intervention that has the potential to significantly impact the future of the devastating HIV/AIDS epidemic. Whilst it is not possible to cover every aspect of microbicide development in detail, efforts have been made to point the reader toward other sources of information that may be helpful in filling any gaps and providing a more comprehensive understanding of the issues associated with microbicide development.

I would like to thank all the authors for the high quality of their contributions, and their patience and support in putting this edition together. I would also like to acknowledge the team at the International Partnership for Microbicides, and colleagues in many other organizations whose collaborations have helped move the field forward to the point where we now have products that are in the final stages of development, and are moving ever closer to getting them into the hands of those that so desperately need them.

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