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Methodological Challenges in Biomedical HIV Prevention Trials

Committee on the Methodological Challenges in HIV Prevention Trials, Board on Global Health, Institute of Medicine

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The number of people infected with HIV or living with AIDS is increasing at unprecedented rates as various scientists, organizations, and institutions search for innovative solutions to combating and preventing the disease. At the request of the Bill & Melinda Gates Foundation, *Methodological Challenges in Biomedical HIV Prevention Trials* addresses methodological challenges in late-stage nonvaccine biomedical HIV prevention trials with a specific focus on microbicide and pre-exposure prophylaxis trials. This book recommends a number of ways to improve the design, monitoring, and analysis of late-stage clinical trials that evaluate nonvaccine biomedical interventions. The objectives include identifying a beneficial method of intervention, enhancing quantification of the impact, properly assessing the effects of using such an intervention, and reducing biases that can lead to false positive trial results.

According to *Methodological Challenges in Biomedical HIV Prevention Trials*, the need to identify a range of effective, practical, and affordable preventive strategies is critical. Although a large number of promising new HIV prevention strategies and products are currently being tested in late-stage clinical trials, these trials face a myriad of methodological challenges that slow the pace of research and limit the ability to identify and fully evaluate effective biomedical interventions.

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