

Abstract Submitted
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Coupled gel spreading and diffusive transport models describing microbicidal drug delivery CLAIRE FUNKE, KELSEY MACMILLAN, Univ of California - Berkeley, ANTHONY S. HAM, Imquest BioSciences, ANDREW J. SZERI, Univ of California - Berkeley, DAVID F. KATZ, Duke University — Gels are a drug delivery platform being evaluated for application of active pharmaceutical ingredients, termed microbicides, that act topically against infection by sexually transmitted HIV. Despite success in one Phase IIb trial of a vaginal gel delivering tenofovir, problems of user adherence to designed gel application regimen compromised results in two other trials. The microbicide field is responding to this issue by simultaneously analyzing behavioral determinants of adherence and pharmacological determinants of drug delivery. Central to both user adherence and mucosal drug delivery are gel properties (e.g. rheology) and applied volume. The specific problem to be solved here is to develop a model for how gel rheology and volume, interacting with loaded drug concentration, govern the transport of the microbicide drug tenofovir into the vaginal mucosa to its stromal layer. The analysis here builds upon our current understanding of vaginal gel deployment and drug delivery, incorporating key features of the gel's environment, fluid production and subsequent gel dilution, and vaginal wall elasticity. We consider the microbicide drug tenofovir as it is the most completely studied drug, in both *in vitro* and *in vivo* studies, for use in vaginal gel application. Our goal is to contribute to improved pharmacological understanding of gel functionality, providing a computational tool that can be used in future vaginal microbicide gel design.

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