

HerShield: Empowering Women through Innovative Drug Delivery ID: 3899, 3959 Featured Innovators: Lisa Rohan, PhD, Katherine Bunge, MD MPH, and Sravan Patel, PhD

Genital herpes is a lifelong infection affecting more than 500 million people worldwide. In the US alone, each year approximately one million people are newly diagnosed with herpes and \$1 billion is spent on treatment. Individuals infected with herpes experience painful viral outbreaks along with significant psychological stress, social stigma, and anxiety. Current therapies suppress viral load to decrease the length and severity of symptoms, but they are not curative. Even though women are more prone to genital herpes, available prevention options are controlled by the male partner, and proper use may not be negotiable. A new female-controlled vaginal film called HerShield empowers women to protect themselves against genital herpes.

Technology Description

HerShield, is a biodegradable film applied intra-vaginally; containing an antiviral drug – tenofovir that has demonstrated activity against herpes (HSV-2) infection when used vaginally. HerShield does not require an applicator. It is both portable and discreet. HerShield is also environmentally-friendly and inexpensive. Two phase I clinical trials have demonstrated that the first generation prototype of HerShield is safe and delivers sufficient quantities of drug for protection from herpes infection.

Advantages

- Female-controlled
- Portable
- Discreet
- Biodegradable
- Low cost

Applications

- Prevention of herpes and other STDs
- Contraception
- Platform for vaginal drug delivery can provide both immediate and extended drug release
- Delivery of probiotics and other agents for improved vaginal health
- Convenient delivery of drugs for a range of therapeutic areas

Stage of Development

Prototype tested in phase I clinical trials

IP Status

Two patent applications have been filed

Notable Mentions

Funded by the Bill and Melinda Gates Foundation for development of vaginal film manufacturing advancements, which have been incorporated into the HerShield product to reduce cost and optimize ease of use.



Innovators



Lisa Rohan, PhD
Professor
Pharmaceutical Sciences
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EducationPhD University of Pittsburgh
BS West Virginia University

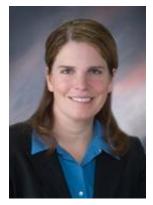
Dr. Rohan has 23 years of drug product development experience. She has consulted for over a dozen companies and has spent six years working in industry. he studies the role of chemical, physical, and biological properties of vaginal and cervical tissues and fluids in the development of vaginal and cervical products for infectious disease and gynecologic oncology. This knowledge is being used to develop products for prophylactic use against sexually transmitted diseases and HIV. Her research also involves the development and optimization of imaging techniques for sentinel node identification in cervical cancer as well as novel delivery systems for chemotherapeutic agents.



Sravan Patel, PhDPostdoctoral Associate
Pharmaceutical Sciences
University of Pittsburgh

Education
PhD Duquesne University
MS University of Georgia, Athens
BPharm BITS, Pilani, India

Dr. Patel has been working on drug product development for six years. He has interdisciplinary training in synthetic chemistry, biological imaging, analytical chemistry, and formulation development – particularly nanomedicine for imaging and drug delivery in inflammatory diseases. His current work focuses on film dosage form development, characterization, overseeing scale-up, dissolution method development for films, and microparticles. He is also interested in the application of statistical, chemometric, and image analysis methods to optimize pharmaceutical processes and products, with special focus on extrusion-based unit operations.



Katherine Bunge, MD MPH
Assistant Professor
Obstetrics, Gynecology, and
Reproductive Sciences
University of Pittsburgh

EducationMD Johns Hopkins School of Medicine MPH Johns Hopkins School of Medicine

Dr. Bunge has a decade of experience with vaginal product evaluation. Her primary research responsibilities are housed within the Microbicide Trials Network (MTN), an NIH funded HIV prevention network. She serves as a Safety Physician overseeing the pharmacovigilance activities within the MTN studies. In addition, she has served as the protocol co-chair for two adolescent trials within the MTN examining the safety and acceptability of vaginal microbicides in a teen population. Under the auspices of the MTN, she works closely with the Contraceptive Action Team to expand the contraceptive methods mix at HIV prevention research sites. Outside of the network, she runs the clinical trials within a U19 evaluating novel film formulations for the delivery of antiviral microbicide products.

Publications

- Fan M, Kramzer L, Hillier S, Chang J, Meyn L, Rohan L. Preferred Physical Characteristics of Vaginal Film Microbicides for HIV Prevention in Pittsburgh Women. Arch Sex Behav. 2017; 46(4):1111-1119. PMID: 27571742.
- Bunge KE, Dezzutti CS, Rohan LC, Hendrix CW, Marzinke MA, Richardson-Harman N, Moncla BJ, Devlin B, Meyn LA, Spiegel HM, Hillier SL. A Phase 1 Trial to Assess the Safety, Acceptability, Pharmacokinetics, and Pharmacodynamics of a Novel Dapivirine Vaginal Film. J Acquir Immune Defic Syndr. 2016; 71(5):498-505. PMID: 26565716.
- Akil A, Agashe H, Dezzutti CS, Moncla BJ, Hillier SL, Devlin B, Shi Y, Uranker K, Rohan LC. Formulation and characterization of polymeric films containing combinations of antiretrovirals (ARVs) for HIV prevention. Pharm Res. 2015; 32(2):458-68. PMID: 25079391.
- Patel SK, Rohan LC. On-demand microbicide products: design matters. Drug Delivery and Translational Research. Published Online: June 6 2017. PMID: 28589452.

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