

## An uncomfortable truth: How stigma and a lack of funding has set back research and treatments for vulvovaginal disorders

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Caroline Mitchell, MD, MPH, studies the vaginal microbiome. Credit: Mass General Research Institute

The world of medicine has made remarkable strides in diagnosing and



treating various health conditions, but when it comes to many women's health issues, progress is lacking.

Why is it so hard for women to seek and obtain treatment for issues related to sexual and <u>reproductive health</u>?

Mass General physician-investigator Caroline Mitchell, MD, MPH, discusses the many obstacles to treatment—and how she is working to advance the field.

Dr. Mitchell is the Director of the Vulvovaginal Disorders Program at Massachusetts General Hospital, an investigator at the Vincent Center for Reproductive Biology, and an Associate Professor at Harvard Medical School. She has dedicated her research career to investigating the vaginal <u>microbiome</u> in hopes of helping those suffering from a variety of conditions find effective treatments.

It has not been an easy path to travel. From a lack of research funding to the overall stigma associated with discussing vaginal health, Mitchell and other researchers still have a long way to go to creating successful and accessible treatments.

## A need for new treatments

Antibiotic treatments for bacterial vaginosis (BV), which the most common health issue in the vaginal microbiome, have remained virtually unchanged since 1982. The treatments also have a failure rate of up to 60% within six months.

This outdated approach fails to address the complex nature of the vaginal microbiome, which is exactly what Mitchell and her colleagues are looking to solve with their research.



Misconceptions surrounding vaginal health often also lead individuals to feel dirty or ashamed when experiencing problems. The lack of research into these disorders perpetuates these misunderstandings, leaving patients feeling frustrated and isolated.

"People have this idea when they have a vaginal problem, that it's because they're dirty or unclean, or doing something wrong. And that's not true," Mitchell says. "The reason people feel frustrated and alone is because no one has paid attention, and no one has done the work. And we're trying to do that work now."

## **Barriers to improving care**

Before a new treatment is approved for patients, researchers spend years—and sometimes decades— putting multiple potential treatments through extensive scientific testing and development. But this can only be done if there is funding for the work.

Funding is the lifeblood of scientific research, and the vaginal microbiome field faces a significant shortfall compared to other areas of study.

Shockingly, cancer-related gut microbiome research receives between two and sixteen times more NIH funding per potential patient than research into the vaginal microbiome, according to Mitchell. This discrepancy reflects a larger issue of prioritization within the scientific community, where women's health issues and specifically vaginal health disorders are often overlooked.

Mitchell believes that the study of the microbiome has been undervalued historically because of the stigma that comes along with it.

"Vaginal health, which correlates with <u>sexual health</u>, is not considered a



priority for women [by payors, funding agencies and other healthcare stakeholders]. For example, vaginal estrogen for <u>postmenopausal women</u>, which treats <u>vaginal dryness</u>, sexual pain in postmenopausal people, is considered a lifestyle medication and it is not covered by Medicare," Mitchell explains. "I don't even know what to do with that, except be angry."

Another challenge that this area of research has faced is the absence of suitable animal models that replicate the unique (Lactobacillus dominant) microbial composition of the human vaginal microbiome. In the scientific process of finding successful treatments, researchers normally start by testing a new drug in animal models, and if they are successful, they then move onto clinical trials where human patient volunteers test out the treatment before it becomes fully available to the general public.

But with the vaginal microbiome, this is not possible.

"There's just no other species that has the same pattern of vaginal microbes as humans, which is fascinating but also totally frustrating, Mitchell says. "Because there's no <u>mouse model</u>, clinical trials in humans are the only way for us to test our treatments and move the field forward."

A lack of understanding of the microbiome also makes it very challenging to develop strategies to reduce the risk of HIV transmission effectively as well.

Studies by Doug Kwon, MD, Ph.D., a physician-investigator in Infectious Disease at Massachusetts General Hospital and the Ragon Institute of MGH, MIT and Harvard, have shown that alternations in the vaginal microbiomes of women in South Africa may make them more susceptible to contracting HIV during vaginal intercourse, and could in



part explain the devastating impact of the disease there.

## The optimistic future of vaginal microbiome research

Despite all of these challenges, there is still plenty of optimism on the horizon. Mitchell and her team are currently part of a consortium of vaginal microbiome researchers across the world that are all working together to find solutions.

One of the consortium members, Don Ingber, MD, Ph.D., at the Wyss Institute, has developed a "vagina on a chip" lab model, which provides a new model system for testing novel therapeutics and gaining insights into the vaginal microbiome.

Pioneering studies are also showing essential steps towards advancing our knowledge in the field. Mitchell and her team are running two <u>clinical trials</u> of novel treatments for BV in humans.

"We're the first randomized trial of vaginal microbiome transplant for BV not just in the US, but the world," Mitchell states. The second trial is of a novel vaginal live biotherapeutic created by the Vaginal Microbiome Research Consortium.

The consortium and other researchers in the field are also now actively mentoring and supporting the next generation of researchers, ensuring that progress continues into the future as well.

"There is definitely a core group of <u>vaginal microbiome</u> scientists, who have been training and supporting and developing the next generation. While we are slowly growing, we are still growing," says Mitchell.

Provided by Massachusetts General Hospital



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