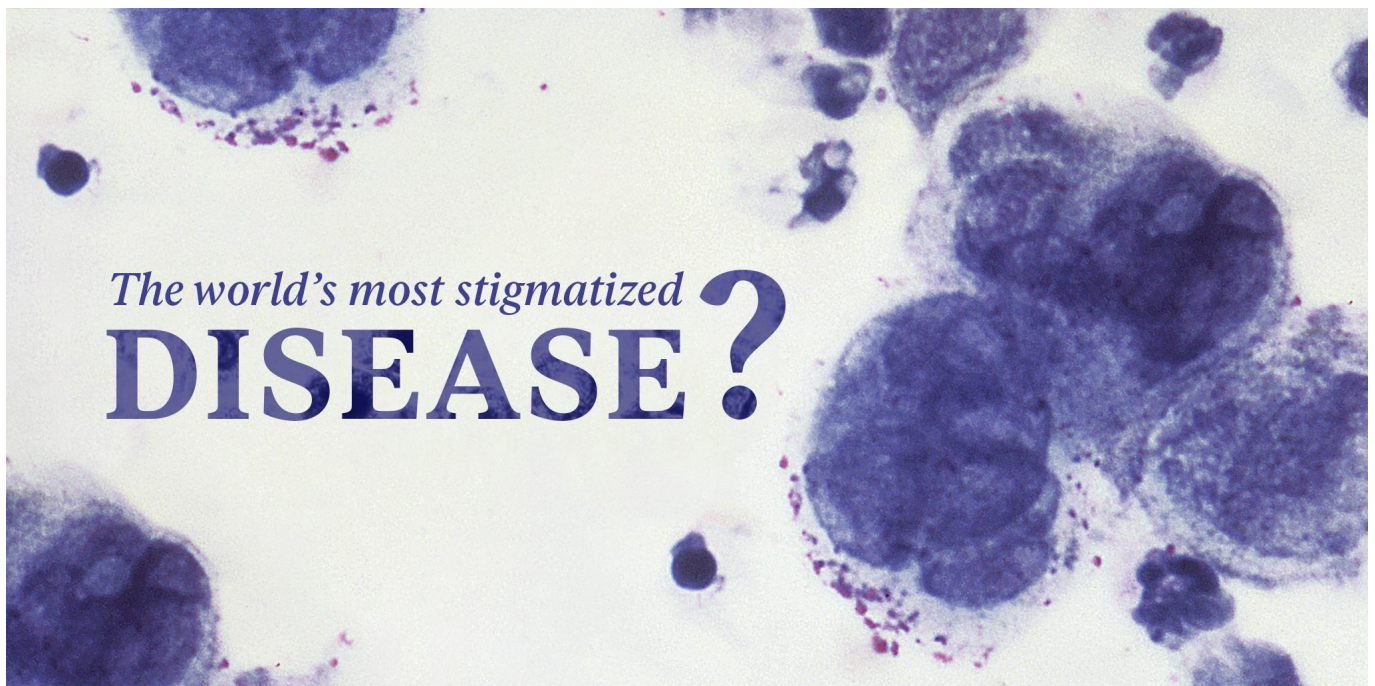


After Covid-19 success, patients with the world's 'most stigmatized' infection push for their own Operation Warp Speed

by Jason Mast on April 6th, 2022



When Kimberly woke one morning in the final days of 2020 and couldn't pee without pain, she had no idea what it might be. But as the symptoms persisted, she gathered a possible hunch, even as she frantically googled for alternative explanations.

She was married, on paper, but they were separated and there had been a new man one night a month ago. He said he was tested and STI-free, but that was just his word.

Five days later, Kimberly went to her OB-GYN, who took one look and told her it was either a yeast infection or herpes. She swabbed and promised an answer in a few days. But when the call came, the doctor didn't seem as concerned as Kimberly was about the results: herpes. She just asked, "Do you have any questions?"

Kimberly had many. Too many, in fact, coming in at too high a velocity, for her to actually ask any in the moment.

“It’s devastating. You know, you’re like, ‘What did I do wrong?’ And you’re just in shock,” she told *Endpoints News*. “It’s chronic, you cannot cure it. You have to live with it. And I was afraid: What’s my whole life going to be like? What are the symptoms going to be like? Then I went through a really dark period, where I was suicidal.”

For most people, herpes is closer to a punchline than a disease. That’s remained true, even as studies have repeatedly shown that the majority of humans actually have some form of the virus. *The Hangover*, as Vice [noted](#) in a non-exhaustive list of references, called it the only thing that doesn’t stay in Vegas. John Oliver compared it to terrorism because they’re both “impossible to get rid of.”

Yet those same jokes also underscore — and reinforce — the trauma a herpes diagnosis can bring. In one bit from “Bob’s Burgers,” the mom, Louise, warns her teenage daughter Tina against kissing a boy: “You’re going to get yourself killed,” she says. “Or worse ... Have you heard of herpes?” As Kimberly puts it, “it’s probably the world’s most stigmatized STI.”

That view is often shared by healthcare professionals, who regard the disease as a minor nuisance, despite the toll it can take on a patient’s personal life and the associated health risks it brings. Although almost never fatal, herpes can more than triple a person’s risk of contracting HIV, and growing — albeit much-disputed — [evidence](#) suggests it may drive Alzheimer’s in some patients. There are only two treatments, both of which were approved in the 1980s and are only mildly effective. In part because of its anodyne reputation, drug companies have mostly ignored it.

(And herpes *can* be fatal. Between 1995 and 2017, at least 1271 infants died in the US of neonatal herpes [contracted](#) from mothers during birth — compared to 271 HIV-related infant deaths over the same period. Many who survive suffer long-term neurological damage. And the immunocompromised can also suffer severe symptoms.)

Over the last year, though, Kimberly and a handful of other patients have quietly pushed to change herpes’ reputation and drug companies and policy makers’ attitudes toward it. They found each other via [Reddit](#), where Kimberly and others initially turned for advice and community amid the despair of diagnosis. But emboldened by the success of Operation Warp Speed in rapidly developing coronavirus treatments and vaccines, many started raising money for treatments and lobbying lawmakers, public health officials and pharma executives.

In the process, they’ve created something that exists for hundreds of diseases but, because of the stigma, has never existed for herpes: a disease advocacy group.

“There has not been any kind of herpes advocacy in the 30 years that I’ve been involved in STI prevention and research. It was something that was just never addressed,” said Jeff Klausner, an infectious disease physician at UCLA and the former director of STD prevention and control at San Francisco’s public health department. “There’s just been no one who’s tried. Except now Kimberly.”

The work is still small-scale — small enough that few of Kimberly’s coworkers and friends know she’s doing it and that she asked to use only her first name for this article. (She acknowledges the irony of advocating against stigma while staying anonymous, but points to it as further evidence of what herpes patients face.) But her organization, Herpes Cure Advocacy, has already managed to enlist a team of leading researchers and land herpes-specific language into the Senate budget bill.

If they succeed, not only could it mean some of the first breakthroughs in decades in what experts call a “silent epidemic,” it will also provide an early test for the millions of Alzheimer’s and cancer and rare disease patients who, seeing the success of Covid-19 research, have been [asking](#), “Where’s our Operation Warp Speed?”

Because if OWS can be replicated, where better to start? Herpes, after all, is just another virus — albeit, experts warn, a far, far wilier one. And although no one is arguing it represents the same threat as Covid-19 or HIV, advocates are only a fraction for a small fraction of the funding those threats have received.

“You can really tell, when you prioritize something with funding and urgency, scientific and medical miracles can happen,” Kimberly said. “I don’t really accept the idea that it’s tricky to cure.”

How herpes drugs once ‘changed the world’

Herpes hasn’t always been the ugly stepchild of infectious disease research. In fact, in 1978, it was the site of one of the most important developments in the history of medicine.

That year, [Gertrude Elion](#), a pioneering biochemist working for Burroughs Wellcome, a forerunner of GSK, got on stage at an Atlanta conference and detailed what would become the world’s first antiviral therapy.

Previously, viruses were considered undruggable. Antibiotics for bacterial infections were by then commonplace, but viruses were different: They burrow inside human cells, tangling their proteins and genetic material with our own. It seemed impossible to hit one without damaging the other.

But Elion showed a compound called acyclovir struck like God on the 10th day, killing herpes inside the cell while passing over human machinery next to it. Acyclovir was approved for treating herpes in 1981, but, perhaps more importantly, researchers copied Elion’s strategy and used it to develop the medicines that made HIV treatable, cured hepatitis C, and most recently dramatically reduced the odds of hospitalization from Covid-19.

“I tend to think acyclovir changed the world,” said Larry Corey, who worked with Elion to direct acyclovir through clinical trials.

HIV, though, was a double-edged sword for the herpes field. In 1981, Corey help set up a herpes patient

advocacy group called [HELP](#), and they had a few meetings. But the AIDS crisis rapidly eclipsed any other viral issue, sapping attention and resources. Herpes became an afterthought. HELP dissolved. “It really fizzled out,” Corey said.

In the early days of the HIV epidemic, there was still tangential interest in herpes. With HIV-targeted drugs years away, some researchers hoped to treat HIV by treating herpes, because of epidemiological studies showing herpes elevated your risk of contracting the deadly disease. But as those studies failed, so did any interest in tackling a mostly non-fatal infection — at least not when there were other threats.

Klausner, the advisor to Kimberly’s effort, said he worked to start herpes programs when he was director of STD prevention at San Francisco, widely regarded as the best public health department in the country because of its HIV work.

“I tried,” he said. “But HIV just eclipsed herpes as a major sexual health concern.”

The ‘herpes queen’

Last April, Kimberly wrote Corey a cold email explaining her diagnosis and asking how one might accelerate vaccine research. “Do you think more advocacy work would help in any way?” she wrote.

Corey, now a 75-year-old investigator at Fred Hutch and famous for his pioneering work in HIV, is responsive but often terse. “You are correct,” he wrote back late that night. “Advocacy is needed.” And he CC’d Anna Wald.

Wald, Corey’s former mentee and now a clinical virologist at the University of Washington, has been studying herpes and advocating for herpes patients for more than two decades. She introduces herself in interviews with a wily smile and a simple declaration: “I am the herpes queen.” Every week, she receives emails from panicked, newly diagnosed herpes patients. She responded to Kimberly, as she responded to most of them: Are you sure?

Herpes testing, as Kimberly had already learned, is a [mess](#), a shifting labyrinth that leaves disease-free patients thinking they’re infected and disease-carrying patients thinking they’re healthy. The “herpes” most people talk about is actually two viruses: HSV-1, which causes oral herpes and the hallmark cold sores, and HSV-2, the genital herpes that triggers the most public and private concern. Commercial tests are bad at distinguishing between the two.

“They miss HSV-1 and they over-diagnose HSV-2,” said Wald, with a note of frustration. Her lab has a labor-intensive but more accurate test they run for patients who ask, and it often reveals an initial misdiagnosis. “We really just shouldn’t have tests on the market that are just inaccurate.”

A 2016 [report](#) found that as many as half of positive HSV-2 tests were in fact false-positives. Consequently, the CDC recommended against routine testing for the virus, unless someone has

symptoms, and, often unbeknownst to patients, most providers don't include it as part of standard STI testing.

Kimberly discovered that's what happened to her. Her partner had gotten STI testing but didn't know that HSV wasn't included. He was asymptomatic, but asymptomatic people can still transmit the virus. As with Covid-19, it's one of the key features that allows HSV to spread so widely.

Kimberly, however, was certain she had it, as she explained to Wald, because the test for symptomatic patients — a swab of the lesions, as opposed to a blood test — is highly accurate. The entire situation had made her furious.

"It's absurd," she said. "It seems like nobody has ever cared enough to make a better test."

In other situations, it can be deadly. Breanna Waid, a 26-year-old postal worker in Indiana, started advocating around HSV after she became pregnant in 2019 and her doctor ran standard STI tests. "I figured that, you know, they would test for everything," she said.

They hadn't. Waid was HSV-positive but asymptomatic and her son contracted neonatal herpes upon birth. Within weeks, he was having seizures — so many that doctors had to put him in deep sedation to slow his brain activity. If he survived, they told her, it would be with severe brain damage. He died after five days in the hospital and four weeks on earth.

Distraught, Waid called her doctor demanding answers: Why wasn't she tested?

"I was so angry because I felt like this could have been avoided," she said. "And she told me that it's because the tests aren't reliable. But I feel that even if they're not reliable, it could have told me something. It could have."

A pitch for a \$2.5 billion HSV plan

Kimberly and her new allies started organizing. An advertising executive with no public experience, she began working the equivalent of two jobs, toggling between calls with clients and calls with legislators while reading everything she could.

Klausner, also a cold email recipient, began advising her, drawing on tactics HIV advocates employed decades prior. He helped connect her with aides to Washington Sen. Patty Murray, who had a long record on public health, and advised her to ask for a Senate subcommittee hearing and a \$2.5 billion national HSV prevention and treatment plan.

Corey, who had known Murray for years, wrote a letter in support, noting the correlation with HIV and Alzheimer's and arguing that a vaccine for herpes could help prevent both.

“One thing the Covid-19 pandemic has done is brought the injustice and inequality of health care and resources for infectious diseases to light in a way not previously advertised,” he concluded. “We are at a crossroads now with great levels of advocacy and the ability to make real change with new technologies to tackle these silent epidemics.”

It wasn't hard to find allies, at least among academics. Political momentum around herpes had stalled but research hadn't. And Kimberly soon had more than a half-dozen academics, doctors and nurses, many of whom had long labored to justify their focus, helping her make her case.

On Reddit, where Kimberly and a couple other activists post regularly, legions of HSV-positive patients organized on a smaller scale. Industry funding for treatments and vaccines had all but dried up. GSK mounted a large vaccine effort in the 2000s but it ultimately [failed](#) to provide enough protection to garner approval. Sanofi teamed with a small biotech to develop a therapeutic vaccine but then quietly bailed.

So patients used the forum to raise money for the couple academics developing what they saw as the most promising vaccines and treatments. They helped muster \$355,000 for Harvey Friedman, a University of Pennsylvania researcher developing an mRNA vaccine for HSV-2 in collaboration with BioNTech.

And they helped raise \$575,000 for Keith Jerome, a Fred Hutch researcher developing a gene editing treatment for herpes. Because herpes can coil deep into nerve cells, beyond the reach of drugs or the immune system, gene-editing approaches that can seek and slice specific sequences of the HSV genome presents one of the more promising paths to a cure.

It's impossible to say how much of the \$500,000 came as a result of the group, but the page filled with [posts](#) and [memes](#) supporting Jerome, and a Fred Hutch administrator emailed one forum member to [say](#) it had been essential. Jerome himself was shocked, weathered by years trying to justify his research to NIH committees, who often responded to his grant applications with notes that amounted to: Why are you even working on this?

“I was flabbergasted,” he said. But it confirmed what he had been telling those review committees: “People care about this infection.”

This is ‘going to be much more difficult’

Jerome is grateful for the funding, which allowed him to hire new staff and accelerate his research. He says herpes research has long needed more vocal advocacy and central organization, as there was with AIDS and other viruses.

“We host a meeting every other year on HIV cure, the NIH funds it... people come from all over the world,” he said. “Why don't we have that for HSV? Well, because there is no program, there is no

scientific community.”

Still, Jerome is clear-eyed about the challenges. In a video thanking supporters last October, he cautioned against comparing herpes to Covid-19, or expecting a vaccine to appear in a year, even if the federal government suddenly gave it the Operation Warp Speed treatment advocates think it deserves. “A vaccine for herpes is going to be much more difficult,” he [said](#). “Herpes is really great at evading the immune system.”

Friedman, the UPenn researcher, agreed. He started researching HSV back in the 1970s, when it was still the most intriguing virus around but he didn’t focus on vaccines or drugs. Instead, Friedman tried to decipher the biological spycraft that allowed herpes to so persistently duck our bodies’ defenses. A little over a decade ago, after the failures of GSK’s vaccine and a vaccine from Chiron (now Novartis), he decided to put everything he learned to the test.

Herpes evades the immune system, Friedman had shown, because it can turn off two key defenses. It has a hook that latches onto and defuses a key protein in an early warning system called the complement system, and a hook that does the same antibodies. So Friedman designed a three-armed shot designed to neutralize each of the immune-silencing hooks, plus the hook herpes uses to enter human cells.

Early results have been promising: The mRNA shot gave guinea pigs — the best animal model for herpes — “outstanding” protection from infection or genital lesions for eight months, researchers [found](#) last year. But Friedman still urges caution; herpes is just so well-adapted to humans.

“Let’s face it, I don’t know. It works great in mice and guinea pigs,” he said. “But people have gone down that path before and taken it to humans, and were disappointed.”

A therapeutic vaccine – the kind that most excites HSV-positive Redditors and advocates like Kimberly because it could prevent their lesions from recurring — will be even harder, Friedman said. It’s difficult to suppress the virus once it’s already found a home. But it’s been done once: GSK’s Shingrix, which prevents the virus that causes chickenpox from recurring decades later as shingles.

“And that’s a close cousin of [HSV],” Friedman said. “So it gives us hope.”

‘Excuse me, that’s medical paternalism’

Kimberly has now had about a dozen meetings with government agencies, legislators and companies, often joined by other patient advocates and experts like Klausner and Corey, and won key gains. Murray’s office inserted into Senate budget language that “urges the Assistant Secretary for Health to develop a national strategy and strategic plan for the treatment and prevention of HSV types 1 and 2.”

Herpes Cure Advocacy is now registering as a 501c3 nonprofit and Kimberly is raising money to hire a

full-time lobbyist and other staff, with Corey and others as formal advisors. “They picked the wrong person to get herpes,” she likes to joke.

But not every meeting has gone as well as hoped. The budget bill calls for an HSV plan but doesn’t apportion any money for it. And while she lobbied the government, the CDC released guidelines reiterating that herpes shouldn’t be routinely tested for.

In November Kimberly and Klausner met with CDC’s director of HIV/AIDS prevention, Demetre Daskalakis, and other officials about revising testing guidelines. Kimberly said it went well, but Klausner doubted they would act quickly. In response to an interview request, a CDC spokesperson sent *Endpoints News* a statement that “CDC acknowledges that innovation is greatly needed for new tools to address this infection” but that “the risk of false test results is too great to recommend this test for screening of the general population.”

A meeting with FDA officials in September about raising the standards for such tests grew acrimonious after Kimberly said one medical officer questioned why better tests were even necessary, saying there CDC data suggested people don’t change behavior post-diagnosis.

“I said excuse me, that’s medical paternalism,” Kimberly recalled.

An FDA spokesperson disputed the account, saying the call had been about why the CDC does not recommend widespread herpes testing and not about the need for better tests, adding the “FDA representative simply stated information that is publicly available” in CDC guidelines. The FDA works “to ensure that the standards for HSV tests have the necessary sensitivity...without implementing overly-strict standards that would hamper the availability,” he said.

But Terri Warren, a nurse practitioner who runs an HSV clinic in Portland, Oregon and was also on the call, confirmed Kimberly’s account. And emails shared with *Endpoints* show Kimberly requesting the meeting with the FDA in order to “start holding... manufacturers accountable” for accurate testing.

A week later NIAID officials told Kimberly and Klausner that they don’t fund many herpes grants simply because academics don’t submit many. They’re a reactive organization, they said.

That’s true, Klausner said, except when it isn’t. In areas like coronavirus and HIV research, Congress allocated funds and NIH put out specific calls for grants. “NIH has a lot more capacity to be proactive,” he said.

A NIAID spokesperson said the agency is in contact with advocacy groups and is setting up an HSV workshop with researchers and advocacy groups to identify how better to move the field forward.

Klausner said Kimberly is a persuasive advocate. She’s energetic and sympathetic, but doesn’t attack or

criticize officials as can often happen in patient meetings. But bureaucrats are incentivized to be conservative, not proactive.

Kimberly saw the same: Most officials agreed there was a problem, but no one wanted to lead a solution.

Still, there have been glimmers of progress. They met with Abbott about repurposing the tech behind one of their new Covid-19 antibody diagnostics into a more accurate HSV test. And in February Moderna announced that it would develop a herpes vaccine as part of its post-Covid-19 expansion. BioNTech said in March it hopes to put Freidman's shot in the clinic this year, setting up a competition between the two mRNA powerhouses.

As 2023 budget negotiations begun, Kimberly has recalibrated her hopes, asking this time for \$200 million in funding for an HSV prevention and treatment plan. She has meetings lined up with staff from Murray, Sen. Tammy Baldwin, Sen. Richard Shelby, and others, but she hopes to move to an advisory role soon, if the NGO can raise enough money to hire full-time lobbyists.

As the crowdfunding campaigns showed, there's clearly money — and desperate patients — out there. Wald, the self-proclaimed “herpes queen,” still hears from new ones every week, voices that fill her inbox, asking for help, if not a cure.

“I get emails twice a week from people who find me on the internet and who want gene therapy,” she said. “It's so stigmatized.”

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