

Outdated corneal donation policies prevent sight-restoring surgery

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Some forms of blindness and visual impairment can be cured with a corneal transplant surgery using donated eye tissue. However, federal regulations in the United States and Canada severely restrict the ability of sexually active gay and bisexual men from donating their eye tissue.

Corneal donation in the United States is limited by a decades-old policy that bans men from becoming donors if they have had sex with another man in the past five years. Canada similarly bans corneal donations from men who had sex with another man during the previous 12 months.

These restrictions disqualified as many as 3,217 corneal donations from gay and bisexual men in 2018, despite a worldwide need for corneas for vision-restoring surgery and a lack of scientific evidence of harm caused by corneas from these men, according to a new study published in the September 24 issue of the journal *JAMA Ophthalmology*.

"With millions of people across the world in need of corneal transplants, these discarded corneas from gay and bisexual men could be used to address the shortage and safely restore vision to thousands of patients with corneal blindness or visual impairment," said lead author Michael A. Puente, MD, assistant professor of ophthalmology at the University of Colorado School of Medicine.

The study is the first of its kind to review how these policies have restricted corneal donations and prevented patients from receiving sight-restoring care.

The U.S. Food and Drug Administration's prohibition on corneal donation by men who have sex with men was instituted in May 1994, out of concern that HIV rates were disproportionately high in that demographic. At the time, HIV tests were unreliable up to six months after viral exposure. Since then, however, HIV testing has become faster and increasingly reliable, identifying infection within four to eight days of exposure. All corneal donors in the United States are required to undergo three separate HIV tests. Despite these advances, the FDA continues to require gay and bisexual corneal donors to be abstinent for five years, even if all three HIV tests are negative.

"With modern virologic testing and a better understanding of the low risk of HIV transmission through corneal transplants, this five-year deferral policy for gay men is not supported by current science," Puente said. "We ask [federal regulators](#) to reconsider these outdated policies which are depriving patients of the possibility of sight restoration."

The United States and Canada are outliers when it comes to restricting corneal donations from gay and bisexual men, the article says. Many countries, including Spain, Italy, Mexico, Chile, and Argentina, allow gay and bisexual men to donate their eye tissue just as easily as heterosexual donors. Other countries have deferral periods far shorter than five years. For example, the United Kingdom allows corneal donation by gay and bisexual men after only three months of abstinence, while the Netherlands and France only require gay and bisexual corneal donors to be abstinent for four months.

The article in *JAMA Ophthalmology* also reports that the risk of HIV transmission via corneal transplantation is low, further indicating that the restrictions should be reconsidered.

There has never been a reported case of HIV transmission through corneal transplant surgery. In 10 reported cases of corneal transplants from the 1980s and 1990s using tissue from donors who were found to be HIV-positive after surgery, none of the corneal recipients contracted the virus. Meanwhile, all 12 patients who received solid organ transplants, such as hearts, lungs, and kidneys, from those same donors did contract HIV, indicating that the corneas did not carry enough virus, if any, for transmission. These cases date from a time when HIV tests were unreliable, but now all corneal donors in the United States and Canada are required to undergo three separate highly reliable modern HIV tests. The cornea's avascularity likely prevents it from being a major reservoir of the virus, the *JAMA Ophthalmology* article says.

To calculate the number of corneal donations lost in one year due to the federal restrictions on corneal donation by gay and [bisexual men](#), Puente and his co-authors surveyed all 65 eye banks in the United States and Canada to investigate how many potential corneal donors were disqualified in 2018 due to these federal restrictions. The [survey data](#) was gathered from May 2019 to February 2020.

Fifty-four of the 65 eye banks responded to the inquiries. Of those responding, 24 were able to provide a specific number of donation referrals that were rejected specifically due to the federal restrictions on gay and bisexual corneal donors. Using the reported data, Puente and his colleagues calculated an estimated number of potential corneal donations that were discarded in 2018 due solely to the donors' sexual orientation. They estimate it was between 1,558 and 3,217 eyes.

The need for donated corneas is substantial. An estimated 12.7 million people around the world need a corneal transplant, with only one cornea available for every 70 corneal transplants needed. Despite improvements in the reliability and efficiency of HIV tests, restrictive federal policies for cornea donations have not changed, even as limits on blood donation have been relaxed.

Prior to 2015, gay men in the United States were subject to a lifetime ban on [blood donation](#). In 2015, an FDA review concluded that a lifetime ban was no longer scientifically justified and subsequently recommended that gay blood donors must be abstinent for one year. In April 2020, the FDA announced that blood donors should be deferred for only three months in cases when a man had sexual contact with another man. In cases of solid-organ donation, there is no deferral period at all. Meanwhile, gay corneal donors are still required to be abstinent for five years.

"If it's safe for gay men to donate their blood after three months of

abstinence, I can think of no scientific reason to continue to require gay men to be abstinent for five years to donate their eyes," Puente said. "This policy can be changed without increasing the risk of HIV transmission, and I would urge authorities to act as soon as possible to help patients who are waiting for sight-restoring surgery."

More information: *JAMA Ophthalmology* (2020). [DOI: 10.1001/jamaophthalmol.2020.3630](https://doi.org/10.1001/jamaophthalmol.2020.3630)

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