



[Home](#)

News

Money

[Money briefs](#)

Markets

[Markets Report](#)

[Most active stocks](#)

[World stocks](#)

[Commodities](#)

[Currencies](#)

[Key interest rates](#)

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Research

[Stock Screener](#)

[Mutual funds](#)

[screener](#)

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[Columns and tips](#)

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[calculators](#)

[CD and loan rates](#)

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[Economic](#)

[Company](#)

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[Autos](#)

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[Money eXchange](#)

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Scope-cleaning procedures debated

By Julie Appleby, USA TODAY

Two days after Mary Greene went for a routine colonoscopy in September 2000 at her doctor's clinic, she fell ill. After a round of strong antibiotics, she recovered and didn't think too much of it.

But four months later, Greene picked up the local paper and read that the clinic was contacting some patients because its machine for cleaning the medical scopes might have been faulty.

"I'm very upset that such a thing could happen in this day and age," says Greene, 72, who has joined a lawsuit against the clinic and is convinced that her infection with a bacterium after the exam wasn't a coincidence, although a direct link will likely never be proved.

Stories such as Greene's have renewed a long-standing debate about scopes' potential for transmitting disease from one patient to another. Like so many other debates in health care, cost is at the crux.

At a time when health care costs are rising faster than inflation, insurers, hospitals and doctors say they need proof that medical scopes pose a danger before they switch to more expensive disposable models or harsher cleaning methods that wear equipment out faster.

"Endoscopy is an extremely safe procedure," says Douglas Nelson, a gastroenterologist and associate professor of medicine at the University of Minnesota. Replacing all the existing scopes with disposable models, he says, would "double the cost to consumers and vastly increase the cost of medicine at a time when we're trying to control costs."

Critics question safety

But critics say the number of cases of scope-transmitted infections is probably higher than reported.

"If properly informed of how important it is to clean the endoscopes better, the average person wouldn't mind paying the extra money," says Jeff Klein, a New York state assemblyman.

Klein introduced legislation last year to require that medical scopes either be soaked for a minimum of 45 minutes in disinfectant or replaced with disposable models. The bill was tabled, but Klein says he wants to bring it back.

More than 15 million Americans each year have a medical test involving an endoscope, a device with a flexible, reusable tube that snakes inside patients' throats, lungs or intestines, helping physicians find and treat disease without surgery.

The vast majority of those patients suffer no ill effects. Proponents cite figures of one infection per 1.8 million procedures.

Critics say those numbers are too low because problems can crop up days, weeks or months after the initial test, and no one links them with the scopes. No large study has been performed to follow patients after exams to see if they develop infections.

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Endoscopes are cleaned after each use with a series of steps including brushing and soaking them in disinfectant for 20 to 45 minutes. The devices are considered disinfected, but not sterile.

The biggest crusader for new cleaning methods has been microbiologist David Lewis, a researcher at the University of Georgia. "Doctors have a false sense of security based on the low numbers of documented cases," Lewis says.

He advocates soaking the devices in peracetic acid, a stronger solution than the disinfectants used commonly now. But the acid wears out the equipment faster and is not recommended by the devices' manufacturers. Lewis also supports scopes with disposable parts replaced after each use.

His critics say Lewis doesn't have any documentation to prove his estimate that up to 275,000 Americans are infected by scope procedures each year.

"That is based on specious data," says Lawrence Muscarella, a biomedical engineer who works for a company that cleans scopes, Custom Ultrasonics of Ivyland, Pa.

Disposable devices add costs

To really answer the question about how often scopes transmit disease, researchers would need to follow a large group of patients after they have exams, monitoring them regularly to see if they develop infections.

Muscarella says the National Institutes of Health should conduct such a study. Until then, he says, "The question is, do we pay considerably more for something when the data doesn't suggest there is a real risk?"

In the early 1990s, when concern about AIDS was at the forefront, a small company called Vision Sciences in Natick, Mass., introduced disposable scopes.

Originally, the disposable parts of the Vision Sciences endoscopes cost about \$100. The scopes themselves cost about the same as conventional models, ranging from \$7,000 to \$15,000 or more.

"It's a great concept, but it came at a tough time," says James Harrell, a professor of medicine at the University of California at San Diego. "In an era of managed care, when everyone ratcheted down, that \$100 really hurt the company."

Medicare and most insurers don't pay extra for the disposable devices, so doctors who use them eat the cost, or pass the extra charge to patients.

Still, even Olympus Optical has explored making disposable scopes. Olympus holds more than two dozen patents on the technology, issued during the mid-1990s. Those patents point out that cleaning conventional scopes is difficult and time consuming and might not be satisfactorily performed.

But the company has not made disposable scopes.

"They received limited interest by physicians, and we have never commercialized a product," says David Barlow, director of technical assessment for Olympus, a privately held company based in Japan.

While the debate continues, what both sides appear to agree on is that patients should not avoid procedures that involve medical scopes.

"Patients should not feel they are putting themselves at risk by getting a colonoscopy," says Philip Schoenfeld, an assistant professor of medicine at the University of Michigan. "What we're most frightened of is that patients will avoid undergoing a potentially life-saving endoscopy procedure because they're worrying about an infinitesimal risk of getting an infection."

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