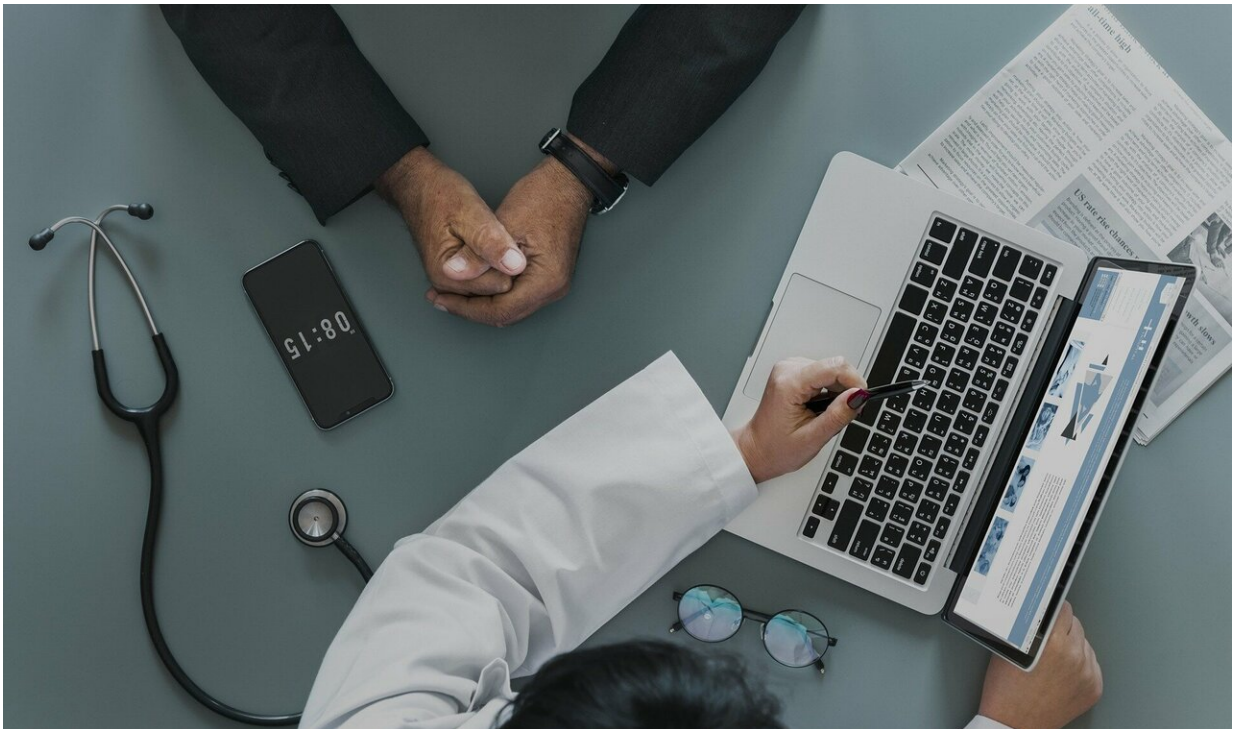


# Elite hospitals plunge into unproven stem cell treatments

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Credit: CC0 Public Domain

The online video seems to promise everything an arthritis patient could want.

The six-minute segment mimics a morning talk show, using a polished TV host to interview guests around a coffee table. Dr. Adam Pourcho

extols the benefits of stem cells and "[regenerative medicine](#)" for healing joints without surgery. Pourcho, a sports medicine specialist, says he has used platelet injections to treat his own knee pain, as well as a tendon injury in his elbow. Extending his arm, he says, "It's completely healed."

Brendan Hyland, a gym teacher and track coach, describes withstanding intense heel pain for 18 months before seeing Pourcho. Four months after the injections, he says, he was pain-free and has since gone on a 40-mile hike.

"I don't have any pain that stops me from doing anything I want," Hyland says.

The video's cheerleading tone mimics the infomercials used to promote stem cell clinics, several of which have recently gotten into hot water with federal regulators, said Dr. Paul Knoepfler, a professor of cell biology and human anatomy at the University of California, Davis School of Medicine. But the marketing video wasn't filmed by a little-known operator.

It was sponsored by Swedish Medical Center, the largest nonprofit health provider in the Seattle area.

Swedish is one of a growing number of respected hospitals and health systems—including the Mayo Clinic, the Cleveland Clinic and the University of Miami—that have entered the lucrative business of stem cells and related therapies, including platelet injections. Typical treatments involve injecting [patients'](#) joints with their own fat or [bone marrow cells](#), or with extracts of platelets, the cell fragments known for their role in clotting blood. Many patients seek out regenerative medicine to stave off surgery, even though the evidence supporting these experimental therapies is thin at best, Knoepfler said.

Hospitals say they're providing options to patients who have exhausted standard treatments. But critics suggest the hospitals are exploiting desperate patients and profiting from trendy but unproven treatments.

The Food and Drug Administration is attempting to shut down clinics that hawk unapproved stem cell therapies, which have been linked to several cases of blindness and at least 12 serious infections. Although doctors usually need preapproval to treat patients with human cells, the FDA has carved out a handful of exceptions, as long as the cells meet certain criteria, said Barbara Binzak Blumenfeld, an attorney who specializes in food and drug law at Buchanan Ingersoll & Rooney in Washington.

Hospitals like Mayo are careful to follow these criteria, to avoid running afoul of the FDA, said Dr. Shane Shapiro, program director for the Regenerative Medicine Therapeutics Suites at Mayo Clinic's campus in Florida.

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While hospital-based stem cell treatments may be legal, there's no strong evidence they work, said Leigh Turner, an associate professor at the University of Minnesota's Center for Bioethics who has published a series of articles describing the size and dynamics of the stem cell market.

"FDA approval isn't needed and physicians can claim they aren't violating federal regulations," Turner said. "But just because something is legal doesn't make it ethical."

For doctors and hospitals, stem cells are easy money, Turner said. Patients typically pay more than \$700 a treatment for platelets and up to \$5,000 for fat and bone marrow injections. As a bonus, doctors don't

have to wrangle with insurance companies, which view the procedures as experimental and largely don't cover them.

"It's an out-of-pocket, cash-on-the-barrel economy," Turner said. Across the country, "clinicians at elite medical facilities are lining their pockets by providing expensive placebos."

Some patient advocates worry that hospitals are more interested in capturing a slice of the stem-cell market than in proving their treatments actually work.

"It's lucrative. It's easy to do. All these reputable institutions, they don't want to miss out on the business," said Dr. James Rickert, president of the Society for Patient Centered Orthopedics, which advocates for high-quality care. "It preys on people's desperation."

In a joint statement, Pourcho and Swedish defended the online video.

"The terminology was kept simple and with analogies that the lay person would understand," according to the statement. "As with any treatment that we provide, we encourage patients to research and consider all potential treatment options before deciding on what is best for them."

But Knoepfler said the guests on the video make several "unbelievable" claims.

At one point, Dr. Pourcho says that platelets release growth factors that tell the brain which types of stem cells to send to the site of an injury. According to Pourcho, these instructions make sure that tissues are repaired with the appropriate type of cell, and "so you don't get, say, eyeball in your hand."

Knoepfler, who has studied stem cell biology for two decades, said he

has never heard of "any possibility of growing eyeball or other random tissues in your hand." Knoepfler, who wrote about the video in February on his blog, The Niche, said, "There's no way that the adult brain could send that kind of stem cells anywhere in the body."

The marketing video debuted in July on KING-TV, a Seattle station, as part of a local lifestyles show called "New Day Northwest." Although much of the show is produced by the KING 5 news team, some segments—like Pourcho's interview—are sponsored by local advertisers, said Jim Rose, president and general manager of KING 5 Media Group.

After being contacted by KHN, Rose asked Swedish to remove the video from YouTube because it wasn't labeled as sponsored content. Omitting that label could allow the video to be confused with news programming. The video now appears only on the KING-TV website, where Swedish is labeled as the sponsor.

"The goal is to clearly inform viewers of paid content so they can distinguish editorial and news content from paid material," Rose said. "We value the public's trust."

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Federal authorities have recently begun cracking down on doctors who make unproven claims or sell unapproved stem cell products.

In October, the Federal Trade Commission fined stem cell clinics millions of dollars for deceptive advertising, noting that the companies claimed to be able to treat or cure autism, Parkinson's disease and other serious diseases.

In a recent interview Scott Gottlieb, the FDA commissioner, said the agency will continue to go after what he called "bad actors."

With more than 700 stem cell clinics in operation, the FDA is first targeting those posing the biggest threat, such as doctors who inject stem cells directly into the eye or brain.

"There are clearly bad actors who are well over the line and who are creating significant risks for patients," Gottlieb said.

Gottlieb, set to leave office April 5, said he's also concerned about the financial exploitation of patients in pain.

"There's economic harm here, where products are being promoted that aren't providing any proven benefits and where patients are paying out-of-pocket," Gottlieb said.

Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, said there is a broad "spectrum" of stem cell providers, ranging from university scientists leading rigorous clinical trials to doctors who promise stem cells are "for just about anything." Hospitals operate somewhere in the middle, Marks said.

"The good news is that they're somewhat closer to the most rigorous academics," he said.

The Mayo Clinic's regenerative medicine program, for example, focuses conditions such as arthritis, where injections pose few serious risks, even if that's not yet the standard of care, Shapiro said.

Rickert said it's easy to see why hospitals are eager to get in the game.

The market for arthritis treatment is huge and growing. At least 30 million Americans have the most common form of arthritis, with diagnoses expected to soar as the population ages. Platelet injections for arthritis generated more than \$93 million in revenue in 2015, according

to an article last year in The Journal of Knee Surgery.

"We have patients in our offices demanding these treatments," Shapiro said. "If they don't get them from us, they will get them somewhere else."

Doctors at the Mayo Clinic try to provide stem cell treatments and similar therapies responsibly, Shapiro said. In a paper published this year, Shapiro described the hospital's consultation service, in which doctors explain patients' options and clear up misconceptions about what stem cells and other injections can do. Doctors can refer patients to treatment or clinical trials.

"Most of the patients do not get a regenerative (stem cell) procedure," Shapiro said. "They don't get it because after we have a frank conversation, they decide, 'Maybe it's not for me.'"

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Although some hospitals boast of high success rates for their stem cell procedures, published research often paints a different story.

The Mayo Clinic website says that 40 to 70% of patients "find some level of pain relief." Atlanta-based Emory Healthcare claims that 75 to 80% of patients "have had significant pain relief and improved function." In the Swedish video, Pourcho claims "we can treat really any tendon or any joint" with PRP.

The strongest evidence for PRP is in pain relief for arthritic knees and tennis elbow, where it appears to be safe and perhaps helpful, said Dr. Nicolas Piuzzi, an orthopedic surgeon at the Cleveland Clinic.

But PRP hasn't been proven to help every part of the body, he said.



PRP has been linked to serious complications when injected to treat patellar tendinitis, an injury to the tendon connecting the kneecap to the shinbone. In a 2013 paper, researchers described the cases of three patients whose pain got dramatically worse after PRP injections. One patient lost bone and underwent surgery to repair the damage.

"People will say, 'If you inject PRP, you will return to sports faster,'" said Dr. Freddie Fu, chairman of orthopedic surgery at the University of Pittsburgh Medical Center. "But that hasn't been proven."

A 2017 study of PRP found it relieved knee pain slightly better than injections of hyaluronic acid. But that's nothing to brag about, Rickert said, given that hyaluronic acid therapy doesn't work, either. While some PRP studies have shown more positive results, Rickert notes that most were so small or poorly designed that their results aren't reliable.

In its 2013 guidelines for knee arthritis, the American Academy of Orthopaedic Surgeons said it is "unable to recommend for or against" PRP.

"PRP is sort of a 'buyer beware' situation," said Dr. William Li, president and CEO of the Angiogenesis Foundation, whose research focuses on blood vessel formation. "It's the poor man's approach to biotechnology."

Tests of other stem cell injections also have failed to live up to expectations.

Shapiro published a rigorously designed study last year in *Cartilage*, a medical journal, that found bone marrow injections were no better at relieving knee pain than saltwater injections. Rickert noted that patients who are in pain often get relief from placebos. The more invasive the procedure, the stronger the placebo effect, he said, perhaps because



patients become invested in the idea that an intervention will really help. Even saltwater injections help 70% of patients, Fu said.

A 2016 review in the *Journal of Bone and Joint Surgery* concluded that "the value and effective use of cell therapy in orthopaedics remain unclear." The following year, a review in the *British Journal of Sports Medicine* concluded, "We do not recommend stem cell therapy" for knee arthritis.

Shapiro said hospitals and health plans are right to be cautious.

"The insurance companies don't pay for fat grafting or bone-marrow aspiration, and rightly so," Shapiro said. "That's because we don't have enough evidence."

Rickert, an orthopedist in Bedford, Ind., said fat, bone marrow and platelet injections should be offered only through clinical trials, which carefully evaluate experimental treatments. Patients shouldn't be charged for these services until they've been tested and shown to work.

Orthopedists—surgeons who specialize in bones and muscles—have a history of performing unproven procedures, including spinal fusion, surgery for rotator cuff disease and arthroscopy for worn-out knees, Turner said. Recently, studies have shown them to be no more effective than placebos.

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Some argue that joint injections shouldn't be marketed as stem cell treatments at all.

Piuzzi said he prefers to call the injections "orthobiologics," noting that platelets are not even cells, let alone stem cells. The number of stem cells

in fat and bone marrow injections is extremely small, he said. In fat tissue, only about 1 in 2,000 cells is a stem cell, according to a March paper in *The Bone & Joint Journal*. Stem cells are even rarer in bone marrow, where 1 in 10,000 to 20,000 cells is a stem cell.

Patients are attracted to regenerative medicine because they assume it will regrow their lost cartilage, Piuzzi said. There's no solid evidence that the commercial injections used today spur tissue growth, Piuzzi said. Although doctors hope that platelets will release anti-inflammatory substances, which could theoretically help calm an inflamed joint, they don't know why some patients who receive platelet injections feel better, but others don't.

So, it comes as no surprise that many patients have trouble sorting through the hype.

Florida resident Kathy Walsh, 61, said she wasted nearly \$10,000 on stem cell and platelet injections at a Miami clinic, hoping to avoid knee replacement surgery.

When Walsh heard about a doctor in Miami claiming to regenerate knee cartilage with stem [cells](#), "it seemed like an answer to a prayer," said Walsh, of Stuart, Fla. "You're so much in pain and so frustrated that you cling to every bit of hope you can get, even if it does cost you a lot of money."

The injections eased her pain for only a few months. Eventually, she had both knees replaced. She has been nearly pain-free ever since. "My only regret," she said, "is that I wasted so much time and money."

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