Fall 12-18-2020

Hips that harm: when medical devices fail women

Sophie N. Putka
Craig Newmark Graduate School of Journalism

Hips that harm: when medical devices fail women

A medical system that puts joint replacements in female bodies still hasn't repaired its male bias

By Sophie Putka

When Linda Radach got her new left hip in 2006, she was so pleased with the results that she got the other hip done. She'd been in pain from osteoarthritis for years and finally, for the first time, there was relief. "The first one was so glorious," she said. "I was completely pain free immediately.'"

But that feeling was short-lived. Radach would soon join the ranks of other women* whose joint replacements stole their health instead of restoring it. And though government agencies and researchers have acknowledged the risks of some kinds of medical devices that are used in both sexes, studies suggest that they harm women disproportionately. Even less is known about older and non-white women.

It's part of a bigger problem that has plagued medical research. "Whether that's research on devices, research on new drugs or research on other sorts of interventions for health care, whether it's preventive or curative or treatment wise, we don't pay attention to the role of sex as a biological variable and gender," said Melissa Laitner, Director of Science Policy at the Society for Women's Health Research. "If we only use men's bodies to study something, we're missing how these things work in women, and women have different metabolisms, women have different immune systems. Women are built differently."

When it comes to hips, other joint replacements, and even heart devices, female bodies are different from male bodies. But women are often underrepresented in medical trials for device approval. And though women's participation in testing for devices has increased, there's rarely an detailed analysis of performance by sex, and even less information on women by race or age. Lax regulations and bias in medicine also make it difficult to identify the problems and correct them.

In 2006, Radach was working as an elementary school music teacher in the Seattle area. She liked hiking with her husband, and cross-country skiing. She was in pain because of chronic osteoarthritis for years, and she said a sports medicine doctor who read the one of the first CT scans of her hip told her he knew of a good orthopedist, Dr. James Pritchett. "He was recommended to me as being the guru of this procedure," Radach said.

She had her hip resurfaced - a procedure similar to a total hip replacement where the top of the femur isn't removed, and instead, a shorter stem is put in to support the joint ball. It was made by Wright Orthopedics. Radach said Pritchett told her she'd be getting a device that was bone conserving, and good for active people. "If I had known then what I know now, I would have told him he was full of hot air," she said "There's no way that he could tell me - and he did tell me - that it would last 20 years, possibly my lifetime."

Since her first hip resurfacing in 2006, Radach has undergone six surgeries in 11 years, with more expected to come. The devices in her body haven't fit correctly into her bone. They've corroded and come loose. They've shed particles into her blood, giving her metallosis, a kind of blood poisoning. Radach can't walk without crutches except for short differences within her home, and feels constant pain. The problems she's experienced mirror what studies have found since her surgeries: that certain hip devices often don't work as well in women.

Hip devices harming female bodies

Hip replacements are one of the more "successful" medical interventions orthopedists have at their disposal. A 2017 study from Lancet that looked at 63,158 total hip replacements found the survival rate was 95.6% after 10 years. But, and perhaps for this reason, they're one of the most commonly performed joint replacement surgeries. 2.5 million Americans had artificial hips in 2010, according to one estimate with the most recently available data. That means that even a four percent failure rate could leave 100,000 people in the US with hip implants that fail and must be revised - redone - within 10 years.

But the rate of failure and revision, the corrective operation after an initial hip replacement fails, is much higher in women than men. One study, conducted with a sample of 35,140 patients, found that women who had total hip replacements had a 29% higher risk of implant failure than men. With hip resurfacing, a procedure meant to preserve bone, the outcomes weren't much better.

A review of studies that looked at metal-on-metal hip resurfacing found that women were more likely to develop adverse local tissue reaction, dislocation, loosening, and revision. Another study of patients with one of the more problematic models, found that female patients had higher levels of cobalt and chromium levels in their blood, consistent with other studies. Experts and studies say it's widely known that these kinds of hips don't work in women, and have begun using less of them.

But the system we still use to evaluate how safe medical devices are hasn't changed much - and the quality of research on women is still lacking, experts say. The problem of hips is one example. Radach's hip followed the flawed path that many other medical devices do to get from the manufacturer to the inside of a human body, beginning with devices whose design didn't work for female bodies, and continuing to a regulatory process that prizes quick device approval, testing that often under-represents women, especially older and non-white women, and gender bias within medicine overall.

Clinical trials don't account for physiological differences

To understand what went wrong with Radach's replacement and others that failed, it's important to understand how male and female bodies are different. The differences begin at the cellular level, and go far beyond the reproductive system. Research shows that the "sex of cells" can

have far-reaching effects, and these differences can control anything from the visible - facial hair and fat distribution - to the invisible: how arterial blockages happen or how dense our bones are.

Sex-based differences in body composition are fairly well-known: women generally have less muscle mass, less bone mass, and higher body fat as a result of sex steroid hormones like estrogen and testosterone. Less acknowledged are sex differences present in many (if not most) organ structures that can affect their function. Males have larger lungs, which can affect exercise capacity. Structural brain differences can affect pain threshold or regulatory processes like body temperature. Females have a smaller left ventricular mass and chamber sizes in their heart, and have lower resting blood pressure and higher resting heart rate. Hormonal differences seem to interact with the cardiovascular system in ways that are not yet fully understood, but experts say it's clear males and females experience heart disease differently.

"In science, it has been that men have been the standard and women were considered a subgroup," said Alyson McGregor, the Director of the Division of Sex and Gender in Emergency Medicine and an Associate Professor of Emergency Medicine at the Warren Alpert Medical School of Brown University. "Women? We're not a subgroup. We are a different human species. We have a different physiology and anatomy, and different DNA."

Beyond reproduction, our clinical understanding of how male and female bodies differ has a relatively short history. You only have to look back a few decades to find that women were largely absent from clinical trials for a number of reasons - including a recommendation from the FDA in 1977 which, in effect, banned women "of childbearing potential" from clinical trials because of the the influence of their hormones on medical outcomes and the potential dangers to embryos in pregnant women.

In 1993 - just a generation ago - Congress passed the NIH Revitalization Act, which required for the first time that women and minorities be included in clinical trials funded by the National Institutes of Health. The FDA, which regulates drugs and medical devices, issued guidance in 1998 strongly encouraging companies to include and analyze data on women and other "subgroups," including the elderly and minorities, but do not explicitly require quotas or representative data in clinical trials.

Diana Zuckerman, President of the National Center for Health Research, wrote in an article for JAMA Internal Medicine on the issue, "What is urgently needed is long-term comparative effectiveness research based on large sample sizes, indicating which THA [total hip arthroplasty] devices are less likely to fail in women and in men, with subgroup analyses based on age and other key patient traits."

And though the participation of female patients in clinical research has increased significantly - one study found that they made up 49% of participants in clinical trials - experts say there's still a lack of meaningful analysis in the research. Simply including women in trials without going further, Zuckerman says, doesn't do much for women if they don't have detailed information on how the device worked in someone like them.

“What I want to know is, how effective is it? For me as a woman or for every woman on average? Or for women of a certain age, on average? Or women of a certain race or ethnicity on average?” she said. “Instead of just looking at everybody all mushed together, did the benefits outweigh the risk for people on average, when maybe those averages are hiding something?”

If the hip doesn’t fit

But decades of information suggest that the devices themselves also play a role. When it comes to joint replacements and implants, female bodies are not only shaped differently - they are also more likely to develop the problems that lead to joint replacement, have bones that may not be as receptive to implants. Doctors interviewed and a number of studies said that metal on metal hips are associated with worse outcomes for women, like dislocation, revision or wear on the implant, due in part to the size, shape and material of the devices.

In the UK, Dr. David Langton runs an independent organization called ExplantLab, where he has studied devices that fail after they come out of patients’ bodies for years. He provided some of the earliest data that showed that Johnson & Johnson’s Pinnacle metal-on-metal hip implants were affecting female patients disproportionately. “Women were definitely being exposed to larger concentrations of metal in general,” he said, “because with these types of hip replacements, the smaller implants tended to throw off more metals. And the size of your implant was determined by your pre-existing anatomy. So women are smaller, they got smaller implants.”

Here’s how a hip works: the top of the femur, or upper leg bone, bends at the top and ends in a head or ball, which fits into a socket in the pelvis. The cup cradles the ball and allows it to hinge. Among other differences, male pelvises are narrower, and the hip sockets generally shallower and tilted at a different angle to accommodate the ball. Male femurs, or the bone that fits into the socket, are generally thicker, with a bigger head, and don’t tilt inward as much as female hips do. Male bones have higher mineral density than female bones, which means females are more likely to experience fracture with their prosthetic hips.

Radach was only 53 at the time of her first hip surgery, but had struggled with symptoms of osteoarthritis for years. She said she felt pain when she sat, stood, or lay down, and that her husband told her she’d whimper in her sleep. Osteoarthritis, the most common reason for hip replacement, occurs when cartilage between joints is worn down, and female patients get it at higher rates than males.

And though orthopedic surgeons say they can customize a hip replacement to an extent by using devices of different sizes and shapes, some devices, like Radach’s second left hip, just didn’t fit right. Bone didn’t grow into it like it was meant to, and part of it loosened and moved out of place. In a book from 2020 that describes surgical techniques for hip and knee joint replacements, the authors write, “These anatomical differences and their impact on joint

replacement were quite evident with metal-on-metal hip resurfacing, where the smaller head size and acetabular orientation lead to a higher risk of failure."

Conflicting accounts of hip issues

One orthopedist, Dr. Monti Khatod, who has studied sex disparities in hip replacements, said, "females are no longer getting hip resurfacing because their failure rates were so high, most likely due to the size of the implant, them having smaller implants overall." Many doctors now acknowledge that hip resurfacing isn't a good idea for female patients - he said "Female gender is a contraindication now for hip resurfacing"* - but the surgery is still performed. But he said that hip replacements don't do as well in older women, not necessarily the devices, but because of differences in their bone density which make them more prone to fractures.

Radach's doctor, Pritchett, still uses hip resurfacing, and disputes that resurfacing isn't good for female patients. "In my practice, I do more resurfacing than I do total hip, but that's what people ask for. It's always been true, every single year it's true, people are asking for it," he said. "What implant they get, you give them the best implant you have at the time." He said that he doesn't use metal-on-metal resurfacing anymore.

In a total hip replacement, the top of the femur with the ball, known as the femoral head, is removed and prosthetic parts are put in: a stem in the femur and a ball that attaches to the stem. The surgeon makes space for the cup or socket, and the cup is put in with surgical screws. The ball moves inside the shell, mimicking the movement of a ball and socket of a regular hip.

In a hip resurfacing, the top of the femur is covered with a ball with a short stem, instead of removed. Radach's first hip resurfacing used Wright Medical Technology's Conserve Plus Cup and a Conserve Superfinish Femoral Resurfacing Component. Radach recalled Pritchett's explanation of the advantages of hip resurfacing:

"He explained the difference between the two and why resurfacing would be a better option, because I was a younger, more active patient." said Radach. "What he did is what he proposed, and I didn't find any information on it that would tell me otherwise."

Pritchett, on the other hand, said that "The same patient was absolutely adamant that she received this in the first place. No one twisted her arm, she came to me demanding a hip resurfacing, not the other way around." Regardless, her hip resurfacing wouldn't last, and she'd move on to revision surgery - a redo where her doctors would perform total hip replacement.

Linda's first hip

About two years after the first surgeries, something went wrong with Radach's new hip. "I stepped off a stairway to go out to the playground for the first day of school activities. And I froze in pain. I couldn't move, it was just sudden," she said. "It was just this incredible, painful

stab and burn." She returned to Pritchett. "He blew me off, like, 'well, there's nothing wrong.'" But the pain continued, and she said she went to see him two more times before X-rays revealed that the hip socket had come loose.

When asked why Radach's hip resurfacing and subsequent revision failed, Pritchett blamed Radach's other medical issues, like nerve damage from a spinal problem and an elevated sedimentation rate, which is a condition that causes inflammation. "This was a complicated issue that went a lot of different directions." He said the metal in her implant wasn't a problem.

In medical records, a note from Pritchett read that "She continued to have failure of the acetabular component to bond with migration, loosening," which means the cup in her hip socket had come loose and moved. The note also reads, "there was modest metallosis and the acetabular [socket] bone was damaged by a mobile implant." Metallosis is a dangerous buildup of metal debris in the body that happens when metal components from joint replacements rub against each other.

When "female gender" is a risk factor

The problem was, Radach's hip as a whole wasn't approved based on testing in human bodies until 2009, three years after she had her operation. The components had been approved separately through a process used for 82% of medical devices that fast tracks approval based on comparing the new device to older devices that are similar, called the 510(k) path. The fast track approval process doesn't require trials in people. The components were approved together as a "hip system" in 2009 using clinical data. The trials, which began in 2000, included far fewer females than males: 90 female patients and 202 male.

Two of these original devices were metal-on-metal hip joint prosthetics, meaning that a metal ball turns inside of a metal cup in the hip socket. The components implanted into Radach's hip were found to be "substantially equivalent" to what are called "predicate devices," or devices that could be traced back to a number of original devices that were not required to submit clinical data back when the FDA created a device approval process in 1976. Since then, these components and their descendents have proven to be problematic - in fact, some of the original 25 devices mirror ones that the FDA's Health of Women flagged as problematic even in 2019.

In 2009, Wright submitted their application for Pre Market Approval for their Conserve Total Hip System based on their clinical investigation, which included their Femoral Shell and Acetabular Component, like the ones Radach had implanted.

Early warning signs were noticeable, even in Wright's application, which included an evaluation of their own data. In the patient group they studied, 69.2% of the participants were male, and 30.8% were female. The top risk factor listed, according to the level of risk, was "female gender."* Seven percent of those who underwent resurfacing with the Wright system had revision surgery within their follow up period of only two years - meaning that the surgery had to be redone, like Radach's.

Another sign of what was to come had to do with the shedding of metal particles into the body that happens when two metal components run against one another. A study Wright cited in a special section devoted to “metal ions,” found that in a number of hip resurfacing cases - 5 females and one male out of their study group - patients developed “pseudotumors” that were associated with elevated metal levels in their body. They concluded, “The current study also shows a very high (15%) incidence of asymptomatic abnormal soft tissue reaction in females.” Still, the Wright Conserve Total Hip System was approved.

Several other hips that have come up in multi-million dollar lawsuits were also tested on small groups of women - with even less information on race or age. Smith & Nephew tested their Birmingham Hip System, which did have to submit a clinical investigation, on a group that was less than 30% women. Pinnacle’s Complete Acetabular Hip System had better representation, at 43% female, but only tested the system in 114 patients overall. Neither noted much much beyond the number of women they included, but both of their safety summaries noted a contraindication for their implants: “Females of child-bearing age due to unknown effect on the fetus of metal ion release.”

The metal problem

The problem with metals in implantable devices is a complex one. Linda suspected there was more than loosening wrong with her first hip resurfacing. She was breaking out in rashes she’d never seen before, had a tremor in her hands, and felt more tired than usual. She had her blood tested for cobalt and chromium levels, which were higher than normal - but based on some medical guidelines, not high enough to raise red flags.

Herein lies the problem with metal-on-metal joint implants. The rubbing of metal components has been shown to release metal particles into the surrounding tissue, which can result in metallosis - blood poisoning from blood which has been linked to a wide range of symptoms, from heart including heart failure, visual impairment, cognitive impairment, problems with hearing, like tinnitus, skin rashes, thyroid problems and implant loosening.

Dr. Stephen Tower, who published some of the first research on the harmful effects of the popular cobalt-chromium metal alloy used in implants, has studied the metal issue for over a decade. Tower, who had a metal-on-metal hip himself, said that for that device, “As a class, just because of size differences, the women were more likely to get into trouble with having elevated levels, generating cobalt chrome metallosis.” Doctors like Tower and Langton agree that women had worse outcomes with hip implants because of problems with fit and size that led to more metal “shedding.”

It gets fuzzier when trying to determine what level of metal in the blood is too high. Tower said an obvious sign of something amiss is metal buildup at the joint, with discoloration, loosening, and the deterioration of surrounding muscle. Less obvious is a spread of metal ions, throughout the body, or “systemic cobalt poisoning.” Mayo Clinic writes puts the toxicity level for ingest cobalt at levels above 5 nanograms per milliliter (1ng/mL), but didn’t specify what level might be

too high for patients with metal implants. Tower wrote in a briefing to the FDA Medical Devices Advisory Committee that although different levels could have varying meanings by device, levels above 3 ng/mL could indicate a patient at risk for metallosis. In 2017, long after both of Radach's metal-on-metal hips had been removed, a lab test showed her cobalt levels were three times higher: 9.1 ng/mL.

What makes the problem difficult to grasp is that, Tower explained, some people can have bad responses to metal just from a small amount. "One thing that I think plays through as being very gender specific and somewhat unrelated to body size per se," he said, "is I think it's pretty clearly established that women are much more likely to have a idiosyncratic hypersensitivity 'Type two' allergic response to the cobalt chrome alloy."

"It's like getting anaphylaxis from a bee sting or something, it's strictly an immune phenomena." Surgeons who put in the hips, and the device companies that make them, are often dismissive of the problems, Tower said. Their blood levels might not show toxic levels of metal. "They might say, 'Oh, that's like a meteorite strike that happens, but it's incredibly rare. So, you know, it wasn't the fault of the company, you know, that was an act of God.'"

Problems with other implantable devices

Hips aren't the only implantable devices that have shown poor outcomes in female patients. The FDA, in its Center for Devices and Radiological Health's Office of Women's Health Strategic Plan, noted that women with heart devices, like left ventricular assist devices (LVADs) and endovascular grafts, also showed worse outcomes. The FDA's Health of Women Program Strategic plan noted that with LVADs, pumps that are connected to the heart but have batteries and controllers outside the body. "Women have a higher risk for right ventricular failure, stroke, other neurologic complications, arrhythmias, bleeding and thrombosis."

In a pre-market clinical investigation for one LVAD, Thoratec doesn't even mention female sex in their data. included 121 patients of "male sex" - 79.6% - which means that 31 patients were female. Fewer women receive LVAD devices for heart failure, but a study from 2019 showed that women who received LVADs were significantly more likely to be Hispanic or African American. The device approval study includes no breakdown of women by race - or any analysis by sex or race at all.

Other LVADs on the market, like Thoratec's earlier version included very small sample sizes of female patients: 17% for the Heartmate II, and 28% for HeartWare. Neither application included a breakdown by race or age. A 2019 study on LVADs concluded that even when women were matched with similar men, women experienced "lower survival" but that their ability to provide more detailed analysis on these outcomes was limited by the data available to them.

Even if device companies aren't required to submit information on real patients before they sell their products, patients might expect there to be extensive research conducted after surgeons begin to use them. This kind of information is known as "post-market" research. Here, too, there

are problems. Langton, the researcher who studies implants after they're removed, said that usually, devices taken out because of a problem aren't sent back to the manufacturer - but the company expects to sell a new joint to the hospital.

"Joint replacements, you just throw it in the bin. It's like taking your car to the manufacturer, saying there's a problem with the steering or whatever, and they just throw it away, scrap it in front of you and expect you to buy a new one," he said. "It's absolutely ridiculous. Not only is it ridiculous for the actual individual patient, it's ridiculous for the long term, because how do you know to improve things?"

Systems for tracking device problems fall short

The system the FDA set up to track devices after they're sold is called the MAUDE database. It's home to hundreds of thousands of reports on "adverse events" - when something goes wrong with a device - submitted by companies, patients, doctors, and lawyers. But this system has come under fire in recent years for issues with reporting and it's difficult-to-use interface.

Madris Tomes, a former FDA device analyst, created her own adverse events database after leaving the FDA, to address some of the problems. When it came to hips, "It's probably the dirtiest data the FDA has. that's just the problem with the hip data," said Tomes. It's not well classified. It really was just a huge mess." The FDA has begun to roll out a system that will require unique identification numbers for medical devices, but it won't be enforced until 2022.

If a patient wanted to see how a device performs in women now, she might have a hard time. The FDA doesn't require disclosure of the patient's sex in their adverse reporting system. Filing adverse event reports is voluntary for doctors and patients, and mandatory for device manufacturers and importers.

But, among a number of other problems, Zuckerman, the National Center for Health Research president, said that device companies can conclude that a problem was due to surgeon error instead of their device. "I don't think the companies have particularly good data on all the people harmed for the simple reason that they don't want to have it," she said. "It's always somebody else's fault. It's not their device. So they definitely under-count."

Gender bias in medicine

Sex, which is assigned at birth, is only one part of the equation when it comes to medical care. Gender, or the role imposed on someone within society or that they take on, also impacts health. Sex and gender don't always overlap, and when they are considered together, the problems with medical devices can magnify. One orthopedist, though she said she didn't believe devices themselves weren't to blame for worse outcomes in women, said women may come in later with problems and may not even be considered for joint replacement surgery as often if they bring them up.

“They [women] may think that joint pain is to be anticipated with aging, they may not think it's important, and so they may not be empowered to speak up,” said Dr. Kim Templeton, Professor of orthopedic surgery at the University of Kansas Medical Center and past president of the American Medical Women's Association. “On the other hand, if you look at data from the physician side, women tend to be less likely to be referred to discuss surgery than a man.”

Some studies suggest this may be the case. One said that while women might be more likely to seek treatment for joint operations, they might be willing to accept more pain and adjust to a “lower functional level,” and noted that physicians “reportedly minimized women’s symptoms and attributed them to emotional rather than physical causes.” Another found that women were more disabled by the time they had total hip replacement.

Medical schools play a role in disseminating information about sex differences. A report on a conference related to sex and gender based medical education noted that though research on women’s health had made progress, it wasn’t being applied well to care. Dr. Marjorie Jenkins, former chief scientific officer at the Laura W. Bush Institute for Women’s Health, presented on a survey that found 70% of 46 US medical schools did not have formal sex and gender specific curriculum in 2011. Fewer women are orthopedic surgeons, and tend to have lower academic ranks.

Women also described not being believed time after time, as they described the pain in their medical implants. Radach remembers her right hip being in so much pain after her first resurfacing that she visited another doctor, who told her everything was fine. She remembers thinking, “Well, this is nuts because I know I'm not making this up,” she said. “He looked at the X rays, and he said, ‘Well, your right side is fine.’ I said, ‘No, it's not.’ ‘Yes, it is,’ ‘No, it’s not.’ A classic argument. Because he can't see it on the X-ray he thinks it's fine.”

It wasn’t until years later that she finally had it, too, revised - there was a bone spur that had grown when the ill-fitting hip component was hitting it. All three women interviewed for this story recall almost identical conversations, and in online groups and forums, patients echo the same narrative: their doctors didn’t believe their pain was a sign anything was wrong.

Device companies and lawsuits

Zimmer, Stryker and Smith & Nephew did not respond to multiple requests for comment about their hips. DePuy declined to talk and suggested speaking to the FDA. Companies who manufactured problematic hips: Wright, DePuy Orthopedics, Zimmer Biomet, Stryker - have been embroiled in lawsuits that have resulted in recalls and settlements. Documents from the legal proceedings show that in some cases, device companies mislead the medical community and patients with their research promises that their devices were safe and effective. Wright’s Conserve, Profemur, and Dynasty models - all of which Radach had implanted either in her first resurfacing or subsequent revision, were named in the roughly 2,000 lawsuits against them, and settled them in 2016 and 2017 for a combination of $330 million.

DePuy Synthes, a division of Johnson & Johnson, has faced similar problems involving it's ASR and Pinnacle models. The ASR systems were recalled worldwide in 2010 after studies showed the devices were failing at an unexpectedly high rate, and DePuy stopped selling their all-metal Pinnacle hips after many patients claimed their faulty devices had caused metallosis. Other Pinnacle hips are still on the market.

As for the FDA, they've issued updated guidance on their preferences for representation of female patients, racial and ethnic minorities, and people of different ages in clinical trials. But it remains just that - guidelines. There's even a disclaimer at the top of every page, reminding industry reps that what they're reading "Contains Nonbinding Recommendations."

"You don't want an innovator or scientists to just include women on clinical trials because they're told to do that," said Terri Cornelison, Chief Medical Officer and Director for the Health of Women Program at the FDA's Center for Devices and Radiological Health. "What you want is for the scientists and innovators to understand the importance, because that's where the ideas come, that's where the innovation comes."

How to fix the problem

The FDA can't change its own laws - only Congress can do that. But it can enforce regulations. Agencies like the Governmental Accountability office have called for routing high risk device approvals out of the 510(k) fast track, and experts like Zuckerman said the FDA could reject device applications that don't include good quality data from clinical trials - data that includes a large and robust group of patients. Law experts have recommended Medicare pay less for devices that don't undergo clinical testing or aren't evaluated by independent studies.

"Even though the companies do complain about how expensive clinical trials are, they're the ones that are going to make a lot of money if their product is approved. And they're the ones that are going to get sued if their product is dangerous," said Zuckerman, the National Center for Health Research president. "So you would wish that they would be willing to spend that extra money and take that extra time to recruit the people they need to recruit and to provide the incentives that make it possible for people who want to participate in clinical trials to participate."

To encourage participation, Zuckerman said that companies making devices could make it easier by removing barriers for communities with limited resources. A STAT e-book on representation and diversity in clinical trials suggested offering mothers with children childcare, or engaging younger community members as a bridge to older family members. Recruiters for trials could offer taxi fare for people with no access to a car. The e-book suggested having doctors that live in neighborhoods near the trial participants conduct trials, and providing flexible dates and timing for participants.

According to Tomes, the FDA could also make their adverse-event reporting database better by asking for both sex and gender, and making information about devices easy to find and compare with others - by all demographics. Patient groups have called for devoting more

funding from user fees to tracking devices after they enter the market. Earlier this year, the FDA did announce a number of small changes to the adverse event reporting system, including an option to report “gender.”

Langton emphasized the importance of studying devices after they’ve failed in order to make improvements on them, which he says can be done inexpensively. “For thirteen years now, I've been banging my head against a brick wall about this,” he said. “But the bottom line is, there's just basically inertia, there's just sort of ‘oh, we're just going to throw them in the bin, because that's what we do.’”

In a 2013 report called “The Business Case for Medical Device Quality,” the consulting group McKinsey & Company made the case that improving product quality early on could indeed save device companies money in the long run. “The risk that a major quality event will cause serious, long-term value destruction is high and rising,” they wrote.

“Financially, it's beneficial to look at it that early on, because then you're not pulling these devices off the shelf,” said McGregor, the director of the Division of Sex and Gender in Emergency Medicine. “Take the time and enroll both men and women in the study in the beginning and you'll save time, money, and lives.”

*Note on language: this story distinguishes between the role of sex and gender in device outcomes when possible, but it isn't always clear when they overlap, partially because some studies and experts use gender and assigned sex interchangeably. For simplicity, the gender-related word "woman" or "women" (rather than sex-related "female") is used when the distinction was not evident.

Title GIF concept vectors by: Vecteezy and the American Academy or Orthopedic Surgeons