Caroline Hopkins
May 20, 2019

East Harlem's new cancer treatment center: Safer for patients, but at what cost?

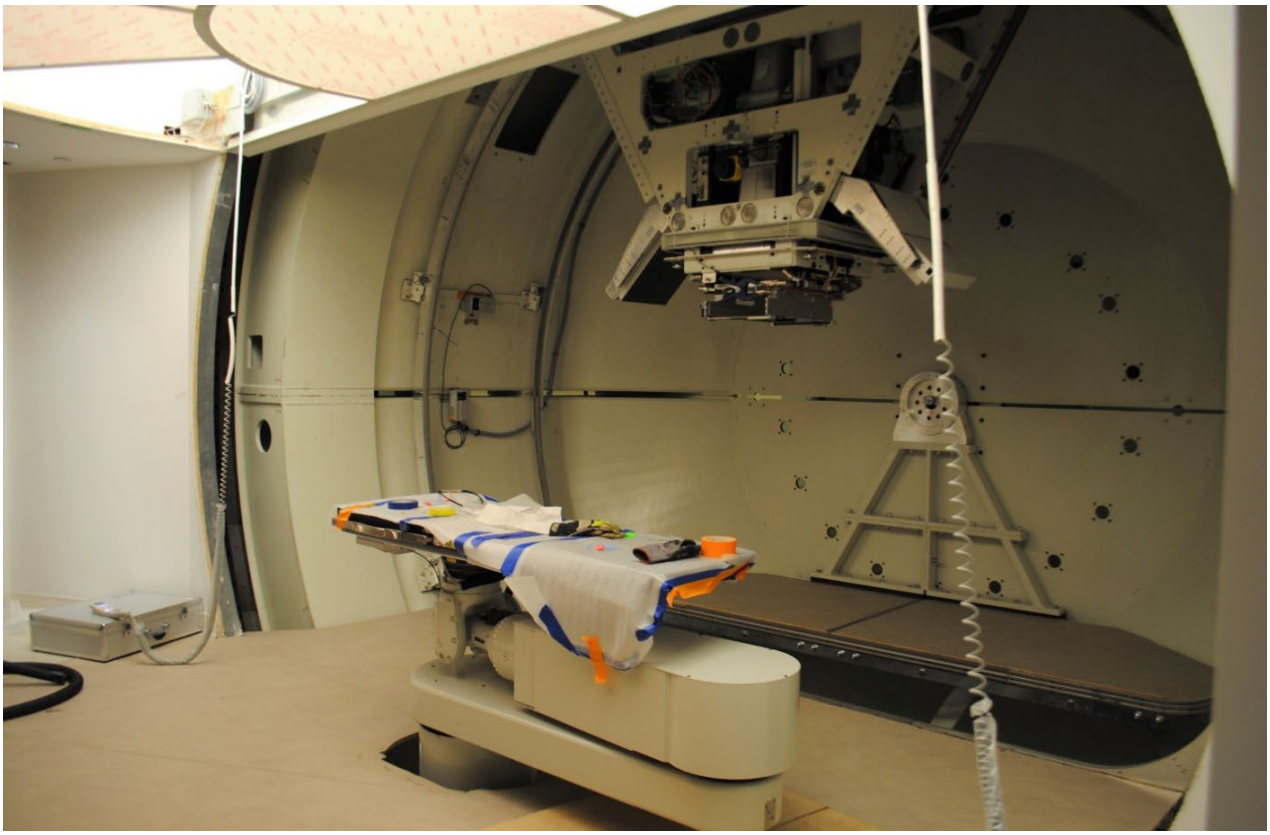


The New York Proton Center is located at 225 East 126th St., between 2nd and 3rd Avenues.

It would take four and a half NASA space shuttles to equal the weight of just one of the proton beam therapy machines inside the New York Proton Center, East Harlem's new, 140,000-square-foot cancer treatment facility.

With their tubes, lights, bolts and buttons, these 300-ton machines somewhat resemble a fleet of space shuttles, too. Or maybe, if you're a patient lying stock-still on an elevated table beneath one of the machine's cylindrical, rotating openings staring up at a suspended arm-like nozzle as it emits positively-charged proton particles in a precise path through your skin, fat, muscle, and organs at 125,000 miles-

per-second to target a cluster of cancer tissue somewhere deep inside your body, the more apt comparison might be that of a UFO staffed with benevolent robots.



Patients must lie completely still while proton beam therapy is delivered.

It's difficult to grasp the physical magnitude of a medical technology meant to target tumors smaller than a centimeter—difficult, even, for the center's lead radiation therapist, Shane Ikner. On the morning of March 15, Ikner, who is short with a patchy goatee and a wide smile, walked down a fluorescent-lit hallway spanning the length of the center, an entire city block. He was dressed in a red and white striped t-shirt, dark denim blue jeans, and athletic sneakers. He wouldn't need his medical scrubs until two months from now, when the center would officially begin treating patients. Today, his patients were computer simulations. Throughout the new center, nature-themed accents—leaves pressed behind glass frames, colorful paper butterflies suspended from the ceiling, and a towering artificial tree in the

center of the lobby—had been thoughtfully installed, softening the facility's otherwise sterile atmosphere.



The New York Proton Center's lobby

The Proton Center's opening has been nine years in the making, and its physical construction began in July 2015. But this morning, several stacks of leftover plywood and one or two bunched up sheets of construction film were all that remained of the center's four-year construction. The facility was nearly complete.

To Ikner, who moved to Manhattan in October after nearly 13 years of administering proton therapy at the MD Anderson Cancer Center in Houston, the New York Proton Center, which is the first of its kind in the state of New York, is long overdue. It was 1946 when nuclear physicists first suggested using protons

to treat cancer, and oncologists have been using it in the clinical setting since the 1970s. And yet today, there are only 26 cancer centers in the United States that offer it. The new center will make 27.

In a room toward the end of the hallway, Ikner passed through a heavy metal door that separated the patient treatment area from the back side of one of the enormous machines. He craned his head upward and admired the equipment, as though he were viewing it for the first time.

"'Wow, right?'"



The mechanism that makes the entire 300-ton machine rotate 360 degrees around the patient is called a "gantry."

The machinery that loomed above and below him—really all around him—has the power to eradicate even the smallest of cancer tumors, delivering the most precise dose of radiation available in modern oncology.

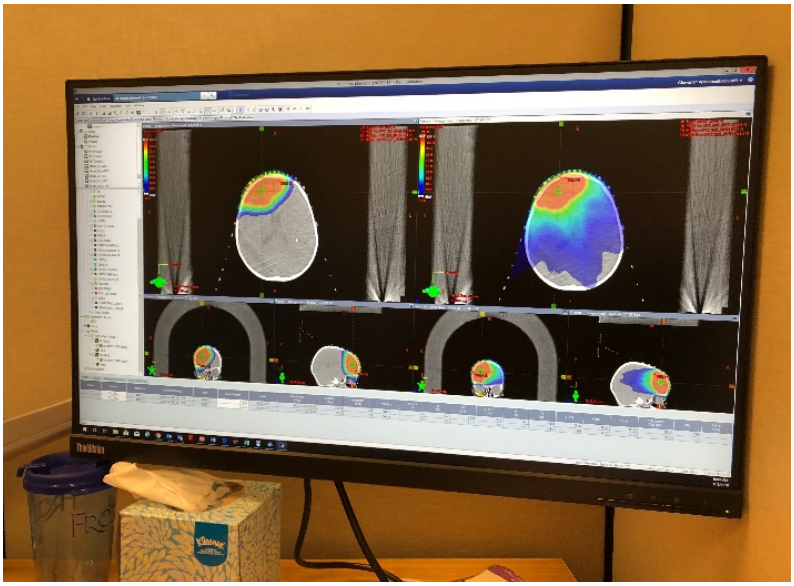
The center's chief radiation therapist, Chuck Merrifield, had to concentrate as he explained how the system works. At the back of the machine, a particle accelerator called a cyclotron rotates rapidly, using magnetic fields to speed up atoms (in this case, the atoms from hydrogen gas, the machine's "fuel") until the atoms' protons separate from their nuclei. The stray protons then zip through a tube the length of a football field, called a beamline, and into the largest part of the machine, the 280-ton rotating structure, called a gantry. The gantry then uses a programmable magnetic field to guide the protons through the machine's arm-like nozzle and into the patient's body. The beam of positively-charged protons that shoots out of the machine at two-thirds the speed of light is so precise that it can accomplish a feat no other cancer radiation can boast: sparing the healthy, non-cancerous tissue it must pass through on its way to hit the tumor.

***

Every cancer is different, but the common root of the disease is a single cell or group of cells that develop a gene mutation that cause them to grow and divide uncontrollably. Once oncologists identify this uncontrollable divide somewhere in a patient's body, they face a critical challenge: how to get rid of the cancerous cells before they grow or metastasize to the point where vital organs can no longer function? Surgery, chemotherapy, and immunotherapy are options for many cancers. But for those that produce physical masses of malignant cells (tumors), doctors often turn to radiation.

Non-proton, standard radiation typically uses x-rays or gamma rays. The rays are comprised of high-energy particles, which break up the DNA inside of cells to keep them from dividing and growing. Standard radiation has grown more precise in recent years, but even the best version of the treatment, called image-guided radiation therapy, or IMRT, can still emit residual cell-killing energy, which is harmful to healthy tissue.

Dr. Andrew Chang, president of the Proton Doctors Professional Corporation and a radiation oncologist at California Protons, has been administering proton therapy for 18 years. When he describes the treatment to his patients, Chang usually draws a circle in the center of a blank piece of paper. He then asks his patients to imagine the circle is a target, and that they have been given two different weapons to hit it: a shotgun and a target rifle.



At left, the amount of radiation delivered to the brain with proton therapy, compared with traditional radiation, at right (deidentified for dosimetry practice; no patient data shown).

"When you use your shotgun, some bullets will hit inside that circle, but a lot of them are going to hit the paper around it," Chang tells his patients. "But if you use your target rifle, you can do a much better job of getting all those bullets inside the circle. You'll hit the circle both ways, but the difference is where else those bullets are placed."

Chang tells his patients that the same applies when that piece of paper is the human body. The cancer is the circle, the non-cancerous tissue is the paper outside the circle, and standard radiation and proton therapy are the shotgun and the target rifle, respectively.

For tumors nestled in vital organs, like the brain or heart, the possibility of radiating outside that circle makes standard radiation undesirable, if not deadly. While radiation's acute side effects, such as hair loss, skin irritation, pain, and nausea, usually go away on their own, the long-term side effects can be permanent: heart disease, tooth decay, infertility, difficulty swallowing, memory loss, and the potential to develop another type of cancer down the line. With its target-rifle precision, proton therapy can dramatically lower these risks.

***

In November 2017, Randy Montgomery, then a 58-year-old man living in Wichita Falls, Texas, visited an ear, nose, and throat doctor complaining of swollen lymph nodes. Like so many patients, Montgomery was shocked by the words “you have cancer.” The doctors told him he had advanced-stage throat cancer, and that he would need immediate surgery to remove the tumors coating his tonsils.

But when Montgomery visited an oncologist at MD Anderson in Houston for a last-minute second opinion before his surgery, he was told that, for his type and stage of cancer, surgery would be pointless; his cancer had spread to most of his lymph nodes, and would continue to spread even if he had the tonsil tumors surgically removed. His oncologist at MD Anderson, Dr. Steven Frank, said he would be more inclined to recommend radiation than surgery, but with the devastating side effects that radiating the neck could bring, such as damage to the brain stem, tongue, jaw, and roof of the mouth, Montgomery faced the possibility of losing his voice and his ability to swallow, maybe for life. His safest option would be proton beam therapy.

***

Eyes still fixed on the massive machine in the New York Proton Center, Ikner sang the treatment’s praises. “I think protons should be used to treat every cancer.” He said before pausing to let out a heavy sigh. “But I’m biased, right?”

Ikner knows things are more complicated than that. Even though proton therapy can spare healthy tissue—the area outside the circle, in Chang’s example—it doesn’t do a better job of actually hitting that

circle than the standard radiation “shotgun” does. Doctors know that proton therapy, while safer, is no more effective in treating a cancer than its alternatives.

Unfortunately, private insurance companies know this, too.

At the opposite end of the center’s long, bright hallway, Ikner passed through another heavy door, this time entering a vast office space mazed with dozens of corporate cubicles. Each cubicle had its own many-buttoned office phone and computer monitor. Some had two. Although the center was not yet treating patients, several of the desks were occupied. Employees furrowed their brows as they spoke into headsets and clicked on keyboards. Ikner kept his voice to a whisper as he wove through the cubes.

“This is where the battles go down,” he said, his voice dropping to an ominous tone.

The employees stationed at these cubicles, Ikner explained, will spend their days entrenched in arguments with the private insurance companies that will inevitably refuse to cover proton beam therapy. For the employees settled into their cubicles, these battles had already started.

With costs ranging from $30,000 to $120,000 per patient, proton beam therapy far more expensive than traditional radiation, which costs $8,000 to $12,000. To minimize expenses, most private insurance companies refuse to cover the more expensive treatment, falling back on the similar efficacy to argue that it is “not medically necessary.”

These private insurers—which make up 67.2 percent of our country’s health coverage—have a long history of denying proton therapy on these grounds. According to a recent report by the Alliance for Proton Therapy Access, an advocacy group that calls for legislation requiring proton beam therapy coverage, nearly two-thirds (63 percent) of patients between the age of 18 and 64 receive denials from their insurers. After appealing these denials with the help of their doctors—often repeatedly, in a cycle

of appeals and denials that can last months after the treatment has already ended—the insurers ultimately uphold those denials roughly half the time.

“For every hour I spend treating a patient, I spend three hours trying to fight their insurance company,” Chang said. “And I don’t think that’s uncommon.”

Children with cancer were not factored into the Alliance’s report. Because most pediatric solid-tumors occur in the brain or eye, where they’re surrounded by vital, still-developing tissue, insurers have recognized proton therapy as medically necessary for children, and will usually approve coverage. But Chang said that insurers’ decision to approve coverage for pediatric cancers is cost-driven, too. When children receive standard radiation, they are more likely to develop long-term side effects during their private insurance coverage years. When this happens, insurers are responsible for covering medical care associated with those side effects, which might equal, if not exceed, the initial cost of proton therapy.

But for adult patients—particularly those in their 40s or 50s—insurers know that, by the time these expensive side effects develop, ten-to-fifteen years after standard radiation, it is likely that the patients will be retired and no longer on their private health plans. After these patients reach 65, the financial responsibility shifts to the government.

“If a 50-year-old patient has a heart attack 20 years after receiving standard radiation, it’s no longer the insurer’s problem,” Dr. Chang said. “I know that’s a cynical way of looking at it, but unfortunately, that’s part of their calculation.” Unlike private insurers, Medicare does cover proton beam therapy.

***

When Randy Montgomery’s doctor suggested proton beam therapy, he was careful to explain this important caveat. He told Montgomery he should prepare to face insurance troubles.

But with the rate at which his cancer was spreading, Montgomery didn't have time to consider what "insurance trouble" might mean. He signed up for proton therapy right away, confident that his doctor's team would defend the necessity of his therapy should his insurance company, Blue Cross Blue Shield, deny his claim. "At that point, insurance wasn't really a question for me," Montgomery said. "The question was either tear up all kinds of organs and tissue, or don't."

He moved forward with the therapy, and wasn't surprised when Blue Cross Blue Shield stated that his treatment was "not medically necessary." Frank had prepared him for this. But Montgomery was not prepared for the response he received after his doctor's team helped him appeal the claim with detailed documentation of his case. Blue Cross Blue Shield again denied his claim on the same grounds, and this time informed him that, should he appeal the claim a third time, the company would deny it again.

The cycle of denials and appeals continued for months. As Montgomery underwent his proton beam therapy, his cancer began taking a toll on his energy and his ability to speak or swallow. Still, he would call Blue Cross Blue Shield daily, waiting on hold for hours, only to hear the identical message from the other end of the receiver: "Not medically necessary."

"It was like talking to a robot," Montgomery said. "I got the feeling they were just rubber-stamping denials without even reading my case."

Daniel Smith, director of the Alliance for Proton Therapy Access, said that in many cases, the insurance reviewers know little about how proton therapy works. "It is our view that these reviewers aren't medically qualified to make these decisions," Smith said. "Whereas the doctors recommending the therapy are from places like MD Anderson or Memorial Sloan Kettering, the best cancer centers in the country." (Blue Cross Blue Shield of Texas did not respond to a request for comment on their proton therapy approvals process.)

Six months and $100,000-worth of unpaid bills later, Montgomery received some welcome news: his cancer was contained, and Frank said he could expect swallow normally again in a matter of weeks. The proton therapy had worked, but his ongoing battle with Blue Cross Blue Shield made it difficult for him to celebrate. He still owed $100,000 he didn't have. He began considering his options: fundraising campaigns, mortgaging his house, selling valuables, or taking legal action. In the meantime, he decided to contact the Alliance for Proton Therapy Access to help him take his story public.

Less than a day after a local T.V. station ran Montgomery's story, Blue Cross Blue Shield contacted him yet again, this time agreeing to pay for his treatment. "The fact that they didn't budge after letters from my oncologist, but a little bad press got to them…" Montgomery trailed off, his voice cracking for a moment. "It's just… really, really sad."

But Montgomery recognized that he was lucky. Many patients in his situation go bankrupt, and many more, unable to risk the debt, choose not to receive proton therapy at all.

For many common cancers, such as prostate cancer, for which proton beam therapy can save patients the devastating effects of damaging tissue around the prostate gland, insurance appeals are all but impossible to win. Before 2014, Chang said insurers would occasionally approve coverage for patients with prostate cancer, but now these instances are rare. When I asked Chang why the coverage landscape had gotten worse over time, his response was troubling: "They pulled back because they could," he said. "A couple major companies did and then the rest followed suit. They just said, 'We're not gonna pay for it.'"

The refusals were likely bolstered by the results of several early-phase clinical studies that year, which reconfirmed that proton beam therapy was not more effective in treating prostate cancer than standard

radiation. Within the medical community, prostate cancer remains the most controversial use of the treatment.

Oncologists debated the use of proton therapy in a video series for SurvivorNet.com titled “Doctors Disagree.”

“There are few cases where you're going to want to spend money that you need for housing, for food, and for basic life functions on this type of technologically advanced therapy,” Dr. Keith Cengel of the University of Pennsylvania argued. “And x-rays are a pretty gosh darn good solution.”

Dr. Charles Simone, now the Chief Medical Officer at the New York Proton Center, argued the other side of the debate. “If we can reduce side effects, we may be able to treat the cancer with higher doses of proton therapy that then can be more effective at killing the tumor,” he said.

But despite the inevitable insurance denial and controversial benefit, Ikner said that most of the patients who have already called the new center to sign up for treatment have been those with prostate cancer.

I asked Ikner if these patients know what costs they might be in for. “We’re already trying to be up-front about insurance,” he said. “And once we open, we’ll try our best to get their denials overturned.”

***

In the coming months, as the new center’s patients struggle to secure coverage for their treatment, the New York Proton Center may face its own uphill financial battle. The center’s development costs totaled $300 million, including $14 million for the property and $115 million to purchase and install the gigantic equipment. The price of developing the center was so high, in fact, that no one cancer hospital in the New York metro area—even the resource-rich Memorial Sloan Kettering—could afford to go it alone.

Instead, the center is the result of a rare display of camaraderie, established by a consortium of four partners: Memorial Sloan Kettering, Mount Sinai, Montefiore hospitals and the health management firm, ProHEALTH.

The consortium's ability to break even on the center's development costs will rest on how many patients it treats. And in recent years, as a result of overly-optimistic patient projections, several other proton centers have shuttered their doors. This was the case for the Indiana University Health Proton Center, which closed in 2014. California Protons, where Chang works, is under new ownership after filing for bankruptcy in 2017, and the Maryland Proton Treatment Center, where Simone, the New York Proton Center's chief medical officer, used to work, underwent major financial restructuring last year, entering a bond deal to avoid a similar fate.

The New York Proton Center is projecting 1,400 patients per year. It's difficult to say whether the center will hit this number. If they do, most of these patients will likely come from outside of East Harlem, a neighborhood where 11.5 percent of residents have no form of health insurance, and over a third of families in live below the poverty line.

Instead, the center's new patients—those who can afford to risk insurance denials and substantial debt—will likely come from the greater New York Metro Area and beyond. The influx of visitors may impact the neighborhood, though it isn't clear whether the effects will be positive.

The New York City's Economic Development Corporation (NYCEDC) believes they will. It was NYCEDC that sold the 126th Street plot to the center's real estate developer, Murphy & McManus, looping the facility into its ongoing 125th Street Revitalization Project, a decade-long initiative to transform 125th Street and its immediate vicinity into a hub of culture and economic growth. In a 2015 statement, then NYC Council Speaker Melissa Mark-Viverito also cited the new center's promise to provide local jobs in

the health sector. “Having the first Proton Center ever in the state to be debuted in El Barrio/East Harlem is a welcome change,” Mark-Viverito said. “It will put this neighborhood on the map as an area where new cutting-edge technology is found.”

To be sure, the new center’s location was not chosen exclusively “to put East Harlem on the map.” The decision was based in-part on physical space requirements; the 126th Street lot was the only place in Manhattan that could accommodate the football-field length of the beamline.

***

The question as to the actual benefit the New York Proton Center will bring to New York City’s cancer treatment landscape isn’t easy to answer. It’s possible that, unable to risk insurance denials and debt, many patients—especially those in East Harlem—will never step foot in the center. The center may fall short of its projected patient numbers, and it may struggle to break even. Its doors, which cost millions to open, may abruptly close.

But it’s also possible that private insurers may come around to proton beam therapy as more patients take their denial stories public. Legislation may pass requiring coverage, and research may shed new light on the treatment’s benefits. It’s possible that someday, doctors will consider proton therapy standard-of-care, and the New York Proton Center will see a waitlist of patients, not a costly vacancy.

Chang is optimistic. “I think in 20 to 50 years, people will look back on standard radiation the way we look back on the radical surgeries doctors performed on cancer decades ago. We’ll be like, ‘Why did we used to do that?’ But it won’t happen overnight. It will take time to get there.”