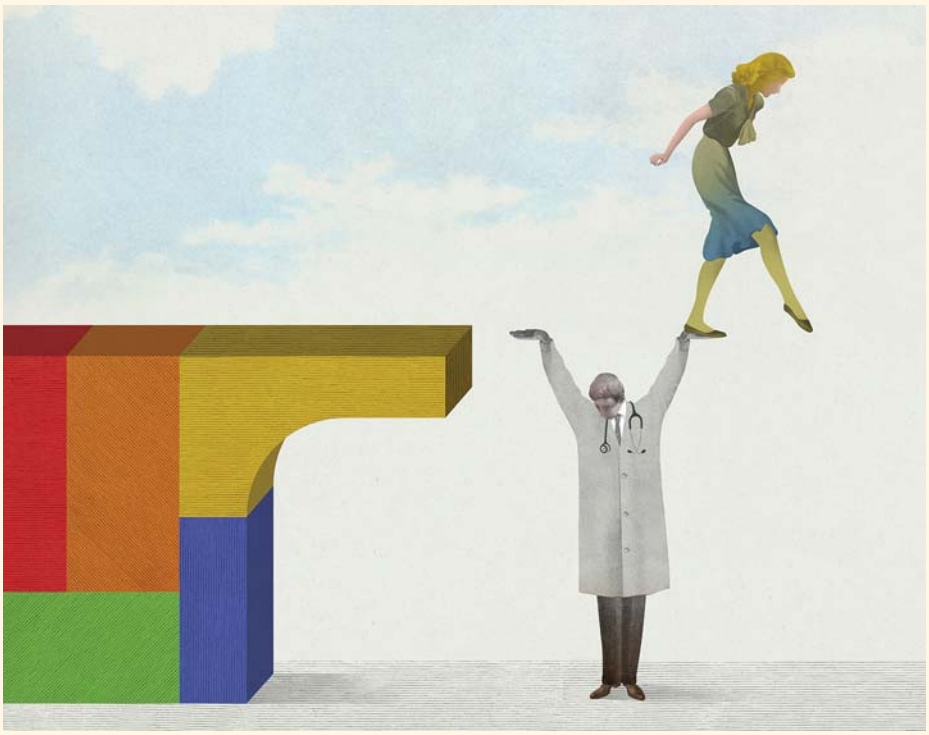

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My Struggle To Access Lifesaving Mental Health Care

A patient must overcome systemic hurdles to stay on the only effective treatment for her depression: ketamine.

BY ASHLEY R. CLAYTON

I was about twenty-six months into my latest major depressive episode when my brain stopped working the way it always had. My memory and concentration were spotty at best. I'd lost interest and pleasure in almost everything and was enervated by fatigue. I've struggled with major depression with suicidal thoughts and post-traumatic stress disorder for most of my life, but these functional impairments were new to me. I have a very demanding job as a mental health researcher, so these cognitive deficits and extreme exhaustion were making work painfully difficult. I had always taken great pride in my ability to work hard and achieve my goals despite psychic distress, but after years of fighting, my will had met its match.

Searching For An Effective Treatment

My psychiatrist recommended a partial medical leave from work, but conceding to my mental illness felt unbearable. Desperate for a better solution, I reached out to a colleague who does research involving ketamine and asked whether it could be a viable treatment option for my depression. Ketamine is a sedative that was first approved by the Food and Drug Administration (FDA) in 1970. Originally developed as an anesthetic, it has been used experimentally for over a decade for the treatment of severe depression, with fast-acting and robust antidepressant effects. However, regulatory requirements have hindered research progress, and lack of insurance coverage for the "off-label" use of ketamine has severely restricted clinical access to this treatment. My colleague put me in contact with Gerard Sanacora, a leading expert on ketamine and mood disorders.

When I met with Dr. Sanacora a few days later, he listened carefully to my story and identified a study that might be appropriate for me: a Phase II clinical trial designed to determine the most efficacious dose of ketamine. It was a double-blind controlled trial in which I would be randomly assigned to receive a single infusion of one of five options: four different dosages of ketamine and an active placebo (midazolam). After a lengthy interview and a frank discussion of risks and uncertainties, I enrolled in the study and was scheduled for treatment. A few days later I was admitted to the hospital's research unit, ready for my infusion.

When the treatment began, things got fuzzy. I eventually dozed off. The next thing I knew, the infusion was over, and I was sweating and felt as if I was going to vomit. I was discharged home to sleep off that hit-by-a-truck feeling. The next morning, I felt like a new person—or rather, like a not-depressed version of myself. I had energy and excitement! I felt a strange and unfamiliar sense of self-worth. One week later I returned to work full time.

The exhilarating effects of this first treatment lasted about two weeks, followed by a precipitous decline back into what I can describe only as a dark laby-

Illustration by Brett Ryder

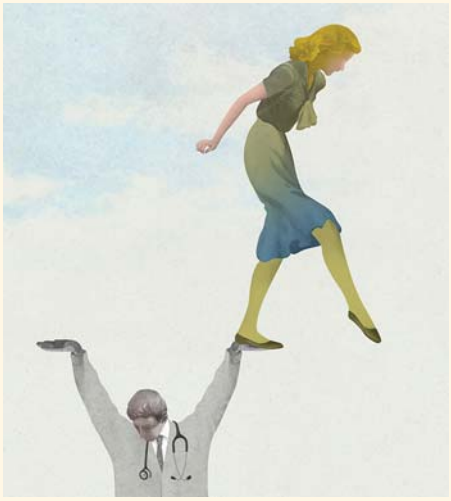
rinth of suffering. I was consumed once again by suicidal thoughts and devastated to have lost the sense of self that the ketamine had, seemingly miraculously, restored. The trial infusion had worked, but now what? (When the study was complete and unblinded, it was confirmed that I had received ketamine, not the placebo.) Intravenous ketamine held the most hope for my recovery, but I needed sustained access to the treatment.

Nowhere To Go

The university-affiliated hospital has an interventional psychiatry program that treats people who have severe, treatment-resistant depression and offers ketamine as a clinical treatment. However, my university-sponsored health insurance would not pay for ketamine treatment, and I simply didn't have the money to pay out of pocket. Furthermore, admission to this program was uncertain at best.

My study doctors said that they would work on getting me into the program, but this process and its timeline were vague and unclear. I had a team of good doctors—likely some of the very best—but the next three months would be an exercise in poor communication, frustration, and despair. I continuously reached out to my doctors to ask if progress had been made, but my efforts were met with silence, punctuated by the occasional vague assurance that they were "working on it."

By this time, I was close to hopeless and all but certain that I was going to die by suicide. Although I strongly believe that mental illness should be treated like any other medical illness, I am painfully aware of the ways that it is not—both inside and outside of the medical community. When someone dies from cancer, we know it is the treatment that failed in fighting the illness. But when someone dies by suicide as a direct result of mental illness, many speak as if it is not the treatment that "failed," but the person. I needed my loved ones who would be left behind to know that I had tried to live, that I hadn't given up. And in the depths of my despair, that dogged resilience bought me time.



'Very Thin Ice'

After three months with no progress, I reached out to another colleague, hoping he would have advice. When I updated him on my health, he said to me: "Ashley, I can't believe you're sitting here, at work, given how sick you are. I know you think you know what you're doing, but you can't go around being this suicidal all the time. You are on very thin ice, and you are going to fall through."

Given the severity of my situation, he pressed me to consider electroconvulsive therapy (ECT).

ECT is a psychiatric procedure that involves passing mild electrical currents directly through the brain to induce controlled seizures. With 60 percent of treated patients responding well to the procedure, it is still the best treatment we have for severe depression. However, it carries a serious possibility of significant cognitive side effects, and I had resisted considering this treatment in the past. My colleague knew me as an academic and understood how much I loved my work and how strongly I valued my intellect. Yet he felt that ECT was warranted, possible side effects and all. Later that day I met with my psychiatrist, and we both agreed that ECT was the best next step. He made a referral to a private psychiatric hospital, and I was admitted that night.

For my first ten treatments I was on an inpatient unit, but after four weeks in the hospital, my insurance would cover continued treatments only on an outpatient basis. I was discharged, and my care was transferred to the university-affiliated hospital. A standard acute series of ECT is typically twelve treatments, but when I finished the twelfth treatment, I was immediately scheduled to come back for three more. At the fifteenth treatment I was switched to a more aggressive form of ECT that often carries better results but also significantly higher risk of major cognitive side effects.

The sixteenth and seventeenth treatments came and went, and I had still received no update from my doctors on the status of my ketamine appeal. By this time, the side effects of ECT were making it nearly impossible for me to negotiate my daily life: With a brain that works at the pace of a snail, the simplest tasks are overwhelming. I had started ECT in an attempt to get my life back, but that life was unlivable with the side effects I was experiencing.

At my next treatment I asked Robert Ostroff, one of the head doctors at the hospital, to come see me. When he arrived, I asked about the status of my ketamine appeal. "What ketamine appeal?" he asked. I was aghast.

"What do you mean?" I asked. "We've been trying since August!"

"I don't know anything about this," he said. "I'll reach out to Dr. Sanacora. Let's plan to meet the day after tomorrow to talk more."

As he walked away, I lay in my bed feeling equal parts disbelief, rage, and fear. What the hell was happening?

Two days later I walked into the hospital to meet with Dr. Ostroff. He greeted me: "It seems like ketamine is the best treatment for you. So let's do that." I couldn't believe what I was hearing.

"You don't understand," I told him. "I can't afford to pay for this treatment."

"Don't worry about it," he said casually. "I'll make sure it's taken care of."

I had never been so relieved or so confused. Trying to access ketamine treatment had been a grueling process, and this seemingly simple solution had me feeling whiplashed. However, I needed Dr. Ostroff's words to be true more than I needed them to make sense, so I pushed away the doubt from my mind. That very day, I received a ketamine treatment. I walked out of the hospital with a little more hope than I'd had when

Policy Checklist

The issue: Difficulties accessing ketamine for the treatment of depression highlight health system–wide issues, including insurance coverage of off-label treatments; care coordination by providers and effective communication between them and patients; and the funding of medical research for proven, but not commercially profitable, treatments.

Related reading:

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I had walked in. It was December 20, snow was on the ground, and my Christmas miracle had come early.

A Life-Or-Death Matter

When the new year came, I was back to working part time. I had received four ketamine treatments during the first three weeks of January and was beginning to feel better, but my next treatment wouldn't be for ten more days. I was worried. I remembered what crashing from ketamine felt like: It was abrupt. Brutal. Not a descending staircase, but a rattletrap elevator plunging straight into the abyss. I still felt weak, depleted. I explained this to my doctors and was told to come back in ten days as planned. I didn't push back—after all, how could I advocate for faster access to a treatment for which I wasn't even paying?

I crashed a few days before that next treatment. I was thankful that I had gotten some good days, but as the depression resurged, everything quickly began to feel high stakes again. After finally receiving the treatment, I was told that the next would not be for two more weeks. I begged the attending physician not to space my treatments out so far just yet. This appeal and multiple follow-ups with all of my doctors were met with silence. The next weekend my husband took me on a trip to see my favorite band, which was playing a couple of shows at a small venue in one of our favorite New England towns. I was glad to get away and be by his side, but I was crashing hard. I managed to get through the concerts but slept for most of the rest of the weekend. When I wasn't sleeping, I lay frozen, consumed by terror and guilt. I was not going to survive. Every time I looked at my husband I felt crushed, because I knew my death would profoundly hurt him. But my love for him and his for me weren't enough to save me. So I prayed and begged God, or the universe, that he would understand that I died from an illness—that I didn't give up.

That Monday I reached out to one of my doctors from the ketamine program. The lack of responsiveness from my doctors since the initial ketamine study had ended left me feeling as if they were not taking me or my depression seriously. I tried to help him understand: "I need four consecutive weeks of treatment so I can rest and replenish my internal resources. I am dying here. I can't afford to keep delegating the few resources I have left to surviving these crashes and fighting for treatment."

He said we could talk more when I came in for my treatment the following morning. After I got off the phone, I felt completely numb. My doctors didn't understand the seriousness of my illness, and by the time they did, it would be too late. I experienced a shift in my thinking that was petrifying: I was no longer worried that I would kill myself. Rather, I was convinced that my depression was going to kill me. What had once felt like an internal drowning now felt like an external force against which I stood no chance. I was left to face the devastating reality that without better access, this treatment would not save me. I was not going to survive.

Approval for my care was on a treatment-by-treatment basis, but my life depended on having access to the treatment at a frequency that kept me from hitting rock bottom in the interim. Later that week I met with my private psychiatrist and begged him to call my hospital doctors and ask them to allow me to receive a few more weekly treatments.

"It might help if you shift the way you're thinking and focus on being grateful that you are receiving a treatment most people don't have access to at all," he responded.

Incredulous, I found myself screaming, "Gratitude will not save my life!" My head and arms collapsed into my lap, as I realized that I had just exhausted all the fight left in me.

The ninth treatment came a few days later, accompanied by propitious, lifesaving news: I would be getting a few more weekly treatments. *I would not die quite yet*. The extended weekly treatments likely saved my life, as I could not have withstood another crash. After five weekly treatments, I was feeling back to that not-depressed version of myself that I'd experienced after my first experimental infusion. This "lifesaving treatment" would indeed save my life.

On The Other Side

I went through a life-threatening depression, navigating a complicated health care system in search of an effective treatment. Luckily, I find myself on the other side, life mostly intact, but it is uncomfortably easy to imagine a very different outcome. The amount of pure luck required to save my life terrifies me. I am deeply grateful for the efforts of my doctors, and I also do not want to minimize the role my personal strengths and resources played in this narrative. But that's the thing: I have some of the most talented and compassionate doctors, and I—with all of my knowledge and training, good insurance, and role as a well-educated white woman working in one of the world's top medical schools—was better positioned than most to navigate the system. And yet I barely survived. Securing access to the care I needed was almost impossible. As a mental health and health policy researcher, I am left to wonder: How can others less privileged and connected than I am find their way to the other side?

Ketamine infusions saved my life. I now find joy and vitality in living that I had not previously known. I am vigilant in managing my depression—ketamine is not a cure, and I continue to rely on access to free, cutting-edge care for my well-being. But if hospital administrators decide they can no longer absorb the cost of my care, I may find myself unable to access the treatment I need to live. Doctors are free to prescribe ketamine off-label, but reimbursement for the treatment remains a huge barrier. Some insurance companies have agreed to cover ketamine treatment as a result of the growing body of basic and clinical research supporting its antidepressant efficacy and the consensus guidelines published in 2017 in *JAMA Psychiatry* for its appropriate use. However, insurance coverage is far from universal, and unequal access to care is a significant problem, even among those with "good" insurance.

Drug Trials, Approvals, And Access

The drug approval process in the United States requires a series of clinical trials to ensure the efficacy and safety of drugs. These trials are critically important but incredibly expensive. Thus, almost all Phase III (long-term safety and efficacy) trials are funded by pharmaceutical companies, which are better positioned to expend capital and risk to test a drug that they stand to make billions of dollars selling. In the case of ketamine, which no longer has patent protection, it's hard to muster political or commercial will to finance the necessary Phase III trial. Even without the promise of profit, ketamine has become "a prototype for a new generation of antidepressants," as Chadi Abdallah and colleagues wrote in a 2015 article in the *Annals of the New York Academy of Sciences*. Some of these next-generation antidepressants are in the final phases of industry-sponsored trials and will likely receive FDA approval in the next year or two. For example, the FDA recently approved esketamine, a chemical cousin of ketamine, to treat depression in patients who have failed to respond to at least two other antidepressant drugs. These new drugs might not be any more effective than ketamine, but without a publicly funded clinical trial system that can support the high cost of the Phase III trial, it is improbable that ketamine will receive the FDA indication for the treatment of depression that these newer (and likely more expensive) drugs likely will. FDA approval does not guarantee drug coverage by health insurers, but the two are closely linked—and without coverage, access to ketamine will continue to be a challenge for patients who need it.

I find myself on the other side, life mostly intact, but it is uncomfortably easy to imagine a very different outcome. The amount of pure luck required to save my life terrifies me.

My transition from research to clinical care was onerous, and I later learned that outside of research and inpatient care there is incredibly limited mental health care available through the Department of Psychiatry and the university-affiliated hospital. My doctors were in a situation where there was not even a system of care to navigate—they had to create one. Even so, access to care coordination would have afforded more continuity in my care and might have spared me three months of rapidly declining health with no forward movement. One possible, and relatively low-cost, solution would be for clinical trials to include funding to support care coordination when patients transition out of studies, to ensure that they are connected with the most appropriate follow-up care. This modification to how clinical trials are conducted would not only improve patient experience and outcomes, but it would also likely increase study recruitment and retention.

Person-Centered Care

Transitions in care across institutions are also notoriously difficult, and my experience transitioning from inpatient to outpatient ECT, and subsequently into the clinical ketamine program, highlights some of these challenges. It was not clear to me who was overseeing my care or who had the decision-making power to help me gain access to ketamine treatment. Even after I entered the ketamine program, I was largely left out of decisions about my care and had significant difficulty getting face time with my doctors. My doctors faced much uncertainty as they worked hard behind the scenes to get me continued access to the care I desperately needed. For instance, they truly did not know how many times or for how long I could receive ketamine treatments, and I understood that. But amid all the uncertainty, I also felt abandoned—I had no sense that I had a team of doctors who would help me find ways to manage an illness that I believed would kill me, even if they could not secure me access to ketamine treatments. I wish I had known then what I know now: that my doctors will never give up on me.

I am certain my doctors had no idea that this was how I felt. After all, they were spending time advocating for me within an overburdened and underfunded mental health care system. Here, too, access to care coordination would have been helpful. Having an accessible care team member with whom I could be

in relatively frequent contact while I was in crisis would have helped me make better sense of what was happening and helped my doctors be more aware of my needs. Having this access would have made a terrifying experience a little less scary.

The health care system imposes tremendous demands on doctors, and, in turn, doctors inadvertently place incredible demands on patients. Communicating with patients takes time and is difficult. Even when a physician can bill for these interactions, reimbursement rates do not reflect the time and cognitive effort involved. But communication and attentiveness are enormously important and reflect the kind of person-centered care for which I continue to advocate. The system is set up to discourage spending time with patients, but, in truth, patient outcomes can depend on how much time doctors give them. We need to restructure health care so there is more emphasis and accompanying funding associated with face-to-face interactions, including care coordination.

I am lucky: I have some of the very best doctors. Since managing my latest depressive episode, we have been able to talk about my experiences, and I truly feel that they understand and respect my needs. They are working on adding a care coordinator to the team, and we frequently have brief check-ins when I go in for treatment. My insurance covers office appointments with most of my hospital doctors, so I set up appointments to talk in earnest about how I am doing and adjust my treatment regimen when needed. Other times, the low-level anxiety that accompanies relying on free care flares up, and I just need a few minutes of face time to be reassured. We have learned to trust each other, and I no longer feel alone.

Those of us in the medical field know that medicine advances because of attention from funders, scientists, and policy makers. Yet psychiatry in particular faces a large imbalance between the magnitude of illness and the attention and funding it receives, which reflects how society continues to undervalue mental health. Even after mental health parity was legislated, reimbursement rates and coverage for psychiatric care remain low, leaving programs underfunded and limiting the number of patients who can receive adequate care. Navigating the health care system while managing an illness is a Herculean task; harder still is doing this while suffering an illness that does not elicit the same level of empathy and urgency as physical illnesses of similar severity. All patients need access to effective treatments before things become unmanageable—the time to intervene is before their illness becomes a life-or-death matter.

It is a grave error that our systems are structured in such a way that face time is seen as ancillary. Communication can mean the difference between life and death.

Clinical trials are generally intended to benefit future patients rather than study participants, and participation is often costly and time intensive for patients. We need to carefully reconsider the ways in which trials are carried out and revise them to be of greater direct benefit to patient participants. A paradigm shift is already under way, as patient involvement throughout the entire research process is increasingly recognized as critical to advancing medical research. The development of the Patient-Centered Outcomes Research Institute is evidence of this, as is *BMJ*'s launch of its patient partnership strategy, which requires investigators to report how patients were included in the development of the research question, design, and implementation and the dissemination of findings of clinical research studies across its journals.

The involvement of patients is not new—Larry Davidson and colleagues have been leading this work in the mental health field over the past few decades—but the expansion of patient involvement in research and development for drugs and medical devices is in its infancy. Early adaptations and modifications to study protocols are already demonstrating positive effects, including increased study recruitment, retention, and compliance, according to a 2017 study in *Patient Preference and Adherence* by Sam Lim and colleagues. They also result in substantial savings, according to other research. Rigorous study design does not have to come at the expense of participants' well-being.

As we collectively work to build and improve health care and health care payment systems, we should hold in the front of our minds the fact that adjustments to these systems must expand access to both standard and cutting-edge care—especially potentially lifesaving interventions such as ketamine. We must restructure the health care system to promote the practice of attentive and person-centered care. It is a grave error that our systems are structured in such a way that face time is seen as ancillary, valuing procedures more than care. Communication can mean the difference between life and death. The doctor-patient relationship is foundational to the practice of good medicine and healing: It keeps intact the dignity of patients and the humanity of medicine. For me, knowing that my doctors are committed to helping me manage my illness is powerful medicine. ■

This essay is dedicated to my husband, Stephen Thomas, and to my dear friends Asha Evans and Linda Mayes—thank you for carrying me all the way through; to Juno Pinder, for championing this essay and endless patience and generosity; to my colleagues William Sledge, Phil Corlett, and Al Powers for helping me navigate this mess and incredible support along the way; to my nurses, especially Stephen Majoros and Herty Lawson, for caring for me with such love and kindness; and to Robert Ostroff, Gerard Sanacora, and Samuel Wilkinson, thank you for saving my life—all words fall short. **Ashley R. Clayton** (ashley.clayton@yale.edu) is director of research and evaluation at the Center for Wellbeing of Women and Mothers in the Department of Psychiatry at the Yale School of Medicine, in New Haven, Connecticut.