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FROM THE EDITOR

Clinical and Social Contexts of Ethical Issues in Mental Health Care

Psychiatry is a critical yet often neglected area of medicine. Although mental health and substance use disorders are the leading cause of disability worldwide [1], World Health Organization (WHO) statistics from 2014 indicate that the median number of practicing psychiatrists worldwide is 0.1 per 10,000 people [2]. In the United States, we have more than ten times that number—1.2 psychiatrists per 10,000 people [2]—and yet federal statistics suggest that more than half the counties in this country do not have a single practicing behavioral health worker [3]. One recent study found that the average wait time for a first outpatient psychiatry visit in large urban areas is 25 days [4].

The value of investment needed to scale up care for depression and anxiety in 36 countries over the next 15 years is estimated to be $147 billion in present-day dollars [5]. It makes sense, then, that access to and parity for mental health care have remained critical issues for discussion during this presidential election season in the United States. Yet this huge unmet need also represents an area of tremendous potential. For example, the WHO estimates that in the United States, the return on investment for improving mental health care delivery is roughly 4 to 1 [5].

Psychiatry has always been an area of medicine with unique ethical challenges. Indeed, the very nature of psychiatric illnesses can raise challenging questions about patient autonomy. How do we best address decision making in complex psychiatric cases, when failures of reality testing and insight can sometimes be the primary symptoms of disease? Do patients have “the right to be crazy” if they do not have insight into their illnesses or, perhaps for another reason, wish to refuse treatment that members of their care team deem medically necessary? These challenging questions are addressed by James Sabin in his commentary on a case of a man with schizophrenia who wishes to discontinue taking antipsychotic medication.

Psychiatric diagnosis is another area with unique challenges, as the vast majority of diagnoses in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) [6] have no objective tests to confirm the clinical impression of an evaluator. To deal with the challenges of diagnostic imprecision, the National Institute of Mental Health has launched an initiative called the Research Domain Criteria (RDoC) that attempts to take a more dimensional approach to the scientific classification of the mental disorders by separating human mental functions into broad categories called “domains” and preferentially supporting research into the biological correlates of these
functions across diagnostic categories [7]. Until this work yields more precise biological characterizations of mental illness, physicians and other mental health practitioners must continue to make diagnoses using the standard criteria in *DSM-5* [6] and the “International Statistical Classification of Diseases and Related Health Problems” [8]. The limitations of diagnostic categories and the ways we might address a patient’s resistance to being labeled with a specific diagnosis are discussed in Julie M. Aultman’s commentary on a case of a college student who does not clearly meet the criteria for bipolar II disorder but demands a prescription—and that her diagnosis not be recorded in her medical record.

Ethical challenges also arise in connection with the choice of psychiatric treatments. Since the pathophysiology of mental illnesses remains incompletely understood, it’s inevitable that there are similar gaps in our knowledge regarding mechanisms of action of pharmacological treatments. Such incomplete knowledge can lead to misinformation or uncertainty regarding the appropriate use of psychotropic medications, which in turn can have adverse effects on patients and their families. Andrea L. Kalfoglou thoughtfully addresses this challenge in her article weighing the risks and benefits of the use of antidepressant medication during pregnancy.

Given significant overlap in symptom and medication response profiles between psychiatric diagnoses, off-label medication use is particularly common in psychiatric practice [9]. Katrina Furey and Kirsten Wilkins thoughtfully address the appropriateness of off-label prescribing and its ethical and legal implications in their commentary on a case about informed consent for off-label use of an antipsychotic to control an elderly patient’s agitation and paranoia.

Challenges of treatment selection are not unique to pharmacological interventions. Annette Mendola and Richard L. Gibson evaluate the effectiveness of widely used programs for substance use and addiction treatment and the ways a clinician might ethically operate in light of the limited evidence available. Challenges also might arise from patients’ attitudes toward treatment. In a case commentary, Constance E. George discusses the ethical challenges that psychiatrists face when all treatments fail; she wonders whether and when depression should ever be considered a terminal illness and considers the nature, scope, and appropriateness of a physician’s role in fostering hope for patients with refractory depression.

Stigma—even for patients who do not yet have psychosis but are at high risk for it—remains a significant challenge in mental health care. Dominic A. Sisti and Monica E. Calkins discuss the lexical complexities of the psychosis risk label and its implications for social and self-stigma. Cheryl M. Corcoran also evaluates evidence of potential harms of the psychosis risk label.
Finally, we must remember that mental health is an issue that physicians face not only as practitioners but also as patients and human beings. A recent meta-analysis estimated that almost 30 percent of resident physicians met criteria for clinical depression [10], and statistics show that we lose between 300 and 400 physicians each year to suicide [11, 12]. The existence and treatment of depression, suicidality, and burnout in medical trainees and next steps to limit the toll that stress takes on physicians-in-training are discussed in an article by Kathryn Baker and Srijan Sen and in the podcast with Srijan Sen. From a more personal perspective, pediatrician and memoirist Mark Vonnegut provides insight into his decision to publically acknowledge his history of mental illness and how that disclosure has influenced his interactions with patients and colleagues.

The future of the field of psychiatry is a bright one, and I am excited to be joining such a dynamic field at this time in its development. Certainly the ethical issues associated with psychiatric practice will change as knowledge progresses and treatments become more precise. In a recent interview with NPR, Shekhar Saxena of the World Health Organization underscored the importance of continued improvements in mental healthcare: “[W]hen it comes to mental health, all countries are developing countries” [13]. As a future psychiatrist, I agree.

Furthermore, the severe shortage of mental health practitioners means that anything approaching universal access to mental health care will likely need to involve primary care, emergency care, and women’s health practitioners who also respond to patients’ mental health care needs. When all clinicians strive to meet those needs, we can all look forward to the health and social benefits. Responding to ethical and justice issues in mental health care is an obligation for all of us.

References


Marguerite Reid Schneider

MS-4

University of Cincinnati College of Medicine

Marguerite Reid Schneider is in her final year of the Medical Scientist Training Program at the University of Cincinnati. Her dissertation research focuses on executive function in
adolescents with and at risk for bipolar disorder. She will join the Harvard Longwood Psychiatry Residency Program as a research track resident this summer.

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ETHICS CASE
Medication Refusal in Schizophrenia: Preventive and Reactive Ethical Considerations
Commentary by James Sabin, MD

Abstract
Clinicians treating patients with recurrent psychosis should encourage contingency planning with patients and families for how to respond to potential recurrences. Whether or not patients create a formal psychiatric advance directive, patients, families, and clinicians will be better prepared to deal with emergencies if they include “scenario planning” as part of ongoing clinical care. In the case under discussion this was not done, resulting in an ethical conundrum as to whether it was ethically justifiable to override the proxy decision maker’s refusal of medication. Law on this question is unsettled, but the author argues that from the perspective of ethics, overriding medication refusal is sometimes ethically permissible.

Case
Charlie, a 55-year-old man with a history of schizophrenia, had been stable and functioning for more than a decade. Due to his significant concerns regarding the adverse effects of antipsychotic medications, he discontinued pharmacological treatment in close collaboration with his psychiatrist two years ago. Until recently, he was able to function well without medications and reported feeling much healthier overall, despite some worsening of his psychiatric symptoms. In particular, he was able to lose a significant amount of weight and no longer suffered from lipid and blood sugar abnormalities that he was experiencing while on antipsychotic medications. He continued to meet regularly with his psychiatrist throughout this period, and with the support of his wife, Reina, and his adult daughter, Laura, he and his psychiatrist developed a plan to enable a medication-free lifestyle that involved biweekly visits with a therapist and regular engagement with a community support group. He has repeatedly expressed his desire to avoid all medication treatment in the future.

Two weeks ago, his schizophrenia symptoms worsened, and he began experiencing paranoid delusions. He was involuntarily hospitalized after he attacked Laura, accusing her of being an imposter. Out of respect for his desire to avoid medications, his inpatient treatment care team tried to manage his care without medications. After two weeks of this inpatient approach, however, he remains psychotic and a significant risk to others.
Laura and the inpatient treatment team wonder whether it’s possible to reintegrate him into his family and community without at least a short stabilizing course of antipsychotic medication. Reina, however, supports his choice to continue to refuse medication and, in a family meeting, reminds Laura and the treatment team that while Charlie does not have capacity to make decisions in his current state, he expressed his wishes clearly when he was well. Given that he has been involuntarily admitted, Reina is legally responsible for making medical decisions for Charlie, and she repeatedly asserts that she will not authorize treatment to which she does not think Charlie would consent if he were well, including antipsychotic medications. Reina is also aware, however, that not using at least a short course of medication makes managing Charlie’s symptoms much more difficult for her, Laura, and the clinicians trying to care for him as best they can.

On the adult inpatient psychiatric unit, Charlie frequently acts out in response to his delusions, yells at staff members, and refuses to eat most of his meals because he fears the food is poisoned. During his stay he has repeatedly disrupted group therapy sessions with his outbursts. One of his dedicated nurses, Sheni, is becoming increasingly frustrated. She approaches the attending psychiatrist, Dr. Naobi, with her concerns, saying, “I don’t think that it’s fair to Charlie or the other patients on the unit if we are not going to manage his symptoms appropriately. How can we treat him with compassion and respect if we don’t treat the symptoms from which he’s suffering so acutely? It’s just not good care to let his symptoms go untreated, and the other patients are suffering because we have to spend so much time managing Charlie’s symptoms.”

Dr. Naobi agrees that another family meeting would be worthwhile to try to address these concerns. During that meeting, Sheni describes in detail the severity of Charlie’s symptoms and the effects those symptoms have on her, her colleagues, and other patients. After hearing Sheni speak, Laura confronts her mother, insisting that she authorize medications. Reina, however, is adamant in her refusal, saying, “He has told me time and time again what he wants. We are his best advocates. I know it’s hard on everyone, and I regret that, but I must follow his wishes.” Dr. Naobi also expresses concerns that allowing Charlie to suffer by continuing the current course of action is clinically and ethically inappropriate. “We’ve tried this for two weeks and it’s just not working,” he says. “From a clinical standpoint, many would just regard our current approach as medical mismanagement, as harmful and substandard care.” Reina becomes angry upon hearing this and replies, “You don’t know Charlie as well as I do. I remember how much he suffered due to those medications. Yes, they controlled his symptoms, but they also made him fat and left him feeling sluggish all the time. We talked about it for a long time before we decided that he wasn’t going to take them anymore. It wasn’t a decision that we made lightly, and I am not going to betray his trust in me because managing his illness is inconvenient for you.”
Dr. Naobi feels very conflicted, but he manages to respond calmly. He continues, “I also believe that Charlie’s wishes deserve respect. Let’s end this meeting on that common ground and take another day to think this over together.” Dr. Naobi knows that Reina has legal authority to make treatment decisions for Charlie, but he suspects that perhaps the scope of her influence has now entered the realm of medical management, which ought to be the clinician’s prerogative. He wonders how best to communicate this concern to Reina. He also wonders about what the best strategies might be for acting in solidarity with Sheni and his other nurse colleagues.

**Commentary**

Before discussing the clinical and ethical issues raised by Charlie’s current situation, we should reflect on the important distinction between *preventive* ethics (i.e., anticipating and preventing ethical problems before they arise) and *reactive* ethics (i.e., dealing with ethical problems after they surface) [1, 2]. With Charlie’s experiencing the recurrence of a severe episode of paranoid psychosis, the ethical problems in his care have hit the fan, posing difficult questions for Reina, Laura, and the clinical team. They must react. But if the right kind of discussion, which is recommended in what follows, had taken place when Charlie discontinued antipsychotic medication two years ago, the ethical complexities Charlie’s care poses now might have been prevented.

**Planning for the Possibility of Psychosis Recurrence**

The case scenario tells us that Charlie discontinued medication “in close collaboration with his psychiatrist.” Nothing is said, however, about discussion of contingency plans with Charlie and his family for what to do if a relapse were to occur. Although Charlie’s psychiatrist would want to approach the discontinuation of medication in an optimistic manner, the nature of schizophrenia is such that the potential for a recurrence of psychosis is real and should be planned for [3]. The psychiatrist must find a way to combine recognition of Charlie’s strengths, respect and support for his very understandable wish to stop taking antipsychotic medication, and encouragement of hope with recognition of the possibility of relapse. Doing this isn’t easy, but it can be done. Here’s the essence of what the psychiatrist might say:

*Charlie, it’s been great to see how well things have been going for the last eight years! Taking the medication despite the miserable side effects has required a lot of strength on your part. Tapering and stopping it is an excellent step for us to take. I feel very optimistic about the future, and I’m happy about what we’re doing. But we know that episodes like the ones you’ve experienced years ago can recur. Let’s talk about how we should handle things if the paranoia came back…*

The process that should have happened has been much discussed as a “Ulysses contract” or, more formally, as a psychiatric advance directive [4]. The reference to
Ulysses in Homer’s epic poem *The Odyssey* is this: Ulysses knew that the Siren’s singing could lure sailors to their death, but he wanted to hear their enchanting song. He solved the dilemma by having his crew put wax in their ears, tie him to the mast, and not release him under any circumstances until the ship was past the danger. On hearing the song he temporarily lost his reason and begged to be untied, but since the crew could not hear his pleading or the Sirens they followed his orders, and the ship sailed to safety. As the story goes, Ulysses was saved from a foreseeable loss of reason by planning ahead.

It is worth noting that Charlie’s psychiatrist need not ask Charlie to sign a formal document. What is important is to discuss with Charlie his values and goals of care as well as contingency planning should his psychotic symptoms recur. Such discussions are also fundamental to end-of-life care planning.

Clinicians might fear that raising “what if” questions about how best to handle a potential relapse might alienate or discourage patients. Evidence, however, suggests the opposite—that the process of exploring a patient’s values with regard to future treatment can strengthen the alliance between patients, families, and clinicians [5]. In light of these findings, Virginia has undertaken a statewide effort to incorporate completion of a psychiatric advance directive into routine care for persons with serious mental illness in the public mental health system [6]. Unfortunately, Charlie does not appear to have received this kind of anticipatory planning, with the result that Reina, Laura, and the clinical team are now faced with difficult ethical questions that potentially could have been prevented. If Charlie, Reina, and Laura had discussed “how we should handle things if the paranoia came back,” as suggested above, Charlie might have endorsed restarting medication, with the result that Reina might not have felt that she was betraying him if she agreed to using antipsychotic medication.

**Dealing Ethically with Conflict Once Psychosis Recurs**

In Charlie’s current state of decisional incompetence, Reina is his proxy decision maker. She tells us that Charlie “has told me time and time again what he wants”—namely, to avoid all medication treatment in the future. On medication Charlie experienced weight gain and what sounds from the case scenario like type II diabetes. When he came off medication, these side effects improved and he felt much better. In addition to the fact that Charlie has a right to refuse treatment (directly or via his proxy), he has a strong, readily understandable rationale for his preference. Reina feels duty-bound to follow his wishes.

The case tells us that when Reina refuses medication for Charlie, Dr. Naobi “suspects” that she has “entered the realm of medical management, which ought to be the clinician’s prerogative.” His suspicion is incorrect. The right of a decisionally competent patient—or, in a situation like Charlie’s, his proxy—to refuse treatment is well
established. Even though Reina’s stance goes against what the team sees as good care, she is ethically justified in following what she takes to be Charlie’s wishes.

But did Charlie’s statements really mean that there were no circumstances whatsoever in which he would accept antipsychotic medication? That’s how Reina interprets his wishes, and that’s why she continues to refuse to allow him to receive antipsychotic medication. Her interpretation, however, may not be correct. Here’s how Dr. Naobi and the nurse, Sheni, could raise a question about Charlie’s real intentions at the meeting with Reina tomorrow:

_Reina, we all understand why Charlie spoke so strongly against medication. It made him fat and gave him diabetes, and he felt much better when he stopped. If I had his experience, I wouldn’t want to take medication, either. We’ve tried to follow his wishes and help him get better without medication, but it isn’t working. Here’s the question I’ve been thinking about: If Charlie had imagined getting so paranoid that he would attack Laura, would he have taken such an absolute position about medication? From what you and Laura have said about him as a loving father and husband, my guess is that he’d be open to using medication in the lowest possible dose so that we could get the paranoia under control and make it safe for him to return home. What do you think?_

Dr. Naobi could point out that, in the area of planning for end-of-life care planning, it’s not unusual for people to make global statements like “I never want to be kept alive on a machine,” because they have in mind the image of a frail person with dementia who will never recover cognitive capacity “vegetating” on a ventilator. If at a later time that person is otherwise healthy but develops severe pneumonia that will be fatal without short-term use of a ventilator—and is likely to return to full health if the ventilator is used—would we be bound by the emotional statement about not living on a machine? People sometimes speak in terms of specific interventions when their real intention is to convey underlying values and goals. If a person who says, “I never want to be kept alive on a machine,” is asked, “would you object to using a ventilator for a couple of days if you had a pneumonia you would completely recover from?”, that person might give more nuanced guidance, such as “I really meant that if my condition won’t improve, I don’t want to vegetate on a machine…”

My guess is that this is Charlie’s situation, since he had good reason to hate taking antipsychotic medication and he expressed that attitude vehemently. The challenge for Reina and the team is to decide if Charlie meant those statements literally and absolutely, or if he was expressing something more like “I hate taking medication, so if a situation like what happened years ago happened again, I’d want to use the medication least likely to cause bad side effects at the lowest effective dose…”
If Reina concludes that this is what Charlie really meant, she will authorize use of antipsychotic medication. But suppose she doesn’t. What then?

In the United States, we’re devoted to individual autonomy. We accord supreme value to the right of persons to make their own decisions about health care. But as John Donne wrote almost four hundred years ago: “No man is an island, entire of itself; every man is a piece of the continent, a part of the main” [7]. State laws typically allow involuntary commitment of persons who are dangerous to themselves or others because of mental illness [8]. Thus even if Charlie had said, “I never want to be hospitalized ever again,” when his paranoia created danger for Laura, his directive could be overridden.

But what about Reina’s refusing to have Charlie medicated now that he is hospitalized? Law on this question is unsettled [9], but from the perspective of ethics, Dr. Naobi and the hospital can reasonably challenge Charlie’s wish to avoid medication. His wishes deserve respect, but they do not necessarily trump respect for the other patients, staff, and his daughter Laura, who are put at risk by his paranoia. And if medication refusal resulted in an otherwise avoidable hospitalization that might last for months, it is reasonable to ask whether patients like Charlie have the right to commandeer funds from public or private insurance to satisfy their wish to avoid medication [10].

The case tells us that Dr. Naobi “feels very conflicted, but he manages to respond calmly,” and that he ends the contentious meeting with Reina with a recommendation that they seek to find “common ground and take another day to think this over together.” Conflicts about ethics typically evoke strong emotions, and Dr. Naobi shows excellent judgment in recognizing his agitation, calming himself, and proposing further deliberation and a cooling-off period. Overriding Charlie’s advance directive should be avoided if possible and chosen only as a last resort. But if his clinical condition continues to pose a significant risk of injury to others despite the best possible treatment that does not include medication, after appropriate consultation with an ethics committee and legal counsel, antipsychotic medication should be given.

References

4. For an evaluation of the effectiveness of advance psychiatric directives, see, for example, Campbell LA, Kisely SR. Advance treatment directives for people with severe mental illness. *Cochrane Database Syst Rev.* 2009;(1):CD005963.


James Sabin, MD, is a clinical professor in the departments of population medicine and psychiatry at Harvard Medical School in Boston, Massachusetts, and the director of the ethics program at Harvard Pilgrim Health Care, a not-for-profit health plan. His research interests include the ethics of health care resource allocation.

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ETHICS CASE
Psychiatric Diagnostic Uncertainty: Challenges to Patient-Centered Care
Commentary by Julie M. Aultman, PhD

Abstract
In this case and commentary, a patient’s request to be treated for depression without a stigmatizing diagnostic label of bipolar II disorder challenges a clinician’s obligation to provide a clinically and ethically appropriate diagnosis and safe treatment consistent with the patient’s family medical history. Sensitively recognizing and responding to patients’ concerns and values, even when they might conflict with the delivery of reasonable psychiatric care, is essential when gauging the appropriateness of such therapeutic practices. Furthermore, developing honest and open communication; recognizing that patients, like some psychiatric diagnoses, do not fit into discrete boundaries or cannot be categorized by a single label; and placing the patient at the center of care can all serve to resolve value conflicts, protect patient privacy, and promote accurate diagnostic and treatment practices.

Case
Tina, an 18-year-old college freshman, presents to a university mental health clinic complaining of symptoms of depression. She reports that she has been experiencing very low moods, crying spells, and a profound lack of energy and motivation, making it difficult to do even the most basic activities in her life. Moreover, the lack of motivation and problems with concentration have made it very difficult to keep up with her work, and Tina expresses the concern that she might fail out of school. She reports that one of her good friends from high school had something similar happen to her and responded well to sertraline, and that she was hoping that she could get a prescription for that.

A careful history and lab tests reveal that Tina’s symptoms are primarily isolated to the areas of mood, attention, motivation, and energy and that there is no medical or substance-induced cause of her symptoms. Tina reports no change in her appetite or sleep habits, no psychomotor agitation or retardation, no feelings of worthlessness or guilt, and no thoughts of suicide. When asked about the past, she says that for about a month after arriving at school she felt “fabulous.” She was getting As in all her classes and excelling as a member of the cross-country team. Although she had been very worried about meeting new friends when she started college, she states, “Then I realized that I didn’t have to worry about that at all, and that I was actually much more social...
than I thought. I made a ton of friends really fast.” Tina wasn’t sleeping as much as she had in high school at that time, but she thinks this was just “normal college stuff.” After about a month, she “settled in” and got on a more routine schedule. She does not express impulsivity, grandiosity, or psychosis. When asked about family members, she notes that both her father and older sister have bipolar disorder and quickly seems to want to separate her experience from theirs; she immediately adds, “I’m not like them at all. They’re crazy and irresponsible when they’re sick. I’ve never had anything like that.”

Despite this protestation, Tina’s physician, Dr. Kalif, suspects that Tina might be suffering from a depressive episode associated with bipolar II disorder. Tina is adamant that she is only concerned about her depression and wants to try a selective serotonin reuptake inhibitor (SSRI). Dr. Kalif convinces her that there is significant risk of a bad reaction to SSRIs given her personal and family history. Tina agrees to try lurasidone instead on the condition that Dr. Kalif agrees not to name bipolar disorder in her health record. Tina clarifies, “I’ve seen how people look at my dad and my sister based on those words, and I don’t want anyone to think I have that.”

Dr. Kalif can understand Tina’s wish not to have a diagnosis of bipolar disorder in her health record, particularly since Tina’s symptom history does not clearly include hypomania and Tina does not currently meet full criteria for bipolar disorder. But she suspects that Tina’s health insurance will not cover lurasidone for depression, and Tina could be upset about the resulting high cost. Dr. Kalif is also concerned that a prescription for lurasidone will look strange without a diagnosis of bipolar disorder recorded. Finally, she’s concerned that, at some point, if bipolar disorder does turn out to be the best description of Tina’s symptoms, she’ll have to betray Tina and name it officially in her health record.

Commentary
Other doctors may act upon the body, but the psychiatrist acts upon the soul. And it is the rich evaluative complexity of the self—the seat of evaluations, preferences, changes of mind, wishes, poetry, and passion—that sets the stage for the ambiguities of diagnosis.

John Sadler [1]

Mental disorder classification systems such as the Diagnostic and Statistical Manual of Mental Disorders (DSM) and the “International Statistical Classification of Diseases and Related Health Problems” (ICD) are designed to eliminate wide variations in diagnosis through the use of common terms and definitions, but without creating overly narrow diagnostic criteria that can exclude persons who are in need of treatment. The writers of the newest edition of the DSM—the DSM-5 [2]—recognize that the manifestations of mental disorders can map onto multiple overlapping criteria and that a “one-size-fits-all” approach to diagnosis and treatment is not optimal; accordingly, they developed dimensional metrics and spectra that combine many specific disorders into a single
category (e.g., autism spectrum disorder). Despite efforts to create single-spectra categories, bipolar disorder (BD) and major depressive disorder (MDD), once captured in a single, mood disorders chapter of the DSM due to their similarities, are now separated into two different chapters in the newest edition [2].

Having classification standards, diagnostic methods, and labels or names to refer to particular phenomena provides health care professionals the tools to offer beneficial treatment, hopefully helping patients achieve vital goals through the reduction or elimination of pain and suffering [3]. The validity, reliability, and ethical appropriateness of a diagnosis depends on the nature, severity, and duration of the symptoms, the level of expected and actual benefits from treatment, clinical observations, and the self-reported unique needs and life story of the patient. However, even when applying DSM-5 criteria, mental health professionals might ignore the needs and values of patients, mislabel their symptoms, or misappropriate diagnostic terms, particularly when using classification systems in a cookbook fashion or assigning diagnostic labels to patients whose symptoms don’t actually fully meet criteria for a diagnosis. Additionally, any disease label has moral and social implications, which can include discrimination, dehumanization, disrespect of persons, and lack of access to vital resources and opportunities, which further perpetuate the social stigma of mental illness.

Turning to the case, Tina’s resistance to the diagnostic label of BD might stem from a lack of understanding and acceptance of her father and sister’s diagnoses and the overall stigma of mental illness. She’s observed and possibly been the subject of disrespect or discrimination as a member of a family with mental illness. Thus, before addressing Tina’s request that BD not be entered into her health record, it is critical for Dr. Kalif to address Tina’s concerns about the diagnostic label of BD, to try to better understand her relationships with her father and sister and the overall impact that mental illness has had on her family, and to provide education and support to help her gain a better understanding of her own mental health. Although Tina’s concerns about stigma associated with BD should not influence Dr. Kalif’s diagnostic decision, they should be discussed and reported in Dr. Kalif’s notes, particularly given their relevance to Tina’s story. To help reduce stigma experienced by their patients during clinical encounters, it is essential that practitioners remain as impartial and honest as possible in their diagnostic decisions and reporting, uninfluenced by patients’ fears, concerns, or demands, and at the same time that they recognize that psychiatric diagnoses are moving targets and that each patient has unique needs. As John Sadler writes,

Diagnosis does not just address the self; it also addresses a self engaged in the continuous modification and reinventing of itself. Who the patient “is” is under constant modification, and whichever mental disorder the person “has” is revised in concert with the self. . . . Psychiatric diagnosis,
in turn, becomes a moving target, and mental disorders mutate within a complex biocultural interchange [1].

Sadler’s message is an important one to convey to persons with mental illness, who might feel as though their diagnoses define who they are as persons. Persons modify themselves in response to, or are modified by, a number of factors, including pharmaceutical and behavioral interventions, which contribute to their ability to gain insight about themselves in relation to others and to develop the necessary tools to manage, if not eliminate, mental health symptoms. In such cases, the psychiatric diagnosis may also change, revealing how mutable mental disorders really are. Thus, it is critical for health care professionals to provide continuity of comprehensive care to identify changes in the person in relation to the original diagnosis and to modify diagnoses and treatments based on those changes.

**Clinically Appropriate Diagnosing**

A trusting therapeutic relationship is essential, particularly when the diagnosis does not meet full diagnostic criteria and when a patient is wary about a diagnostic label. In Tina’s situation, her diagnosis neither fully meets the criteria of BD-II or (unipolar) MDD, yet she experiences the same type of depression specific to both [4]. Because BD shares similar symptoms with MDD, it is often difficult to distinguish the subtle differences between the two disorders. However, because Tina has experienced features of BD II, i.e., depression, and has a family history of BD, she is at increased risk of developing the disorder. Nevertheless, Dr. Kalif’s instinct is probably right that there is not enough evidence at this time to fully diagnose Tina with either BD-II or MDD, i.e., Tina currently experiences only 4 of a minimum of 5 of 9 required symptoms for MDD, and has not experienced a high episode of euphoria characteristic of BD-II.

Because Tina does not meet the full criteria for these disorders and the therapeutic relationship between her and Dr. Kalif is in its infancy, a *provisional* diagnosis of BD-II is an ethically and clinically appropriate alternative to simply labeling Tina with a disorder she might not have. Another option is for Dr. Kalif to diagnose Tina with “Other Specified Bipolar and Related Disorder,” which is designated in *DSM-5* for those cases in which patients express too few symptoms to meet the BD-II criteria [5]. If future observations or patient self-reporting were to suggest BD-II (or even MDD), then the diagnosis could change; as mentioned earlier, diagnoses are moving targets. Furthermore, the mental health community recognizes that patients do not always meet the full diagnostic criteria for classified diagnoses and has, for the most part, captured this issue with the use of “provisional,” “not otherwise specified,” “other,” or “related” diagnoses. A provisional diagnosis promotes objective diagnosing and honest reporting, which is essential for providing effective treatments and advancing medical science and classification practices.
In recognizing that even a provisional diagnosis of BD-II or “Other Specified Bipolar and Related Disorder” may upset Tina, Dr. Kalif can further emphasize the fact all patients are different and may experience a range of symptoms of varying degrees; although Tina’s sister and father may be diagnosed with BD, their experiences and circumstances are unique. Such a conversation is important for reassuring her that while classifications of mental disorders are useful for research, identifying commonalities of etiology and symptoms, and access to care and resources (e.g., medications), they do not define patients. One is not “bipolar” but simply a person who experiences symptoms (e.g., depressive episodes) of the category BD-II, and each person diagnosed with BD is unique.

Ethically Appropriate Diagnosing and Sensitivity to the Patient
Dr. Kalif has an obligation to accurately report her findings in Tina’s health record, and neither patient demands nor insurance reimbursement concerns should influence her diagnosis, treatment, or reporting. By appropriately fulfilling such obligations, Dr. Kalif is preserving the integrity of diagnostic and treatment practices.

This is not to say that Dr. Kalif should ignore Tina’s plea to not report BD-II in her medical record, as her request is not only a catalyst for further discussion about her familial relationships and the identification of specific psychosocial issues in her life, but also expresses respect for and a deeper understanding of Tina’s social needs and values. Furthermore, if Dr. Kalif is more comfortable with a particular pharmaceutical intervention (lurasidone) and feels as though such treatment is more effective and safer than alternatives (SSRIs), intentionally misdiagnosing or assigning a diagnosis to a patient for purposes of accessing this treatment is dishonest, possibly fraudulent, and could have negative repercussions later (e.g., enhanced stigma, unnecessary economic burdens, and side effects, such as increased weight gain, that can be worse than the chief complaint).

A temporary alternative to reporting a diagnosis of BD-II (or even provisional BD-II or “Other Specified Bipolar and Related Disorder”) would be: (1) to report in her health record Tina’s family history of BD to call attention to the risks of using an SSRI and the justification for prescribing lurasidone and (2) to give Tina a provisional diagnosis of MDD, so long as the clinical presentation does not at this juncture favor BD. This approach might be the best way for Dr. Kalif to respond to Tina’s immediate clinical needs and abate her fears of being diagnosed with BD until she is able to develop a more long-standing, deeper, and more trusting therapeutic relationship in which to address these and related familial issues while also hopefully arriving, over time, at a more concrete diagnosis.

Protecting Tina’s Privacy
One possibility is that Tina would feel better about a recorded diagnosis if she knew her privacy was being protected as much as possible. Efforts to protect Tina’s privacy could involve Dr. Kalif keeping a separate record—not in Tina’s official health record—of her notes. A drawback to separate record keeping, which the American Psychiatric Association is strongly advocating against [6], is that such practices can reinforce stigma, promote confusion among health care professionals who might rely on the official health record as accurate and up-to-date, promote discontinuity of care, and contribute to harm (e.g., drug interactions).

Nevertheless, it is not uncommon, or unethical, for clinicians—in well-intentioned attempts to protect patients’ privacy—to keep sensitive, nonclinical patient information separate from the clinically relevant, or standard, health records, which are accessible to multiple health care providers and administrators who are relevant to the overall care of the patient. In this case, Tina’s life story, including her thoughts, feelings, and beliefs, captured through a psychotherapy session, could be contained in a nonclinical record that can only be seen by Dr. Kalif. Privacy regulations protect psychotherapy notes from being released to others without patient authorization; such protections are not afforded to any other medical records [5]. The primary health record, then, may contain limited but relevant mental health information, such as diagnoses, treatments, and family history. Thus, in this case, a provisional diagnosis of MDD, if appropriate, along with a description of relevant family history, should be listed on the primary health record—accessible for purposes of coding and billing, health care insurance coverage, determining if existing or future physical conditions and treatments might affect or be affected by Tina’s mental health status, and potentially for chart reviews in research. Tina’s privacy, to an extent, is protected, and appropriate safeguards are in place to prevent potential harm. Tina may pay for care and resources out of pocket if she is financially able to do so, thus limiting the number and type of entities that have access to her primary health record (e.g., insurance companies).

Such discussions between Dr. Kalif and Tina are significant to Tina’s overall care, as are conversations about how well the lurasidone is working, her relationships with friends and family, and the future possibility of a confirmed diagnosis of BD-II. These therapeutic conversations—along with accurate, up-to-date health records (including a separate, private record to capture Dr. Kalif’s psychotherapy notes) that accommodate evolutions in diagnostic process and a patient’s access to treatment and care—can best help Tina achieve her goals, improve her quality of life, and avoid unnecessary harm.

**Conclusion**

In conclusion, sensitivity to Tina’s concerns about BD is important for ethical considerations, but, ultimately, Dr. Kalif should base her diagnosis and treatment plan on clinical knowledge and professional integrity rather than her patient’s wishes, which may be generated by fear, misunderstanding, and a lack of proper support and guidance.
References


4. According to the DSM-5, for a BD-I diagnosis, it is necessary to meet criteria for a manic episode, which may have been preceded by, and may be followed by, a hypomanic or major depressive episode. On page 124 of the DSM-5, a manic episode is defined as a “distinct period of abnormally and persistently elevated, expansive, or irritable mood and abnormally and persistently increased goal-directed activity or energy, lasting at least 1 week and present most of the day, nearly every day (or any duration if hospitalization is necessary).” Manic episodes cause social or occupational functioning impairment and are not attributed to substance abuse. Under the DSM-5, BD-II includes a hypomania episode (high episodes of euphoria and low episodes of depression), has one or more major depressive episodes and at least one hypomania episode that must last for at least four days. Hypomania is an elevated mood that is not as elevated as mania and is not easily observable or reportable given that it does not contain psychosis or life-threatening consequences.


Julie M. Aultman, PhD, is a professor of family and community medicine at Northeast Ohio Medical University in Rootstown, Ohio, where she directs and teaches in the bioethics programs. She holds a doctorate in philosophy with a concentration in health care ethics and a specialization in cognitive science from Michigan State University and a master’s degree in bioethics from Case Western Reserve University. Her research interests extend to psychiatric ethics, health care justice, international studies in health care systems and community-based rehabilitation programs, and moral and professional development in medical education.

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ETHICS CASE
Prescribing “Off-Label”: What Should a Physician Disclose?
Commentary by Katrina Furey, MD, and Kirsten Wilkins, MD

Abstract
This case highlights clinical dilemmas faced by physicians when treating patients with conditions for which there are limited or no FDA-approved treatment options. First, it raises questions about when it is appropriate to prescribe medications for “off-label” indications and what might be the ethical and legal implications of doing so. It also prompts us to consider why pharmaceutical companies might or might not pursue FDA approval for new indications when a drug has already been approved for use in another condition. Finally, this case demonstrates the importance of employing shared decision making when discussing complex clinical decisions and how such techniques might have led to different outcomes and better understanding between Dr. Shannin, Maxine, and Heather.

Case
Heather brings her 89-year-old mother, Maxine, to the office of her psychiatrist, Dr. Shannin, for an evaluation. Maxine lives with Heather’s family, and though she has been diagnosed with dementia, she still sees Dr. Shannin in his office by herself while Heather waits for her in his office lobby. During her last visit with Dr. Shannin three months ago, Maxine reported that whenever she got confused, she began to think that the people around her were going to harm her. Heather also expressed concerns about Maxine’s confusion and paranoia, since Maxine would typically respond to those feelings by acting out as if she were being threatened. Maxine was unable to remember these outbursts, but she did remember feeling agitated and did note that Heather seemed very upset when she felt that way. At that time, Dr. Shannin suggested that Maxine try an atypical antipsychotic, olanzapine, to help control her agitation and paranoia. He explained the risks and benefits in detail and also explained that while he’d had good results with several patients with this medication in the past, managing confusion, agitation, and paranoia was not what this medication is really for. Maxine felt confident that Dr. Shannin had used this medication to manage these symptoms for his other patients, however, and so she agreed to begin taking olanzapine, which has managed her symptoms well for the last three months.

Maxine’s dementia has progressed significantly since her last visit with Dr. Shannin, and she is having a particularly bad day today: she doesn’t recognize her longtime physician.
and is unable to correctly answer questions about being oriented to time and place. It seems that from this point forward, Maxine will no longer be able to participate meaningfully in decisions about her own care, so Heather now takes a more active role in Maxine’s care planning and accompanies Maxine during her appointment with Dr. Shannin.

Dr. Shannin asks Heather if she has any questions for him about Maxine. “Yes,” she says, “What’s olanzapine? I know she’s been taking that for a while, but when I looked it up, it seems to be used for treating psychosis. I’m puzzled. My mother’s not psychotic.” Dr. Shannin explains his rationale. Heather follows his explanation closely and confirms that while Maxine’s memory and functioning have declined over the last three months, she appreciates that she has been less confused, agitated, and paranoid. However, Heather worries about her mother continuing to take a drug that’s “off-label” and contains a black box warning in the package. “It just doesn’t seem safe, particularly since the black box warning notes an increased risk of death,” she explains to Dr. Shannin. “I assume you explained the risks to her when she consented to take this medication three months ago. You’ve taken good care of my mom and I don’t doubt your good intentions. But, as a physician, I guess I don’t understand how you’re really even allowed to prescribe medications in ways that aren’t approved by the Food and Drug Administration.”

Dr. Shannin wonders how to respond.

Commentary

Approval by the Food and Drug Administration (FDA) implies that available evidence shows that a drug is safe and effective for the specific indication (disease or symptom) for which it was tested [1]. “Off-label” drug use commonly refers to prescribing currently available medication for an indication (disease or symptom) for which it has not received FDA approval [1, 2]. Off-label use also includes prescribing a drug for a different population or age range than that in which it was clinically tested and using a different dosage or dosage form [1, 2]. Contrary to what patients might assume, off-label drug use is not the same as experimental or research use. Once a drug is FDA-approved for a specific indication, legally it can be used for any indication [3, 4]. Off-label prescribing is common; it accounts for 10 to 20 percent of all prescriptions written [5], although the practice is more common in specific patient populations like children and the elderly [1, 2, 5]. Physicians also might be more likely to prescribe off-label medications for patients facing life-threatening or terminal medical conditions for which there are limited or no FDA-approved alternatives [1, 5].

There are several reasons why off-label prescribing is so common. Advances in clinical medical practice often outpace the FDA’s ability to approve new drugs or relabel previously approved drugs with new indications [1, 2, 5]. The FDA approves only 40 to 60 percent of all drugs submitted for review, and it can take six to eight years and approximately $1.7 billion to get a new drug approved [4]. Moreover, the revenue
associated with relabeling a drug with additional indications might not offset the expense required to conduct the necessary clinical trials, which discourages most pharmaceutical companies from relabeling drugs once they have already been FDA-approved for one indication [1].

Another reason that off-label prescribing is common is that there is limited evidence of the effectiveness of “on-label” use in certain patient populations frequently excluded from clinical trials, such as children, pregnant women, the elderly, and psychiatric patients [1, 2, 5]. In psychiatric patients, in particular, symptom similarity between disease states might contribute to use of one medication off-label for various conditions [1]. Specifically, off-label use of antidepressants, anticonvulsants, and antipsychotics is high and such use increases in prevalence with patients’ advancing age [1, 6]. Elderly patients with dementia, like Maxine, belong to two of the aforementioned groups.

It is important to note that there are no FDA-approved treatment options for dementia-related behavioral disturbances (e.g., psychosis, agitation) [7]. However, randomized controlled trials suggest modest efficacy of atypical antipsychotics in reducing these symptoms [7], and expert consensus and professional guidelines support the use of antipsychotic medications like olanzapine in clinically appropriate circumstances when nonpharmacologic management has failed [8, 9]. In fact, the use of off-label atypical antipsychotics for conditions like dementia has increased in recent years [1]. In Maxine’s case, if medications are deemed necessary for behavioral symptom management (i.e., nonpharmacologic management has failed or her symptoms have become significantly distressing or dangerous), it is reasonable from clinical and ethical standpoints for Dr. Shannin to prescribe olanzapine off-label for her.

**Legalities of Off-Label Prescription Drug Marketing and Use**

Physicians like Dr. Shannin might worry about legal implications of prescribing off-label. It is important to remember that though FDA approval is based on available evidence of the effectiveness and safety of a drug for the specific indication for which it was tested, it does not guarantee either, even for on-label uses [4]. For example, the FDA has approved drugs, like Vioxx, that were actually unsafe for on-label uses [3]. Because of the associated risks, the FDA has limited manufacturer marketing of off-label uses of FDA-approved drugs [1, 4]. The FDA Modernization Act of 1997 [10] ruled that manufacturers are allowed to distribute peer-reviewed journal articles about off-label uses of medications to health care professionals upon request [1]. Such off-label drug use publications must be accurate and unedited, and the relationship between information distribution and the sponsoring pharmaceutical company must be clearly disclosed in the marketing materials [1]. The FDA has continued to ban direct-to-consumer marketing of off-label uses by preventing such indications from being advertised in package inserts, TV advertisements, or patient education materials [1]. Nevertheless, off-label marketing by pharmaceutical companies has been one of the most common causes of Medicaid fraudulent claim investigations [11].
The FDA does not prohibit physicians from prescribing drugs off-label [4], and Congress has repeatedly taken legal steps to prevent the FDA from interfering with the practice of medicine [4]. Although many malpractice lawsuits have been filed on behalf of patients arguing that they did not give informed consent to take a drug because they were not informed that use for their particular condition was actually off-label, the law has generally sided with physicians in finding that they have no legal duty to inform patients of a drug’s regulatory status [3, 4]. Such rulings enforce that off-label is an FDA regulatory term that denotes nothing about clinical risks or benefits [4]. The physician’s duty is to provide clinical information and some have argued that taking the time to explain the legal complexities of FDA approval versus off-label drug use could distract from shared clinical decision making [3, 4].

Weighing the Evidence
Because physicians often treat clinically complex patients, they must balance a patient’s needs and individual characteristics with available scientific evidence when deciding whether to prescribe medications off-label [5]. Off-label use is appropriate when it is in the best interest of the patient on the basis of credible, published scientific data supporting the use of the drug in that manner [1, 5]. Furthermore, the risks of using a medication off-label should not outweigh the benefits, although this distinction might be less clear in complicated situations or for patients with many comorbidities [5].

Atypical antipsychotics used off-label to treat dementia-related behavioral disturbances carry significant risks, which, some have argued, outweigh their benefits [12]. The risks posed to Maxine by using olanzapine include general risks to all patients taking antipsychotics (e.g., parkinsonism, akathisia, tardive dyskinesia, metabolic syndrome) as well as risks specific to patients with dementia (e.g., stroke) [13]. In addition, all antipsychotic medications carry a black-box warning of increased risk of death compared to placebo in patients with dementia [13]. In this case, the risks of using olanzapine off-label must be weighed against the risks of not treating Maxine’s escalating paranoia and agitation. Untreated behavioral symptoms of dementia have been associated with an increased risk of nursing home placement and higher rates of caregiver burden, which could lead to decreased quality of life for Maxine and her daughter [7]. Some studies have also shown that dementia-related psychosis and agitation have been associated with more rapid cognitive decline and an increased mortality risk [7].

Shared Decision Making
A key question in this case is whether Maxine had decisional capacity to consent to the initial prescription of olanzapine. She accepted the medication after a discussion of risks and benefits, likely because of her trust in Dr. Shannin. The power dynamic in physician-patient relationships can be such that patients and families trust their physician implicitly; this has its merits and drawbacks, from clinical and ethical standpoints. Although Dr. Shannin indicated to Maxine that he was using olanzapine to treat a
condition for which it was not originally intended, he did not specifically disclose to Maxine its lack of FDA approval to be used to treat her specific symptoms. As discussed above, he is not legally required to do so, but, from an ethics point of view, we might still wonder how his nondisclosure might have affected his alliance with Maxine and Heather. For example, Heather was surprised to learn that her mother had been prescribed a medication typically used in patients with psychotic disorders. Given Maxine’s cognitive decline, Heather will likely be assuming a much greater role in medical decision making. Will she trust Dr. Shannin to fully disclose treatment risks in the future? A potential worry is that if nondisclosure undermines Heather’s trust in Dr. Shannin, she might not feel comfortable reaching out to him in a crisis or when her mother’s treatment needs escalate.

The practice of patient-centered medicine requires that patients and families experience medical treatment decisions as a collaborative and shared process. In his initial discussion with Maxine about olanzapine, Dr. Shannin could have employed additional communication strategies that are key to shared decision making. Whether or not a patient with dementia has decision-making capacity, it is reasonable to ask the patient’s permission to include a trusted family member in discussion of treatment options. Maxine might not later recall specific details of the conversation, and, given the typical progressive decline of patients with dementia, she will likely need increasing family involvement in the future. Bringing a family member into the discussion allows a physician to inquire about the effects of the symptoms on the patient’s and family’s quality of life and to ascertain specific treatment goals of a patient and her family, which might not always be congruent with those of the physician. In this case, Dr. Shannin’s goal could be to ensure Maxine’s safety and to reduce caregiving burden on Heather. However, Maxine might want a medication to calm her nerves or help her sleep, and Heather might want to reduce familial stress or delay Maxine’s placement in a nursing home.

How can shared decision making be implemented? Elwyn et al [14] propose a practical three-step communication model for shared decision making: (1) “choice talk,” the step at which patients are made aware that reasonable options exist; (2) “option talk,” the step at which patients are provided information about the options; and (3) “decision talk,” the step at which patients are supported in considering preferences and making a decision. In this case, if Maxine had not yet been treated for her symptoms, choice talk might include making Maxine and Heather aware that both nonpharmacologic and pharmacologic treatment options exist for agitation and paranoia in dementia. Option talk could include Dr. Shannin’s noting that pharmacologic options are limited and that no medications are FDA-approved for this indication. He could then discuss the risks, benefits, and off-label use of olanzapine, and provide a lay summary of the scientific evidence and practice standards that guide use of this medication despite its lack of FDA approval in dementia. Dr. Shannin could also explain nonpharmacologic alternatives (e.g.,
patient reassurance and redirection) and pharmacologic alternatives (e.g., antidepressants) to olanzapine. Option talk might also make use of decision support aids such as pamphlets, videos, or reputable websites, which have been shown to lead to improved patient knowledge, more accurate perception of risks and benefits, and greater participation in decision making [15]. The idea is that patients are supported in the deliberation process throughout and given ample time to make a final decision, which can take more than one encounter [14].

Conclusion
Off-label prescribing is a common and legal practice in medicine. This practice is justified when scientific evidence suggests the efficacy and safety of a medication for an indication for which it does not have FDA approval and when the practice is supported by expert consensus or practice guidelines. Through shared decision making, patients and families are equal partners in clinical decision-making processes, which can help a physician carefully weigh risks and benefits of a given treatment according to the patient’s unique circumstances.

References


Katrina Furey, MD, is a second-year resident in the Department of Psychiatry at Yale University School of Medicine in New Haven, Connecticut.

Kirsten Wilkins, MD, is an associate professor of psychiatry and the director of the psychiatry clerkship at Yale University School of Medicine in New Haven, Connecticut. Dr. Wilkins is board certified in general psychiatry, geriatric psychiatry, and psychosomatic medicine.

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ETHICS CASE

When Is Depression a Terminal Illness? Deliberative Suicide in Chronic Mental Illness

Case and Commentary by Constance E. George, MD, MA

Abstract
This commentary explores the utility of hope as a therapeutic tool for intervention in the case of a patient with a mental illness that is refractory to treatment over time, who expresses her intention to commit suicide. It begins with a short discussion differentiating a deliberative consideration of suicide from an impulsive act. Then the commentary defines hope, how it might be used as a therapeutic tool, and which limitations a clinician might confront in such a case. This commentary also considers the role of a physician in orientation not only to the patient but also to her own thoughts, feelings, and emotions regarding a patient’s expressed desire to end her life.

Case
Ms. G is a 55-year-old white female who is treated in Dr. C’s office for bipolar affective disorder. A lifetime of relapsing mood episodes resulted in failures at school, limited capacity to hold steady employment, and an inability to sustain intimate relationships or friendships. She lives with her father, who is currently ill and unlikely to survive long. Her mother died recently, and Ms. G has no siblings.

Over the years, Ms. G’s depressions varied in severity but she never fully recovers. She survives in a state of chronically depressed mood. At this point, however, she does not meet criteria for clinical depression. Dr. C’s treatment for Ms. G over the last 10 years has covered the range of pharmacotherapy, psychotherapy, electroconvulsive therapy (ECT), and experimental agents offered through a number of clinical trials and second opinions. In a session one day, Ms. G states to Dr. C that she will live as long as her father is alive, but, after his death, she will elect to stop her medications and commit suicide. When asked by Dr. C to explain this more fully, she states, “I see no hope for my future. After he dies, no one, other than you, Dr. C, will be left to grieve for me.” Dr. C wishes the patient to live, but even she is doubtful an effective treatment for Ms. G exists.

Commentary

Dr. C is uncomfortable and wonders what to do next.
This case introduces three important ethical questions. The first two have to do with whether and when hopefulness is an appropriate therapeutic goal to cultivate. The third has to do with how Dr. C should orient herself personally and professionally to Ms. G.

To begin, the contemplation of suicide in this case should not be characterized as an impulsive act under conditions of stress but as a reasoned choice based on the consideration of alternative courses of action [1]. This distinction is important when considering the relative autonomy of the impulsive versus the deliberative patient and how that might affect a psychiatrist’s decision to intervene and whether suicide is considered a reasonable choice. If we employ the “three condition” theory regarding autonomy as put forth by Beauchamp and Childress [2], autonomous action is framed in terms of a normal chooser who acts with intent, with understanding, and without controlling influences, be they internal (within the chooser) or external (outside of the chooser). By contrast, an impulsive patient makes a decision to commit suicide without autonomy, that is, his or her decision is influenced—internally controlled—by the acute symptoms of an illness, for example, by auditory hallucinations. The hallucinations result in a distorted view of reality that renders such patients compromised in terms of understanding their action, consequences of their action, or even the reasons they intend an action. A patient in danger of an impulsive suicide provides arguable grounds for psychiatric intervention given that a patient would likely think and act otherwise once the acute symptoms resolve.

The case described above is quite different. Ms. G’s autonomy is intact, as evidenced by her understanding of her illness, her ability to act with intent (pursue a multitude of treatments and adhere to treatment), her ability to recognize consequences of her actions (that her suicide will negatively impact her father and her psychiatrist, for example) and her freedom from influences internal (psychotic symptoms) or external (none apparent). Furthermore, Ms. G states as her reason for electing suicide, “I see no hope for my future.” Since hope is identified as the focal point that is lacking, how should it inform the psychiatrist’s next steps? Should she intervene by addressing hope? Should she abide by the patient’s intention as adequately deliberated and reasonable?

Tempering hope with realism as a therapeutic strategy. Should Dr. C, despite knowing that there is no reliable “cure” for Ms. G’s condition, try to convince Ms. G to abandon her suicide plan by encouraging her to hope for symptom relief?

Hope is difficult to define, let alone use as a therapeutic intervention. Jerome Groopman, in his bestselling book, The Anatomy of Hope: How People Prevail in the Face of Illness [3], gives the following definition: “Hope is the elevating feeling we experience when we see—in the mind’s eye—a path to a better future. Hope acknowledges the significant obstacles and deep pitfalls along that path. True hope has no room for delusion” [4]. A more clinical, but closely related concept of hope is given by the late C.R. Snyder, a specialist in positive psychology and professor at the University of Kansas. He outlines
two components of hope: (1) a belief in, or a perceived capability to produce, workable routes (pathways) to desired goals and (2) the motivation (agency) to use those routes [5]. Applying these definitions of hope to this case, it seems Ms. G has lost hope for a workable route to a life she would find worth living. Ms. G can be described as hopeless, and she certainly has many of the traits one could attribute to hopelessness: sadness, weariness of all the various treatments, and isolation [6].

Dr. C’s difficulty with Ms. G’s decision could lie, in part, with Dr. C’s own internal hope that perhaps there is another answer, an alternative treatment, a better clinician, a drug in the future for Ms. G. What likely began in treatment as the patient’s desire and hope for amelioration of symptoms was laid squarely in the lap of Dr. C. Those feelings were transferred to Dr. C, who now herself has thoughts and emotions regarding the patient; that is, she harbors hope for the patient. In psychiatry, this is referred to as countertransference. Broadly, countertransference encompasses all of the clinician’s feelings toward the patient [7]. This is often a productive process; physicians want to help others and part of this mission to help others is engendered by the interaction between clinician and patient, which constitutes the therapeutic relationship. In this case, however, is Dr. C’s hope reasonable? The patient knows as well as Dr. C that treatment options are likely exhausted. For the patient to hope, there must be a route, a path to the patient’s goals; it cannot be delusional, it cannot be false hope perpetuated by Dr. C.

This commentary is not about losing hope. A physician’s orientation to hope is as important as her clinical acumen. The power of hope to keep the human body going is truly remarkable and well documented [3]. Hopes can vary: hope for a cure, hope for improvement in condition, hope for relief of pain, hope for an easy death. But hope for a cure as an end in itself might not be useful, and like all therapeutic interventions, it is accountable to the truth.

Hope, therapeutic capacity, and outcomes. Should Dr. C continue the course of treatment for Ms. G as it is and count on the strength of the therapeutic capacity of their relationship to maintain the hope that Ms. G will change her mind about committing suicide? As stated in the case report, Dr. C wishes her patient to live. There’s no neat and tidy relationship between the strength or weakness of the therapeutic bond between clinicians and patients and good or poor outcomes for patients, and though the role of hope in the establishment and maintenance of that bond is not clear, caregivers can and should create and hold hope for patients when it’s reasonable to foresee a path to the hoped-for outcome [8]. Dr. C can express, “I have hope for you,” and encourage the patient to draw upon that hope as a route to a better future (achieving her goals). A number of clinically and ethically relevant questions arise here. For example, is Dr. C’s hope enough, or even wanted? Should her hope be modest or robust (or modestly or robustly expressed), both, or neither? Is it fair of Dr. C to ask Ms. G to “hang in there,” to
stay alive, because to Dr. C, any possibility of life is preferable to the finality of death? Is it appropriate for Dr. C, or anyone, to define death as a good or poor outcome for Ms. G and, if so, on which and on whose terms?

In my experience, for many seriously ill patients there often comes a time at which hope for a good outcome becomes the hope for a good death, for example, a peaceful death, or a death with as little pain as possible but, notably, a death under the control of the person dying [9]. Is it possible that this is what Ms. G wants? A good death for Ms. G might mean an end to her painful symptoms without causing others (her father, especially) pain. Dr. C's hoping Ms. G will change her mind could, once again, be indicative of countertransference. Dr. C's inability to accept Ms. G's death (and death wish) reflects Dr. C's feelings about the loss (or pending loss) of Ms. G, not Ms. G's readiness for death.

Perhaps an ethical way through for Dr. C lies in the consideration of Ms. G's condition as terminal. The difficulty here is elucidated by Michael F. Myers and Glen O. Gabbard in their book, The Physician as Patient:

> Most of medicine is palliative, except for certain infectious diseases and surgical procedures. Some outcomes are not preventable. Psychiatrists in particular may have difficulty accepting the idea that some psychiatric disorders in some patients are terminal [10].

The thought of suicide by a reasonable human being who contemplated options, remained compliant with treatment for years, diligently looked at alternatives, and tried various treatments but now comes to the conclusion that she can't endure the day to day pain of her illness is not palatable because, as just alluded to, suicidality is popularly considered a symptom, not a terminal response to symptoms of another illness, such as refractory depression. Suicide for Ms. G in this case might be assumed by some to be too self-indulgent to be characterized as a good death. Historically, this stance has support; there are and have been social and legal proscriptions against the act of suicide [1]. Similarly, psychiatrists could face malpractice lawsuits involving the suicide of a patient that is deemed to be caused by professional negligence [11].

The deliberative suicide, however, might not be so different than those decisions made every day by, say, oncology, endocrinology, nephrology, or neurology patients who are terminally ill and make reasoned decisions to stop treatment and find their own paths to a good death. In Oregon, for example, the Death with Dignity Act [12] expresses legal acceptance that terminally ill patients should have recourse to hasten death given the potential for suffering. Similarly, unendurable psychological suffering could be a legitimate reason for stopping treatment and hastening death by suicide [11]. Without delving into the meaning of unendurable psychological suffering, we might consider that a lifetime of refractory mental illness might be unendurable and can—and, for many,
does—result in a shortened life span [11]. The illness, in fact, proves terminal, be it from
disease, accident, or intent.

But even if Dr. C accepts this view of Ms. G's condition as terminal, she still might feel
uncomfortable acquiescing to Ms. G's plan and wonder what to do.

*Psychiatrists' personal and professional orientation to suicidality.* If Ms. G's suicide cannot be
prevented, but Dr. C finds it untenable, should Dr. C inform Ms. G of the need to find
alternative care that could honor Ms. G's right to take her own life after her father's
death? Or would that constitute Dr. C's abandonment of Ms. G?

This is a difficult set of questions. On one hand, Dr. C can acknowledge Ms. G's right to
take her own life and stay with her until the end despite her objections. But Dr. C might
also wish to divest herself of an option she sees as untenable both personally and
professionally. If Ms. G takes her own life, Dr. C might experience feelings of failure, guilt,
and loss. Given the issues involving countertransference already discussed, this is likely
given Dr. C's orientation as a healer and her long-standing relationship with the patient.
There is a tangible risk to Dr. C's mental health. Is Dr. C obliged to stay with a patient who
is making a decision Dr. C profoundly disagrees with and could cause harm to her? Is Dr.
C obliged to watch the patient die? Perhaps not. Dr. C is not refusing to find the patient
alternative care; transfer of care occurs in medicine on a frequent basis when differences
between patients' and professional treatment goals arise. Dr. C could simply express to
Ms. G that she is unable to help her with this particular goal and that another clinician
could be more supportive, at least from an ethical standpoint, if not from a clinical or
legal standpoint.

However, in this particular case, if Dr. C chooses to refer Ms. G to another psychiatrist, it
could cause harm to Ms. G. Dr. C knows she is the last person that matters to Ms. G, the
patient has clearly said so, and the years of working together has likely made this clear.
The patient has no one else. Is there a point at which the interests of Ms. G outweigh the
interests of Dr. C or vice versa? Dr. C is a professional and is thus held to standards of
professionalism that Ms. G is not. In general, professionalism not only demands a level of
medical competence, but also requires one to act ethically, that is, to express a respect
for others, to act with beneficence and to do no harm, to be compassionate and, put
simply, to abide with patients, to reside in the patients' corner [13, 14]. Perhaps in this
case, part of what it means for Dr. C to abide by Ms. G's decision is to acknowledge that
though Ms. G's actions affect her, they are not about her. Dr. C's hope is not the patient's
hope; Dr. C's desire for Ms. G to live is not the patient's desire; and the possible death of
Ms. G is not a reflection of Dr. C's success or failure as a physician.

**Conclusion**

Ultimately, regardless of whether Ms. G lives or dies, the tragedy for both Ms. G and Dr. C
lies not in culpability, but in isolation. Ms. G will be alone in her life or in her death. In all
likelihood, in the case of Ms. G’s death, Dr. C will not sit at the bedside and hold her patient’s hand during her final moments; she will not receive cards from loved ones or kudos from colleagues. It is a lonely place for both patient and physician.

So, an important lesson for physicians and physicians-in-training from cases like this one has to do with understanding that mental illness can be a terminal illness and that the concept of hope has therapeutic limitations. Patients’ concerns that the symptoms of their illness might be refractory and that their physician might not have treatments that can ameliorate their symptoms must be discussed. The patient must be free to speak—and to speak openly—about suicide, and, in a case such as this, the discussion must occur in the context of suicide as a deliberative decision from an autonomous patient, agreed with or not. Given the finality of death, the physician is obligated to motivate hope when it is reasonable to foresee a path to the hoped-for outcome. By the same token, a physician is obligated to avoid perpetuating false hope and therefore must address his or her own thoughts and feelings regarding the patient, his or her own fears of loss and failure, in order to avoid perpetuating a false hope that only serves his or her ends and not those of the patient. In this case, the utilization of hope as an intervening tool in this patient’s suicide plan might not be justifiable from an ethical perspective.

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Constance E. George, MD, MA, is a general adult psychiatrist who practices in Austin, Texas. She works in a small group clinic and is also active in the Texas Society of Psychiatric Physicians Council on Ethics.

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The AMA Code of Medical Ethics' Opinions on Patient Decision-Making Capacity and Competence and Surrogate Decision Making
Danielle Hahn Chaet, MSB

Although the Code of Medical Ethics does not have much to say about mental health per se, the Code does consider patient decision-making capacity, mental competence, and surrogate decision making for those who are unable—over the short-term or the long-term—to make their own health care decisions. These concepts are discussed in opinions 2.20, “Withholding or Withdrawing Life-Sustaining Medical Treatment” [1], 8.08, “Informed Consent” [2], and 8.081, “Surrogate Decision Making” [3].

Decision-Making Capacity and Competence
Generally, patients are free to exercise their autonomy in making decisions about their own health care. However, patients can only do so if they are given information about and understand the risks and benefits of a specific treatment and can apply this information to their health. As noted in Opinion 8.08, “Informed Consent,” “the patient’s right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice.” However, we know that not all patients have capacity (a clinical standard applying to a particular decision at a particular point in time) or competence (a legal standard applying to all decisions at all times) to make these informed choices about their health care [4]. For patients with mental illnesses that can interfere with their insight into their health or with their decision making, physicians have obligations to assess their capacity in order to evaluate their ability to make a particular health care decision at a particular point in time.

Because patients with mental illnesses can be vulnerable—particularly when they are severely chronically disabled by an illness or experiencing an acute exacerbation of an illness—they might not fully understand or be able to integrate information about risks and benefits of possible interventions. Opinion 8.081, “Surrogate Decision Making,” explains that “in some instances, a patient with diminished or impaired decision-making capacity can participate in various aspects of health care decision making. The attending physician should promote the autonomy of such individuals by involving them to a degree commensurate with their capabilities.” The higher the risk of a particular decision, the more important it is that the patient has appropriate decision-making capacity. That is, a patient suffering an acute exacerbation of a mental illness at a particular point in time might have capacity to decide what she will eat for breakfast, but she might not have capacity to decide whether to begin a course of psychotropic medications.
More about Surrogate Decision Making

When a patient does not have the capacity to make her own decisions at a particular point in time (or when her decisions are not covered by an advance directive, as noted in Opinion 2.191, “Advance Care Planning” [5]), someone else must do so for her. This person, known as the *surrogate decision maker*, or *proxy*, has either been named by the patient at a time when she had capacity or is a family member or close acquaintance designated by law or statute. Opinion 2.20, “Withholding or Withdrawing Life-Sustaining Medical Treatment,” outlines an example of this process for a patient who has been deemed to be incompetent by a court.

If the patient receiving life-sustaining treatment is incompetent, a surrogate decision maker should be identified. Without an advance directive that designates a proxy, the patient’s family should become the surrogate decision maker. Family includes persons with whom the patient is closely associated. In the case when there is no person closely associated with the patient, but there are persons who both care about the patient and have sufficient relevant knowledge of the patient, such persons may be appropriate surrogates.

Opinion 8.081, “Surrogate Decision Making,” also applies to patients who are competent but can, at a point in time, lack capacity. This opinion notes that “If a patient lacks the capacity to make a health care decision, a reasonable effort should be made to identify ... a health care proxy.” Surrogate decision makers should base their decisions on the substituted judgment standard; in other words, they should use their knowledge of the patient’s preferences and values to determine as best as possible what the patient would have decided herself. If there is not adequate evidence of the incapacitated or incompetent patient’s preferences and values, the decision should be based on the best interests of the patient (what outcome would most likely promote the patient’s well-being). Opinion 8.081 explains “factors that should be considered when weighing the harms and benefits of various treatment options.” These factors “include the pain and suffering associated with treatment, the degree of and potential for benefit, and any impairments that may result from treatment.” Opinion 8.081 elaborates that in applying the best interest standard,

Any quality of life considerations should be measured as the worth to the individual whose course of treatment is in question, and not as a measure of social worth. One way to ensure that a decision using the best interest standard is not inappropriately influenced by the surrogate’s own values is to determine the course of treatment that most reasonable persons would choose for themselves in similar circumstances.
Opinion 8.081 also dictates that in special circumstances involving incompetent patients, state laws should be consulted and may require court interventions: “When reasonable efforts have failed to uncover relevant documentation [such as a pertinent living will], physicians should consult state law. Physicians should be aware that under special circumstances (for example, reproductive decisions for individuals who are incompetent), state laws may specify court intervention.”

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Danielle Hahn Chaet, MSB, is a research associate for the American Medical Association Council on Ethical and Judicial Affairs in Chicago. Her work involves researching, developing, and disseminating ethics policy and analyzing current issues and opinions in bioethics. She obtained her master of science degree in bioethics, with a focus on clinical policy and clinical ethics consultation, from the joint program of Union Graduate College and the Icahn School of Medicine at Mount Sinai.

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Abstract
In this article, we discuss current perceptions of the model physician and how these perceptions conflict with stressful realities of training environments and contribute to the staggering rates of burnout and depression faced by medical students and residents. We suggest a multi-tiered interventional approach to address these problems, with innovations for individual trainees, programs, institutions, and the health care system. Finally, we discuss the medical community’s ethical obligations to ensure that it is appropriately and thoughtfully investing in the wellness of medicine’s next generations of practitioners.

As they develop educationally and clinically, medical students and residents are also cultivating their professional identities. This can be a nebulous process, as our model of an ideal physician is not easily defined. In fact, what it means to be a “good doctor” has been discussed for decades, with physicians debating how that should be defined, assessed, and taught [1]. Reviews of literature on professionalism in medicine have identified as many as 90 different attributes [2] and shown that there is no comprehensive, universally accepted definition of medical professionalism to date [3]. Despite these complexities, professional identity formation is considered an important aspect of medical training [4], with trainees forming influential ideals about how they should think, feel, and behave as physicians.

As relatively recent residency graduates, we (the authors) run a mental health clinic for medical students and residents at the University of Michigan, and we frequently hear the trainees speaking in the same language with which we were indoctrinated as trainees. Common across their stories seems to be a predominant core belief that one’s own pain and suffering, occurring in service to the art or science of medicine, should be quietly tolerated. One of us was recently speaking with a resident who shared that the mantra among his cohort was to “tough it out” and “power through” any physical or emotional suffering. We routinely hear phrases like this, coupled with the fear that to do anything else would be to risk being seen by peers and supervisors as weak, vulnerable, or flawed in some way [5–7].
A predominant assumption in medicine is that we should be supernaturally resilient [5-7]. Given the rigors of medical education, residency, and a career in medicine, our ability to navigate this journey successfully while remaining psychologically and physically resilient is an understandable source of pride. But in harboring this ideal and reinforcing it throughout training, do we create a culture in which physicians easily lose sight of the fact that we are also human beings subject to illness vulnerabilities, just like the patients we treat? Do the stressors of training and their psychological consequences negatively impact our ability to be “good” doctors?

**Stress, Burnout, and Depression**

Physician trainee mental health has been spotlighted recently in prominent newspapers and magazines [8-12] as well as in the academic literature [13-18], suggesting a growing interest in challenges that developing physicians face and the consequences of those challenges. In their influential systematic review on the topic, Dyrbye and colleagues found that medical students consistently demonstrate higher overall psychological distress relative to samples of both the general population and age-matched peers [19]. Moreover, a recent survey suggests that psychological distress increases during training itself, because compared to age-similar college graduates, matriculating medical students at six US medical schools began their medical education with lower rates of burnout (27.3 percent versus 37.3 percent) and depression (26.2 percent versus 42.4 percent) and higher quality of life scores after adjusting for age, sex, relationship status, and race/ethnicity [20]. Factors contributing to psychological distress include academic pressures [19, 21-22], financial burdens [19, 21-22], student mistreatment [19, 23], and developing professional cynicism [19, 24], to name a few. The negative impacts of this psychological distress are exacerbated during residency by long hours [25], overnight shifts [26], debt [27], dissatisfaction with lifestyle [28] and with job [29], and lack of autonomy [29]. Furthermore, there is little time to develop aspects of identity unrelated to medicine that could contribute to a solidly grounded sense of self [30], and the quality of relationships that might provide a secure base of social support often suffer [31].

Given these psychological challenges, it is not surprising that rates of burnout and depression are high among trainees; the largest multicenter study on resident burnout showed rates of 51.5 percent in a sample of 16,192 internal medicine residents in the 2008-2009 academic year [27]. Medical students and residents also have significantly higher rates of burnout and depressive symptoms than population control samples [13]. A meta-analysis on resident depression published in *JAMA* in December 2015 by Mata and colleagues revealed an overall prevalence of depression or depressive symptoms of 28.8 percent in 17,560 resident physicians—with similar rates across specialties, postgraduate year, and country of practice—and a 15.8 percent median increase in depressive symptoms within one year of beginning training in 4,255 resident physicians [14]. These findings suggest that residency training is fundamentally stressful and that
Residents pay a substantial price in terms of their mental health for enduring this stress. Furthermore, the literature has consistently shown a correlation between degree of burnout, distress, and fatigue and the frequency of perceived or self-reported medical errors [32-35], suggesting that it might not only be the physicians who pay the price, but their patients as well.

First in 2003 and then again in 2011, the Accreditation Council of Graduate Medical Education (ACGME) made efforts to implement duty-hour restrictions in order to foster a “humanistic environment” promoting “excellent and safe patient care” [36]. A longitudinal cohort study has shown that though these changes have led to a small but statistically significant reduction in work hours (from 67.0 to 64.3 hours on average), that reduction was not associated with statistically significant changes in sleep, depression, or well-being; moreover, there was an unexpected increase in self-reported medical errors [37]. In their recent narrative review on resident burnout, Dyrbye and Shanafelt argue that “work compression” (a concept previously described as the same workload and educational requirements being compressed into a shorter time frame [38]) is adding additional stress during the shorter hours such that the net effect of work hour restriction on resident mental health is zero [18]. Regardless of its cause, it would seem that resident burnout and depression cannot be solved solely by addressing work hours.

The Need for a Multifaceted Interventional Approach
In order to provide medical training that both prepares trainees to become skilled physicians and preserves their mental health in the process, we must implement innovative, evidence-based interventions aimed at individual trainees, medical schools and residency programs, health care institutions, and educational systems. Despite the alarmingly high rates of burnout and depression among medical trainees, they do not readily seek appropriate mental health treatment from qualified professionals due, in part, to concerns about confidentiality and stigma [39]. Understanding more fully the barriers to accessing care and finding solutions to overcome those barriers is essential. In our House Officer Mental Health Program at the University of Michigan, faculty psychiatrists see residents for a confidential initial evaluation that is not documented in their medical charts, offer onsite appointments at the hospital, and hope to soon add “after hours” appointments.

Since the stigma of seeking treatment persists, we also need academically rigorous research on reasonable alternatives to traditional, in-office psychiatric treatment. Finding creative and effective ways for trainees to readily and privately utilize multimodal technologies (such as telemental health), and grounding these approaches in good science, seems like a worthy investment. For example, a recent randomized clinical trial showed that a web-based cognitive behavioral therapy intervention for the prevention of suicide in medical interns was successful in reducing suicidal ideation [15]. However, the interventional literature is lacking in such gold-standard studies and more
are clearly needed. A 2014 review and meta-analysis of interventions to reduce anxiety, stress, and burnout in physicians initially identified 87 studies, but only 12 were methodologically sound enough to be included in the analysis [40]. The interventions studied did, however, show promise for cognitive, behavioral, and mindfulness-based interventions [40, 41].

Nonclinical interventions could also be useful. Mentorship and coaching programs addressing personal and professional development and peer-to-peer support systems, such as big/little sibling programs and “process” groups in which residents are encouraged to speak candidly about their shared experience, may also provide opportunities for therapeutic outreach and open communication. A recent randomized controlled trial of facilitated small-group intervention for physicians—with protected time to focus on mindfulness, reflection, and shared experience—demonstrated significant differences between the intervention and control arms in improvements in participants’ ratings of meaning and engagement at work but did not show reductions in depression [42], suggesting that small group interventions alone may not be sufficient. We could be missing a larger foundational issue associated with the nature of medical training by focusing our efforts on treatment of depression, anxiety, and burnout once they have developed rather than working to innovate our educational and training environments so that they would be less likely to cause these problems in the first place.

In fact, within the past decade attention has been paid to prevention through proactively improving wellness as opposed to reactively treating the mental health issues that arise during medical training [42-45] and to evaluating the impact of wellness programs. The American Medical Association (AMA) recently released a learning module intended to provide a framework for developing successful wellness programs; the organization also outlined several wellness models that have already been implemented at various institutions across the country [43]. These wellness programs could prove to be a valuable resource at medical school and graduate medical education levels. The Vanderbilt Medical School Wellness Program is the first published model of a comprehensive medical student wellness initiative [44], and though subsequent analysis of the impact of its programming has not, to our knowledge, yet been published, it did show high levels of participation and satisfaction [40]. Other physician wellness programs have shown reductions in physical and emotional exhaustion [42] as well as stress and anxiety [43]. Although preliminary data is promising, a systematic review of 13 studies on medical school stress management programs revealed that only one study was randomized and considered of very high quality [46]. Evaluating our interventions in an academically rigorous way to expand the evidence base will be a critical addition to the expanding body of literature on this topic.

Finally, research has also shown that institutions have greater influence than specialty on residents’ satisfaction with their learning environment and workload, suggesting that
attention to institutional culture will be critical in improving education and reducing burnout and psychiatric illness [47]. The ACGME is paying formal attention to the quality of training environments through its Clinical Learning Environment Review (CLER) program, which sets an expectation that programs provide education about and measurements of burnout annually [48]. It is important not only to track burnout, but also to address its underlying causes while offering effective interventions to combat it.

**Revisiting the “Good Doctor”: An Ethical Obligation**

Given what we now know about the negative mental health consequences of medical training, is it ethical for us to maintain the cultural status quo? Can we provide optimal care for our patients when one-third of our trainees are depressed [14] and half are burned out [27]? And given that it is fundamentally a healing art that we practice, is it ethical to ignore the suffering of our own? Our trainees are intelligent, enthusiastic people who begin their journey with lower rates of burnout and depression than age-matched college graduates [20] but are subjected to environmental stressors in training that foster a dramatic prevalence of depression, anxiety, and burnout [13, 14, 19]. If the nature of our training contributes to this decline in mental health, is it ethical to ignore it? The empirical evidence indicates that residency is fundamentally stressful and has negative health consequences for trainees; this demands efforts to fundamentally change the system, to promote wellness, reduce illness burden, and improve access to effective mental health treatments for our own. We must heal a broken system, each other, and ourselves in the process.

In medical schools and residency programs, we need to create a culture in which trainees are encouraged to take care of themselves, to recognize when they are struggling, and to reach out for support when needed. Our faculty leaders must do their part to destigmatize mental illness, promote wellness, and encourage trainees to seek help when needed. They should not shy away from talking about resident distress, depression, anxiety, and burnout, as these are realities that exist as a part of our current training environment [13, 14]. We would go a step further and argue that focusing solely on burnout without also discussing depression and suicide, the latter of which are real risks for trainees [14, 49–50], might reinforce stigma-driven beliefs that it might be acceptable for a trainee to be burned out, but not to have depression. We suggest here that an open dialogue about mental illness, appropriately named and discussed, should be an expectation for training programs. And, finally, we cannot simply react to these difficulties once they have arisen. We also need to proactively address the foundational stresses of medical training and promote wellness in trainees.

When we see trainees for treatment in our offices, we see bright, empathic, and dedicated men and women who are willing to acknowledge their own suffering and take action to ameliorate it. We applaud their introspection and courage and their willingness to swim against the predominant cultural stream of “power through” and “tough it out.”
The medical community has now shed light on the realities of the physician training experience, and we hope it will continue developing innovative ways to promote wellness, positive learning environments, and mental health awareness, and to reduce the burden of mental illness in physicians. We must change the way we define what it means to be a “good doctor” by acknowledging our humanity and our human vulnerabilities, and we must encourage medical students and residents to ally with us to become champions in these efforts, advocating for themselves and their futures in medicine.

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Kathryn Baker, MD, is a clinical instructor in the Department of Psychiatry at the
University of Michigan in Ann Arbor. She is also the director of the University of Michigan
Medical Student Mental Health and House Officer Mental Health programs.

Srijan Sen, MD, PhD, is an associate professor in the Department of Psychiatry and in the
Molecular and Behavioral Neuroscience Institute at the University of Michigan in Ann
Arbor. He is the principal investigator of the Intern Health Study.

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Abstract
Approximately 15 percent of women experience depression while pregnant or in the year following pregnancy. While antidepressants are usually effective and considered standard treatment for depression, concerns arise that what might be good for mom could be harmful for the baby. Medical evidence demonstrates that, on balance, treating mental illness with psychotropic medication along with talk therapy is in the best interest of both mother and baby; however, women may resist treatment because they overestimate the risks of medication and underestimate the risks of untreated mental illness. Clinicians can help address this perceived ethical dilemma and provide optimum care to their pregnant patients by collaborating with their patients on a treatment plan, informing them about the risks of untreated mental illness, and providing reassurance that selective serotonin reuptake inhibitors (SSRIs) and many other psychotropic medications are appropriate care even if a woman is pregnant or breastfeeding.

Treatment of depression and other mental illnesses with psychotropic medications during pregnancy can be confusing for both clinicians and pregnant women. The health and well-being of the woman must be considered, but so must that of the fetus. These considerations frequently create an ethical dilemma for a depressed pregnant woman: Should I take psychotropic medication while I’m pregnant?

Perinatal Depression
Perinatal depression occurs during pregnancy and up to 12 months after giving birth [1]. Risk factors include the following:

- A personal or family history of depression, anxiety, or postpartum depression
- Premenstrual dysphoric disorder (PMDD)
- Inadequate support in caring for the baby
- Financial stress
• Marital stress
• Complications in pregnancy, birth, or breastfeeding
• A major recent life event (e.g., loss, including job loss; moving to a new home)
• Being a mother of multiple children
• Being a mother of an infant in a neonatal intensive care unit (NICU)
• Being a mother who has gone through infertility treatments
• Thyroid imbalance
• Diabetes (type 1, type 2, or gestational) [2]

Generally, women of reproductive age experience major depression at twice the rate of men the same age [3, 4]. Major depression is the leading cause of disability for women in this age group [5], and antidepressants are one of the most common drugs prescribed to women of reproductive age [6]. While the myth persists that pregnancy is a time of joyful anticipation, the reality is that pregnancy is not protective for perinatal depression. In fact, 7-20 percent of pregnant women in economically developed countries experience clinical depression [7-9], and being low income, minority, young, or single only increases this risk [10, 11]. Although there are many approaches to treating depression during pregnancy, with varying levels of efficacy, antidepressants have been shown to reduce depressive symptoms and improve maternal function [12].

Should I Take Psychotropic Medication While I’m Pregnant?
Women with a history of depression have already faced the stigma of having a mental illness and might have internalized messages from clinicians, the media, and warning labels on medications that psychotropic medications and pregnancy are incompatible [13-17]. Pregnancy often motivates women to discontinue pharmacotherapy out of concern that the drugs will be harmful to the developing baby [18, 19]. Women without this history of depression, who screen positive for depression during prenatal care, might experience confusion, guilt, and shame over their feelings of sadness or anxiety—especially women facing an unplanned pregnancy—when messages from the social and cultural milieu suggest that pregnancy is a time when they should glow and be happy. These feelings, along with decreased concentration, might impair a woman’s ability to understand and recall information or think through the risks and benefits of treating depression with medication [20]. Indeed, pregnant women routinely overestimate the teratogenic risk of antidepressants [21, 22]. Moreover, women are socialized to believe that good mothers are willing to sacrifice their own well-being for the well-being of their children.
On the other hand, untreated perinatal depression can actually be more harmful than depression experienced at other times in a woman’s life [12, 23, 24]. Women with chronic mental illness who abruptly discontinue pharmacotherapy have a very high risk of relapse during pregnancy [25, 26]. For example, in one study, 68 percent of pregnant women who discontinued antidepressants during pregnancy suffered a relapse of their illness [25], and, in another study, 85 percent of study participants—pregnant women with a history of bipolar disorder who discontinued use of mood stabilizers—experienced a relapse of their illness during pregnancy [26]. Untreated perinatal depression creates additional risks for both mother and baby. Perinatal depression contributes to reduced use of prenatal care, self-neglect, substance abuse, and lower birth weight infants [12, 23, 24]. And suicide causes more maternal deaths than any other pregnancy-related complication [27].

If untreated perinatal depression creates risks for mother and baby, the question remains: Are antidepressants risky for developing fetuses? In light of an observational study that reported adverse neonatal outcomes associated with maternal antidepressant use [28], the US Food and Drug Administration (FDA) released a public health advisory warning in 2006 about the risk of perinatal complications with antidepressants [29]. Although the warning did not explicitly advise women to avoid or discontinue use of antidepressants during pregnancy, it received widespread media coverage [30] and had a chilling effect on antidepressant use among pregnant women [31]. Follow-up studies called into question the findings that led the FDA to issue the warning [12, 24, 32, 33]; in 2011, the FDA announced that since research findings were conflicting, the warning would be removed from selective serotonin reuptake inhibitor (SSRI) labeling [34]. Two decades of experience have demonstrated that SSRIs are not a major teratogen like thalidomide or even cigarette smoking. Reviews of observational studies have argued that observed risks to the fetus may be due to detection bias and confounding factors including maternal depression; in all cases, the absolute risk is very small [23, 35]. Clinicians should keep in mind that the baseline rate of birth defects is 3 percent, with no known cause [36].

**Undertreatment of Perinatal Depression**

Clinicians also might be confused about how to diagnose and treat maternal mental illness. A 2011 literature review found that though obstetricians and gynecologists view mental health issues as important, they are not confident in their abilities to diagnose these conditions and are concerned about the adequacy of their training [37]. Recent research has found that clinicians might actually be limiting pregnant women’s access to antidepressants by advising them to discontinue medication or even refusing to renew prescriptions once a woman is pregnant [12, 38, 39], and a nationwide survey found that only 12 percent of depressed pregnant women had accessed mental health care in the past 12 months [40].
Providing Care for Pregnant Women with Depression

ACOG guidelines. The American College of Obstetricians and Gynecologists (ACOG) has developed empirically based guidelines for how to diagnose and treat perinatal depression [23]. ACOG recommends that pregnant women with a history of major depressive disorder who are being maintained on an antidepressant should be encouraged to continue medication, and women who choose to discontinue medication ought to taper off and be carefully monitored [23]. Because 1 in 7 pregnant women experience perinatal depression, ACOG further recommends that “clinicians screen patients at least once during the perinatal period for depression and anxiety symptoms ... screening must be coupled with appropriate follow-up and treatment when indicated [and] clinical staff ... should be prepared to initiate medical therapy, refer patients to appropriate behavioral health resources when indicated, or both” [1]. Additionally, “systems should be in place to ensure follow-up for diagnosis and treatment” [1]. Consistent with these guidelines, researchers have found that simply screening women for depression is not sufficient. Having resources available for women, training for clinicians, onsite assessment, and access to mental health consultation for clinicians treating women in the perinatal period can dramatically improve pregnant women’s access to mental health care [41].

Treatment cessation. Women of reproductive age should be reminded not to discontinue medication abruptly [42], as it can lead to side effects and relapse of symptoms—if they become pregnant. Ideally, women should be advised to schedule an appointment before they become pregnant to work out a treatment plan and coordinate care with whoever will be providing prenatal care.

Screening. Depression screening is now recommended for all pregnant women. The Edinburgh Postnatal Depression Scale is recommended by ACOG for perinatal depression screening and can be completed by the patient in only a few minutes [1]. Depressed women must be further screened for possible bipolar disorder before prescribing an antidepressant because an antidepressant can trigger a manic episode if the woman is actually bipolar [43]. Once bipolar disorder is ruled out, there are guides to help a clinician select appropriate medication, depending on a patient’s level of depression [43].

Treatment decisions. Clinicians need to give as much clinical and ethical consideration to the risks of untreated perinatal depression as they do to the risks of psychotropic medication [44]. The Massachusetts Child Psychiatry Project (MCPAP) for Moms has a discussion guide to help clinicians review the risks and benefits of treatment versus no treatment for depression [43]. To help their patients make decisions, clinicians need to be able to explain differences between relative risk and absolute risk. What sounds like a high relative risk might be clinically insignificant. For example, a study may find that women who take a particular medication during pregnancy are 4 times more likely to have a child with a birth defect than women who do not take the drug; however, this may
mean that in a single study there were 4 cases of the birth defect among 4,000 women who took the medication. This translates to an absolute risk of 0.1 percent or one case in 1,000 among women who took the medication compared to 0.025 percent or 1 in 4,000 among women who did not. Finally, women might be comforted to know that millions of women have taken SSRIs during pregnancy and have had healthy babies.

Although shared decision making for treatment of depression is the ideal [45], it is important to realize that women’s decision-making ability can be compromised by their depression and that they could have been misled—perhaps by media—about risks of antidepressants. In this case, directive counseling can be in the patient’s best interest [46]. It builds on a patient’s own values and impulse to do what is in the best interest of her baby. Hearing a clinician say things like, “It’s OK to take your symptoms seriously,” “perinatal depression is extremely common,” and “when you take care of yourself, you are also taking care of your baby,” can validate for a woman that continuing or beginning treatment for depression is a sound decision her clinician supports.

Support Services
Many state and local public health departments as well as academic medical centers and websites are developing resources for perinatal mental health. MCPAP for Moms is a program in Massachusetts that has developed many resources for clinicians to help them manage mental illness in pregnancy. It even has a hotline for clinicians who have specific questions [43]. In a conversation with Nancy Byatt, director of MCPAP for Moms, Byatt said, “this model has been copied by more than 30 states” (personal communication, March 8, 2016). Additionally, academic medical centers are establishing maternal mental health centers that can help not only with the clinical management of specialized cases but also with developing resources and educational programs for community-based clinicians. There are also web-based resources available for clinicians and pregnant and breastfeeding women. At MotherToBaby.org [47], for example, clinicians and concerned women can look up drugs by name and get an up-to-date, evidence-based fact sheet on what is known about the risks of their use during pregnancy and lactation. If a drug is not part of its existing database, MotherToBaby.org provides access to a teratology expert, who is just a phone call away. (Clinicians in Canada might wish to use Motherisk.org [48]).

In addition, a growing number of organizations support the needs of pregnant women, women who have experienced pregnancy loss, and new mothers. Postpartum Support International (PSI) [49] has chapters in most states that provide support groups and, in some cases, hotlines. PSI has a support group through Facebook, special phone applications, and other online media so that women might feel less alone in their struggles to manage their illness and be good mothers. Local health care organizations also sometimes run support groups for women experiencing pregnancy loss and for pregnant or postpartum women struggling with depression.
Conclusion
Because 1 in 7 women will experience depression during the perinatal period [39], clinicians must be prepared to engage in conversations with their patients concerning the management of depression during pregnancy. As discussed, many women with depression can feel conflicted about using medication to treat their depression; therefore, clinicians have obligations to dispel myths about risks of antidepressants and discuss the risks of untreated depression. For women who require treatment for other mental illnesses for which risks and benefits of treatment options are not as established as for depression, longer discussions might be required, along with referrals to perinatal psychiatrists. Fact-based clinical recommendations, good communication that’s responsive to women’s needs, and a shared decision-making model for developing treatment plans can help motivate better clinical and ethical outcomes for both mothers and their babies.

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Andrea L. Kalfoglou, PhD, is an associate professor in the Department of Sociology and Anthropology at the University of Maryland Baltimore County in Baltimore. She is a graduate of the University of Virginia and received her doctorate from the Johns Hopkins University Bloomberg School of Public Health. She conducts empirical research and also writes about reproductive ethics; her current projects explore the barriers to and facilitators of mental health care for pregnant women and the integration of pre-conception counseling into primary care.

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Abstract
Schizophrenia and other psychosis spectrum disorders do not develop de novo but emerge from prodromal stages that are named and operationalized differently depending on the research group or consortium and its theoretical orientation. As a result, a complex lexicon now exists for characterizing individuals’ risk of subclinical symptoms converting to psychosis. Researchers aim to develop instruments and methods to identify people at risk of psychosis, better understand their risks, and offer preventative treatments to arrest conversion to psychosis; ethical and policy questions loom large with each of these projects. In this paper, we canvass the lexical complexities of the at-risk status for psychosis and then consider ethical and policy challenges that researchers and clinicians face in disclosing, preventing, and treating psychosis risk.

The Costs of Psychosis
Schizophrenia and schizoaffective disorder, among other psychotic disorders, can be devastating illnesses and pose serious public health challenges. Typically developing in young people between the ages of 18 and 25, schizophrenia affects about 1 percent of the population. Of patients with schizophrenia, 5 to 6 percent die from suicide, with the majority of deaths occurring in patients between the ages of 18 to 34 [1]. There are also significant financial costs of treating and supporting patients with schizophrenia—estimated to be over $60 billion annually in the US—including costs associated with comorbid substance use disorders found in half the affected population, a proportion that is well above that of the general population [2-5]. Efforts to reduce these human and financial costs focus on early detection and intervention.

The idea that psychotic illness does not emerge de novo from an otherwise healthy brain—and therefore that prevention might be possible—is long-standing [6, 7]. Kraepelin and Bleuler recognized premorbid cognitive impairment and “characteristic peculiarities in the manner of their being” of persons with schizophrenia [3]. The promise of early detection and prevention originates from clinical observations and retrospective studies of attenuated psychotic symptoms in patients who later developed psychotic illnesses [8, 9]. Retrospective and prospective investigations into the clinical,
physiological, and genetic factors leading to psychosis reveal a high-risk prodromal stage [10-12].

**Psychosis Risk: A Complex Lexicon**

Yung et al. identified three prodromal syndromes typically associated with psychotic illness: brief frank psychosis, attenuated psychotic symptoms, and functional decline with genetic risk [13, 14]. Researchers now describe the state referred to by these alternate terms as “high risk,” “clinical high risk,” “ultra-high risk,” or “at-risk mental state (ARMS).” Some have advocated for a “psychosis risk syndrome” or “attenuated psychosis syndrome (APS)” as the diagnostic penumbra under which high-risk patients should be classified for research purposes [15]. Although APS was nearly codified within the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)* [16], it was instead included in the appendix devoted to conditions for further study, due in large part to concerns about the limitations of current evidence and the broader implications of labeling persons in a putative prodromal phase [17], which we discuss. Others have advocated making “psychosis spectrum disorder” part of *DSM-5*'s research criteria [18]. The term “psychosis spectrum,” which we prefer, is a broader construct that does not require recent symptom onset or significant impairment and includes negative symptoms not necessarily captured in other constructs [19].

This conceptual and lexical complexity is a result of decades of independent research consortia working across three regions (Oceana, Europe, and North America) [20]. We believe that prevention will ultimately require clarifying and harmonizing the many theories, definitions, and assays used to detect emerging psychotic symptoms, recognizing that psychiatric categories are fluid and spectral, not static and discrete.

**Detecting Psychosis Risk**

There are at least 22 instruments used to detect psychosis risk that can be grouped into three categories [21]. The first category aims to assess attenuated psychotic symptoms and highlight clear precursors of psychosis. The second category tracks basic symptoms (i.e., subtle, subjective deficits) and first phases of subjective alterations in experiences that occur early in the development of psychosis. The third category aims to incorporate features of both attenuated symptoms and early subjective experiences; the comprehensive assessment of at-risk mental states (CAARMS) is one such instrument. Instruments also vary in how they measure and categorize genetic risk and how they categorize positive symptoms (such as visual or auditory hallucinations, disorganized speech, and delusions), timing of onset, persistence of symptoms, and self-report of disturbances [22].

Each instrument is constructed upon different concepts of the psychosis spectrum and employed in major research centers and research networks worldwide [23]. Because they aim to measure different things in different ways, these instruments’ results
inevitably will vary. This variation might influence how conversion risk is ultimately understood by and described to research participants and patients [24]. There are obvious advantages to researchers and clinicians in having access to a diverse portfolio of screening tools. Comprehensive data sets can be compiled that reveal composite risk factors for an individual. And subtleties can be drawn from analysis of comprehensive data sets that would otherwise be missed by instruments within a single category.

Talking About “It”—Whatever “It” Is
The diversity of assessment methods contributes to conceptual and lexical complexity, with clinical implications for individuals and their families. For example, any attenuated symptoms detected by an instrument designed largely to detect such symptoms might be interpreted as an inevitable cascade of events leading to the full illness, triggering a physician’s premature prescription or administration of medication.

Conversely, when instruments are used to detect subtle symptoms, researchers might be wary of disclosing results because of low conversion rates. We see this now: across the many research and clinical centers where psychosis risk research is happening, there is no stated consensus on how best to disclose and discuss the findings of screening instruments [25].

Disclosure methods are ethically important. In one study, healthy research participants anticipated the negative impact of hypothetical psychosis risk to be similar to the hypothetical risk of cancer [26]. A level of distress related to psychosis risk is unavoidable. However, poorly designed or overly pessimistic communication strategies could cause patients and families additional unnecessary distress, anxiety, stigmatization, and feelings of helplessness. These iatrogenic stressors might, in turn, exacerbate the impact of psychotic symptoms. In contrast, overly hopeful messaging could leave patients with the incorrect impression that they are at little-to-no risk of conversion to a psychotic disorder. Given the uncertainty and risks related to psychotic spectrum diagnoses, ethicists have proposed a hybrid disclosure model that balances full and partial disclosure, with caveats [25]. Deciding on the appropriate amount of information to present and how to present that information suitably remains a matter of an individual physician’s judgment and experience, as randomized controlled trials on physicians’ communication strategies have yet to be conducted [27].

Questions related to autonomy and free will also emerge: if early detection of attenuated psychosis becomes a bona fide diagnosis, what expectations should we hold for people with this diagnosis [28]? Early diagnosis also has implications for both public and self-stigma [29], discussed in more detail below.

Implications of the Psychosis Spectrum for Stigma
The debate surrounding the inclusion of attenuated psychosis syndrome in DSM-5 highlights the need for research into the ways risk assessments can cause or contribute
One concern about communicating psychosis risk is that it could lead to stigma and adversely affect children and adolescents for their entire lives, whether they eventually develop schizophrenia or not [30]. But it is unclear whether stigma experiences created by risk-based labels are comparable to those of their corresponding illnesses. In other words, do persons who are at risk for psychosis experience the same kinds of social distancing, marginalization, and discrimination as those with schizophrenia? This is an unanswered empirical question that could be used to stimulate subsequent research.

Intuitively, it seems important to appreciate differences between persons’ experience of stigma for risk-based diagnoses and their experience of stigma for a schizophrenia diagnosis. In the former case, public stigma might be less of a concern, because these people typically have yet to exhibit dramatic symptoms that would increase public discomfort. On the other hand, people assigned a risk-based label might have heightened insight into their health risks and experience self-stigma. A recent study by Yang and colleagues seems to bear this out [31]. They demonstrated that the clinical high-risk label is a significant source of stigma. And, as this study suggests, some features of “symptom-based stigma”—for example, heightened shame and discrimination—appear to be more distressing than the stigma experienced by being labeled with a mental illness.

Stigma and its effects can reverberate through the at-risk person’s social network. The impact on families is multifaceted. Parents and siblings will need to become well educated about the distinction between at-risk versus disease states. Parents should be careful not to treat their at-risk child as having a psychotic disorder. One worry is that parental confusion or anxiety could exacerbate sub-psychosis symptoms and lead to greater social distancing, diminishing their child’s quality of life overall. Although parents might want to rethink priorities, expectations, and adjust their child’s plans (e.g., encouraging their child to attend college nearby instead of across the country), they will also likely be challenged to balance protective measures against opportunities for their child’s personal growth [32]. Deciding on a reasonable balance will be an individual clinical or family decision and will be complicated by public misunderstandings and stigma. These dynamics require additional research, although clinicians should stand ready to assist families with these challenging choices.

**Public Health and Policy Ramifications of Psychosis Spectrum Disorders**

Primary prevention of psychosis spectrum disorders based on a theory of gene-environment interplay will have several aims [33]. For example, to decrease the incidence of psychosis, public health interventions aimed at reducing adverse childhood experiences, exposure to environmental toxins, and improvement of prenatal health could be deployed. Tertiary prevention aims to cure or alleviate the severity of schizophrenia; efforts toward this end have been long underway.
Strategies have also been proposed to detect, reduce, or arrest emerging symptoms at the secondary level of prevention, in which schizophrenia is viewed as a neurodevelopmental disorder [6, 25]. For example, by providing educational resources and psychometric instruments to primary care providers, broader public health strategies will aim to enhance overall wellness. The ethical controversies at this level are manifold, resulting in part from the fact that, at present, prediction batteries have considerable false positive rates. A further complication stems from evidence that the at-risk or psychosis spectrum state can itself be associated with functional impairment, comorbid psychopathology, and distress, suggesting that it can be an appropriate intervention target, regardless of eventual conversion to a psychotic disorder [34].

A first important ethical question considers risks and benefits associated with initiating an active intervention—such as psychoeducation, cognitive behavioral therapy, or stress management strategies—or a “wait-and-watch” approach for an individual patient [35]. A second question is whether a patient with elevated risk of conversion to psychosis should be treated with antipsychotic medications. Given the risks of antipsychotic drugs—such as weight gain, diabetes, and adverse cognitive effects on the developing brain—research will be necessary to gain certainty about the probability of conversion to schizophrenia in order to justify the preventative use of such medications [36]. As antipsychotic medications are marketed and used more and more for off-label purposes, clinicians might become increasingly willing to consider prophylactic use of antipsychotics in at-risk patients [37].

Monitoring patients with psychosis spectrum symptoms might be accomplished by any number of methods. Self- and family-monitoring and regular check-ins with primary care clinicians or psychiatrists should be recommended and encouraged. New automated hovering devices and mobile device applications offer means for self-monitoring, medication compliance, and interaction with clinicians without face-to-face meetings [38]. Ethical issues pertaining to patient privacy and concerns about coercion can arise with these technologies, however. Of course, in this population—a group in which some individuals might have a heightened predisposition to paranoid ideation and sensitivity to surveillance—automated hovering and tracking methods should be used with particular care to ensure they do not trigger or exacerbate symptoms.

Conclusion
At-risk states along the psychosis spectrum are not clearly definable disease entities like a microbe or genetic lesion that causes illness. On the contrary, they exist only insofar as the precision of our diagnostic technology and our prognostic confidence increases. Therefore, at-risk states should be understood as pragmatic constructs that will necessarily be refined and reconceived as new evidence is revealed.
In ways similar to the *DSM-5* revision process, it will be important for researchers, clinicians, and other stakeholders—including mental health patients and their advocates—to routinely revisit, refine, and revalidate points along the psychosis spectrum. Inclusive and democratic deliberative processes should be used to ensure that categories reflect both scientific evidence and shared values and priorities of mental health clinicians and patients [39]. These processes could include public meetings and web-based educational materials, conferencing, and open commenting periods. The National Institute of Mental Health (NIMH), for example, seems like the appropriate public institution to lead and facilitate such an important endeavor.

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symptoms: predictive validity, interrater reliability, and training to reliability. 


**Dominic A. Sisti, PhD**, is director of the Scattergood Program for Applied Ethics of Behavioral Health Care and an assistant professor of medical ethics and psychiatry in the Perelman School of Medicine at the University of Pennsylvania in Philadelphia.

**Monica E. Calkins, PhD**, is an associate professor of psychology and the director of clinical research assessment in the Department of Psychiatry, Neuropsychiatry Section, at the Perelman School of Medicine at the University of Pennsylvania in Philadelphia.

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**Related in the AMA Journal of Ethics**

*Diagnosing and Treating Schizophrenia*, January 2009

*Ethical and Epidemiological Dimensions of Labeling Psychosis Risk*, June 2016
**Abstract**

The past two decades have marked an increase in research on the prodromal stages of schizophrenia that precede a first episode of psychosis. Criteria for a clinical high risk (CHR) state for psychosis have been validated and included in the *DSM-5* as the attenuated psychosis syndrome and as requiring further study. This was hotly debated, given the concern of stigmatizing young people who would receive this psychosis risk label. In this article, I review ethical issues related to the psychosis risk label, including the potential harm of stigma and paternalism if risk labels are withheld in the context of the observed low predictive power of the psychosis risk designation. I review data that supports that the psychosis risk label need not be harmful, and could even confer benefit, and set out strategies for reducing stigma through individualized risk assessment and public health education.

**Introduction**

Schizophrenia is a neurodevelopmental disorder with antecedents in childhood and adolescence. Eighty percent of all persons with schizophrenia have had a prodromal period preceding their first episode of psychosis, which has been estimated to last from months to years [1]. This prodromal period is characterized by functional decline; decreased motivation; nonspecific symptoms such as anxiety, dysthymia, and poor concentration; and the *forme fruste* of psychosis, e.g., attenuated or subthreshold psychotic symptoms [2]. These subthreshold psychotic symptoms include overvalued odd ideas and suspiciousness (subthreshold delusions), perceptual disturbances (subthreshold hallucinations), and subtle disturbances in speech and language (subthreshold thought disorder). What distinguishes psychotic symptoms as subthreshold is that insight and reality testing are retained.

This putative prodromal period has formed the basis for early identification of and preventative interventions for schizophrenia and related psychotic disorders. Young people who have these subthreshold psychotic symptoms and who are help-seeking have been identified as at ultra-high risk or clinical high risk (CHR) for psychosis, labels that have been employed in this field of “prodromal” schizophrenia research for the past 15 to 20 years [3]. The subthreshold psychotic symptoms must have begun or worsened
for the patient in the year prior to having been identified as CHR and cannot be accounted for by another psychiatric disorder, criteria adopted in the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders (DSM)* [4]. Among teens and young adults who meet these CHR criteria, roughly a third will develop psychosis in the ensuing one to three years [5-7]. Although this positive predictive value (PPV) is more than tenfold the prevalence of psychosis onset among young people in the general population [8], CHR still yields a high “false positive” rate (i.e., diagnostic instruments have high sensitivity but low specificity) [9], such that nearly two-thirds of those with CHR will not develop psychosis within three years [6, 7]. The CHR designation has fairly good validity and reliability [10], meaning that the psychosis risk syndrome can be differentiated from the norm and from psychosis itself, and that different clinicians tend to reach the same conclusion about whether the risk syndrome is present or not. But beyond the aforementioned subthreshold psychotic symptoms, with measures of auditory processing being among the most replicated of potential risk biomarkers thus far [11, 12], no biological assay is available yet for predicting psychosis onset among persons with CHR. Moreover, there is no established evidence base of treatment yet for CHR syndrome: antipsychotics lead to significant side effects, such as weight gain, although psychological treatments such as cognitive behavioral therapy (CBT) might have efficacy [13].

In 2011, it was proposed that the constellation of symptoms consistent with increased psychosis risk be considered for inclusion in the *DSM*-5 as attenuated psychosis syndrome [14]. This proposal was hotly debated among investigators [4, 15, 16] in large part because of the concern about stigmatizing young people with the label of “psychosis risk” and subsequent risks of discrimination [4, 17]. Based on concerns about stigma (and unnecessary exposure to antipsychotics), especially in the context of a high false positive rate, the syndrome was placed in *DSM*-5’s appendix as requiring further study [4]. In this paper, I briefly review the ethical issues that were raised at the time [17], when no empirical data were available yet on the actual stigma perceived by the young people who themselves have subthreshold psychotic symptoms, and who, by virtue of such symptoms, receive a label of “psychosis risk.” I then present the data on self-stigma related to CHR that have been reported within the past five years and set out a proposal for reducing potential harm from labeling.

**Ethical Concerns**

**Stigma (threat to nonmaleficence).** In 2011, when attenuated psychosis syndrome was proposed for inclusion in the *DSM*-5, there was a scarcity of research on the stigma associated with CHR syndrome symptoms and labeling. Many psychiatrists and family advocacy organizations were concerned that the stigma of schizophrenia—with its associations of otherness, dangerousness, and hopelessness [18, 19]—would attach itself also to the label of psychosis risk [17]. Potential harmful consequences for young people could include internalized stigma (youths see themselves as bad, defective, or unworthy); identity engulfment (youths see illness as defining who they are, rather than
as something they have); shame (the label is kept secret and concealed); and, finally, discrimination from others, expressed as devaluation or unfair treatment [20]. Clinicians and researchers were concerned that the label of psychosis risk could threaten a young person’s sense of self (by incurring subsequent identity labeling, such as fragile, damaged, sick, or crazy) and curtail his or her aspirations in terms of education, employment, or romantic attachments [4]. Family members might not encourage healthy risk-taking necessary for growth and achievement, fearing that stress could trigger psychosis or, worse, that risk-taking is a doomed enterprise in the face of impending major mental illness [4]. Schools might become wary of students with the psychosis risk label, as might peers [4]. Even if clinicians and researchers maintained confidentiality, young people and their families might disclose the label—which could be easily misperceived as a label of actual psychosis—to others in their community [4]. And if psychosis risk syndrome treatment was reimbursable through insurance, then a young person could be labeled with a pre-existing condition that influences insurability and employability [4], a concern that has since been reduced significantly with the passing of health care reform legislation.

**Paternalism (threat to autonomy).** Whether a young person who receives a diagnosis of psychosis risk ultimately develops psychosis or not, all young people with attenuated psychotic symptoms who seek help are primarily doing so from a sense of distress and require our attention [16]. However, their distress often is not focused on their subthreshold psychotic symptoms but instead on trouble with concentration, loneliness, anxiety, fear, or lack of motivation, among other problems [21]. One approach, then, has been to consider limiting information given to patients and families and to avoid mentioning psychosis or schizophrenia risk in an effort to avoid “labeling” and its possible harms. However, this approach raises concerns about paternalism. Across medicine, physicians tend not to censor or greatly filter information they provide to patients and their families, even if the goal is to protect them, as this behavior is not consistent with the ethical principle of patient autonomy and patients’ right to informed consent. It has also long been argued that avoidance of words like psychosis and schizophrenia actually reifies their stigmatizing effects by promoting secrecy and shame [22]. Generally, such linguistic avoidance is not effective, as smart young people tend to look up their symptoms online; they also might look up a clinical research program they are considering attending, or even the publications and curricula vitae of researchers they meet. Then, if young people obtain from other sources information that their clinicians had withheld from them, they might not trust their clinicians. Also, if someone—a teacher, physician, family member—has referred young people with the psychosis risk label to a program for evaluation and treatment of attenuated psychotic symptoms, these young people might already think that they are at risk for psychosis.

**Epidemiological Questions and Prognostic Uncertainty**
The potential harmful effects of stigma are especially worrisome, considering the high false positive rate of the psychosis risk designation, which is nearly two-thirds after
three years, according to a meta-analysis [7]. Moreover, in one study [23], the false positive rate was estimated to be as high as 84 percent after two years among those referred for intervention, which means that more than 8 of 10 young people who were referred for mental health or community intervention after being given this label turned out not to have been at real risk for psychosis at all, at least in the short term; this high false positive rate has been interpreted as untenable from an ethical perspective by researchers in the field [4]. The high false positive rate results from a number of factors: (1) not everyone at risk develops psychosis; (2) clinicians have high rates of misdiagnosis of risk (only about half of community clinicians’ diagnoses are confirmable by experts [23]); and (3) the base rate of psychosis risk in the general population is low—only 1-3 percent.

It is unclear how many of these false positives could in fact be false positives—persons with the psychosis risk label who would have eventually developed psychosis had they not received treatment that prevented its onset. Although there is not a sizable evidence base for treatment of attenuated psychosis syndrome yet, data support that both antipsychotic medications and psychological treatments might be efficacious in preventing psychosis onset [13]. One could also argue about the nature and scope of the benefit that an early risk label has on the “true positives”—those who do in fact develop psychosis, sometimes even despite preventative treatment [24]. What, for example, is the benefit of learning you are at risk for something that might not have been preventable?

The Role of Data in Determining Harm

Some earlier studies that my colleagues and I conducted suggested that stigma associated with a label of psychosis risk might be less than that associated with the label of schizophrenia. For instance, we found that family members of young people identified as at risk for psychosis had low “associative” family stigma; they reported that at-risk youths should vote and work, and they denied any sense of shame about their family members or need to conceal their symptoms [25]. Further, we found that, among college students, public stigma elicited by a clinical vignette describing attenuated psychotic symptoms was similar regardless of whether the diagnosis was psychosis risk or schizophrenia, unless the psychosis risk label also had a few brief informational sentences attached to it stating that the real risk of psychosis was 35 percent in 2.5 years, in which case public stigma, expressed as a desire for social distance, was greatly reduced [26].

It is only in the past few years that data have become available on stigma experienced by young persons with attenuated psychotic symptoms. More specifically, studies of young people with attenuated psychotic symptoms, or with a history of hypomanic symptoms (consistent with an increased risk for bipolar disorder), have focused on the relationship between self-labeling as mentally ill and stigma stress, defined as perceived harm of
mental health stigma in excess of perceived resources to cope with it. These studies found that, after adjusting for age, gender, symptoms, and functioning, self-labeling as mentally ill was associated with greater stigma stress and reduced well-being [27, 28], more suicidal ideation (mediated by social isolation) [29], and higher rates of developing schizophrenia [30], although self-labeling also was associated with more positive attitudes toward treatment [31]. Thus, these studies suggest that self-labeling as mentally ill is harmful overall for youths at risk for mental illness, although they do not provide any data as to the specific effects of clinicians’ use of diagnostic labels.

Although these studies on self-labeling are informative and advance our understanding of the harms of self-labeling, questions remain. It is plausible that self-labeling and its attendant stigma stress derive from the very symptoms that place persons at risk for psychosis rather than from an external label of psychosis risk given by a clinician or researcher. For example, “perceived negative attitude of others”—which is correlated with symptoms such as ideas of reference and suspiciousness [32]—like stigma stress, predicts psychosis onset [33]. But “perceived negative attitude of others” might have some basis in reality; others might be responding negatively or in a stigmatizing way to symptomatic behavior or speech. Also, this sort of self- and other-labeling as mentally ill can occur in a community long before persons seek help or receive any official labels of psychosis risk, which can take years, if in fact help is sought at all. Analysis of the Collaborative Psychiatric Epidemiology Surveys found that more than two-thirds of persons with psychotic-like experiences do not seek help [34]. In fact, in a large Chinese study of 524 persons who had no lifetime history of psychiatric disorder, perceived public stigma was associated with the degree of psychotic-like experiences, specifically delusion proneness [35]. Thus, stigma was experienced by people with psychotic-like experiences who had never met a psychiatrist, much less been given a label by one.

In an effort to study the degree to which "official" labels of psychosis risk might be harmful and stigmatizing, our group specifically queried at-risk youths in New York about stigma associated with coming to our psychosis risk program, while accounting for stigma related to symptoms [36]. Upon enrollment in our program, youths were informed that they met criteria for being at risk for psychosis and that psychosis was like the experiences and symptoms that they already had, only more severe. They were told that about two-thirds of the people in the program would not develop psychosis, and that if they were in fact among the third who did, they would immediately receive treatment for it. To study stigma, we used the "labeling processes" heuristic developed by the sociologist Bruce Link, which describes how patients, upon receiving a psychiatric diagnosis, begin to identify with and internalize negative stereotypes associated with mental illness, in particular schizophrenia, such that they feel discouraged and ashamed and withdraw from others [20]. Using Link’s measures adapted for an at-risk group, we assessed participants’ awareness of and agreement with stereotypes related to the psychosis risk label we conferred, controlling for symptom severity; and we also queried
participants about negative emotions (e.g., shame) and positive emotions (e.g., relief) they experienced with respect to both the psychosis risk label and the symptoms that they had [36]. Overall, we found that these youths were aware of stereotypes associated with “emotional problems” (such as impaired, dangerous, less trustworthy), even more so than youths with nonpsychotic mental health disorders. However, they largely did not agree with or endorse these stereotypes. Participants also reported significantly more shame and discrimination related to their symptoms rather than to the label itself, which instead evoked more positive emotions, such as feeling understood, hopeful, and relieved [36].

Altogether, these data support that the psychosis risk label need not be harmful and might even confer considerable benefit, as it offers an explanatory framework for symptoms experienced that could then be treated, a quantification of risk for psychosis, and potential strategies for minimizing risk.

**Future Directions**

Efforts at early intervention in schizophrenia are based on the premise that identification of youths at risk for psychosis will facilitate earlier and better intervention that addresses current morbidity and delays or even prevents psychosis and its consequent functional disability. A number of interventions hold promise, in particular psychological interventions and pharmacological approaches that, unlike antipsychotics, target abnormal glutamatergic function [37] or oxidative stress [38], as these may be more relevant to the pathophysiology of the early stages of schizophrenia than the abnormal dopaminergic function that underlies later full-blown psychosis. In the coming years, individualized risk assessment for psychosis might follow the lead of personalized medicine, such that risk could be stratified by severity or quantified, especially with the emergence of biomarkers and greater understanding of underlying neural mechanisms. This development should lead to both a reduction in the false positive rate and the development of more effective intervention strategies.

But the emotional risks of stigma and discrimination associated with the label of psychosis risk are real, especially if the label occurs without information about what it means. Autonomy—including the right to be informed of one’s diagnosis—is a relevant ethical concept, but so is nonmaleficence, specifically the Hippocratic Oath and the promise “to do no harm” (i.e., *primum non nocere*). In a thoughtful review of these complexities in disclosing psychosis risk, Mittal and colleagues [39] argue that the conveying of diagnostic or prognostic labeling information should be tailored to each individual, particularly when working with minors. They also argue that legal standards and the promotion of autonomy support full disclosure of at-risk status to adults and parents of minors in order to facilitate informed treatment decisions. The provision of information to minors themselves, however, must take into account age and developmental sensitivities, such as social context, identity formation, cognitive capacity,
and comorbidities [24]. Moreover, clinicians must remain cognizant that the interests of the minor (and his or her feelings) might not be entirely isomorphic to those of his parents (which shape how he behaves) [24]. Overall, it is important to take time to speak with young people and their families, provide clear and easy-to-understand information, solicit and answer questions, and to do these things on an ongoing basis, not as a one-time discussion [39]. It is also important to recognize the personal strengths each person has and to promote hope and recovery.

Finally, the potential stigma of a psychosis risk label can be addressed at the structural or public health level. This strategy has worked in Australia, where ultra-high risk clinical research programs were first located in community centers instead of hospitals or universities [22] and then embedded entirely in nationwide strategies to promote teen mental health and well-being support [40]. Furthermore, being considered as at risk for psychosis is not inherently pejorative, and stigma can be tackled head on by those who have attenuated psychotic experiences. For example, there are now movements afoot, such as Intervoice, that conceptualize hearing voices as not necessarily pathological but as a variant, such as being left-handed [41].

References


Cheryl M. Corcoran, MD, is on the research faculty in the Department of Psychiatry at the New York State Psychiatric Institute (NYSPI) at Columbia University Medical Center in New York City. Dr. Corcoran founded the Center of Prevention and Evaluation at NYSPI, a setting for a longitudinal cohort study of youths at clinical high risk for psychosis. She has authored more than 50 manuscripts on the schizophrenia prodrome encompassing natural language and sensory processing, social cognition, imaging and EEG studies, the relevance of cannabis and stress exposures, nosology, and stigma.

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Recovery and Service: On Being a Physician with Mental Illness
Mark Vonnegut, MD

Abstract
For physicians with psychiatric illness, especially when newly diagnosed, one concern can be what effect patients’ knowledge of their physician’s diagnosis can have on their relationship. As a pediatrician with bipolar disease, about which many patients and the community are well aware, I’ve found that patients are much more concerned with the quality of care they receive than with whatever psychiatric problems their physician might have. I offer this narrative in hopes that it will allay other physicians’ fears of “disclosure.”

I started writing about mental illness before I thought about becoming a doctor. My original—now 45-year-old—diagnosis was schizophrenia. Having been profoundly paranoid and suffered three psychotic breaks in quick succession, I received a guarded prognosis. But I did well and began writing, then landscaping, and then substitute teaching. I cleared up gradually and regained some of the 30 pounds that had melted away during the not-eating-or-sleeping parts of the illness. I was promoted to “a schizophrenic who might do well on lithium.” The care I received was in many ways better than what happens today, mostly because I was allowed to be hospitalized long enough to get a clue as to what was wrong with me. Back then, doctors got to say how long people were hospitalized. However, the verbiage around psychiatric diagnosis and treatment was then—and still is—rarely helpful.

I wrote a book about my experiences [1], thinking a good first-person account of psychosis would lead to definitive tests and better treatments. I also published a few articles about mental illness. I was excited about the medical model as a way to get past the shame, blame, and stigma. Curiously, my ability to do math and science, which had started drifting away in high school, came back, and I started thinking that I should try to go to medical school. I went to University of Massachusetts Boston and did well.

I was six years older than most applicants for medical school and had some marginal grades in my previous college career, but the few medical schools that wanted to interview me were more interested in my writing than in my undergraduate record. If my mental health was mentioned at all, my interviewers said that they were sure I wasn’t schizophrenic and we left it at that.
Some of the stigma surrounding mental illness would go away if the many people—including more than a few physicians and medical students—who recover well enough to pass for “normal” didn’t do such a good job of it. That path was not open to me. Through a series of incidents I wouldn’t have chosen, including a psychotic break four years after residency, the fact that I have mental illness is not a secret. It’s been well known to anyone who cares to know it throughout my career [2].

Two nurses whose children I took care of saw me actively psychotic, one of them when I was in the emergency room in four point restraints and boxer shorts. She said she hoped I would get better. I told her I was doing my best and asked how her son was doing. Another nurse who happened to work at the psychiatric hospital I was taken to had six sons I took care of. She very helpfully told me that I had been a good diagnostician before I got sick and would probably be a good one again, and that maybe an AA meeting would be helpful. (The amount of Jack Daniels I had been using as a mood stabilizer had gotten out of hand.)

From a practical point of view, having a famous father is more of a distraction than having mental illness.

“I’ve read everything he ever wrote.”

“Great. Is there any fever, vomiting, or diarrhea? How long has your child had this hideous rash?”

Most of my patients don’t know or care that I have a mental illness. They are appropriately much more concerned with the symptoms and problems they hope I can help them with. It helps that I’ve spent 35 years in the same community taking care of their neighbors, friends, and families. Patients don’t come to me because I have bipolar disease, but it doesn’t keep them away. I’m now taking care of babies of patients I took care of when they were babies. If I can hold on a few more years, there will be yet another generation.

Aside from my own community, I’ve visited several places where clinicians are trying to help people with mental illness. When I ask the best ones, “What diagnosis do these people have?,” they look at me quizzically, a little abashed and say, “We have no idea.” Effective treatment—whether it’s a medication, group therapy, or an empathic nurse—leads to more effective treatment. It all works together. Attacking problems directly works. Hungry people should be fed. Homeless people need homes. Anything we can do to make the unemployable employable is helpful. The role of good diagnosis turns out to be less important than people think.

What matters most are empathic, healing relationships. There shouldn’t be any stigma around medication, and it’s important for clinicians to recognize that it helps some and
doesn’t help others. The point is that we should help patients have a good life. Whether or not a patient needs medication should be a relatively minor detail. I take medication. My experiments and my optimism and hope that I won’t need medication someday have yet to pan out.

When I talk to patient and family groups, I usually say, “If nothing I say sparks any interest, it’s possible you’re taking too much medication. If it’s the greatest talk you’ve ever heard, maybe you should take a little more.”

The medications used to treat mental illnesses have serious side effects. You’d be crazy to take them if you didn’t need them but even crazier not to take them if you do need them. By the way, I don’t mind the word “crazy,” although I appreciate how some folks with mental illness don’t like it. Words and labels can mean different things to different people, and what they mean is worthy of respect. I also have reservations about calling patients “clients” because it makes it sound like there’s something wrong with being a patient who has a mental illness.

So my conclusion from all of this is that if you’re lucky enough to get a medical education and have the privilege of being able to take care of two—going on three—generations of children in the same community, having mental illness is no big deal.

References

Mark Vonnegut, MD, runs a small pediatric practice in Quincy, Massachusetts; teaches at Harvard Medical School; and writes and speaks on mental health issues.

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Addiction is a complex phenomenon characterized by a loss of control and compulsive, habitual behavior. Since there is no single, specific cause for addiction, there is no single, standard treatment for it. A variety of approaches are used, including counseling, psychotherapy, medications, and mutual help groups (MHG). The best known and most widely available approach to addiction is 12-step (TS) programs of recovery, a variety of MHG. These have been lauded as lifesaving by some and criticized by others. We argue that TS programs are an appropriate mode of help for those seeking to quit an addiction but should not be the only approach considered.
Persistence in the chosen modality and solid, healthy relationships with the people facilitating recovery could be more important than the modality itself [4-6].

**Twelve-Step Programs of Recovery**

*TS philosophy.* The original TS program was developed by *Alcoholics Anonymous®* (AA®). AA was founded in 1935 by physician Bob Smith and businessman Bill Wilson, who were both addicted to alcohol and looking to maintain sobriety. The 12 steps used in the program appeared in print in 1939, when Wilson and Smith published *Alcoholics Anonymous: The Story of How More than One Hundred Men Have Recovered from Alcoholism* [7]. Since then, other TS groups using similar principles have emerged to address other addictions, including Gamblers Anonymous® (GA®), Overeaters Anonymous® (OA®), Narcotics Anonymous® (NA®), and others.

The official AA position is that alcohol addiction is a progressive condition [8], characterized by “powerlessness over alcohol” [9]. On this view, alcoholism cannot be “cured”—an alcoholic cannot expect to be able to drink moderately—but the illness can be arrested by abstaining from drinking alcohol [8]. The essence of the method is that members help one another stay sober by “working the steps.” The steps are simple and can be summarized as follows [10]: (a) acknowledgement that one has become “powerless” to control one’s drinking; (b) trust that “a Power greater than ourselves” [11] can help one stay sober; and (c) acceptance of responsibility for one’s behavior, including admission of character defects, making amends for past mistakes, and striving to be honest with self and others. Thus, on this view, alcoholics are powerless over alcohol but do have power to abstain, with help, one day at a time. While AA’s position is clear that alcoholism is not a moral failing, it is equally clear that recovery depends on alcoholics’ taking responsibility for living with their condition, much like asthmatics must take responsibility for maintaining treatment of their illness.

Although not a treatment *per se* [12], TS groups do have something important to offer people who are attempting to quit an addiction: they provide a social network that supports recovery; they emphasize both the powerfully compulsive nature of addiction and the importance of harnessing an individual addict’s personal responsibility; there are no dues or fees for members; there are no requirements, pledges, or oaths to become a member; meetings are available in many places and at many times of the day and night; and they are compatible with other measures.

*Do 12-Step Groups “Work”?* Ferri, Amato, and Davoli’s conclusion in a 2006 meta-analysis published in the *Cochrane Review* [13] has been widely quoted (see e.g., [14]): “No experimental studies unequivocally demonstrated the effectiveness of AA or [Twelve-Step Facilitation] TSF approaches for reducing alcohol dependence or problems” [13]. Less widely quoted is the earlier discussion in which the authors say “there is no conclusive evidence to show that AA can help to achieve abstinence, nor is there any
conclusive evidence to show that it cannot” [13]. To us, it appeared there was little
difference among the treatments analyzed.

Several studies do support some efficacy of TS programs of recovery [15-19]. AA
participation is associated with fewer drinks and more abstinent days [15-17], and
recent studies show that AA attendance improves sobriety even while controlling for
self-selection bias [18]. While these studies do not show unequivocal evidence of
success—and are not evidence of sufficient effectiveness to recommend AA/TS
programs for everyone—they do support inclusion of TS in the set of appropriate
interventions.

Before turning to criticisms of TS, it is worth noting that TS groups (e.g., AA, GA, OA) are
distinct from both professionally led treatment programs (inpatient or outpatient) that
use TS as their foundation and the therapeutic technique grounded in the TS principles
known as TSF [20].

Critiques of TS. Several features of TS programs make them a poor fit for some people
who are seeking recovery. To begin with, some who eschew TS programs might find
the emphasis on spirituality off-putting. AA maintains that the “Power greater than
ourselves” can be construed as a non-theistic power, such as the power of the
community [11], but this rings hollow for some recovery seekers. Additionally, TS
programs promote the goal of abstinence, but moderation is a better goal for some
people. Some people find that the emphasis on powerlessness erodes their confidence,
and others dislike the group format inherent in TS. And some are bothered by the
inconsistent, somewhat sloppy reasoning that runs through the TS philosophy. For
example, AA’s position that alcoholism is an illness or malady (akin to an allergy) [7]
seems out of step with its view that it’s a spiritual problem; and the claim that
alcoholism is not a moral failing seems at odds with phrases like make “a searching and
fearless moral inventory of ourselves” [21] and “remove all defects of character” [22]
found in Step 4 and Step 6.

Perhaps the most damning criticism of AA and other TS programs concerns the
variability in adherence to core tenets from group to group. Since it is nonprofessional by
design, quality control measures are minimal, and there is no way to ensure that every
group adheres consistently to all of its principles. Thus, some criticisms of TS refer to
beliefs and attitudes that can be found in some individual TS groups or members but that
are inconsistent with the official position of AA. These include that it is a religious
(specifically Christian) organization; that it shames addicts as being morally flawed [23];
that members are not allowed to use medications to support sobriety [24]; and that AA
claims that it is the only way someone can get sober. Of course, variability of beliefs and
attitudes among members of any organization is not uncommon and can lead to
assumptions and misunderstandings about other members or the organization as a whole.

A related point is that some critiques of TS do not maintain a clear distinction between TS groups and rehabilitation programs and facilities that use TS groups, principles, or TSF [3, 25]. These criticisms take aim at the enormous expense of many inpatient rehabilitation units and the marketing used to encourage their use. They note that while hospitalization might provide a pleasant respite for those beginning recovery, the stressors of real life are waiting on the other side of discharge, which might account for these programs’ low rates of success despite the huge investment of money and time involved. It’s important to note that these are sound critiques of the rehabilitation industry, but not of TS programs as such. Moreover, some TS critics acknowledge that TS programs do help many people achieve recovery, but they are distressed about the lack of knowledge of and support for other addiction treatment modalities [3, 25]. Creating awareness of all the interventions that can help facilitate recovery is important, although the antagonistic tone of the addiction debate in popular media can, unfortunately, obscure points of agreement.

In sum, TS programs of recovery are a respectable modality to recommend to those seeking help with addiction; however, the effect is not sizeable enough for clinicians to insist on TS for everyone seeking treatment for addiction.

Other Addiction Treatments

Psychosocial approaches. There are many interventions available that address the emotional, social, and spiritual dimensions of addiction. Psychotherapeutic approaches, including cognitive behavioral therapy (CBT), aim at helping addicts understand why they have adopted addictive behavior and encourage self-reflection and self-efficacy. Motivational Interviewing (MI) and Motivation Enhancement Therapy (MET) aim at enhancing the addict’s intrinsic motivation to change. Family-based approaches, such as the Community Reinforcement Approach (CRA) and Community Reinforcement and Family Therapy (CRAFT), encourage recovery by changing the addict’s social environment. Other MHGs for addiction include SMART Recovery® (Self-Management and Recovery Training), Moderation Management™, and Celebrate Recovery®. These differ from TS groups in their philosophy and/or goal of recovery and are a better fit for some people. Brief interventions use a variety of approaches, often in emergency or one-time settings. Inpatient and intensive outpatient (IOP) programs also use different approaches, which may or may not include TS groups, TS principles, or TSF [26].

It should be noted that psychotherapeutic interventions are vulnerable to one of the problems that plague TS programs: variability. Even among licensed therapists, there is variability in skill and expertise. Additionally, an important component in the success of a
therapeutic encounter is the “fit” or rapport between client and therapist [27-29]. Thus, if any intervention fails—or succeeds—it might be hard to say exactly why.

Medication. Several kinds of pharmacotherapy are available to treat addiction, including replacement therapies, such as methadone and nicotine patches, and others that block the rewarding effects of alcohol and opioids, such as acamprosate and naltrexone; we will confine ourselves here to the latter. While the evidence suggests that these medications can contribute to recovery, it does not provide strong support for preferring one treatment over another or for preferring pharmacotherapy over behavior therapy [27, 30].

Combining modalities. The COMBINE study randomized 1,383 alcohol-dependent patients to 9 groups of pharmacologic and behavioral interventions. All received medical management (a type of addiction counseling, delivered by a health care professional) and differing combinations of naltrexone, acamprosate, placebo, and/or behavioral interventions. A reduction in drinking was found in all groups, although patients who received medical management and either naltrexone or psychosocial therapy had the highest percentage of abstinent days [30].

We think the COMBINE study provides good support for considering a multifaceted approach to therapy [31], since patients receiving all combinations of psychosocial and pharmacological therapies showed improvement. It also opens the door to considering new lines of research. Notably, patients in the “medical management plus placebo” arm did as well as patients in the “active” treatment arms. Why? Common factors might be at least part of the answer. Briefly, common factor theory holds that all therapies share common factors, such as the client-therapist relationship, and that these common factors account for as much or more of the therapeutic effect as the specific technique used in therapy [28, 29].

Framing the Issue
Relapse rates within six months of addiction treatment are estimated to be at least 40-60 percent in the general population [32], and no treatment has been shown to be far superior to another for a particular person [33-36]. These findings may lead some to question whether any treatment for addiction can be recommended. However, if we compare relapse rates for drug addiction to those for chronic medical illnesses, the results are not so gloomy. Figure 1, reproduced from a National Institute of Drug Abuse (NIDA) report [36], compares addiction relapse rates to relapse rates among patients with diabetes, asthma, and hypertension.
Figure 1. Comparison of relapse rates between drug addiction and other chronic illnesses [36].

Although whether to consider addiction a disease (as NIDA does) is beyond the scope of this paper, we do suggest that the addiction treatment paradigm of an acute disorder with a cure should be reframed as a chronic and relapsing condition needing continued care [31]. Similarly, perhaps a change in the focus of addiction research from a model that seems to favor named treatments in prescribed doses, whether pharmacological or psychosocial, to a model that looks at therapist and treatment delivery factors is needed [37, 38]. Moreover, we suggest that anticipating relapse and considering relapses an opportunity to think about different interventions might lead to decreased stigma and overall better outcomes.

Navigating an Evidence-Poor Zone

As we can see, then, research on the efficacy of approaches to addiction recovery is not conclusive; we are in an evidence-poor zone. Although we may wish for randomized controlled trials that conclusively demonstrate the effectiveness of each modality for each type of addiction, such studies are few. The many variables among addicts, treatment modalities, and practitioners make reliable generalizations difficult. Different treatment goals—abstinence versus harm reduction—and differing attitudes toward relapse further complicate whether to conclude that an intervention “works.” There is also the general difficulty of using quantitative methods with qualitative phenomena. Moreover, addiction does not appear to be a natural kind—that is, addictions don’t appear to share a common set of physiological or psychological mechanisms [39]. What they do seem to have in common is the lived human experience of compulsion. This is not to say that research is useless; studies of different interventions still yield useful
information. But we do not expect precise and certain answers to emerge from research, at least not any time soon.

How, then, can a physician proceed ethically in an evidence-poor zone? In part, by recognizing both the importance and the limits of evidence-based medicine. Current data suggest that TS programs are quite appropriate to suggest for many who are struggling with addiction, although other available approaches should be suggested as well. Don’t insist on anything in particular, but do insist on something, and it should be something to which the patient can commit. People who are not comfortable with TS are less likely to stick with it. Encourage other modalities and be vigilant for opportunities to enhance self-efficacy and internal motivation. In making recommendations, consider the person’s goal for recovery (abstinence or moderation) and the financial and social costs of the modality relative to the likelihood of success [40]. Facilitate plans for when (not if) relapse occurs. Encourage the relationships and the ancillary habits that support recovery. Finally, advocate for accessible resources that treat addiction as a chronic, relapsing condition with psychosocial, environmental, neurological, and genetic dimensions.

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2. MHGs are also called self-help groups, but that term lacks emphasis on the essential feature of one person helping another.


20. TSF is not officially related to or sanctioned by AA. It is available as a manual for standardized use by addiction treatment facilitators with a focus on abstinence as a treatment goal. Participation in AA meetings and other official AA activities (such as service and AA social events) is encouraged as a means to that end. See Nowinski J, Baker S, Carroll K. Twelve Step Facilitation Therapy Manual: A Clinical Research Guide for Therapists Treating Individuals with Alcohol Abuse and Dependence. Bethesda, MD: National Institute on Alcohol Abuse and Alcoholism; 1991. Project MATCH Monograph Series; vol 1. NIH publication 94-3722.


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40. For example, if a stay at a rehabilitation facility is going to drain a family’s resources, the outcome would have to be certain, positive, and profound to be an ethical recommendation.

**Annette Mendola, PhD**, is the director of clinical ethics and an assistant professor in the Department of Medicine at the University of Tennessee Medical Center in Knoxville. Her research interests include clinical ethics, mental health ethics, and ethical issues with addiction.

**Richard L. Gibson, MD, MPH**, is an associate professor of medicine at the University of Tennessee in Knoxville and a clinical investigator at the New Orleans Center for Clinical Research. He is board certified in internal medicine, nephrology, and psychiatry.

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ABOUT THE CONTRIBUTORS

Theme Issue Editor
Marguerite Reid Schneider is in her final year of the Medical Scientist Training Program at the University of Cincinnati. Her dissertation research focuses on executive function in adolescents with and at risk for bipolar disorder. She will join the Harvard Longwood Psychiatry Residency Program as a research track resident this summer.

Contributors
Julie M. Aultman, PhD, is a professor of family and community medicine at Northeast Ohio Medical University in Rootstown, Ohio, where she directs and teaches in the bioethics programs. She holds a doctorate in philosophy with a concentration in health care ethics and a specialization in cognitive science from Michigan State University and a master’s degree in bioethics from Case Western Reserve University. Her research interests extend to psychiatric ethics, health care justice, international studies in health care systems and community-based rehabilitation programs, and moral and professional development in medical education.

Kathryn Baker, MD, is a clinical instructor in the Department of Psychiatry at the University of Michigan in Ann Arbor. She is also the director of the University of Michigan Medical Student Mental Health and House Officer Mental Health programs.

Monica E. Calkins, PhD, is an associate professor of psychology and the director of clinical research assessment in the Department of Psychiatry, Neuropsychiatry Section, at the Perelman School of Medicine at the University of Pennsylvania in Philadelphia.

Danielle Hahn Chaet, MSB, is a research associate for the American Medical Association Council on Ethical and Judicial Affairs in Chicago. Her work involves researching, developing, and disseminating ethics policy and analyzing current issues and opinions in bioethics. She obtained her master of science degree in bioethics, with a focus on clinical policy and clinical ethics consultation, from the joint program of Union Graduate College and the Icahn School of Medicine at Mount Sinai.

Cheryl M. Corcoran, MD, is on the research faculty in the Department of Psychiatry at the New York State Psychiatric Institute (NYSPI) at Columbia University Medical Center in New York City. Dr. Corcoran founded the Center of Prevention and Evaluation at NYSPI, a setting for a longitudinal cohort study of youths at clinical high risk for psychosis. She has authored more than 50 manuscripts on the schizophrenia prodrome encompassing...
natural language and sensory processing, social cognition, imaging and EEG studies, the relevance of cannabis and stress exposures, nosology, and stigma.

Katrina Furey, MD, is a second-year resident in the Department of Psychiatry at Yale University School of Medicine in New Haven, Connecticut.

Constance E. George, MD, MA, is a general adult psychiatrist who practices in Austin, Texas. She works in a small group clinic and is also active in the Texas Society of Psychiatric Physicians Council on Ethics.

Richard L. Gibson, MD, MPH, is an associate professor of medicine at the University of Tennessee in Knoxville and a clinical investigator at the New Orleans Center for Clinical Research. He is board certified in internal medicine, nephrology, and psychiatry.

Andrea L. Kalfoglou, PhD, is an associate professor in the Department of Sociology and Anthropology at the University of Maryland Baltimore County in Baltimore. She is a graduate of the University of Virginia and received her doctorate from the Johns Hopkins University Bloomberg School of Public Health. She conducts empirical research and also writes about reproductive ethics; her current projects explore the barriers to and facilitators of mental health care for pregnant women and the integration of pre-conception counseling into primary care.

Annette Mendola, PhD, is the director of clinical ethics and an assistant professor in the Department of Medicine at the University of Tennessee Medical Center in Knoxville. Her research interests include clinical ethics, mental health ethics, and ethical issues with addiction.

James Sabin, MD, is a clinical professor in the departments of population medicine and psychiatry at Harvard Medical School in Boston, Massachusetts, and the director of the ethics program at Harvard Pilgrim Health Care, a not-for-profit health plan. His research interests include the ethics of health care resource allocation.

Srijan Sen, MD, PhD, is an associate professor in the Department of Psychiatry and in the Molecular and Behavioral Neuroscience Institute at the University of Michigan in Ann Arbor. He is the principal investigator of the Intern Health Study.

Dominic A. Sisti, PhD, is director of the Scattergood Program for Applied Ethics of Behavioral Health Care and an assistant professor of medical ethics and psychiatry in the Perelman School of Medicine at the University of Pennsylvania in Philadelphia.

Mark Vonnegut, MD, runs a small pediatric practice in Quincy, Massachusetts; teaches at Harvard Medical School; and writes and speaks on mental health issues.
Kirsten Wilkins, MD, is an associate professor of psychiatry and the director of the psychiatry clerkship at Yale University School of Medicine in New Haven, Connecticut. Dr. Wilkins is board certified in general psychiatry, geriatric psychiatry, and psychosomatic medicine.