Defining and Managing Suicidal Risk in Patients Taking Psychotropic Medications

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Physicians reflect on the US Food and Drug Administration warnings about the risk of suicidality in patients taking psychotropic medications. In this *Commentary*, learn about the risks and benefits of medications used to treat psychiatric disorders and how to identify and manage suicidal thoughts and behaviors in patients.

On November 24, 2008, Jan A. Fawcett, MD, from the Department of Psychiatry at the University of New Mexico, assembled a group of experts to discuss the definition of suicidality, the risk of suicidal ideation and suicide in patients taking psychotropic agents, and strategies to identify, manage, and prevent suicidal behaviors in clinical practice. Their discussion appears here.

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In March 2004, the US Food and Drug Administration (FDA) issued a public health advisory[1] warning that antidepressant treatment may increase suicidality and worsen depression in adult and pediatric patients. Then, in May 2007, the FDA proposed that the black box warning in the prescribing information for antidepressants and other drugs used to treat depression be updated to include a warning about an increased risk of suicidality in young adults.[2] In January 2008, the FDA announced that antiepileptic medication labeling will be required to include a warning about an increased risk of suicidality.[3]

These warnings have generated concern about the risks and benefits of prescribing psychotropic medications for psychiatric disorders. Many vital questions need to be answered so that clinicians can better recognize suicidal risk factors, manage these risks during treatment, and prevent suicidal behaviors and suicide in patients. Before addressing these topics, the experts defined the term *suicidality*.

DEFINING SUICIDALITY

Dr. Fawcett: The word *suicidality* is often used, but I am not sure that the intended meaning is consistent. What does this word actually mean, and what is its clinical significance?

Dr. Silverman: I do not like to use the term *suicidality*, because it does not convey specific clinical information (eg, whether the patient has experienced suicidal ideation, has made an attempt, or has been exposed to suicidal behaviors). Thus, the term is too broad. Patients who are acutely suicidal should be differentiated from those who are chronically suicidal, and, once the risk of suicide is recognized, the precipitating factors that caused the individual to be suicidal should be examined.

Dr. Fawcett: Would you agree that the term has been widely used since the FDA analyses?

Dr. Silverman: Yes. *Suicidality* has come to mean suicidal ideation, intent, and attempt, but, despite certain similarities, patients with suicidal ideation, those with a plan, and those who attempt suicide are 3 distinct groups.

Dr. Baldessarini: I strongly agree. Different levels of suicidal thought or behavior most likely have distinct epidemiology and pharmacology, which is another reason for making distinctions. *Suicidality* has become a journalistic term with various political implications but little clinical meaning.

Dr. Coryell: The way that intentional self-harm is classed within the psychiatric field may also obscure the meaning of *suicidality*. In some data

FOR CLINICAL USE

- Closely monitor patients for emergent suicidal ideation and behavior before and after prescribing psychotropic medications or other treatments, especially at the beginning of treatment. Monitor younger patients even more vigilantly.
- Discuss the possibility of adverse events, including behavioral agitation or anger, with patients and their support networks when prescribing medications, and encourage them to contact you if they experience problems.
- Deal with the subject of suicide directly, especially when patients are at increased risk (eg, personal or family history of attempt or suicide, mood disorder, substance abuse, sudden worsening of symptoms, losses, separations, or other traumatic life events).

analyses, all patients with intentional self-harm are being classed as suicidal. However, often, self-harm behaviors are performed to inflict pain to relieve inner tension, with no suicidal intent. Whether or not these individuals should be considered suicidal remains an issue.

Dr. Silverman: I completely agree. In the European literature, the term *deliberate self-harm* refers both to individuals who are suicidal and to those who are engaged in self-destructive behaviors for reasons other than suicide. The label of *deliberate self-harm* confirms only that the behavior occurred, but the motivation behind the action remains unknown.

Dr. Fawcett: The term *nonsuicidal self-injury* has been suggested to distinguish between self-harm with and without suicidal intent. This term may resolve some of the confusion.

Dr. Stein: There are a number of problems with the use of the Columbia Classification Algorithm of Suicide Assessment[4] in data analyses by the FDA. The data were not prospectively collected to assess suicidal intent or planning, and the term *suicidality* served as a composite variable that does not appear to have much validity.[5]

Dr. Fawcett: What is the clinical significance of saying that suicidality has been manifested by a patient?

Dr. Baldessarini: The relationship between suicidal ideation, attempts, and completed suicide is unclear. Kessler and colleagues[6] reported that, in the United States, the ratio of suicide attempts to completed suicides is approximately 30:1. The ratio drops dramatically in individuals with major affective illness.

Dr. Stein: Although the term *parasuicide* may also have limitations, it is useful in drawing attention to the clinical point that not all suicide phenomena involve the intent to die.

SUICIDAL IDEATION AND ATTEMPTS DURING TREATMENT WITH PSYCHOTROPIC MEDICATIONS

Dr. Fawcett: What is the evidence that treatment with antidepressants and other medications can cause suicidal ideation or attempts?

Dr. Silverman: The FDA data[1–3] suggested that, in the early stages of treatment with antidepressants (ie, the first month or 2), patients were at increased risk for emergent suicidal thinking and behaviors. No suicides were observed in the pediatric antidepressant clinical trials reviewed by the FDA.[7,8] However, the antiepileptic drug trials[3] did report 4 completed suicides with active drug (N = 27,863) versus 0 with placebo (N = 16,029).

Dr. Stein: Base rates of completed suicide are also relatively low in some observational studies of patients taking antidepressant treatments.

Dr. Baldessarini: Some researchers, including statisticians,[5,9,10] are skeptical of the FDA data on suicide and antidepressants and think that a major reporting artifact may be responsible for a great deal of what has been detected.

Managing Suicide Risk During Depression Treatment

Dr. Fawcett: How would you advise clinicians to deal with the possible risk of suicidal ideation or attempts in patients taking antidepressants or anticonvulsants?

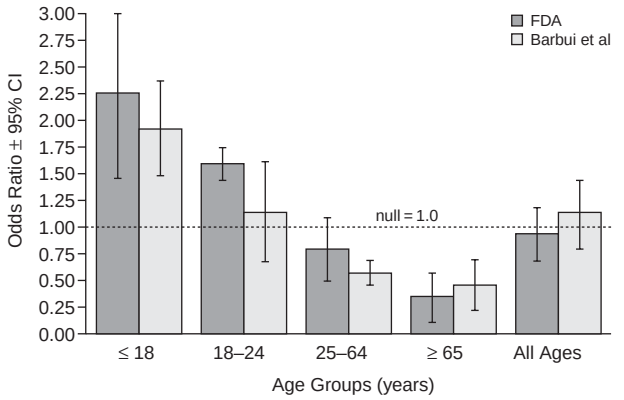
Dr. Coryell: Clinicians should keep the larger picture in mind when treating patients. Although placebo-controlled antidepressant trials[1,2,7,8] show that young people are at increased risk for suicidal ideation and nonfatal suicidal behavior in the short-term (Figure 1),[11] other studies[12,13] indicate that depression treatment prevents suicide in the long-term.

Thus, withholding antidepressant treatment does not decrease the risk of eventual suicide and may, in fact, increase it. My advice to clinicians is to vigilantly monitor patients, especially younger patients, at the beginning of therapy, and not to deny treatment when it is needed.

Dr. Stein: Clinicians need to understand that, in suicide risk management, decisions about using psychotropic medications and other interventions will flow naturally from an evaluation of the individual patient's risk for suicide (eg, demographic considerations and mental health status). After identifying risk factors, treatment decisions should be made.

Dr. Baldessarini: Recently, the FDA drafted some reasonable guidelines[14] for the clinical management of depressed patients. The overall message is to take depressed patients seriously, try to get to know them, and follow

Figure 1. Odds Ratios by Age Group for Suicidal Behavior[a]



[a]Data from the US Food and Drug Administration (FDA; included suicidal behavior and ideation)[11] and Barbui et al (included only attempted and completed suicides).[23] Additional statistical analysis provided by RJB. Values > 1.0 represent an elevated risk of suicidal behavior for patients assigned to an antidepressant relative to placebo, while values < 1.0 represent a protective effect, and values of 1.0 indicate neither an elevation in risk nor a protective effect.
Abbreviation: CI = confidence interval.

them closely during the first few weeks of treatment. Conversely, many clinicians prescribe antidepressants and say, "Call me if you need anything," without scheduling regular follow-ups or really getting to know patients.

Dr. Silverman: I agree that we need individual suicide risk assessments as well as suicide risk management protocols. If the physician is worried about what to do after discovering that a patient is suicidal, that is a barrier to treatment.

Dr. Baldessarini: Yes, the need for protocols may be why the FDA felt compelled to create guidelines, but, nevertheless, the guidelines do not recommend, for example, a specific number of follow-up visits in the first month. Because individual patients' situations are different, following guidelines in a strict way can be perceived as onerous.

Discussing Medication Risks With Patients

Dr. Fawcett: Should the physician warn patients about the possibility of suicidal ideation when starting psychotropic medication?

Dr. Baldessarini: People have argued about whether or not warning patients about suicide will put suicidal ideas into their minds. In my opinion, clinicians should simply be honest with patients and tell them that sometimes people experience adverse effects and become uncomfortable or agitated; if this happens, patients should contact their clinicians. The idea is to encourage patients to report any worsening. Depending on individual circumstances, you may not have to explicitly mention suicide.

Dr. Stein: I recommend tailoring one's message for each individual patient based on his or her current situation. As a general principle, clinicians should be open and honest, but making absolute rules to serve every situation is difficult.

Dr. Fawcett: Should clinicians tell patients that, in a small percentage of people, depression worsens while taking antidepressants?

Dr. Baldessarini: Yes.

Dr. Coryell: Is it reasonable to tell patients, "If you feel worse, call me. I can try to make you feel better"?

Dr. Fawcett: Usually, you can. In the few case reports[15,16] in which patients did become seriously suicidal, researchers found that treating the agitated state with the addition of propranolol or benzodiazepines relieved akathisia and suicidal thinking.

Dr. Stein: So, to clarify, should clinicians tell patients that they may have *de novo* suicidal ideation, even if the patient currently shows no evidence of suicidal thinking?

Dr. Fawcett: No. I do not believe that describing any specific type of potential worsening is necessary. I just tell patients that a small percentage of people feel worse instead of better when taking antidepressants, and, if this happens, I can help.

Dr. Coryell: Coupled with that, patients should also be told that the medication may not work immediately.

Dr. Baldessarini: That is another reason to closely monitor patients during the first few weeks of treatment.

Dr. Coryell: In addition to informing patients about any risks associated with antidepressant treatment, clinicians should discuss these risks with significant others (eg, the patient's spouse, partner, or parents). The patient may not be in the best position to observe his or her own behavior or to report any problems, especially when extremely depressed. Bringing in a support network is part of treatment.

PREVENTING SUICIDE WITH DEPRESSION TREATMENT

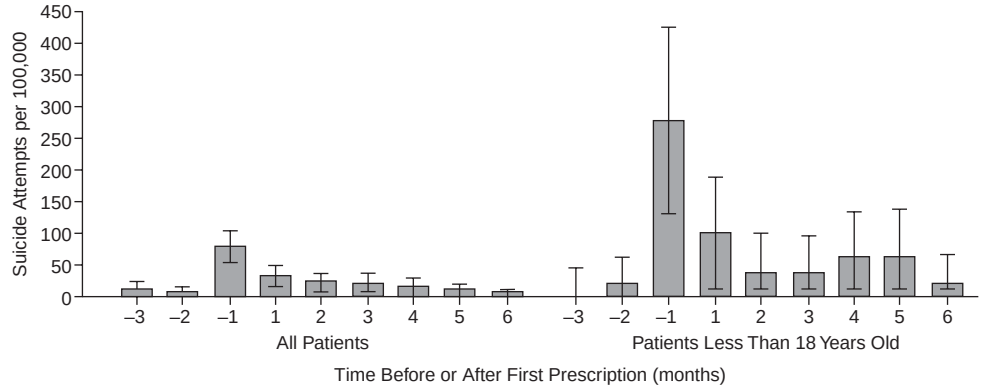
Dr. Fawcett: What is the evidence that treatment can prevent suicide?

Dr. Silverman: Certain nonpharmacologic approaches such as cognitive-behavioral therapy and dialectical behavioral therapy have been proven to reduce suicidal behaviors.[17] Newer methodologies are being developed to determine whether or not a particular intervention has a positive effect.

Dr. Baldessarini: The only medication treatment that has been FDA-approved to prevent suicide is clozapine (for patients with schizophrenia). However, even with clozapine, evidence does not conclusively prove that it prevents deaths, only that suicidal behaviors are reduced.[18]

Long-term treatment with lithium lowers the risk of attempted and completed suicide in patients with bipolar disorder, and perhaps, in patients with major depressive

Figure 2. Rates of Suicide Attempts During the 3 Months Before and the 6 Months After Initial Antidepressant Prescription[a]



[a]Reprinted with permission from Simon et al.[24] Bars indicate 95% confidence intervals.

disorder.[19] The literature[20] concerning antidepressants in adults has consistently concluded via randomized controlled studies that antidepressants are more efficacious than placebo for reducing suicidal thinking in depressed adults.[21] Data from epidemiologic studies supporting their efficacy for reducing rates of acting on suicidal thoughts (ie, attempting or completing suicide) are less conclusive.[22] However, in close parallel with the FDA review of data from randomized trials of modern antidepressants,[2,11] a recent review of clinical cohort studies[23] found evidence of age-related increases (adolescents) and decreases (older adults) of suicidal risks that included attempts and fatalities (see Figure 1).

Dr. Fawcett: Simon et al[24] reported data showing that suicide attempt risk was highest during the month prior to antidepressant prescription and decreased throughout treatment (Figure 2).

Dr. Baldessarini: Most large case series or cohort studies look favorable, but, in the randomized controlled literature, little evidence clarifies whether antidepressants specifically worsen or help suicidal behaviors (as opposed to self-reported suicidal ideation).[1–3]

Dr. Fawcett: Angst et al[25] conducted a 40- to 44-year follow-up in 406 patients who had been hospitalized for mood disorders between 1959 and 1963. The group of individuals who received long-term treatment with lithium, antidepressants, or neuroleptics had lower rates of suicide than the group that did not receive long-term medication (Table 1). This finding suggests that, to prevent suicide, medications must be taken for a long period of time.

In an analysis of the FDA trials, in which patients typically received medication for shorter periods of time than in clinical practice, Kahn et al[26] found no difference between antidepressants (selective serotonin reuptake inhibitors or otherwise) and placebo in terms of suicide rates. Therefore, my sense is that the amount of time that patients take medications has a lot to do with their antisuicidal effects.

Table 1. Prevalence of Suicide in Patients With Mood Disorders Who Did or Did Not Receive Long-Term Pharmacologic Treatment[a]

	Treated	Nontreated	
Medication Group	Deaths (%)	Deaths (%)	*P* Value
Lithium[b]	7.1	11.7	NS
Neuroleptics	8.8	16.7	.05
Antidepressants[c]	10.0	21.2	.09

[a]Adapted with permission from Angst et al.[25]
[b]Computed only for patients with bipolar disorder.
[c]Computed only for patients with depressive disorders.
Abbreviation: NS = not significant.

Dr. Baldessarini: That is probably correct. This is something that is special about both clozapine and lithium relative to antidepressants—that they are used for long periods of time. That brings up a criticism of contemporary practice with antidepressants—it is uncommon to see a patient who continues taking them for 2 to 3 months or longer.

Dr. Fawcett: I agree. So, it is probably part of our job to keep patients on antidepressant treatment as long as possible to reduce the risk of suicide.

Dr. Stein: I would like to discuss evidence for nonpharmacologic interventions such as suicide hotlines and school-based counseling programs. One study[27] found that high school students (N = 519) had more negative attitudes toward hotlines than other methods of assistance, and those who had the most negative attitudes toward hotlines were most in need of help.

Dr. Baldessarini: In a well-designed, controlled trial,[28] high school students (N = 4,133) were assigned to either participate in a suicide prevention program or not to participate. The suicide intervention information significantly reduced suicide attempts among students ($P < .05$).

Table 2. Factors to Evaluate When Assessing Suicidal Risk in Patients[a]

Current Presentation of Suicidality
Suicidal or self-harming thoughts, plans, behaviors, and intent
Specific methods considered for suicide, including their lethality and the patient's expectation about lethality, as well as whether firearms are accessible
Evidence of hopelessness, impulsiveness, anhedonia, panic attacks, or anxiety
Reasons for living and plans for the future
Alcohol or other substance use associated with the current presentation
Thoughts, plans, or intentions of violence toward others
Psychiatric Illnesses
Current signs and symptoms of psychiatric disorders with particular attention to mood disorders (primarily major depressive disorder or mixed episodes), schizophrenia, substance use disorders, anxiety disorders, and personality disorders (primarily borderline and antisocial personality disorders)
Previous psychiatric diagnoses and treatments, including illness onset and course and psychiatric hospitalizations, as well as treatment for substance use disorders
History
Previous suicide attempts, aborted suicide attempts, or other self-harming behaviors
Previous or current medical diagnoses and treatments, including surgeries or hospitalizations
Family history of suicide or suicide attempts or a family history of mental illness, including substance abuse
Psychosocial Situation
Acute psychosocial crises and chronic psychosocial stressors, which may include actual or perceived interpersonal losses, financial difficulties, or changes in socioeconomic status, family discord, domestic violence, and past or current sexual or physical abuse or neglect
Employment status, living situation (including whether or not there are infants or children in the home), and presence or absence of external supports
Family constellation and quality of family relationships
Cultural or religious beliefs about death or suicide
Individual Strengths and Vulnerabilities
Coping skills
Personality traits
Past responses to stress
Capacity for reality testing
Ability to tolerate psychological pain and satisfy psychological needs

[a]Reprinted with permission from the American Psychiatric Association.[29]

SUICIDE RISK FACTORS

Dr. Fawcett: The American Psychiatric Association lists several characteristics to evaluate in patients with suicidal behavior (Table 2).[29] What risk factors for suicide do you especially look for in patients?

Dr. Silverman: I think that the issue of anxiety needs to receive more attention. Anxiety, agitation, irritability, and impulsivity are all part of a state of negative arousal. This arousal leaves people uncomfortable in a number of ways, both physically and psychologically, and increases the likelihood of engaging in self-destructive behaviors.[30,31]

Dr. Baldessarini: Another variable is mania[31]; if the patient has bipolar depression, impulsivity and agitation may be increased and can contribute to suicide risk. In patients with various types of depression, we see a spectrum of risk and severity. Usually, rising risks can be identified in time to allow for an intervention, provided that the patient is followed reasonably closely.

Dr. Fawcett: Clinicians often see patients who have several risk factors and are unsure of which ones to address first. I think that anxiety should be treated immediately.[32] Suicidal planning is another factor that requires urgent attention.

Dr. Silverman: Clinicians should also examine the area of perceived loss—sudden losses that an individual is not prepared to handle.[30] This brings up issues involving coping skills and cognitive functioning, having a repertoire of behaviors to draw upon or an ability to sort out what is happening at a cognitive level. These are critical factors that need to be assessed.

Dr. Stein: A range of psychiatric disorders could increase the risk of suicide.[31] Psychosis has been discussed as increasing impulsivity and aggression.[33] Suicide attempts are probably related to more than one factor, but I agree with focusing on anxiety, acute loss, and adversity.

Dr. Fawcett: Data[31] show that the presence of psychiatric comorbidity (3 or more disorders) increases the risk of attempts.

Additive factors probably contribute to suicide risk, but this depends on how much each factor means to a particular person.

Dr. Baldessarini: Also, clinicians should not rely solely on checklists or a list of risk factors. These methods are appropriate when trying to learn something about a patient, but, as I mentioned earlier, there is no substitute for getting to know the patient and establishing a relationship. This way, the patient is more likely to tell you if things are not going well or if he or she is feeling bad.

Dr. Stein: Even that does not always work.

Dr. Baldessarini: Yes, a patient may be thinking about suicide but keep these thoughts a secret.[34]

Dr. Silverman: The patient may fear that any mention of suicide will immediately result in being hospitalized, so the patient remains silent.

Dr. Fawcett: Still, when you see a patient, you come to some decision about his or her mental state. Some of Dr. Coryell's studies[35,36] have shown that patients with prior suicide attempts were at high risk for completed suicide. We see so many patients like this. The question is—how do we decide if today is the day to do something special to prevent suicide? We all must make that decision somehow, every time we see a patient.

Dr. Silverman: We need to try to understand prior behavior. I agree that past behavior often predicts future behavior. However, a number of studies do not provide a thorough analysis of why the attempt was made. What was the context? What was the motivation? Further, what was the outcome of that attempt? How are we

working with the patient to avoid similar situations or stimuli?

Dr. Fawcett: Any history of past suicidal behavior should be discussed. Many patients are more willing to discuss past behavior than present behavior; this can lead to questioning about their present mental state. I also discuss with patients whether they have had any mental rehearsals that did not necessarily involve any behavior. The Multi-Attitude Suicide Tendency Scale[37] could be used to assess tendency.

Dr. Coryell: The most frequently described acute risk is prior suicide attempts. Additive acute risk factors include being an inpatient and feeling hopeless.[35] Less robust risk factors include being male and being separated or divorced at the time of the index depressive episode.[35]

In addition, many completed suicides occur in a matter of weeks to months after the crisis that brings the person to clinical attention[35]; this should be the period of maximum surveillance.

Dr. Fawcett: Exactly. We must be more aware of the patient's vulnerabilities during that time period.

WHEN TO ASSESS SUICIDAL RISK

Dr. Fawcett: When should a suicide assessment be done and recorded in the patient's chart? Should it be done every time you see the patient?

Dr. Baldessarini: Doing a substantial suicide assessment at every visit seems rather cumbersome, but it should at least be a part of the initial assessment, particularly for patients at increased suicidal risk (especially those with a major mood or substance use disorder). Suicidal risk should be considered repeatedly during follow-ups, and ideally, at least briefly documented in the patient's clinical record.

Dr. Fawcett: What about after the initial assessment?

Dr. Coryell: Inquire anytime the acute risk level increases, particularly in patients with alcohol use disorder. When patients have experienced a recent accumulation of losses (eg, job loss, divorce), asking about suicidal tendencies is worthwhile, even if patients are not overtly threatening suicide.

Dr. Silverman: I agree. If a patient is experiencing a perceived crisis and comes to you saying, "Something's changed dramatically, and I'm struggling with it. I feel hopeless," these are clear signals to pursue a discussion about the risk of suicide.

Dr. Stein: A sudden change in clinical presentation such as worsening of depression or increase in manic symptoms warrants assessing mental status and the risk of suicide.

Dr. Fawcett: What if a patient shows rapid improvement? Is there evidence to support this being a cause for concern?

Dr. Coryell: No. I am unaware of any evidence to support that.

Dr. Fawcett: What do you think about the so-called "suicide contracts" that the patient signs to agree that he or she will not commit suicide?

Dr. Baldessarini: These contracts are largely a waste of time. They may make clinicians feel better but are not supported by evidence.

Dr. Fawcett: Having patients sign contracts started out with therapeutic intent but became a way for busy clinicians to reassure themselves. I think that this is often more harmful than useful.

Dr. Baldessarini: Yes, having a signed contract makes some clinicians too comfortable—they may stop listening to the patient and their wariness may drop, which can be dangerous.

HOSPITALIZATION FOR SUICIDAL PATIENTS

Dr. Fawcett: How about managing patients whom you deem to be at high risk for suicide? Dr. Silverman stated that we do not necessarily want the mention of suicidal risk factors to make patients think that they will be hospitalized. What if you highly suspect that a patient is at high risk but he or she is not technically committable?

Dr. Baldessarini: I recommend talking overtly with the patient about the likelihood of hospitalization. Find out what this would mean to the person. Is he or she willing or resistant, and why? Clinicians need to know this information.

Dr. Fawcett: Hospitalization should be recommended when the clinician thinks it is necessary.

Dr. Coryell: If a patient is opposed to hospitalization or it is not the appropriate strategy, enlisting family members to vigilantly monitor him or her is another viable option.

Dr. Baldessarini: Recently, this approach did not prevent one patient's death. The patient was sent home from a hospital under 24-hour family surveillance. A relative's vigilance lapsed for about 15 minutes, and this was enough time for the patient to complete suicide. The family was devastated.

Dr. Coryell: What conclusions can you make from this misfortune?

Dr. Baldessarini: It is a risky situation without simple answers. Family surveillance can be helpful, but the clinician must still be available to intervene and rehospitalize the patient if necessary.

Dr. Fawcett: Additionally, family members need to be told when the risk is high and that we will make every effort to prevent suicide. Nonetheless, there is a limit to what can be done.

Dr. Coryell: We are limited to doing what is reasonable. All that we can do is to try our best to reduce the risk of suicidal behaviors. We have tools and techniques to help us reduce this risk. To say that we can prevent all suicides is unrealistic.

We need to explain to the patient and to his or her family members or support network that we are all in this together. Although we cannot necessarily predict the outcome of our efforts, we can do things to decrease the likelihood that someone will die by suicide.

Dr. Fawcett: It is important for people to understand that we cannot control everything that happens.

Dr. Baldessarini: Even if the clinician has done a satisfactory job of trying to prevent suicide (ie, assessing risk clinically with possible guidance by checklists and providing documentation in the clinical record), if a patient completes suicide, the clinician may still be sued.

Dr. Fawcett: That supports the need for documentation. There is likely too little documentation of the efforts that clinicians make. Many times, when patients have experienced difficulties and I look at their charts, little information is there to help me. More attention should be paid to documentation to prove that everything possible was done to assess and manage risks.

Dr. Silverman: I agree. I find it troubling when all I can find in a hospital record is "denies suicidal ideation." However, the patient has been hospitalized—either with an acute episode of a psychiatric illness that is associated with suicide or, more likely, because of a suicide concern or attempt. Merely saying that the patient "denies suicidal ideation" is not sufficient.

Dr. Stein: All that we can do is make the best decision based on the provided documentation. This is a complex problem.

Dr. Fawcett: Thank you all for your participation in this discussion. It should also be noted that, in May 2009, the FDA announced its approval of the updated labeling for antiepileptic drugs. The FDA also required that manufacturers develop a Medication Guide to help patients understand the increased risk of suicidal thoughts or actions when taking these medications.[38]

Drug names: clozapine (Clozaril, FazaClo, and others), lithium (Lithobid, Eskalith, and others), propranolol (Innopran, Inderal, and others).

Disclosure of off-label usage: The chair has determined that, to the best of his knowledge, lithium is not approved by the US Food and Drug Administration for the prevention of suicide and propranolol is not approved for the treatment of akathisia.

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