Challenges and Strategies in Foster Care

Jeanette M. Scheid, MD, PhD

On any given day, there are more than 400,000 children in foster care in the US (Table 1, Figure). Children in foster care are at a higher risk for health and mental health problems. They are also connected to multiple systems, which require and challenge coordinated care. Further complicated by histories of maltreatment (Sidebar) and issues in assessment, diagnosis and treatment can be challenging—for children, their families and guardians, and their clinicians. In honor of National Foster Care Month, this article sheds light on these issues and provides information for psychiatrists caring for this vulnerable population.

CASE VIGNETTE

"Joseph" is a 3-year-old in foster care. After 2 out-of-home placements, he was returned to his parents. Each removal was connected to allegations of physical abuse. His permanency goal is changing to adoption, but he still has visits with his parents. He is physically healthy but hyperactive and impulsive and has problems sleeping. When Joseph first arrived at his current foster home, he had temper outbursts at least once a day that included screaming, hitting, kicking, and breaking things. Over the course of a few months, the outbursts decreased to...

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A NEW DAY BEGINS WITH SPRAVATO™

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Device as shown does not depict actual position for administration.

Indication
SPRAVATO™ (esketamine) CIII Nasal Spray is indicated, in conjunction with an oral antidepressant (AD), for the treatment of treatment-resistant depression (TRD) in adults.

SPRAVATO™ is not approved as an anesthetic agent. The safety and effectiveness of SPRAVATO™ as an anesthetic agent have not been established.

Important Safety Information

WARNING SEDATION, DISSOCIATION; ABUSE AND MISUSE; and SUICIDAL THOUGHTS AND BEHAVIORS

See full prescribing information for complete boxed warning

- Risk for sedation and dissociation after administration. Monitor patients for at least two hours after administration (5.1, 5.2).
- Potential for abuse and misuse. Consider the risks and benefits of using SPRAVATO™ prior to use in patients at higher risk of abuse. Monitor for signs and symptoms of abuse and misuse (5.3).
- SPRAVATO™ is only available through a restricted program called the SPRAVATO™ REMS (5.4).
- Increased risk of suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants. Closely monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors. SPRAVATO™ is not approved for use in pediatric patients (5.5).

CONTRAINDICATIONS

SPRAVATO™ is contraindicated in patients with:

- Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation
- History of intracerebral hemorrhage
- Hypersensitivity to esketamine, ketamine, or any of the excipients

WARNING AND PRECAUTIONS

Sedation: In clinical trials, 49% to 61% of SPRAVATO™-treated patients developed sedation and 0.3% of SPRAVATO™ treated patients experienced loss of consciousness. Because of the possibility of delayed or prolonged sedation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.

Closely monitor for sedation with concomitant use of SPRAVATO™ with CNS depressants [see Drug Interaction (7.1)].

SPRAVATO™ is available only through a restricted program under a REMS.

Dissociation: The most common psychological effects of SPRAVATO™ were dissociative or perceptual changes (including distortion of time, space and illusions), derealization and depersonalization (61% to 75% of SPRAVATO™-treated patients developed dissociative or perceptual changes). Given its potential to induce dissociative effects, carefully assess patients with psychosis before administering SPRAVATO™; treatment should be initiated only if the benefit outweighs the risk.

Because of the risks of dissociation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.

SPRAVATO™ is available only through a restricted program under a REMS.

Abuse and Misuse: SPRAVATO™ contains esketamine, a Schedule III controlled substance (CIII), and may be subject to abuse and diversion. Assess each patient’s risk for abuse or misuse prior to prescribing and monitor all patients for the development of these behaviors or conditions, including drug-seeking behavior, while on therapy.

Individuals with a history of drug abuse or dependence are at greater risk; therefore, use careful consideration prior to treatment of individuals with a history of substance use disorder and monitor for signs of abuse or dependence.

SPRAVATO™ is available only through a restricted program under a REMS.

Please see additional Important Safety Information and Brief Summary of full Prescribing Information, including Boxed WARNINGS, on following pages.

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SHE THOUGHT HER DEPRESSION SYMPTOMS WOULD NEVER GET BETTER

NMDA=N-methyl-D-aspartate.

Important Safety Information (continued)

SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS): SPRAVATO® is available only through a restricted program called the SPRAVATO® REMS because of the risks of serious adverse outcomes from sedation, dissociation, and abuse and misuse.

Important requirements of the SPRAVATO® REMS include the following:

- Healthcare settings must be certified in the program and ensure that SPRAVATO® is:
  - Only dispensed in healthcare settings and administered to patients who are enrolled in the program.
  - Administered by patients under the direct observation of a healthcare provider and that patients are monitored by a healthcare provider for at least 2 hours after administration of SPRAVATO®.
  - Only dispensed in healthcare settings and administered to patients who are enrolled in the program.
- Pharmacies must be certified in the REMS and only dispense SPRAVATO® to healthcare providers that are certified in the program.

Further information, including a list of certified pharmacies, is available at www.SPRAVATOrems.com or 1-855-382-6022.

Suicidal Thoughts and Behaviors in Adolescents and Young Adults: In pooled analyses of placebo-controlled trials of antidepressant drugs (SSRIs and other antidepressant classes) that included adult and pediatric patients, the incidence of suicidal thoughts and behaviors in patients age 24 years and younger was greater than placebo-treated patients. SPRAVATO® is not approved in pediatric (<18 years of age) patients.

There was considerable variation in risk of suicidal thoughts and behaviors among drugs, but there was an increased risk identified in young patients for most drugs studied.

Monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy and during periods of dosage changes.

- Counsel family members or caregivers of patients to monitor for changes in behavior and to alert the healthcare provider.
- Consider changing the therapeutic regimen, including possibly discontinuing SPRAVATO® when concomitant oral antidepressant, in patients whose depression is persistently worse, or who are experiencing emergent suicidal thoughts or behaviors.

Increase in Blood Pressure: SPRAVATO® causes increases in systolic and/or diastolic blood pressure (BP) at all recommended doses. Increases in BP peak approximately 40 minutes after SPRAVATO® administration and last approximately 4 hours. Approximately 8% to 17% of SPRAVATO®-treated patients experienced an increase of more than 40 mmHg in systolic BP and/or 25 mmHg in diastolic BP in the first 1.5 hours after administration at least once during the first 4 weeks of treatment.

A substantial increase in blood pressure could occur after any dose administered even if smaller blood pressure effects were observed with previous administrations. SPRAVATO® is contraindicated in patients for whom an increase in BP or intracranial pressure poses a serious risk (e.g., aneurysmal vascular disease, arteriovenous malformation, history of intracranial hemorrhage, uncontrolled hypertension, patients with cardiovascular or cerebrovascular conditions should be carefully assessed to determine whether the potential benefits of SPRAVATO® outweigh its risk.

Assess BP prior to administration of SPRAVATO®. In patients whose BP is elevated prior to SPRAVATO® administration (as a general guide: >140/90 mmHg), a decision to delay SPRAVATO® therapy should be taken into account to balance the benefit and risk in individual patients.

BP should be monitored for at least 2 hours after SPRAVATO® administration. Measure blood pressure around 40 minutes post-dose and subsequently as clinically warranted until values decline. If BP remains high, promptly seek clinical warranted until values decline. If BP remains high, promptly seek prompt evaluation and treatment. In patients with a history of hypertension or cerebrovascular disease, it is recommended that at least twice that of placebo nasal spray plus oral AD) were dissociation, disorientation, insomnia, flashback, hallucinations, and feelings of floating, detachment and to be “spaced out.” Monitoring for signs of abuse and misuse is recommended.

CNS depressants.

DRUG INTERACTIONS

CNS depressants (e.g., benzodiazepines, opioids, alcohol): Concomitant use may increase sedation. Closely monitor for sedation with concomitant use of CNS depressants.

Psychostimulants (e.g., amphetamines, methylphenidate, modafinil, armodafinil): Concomitant use may increase blood pressure. Closely monitor blood pressure with concomitant use of psychostimulants.

Monoamine oxidase inhibitors (MAOIs): Concomitant use may increase blood pressure. Closely monitor blood pressure with concomitant use of MAOIs.

USE IN SPECIFIC POPULATIONS

Pregnancy: SPRAVATO® is not recommended during pregnancy. SPRAVATO® may cause fetal harm when administered to pregnant women. Advise pregnant women of the potential risk to an infant exposed to SPRAVATO® in utero. There are risks to the mother associated with untreated depression in pregnancy. If a woman becomes pregnant while being treated with SPRAVATO®, treatment with SPRAVATO® should be discontinued and the patient should be counseled about the potential risk to the fetus.

Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antidepressants, including SPRAVATO®, during pregnancy. Healthcare providers are encouraged to register patients by contacting the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or online at https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants.

Lactation: SPRAVATO® is present in human milk. Because of the potential for neurotoxicity, advise patients that breastfeeding is not recommended during treatment with SPRAVATO®.

Females and Males of Reproductive Potential: SPRAVATO® may cause embryo-fetal harm when administered to a pregnant woman. Consider pregnancy planning and prevention for females of reproductive potential during treatment with SPRAVATO®.

Pediatric Use: The safety and effectiveness of SPRAVATO® in pediatric patients have not been established.

Geriatric Use: Of the total number of patients in Phase 3 clinical studies exposed to SPRAVATO®, 12% were 65 years of age and older, and 2% were 75 years of age and older. No overall differences in safety profile were observed between patients 65 years of age and older and patients younger than 65 years of age.

The mean eseketamine Cmax and AUC values were higher in elderly patients compared with younger adult patients.

The treatment of TRD in geriatric patients was evaluated in a 4-week, randomized, double-blind study comparing flexibly-dosed intranasal SPRAVATO® plus a newly initiated oral antidepressant compared to intranasal placebo plus a newly initiated oral antidepressant in patients ≥65 years of age. At the end of four weeks, there was no statistically significant difference between groups on the primary efficacy endpoint of change from baseline to Week 4 on the Montgomery-Åsberg Depression Rating Scale (MADRS).

Hepatic impairment: SPRAVATO®-treated patients with moderate hepatic impairment may need to be monitored for adverse reactions for a longer period of time.

SPRAVATO™ has not been studied in patients with severe hepatic impairment (Child-Pugh class C). Use in this population is not recommended.

DRUG ABUSE AND DEPENDENCE

Controlled Substance: SPRAVATO® contains esketamine hydrochloride, the racemic mixture of ketamine and a Schedule III controlled substance under the Controlled Substances Act.

Abuse: Individuals with a history of drug abuse or dependence may be at greater risk for abuse and misuse of SPRAVATO®. Abuse is the intentional, non-therapeutic use of a drug, even once, for its psychological or physiological effects. Misuse is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a healthcare provider or for whom it was not prescribed. Careful consideration is advised prior to use of individuals with a history of substance use disorder, including alcohol.

SPRAVATO® may produce a variety of symptoms including anxiety, dysphoria, disinhibition, insomnia, flashback, hallucinations, and feelings of floating, detachment and to be “spaced out.” Monitoring for signs of abuse and misuse is recommended.

ADVERSE REACTIONS

The most common adverse reactions with SPRAVATO® plus oral AD (incidence ≥5% and at least twice that of placebo nasal spray plus oral AD) were dissociation, disorientation, nausea, sedation, vertigo, hypotension, anxiety, lethargy, blood pressure increased, vomiting, and feeling drunk.

Please see Brief Summary of full Prescribing Information, including BOXED WARNINGS, on following pages.
SPRAVATO® (esketamine) nasal spray, CIII

Brief Summary

BEFORE PRESCRIBING SPRAVATO®, PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

WARNING: SEDATION; DISSOCIATION; ABUSE AND MISUSE; AND SUICIDAL THOUGHTS AND BEHAVIORS

Sedation
- Patients are at risk for sedation after administration of SPRAVATO® (see Warnings and Precautions).

Dissociation
- Patients are at risk for dissociative or perceptual changes after administration of SPRAVATO® (see Warnings and Precautions).

Because of the risk of sedation and dissociation, patients must be monitored for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting (see Warnings and Precautions).

Abuse and Misuse
- SPRAVATO® has the potential to be abused and misused. Consider the risks and benefits of prescribing SPRAVATO® prior to use in patients at higher risk of abuse. Monitor patients for signs and symptoms of abuse and misuse (see Warnings and Precautions).

Because of the risks of serious adverse outcomes resulting from sedation, dissociation, and abuse and misuse, SPRAVATO® is available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the SPRAVATO REMS (see Warnings and Precautions).

Suicidal Thoughts and Behaviors

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients with major depressive disorder (MDD) in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. SPRAVATO is not approved for use in pediatric patients (see Warnings and Precautions).

INDICATIONS AND USAGE

SPRAVATO® is indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults (see Clinical Studies (14.1) in Full Prescribing Information).

Limitations of Use:
- SPRAVATO® is not approved as an anesthetic agent. The safety and effectiveness of SPRAVATO® as an anesthetic agent have not been established.

CONTRAINDICATIONS

SPRAVATO® is contraindicated in patients with:
- Anomalous vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation (see Warnings and Precautions).
- History of intracranial hemorrhage (see Warnings and Precautions).
- Hypersensitivity to esketamine, ketamine, or any of the excipients.

WARNINGS AND PRECAUTIONS

Sedation

In clinical trials, 4% to 6% of SPRAVATO®-treated patients developed sedation based on the Modified Observer’s Alertness/Sedation scale (MOAA/s) (see Adverse Reactions), and 0.3% of SPRAVATO®-treated patients experienced loss of consciousness (MOAA/s score of 0). Because sedation or prolonged sleep is a risk in patients who are monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting (see Dose and Administration (2.4) in Full Prescribing Information).

Closely monitor for sedation with concomitant use of SPRAVATO® with CNS depressants (see Drug Interactions).

Dissociation

The most common psychological effects of SPRAVATO® were dissociative or perceptual changes (including altered time, space, and illusions), derealization and depersonalization (6% to 70%) of SPRAVATO®-treated patients developed dissociative or perceptual changes based on the Clinician Administered Dissociative Symptoms Scale (see Adverse Reactions). Given its potential to induce dissociative effects, carefully assess patients with psychosis before administering SPRAVATO®. Treatment should be initiated only if the benefit outweighs the risk.

Because of the risks of dissociation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting (see Dose and Administration (2.4) in Full Prescribing Information).

SPRAVATO® is available only through a restricted program under a REMS (see Warnings and Precautions).

Abuse and Misuse

SPRAVATO® contains esketamine, a Schedule III controlled substance (CIII), and may be subject to abuse and diversion. Assess each patient’s risk for abuse or misuse prior to prescribing SPRAVATO® and monitor all patients receiving SPRAVATO® for the development of these behaviors or conditions, including drug-seeking behavior, while on therapy. Contact local state professional licensing board or state-controlled substances authority for information on how to prevent and detect abuse or diversion of SPRAVATO®. Individuals with a history of drug abuse or dependence are at greater risk; therefore, use caution prior to treatment of individuals with a history of substance use disorder and monitor for signs of abuse or dependence. (see Drug Abuse and Dependence).

SPRAVATO® is available only through a restricted program under a REMS (see Warnings and Precautions).

SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS)

SPRAVATO® is available only through a restricted program under a REMS called the SPRAVATO REMS (see Warnings and Precautions).

Important requirements of the SPRAVATO REMS include the following:
- Healthcare settings must be certified in the program and ensure that SPRAVATO® is:
  - Only dispensed in healthcare settings and administered to patients who are enrolled in the REMS.
  - Administered by patients under the direct observation of a healthcare provider and that patients are monitored in a healthcare setting for at least 2 hours after administration of SPRAVATO® (see Dose and Administration (2.4) in Full Prescribing Information).
  - Pharmacies must be certified in the REMS and must only dispense SPRAVATO® to healthcare settings that are certified in the program.

Further information, including a list of certified pharmacies is available at www.SPRAVATOREMS.com or 1-855-382-4022.

Suicidal Thoughts and Behaviors in Adolescents and Young Adults

In pooled analyses of placebo-controlled trials of antidepressant drugs (SSRIs and other antidepressant classes) that included approximately 17,000 adult patients and 4,500 pediatric patients (SPRAVATO® is not approved in pediatric patients), the incidence of suicidal thoughts and behaviors in patients age 24 years and younger was greater than in placebo-treated patients. There was considerable variation in risk of suicidal thoughts and behaviors among drugs, but there was an increased risk identified in young patients for most drugs studied. There were differences in absolute risks across the various indications, and behaviors across the different indications, with the highest incidence in patients with major depressive disorder (MDD). The drug-placebo differences in the number of cases of suicidal thoughts and behaviors per 1000 patients treated are provided in Table 1.

<table>
<thead>
<tr>
<th>Age Range (Years)</th>
<th>Drug-Placebo Difference in Number of Patients with Suicidal Thoughts or Behaviors per 1000 Patients Treated</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;18</td>
<td>Increases Compared to Placebo</td>
</tr>
<tr>
<td>18-24</td>
<td>Decreases Compared to Placebo</td>
</tr>
<tr>
<td>≥25</td>
<td></td>
</tr>
</tbody>
</table>

<18 1 fewer patient
18-24 5 additional patients
≥25 6 fewer patients

* SPRAVATO® is not approved in pediatric patients.

It is unknown whether the risk of suicidal thoughts and behaviors in children, adolescents, and young adults extends to longer-term use, i.e., beyond four months. However, there is substantial evidence from placebo-controlled maintenance studies in adults with MDD that antidepressants delay the recurrence of depression and that this delay itself is a risk factor for suicidal thoughts and behaviors.

Monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy and at times of dosage changes. Counsel family members or caregivers of patients to monitor for changes in behavior and to alert the healthcare provider. Consider changing the therapeutic regimen, including possibly discontinuing SPRAVATO® and/or the concomitant oral antidepressant, in patients whose depression is persistently worsened, or who are experiencing emergent suicidal thoughts or behaviors.

Increase in Blood Pressure

SPRAVATO® causes increases in systolic and/or diastolic blood pressure (BP) at all recommended doses. Increases in BP peak approximately 40 minutes after SPRAVATO® administration and last approximately 4 hours (see Adverse Reactions).

Approximately 6% to 11% of SPRAVATO®-treated patients and 1% to 3% of placebo-treated patients experienced an increase of more than 40 mmHg in systolic BP and/or 25 mmHg in diastolic BP in the first 1.5 hours after administration at least once during the first 4 weeks of treatment. A substantial increase in blood pressure could occur after any dose administered even if smaller blood pressure effects were observed with previous administrations. SPRAVATO® is contraindicated in patients for whom an increase in BP or intracranial pressure poses a serious risk (e.g., patients with unstable cerebrovascular disease, arteriovenous malformation, history of intracerebral hemorrhage) (see Contraindications).

Before prescribing SPRAVATO®, patients with other cardiovascular and cerebrovascular conditions should carefully assess to determine whether the potential benefits of SPRAVATO® outweigh its risks.

Assess BP prior to administration of SPRAVATO®. In patients whose BP is elevated prior to prescribing SPRAVATO®, and as a general guide >140/90 mmHg a decision to delay SPRAVATO® therapy should take into account the balance of benefit and risk in individual patients.

BP should be monitored for at least 2 hours after SPRAVATO® administration (see Dose and Administration (2.4) in Full Prescribing Information). Measure blood pressure around 40 minutes post-dose and subsequently as clinically warranted until values decline. If BP remains high, promptly seek assistance from practitioners experienced in BP management. Refer patients experiencing symptoms of a hypertensive crisis (e.g., chest pain, shortness of breath) or hypertensive encephalopathy (e.g., sudden severe headache, visual disturbances, seizures, diminished consciousness or focal neurological deficit) immediately for emergency care.

Closely monitor blood pressure with concomitant use of SPRAVATO® with psychostimulants or monoamine oxidase inhibitors (MAOIs) (see Drug Interactions).

SPRAVATO® is available only through a restricted program under a REMS (see Warnings and Precautions).

SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS)

SPRAVATO® is available only through a restricted program under a REMS called the SPRAVATO REMS (see Warnings and Precautions).

Important requirements of the SPRAVATO REMS include the following:
- Healthcare settings must be certified in the program and ensure that SPRAVATO® is:
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  - Administered by patients under the direct observation of a healthcare provider and that patients are monitored in a healthcare setting for at least 2 hours after administration of SPRAVATO® (see Dose and Administration (2.4) in Full Prescribing Information).
  - Pharmacies must be certified in the REMS and must only dispense SPRAVATO® to healthcare settings that are certified in the program.

Further information, including a list of certified pharmacies is available at www.SPRAVATOREMS.com or 1-855-382-4022.

SPRAVATO® (esketamine) nasal spray, CIII

in risk of suicidal thoughts and behaviors among drugs, but there was an increased risk identified in young patients for most drugs studied. There were differences in absolute risks across the various indications, and behaviors across the different indications, with the highest incidence in patients with major depressive disorder (MDD). The drug-placebo differences in the number of cases of suicidal thoughts and behaviors per 1000 patients treated are provided in Table 1.
Table 2: Adverse Reactions Occurring in ≥2% of TRD Patients Treated with SPRAVATO + Oral AD at Any Dose and at a Greater Rate than Patients Treated with Placebo Nasal Spray + Oral AD

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Placebo + Oral AD (N=34)</th>
<th>Placebo + Oral AD (N=222)</th>
<th>SPRAVATO + Oral AD (N=346)</th>
<th>SPRAVATO + Oral AD (N=222)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>12 (3%)</td>
<td>0 (0%)</td>
<td>21 (6%)</td>
<td>15 (6%)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>19 (5%)</td>
<td>1 (0.5%)</td>
<td>34 (10%)</td>
<td>13 (6%)</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood pressure increased*</td>
<td>36 (10%)</td>
<td>6 (3%)</td>
<td>97 (28%)</td>
<td>24 (11%)</td>
</tr>
<tr>
<td>Systolic blood pressure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥110 mmHg</td>
<td>13 (4%)</td>
<td>1 (0.5%)</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>≥60 mmHg decrease</td>
<td>6 (2%)</td>
<td>1 (0.5%)</td>
<td>15 (4%)</td>
<td>3 (1%)</td>
</tr>
<tr>
<td>≥20 mmHg decrease</td>
<td>1 (0.3%)</td>
<td>1 (0.5%)</td>
<td>7 (2%)</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>≥180 mmHg</td>
<td>9 (3%)</td>
<td>0 (0%)</td>
<td>6 (2%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Diastolic blood pressure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥90 mmHg</td>
<td>26 (6%)</td>
<td>2 (1%)</td>
<td>24 (7%)</td>
<td>3 (2%)</td>
</tr>
<tr>
<td>≥40 mmHg increase</td>
<td>12 (4%)</td>
<td>1 (0.5%)</td>
<td>3 (1%)</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>≥150 mmHg decrease</td>
<td>9 (3%)</td>
<td>0 (0%)</td>
<td>1 (0.3%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>≥25 mmHg decrease</td>
<td>6 (2%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>101 (29%)</td>
<td>17 (8%)</td>
<td>259 (74%)</td>
<td>49 (22%)</td>
</tr>
<tr>
<td>Dysarthria*</td>
<td>15 (4%)</td>
<td>0 (0%)</td>
<td>35 (10%)</td>
<td>10 (4%)</td>
</tr>
<tr>
<td>Dysesthesia*</td>
<td>66 (19%)</td>
<td>30 (14%)</td>
<td>112 (32%)</td>
<td>29 (13%)</td>
</tr>
<tr>
<td>Headache*</td>
<td>70 (20%)</td>
<td>38 (17%)</td>
<td>140 (40%)</td>
<td>36 (16%)</td>
</tr>
<tr>
<td>Hypoesthesia*</td>
<td>63 (18%)</td>
<td>5 (2%)</td>
<td>74 (21%)</td>
<td>15 (7%)</td>
</tr>
<tr>
<td>Lethargy*</td>
<td>37 (11%)</td>
<td>12 (5%)</td>
<td>71 (20%)</td>
<td>20 (9%)</td>
</tr>
<tr>
<td>Sedation*</td>
<td>50 (14%)</td>
<td>2 (1%)</td>
<td>78 (22%)</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>Tremor</td>
<td>12 (3%)</td>
<td>2 (1%)</td>
<td>28 (8%)</td>
<td>4 (2%)</td>
</tr>
</tbody>
</table>

Table 3: Incidence of Sedation (MOAA/s <5) in Double-blind, Randomized, Placebo-controlled Fixed-Dose Study with Patients ≥65 Years of Age and Double-blind, Randomized, Placebo-controlled Fixed-dose Study with Patients <65 Years

<table>
<thead>
<tr>
<th>Group</th>
<th>Patients ≥65 years</th>
<th>Patients &lt;65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo + Oral AD</td>
<td>56 mg</td>
<td>84 mg</td>
</tr>
<tr>
<td>Placebo + Oral AD</td>
<td>28 mg</td>
<td>84 mg</td>
</tr>
<tr>
<td>SPRAVATO + Oral AD</td>
<td>56 mg</td>
<td>84 mg</td>
</tr>
<tr>
<td>SPRAVATO + Oral AD</td>
<td>28 mg</td>
<td>84 mg</td>
</tr>
</tbody>
</table>

Table 4: Incidence of Dissociation (CADSS total score >4) in Double-blind, Randomized, Placebo-controlled Fixed-dose Study with Patients ≥65 Years

<table>
<thead>
<tr>
<th>Group</th>
<th>Patients ≥65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo + Oral AD</td>
<td>56 mg</td>
</tr>
<tr>
<td>Placebo + Oral AD</td>
<td>28 mg</td>
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<td>SPRAVATO + Oral AD</td>
<td>56 mg</td>
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<tr>
<td>SPRAVATO + Oral AD</td>
<td>28 mg</td>
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Table 5: Increases in Blood Pressure in Double-blind, Randomized-controlled Short-term Trials of SPRAVATO + Oral AD Compared to Placebo Nasal Spray + Oral AD in the Treatment of TRD

<table>
<thead>
<tr>
<th>Group</th>
<th>Patients ≥65 years</th>
<th>Patients &lt;65 years</th>
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<tbody>
<tr>
<td>Placebo + Oral AD</td>
<td>56 mg</td>
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<td>SPRAVATO + Oral AD</td>
<td>28 mg</td>
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Table 6: Incidence and Severity of Nausea and Vomiting in Double-blind, Randomized-controlled, Fixed-dose Study

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Patients ≥65 years</th>
<th>Patients &lt;65 years</th>
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<tr>
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<td>SPRAVATO + Oral AD</td>
<td>28 mg</td>
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Table 7: Incidence of Nausea and Vomiting in Double-blind, Randomized, Placebo-controlled Fixed-dose Study with Patients ≥65 Years of Age and Double-blind, Randomized, Placebo-controlled Fixed-dose Study with Patients <65 Years

<table>
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<tr>
<th>Reaction</th>
<th>Patients ≥65 years</th>
<th>Patients &lt;65 years</th>
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<tbody>
<tr>
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<td>SPRAVATO + Oral AD</td>
<td>28 mg</td>
<td>84 mg</td>
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</table>
Esketamine is present in human milk. There are no data on the effects of SPRAVATO on the breastfed exposure (AUC) that was 0.07-times the AUC exposure at MRHD of 84 mg/day.

≥ 15 mg/kg/day. In addition, a dose-dependent delay in the age of attainment of Preyer response reflex 0.5, and 0.7 times the MRHD of 84 mg/day, respectively. Maternal toxicity was observed at doses ≥ 30mg/kg/day, which were maternally toxic. The NOAEL for skeletal malformations was associated with a plasma esketamine exposure (AUC) that was intranasally from gestational day 6 to 18 at doses of 10, 30, and 100 mg/kg/day. The high dose was administered twice-weekly. At the end of four days, there was no statistically significant difference between groups on the primary efficacy endpoint of change from baseline to Week 4 on the Montgomery-Asberg Depression Rating Scale (MADRS).

Based on published data, when female monkeys were treated intravenously with racemic ketamine administration of esketamine to pregnant rats during pregnancy and lactation at exposures that were similar to those at the MRHD resulted in a delay in sensorimotor development in pups during the preweaning period.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Clinical Considerations

Drug/Other/Alcohol/Maternal and/or Fetal Risk

A prospective, longitudinal study followed 201 pregnant women with a history of major depressive disorder who were euthymic and taking antidepressants at the beginning of pregnancy. The women who discontinued antidepressants during pregnancy were more likely to experience a relapse of depression. The range of plasma esketamine exposure (AUC) was 12-times the AUC exposed to the MRHD of 84 mg/day.

In pregnant rabbits, racemic ketamine was administered to a pregnant woman being treated with SPRAVATO, treatment with esketamine should be discontinued and the patient Spontaneous abortion was observed at dose levels in the third trimester of pregnancy, neuronal cell death was observed in the developing brain of the offspring. There are no data on pregnancy exposure in primates corresponding to periods prior to the third trimester in humans (See Use In Specific Populations).

In an intraperitoneal reproduction study in rabbits, skeletal malformations were noted at maternally toxic doses when ketamine was intranasally administered with a No Observed Adverse Effect Level (NOAEL) at estimated esketamine exposures 0.3 times the exposures at the maximum recommended human exposure (MRHD) of 84 mg/day. In addition, intranasal administration of esketamine to pregnant rats during pregnancy and lactation at exposures that were similar to those at the MRHD resulted in a delay in sensorimotor development in pups during the preweaning period and a decrease in motor activity in the post-weaning period.

The est
Opening Up

This month’s Special Report looks at preventing premature mortality, one of medicine’s noble goals. The US has made progress in this endeavor via education and awareness campaigns. Unfortunately, we still have a long way to go in preventing premature mortality, as psychiatrists can sadly attest. Suicide continues to be among the top 10 causes of death in this country, and the opioid epidemic has put the spotlight on the addiction woes that cripple the country.

Patients with psychiatric illness face additional challenges resulting in unique morbidity and mortality issues. Studies have estimated shorter life expectancy—by as many as 20 years—for patients with mental illness. The literature on premature mortality originally focused on patients with schizophrenia, but data now support increased mortality associated with attention-deficit hyperactivity disorder, obsessive compulsive disorder, personality disorders, and mood and anxiety disorders. Accidents, lifestyle, socioeconomic, and limited access to care impact lifespan, despite advances in diagnosis and treatment for psychiatric disorders. The articles in this Special Report provide a glimpse into what can be else done to reduce premature mortality.

It is no coincidence that this Special Report falls in the midst of our fight against the coronavirus. As medical health care professionals fight the virus head-on in hospital rooms across the country, psychiatry continues to be the voice of reason and calm. In the last issue, Psychiatric Times explored resiliency. In this issue, we take a closer look at the enemy and our responses. Editor Emeritus Ron Pies, MD, eloquently discusses the virus’s psychological assault and provides tips for healing the soul during this unprecedented time. Meanwhile, Greg Eghigian, PhD, ponders lessons learned—and not learned—from last century’s flu pandemic. And, as the government begins to consider reopening the country, Sheldon Preskorn, MD, explores how we can prepare to ensure the safest return to normalcy possible.

As we consider the most vulnerable, this issue of Psychiatric Times discusses other matters that affect your patients. From understanding recovery in depression to special issues for patients with substance use disorders undergoing surgery, you are sure to find practical tips and useful information to help you help your patients.

Stay well and safe!

Mike Hennessy Sr
Chairman and Founder, MJH Life Sciences

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FROM THE EDITOR

COVID-19: The Long, Slow Recovery

John J. Miller, MD  Editor in Chief

F irst and foremost, we at Psychiatric Times send our thoughts, prayers, and best wishes to all. This is truly a global event that is impacting all of us in some meaningful way. As I write this on April 8th, in the US there are officially more than 400,000 cases of COVID-19, and there have been more than 14,000 deaths. COVID-19 is currently ravaging through all 50 states, with half of the documented cases in just 2: New York and New Jersey. The country continues to grapple with a significant shortage of personal protective equipment and ventilators, and the national stockpile is now depleted.

My flight home from Denver to Boston on March 13th feels like forever ago. Even then the airports were eerily quiet, and an occasional traveler was wearing a mask. Arriving in Boston, my home airport where I spend a great deal of time, a heaviness filled the air of the terminal as travelers scurried about, everyone preoccupied and subdued. I was naively unaware of the impending catastrophic health crisis that had already seeded our country and was about to blossom into a life changing pandemic, the likes of which I had previously only read about in medical textbooks.

“I interestingly and appropriately, the narrative has become one of the US being at war with COVID-19.”

Today I saw a photograph that was simultaneously surreal and anticipated: a refrigerated truck parked next to a hospital in NY with the back door wide open as a recently deceased person wrapped in white sheets was being carried inside. The truck was lined with a 2 x 4 framed scaffolding built along each inside wall, with sheets of plywood serving as shelves in a makeshift morgue, each shelf wide enough and long enough to hold one person. Sadly, every shelf held a recent victim of COVID-19, wrapped in white sheets, with no time frame in place to allow for the preparation of a farewell ceremony. As disturbing as this photo was, I am more disturbed by the lack of a national integrated and aggressive response to this pandemic in our great country. I realize it is easy for me to play Monday morning quarterback, but as I learn more and more about the information available to us in December, January, and February, I am befuddled by the inaction, lack of preparedness, and the minimizing of our national vulnerability to this pandemic as COVID-19 established its deep roots prior to emerging to assault us. Remarkably, and against the strong recommendation of all of the experts in the fields of infectious disease, epidemiology, and public health, today there re-
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ADDRESSING PREMATURE MORTALITY

Living With Serious Mental Illness

Benjamin Druss, MD, MPH

This Special Report on premature mortality provides a review of current research as well as clinical and policy innovations to improve the physical health of patients with serious mental illness. Living with a mental illness is all too often accompanied by poverty and social disadvantage, stigma, adverse health behaviors, and poor access to medical care. Taken together, these factors contribute to shortened life spans and reduced quality of life. The articles in this Special Report present approaches for addressing many of the preventable causes of poor health and mortality in this patient population.

Numerous studies from the general medical literature have demonstrated the benefits of exercise in increasing physical fitness, promoting weight loss, optimizing cardiovascular health, and improving mood. As Martino Belvederi Murri, MD, and Panteleimon Ekkekakis, PhD, note, while the literature among individuals with major depression is more limited, there is every reason to expect that exercise would confer similar—if not greater—benefits as those seen in general populations, given the elevated risks. As long as a regimen is appropriate to a patient’s fitness level—150 minutes of moderate activity is a good starting point for most individuals—exercise provides one of the most favorable risk-to-benefit profiles of any treatment that is currently available. The authors highlight the value of focusing on enjoyment as a strategy to engage patients in initiating and adhering to exercise programs.

The social determinates of health have been referred to as the “causes of causes” of preventable mortality. As Lilanthi Balasuriya, MD, Eliza Buelt, MD, and Jack Tsai, PhD highlight in their overview, individuals with serious mental illness who also experience homelessness are at extremely high risk. For these patients, stigma, medical comorbidity, and challenges in meeting basic daily needs can lead to adverse physical health outcomes and early death. Successfully addressing the housing and basic economic needs of this population can provide a foundation for engagement in mental and general medical services.

Finally, these interventions require federal and state policies to support their broader uptake in clinical practice. Emma E. McGinty, PhD, MS, and Gail L. Daumit, MD, MHS highlight how a number of legislative and regulatory interventions beginning with the Affordable Care Act have increased opportunities to facilitate the more widespread adoption of integrated services for individuals with serious mental illness. The majority of these innovations have occurred within Medicaid, the most important funder of services for this population.

We hope that this Special Report provides you with an overview of the impressive and growing array of interventions available to improve the physical health of individuals with serious mental illness. As you read, please think about ways in which you can incorporate these strategies into your practice. By doing so, you can play an important role in helping to improve the duration and quality of your patients’ lives.

Dr Druss is Professor (Graduate Faculty), Rosalynn Carter Chair in Mental Health, School of Public Health: Health Policy and Management, Emory University, Atlanta, GA. He reports no conflicts of interest concerning the subject matter of this Special Report.

Special Report Chairperson
Benjamin Druss, MD, MPH

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Physical Exercise: Lowering Mortality Among Patients With Depression
Martino Belvederi Murri, MD, and Panteleimon Ekkekakis, PhD

Psychosocial Interventions To Reduce Premature Mortality
Andrea Fioritto, MD, PhD, Gaia Sampogna, MD, Mario Luciano, MD, PhD
Early Mortality in SMI
Federal and State Policy Initiatives

Emma E. McGinty, PhD, MS, and Gail L. Daumit, MD, MHS

People with serious mental illnesses (SMIs) like schizophrenia, bipolar disorder, and major depressive disorder pass away 10 to 20 years prematurely relative to the overall population.1,2 This excess mortality is driven by cardiovascular disease and other medical conditions including cancer, liver disease, chronic lung disease, and HIV/AIDS. The high burden of these conditions among people with SMI is driven by multiple factors, including the metabolic adverse effects of psychotropic medications. Social risk factors for chronic disease include poverty, unemployment, housing instability, and criminal justice involvement—all of which are overrepresented among people with SMI.3 Cognitive and communication impairments experienced by some people with SMI, as well as low social support, can present challenges for patient-provider communication, shared decision-making, and navigation of complex health care systems.

Effective interventions to address medical conditions in the population with SMI exist. Evidence-based screening, diagnosis, and treatment of chronic medical conditions is largely the same for people with versus without SMI, and tailored behavioral interventions have been shown in clinical trials to support weight loss and tobacco smoking cessation in SMI.2 Clinical trial evidence also shows that supportive employment and housing programs tailored to SMI can reduce unemployment and housing instability, important social determinants of chronic disease among people with SMI and the overall population. Many people with SMI, particularly the 70% covered by Medicaid, do not receive guideline-concordant medical care.4 Moreover, tailored health behavior and supportive employment and housing interventions have not been widely implemented in the US.

The role of state and federal policy

State and federal policies have a key role in scaling up evidence-based interventions to prevent and treat the medical conditions driving premature mortality in SMI. Policies at multiple levels, ranging from federal laws to clinic-level policies, delineate the rules by which interventions are financed and delivered. In this article, we focus on federal and state-level policy initiatives.

To date, federal and state policy efforts have predominantly focused on supporting integration of primary care and specialty mental health services for people with SMI. The collaborative care model of integrated care can improve both physical and mental health care quality and outcomes. Collaborative care is a primary care-based model in which primary care physicians collaborate with a mental health care manager and a psychiatric consultant to proactively identify, treat, and monitor mental illness.5 The evidence supporting collaborative care is strongest for depression, although findings from limited clinical trials suggest this model may also benefit people with schizophrenia and bipolar disorder.6 Specialty mental health-based integrated care models that operate in a manner conceptually similar to collaborative care but with the specialty mental health program as the locus of care, have the potential to improve quality of medical care and physical health outcomes for people with SMI.7 Insurance reimbursement challenges have been cited as a major barrier to adoption of integrated care models.8 Three federal and state policy initiatives are designed to address insurance reimbursement challenges: Centers for Medicare and Medicaid (CMS) behavioral health integration billing codes, the Affordable Care Act Medicaid health home waiver, and removal of same-day billing laws (Table).

CMS behavioral health integration billing codes

CMS introduced four new billing codes for behavioral health (mental health and substance use) integration services in 2017. Three of these codes reimburse services provided within the collaborative care model and the fourth code reimburses services provided under other integrated care models. These codes can be billed by primary care or other general medical clinicians. To be eligible to bill the collaborative care codes, practices must be able to demonstrate that they have implemented the core elements of the collaborative care model.

The elements of the model include: a care team consisting of a general medical clinician, a behavioral health care manager, and a psychiatric consultant; use of validated instruments to identify and monitor mental illness; measurement-based treatment that uses a registry to monitor and track adjustments to patients’ care; and regular case reviews.7 To bill for care management that is not embedded in collaborative care, practices must demonstrate that their integrated care model includes systematic patient assessment and monitoring using validated instruments and behavioral health care planning, monitoring, and coordination.

These behavioral health integration billing codes have been adopted by Medicare and some state Medicaid and commercial plans. However, Cross and colleagues’ found that only 0.1% of Medicare beneficiaries with a mental health or substance use disorder diagnosis received behavioral health integration services billed with these codes from 2017 to 2018. The majority of behavioral health integration codes were billed for general care management services as opposed to collaborative care services. While use of these codes may increase over time, these findings suggest that the primary care and other general medical practices allowed to bill these codes face challenges meeting the staffing, infrastructure, and workflow requirements, particularly for the intensive collaborative care model.

ACA Medicaid health home waiver

The Patient Protection and Affordable Care Act (ACA) of 2010 included a provision that allowed state Medicaid programs to apply for a waiver to use Medicaid funds to create health homes. The homes were for high-cost, high-need subpopulations of Medicaid beneficiaries, including but not limited to people with SMI. In practice, this waiver allowed states to bill Medicaid for 6 previously non-billable services: comprehensive care management; care coordination; health promotion; transitional care; individual/family support; and referral to community and social support services. As of November 2019, 17 states and the District of Columbia had used the waiver to implement health home programs for people with SMI. Of these 18 total programs, 10 are specialty mental health care-based and 8 allow either primary care or specialty mental health settings to implement health homes for Medicaid beneficiaries with SMI.9 Early research on waiver-established health homes suggest limited benefits. For example,

Table. Policy initiatives designed to address insurance barriers to integrated care delivery

<table>
<thead>
<tr>
<th>Policy</th>
<th>Purpose</th>
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<tr>
<td>Centers for Medicare and Medicaid behavioral health integration billing codes</td>
<td>Allow general medical providers to bill Medicare and other payors for behavioral health integration services, such as behavioral health care management</td>
</tr>
<tr>
<td>Affordable Care Act Medicaid Health Home Waiver</td>
<td>Allows state Medicaid programs to create health home programs for beneficiaries with serious mental illness and to bill Medicaid for services including comprehensive care management, care coordination, health promotion, transitional care, individual/family support, and referral to community and social support services</td>
</tr>
<tr>
<td>Removal of same day billing laws</td>
<td>The federal 21st Century Cures Act of 2016 clarified that federal law does not prohibit organizations from billing Medicaid for both a primary care service and a mental health service delivered to a single patient in the same day; but, same-day Medicaid billing prohibitions (a barrier to integrated care) still persist in many states</td>
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Maryland’s waiver was associated with increased rates of cancer screening but had no effects on receipt of guideline-recommended cardiovascular care for participants with SMI.10,11

**Same-day billing laws and requirements**

The federal 21st Century Cures Act of 2016 clarified that federal law does not prohibit organizations or individual clinicians from billing Medicaid for both primary care service(s) and mental health service(s) delivered to a single patient on the same day. Prior to this clarification, the federal Medicaid statute was frequently interpreted as prohibiting same-day billing. Despite the clarification at the federal level, the same-day billing prohibition persists in many state laws.

In the most recent comprehensive assessment of state Medicaid laws that was conducted in 2015, 24 state Medicaid programs prohibited same-day billing by some or all settings and provider types.12 Since the clarification of federal law in 2016, some states have introduced and passed legislation to do away with the same-day billing prohibitions in state Medicaid laws. Medicaid is the largest payer of mental health services in the US, and same-day billing prohibitions have been cited as an important barrier to delivery of integrated care for people with SMI. No studies have assessed the effects of eliminating same-day billing requirements on care quality or health outcomes among people with SMI.

**Federal and state policy gaps and next steps**

To date, federal and state policies have focused on insurance billing for integrated care. However, new behavioral health integration billing codes have had low uptake and early research shows that the Medicaid health home waiver had limited effects on quality of physical health care for people with SMI. These findings suggest that the existing billing policies are insufficient to support adoption and high-fidelity implementation of the complex integrated care models that improved the physical health conditions driving premature mortality in SMI as shown in clinical trials.

There are many challenges to implementing integrated care for patients with SMI. One-sided financial incentives, lack of accountability, and carved-out financing of general medical and specialty mental health services are barriers to implementation. The behavioral health integration billing codes and most Medicare-Medicaid home waiver reinsurance only one side of the general medical/ specialty mental health duo. For example, the entire reimbursement for the collaborative care billing codes goes to the billing general medical provider, despite the central roles of the behavioral health care manager and psychiatric consultant on the care team.

Alternative financing arrangements, such as bundled payments or hub-and-spoke models, may alleviate this issue. Lack of accountability for physical health outcomes in SMI among either medical or mental health providers can impede care integration. Accountability could be improved through models tying payment to performance metrics, particularly models such as accountable care organizations, which can be structured so that both general medical and specialty mental health providers are subject to the same incentives.

Finally, carve-out of mental health insurance benefits so that such benefits are administered by a different organization than general medical benefits may obstruct delivery of integrated care. Carve-outs are particularly common in Medicaid, and many states are considering policies to integrate, or carve-in, mental health and general medical benefits. The effects of such policies on quality of care and health outcomes among people with SMI have not been rigorously studied.

In addition to these financing challenges, insufficient health information technology (IT) infrastructure and provider training have been identified as barriers to integrated care in multiple studies. Shared electronic medical records across general medical and specialty mental health care providers as well as electronic patient registries that track patients’ health indicators and needed/used services are core components of effective integrated care models but lacking in many settings. Policy models, such as the federalHITECH Act, could be used as the basis for new policies specifically focused on incentivizing health IT infrastructure for integrated care. Siloed primary care and specialty mental health training could be addressed through policies requiring incorporation in medical training curricula.

Critically, better integration of specialty mental health and general medical care for people with SMI is not enough to reduce premature mortality in the SMI patient population. Policies must also support delivery of effective health behavior interventions and address social determinants of health.

Obesity is a major driver of excess mortality in SMI, and tailored behavioral interventions have been shown to lead to clinically significant weight loss.14,15 Obesity is a major driver of excess mortality in SMI, and tailored behavior interventions have been shown to lead to clinically significant weight loss in this group. Financing strategies to support the weight management and group exercise sessions included in such interventions are needed. Medicare’s reimbursement strategies for its Diabetes Prevention Program sets a precedent for coverage of weight loss interventions that could be adapted.

Accreditation policies could be used to require health care or other types of organizations (eg, psychiatric rehabilitation programs) to have an on-staff trainer certified to deliver tailored behavioral weight loss interventions for SMI. Policies addressing the social determinants contributing to premature mortality from cardiovascular disease and other medical conditions in SMI are also needed. While some policies could be society-wide (eg, expansions of federal cash assistance or nutrition benefits policies) other policies could target SMI specifically. For example, federal and state laws can allow resources to evidence-based supportive housing and employment programs.

**REFERENCES**

The Never-Ending Loop: Homelessness, Psychiatric Disorder, and Mortality

Lilanthi Balasuriya, MD, Eliza Buelt, MD, and Jack Tsai, PhD

With a lifetime and 1-year prevalence of homelessness in the US population found to be 4.2% and 1.5%, respectively, and the total number of people who experience some form of homelessness over the course of a year is estimated to be 2.5 to 3.5 million individuals, homelessness is a serious problem. Mental illness, in addition to adverse childhood experiences and substance use, are risk factors for homelessness. Although estimates of the prevalence of mental illness vary, studies looking at mental illness in the homeless population have generally found a high prevalence of mental disorders. The most common disorders may be alcohol and drug dependence (Figure). There is clearly a link between psychiatric disorders and homelessness; disentangling the nature of this relationship is complicated. Regardless of mental health status, people who are homeless generally have a history marked by poverty and social disadvantage, including considerable poverty in childhood and lower levels of education, and they are likely to belong to an ethnic minority. Mental illness had preceded homelessness in about two-thirds of the cases.

Homelessness in turn has been associated with poorer mental health outcomes and may trigger or exacerbate certain types of disorders. For example, findings indicate that homelessness is related to higher levels of psychiatric distress and lower perceived levels of recovery from serious mental illness. Impact of homelessness on premature morbidity Homelessness is associated with substantially increased morbidity and mortality from many causes including infectious diseases, cardiovascular disease, cancer, unintentional injury, suicide, homicide, and substance use. The unsheltered homeless have an even greater burden, with higher mortality than sheltered homeless. Among a large group of homeless adults in Boston, disparities in deaths attributed to tobacco, alcohol, and drug use accounted for almost 60% of the mortality gap between homeless adults and the general population. In accordance with findings in the general population, there also is a strong association between psychiatric disorders and suicide in homeless populations. The prevalence of suicidal ideation and suicide attempts is extremely high in mentally ill homeless persons. In a large sample of homeless adults with serious mental illness, almost 8% reported a suicide attempt within the previous 30 days. The highest rates of suicidal ideation and suicide attempts were in the group aged 30 to 39 years, in contrast to the general population with peaks of suicidality in young adults and the elderly.

Challenges in accessing psychiatric care General guidelines were created for primary care physicians working with the homeless in the US in 2004, and in 2018 the Street Medicine Institute began publishing international clinical guidelines targeting the primary care needs of specifically street-dwelling homeless individuals. Unfortunately, similar guidelines for psychiatrists working with the street-homeless population are still lacking. When thinking about challenges to accessing care, it is critical to understand the heterogeneous nature of homelessness. The structures of support and oppression for each individual may vary significantly based on the surrounding community and resources.

Fundamental basic needs. Having mental health care needs itself may be a barrier to accessing psychiatric care. Motivation to make and attend appointments may be low if an individual is suffering from depression, amotivation, anhedonia, anxiety, paranoia, hypervigilance, history of trauma, substance use, or negative past experiences with the health care system related to mental illness. Moreover, homeless people may have experienced greater trauma, have

Many homeless people have special issues affecting interactions with the health care system and health literacy. These issues may include traumatic brain injuries, and cognitive impairment—all of which may affect interactions with the health care system and health literacy. Similarly, comorbid medical illness may be a barrier, as these needs may take priority over psychiatric care. Many homeless people have medical issues such as diabetes, hypertension, tuberculosis, and ischemic heart disease. These issues often necessitate resources such as intensive case management and assertive outreach to maintain treatment.

Transportation. Homeless individuals often lack adequate transportation; consequently they are unable to do the necessary tasks involved in care—getting laboratory work completed, picking up medications, and getting to mental health appointments. Public transportation may not always be a solution, as it often requires multiple transfers, can be unreliable, and, in some areas, may be limited or may not exist. Most significantly, homeless individuals may lack the resources to pay for fares.

Cost of care. For persons who are homeless, small expenses can be a significant barrier to accessing mental health care. Moreover, they may not be cognizant of resources available to them through Medicaid or the

### Table 1. Solutions to addressing barriers to mental health care in homeless populations: care options

<table>
<thead>
<tr>
<th>Models of care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street psychiatry</td>
</tr>
<tr>
<td>- Providing care directly to homeless individuals through outreach and mobile services on the streets; brings services directly to the patient</td>
</tr>
<tr>
<td>Collaborative, integrated mental health care in primary care settings</td>
</tr>
<tr>
<td>- Evidence-based systematic approach in which behavioral health providers deliver treatment in primary care settings; patients may be accepting when paired with medical care</td>
</tr>
<tr>
<td>Veterans Administration Homeless Models (H-PACT)</td>
</tr>
<tr>
<td>- Clinics with multidisciplinary staff providing a large range of integrated services (eg, family support, housing, income)</td>
</tr>
<tr>
<td>- This model reduces emergency department use and hospitalizations</td>
</tr>
<tr>
<td>- Five key tenants:</td>
</tr>
<tr>
<td>1. Open access to care, flexible scheduling/walk-in options, with outreach in shelters, on the street, or in community locations;</td>
</tr>
<tr>
<td>2. Integrated mental health care with primary care (either in the same location or in close proximity);</td>
</tr>
<tr>
<td>3. Continuous health care management partnered with local community organizations;</td>
</tr>
<tr>
<td>4. Continuous staff training;</td>
</tr>
<tr>
<td>5. Accountable data-driven processes</td>
</tr>
<tr>
<td>Support employment programs</td>
</tr>
<tr>
<td>- Emphasize rapid access to jobs while providing supportive services</td>
</tr>
<tr>
<td>ACT teams</td>
</tr>
<tr>
<td>- Provide intensive community support using case management and outreach (using a shared caseload model); ACT may reduce psychiatric symptoms and improve overall housing outcomes</td>
</tr>
<tr>
<td>Intensive case management</td>
</tr>
<tr>
<td>- Provide access to/coordination of medical and psychosocial services; includes assessment, planning, connection to services, and ongoing monitoring; can reduce hospital use when paired with supported housing; when paired with coordinated services, can reduce substance use</td>
</tr>
<tr>
<td>Team-based approaches</td>
</tr>
<tr>
<td>Multidisciplinary approach</td>
</tr>
<tr>
<td>- Includes case managers, social workers, housing specialists, employment specialists, peer support specialists, medical and psychiatric providers; social workers ensure equitable access to services, assist with trauma-informed services and other resources</td>
</tr>
<tr>
<td>Patient navigators</td>
</tr>
<tr>
<td>- Assist with scheduling/appointments/care plans; identify needs and barriers to the treatment plan; provide emotional support; build trust to overcome stigma; assist with patient education; increase patient’s ability to self-manage</td>
</tr>
<tr>
<td>Housing and rehabilitation services</td>
</tr>
<tr>
<td>- Are familiar with specialized housing options for those with severe mental illness, comorbid substance use, or other special populations</td>
</tr>
<tr>
<td>Recovery and holistic trauma-informed approaches</td>
</tr>
<tr>
<td>Recovery model</td>
</tr>
<tr>
<td>- Meets patients on their own turf and works to provide personalized, patient-centered care</td>
</tr>
<tr>
<td>Holistic and trauma-informed patient approach</td>
</tr>
<tr>
<td>- Provides basic human needs such as socks, a blanket, or food; focuses on the whole patient; trauma-informed care</td>
</tr>
</tbody>
</table>

### Table 2. Solutions to addressing barriers to mental health care in homeless populations: special issues

<table>
<thead>
<tr>
<th>Addressing special populations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concomitant substance use and mental health care needs</td>
</tr>
<tr>
<td>- Addresses comorbid substance use; ranges from abstinence to harm reduction; harm reduction models include contingency management and supervised injection centers</td>
</tr>
<tr>
<td>Women</td>
</tr>
<tr>
<td>- Screen for/address housing instability, given that it may be an issue in intimate partner violence</td>
</tr>
<tr>
<td>Families</td>
</tr>
<tr>
<td>- Weekly health screening teams educate about prevention, nutrition, wellness, and screen for mental health conditions</td>
</tr>
<tr>
<td>Children</td>
</tr>
<tr>
<td>- Refer to services that address developmental issues; encourage routine wellness and prevention standards (eg, well-child visits, immunizations, screening for lead-poisoning)</td>
</tr>
<tr>
<td>Communication barriers</td>
</tr>
<tr>
<td>Technology/location</td>
</tr>
<tr>
<td>- Smart-phones-based interventions may improve health care delivery; mobile apps can increase access to care management and crisis interventions</td>
</tr>
<tr>
<td>- Ascertain schedules for certain days to plan future visits (eg, soup kitchens, train stations, libraries)</td>
</tr>
<tr>
<td>Language barriers</td>
</tr>
<tr>
<td>- Improve accessibility of language services when applicable</td>
</tr>
<tr>
<td>Health literacy</td>
</tr>
<tr>
<td>- Providing a non-judgmental atmosphere; use multiple means of delivering information</td>
</tr>
<tr>
<td>Continuity of care and coordinating care efforts</td>
</tr>
<tr>
<td>- Operate in a coordinated, collaborative, and supportive manner</td>
</tr>
<tr>
<td>Distrust of the health care system and stigma surrounding mental health care</td>
</tr>
<tr>
<td>Non-judgmental, patient-centered approach</td>
</tr>
<tr>
<td>- Shared decision-making and sustained continuity of care lead to trust and alliance</td>
</tr>
<tr>
<td>Staff training</td>
</tr>
<tr>
<td>- Ongoing training is essential</td>
</tr>
<tr>
<td>Policy solutions</td>
</tr>
<tr>
<td>Housing (eg, supported housing and transitional housing)</td>
</tr>
<tr>
<td>- Provide a continuum of options</td>
</tr>
<tr>
<td>Affordable housing models</td>
</tr>
<tr>
<td>- Provide safe and affordable low-income housing to stop the homelessness trajectory</td>
</tr>
<tr>
<td>Improved medical education</td>
</tr>
<tr>
<td>- Exposure and inclusion in medical school curriculum may result in attitudinal shifts toward homeless population</td>
</tr>
</tbody>
</table>

H-PACT, homeless patient aligned care teams; ACT, assertive community treatment.
Affordable Care Act.

Communication. Although some homeless adults and youth have access to cell phones, there is higher turnover of both phones and phone numbers, which can pose a barrier to consistent communication. Keeping a cell phone charged is a challenge for those without reliable access to electricity. Similarly, with lower internet use, homeless people are likely to have less access to important information, including care and resources. Language barriers may also affect access to care, particularly in limited resource settings.

Stigma and vulnerability. Stigma and discrimination continue against homeless individuals who also have mental health conditions. Setting health care goals may feel unattainable when pressing issues like basic survival are more salient. Homeless people with mental illness are also highly vulnerable to violence, with a reported lifetime incidence of 74% to 97% of violence being perpetrated against them.3 Psychiatric care may include prescribed psychotropics that affect alertness and pose a danger for someone who is at increased risk for victimization and violence. Furthermore, those who have a history with the legal system, re-integrating into society, parole, or strained finances may further impact their ability to acquire care.

Solutions

Briefly, solutions to the problem of homelessness include finding and implementing innovative models of care such as street psychiatry, integrated primary care, and mental health care models; Veterans Administration Homeless Models (Homeless Patient Aligned Care Teams H-PACT); and utilizing allies in the housing and rehabilitation services domains to find specialized housing opportunities. Taking a team-based approach, as well as the mental health care needs of homeless people are often complex and include many aspects of the social determinants of health. Multidisciplinary teams often include case managers, social workers, housing specialists, and vocational specialists. Medical students can also play an integral part in providing mental health care for homeless persons. (For a full and detailed list of potential solutions, please see Table 1 and Table 2.)

Recovery models and holistic, patient-centered, trauma-informed care are important as perceived discrimination, stigma, and distrust may be present. Communication barriers must also be addressed. This includes the advance development of plans regarding communications and finding creative ways to address potential barriers. Solutions should be tailored to fit the individual needs of the patient, including special needs that may occur around patients with dual diagnoses, women, families, and children. Although beyond the scope of this article, effective public policy can play a role in reducing homelessness.

Conclusion

Mental health conditions are highly prevalent in homeless populations. Although homeless individuals have higher mortality related to many causes, access to care is poorer than that for the general population. Further research and advocacy are needed to address the obstacles that homeless individuals encounter in accessing mental health care.

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Brief Psychotic Disorder Triggered by Fear of Coronavirus?

Elliott B. Martin Jr, MD

ack in July 2015, I wrote an article for Psychiatric Times titled “Managing Ebola: The Archaeology of a Disease” at the early stages of the burgeoning Ebola outbreak. I quoted Dr Adrian Hill, director of the Jenner Institute on vaccine research at Oxford: “We know there will be more outbreaks . . . Many viruses are lurking, and then there are going to be new viruses.” Here we are, only 5 years later, in the face of a pandemic, literally tracing the archaeology of a new disease.

As across the country, COVID-19 has become the primary focus of hospitals in my geographic region (the greater Boston area). At time of this writing, we have not yet been overwhelmed, but cases are growing. The psychological warfare waged by this virus has been overwhelming, both for patients and for health care providers. Patients are afraid of contracting and transmitting the virus. But health care workers, especially those used to a degree of predictability, seem to be susceptible to the stress of uncertainty and loss of control engendered by the COVID-19 pandemic.

Since the declaration of the pandemic, we have had several cases in our emergency department (ED) of what I have referred to as corona psychosis; 3 of which are presented here.

**CASE VIGNETTE 1**

“Dr Smith” is in her 40s; she is a practicing physician and administrator at a medical center. She was brought unwillingly to the ED by her husband. She had no prior documented psychiatric history and no significant medical history. She was almost 2 years out of the postpartum period. She did not drink alcohol or use other psychoactive substances. Her husband learned of staff concerns that she was becoming increasingly irritable and erratic at work, corresponding to the dramatic increase in media coverage of the coronavirus.

Upon psychiatric evaluation, Dr Smith’s speech was pressured and she was paranoid. Despite being asymptomatic, she convinced staff at another hospital to test her for the virus; the test came back negative. Dr Smith then became belligerently mistrustful of “the system,” refusing to believe she did not have the virus. Dr Smith became convinced that not only was she infected, but her family was infected as well. She believed that the Center for Disease Control had specifically targeted her and her family, transmitting the disease surreptitiously by means of drones while they slept.

As a result, Dr Smith had not slept for 3 days. She denied any hallucinations; she maintained good behavioral control throughout the drama. As people are more socially isolated—there will be an increase in these brief psychotic reactions. Based on these cases, anxiety (and perhaps depression) may be a contributing factor, the more acute symptoms responding (at least temporarily) well to lorazepam.

Although she was convinced that she would die within 2 weeks, Ms Rogers agreed to a voluntary admission to the psychiatric unit. She responded well to low-dose lorazepam in the ED. Her symptoms are currently being treated with a combination of an antipsychotic and an antidepressant medication.

**DISCUSSION**

Although this is a small series of patients from a single community hospital, I anticipate as this crisis unfolds—and as people are more socially isolated—there will be an increase in these brief psychotic reactions. Based on these cases, anxiety (and perhaps depression) may be a contributing factor, the more acute symptoms responding (at least temporarily) well to lorazepam.

What is otherwise striking is the commonality of all 3 patients working in hospitals at the forefront of the current crisis. I am concerned about the toll this crisis is taking on those in the trenches. There have been many subtle signs of stress vulnerability in providers, increasingly outward signs of a more generalized helplessness at the loss of control.

The anxiety is growing more palpable—both for patients and health care professionals—and I would urge everyone involved in these efforts to seek and to provide ongoing support for you and your teammates. As psychiatrists, we need to be attuned to colleagues as this drama unfolds. Like all crises, this too will end, and hopefully, these and other “corona psychosis” cases and anxiety will resolve.

The cases discussed here are composites and not meant to identify any one person—Ed.

**CASE VIGNETTE 2**

“Ms Rogers” is a nurse in her mid-40s. Married with teenage children, she had a history of depression and anxiety, as well as some concerns for a possible alcohol use disorder. She had no documented history of psychotic symptoms. She self-presented, complaining of worsening depression since the expanded media coverage of coronavirus. Ms Rogers noted she was feeling quite hopeless and suicidal.

Ms Rogers wrote a detailed suicide note to her husband, making it clear that she “was already in the process” of committing suicide. She explained, both in her note and to us, that she had infected herself with coronavirus with the intent of dying. She tested negative for the virus at an outside hospital. When asked how she had infected herself, Ms Rogers explained that she “went 24 hours without washing her hands.” She was not intoxicated, and there was no evidence of withdrawal.

Although she was convinced that she would die within 2 weeks, Ms Rogers agreed to a voluntary admission to the psychiatric unit. She responded well to low-dose lorazepam in the ED. Her symptoms are currently being treated with a combination of an antipsychotic and an antidepressant medication.

**CASE VIGNETTE 3**

“Ms Greene” presented while still working her shift as a hospital custodian. She was in her 40s, and married with grown children. Ms Greene worked on the hospital housekeeping staff for many years without incident. She had a long history of intermittent anxiety treated well by her primary care physician with minimal use of as-needed alprazolam.

Ms Greene was cleaning a patient’s room on the psychiatric unit when a nurse entered the next room, gloved, gloved, and masked, to perform a routine influenza/RSV swab on a different patient. Upon witnessing this, Ms Greene became convinced that she had contracted coronavirus. She became quite agitated, started pulling at her hair and shouting nonsensically in her native language. She could not be calmed down verbally, and she had to be escorted to the ED by hospital security.

Upon examination, there was no indication that Ms Greene was at increased risk of coronavirus; and she was asymptomatic. Due to Department of Public Health guidelines, therefore, she was not tested for coronavirus. She partially responded to lorazepam, but she remained delusional that she was “infected.” Family members took her home. Ms Greene has been on medical leave since then.

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Care of the Soul in the Time of COVID-19

“The reward of suffering is experience.” —President Harry S. Truman

In our profession, the term psyche is usually defined as “mind,” but the term’s history and etymology are more complex. The ancient Greek term psyche had a range of meanings, including mind, spirit, or soul. It is this last meaning that I want to explore in relation to the frightening pandemic we are now encountering.

A good deal has already been written regarding the possible psychiatric complications of the COVID-19 pandemic. For example, Drs Nidal Moukaddam and Asim Shah have rightly noted that:

On an individual level, [the pandemic] may differentially exacerbate anxiety and psychosocial-like symptoms as well as lead to non-specific mental issues (e.g., mood problems, sleep issues, phobia-like behaviors, panic-like symptoms).1

Less has been said regarding what I would call “the care of the soul” in the midst of this pandemic. I borrow the phrase from the classic work Care of the Soul (1992), by the psychotherapist and former Catholic monk Thomas Moore. Moore was heavily influenced by proponents of archetypal psychology, such as Carl Jung and James Hillman. Moore admits that defining the term soul is nearly impossible but tells us that it “…has to do with depth, value, relatedness, heart and personal substance.”2 In any case, Moore points out that when we discuss “the soul,” we are entering the realm of the sacred.

Moore sees “the great malady” of our age as “loss of soul”—a sweeping topic for another time. For now, I would like to suggest that—beyond unsettling our minds—the current pandemic also unsettles our souls in ways we are just beginning to understand. Just as the COVID-19 virus attacks the respiratory tract, the pandemic itself can assault the soul.

Here I identify 5 manifestations: impotence, grief, loneliness, mistrust, and displacement. After exploring these manifestations, I will suggest some ways by which we might care for our souls during these perilous times.

The 5-fold assault on the soul

Impotence. There are few states of the soul more difficult to bear than the feeling of powerlessness. This was painfully brought home by a woman in a small Italian town, whose husband, age 85, had just died from the coronavirus. Five days later, his body still lay in a coffin, as the local cemetery was closed and traditional funeral services were prohibited throughout the country. The man’s wife of 50 years struggled to explain her feelings. “It’s not anger,” she said. “It’s impotence in the face of this virus.”

Grief. Grief and its attendant rituals of mourning are expected and healthy adaptations to loss, as Cynthia Gephart, MD, MA, MPH, MSBE, DPS, and I discuss in the context of pastoral care. Grief differs substantially from major depressive disorder, although the two conditions may co-occur.3 Thus, it is perfectly understandable that those who have lost loved ones to the COVID-19 pandemic will feel deep and consuming grief.

But this pandemic may evoke grief on more levels than we are used to in our everyday life. For some, this multi-pronged attack may overwhelm our usual, adaptive mechanisms for handling grief. Writing in The New York Times, Michelle Goldberg put it this way: “There is a lot to mourn right now. Many...are mourning dead loved ones. People are mourning lost jobs, lost savings, lost security. Senior citizens in locked down nursing homes are mourning the loss of visitors. I’m lucky. I’m just mourning the city...So many of the pleasures and conveniences [of city life] have disappeared.”4 And, on a deeper level, I suspect that many of us are grieving the loss of what we imagined were our relatively safe, stable, and protected lives.

Loneliness. There is a cruel, soul-crushing paradox at work in this pandemic, as Frank Bruni observed. We are dealing with “…a psychological contradiction and emotional oxymoron that are peculiar to a pandemic. At the very moment when many of us hunger most for the reassurance of company and the solace of community, we’re hustled into isolation.”5 For those without family, friends, or a supportive community, the ensuing sense of loneliness—sometimes accompanied by feelings of abandonment—can be overwhelming. Although social connections via the internet are often helpful, they are no substitute for the embrace of a friend or loved one.

Mistrust. Drs Moukaddam and Shah identified one type of mistrust that can arise during infectious pandemics:

…a lack of trust in medical treatment and advances... During infectious pandemics, medical mistrust has been linked to conspiracy theories. In one US study, up to half of those surveyed endorsed belief in at least one health-related conspiracy theory.6

Furthermore, during pandemics, there is a strong tendency to scapegoat “the Other”—the stranger, the foreigner, the outcast. In this regard, we should recall that during the Black Death—the bubonic plague that killed one-third of the European population in the fourteenth century—Jews were maliciously blamed for spreading the plague by poisoning the wells.7

Let’s recall that the first stage of Erikson’s theory of psychosocial development is called “Trust vs Mistrust.”8 We may reasonably surmise that individuals who did not successfully negotiate this crucial stage will be especially vulnerable to strong feelings of mistrust during the present pandemic—but on some level, these feelings may affect most of us. (And, yes—there are sound reasons to be mistrustful in certain instances, eg, when dealing with scams aimed at exploiting others during the pandemic.)9

During the present pandemic, the mistrust that can afflict the soul may prove broader, deeper, and more in...
Thomas Moore points out, the soul is not grounded primarily in reason and logic; rather, “. . . it persuades more with desire than with reasonableness.”

Anxiety & Stress Disorders

Ditch the Quarantine: Healthy Options for Psychological Well-Being

Sharon Packer, MD


From Tragedy to Realism: The Role of Optimism in Pandemic Recovery

H. Steven Moffic, MD

https://www.psychiatrictimes.com/coronavirus/tragedy-realism-role-optimism—pandemic-recovery

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17. Friedman has observed, sometimes it is better to know we have not mastered the universe.”18


Special Issues for Patients With SUDs Undergoing Surgery
Advantages of Simultaneous Administration of Buprenorphine With Opioids

Gregory Alexander Acampora, MD

Given the mortality and morbidity burden of opioid use disorder, strategies to prevent further addiction are key goals among public health officials and clinicians. Nonetheless, there continue to be circumstances in which patients need adequate acute pain control. The perioperative phase is a vulnerable time for patients with opioid use disorders, but there is very little research on managing post-operative pain in these patients.

Meanwhile, the Substance Abuse and Mental Health Services Administration has made medication-assisted treatment (MAT) a priority to address the opioid problem. Emphasis was placed on buprenorphine as a novel office-based MAT with the introduction of the Suboxone, a combination buprenorphine/naloxone sublingual product available in a 4/1mg ratio.

Buprenorphine’s background

Early records indicate the sap from Papaver somniferum (opium poppy) was used for both analgesic and euphoric effects. The poppy plant accumulates several benzylisoquinoline alkaloids including morphine, codeine, and thebaine. Thebaine is the raw material for hydrocodone, hydrocodone including morphine, codeine, and thebaine. Thebaine is the raw material for hydromorphone, oxycodone, and other semisynthetic opiates.

To separate analgesia from euphoria, synthetic opioids were created. Unfortunately, with more analgesic potency also came increased abuse potential. In 1966, buprenorphine was synthesized; it included a cyclic propyl group which yields antagonistic effects, hence its agonist-antagonist properties. It seemed the long sought-after safe potent oral analgesic had been found.

Instead of achieving stardom as a pain reliever, buprenorphine became tasked for MAT because of its unique actions. Buprenorphine is a mu-opioid receptor partial agonist with properties that can provide long-lasting craving and withdrawal suppression. It has the added benefit of partial blockade of the effects of mu-opioid receptor full agonists such as heroin, oxycodone, and fentanyl. A ceiling effect on respiratory depression adds to the protective quality of this drug. It ultimately garnered attention with Suboxone’s approval in 2002 for detoxification and long-term maintenance therapy in opioid dependency.

Historically, the predicted results of mixing agents with agonist effects of varied potency at the mu-opioid receptor were based on an understanding of in-vitro binding affinities. With a more sophisticated understanding of the pharmacokinetic and pharmacodynamics interactions of buprenorphine, clinicians can now use this medication knowing that all mu-receptor active agents interact competitively, regardless if they are full or partial agonists.

When patients on buprenorphine require an interventional procedure that often results in acute pain, the question arises: How do we treat this patient? Solving the perioperative strategy for a patient receiving psychopharmacology for opioid use disorder (specifically a buprenorphine product), must encompass provision for adequate analgesia while protecting the patient from a relapse. This is especially true in the face of the current opioid crisis, with increased risk of death risk from a single exposure to adulterated illicit high potency synthetic opioids.

Clinicians and patients historically have been skeptical about using buprenorphine products in time-proximity to mu-opioid receptor full agonists; there are concerns about precipitated withdrawal and hindered analgesia. Given the high mu-receptor affinity of buprenorphine, providers of perioperative care have been worried about inadequate or complicated analgesia management. Fortunately, a more sophisticated understanding of buprenorphine that accounts for specific dose-timing proves that the simultaneous administration of buprenorphine with mu-opioid receptor full agonists is not only possible, it can produce advantages.

Developing a treatment protocol

Developing an evidence-based strategy to satisfy the conflicting priority of peri-proceduralists and addiction specialists during perioperative care of such patients required a review of extant literature to propose a consensus guideline. The goal was to create a simple yet sound protocol allowing for cooperation and communication between stakeholders.

Extant clinical data provided examples of co-administration of buprenorphine and full mu agonist opioids, and evidence of success was found (mostly in obstetrics literature). There were other reports with less than ideal outcomes, but these did not represent a persuasive pattern. Similarly, there was limited data for mixing buprenorphine and full mu agonist opioids in large-scale surgeries (eg, thoracic, abdominal and orthopedic). Preclinical data suggested that buprenorphine exerted overriding antagonistic effects on full mu agonist opioids at high doses, but it yielded additive analgesia with full mu agonist opioids when used at lower doses.

Interestingly, buprenorphine’s efficacy at low doses was similar to higher potency full mu agonist opioids. The dose of buprenorphine to optimize analgesia seemed to be in the 3–4 mg range. Unfortunately, data on subjective craving or threshold for
risk of relapse was lacking.

In a series of elegant experiments, Greenwald et al. used carbon 11-tagged carfentanil positron emission tomography imaging (11C-cPET) of μ opioid receptor (μOR) occupancy to study availability in subcortical brain substructures of patients with heroin use disorder on varying doses of buprenorphine. The authors concluded that craving reduction occurs in the 50% μOR occupancy range, which correlates to a 2-4mg buprenorphine dose range. Notably, in a reverse effect arm using 11C-cPET, 50% of receptors became available by 28 hours following the last exposure to a steady state dose of 16 mg buprenorphine (Figure).

Using all literature reviewed, and strongly guided by the 11C-cPET data,[10] a new guideline was proposed based on these key features:

- Buprenorphine provides significant analgesia at low sublingual doses, ideally 4 mg bid.
- When this dose is used in combination with full agonist opioids, it can produce a synergistic analgesic effect.
- Withdrawal symptoms are suppressed with μOR availability of 50% to 60%; μOR receptors are clinically available for analgesia within 24 hours of buprenorphine cessation in doses as high as 16 mg.

A clinical guideline was then proposed using the following parameters:

1. For procedures with minimal pain levels, continue buprenorphine doses and rely on its analgesic potency.
2. For procedures where moderate to high pain is expected (i.e., historically require perioperative full μ agonist opioids):
   - A. Continue buprenorphine through the day before surgery; if usual doses are >16mg buprenorphine a day, taper to 16 mg the day prior to surgery (ideally 8 mg BID).
   - B. Use 4mg bid throughout the perioperative period.
   - C. Use full μ agonist opioids as required. (For clinical ease, use readily available buprenorphine or buprenorphine/naloxone SL film product of 4 mg.)

Pre-operative and postoperative communication amongst those caring for the patient is critical.

The buprenorphine-MAT provider should be involved to help reach consensus on the management plan. Addiction and/or pain consultation services should be engaged peri-operatively. Discharge planning should identify the patient’s postoperative resources and support. The hospital teams should contact the patient’s MAT prescriber to transfer buprenorphine management course and post-discharge plans and responsibilities. Non-opioid adjunct pain medications should be considered postoperatively and post-discharge.

When buprenorphine is delivered with a careful dose/time relationship relative to administration of typical opioids, the result will yield the best balance of analgesia and protection from relapse. Specifically, by occupying approximately 50% of μOR receptors with buprenorphine, both analgesia and relapse prevention are maximized in the setting of an invasive intervention (Figure). Moreover, this strategy accounts for the fact that buprenorphine is a potent stand-alone analgesic in low doses.

Patient safety and comfort is the priority of limiting disruption of the pre-operative buprenorphine-MAT dose and continuing buprenorphine perioperatively and postoperatively. By emphasizing interdisciplinary communication while satisfying specialty clinician priorities, patient care is optimized. This protocol has been implemented at Massachusetts General Hospital since March 2018.[11]
With the emergence of new therapeutic strategies, we now have more options for improving the quality of life for people diagnosed with psychiatric disorders. As the field continues to progress it is important for you and your colleagues to understand the current clinical data and best practices when caring for your patients.

The Annual Psychiatric Times® World CME Conference™ is an event specifically designed to help you apply new evidence-based clinical concepts in psychiatry to real-world clinical practice. This 3-day meeting will feature expert presentations and panel discussions addressing emerging psychiatric treatments and newest clinical trial data, and best practices for managing challenging psychiatric diagnoses including mood disorders, anxiety disorders, eating disorders, postpartum depression, substance abuse disorders, and more. This experience provides the ideal curriculum with a focus on challenging patient case scenarios, integrating relevant evidence into real-world patient management, and comparing your practices with those of experts and peers.

**Overview:**

With the emergence of new therapeutic strategies, we now have more options for improving the quality of life for people diagnosed with psychiatric disorders. As the field continues to progress it is important for you and your colleagues to understand the current clinical data and best practices when caring for your patients.

The Annual Psychiatric Times® World CME Conference™ is an event specifically designed to help you apply new evidence-based clinical concepts in psychiatry to real-world clinical practice. This 3-day meeting will feature expert presentations and panel discussions addressing emerging psychiatric treatments and newest clinical trial data, and best practices for managing challenging psychiatric diagnoses including mood disorders, anxiety disorders, eating disorders, postpartum depression, substance abuse disorders, and more. This experience provides the ideal curriculum with a focus on challenging patient case scenarios, integrating relevant evidence into real-world patient management, and comparing your practices with those of experts and peers.

**Benefits of Attending:**

- Learn about emerging treatments for the management of psychiatric disorders
- Hear about strategies for early diagnosis and intervention to improve outcomes
- Learn about how new therapies work to treat various psychiatric conditions
- Get a better understanding of the impact of psychiatric disorders for those affected
- Explore future directions for treating psychiatric disorders
- Earn CE credit while interacting with psychiatric experts and peers

**Agenda:**

**Thursday, October 15, 2020**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:00</td>
<td>Registration and Lunch</td>
</tr>
<tr>
<td>1:00</td>
<td>Interventions for Sleep Disturbances in Psychiatric Disorders</td>
</tr>
<tr>
<td>1:15</td>
<td>The Interplay of Migraines and Psychiatric Disorders: Treatment Implications</td>
</tr>
<tr>
<td>1:30</td>
<td>Panel Discussion, Q&amp;A</td>
</tr>
<tr>
<td>1:45</td>
<td>Clinical Psycho-Oncology: Assessment and Management</td>
</tr>
<tr>
<td>2:15</td>
<td>Audience Q&amp;A</td>
</tr>
<tr>
<td>2:30</td>
<td>BREAK</td>
</tr>
<tr>
<td>3:00</td>
<td>Cannabis in Psychiatry: Clinical, Legal, and Ethical Issues</td>
</tr>
<tr>
<td>3:20</td>
<td>The New Role of Psychedelics</td>
</tr>
<tr>
<td>3:40</td>
<td>Panel Discussion, Q&amp;A</td>
</tr>
<tr>
<td>4:00</td>
<td>Diagnosing and Treating PTSD</td>
</tr>
<tr>
<td>4:30</td>
<td>Special Guest Speaker</td>
</tr>
<tr>
<td>5:00</td>
<td>ADJOURN</td>
</tr>
<tr>
<td>5:00</td>
<td>Welcome Reception</td>
</tr>
</tbody>
</table>

**Accreditation/Credit Designation**

Physicians’ Education Resources®, LLC is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. Physicians’ Education Resources®, LLC designates this live activity for a maximum of 16.5 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity. Physicians’ Education Resources®, LLC is approved by the California Board of Registered Nursing, Provider #16669 for 16.5 Contact Hours.
**Friday, October 16, 2020**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00</td>
<td>Registration and Breakfast</td>
</tr>
<tr>
<td>8:00</td>
<td>Welcome, Introductions, and Presession Questions</td>
</tr>
<tr>
<td>8:10</td>
<td>Plenary Session: Special Report on Major Depressive Disorder</td>
</tr>
<tr>
<td>9:00</td>
<td>Treatment-Resistant Depression</td>
</tr>
<tr>
<td>9:15</td>
<td>Treating Major Depressive Disorder Beyond MAOIs and SSRIs</td>
</tr>
<tr>
<td>9:30</td>
<td>BREAK</td>
</tr>
<tr>
<td>10:00</td>
<td>Plenary Session: Special Report on Bipolar Disorder</td>
</tr>
<tr>
<td>10:30</td>
<td>Medical Crossfire®: Should Bipolar Depression Be Treated With Antidepressants?</td>
</tr>
<tr>
<td>10:45</td>
<td>Combination Therapy in Bipolar Disorder</td>
</tr>
<tr>
<td>11:00</td>
<td>Maintenance Therapy in Bipolar Disorder</td>
</tr>
<tr>
<td>11:15</td>
<td>Postsession Questions</td>
</tr>
<tr>
<td>11:30</td>
<td>Keynote Lecture</td>
</tr>
<tr>
<td>12:00</td>
<td>Non-CME Lunch</td>
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</table>

**Specialist Track: Clinical Conundrums and Commentary**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:30</td>
<td>Major Depressive Disorder</td>
</tr>
<tr>
<td>2:15</td>
<td>Bipolar Disorder</td>
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</table>

**Primary Care Track**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:30</td>
<td>Treating Major Depressive Disorder in a Primary Care Setting</td>
</tr>
<tr>
<td>2:00</td>
<td>Treating Anxiety in a Primary Care Setting</td>
</tr>
<tr>
<td>2:30</td>
<td>Panel Discussion, Audience Q&amp;A</td>
</tr>
<tr>
<td>3:00</td>
<td>BREAK</td>
</tr>
</tbody>
</table>

**Plenary Session: Hot Topics**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>3:30</td>
<td>Presession Questions</td>
</tr>
<tr>
<td>3:35</td>
<td>Treatment Strategies for Attention-Deficit/Hyperactivity Disorder</td>
</tr>
<tr>
<td>3:45</td>
<td>Symptoms, Causes, and Treatment of Binge Eating Disorder</td>
</tr>
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</table>

**Plenary Session: Special Report on Psychiatry and Women’s Health**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
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<tbody>
<tr>
<td>4:05</td>
<td>Practical Psychoneuroendocrinology: How the Brain, Nervous System, and Endocrine System Interact</td>
</tr>
<tr>
<td>4:25</td>
<td>Psychological and Psychopharmacological Options for Postpartum Depression</td>
</tr>
<tr>
<td>4:40</td>
<td>Effective Strategies for Hypoactive Sexual Desire Disorder</td>
</tr>
<tr>
<td>4:55</td>
<td>Postsession Questions</td>
</tr>
<tr>
<td>5:00</td>
<td>ADJOINT</td>
</tr>
<tr>
<td>5:30</td>
<td>RECEPTION</td>
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**Saturday, October 17, 2020**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
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<tbody>
<tr>
<td>7:00</td>
<td>Registration and Breakfast</td>
</tr>
<tr>
<td>8:00</td>
<td>Welcome, Introductions, and Presession Questions</td>
</tr>
<tr>
<td>8:10</td>
<td>Plenary Session: Special Report on Substance Abuse</td>
</tr>
<tr>
<td>9:00</td>
<td>Treatment for Opioid Use Disorder</td>
</tr>
<tr>
<td>9:40</td>
<td>Medication-Assisted Treatment and Alternative Therapies for Addressing Addiction</td>
</tr>
<tr>
<td>9:50</td>
<td>Methamphetamine Abuse and Treatment Options</td>
</tr>
<tr>
<td>9:50</td>
<td>Medical Crossfire®: Should Benzodiazepines and Opioids Be Used Concurrently?</td>
</tr>
<tr>
<td>9:35</td>
<td>Audience Q&amp;A</td>
</tr>
<tr>
<td>9:45</td>
<td>BREAK</td>
</tr>
<tr>
<td>10:15</td>
<td>Plenary Session: Special Report on Schizophrenia</td>
</tr>
<tr>
<td>10:45</td>
<td>Diagnosing Schizophrenia</td>
</tr>
<tr>
<td>10:55</td>
<td>State-of-the-Art Treatment in Schizophrenia</td>
</tr>
<tr>
<td>11:15</td>
<td>Long-Acting Injectables for Schizophrenia</td>
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<tr>
<td>11:30</td>
<td>Postsession Questions</td>
</tr>
<tr>
<td>11:45</td>
<td>Keynote Lecture</td>
</tr>
<tr>
<td>12:00</td>
<td>Non-CME Lunch</td>
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</table>

**Breakout Sessions**

**Specialist Track**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
</tr>
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<tbody>
<tr>
<td>1:30</td>
<td>Clinical Conundrums and Commentary: Substance Abuse</td>
</tr>
<tr>
<td>2:15</td>
<td>Clinical Conundrums and Commentary: Schizophrenia</td>
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</table>

**Primary Care Track**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
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<tbody>
<tr>
<td>1:30</td>
<td>Addressing Opioid Use Disorder</td>
</tr>
<tr>
<td>2:00</td>
<td>Practical Strategies for Addressing Sleep Disorders</td>
</tr>
<tr>
<td>2:30</td>
<td>Panel Discussion, Audience Q&amp;A</td>
</tr>
<tr>
<td>3:00</td>
<td>BREAK</td>
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**Hot Topics: Overcoming Challenges Associated With Antipsychotics**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>3:30</td>
<td>Advances in Predicting and Treating tardive dyskinesia</td>
</tr>
<tr>
<td>3:45</td>
<td>Diagnosis and Management of Metabolic Syndrome</td>
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</table>

**Future of Psychiatry**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
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<tbody>
<tr>
<td>4:00</td>
<td>Genetics, Genomics, and Psychiatry: What Do We Know?</td>
</tr>
<tr>
<td>4:25</td>
<td>Update on Neuroimaging for Psychiatric Disorders</td>
</tr>
<tr>
<td>4:30</td>
<td>New Pharmacological Targets for Psychiatric Disorders</td>
</tr>
<tr>
<td>4:45</td>
<td>Advances in Clinical Studies: Implications for Your Practice</td>
</tr>
<tr>
<td>5:00</td>
<td>ADJOINT</td>
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</tbody>
</table>
COVID-19: Protecting the Vulnerable and Opening the Economy

Sheldon H. Preskorn, MD

While the coronavirus disease 2019 (COVID-19) can infect virtually every person in the population, based on data from China, the US, and Europe, only about 5% are susceptible to severe infection requiring admission to an intensive care unit (ICU) and/or causing mortality; this vulnerable population is identified by medical comorbidity and/or age. While 5% may initially seem like a small number, it nevertheless represents potentially 16.5 million people given a US population of 330 million. That is a tremendous number of people requiring ICU admission, potential deaths, and can easily overwhelm the US health care system, especially in hotspots. Nonetheless, it is important to consider the data for at-risk populations as part of mitigation strategies in attempts to re-open the country and the US economy.

This piece was written with the hope of helping psychiatrists understand the issues so that they can explain the complexities of this crisis to their patients as well as to share thoughts on minimizing the damage caused by COVID. It is a personal synthesis of the implications of the extant literature in the public domain.

The piece will aim to address the following questions:

1. What are the 3 aspects of the race to minimize damage?
2. What data are currently available and can they inform decisions?
3. How successful are the strategies employed to date?
4. Might risk stratification minimize the damage: impact of the illness and economic damage (which also can devastate and cost lives)?

Background

COVID-19 is caused by the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). This virus, which jumped from an animal species (possibly a bat or an anteater) to humans in China in December 2019, causes illness that ranges in severity from no symptoms to cold-like symptoms to a severe, even fatal, respiratory illness.2–5

COVID-19 is commonly referred to as a novel coronavirus because of its recent emergence as a human pathogen. Due to its novel nature, humans had little to no immunity when it emerged, and data were not available about the severity of the illness, the percentage of the population that could be affected, and whether risk factors could be identified for its severest forms. The concern was heightened by the fact that since 2002, 2 other novel coronaviruses (the SARS-CoV-1 and the Middle East respiratory syndrome [MERS] viruses) jumped from animals to man and caused serious, even highly fatal, illnesses. As it turned out, these earlier viruses had much higher fatality rates than COVID-19 infections: 10% for SARS-CoV-1 and 34% for MERS versus 2% for COVID-19’s SARS-CoV-2 and < 0.1% for seasonal flu.6

It is important to keep a caveat in mind for the SARS-CoV-2 death rate. It is a general number for the whole population, but it varies widely based on subpopulations, as it is less than 1% in adults who are not of advanced age (ie, ≥85 years) and those without specific comorbid medical conditions. When these 2 groups are excluded, most people will have minimal to mild-moderate symptoms and will not require hospitalization. Thus, the fatality rate estimates are influenced by at least 2 factors: rates will be higher based on the percentage of the population that has the risk factors of comorbid medical illness and/or ≥85 years of age (eg, nursing home populations versus the general population) and estimates may be substantially lower once sufficient antibody testing results can determine the percentage of the population who have been asymptomatic or mildly symptomatic and have developed an antibody response.

Suffice it to say that COVID-19 did overwhelm the health care system in many countries and some areas of the US. Since there were no scientifically proven effective and safe treatments nor a vaccine in the earlier phases of this pandemic—and that those limitations continue as of the writing of this article (April 20th), the response has been to try to limit the spread of the virus by good hygiene practices and social distancing. This strategy has included orders to shelter in place, quarantining exposed individuals, and isolating infected people. This approach has resulted in the shutdowns of major parts of the economy and sudden high levels of unemployment, which has its own negative consequences.

The 3 components of the race

The 3 components of the race are the important pieces needed to address the previously noted unknown factors. We have needed and continue to need more knowledge about: 1 - the nature of the disease and its treatment or prevention; 2 - how to best safeguard public health and avoid overwhelming the health care system; and 3 - how to minimize the societal damage caused by the substantial disruption of the economy. These are 3 quite different dilemmas, and they require different expertise. To win the race, we need to balance risk in these different domains.

The need for knowledge

The good news is that we have learned a lot about the virus and the illness over the past 4 to 5 months. Within 2 weeks of the discovery of COVID-19, researchers at the National Institute of Allergy and Infectious Diseases determined how the virus enters human cells and, within 2 months, sites began Phase I trials of a potential mechanism-based treatment (remdesivir) and a vaccine (mRNA-1273).7 The problem is that treatment and vaccine trials historically take more than a year at the earliest to be successful. So, while these 2 possibilities are the most likely game changers, there will still be loss of lives and negative economic fallout. For this reason, there are 692 trials listed on clinicaltrials.gov examining the potential efficacy and safety of different treatments as of April 20th.8 Most (if not all) of these studies are examining already marketed drugs, because it takes many years to develop a completely new molecular entity specifically targeted for a given illness.

Current data and principles

Much has also been learned about the natural history of the COVID-19 illness. The virus has a high enough basic reproduction number (R0) to be significantly contagious. The R0 value refers to the expected number of cases directly generated by one case in a population where all individuals are susceptible to infection, as was the case for the world human population when this virus became a human pathogen. The R0 values for COVID-19 range from 1.4 to 3.7. In comparison, the COVID-19 R0 values are higher than reported for the 2 earlier coronaviruses (ie, SARS-CoV-1 and MERS) and higher than that for seasonal strains of influenza (R0 values range from 0.9 to 2.1), but are substantially lower than the R0 values for
measles, one of the most infectious of all human viruses (R, values range from 12 to 18). The basic reproductive number, or R, value can be used to estimate the fraction of the population that needs to be immune to the virus—whether by natural exposure or vaccination—to slow or stop the spread of the virus among nonimmune individuals. This fraction is referred to as community (or herd) immunity. Due to its very high R, values, the threshold for effective community immunity for measles is 93% to 95% of the population being immune to the measles virus. The threshold to achieve community immunity for COVID-19 is estimated to be between 50% and 66%, according to Justin Lessler, PhD, associate professor of epidemiology at Johns Hopkins University. These figures are consistent with estimates that 50% to 70% of American and European populations will likely become infected with the SARS CoV-2 virus. Complicating this problem is the fact that somewhere between 25% and 50% of people infected with the virus are at least initially asymptomatic but nevertheless infectious to others based on data from the Centers for Disease Control and Prevention (CDC) and epidemiology studies in Iceland. Much has also been learned about risk factors for the seriousness of the illness as reflected in Table 1.

Clearly, age is an important risk factor but so also are comorbid medical illnesses, particularly pre-existing respiratory and cardiovascular disease, immunocompromised status, morbid obesity (ie, body mass index ≥40), significant kidney or liver impairment, and/or diabetes. Age and these comorbid medical illnesses are correlated—that is, the older a person is, the more likely they have one or more of these comorbid illnesses. However, what is not known is whether age is simply a surrogate for having a comorbid illness or an independent risk factor. When younger people (<55 years) have serious and even fatal outcomes, they most often have one or more of the medical illnesses listed, including severe asthma. In fact, almost 90% of all patients hospitalized for COVID-19 independent of age had one or more of the listed comorbid conditions. That means that 90% of the individuals who were hospitalized, admitted to the ICU, or died (Table 1) had comorbid medical illness. When these individuals are removed, the likelihood of those 3 adverse outcomes drops dramatically, in some cases approaching zero. For these reasons, it is probably best to consider both age and medical status when stratifying risk; this was not done in Table 1. Age is likely mainly a surrogate for comorbid medical illness, but by age 85 and above, the vital capacity of many organs, such as forced vital capacity, a measure of lung function, has often declined to a significant degree. On the basis of this information, 5 potential severity levels can be identified (Table 2). There are some caveats concerning the data in Table 1, which represents cases from February 12 to March 16, 2020. First, early recognition and medical care have since improved substantially, which could produce a drop in these numbers even in vulnerable populations. Second and even more important, the data are based on approximately 2500 cases; more than 775,000 US cases have now been reported, a number that almost undoubtedly includes more individuals at severity levels 0 or 1 because cases in the early days were first diagnosed on the basis of symptoms that would have been missed in these people. Because the number of cases is now so much higher, the CDC will be able to determine whether the larger numbers replicate the earlier findings shown in Table 2, which will give greater confidence in the results. Such an analysis has not yet been posted in the public domain, but this will likely happen and/or the results will be shared with policy makers.

**What strategies have been utilized?**

The most widely adopted strategies have involved the epidemiological approach of encouraging good hygiene practices and social distancing, including orders to shelter in place and quarantine. (Parenthetically, the term quarantine refers to the situation in which an individual has been in close contact with someone known to be actively shedding virus. Individuals in quarantine may be grouped together while following social distancing and they may use masks as an added precaution. The term isolation refers to the situation in which an individual is infected and is isolated from others to prevent further spread of the virus.) These strategies have met with varying degrees of success depending on the country, with smaller countries in terms of land mass and population generally doing better than larger countries. Not all countries have taken these approaches, with Taiwan, Iceland, and Sweden being perhaps the most notable exceptions. While those 3 countries have not experienced the same epidemiologic or economic consequences as have occurred with the more restrictive policies elsewhere, it is too early to tell how they will do with the spread of the illness. Taiwan seems to being doing remarkably well, relying not on sheltering policies for the general population but instead case detection followed by establishing at-risk contacts and quarantining those individuals through the period of risk of developing illness and recovery using extensive testing for active infection and viral shedding.

The common phrase used to describe the goal of this epidemiological approach is flattening the curve. This term refers to reducing the height of the peak of the infection, which was critical in the earliest days of the infection when a steep peak could have catastrophic consequences by overwhelming the health care system and society. This approach was also a way of buying time to learn more about the disease and to find more effective ways to deal with it, ie, developing validated treatments and vaccines. Unfortunately, as previously mentioned, treatments and vaccines take time. There is also the possibility that COVID-19 might follow the same pattern of seasonal variation as seen with seasonal strains of influenza—the onset of spring will test this possibility.

This epidemiologic approach has 2 potential downsides. The most obvious is its profound effect on the economy. The other is whether it simply delays—but does not meaningfully prevent—the spread of the virus. Prescribers can consider the analogy with immediate versus delayed or extended-release formulations of drugs. While the latter produce a lower peak level, they may have the same area under the curve (AUC)—in pharmacokinetics, the same AUC means that the amount of drug absorbed is essentially the same for the 2 formulations (ie, they are bioequivalent). In the case of the spread of the virus, it might mean that the total number of infected people will be the same but that the infections will be spread out over a longer interval. While this approach is good in terms of not overwhelming health care resources, it could prolong the economic impact, which is not without adverse consequences; it can also delay the time when sufficient community immunity will have been acquired in order to eradicate the infection and protect the vulnerable subset of the population susceptible to serious adverse outcomes. As previously mentioned, the estimate is that 50% to 66% of the population will need to have immunity to substantially reduce the spread to those who are not immune and possibly even eradicate the current version of the virus.

The last caveat concerning the current version of the virus is included because some viruses mutate enough that they are no longer recognized by the immune system, an example of such are the seasonal strains of influenza, which is why new vaccines are produced before the start of the flu season.

**Might risk stratification work?**

Based on what it is now known, a small percentage of the population (5% to 10%) is at risk for a serious infection, which occurs at severity levels 3 and 4 (Table 2). Moreover, the vulnerable population can be identified and can shelter until the current version of this virus is essentially eradicated.

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### Table 1. Hospitalization, intensive care unit (ICU) admission, and case-fatality percentages for reported COVID-19 cases—United States, February 12-March 16, 2020

<table>
<thead>
<tr>
<th>Age group (yrs)</th>
<th>%</th>
<th>No. of cases</th>
<th>Hospitalization</th>
<th>ICU admission</th>
<th>Case-fatality</th>
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</thead>
<tbody>
<tr>
<td>&lt;19 (123)</td>
<td></td>
<td>1.6-2.5</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>20-44 (705)</td>
<td></td>
<td>14.3-20.8</td>
<td>2.0-4.2</td>
<td>0.1-0.2</td>
<td>0</td>
</tr>
<tr>
<td>45-54 (429)</td>
<td></td>
<td>21.2-28.3</td>
<td>5.4-10.4</td>
<td>0.5-0.8</td>
<td>0.2-0.5</td>
</tr>
<tr>
<td>55-64 (429)</td>
<td></td>
<td>20.5-30.1</td>
<td>4.7-11.2</td>
<td>1.4-2.6</td>
<td>0.2-0.5</td>
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<tr>
<td>65-74 (409)</td>
<td></td>
<td>28.6-43.5</td>
<td>8.1-18.8</td>
<td>2.7-4.9</td>
<td>0.2-0.5</td>
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<tr>
<td>75-84 (210)</td>
<td></td>
<td>30.5-58.7</td>
<td>10.5-31.0</td>
<td>4.3-10.5</td>
<td>0.2-0.5</td>
</tr>
<tr>
<td>≥85 (144)</td>
<td></td>
<td>31.3-70.3</td>
<td>6.3-29.0</td>
<td>10.4-27.3</td>
<td>0.2-0.5</td>
</tr>
<tr>
<td>Total (2,449)</td>
<td></td>
<td>20.7-31.4</td>
<td>4.9-11.5</td>
<td>1.8-3.4</td>
<td>0.2-0.5</td>
</tr>
</tbody>
</table>

* Lower bound of range = number of persons hospitalized, admitted to ICU, or who died among total in age group. Upper bound of range = number of persons hospitalized, admitted to ICU, or who died among total in age group with known hospitalization status, ICU admission status, or death.

Source: CDC COVID-19 Response Team.
During the preceding 4 months, 2 approaches have generally been suggested to deal with the current crisis: 1- continue the epidemiological approach focused on slowing the infection rate and its most serious health consequences, and 2- relax the most rigorous social restrictions to end economic consequences. The White House guidelines announced on April 16th1 recommend a phased movement from a shelter-in-place approach to a gradual reduction in social restrictions and an opening up of the economy. Such opening would be based on regions meeting specific criteria in terms of their ability to contain the virus, coupled with vigorous monitoring for outbreaks, followed by case monitoring, quarantining of exposed individuals, isolation of infected individuals, and increased use of testing for active disease as well as for immunity (ie, the presence of sufficient titers of antibodies against the virus in the blood). This approach has been successful in smaller countries such as Taiwan. Testing for antibodies will also help estimate how far the country is from developing effective community immunity. However, these guidelines do not take the data outlined earlier into consideration, which suggest that individuals younger than 85 years without specific comorbid illnesses have little risk of developing a serious illness from the current form of this virus. In this population, more rapid movement through the phases of lifting restrictions and opening up the economy seems possible, while continuing to practice good hygiene and social distancing, and simultaneously—and perhaps even more vigorously—focusing on sheltering the vulnerable population until the critical threshold for community immunity has been reached, whether through natural exposure alone or with the addition of vaccination.

This approach would have several benefits. First, it would more quickly restore the economy and thus help avoid the adverse societal and health effects of a serious recession or depression. Second, it would increase community immunity, which would drive down the risk for everyone, including those most susceptible to serious adverse outcomes. Third, those who develop immunity could donate antibody enriched serum (what has been called convalescent serum) to vulnerable individuals with serious adverse outcomes, which could potentially provide effective treatment while the development and testing of vaccines proceed.

However, there are also downsides to this approach. First, it assumes that immunity will develop. Anthony Fauci, MD, director of the National Institute of Allergies and Infectious Diseases, has been quoted as saying that he would be “willing to bet anything that people who recover are really protected against reinfection” and “Ultimately, the showstopper will be obviously a vaccine.” Both statements seem almost truisms and necessary conditions to resolve this situation. Second, this approach involves risk but so, too, does either of the first two alternatives; the risk with this proposed approach is arguably more calculated and nuanced. Third, individuals who are younger than 20 years old (or as old as the data indicate have minimal risk of serious adverse outcomes) and without comorbid medical illnesses will undoubtedly have contact with older individuals, but that is also true for the other 2 approaches. Therefore, public awareness of the need to exercise heightened concern for the vulnerable population must be understood and acted upon rather than taking a one size fits all approach, which has been the approach so far. That approach has led to many younger and healthy individuals incorrectly believing that they have the same risk as the vulnerable population and, at the same time, has diminished the understanding of the need for heightened concern for the population that is at high risk.

### Table 2. Potential outcomes of different infection severities

<table>
<thead>
<tr>
<th>Severity level</th>
<th>Description</th>
<th>Definition</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Asymptomatic infection</td>
<td>Individuals who have been found to be shedding the virus but otherwise have no signs of infection at the time of testing; Represents between 25% - 50% of the population; however, some of these individuals may later become symptomatic; data is not yet available</td>
<td>This group is particularly important in terms of spreading the disease because they are asymptomatic; asymptomatic individuals should avoid the 5% - 10% of the population who are susceptible to serious, even fatal, infections; if they are 3 weeks out from previous testing, they should be past the viral shedding, which could be confirmed by another active infection test</td>
</tr>
<tr>
<td>1</td>
<td>Mild infection</td>
<td>Individuals who either have mild to moderate flu-like symptoms but do not require hospitalization; Likely represents an additional 50% of the population who are not &gt;85 years and/or do not have comorbid conditions that place them at risk to a clinically meaningful degree</td>
<td>This group also must remain vigilant in protecting more vulnerable populations; they also will represent increased sick days and loss of productivity as well as a potential albeit relatively small drain on health care resources</td>
</tr>
<tr>
<td>2</td>
<td>Moderate infection</td>
<td>Individuals with sufficient symptoms and functional impairment such that hospitalization is required, usually for several days, often to treat fever, dehydration, and concurrent infection (eg, bacterial pneumonia); The size of this group may be reduced as physicians have more experience treating this illness; such a reduction would be enhanced if clinical trials prove that 1 or more of the treatments are capable of preventing or treating the disease; Likely occurs in 1% - 7% in the nonvulnerable population and up to 70% of those &gt;85 years or with those significant comorbid conditions*</td>
<td>Increased use of health care resources; increased risk of complications and thus negative outcomes for patients; impact on families and economy</td>
</tr>
<tr>
<td>3</td>
<td>Severe infection</td>
<td>Individuals with sufficient symptoms and functional impairment requiring hospital ICU services; Likely occurs in &lt;2% of nonvulnerable population (ie, no comorbid medical conditions*) and 6% - 29% of &gt;85 years*</td>
<td>Significant impact on health care resources; increased risk of complications and negative outcomes, including fatality; impact on family units and economy</td>
</tr>
<tr>
<td>4</td>
<td>Death due to COVID-19</td>
<td>Represents 0.1% - 5% of population &lt;75 years, and 10% - 27% &gt;85 years*</td>
<td>Prior to death, significant use of health care resources; direct and significant impact on family units</td>
</tr>
</tbody>
</table>

**Conditions include pre-existing respiratory and cardiovascular disease, immunocompromised status, morbid obesity (ie, body mass index >40), diabetes mellitus, and possibly significant kidney or liver impairment.**

**Estimates are based on Table 1, which includes individuals without regard to comorbid medical conditions. Given that approximately 90% of hospitalized patients for COVID-19 had comorbid medical illness, these rates would be 10x less in the nonvulnerable population.**
The caveats
Although a tremendous amount has been learned, much still remains unknown. First and foremost, we need to determine how many individuals in different regions of the country have been infected. That information should increasingly become available over the next weeks to months as antibody testing is undertaken. That information will help determine both the infectivity of the virus (its reproductive number or $R_0$) and its fatality rate. A second major question is whether the antibodies that are produced convey immunity to reinfection and, if so, how long that immunity lasts. Another key question is how much of a role cell-mediated processes play in the development of immunity. This will also determine if convalescent plasma enriched with antibodies from recovered individuals can help treat infected individuals and whether this treatment will help determine both the development of immunity. This will take time. Meanwhile, hopefully this information will help to mitigate the damage done by the virus, whether directly as a result of the infection or indirectly due to its effects on the economy.

Concluding thoughts
The future is not as clear as anyone would like. This article reviewed the great progress that has been made in understanding COVID-19 and possible pathways for moving forward. Perhaps the words Winston Churchill used in speaking of the Allied victory in the Battle of Egypt describe the current war with COVID-19 as succinctly as possible: “Now this is not the end. It is not even the beginning of the end. But it is perhaps, the end of the beginning.”

Dr Preskorn is Professor in the Department of Psychiatry and Behavioral Sciences at the University of Kansas School of Medicine-Wichita. The author notes that he has received grants/research support from or has served as a consultant on the advisory board or speaker’s bureau for Alexion, BiocXel, Eisai, Jansen, National Institute of Mental Health, Sunovion, and Usona Institute. All clinical trial and study contracts were with and payments made to The University of Kansas Medical Center Research Institute, a research institute affiliated with The University of Kansas School of Medicine-Wichita. The author acknowledges Galardon Mimos, MD, Dean of the University of Kansas School of Medicine-Wichita and an expert on infectious diseases, for his review of this article.

This article was originally published in the Journal of Psychiatric Practice and has been adapted with permission from Lippincott Williams & Wilkins.

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Reflections on the New Normal

Robert Boland, MD

As with many institutions, the Brigham and Women’s Hospital has switched to virtual meetings. In the last two weeks, I have used my computer, phone, and tablet to meet with groups large and small. These online encounters have ranged from one-on-one supervisory meetings that would usually happen in my office to groups of 100 or more that would normally have required an auditorium. We are also conducting our telephone consultations and individual supervisory check-ins. Perhaps we should use this opportunity to cuss what changes make sense, and in which cases they are not. I hope to have occurred anyhow, but this may greatly hasten change us as a society. Many of the changes would minimize unnecessary exposure. If these patients continue to do well—and I wholeheartedly hope that they do—we shouldn’t insurance companies suggest that we move to less frequent in-person appointments and more frequent (and less expensive) virtual check-ins? And won’t other services question the need for traditional consultations?

Like most of us, I don’t have time to worry about this right now. I am too preoccupied with the health and safety of my patients, trainees, and faculty. However, I am hoping that at some more reasonable point we can reflect on this change. I am hardly the first to suggest that, long after we all receive the coronavirus vaccine, this pandemic may forever change us as a society. Many of the changes would have occurred anyhow, but this may greatly hasten them. Perhaps we should use this opportunity to learn as much as we can from this experience so that, once we are past this, we can intelligently discuss what changes make sense, and in which cases the old ways were the better ways.

Dr Boland is Vice-Chair for Education at Brigham and Women’s Hospital and Associate Professor at Harvard Medical School. He is also a member of the Psychiatric Times Editorial Board.
The Spanish Flu Pandemic and Mental Health: A Historical Perspective

Exploring the pandemics

Since the Spanish flu, researchers dedicated themselves to identifying the origins and nature of that virus. It took decades, however, before virologists succeeded. Starting in the mid-1990s, Jeffrey Taubenberger, MD, PhD, and his team carried out a sequence and phylogenetic analysis of 1918 influenza virus genes and identified it as an H1N1 virus of avian origin.1

Until around 1970, historical research about the pandemic had been virtually non-existent. Some novels and popular histories appeared over the decades, but it was Alfred Crosby’s 1976 book Epidemic and Peace, 1918 (reissued in 1989 under the title America’s Forgotten Pandemic: The Influenza of 1918) that paved the way for international research on the subject.2 One of the book’s major achievements was to draw attention to the fact that the pandemic quickly disappeared as a topic of public conversation soon after it was over, ignored by periodicals and textbooks for decades. To many historians, this collective silence is as much a part of the pandemic’s story as the course of the disease itself.

The mental health links

In comparison to other aspects of the pandemic, little research has been done on the long-term impact of the Spanish flu on mental health. One of the few researchers to investigate the subject was historical demographer Svem-Erik Mamelund, PhD. Looking at asylum hospitalizations in Norway from 1872 to 1929, Mamelund found that the number of first-time hospitalized patients with mental disorders attributed to influenza increased by an average annual factor of 7.2 in the 6 years following the pandemic.3 In addition, he pointed out that Spanish flu survivors reported sleep disturbances, depression, mental distraction, dizziness, and difficulties coping at work, and that influenza death rates in the United States during the years 1918-1920 significantly and positively related to suicide.4 Mamelund is among a number of scholars who have noted what many psychiatrists and neurologists first noticed encephalitis lethargica symptoms in 1916 and 1917 in Austria and France. By 1919, cases were common throughout Europe, the United States, Canada, Central America, and India. All told, approximately 1 million people worldwide were affected by it between its outbreak in 1916 until the early 1930s. While many clinicians (both at the time and since) have surmised an association between encephalitis lethargica and the Spanish flu, there’s no conclusive evidence of causality.

“Spanish flu survivors reported sleep disturbances, depression, mental distraction, and difficulties coping...”

Collateral damage

Some medical and social historians have traced connections between the Spanish flu pandemic and the other catastrophic global event of the time—World War I. In this regard, historians flagged the ways in which the war efforts depleted medical personnel, helped disseminate the virus through the mobilization of troops, and created the conditions that allowed for the mutation of an otherwise mild flu virus.5 When it comes to mental health, the historical record shows that the pandemic, like the war, took a toll on the emotional resilience of those not (or not yet) in harm’s way. The massive and sudden loss of life plunged many into a chronic state of helplessness and anxiety. A large portion of the population were affected by the loss of loved ones. Parents had to come to grips with losing a child (or even several children) while children suddenly found themselves parentless. In November 1918, 31,000 children in New York City alone had lost one or both parents. For others, the experience left them feeling a mix of guilt, anger, confusion, and abandonment. Surviving health professionals would not intimate to such sentiments with many noting that they were haunted by a sense of frustration and grief, even years later.6

Like all mass encounters with infectious disease, the Spanish flu pandemic had its own unique features. If history teaches us anything, it is that we should always be measured in how we glean lessons from the past. That said, the example of the influenza of 1918-1920 gives us reason to expect that the present pandemic will carry in tow its own set of mental health challenges.

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Greg Eghigian, PhD

Dr Eghigian is Professor of History at Penn State University. He specializes in the history of psychiatry and mental health and is member of the Psychiatric Times Editorial Board.
What Leonard Cohen Can Teach Us About Depression

Chris Aiken, MD

Leonard Cohen had a problem, and the medications were not solving it. “I’ve taken a lot of Prozac, Paxil, Wellbutrin, Effexor, Ritalin, Focalin. I’ve also studied deeply in the philosophies of the religions but cheerfulness kept breaking through.”

The “cheerfulness” Cohen complained of was a way euphemism for something darker. The poet, novelist, and songwriter had “dealt with depression ever since my adolescence... Moving into some periods, which were debilitating, when I found it hard to get off the couch, to periods when I was fully operative, but the background noise of anguish still prevailed.”

By his mid-60s, Cohen had been through several hospitalizations and tried tricyclics, monoamine oxidase inhibitors, second generation antidepressants, and anticonvulsants without success. Despite releasing one of the most successful albums of his career, The Future, he found himself “really, really low, on many medications... I pulled my car over to the side of the road. I took out all the medication and threw it out the window.”

A few years later the depression lifted and, by Cohen’s report, it did not return. Depression is overdetermined, to borrow Freud’s phrase, and its resolution is equally mysterious. But a new study sheds light on some of the forces that may have been at play in Cohen’s recovery.

The Recovery

Cohen’s depression had reached “a certain unendurable point” in 1994. He retreated from public life and joined a Buddhist monastery, where he was later ordained as a monk. There he learned to shift his focus away from the “loyalty and the tyranny” of his inner thoughts—the self-focused, ruminative kind that come with depression.

Ruminative is a repetitive pattern of thinking that plagues many patients with depression. It is also a strong predictor of depressive relapse. Rumination is problem-solving gone awry, brooding over unresolved conflicts and questions that cannot be answered. “Why am I such a loser... When will this end... What do people really think of me... What is the point?”

Rumination arises from the brain’s default mode network, which engages in thoughts about the self, the future, and the social world. The default mode is activated when we are bored, uncomfortable, or lonely. For people who are prone to depression, the slightest trigger will turn it on.

Yet there is a brighter side to the dark imaginations of the default mode. When not conjuring foreboding possibilities, it can dream up creative solutions and inspire great art. That might explain why so many creative thinkers have strong ruminative tendencies. That dogged style of thought also lends itself to the persistence that is necessary to create great works. As Cohen described it, songwriting was an act of drudgery where “you’re not doing anything else but trying to find the rhyme for ‘orange.’ It doesn’t exist. Some people say it’s ‘door hinge,’ but that’s not right.”

Buddhism did not answer Cohen’s ruminative questions. In his words, it simply “dissolved them.” Psychologists call this metacognitive awareness. It is the ability to see one’s thoughts objectively, with some detachment, and it is a strong predictor of sustained remission from depression. It is also a key ingredient in mindfulness, which is derived from the kind of Buddhist practice that Cohen pursued.

The study

Twenty years after Cohen’s recovery, a remarkable study came out of Mumbai, the same Indian city where Cohen broke free from his depression. It was a controlled trial of Buddhist meditation for bipolar II depression. By psychotherapy standards, the study was huge, with 622 patients. Half were randomized to cognitive behavioral therapy, and the other half underwent training in meditation. The study lasted 2 years, during which the meditation group was advised to follow a simple 30-minute practice once a week (see Sidebar). That is correct—only 30 minutes per week. The teaching was also low intensity: 5 to 10 two-hour sessions interspersed throughout the 2-year study.

At the end of the study, the meditation group improved over the cognitive behavioral therapy (CBT) group with a large effect size (0.7). How did this mild intervention outperform CBT with such a large effect?

The secret may lie in the 2-year duration. That is how long it took Leonard Cohen’s mood to lift “by imperceptible degrees” while he studied meditation in Mumbai. Other behavior changes, like exercise and social rhythm therapy, also show more robust effects when allowed to build for 6 to 12 months. The challenge is to help patients stay motivated through those imperceptible degrees of progress.

Dr Aiken is the Mood Disorders Section Editor for Psychiatric Times, the Editor in Chief of The Carlat Psychiatry Report, and the Director of the Mood Treatment Center. He has written several books on mood disorders, most recently The Depression and Bipolar Workbook. He can be heard in the weekly Carlat Psychiatry podcast with his co-host Kellie Newsome, PMH-NP. Dr Aiken does not accept honoraria from pharmaceutical companies but receives royalties from PESI for The Depression and Bipolar Workbook and from WW Norton & Co for Bipolar, Not So Much.

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Foster Care Challenges

Challenges in collaboration
Providing psychiatric services to children and adolescents in foster care require collaboration not only with the clinical team, but also the child welfare team. Team members include parents, foster parents, and the social worker, at minimum. The team may also include representatives from courts and others engaged by the child welfare system to conduct assessments (eg, psychological, neuropsychological). Child welfare services’ organizational structure varies from state to state. State and/or local policy defines practice related to permanency and broader case planning, defining the consenting parties for health and mental health treatment, practices for obtaining informed consent for psychotropic medication, and tracking and oversight of psychotropic medication use for children in foster care.

Foster care workers typically serve 10 to 15 families. They are responsible for all aspects of case planning including monitoring placements, ensuring safety, arranging parental visitation, preparing for court, and planning for permanency. Case workers are often very knowledgeable about the youth and families they serve and can be a true partner in care. Psychiatrists and their office staff should reach out to local child welfare leadership to build collaborative relationships. In doing so, it is helpful to share office hours, emergency service policies, duration of initial assessment and follow up appointments, information needed prior to an initial assessment, and preferred pathways for communication between the office and the child welfare team. These outreach efforts are useful during usual care as well as when challenges or crises arise.

Children in foster care often experience placement changes. Maintaining continuity of care during treatment within a single organization as well as ensuring that comprehensive clinical information transfer occurs when children transition to new treatment providers presents a challenge. Psychiatrists should provide leadership in policy and practice development to accomplish this goal.

Diagnostic challenges
Child welfare systems present unique challenges for comprehensive psychiatric assessments. Psychiatrists must receive complete prior mental health records, including those prior to foster care placement; as such, they should establish mechanisms to obtain collateral history from parents, foster parents, and other caregivers (eg, staff in residential placement), and obtain health and school records. Psychiatrists should communicate these needs to the team, assist in developing protocols for consent for release of information documents, and maximize information transfer within systems. Although most, if not all children, in foster care have suffered maltreatment exposure, the type, duration, and impact of such before foster care varies. Children may also experience traumatic exposures during foster care, including stress related to parental circumstances, separation from siblings, placement change, termination of parental rights, as well as illness and death of family members.

Although it may not be necessary or appropriate to ask children to recount specific experiences and/or exposures, psychiatrists should make the child and their family aware that they know that stressful events have occurred and provide psychoeducation on the impact of ongoing stressors in the context of maltreatment. Exposures need to be considered when conducting assessments. Doing so may include asking the child and caregivers to complete screening tools or diagnostic assessments specific to traumatic exposures as well as those related to other psychiatric diagnoses.

When a child in foster care is scheduled for a psychiatric assessment, clinical staff should inquire about the legal status of the child, the names and contact information for the person legally empowered to consent for treatment, and who will be bringing the child to the appointment. Unless the child and parent are prohibited from contact, arranging for parents to be present is optimal so that they can provide history, sign consents for release of information, and engage in consent for treatment. If a parent cannot be present, they can be contacted before the appointment for needed information.

The long-term priorities of the welfare systems are reuniting children and parents when possible and supporting...
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Understanding Child Maltreatment

Jeanette M. Scheid, MD, PhD

The Child Abuse Prevention and Treatment Act defines child abuse and neglect as “Any recent act or failure to act on the part of a parent or caretaker which results in death, serious physical or emotional harm, sexual abuse or exploitation; or an act or failure to act, which presents an imminent risk of serious harm.” Each state sets its own definitions of child abuse and neglect within the standard of federal law.

There were about 4.3 million reports of abuse and neglect in 2018, representing approximately 7.8 million children. Astoundingly, almost 1800 children died of abuse and neglect, at a rate of 2.39 per 100,000 US children. The most common form is general neglect, representing 60.8% of the cases. This was followed by physical abuse (10.7%), sexual abuse (7.3%), and psychological maltreatment (2.3%). Parents are most commonly identified as perpetrators (77.5%). Almost half (49.6%) of the perpetrators were white; drug use disorder was common (30.7%) among maltreatment perpetrators.

The child’s developmental age during maltreatment exposures is an important consideration in assessment, diagnosis, and treatment. There are likely sensitive developmental periods that affect risk for psychopathology. For instance, maltreatment exposure during infancy and early childhood disrupts normative attachments necessary for subsequent development, including capacity for trust, recognizing cause and effect, emotional regulation, and frustration tolerance. Similarly, developmental stage affects the diagnosis of posttraumatic stress disorder.

Without normative attachment, children can move into their middle years without the tools to succeed in peer relationships, school, and extracurricular activities. In adolescence, the impact of earlier maltreatment increases the likelihood of risk-taking behavior and subsequent health effects, including risky sexual behavior leading to sexually transmitted diseases, substance use, and suicide attempts. Subsequently, the increased risk of health and mental health problems persists through adulthood. Because of these potential long-term effects, obtaining a comprehensive social history, including maltreatment exposures and the characteristics of subsequent environments, is important when conducting a comprehensive psychiatric assessment and considering treatment approaches.

Dr Scheid is Associate Professor, Department of Psychiatry, Michigan State University, East Lansing, MI and Medical Consultant to the Michigan Department of Health and Human Services, Children’s Services Agency.

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Family functioning. Engaging parents throughout their children’s time in foster care supports these goals; engaged parents are better equipped to address their children’s physical and mental health needs.

Unfortunately, involving parents is complicated by many factors. Maternal characteristics such as poverty, substance use, co-occurring disorders, and domestic violence as well as perception of the effects of sharing information may discourage involvement. Addressing parental needs (eg, substance use disorder treatment) is important for successful reunification, but may present a barrier to simultaneous engagement in a child’s health care. Given that reunification is the most common goal, educating all team members about the importance of parental engagement is important throughout foster care placement.

CASE VIGNETTE

“James” is a 16-year-old admitted to a residential treatment facility after running away from 2 foster homes. His entrance into the foster care system was predicated by ongoing but undisclosed sexual abuse perpetrated by his stepfather that occurred for at least 5 years before discovery. At that time, he was diagnosed with bipolar disorder and anxiety. He was treated with aripiprazole, titrated to 15 mg daily and 0.5-mg alprazolam up to 3 times daily for acute anxiety. During residential assessment, James reported periodic temper outbursts and moodiness without clear episodes of depression or mania. Also during this time, he reported significant anxiety and occasional panic attacks.

During residential treatment, he participated in individual and group therapy. The aripiprazole was gradually tapered and discontinued, alprazolam was also tapered. He made plans to transition from the residential facility to an independent living program.

Common diagnoses

There are a wide variety of psychiatric diagnoses among children in foster care (Table 2). Rubin and colleagues looked at Medicaid claims data (2002 to 2007) from a national sample of youths aged 3 to 18 years who were enrolled in foster care. The findings indicated that rates of mental health diagnoses generally increased over this time with 2 exceptions: depression was stable from 2002 to 2005 but decreased from 2006–2007, and schizophrenia remained stable throughout.

Because of maltreatment, children in foster care often have trauma-related diagnoses, with posttraumatic stress disorder as the most specific trauma-related diagnosis. DSM-5 includes guidance about how PTSD may manifest in childhood. More general responses to trauma exposure may be captured by “trauma and stressor related disorder unspecified” if PTSD cannot be diagnosed with confidence.

To diagnose disorders common in childhood (eg, ADHD, anxiety disorders, and depressive disorders), psychiatrists should determine whether symptoms are present, the timing and duration of symptoms in relation to trauma exposures, and persistence after substantial reduction in trauma-related symptoms. Emotional dysregulation is a common response to traumatic exposures; if considering bipolar disorder or disruptive mood dysregulation disorder, clinicians must determine if full symptom, duration, and pattern criteria are met or if symptoms may be better explained by trauma.

Perception and thought disturbances are also relatively common in children with maltreatment exposure. Explanations may include intrusion of traumatic experiences (eg, nightmares, flashbacks, involuntary memories) and negative thoughts and feelings (eg,
an in-depth discussion of manifesta-
mid-2000s, psychotropic medication
mental exposure. Since its peak in the
family/genetic history and maltreat-
sidered, eg, a higher risk of emotion-
this trend has raised over-medication
Network (www.nctsn.org) provides
and adolescents through mid-2000.10
Pharmacotherapy
havioral catchup (ABC), which has
to 7 years to improve parenting skills
behavioral therapy (TF-CBT); par-
Strategies with empirical support in-
mental and stressor-related emotional
—such as exposure to substances
ment in utero, perinatal stress related to
mental abstinence syndrome, and the effect of any
use-related physical or neurologi-
jury—must be included in dif-
differential, treatment planning,
and assessment of longer-term
services, supports, and prognosis.
(See Keshin et al1 and Sege et al3
an in-depth discussion of manifesta-
tions of maltreatment and impact on
psychiatric diagnosis.)

Treatment approaches
Psychotherapy
Psychotherapy is generally consid-
ed first line when addressing trau-
and stimulus-related emotional
and behavioral difficulties relat-
to trauma. However, evidence-based
for existing disorders, and judi-
cious use to target symptoms that
not be managed by psychosocial treat-
ments alone, may be considered.
Psychopharmacological treatment
psychiatric diagnosis such as
major depressive disorder, and bipolar disorder.
In the context of
sequent existing recommendations and guidelines.
However, closer monitoring
—such as suicidal ideation
—difficult to assess individual medica-
tions. After any transition that involves
a new treatment team, both written and verbal communica-
important—in some medications
need to be discontinued (Table 4).

Table 4. Tips for discontinuing medications

<table>
<thead>
<tr>
<th>Treatments</th>
<th>Tips</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antidepressants</td>
<td>Taper medication prescribed at a sub-therapeutic dose without obvious justification.</td>
</tr>
<tr>
<td>Mood stabilizers</td>
<td>Taper medication prescribed at sub-therapeutic dose or limited evidence of efficacy for the condition in question.</td>
</tr>
<tr>
<td>Psychostimulants</td>
<td>Schedule the taper and discontinuation of any medication based on its half-life or other pharmacologic properties.</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>When considering tapering/discontinuing multiple medications, do so one at a time to improve ability to monitor adverse responses or return of psychiatric symptoms.</td>
</tr>
</tbody>
</table>

Use has plateaued, possibly a conse-
quence of oversight efforts.32
Treatment with psychotropic
should not be consid-
first line when targeting emo-
tional and behavioral difficulties relat-
to trauma. However, evidence-based
for existing disorders, and judi-
cious use to target symptoms that
not be managed by psychosocial treat-
ments alone, may be considered.

Psychopharmacological treatment
psychiatric diagnosis such as
major depressive disorder, and bipolar disorder.
In the context of
sequent existing recommendations and guidelines.
However, closer monitoring
—such as suicidal ideation
—difficult to assess individual medica-
tions. After any transition that involves
a new treatment team, both written and verbal communica-
important—in some medications
need to be discontinued (Table 4).

Concluding thoughts
Young adults transitioning out of
foster care may be less inclined to accept
recommendations from treatment providers, if only because they
perceive lack of control over their lives.

May they also have fewer natural
supports to help them navigate adult
responsibilities. It is, therefore,
important to inquire about support sys-
tems as well as to acknowledge their
lived experience and engage them in
shared treatment decision-making.

Children in foster care present
with extra challenges and unique
situations, but with thoughtful assess-
ments and coordination, they can
have positive outcomes. Psychiatrists
are in a unique position to provide
comprehensive clinical care and pol-
icy leadership supporting all chil-
dren’s health and well-being.

Dr Scheid is Associate Professor, Department of Psychiatry, Michigan State University, East Lansing, MI and Medical Consultant to the Michigan Department of Health and Human Services, Children’s Services Agency. She reports no conflicts of interest concern-
ing this article.

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Orthorexia Nervosa
Pathologically Healthful Eating or Pathologizing Healthy Eating?

Thomas M. Dunn, PhD, and Nicole Hawkins, PhD, CEDS

The term orthorexia nervosa was coined in 1997 by the alternative medicine physician Steven Bratman, MD, MPH; it is based on the Greek terms “ortho” meaning “correct” and “orexis” meaning “appetite” to describe individuals whose drive for healthy eating has resulted in malnutrition or social impairment. Bratman describes a period in his life where his drive for a diet to help him be clear headed and strong drove him to a preference for food that had been harvested from the ground less than 15 minutes before eating it. When he was obsessively scrabbling the ground for vegetables, he ultimately realized that his diet—and self-righteousness about it—was leaving him lonely and depressed. He also realized that there were others with similar behaviors. In 2000 he wrote the book, Fast Food Junkies.

With the exception of a JAMA review of Bratman’s book, ON was largely unknown to most academics and practitioners. Work in the area would languish until 2004, when a group of Italian investigators published research on what they referred to as a “maniacal obsession for healthy foods.” Their work led to a later publication introducing “ORTO-15,” an instrument designed to detect ON. Using this instrument, they suspected that roughly 6% of a community sample in Italy met the criteria for ON. A blizzard of papers followed, all generally trying to estimate the prevalence of the condition among different samples. Many of these studies were conducted in other

ACTIVITY GOAL
The goal of this activity is to provide an understanding of orthorexia nervosa.

LEARNING OBJECTIVES
After engaging with the content of this CME activity, you should be better prepared to:
• Discuss the problems associated with pathologically healthful eating.
• Recognize that orthorexia nervosa is distinct from other eating disorders.
• Define the diagnostic criteria that exist for orthorexia nervosa.

TARGET AUDIENCE
This continuing medical education (CME) activity is intended for psychiatrists, psychologists, primary care physicians, physician assistants, nurse practitioners, and other health care professionals who seek to improve their care for patients with mental health disorders.

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countries and required ORTO-15 to be translated into other languages.

Much of the work carried out with ORTO-15 (or a derivative) showed a very high prevalence in community samples for a type of disordered eating that was largely unknown to eating disorder specialists. Many of these studies reported an absurdly high prevalence, such as nearly 89% in a Brazilian study, 86% in a Spanish sample, and 69% in a German study.1

Eventually, it became clear that ORTO-15 does not truly measure pathologically healthful eating and has poor psychometric properties, and it fell out of favor with serious ON researchers.4 Most studies involving ORTO-15 or a derivative are highly suspect. Unfortunately, the bulk of the conclusions drawn about ON, in particular its prevalence, comes from these studies.

More recently, a 2017 study identified individuals in a college sample who endorsed excessive healthy eating, and highlighted their resulting malnutrition/being underweight or significant impairment in social functioning as a consequence of the diet. The investigators estimate that the true prevalence of ON is less than 1%, which puts it on a par with AN and BN but makes it less common than binge eating disorder.3

### Pathologically “healthy” eating

Case studies in the literature detail patients with severe health complications who used diet to control medical conditions. In one case, profound medical complications (including hypotenatemia, pancytopenia, pneumomediastinum, and pneumothorax) were seen in a 30-year-old man.6 His restricted eating consisted of limited amounts of brown rice and fresh vegetables for the exclusive purpose of treating a tic disorder.

In a second case, severe malnutrition and a body mass index (BMI) of 10.7 were seen in a 28-year-old woman. To treat her acne, she had been eating only uncooked vegetables after slowly reducing items she would eat—a nutritionist had suggested removing fats from her diet.7

Finally, a third case involved a 28-year-old man whose drive for achieving purity and health by dieting resulted in severe malnutrition and a BMI of 12.3.1 This last case study was notable in that it was the first to appear in a mainstream US psychiatric journal and the first to codify proposed diagnostic criteria in a peer-reviewed publication.

### Diagnostic criteria

There are 4 different proposed diagnostic criteria sets meant to identify individuals suffering from ON: 3 have been developed since 2015. The earliest set was developed by a US dietitian in a self-published quick reference guide for health care providers. It is not in wide circulation, nor has it been peer reviewed. There are also criteria developed by Barthels and her group that are published in German.2 The most widely cited criteria are those put forth by Moroze and colleagues8 (Table 1) and those generated in a later publication by Dunn and Bratman3 (Table 2).

### The prominent features of the proposed criteria sets are as follows:

- Preoccupation with nutrition or healthy eating resulting in malnutrition, health complications, being underweight, and/or social impairment;
- Drive for health and not for thinness; no disrupted body image;
- Anxiety, even panic, about unhealthy food;
- Guilt or distress after violating diet;
- Insistence on eating a “healthy” diet despite resulting medical complications;
- Rigid avoidance of unhealthy foods;
- Unrealistic ideas about how foods can cure disease or promote health;
- Fears about not eating healthfully reduced by ritualized preoccupation with food;
- Positive sense of self strongly associated with compliance in self-imposed healthy dieting;
- Sense of superiority over others because ones own diet is better.

All of the proposed criteria sets include important exclusions. For example, caution is warranted in applying ON in instances where intake is restricted based on food allergy, food intolerance, or on religious beliefs. ON would also be an inappropriate diagnosis for an individual whose presentation is due to another psychiatric condition, such as someone with schizophrenia that includes delusional beliefs about the benefits of food.

Although ON is distinct from AN, the two share significant overlap. Both conditions start with a sensible premise. For individuals with AN, it is sensible to avoid obesity, and for ON, it is sensible to have a healthy diet. In both conditions, however, individuals transition to pathological dieting that may affect their health or cause clinical impairment. It is our experience that both conditions involve a denial on the part of individuals about the functional impairment of their diet and have significant obsessive-compulsive features.

Although evidence is lacking, we have observed that traits of perfectionism, inflexibility, and extremism (refusing to see other points of view) are present in both conditions, as are deeply held ideologies that help provide order and structure to one’s life and help exert control over their environment. Finally, based on clinical observations, both patients with ON and patients with AN tend to be achievement oriented and can have cognitive distortions about food.

ON is also different from ARFID. Although patients with ARFID become malnourished or underweight because of their food intake, the majority of those patients restrict their intake because of an aversive experience that they have had with food. Aversion is defined in the classical conditioning sense that eating has become paired with a noxious experience, such as choking, vomiting, or constipation. Less frequently, those with ARFID are underweight because of extremely picky eating, or objections to the sensory properties of food. Based on case studies of ON, none of these

### Table 1. Moroze and colleagues’ proposed diagnostic criteria for ON

| Criterion A: Obsessional preoccupation with eating “healthy” foods, focusing on concerns regarding the quality and composition of meals (two or more of the following) |
| 1. Consuming a nutritionally imbalanced diet due to preoccupying beliefs about food “purity” |
| 2. Preoccupation and worries about eating impure or unhealthy foods and about the impact of food quality and composition on physical and/or emotional health |
| 3. Rigid avoidance of foods believed by the patient to be “unhealthy,” which may include foods containing fat, preservatives, food additives, animal products, or other ingredients considered by the subject to be unhealthy |
| 4. For individuals who are not food professionals, excessive amounts of time (eg, ≥3 hours daily) spent reading about, acquiring, and/or preparing specific types of foods based on their perceived quality and composition |
| 5. Guilty feelings and worries after transgressions in which “unhealthy” or “impure” foods are consumed |
| 6. Intolerance of others’ food beliefs |
| 7. Spending excessive amounts of money relative to one’s income on foods because of their perceived quality and composition |

| Criterion B: The obsessional preoccupation becomes impairing by either of the following |
| 1. Impairment of physical health due to nutritional imbalances, eg, developing malnutrition due to unbalanced diet |
| 2. Severe distress or impairment of social, academic, or vocational functioning due to obsessional thoughts and behaviors focusing on patient’s beliefs about “healthy” eating |

| Criterion C: The disturbance is not merely an exacerbation of the symptoms of another disorder, such as OCD, schizophrenia, or other psychotic disorder |

| Criterion D: The behavior is not better accounted for by the exclusive observation of religious food observance, or when concerns with specialized food requirements are in relation to professionally diagnosed food allergies or medical conditions |

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3Reprinted with permission from Moroze et al.4
postprandial anxiety. Behavior modification strategies surrounding food, eating, and health. It is beneficial for dichotomous thinking, overgeneralization, catastrophizing, and other cognitive distortions that are prominent for a given patient’s sense of superiority. Not only can these individuals have poor insight, they are often bombarded with messages about healthful eating that contradict treatment options for their recovery. When it comes to treating patients with ON, interventions should be individualized and based on the symptoms that are prominent for a given patient. It is critical to work with a dietitian when setting up a care plan. Cognitive restructuring is likely beneficial for dichotomous thinking, overgeneralization, catastrophizing, and other cognitive distortions surrounding food, eating, and health.

Relaxation training may assist with pre- and postprandial anxiety. Behavior modification strategies are also helpful. These strategies include systematic desensitization (patients gradually work up to eating food that causes them anxiety), flooding (early on in treatment insisting that patients eat “unhealthy” food and later process the experience), and positive reinforcement (providing a reward for achieving a goal related to eating).

Flooding is effective with inpatient care, but outpatients and day patients tend to respond better to systematic desensitization and positive reinforcement. These interventions may be useful to expand one’s food repertoire, increase socialization during meals, and diversify activities not spent in pursuit of health.

Psychoeducation about empirically validated dietetic science may help disabuse patients with orthorexia of false food beliefs. Patients with ON typically have endless environmental triggers, such as coming down with a cold, odd aches or pains, and perceived changes in mood and energy level. Identifying these triggers can be beneficial. For example, the patient can be taught to normalize minor health complications as a typical part of life or to avoid following those on social media who are fervent about being healthy. Identifying and coping with triggers are excellent topics for both individual and group psychotherapy.

Dysfunctional family relationships may prompt rigid dieting as a coping mechanism for some patients with ON. Conversely, patients can develop a sense of superiority over others and can provoke strife by judging their diet choices. Family therapy can help manage conflict among family members and sometimes deal with the root of family dynamics that leads to rigid dieting. Family therapy can educate family members about the nature of ON and provide coping skills to deal with the patient’s sense of superiority.

A search through the literature shows only one article on using psychiatric medication to treat ON. Moroze and colleagues8 were treating a young man who had a pathological focus on dietary science, believing their strict diet will lead to a better outcome. Given these stakes, there is considerable need for additional research and for psychiatrists who can diagnose and treat the condition.

REFERENCES
Physicians
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San Joaquin County Behavioral Health Services is seeking to fill Outpatient Adult [General], and Sub-Specialty Psychiatry (Child Psychiatry, Geriatric, Forensic, Addiction and Psychosomatic Medicine) positions in a multidisciplinary, recovery-oriented clinical setting. Services are provided either on-site or using a hybrid model of on-site and tele-psychiatry practice. The positions offer a very competitive salary with a guaranteed base, plus incentive opportunities, board certified Psychiatrists have the potential to easily earn over $300k+ a year; comprehensive health insurance; up to three retirement and pension programs; 35 days of vacation and CME time that increase with tenure. Signing and moving bonuses are also available. Interested J-1 and H-1B candidates are welcome to apply.

Fax your CV to 209-468-2399 or email to BHSAdministration@sjcbhs.org. EOE

The doctors of TRADITIONS BEHAVIORAL HEALTH are the largest provider of MD psychiatric services to adult populations all over California and also now in WA and NV! We provide services to the seriously and persistently mentally ill and have openings in the San Francisco Bay Area, Santa Barbara, San Diego, Los Angeles, Reno and Seattle. Overall we plan to add 50 more Fulltime psychiatrists to bring our medical staff team to 400 psychiatrists. Our packages vary from a minimum of $300,000 per year plus $10,000 in bonuses and a benefit package valued at approximately $90,000, to up to $500,000, for the industrious physician. Our generous benefit package includes over 6 weeks paid time off per year. If you are creative and think outside the box, if you value diversity and cultural competency, if you like innovative programs that are patient driven, using a rehabilitative, rather than illness model, if you want more time to work with patients, to get the best results, then TBH is the company for you. To learn more about the specific job openings and salary and benefit packages, check out our Website at: www.tbhcare.com or Email your letter of interest and CV to our company VP of Recruitment, Derek Sawyer at: Derek@tbhcare.com. EOE

TBH is an equal opportunity employer.

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FLORIDA

► UNIVERSITY OF MIAMI, DEPARTMENT OF PSYCHIATRY
SYLVESTER COMPREHENSIVE CANCER CENTER
EXCEPTIONAL PSYCHIATRY OPPORTUNITY

Consultation-Liaison Psychiatrist

The Department of Psychiatry at the University of Miami and The Sylvester Comprehensive Cancer Center announces a search for an academic psychiatrist with interest and experience in psychosomatic medicine and psycho-oncology. Applicants can anticipate working collaboratively with fellow psycho-oncology providers including five psychologists, a psychiatrist and a team of oncology social workers.

JOB DESCRIPTION

Providing psychiatric consultation-liaison services in either inpatient, outpatient or both oncology settings across the oncology enterprise. Participation as a member of the Department of Psychiatry and Behavioral Sciences Participating in teaching activity for advanced trainees to ensure the highest level of educational excellence.

QUALIFICATIONS OF THE PSYCHIATRIST

• Board certification in Psychiatry.
• Board eligibility/certification in C-L Psychiatry would be preferred but experience will be considered.

COMPENSATION & BENEFITS

This dynamic position commands an extremely competitive salary enhanced by an attractive benefits package, including but not limited to:

• Competitive compensation including bonus programs, vacation
• Comprehensive benefits include: health/dental/vision, paid malpractice, 403(b) plan

For additional information, please contact:
Kristen Smith
(442)265-1606
kristensmith@co.imperial.ca.us

► SEACOAST
MENTAL HEALTH CENTER
PROVIDING HOPE. PREVENTING SUICIDE.

Seeks a full-time Psychiatrist

• Location: Rye, NH

EOE M/F

► MASSACHUSETTS

Cape Cod Healthcare is an integrated health system located on Cape Cod, Massachusetts. Over 6,500 employees are united in our mission to provide excellent health care services to our communities.

Cape Cod Healthcare Psychiatry – Outpatient Only – Cape Cod Healthcare

LIVE AND WORK OCEANSIDE!!

Immaculate full-time opening for BC/BE psychiatrist. Responsibilities include evaluations and follow-up appointments for adult psychiatric patients requiring medication management.

40 hour-per-week position in our outpatient clinic in Hyannis, MA. Schedule is Monday through Friday. May also work one weekend on-call. No weekend on-call duty is required but available if interested with extra compensation attached. Consultation/collaboration with other clinical staff on shared cases as needed. This will be an employed position by Cape Cod Healthcare with a generous base salary, sign-on bonus, and relocation support.

Please see below for a list of the top reasons to consider this position:

1. Competitive compensation including bonus programs, vacation
2. Comprehensive benefits include: health/dental/vision, paid malpractice, 403(b) plan
3. Locations:
   - Cape Cod: Over 20 miles of sandy beaches and numerous outdoor activities
   - South Coast: Miles of sandy beaches and numerous outdoor activities

New England is a great place to practice medicine, with competitive salaries and a high quality of life.

Interested candidates apply at: https://shmc-nh.org/job-openings

Email: ananda@ccf.org

► OHIO

Clinical Neuroscience of Mood Disorders Fellowship is looking to fill an available position.

Requirements for this position is to be a MD who has completed residency in psychiatry or related field or a PhD in Clinical Psychology. Candidate should be eligible for an Ohio Trainee License to conduct clinical work. This is a 1 - 2 year program and is accredited by the Cleveland Clinic. Position can be filled any time during the year on a rolling basis. The fellowship is designed to train fellows in clinical care and neurobiological basis of depression and bipolar disorder. Current research is focused on neurochemical, imaging and genetic biomarkers for diagnosis and treatment as well as on clinical trials of novel pharmacological agents and strategies.

Please contact Amit Anand, MD at ananda4@ccf.org

► VIRGINIA

The Mann Grandstaff V A Medical Center in Spokane, Washington is looking for a Psychiatrist to serve as Chief of the Psychiatry Section.

The Section Chief is responsible for direct patient care, ensuring the overall quality and efficiency of psychiatric services, advising the Behavioral Health Service Chief on matters related to psychiatric service provision, and is the supervisor for 15 physicians and nurse practitioners, as well as a PA and a clinical pharmacy specialist.

The Mann Grandstaff VAMC consistently rates very high in the VA’s annual staff satisfaction and patient satisfaction surveys.

Please contact:
Gregory Winter, MD,
Psychiatry Section Chief
Gregory.Winter20@va.gov
509-434-7389

Qualify For A Free Subscription Online @ www.psychiatrictimes.com
**INGREZZA** (valbenazine) capsules for oral use

**Brief Summary:** for full Prescribing Information and Patient Information, refer to package insert.

**INDICATION AND USAGE**

**INGREZZA** (valbenazine) capsules is indicated for the treatment of adults with tardive dyskinesia.

**CONTRAINDICATIONS**

**INGREZZA** is contraindicated in patients with a history of hypersensitivity to valbenazine or any components of **INGREZZA**. Rash, urticaria, and reactions consistent with angioedema (e.g., swelling of the face, lips, and mouth) have been reported.

**WARNINGS AND PRECAUTIONS**

**Somnolence**

**INGREZZA** can cause somnolence. Patients should not perform activities requiring mental alertness such as operating a motor vehicle or operating hazardous machinery until they know how they will be affected by **INGREZZA**.

**QT Prolongation**

**INGREZZA** may prolong the QT interval, although the degree of QT prolongation is not clinically significant at concentrations expected with recommended dosing. In patients taking a strong CYP2D6 or CYP3A4 inhibitor, or who are CYP2D6 poor metabolizers, **INGREZZA** concentrations may be higher and QT prolongation clinically significant. For patients who are CYP2D6 poor metabolizers or are taking a strong CYP2D6 inhibitor, dose reduction may be necessary. For patients taking a strong CYP3A4 inhibitor, reduce the dose of **INGREZZA** to 40 mg once daily. **INGREZZA** should be avoided in patients with con genital long QT syndrome or with arrhythmias associated with a prolonged QT interval. For patients at increased risk of a prolonged QT interval, assess the QT interval before increasing the dosage.

**Parkinsonism**

**INGREZZA** may cause parkinsonism in patients with tardive dyskinesia. Parkinsonism has also been observed in patients treated in studies. In the 3 placebo-controlled clinical studies in patients with tardive dyskinesia, the incidence of parkinson-like adverse events was 3% of patients treated with **INGREZZA** and <1% of placebo-treated patients. Postmarketing safety reports have described parkinson-like symptoms, some of which were severe and required hospitalization. In most cases, severe parkinsonism occurred within the first 2 weeks after starting or increasing the dose of **INGREZZA**. Associated symptoms have included tremor (tremor, dystonia, tremor, drooling, and hypokinesia). In cases in which follow-up clinical information was available, parkinson-like symptoms were reported to resolve following discontinuation of **INGREZZA** therapy. Reduce the dose or discontinue **INGREZZA** treatment in patients who develop clinically significant parkinson-like signs or symptoms.

**ADVERSE REACTIONS**

The following adverse reactions are discussed in more detail in other sections of the labeling:

- **Hypersensitivity**
- **Somnolence**
- **QT Prolongation**
- **Parkinsonism**

**Clinical Trials Experience**

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

**Variable and Fixed Dose Placebo-Controlled Trial Experience**

The safety of **INGREZZA** was evaluated in 3 placebo-controlled studies, each 6 weeks in duration (variable dose, fixed dose, and fixed dose escalation, dose reduction), including 445 patients. Patients were 26 to 84 years of age with moderate to severe tardive dyskinesia and had concurrent diagnoses of mood disorder (27%), anxiety (12%), schizophrenia or schizoaffective disorder (72%). The mean age was 59 years. Patients were 57% Caucasian, 39% African-American, and 4% other. With respect to ethnicity, 28% were Hispanic. **INGREZZA**-associated symptoms have included parkinsonism (tremor, dystonia, tremor, drooling, and hypokinesia). In cases in which follow-up clinical information was available, parkinson-like symptoms were reported to resolve following discontinuation of **INGREZZA** therapy. Reduce the dose or discontinue **INGREZZA** treatment in patients who develop clinically significant parkinson-like signs or symptoms.

**Other Adverse Reactions Observed During the Premarketing Evaluation of **INGREZZA**

**Other adverse reactions of ≥1% incidence and greater than placebo are shown below. The following list does not include adverse reactions: 1) already listed in previous tables or elsewhere in the labeling, 2) for which a drug cause was remote, 3) which were so general as to be uninformative, 4) which were not considered to have clinically significant implications, or 5) which occurred at a rate equal to or less than placebo.**

**Endocrine Disorders:** blood glucose increased

**General Disorders:** weight increased

**Infectious Disorders:** respiratory infections

**Neurologic Disorders:** dizziness, parkinsonism, extrapyramidal symptoms (non-akathisia)

**Psychiatric Disorders:** anxiety, insomnia

**Skin and Subcutaneous Tissue Disorders:** rash

**DRUG INTERACTIONS**

**Drugs Having Clinically Important Interactions with INGREZZA**

**Table 2: Clinically Significant Drug Interactions with INGREZZA**

**Table 1: Adverse Reactions in 3 Placebo-controlled Studies of 6-week Treatment Duration Reported at ≥2% and >Placebo**

**Adverse Reaction**

**INGREZZA** (n=282) (%) Placebo (n=183) (%)

**General Disorders**

*Somnolence (somnolence, fatigue, sedation)*

10.9% 4.2%

**Nervous System Disorders**

Anticholinergic effects (dry mouth, constipation, disturbance in attention, vision blurred, urinary retention)

5.4% 4.9%

Balance disorder (tall, gait disturbance, dizziness, balance disorder)

4.1% 2.2%

Headache

3.4% 2.7%

Akathisia (akathisia, restlessness)

2.7% 0.5%

**Gastrointestinal Disorders**

Vomiting

2.6% 0.6%

Nausea

2.3% 2.1%

**Musculoskeletal Disorders**

Arthralgia

2.3% 0.5%

*Within each adverse reaction category, the observed adverse reactions are listed in order of decreasing frequency.*

1 The induction potency of St. John’s wort may vary widely based on preparation.
IN ADULT PATIENTS WITH TARDIVE DYSKINESIA (TD)

Choose INGREZZA for results you can see¹

INGREZZA® (valbenazine) capsules reduced TD severity at 6 weeks, with results you can start to see as early as 2 weeks¹ ³

Important Information

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IMPORTANT SAFETY INFORMATION

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WARNINGS & PRECAUTIONS (continued)

Parkinsonism

INGREZZA may cause parkinsonism in patients with tardive dyskinesia. Parkinsonism has also been observed with other VMAT2 inhibitors. Reduce the dose or discontinue INGREZZA treatment in patients who develop clinically significant parkinson-like signs or symptoms.

ADVERSE REACTIONS

The most common adverse reaction (≥5% and twice the rate of placebo) is somnolence. Other adverse reactions (≥2% and >Placebo) include: anticholinergic effects, balance disorders/falls, headache, akathisia, vomiting, nausea, and arthralgia.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see the adjacent page for Brief Summary of Prescribing Information and visit www.INGREZZAHCP.com/PI for full Prescribing Information.