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Mark Moran

Olympic gold medal swimmers Michael Phelps and Allison Schmitt spoke candidly about wrestling with depression even as they were at the peak of their athletic achievement. See story below.


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Being abused as a child can influence addiction recovery.

SAMHSA Child MH Event Features Olympic Gold Medalists

Health and Human Services Secretary Tom Price presented awards to honorary chairs Michael Phelps and Allison Schmitt. **BY MARK MORAN**

"For the longest time, I was really good at compartmentalizing things so I never had to deal with them. That brought me to a point in my life when I was at an all-time low. I remember sitting in my room alone for four or five days, wanting only to kill myself. ... It was then I realized I needed help, and I couldn't do it alone."

Those are the words of Olympic swimmer Michael Phelps, the most decorated Olympian in history, at a special event last month celebrating National Children's Mental Health Awareness Day. The event, of which APA was a partner, was sponsored by the Substance Abuse and Mental Health Services Administration (SAMHSA) and held at George Washington University in Washington, D.C. Phelps and close friend Allison Schmitt, also an Olympic medalist swimmer, served as honorary chairs.

Phelps and Schmitt spoke of their own experience with mental illness and seeking treatment that helped them move toward recovery. They emphasized the importance of modeling for children that, as Schmitt said, "It's OK not to feel OK." Schmitt sought care for depression following the suicide of a 17-year-old cousin. "I've become passionate about mental health," she said.

"Communication is so important, and we make it harder than it needs to be," Phelps said. "Teaching kids to be aware of their emotions and aware that it is OK to talk about their feelings—I think that is very powerful."

The national event, viewable on the SAMHSA website, especially emphasized the importance of integrated behavioral and general health care and highlighted community programs supported by SAMHSA that employ coordinated systems that

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PERIODICALS: TIME SENSITIVE MATERIALS

House Passes AHCA Bill Amid Protests From APA, Other Groups

APA and five other medical organizations have urged the Senate to "put aside" the AHCA and work with them to "achieve real bipartisan solutions" to improve affordability, access, and coverage for all. **BY HARRIET EDLESON**

The U.S. House of Representatives voted 217-213 to pass the American Health Care Act (AHCA) last month after the bill had been amended to garner enough votes.

Immediately after the vote was announced, APA released a statement with five other major medical organizations to urge the Senate to "put aside" the AHCA and instead work with them to "achieve real bipartisan solutions to improve affordability,

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Congress Rejects White House Proposal To Cut NIH Funding

Agencies that support mental health research and programs are given a $2 billion boost. ***BY HARRIET EDLESON***

NIH

When the U.S. House of Representatives and U.S. Senate voted in favor of passing a $1.1 trillion federal spending package last month, it signaled significant good news for medicine in general and mental health and psychiatry in particular.

In a rejection of the White House proposal to cut $1.2 billion from the budget of the National Institutes of Health (NIH), Congress pushed through a bipartisan deal that increased funding for NIH. Passage of the legislation, which was signed by President Trump on May 5, averted a government shutdown and provides funding through September, the end of Fiscal 2017.

Overall, the Department of Health and Human Services (HHS) was appropriated $2.8 billion more than in Fiscal 2016, mostly due to the $2 billion increase for NIH. With that increase, the total appropriated to NIH through September is $34 billion, a 6.2 percent increase.

The mental health institutes under NIH are also winners in the budget: the National Institute of Mental Health (NIMH), the National Institute on Drug Abuse (NIDA), and the National Institute on Alcohol Abuse and Alcoholism (NIAAA) all received funding increases (see table on page 33).

Among the research areas benefiting from passage of the package are Alzheimer's disease, the Precision Medicine Initiative, and the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative. They received increases of, respectively, $400 million, $120 million, and $110 million.

The Substance Abuse and Mental Health Services Administration was given a total budget of $3.6 billion, including $650 million over Fiscal

see **Funding** *on page 33*

IN THIS ISSUE

DEPARTMENTS

Interested in Expanding Your Practice?

Collaborative care continues to be an exciting area of growth and opportunity for psychiatrists. APA is offering free training under the Transforming Clinical Practice Initiative (TCPI) supported by a $2.9 million, four-year federal grant. More information about the training is posted at www.psychiatry.org/TCPI.

Proposed Anthem-Cigna Merger Terminated Following Appeals Court Ruling

Opposition to the Anthem-Cigna merger by APA and other medical and patient advocacy groups has been part of a broader concern about consolidation in the insurance industry and its effect on access to care. **BY MARK MORAN**

A proposed merger between health insurance giants Anthem and Cigna Inc. has finally hit a dead end.

Anthem issued a statement last month terminating the proposed merger after a U.S. appeals court upheld a lower district court ruling blocking the merger on the grounds that it would have diminished competition and raised prices for consumers. Cigna exited the agreement in February after another district court ruling blocked the merger, and now the two companies are feuding over the terms of disengagement.

"In light of [the appeals court] decision and Cigna's refusal to support the merger, … Anthem has delivered to Cigna a notice terminating the Merger Agreement," according to a statement from Anthem. "Cigna has failed to perform and comply in all material respects with its contractual obligations. As a result, Cigna is not entitled to a termination fee. On the contrary, Cigna's repeated willful breaches of the Merger Agreement and its successful sabotage of the transaction has caused Anthem to suffer massive damages, claims which Anthem intends to vigorously pursue against Cigna."

The statement effectively puts an end to the merger, which was first proposed in September 2015.

APA and other medical groups strongly opposed the Anthem-Cigna merger, as well as a potential consolidation between Aetna and Humana, also blocked by the courts. APA leaders met with officials from the Department of Justice about the dangers of the proposed mergers. They argued that the mergers would be detrimental to health care generally, but could especially be harmful to patients with mental illness because the mergers would diminish competition in setting rates and determining conditions of psychiatrist participation in health networks. APA also emphasized to the department that diminished access could result in violations of the federal Mental Health Parity and Addiction Equity Act.

"The trend toward consolidation in the insurance market is a troubling one that threatens patient choice, which is critical in our health care system," said then APA President Maria A. Oquendo, M.D., Ph.D. "We are pleased that the court sided with the Justice Department and agreed that the Anthem-Cigna merger would reduce competition and limit patients' coverage options."

APA CEO and Medical Director Saul Levin, M.D., M.P.A., concurred. "The termination of the Anthem-Cigna merger ends a long chapter in which the AMA, along with APA and other medical specialties, fought to preserve competition in the health insurance market and prevent insurers from acquiring unprecedented market power that would have been detrimental to network adequacy and to patients," Levin said. "APA will continue to advocate on behalf of patients and physicians to foster more competitive health insurance markets."

In the April 28 ruling by the U.S. Court of Appeals of the District of Columbia, Judge Judith Rogers, writing for the majority, said the U.S. District Court of the District of Columbia was correct in its February ruling that whatever market efficiencies might be achieved by consolidation were not sufficient to outweigh the harm to competition.

"[W]e hold that the district court did not abuse its discretion in enjoining the merger based on Anthem's failure to show the kind of extraordinary efficiencies necessary to offset the conceded anticompetitive effect of the merger in the 14 Anthem states: the loss of Cigna, an innovative competitor in a highly concentrated market," the judge wrote. "Additionally, we hold that the district court did not abuse its discretion in enjoining the merger based on its separate and independent determination that the merger would have a substantial anticompetitive effect in the Richmond, Virginia, large group employer market."

Consolidation in the insurance market has been a growing concern among

see **Merger** *on page 23*

Penn State Named Site Of National Child Abuse Prevention Center

Eunice Kennedy Shriver National Institute awarded $7.7 million to new center for child maltreatment studies. **BY JOANN BLAKE**

Pennsylvania State University—known widely for its winning sports teams and the notorious Sandusky sex scandal—will become home to the first national child abuse prevention center.

The university announced in April that it had been selected by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) to receive a $7.7 million grant over the next five years. In addition, Penn State has committed an additional $3.4 million to the center, bringing the total to over $11 million.

The goal of the new center, which will supplement the university's Child Maltreatment Solutions Network, is to prevent child maltreatment and promote the health and well-being of abuse survivors. Since 2012—the year former Penn State assistant football coach Jerry Sandusky was found guilty of 45 counts of sexual abuse—the university has hired nine new faculty who are conducting research in this area.

"This is an example of something good coming out of something so devastating and painful," said Judith A. Cohen, M.D., medical director for the Center for Traumatic Stress in Children and Adolescents in Pittsburgh, referring to the Jerry Sandusky case. Cohen is also a professor of psychiatry at Temple University's Medical School in Philadelphia. "At times, we have to learn the hard way that a change in culture and practice is needed across the state and nationwide."

The overarching goal of the center is to translate research into solutions that will help implement new, targeted, and optimized interventions designed to positively impact children's lives.

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One of several projects to be supported by the award will invite 1,200 children aged 8 to 13 from around the Commonwealth of Pennsylvania to participate in a study focused on eradicating health disparities for children who have experienced the child welfare system. The large cohort study "will include health screenings, monitoring, and education in the areas of emotional and behavioral well-being as well as physical health," according to a university press release.

"Maltreatment is a critical issue requiring tangible solutions. There needs to be a heightened focus on raising the bar for research in this area so we can develop specific ways to prevent maltreatment and promote health and well-being for survivors," Jennie Noll, director of the Child Maltreatment Solutions Network and principal investigator of the NIH award, said in a press release. "We don't yet have a comprehensive understanding of exactly why maltreatment leads to such dire consequences for some, while others may exhibit remarkable resilience. This is why it is vitally important that we identify the mechanisms involved in these health disparities."

Cohen told *Psychiatric News* she is "gratified and excited" to see more funding sources support psychotherapy and children's issues, despite fewer funds to go around. Among the organizations leading the way is the National Center for Traumatic Stress Network (NCTSN.org), she said. It coordinates national education and training, and provides information on a wide variety of child topics including trauma, treatment and services, and policy. **PN**

Rethinking the 15-Minute Medication Management Visit: Does it Work?

A redesigned basic psychiatric care visit would incorporate evidence-based care and a recovery orientation. **BY MARK MORAN**

The 15-minute medication management visit has become one of the standards of psychiatric practice. But is it as effective in helping patients as it could be? Does it engage all the skills a psychiatrist brings to patient care?

And is anyone—patient or physician—happy with the current "med check" model?

William Torrey, M.D., a professor of psychiatry and vice chair for clinical services at the Dartmouth Geisel School of Medicine, said that the answer to those questions is a resounding no, and he argued, in an Open Forum article posted March 1 in *Psychiatric Services in Advance,* for a reconceptualization and redesign of the medication management visit. Torrey's co-authors were Ida Griesemer of the School of Global Public Health at the University of North Carolina, Chapel Hill, and Elizabeth Carpenter-Song, Ph.D., a medical anthropologist at Dartmouth College.

Torrey and colleagues also proposed a team-based redesign of the psychiatric visit based on research he has conducted through the Patient-Centered Outcomes Research Institute (PCORI). According to PCORI, its mission is to fund research that can help patients and caregivers make better-informed decisions about health care choices.

"As professionals, it is our job to sort out how to organize care so that when people are experiencing difficulties, they walk into a system that actually addresses their needs," he told *Psychiatric News*.

Torrey said that he believes the term "medication management visit" should be scrapped. "Even the way we talk about the work, as a 'medication management' visit or 'med check' frames the process in a way that isn't helpful," he said. "If you start by framing the visit as being all about medicine, you miss much of what psychiatrists can offer—real connection and the ability to help people be more hopeful and get on with their lives.

"Instead of thinking of the work as providing medication management, we should emphasize 'care' and call it 'psychiatric care'—just like 'primary care.' As in a primary care visit, what really matters is the expert care you receive, whether or not you leave with a prescription."

Based on ongoing research Torrey has conducted with PCORI comparing different team-based approaches, the authors of the *Psychiatric Services* paper proposed a redesigned visit in which much of the essential history gathering—symptoms, side effects, and vital signs—is done prior to the psychiatrist's and patient's meeting.

"The redesigned visit might look more like a smooth-running primary care office where history taking, basic assessment, and measurements of vital signs are gathered before the physician enters the room and where designated team members are prepared to put the treatment plan into action at the end of the visit," they wrote. "Common clinical scenarios can be anticipated, allowing psychiatric care clinicians to design effective and efficient clinical pathways ... that can be ordered with the check of a box when indicated. ... With well-designed workflows, psychiatric care providers can use their limited time for the essential health-promoting work: connecting therapeutically, integrating patient-specific aggregated data with what is known from the scientific literature, and partnering with each patient to develop a practical shared biopsychosocial plan."

William Torrey, M.D., says his work as a services researcher for the Patient Centered Outcomes Research Institute (PCORI) has convinced him that a redesign of the standard 15-minute psychiatric visit can better serve the goal of recovery.

Torrey said he believes a redesigned basic "psychiatric care" visit should incorporate principles from the best trends in recent years: the movement toward evidence-based care and recovery-oriented treatment. "The more the individual can understand about the illness and be activated to manage his or her own illness and be part of the health care process, the better he or she does over time," Torrey said. "People who do the best are those who move from being passive recipients of care to active participants in co-creation of health. We can help people build the knowledge, skills, and confidence to play an active role. This is what the psychiatric care visit should be focused on."

Concern about the "med check" and a corresponding drop in psychotherapy provided by psychiatrists is not new, and the phenomenon is supported by research: a 2008 report in the *Archives of General Psychiatry* by Ramin Mojtabai, M.D., M.P.H., and Marc Olfson, M.D., M.P.H., found that between 1996-1997 and 2004-2005, the percentage of office-based visits to psychiatrists involving psychotherapy decreased by 44.4 percent.

Eric Plakun, M.D., chair of the APA Psychotherapy Caucus, commenting on the Open Forum article, agreed that the 15-minute med check pleases no one. "We already know the doctor/patient relationship predicts whether medications will be taken, and, independently, whether they will work," he told *Psychiatric News*. "How does this trusting relationship get created in 15 minutes or even when using an efficient team of providers, as proposed in the editorial?"

Plakun is the associate medical director and director of biopsychosocial advocacy at the Austen Riggs Center in Stockbridge, Mass.

"There is clear evidence that the combination of medication and therapy is superior to either alone for many disorders," Plakun said. "How does it make sense for psychiatrists to [be forced to] pick only one of these demonstrably powerful tools that are effective and associated with brain change? The 15-minute med check is a *reductio ad absurdum* of the biomedical model that threatens to supplant the biopsychosocial model for the etiology and treatment of mental disorders—especially when a third to half of the time is spent interfacing with an electronic health record."

Plakun said the Psychotherapy Caucus stands for "the importance

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CMS Final Rule Shortens 2018 Enrollment Period in Effort to Stabilize Insurance Markets

The Centers for Medicare and Medicaid Services (CMS) last month issued a final rule to increase choices and encourage stability in the Affordable Care Act health insurance market for 2018. For psychiatrists and their patients, among the most important aspects of the rule—which is designed to address market instability created by departures of insurance companies from the health care exchanges—is the abbreviated enrollment period for 2018. Under the rule, the annual open enrollment period for 2018 will more closely align with Medicare and the private market; it will begin on November 1 and end on December 15.

The change is designed to encourage individuals to enroll in coverage prior to the beginning of the year. CMS believes the proposed change will "improve individual market risk pools by reducing opportunities for adverse selection by those who learn they will need medical services in late December and January and will encourage healthier individuals who might have previously enrolled in partial year coverage after December 15 to instead enroll in coverage for the full year."

According to CMS, the final rule also does the following:

- Requires individuals to submit supporting documentation for special enrollment periods to ensure that only those who are eligible are able to enroll. The rule is designed to encourage individuals to stay enrolled in coverage all year, reducing gaps in coverage and resulting in fewer individual mandate penalties.
- Allows issuers to require individuals to pay back past due premiums before enrolling in a plan with the same issuer for the next year.
- Allows issuers additional actuarial value flexibility to develop more choices with lower premium options for consumers and to continue offering existing plans.
- Allows states oversight of "network adequacy" in exchange plans—that is, determining if plans have enough providers to ensure real access to care.

The CMS final rule is posted at https://www.federalregister.gov/documents/2017/04/18/2017-07712/patient-protection-and-affordable-care-act-market-stabilization. APA members seeking more information about how the final rule on market stabilization may affect their patients and their practice may contact Michelle Dirst at mdirst@psych.org.

Emergency Department Intervention May Reduce Suicide Attempts in At-Risk Patients

Secondary suicide risk screening by the ED physician, discharge resources, and post-ED telephone calls led to a reduction in the proportion of participants who attempted suicide over the 12-month observation period. **BY NICK ZAGORSKI**

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Suicide attempts fell significantly in at-risk patients seen in several U.S. emergency departments after the sites began offering a multifaceted intervention program, according to a study published April 29 in *JAMA Psychiatry.* The findings suggest that it may be possible to reduce the risk of suicidal behaviors in at-risk patients without overburdening emergency settings.

The emergency department (ED) has long been recognized as a place where people at high risk of suicide interact with the health care system. (One study estimated that up to 40 percent of all people who die by suicide visit the ED in the year before death, including 15 percent due to self-harm.) While this makes EDs a prime location for identifying and treating those at greatest risk of suicide, most departments lack the resources needed to effectively manage these patients.

Ivan Miller, Ph.D., a professor of psychiatry and human behavior at the Warren Alpert Medical School of Brown University, set out to see if a brief in-ED intervention and a series of telephone calls after ED discharge could make a difference in the lives of at-risk patients. Compared with usual ED treatment, the number of patients who attempted suicide dropped by about 20 percent and the total number of suicide attempts dropped by about 30 percent.

The clinical trial, known as the Emergency Department Safety Assessment and Follow Up Evaluation (ED-SAFE) took place in eight EDs in the United States. The participating sites ranged from small community hospitals to large academic centers, and none had an on-site or adjacent psychiatric center, in an effort to make the study more generalizable to any ED in the U.S. The study was the largest suicide intervention trial to date, Miller told *Psychiatric News.*

For the three-phase study, Miller and colleagues enrolled 1,376 adults with a recent suicide attempt or ideation who presented at one of the eight emergency departments. During the first phase, all patients who enrolled received treatment according to the customary care at each ED; patients enrolled during the second phase received usual care plus a universal suicide risk screening assessment (the Patient Safety Screener); and patients in the third phase received a three-part intervention plan.

The intervention featured a secondary suicide risk screening designed for emergency department physicians, a self-administered safety plan provided by nursing staff, and weekly check-ins with the patient and/or a significant other by a trained coping advisor for one year after discharge. In addition to these calls, all participants received periodic follow-up phone interviews to assess their status and to refer them to a suicide hotline if necessary.

There were 548 suicide attempts during the study period, with 288 participants making at least one suicide attempt (53 patients had two attempts and 67 had three or more).

There were no significant differences in the number of patients who made an attempt between the usual-care and universal-screening groups (23 percent versus 22 percent) or total number of attempts (0.45 per participant versus 0.44 per participant). These numbers did drop during the intervention phase, however, which saw only 18 percent of participants attempt suicide and 0.31 attempts per participant.

The study authors estimated that this reduction translated to a number needed to treat (NNT) of 22. "This level of risk reduction compares favorably with other interventions to prevent major health issues, including statins to prevent heart attack (NNT=104), antiplatelet therapy for acute ischemic stroke (NNT=143), and vaccines to prevent influenza in elderly individuals (NNT=20)," Miller and colleagues wrote.

"Given that our study design had many limitations that are a fact of suicide prevention research, these results are impressive and encouraging," Miller said. For example, Miller highlighted that every participant received follow-up to assess risk, and this safety measure may have decreased suicide rates in the non-intervention groups.

And though the intervention was designed to be readily implemented in EDs without strong mental health resources, Miller believes it can be also useful in places with a strong psychiatric presence. "The telephone follow-up by trained coping specialists we included is not routinely done in psychiatric emergency settings, for example, so that is something that could be incorporated into existing strategies," he said.

Miller added that more research is needed to understand whether each of the three components of the intervention—the secondary screen, safety plan, or follow-up calls—contributed equally to reducing suicidal behaviors in at-risk patients.

"We applaud the investigators for conducting a rigorous test of an innovative screening and intervention strategy to help reduce suicide risk in adult ED patients," wrote Jeffrey Bridge, Ph.D., of Ohio State University and colleagues in an accompanying editorial. "Now, we must ensure that the implicit message to patients at risk for suicide is that they are as welcomed in the ED as patients with chest pain or broken bones and are equally deserving recipients of standardized, algorithm-driven care."

The ED-SAFE study was supported by an award from the National Institute of Mental Health. **PN**

An abstract of "Suicide Prevention in an Emergency Department Population: The ED-SAFE Study" is posted at http://jamanetwork.com/journals/jamapsychiatry/fullarticle/2623157. The accompanying editorial, "ED-SAFE—Can Suicide Risk Screening and Brief Intervention Initiated in the Emergency Department Save Lives?" is posted at http://jamanetwork.com/journals/jamapsychiatry/fullarticle/2623156.

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of psychiatrists thinking beyond meds alone, and for ensuring that psychotherapy remains an essential part of the training and skills of psychiatrists."

Grayson Norquist, M.D., chair of the APA Council on Quality Care and chair of PCORI's Board of Governors, said the reform proposed by Torrey and colleagues is thoughtful but requires buy-in and collaboration from multiple stakeholders. "This is a 'system' problem and will require new models for organization of care and financing before anything changes," Norquist said. "It's not clear that much will change until these models, especially those that focus on team approaches to patient care, are implemented in local and state systems."

Torrey acknowledges that the market and social forces that have made the 15-minute med check a prominent feature of the mental health landscape will not be reversed easily. But he said psychiatrists with whom he has spoken are energized by the idea of transforming care, and he invites APA members to contact him with their thoughts and perspectives.

"Doctors get excited about this, and they feel demoralized by the 15-minute visit as it is practiced today," he said. "People feel diminished by being called a 'prescriber,' and we know that as psychiatrists we can offer much more. Therapeutic engagement—being a force for health—is possible and very important even in brief visits. If learning what medications to prescribe at what doses were all that I needed to learn to be a psychiatrist, my residency would have been one year rather than four years." **PN**

"Beyond 'Med Management' " is posted at http://ps.psychiatryonline.org/doi/full/10.1176/appi.ps.201600133. Torrey can be contacted at William.C.Torrey@dartmouth.edu.

From left: John Straus, M.D., Tiffany Moore-Simas, M.D., U.S. Rep. Jim McGovern (D-Mass.), and Nancy Byatt, D.O., M.B.A., gathered in Washington, D.C., to discuss how to expand the Massachusetts Child Psychiatry Access Program for Moms into other states.

UMass Researcher Turns Idea Into A Nationally Recognized Program

MCPAP for Moms offers coordinated psychiatry consults to OB-GYNs to help better prepare them to assess and manage perinatal mental health. **BY NICK ZAGORSKI**

During her psychosomatic medicine fellowship at Brigham and Women's Hospital in Boston, Nancy Byatt, D.O., M.B.A., had the opportunity to work as a perinatal psychiatrist at an obstetrics and gynecology (OB-GYN) clinic.

As she learned first-hand just how common depression is among new and expectant mothers, she found herself questioning how psychiatrists could ever effectively handle the burden.

"It also really struck me that the OB-GYNs, who saw these women regularly, wanted to help," Byatt said. "But, they felt they didn't have the training to provide adequate care."

Byatt saw this as a missed opportunity. After finishing her fellowship and taking an academic position at the University of Massachusetts Medical School in Worchester, she began to develop a model that could leverage the OB-GYN community to provide much-needed mental health care to pregnant and postpartum women.

What followed was a whirlwind period where a modest grant proposal would lead to a statewide initiative and a successful program—MCPAP for Moms—that would eventually find its way into federal legislation.

Research Interests Dovetail With State Priority

It all began in early 2013 when Byatt applied for a "K award" (NIH grants aimed at early stage investigators to help them establish a research program) to fund a pilot program she called PRISM (for PRogram In Support of Moms). The program aimed to train OB-GYNs on how to screen and diagnose patients with depression, monitor patient progress, educate them about the benefits and risks of antidepressant therapy during pregnancy and nursing, and connect OB-GYNs with psychiatrists.

A few years prior, the state legislature of Massachusetts formed a commission that was charged with coming up with a statewide initiative to address postpartum depression, with an emphasis on screening.

"The commission was pushing hard for mandatory depression screening for new mothers, but I thought we shouldn't do it when we had nothing to offer the women who screened positive," said Tiffany Moore-Simas, M.D., M.P.H., an OB-GYN at the University of Massachusetts Medical School, who served on the state's Postpartum Depression Commission.

Moore-Simas also happened to be collaborating on research with Byatt. "I knew she was working on a K award on this topic and thought that it would be good for the commission to hear her ideas."

Byatt agreed that something like PRISM might be able to help women with depression to connect with services, but the project was still too preliminary for any large-scale implementation.

However, the state already had an existing and effective collaborative program known as the Massachusetts Child Psychiatry Access Program (MCPAP), which provided quick access to psychiatric support for pediatricians and family doctors. She realized that by incorporating elements of PRISM into MCPAP, she might be able to make an extension of the program aimed at new or expectant mothers.

She worked closely with pediatrician John Strauss, M.D., the founding director of MCPAP, to develop a strategic plan for the extension, known as MCPAP for Moms. In November 2013, she was notified that the MCPAP for Moms program would be funded (which was just two months after her K award was also funded). MCPAP for Moms is funded by the Massachusetts Department of Mental Health.

"The only hitch was we only had eight months to fully develop and conceptualize our program," Byatt said.

Byatt was hardly deterred. "I had already spent years thinking about integrating depression and obstetric care [for the PRISM proposal], just on a smaller scale," she said. After Byatt met with focus groups and received feedback from providers and staff at different clinics, the MCPAP for Moms was launched in July 2014.

MCPAP for Moms Sees Early Success

MCPAP for Moms connects OB-GYN clinics with perinatal psychiatrists who provide on-site training on how to detect, assess, and manage depression and other mental health concerns in pregnant and postpartum women. All of the assessment guidelines, screening tools, and treatment algorithms are also available online for the clinicians to use.

Once enrolled, an OB-GYN provider can also call a MCPAP for Moms care coordinator if additional assistance is needed; the coordinator will link the provider with an on-call psychiatrist for an immediate telephone consultation about the patient.

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HPMA Announces New Executive Council

The Hawaii Psychiatric Medical Association (HPMA) has announced the following members of its 2017-2018 Executive Council:

President: Michael Champion, M.D.
Secretary: Brian Schultz, M.D., Ph.D.
Treasurer: Julienne Ong Aulwes, M.D.
Immediate Past President (2016-2017): Julienne Ong Aulwes, M.D.
Assembly Reps: Iqbal "Ike" Ahmed, M.D., Leslie Gise, M.D.
Membership Committee Co-Chair: Douglas Smith, M.D.
Membership Committee Co-Chair: Leslie Gise, M.D.
Ethics Committee Chair: Gregory A. Prier, D.O.
Legislative Chair: Jeffrey Akaka, M.D.
Resident Fellow Member Rep: Raissa Tanqueco, M.D.
Public Affairs Chair: Trisa Danz, M.D.
Chair of the HPMA Task Force on Access to Care: Julienne Ong Aulwes, M.D.

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The consults between an OB-GYN and MCPAP for Moms psychiatrist are meant to be educational and develop the provider's knowledge base. Byatt emphasized that the consulting psychiatrists do not initiate treatment—they make recommendations and let the OB-GYN choose the treatment they feel is best for the patient. For particularly difficult cases, one-time, in-person consults between a patient and psychiatrist can also be scheduled.

It's a simple approach that has produced impressive results; two and a half years after launching, MCPAP for Moms has enrolled over 100 OB-GYN practices (more than half of the OB-GYN practices in the state) and served over 2,400 women.

Beyond the number of women served, there is also evidence that the women are getting better, Byatt said. "Some of our latest pilot data show that patients who were served by practices that are enrolled in MCPAP for Moms improved by five points on the EPDS [Edinburgh Postnatal Depression Scale]."

Many individuals and groups have taken notice, including APA, which recently awarded MCPAP for Moms with the 2016-2017 Psychiatric Services Gold Achievement Award for academic programs.

MCPAP for Moms also attracted the attention of U.S. Rep. Katherine Clark (D-Mass.). Clark later sponsored a bill known as the Bringing Postpartum Depression Out of the Shadows Act, which aims to provide funding to states "to establish, expand, or maintain culturally competent programs for screening and treatment of women who are pregnant, or who have given birth within the preceding 12 months, for maternal depression."

Rep. Clark, together with James S. Gessner, M.D., president of the Massachusetts Medical Society, and Maryanne C. Bombaugh, M.D., chair of the Massachusetts section of the American Congress of Obstetricians and Gynecologists, wrote of the impact of MCPAP in an opinion piece in *STAT* in January: "In the first 18 months of the MCPAP for Moms program, more than 1,100 women were screened and treated for postpartum depression. We believe that the Bringing Postpartum Depression Out of the Shadows Act will allow this successful state program to be scaled nationally and, in doing so, positively affect the well-being of women and their families across the country."

The Bringing Postpartum Depression Out of the Shadows Act was eventually folded into the comprehensive 21st Century Cures Act, which was signed into law in December 2016 (*Psychiatric News*, January 6).

"This is beyond what I ever would have imagined when I first started my grant application just a few years ago," Byatt said. "But it would not have been possible without the support of so many parties, from the leadership at MCPAP, our program director Kate Biebel, the members of the commission, my mentors and colleagues at UMass, and especially Tiffany and the OB-GYN community, whose eager buy-in was essential."

"For mentors like myself, seeing research ideas germinate into nationally recognized programs is extremely satisfying," said Douglas Ziedonis, M.D., chair of the psychiatry department at the University of Massachusetts Medical School, who advised Byatt on her K award application.

"Equally fulfilling has been witnessing the transition of Byatt from gung-ho clinician into a leader in the field of postpartum depression," he added.

Ziedonis added that Byatt's journey highlights the wide range of research options that can align with a clinician's passion.

"It's not just test tubes and statistics," he said. "For Byatt, there were opportunities in implementation science that helped build her program." **PN**

More information on MCPAP for Moms is posted at https://www.mcpapformoms.org/Default.aspx.

RESIDENTS' FORUM

Residents Bring APAF's 'Typical or Troubled' Program to Puerto Rico

BY HECTOR COLON-RIVERA, M.D.

Being a full-time teacher is a difficult job, especially considering that a variety of psychosocial stressors, mental health concerns, and health as a whole can affect school children's academic performance. It is estimated that 1 in 5 children has or will have a severe mental health disorder. According to the American Association for World Health, 9 of 10 people who develop a mental disorder show warning signs during their teen years. It is for this reason that teachers must have proper training in identifying and interacting with at-risk children. It is also essential that teachers know who to refer these children to.

This year, through the support of APA, we were able to visit a series of schools in Vieques, Puerto Rico, as part of our third consecutive APA Mental Health Awareness Tour. Vieques Island is a forgotten paradise that is in trouble. It lies about eight miles east of the Puerto Rican mainland and measures about 21 miles long by 4 miles wide. Vieques's youth suffer challenges that other adolescents from the main island of Puerto Rico do not. There are no full-time mental health professionals or hospital on the island, leaving the quality of mental health services to be minimal at best. There is also limited transportation to the main island—few ferries and overpriced airplanes. There are no universities and very few job opportunities on the island. Those with more persistent mental health challenges usually do very well with treatment, peer and professional support and services, and a family and social support network. However, without treatment, resources, and proper support, individuals are not able to thrive. Unfortunately, the limited resources on the island have been reflected at the schools.

During this recent visit, our efforts included the implementation of Typical or Troubled, a school-based mental health education program created by the American Psychiatric Association Foundation (APAF); the APAF also offers a variety of professional education opportunities to provide training within the field of psychiatry for residents and fellows in research, public health, education, and leadership (see www.americanpsychiatricfoundation.org/get-involved/fellowships).

Our bilingual team consisted of a teacher, a medical student, one psychiatry resident, and three psychiatrists who represented the subspecialties of child and adolescent, consultation liaison, and addiction psychiatry. We tailored the Typical or Troubled curriculum to fit the high school's needs in Puerto Rico for an effective intervention. To better understand the student population in Vieques, we also distributed surveys to the students at the three main schools on the island. The purpose of the survey was to better understand the students' knowledge and exposure to illicit substances. These surveys were developed in collaboration with Carlos Albizu Campos University.

Hector Colon-Rivera, M.D., is an addiction fellow at Yale University and chair of the APA Minority Fellowship Program and Diversity Fellowship Program.

The participants included social workers, nurses, teachers, and family members, all of whom have encountered signs and symptoms of mental difficulties among their students. Some of them talked about their biggest issue: staff capacity.

"We have almost 300 students in our school and one full-time nurse, one full-time mental health counselor, and no full-time general psychiatrist or psychologists on the island," Asunción Rivera explained. It was clear that without adequate mental health services in schools, the burden falls on the teachers. The first step in addressing these mental health needs is to help teachers recognize mental health disorders when they encounter them.

The APAF recommends as part of its Typical or Troubled program the following three steps to help raise awareness, recognize symptoms early, and provide resources to address burnout and possible mental illness:

- **Notice** if you are seeing troubling signs in a student. You may also share what you're noticing with other teachers to confirm whether they are seeing these same signs.

- **Talk** with the student. Ask how he or she is doing and suggest a talk with someone on the mental health staff. Even offer to take the student to the appropriate counselor. You can focus on observable behaviors or actions you've noticed.

- **Act** by sharing what you've noticed with the school mental health staff. This will put it on their radar screen and get the student connected to help. Due to confidentiality, however, they may not be able to share information with you regarding the student's diagnosis.

It is time for better prevention and intervention. We understand that meeting the students and staff members at the school offered an opportunity to bridge a significant gap in preventing and treating mental health disorders. We hope that by better understanding their need and current resources, we will be able to assist in the creation of more and better supports and services, more effective educational programs to further adapt our Mental Health Tour, and, ultimately, healthier children and adults. **PN**

Charleston Area Medical Center/West Virginia University (Charleston Division)

Jamaica Hospital Medical Center

Maimonides Medical Center

Medical College of Wisconsin

New Benefits Offered

The benefits of 100% Club membership were revamped for the 2016-2017 academic year. They were designed to support the educational and career-development needs of psychiatry residents and build a collaborative community of psychiatric programs. More information can be found at psychiatry.org/100club.

Resident Benefits

- SET for Success, featuring more than 60 free on-demand courses on the APA Learning Center
- A unique practice resource gift
- Priority access to new learning formats on the APA Learning Center
- Priority access to moderator positions at the Annual Meeting and IPS: The Mental Health Services Conference (includes meeting registration reimbursement)

Program Director Benefits

- Access to SET for Success courses (including free CME credit)
- A unique practice resource gift
- Welcome kits for all incoming chief residents
- Exclusive to Platinum Level: on-site grand rounds presentation with an APA leader/expert

Community Benefits

- Recognition in *Psychiatric News*
- Recognition certificate for the residency program
- Opportunity to showcase program highlights in *Psychiatric News*
- Access to opportunities and special events to engage with other programs

APA Honors Platinum-Level 100% Club Members

Congratulations to the psychiatry residency programs that achieved Platinum-Level status in APA's 100% Club this year! The 100% Club was established to encourage residents throughout the United States and Canada to become APA members and take advantage of the variety of membership benefits available to them.

The Platinum Level is the highest level of membership in the 100% Club—these are programs that have remained at the 100% Club Gold Level for the past five consecutive years. Gold Level programs have 100% of their residents as APA members. Silver Level programs have 90 to 99 percent of their residents as APA members, and Bronze Level programs have 80 to 89 percent of their residents as APA members.

"I want to thank the residency training directors for emphasizing the benefits of APA membership to their trainees and supporting their efforts to join," said APA CEO and Medical Director Saul Levin, M.D., M.P.A. "The future of psychiatry depends on the outstanding men and women in our training programs today. That so many of our best and brightest are dedicated to their profession by being involved in APA gives us assurance that psychiatry's future is strong indeed."

Residency training programs can expect to receive recruitment materials from APA in the coming months. October 31 is the deadline for enrolling a program's general psychiatry residents to qualify for 100% Club membership for the current training year. More information is available by contacting Claire Van Wagner at cvanwagner@psych.org. **PN**

Updates From the 100% Club Community

New Grand Rounds Benefit Deemed a Success!

"The grand rounds was found to be interesting and engaging. The residents think that more in the future would be enjoyable, as well as informative."

—Jamaica Hospital Medical Center

"The presentation by Mr. Irvin Muszynski [APA's director of parity enforcement and implementation] was very informative and helpful for us as residents. We discussed various practice opportunities, reimbursement/compensation in practice, and the different APA resources that are available to us as members. He answered all our questions and provided great advice for us in training and for us that are about to graduate."

—Morehouse School of Medicine

"This is an outstanding benefit for our program and community. We gained important knowledge about the process of negotiating for change in mental health resources at the federal level. It was a great way to see how APA is really working in Washington, D.C., to advocate for patients and providers and why it is such an important organization in which to participate. APA is really doing a great job of giving tangible benefits to our members in training. Thanks for the opportunity"

—University of Cincinnati Medical Center

100% Club Program Achieves New Accreditation

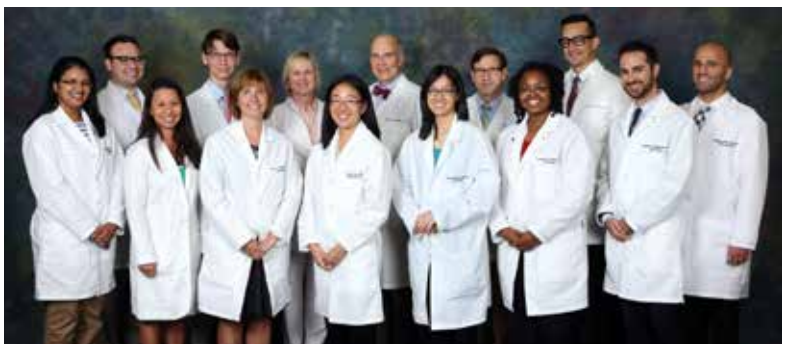
Congratulations to the Detroit Wayne County Health Authority–GME Psychiatry Residency Program for receiving accreditation from the Accreditation Council for Graduate Medical Education.

Morehouse School of Medicine

Nassau University Medical Center

San Mateo County Behavioral Health and Recovery Services

University of Cincinnati Medical Center



University of South Alabama

Wake Forest University School of Medicine

Congratulations to 2016-2017 100% Club Programs!

Platinum Level Programs

Charleston Area Medical Center/West Virginia University (Charleston Division)
Charleston Area Medical Center/West Virginia University (Charleston Division) Internal Medicine
Jamaica Hospital Medical Center
Maimonides Medical Center
Medical College of Wisconsin
Morehouse School of Medicine
Nassau University Medical Center
San Mateo County Behavioral Health and Recovery Services
University of Cincinnati Medical Center
University of South Alabama
Wake Forest University School of Medicine

Gold Level Programs

Advocate Lutheran General Hospital
Albany Medical Center
Albert Einstein Healthcare Network
Allegheny General Hospital
Berkshire Medical Center
Boston University Medical Center
Brookdale University Hospital and Medical Center
Brown University (Butler Hospital)
Carilion Clinic–Virginia Tech Carilion School of Medicine
Cleveland Clinic Foundation
Community Health Network Inc. Program
Cooper Medical School of Rowan University
Delaware Psychiatric Center
Detroit Wayne County Health Authority
Eastern Virginia Medical School
Grandview Hospital & Medical Center
Harvard Longwood Medical School
Henry Ford Hospital
Howard University
Interfaith Medical Center
Jackson Memorial Hospital/Jackson Health System
Kaweah Delta Health Care District
Unity Health–White County Medical Center
Larkin Community Hospital
LECOMT/Arnot Ogden Medical Center
Louisiana State University–Shreveport
Marshall University School of Medicine
Medical University of South Carolina
Michigan State University
Mount Sinai School of Medicine–Elmhurst
Naval Medical Center San Diego
New Jersey Medical School
New York Presbyterian Hospital–Cornell Campus
Orange Regional Medical Center
Oregon Health & Science University
Palm Beach Consortium
Pine Rest Christian Mental Health Services
Providence Sacred Heart Medical Center
St. Barnabas Hospital
Samaritan Health Services–Corvallis
Seton Hall University School of Graduate Medical Education
University of South Dakota
Southern Illinois University
Stony Brook Medicine/Mather Hospital Program
Thomas Jefferson University
University of Alabama Medical Center
University of California, San Francisco/Fresno
University of Florida College of Medicine
University of Hawaii
University of Illinois College of Medicine at Peoria
University of Kansas Medical Center
University of Kansas–Wichita
University of Louisville
University of Massachusetts
University of Minnesota
University of Mississippi Medical Center
University of Toledo
University of Virginia

Silver Level Programs

Bergen Regional Medical Center
Central Michigan University College of Medicine
Creighton University/University of Nebraska
Indiana University School of Medicine
Lincoln Medical and Mental Health Center
Loyola University
Medical College of Georgia
Ohio State University Hospital
St. Mary Mercy Hospital Program
University at Buffalo
University of California–Irvine
University of South Carolina–Greenville
Virginia Commonwealth University Health System
Walter Reed National Military Medical Center

Bronze Level Programs

California Pacific Medical Center
Creedmoor Psychiatric Center
Geisinger Health System
Hennepin County Medical Center
Louisiana State University
McGaw Medical Center of Northwestern University
New York Bronx–Lebanon Hospital Center
New York Medical College–Metropolitan)
New York Presbyterian Hospital–Columbia Campus/New York State Psychiatric Institute
Penn State Health Milton S. Hershey Medical Center
Richmond University Medical Center
St. Louis University School of Medicine
Staten Island University Hospital
Stony Brook Medicine/University Hospital
University of Maryland/Sheppard Pratt
University of Massachusetts Medical School–Baystate
University of Missouri–Columbia
University of Nevada School of Medicine–Las Vegas
University of Nevada School of Medicine–Reno
University of New Mexico
University of Oklahoma School of Community Medicine–Tulsa
West Virginia University

BPH Medications May Increase Risk Of Self-Harm, Depression

This study, which assessed seniors taking finasteride or dutasteride for benign prostatic hyperplasia (BPH), found that the greatest risks were during the first 18 months of treatment. **BY NICK ZAGORSKI**

There have been growing concerns that the 5α-reductase inhibitors (5ARIs) finasteride and dutasteride—known to reduce the risk of urinary tract problems in men with benign prostatic hyperplasia—might increase the risk of suicide, self-harm, and depression. Despite regulatory warnings about these side effects, though, very little population research has assessed the potential mental health risks associated with 5ARI use.

A study published March 20 in *JAMA Internal Medicine* suggests older men who take 5ARIs may not be at an increased risk of suicide, but they may be more likely to experience depression or self-harm. The most pronounced risks occurred during the first 18 months of use.

"The recognition of depression and self-harm as potential adverse effects of 5ARIs is important given their significant impact. However, the relatively small magnitude of these risks should not dissuade physicians from prescribing these medications in appropriate patients," Blayne Welk, M.D., an assistant professor of surgery at Western University in London, Ontario, and colleagues wrote. "This research may help physicians counsel patients on the risks of 5ARIs."

Welk told *Psychiatric News* that it was important to quantify the risks of 5ARIs in older adults as many of the post-marketing reports of suicide and depression involved younger men who took finasteride for alopecia, or male pattern baldness.

"The daily dose of finasteride for hair loss is 1 mg [daily], but older men who take these agents for BPH require stronger doses of 5 mg daily, which potentially heightens the risks," he said.

Welk and his colleagues examined administrative databases to gain clinical and prescription information on 93,197 men aged 66 and older in Ontario who started taking finasteride or dutasteride between 2003 and 2013, as well as a matched number of older men not prescribed these medications.

During the follow-up period, there were a total of 38 suicides among patients taking 5ARIs and 36 among the control group, which equated to no statistical difference. There were also 169 incidents of self-harm and 1,750 cases of depression in the 5ARI group, and 130 cases of self-harm and 1,231 cases of depression in the control group—differences that were found to be statistically significant.

When the investigators stratified these incidents of depression and self-harm over time, they found that the biggest differences in risk were in the first 18 months of therapy. During this time, there was a 1.94-fold increased risk of self-harm and a 1.88-fold increased risk of depression among 5ARI users. After 18 months, the risks of self-harm were no longer different between the 5ARI and control groups. However, depression risk remained slightly elevated (1.22-fold) in men taking 5ARI.

When the researchers compared mental health outcomes in men taking finasteride with those taking dutasteride, they found the men appeared to be at a similar risk of suicide, self-harm, and depression.

Welk pointed out that since his group used administrative data to identify depression diagnoses, they were unable to make any qualitative interpretations, such as the severity of depressive symptoms or if the patients had stopped taking their medication prior to the onset of symptoms.

Stephen Thielke, M.D., M.P.H., an

associate professor of psychiatry at the University of Washington, commended Belk and his colleagues for undertaking this study. "These investigators are not psychiatrists but they conducted a thoughtful analysis of mental health symptoms and outcomes," he said. "More efforts like this by other medical specialists would be welcome."

Thielke added that the results lead to a classic conundrum: "Physicians always like it when everything points in the same direction in terms of risks and benefits. In this case, we have two disparate outcomes; a tangible benefit for prostate health but a very real risk of depression."

In such cases, physicians must rely on their own personal and moral judgments, and no amount of scientific evidence will delineate the right choice, he said, echoing thoughts he wrote in an accompanying *JAMA* commentary.

For psychiatrists treating a depressed patient on 5ARIs, the decision poses the quandary of deciding whether or not to advise a patient to stop taking a medication that the psychiatrist did not prescribe in the first place. Therefore, it's important to exclude all other possibilities that may explain the onset or worsening of depressive symptoms, Thielke said.

Fortunately, if finasteride or dutasteride are posing a serious mental health risk, Welk noted that there are other options for treating BPH-related urinary problems, including other medications or prostate surgery.

This study was supported by the Institute for Clinical Evaluative Sciences Western site. **PN**

An abstract of "Association of Suicidality and Depression With 5α-Reductase Inhibitors" is posted at http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2610105. The accompanying commentary, "The Risk of Suicidality and Depression From 5α-Reductase Inhibitors" is posted at http://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2610100.

Report Highlights Alternative Treatment Options for OCD

For patients who fail to respond to first-line treatments, remote cognitive-behavioral therapy, adjunctive use of antipsychotics, and neuromodulatory techniques may offer some relief. **BY JOANN BLAKE**

While in-person cognitive-behavioral therapy (CBT) with or without medication remains the preferred initial treatment for obsessive-compulsive disorder (OCD), studies suggest that some 25 to 35 percent of OCD patients continue to experience symptoms of the disorder after treatment.

There is growing evidence to suggest computer-based CBT, novel pharmacological agents, and neuromodulatory techniques also might benefit these patients, according to a review article published April 4 in the *Journal of the American Medical Association.*

For the report, Matthew Hirschtritt, M.D., M.P.H., a PGY-3 at the University of California, San Francisco School of Medicine, and colleagues searched PubMed, EMBASE, and PsycINFO for studies published between January 1, 2011, and September 30, 2016, that addressed screening, diagnosis, and treatment approaches for OCD in adults 18 and older. Of the 792 articles identified, 27 were analyzed for the review.

The authors noted that while the latest data indicate that CBT continues to be the most effective psychotherapy for OCD—and most effective therapy overall when performed by experienced practitioners—there are

significant barriers to CBT treatment. Such barriers include a lack of available therapists, high out-of-pocket costs, and intense time demands on the patient.

Remote treatment for OCD may offer one way to begin to chip away at these barriers. "Evidence from a meta-analysis suggests that remote CBT (via an online platform) demonstrates efficacy similar to that of in-person treatment," Hirschtritt and colleagues wrote.

"The reassurance and knowledge patients gain [using remote CBT via online platform] can be therapeutic and quite effective," Hirschtritt said in an interview with *Psychiatric News*. He emphasized that online therapy is best used as a supplementary treatment between in-person visits with health care practitioners and to provide structure. "For clinicians across psychiatry, this is another tool in their tool box," he said.

Selective serotonin reuptake inhibitors (SSRI) remain the recommended first-line pharmacologic intervention for OCD. For patients who do not respond to SSRIs, the adjunctive use of typical or atypical antipsychotics may offer some relief, the authors noted.

Preliminary evidence suggests augmentation with ketamine, riluzole, N-acetylcysteine, memantine, lamotrigine, celecoxib, ondansetron, and some nutraceuticals may also reduce OCD symptoms in treatment-resistant patients, but the authors noted that more work is needed to support the routine use of these agents in treating OCD.

For the most severe treatment-resistant OCD cases, there is some evidence to suggest neurosurgery and deep-brain stimulation may decrease symptoms of the disorder, the authors wrote.

"Despite the severe impairment and burden of OCD, it often goes unrecognized and undertreated or untreated," Hirschtritt and colleagues noted. "Conditions that can commonly be confused with OCD, such as generalized anxiety disorder, should be considered and ruled out. Important moderators of treatment efficacy (presence of comorbid tics or hoarding symptoms, level of insight) should also be assessed because these may help guide choice of initial treatment."

The study was funded by the Tourette Syndrome Association of America, the Brain and Behavior Research Foundation, the Patterson Foundation, and the State of Connecticut Department of Mental Health and Addiction Services. **PN**

An abstract of "Obsessive-Compulsive Disorder: Advances in Diagnosis and Treatment" is posted at http://jamanetwork.com/journals/jama/fullarticle/2614194.

Merger

continued from page 13

physician and patient advocacy groups in the past several years. In September 2015, soon after the merger was proposed, the AMA released "Competition in Health Insurance," an annual analysis of insurance markets that showed nearly half of all states could see diminished competition in local health insurance markets if the Anthem-Cigna and Aetna-Humana mega-mergers were allowed to proceed.

"The U.S. Court of Appeals of the District of Columbia sent a clear message to the health insurance industry: a merger that smothers competition and choice, raises premiums, and reduces quality and innovation is inherently harmful to patients and physicians," said AMA President Andrew W. Gurman, M.D., in a statement in response to the appellate court ruling. **PN**

The ruling by the U.S. Court of Appeals of the District of Columbia is posted at https://www.cadc.uscourts.gov/internet/opinions.nsf/55EC55639C87835E85258110004F41B9/$file/17-5024-1673054.pdf. "Competition in Health Insurance" is posted at https://www.cadc.uscourts.gov/internet/opinions.nsf/55EC55639C87835E85258110004F41B9/$file/17-5024-1673054.pdf.

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Study Finds Selenium, Vitamin E Do Not Prevent Dementia

There was no difference in the incidence of dementia among men who took supplements of selenium and/or vitamin E or placebo. **BY NICK ZAGORSKI**

One of the largest and longest-running dementia prevention studies has found that older men who take the popular antioxidants vitamin E and selenium—either alone or in combination—appear to be no less likely to develop dementia than those who do not take these supplements.

Despite several methodological limitations of the study, the findings suggest the antioxidants should not be used to prevent dementia.

The Prevention of Alzheimer's Disease by Vitamin E and Selenium (PREADViSE) trial grew out of an older clinical trial called the Selenium and Vitamin E Cancer Prevention Trial (SELECT). SELECT, which enrolled males only, started in 2002 and tested whether selenium (200 mg/day) and/or vitamin E (400 IU/day) supplements could help prevent prostate cancer. After that trial was stopped for showing no benefits in 2009, about 4,000 of the participants agreed to continue taking one or both supplements or placebo as part of a dementia study. All the PREADViSE participants were free of dementia or any neuropsychiatric disorders that might affect cognition at the start of the trial.

At the conclusion of the study, the incidence of dementia was between 4 percent and 5 percent in each of the four groups (vitamin E, selenium, both, or placebo) with no statistical differences among them, Richard Kryscio, Ph.D., a professor at the Sanders Brown Center on Aging at the University of Kentucky, and colleagues reported March 20 in *JAMA Neurology*.

"The supplemental use of vitamin E and selenium did not forestall dementia and are not recommended as preventive agents," Kryscio and colleagues concluded. They noted that in addition to the lack of benefits, research has shown that extended selenium and vitamin E use might increase the risks of diabetes and prostate cancer, respectively.

In a related editorial, Steven DeKosky, M.D., of the University of Florida and Lon Schneider, M.D., of the Keck School of Medicine of the University of Southern California noted that the dementia rates reported in the trial were low compared with national averages and may reflect another important limitation of this study—the young age of the participants. The average age at the start of PREADViSE was 67 years, with many participants as young as 60. Typically, dementia studies try to enroll adults in their 70s or older.

"Thus, it is unlikely that the PREADViSE trial could have detected a salutary effect from the vitamin E or selenium interventions, if indeed there was one to be had," DeKosky and Schneider wrote. The pair acknowledged the challenges the researchers leading the PREADViSE trial faced, including finding a suitable, diverse population, and maintaining adherence over the long period required to see an effect.

"While there are study limitations such as inclusion of only men, loss of participants in switching from a study of prostate cancer to prevention of dementia, and dosing considerations, the findings clearly suggest a lack of usefulness of these supplements in preventing dementia in older adults," said Dilip Jeste, M.D., a distinguished professor of psychiatry and neurosciences at the University of California, San Diego, and past president of APA.

Jeste told *Psychiatric News* that while more research is needed to develop medications to prevent dementia, there are steps older adults can take to delay the onset of dementia.

"It is worth remembering that considerable evidence exists to demonstrate the neuroplastic effects of physical activity, cognitive stimulation, social support, stress reduction, general health care, and other positive psychosocial factors including resilience and positive attitude," he said. "Healthy lifestyle does not prevent dementia, but may delay the onset."

The initial SELECT study was funded by grants from the National Cancer Institute, with further support from the National Institute on Aging to continue with PREADViSE. **PN**

An abstract of "Association of Antioxidant Supplement Use and Dementia in the Prevention of Alzheimer's Disease by Vitamin E and Selenium Trial (PREADViSE) is posted at http://jamanetwork.com/journals/jamaneurology/fullarticle/2612477. The accompanying editorial, "Preventing Dementia" is posted at http://jamanetwork.com/journals/jamaneurology/fullarticle/2612473.

PSYCHIATRY & PSYCHOTHERAPY

CBT in Patients With Chronic Illness

BY DONNA M. SUDAK, M.D.

Psychiatrists are increasingly responsible for the care of individuals who have comorbid psychiatric and medical illnesses. Many medical illnesses, for example coronary artery disease, diabetes mellitus, and malignancies, are associated with both subclinical and full-blown anxiety and mood disorders.

Practitioners who employ a formulation-driven "toolbox" of interventions to facilitate patients' adaptation to medical illness will improve their quality of life and adherence to treatment. Numerous meta-analyses and systematic reviews show cognitive-behavioral therapy (CBT) to be quite useful to these patients. The principles employed in CBT treatment protocols for medical disorders have been shown to help practitioners help patients cope more effectively.

A starting point to understand the CBT approach is to consider how people effectively manage adverse events. When encountering adversity, there is generally a variety of cognitive and emotional responses. Coping requires strategies in place to effectively manage emotions until they eventually become attenuated. Cognitively, people are "wired" to make sense of adversity; effective coping occurs when such explanations are not damaging (for example "this illness is my fault"). The presence of adaptive coping skills that can be deployed in emergencies increases good outcomes. Finally, developing a sense of a meaningful and positive future even in the presence of adversity is necessary for good adjustment. In conceptualizing the interventions needed, it is necessary to understand the patient's mental model of the illness and its prognosis, as well as to obtain a history of how the patient has previously managed adversity. This assessment determines skills deficits (that is, an inability to decrease arousal), and sets targets for cognitive restructuring.

One critical skill to develop is to help a patient be a good consumer of health care. The complexity of medical decision making, the shift of treatments from inpatient to outpatient settings, the frustration of delayed appointments and test results: these are but a few examples of how navigating treatment can be burdensome,

continued on facing page

Donna M. Sudak, M.D., is a professor of psychiatry and senior associate training director and director of psychotherapy training at Drexel University College of Medicine. She is also secretary of the American Association of Directors of Psychiatric Residency Training. This column is coordinated by the Committee on Psychotherapy of the Group for the Advancement of Psychiatry.

History of Childhood Adversity May Predict Naltrexone Response

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Findings suggest that people with significant childhood adversity might benefit from a combined program of naltrexone and coping/skills therapy. **BY NICK ZAGORSKI**

A history of childhood adversity is known to be common in people with alcohol use disorder (AUD), but a study in *Translational Psychiatry* suggests such history might also help to predict AUD patients most likely to respond to naltrexone.

Specifically, this study led by Karen Ersche, Ph.D., a lecturer in the Department of Psychiatry at the University of Cambridge, found that the more severe the adversity, the greater the potential ameliorative effect of naltrexone.

Some preclinical research has suggested there is link between abuse and response to naltrexone, but this study is the first to show an effect in humans, Ersche said.

Naltrexone acts on opioid receptors to dampen the brain's reward pathways and make alcohol less appealing. However, trials of people with substance use disorders also suggest naltrexone may increase negative feelings and anxiety in response to stressful stimuli—a response Ersche noted may explain why many people do not respond to naltrexone therapy.

Previous research in combat veterans found that exposure to stress changes the activity of some opioid receptors known to be targets of naltrexone. Ersche wondered if the same was true of people who experienced significant childhood adversity. If so, could this lead them to respond differently to naltrexone compared with others without a history of abuse?

To answer this question, Ersche and colleagues recruited 60 adults to take part in a task that measured their responses to a series of images, using functional MRI (fMRI). The participants included 21 people with a diagnosed history of alcohol dependence, 21 with a history of co-dependence on alcohol and drugs, and 18 controls. To prevent alcohol or drugs from interfering with the imaging, all the participants had to be abstinent for at least four weeks.

"[I]mprovements in coping can then make naltrexone more effective at reducing cravings."
—Karen Ersche, Ph.D.

At the beginning of the trial, all participants completed a Childhood Trauma Questionnaire (CTQ), from which the researchers were able to determine exposure to physical, sexual, and emotional abuse.

Each participant was then given either 50 mg of naltrexone or placebo orally and proceeded to look at various neutral or emotionally aversive images during fMRI. The study was a crossover design, so each participant did the test under both naltrexone and placebo conditions, but in a random order.

When exposed to the negative images, participants in the placebo group demonstrated heightened activity in the prefrontal cortex and anterior cingulate cortex—two areas associated with mood regulation. This activity was the greatest in people who had higher CTQ scores. When participants took naltrexone, this activity decreased, with the greatest decreases seen in people with the highest CTQ scores. This trend was seen across all three groups; it was not limited to people with substance use problems.

"This paper does not actually show that naltrexone reduces stress-related alcohol cravings or propensities to drink," said John Krystal, M.D., director of Yale's Center for the Translational Neuroscience of Alcoholism, who was not involved with this study. "But the data might be interpreted to suggest that naltrexone could be helpful in this regard," he told *Psychiatric News*. Krystal is also the chair of the Department of Psychiatry at Yale School of Medicine.

Ersche said she believes these results are ready to be applied in alcohol treatment programs, since a lot of the elements in effective relapse prevention are already in place; it's just a matter of pairing the right interventions with the right people.

"People with a history of severe childhood adversity might make good candidates for a combined approach of naltrexone and coping strategies like skills training or stress resilience training," she said.

She explained that for people with an alcohol disorder and a history of adversity, coping strategies may induce too many negative feelings since they involve managing one's emotions.

"Giving naltrexone can take the edge off, and help with the training needed to learn important coping skills," she said. "And the improvements in coping can then make naltrexone more effective at reducing cravings."

An interesting secondary finding of this imaging study was that people with co-occurring alcohol and drug use showed heightened amygdala activity in response to aversive images as well as neutral ones (this was regardless of trauma history). Naltrexone reduced this abnormal response to neutral stimuli in this group. The amygdala is a key regulator of stress response, and Ersche suggested these findings may point to naltrexone being effective in people with an addiction and comorbid stress disorder like posttraumatic stress disorder.

This study was supported by the National Institute for Health Research (NIHR) Clinical Research Facility at Imperial College Healthcare NHS Trust, the NIHR/Wellcome Trust Cambridge Research Facility, and Clinical Trials Unit at Salford Royal NHS Foundation Trust. **PN**

"Effects of Naltrexone are Influenced by Childhood Adversity During Negative Emotional Processing in Addiction Recovery" is posted at http://www.nature.com/tp/journal/v7/n3/full/tp201734a.html.

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particularly when anxiety, grief, and physical pain are present. Education about the condition is vital and must be tailored to the needs of the patient. Such information may need to be repeated several times because of disturbances of concentration and memory associated with high stress, or co-occurring mood and anxiety disorders. The Internet as an educational tool is a double-edged sword, and clinicians should help patients access reliable websites.

Specific targets for treatment with CBT techniques include managing arousal with breathing training, progressive muscle relaxation, activity scheduling to help the patient take control of his or her time, and helping patients manage grief. Cognitive restructuring may be employed in situations where patients' thoughts and behaviors in response to the illness are interfering with a good quality of life. For example, patients may withdraw from valued pursuits in response to the illness because of faulty assumptions (for example, "I won't enjoy myself like before"). Cognitive restructuring may establish more functional and accurate ways to evaluate prospective situations and help patients be more fully engaged.

Adherence enhancement, another helpful strategy developed with CBT principles, significantly impacts illness management. It focuses attention on developing a collaborative therapeutic alliance that allows the patient to honestly discuss any problems adhering to treatment. The therapist then determines if such problems are practical (for example, financial, inadequate education) or psychological (for example, inadequate motivation, overwhelming stress, inaccurate beliefs, family beliefs) and then focuses on these problems with strategies that are tailored to increase the likelihood of adherence.

Psychiatrists may positively impact health and well-being by using these interventions in their patients with chronic health conditions. **PN**

High Mortality Rate Found in Youth Newly Diagnosed With Psychosis

Psychiatrists know that young patients with psychosis entering adulthood are particularly vulnerable. A new study shows just how serious a risk they face. **BY JOANN BLAKE**

Young people experiencing first-episode psychosis (FEP) are 24 times more likely to die within the year of diagnosis than their age-matched peers, reported a study published April 6 in *Schizophrenia Bulletin*. The findings highlight the importance of intensive clinical intervention at the early stages of psychotic illness and the need for widely available coordinated specialty care programs.

"We expected to see the elevated mortality from previous research, but none of that prepared us for the excess mortality on the scale we observed," said Michael Schoenbaum, Ph.D., lead author and senior advisor for mental health services, epidemiology, and economics at the National Institute of Mental Health (NIMH).

The unusually high 12-month death rate in youth with FEP—1,968 per 100,000—should be a "wake-up call," Schoenbaum told *Psychiatric News*. In the general population, only people over 70 years old have 12-month mortality approaching the rates observed among patients with psychosis in this study.

"Right now, we're a long way from providing meaningful and effective care. Here is one particular catastrophic result of what happens when patients fall through the cracks," he said. "We need to invest heavily in establishing and maintaining a close therapeutic relationship with the psychosis patient."

Furthermore, the health care system is failing these patients, said William T. Carpenter, Jr., M.D., a professor of psychiatry and pharmacology at the University of Maryland School of Medicine and editor-in-chief of *Schizophrenia Bulletin*. "These data substantiate the human cost of a health care system that doesn't implement evidence-based care for people with psychotic disorders." Carpenter was not directly involved with the study.

Schoenbaum and colleagues used health care insurance claims data from the Multi-Payer Claims Database (MPCD) to assess the 12-month health outcomes in a group of 5,488 insured young adults aged 16 to 30 years who received a diagnosis of FEP. MPCD links to information from the Social Security Administration's full Death Master File, allowing documentation associated with all-cause mortality associated with FEP.

NIMH's Michael Schoenbaum, Ph.D., hopes this study's findings will alert mental health professionals to improve the follow-up care of young patients with psychosis.

"It's rare to be able to look at mortality in population health data. We happen to have access to a population-based data set that contains health information linked to information on mortality," Schoenbaum said. The data, however, did not tell the researchers how these young people died.

Given the high death rates, the team expected that patients with FEP would have received more care. However, that's not what they found. A total of 61 percent of the patients studied did not fill any antipsychotic prescriptions, and 41 percent did not receive psychotherapy in the year following FEP diagnosis.

"On the one hand, it's encouraging that many did receive some psychotherapy, which has been declining in the United States, but it's surprising that so few received antipsychotic medication," Schoenbaum said. He added that detailed clinical information would be needed to determine whether the kind of treatment these patients received was appropriate or effective.

Overall, 69 percent of the youth with FEP had at least one visit with a mental health specialty provider for

see **Mortality** *on page 32*

FROM THE EXPERTS

Assessment of Psychotic Features in Children and Adolescents

BY CLAUDIO CEPEDA, M.D.

The evaluation of psychotic symptoms in children and adolescents is straightforward when the psychotic features are the presenting problem or are mentioned as one of the presenting problems. What child psychiatrists need to do in these cases is expand on the presenting complaint and explore other psychotic features or associated psychiatric conditions.

In children in whom psychosis is not identified as the presenting problem, a good area to explore is nighttime behaviors preceding sleep. For a number of children and adolescents, nighttime is an anxiety- and fear-producing time.

A good opening question is, How do you sleep at night? If the child says that he or she has problems falling asleep, the examiner can ask whether there is something that keeps him or her from sleeping. The child may begin to talk about scary things that happen at night. A systematic review of night fears may reveal psychotic symptoms:

- At night, do you hear scary noises or creepy sounds? Do you ever hear voices talking to you when no one is around?

- Do you ever see things that are not real? Do you ever see monsters? Ghosts? People? Shadows?

- Do you ever feel somebody is touching you when no one is around?

This inquiry is followed by the exploration of delusional features, mainly paranoia:

- Do you feel people say bad things about you? If the child answers in the affirmative, the examiner can ask, What do you think people say about you, and so on?

- Do you feel people watch you? If the child endorses that question, the examiner could ask the child to explain or more specifically ask, Where do you feel like that? Some people endorse these feelings as soon as they leave their homes or when they go outside. Children also report being watched when they take a shower, when they are dressing, and so on.

- Do you feel followed? Some children endorse the symptom when asked this question; others respond to an elaboration of that question: Do you need to watch your back when you are walking?

- Do you feel somebody is after you? Who? How come?

In my experience, paranoid ideation is generally more enduring than perceptual disturbances.

Some children are scared of closets, believing that someone or something is in the closet (a monster, Freddie Kruger, or the like). Other children are afraid of windows, believing that somebody might come in through the window at night to either do something bad to them or to take them away. Some children are afraid of the space underneath the bed: they think someone may be hiding there. The bathroom is another place that elicits a variety of fears. Some children are scared to go to the bathroom, even during the day.

Depending on the clinical presentation, that is, complex partial symptomatology (temporal lobe epilepsy), the examiner may ask, Do you ever smell things that others do not? Do you ever experience weird tastes in your mouth? Do you ever experience any sense of estrangement? Do you ever feel the world looks weird to you? Can you predict the future?

Psychotic features are relatively common in mood disorders, eating

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Claudio Cepeda, M.D., is a senior child and adolescent psychiatrist and medical director at the Westover Hills Clinic, Clarity Child Guidance Center, in San Antonio, Texas. He and Lucille Gotanco, M.D., are the coauthors of *Psychiatric Interview of Children and Adolescents.* APA members can purchase the book at a discount at https://www.appi.org/Psychiatric_Interview_of_Children_and_Adolescents.

VNS Improves 5-Year Outcomes in Treatment-Resistant Depression

Patients receiving adjunctive VNS had significantly higher rates of symptom improvement and depression remission compared with patients receiving usual care. **BY NICK ZAGORSKI**

Adding vagus nerve stimulation (VNS) to the treatment regimen of a patient with treatment-resistant depression (TRD) may lead to better long-term outcomes, according to a report published March 31 in *AJP in Advance*. The findings, based on the longest and largest naturalistic study of efficacy outcomes in TRD, suggest the superior outcomes of VNS may last up to five years.

VNS—a technique that delivers electrical impulses to the vagus nerve via an implanted device in the neck—has long been recognized as a possible adjunctive option for patients with TRD. APA's practice guidelines recommend VNS as an add-on option for anyone who has not responded to at least four other approved depression therapies.

As a condition for approving VNS as an adjunctive treatment for TRD, the U.S. Food and Drug Administration (FDA) required a post-marketing surveillance study. In 2006, the Treatment-Resistant Depression Registry was established to track the clinical course and outcomes over five years of patients with TRD receiving adjunctive VNS and compare their health outcomes to TRD patients receiving usual care.

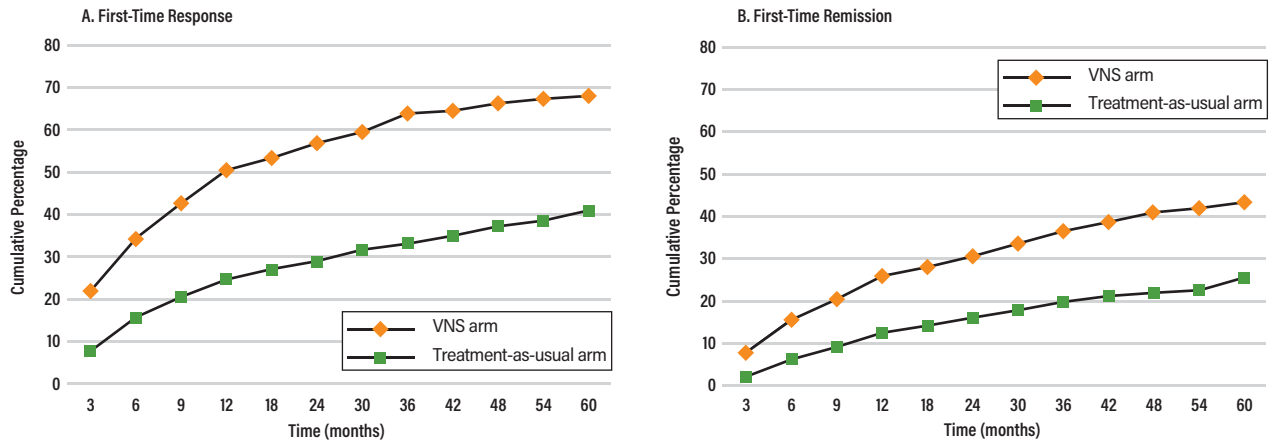
A total of 795 study participants were included in the study, 494 of whom received a VNS implant in addition to their usual treatments (which included medication, psychotherapy, and/or electroconvulsive therapy) and 301 of whom received usual treatment only. Both groups of patients had failed to respond to multiple therapies; at baseline, the mean number of failed treatments for depression was 8.2 in the VNS arm and 7.3 in the treatment-as-usual arm.

Follow-up visits, which included an assessment of changes in mood, occurred every three months for the first year and every six months for the remainder of the study. Response rate was defined as a 50 percent or greater reduction in a patient's

see **VNS** *on page 32*

Depression Patients Receiving Add-On VNS Report Greater Improvements Over Time

Response is defined as an ≥50% improvement in Montgomery-Åsberg Depression Rating Scale (MADRS) score from baseline, while remission is defined as achieving a MADRS score ≤9 at any post-baseline visit.



Source: Scott Aaronson, M.D., et al. *American Journal of Psychiatry*, March 31, 2017

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disorders, substance use disorders, and in neurodevelopmental disorders, mainly 22qll genetic syndromes. Examiners need to consider the rare condition of very early onset schizophrenia in preadolescents, and in children in middle or late adolescence, early onset schizophrenia, which is not rare.

In manic cases, the examiner must explore grandiose delusions, such as these:

- Do you ever feel you are a superhero? Give me details.
- Have you ever tried to fly? Tell me about that.
- Do you feel you can do things others can't?
- Do you feel you have special powers?

At times, the discovery of psychosis requires additional exploratory means. Trisha, an 8-year-old Caucasian, was evaluated for a suicidal verbalization: she told the school counselor that she had a plan to kill herself with a knife. She also had difficulties controlling her anger; she threw frequent tantrums, slammed doors, screamed frequently, and voiced that nobody liked her. The biological mother had five children; the oldest child and a 13-year-old girl were still living with her. Trisha's maternal grandmother was raising Trisha and two of her siblings; the biological mother saw them only sporadically. The grandmother suspected a great deal of neglect and even sexual abuse.

Trisha had been retained in first grade. A cognitive assessment nine months before the psychiatric evaluation revealed that Trisha had borderline intellectual abilities. She was reading at a kinder level, and her scores in spelling and arithmetic were at a first-grade level. The biological mother had a history of drug abuse and had been in jail five times. Trisha looked regressed and childish and sometimes she laughed inappropriately.

During the Mental Status Examination, Trisha endorsed hearing steps at night and having a feeling that people were watching her. She also endorsed homicidal ideation, and her grandmother reported that she frequently threatened to kill or hurt others with a gun. There were no guns at home, but she made hand gestures as if she were shooting a gun.

When she was asked to draw, following the guidelines sketched in *Psychiatric Interview of Children and Adolescents* (see biography), she evidenced signs of psychotic thinking and preoccupation: "Bloody Mary" appeared in *all* the drawings. When the examiner, for instance, asked her to draw a person, she drew herself with Bloody Mary at her side. In another drawing, she is walking with her brother to the house. He has Bloody Mary eyes. The drawings put a light on the extensive paranoid symptomatology that had not been appreciated by the verbal exploration.

When she was asked to explain the drawing, she mentioned that Bloody Mary was around her most of the time. This alerted the examiner to the presence of psychotic, paranoid thinking, which the patient had not explicitly endorsed.

A word of caution about evaluating psychosis in preadolescents and late preschoolers: I have witnessed the strongest denial and rationalizations and defensiveness in the parents of these subjects. Parents justify that their children's endorsement of these symptoms is due to recently watched movies, TV shows, video games, or the like; some parents normalized those abnormal experiences or have accepted false reassurance from others, even experts, that the child will grow out of these symptoms, that these problems will go away, or the like. Even worse, some parents believe that the child has some supernatural abilities. Other parents state that the child's endorsement of the psychotic exploration is due to the suggestive questioning by the interviewer (leading questioning).

To avoid this rationalization, I recommend the following strategy: Ask the parents(s) to assist in the evaluation by posing a number of questions: Please ask Jimmy if he is scared at night. Ask Jimmy if he hears weird noises, scary sounds. Does he hear voices talking to him when nobody is around? And so on. When the child endorses unusual experiences, perceptual disturbances, or paranoid feelings, it is harder for a parent to deny or explain away what the child asserted. **PN**

BY NICK ZAGORSKI

Novel ADHD Compound Passes Phase 3 Test In Youth

Sunovion Pharmaceuticals in April reported positive results from the phase 3 study of ***dasotraline***—a dopamine and norepinephrine reuptake inhibitor (DNRI)—in children with attention-deficit/hyperactivity disorder (ADHD).

For the trial, 112 children aged 6 to 12 were randomized to receive 4 mg of dasotraline or placebo daily and evaluated on classroom performance over 15 days. The primary outcome was change in the Swanson, Kotkin, Agler, M-Flynn, and Pelham combined score (SKAMP-CS), a validated rating scale for measuring functional impairment in classroom settings.

The children taking dasotraline showed statistically significant improvements in overall SKAMP-CS as well as the SKAMP subscales of attention and deportment compared with placebo. These improvements were evident at multiple times over the course of the day (12 to 24 hours post-dose).

Dasotraline was also well tolerated, with insomnia, decreased appetite, and headache among the most commonly reported adverse events.

Sunovion plans to submit a New Drug Application to the U.S. Food and Drug Administration (FDA) for dasotraline for the treatment of ADHD by March 2018, according to a company press release.

FDA Issues New Warnings On Codeine/Tramadol Use In Children

In an effort to restrict the prescribing of ***tramadol*** and ***codeine*** to children, the FDA in April announced the following labeling changes:

- Labels will now feature a contraindication warning that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than age 12. In addition, the tramadol label will feature a contraindication warning against the use of the medication in children younger than 18 to treat pain after tonsil/adenoid removal.

- The labels will also feature a warning, recommending against the use of either drug in adolescents between 12 and 18 years who have conditions that increase the risk of breathing problems, such as obesity, sleep apnea, or severe lung disease.

- Both medications will feature a strengthened warning that breastfeeding is not recommended for mothers taking codeine or tramadol due to the risk of serious adverse reactions in breastfed infants, including excess sleepiness and serious breathing problems.

A boxed warning cautioning against prescribing codeine to treat pain after tonsil or adenoid surgery is already featured on the medication. Additionally, both opioids have warnings about the risk of serious breathing problems in some children who metabolize codeine and tramadol faster than usual (called ultra-rapid metabolism).

Shortages Expected for Pernix's Controlled-Release Hydrocodone

Pernix Therapeutics, maker of ***Zohydro ER (hydrocodone)***, announced last month that due to a manufacturing problem, the 20-mg strength version of the medication is not available. Zohydro ER is a controlled-release, tamper-resistant opioid pain medication.

The company said in a statement that it expects the 20-mg version of this drug will be on backorder until early 2018. Zohydro will continue to be available in the other strengths, including 10 mg, 15 mg, 30 mg, 40 mg, and 50 mg strengths, but Pernix anticipates that as doctors who were prescribing 20-mg doses switch to other strengths, there may be other shortages.

Pernix said it is evaluating what the "scope of any potential impact" might be and will provide updates as new information emerges. The company also said it is working with its supplier to ensure the return of the 20-mg strength to the marketplace as soon as possible.

FDA to 'Fast Track' NMDA Antagonist for MDD

Relmada Therapeutics Inc. in April announced that the FDA has granted a Fast Track designation to ***REL-1017 (dextromethadone)***—a NMDA receptor antagonist—for the adjunctive treatment of major depressive disorder. Drugs that receive a Fast Track designation receive accelerated reviews and priority approval to speed their development.

Dextromethadone, or d-methadone, is an enantiomer (mirror image) of methadone that primarily blocks N-methyl-D-aspartate (NMDA) receptors, which are linked with both depression and neuropathic pain. However, no currently approved drugs to treat depression target NMDA receptors.

Relmada has completed multiple phase 1 studies for REL-1017 that confirmed safety, tolerability, and effective dose range. They are now planning a phase 2a randomized, placebo-controlled study in patients with major depressive disorder. **PN**

Mark Moran

Medalists

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address children's health holistically.

"Often families have to go through a dozen or more agencies to get help," said Paolo del Vecchio, M.S.W., director of SAMHSA's Center for Mental Health Services. "Too often they fall through the cracks. What we really need is comprehensive, coordinated care models that use a team-based approach with a centralized contact to provide individualized patient care."

Child psychiatrist Adair Parr, M.D., representing APA at the event, spoke about her experience working with Potomac Pediatrics, a group practice in Rockville, Md., where she is implementing an integrated/collaborative care model to care for children with emotional and behavioral health needs. Parr received training from APA in collaborative care. She told the audience that the collaborative care model promises to extend quality mental health care through the collaboration of psychiatrists with primary care physicians to millions of people who otherwise might not receive care.

"I work with the pediatrician and nurse care manager to help primary care manage anxiety and depression," Parr said. "We are also able to identify patients who are not progressing toward recovery, and who need the more intensive attention I can provide. It's a great way to provide access quickly to patients who do not otherwise have access to a child psychiatrist."

Parr cited the example of a teenage patient who came in for a well-child visit and was screened for depression using the PHQ-9. The screen identified suicidal thoughts in the patient requiring psychiatric care. "It's an example of how our system was able to identify a young person who really needed help and might otherwise go without it," she said. "As a child and adolescent psychiatrist, I have been trained to look at the medical, psychological, and social determinants of children's health in the context of the whole family."

Also attending the event was Health and Human Services (HHS) Secretary Tom Price, M.D., who presented Phelps and Schmitt with the 2017 SAMHSA Special Recognition Award. Price said HHS, under the Trump administration, was prioritizing serious mental illness, childhood obesity, and substance use disorders.

"These three interrelated problems are among our country's most pressing challenges, requiring public and private collaboration and a commitment to prioritizing evidence-based systems of care," Price said. He cited evidence from SAMHSA's National Survey on Drug Use and Health showing that adolescents who have diabetes or are overweight are more likely than their peers to experience depression.

In presenting the awards to Phelps and Schmitt, Price hailed their outspoken support of SAMHSA's efforts. "Michael and Allison's stories are so important because they prove that mental illness impacts people of all backgrounds, even those who appear to have it all." Price added that an athlete's success is "is determined less by the strength of [one's] body than the resilience of [one's] mind. ... Michael and Allison are living proof of this fact." **PN**

A webcast of the SAMHSA event is posted at http://fda.yorkcast.com/webcast/Play/ef139de1471545149dcbd537aa4529831d.

VNS

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Montgomery-Åsberg Depression Rating Scale (MADRS), and remission was defined as achieving a MADRS score of 9 or less.

Patients in the VNS group showed a five-year cumulative response rate of 67.6 percent, which was significantly higher than the 40.9 percent response rate in the usual-treatment group. VNS patients also had a higher remission rate of 43.3 percent compared with 25.7 percent in the usual care group.

Mark George, M.D., of the Medical University of South Carolina (MUSC) in Charleston, who was not involved with this study, told *Psychiatric News* that he is not surprised to see the long-term positive effects of VNS. George, who implanted the very first VNS device for depression in a patient in 1997, said he has been informally monitoring dozens of depression patients who have undergone this procedure at MUSC and said he had been "amazed by the long-term effects."

"The patients by and large seem much more social and active than before," George said. "When you get questions such as, 'Is it okay if I scuba dive with my VNS implant?' it suggests the patient is doing well."

At the moment, however, VNS is not considered a standard treatment for TRD and thus is not generally reimbursed by Medicare or other health insurance plans. Scott Aaronson, M.D., director of clinical research at Sheppard Pratt Health System in Baltimore and lead author of the study, told *Psychiatric News* that he hopes that these results will one day lead to changes in coverage for VNS for people with depression.

Aaronson noted that while the registry allowed for comprehensive analysis (patients included those with unipolar and bipolar depression, as well as comorbid anxiety disorder), treatment assignment in the registry was not blinded, which could have led to an increased expectation of therapeutic improvement.

"Before we can consider VNS as a routine part of depression management, we do need prospective data from a randomized, blinded, controlled trial with an improved design that incorporates what we have learned about the device from previous studies," Aaronson said.

George said he hopes future studies might also point researchers toward biomarkers and screening tools that can help predict response to VNS. The procedure itself is minimally invasive and safe to use, but VNS does require surgery. Additionally, as the study showed, one in every three people will fail to respond to the therapy.

George suggested transcutaneous vagus nerve stimulation (tVNS)—a procedure that involves clipping electrodes to the ear (which contains terminals of the vagus nerve)—might offer a noninvasive option for determining patients most likely to respond to VNS,

Some pilot studies have shown that tVNS can reduce depressive symptoms, but George cautioned that non-invasive stimulation is still very much experimental (*Psychiatric News*, September 2, 2016), and likely cannot produce a strong or sustained therapeutic effect. However, he noted that if tVNS proves reliable, then people who respond to the therapy might be considered good candidates for traditional VNS.

The Treatment-Resistant Depression Registry was sponsored by Cyberonics, Inc., which manufactures VNS devices. **PN**

"A 5-Year Observational Study of Patients With Treatment-Resistant Depression Treated With Vagus Nerve Stimulation or Treatment as Usual: Comparison of Response, Remission, and Suicidality" is posted at http://ajp.psychiatryonline.org/doi/full/10.1176/appi.ajp.2017.16010034.

Mortality

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medication management, psychotherapy, or both over the 12-month period. These individuals had about one outpatient contact per month. Among those using hospital services, 23 percent were hospitalized in the year after the initial diagnosis. More than half of these individuals had at least one visit to the emergency department in the year following the diagnosis.

Although several countries have implemented comprehensive treatment programs for young FEP patients, including lower-dose antipsychotic medication, psychotherapy, family education, and support services, the United States has been slow to adopt early intervention, according to Schoenbaum. "People in these countries that have national health systems are less likely to fall through the cracks because they are treated by the same system throughout their lives," Schoenbaum said.

"Other studies have shown that early coordinated treatment for psychosis produces the best results. However, we know that the typical duration of untreated psychosis in the United States is around 17 months," Robert Heinssen, Ph.D., director of the Division of Intervention Services at NIMH and co-author on the paper, said in a press release. "This study reinforces federal and state support for funding evidence-based psychosis treatment programs across the country, and the need for communities to invest in more treatment programs."

The study was funded by NIMH. **PN**

An abstract of "Twelve-Month Health Care Use and Mortality in Commercially Insured Young People With Incident Psychosis in the United States" is posted at https://academic.oup.com/schizophreniabulletin/article-abstract/doi/10.1093/schbul/sbx009/3111212/Twelve-Month-Health-Care-Use-and-Mortality-in?redirectedFrom=fulltext.

AHCA

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access, and coverage for all."

The five groups that signed onto the statement with APA were the American Academy of Family Physicians, American Academy of Pediatrics, American College of Physicians, American Congress of Obstetricians and Gynecologists, and American Osteopathic Association. They represent more than 560,000 physicians and medical students. APA was part of the same coalition of organizations that had expressed its strong opposition to the AHCA in late April.

The AHCA, a proposed replacement of the Affordable Care Act, initially was scheduled for a House vote on March 24, but House Speaker Paul Ryan (R-Wis.) opted to postpone the vote because at that time there were not enough votes to pass the bill.

There were concerns at the time that millions of people would be unable to afford health insurance because of lower federal subsidies as well as higher premiums, copayments, and deductibles. Other issues were whether people with pre-existing conditions would lose coverage, and the proposal to allow states to drop the mandate to cover 10 "essential health benefits," of which mental health care is one. Instead, states would have been permitted to define which benefits must be a part of that state's marketplace.

Under the version of the bill that passed the House, $8 billion over five years has been added to the bill to help cover insurance costs for those with pre-existing conditions. The provision, which enabled the bill to garner enough votes in the House, is expected to face opposition in the Senate, however, because some members say it will not guarantee health care to those with pre-existing conditions.

"There are two schools of thought" on what will happen in the Senate, said Ariel Gonzalez, J.D., APA's chief of government affairs. One is that the Senate version of the health care bill will move quickly—within 90 days. The other is that the Senate bill will take much longer to draft and will be "extremely different" from the House bill. When the House and Senate go to conference to reconcile the bill, it could die, Gonzalez said.

"Before and throughout the AHCA debate, our organizations continually offered constructive ideas on achieving agreement on legislation consistent with our shared principles," APA and the five other organizations wrote in their statement. "Regrettably, the AHCA, as amended and passed by the House, violates our principles, dramatically increasing costs for older individuals, resulting in millions of people losing their health care coverage, and returning to a system that allows insurers to discriminate against people with pre-existing conditions."

The six groups also oppose the AHCA's Medicaid cuts, including "capping and cutting the federal government's contribution to Medicaid, sunsetting federal funding for Medicaid expansion, and eliminating Medicaid coverage of essential benefits.

In addition to encouraging the Senate to not take up the AHCA "in any form," the statement urges the Senate to take the following actions:

- Work to achieve real bipartisan solutions to ensure that coverage remains affordable.
- Stabilize the individual market.
- Ensure long-term, adequate funding for the Children's Health Insurance Program.
- Make primary, preventive, and mental health and substance use services more readily available to all Americans.
- Lower the costs of pharmaceutical treatments.
- Reform medical liability laws.
- Reduce the administrative and regulatory burdens that add costs and take time away from patients.

The statement concluded, "We stand ready to assist the Congress on achieving these and other necessary improvements." **PN**

Funding

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2016 to address the opioid crisis. This represents an increase of $150 million for prevention and treatment programs for opioid and heroin use disorders, as well as $500 million in funding authorized by the 21st Century Cures Act.

The funding level for the Substance Abuse Prevention and Treatment Block Grant has been maintained at $1.8 billion, while the Mental Health Block Grant funding was increased from $533 million to $563 million.

"The federal government and the Congress play a vital role in advancing research into the causes of, and new treatments for, mental health and substance use disorders," said CEO and Medical Director Saul Levin, M.D., M.P.A. "The increased funding that Congress has appropriated this year gives us renewed hope that people with mental illness and substance use disorders will one day benefit from the growing understanding of mental disorders and new, personalized health and treatment options. We sincerely appreciate Congress considering our requests for additional funding for those governmental entities helping those with mental illness and substance use disorders get the best treatment and care through research."

Ariel Gonzalez, APA's chief of government affairs, agreed. "We were pleased to see that the budget for HHS has been increased $2.8 billion above the Fiscal 2016 level. We will continue to advocate for additional funding to address the needs of those impacted by mental health issues and those in need of substance use disorders treatment." **PN**

Mental Health Gets Increases Across the Board

The National Institutes of Health budget got a 6.2 percent increase from Fiscal 2016 to 2017 from $32 billion in Fiscal 2016 to $34 billion in Fiscal 2017.

Agency	2016	2017	Increase
NIMH	$1.5 B	$1.6 B	+6.6%
NIDA	$1.08 B	$1.09 B	+.92%
NIAA	$468 M	$483 M	+3.2%

Source: NIH