**Spring 2016**

### President’s Corner

Spring is the season of renewed hope. There is good cause for hope within our NAMI family as reports of new legislation, studies, and medications to help our loved ones surface. In this spring newsletter, you will find information about a groundbreaking discovery with the potential for early detection and new treatments for schizophrenia that were unthinkable just a year ago; and two new medications, one for tardive dyskinesia, and another new atypical antipsychotic which may also be used to improve outcomes for depression when added to antidepressants. We are beginning to understand that schizophrenia need not be a progressive deteriorating brain disease in the majority of cases. In addition, Clozapine (Clozaril) use is being encouraged by the New York State Office of Mental Health for treatment-resistant schizophrenia, with significantly successful results.

We have a new Senate mental health bill on the horizon which pairs with the one Representative Tim Murphy introduced. For those of us waiting for meaningful federal legislation, it hasn’t come too soon! We need to demand long-awaited action, reminding our senators that we need their help to co-sponsor and promote final mental health legislation that includes the provisions of the Helping Families in Mental Health Crisis bill.

New York State Assemblymember Aileen Gunther introduced a bill (A01275) to make Kendra’s Law permanent that has stagnated in the assembly far too long. It would make the law that has saved many a life, permanent and improve care of those with the most serious mental illnesses. It is currently necessary to renew Kendra’s Law, which again sunsets in 2017, every five years.

Winter has been a busy season for NAMI Buffalo, with Christmas is For Kids successfully completing its 25th year with...
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Mary Kirkland and Tom McNulty co-chairing with Mary Lou Bond. They, and our generous donors and volunteers, deserve well-earned kudos.

For the Christmas season, NAMI Buffalo piloted a new program aimed at helping homeless and mentally ill people who come to Erie County Medical center for treatment lacking clothing appropriate for our cold winters. Socks, gloves, scarves, underwear, candy and a few transistor radios for use on the units, were collected and delivered by Ann Venuto and Jackie Thompson to ECMC. We are looking for this to be an annual event, and possibly more NAMI members getting involved next year. Those of you who would like to be involved, please call our office.

Unfortunately, not all is happy news. Jim Kirkland, the husband of Mary Kirkland, our former president, passed away on February 5, 2016, after a short illness. Jim was an important part of NAMI for decades up until the time of his death, and faithful partner with Mary in dedication to our advocacy and efforts. He was there to do menial and repetitive chores as requested by his “president wife” and ever-smiling. No job was too difficult for him to tackle and his energy was boundless. We will all miss him and his kind, cheerful ways. A memorial celebration of Jim’s life will take place in July.

As the weather warms, may you all find renewed energy and hope.

Marcy Rose, President

Sunshine
Our best wishes to Donna Matecki, our dedicated bookkeeper for over 20 years, who retired on January 1.

A warm welcome to Megan Gallagher who has become our new bookkeeper.

Welcome also, to Michele Brooks, on the Board of Directors. We’re glad to have you aboard!

Thank you
Ann Venuto, Jackie Thompson, Mary Kirkland, and Liz Carone for collection of donations for Christmas is for Adults, Too! for ECMC. Special thanks for help in this first year’s effort to Watts Architectural & Engineering and Savarino Companies for collecting gifts.

Judy Capodicasa, Liz Carone, Mary Lou Bond and Jackie Thompson for helping with membership work and opening mail.

32nd Annual Awards & Dinner Celebration
Wednesday, April 27th at Salvatore's Italian Gardens

Join us and our special keynote speaker, Judge Robert T. Russell who revolutionized the courts system with the formation of the nation's first Drug Court, Mental Health Court and--most recently--Veterans Court.

Invitations will be out soon. For more information about sponsorship or reservations, call the office at 226-6264.

Note: there will be regular education meetings in April and in May. These are in addition to the 32nd annual dinner on April 27th. On April 14th, we will show the critically acclaimed film “Voices”, about 3 individuals living with mental illness. Please plan to attend--and bring a friend who may be interested. Pre-registration is not necessary. Light refreshments will be available.
For the first time, scientists have pinned down a molecular process in the brain that helps to trigger schizophrenia. The researchers involved in the landmark study, which was published Wednesday in the journal Nature, say the discovery of this new genetic pathway probably reveals what goes wrong neurologically in a young person diagnosed with the devastating disorder.

The study marks a watershed moment, with the potential for early detection and new treatments that were unthinkable just a year ago, according to Steven Hyman, director of the Stanley Center for Psychiatric Research at the Broad Institute at MIT. Hyman, a former director of the National Institute of Mental Health, calls it “the most significant mechanistic study about schizophrenia ever.”

“I’m a crusty, old, curmudgeonly skeptic,” he said. “But I’m almost giddy about these findings.”

The researchers, chiefly from the Broad Institute, Harvard Medical School and Boston Children’s Hospital, found that a person’s risk of schizophrenia is dramatically increased if they inherit variants of a gene important to “synaptic pruning” -- the healthy reduction during adolescence of brain cell connections that are no longer needed.

In patients with schizophrenia, a variation in a single position in the DNA sequence marks too many synapses for removal and that pruning goes out of control. The result is an abnormal loss of gray matter.

The genes involved coat the neurons with “eat-me signals,” said study co-author Beth Stevens, a neuroscientist at Children’s Hospital and Broad. “They are tagging too many synapses. And they’re gobbled up.”

The Institute’s founding director, Eric Lander, believes the research represents an astonishing breakthrough. “It’s taking what has been a black box...and letting us peek inside for the first time. And that is amazingly consequential,” he said.

One area in particular, when graphed, showed the strongest association. It was dubbed the “Manhattan plot” for its resemblance to New York City’s towering buildings. The highest peak was on chromosome 6, where McCarroll’s team discovered the gene variant. C4 was “a dark corner of the human genome,” he said, an area difficult to decipher because of its “astonishing level” of diversity. C4 and numerous other genes reside in a region of chromosome 6 involved in the immune system, which clears out pathogens and similar cellular debris from the brain. The study’s researchers found that one of C4’s variants, C4A, was most associated with a risk for schizophrenia.

“This paper is really exciting,” said Jacqueline Feldman, associate medical director of the National Alliance on Mental Illness. “We as scientists and physicians have to temper our enthusiasm because we’ve gone down this path before. But this is profoundly interesting.”

There have been hundreds of theories about schizophrenia over the years, but one of the enduring mysteries has been how three prominent findings related to each other: the apparent involvement of immune molecules, the disorder’s typical onset in late adolescence and early adulthood, and the thinning of gray matter seen in autopsies of patients.

The study offers a new approach to schizophrenia research, which has been largely stagnant for decades. Most psychiatric drugs seek to interrupt psychotic thinking, but experts agree that psychosis is just a single symptom -- and a late-occurring one at that. One of the chief difficulties for psychiatric researchers, setting them apart from most other medical investigators, is that they can’t cut schizophrenia out of the brain and look at it under a microscope. Nor are there any good animal models.

All that now has changed, according to Stevens. “We now have a strong molecular handle, a pathway and a gene, to develop better models,” he said. Which isn’t to say a cure is right around the corner.

“This is the first exciting clue, maybe even the most important we’ll ever have, but it will be decades” before a true cure is found,” Hyman said. “Hope is a wonderful thing. False promise is not.”
Clozapine remains the only medication approved for treatment-resistant schizophrenia. But underuse is the norm. In 2010, the New York State Office of Mental Health began a multifaceted initiative to promote the evidence-based use of clozapine. From 2009 to 2013, in the absence of a well-funded pharmaceutical marketing campaign, the proportion of new clozapine trials among all new outpatient antipsychotic trials increased 40% among adult New York Medicaid recipients with a diagnosis of schizophrenia. The largest gains occurred in state-operated clinics. New York's experience demonstrates the feasibility of making clozapine more accessible to patients who stand to benefit most.

**Introduction invited by the column editor:** Evidence for the advantages of clozapine for some patients has been available for more than a decade. Patients who could benefit from clozapine disproportionately receive care in the public sector. However, public-sector prescribers have been hesitant to use clozapine because it has immediate life-threatening side effects for a small percentage of patients. Clozapine also has life-shortening side effects, such as weight gain, insulin resistance, and dyslipidemia, that require long-term intervention with agents that prescribers in the public mental health system may not be familiar with or are uncomfortable using—and collaborative primary care is not consistently available in public mental health settings. Prescribers' hesitancy is understandable. However, we would be horrified if oncologists avoided using chemotherapy because the agents had life-threatening side effects and because knowledge and skill are necessary to prescribe them appropriately. This column shows that the approach taken in New York—combining assistance to public-sector prescribers with clear directives for appropriate clozapine use—has been successful. We have too long valued the comfort of prescribers over the well-being of patients with severe mental illness. It is time for prescribers to step up, and we should assist them.—Joseph P. McEvoy, M.D., Georgia Regents University, Augusta

Nearly three decades after its approval by the U.S. Food and Drug Administration (FDA), clozapine remains the only medication approved for treatment-resistant schizophrenia. No other antipsychotic or combination of antipsychotic medications is as effective as clozapine for treatment-resistant schizophrenia. Despite its well-established superior efficacy, delays and underuse of clozapine continue to be the norm nationally and internationally. Treatment guidelines recommend consideration of clozapine for individuals for whom two prior antipsychotic trials have failed. Yet survey data suggest that delays in clozapine prescribing range from five to ten years, with prescribers often resorting to practices unsupported by evidence (1). An investigation that examined clozapine use in 2009 for Medicaid recipients in New York with a diagnosis of schizophrenia found that clozapine accounted for only 2% of new antipsychotic starts (2). A subsequent national study found that patterns of clozapine use in the rest of the United States resembled the modest usage in New York (3). Although estimates vary depending on study criteria, it is generally accepted that approximately a third of individuals with a schizophrenia diagnosis who have had two or more antipsychotic trials had less than adequate responses to those trials. However, the percentage of individuals with schizophrenia who have had a trial of clozapine falls far short of this. The national study found significant variation in prescribing at the state and county levels, suggesting that local practice patterns significantly influence clozapine use (3). Local patterns were more strongly associated with clozapine use than several clinical factors, such as frequent medication changes and high levels of mental health service use.

Many reasons for clozapine underuse are cited: insufficient prescriber training; clinical concern over rare but serious medical risks, including agranulocytosis and myocarditis; frequent blood draws for granulocyte monitoring; relatively high administrative burden; and troublesome side effects, including weight gain, sedation, and drooling (4). Moreover, clozapine's visibility has decreased because generic forms have been available for many years, and pharmaceutical company efforts to market it have largely ceased.  

Continues next pg.
The New York State Initiative

Considering the low rates of clozapine use in New York, the medical director of the New York State Office of Mental Health (NYS OMH) introduced the “Best Practices Initiative—Clozapine” in 2010 to promote its evidence-based use in state-operated facilities. To enhance clozapine access among individuals who stand to gain the most, the initiative targets both perceived “supply side” and “demand side” barriers; it provides a host of supports for prescribers and a decision aid tool for consumers grounded in the principles of shared decision making. With adequate supports for consumers and prescribers, the expectation was that clozapine could play an important role in individual recovery plans.

Although definitions of treatment-resistant schizophrenia vary, the initiative adopted a broad interpretation that included adults with schizophrenia spectrum disorders whose illness materially impeded their recovery—for example, prevented them from attending school, developing and maintaining supportive social relationships, or acquiring employment—despite two antipsychotic trials.

The initiative engaged academic partners at Columbia University Medical Center, the New York State Psychiatric Institute, New York University, and the Nathan S. Kline Institute for Psychiatric Research as well as clinical leaders from NYS OMH state-operated psychiatric centers (PCs). Led by the medical director’s office, these collaborators developed a manual for clinicians and made a series of statewide grand rounds presentations. Several senior psychiatrists agreed to participate in a telephone consultation service, receiving clozapine-related calls from any NYS OMH prescriber (staff psychiatrists and nurse practitioners) on weekdays during business hours.

In 2011, the medical director’s office began tracking clozapine prescribing at the 16 adult state-operated PCs, focusing primarily on the 66 outpatient clinics within those care systems that represent approximately 20% of all adult outpatient clinics in the state’s public mental health system. These 16 PCs employ nearly 400 psychiatrists and 50 nurse practitioners and serve approximately 27,000 individuals with serious mental illness each year, most of whom have a diagnosis of treatment-resistant schizophrenia. Detailed action plans were required from centers with low levels of clozapine use. NYS OMH provided clinical directors with quarterly feedback on progress by means of a report showing clozapine use trends over time for each PC and comparisons among the 16 PCs.

NYS OMH partnered with the Center for Practice Innovation at the New York State Psychiatric Institute to create interactive Internet-based educational programs to provide information about clozapine to consumers, family members, and clinicians. The first program, “Considering Clozapine,” is a publicly available Web-based module that provides information for consumers and family members about clozapine, including benefits and risks. A key component is a series of testimonials from consumers, who describe personal benefits from clozapine along with its challenges. The second Internet-based educational program, “Motivating Clozapine Use,” is directed at clinicians. It includes testimonials from consumers and family members and provides tips for presenting clozapine as an option to patients in a balanced way consistent with principles of shared decision making.

Program Evaluation

Below we describe an evaluation of the initiative—a retrospective longitudinal study (2009–2013) of patterns of new antipsychotic starts for individuals identified by Medicaid data as having schizophrenia (N=42,310). New starts of antipsychotics (N=115,320) were defined as an outpatient filled prescription immediately preceded by 90 or more days during which no prescription for the same antipsychotic was filled. The percentage of clozapine new starts among all new antipsychotic trials increased from 1.5% (2009) to 2.1% (2013).

Individuals who received services from state-operated facilities at any point during the study were compared with all others (those receiving non–state-operated services). A total of 2,768 individuals were served in state-operated settings and accounted for 7,551 new antipsychotic starts. The rate of clozapine new starts per quarter also increased.

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NYS Clozapine Initiative cont’d from pg. 5

when compared with all new antipsychotic starts, with the greatest change seen at state-operated facilities. The average quarterly percentage change in the rate of clozapine new starts in these facilities was more than three times that in other settings (3.77% compared with 1.13% in other settings).

Discussion

More than 25 years after its FDA approval for treatment-resistant schizophrenia, clozapine remains the only antipsychotic approved for this indication. However, its low use remains the quintessential science-to-service gap in behavioral health services. The NYS OMH experience suggests that clozapine prescribing can be positively influenced by a commitment to quality improvement, strategic public-private partnerships, and provision of supports for prescribers and consumers. Sustained support from NYS OMH leadership led to a 40% increase in clozapine new starts among the Medicaid cohort and a doubling in the estimated rate of new clozapine prescriptions at state-operated facilities (an increase of 36 to 71 per 1,000 new starts). These changes were achieved in settings where prescribers had already completed postgraduate training—that is, when practice patterns may be relatively inelastic. Furthermore, increasing clozapine uptake occurred for a generic medication in the absence of a well-funded pharmaceutical marketing campaign.

How can we build on the progress in New York and broaden access to clozapine? With the FDA’s recent announcement allowing more individuals (such as those with benign ethnic neutropenia) to receive clozapine, the United States joins other nations that have had similar policies for years. Advances in point-of-care granulocyte testing may also offer improved clozapine access by making blood monitoring more convenient for consumers. Furthermore, the focus on integrated care, care coordination, and increased use of decision support tools in electronic medical records may provide a more favorable infrastructure for systematic clozapine use. In the United States, payers and managed care organizations could adopt policies that incentivize earlier access to clozapine. Training in clozapine use during psychiatric residency is another important opportunity to broaden access.

A multicomponent initiative to improve clozapine prescribing in NYS led to an increase of new clozapine starts. Further increases will require sustained efforts to identify patients likely to benefit from clozapine, minimize demand- and supply-side barriers, and develop a workforce skilled in its use. Until more effective medications become available for treatment-resistant schizophrenia, improving safe access to clozapine must be a priority.

Dr. Carruthers, Dr. Radigan, Dr. Erlich, Mr. Gu, Mr. Wang, Dr. Frimpong, Dr. Miller, and Dr. Sederer are with the New York State Office of Mental Health, Albany (e-mail: jay.carruthers@omh.ny.gov). Dr. Carruthers is also with the Department of Psychiatry, Albany Medical College, Albany, New York. Dr. Radigan and Dr. Erlich are also with the Department of Psychiatry, Columbia University College of Physicians and Surgeons, New York City, where Dr. Essock and Dr. Stroup are affiliated. Dr. Sederer is also with the Mailman School of Public Health, Columbia University, New York City. Dr. Essock and Dr. Stroup are also with the New York State Psychiatric Institute, New York City, where Dr. Olfson is affiliated. Dr. Olfson is also with Columbia University Medical Center, New York City. Dr. Castillo is with the Robert Wood Johnson Foundation Clinical Scholars Program, University of California, Los Angeles. Marcela Horvitz-Lennon, M.D., M.P.H., is editor of this column.

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Please consider naming NAMI in Buffalo & Erie County in your will. Your generosity will help us make important progress for better lives for families and individuals who live with serious mental illness now and into the future. Thank you!
Experimental Tardive Dyskinesia Drug Hits Mark in Phase

Megan Brooks
Excerpted from Medscape Medical News, October 9, 2015

NBI-98854, an experimental drug for tardive dyskinesia being developed by Neurocrine Biosciences, led to a statistically significant reduction in symptoms of TD. NBI-98854 is a selective inhibitor of dopamine levels. It is designed to provide “low, sustained, plasma and brain concentrations of active drug to minimize side effects. “Modulation of dopamine levels in diseases such as tardive dyskinesia, Tourette syndrome, Huntington’s chorea, schizophrenia, and tardive dystonia, which are characterized, in part, by high levels of dopamine, should provide symptomatic benefits for patients with these diseases.

The US Food and Drug Administration (FDA) granted NBI-98854 Breakthrough Therapy Designation for the treatment of tardive dyskinesia in October 2014.

The Kinect 3 study involved 234 patients with moderate to severe tardive dyskinesia with underlying schizophrenia, schizoaffective disorder, bipolar disorder, or major depressive disorder.

NBI-98854 was generally well tolerated during the 6-week, placebo-controlled treatment period. The frequency of adverse events was similar among all treatment groups, and treatment-emergent adverse effects were consistent with those of prior studies, the company says.

At baseline, patients had “minimal symptoms” on the Barnes Akathisia Ratings Scale for akathisia and the Simpson-Angus Scale for parkinsonism, and there was no worsening during 6 weeks of treatment. No drug-drug interactions were identified in study patients, who were taking a wide range of psychotropic and other medications.

“We are very pleased with the outstanding efficacy and side effect profile demonstrated by NBI-98854 in the Kinect 3 study. The efficacy data from this pivotal phase 3 study completes our placebo-controlled dataset for NBI-98854 in tardive dyskinesia,” Kevin C. Gorman, PhD, Neurocrine president and chief executive officer, said in the release. “We will now turn our focus to completing the open-label safety portion of the studies in tardive dyskinesia patients and compiling the data for both doses of NBI-98854 to be included in the New Drug Application we intend to file with the FDA in 2016,” he said.

The Myth of Schizophrenia as a Progressive Brain Disease

Robert B. Zipursky, Thomas J. Reilly, Robin M. Murray

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Schizophrenia has historically been considered to be a deteriorating disease, a view reinforced by recent MRI findings of progressive brain tissue loss over the early years of illness. On the other hand, the notion that recovery from schizophrenia is possible is increasingly embraced by consumer and family groups.

Evidence shows that although approximately 25% of people with schizophrenia have a poor long-term outcome, few of these show the loss of function that is characteristic of neurodegenerative illnesses. MRI studies demonstrate subtle developmental abnormalities at first onset of psychosis and then further decreases in brain tissue volumes; however, these latter decreases are explicable by the effects of antipsychotic medication, substance abuse, and other secondary factors. While patients do show cognitive deficits compared with controls, cognitive functioning does not appear to deteriorate over time.

The majority of people with schizophrenia have the potential to achieve long-term remission and functional recovery. The fact that some experience deterioration in functioning over time may be due to poor access or adherence, to treatment, the effects of concurrent conditions or social and financial impoverishment. Mental health professionals need to join with patients and their families in understanding that schizophrenia is not a malignant disease that inevitably deteriorates over time but rather one from which most people can achieve a substantial degree of recovery.
New Atypical Antipsychotic Drug Brexpiprazole Improves Depression When Added to Antidepressants

JANUARY 25, 2016 · POSTED IN PEER-REVIEWED PUBLISHED DATA, POTENTIAL TREATMENTS

Two studies published in the Journal of Clinical Psychiatry in 2015 suggest that the new atypical antipsychotic brexpiprazole (trade name Rexulti) safely improves depression when added to antidepressant treatment. The 6-week studies, both by Michael E. Thase and colleagues, compared brexpiprazole to placebo in people who had not responded adequately to one to three antidepressants and were taking at least one antidepressant at the time of the study.

The studies examined the effectiveness of different doses of brexpiprazole. Doses of 2mg/day and 3mg/day were more effective than placebo, while a dose of 1mg/day was not. The drug was well-tolerated by patients at each of these doses, although those taking the 3mg/day reported more side effects than those taking 2mg/day. The side effects included restless legs, weight gain, and headaches.

Like the atypical antipsychotic aripiprazole (Abilify), brexpiprazole partially blocks and partially stimulates dopamine receptors. While aripiprazole allows 61% activity at dopamine D2 receptors, brexpiprazole allows 43%. It is not yet clear how the new drug’s effects may differ from those of aripiprazole.

Another relatively new atypical antipsychotic drug, cariprazine (Vraylar) is approved by the Food and Drug Administration for schizophrenia and mania, but not yet for bipolar depression or as an add-on treatment to antidepressants in unipolar depression, although there are placebo-controlled trials showing that cariprazine can also treat these conditions.

Like aripiprazole and brexpiprazole, cariprazine also partially blocks and partially stimulates dopamine receptors. Unlike them, cariprazine is more potent at dopamine D3 receptors, which are linked to mood, motivation, and drug reward, than at D2 receptors, which are linked to motor control. It is not yet clear how these differences may change treatment outcomes or side effects.

New Mental Health Bill

A new bill, The Comprehensive Behavioral Health and Recovery Act of 2016 (H.R. 4435), has been introduced by House Democrats in Congress. This bill joins the bipartisan H.R. 2646, the Helping Families in Mental Health Crisis Act of 2015, which had a lengthy hearing in November 2015.

The Comprehensive Behavioral Health and Recovery Act of 2016 includes a number of provisions designed to improve the availability of quality mental health services and supports. The House Energy and Commerce Committee will now schedule a “mark up” of the proposed bill and bring it to a vote by the full House of Representatives.

NAMI sends legislative action alerts via email to those who sign up for them. To receive these Legislative Action Alerts, go to www.nami.org and click on “Get involved” at the top of the homepage.

It is vital that NAMI advocates stay aware of what is happening with this important piece of legislation.

There will likely be compromise and rewriting of the Tim Murphy Bill (H.R. 2646) as these pieces of legislation are debated. Please help us achieve meaningful federal legislation that will meet the needs of seriously mentally ill people across our nation, and their families, who have waited too long for relief.

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“If you can’t fly then run,  
if you can’t run then walk,  
if you can’t walk then crawl,  
but whatever you do  
you have to keep moving forward.”  
~ Martin Luther King, Jr.