

News Release

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New Real-World Evidence Highlights Need for Interventions to Improve Outcomes for Patients Who Have Been Diagnosed with Major Depressive Disorder (MDD) and Suicide Ideation or Attempt

Data Presented at the American Psychiatric Association 2019 Meeting Suggest a Low Rate of Psychiatric Care Received by Adult Patients with MDD Before Suicide Ideation or Attempt Diagnosis

Additional Data Show Patients Have a High Risk of Hospital Readmission or Subsequent Emergency Department Visit after Suicide Ideation or Attempt

SAN FRANCISCO, CA, (May 18, 2019) – The Janssen Pharmaceutical Companies of Johnson & Johnson presented new real-world data at the American Psychiatric Association (APA) 2019 Meeting which suggest that, among adult patients with major depressive disorder (MDD), psychiatric treatment in the year prior to a diagnosis of suicide ideation or attempt is markedly low. Additionally, 18.4 percent of adult patients diagnosed with MDD and suicide ideation or attempt during a hospitalization or emergency department (ED) visit had a readmission or subsequent ED visit to the same institution during the six months after discharge. Among those initially hospitalized, nearly half of readmissions or subsequent ED visits occurred within the first 30 days. Taken together, these findings suggest the need to increase and improve interventions to deliver better outcomes for these individuals who are at high risk for readmission and additional ED visits.

"Sadly, approximately 47,000 people in the U.S. died by suicide in 2017, with rates rising sharply over the last 20 years, according to the National Institute of Mental Health," said Ella Daly, M.D., Therapeutic Area Leader, Mood Disorders at Janssen Scientific Affairs, LLC. "We also know that the psychiatric diagnosis most commonly associated with suicide is depression. These findings heighten the critical unmet need to improve care for these patients to improve outcomes."

<u>Click to Tweet:</u> NEWS: New real-world evidence at #APAAM19 highlights the need for interventions that could improve outcomes for people diagnosed with

MDD and suicide ideation or attempt. Learn more: po.st/WldZjn #suicideawareness #APA175

The first study characterizing psychiatric treatment received by adult patients utilized The Optum® electronic health records database, which contains information from Integrated Delivery Networks (IDNs) and large multi-specialty practices. Recorded diagnosis codes were examined and 63,855 adult patients with MDD and suicide ideation or attempt were identified. Psychiatric and medical comorbidities were common, and most adult patients had insurance coverage. Psychiatric treatment was observed to have increased in the weeks immediately preceding the diagnosis of suicide ideation or attempt, suggesting a potential window of opportunity for intervention. Nevertheless, less than half were observed to have received an antidepressant in the year prior to their diagnosis of suicide ideation or attempt.

Two additional studies analyzed adult patients identified in the Premier Hospital Database who were diagnosed with MDD and suicide ideation or attempt during an inpatient hospital stay or ED visit. These patients were evaluated during the six-month period following the first qualifying inpatient hospital stay or ED visit.

In the first study from the Premier Hospital Database, of the 251,259 adult patients identified, 63.8 percent were admitted to the hospital while 36.2 percent had an ED visit only at the facility where suicide ideation and/or attempt was diagnosed. Approximately 18 percent of patients were either readmitted or returned to the ED at the same hospital within six months. After controlling for differences in patient socio-demographics and hospital characteristics, those who were initially admitted had a 22 percent higher risk of a rehospitalization or subsequent ED visit compared to those who only received care in the ED.

A separate study evaluating the 160,343 adult patients from the Premier Hospital Database who were hospitalized showed that 19.2 percent had a readmission or subsequent ED visit within six months, and nearly half of these events occurred within 30 days. Patients whose stays were longer were at elevated risk of a readmission or subsequent ED visit to that same institution within six months. For example, patients who were hospitalized for six or more days were estimated to have an approximately 40 percent higher risk compared to those whose initial hospital stay was only one to three days after controlling for variation in patient socio-demographics and hospital characteristics.

"These data yield valuable insights to help us better identify patients at the highest risk," said Cheryl Neslusan, Ph.D., Director of Market Access, Scientific and External Strategy,

Janssen Scientific Affairs, LLC. "Having major depressive disorder and active suicidal thoughts or behavior further contributes burden and risk to what is already a devastating illness. At Janssen we understand the urgent need and are committed to identifying potential ways to improve the care for the millions who are continuing to fight this battle."

About Major Depressive Disorder (MDD) and Suicide

Major depressive disorder (MDD) is the leading cause of disability worldwide.³ With approximately 17 million adults diagnosed in the U.S., people with MDD experience suffering from a serious, biologically based disease which has a significant negative impact on all aspects of life, including quality of life and function.^{4,5} Depression is the psychiatric disorder most commonly associated with suicide.² According to the National Institute of Mental Health, 9.8 million adults reported having serious suicidal thoughts, 1.3 million adults attempted suicide, and approximately 47,000 Americans died by suicide in 2017.¹

About the Studies

Mental Health Treatment Usage Study

The retrospective cohort study analyzed data from The Optum® de-identified electronic health record (EHR) database containing information on outpatient visits, diagnostic procedures, medications, laboratory results, hospitalizations, clinical notes, and patient outcomes. Approximately 80 percent of the data comes from Integrated Delivery Networks (IDNs) that represent the continuum of care from ambulatory to inpatient/facility settings, while the remaining 20 percent comes from large multispecialty practices. The study analyzed patients ≥18 years of age diagnosed with MDD and suicide ideation or attempt between January 1, 2014 and December 31, 2016. Patients were excluded if they had diagnoses of psychosis, schizophrenia, bipolar disorder, mania, or dementia. Psychiatric treatment examined in the six months prior to the diagnosis of suicide ideation or attempt included both pharmacotherapy and nonpharmacological treatment options (psychotherapy, electroconvulsive therapy, and transcranial magnetic stimulation). Study limitations included: encounters/treatments occurring outside The Optum EHR system not captured; treatment adherence not assessed; patients were largely Caucasian, non-Hispanic, and from the Midwest, limiting generalizability of results to other populations; and misclassification of patients and study measures could have occurred due to limitations of diagnosis coding.

Care Setting Study

The study analyzed patients ≥18 years of age diagnosed with MDD and suicide ideation or attempt during an inpatient hospital admission or emergency department (ED) visit

from the Premier Hospital database over a three-year period from January 2014 to June 2017. Patients were excluded if they had diagnoses of psychosis, schizophrenia, bipolar disorder, mania, or dementia. Descriptive analyses were performed to characterize the population overall and by care-setting (inpatient stay or ED visit only at that institution). Statistical analyses were carried out to evaluate whether the care setting of the index event was associated with the likelihood of a readmission or subsequent emergency room visit controlling for variation in patient socio-demographics and hospital characteristics. Study limitations included: data from hospitals outside of the Premier system are not captured; outpatient care is not captured; results may not be generalizable to hospitals outside of the Premier database; misclassification of patients and study measures could have occurred due to limitations of diagnosis coding.

Length of Hospital Stay Study

The study analyzed patients ≥18 years of age diagnosed with MDD and suicide ideation or attempt during an inpatient hospital admission from the Premier Hospital database over a three-year period from January 2014 to June 2017. Patients were excluded if they had diagnoses of psychosis, schizophrenia, bipolar disorder, mania, or dementia. During a six-month follow-up after initial (index) hospital discharge, rates of readmissions or ED visits were evaluated and compared for patients by inpatient length of stay (categorized as short: 1-3 days; medium: 4-5 days; long: ≥6 days). Descriptive analyses were performed to characterize the population overall and by length of stay categories. Statistical analyses were carried out to evaluate whether initial hospital length of stay influenced the likelihood of a readmission/ED event, controlling for variation in patient socio-demographics and hospital characteristics. Study limitations included: data from hospitals outside of the Premier system are not captured; outpatient care is not captured; results may not be generalizable to hospitals outside of the Premier database; misclassification of patients and study measures could have occurred due to limitations of diagnosis coding.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal. Janssen Pharmaceuticals, Inc. and Janssen Scientific Affairs, LLC are members of the Janssen Pharmaceutical Companies of Johnson & Johnson.

References:

- 1. National Institute of Mental Health. Suicide. https://www.nimh.nih.gov/health/statistics/suicide.shtml. Accessed May 16, 2019.
- 2. Bachmann S. Epidemiology of Suicide and the Psychiatric Perspective. *Int. J. Environ. Res. Public Health.* 2018;15:1425.
- 3. World Health Organization. Depression. http://www.who.int/news-room/fact-sheets/detail/depression. Accessed May 16, 2019.
- 4. National Institute of Mental Health. Major depression among adults. https://www.nimh.nih.gov/health/statistics/prevalence/major-depression-among-adults.shtml. Accessed May 16, 2019.
- 5. Hofmann S et al. Cogn Behav Ther. 2017;46(4):265–286

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