Brintellix (vortioxetine) and Brilinta (ticagrelor): Drug Safety Communication - Name Confusion

US Food & Drug Administration, July 30, 2015

ISSUE: FDA is warning health care professionals and patients that reports of confusion between the antidepressant Brintellix and anti-blood clotting medication Brilinta have resulted in the wrong medication being prescribed or dispensed. FDA determined that the main reason for the confusion between these two medications is the similarity of their brand (proprietary) names. None of the reports indicates that a patient ingested the wrong medication; however, reports of prescribing and dispensing errors continue.

BACKGROUND: Brintellix (vortioxetine) is used to treat a certain type of depression called major depressive disorder (MDD) in adults. It is in a class of antidepressants called selective serotonin reuptake inhibitors (SSRIs). Brilinta (ticagrelor) is an antiplatelet, anti-blood clotting medication used to lower the risk of having another heart attack, or dying from a heart problem after a heart attack or severe chest pain.

RECOMMENDATION: Health care professionals can reduce the risk of name confusion by including the generic (established) name of the medication, in addition to the brand name, and the indication for use when prescribing these medications. Patients should check their prescriptions to ensure that the correct medication was dispensed. See the FDA Drug Safety Communication for more detailed recommendations.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA’s MedWatch Safety Information and Adverse Event Reporting Program:
Complete and submit the report Online: www.fda.gov/MedWatch/report


Patient–Physician End-of-Life Discussions in the Routine Care of Medicare Beneficiaries
Keary S, Moorman S

Medicare reimbursement for physicians who discussed end-of-life care and planning with a patient during an office visit was cut from the 2010 Affordable Care Act. We assessed the characteristics of patients who reported having had such discussions, and whether these discussions are associated with trust in one’s physicians and with rates of family advance care planning (FACP).

Method: The sample consisted of 5,199 Medicare beneficiaries who reported having an ongoing relationship with a primary care physician. We estimated ordinal and multinomial logistic regressions that controlled for health care utilization, current health, and recent family deaths. Results: Less than 1% ($n = 310$) reported an end-of-life conversation with a physician during the course of routine care. However, conversations were associated with greater trust in one’s physician and higher rates of completion of FACP. Discussion: Findings support renewed efforts to reimburse physicians for discussing end of life with their Medicare patients. J Aging Health 2015;27(6):983-1002
The Experiences and Needs of Family Carers of People with Diabetes at the End of Life
Savage S, Dunning T, Duggan N, Martin P

Diabetes is a common, increasingly prevalent chronic disease. Many people requiring palliative care have diabetes. Diabetes requires lifelong self-care tasks. Family carers frequently perform these tasks when the person with diabetes is no longer able to perform them, but there is a lack of information about carers’ needs to enable them to undertake their new care tasks. The study aimed to collect information from family carers of people with diabetes requiring palliative care about their views and experiences of managing a family member’s diabetes at the end of life and identify their needs to enable them to undertake diabetes care tasks. Data were collected during individual, semistructured interviews with 10 family members caring for a person with diabetes receiving palliative care. The 4 key themes identified were as follows: I didn’t know what to do; it’s a big responsibility; I need education; and it’s important to manage diabetes. Family members/carers feel anxious about their increasing responsibility when caring for their family member’s diabetes and need information and education to help them monitor and interpret blood glucose levels, manage high or low blood glucose levels, and administer glucose-lowering medicines safely and confidently. J Hosp Palliat Nurs 2015;17(4):293-300

Barriers to Chronic Pain Measurement: A Qualitative Study of Patient Perspectives
Robinson-Papp J, George M, Dorfman D, Simpson D

Preliminary evidence suggests that chronic pain patients complete pain intensity measures using idiosyncratic methods. Our objective was to understand these methods and how they might impact the psychometric properties of the instruments. DESIGN: A qualitative focus-group based study. SETTING: An academic center in New York City. SUBJECTS: Outpatients (n = 36) with chronic low back pain, or neuropathic pain due to diabetes or HIV. METHODS: Participants were divided into three focus groups based on their pain condition, and asked to discuss pain intensity measures (visual analog and numeric rating scales for average pain over 24 hours; Brief Pain Inventory; and McGill Pain Questionnaire). Audio-recordings were transcribed and analyzed using an inductive thematic method. RESULTS: We discovered four main themes, and five sub-themes: 1) doubt that pain can be accurately measured (subthemes: pain measurement is influenced by things other than pain, the numbers used to rate pain do not have an absolute meaning, and preference for pain intensity ratings "in the middle" of the scale); 2) confusion regarding the definition of pain; 3) what experiences to use as referents (subthemes: appropriate comparator experiences and the interpretation of the anchors of the scale); and 4) difficulty averaging pain. CONCLUSIONS: The themes discovered suggest that patients include sensations and experiences other than pain intensity in their ratings, experience the rating of pain as a comparative task, and do not use the scale in a linear manner. These themes are relevant to understanding the validity and scale properties of commonly used pain intensity measures. Pain Med 2015;16(7):1256-1264
New Pediatric Resource Helps Focus Attention on Children’s Unmet Needs
NHPCO, July 30, 2015

A new report released by the National Hospice and Palliative Care Organization provides insight into the care needs of young people who might benefit from pediatric palliative/hospice care. These are children with chronic, complex and/or life-limiting conditions. The 11-page report, “NHPCO Facts and Figures: Pediatric Palliative and Hospice Care in America,” can help hospice and palliative care providers—as well as policymakers, funders and the media—to better understand both the current challenges and the unmet needs of children and their families across the country. Pediatric palliative/hospice care provides children and their families with high quality, compassionate, and consistent care delivered through the collaborative efforts of an interdisciplinary team. PP/HC may be provided along with concurrent disease-modifying therapy and can transition to be the main focus of care when disease-modifying therapy is no longer effective and comfort becomes a priority. Due to the complexity of care involved, children with life-threatening conditions and complex chronic conditions are likely to benefit from PP/HC services. The U.S. Department of Health and Human Services reports that the number of children with special health care needs in increasing. Overall, 15.1 percent of U.S. children ages 0 – 17 (11.2 million children) are in this category.

Traditionally, three-quarters of pediatric deaths have been thought of as PP/HC appropriate. (Children aged 0 – 19 years accounted for 1.6 percent of all deaths in the U.S. in 2013.) However, as PP/HC services have grown, they are better able to provide short term services, including grief and bereavement support, to the cohort of patients and families affected by trauma or sudden serious illness or death. Payment and reimbursement for PP/HC care remains a complex issue. Passage of the Patient Protection and Affordable Care Act in 2010 carries great potential for positive change allowing for concurrent care for children. A recent survey of children’s hospitals in the U.S. found that 69 percent have a palliative care team. Nearly 30 percent of the programs offer home visit services. An early survey conducted by NHPCO found that 78 percent of responding member hospices reported that they serve pediatric patients and 36.6 percent have a formal pediatric program in place. The report was written by Sarah Friebert, MD, director of the Haslinger Family Pediatric Palliative Care Center at Akron Children’s Hospital, and Conrad Williams, MD, medical director, palliative care, Department of Pediatrics at Medical University of South Carolina. NHPCO is committed to improving access to hospice and palliative care for children and their families - both nationally and internationally. ChiPPS (Children’s Project on Palliative/Hospice Services) serves as NHPCO’s pediatric advisory council. Download the report and access additional resources on pediatric hospice and palliative care atwww.nhpco.org/pediatrics.

Caregiving for a Loved One With Dementia at the End of Life: An Emergent Theory of Rediscovering
Lewis L

Millions face the challenges of caregiving for a loved one with dementia. A classic Glaserian grounded theory methodology was used to discover the problem that caregivers of individuals with dementia face at the end of life and how they attempt to resolve that problem. Data were collected from a theoretical sample of 101 participants through in-person interviews, online interviews, book and blog memoirs of caregivers, and participant observation. Constant comparative method revealed a basic social psychological problem of role entrapment. Caregivers attempt to resolve this problem through a 5-stage basic social psychological process of rediscovering including missing the past, sacrificing self, yearning for escape, reclaiming identity, and finding joy. Health care professionals can support caregivers through this journey by validating, preparing caregivers for future stages, and encouraging natural coping strategies identified in this process. This study provides a substantive theory that may serve as a framework for future studies. *Am J Alzheimers Dis Other Demen* 2015;30(5):488-496

Melatonin for Sleep Disorders and Cognition in Dementia: A Meta-Analysis of Randomized Controlled Trials
Xu J, Wang L, Dammer E, Li C, et al

The current review aims to examine melatonin therapy for both sleep disturbances and cognitive function in dementia. We searched all randomized controlled trials published in Medline, Embase, the Cochrane Library, China National Knowledge Infrastructure, the Cochrane Dementia and Cognitive Improvement Group’s Specialized Register, and Clinical Trials.gov. The grading of recommendations assessment, development and evaluation framework was used to assess the quality of evidence. Seven studies were included (n = 520). Treated participants showed prolonged total sleep time (TST) by 24.36 minutes (P = .02). Sleep efficacy (SE) was marginally improved (P = .07). This effect was stronger under a longer intervention period lasting more than 4 weeks (P = .02). Conversely, cognitive function did not change significantly. Additionally, there was no report of severe adverse events. Given the current studies, we conclude that melatonin therapy may be effective in improving SE and prolonging TST in patients with dementia; however, there is no evidence that this improvement impacts cognitive function. *Am J Alzheimers Dis Other Demen* 2015;30(5):439-447

Time to Death and Reenrollment After Live Discharge From Hospice: A Retrospective Look
LeSage K, Borgert A, Rhee L

Background: The purpose of our study was to identify time to death and/or reenrolled patients alive at the time of hospice discharge. Methods: Medical records of all adults alive at hospice discharge during a 5-year period were retrospectively reviewed. Results: In all, 83 patients were alive at discharge, with 3 lost to follow-up. Average time from discharge to death was 199.9 days for all patients and 50 days for the 17 patients who reenrolled. Average time from discharge to reenrollment was 245 days. Conclusion: Our research supports past findings that over a third of patients disenrolled from hospice die within 6 months, indicating ongoing hospice eligibility up to the time of death. Interestingly, if enrollment was revoked by patient or family, as often was done to allow the patient to pursue more aggressive treatments, the mortality risk was higher in the 6 months after discharge. This should prompt careful reevaluation of disenrolled hospice patients in the months after disenrollment, and hospice reenrollment should be continually available and offered during this time. *Am J Hosp Palliat Med* 2015;32(5):563-567