Non-aspirin Nonsteroidal Anti-inflammatory Drugs (NSAIDs): Drug Safety Communication - FDA Strengthens Warning of Increased Chance of Heart Attack or Stroke
Food & Drug Administration, July 9, 2015

Patients and health care professionals should remain alert for heart-related side effects the entire time that NSAIDs are being taken. FDA is strengthening an existing label warning that non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs) increase the chance of a heart attack or stroke. Based on FDAs comprehensive review of new safety information, FDA is requiring updates to the drug labels of all prescription NSAIDs. As is the case with current prescription NSAID labels, the Drug Facts labels of over-the-counter (OTC) non-aspirin NSAIDs already contain information on heart attack and stroke risk. FDA will also request updates to the OTC non-aspirin NSAID Drug Facts labels. See the FDA Drug Safety Communication for a list of non-aspirin nonsteroidal anti-inflammatory drug products.

Full text of this FDA Drug Safety Communication is available at http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm454141.htm

Right to Try Act of 2015 – A Serious Challenge to FDA Control of Expanded Access?
FDA Law Blog, July 13, 2015

On July 9, 2015, Representatives Matt Salmon (R- AZ), Paul Gosar (R-AZ) and Marlin Stutzman (R-IN) introduced H.R. 3012, the Right to Try Act of 2015. The bill seeks to expand the access of terminally ill patients to experimental drugs in a novel way, by prohibiting the federal government, including FDA and DEA, from taking action to stop such access. The bill is short and straightforward. It simply states that, notwithstanding any law, including the Federal food, Drug, and Cosmetic Act, the federal government shall not take “any action to prohibit or restrict the production, manufacture, distribution, prescribing, dispensing, possession, or use of an experimental drug, biological product, or device that - (1) is intended to treat a patient who has been diagnosed with a terminal illness; and (2) is authorized by, and in accordance with, State law. An “experimental product” is defined as one that “has successfully completed a phase 1 clinical investigation,” remains under investigation in an FDA-approved clinical trial, and is not FDA “approved, licensed, or cleared.” The term “terminal illness” is defined as the meaning given to such term under relevant State law.

Excerpted from FDA Law Blog, full text available at: http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2015/07/

Move towards Full Use of Metric Dosing  
Institute for Safe Medication Practices

A fatal event was reported recently to the ISMP National Medication Errors Reporting Program in which a nurse confused two dosing scales that appear on a plastic oral liquid dosing cup. It has an archaic measure—drams (fluid drams)—which the nurse confused as mL. This particular dosing cup is commonly used in US healthcare facilities today. Many healthcare professionals are familiar with mixups that have occurred when measuring doses of liquid medicine using dosing cups, sometimes causing serious medication errors. To prevent mix-ups between variable measurement systems, multiple national organizations have called for the adoption of the metric system (milliliter) as the standard for prescribing and measuring doses of liquid medications. While progress is being made in hospitals in regards to prescribing liquids in mL, many hospitals still use dosing devices that have household measures (e.g., teaspoonful, dessertspoonful, tablespoonful) and, as above, even drams and ounces. This sets healthcare professionals up to fail because the dosage scales on embossed cups are difficult to read, have dangerous abbreviations that are easily confused (e.g., TBS and TSP), and measures that are no longer used (e.g., drams). National Alert Network  June 30, 2015  
Full text of this article freely available at  http://www.ismp.org/NAN/files/NAN-20150630.pdf

Prevalence and Factors Associated with Polypharmacy in Long-Term Care Facilities: A Systematic Review  
Jokanovic N, Tan E, Dooley M, Kirkpatrick C, Bell J

The objective of the study was to investigate the prevalence of, and factors associated with, polypharmacy in long-term care facilities (LTCFs). Methods: MEDLINE, EMBASE, International Pharmaceutical Abstracts, Cumulative Index to Nursing and Allied Health Literature, and the Cochrane Library were searched from January 2000 to September 2014. Primary research studies in English were eligible for inclusion if they fulfilled the following criteria: (1) polypharmacy was quantitatively defined, (2) the prevalence of polypharmacy was reported or could be extracted from tables or figures, and (3) the study was conducted in a LTCF. Methodological quality was assessed using an adapted version of the Joanna Briggs Institute Critical Appraisal Checklist. Results: Forty-four studies met the inclusion criteria and were included. Polypharmacy was most often defined as 5 or more (n=11 studies), 9 (n=13), or 10 (n=11) medications. Prevalence varied widely between studies, with up to 91%, 74%, and 65% of residents taking more than 5, 9, and 10 medications, respectively. Seven studies performed multivariate analyses for factors associated with polypharmacy. Positive associations were found for recent hospital discharge (n=2 studies), number of prescribers (n=2), and comorbidity including circulatory diseases (n=3), endocrine and metabolic disorders (n=3), and neurological motor dysfunctioning (n=3). Older age (n=5), cognitive impairment (n=3), disability in activities of daily living (n=3), and length of stay in the LTCF (n=3) were inversely associated with polypharmacy. Conclusions: The prevalence of polypharmacy in LTCFs is high, varying widely between facilities, geographical locations and the definitions used. Greater use of multivariate analysis to investigate factors associated with polypharmacy across a range of settings is required. Longitudinal research is needed to explore how polypharmacy has evolved over time. J Am Med Direct Assoc 2015;16(6):535e1-535e12
Reducing Antipsychotic Medications: A Systematic Process
Martin CM

In 2012, the Centers for Medicare & Medicaid Services began initiatives aimed at reducing the use of antipsychotic medications for behaviors related to dementia. These initiatives are based both on the high risk of serious side effects from these medications as well as a lack of documented efficacy for their use in controlling behaviors related to dementia. This article offers examples of systematic processes at both the corporate and individual practitioner/individual facility level to reduce these medications and more appropriately manage behaviors related to dementia. Consult Pharm 2015;20(7):378-384

Rationales that Providers and Family Members Cited for Use of Antipsychotic Medications in Nursing Home Residents with Dementia

Objectives: To describe the rationales that providers and family members cite for the use of antipsychotic medications in people with dementia living in nursing homes (NHs). Design: Qualitative, descriptive study. Setting: Twenty-six medium-sized and large facilities in five Centers for Medicare and Medicaid Services regions. Participants: Individuals diagnosed with dementia who received an antipsychotic medication. Measurements: Data were collected from medical record abstraction and interviews with prescribers, administrators, direct care providers, and family members. Textual data from medical record abstraction and responses to open-ended interview questions were analyzed using directed content analysis techniques. A coding scheme was developed, and coded reasons for antipsychotic prescribing were summarized across all sources. Results: Major categories of reasons for use of antipsychotic medications in the 204 NH residents in the study sample were behavioral (n = 171), psychiatric (n = 159), emotional states (n = 105), and cognitive diagnoses or symptoms (n = 114). The most common behavioral reasons identified were verbal (n = 91) and physical (n = 85) aggression. For the psychiatric category, psychosis (n = 95) was most frequently described. Anger (n = 93) and sadness (n = 20) were the most common emotional states cited. Conclusion: The rationale for use of antipsychotic drug therapy frequently relates to a wide variety of indications for which these drugs are not approved and for which evidence of efficacy is lacking. These findings have implications for clinical practice and policy. J Am Geriatr Soc 2015;63(2):302-308

Management of Radiation Therapy-Induced Skin Reactions
Trueman E

Radiotherapy is a highly effective cancer treatment that not only offers cure but also excellent palliation of disease related symptoms and complications. Although radiotherapy is primarily an outpatient treatment, delivered within specialist centres, a diverse range of health professionals may be involved in the treatment pathway before, during and after treatment. Radiotherapy can, and does, make a significant contribution to improving a patient’s wellbeing through effective symptom management. However, treatment-related side-effects do occur, with an acute skin reaction being one of the most common. It is imperative that radiotherapy-induced skin reactions are correctly assessed and appropriately managed in promoting patient comfort, treatment compliance and enhanced quality of life. This article describes how the use of a recognised assessment tool and evidence-based guidelines can facilitate consistent, high-quality care in the management of radiotherapy-induced skin reactions. Int J Palliat Nurs 2015;21(4):187-192
Heart Failure Prognosis: Comorbidities Matter
Kheirbek R, Farrokh A, Ross F

Prior risk prediction models have included a selective group of broad comorbidities in scoring prognosis of heart failure (HF) patients. Objective: We examined whether scoring a comprehensive set of comorbidities separately, could improve the performance and accuracy of predicting HF prognosis. Methods: This is a cross-validated, longitudinal, retrospective, observational study. Data were collected on 602,050 unique HF patients, who received care through the Veterans Administration (VA) between October 1, 2006 and September 30, 2011. The dependent variable was mortality in six months. The independent variables were all International Classification of Disease (ICD) comorbidities, without grouping into broad disease categories. Results: The area under the receiver–operating curve (AROC) for the multimorbidity (MM) index was 0.784 (95% confidence interval [CI]: 0.781–0.786). The MM index was significantly (alpha <0.05) more accurate than the Quan variant of the Charlson Index (AROC=0.656), the comorbidity categories within the Care Assessment of Need (CAN) Index (AROC=0.677), the von Walraven variant of the Elixhauser Index (AROC=0.639), chronological age (AROC=0.649), or ejection fraction (EF) (AROC=0.533). Conclusion: Inclusion of additional comorbidities improves the accuracy of HF prognostic indices. Future studies are needed to drive HF prognostic indices with the MM index as a component. J Palliat Med 2015;18(5):447-452

Decisional Dilemmas in Discontinuing Prolonged Disease-Modifying Treatment for Multiple Sclerosis
Butler M, Forte M, Schwehr N, Carpenter A, Kane R

Objective: We conducted a systematic review to examine the long-term consequences of discontinuing disease-modifying treatment (DMT) for multiple sclerosis (MS) by examining the long-term benefits and harms, and the reasons for discontinuing treatment. We also examined the evidence for people’s values, beliefs, and preferences regarding discontinuing DMT. Data sources: We searched Medline®, PsycInfo®, Scopus, and the Cochrane Clinical Trials Registry through August 2014 plus reference lists of included studies and recent systematic reviews. Methods: Two investigators screened abstracts and full texts of identified references for eligibility. Eligible studies included studies of over 3 years that examined Food and Drug Administration–approved DMTs compared with placebo, other active DMT, or no DMT for adults with clinically isolated syndrome or MS in outpatient settings for patient-centered outcomes. We excluded studies of mitoxantrone, since it has a maximum lifetime dosage. Timing was relaxed for women who were considering pregnancy or already pregnant or patients discontinuing natalizumab due to risk factor changes. We extracted data, assessed risk of bias of individual studies, and evaluated strength of the body of evidence for each comparison and outcome. We also evaluated, using Technical Brief methods, studies of any design that examined individuals’ attitudes, values, and preferences for discontinuing treatments and health states, or factors and processes patients with MS and clinicians use in shared decision-making. Results: We identified 27 unique studies with discontinuation information: 16 of these contained complete information to allow full analysis of long-term benefits and harms. Evidence was insufficient for long-term benefits of DMTs for secondary progressive MS patients and most outcomes for relapsing-remitting MS (RRMS) patients. Low-strength evidence suggests higher long-term all-cause survival for treatment-naïve RRMS patients who did not delay starting interferon beta-1b by 2 years and used DMTs for a longer duration than for those who started later. Low-strength evidence suggests that interferon did not change RRMS patients' disability progression. Limited low-strength evidence suggests that long-term harms do not differ from short-term harms. The majority of discontinuation tends to occur within 2 to 3 years. Another 25 unique studies provided intrapersonal, interpersonal, and shared decision-making information. No study directly asked why people may be reluctant to discontinue when treatment no longer seems effective; taken as a whole, the literature set provides some insight. The preferences literature underscores the complexity of the topic and the processes underlying decision-making. Conclusions: MS patients and providers have little information to guide decisions to discontinue DMT. AHRQ Comparative Effectiveness Reviews no. 150; 15-EHC012-EF; April 2015.

Full text of the AHRQ report is freely available at http://www.ncbi.nlm.nih.gov/books/NBK294204/