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SPECIAL DRUG SHORTAGE EDITION

Management and Communication of Drug Shortage Information Survey

Elizabeth Wade, PharmD, BCPS; Kanizeh Visram, PharmD Candidate

Introduction

Many health-systems are struggling to keep up with drug shortages. MSHP recognizes the importance of health-systems' developing strategies and methods to manage the drug shortage process while minimizing unintended consequences for safe patient care. On June 4, 2011, MSHP held a Drug Shortages Summit to discuss these strategies with hospitals and health-systems from across the state. The summit participants also completed a survey, for which the purpose was to determine how health-systems are managing drug shortages in terms of resource utilization and communication strategies. The purpose of this survey is to determine how health-systems are using technology and automation to help manage drug shortages.

Executive Summary

The drug shortage environment has created an urgency to communicate important information to a multi-disciplinary group. Furthermore, Departments of Pharmacy must utilize many resources to gather, plan, and disseminate critical information to frontline healthcare professionals in a relatively short time period. There are inherent communication challenges to send information effectively both within the pharmacy department and externally to providers and nursing. Furthermore, the communication process has created challenges with medication safety efforts.

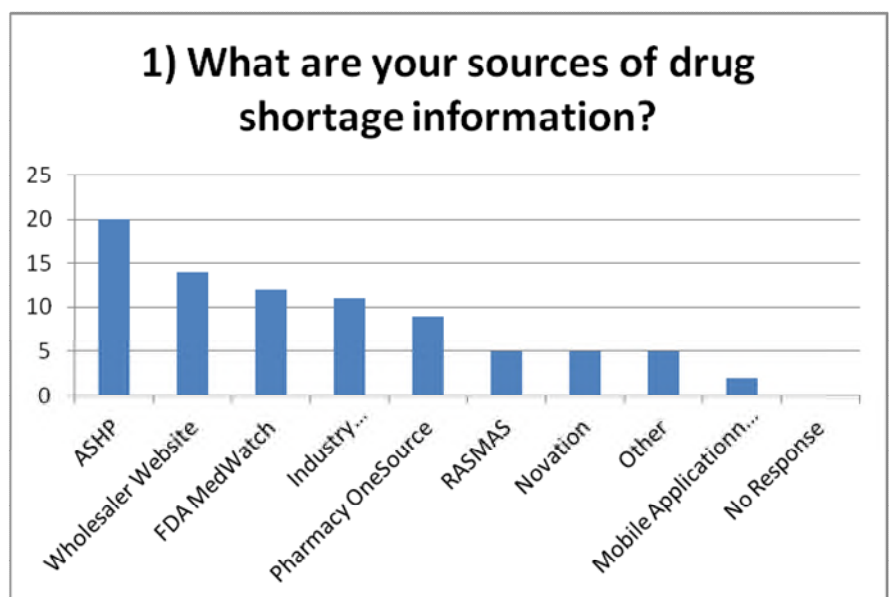
The survey is focused on how departments of pharmacy are managing communication strategies and action plans in this volatile landscape of drug shortages. The objective of this survey is to examine what technological tools are being used both for the management and communication of drug shortage information. The survey was distributed to institutions both with computerized provider order entry (CPOE) and non-CPOE environments and there were a total of 24 respondents. Most survey respondents stated that their hospital is dedicating between 11-30 hours per week total to manage drug shortages. Sixteen respondents indicated that they know of at least one adverse event occurring as a result of a drug shortage. Overall, the management of drug shortages is a time-consuming process that encompasses many different areas of expertise.

Survey Question Results

There were 24 Maryland health-system respondents to the eight-question survey. The survey was anonymous. The number of different health-systems that responded was not obtained.

Question #1 What are your sources of drug shortage information?

Obtaining fast accurate information on drug shortages is paramount for an institution to develop a strategy to address drug shortages. When asked about resources used for finding drug shortage information, most health-systems responded that they utilize the American Society of Health-System Pharmacists (ASHP) web site (20), wholesaler websites (14), and FDA MedWatch web site (12) to receive information [Figure 1].



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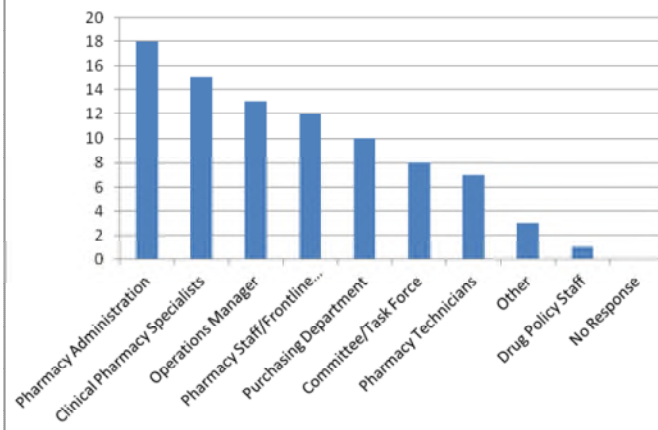
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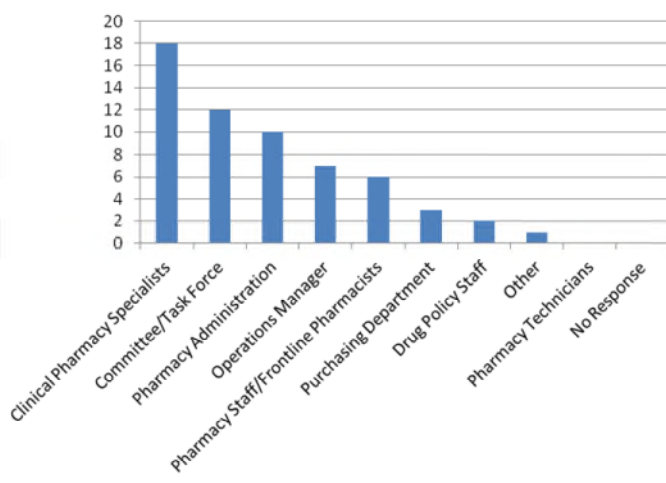
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Question #2 Who is responsible for managing drug shortages? After the issue has been identified institutions it takes a multidisiplinary approach to develop the strategy and communicate the action. The responses identified the pharmacy administration, clinical pharmacy specialists, operations managers and pharmacy staff/frontline pharmacists as the vital personnel responsible for managing drug shortages in their respective health care settings [Figure 2].

2) Who is responsible for managing drug shortages?



3) Who is responsible for determining alternative therapies?



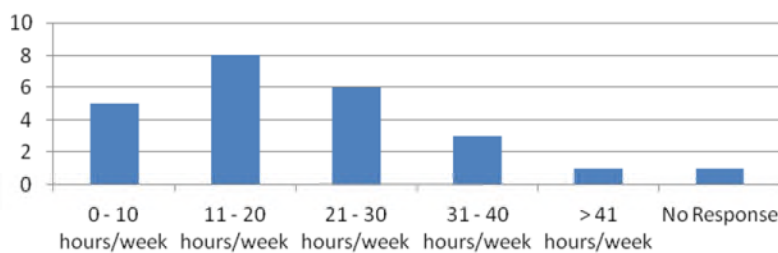
Question # 3 Who is responsible for determining alternative therapies?

When it came down to determining the actual alternative therapy, use of clinically pharmacy specialists was the greatest (18), followed by a committee or a task force (12), and pharmacy administration (10). Operations managers (7) and front-line pharmacists (6) may also be involved.

Question # 4: What is the estimated total time among all pharmacy employees (hours/week) that is needed to manage drug?

It was interesting to note that only one of the health systems participating in the survey utilizes an average estimated total time of greater than 41 hours which equals about one full time employee in managing the drug shortage challenges. Most respondents cited that their health-system spends an average of 11-20 hours per week (8) or 21-30 hours per week (6) managing drug shortage issues [Figure 4].

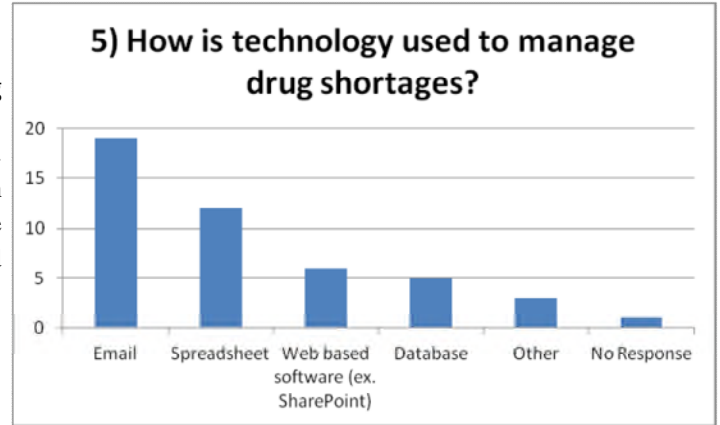
4) What is the average estimated total time (hours/week) that is needed to manage drug shortages among all employees?



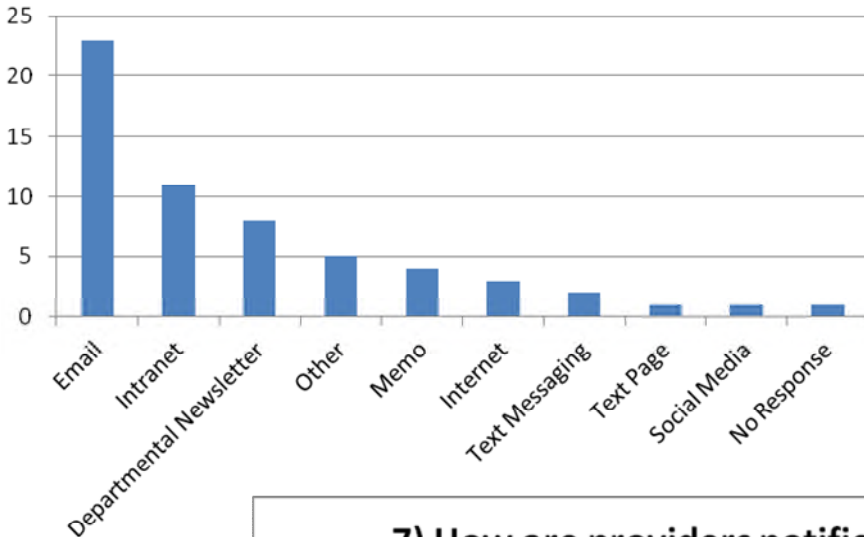
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Question #5: What technology is used to manage drug shortages?

Institutions utilize technology to effectively manage shortages. Most participants listed email (19) as their main communication strategy for managing drug shortages [Figure 5], and twelve respondents indicated that a spreadsheet was currently being used as a management tool.



6) How do you communicate with providers of drug shortages in non-CPOE environments?

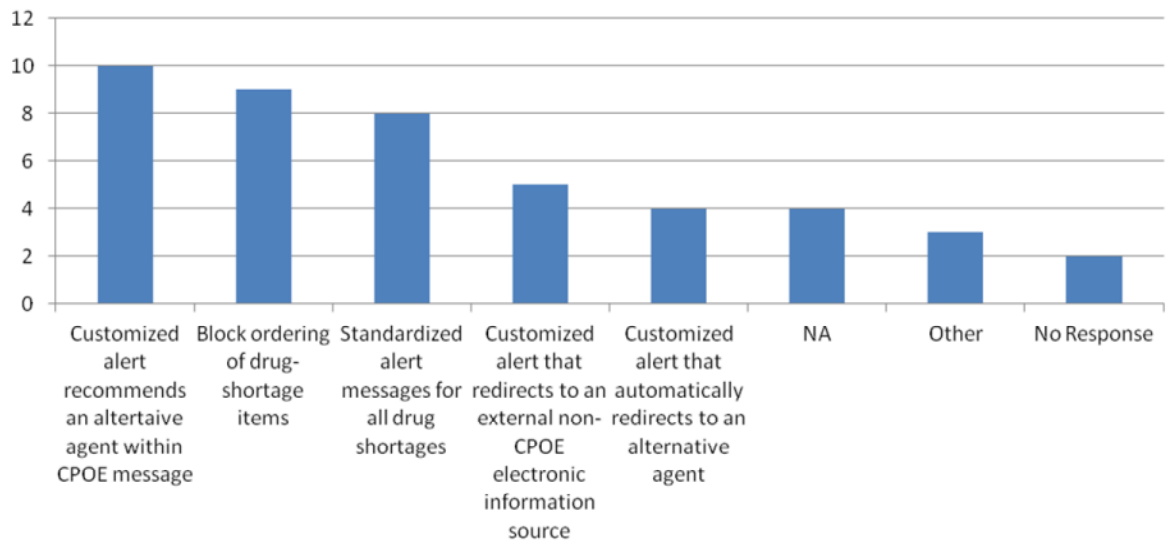


Questions 6 and 7:

Computerized provider order entry (CPOE) provides additional mechanisms to communicate drug shortages. The vast majority of respondents indicated that their main method of communication with providers regarding drug shortages in non-CPOE environments was email (23) [Figure 6].

For respondents who work in CPOE environments, many (10) indicated that they are using customized alerts that recommend an alternative agent, block the ordering of the drug that is on shortage (9), or have a standardized alert message for all drugs on shortage (8) [Figure 7].

7) How are providers notified in CPOE environments?

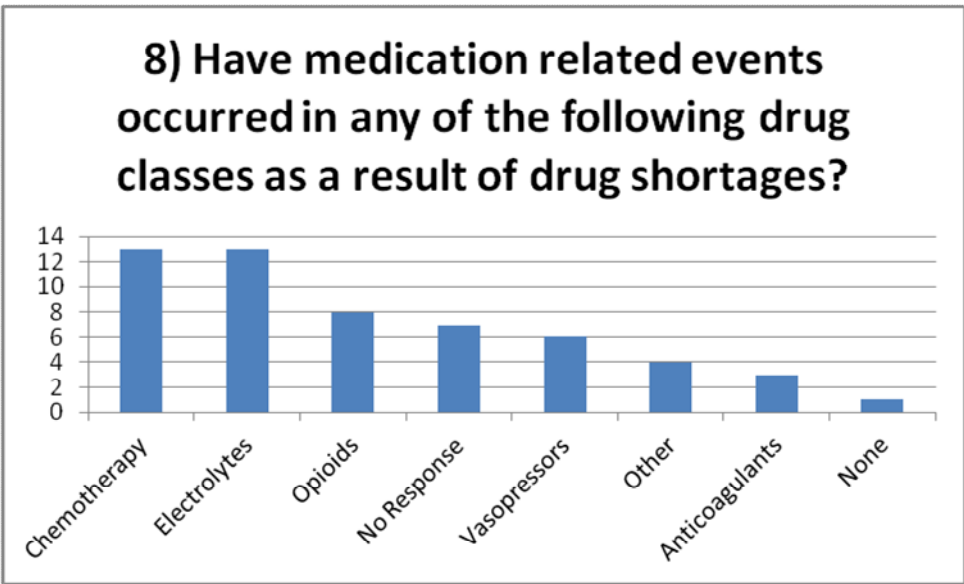


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Question # 8: Have medication-related adverse events occurred in any of the following drug classes as a result of drug shortages?

Our survey also reported that most of the voluntarily reported medication-related events have occurred with chemotherapy drugs and electrolytes as a consequence of drug shortages [Figure 8]. Sixteen respondents indicated that they know of at least one adverse event occurring as a result of a drug shortage.

Some of the medication related events reported as a result of drug shortages include incorrect conversion of electrolytes, dosing errors with opioid drugs leading to overdose, and delayed treatment with chemotherapy agents.



Conclusion

Drug shortages remain to be a common challenge across all the institutions surveyed. Most commonly, Departments of Pharmacy are utilizing multiple departmental resources to manage shortages and devise an action plan. Moreover, hospitals have to divert their existing resources to continuously attend to the national crises. This has led to various medications safety events in multiple drug classes and has been a threat to patient safety. Hospitals across the country are using multiple technological solutions which are primarily email and the intranet for non-CPOE environments and customized alerting in hospitals with CPOE. Effective

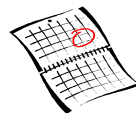
communication both within the Departments of Pharmacy and externally to providers continues to remain a key challenge in the climate of increasing drug shortages.

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Participant evaluation forms will now request your e-profile number as well as the month and date of your birth in order to begin filing participant information electronically sometime next year.

If you have not yet registered for your NABP e-profile number go to www.mycpemonitor.net to register or contact customer service at NABP by phone at 1-847-391-4406.



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Saturday, November 12, 2011

Conference Center at the Maritime Institute

Preliminary Programming & Schedule



TIME IS SHORT!!!
REGISTER TODAY

7:00 am - 8:25 am

Registration, Continental Breakfast & Exhibitor Visits

7:00 - 8:15 am - Directors of Pharmacy Leadership Breakfast

8:30 am -9:20 am

Optimizing Bone Health in Cancer Patients

Jane M Pruemer, PharmD, BCOP, FASHP, Professor
James L. Winkle College of Pharmacy
University of Cincinnati

9:30 am-10:30 am

The Pharmacist's Role in the Prevention & Treatment of Breast Cancer

James Trovato, PharmD, MBA, BCOP
Associate Professor, University of Maryland School of Pharmacy

10:30 am - 11:00 am Break with Corporate Sponsors

11:00—12:00 noon

Health Care Reform

David Chen, RPh, MBA, Director of Pharmacy
Practice Sections, ASHP

12:00 - 1:30 pm

Luncheon, Fall Awards Presentation, Installation of 2012 MSHP Board & Officers

1:30 - 2:30 pm

New Antibiotics: In Short Supply and Fewer to Come

Edina Avdic, Pharm.D., MBA, BCPS, AQ-ID,
Clinical Specialist, The Johns Hopkins Hospital

2:30 - 3:30 pm

Keep Young and Beautiful: HIV and Women 2011

Beulah Perdue Sabundayo, PharmD

3:30 - 4:30 pm

Drug Dependency & Recovery

A First Hand Account

TECHNICIAN TRACK

Too Many to Count: Herbal Drug Interactions with Warfarin

Kathryn Kiser, PharmD
Assistant Professor,

University of Maryland School of Pharmacy

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9:30 am-10:30 am

Cervical Cancer Update

Katharine McGrath Kinsman, PharmD
The Johns Hopkins Hospital

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Statin Use in HIV patients for Treatment of Dyslipidemias

Brendon McQuighan

Due to recent advances in antiretroviral therapy and more knowledge of HIV, people infected with the virus are living longer. The treatment of non-HIV medical conditions is becoming more important in this population. HIV infected patients commonly have metabolic abnormalities such as dyslipidemia^{1,2}. Dyslipidemia appears to occur in a higher rate in HIV patients than then general population². HIV is associated with dyslipidemia even without treatment with antiretroviral drug therapy. The exact mechanism of how HIV and antiretroviral therapy cause dyslipidemia is not known. Dyslipidemia seems to be more common and more severe in patients receiving antiretroviral therapy than patients who are not receiving treatment².

Studies have not yet proven that HIV patients have an increased risk of cardiovascular events. However, there is no evidence to suggest that HIV patients are not susceptible to the increased CV risk associated with dyslipidemia in the general population². A study on the adverse events of anti-HIV drugs showed that HIV patients have a relative risk of MI that increased 26% per year².

Just as within the general population, prevention is key. More frequent screenings for dyslipidemia and other cardiovascular risk factors should be implemented in HIV patients. Treatment in these patients regardless of age should be started just as it would in the general population. Current guidelines for treating dyslipidemias in HIV patients include statins as the first line treatment for patients with elevated LDL-C or non-HDL cholesterol with TGs <500mg/dL². If the primary risk factor is elevated triglycerides, treatment with fibrates is recommended². Adjusting the anti-retroviral drug regimen can be considered, but is might not be an option due to the limited number of therapies available².

Patients using antiretroviral drugs are at a increased risk for drug interactions. Many HIV drugs and common statins are metabolized by the CYP3A4 enzyme. These interactions can cause increased drug levels that can increase the risk of toxicity. Pravastatin is not metabolized by CYP3A4 and is generally regarded as safe for use¹. Rosuvastatin is also not metabolized by the CYP3A4 enzyme but its use has been limited in HIV patients. When the guidelines for statin use in HIV patients were written by the HIV Medical Association of the Infectious Disease Society of America and the AIDS Clinical Trials Group were written, rosuvastatin was not yet approved by the FDA so it was not included¹.

In order to provide better care to patients with HIV-associated dyslipidemias, the *Comparative Effectiveness and Toxicity of Statins Among HIV Infected Patients* trial was completed. This study evaluated two of the most potent statins, atorvastatin and rosuvastatin, along with pravastatin to determine differences in safety and efficacy in the HIV population. The study included 700 patients over the age of 18 with HIV who started statins between January 1, 2000 and March 1, 2008. The mean age of

patients was 43 years and 86% were men¹. Dosing guidelines were not set by the researchers so various statin does were used. The three most common statins were atorvastatin (43%), pravastatin (40%), and rosuvastatin (14%). Median doses were 20 mg for atorvastatin, 40 mg for pravastatin, and 10 mg for rosuvastatin¹.

Lipid levels including LDL-C, HDL-C, triglycerides, non-HDL-C and total cholesterol were measured over the follow up period. These values were measured as part of regular clinical care. Baseline antiretroviral medications by class were also studied¹.

After 24 months, the mean total cholesterol, LDL-C, and triglyceride levels were lower than baseline values. HDL-C levels did not change significantly over time. Patients treated with atorvastatin vs. pravastatin had a greater decrease in total cholesterol, LDL-C, and non-HDL-C levels. Patients treated with rosuvastatin had a greater decline in total cholesterol, LDL-C, triglyceride, and non-HDL-C levels after 12 months.

Percent Change From Baseline Cholesterol Levels ¹					
Statin	TC	LDL	TRIG	non-HDL	HDL
Pravastatin	10.4	8.6	6.8	13.2	-2.8
Atorvastatin	16.2	18.7	17.0	19.8	-1.5
Rosuvastatin	17.8	16.5	23.6	23.9	+1.5

HIV infected patients who received rosuvastatin or atorvastatin had greater declines in total cholesterol, LDL-C, triglyceride, and non-HDL-C values than patients who received pravastatin. Patients receiving rosuvastatin were most likely to reach non-HDL-C goals, and patients receiving either rosuvastatin or atorvastatin were most likely to reach LDL-C goal levels. These results are important because they may differ from the results found in the general population due to differing dyslipidemia patterns, treatment response, and drug interactions in the HIV population versus the general population¹.

Toxicity was separated into two groups, potentially serious, and symptomatic. Potentially serious toxicity included patients who discontinued therapy because of CPK levels, creatinine, or liver enzymes doubled. Toxicity was considered symptomatic if patients discontinued the medication because of myalgias, GI symptoms, fatigue, or for discontinuations without known lab values¹.

FDA Approves Fingolimod (Gilenya®), First Oral Medication to Reduce Multiple Sclerosis Relapses

Liana Mark, Pharm.D., PGY-1 Pharmacy Practice Resident, The Johns Hopkins Hospital

In September 2010, the FDA announced the approval of fingolimod (Gilenya®), the first oral agent proven to delay disability progression and reduce the frequency and severity of symptoms in relapsing multiple sclerosis (MS).¹ Approval of this agent offers an alternative to currently available injectable therapies.

Multiple sclerosis is an autoimmune, inflammatory disease of the central nervous system (CNS) in which nerves are demyelinated and subsequently scarred, or sclerosed. Damage to the myelin sheath and/or nerve fiber distorts or interrupts nerve impulses traveling to and from the brain and spinal cord, resulting in symptoms that include fatigue, gait and balance disturbances, bladder and bowel dysfunction, vision irregularities, and spasticity. Inter-individual symptoms vary widely, based on the affected nerve and extent of sustained nerve damage.² Onset of MS is typically between the ages of 20 to 40 years old and affects females more frequently than males.³

Fingolimod is the first in a new class of drugs, sphingosine-1-phosphate receptor modulators, that inhibits the exit of lymphocytes from lymph nodes. This inhibition leads to a reduction in circulating lymphocytes available to mount an autoimmune reaction to the myelin sheath surrounding axons.^{4,5} FDA approval was based on the results of two trials, the FTY720 Research Evaluating Effects of Daily Oral therapy in Multiple Sclerosis (FREEDOMS) trial and the TRial Assessing injectable interferon vS FTY720 Oral in RrMS (TRANSFORMS).^{5,6} Both studies showed benefit with the use fingolimod in reducing relapse rates and new or enlarging lesions on MRI imaging when compared to placebo and to interferon beta, respectively.

The FREEDOMS trial was a 24-month, double-blind, randomized study in 1033 patients with relapsing-remitting multiple sclerosis. The investigators compared fingolimod doses of 0.5 mg and 1.25 mg to placebo, with a primary endpoint of annualized relapse rate and a secondary endpoint of time to disability progression. The FREEDOMS group found that both doses of fingolimod significantly reduced the risk of disability progression over the 24-month study period (HR 0.70 and 0.68, respectively; $P = 0.02$ vs. placebo). The authors also reported a reduction in the cumulative probability of disability progression with fingolimod compared to placebo.⁵

The TRANSFORMS trial was a 12-month, double-blind, double-dummy, study in 1153 patients with relapsing-remitting multiple sclerosis. The investigators compared fingolimod doses of 0.5 mg and 1.25 mg to intramuscular interferon beta-1a 30 mcg weekly, an established therapy for multiple sclerosis. The primary endpoint for this trial was annualized relapse rate; secondary endpoints included number of new or enlarged lesions on MRI scans at 12 months and progression of disability that was sustained for at least three months. The TRANSFORMS Study Group found a significantly lower annualized relapse rate in both groups receiving fingolimod: 0.20 (95% CI, 0.16 to 0.26) and 0.16 (95% CI, 0.12 to 0.21) in the 1.25 mg and 0.5 mg groups, respectively, as

compared to the interferon group (0.33; 95% CI, 0.26 to 0.42). MRI findings supported these results; however, no differences were seen among the study groups with respect to disability progression.⁶

Based on the FREEDOMS and TRANSFORMS trials, the approved dosing for fingolimod is 0.5 mg orally once daily, the lower of two doses investigated in these phase 3 trials. Patients receiving fingolimod should be monitored for bradycardia for 6 hours after the first dose is administered; treatment is also associated with increased infection risk. Macular edema has also been reported, and ophthalmologic evaluation is recommended prior to therapy initiation. The most frequent adverse effects reported in clinical trials include headache, influenza, diarrhea, back pain, elevation of liver enzymes, and cough.⁵⁻⁷

Fingolimod has been approved with a Risk Evaluation and Mitigation Strategy (REMS), which includes a medication guide for patients and a letter and safety information guide for healthcare providers. The estimated yearly cost of fingolimod for an individual patient is \$48,000, placing it among the most expensive multiple sclerosis agents available on the market. Other oral MS treatments in development include laquinimod (Teva), teriflunomide (Sanofi-Aventis), and BG-12 (Biogen).^{7,8}

References

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PPIs and Increased Fracture Risk

Natalie Yeakle, PharmD Candidate
Shenandoah University

The FDA has made a decision to revise the “Warnings and Precautions” section of prescription labeling as well as the OTC “Drug Facts” label for proton pump inhibitors. This decision was made based on the FDA’s review of the findings from seven published epidemiological studies in which claims data from computerized administrative databases was used to evaluate fracture risk in patients treated with PPIs compared to those who were not using PPIs. Those found to be at greatest risk were individuals receiving high doses of PPIs or used them for ≥ 1 year. The majority of the studies evaluated individuals ≥ 50 years old and the increased risk was primarily observed in this age group.

While the mechanism for this increased risk of fracture with PPI use is not completely understood, the most widely accepted explanation involves a decrease in calcium absorption. Calcium solubility is a prerequisite to calcium absorption, and the solutions of calcium salts are highly dependent on an acid PH (2). PPIs as a general class inhibit the production and intragastric secretion of hydrochloric acid, which is believed to be an important mediator of calcium absorption in the small intestine (3). Although there have been multiple studies that have made this issue a focal point, questions still remain regarding the potential risk associated with long term PPI use and fracture risk. Based on the accumulation of evidence, it is prudent for clinicians to periodically reevaluate the need for long-term PPI therapy. For those older adults who do require long-term PPI therapy, it is reasonable to focus on using the lowest effective dose, ensuring adequate dietary calcium intake and adding calcium supplements when necessary (4). As a possible preventative measure, when choosing an appropriate oral calcium supplement, **calcium citrate should be recommended for individuals treated with PPIs**, as it does not require an acidic environment to be dissolved and therefore absorbed (5).

References:

1. US Department of Health and Human Services. FDA Drug Safety Communication: possible increased risk of fractures of the hip, wrist, and spine with the use of proton pump inhibitors. (<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm213206.htm>). Written 25 May 2010. Accessed 29 June 2010.
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Statin Use

(Continued from page 6)

This study found that none of the 28 patients that were started on rosuvastatin with a ritonavir-boosted PI had any signs of toxicity. Rosuvastatin also has no proven interactions with NNRTI-based therapy and has greater effectiveness than other statins. It was also found that rosuvastatin and atorvastatin were more effective at lowering lipid levels than pravastatin, and did not have significantly higher incidences of toxicity¹.

Current guidelines for treatment of dyslipidemias in HIV patients do not include rosuvastatin. Pravastatin has been generally used more often due to its perceived lower risk of drug interactions.

More recent European guidelines have included rosuvastatin with a low initial dose in their recommendations¹. This potent statin could be a more effective medication for use in HIV patients. The efficacy of pravastatin was shown to be inferior to both atorvastatin and rosuvastatin in this trial¹. Rosuvastatin was actually found to have a lower discontinuation rate due to toxicity than pravastatin (5.3% vs. 6.1%)¹. Although more research on rosuvastatin in HIV patients is necessary, this trial shows that its use could be considered.

References:

1. Singh, S et. Al, Comparative Effectiveness and Toxicity of Statins Among HIV-Infected Patients. *Clinical Infectious Diseases* 2011;52(3):387-395.
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Affordable Care Act Program to Help Healthcare Professionals Improve Care for Patients

The Centers for Medicare & Medicaid Services announced that they are accepting applications for a new Innovation Advisors Program to help health professionals with the skills to improve patient care and reduce costs.

Crucial to the efforts of transforming the healthcare system is supporting individuals who can test and refine new models to drive delivery system reform. The Innovation Center seeks to deepen the capacity for transformation by creating a network of experts in improving the delivery system for Medicare, Medicaid and CHIP beneficiaries.

The Innovation Advisors Program will select and develop as many as 200 individuals from across the nation in its first year. The first group of Innovation Advisors will start their six-month intensive orientation and applied research period in December 2011.

The deadline to submit applications is November 15, 2011. For additional information and application instructions go to: <http://www.orise.orau.gov/IAP/index.html>.