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Illinois Department of Financial and Professional Regulation Pharmacy Newsletter

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A Message From Secretary Schneider

Greetings,

Welcome to the May issue of the *Illinois Department of Financial and Professional Regulation Pharmacy Newsletter.*

During the past months, the Illinois Department of Financial and Professional Regulation (IDFPR) has been implementing different phases of its paperless licensing and renewal initiative. The move to paperless technology is part of the IDFPR's ongoing efforts to modernize and save the State nearly $3 million in postage, paper, and printing costs over the next five years.

The most recent phase of the paperless licensing and renewal initiative has been the creation of an electronic license that licensees can view and print at any time, free of charge. The IDFPR recently enhanced the process for retrieving electronic licenses at *www.idfpr.com/GetMyLicense.*

If you have not done so already, I encourage you to visit the new web address above and view, download, and print your licenses. The pharmacy-related licenses were some of the first professions to be a part of the IDFPR's paperless licensing and renewal initiative. The electronic license functionality is also mobile device-friendly and can be accessed on smartphones and tablets. The IDFPR recognizes that many of its licensees are often on the go and may need access to their licenses from their mobile devices. Thank you all for being a part of this exciting new process.

Very truly yours,

Bryan A. Schneider
Secretary, IDFPR
bryan.schneider@illinois.gov, 312/793-3676

Upcoming Board Meetings

The IDFPR, Division of Professional Regulation – State Board of Pharmacy is scheduled to meet:

- May 10, 2016 – Chicago, IL
- July 12, 2016 – Chicago
- September 13, 2016 – Chicago
- November 15, 2016 – Chicago
- January 10, 2017 – Chicago
- March 14, 2017 – Springfield, IL
- May 9, 2017 – Chicago

Chicago location: 100 W Randolph St, 9th Floor
Springfield location: 320 W Washington St

Pharmacists Assisting in Reducing Negative Outcomes of Opioid Overdose in Illinois

By Garth K. Reynolds, RPh, IPhA Executive Director, and Jess Kerr, PharmD, Assistant Chair and Associate Professor, SIUE School of Pharmacy, Department of Pharmacy Practice

According to the Centers for Disease Control and Prevention, the number of opioid overdoses in the State of Illinois is increasing. Prescription pain relievers and heroin are the primary cause for these increasing rates. In 2014, the State of Illinois had an overall 8.3% increase rate of opioid overdose compared to 2013, according to data from the National Vital Statistics System. Within our local communities we are also seeing alarming reports of patients who have died from opioid overdose. It is known that the number of opioid prescriptions dispensed in a given year continues to increase without necessarily an increase in pain control. Dr Chris Herndon of Southern Illinois University Edwardsville (SIUE), who sees this firsthand in his practice, states:

> Often times, chronic pain is multifactorial. Rehabilitation involves much more than medications. Unfortunately, financial barriers to a comprehensive treatment approach are often out of reach for many patients. This leads to over-reliance on medications as the only modality being used, and predictably, inadequate pain relief is the result. Patients suffering with severe pain may take prescribed medications inappropriately, take medications prescribed to someone else, or most concerning, take illicit street drugs in which little is known about what is actually being consumed.

This concern is what prompted the development of Public Act (PA) 099-0480, which was enacted in September 2015.

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FDA Approves Naloxone Nasal Spray to Prevent Opioid Overdose Deaths

Food and Drug Administration (FDA) has approved Narcan® Nasal Spray (also known as naloxone), a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan Nasal Spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, which can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan Nasal Spray should seek further immediate medical attention on the patient's behalf. The use of Narcan Nasal Spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan Nasal Spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm.*

Selected Medication Safety Risks to Manage in 2016

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

It is a nearly impossible task to list all the risks associated with medication use that could lead to harmful medication errors. So where do health care professionals start to improve medication safety? Most people frequently resort to playing "whack-a-mole," addressing risks only after they pop up and become visible after an adverse event.

Listed below are two serious medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. Additional serious risks will be published in future issues of the National Association of Boards of Pharmacy® *National Pharmacy Compliance News.*

Patient Information – Placing Orders on the Wrong Patient's Electronic Health Record

A potentially hidden vulnerability that can lead to serious errors is placing orders on the wrong patient's electronic health record. A recent study published in the *Journal of the American Medical Informatics Association* identified and quantified close calls that would have resulted in wrong-patient errors. According to this study, about 14 wrong-patient electronic orders are placed every day in a large hospital system with approximately 1,500 beds, or about 68 wrong-patient errors per 100,000 medication orders. By this measure, one in 37 hospitalized patients will have an order placed for them that was intended for another patient.[1]

These errors are sometimes due to juxtaposition but more often caused by interruptions and having more than one patient's electronic health record open.

Multiple studies have demonstrated ways to reduce these events. Requiring verification of the patient's identity has reduced errors by 16% to 30%, and requiring re-entry of the patient's identification has reduced errors by 41%.[1,2] Prompting clinicians for an indication when certain medications are ordered without an indication on the patient's problem list has intercepted errors at a rate of 0.25 per 1,000 alerts.[3] In one study, most emergency department (ED) staff (81%) felt a room number watermark on the patient's electronic health record would eliminate most wrong-patient orders in the ED.[4]

Communication About Drug Therapy – Confusing the Available Concentration as the Patient's Dose on Electronic Records

Another risk deals with how home medications appear on computer screens. For example, a physician accidentally ordered 100 units of Lantus® (insulin glargine) instead of the correct dose of six units because the list of medications used at home displayed the concentration right next to the drug name on the first line, and the patient's dose below it on the second line: "Insulin glargine (Lantus) 100 units/mL," followed on the next line with "6 units subcutaneous daily every evening."

Now that insulin is available in 100 units/mL, 200 units/mL, 300 units/mL, and 500 units/mL concentrations, the risk

of receiving an overdose of insulin is high if the presentation of the order lists the product's concentration before the patient's dose. ISMP's recommendation is to list the drug name, patient-specific dose, and directions for use on the first line of the electronic medication administration record and patient medication lists, and the available concentration and any directions on how to measure the patient's dose below it.

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FDA Provides Training Videos on MedWatch Resources and Breakthrough Therapy

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch Safety Information and Adverse Event Reporting Program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Reading Medicine Labels Helps Reduce Acetaminophen Overdoses

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use.

AAC's "Know Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:

(1) Always read and follow the medicine label.
(2) Know if their medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.
(4) Ask their health care provider about any questions.

Additionally, pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website at *www.knowyourdose.org.*

Over-the-Counter Children's Medicine Recalled Due to Incorrect Dose Markings

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, *www.perrigo.com,* under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch.*

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information, CDER, presents a series of continuing education webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Upcoming webinars, previous webinars, and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm.*

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The Act is comprehensive and has a heavy focus regarding opioid overdose and preventative measures to help decrease the death rate in the State of Illinois as well as creating pathways to assistance with treatments and preventative education in our communities. A large focus of PA 099-0480 allows the following persons to administer naloxone, an opioid reversal agent, to any person who is having an opioid overdose: patients at risk for an opioid overdose; any person who may be able to assist a person at risk for an overdose; law enforcement officers/firefighters; and school nurses/ trained individuals employed by a public/non-public school.

Pharmacists within the community are required to complete the State-approved opioid antagonist training before engaging in advanced clinical practice to help assist the at-risk populations. However, once all components of the training program have been completed, participating pharmacies and pharmacists can assist this population with obtaining rescue naloxone therapy. They can also provide the required safety information regarding signs and symptoms of opioid overdose, how to provide rescue breathing, possible adverse effects of naloxone therapy, and instructions for the emergency call for help by contacting emergency medical services to engage acute treatment. All of this assistance can be done by pharmacists without an individual prescription provided to the patient. Patients or caregivers will be able to come into the pharmacy and request these services, assuming the pharmacy is participating and their pharmacists have completed all the components of the training program. The Illinois Department of Public Health, the Department of Human Services, and the IDFPR collaborated on this venture to ensure that pharmacists are aware of the ruling and receive the recommended training to become a community resource for this epidemic. "Pharmacists are the most accessible health care provider in most Illinois communities, and the use of opioid reversal agents, such as naloxone, has saved numerous lives," states Garth Reynolds, Illinois Pharmacists Association (IPhA) executive director. SIUE faculty members Drs Kelly Gable, Chris Herndon, and Jessica Kerr have worked with the IPhA to develop and administer the online training for pharmacists. It is their hope that by further educating the community and health care professionals, everyone can join forces to stop this public health concern. Pharmacists are encouraged to register for the Illinois State Opioid Antagonist Training Program by visiting *www.ipha .org/isoatp-registration.*

Garth K. Reynolds, RPh, is the executive director of the IPhA, www.ipha.org. *The IPhA is dedicated to enhancing the professional competency of pharmacists, advancing the standards of pharmacy practice, improving pharmacists' effectiveness in assuring rational drug use in society, and leading in the resolution of public policy issues affecting pharmacists.*

Editor's Note: The above article is an IPhA press release reprinted at IPhA's request. It has been lightly edited for American Medical Association (AMA) and *Illinois Department of Financial and Professional Regulation Pharmacy Newsletter* style only; the content has not been altered.

The Role of a Health-System Pharmacist – Bridging the Gap

By Robert Pecho, PharmD, Dalila Masic, Student Pharmacist, and Despina Kotis, PharmD

Introduction

Pharmacists who practice in hospitals and health systems play a pivotal role in the evolving health care landscape. Health plans and providers are exploring new ways to deliver cost-effective, patient-centered care. The STEEP framework identifies six health care dimensions on which to focus quality improvement initiatives: safety, timeliness, effectiveness, efficiency, equity, and patient-centeredness. Private and public organizations such as The Joint Commission and the Centers for Medicare and Medicaid Services (CMS) are driving quality measures to align payment with quality and accountability standards. As we shift our focus of health care to a collective system, each member of the health care team must have clearly defined roles to effectively meet patient needs.

The purpose of this article is to define the role of health-system pharmacists and describe their importance in the health care continuum.

Pharmacist-Provided Services

Medication management is one of many services pharmacists can provide. Pharmacists provide medication management across multiple chronic illnesses including diabetes, dyslipidemia, heart failure, asthma, HIV, oncology, etc. CMS reaffirms that medication therapy management programs, which are largely provided by pharmacists, can "strengthen the Part D program and improve its overall value." Medication management conducted by pharmacists improves medication adherence and clinical outcomes for patients with chronic diseases.

Transitions of care, or the movement of patients between health care locations, providers, or different levels of care within the same location as their conditions or care needs change, have been highlighted as an area in need of improvement by many high-profile organizations. As many as 70% of patient care transitions result in medication discrepancies, with one-third of these resulting in adverse drug events. In 2016, The Joint Commission designated medication reconciliation as a National Patient Safety Goal (NPSG.03.06.01). Indirectly related to medication review, CMS has established the Hospital Readmissions Reduction Program with specific measures for unplanned readmission due to heart attack, heart failure, pneumonia, chronic obstructive pulmonary disease, and total hip and knee replacement.

Pharmacist-provided medication reconciliation can detect and reduce medication discrepancies. This is especially important in the post-discharge hospital setting for patients at high risk of readmission.

As the most accessible health care providers, pharmacists play an integral role in preventative care services. They can help develop institutional screening programs (eg, immunization status, undiagnosed medical conditions, antimicrobial stewardship) to increase vaccination rates, optimize drug

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therapy management, and reduce transmission of infections. Pharmacist-led education and behavioral counseling could lead to a well informed patient population helping reinforce physician messages and positive behaviors. For example, targeting health and wellness issues (eg, smoking cessation and weight management) can be beneficial in helping patients achieve health goals.

Effectively utilizing pharmacists in the collaborative care model will significantly impact National Healthcare Quality Initiatives. The health-system pharmacist has the unique ability to bridge the gap between community and hospital-based care. The next few sections will describe the importance of health-system pharmacists in the continuum of care.

Transitions of Care

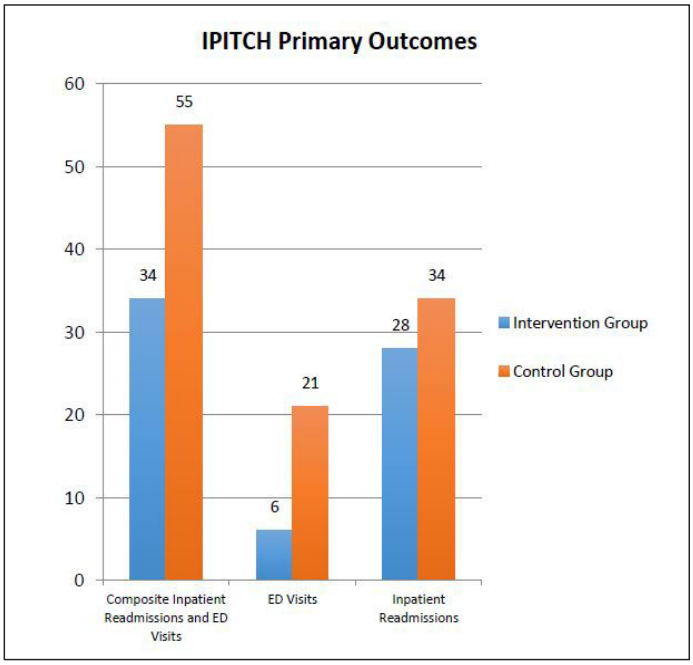
By working with the health care team, inpatient pharmacists play a key role in ensuring that patients receive appropriate transitions of care. The American College of Clinical Pharmacy Improving Care Transitions statement published in *Pharmacotherapy* describes the roles of the inpatient pharmacist. These roles include contributing on medical rounds, performing comprehensive medication reconciliations on admission, applying pharmacotherapeutic knowledge to predict and resolve any issues during transitions of care, assessing the appropriateness of medication regimens, and resolving adherence or health literacy issues. Pharmacists should engage in the development of policies and procedures regarding the medication reconciliation process and continuously improve the process. Each unique role that an inpatient pharmacist has in the continuity of care optimizes the access and quality of patient-centered care.

Outpatient pharmacists play a similar, yet slightly different role in the transitions of care process. Just like inpatient pharmacists, outpatient pharmacists are responsible for collaborating alongside other members of the health care team to evaluate medication therapy and resolve any identified medication problems. However, unlike in an inpatient setting, outpatient pharmacists complete a comprehensive medical therapy review at every visit in order to assess pharmacotherapy in terms of appropriateness, effectiveness, and safety. The outpatient pharmacist is then able to create patient-specific care plans, provide education about chronic disease states, and monitor for patient adherence.

How Do Health-System Pharmacists Help Bridge the Gap?

One case known as "the IPITCH Study," published in the *Journal of Hospital Medicine,* measured the impact of pharmacist involvement in transitions of care at Northwestern Memorial Hospital, an 894-bed academic medical center. A total of 278 patients were included in the study; 141 were in the control arm and 137 were in the study arm. The control arm received the usual standard of care by a clinical pharmacist after discharge, whereas the study arm received post-discharge clinical pharmacist interventions.

The usual standard of care included pharmacist-provided medication reconciliations obtained from the patient chart and discharge counseling that was provided by a physician



or nurse, with only one post-discharge phone call at day 30 to evaluate study endpoints. In the intervention group, pharmacists provided face-to-face medication reconciliation on admission, developed a patient-specific care plan, conducted discharge counseling, and followed up with post-discharge phone calls on days three, 14, and 30 for each patient in the study group.

Ultimately, pharmacist intervention on admission and discharge led to a significant decrease in composite inpatient readmissions and emergency department visits ($p=0.001$) and emergency department visits alone ($p=0.005$) over seven months (see above chart). Pharmacists in the intervention group also found more medication discrepancies than the control group (n=380, 46.2% versus n=205, 19.9%, $p<0.0001$, respectively).

Incorrect transitions of care can lead to detrimental consequences, especially for high-risk patients. Therefore, both inpatient and outpatient pharmacists are capable of playing a significant role in improving the experience and outcomes of patients who are transitioning across care settings.

Disease Prevention and Screening – Antimicrobial Stewardship

Pharmacists have a prominent role in antimicrobial stewardship. Stewardship teams aim to attenuate or reverse antimicrobial resistance, prevent antimicrobial-related toxicity, and reduce costs of inappropriate antimicrobial use and health care-associated infections. At Northwestern Medicine, the antimicrobial stewardship team is composed of infectious disease physicians, pharmacists, and pharmacy residents. The team has developed a new process to review antibiotic usage. Using a clinical decision support software known as TheraDoc, pharmacists are able to track antibiotics ordered for over 72 hours on patients with no positive cultures. The alert flags the pharmacist who then assesses the appropriateness of the order. If intervention is needed, the

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supervising team will be contacted with recommendations. If the recommendation is refused, intervention by the lead infectious disease physician will follow. Over time, prescribers will become more knowledgeable in managing infectious disease. The institutional goal is to decrease antibiotic days by 10% institution-wide.

Benchmarking is the key to determining the efficacy of the process and providing feedback for improvement in the future.

This is in concordance with President Obama's 2014 Executive Order requiring inpatient facilities "to implement robust antibiotic stewardship programs that adhere to best practices" by the end of 2016.

The Joint Commission is proposing the following:

- Leaders establish antimicrobial stewardship as an organizational priority.
- Educate staff and licensed independent practitioners involved in antimicrobial ordering, dispensing, administration, and monitoring about antimicrobial resistance and antimicrobial stewardship practices.
- Educate patients, and their families as needed, regarding the appropriate use of antimicrobial medications, including antibiotics.
- The organization has an antimicrobial stewardship multidisciplinary team that includes the following members, when available in the setting: pharmacist(s), infection disease physician, and infection preventionist(s).
- The organization's antimicrobial stewardship program includes the following core elements: leadership commitment, accountability, drug expertise, action, tracking, reporting, and education.
- The organization's antimicrobial stewardship program uses organization-approved multidisciplinary protocols.
- The organization collects and analyzes data on its antimicrobial stewardship program, including antimicrobial prescribing and resistance patterns.
- The organization takes action on improvement opportunities identified in its antimicrobial stewardship program.

Moving forward, it is critical that pharmacists remain involved in the development of policies and procedures designed to meet these conditions. As drug experts, pharmacists can help implement critical metrics designed to promote optimal use of antimicrobial agents as well as reduce transmission of infections.

Conclusion

Health-system pharmacists have increasing roles in patient care. As drug experts, their insight on interdisciplinary teams and in administration should not be overlooked.

Emerging evidence regarding pharmacist intervention in transitions of care and antimicrobial stewardship has shined light on previous gaps in patient care. As the health care landscape continues to evolve, the role of a pharmacist will expand.

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