

PATIENT SAFETY

Special Issue: Pharmacy Education and Practice
Vol. 4, No. SI (2022)

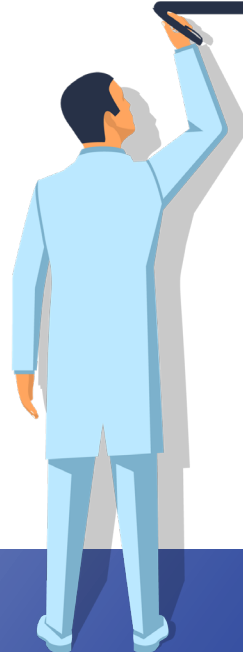
Medication considerations for
children and neonates

Strategies to mitigate vaccine anxiety

Antibiotic stewardship opportunities
in the ER

Rx

Michael Cohen, founder
of the world-renowned
Institute for Safe Medication
Practices (ISMP), shares his
prescription for preventing
pharmacy errors



LETTER

From the Editor



*Regina Hoffman,
Editor-in-Chief
Patient Safety*

While the COVID-19 pandemic continues without an end in sight, it has become increasingly difficult to find reasons to celebrate. Emotions, beliefs, and reactions to this crisis are stronger than ever. There at the convergence of them all—hope and despair, tolerance and impatience, kindness and anger, altruism and selfishness, science and propaganda—are healthcare workers. They see both the best and the worst in humanity every day. One might wonder why anyone would enter or continue a career in healthcare right now. Yet many do because they still see the good, they still have hope, and they want to continue making a difference. Pharmacists are some of these people and today we celebrate them.

In honor of their work, we asked pharmacists and pharmacy students to share their

patient safety manuscripts with us and our readers. Our guest editors, Michael Cohen, ScD (hon.), DPS (hon.), RPh; Daniel D. Degnan, PharmD; and Patrick McDonnell, PharmD, selected four manuscripts to feature in this special issue, Pharmacy Education and Practice.

Elkeshawi, et al. from Arnold & Marie Schwartz College of Pharmacy and Health Sciences, Long Island University highlight medication safety risk to some of our most vulnerable patients: children and babies. They also share with us several of the advancements in the industry to help make the medication-use system for this population safer.

Fuentes, et al. from the University of Houston, College of Pharmacy share with the reader an inside perspective of the culture of safety that starts at the very foundation of pharmacy education and integrates with the healthcare system. A safety mindset established early in the education process sets a new pharmacist up for success throughout their career—and helps keep patients safer.

Bauman, et al. from St. Vincent's Hospital remind us that previously identified safety issues, like inappropriate antibiotics, haven't gone away. This study evaluated the antibiotic regimen of 492 emergency department patients and demonstrated that there is still room for improvement.

Mast and Li from the University of Pittsburgh School of Pharmacy present a topic that we may not know by name, although chances are we know someone who experienced it: immunization stress-related response (ISRR). The authors not only discuss common symptoms of ISRR, like feelings of apprehension and increased heart and breathing rates associated with receiving an immunization, but also share mitigation strategies that vaccination clinics and health systems can take to keep patients safe.

In addition to these four manuscripts, our guest editors shared through interview and commentary some of their own experiences and perspectives. Patrick McDonnell, a professor of Pharmacy who has spent nearly three decades at Temple University School of Pharmacy, spoke with our guest managing editor, Eugene Myers, about the pharmacy program and his biggest challenges and successes throughout his pharmacy career.

Michael Cohen, both the founder and president of the Institute for Safe Medication Practices (ISMP), began advocating for safe medication practices in 1974 after learning about a serious medication event. Mike discussed with Eugene the importance of sharing information and the role of pharmacists during the COVID-19 pandemic.

Finally, Daniel Degnan, associate director for the Professional Skills Lab at Purdue University College of Pharmacy, shared with us that while the students he teaches are eager to learn and excited about their profession, they are also fearful of making mistakes. Knowing that some process and design issues may be out of an individual's control, there are still steps individuals can take to reduce the risk of error. Just like developing safe (or unsafe) driving habits, we can also focus on and develop habits that keep our tasks safer in the workplace as well.

I want to thank Patrick, Mike, and Dan for leading this special effort. I'd also like to thank Eugene and the editorial team for ensuring we stayed on track and bringing it all together for our readers. And I'd like to thank the authors of this issue and pharmacists everywhere. Pharmacists across the country and around the world continue to demonstrate the meaning of teamwork as they keep showing up to help us overcome one of the biggest public health challenges of our lives.

A handwritten signature of Regina Hoffman in black ink.

ABOUT PATIENT SAFETY

As the journal of the Patient Safety Authority, committed to the vision of "safe healthcare for all patients," *Patient Safety* (ISSN 2641-4716) is fully open access and highlights original research, advanced analytics, and hot topics in healthcare.

The mission of this publication is to inform and advise clinicians, administrators, and patients on preventing harm and improving safety, by providing evidence-based, original research; editorials addressing current and sometimes controversial topics; and analyses from one of the world's largest adverse event reporting databases.

We invite you to submit manuscripts that align with our mission. We're particularly looking for well-written original research articles, reviews, commentaries, case studies, data analyses, quality improvement studies, or other manuscripts that will advance patient safety.

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CORRECTION TO TAYLOR & PILEGGI (2021)

"Perioperative Delirium/Agitation Associated With the Use of Anesthetics and/or Adjunct Agents: A Study of Patient Behaviors, Injuries, and Interventions to Mitigate Risk" (Vol. 3, No. 4, pp 16–27) was corrected to fix an incorrect percentage in the Discussion section referencing Figure 3. The online versions of this article have been corrected. <https://doi.org/10.33940/med/2021.12.2>

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Vaccination is the best way to prevent infection and serious illness from diseases like influenza and COVID-19, but some people are still nervous about getting that shot. There are some simple things practitioners can do to put patients at ease and reduce the risks of an adverse event.





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Medication
Safety

Medication Error Reporting
Education
Advocating for Change

[Signature]

A Prescription for Safety

Medication Error Reporting, Education, and Advocating for Change

By **Michael R. Cohen**, ScD (hon.), DPS (hon.), RPh[◇]
& **Eugene Myers**, BA^{◆†}

Submitted: December 16, 2021 / Accepted: December 23, 2021

In 1974, pharmacist Michael Cohen learned of a serious adverse event with insulin at a hospital and began sharing information about it with other pharmacists to prevent the error from happening again. Twenty years later, he founded the Institute for Safe Medication Practices (ISMP) with the same goal: collecting healthcare workers' stories and reports about medication errors to improve patient safety.

We spoke with Cohen, guest editor of this issue, about ISMP's ongoing initiatives and the biggest challenges in medication and vaccination safety facing pharmacists today.

Eugene Myers: ISMP has a long history of working with healthcare students to educate them about medication errors and safety. Why is this such an important focus of your work?

Michael Cohen: For one thing, we operate the ISMP National Medication Error Reporting

Program. Education is part of every healthcare professional's responsibility. One way to do that, and an especially important area, is sharing of information about medication errors. So as they go about their professional life, anything you become aware of that could really be important to others to know about from a safety standpoint should be considered as a report of a medication error. For example, if you experience a medication error or identify something that might be potentially harmful, even though there hasn't actually been a problem yet—if that gets reported that can help not just your colleagues, but you as well.

In Pennsylvania we're very fortunate to have the Patient Safety Authority [PSA] doing very similar work, but in a broader way, not just medication errors. The PSA is concerned about any type of patient safety event, but we focus only on medication errors—so just from that standpoint alone there's great importance in what we are doing.

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Disclosure: The authors declare that they have no relevant or material financial interests.

How does ISMP engage with PharmD students in particular?

Here in Philadelphia, we actually do a course at Temple University, School of Pharmacy, as well as Thomas Jefferson University. We also interact with and do live events for different schools; we're doing one in a couple of weeks for Purdue University and we just did one for the University of Texas. We've also done them for other schools upon request. We provide all types of education: background on the reporting program, and also the types of reports that we get.

Lately there's been a lot of interest on the part of students about vaccination-related errors. In pharmacy schools they are taught how to administer vaccinations. And that of course becomes part of their professional life when they go into community pharmacy in particular, or ambulatory care pharmacy. And here in Pennsylvania, for example, pharmacists have the authority and there's an add-on to their license if they're certified to be able to administer vaccines. So there's a big demand now for information about vaccination-related errors, and I've been doing some of that and others that I work with have been doing the same. So any topic that people feel is interesting, we're happy to help where we can.

Speaking of vaccination-related errors: Pharmacists today are probably busier than ever with their role in distributing COVID-19 vaccines. What has been the impact on patient safety?

Giving vaccinations has been one of the most important public health functions that we've ever done in pharmacy. Reporting medication errors is an important public health issue as well. We're giving about 25% or 30% of the vaccinations in the United States now; pretty much every state is doing it and it has made it very easy for people to be able to access vaccinations in their community pharmacy where pharmacists are very available. There was a little bit of a problem when we first started with all the COVID-19 vaccinations: You had to make an appointment and that became problematic because *everyone* wanted to get vaccinated. Well, not everyone, many people wanted to get vaccinated—but not enough, I would say. Today it's very accessible and easy. And in many cases it's covered by insurance or, in this case with the COVID vaccines, it's free, it's covered by the government. So that's really been a big public health improvement that pharmacists and pharmacies have made available.

Absolutely. So what has been one of the biggest challenges in ISMP's work?

In our work we just want to do everything, and we don't have the funding to do it, you know? It's like any other nonprofit organization, you always want to do more. And we have a terrific staff: We're multidisciplinary—nurses, pharmacists. We have a medical director who's a physician. For example, right now, we'd love to start doing videos of the errors that we have reported to us. We would love to make that information more accessible, and a lot of people enjoy things like podcasts or short videos that demonstrate exactly what the concern is and show how to prevent the issue. So we've been looking into that. We have actually had some cooperation from the School of Pharmacy, Temple University, and they have been making some funding available to us. And we do have about six videos now on our website and we're going to be doing a little bit more of that as well. We're also thinking about podcasts.

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It is very important to have large databases so you get a really good feel for how often something is happening, how serious the problem is.

But we have had a really, really good impact, not just on practice-related issues but on product-related issues as well—regulated products. We do a lot with the U.S. Food and Drug Administration and they have a whole group that focuses on medication error prevention. It's called the Division of Medication Error Prevention and Analysis and we have a regular meeting with them once a month and then every day, pretty much, we're in touch with them about specific issues. I've been in touch with them several times about our concern related to the new pediatric COVID vaccine and what our concern is: We're worried that it's going to get mixed up with the adult vaccine, and many other vaccines that have an age-related component to the dosing, they're mixed up, and now I think we're going to be seeing that and we want to take some steps in advance to get that information out there.

Sure. That's related to my next question: What have been some of your biggest successes in in your work?

Being able to turn around the reports that we get from the field. We're very fortunate in that our style of reporting is a bit different than most of the other types of reporting. It is very important to have large databases so you get a really good feel for how often something is happening, how serious the problem is. We know what the usage is of individual products—we can get that information. And if we have a pretty good feel for how often something is happening, we can relate that to how often the product is being used. That's important, and we need large databases to do that.

But our work is really getting the stories from the nurses, the doctors, the pharmacists that are out there in the field, and they're very, very willing out of altruism, pure altruism, to tell us the story, make information available: photographs, screenshots on their computer if it's a drug name mix-up that they chose the wrong item, it could be almost anything. That has been really important to our ability to get information out there to the wide audience, both nationally and internationally. That is a big thing, and also working with the FDA. We've been able to effect product changes on the level of thousands of product labeling changes over the years.

One change alone, that goes into an FDA guidance or a United States Pharmacopeia [USP] standard that industry is required to follow can affect thousands of injectable drugs. Those numbers

are very, very high and we have had great success with these—just individual reports of “Boy, if somebody doesn’t do something, there could be a serious error with this.” We make that available to the public, to FDA, to USP, to the industry, to the individual companies. They get copies of the reports; all the identifying information is redacted so nobody knows where it comes from. So those two issues are probably the most important things for us.

You touched on this with your concerns about the pediatric COVID-19 vaccines, but considering the current state of medication errors and then looking ahead, what are some of the major issues that we need to address?

We’ve always tried to focus on a group of drugs that we named high-alert drugs [www.ismp.org/sites/default/files/attachments/2018-08/highAlert2018-Acute-Final.pdf] and the reason is these are drugs that may not be involved in a lot of errors necessarily but when an error happens, it’s much more likely that a patient would be injured or it could even be fatal. So we’ve tried to focus on those drugs and we have them listed on our website. We are developing one now for community pharmacies as well. And that’s an important area for us to be involved with, making that information more available and getting people focused on these activities.

The other errors that happen that don’t involve high-alert drugs are also important, and certainly getting information out about medication errors and vaccination errors so that people have this information and our recommendations on how to prevent it, which generally are pretty simple to implement. In some cases, we do recommend technology—that’s important.

Michael Cohen is founder and president at the Institute for Safe Medication Practices (ISMP). He is active in many patient safety initiatives, including as co-editor of the ISMP consumer website, chairperson of the International Medication Safety Network, former member of the U.S. Food and Drug Administration (FDA) Drug Safety and Risk Management Advisory Committee and Nonprescription Drugs Advisory Committee, and a current consultant to the FDA. Cohen has been widely recognized for his advocacy and expertise in medication safety, receiving the John M. Eisenberg Patient Safety and Quality Award from the National Quality Forum and The Joint Commission, and the Harvey A. K. Whitney Award from the American Society of Health-System Pharmacists. In 2006, the John D. and Catherine T. MacArthur Foundation recognized him as a MacArthur Fellow.

Cohen is a graduate of Temple University School of Pharmacy, where he received both a bachelor’s in pharmacy (1968) and Master of Science in pharmacy (1984). He was awarded honorary Doctor of Science degrees by Thomas Jefferson University, the University of the Sciences in Philadelphia, and Long Island University, and he also has a Doctor of Public Service from University of Maryland. Cohen served as director of pharmacy at Quakertown Community Hospital in Quakertown, Pennsylvania, and assistant director at Temple University Hospital prior to founding ISMP.

Eugene Myers (eugemyers@pa.gov) is the associate editor of *Engagement and Publications for the Patient Safety Authority*. He previously served as the editor-in-chief of Communications, Office of Institutional Advancement, at Thomas Jefferson University and Jefferson Health. He earned his bachelor’s degree from Columbia University, is a graduate of the Clarion West Writers Workshop, and is an award-winning author of seven novels for young adult readers.

Appropriateness of Antibiotic Prescribing in Patients Discharged From a Community Hospital Emergency Department

By **Emily L. Bauman**, PharmD^{♦◇}, **Justine M. Russell**, PharmD[◇] & **Angela R. Morelli**, PharmD[◇]

DOI: 10.33940/data/2022.1.1

Submitted: July 19, 2021 / Accepted: November 9, 2021

Abstract

IMPORTANCE: Every year, thousands of emergency department (ED) visits result in patients being discharged with oral antibiotic prescriptions. Published studies that assess the appropriateness of these antibiotic regimens are limited.

PURPOSE: The purpose of this study was to examine the appropriateness of antibiotic prescriptions written for patients discharged from a community hospital's ED.

ENDPOINTS: The primary objective was to determine the overall percent of appropriate antibiotic prescriptions for patients discharged from the ED. Secondary objectives included the following: identify reasons for inappropriateness categorized by antibiotic selection, dose, duration, and allergies; identify the most common antibiotics prescribed inappropriately as well as the most common disease states that led to inappropriate prescribing of antibiotics; and analyze prescribing trends based on provider type and time of day the prescription was written.

STUDY DESIGN AND METHODS: Patients eligible for inclusion were adults age 18 and older who presented to the ED during four chosen weeks in 2019 and who were discharged with oral antibiotics. Extracted electronic health record data was reviewed to identify the discharge diagnosis for each patient

that met the inclusion criteria. Pertinent information gathered from the patients' medical records along with a validated antimicrobial assessment tool were utilized to determine the level of appropriateness of the prescribed antibiotic regimens.

RESULTS: A total of 76% of the prescribed antibiotics were appropriate, 16% were inappropriate, and the remaining 8% were not assessable. Duration was the most common reason for a regimen to not be optimal. The most frequently inappropriately prescribed antibiotics included cephalexin (but it is noted cephalexin was included in almost half of the antibiotic regimens in this study), clindamycin, and azithromycin. Infections that were most frequently treated inappropriately were skin and soft tissue infections, dental infections, and sinusitis. Overall, medical residents prescribed the highest percent of appropriate regimens, and the time of day that had the highest percent of appropriate prescriptions was third shift (11 p.m. to 7 a.m.).

CONCLUSION AND RELEVANCE: Almost half of all the nonoptimal antibiotic regimens had an excessive duration. Targeted local education efforts and future clinical decision support can facilitate appropriate prescribing of discharge antibiotics from the ED, ultimately improving antimicrobial stewardship within the community.

Keywords: *emergency room, emergency department, emergency medicine, antibiotic prescriptions, oral antibiotics, discharge antibiotics, antimicrobial stewardship*

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Disclosure: The authors declare that they have no relevant or material financial interests.



Antibacterial resistance is one of the most urgent threats to public health and it arises from the inappropriate prescribing of antibiotics. According to the Centers for Disease Control and Prevention (CDC), more than 2.8 million antibiotic resistant infections occur each year in the United States, leading to thousands of deaths. Inappropriate use of antibiotics can lead to additional complications for patients such as *Clostridioides difficile* infections, requiring hospitalization.¹ According to the CDC, a large number of prescribed antibiotics come from outpatient services, including emergency departments (EDs). In 2018, 13.1 million antibiotic prescriptions were written by emergency medicine physicians in the United States, comprising approximately 20% of the total outpatient antibiotic prescriptions written in the country.² Knowing that a large number of prescribed outpatient antibiotics are from EDs, it is important for them to be as appropriate as possible to minimize antibiotic resistance and antibiotic complications.

Overall, there is not an abundance of research analyzing the appropriateness of prescribed antibiotics for patients discharged from an ED. There are few existing studies that provide context in regard to specific infections that tend to be treated inappropriately and which antibiotics are prescribed often.³⁻⁵ The objective of this study was to gain further insight about the antibiotic prescribing habits of ED providers for patients discharged from the ED in a community hospital.

Purpose

The purpose of this study was to examine the appropriateness of antibiotic prescriptions written for patients discharged from a community hospital's ED and to identify opportunities to facilitate appropriate prescribing of antibiotics upon discharge from the ED.

Study Design and Methods

This study was a retrospective chart review of patients discharged from the ED with oral antibiotic prescriptions during four chosen weeks in 2019 (February 10 through February 16, May 5 through May 11, August 11 through August 17, and November 17 through November 23). These weeks were chosen to minimize seasonal influence, as well as any variation in ED staffing. Inclusion criteria were patients being age 18 or older.

The primary objective was to determine the overall percent of appropriate antibiotic prescriptions for patients discharged from the ED, which is composed of 41 beds and has approximately 58,000 visits annually. Secondary objectives included identifying reasons for inappropriateness categorized by antibiotic selection, dose, duration, and allergy history; identifying the most common antibiotics prescribed inappropriately as well as the most common disease states that led to inappropriate prescribing of antibiotics; and analyzing prescribing trends based on provider type and time of day the prescription was written. This study focused on the appropriateness of the antibiotic regimens for the indications described in the medical records, rather than whether or not antibiotics were indicated.

After institutional review board (IRB) approval was obtained, two pharmacists independently reviewed and assessed the electronic health record (EHR) data extraction for each included patient. When necessary, progress notes and discharge diagnoses in the patient charts were reviewed to determine the indication for antibiotics along with the prescribed antibiotic dose, frequency, and duration. Factors that influence the dosing of antibiotics were evaluated; these include weight and the most recent serum creatinine values if obtained within the past 30 days of the ED visit. If no serum creatinine values were available, the standard, recommended antibiotic dosing was considered most appropriate. Using the patient's weight and creatinine values, the most appropriate dose of the antibiotic was determined using a combination of

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Continual quality improvement initiatives and monitoring are imperative to the core principles of antimicrobial stewardship.

Table 1. Utilized Guidelines

Diagnosed Infection	Guideline Title	Year Guideline Published*
<i>Clostridium difficile</i> infection	Clinical Practice Guidelines for <i>Clostridium difficile</i> Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) ⁶	2018
Community-acquired pneumonia	Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults ⁷	2007
COPD exacerbation	Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2018 Report) ⁸	2018
Dental infection	Evidence-Based Clinical Practice Guideline on Antibiotic Use for the Urgent Management of Pulpal- and Periapical-Related Dental Pain and Intraoral Swelling: A Report From the American Dental Association ⁹	2019*
Diabetic foot infection	2012 Infectious Diseases Society of America Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections ¹⁰	2012
Intra-abdominal infection	Diagnosis and Management of Complicated Intra-Abdominal Infection in Adults and Children: Guidelines by the Surgical Infection Society and the Infectious Diseases Society of America ¹¹	2010
Lyme disease	The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America ¹²	2006
Rhinosinusitis	Executive Summary: IDSA Clinical Practice Guideline for Acute Bacterial Rhinosinusitis in Children and Adults ¹³	2012
Sexually transmitted diseases	Sexually Transmitted Diseases Treatment Guidelines, 2015 ¹⁴	2015
Skin and soft tissue infections	Practice Guidelines for the Diagnosis and Management of Skin and Soft Tissue Infections: 2014 Update by the Infectious Diseases Society of America ¹⁵	2014
Streptococcal pharyngitis	Clinical Practice Guideline for the Diagnosis and Management of Group A Streptococcal Pharyngitis: 2012 Update by the Infectious Diseases Society of America ¹⁶	2012
Urinary tract infections	International Clinical Practice Guidelines for the Treatment of Acute Uncomplicated Cystitis and Pyelonephritis in Women: A 2010 Update by the Infectious Diseases Society of America and the European Society for Microbiology and Infectious Diseases ¹⁷	2010

*The most updated guidelines prior to January 2019 were used for this evaluation.

*Note: These are the first published guidelines from the ADA, which were not available until November 2019.

appropriate guidelines if available, the institution's antimicrobial guide, and Lexicomp^a. The determined appropriate dose was compared to the prescribed dose to see if there were any differences. The guidelines that were utilized can be found in **Table 1**.

Allergies listed in the patient chart were also utilized in determining overall appropriateness. Other information that was gathered included the type of provider that prescribed the antibiotics, the time of day the antibiotic prescriptions were written, whether guidelines existed for the bacterial infection, if the prescribed regimen followed the guideline recommendations, if the prescribed regimen provided too broad of coverage or provided coverage overlap, and if the prescribed regimen was likely to treat the causative pathogen.

Antibiotic appropriateness was determined by using the validated National Antimicrobial Prescribing Survey (NAPS) tool, which can be seen in **Figure 1**. There are five defined levels of appropriateness according to this tool: level one is optimal, level two is adequate, level three is suboptimal, level four is inadequate, and level five is not assessable. Levels one and two are classified as appropriately prescribed antibiotics, and levels three and four are classified as inappropriately prescribed antibiotics.

If there was any discrepancy between the pharmacist designations of the antibiotic appropriateness of the antibiotic regimen, an emergency medicine or infectious diseases physician reviewed the chart to make the final decision on antibiotic regimen appropriateness.

^a Lexicomp is a subscription-based online database containing information about clinical drugs, including practice guidelines, interaction checkers, patient education, and other medication-related resources.

Figure 1. National Antimicrobial Prescribing Survey (NAPS) Tool¹⁸

Appropriateness			If endorsed guidelines are present	If endorsed guidelines are absent or not applicable
Appropriate	1	Optimal*	Antimicrobial prescription follows either the Therapeutic Guidelines [^] or endorsed local guidelines optimally, including antimicrobial choice, dosage, route, and duration [#] , including for surgical prophylaxis	The antimicrobial prescription has been reviewed and endorsed by a clinician with expert antimicrobial prescribing knowledge [§] OR The prescribed antimicrobial will cover the likely causative pathogen(s) and there is not a narrower spectrum or more appropriate antimicrobial choice, dosage, route, or duration available (including for surgical prophylaxis)
	2	Adequate	Antimicrobial prescription does not optimally follow the Therapeutic Guidelines [^] or endorsed local guidelines, including antimicrobial choice, dosage, route, or duration [#] ; however, is a reasonable alternative choice for the likely causative or cultured pathogens OR For surgical prophylaxis, as above, and duration [#] is less than 24 hours	Antimicrobial prescription, including antimicrobial choice, dosage, route, and duration [#] , is not the most optimal; however, is a reasonable alternative choice for the likely causative or cultured pathogens
Inappropriate	3	Suboptimal	Antimicrobial prescription, including antimicrobial choice, dosage, route, and duration [#] , is an unreasonable choice for the likely causative pathogen(s), including: Spectrum excessively broad or an unnecessary overlap in spectrum of activity OR There may be a mild or non-life-threatening allergy mismatch	
	4	Inadequate	Antimicrobial prescription, including antimicrobial choice, dosage, route, or duration [#] , is unlikely to treat the likely causative or cultured pathogens OR An antimicrobial is not indicated for the documented or presumed indication OR There may be a severe or possibly life-threatening allergy mismatch	
	5	Not assessable	The indication is not documented and unable to be determined from the notes OR The notes are not comprehensive enough to assess appropriateness OR The patient is too complex, due to multiple comorbidities, allergies, or microbiology results, etc.	

*Taking into account acceptable changes due to the patient's age, weight, renal function or other prescribed medications, if this information is available.

[^]Antibiotic Expert Group. Therapeutic Guidelines: Antibiotic. Version 15 (2014). <http://online.tg.org.au/ip/>

[#]Duration should only be assessed if the guidelines state a recommended duration and the antimicrobial has already been dispensed for longer than this, or if there is a clear planned "end date" documented.

[§]Examples include infectious diseases physician or registrar, clinical microbiologist or registrar, or specialist pharmacist.

Figure 2. Patient Flowchart

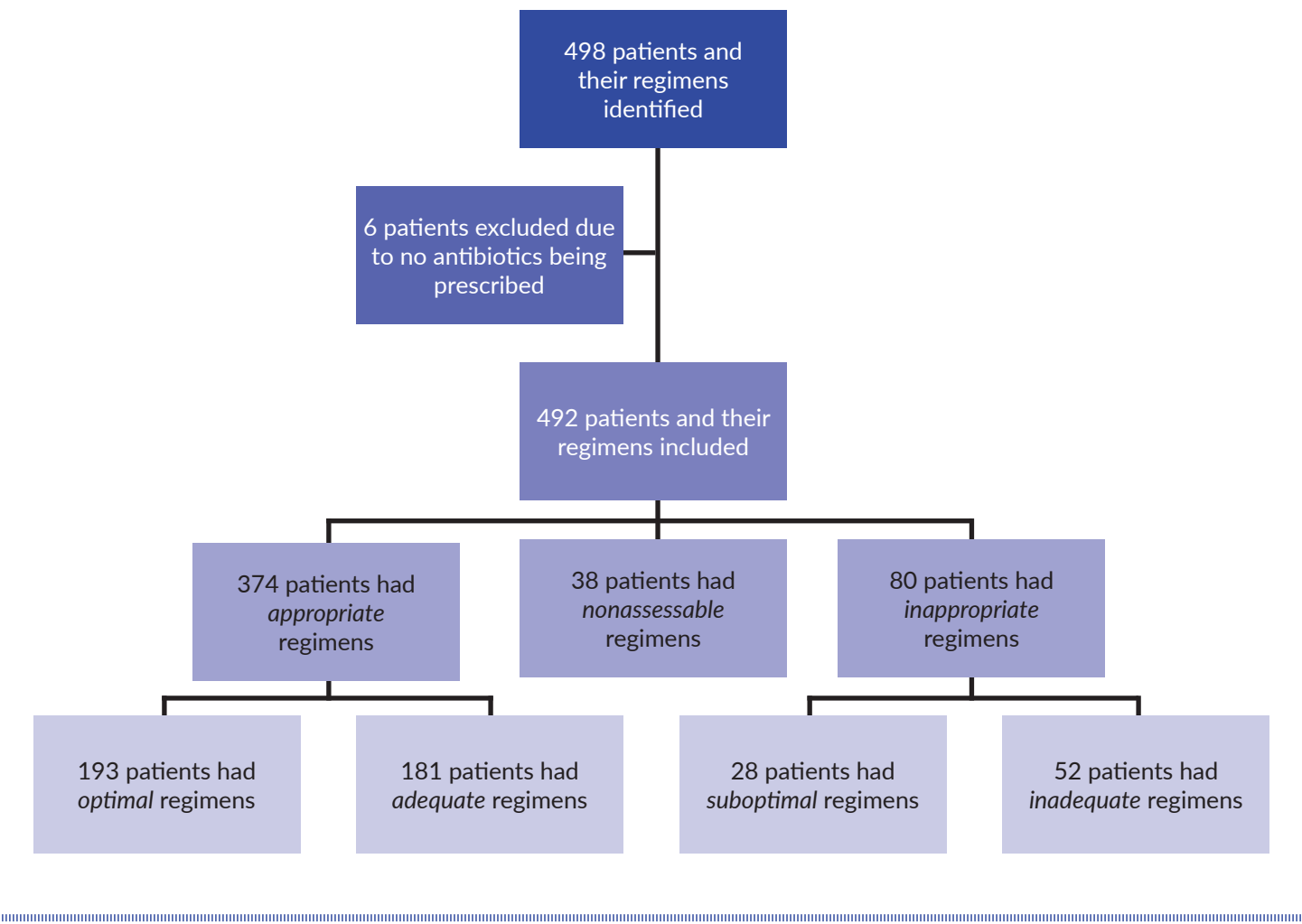


Table 2. Reasons Why Antibiotic Regimens Were Considered Nonoptimal

Reason	Number of patients (%) (n=261*)
Excessive Duration	157 (46)
Inappropriate Antibiotic	103 (30)
Inappropriate Frequency	66 (19)
Inappropriate Dose	12 (4)
Allergy to Selected Antibiotic	2 (1)

*Patients/regimens may have been included in more than one category.

Table 3. Antibiotics Prescribed Inappropriately

Antibiotic	Number of Prescriptions (%) (n=80 patients*)
Cephalexin*	17 (19)
Clindamycin	15 (17)
Azithromycin	10 (11)
Amoxicillin/Clavulanate	9 (10)
Doxycycline	9 (10)
Penicillin V Potassium	8 (9)
Amoxicillin	7 (8)
Sulfamethoxazole/Trimethoprim	5 (6)
Metronidazole	3 (4)
Cefuroxime	2 (2)
Ciprofloxacin	2 (2)
Cefdinir	2 (2)

*Patients/regimens may have included more than one prescription.
*Cephalexin was prescribed most often (218 of 492 patients, 44% of all antibiotics).

Table 4. Infections Treated Inappropriately

Infection	Number of Diagnoses (%) (n=80 patients*)
Skin and Soft Tissue	27 (31)
Dental	25 (29)
Sinusitis	10 (12)
Bronchitis	7 (8)
Pneumonia	4 (5)
Acute Otitis Media	4 (5)
COPD Exacerbations	2 (2)
Pharyngitis	2 (2)
Urinary Tract	2 (2)
Sexually Transmitted	2 (2)
Asthma Exacerbations	1 (1)
Unspecified Upper Respiratory Tract	1 (1)

*Patients/regimens may have included more than one prescription.

Results

Primary Objective:

A total of 498 patients and their antibiotic regimens were identified through the EHR report. Six of those patients were excluded due to no discharge antibiotics being prescribed during their ED visits, leaving 492 patients to be included in the evaluation. The breakdown of these patients and the designation of their respective regimens are displayed in **Figure 2**.

Secondary Objectives:

The 261 patients who had nonoptimal regimens were categorized by reasons as to why they were not optimal, which included excessive duration of the prescribed regimen, inappropriate antibiotic choice, inappropriate frequency, inappropriate dose, and allergy to the selected antibiotic as displayed in **Table 2**.

A total of 80 patients had inappropriate discharge antibiotic regimens. All of the antibiotics found to have been prescribed inappropriately are listed in **Table 3**. The treated infections of each inappropriate regimen were examined to discover which were most frequently treated inappropriately and are listed in **Table 4**.

The additional secondary objectives were to see if there were prescribing trends based on provider type and time of day the prescriptions were written. When comparing the prescriptions written by advanced practice providers (APPs), residents, and attendings, APPs prescribed 206 regimens, residents prescribed 179 regimens, and attendings prescribed 107 regimens. Residents had the greatest percent of appropriate prescriptions, followed by the attendings and the APPs. These results are displayed in **Figure 3**.

Figure 3 also illustrates the numbers of appropriate and inappropriate regimens according to time of day the prescriptions were written. 7 a.m. to 3 p.m. was chosen to represent first shift, 3 p.m. to 11 p.m. for second shift, and 11 p.m. to 7 a.m. for third shift. Second shift had the highest number of prescriptions at 214. First shift had 172 written prescriptions, and third shift had 106. Out of the three shifts, third shift had the highest proportion of appropriate regimens, followed by first shift and second shift.

Discussion

Our evaluation has similar results as compared to a previous study published in 2019.⁴ This past study was conducted in Queensland, Australia, where its authors analyzed the appropriateness of the antibiotics prescribed in an ED for both discharged and admitted adults and children. Antibiotic appropriateness was assessed by a panel of experts who used evidence-based guidelines with the same antibiotic assessment tool used in our evaluation (the NAPS tool). Overall, the study found that 63% of the prescribed antibiotics were appropriate, 33% were inappropriate, and 4.5% were not assessable, which are all fairly similar to our results. The most common inappropriately treated infections were dental and ear, nose, and throat infections, which are also similar to what we found.

It is worth noting that our evaluation had similarities to a study published in 2019 that assessed antibiotic selection, administration, and prescribing practices in EDs across a large hospital system.¹⁹ Instead of focusing on which disease states were inappropriately treated and which antibiotics were inappropriately prescribed as we did, the authors focused on simply the most common diagnoses and administered antibiotics.

Interestingly, during the conduction of this evaluation, a best practice advice summary from the American College of Physicians was published which emphasized the importance of what we found with this evaluation. It confirms unnecessarily long durations of antibiotic therapy for common bacterial infections, such as acute bronchitis with chronic obstructive pulmonary disease (COPD) exacerbation, community-acquired pneumonia, urinary tract infections (UTIs), and cellulitis, contribute to antimicrobial overuse and resistance.²⁰

Continual quality improvement initiatives and monitoring are imperative to the core principles of antimicrobial stewardship. The information from this evaluation was presented to local ED leadership and providers at our community hospital to emphasize the importance of minimizing antibiotic duration of therapy for common infections, noting the tip sheet “Antibiotic Prescribing Tips for Patients Discharged from the ED” we created and distributed among the ED providers (displayed as **Table 5** for reference). We believe residents may have had a slightly higher rate of appropriate prescriptions since they tend to be the population of prescribers that utilize guidelines more often. Third shift’s slight increase of appropriate prescriptions could be due to the fact that fewer prescriptions overall were written during that time of day.

We are hopeful this data will make an impact in overall patient care in our community. This evaluation may lead to the development of clinical decision tools to help providers choose appropriate antibiotic regimens upon discharge (i.e., order set development).

Figure 3. Providers, Time of Day, and Appropriateness of Prescriptions

Number of Prescriptions

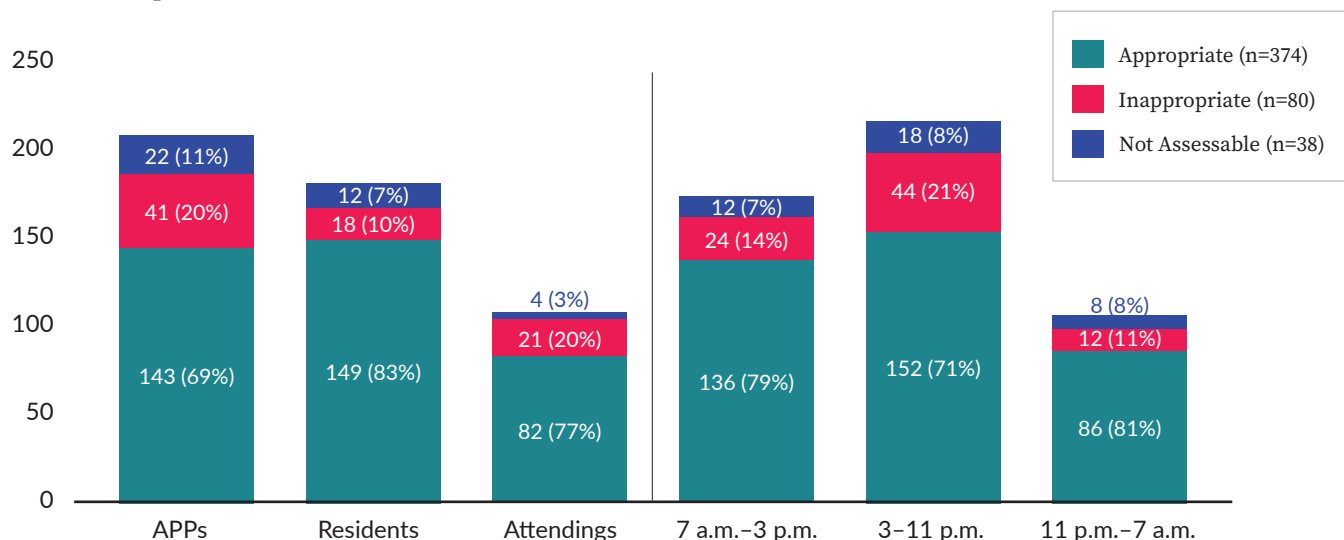


Table 5. Antibiotic Prescribing Tips for Patients Discharged From the ED*

Animal Bites ¹⁵	• Preemptive early antimicrobial therapy of 3–5 days is recommended for moderate-severe animal bites.	• Preferred prophylactic regimen is amoxicillin/ clavulanate 875/125 mg PO BID x 5 days • Doxycycline 100 mg PO BID plus metronidazole 500 mg PO TID x 5 days (<i>only</i> if patient has penicillin allergy)
Dental ⁹	• Antibiotics are <i>only</i> recommended if swelling or abscess is present. • Dental caries or poor dentition <i>do not</i> need antibiotics (ADA guidelines).	• Amoxicillin 500 mg PO TID x 5 days • Penicillin VK 500 mg PO QID x 5 days • Clindamycin 300 mg PO QID x 5 days (<i>only</i> if patient has penicillin allergy)
Lacerations ¹⁵	• Uncomplicated skin lacerations receiving local wound care <i>do not</i> require prophylactic antibiotics	• Cephalexin 500 mg PO QID x 5 days (<i>only</i> if signs of infection present)
Respiratory 1. Bronchitis 2. Pneumonia ⁷ 3. Sinusitis ¹³	• Bronchitis: antibiotics are <i>not</i> typically indicated. • Pneumonia: use combination therapy for community-acquired pneumonia in patients with chronic conditions (heart, lung, liver, or renal diseases; diabetes; alcoholism; cancer; or asplenia). • Cefuroxime 500 mg PO BID x 5 days plus Z-pak x 5 days • Sinusitis: antibiotics not indicated unless symptomatic for at least a week. • Augmentin 875/125 mg PO BID x 5 days	
Urinary Tract ¹⁷	• Asymptomatic bacteriuria <i>should not</i> be treated with antibiotics.	• Cephalexin 500 mg PO BID x 5 days • Nitrofurantoin 100 mg PO BID x 5 days

*These tips are based on guideline recommendations but should not be used to preclude patient-specific factors and clinical judgment.

We are hopeful these efforts will impact overall patient care in our community while minimizing the potential for antibiotic misuse. A further evaluation will be necessary to measure local improvement with this initiative.

Limitations

This was a retrospective evaluation focusing on empiric therapy for the stated diagnoses of each patient. We primarily focused on the appropriateness of the antibiotic regimens prescribed, rather than whether or not antibiotics were indicated. The report obtained from the EHR did not contain handwritten prescriptions.

A large proportion of the patients' charts had limited documentation, making it difficult at times to assess appropriateness. Minor variances between guidelines and institutional recommendations also caused difficulty in assigning a level of appropriateness for a few of the regimens. Due to complexity and limited time, we did not analyze potential drug-drug interactions with the prescribed antibiotics and the patients' home medications.

Conclusions

Overall, the prescribing habits of ED providers in our community hospital are appropriate but have room for improvement. Almost half of the nonoptimal antibiotic regimens had an excessive duration of therapy. Targeted provider education, competencies, and implementation of clinical decision tools can facilitate appropriate prescribing of discharge antibiotics from the ED, ultimately improving the number of optimal antibiotic prescriptions in the community and combating antimicrobial misuse.

Acknowledgements

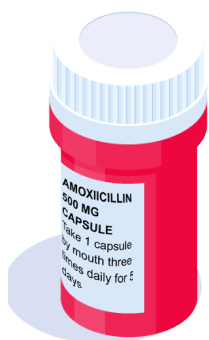
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Integration of Medication Safety Training and Development of a Culture of Safety in Pharmacy Education

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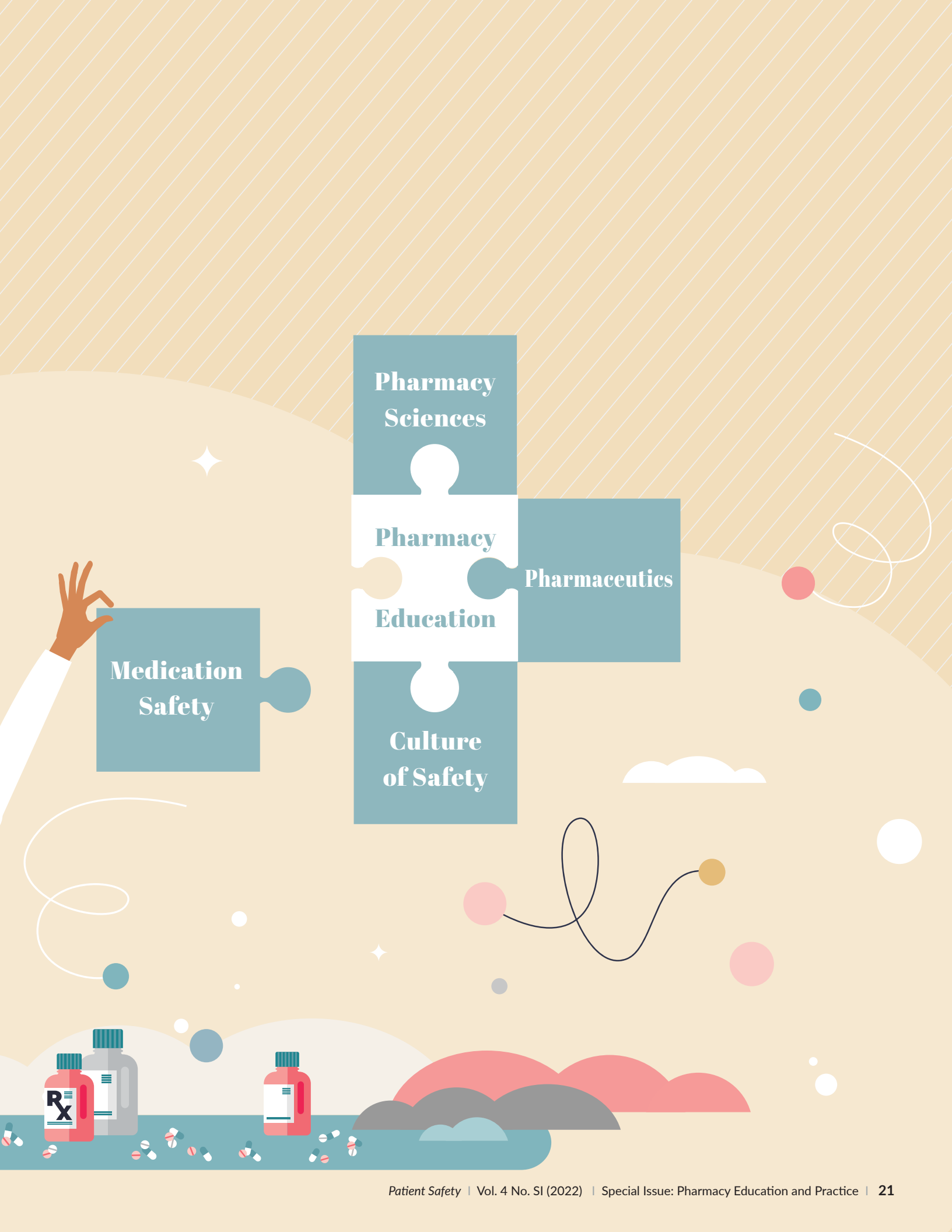
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**Pharmacy
Sciences**

**Pharmacy
Education**

Pharmaceutics

**Medication
Safety**

**Culture
of Safety**

Medication safety events with the potential for patient harm do occur in healthcare settings. Pharmacists are regularly tasked with utilizing their medication knowledge to optimize the medication-use process and reduce the likelihood of error.

To prepare for these responsibilities in professional practice, it is important to introduce patient safety principles during educational experiences. The Accreditation Council for Pharmacy Education (ACPE) and the American Society of Health-System Pharmacists (ASHP) have set forth accreditation standards focused on the management of medication-use processes to ensure these competencies during pharmacy didactic learning and postgraduate training.

The experience described here provides perspective on educational and experiential opportunities across the continuum of pharmacy education, with a focus on a relationship between a college of pharmacy and healthcare system. Various activities, including discussions, medication event reviews, audits, and continuous quality improvement efforts, have provided the experiences to achieve standards for these pharmacy learners. These activities support a culture of safety from early training.

Keywords: *medication safety, pharmacy education, safety culture*

Introduction

Medication errors remain a prevalent patient safety concern in healthcare settings and can result in patient harm, increased healthcare spending, and overall decreased patient confidence in healthcare systems.¹

As noted by the American Society of Health-System Pharmacists (ASHP), all members of the profession of pharmacy have a fundamental responsibility to impact medication safety. Pharmacists routinely lead medication safety efforts through formal medication safety leadership roles, medication error reporting and monitoring, and continuous quality improvement efforts. A pharmacist's medication-centered education makes them distinctively qualified to effectively carry out these responsibilities.²

Focused medication safety training, including participation in the management of medication-use processes and application of a systems approach, has been integrated into Accreditation Council for Pharmacy Education (ACPE) and ASHP accreditation standards of Doctor of Pharmacy and postgraduate pharmacy residency programs, respectively.^{3,4} Analyzing the complexities of the medication-use system and applying process improvement strategies prepares pharmacy professionals to make a meaningful impact on medication safety.

Herein we describe medication safety training for pharmacy learners, with a focus on the collaboration between the University of Houston College of Pharmacy and Houston Methodist. The University of Houston College of Pharmacy is accredited by ACPE. The College offers a four-year professional Doctor of Pharmacy program which graduates an average of 125 students per year. Houston Methodist is a healthcare system consisting of one academic medical center, six community hospitals, and one long-term care facility. There are nine pharmacy residency programs, offered including postgraduate year 1 (PGY1), postgraduate year 2 (PGY2), and combined PGY1/PGY2 programs.

The relationship between the College and Houston Methodist has existed for over three decades, primarily with the academic medical center, fostering the training of pharmacy students from early education to professional practice. Both also maintain relationships with other schools of pharmacy and healthcare systems for pharmacy educational experiences.

Didactic Education

The current University of Houston curriculum includes a two-credit hour "Patient, Medication Safety and Informatics" course in the summer semester of the students' first professional year.⁵ Course proficiencies include identifying information technology resources, principles of electronic clinical decision support tools, and types of medication errors within the medication-use process. In addition, students are also expected to discuss processes used to evaluate and prevent healthcare-related errors and key components in the quality improvement process to promote a culture of safety. Required coursework includes completion of modules from the Institute for Healthcare Improvement (IHI) providing certificates in quality improvement, patient safety, and basic quality and safety.^{6,7}

In the spring semester of their second professional year, students complete a one-credit hour "Leadership and Interprofessional Competence" course designed to foster professional practice roles and responsibilities within an interdisciplinary team. Pharmacy students work in small groups with nursing students and medical students to review components of a treatment plan, emphasizing the importance of effective communication and teamwork in patient care.

Experiential Education

College of Pharmacy

Pharmacy students have an opportunity to choose a medication safety advanced pharmacy practice experience (APPE) elective rotation in their fourth professional year within an institutional setting. Course proficiencies include understanding and performing a systematic approach to medication errors and medication-use safety and collaborating with interprofessional team members to optimize medication safety. These strategies are also applied to numerous other APPE rotations involving direct patient care activities where pharmacy student interventions, presentations, and projects reflect medication safety principles.

Required assignments for this specific rotation include a formal presentation and written assignment with topics approved by the preceptor. Presentations have included reviews of safety events to committees provided in a situation, background, assessment, and recommendation (SBAR) format. Pharmacy students have also provided reviews of Food and Drug Administration labeling updates and safety reviews or concerns provided by the Institute for Safe Medication Practices (ISMP) or other safety organizations. Anecdotally, pharmacy students have described a better understanding of the "ripple effect" of small actions throughout the health system with issues leading to medication errors themselves, and the policies and procedures created to mitigate them. Students also noted the vital role of pharmacists in medication safety initiatives and promoting a culture of safety.

Healthcare System

The Houston Methodist Hospital medication safety rotation experience aligns with ASHP guidelines and is designed to give students a broad perspective of medication management in a healthcare system.⁸

Students participate in medication-use reviews, medication error and adverse event reporting, and identification and implementation of risk reduction strategies. In reviewing medication safety event reports, students utilize critical thinking and problem-solving skills to identify process gaps and apply best practice recommendations to strengthen the medication use process.

Interdisciplinary collaboration is fundamental to improving patient and medication safety. Students shadow pharmacists in various practice settings throughout the institution, such as information technology (IT), the controlled substance diversion prevention team, pharmacy business management, and sterile preparations area. They attend and contribute to discussions at interdisciplinary meetings, including local and system medication safety committees and pharmacy and therapeutic committees.

Reading assignments and topic discussions may include ISMP's 10 Key Elements of the Medication Use System, defining medication errors and adverse drug events, error reduction strategies for improving system reliability and human reliability, Just Culture and human factors, and latent failures and system factors.⁹⁻¹³

Audits and process improvement projects are crucial to assessing the strength of safety nets throughout the medication-use process. Involving pharmacy students in audits helps them become familiar with application of key medication safety principles. Ideas for audits or process improvement may come from internal or external event reports or updated best practice recommendations.

As pharmacists' roles expand and evolve beyond traditional distributive functions, internship programs are tasked with enhancing learning experiences to provide value to the learner and the institution. The hospital offers experiential rotations across 21 clinical, administrative, and management settings where pharmacy learners are expected to incorporate learned medication safety concepts as they build skills in direct patient care, distributive functions, and project management. Longitudinal APPE are also provided at various hospitals in the health system, where a majority of the fourth-year rotations are completed at one site. As part of this experience, continuous quality improvement projects exploring the safety and efficacy of a medication or medication-related process are integrated as longitudinal assignment for successful completion of the program.

Students have made significant positive impact on patient safety through obtaining accurate medication histories; conducting audits of high-risk medications and processes; identifying, reporting, and investigating safety event reports; and educating pharmacy staff and other students on medication safety concepts across APPE rotations. For example, obtaining medication histories for direct admissions and after-hours emergency department admissions is a core component of clinical and institutional internship programs. Accurate medication history and medication reconciliation have been shown to reduce 30-day readmissions.¹⁴

Postgraduate Pharmacy Residencies

To ensure competence in the delivery of patient-centered care and pharmacy services, ASHP has established a set of goals and objectives for postgraduate residency training. Medication safety principles are reinforced as required competencies for PGY1 general practice programs as well as PGY2 programs. The resident is expected to evaluate and contribute to improvements in the medication-use system. Learning experiences should be designed to facilitate active involvement in the organization's medication safety program and continuous quality improvement initiatives.^{4,15}

Pharmacy residents acquire medication safety skills at Houston Methodist during rotational experiences and by completing longitudinal safety projects. On their required medication safety rotation, PGY1 residents participate in activities such as investigation of reported errors, analysis of complex systems, application of methodologies to analyze errors or proactively assess risks (e.g., root cause analysis, failure mode effect analysis), maximizing safety benefits of information technology, assessment of compliance with regulatory standards, and best practice recommendations from safety organizations.

Rotation assignments foster analytical, written, and verbal communication skills in a multidisciplinary teamwork environment. Residents present educational content from internal reviews or recent medication safety publications and prepare meeting minutes for the medication safety committee. In order to establish a foundation for applied practice, the rotation experience includes topic discussions about human, system, organizational, and environmental factors that influence safe and effective medication use. Examples include error categorization, Just Culture, human factors engineering, and review of the medication safety literature, among others. The residents contribute to organizational committee discussions related to medication-use systems and policies.

Rotations are available at the academic medical center hospital as well as at the system level, exposing residents to a myriad of experiences. System-level medication safety rotations focus on project-based strategies to address medication safety issues. This has included opportunities such as evaluation of medication safety self-assessment tools, implementation and review of large information technology updates, and development of metrics for measurement of effectiveness of smart infusion pumps. Regardless of the experience, the sharing of best practices and application of process improvement recommendations developed by these residents is encouraged across the healthcare system.

Continuous quality improvement (CQI) is a priority for healthcare organizations to enhance the quality of care provided while reducing healthcare costs.¹⁶ Pharmacy residents complete a medication safety-based CQI longitudinal project that seeks to systematically optimize medication-use processes. In order to manage these projects for a large residency group, a CQI board was established. The board includes medication safety pharmacists, leadership, and clinical pharmacists from multiple hospitals. The CQI board ensures that competencies related to understanding high-risk medications and medication safety concepts are met, as well as provides guidance in the project development, analysis, and implementation.

Project topics are identified from high-risk medication use, safety event trends, protocols, and frontline staff ideas. Examples of past projects include review of pharmacy-managed anticoagulation protocols and use of paralytic infusions, sulfonylureas, and hypertonic saline solutions, among many others. Residents are matched to projects and develop objectives with pharmacy preceptors. Project outcomes and recommended changes are presented to medication safety committees, nursing leadership, quality leadership, and medical staff. The expected project timeline is three to four months. Recommended changes from these projects have included policy updates, optimization of information technology tools, development of order sets, and educational efforts for clinician staff. The residents are involved in the discussion, implementation, and future evaluation of their CQI efforts which helps them understand the various steps required to execute updates, including education and communication efforts, review and testing of IT enhancements, and policy publication after approval.

Completion of a CQI project develops clinical, analytical, and strategic thinking, and leadership skills. Ensuring safe and effective medication use is a core responsibility of pharmacy professionals who are well positioned to advocate for patient safety.² Medication safety principles acquired during pharmacy residency training are transferable to advanced clinical and leadership roles in the diverse health systems.

Culture of Safety

Supporting a culture of safety within healthcare organizations is an essential component for preventing errors and improving overall healthcare quality.¹⁷ Many of the traits of a safety culture as defined by The Joint Commission exist throughout the pharmacy learner's medication safety journey. These include making safety a priority; valuing transparency, accountability, and mutual respect; recognizing that systems have the potential to fail; reporting errors to address system flaws; and creating a learning organization by learning from continuous improvement.¹⁸

By understanding a systems approach to errors and patient safety, pharmacists are encouraged to work towards change instead of deferring responsibilities on safety issues.¹⁹ In the experience noted here, this is evident among residents that transition to clinical roles within the organization as regular reporters of safety events, active organizers of process improvement opportunities, subject matter experts for high-risk medications or processes, and preceptors for pharmacy learners for the medication safety projects described. The training provided to pharmacy learners is meant to primarily support these safety values in their professional practices, but we have also regularly noted error reports and a desire to work towards improvement from them during their training experiences. A number of pharmacy residents have taken on medication safety efforts or management of medication management protocols in addition to residency requirements and continued their efforts for ongoing review if they remain within the health system after completion of the program.

These efforts have also led to greater discussion of how we care for caregivers in the pharmacy student and resident population. Safety leaders and pharmacy preceptors are tasked with supporting the caregiver through exhibiting the five rights for caregivers, including treatment that is just, respect, understanding and compassion, supportive care, and the transparency and opportunity

to contribute.²⁰ Continuing education opportunities have been developed for pharmacy preceptors to help them integrate caring for the caregiver support in rotation activities. The residency leadership team as well as the preceptors that developed care for the caregivers educational content remain available to support preceptors and residents during these events.

The need for patient safety education has been described across the continuum of clinical education for healthcare professionals.^{21,22} Various resources are available to develop these curriculums from the Agency for Healthcare Research and Quality, the Association of American Medical Colleges, and the American Association of Colleges of Nursing.²³⁻²⁶ Opportunities exist to integrate these concepts into clinical learning and should encourage interdisciplinary patient safety discussions.

Conclusion

Safe, effective delivery of patient care requires that pharmacy learners understand the complexity of the medication-use process and apply safety principles to their professional work. Integrating these concepts early in didactic and experiential training supports new pharmacists in their professional endeavors.

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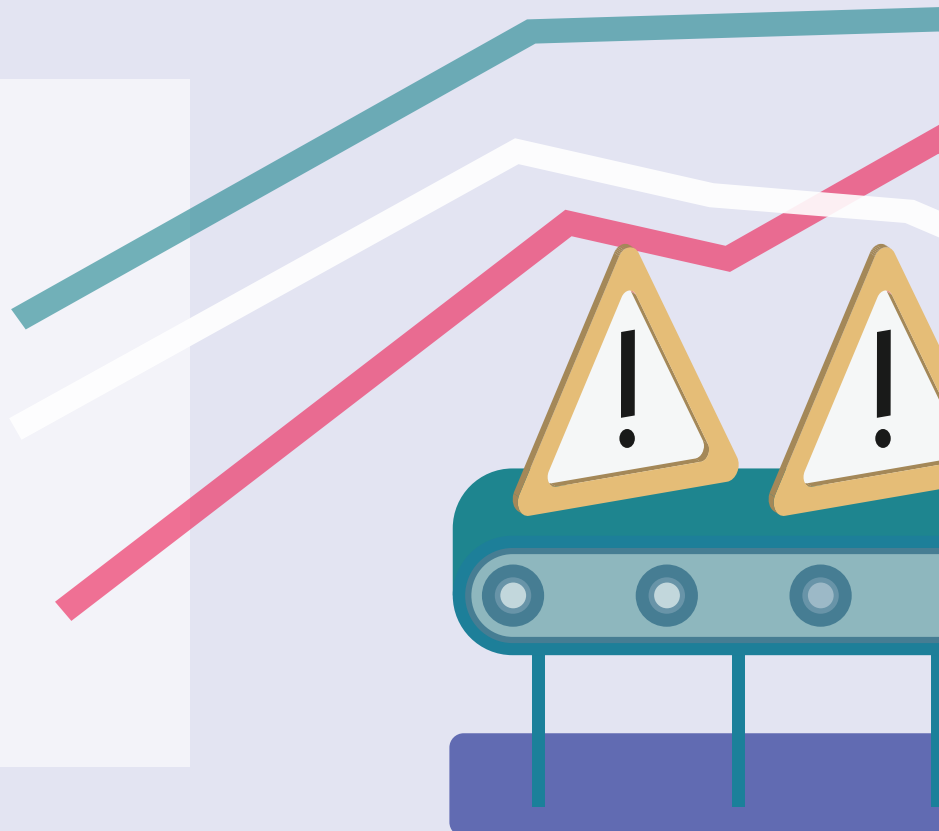
Developing Safe Habits for Practice

By **Daniel D. Degnan, PharmD**[◇]

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Fatal and nonfatal medication errors continue to occur in American healthcare. These are reported in a variety of ways and formats, and can include sensationalistic case reports about a patient receiving the wrong medication or more rigorous science-based research reports. It is often difficult to truly quantify the number of medication errors that occur in the United States each year and the associated costs.¹ Varied definitions used for the terms medication error, adverse drug event, and drug-related problems make for a toxic soup when trying to sort through the true impact and cost associated with medication mistakes.² In most instances, it should be enough to know that U.S. patients are harmed by medications each day by well-intentioned caregivers.



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One day in 1988, I was standing in my driveway about to receive my final grade for my high school driver's education course. The course had taken about two weeks to complete and included both classroom instruction and driving practice behind the wheel with an instructor. While I did well on the classroom portion, the whole process of driving each day for 60 to 70 miles was a nerve-wracking roller coaster of emotion. Frequently, I left the car drenched with sweat and exhausted by the experience. I wanted to do well, and I did not want to cause an accident. Our instructor was a hulk of a man that held a position of authority at my school: the dean of students. I have never forgotten what he told me as he gave me my grade (an A-): "Danny, you did a good job driving. You need to remember though, 'A' students make shoulder checks."

He was referring to checking over your shoulder when attempting to change lanes—a good habit to have while driving. In my own experience teaching the concepts of safety, I frequently find that drivers can identify the habits that accompany safe driving, such as driving the posted speed limit, coming to a complete stop at a stop sign, looking both ways at an intersection, wearing a seat belt, and using a turn signal when changing lanes or initiating a turn. When I ask healthcare practitioners, "What are some safe habits that you can use when providing care to patients?" usually the group can identify some habits, but they are much slower in coming to mind. Why does it seem to be so easy to identify safe habits of driving and so much more challenging to identify these types of activities when practicing pharmacy or other areas of healthcare?

In looking for literature about the application of habit formation and science in patient safety and healthcare, there does not seem to be much available. A study published in 2003 about the concept of improvement in the neonatal intensive care unit (NICU), across 34 medical centers, identified four key habits that organizations should use in improving performance:³ evidence-based practice, change management, collaborative learning, and systems thinking; however, it did not describe individual care practitioner habits that could be used.

A second study, published in *Critical Care Nurse* in 2014, attempted to review the evidence associated with established practice habits to determine if they should be perpetuated. It looked at the practice of turning patients, patient sleep in the acute care setting, feeding tube management in infants and children, and the prevention of venous thromboembolism.⁴ The study challenged established habits and tradition through the exploration of practice evidence for a group of practitioners (nurses) rather than an individual practitioner.

An opinion piece in the *Journal of the American College of Radiology* published in 2019 by Jacob Mandell exhorts the need for good habits to be demonstrated by radiologists.⁵ Dr. Mandell's article describes where bad and good practitioner habits may be on display in the radiologist reading room and even discusses the need for habit formation as it relates to safe practice. The article provides an initial glimpse into the world of habit science, healthcare, and patient safety.

In his bestselling book, *Atomic Habits*, James Clear breaks down the science of habit formation into four primary stages: cue, craving,

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Excellence is an art won by training and habituation.

—Aristotle

response, and reward.⁶ Truthfully, there are several great books that discuss the concepts of individual behavior change and habit formation.^{7,8} Individual practitioners applying these concepts to pharmacy can likely have a significant impact on safety. Behavior change and habit formation (or the elimination of a bad habit) can be hard work. One issue in particular that makes habit formation hard in pharmacy is that the reward associated with safe practice—not harming an individual patient—is often far removed from the actual act of performing safely. A great example of the dissociation between habit accomplishment and reward can be found in hand hygiene; very few practitioners are exposed directly to the reward of a safe patient as a result of washing their hands.

As a courtesy assistant professor at a college of pharmacy, I work with groups of highly talented, motivated, and bright students. As we teach students about patient safety, I find they can become nervous about the possibility of harming a patient by making a mistake. We teach about the system-based nature of error commission: An error is seldom related to a single human mistake, but rather is a result of a cascade of errors that led to a potentially harmful outcome for a patient. While recognizing the system-based nature of errors, students frequently ask me what they might be able to do to minimize their potential for making a mistake. The truth is that there are things that an individual practitioner can do, outside of whatever poorly designed system they may be practicing in, that can improve the ability to practice safely.

Getting a good night's sleep

A growing body of evidence points to the idea that adequate sleep can improve individual performance and minimize the potential for human-based errors.⁹ Industries outside of healthcare have identified this trend and in some cases mandated a minimal amount of sleep to avoid significant errors. As an individual practitioner, improving sleep hygiene can minimize the chance of making a mistake.

Reading the latest information on medication errors

When teaching third-year pharmacy students about the concepts of patient safety, we frequently review cases of tragic medication errors, including the cases of Emily Jerry and Eric Cropp, the 2006 heparin errors in Indianapolis, and the devastating case of Kimberly Hiatt and Kaia Zautner.^{10,11,12,13} The purpose behind discussing these situations is for students to understand the systemic nature of medication errors and the improvement principles needed

to make processes better. As part of the process, students learn how to openly discuss medication problems and about the need to address safety issues transparently.

One way of knowing the types of errors that can happen in your own practice is by learning from the lessons of others. There are many opportunities to further explore the principles of medication safety and error mitigation strategies. In the past year this journal, *Patient Safety*, has published articles on medication errors in outpatient care, the safety of vaccinations, medication reconciliation, and dosing errors that may result from inaccurate patient measurements.^{14,15} The Institute for Safe Medication Practices (ISMP) publishes a newsletter every two weeks that highlights medication error-prone situations and offers helpful and expert-based solutions. The Institute for Healthcare Improvement (IHI) and the American Society of Health-System Pharmacists (ASHP) both offer practitioner certificates in quality and safety.

Every practitioner should incorporate safety as a segment of their practice. The safety principles a practitioner uses should be based on the science of safety rather than just professional opinion, just as with the adoption or use of any other clinical guideline when practicing.

Developing a list of safe practice habits based on your own individual practice

Identifying the safe habits associated with the practice of pharmacy can be an enlightening exercise. In April 2019, I was asked to present on the topic of habit and its impact on patient safety to a national group of pharmacists and nurses. As preparation for that presentation, I asked a series of questions on two medication safety listservs (ASHP and ISMP). Specifically, I asked practitioners, “What are professional habits that may make a practitioner less likely to make an error?” I provided a list of examples as part of the request. I did not receive a significant number of replies; however, those that I did receive may be worth sharing. They included

1. Standardizing through specialization and inviting repetition with pauses
2. Performing checks for accuracy in the same order—every time
3. Taking a pause and physically taking a breath when dealing with complex orders
4. Inviting others to double check your work
5. Asking the same three questions for every medication order reviewed
 - What is the drug treating?
 - How is the drug dosed?
 - What patients should not receive this drug?

The constant quest for improvement is frequently accompanied by behavior change. Using the science of habit formation and behavior change in patient safety and pharmacy practice has the potential to bring exponential improvement to daily practice. Remember this quote by Aristotle, “Excellence is an art won by training and habituation.”¹⁶

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Safety Considerations for the Inpatient Medication-Use Process in Pediatric and Neonatal Patients

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The delivery of safe and effective health-care to pediatric and neonatal patients presents unique challenges to the medication-use system. The diversity of patients within this population and the consequences of ontogeny on pharmacokinetics and pharmacodynamics directly impact the safe use of medications in children and increase the risk of adverse drug events.¹ This review will explore the medication-use system for hospitalized children and neonates, discuss vulnerabilities within this system, and provide examples of advancements made to improve the pediatric medication-use system.

Keywords: *pediatric, neonatal, medication safety, medication use process, formulary, medication reconciliation, administration, ordering, dispensing, computerized physician order entry (CPOE)*

Introduction

The medication-use process within healthcare institutions involves several steps: medication procurement and formulary management, medication reconciliation, ordering, preparation and dispensing, administration, and monitoring.^{2,3} While all steps of this process are prone to medication errors², some steps may be more error-prone than others. An analysis of over 25,000 medication safety incidents reported during a nine-year period in neonatal intensive care units (NICUs) and pediatric intensive care units (PICUs) in England and Wales found that ordering and administration were the most error-prone steps (accounting for 29% and 53.5% of errors, respectively).⁴

This study also highlighted the vulnerability of our smallest patients to flaws in the medication-use system. Forty-eight percent of all medication incidents occurred in neonates (aged $\leq$ 28 days old) and 36.5% of incidents occurred in patients 1 month to 1 year old. Furthermore, while only 12% of incidents went on to cause patient harm, over 50% of these incidents occurred in neonates.⁴ This aligns with a previous study that

postulated that dosing errors due to rapid changes in weight and the use of specialized compounds predisposed patients in the NICU to medication errors with potential for harm.⁵

The Medication-Use System in Pediatric and Neonatal Patients

Despite the frequency of medication-related safety events in the pediatric and neonatal populations, children's hospitals have reported limited medication safety resources. A survey of children's hospitals found that only two-thirds of hospitals had a medication safety pharmacist. A similar amount of respondents reported that nursing spent at least half of a full-time equivalent working on medication safety activities. Additional medication support services came from physicians (30.8% of respondents), a medication safety and informatics coordinator, data analyst, and an industrial engineer.³

The increased risk of medication errors in pediatric and neonatal patients and inconsistent medication safety resources in institutions underscore the importance that all clinicians play an active role in strengthening medication-use system safety. As medication therapy experts, pediatric pharmacists play an important role on the pediatric care team. One study conducted at an 84-bed pediatric teaching hospital showed that pediatric pharmacists were able to reduce medication errors from reaching patients.⁶ Through participation in medical rounds and order verification, pediatric pharmacists identified 1,315 interventions over the course of a two-month period. The most common interventions were "drug therapy recommendations" (46%), where pharmacists recommended to change medication selection due to a change in the patient's clinical status (i.e., culture results) or allergies. "Errors" (24.5%) were the second most common intervention type, of which over 68% were prescribing errors.⁶ While this study underrepresented errors in medication administration, it highlights that pharmacists can reduce medication errors in collaboration with the care team.

Medication Procurement and Formulary Management

The medication-use system for pediatric patients begins with the procurement and management of the hospital formulary. Providing pharmacotherapy to pediatric and neonatal patients may require the use of unique medications and for medications to be used in a different manner compared to adult patients. Because of the intricacies of medication use in this patient population, pediatric clinicians should play an active role in formulary decisions for an institution.² Timely clinical data is typically used to inform institutional formulary decisions; however, this may not be readily available for pediatric and neonatal populations, and clinicians may extrapolate safety and efficacy data from adult studies.⁷ Pediatric clinicians can aid in formulary decision-making, especially given the frequent “off-label” use of medications in this patient population.^{2,7} When possible, it is suggested that a formulary specific to pediatric patients be implemented to limit concentrations and standardize dosages of high-risk and frequently used medications.⁸

Many commercially available medications are not designed for pediatric use. Pharmacies often use commercially available oral and intravenous products to engineer products that are suitable for children (i.e., oral liquid preparations or specific concentrations of intravenous medications).⁷ If unstandardized processes or multistep dilutions are utilized to compound specialized medications for use in pediatrics, the risk of a medication error increases.²

Medication Reconciliation

Medication reconciliation can play a key role in prospectively identifying errors with medications. A single-center, prospective, observational study of children admitted to a university hospital in Spain found that 41% of pediatric patients admitted had a discrepancy between their best possible medication history and their prescribed treatment on admission.⁹ It is crucial that clinicians conducting medication reconciliation are familiar not only with the medications used to treat pediatric patients, but also the dosing regimens and formulations. While clinicians prescribe medications in terms of milligrams, grams, and other standardized units, family members may only know the volume of the medication that they are to administer. Since many medications used to treat children are available in varying concentrations, this can create confusion regarding the dose being delivered to the child. For example, amoxicillin-clavulanate is available in varying concentrations. Although the medication is dosed based on the amoxicillin component, the strengths are not interchangeable due to differing ratios of amoxicillin and clavulanic acid. (See **Table 1**.)

In addition to confusion regarding commercially available products, extemporaneously compounded products are commonly prescribed when treating children and pose unique challenges for medication safety. Compounded medication formulas are not standardized and some formulations have not been extensively studied. Additionally, universal adoption of studied formulas has not been embraced widely within the pharmacy community, and individual compounding pharmacies may develop their own formula. To address and correct these differences, the American Society of Health-System Pharmacists in collaboration with the Food and Drug Administration (FDA), The Joint Commission, and the Institute for Safe Medication Practices began the Standardize 4 Safety initiative. This program aims to regulate concentrations of oral and intravenous medications to decrease medication errors,

Table 1. Amoxicillin-Clavulanic Acid Ratios¹⁰

Concentration of Amoxicillin (per 5 mL)	Concentration of Clavulanic acid (per 5 mL)	Ratio
125 mg	31.25 mg	4:1
200 mg	28.5 mg	7:1
250 mg	62.5 mg	4:1
400 mg	57 mg	7:1
600 mg	42.9 mg	14:1

primarily around transitions of care where medication reconciliation is taking place. In addition to improving the accuracy of medication reconciliation, standardization can benefit other areas of the medication-use process as well.¹¹ Some organizations, like the Michigan Pediatric Safety Collaboration, have launched a statewide coalition to standardize the compounding of oral medications used in pediatrics and publishes validated compounding formulas online (www.mipedscompounds.org). Nationwide Children’s Hospital in Columbus, Ohio, has also published validated compounding formulas online (www.nationwidechildrens.org/specialties/pharmacy-services/compounding-formulas).

Medication Ordering

The medication ordering step of the medication-use process is highly vulnerable to medication errors. The cause of this is multifactorial; however, calculation errors, lack of FDA-approved dosing guidelines, and inconsistent units for dosing regimens likely contribute to the risk of errors in pediatric populations.² Most established doses in pediatric and neonatal patients are weight-based, which may increase risk of calculation errors. These dosing regimens may be reported in a variety of ways, such as milligram/kilogram/dose versus milligram/kilogram/day. This is also seen in critical care settings with the use of continuous infusions (milligram/kilogram/minute vs. milligram/kilogram/hour). Inconsistencies among ordering may lead to discrepancies further along the medication-use process, and careful attention must be paid to units when orders are placed.²

Given that pediatric and neonatal dosing recommendations are typically provided in terms of body weight or body surface area, errors in obtaining anthropometric data are a frequent cause of medication errors. Recording accurate anthropometric information is essential in preventing these errors. One study that measured medication errors in children who presented to the emergency room found that 31% of weight errors included the substitution of weight in pounds for the weight in kilograms and 6% of weight errors included decimal place errors.²¹ Furthermore, this study highlighted that this risk is compounded when the weight is used for multiple medication orders. Forty-three percent of weight errors that were involved in a medication error caused more than one medication error.²¹ An accurate patient height is critical to calculating creatinine clearance for renal function assessment and for calculating body surface area, which is used when dosing certain medications. According to the Pennsylvania Patient Safety Reporting System (PA-PSRS), 679 reports have been identified in relation to an inaccurate patient height.¹² The most common transcription errors

were the use of the wrong unit of measurement, the substitution of another measurement with height, and typographical errors. These inaccurate patient heights most often led to errors in calculation of medication doses or the input of certain laboratory values.¹²

One method used to improve patient safety and standardize ordering practices is the use of computerized physician order entry (CPOE) systems. CPOE systems should be capable of ordering medications based on weight for pediatric and neonatal orders, and should only use one unit of weight to prevent the need for unit conversion.¹³ A 2016 survey of pediatric hospitalist programs reported that 90.6% of programs used order sets or CPOE orders with pediatric weight-based dosing, 79.7% review pediatric medication safety events or concerns, 58.7% were aware that their hospital had defined or documented maximum doses on orders, and 50% had milligram-per-kilogram dosing required to be in the order.¹³

Implementation of CPOE systems eliminates paper transcription in hospital settings and allows for the implementation of clinical decision support (CDS), which are computerized prompts that aid healthcare providers in the implementation of clinical guidelines, and the addition of hard and soft stops when prescribing in real-time. It also streamlines the transcription process, as physicians and pharmacists have access to the same interface. The implementation of CPOE systems, specifically those with CDS systems, in hospitals have shown a decrease in potentially harmful medication errors.¹³ While CPOE and CDS systems have the potential to improve safety, they may also have unintended consequences. One study reported barriers in communication between members of the medical team and between the medical team and patients as a result of CPOE implementation.²² Given the advantages in safety that these systems afford, healthcare professions must collaborate to overcome potential communication issues to enhance patient safety.

CPOE in Parenteral Nutrition

Parenteral nutrition (PN) is the most complicated intravenous (IV) solution ordered in hospitals. Given the multitude of components of PN, the ordering process is highly error-prone. CPOE has been shown to reduce ordering errors for PN. MacKay and colleagues evaluated the rates of medication errors in PN prescription, transcription, preparation, and administration after implementing the CPOE system.¹⁴ The CPOE program was compliant with standards from the American Society for Parenteral and Enteral Nutrition (ASPEN) and integrated hard and soft stops. After seven years, researchers found that there were statistically significant cost reductions and lower error rates (2.7/1000 PN) than the national average (15.6/1000 PN).¹⁴

CPOE systems also allow for increased interdisciplinary management strategies, such as the automatic data transmission including electronic health records (EHR) between all healthcare professionals. The integration of CDS, including the implementation of appropriate hard and soft stops, minimizes potential errors.

Neonatal-Specific CPOE Systems

While the implementation of CPOE systems has led to an overall decrease in medication errors, many systems do not have the proper interfaces to allow for pediatric- and neonatal-specific prescription entries. Integrated CDS alerts also do not take into account this population, and many adult-focused dosing alerts must be overridden,

increasing the time to medication administration. The introduction of pediatric- and neonatal-specific CPOE systems may be beneficial in the prescribing process.

A study published in 2020 designed and developed a neonatal-specific CPOE and investigated the efficacy in medication error reduction. In comparison to handwritten orders, the neonatal-specific CPOE reduced neonatal medication prescription errors, time for dose calculation, and electronic documentation of medical records.¹⁵

Medication Preparation and Dispensing

Pediatric and neonatal patients require personalized care, which includes utilizing weight-based dosing for medication dosing and extemporaneous compounds. Many commercially available dosage forms are designed for adult use and may not be appropriate for use in children based on their size or comorbidities. The commercially available standard adult concentration of some intravenous medications may be too dilute for use in neonates and children who have restrictions on their daily fluid volume.² Additionally, commercially available dosage forms may require manipulation to obtain a weight-based dose for a child.⁶ For example, tablets or suppositories may need to be cut to deliver a smaller dose, capsules may be opened and mixed with food or beverage prior to administration, or medications manufactured for IV use may be given orally.² While these practices may not be avoidable, they are often not validated, may lead to alterations in the bioavailability of the medication, and have unknown beyond use dating.²

Compounding parenteral solutions for children often includes an increased risk of error in comparison to compounding for their adult counterparts. Parenteral solutions designed for pediatric and neonatal patients may involve more calculations, dilutions (i.e., aliquots), and manipulation of commercially available products to achieve the desired dose or concentration. One advancement in IV compounding safety that may be utilized is IV workflow management systems. These systems are designed to automate the preparation and verification of compounded sterile products.²³ By automating calculations, utilizing barcode scanning for each ingredient prior to mixing, and employing gravimetric analysis to confirm the accuracy of the components included in the solution, IV workflow management systems reduce human error in compounding.²³ While not available at all pediatric hospitals, these systems can be used to improve the safety and accuracy of compounding processes, and are becoming more popular among pediatric institutions.

With a variety of products and concentrations used for treating pediatric and neonatal patients, a risk of error is present when dispensing medications. The use of a color-coded medication safety system in a community pediatric emergency setting was shown to decrease medication delay and improved nursing accuracy.¹⁶ During a simulated emergency resuscitation, the use of pre-filled, color-coded syringes led to a reduction in dosing errors.¹⁶

Administration

As described previously, one study showed that errors in medication administration account for over 50% of medication errors in the NICU and PICU.⁴ Further characterizing these errors, another study from Turkey found that the most common types of error in medication administration were time errors or dose errors, with a majority of factors leading to the errors being system-based.²⁵

Other studies have emphasized the drug class as being related to the risk of error, with opiate, antibiotic, and sedative drugs being the most likely to be involved in medication administration errors.²⁶ While the cause of medication-administration errors is multifactorial, proper safeguards and technology should be put into place to reduce the risk of errors.

Despite the risk of error in medication administration, advances in healthcare technology have improved the safety of this process. Bedside barcode scanning is used to validate that the right medication is given to the right patient at the right time. Infusion pumps and syringe pumps can deliver small doses of medications with high accuracy and have programmable soft and hard stops that can catch administration errors.^{1,17} While these technologies have helped to make medication administration safer for pediatric and neonatal patients, they require development and maintenance of barcode and infusion pump libraries.

While the use of syringe pumps and their libraries has improved the safe infusion of medications, risk of inconsistent medication delivery for pediatric and neonatal patients is still present. A 2016 FDA Safety Communication details a risk of poor flow continuity (defined as an inconsistent rate of delivery) at low infusion rates (especially with flow rates less than 0.5–5 mL/hr).²⁴ These rates are commonly used for medication administration in neonates and smaller pediatric patients, especially when titratable medications are used (e.g., fentanyl, midazolam, dopamine, epinephrine). Lack of flow continuity can lead to a delay of therapy, over- or underinfusion, and adverse effects.²⁴ To mitigate these risks, the FDA recommends using the smallest size of syringe that is compatible with the syringe pump, using the shortest length of small-bore or microbore tubing possible, minimizing dead space from inline filters, and limiting the number of connection sites in the line.²⁴ Electronic priming of the syringe pump before starting the infusion or after replacing a near-empty syringe and keeping the syringe pump level with the distal tip of the catheter should be done whenever possible.²⁴

Specialized administration sets have recently been developed to reduce the administration of medications by the incorrect route. Aerosolized medications can be given through Aerogen tubing, which is colored blue.¹⁸ The EnFit system is used to administer enteral nutrition and medications through special tubing, which is colored purple. These systems enhance the safety of administration because they are incompatible with tubing and syringes designed for intravenous use.¹⁹

Monitoring

Pediatric and neonatal patients require thorough, consistent pharmacovigilance monitoring because of their vulnerability to adverse effects of medications and the complexities of the medication-use system. Pediatric pharmacists work with the pediatric care team to ensure safe medication use and monitor response to therapy. Pediatric pharmacists have also been shown to decrease the incidences of medication errors in inpatient pediatric settings, including intensive care units. The Pediatrics Practice and Research Network (PRN) of the American College of Clinical Pharmacy (ACCP) and the Pediatric Pharmacy Association (PPA) advocate for the expansion of qualified clinical pharmacists as a member of the multidisciplinary team for the benefit of pediatric patients.²⁰

Conclusion

The complexity of providing care to pediatric and neonatal patients leaves them vulnerable to medication errors within the medication-use system. These young patients are managed differently because they require specialized dosage forms and utilize weight-based dosing. Advances in patient safety like standardizing extemporaneous medication preparation, CPOE, and EnFit can help to make the medication-use system safer. Clinicians caring for these patients, including pharmacists, can help improve the medication-use system and make a difference in providing safe care for these patients.

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Immunization Stress-Related Responses

Mitigating Patient Fears and Associated Side Effects Amidst a Global Vaccination Effort

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Discussion

Adverse Events Following Immunization

The Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO) defines an adverse event following immunization (AEFI) as “any untoward medical occurrence which follows immunization and does not necessarily have a causal relationship with the usage of the vaccine.” It may manifest as any unfavorable or unintended sign, abnormal laboratory finding, symptom, or disease. There are five subcategories of AEFIs, which differentiate vaccine and immunization-related reactions from coincidental events (**Figure 1**), and a causality assessment is needed to assign an event to one of the subcategories. The subcategories include vaccine product-related reaction, vaccine quality defect-related reaction, immunization error-related reaction, immunization anxiety-related reaction, and coincidental event. In 2015, WHO’s Global Advisory Committee on Vaccine Safety (GACVS) expert working group changed the term immunization anxiety-related reaction to immunization stress-related response. The goal was to more adequately capture all elements of how this cause-specific AEFI may present.²

Healthcare providers are required to report certain adverse events to Vaccine Adverse Event Reporting System (VAERS), a national passive surveillance system that monitors vaccine-related adverse events. These include any shoulder injury related to vaccine administration or vasovagal syncope within seven days of administration and any acute complications or events listed in the manufacturer’s package insert as contraindications to additional doses at any time. Healthcare providers are also strongly encouraged to report other adverse events regardless of if it has been validated that the vaccine caused the event, in addition to vaccine administration errors. Patients are encouraged to report any adverse events directly to VAERS as well.^{2,3}

Following immunization, all patients should be observed in a dedicated area for approximately 15 minutes. If patients had a history of allergic reactions to vaccines, they are asked to wait for 30 minutes, as this increases their likelihood of having an allergic reaction to other vaccines.

The event of receiving a vaccine can lead to feelings of stress and anxiety for many patients and may present as adverse events. With coronavirus disease 2019 (COVID-19) mass vaccination efforts, adverse events following immunization, including immunization stress-related reactions (ISRR), have subsequently increased. Traditionally rare, but increasingly common, cluster events have also become a concern. Demonstrated in recent publications by Hause et al. concerning Janssen (Johnson & Johnson) COVID-19 vaccine clinics, these adverse events can lead to personal apprehension towards receiving vaccines, as well as public distrust towards the immunization process. To combat ISRRs, mass vaccination clinics across the United States must create administration protocols to mitigate these responses. Anticipation and swift management can play a substantial role in minimizing frequency and severity of these reactions and prevent future vaccine hesitancy.

Keywords: medication safety, immunizations, COVID-19, immunization stress-related responses, anxiety, adverse events following immunization, cluster events, Janssen, Johnson & Johnson

Introduction

In the United States alone, coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has claimed the lives of over 700,000 people as of October 2021.¹ Since the start of the pandemic, the nation has seen the development of three novel vaccines all fast-tracked for public use under the Food and Drug Administration’s Emergency Use Authorization (EUA). While research for mRNA vaccines began well before COVID-19’s onset, the pandemic proved an opportune time in their development and distribution for public use. Healthcare organizations subsequently worked for the rapid implementation of vaccinations for the sake of promoting and preserving public health. While Americans have the benefit of several vaccine products to help combat the pandemic, anxiety and stress concerning the vaccination process has proven to be a significant issue of medication safety. When severe enough, stress can manifest as vasovagal-mediated reactions, including tachycardia, hyperventilation, and syncope, surrounding administration. Vaccinators must be aware of the possibilities of these reactions and be prepared to care for patients who are under vaccination-related stress to ensure patient safety and eliminate anxiety as a barrier to vaccination.^{1,2}

Figure 1. Subcategories of Adverse Events Following Immunization (AEFI)²

Vaccine product-related reaction	Vaccine quality defect-related reaction	Immunization error-related reaction	Immunization anxiety-related reaction*	Coincidental event
An AEFI that is caused by or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product	An AEFI that is caused by or precipitated by a vaccine that is due to one or more of the vaccine product including its administration device provided by the manufacturer	An AEFI that is caused by inappropriate vaccine handling, prescribing, or administration	An AEFI arising from anxiety about the immunization *Formally retermed immunization stress-related reaction (ISRR) to more adequately capture all elements of how this cause-specific AEFI may present	An AEFI that is caused by something other than the vaccine product, immunization error, or immunization anxiety

Table 1. Contributing Factors to Immunization Stress-Related Responses^{2,3}

Biological Factors	Psychological Factors	Social Factors
Age Sex at birth Body mass index	Personality Ability to understand and reason Preparedness for the event Underlying anxiety Perception of pain	Community's trust in healthcare Societal norms and values concerning immunization Community and family support Social media influences



Immunization Stress-Related Response

Immunization stress-related response (ISRR) is an AEFI related to the process of immunization and involves a combination of biological, physiological, and psychological factors (Table 1).^{2,3}

Responses as such usually begin with symptoms immediately prior to, during, or after immunization and have been observed to occur in two phases. Initially, the response will manifest as an acute stress response which activates the sympathetic nervous system. Commonly this is described as feelings of apprehension, tachycardia, heart palpitations, difficulty breathing, and hyperventilation. This may be followed by an overcompensatory parasympathetic response in which heart rate or blood pressure significantly decreases, which will produce a vasovagal reaction.² This phase can result in dizziness; syncope; or in severe cases, syncopal hypoxic seizures. ISRR may also manifest as a dissociative neurological symptom reaction (DNSR), most frequently documented as when patients are affected in clusters (mass psychogenic illness). DNSR manifests as weakness or paralysis, abnormal movements or posture, and speech difficulties or even nonepileptic seizures.³ While in general ISRRs that manifest as an acute stress response need not be reported, vasovagal reactions with syncope and DNSR must be reported.

Emergent Cluster AEFIs

A cluster of AEFIs is two or more cases of the same adverse event related in time, place, or vaccine administered.² Clusters of AEFIs without an identifiable physiological cause have been reported in several countries even prior to the pandemic. AEFIs have become a large focus of public concern since the EUA of the COVID-19 vaccines. With the mass movement to vaccinate against COVID-19, there has been a considerable increase in the reporting and incidence of cluster events. Cluster responses often result in loss of confidence in the immunization programs with subsequent reduced vaccine coverage.

An article was released in May 2021 regarding anxiety-related adverse event clusters at mass vaccination sites for the Janssen (Johnson & Johnson) COVID-19 vaccine.⁵ Sixty-four anxiety-related events were reported from five mass vaccination sites in different states from April 7–9, 2021, among 8,624 vaccine recipients. In the report, an anxiety-related event was defined as tachycardia, hyperventilation, dyspnea, chest pain, paresthesia, light-headedness, hypotension, headache, pallor, or syncope during the 15-minute postvaccination observation period. Reports of syncopal events that occurred off-site, over an hour after vaccine administration, and in patients who received diphenhydramine or epinephrine were not included.

Table 2. Immunization Stress-Related Response Mitigation Strategies^{2,4,5}

Screening Strategies	Observation Strategies	Response Strategies
Allergy history Underlying concerns Administration history Administration preferences	Mandated wait time Dedicated personnel	Emergency medical service on-site Supportive care Transport availability

The most commonly reported symptoms were light-headedness or dizziness (56%), diaphoresis (31%), syncope (27%), nausea or vomiting (25%), and hypotension (16%). No event met the VAERS classification of serious. Most events resolved within 15 minutes with supportive care; 13 patients (20%) were transported to an emergency department for further evaluation. Four out of five sites temporarily suspended vaccination after reporting multiple events on a single day. Many sites have previously offered mRNA vaccines without report of similar cluster of events and were administering the Janssen vaccine for the first time on the day the clusters were reported.

The Janssen vaccine was not directly compared in a head-to-head trial with the mRNA COVID-19 vaccines currently available; however, compared to influenza vaccinations, reports of syncope were about 164 times more common after the Janssen COVID-19 vaccination (8.2 per 100,000 vs. 0.05 per 100,000 doses).⁵ Stress due to the pandemic, mass vaccination situations, and needle aversion may contribute to the high rate of syncopal events. For example, those selecting a single dose vaccine may experience a greater aversion to injections in general. Other considerations include possible reporting bias in comparison to the influenza vaccine. VAERS data is limited by the information reported as numbers of adverse events are often underreported.⁵ Unique to the COVID-19 vaccines, a v-safe program was established to prompt responses in reporting that are not in place for other vaccines, such as influenza.⁶

ISRR Mitigation Strategies

In order to mitigate AEFIs, including ISRRs, many mass-vaccination clinics and health systems have emphasized individual procedures and guidelines to screen, observe for, and appropriately respond to vaccine-associated adverse events (**Table 2**).^{2,4}

With widespread
implementation of patient
screening, observation,
and reporting services,
potential for vaccine-
related adverse events can
be minimized

Many vaccine centers inquire a history of vaccine reactions and patient preferences regarding vaccination through screening prior to administration. Discussions with the patient can illuminate preexisting concerns surrounding the vaccination process and dissuade fears through patient education on the drug product and the disease it protects against. Should the patient have any further concerns, private spaces for vaccinating can be offered. The individual can have their vaccine administered in a quiet environment or while in a recumbent position. For those with advanced needs, well-equipped facilities can offer specialized administration rooms that work to minimize sensory concerns amidst a welcoming and comforting environment.

Following immunization, all patients should be observed in a dedicated area for approximately 15 minutes.⁵ While the observation period is not typical of other vaccines, additional precautions should be taken given that the vaccines are continuing to be studied and are administered under an EUA status (with the exception of the Pfizer vaccine for adults as of August 2021).⁷ If patients had a history of allergic reactions to vaccines, they are asked to wait for 30 minutes, as this increases their likelihood of having an allergic reaction to other vaccines. It is important to consider that ISRRs can manifest at any point during the vaccination process, including after. Should there be any immediate reactions, vaccine product- or stress-related, they can be identified and managed early to reduce response severity and potential for residual cluster events.

If a patient should experience an adverse event postvaccination, observation staff should be trained in the proper protocol to address patient needs and contact local or on-site emergency medical services (EMS) as necessary. Many times, mild, anxiety-related responses can be managed with patient reassurance, hydration, and time. However, if symptoms of a true allergic reaction occur shortly after vaccine administration, observation staff should notify on-site EMS personnel who can further assess the patient; triage the patient for further management; and, if necessary, administer pharmacotherapy.^{4,5}

Conclusion

In the wake of the COVID-19 public health emergency, mass vaccination efforts in all populations have driven an increase of ISRR reporting. As medical professionals, it is essential to consider the multimodal origins of this risk and account for it before, during, and after vaccine administration. In the setting of comparatively large vaccination centers, this phenomenon has presented more routinely and has demonstrated a need for

comprehensive systemwide protocol development to mitigate risks. With widespread implementation of patient screening, observation, and reporting services, potential for vaccine-related adverse events can be minimized, including subsequent potential for cluster events. In such an unprecedented time, combating vaccine hesitancy is key to ensuring a return to normalcy amidst a global pandemic and optimizing patient outcomes through disease prevention.

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Mast is employed by the UPMC South Side COVID-19 Vaccine Center and has been instrumental as a community vaccinator in helping families across 10 different counties in Western Pennsylvania achieve full-immunization status. Throughout his time in pharmacy school, Mast has been involved in several quality improvement projects directed toward electronic alert system optimization in both the inpatient and transitions of care settings. He has co-authored a manuscript concerning drug-induced acute kidney injury (AKI) alerting systems, pending approval and publication.

As he approaches graduation, Mast has had the privilege of developing and leading several premiere student organizations at the University of Pittsburgh. Serving as president of the Kappa Psi Beta Kappa Chapter, he has the distinct honor of leading a 107-member organization in receiving international recognition as Top Performing Chapter with individual awards in the categories of COVID-19 Pandemic Advocacy, Philanthropy, and outstanding contributions. Mast also co-founded the first national chapter of the Student Society of Cannabis Pharmacists at the University of Pittsburgh, and has since worked to substantially expand the realm of cannabis education.

Yihan Li is a fourth-year Doctor of Pharmacy candidate at the University of Pittsburgh School of Pharmacy with an area of concentration in the Pharmacotherapy Scholars track. Her areas of interest include critical care and inpatient pharmacy leadership. Her postgraduate goals include completing a PGY1 and a PGY2 in critical care.

Li's recent research projects include evaluating the efficacy of aldosterone antagonists in heart failure with preserved ejection fraction, the performance of an electronic alert system for drug-induced acute kidney failure, and the use of symptom-based benzodiazepine treatment versus phenobarbital prophylaxis in alcohol withdrawal patients.

Li also has a variety of pharmacy leadership involvement. She is a National Member-at-Large of Phi Lambda Sigma Pharmacy Leadership Society and priorly was the president of her local chapter. She has been extensively involved in American Pharmacists Association Academy of Student Pharmacists (APhA-ASP), in which she was the chapter patient care vice president. Li is also a chief pharmacy intern at UPMC Presbyterian Hospital.

Beyond Academics:

Looking at the **Whos**, **Whats**, and **Whys** in Pharmacy Education

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Academic pharmacy is ingrained in Patrick McDonnell's DNA. He has spent nearly three decades of his professional career at Temple University School of Pharmacy: first as a student; then as a resident; and, since 1999, as a teacher. In his coursework he passes on the lessons and experiences learned over years as a practicing pharmacist—especially the thousands of stories he has been collecting about adverse drug reactions.

We spoke with Professor McDonnell, guest editor of this issue, about what draws him to his work in both the hospital pharmacy and the classroom, and the unique and vital role pharmacists play in delivering safe, efficient patient care.

Eugene Myers: Tell us about the PharmD program at Temple University.

Patrick McDonnell: Our program is a four-year program, and it starts off the first year with basic pharmaceutical sciences and background information courses in biochemistry, microbiology, and immunology. These are the foundation courses for which pharmacists will start learning drug therapy and patient-specific application.

We segue into courses such as pharmacology and medicinal chemistry, the structure and the function of the drugs. And then coursework to go over the pathophysiology and the therapeutics of how the drugs actually treat diseases. But more importantly, how to treat diseases in a patient-specific fashion. That's really the finesse of pharmacy. As I always say, "One size doesn't fit all."

Some courses that I teach segue into that mantra, focusing on adverse drug reactions in an organ-system fashion, what I like to call drug-induced disease. For example, in my lecture entitled Drug-Induced Cardiotoxicity, I go over how drugs can actually cause certain disease states, such as arrhythmias or hypertension. What I tried to incorporate in the course is how we can identify patients that are at risk and mitigate the harm from drugs, and—again, one size doesn't fit all—to keep patients safe from the harm from drugs while optimizing efficiency.

Additionally, piggybacking on those courses, I teach and coordinate courses with faculty members from the Institute for Safe Medication Practices, better known as ISMP. These are courses that cover medication error theory, including root cause analysis of error-prone situations along the medication-use process system. We look at the "whys." Why do these errors occur? What went wrong in the system?

And we also focus on a course where the students do what's called an FMEA, failure modes and effects analysis, and how they could apply that to situations to promote medication safety. And the goal of all these courses is to make our future pharmacists ready to practice safely. And that's really apparent with their introductory pharmacy practice experiences, but more so in their last year of pharmacy school, in which they perform 48 weeks of what's called advanced pharmacy practice experiences, which is known as "the rotations." They're doing mandated experiences in community pharmacy, institutional pharmacy, generally which is the hospital setting. And then clinical rotations, one in ambulatory care and one in institutional care.

They also have electives, one of which provides a more in-depth focus on medication safety. Students spend six weeks with patient

safety officers, or pharmacists that act as patient safety officers at certain hospitals. They also spend time with large pharmaceutical companies or "Big Pharma," where they work in adverse event reporting. We also have a rotation with the Poison Control Center. And they sit and they listen to when clinicians and people actually call in and say, "There could be a potential overdose." So we do try to gear some of the experiential experiences for the people that take this safety track to reflect what's going on in the real world practice.

You talked about the community rotations, and right now this is pretty much an unprecedented time in pharmacy with the COVID vaccination efforts. What has that experience been like for the students? How has that been working?

I think it's actually been working very well. In fact, we recognize the importance, particularly in the state of Pennsylvania, where students were allowed to get emergency license to be immunizers. And I'm actually proud to say that over the winter, the efforts of my colleagues actually conducted APhA [American Pharmacists Association] accredited immunization certification programs that met state requirement.

And as of today, I would say 90% of our student body are certified immunizers, including myself. It really shows our role as pharmacists. Pharmacies are everywhere. And our students that work in the pharmacies in the community, they are allowed to vaccinate. We have paired up with many clinics throughout the region where students and faculty are immunizers.

And that includes community clinics and clinics that are in the hospital settings where our faculty practice. So that's one thing that I'm proud of, that we did recognize the need and had a yeoman's effort to get our students to be licensed vaccinators. It's actually a pretty intense course. There's more to just sticking a needle in an arm when giving vaccination. It includes courses in ACLS [advanced cardiac life support] and CPR [cardiopulmonary resuscitation]. So I'm really proud that our administration realized the importance of that.

What's been one of the biggest challenges in your work?

Some of the courses that I teach are very detail oriented. And I tell students, "You're going to pharmacy school, which means you're spending four years just to study drugs. As a member of this integrated healthcare team, you need to know more about drugs than everybody else on that team."

So students sometimes don't like the level of detail that I expect of them, but I think they realize once they start getting out on rotations, and once they start practicing, "Oh yeah, he was right." And the hundreds of graduate pharmacists that are now colleagues and friends, they still remember things that I said in my course that they thought was maybe demanding or too detail oriented, but now appreciate it when they're in practice.

It's almost like the parent knows better, and until they actually see it in practice—sometimes that's a challenge. How do I confer that, the importance of this to them? One of the things that I do is, I tell stories. I collect data on adverse reactions. And over the past 20 years have collected nearly 8,000 adverse drug reactions that occurred in patients, and analyzed them, and reported on them.



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And sharing these stories in, of course, a non-patient-identifiable way really brings the point home to a lot of these. That's how I try to overcome some of the barrier of the details that I expect of them.

Because by telling a story, it may make a better impact. And if they remember something that I said when they're in practice, and they see a certain drug or a certain situation, they may remember this error-prone situation to prevent it from happening again.

There's more than 10,000 FDA [Food and Drug Administration] approved generic drugs. Nobody could understand everything. But if we at least focus on the top 200 that I know you're going to see as a new pharmacist, that's a good start. The details really come with experience, but we focus on some of the most common drugs that can cause patient harm.

On the flip side of my previous question, what's been one of your biggest successes, or your proudest achievements?

When I work at Temple Hospital, I would say 80% to 90% of the pharmacists there were my former students. And working with people that were my students that now are my colleagues, and that they're exceptional pharmacists, and seeing them work in practice and utilizing some of the tools that we all taught them here—that's one of my proudest moments, actually coming into work. They sometimes laugh, they call me "senior pool pharmacist," because I've been working there in the pool for 24 years. But it's having that comradery with them, that type of respect with them as now working pharmacists.

What a gift to be able to see, firsthand, the impact of what you're doing, and what your colleagues are doing at the school.

Yeah. And I still love working as a pharmacist. It might be one or two shifts a week, if that. But it keeps me connected as an educator, that I'm not in the proverbial ivory tower. I'm in the real world working as a pharmacist.

All during COVID, pharmacies didn't go on lockdown. We didn't know what was going on in March 2020. Everyone working at Temple Hospital had to get a pass to put in our car in case we were stopped, that we were considered to be an essential worker. So I'm working at the hospital and wearing my double mask and

goggles, and opening doorknobs with napkins, and in the early time we didn't know what was going on, but it just demonstrated that you're on the front line.

Who would make a good academic pharmacist? What should someone know if they're interested in that field?

I believe teaching is a vocation. I believe that you have to have a drive to want to be a teacher, because certainly in other areas of pharmacy, it can be more lucrative. So number one, it's a calling. It's a vocation. Having a good experience going through postgraduate training, such as residencies, and now where some teaching is introduced in these postgraduate programs. So people may get the taste for it, and then they may decide that is going to be my career. But there has to be an inner passion to be an educator.

Makes sense. So considering the current state of medication errors and looking ahead, what are some of the major issues we need to address in pharmacy and/or in pharmacy education?

It has to be communication. Open communication, not looking at blame, not looking at, "Oh, well, you prescribed this wrong" as a physician, or as a pharmacist. "You missed this," or as a nurse, "You gave this at the wrong time," or the wrong rate, or the wrong route of administration. So it needs to be communication and mutual respect for what everybody does in the healthcare system, and what our roles are, and how they interplay amongst each other.

Patrick McDonnell is a clinical professor of Pharmacy at Temple University School of Pharmacy. He received a Bachelor of Science in biochemistry from the University of Scranton in 1987 and a Doctor of Pharmacy from Temple University in 1997. He completed a residency in Pharmacy Practice at Temple University Hospital in 1998. Professor McDonnell was honored with the Lindback Award for Distinguished Teaching in 2006 and a Fellowship from the American Society of Health-System Pharmacists in 2014. He also serves on the editorial board of the Patient Safety Authority, works in conjunction with the National Association of Boards of Pharmacy and the Institute for Safe Medication Practices, and has numerous publications and presentations in drug-induced disease, medication safety, and adverse drug reactions. At the School of Pharmacy, Professor McDonnell teaches course work on medication safety topics and adverse drug reactions, and is the coordinator of the Medication Safety Track offered to students who wish to focus on the safe use of drugs and to mitigate patient harm from error-prone situations.

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