



Transitions of Care

Pitfalls and Recommendations

James O'Donnell, PharmD, MS; and F. Randy Vogenberg, RPh, PhD

INTRODUCTION

Aspects of health care reform and various payer-driven, quality-of-care initiatives focus on the transition of patients from one site of care to another. Although seamless transition of care has long been a goal of payers and providers, this newly intensified interest among hospitals in meeting that goal is driven, in part, by heightened legal implications, the threat of financial penalties, and the risk of loss of accreditation. Policy decision-makers, including members of P&T committees, should be prepared to implement medication-use policies and procedures designed to minimize these risks.

Maintaining continuity as patients are moved from one level of care to another applies to transitions both in and out of the hospital. As of October 1, 2012, hospitals have greater financial incentives—positive and negative—to prevent lapses in quality of care pertaining to these tran-

Dr. O'Donnell is an Associate Professor of Pharmacology at Rush University Medical Center in Chicago, Ill. As a pharmacist and pharmacologist, Dr. O'Donnell is engaged in academic and consulting practice. His career includes extensive hospital and community practice experience, as well as support to P&T committees, state drug formulary committees, and third party/insurance formularies. He has consulted as an expert witness in dozens of cases, including numerous pharmacy policy-related cases.

F. Randy Vogenberg, the editor of this column, is a pharmacist with a doctorate in health care management. He is a member of P&T's editorial board, and a fellow of the American Society of Health-System Pharmacists. He has lectured on health care policy and law and has presented continuing education seminars on risk management in the health professions throughout his career. Dr. Vogenberg is Principal at the Institute for Integrated Healthcare (IIH) in Sharon, Mass., and Adjunct Assistant Professor of Pharmacy Administration at the University of Rhode Island, College of Pharmacy, in Kingston. His e-mail address is randy@iihonline.net.

sitions. The Hospital-Based Value Purchasing program of the Patient Protection and Affordable Care Act (ACA) rewards hospitals for delivering high-quality care. Separately, the Centers for Medicare & Medicaid Services (CMS) has begun to penalize hospitals with high 30-day re-admission rates through loss of Medicare reimbursement.

As a high-profile and costly disease category, cancer is a good example of the pitfalls inherent in care transitions, in part because cancer treatment involves a number of medications that carry significant risks, such as methotrexate. This column explores various transition-related problems that may leave hospitals and organized health care systems vulnerable to financial losses and legal action.

METHOTREXATE: USE WITH CAUTION

As an individual P&T committee member, you might not have first-hand experience with a "methotrexate daily" error. If you are a pharmacist, chances are that you have not experienced this either, though you probably have read about it in the pharmacy literature. These incidents are memorable because they are frequently fatal.

Oncology therapies can be pharmacologically sophisticated. Given this, as well as the safety risks many of these drugs carry, an expert clinical hypothesis is often necessary to validate their use for specific types of cancers. A treatment can involve an initial cocktail of chemotherapy agents with various regimens, followed by a maintenance regimen to ensure eradication of cancerous cells. At each decision-making juncture throughout the course of therapy, these variables create numerous risks for adverse events—and litigation.

Methotrexate provides an example of the clinical and legal risks inherent with misuse. As an antimetabolite and antifolate first approved in 1951, methotrexate is one of the oldest chemotherapy drugs on the market. In oncology, it is frequently used in combination with other agents. Administration is episodic (i.e.,

not daily), is done according to protocol, and is dependent on the patient's complete blood count.

Within the last 30 years, methotrexate has been used widely as an immunosuppressant and as a disease-modifying antirheumatic drug (DMARD). Commonly used in patients with rheumatoid arthritis, DMARDs help to decrease pain and inflammation, to reduce or prevent joint damage, and to preserve joint structure and function. Some DMARDs are also used to treat other autoimmune conditions, such as ankylosing spondylitis, psoriasis, and systemic lupus erythematosus. Methotrexate can even be used in an off-label fashion as an abortifacient.

The toxicity associated with methotrexate that usually follows is myelosuppression, resulting in neutropenia or pancytopenia. Typically, methotrexate chemotherapy is administered on a daily basis, but for patients with autoimmune disorders, dosing is usually once weekly. For the clinician who is unaware of a patient's weekly dosing schedule, daily use can result in clinical signs that might be attributed to another condition. Frequently, by the time the error is discovered, the patient is moribund.

The Institute for Safe Medications Practices has long reported toxicities associated with methotrexate,¹ and many of those errors occur during transitions of care. As with many medications and categories with a narrow therapeutic index (NTI), methotrexate mistakes are all too frequent, because relatively few medications are dosed weekly, as is methotrexate; clinicians and patients are more familiar with daily dosing.

CASE EXAMPLES

Case reports about confusion in prescribing among professionals are plentiful, especially for agents with a narrow therapeutic index or high-toxicity drugs such as methotrexate.^{1,2} In one example, a patient died after he misread the instructions for methotrexate. He took 2.5 mg every 12 hours for 6 days in a row instead of 2.5 mg every 12 hours for *three doses*

each week, as originally prescribed. Another patient died after he misunderstood the directions on a prescription bottle and took 10 mg every *morning* instead of every *Monday*.

Hospital errors also have been reported, even though safety nets had been in place for pharmacists and nurses. In one case, a physician correctly recorded that a patient had been taking methotrexate 7.5 mg weekly in an outpatient setting. When he prescribed *three 2.5-mg tablets weekly*, however, the order was transcribed incorrectly as *three times daily*. When the patient was transferred to another room in the hospital, the dose was transcribed incorrectly as *three times a week*. In each case, harm was avoided because the errors were detected during a pharmacy review.

Confusion in prescribing is not unique to the U.S. In Australia, one patient took extra doses of methotrexate, as needed, to relieve arthritic symptoms. Three elderly patients took the medication *daily* despite written instructions to take it *weekly*. In two other instances, the dosing schedule was incorrectly transcribed, and three of the six patients died as a result of these errors.

In a case pending in the U.S. court system, a patient was admitted to an acute-care hospital where the admitting physician continued the patient's order for methotrexate every Monday. The order was correctly entered into the hospital's computerized prescriber order entry (CPOE) system and was therefore listed as correctly as "every Monday" on the medication administration record (MAR), generated from the pharmacy computer. However, the pharmacy technician who filled the automated dispensing cabinet placed a 7-day supply of methotrexate in the remote cabinet—six more doses than needed.

The nurses, apparently seeing a several-day supply of methotrexate in the cabinet, administered methotrexate *daily* instead of *once weekly*. The patient developed pancytopenia and died within 7 days of the discovery that she had mistakenly received methotrexate daily. Interestingly, the hospital's attorney defended the pharmacist—who, as a licensed professional, was responsible for the pharmacy technician's error—by stating that the hospital was "not responsible for the pharmacy technician's actions."

These are important examples of the need for an alert that could block the order of a common medication like methotrexate, which has the potential to result in problems with care transitions. Such an alert, as part of a robust risk-management program, might have prompted the pharmacist to conduct a quality-assurance check of the medication cabinet, talk with nursing staff, or prompt the technician that only one dose was needed.³

Because pharmacists receive hundreds of alerts per week, the software should trigger an alert that the order cannot be processed or entered. The term often used to describe this situation is a "hard stop." If the alert can be bypassed easily, it will not be effective. The CPOE system should not allow these types of orders to take place.³

The same problem applies to ambulatory or community-based pharmacy services in clinics. If the pharmacist is unaware that methotrexate should be given *weekly* when it is used as a DMARD, and if there is no additional alert in the CPOE system, there is a danger that the pharmacist will, out of habit, assign *daily* doses of methotrexate—despite a physician's direction for once-weekly administration.

TRANSITIONS OF CARE

Patients frequently experience adjustments in their medications during their hospital stays, namely when they are moved from emergency care to intensive care to acute care; from the operating room to postoperative care; and in and out of special level-of-care settings. Changes in medications also occur when a patient is admitted to or moves from a hospital to a skilled nursing facility, home, or any transition in between. Maintaining quality of care during transitions is also important for emerging care-delivery models that manage financial risk for an episode of care, such as accountable care organizations (ACOs).

All of these changes increase the potential for medication-related errors. These errors may cause adverse events that result in increased costs, toxicity, injury, or even death. On the flip side, if a medication is inadvertently dropped off the list and is not reordered, undertreatment can result. In an effort to minimize these transitional errors, the Joint Commission now requires medication reconciliation

upon admission. Discharge and transfers within the facility generate a similar checklist that explicitly states the need to continue or discontinue one or more medications.

A number of proven mechanisms for accomplishing effective medication reconciliation can reduce legal exposure of a hospital or health care organization from care transitions. Walker et al. described one such method—a pharmacist-facilitated discharge process designed to identify and resolve medication discrepancies before discharge and to help patients manage problems that arise during the transition from hospital to home.⁴ The most common discrepancies reported were missing medications (41%), failure to discontinue unnecessary or inactive medications (24%), and the wrong dose or frequency of administration (16%). Discrepancies occurred most frequently with cardiovascular drugs; analgesics; and endocrine, antimicrobial, and gastric acid-suppression agents. Follow-up telephone calls enabled pharmacists to reinforce discharge instructions and promoted early recognition and resolution of post-discharge medication-related problems.

For transitions within the institution, diligence, along with enforcement of policies and procedures, is rapidly becoming a necessity. Gone are the days of "resume preop medications"; orders must now be rewritten. Too often, however, this simply has become a redundant clerical exercise with a signature by the receiving physician and without consideration of a regimen most appropriate for the patient at this new level of care.

Many new legal and regulatory case actions involving transitions of care are likely to result over the next few years. Forensic pharmacists working for plaintiffs or defendants in recent years have investigated examples of medication errors propagated during transition periods as part of their consultation.⁵

RECOMMENDATIONS FOR P&T COMMITTEES

In recent years, P&T committees have seen their responsibilities expand to many areas of care delivery, medication use, and documentation. Most P&T committees now take an active stance not only to avoid harm to patients but also to establish risk-management strategies that can avert safety or economic disas-

ters for their organizations. As scrutiny intensifies and time pressures increase for all health care professionals, transitions of care have the potential to give rise to numerous legal actions. As such, this aspect of medication use is a particularly important area for cross-collaboration among committees that are responsible for the safety and care of patients in all settings of health care delivery.

Patient misunderstanding is a potential problem with all medications. The reports described in this article illustrate the need for clear instructions and medication counseling at hospital discharge. What is less understandable is why this error continues to occur in hospitals, when there are ways to reduce the incidence of errors. One option is to program the CPOE software to block daily or multiple doses of methotrexate per week. Any attempt to enter "daily" into the system would trigger an alert indicating that the order cannot be processed (a hard stop).³

Yet even this method is not fail-safe. In one case, now settled, a patient underwent orthopedic surgery and subsequently experienced an acute gout reaction. Intravenous (IV) colchicine (no longer marketed in IV form) was ordered. Unfortunately, the pharmacist overrode the high-dose alert and failed to include a maximum dose limit for the acute phase of treatment. Upon transfer to the intensive-care unit, the intensivist renewed the colchicine prescription without considering the maximum dose for the drug. The patient developed pancytopenia and died several days later.

As a consequence, further cautionary recommendations may be appropriate. These include restrictions on prescribing and specific criteria for use.⁶ Packaging can provide a visual reminder of proper dosing; oral methotrexate is available as a Rheumatrex (Dava/Excella GmbH; formerly, Lederle) dose pack, which helps to reinforce the weekly dosing schedule. Dose packs, however, are usually not used in institutional settings such as hospitals or nursing homes.

CONCLUSION

Changes in the regulatory and reimbursement environments compel hospital administrators and clinicians to become increasingly mindful of careful medication use. Prudent practitioners and clinicians should recognize care tran-

sitions involving medications as prone to error, and P&T committees should ensure that adequate policies and procedures for medication reconciliation at each transition of care are established and enforced. Focused education and information forums about seamless transitions should become regular events, as is now done with infection control. These activities become increasingly relevant for safety and optimal outcomes for patients and for economic and legal reasons for health care organizations.

REFERENCES

1. Institute for Safe Medication Practices (ISMP). *ISMP Medication Safety Alert!* Beware of erroneous daily oral methotrexate dosing. Huntingdon Valley, Pa.: ISMP; April 3, 2002. Available at www.ismp.org. Accessed November 2, 2012.
2. Grissinger M. Erroneous dosing of oral methotrexate. *P&T* 2005;30(4):202.
3. Institute for Safe Medication Practices (ISMP). *ISMP Medication Safety Alert!* Safety still compromised by computer weakness. Huntingdon Valley, Pa.: ISMP; August 25, 2005. Available at: www.ismp.org. Accessed November 2, 2012.
4. Walker PC, Berbstein SJ, Jones JT, et al. Impact of a pharmacist-facilitated hospital discharge program: A quasi-experimental study. *Arch Intern Med* 2009; 169(21):2003–2010.
5. O'Donnell J. to Vogenberg F. R., August 9, 2012 (personal communication by telephone).
6. Cohen MR, Smetzer JL, Tuohy NR, Kilo CM. High-alert medications: Safeguarding against errors. In: Cohen MR, ed. *Medication Errors*, 2nd ed. Washington, D.C.: American Pharmacists Association;

Attention Readers:

Do you have a suggestion for improving the P&T committee decision-making process?

Send your experiences to
ssherritze@medimedia.com