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COMMENTARY

10 ways to improve medication safety in community pharmacies

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ABSTRACT

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Summary: Since at least the time of Hippocrates, health care providers have recognized their responsibility to protect patients from potential harm resulting from the care they provide. In pharmacy, such harm typically results from a violation of any of the "5 rights" of safe medication use. However, a memorable adage stops short of providing operational guidance to improve medication safety. Specific actionable recommendations are needed to identify changes that, if implemented, would significantly improve the safety of medication delivery and use.
Conclusion: Most threats to medication safety result from weaknesses or failures in one or more of the key system elements identified by the Institute for Safe Medication Practices. Pharmacists should be advocates for implementing targeted recommendations to strengthen their practice systems and improve medication safety.

Although it does not appear as such in the Greek of the Hippocratic Oath, the sentiment later expressed in *primum non nocere* ("first, to do no harm") has been attributed to Hippocrates (460–370 BCE) and is widely agreed to represent the overarching responsibility of all health care providers. This maxim reminds us that while the care we provide may not always help our patients, we have an obligation to protect them from harm that may result from that care. Actively managing medication safety is therefore both a professional responsibility and a moral and ethical imperative. Patient safety must be job number 1 for every practicing pharmacist and every pharmacy organization within which he or she practices. Moreover, this responsibility applies equally to individual pharmacists and to the organization, because the latter is but an aggregate of the former.

In pharmacy, patient harm typically results from the violation of any of the "5 rights" of safe medication use: right patient, right drug, right time, right dose, and right route of administration. But though this familiar adage is helpful for alerting us to the possible causes of medication errors and related misadventures, it stops short of providing specific operational guidance to improve medication safety.

More helpful for recognizing and avoiding the proximal causes of medication errors are the system-based influences that have been identified and described in detail by the Institute for Safe Medication Practices (ISMP).[1] For that reason, a truly systematic approach to improving the safety of medication delivery and use should begin with the helpful resources that have been developed by this global leader in medication safety.

According to ISMP, weaknesses or failures in one or more of the following 10 key system elements are responsible for most medication errors:

- Inadequate information about the patient.
- Inadequate information about the drug.
- Communication and teamwork failures.
- Unclear, absent, or look-alike drug labels and packages and confusing, look-alike, or sound-alike drug names.
- Unsafe drug standardization, storage, and distribution.
- Nonstandard, flawed, or unsafe medication delivery devices.
- Environmental factors and staffing patterns that do not support safety.
- Inadequate staff orientation, ongoing education, supervision, and competency validation.
- Inadequate patient education about medications and medication errors.
- Lack of a supportive culture of safety, failure to learn from mistakes, and failed or absent error-reduction strategies.

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Key Points

Background:

- Most medication errors result from system-related failures.
- Recognizing the systems-based influences of medication errors can assist in developing targeted recommendations to improve medication safety.

Findings:

- Flaws or inadequacies in key system elements continue to threaten medication safety in community pharmacy.
- If implemented, 10 targeted recommendations would significantly improve the quality and safety pharmaceutical care in the community setting.
- Individual pharmacists can and should advocate for changes to improve practice systems and medication safety.

Guided by ISMP's model of the systems-based influences of medication errors, informed by more than 40 years of experience as a pharmacist and medication safety researcher, and inspired by David Letterman, I offer below my "Top 10" list of specific recommendations to improve the quality and safety of medication delivery and use in community pharmacy practice. In keeping with Mr. Letterman's familiar feature, recommendations are in ascending order of importance based on my opinion of their potential to improve medication safety. Neither the list nor the rankings have any validity beyond conclusions that I have reached from my own experience as a pharmacist, researcher, and scholar in medication safety management.

In some cases, implementation of the recommendation can be made by individual pharmacists, albeit with at least tacit approval of their employers. In other cases, successfully implementing the recommendation would require the active support of pharmacy ownership or management, action by pharmacy regulators (e.g., boards of pharmacy), enhancements by pharmacy technology vendors, improvements in pharmacy education, or advocacy by state and national professional associations. In all cases, however, I believe it is the individual pharmacist's moral and ethical duty to advocate for the recommended changes.

Medication safety management's "Top 10"

10. Better prescriber training

In theory, the prescription order is a mechanism by which prescribers accurately and unambiguously communicate their therapeutic plan for patients to the pharmacist. On its receipt, the pharmacist is expected to implement the prescriber's therapeutic plan exactly as the prescriber intended. The prescription order therefore represents a vital communication link between the prescriber and the patient via the pharmacist as an intermediary. Regrettably, it is a notoriously weak link.

As an anonymous wit once observed, "In theory, theory and practice are the same. In practice, they're not." In actual practice, prescribers' orders are often either incorrect or insufficiently clear or complete to allow for accurate and unambiguous interpretation by the receiving pharmacist. In some cases, the cause is inadequate clinical knowledge by the prescriber, what ISMP would term a "planning error." More often, however, the clinical decision of the prescriber was correct but the medication order was written or entered incorrectly (i.e., an "execution error") either by the prescriber or by someone to whom the task was delegated.

There is perhaps no better justification for encouraging interprofessional education of pharmacists and prescribers than to instill the importance of why, and the skills for how, an accurate and unambiguous medication order should be communicated. A thorough exposure of prescribers-in-training to ISMP's systems-based influences of medication errors is essential. A required shadowing experience in a pharmacy would help to further reinforce the problems and hazards that are created by poor prescribing practices.

9. Implement industry-wide adoption of structured and codified Sigs in electronic prescribing

One of the most quality-sensitive fields of an electronic prescription order is the prescriber's directions for how the patient is to take the medication.[2] Accurate interpretation of these directions, commonly referred to as the Sig (i.e., *signetur*, "let it be labeled"), is essential to ensure adequate pharmacist prospective drug utilization review (proDUR), proper prescription labeling, effective counseling, and safe medication use by patients.

In the National Council for Prescription Drug Program's (NCPDP) SCRIPT e-prescribing telecommunication standard (version 10.6), Sigs may be communicated from prescribers to pharmacists in 1 of 2 ways.[3] First, the current standard allows the Sig to be transmitted from prescriber to pharmacist as a structured and codified data segment. Unfortunately, industry resistance to the adoption and implementation of this option has limited its use. As a result, the majority of Sigs continue to be communicated via a 140-character free-text field.

Research has found that free-text Sigs in e-prescriptions demonstrate a troubling degree of variance that can threaten interpretation at the receiving pharmacy. An analysis of e-prescriptions by Yang et al.[4] found such variability even among free-text Sig strings that expressed apparently simple concepts. For example, a sample of 25,000 e-prescription orders contained 832 different text strings that conveyed the Sig concept, "take 1 tablet by mouth once daily." When reviewed for interpretability, approximately 10% of all free-text Sigs in the sample were judged to contain content that could result in inaccurate interpretation by staff at receiving pharmacies. The potential risk to patients that misinterpretation of the prescriber's intention poses is clear, as is the rationale for eliminating such variance via industry-wide adoption of a structured and codified Sig in e-prescribing.

8. Improve computer-assisted proDUR databases and software applications

On the heels of the implementation of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), pharmacy organizations dramatically ramped up their adoption of (proDUR) databases and software applications designed to assist pharmacists in conducting their reviews. But though these data-driven clinical decision support tools have the potential to significantly improve the quality of proDUR, this potential has yet to be fully realized owing to a number of continuing challenges. Among these are long-recognized shortcomings of the software applications and databases themselves, and the absence of widely recognized best practices and rigorous training programs to adequately prepare people to appropriately use this assistive technology.[5] As a result of these continuing inadequacies and an overwhelming number of perceived nuisance alerts, "alert fatigue" is common and many pharmacists ignore or summarily override the proDUR alerts they receive.[6-8] Until this changes, data-driven proDUR will not achieve its potential for improving the safety and effectiveness of pharmaceutical care.

7. Develop and implement quality metrics for proDUR and patient counseling

ProDUR and patient counseling are nondelegable professional duties that virtually define the practice of pharmacy in most state pharmacy practice acts. But though they are universally recognized to represent essential components of high quality pharmacist care that require the professional judgement of a pharmacist, reliable metrics for both remain elusive.[9] In the absence of valid metrics, it is not possible to legitimately compare and contrast the relative quality of care provided by different pharmacists or pharmacy organizations, an essential prerequisite for the creation of true performance-based pharmacy networks. Metrics with which to accurately and reliably measure these essential professional activities must be created and integrated into Medicare Star ratings and other quality indices that have reimbursement implications in pharmacy services benefit plans.

6. Reform reimbursement to recognize the value of pharmacists' clinical interventions

Although OBRA '90 and resulting revisions to state pharmacy practice acts codified pharmacists' proDUR and counseling responsibilities, these legal mandates did not change the economic realities of pharmacy practice. Indeed, during the ensuing years pharmacy reimbursement under public and private pharmacy benefit programs has grown progressively worse. Many pharmacy organizations have responded by increasing per-pharmacist prescription workloads, thereby further limiting the time pharmacists have for clinical activities.

Regrettably, good practice cannot be mandated by legislation or rule. Rather, it must be encouraged and rewarded if it is to consistently occur. It is well past time that third-party pharmacy benefit programs recognize the value of pharmacists' routine clinical interventions and compensate pharmacy organizations equitably for the time and resources they require and for the value they create, something the American Pharmacists Association (APhA) has been requesting for well over 2 decades.[10]

5. Implement an efficient mechanism for targeted pharmacist–physician clinical communications

Another significant barrier to high-quality proDUR is the difficulty that pharmacists encounter when they attempt to contact prescribers to clarify problematic or questionable medication orders. Although this is particularly frustrating to community pharmacists, many health-system pharmacists experience similar problems. Delays in prescribers' responses to pharmacist contacts interrupt pharmacy workflow, inconvenience patients, and threaten patient safety when a prescriber's eventual response is relayed through intermediaries such as a nurse, medical assistant, or office staff. The NCPDP's SCRIPT e-prescribing telecommunications standard would appear to be an ideal mechanism for such targeted bidirectional clinical exchanges between pharmacists and prescribers related to concerns about a particular prescription order.[11]

4. Require clinical indication or its equivalent on every prescription order

Pharmacists have long recognized their professional and ethical responsibility to assess the safety of prescribed drug therapy. OBRA '90 codified this responsibility by legally mandating that pharmacists perform proDUR to ensure that prescribed drug therapy is appropriate, medically necessary, and not likely to result in adverse events.[12]

But whereas pharmacists are legally obligated to assess the safety and appropriateness of prescribed drug therapy, they typically do not have ready access to key clinical information needed to do so reliably. Perhaps most notably, pharmacists are not privy to the reason why the medication was prescribed. This deficiency severely restricts the pharmacist's ability to identify potentially inappropriate therapy, a limitation that is aggravated by the common practice of off-label prescribing in which the accuracy of an inferred indication is even more tenuous.[13]

Past research has found that providing pharmacists with immediate access to the clinical indication or its equivalent (i.e., problem, diagnosis, or clinical objective) significantly improves the quality of the pharmacist's proDUR clinical decisions and reduces the number of unnecessary prescriber contacts to clarify suspect orders.[14,15] More than 2 decades ago, the National Coordinating Council for Medication Error Reporting and Prevention recommended that "prescription orders should include a brief notation of purpose (e.g., for cough) unless considered inappropriate by the prescriber."[16] Since then, the same sentiment has been expressed by the ISMP, APhA, National Association of Boards of Pharmacy, and NCPDP.[17] Considering that the current e-prescribing telecommunications standard allows for either diagnosis (ICD-10-CM) or clinical indication (SNOMED-CT) to be transmitted with the prescription order, there would seem to be no technical barrier to requiring this information on every

electronic prescription order. Patients could then decide whether they wished to have this information placed on the prescription label.

3. Eliminate handwritten and telephone prescriptions outside of emergencies

Perhaps the lowest hanging fruit for immediately improving medication safety is to eliminate handwritten and telephone prescription orders. With the now ubiquitous use of electronic prescribing, it is increasingly indefensible that handwritten and telephone prescriptions remain legal outside of true emergencies. Indeed, a strong case can be made that every medication error resulting from the misinterpretation of a handwritten or telephone prescription order represents the failure of a board of pharmacy to do the most important job it has: protect citizens.

2. Require all pharmacies to have effective continuous quality-improvement programs

The key word here is "effective." With the recent addition of Arizona, at least 21 states now require pharmacies to maintain a quality-assurance program.[18] Properly designed and implemented, these programs can assist safety managers to identify medication errors and assess their likely causes with the goal of preventing future errors from occurring.[19] However, even in states that currently require such programs, relatively few standards exist for what they should contain or how they should be managed. As a result, enforcement is often lax, which encourages perfunctory compliance by some pharmacy organizations that acquire a basic off-the-shelf program that meets the nominal requirements of the law but does not meaningfully improve quality.

Achieving real continuous quality improvement (CQI) in patient safety requires pharmacy organizations to implement and maintain a more structured and rigorous approach than many now have, even in states where they are required. Primary responsibility for ensuring that every pharmacy has and uses a legitimate CQI program appropriately falls to state boards of pharmacy. However, entities that accredit community pharmacies also have important roles to play to ensure that, at the very least, pharmacies are learning from the mistakes they make and are less likely to repeat them in the future.

1. Require every pharmacy to be adequately staffed

It is an immutable fact that good pharmacy practice takes more time than poor pharmacy practice. Granted, there are other factors that can affect a given pharmacist's ability to provide safe and effective care to patients besides prescription volume and related workload. The list of such contributing factors would include, but is not limited to, the proficiency of the pharmacist; the number and types of other professional responsibilities, such as immunizations, comprehensive medication reviews, and medication therapy management encounters; the number, training, and responsibilities of supportive personnel; the type of automated dispensing technologies available; the adequacy of the pharmacy's practice management computer system; and the policies, procedures, processes, and workflow that are used in the pharmacy.

However, even considering all the other possible mitigating influences, one conclusion is inescapable: For every pharmacy, there is a volume of workload beyond which patient safety is threatened. It is management's responsibility to know what that tipping point is and to staff and supervise each pharmacy to ensure that it is not exceeded. A good CQI program (see #2 above) can play a pivotal role in providing management with the operational intelligence needed to make these decisions. Beyond that, each pharmacist must have the authority to adjust the pace of practice when he or she believes patient safety is threatened. Furthermore, pharmacists must be supported by their organization when they elect to do so.

As a candidate for president in 2011, Mitt Romney famously stated, "corporations are people, my friend."[20] But though Mr. Romney was correct that corporations have been granted "personhood" status in a limited legal sense, they are clearly not human beings. Although created by and consisting of people, corporations—including those that employ or influence the practice of pharmacists—are cold, heartless, soulless entities that have been created for the purpose of achieving selected objectives, typically including the maximization of their own value. Corporations do not have consciences. Corporations do not have morals or ethics or empathy. People have these qualities, and we rely on the people within corporations and similar entities to ensure that their organizations demonstrate these essential qualities of collective responsibility in their activities.

Because the problems they address were created by systems-based influences, implementing most of the recommendations listed above cannot be done by individual pharmacists alone. However, each of the corporations, agencies, associations, and institutions whose actions are required to implement these recommendations are composed of people. As trustees of the legacy of Hippocrates, pharmacists and other health care providers have a responsibility to advocate in and to the entities that have the agency to effect needed changes. That would seem to be literally the least we can do to protect our patients from harm.

References

1. Cohen MR. *Medication Errors*. 2nd ed. Washington, DC: American Pharmacists Association; 2007:58.
2. Dhavle AA, Rupp MT. Towards creating the perfect electronic prescription. *J Am Med Inform Assoc*. 2015;22(e1):e7–e12.
3. Liu H, Burkhart Q, Bell DS. Evaluation of the NCPDP Structured and Codified Sig Format for e-prescriptions. *J Am Med Inform Assoc*. 2011;18(5):645–651.
4. Yang Y, Ward-Charlerie S, Dhavle AA, Rupp MT, Green J. Quality and variability of patient directions in electronic prescriptions in the ambulatory care setting. *J Manag Care Spec Pharm*. 2018;24:691–699.
5. Reynolds JL, Rupp MT. Improving clinical decision support in pharmacy: toward the perfect DUR alert. *J Manag Care Spec Pharm*. 2017;23:38–43.
6. Chrischilles E, Fulda TR, Byrns PJ, Winkler SC, Rupp MT, Chui MA. The role of pharmacy computer systems in preventing medication errors. *J Am Pharm Assoc (Wash)*. 2002;42(3):439–448.
7. Chui M, Rupp MT. Evaluation of online prospective DUR programs in community pharmacy practice. *J Manag Care Pharm*. 2000;6(1):27–32.
8. Sittig DF, Wright A, Osheroff JA, et al. Grand challenges in clinical decision support. *J Biomed Inform*. 2008;41(2):387–392.
9. Rupp MT. Assessing the quality of care in pharmacy: remembering donabedian. *J Manag Care Spec Pharm*. 2018;24:354–356.

10. Rupp MT. It's time to overhaul our drug reimbursement system. *Drug Topics*. September 2, 2007:52.
11. National Council for Prescription Drug Programs. SCRIPT implementation recommendations. December 2017. Available at: http://www.ncpdp.org/NCPDP/media/pdf/SCRIPT-Implementation-Recommendations.pdf. Accessed August 20, 2018.
12. U.S. Congress. H.R. 5385, Omnibus Budget Reconciliation Act of 1990. 101st Congress. 1989–1990. Available at: https://www.congress.gov/bill/101st-congress/house-bill/5835/text. Accessed August 3, 2018.
13. Rupp MT. The pharmacist's role in off-label prescribing. *Arch Intern Med*. 2010;170:658.
14. Warholak-Juarez T, Rupp MT, Salazar T, Foster S. The effect of patient information on the quality of pharmacists' drug use review decisions. *J Am Pharm Assoc*. 2000;40:500–508.
15. Warholak TL, Rupp MT, Leal S, et al. Assessing the effect of providing a pharmacist with patient diagnosis on electronic prescription orders. *Res Soc Admin Pharm*. 2014;10:246–251.
16. Kron K, Myers S, Volk L, et al. Incorporating medication indications into the prescribing process. *Am J Health Syst Pharm*. 2018;75(11):774–783.
17. Institute for Safe Medication Practices. Is an indication-based prescribing system in our future? Available at: https://www.ismp.org/resources/indication-based-prescribing-system-our-future. Accessed November 20, 2018.
18. Mazina N. Does your pharmacy comply with quality assurance requirements? *Drug Topics*; May 10, 2015. Available at: http://www.drugtopics.com/community-practice/does-your-pharmacy-comply-quality-assurance-requirements. Accessed August 23, 2018.
19. Chinthammit C, Rupp MT, Armstrong EP, Modisett T, Snead R, Warholak TL. Evaluation of a guided continuous quality improvement program in community pharmacies. *J Pharm Policy Practice*. 2017;10(26):1–8.
20. Rucker P. Mitt Romney says "corporations are people." *Washington Post*; August 11, 2011. Available at: https://www.washingtonpost.com/politics/mitt-romney-says-corporations-are-people/2011/08/11/gIQABwZ38I_story.html. Accessed February 27, 2019.

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