Recommendations for Improving Patient Safety and Incident Reporting within the Pharmacy Workplace

A White Paper by the Michigan Pharmacists Association Workplace Task Force

Executive Summary

Michigan Pharmacists Association (MPA) identified medication and patient safety as a key strategic issue for 2016 and subsequently formed the Workplace Task Force to address these issues. Since its formation, the task force surveyed approximately three hundred pharmacy personnel to identify trends and challenges to medication safety Michigan pharmacists currently face throughout their pharmacy practices. As a result of the survey, the Workplace Task Force created this document in an effort to define the pharmacy roles, responsibilities and contributions for ensuring patient safety in Michigan.

It is well documented in patient safety literature that fear of reprisal reduces reporting and learning, thus inhibiting improvements in patient safety. Since there is currently no national regulatory body that provides guidance on disciplinary actions for pharmacy professionals involved in medication errors, it is also the goal of this document to request regulators to consider the promotion of "just Culture" when assessing and addressing medication errors. This document provides recommendations to pharmacy practices and associations for improving patient safety from both a local and national perspective. From evaluating the pharmacy workflow, to advocating for appropriate disciplinary actions when an error is made pharmacists and pharmacy professionals have an opportunity to play to improving patient safety.

The MPA Workplace Task Force urges that there be continued advancement in voluntary reporting systems for medication errors and appropriate handling of such errors by regulatory bodies, with the expectation that this will:

1. Create an accountability system that utilizes "just culture,"
2. Promote pharmacist involvement in medication safety through self-reporting of medication errors,
3. Promote wider sharing of risk points across multiple locations in order to focus on learning and prevention.
Introduction

The Institute of Medicine (IOM) defines patient safety as the prevention of harm to patients, with an emphasis on the system of care that prevents errors, learns from errors that occur and is built on a culture of safety involving healthcare professionals, organizations and patients.\(^1\) While advancements in medication therapy have resulted in major health improvements, they are also associated with increased risks for errors. In a 1999 report by the IOM, “To Err Is Human: Building a Safer Health System,” medication errors accounted for one out of every 131 outpatient deaths and one out of every 854 inpatient deaths.\(^1\) This translated to an estimated 7,000 deaths annually attributed to medication-related errors.\(^1\)

Following a medication error, focus often turns toward the individual responsible for the error rather than examining the system and processes which allowed an error to occur. The key to creating a medication safety culture is finding a balance between the extremes of reprimand and absolution to developing a "just culture."\(^2\) Although deliberate human behaviors can be controlled, behavior modification alone will not reduce the likelihood of making an error, as errors are not easily predicted. Individuals should not be held solely responsible for mistakes made within a system they cannot control. Rather than focusing on individual errors, an ideal system utilizing “just culture” focuses on system design and the management of individual choices within this system when an error is made.\(^2\)

As medication experts, pharmacists play a key role in reducing adverse drug events and improving patient safety. In 2016, MPA identified patient and medication safety as a key strategic issue, and formed the Workplace Task Force to examine opportunities for improvements in patient safety across practice areas. This document is the culmination of the Task Force’s efforts, attempting to detail key points in the evolution of patient safety understanding, explore the workplace culture that best promotes patient safety, and suggest recommendations for pharmacy practice and regulatory changes in Michigan to advance patient safety.

Background

“To Err is Human,” a report published in 1999 by the Institute of Medicine’s (IOM) Quality of Health Care in America Committee, highlighted issues related to patient safety and recommended a national agenda for reducing errors in healthcare.\(^1\) The committee noted that a “critical component of a comprehensive strategy to improve patient safety is to create an environment that encourages organizations to identify errors, evaluate causes and take appropriate actions to improve performance in the future.”\(^1\) Specifically, the committee recommended that mandatory and voluntary reporting systems be created to serve as a databank of medical errors. Further analysis of this data could provide insight into ways to prevent future errors from occurring.

David Marx, the founder and architect of Outcome Engenuity, compiled a report in 2001 focused on aiding executives with disciplinary management of erring healthcare professionals.\(^3\) Within this report, Marx described four behavioral concepts that are important to understanding
the relationship between discipline and patient safety: human error, negligence, intentional rule violations and reckless conduct. The definitions are as follows:

1. **Human error**: there is general agreement that the individual should have acted differently than what they did, and in the course of that conduct, inadvertently caused or could have caused an undesirable outcome

2. **Negligence**: failure to exercise the skill, care and learning expected of a reasonably prudent healthcare provider (failure to recognize the risk)

3. **Reckless conduct**: conscious disregard of a visible, significant risk

4. **Intentional rule violations**: an individual chooses to knowingly violate a rule while performing a task (not necessarily related to risk-taking)

Although these four concepts are highlighted separately, it is important to note they are not mutually exclusive and multiple behaviors can occur in the same error. Marx emphasized that individuals can only control our intended behaviors to reduce our likelihood of making a mistake, but people cannot control when or where a human error will occur.³ Thus, executives should avoid using outcomes-based disciplinary measures and should instead create a disciplinary system that allows erring employees to come forward with their mistakes. Furthermore, when investigating an event, it is important to address whether learning from the error outweighs the deterrent effect of punishment against negligent employees. Creating a culture of reporting and positive reinforcement of safe behaviors will promote significant reductions in adverse events.

In 2010, the United States Pharmacopeia (USP) identified the work environment as one of the most commonly reported factors contributing to medication errors.⁴ Under USP <1066> Physical Environments That Promote Safe Medication Use, responsibility falls on the system for ensuring safe physical environments by addressing factors such as noise, interruptions or clutter.⁵,⁶,⁷ In cases of a medication error due to an employee situated in a suboptimal work setting, USP <1066> emphasizes that the organization be required to address the contributing factors in the workplace environment. Thus, these guidelines promote safety from a system perspective versus placing the blame on one individual who made an error due to an unsafe work environment.

Following these recommendations and utilizing reporting systems, the Agency for Healthcare Research and Quality (AHRQ) conducted a survey in 2015 focused on community pharmacy patient safety culture.⁸ The goal of this survey was to determine the culture of patient safety from the viewpoint of community pharmacy staff and utilize survey results to identify areas for improvement. During the course of the survey, 255 pharmacies submitted data for the report with 53 percent representing chain drugstores, and 42 percent of pharmacies reporting an average of 701 to 1,500 prescriptions filled per week.⁸ With the proportion of respondents being 42 percent pharmacy technicians, 35 percent pharmacists, 18 percent pharmacy clerks/cashiers, and five percent pharmacy students/other, the survey was able to draw on varied perspectives of the workflow to give a more comprehensive view.⁸
One survey area focused on responses to mistakes occurring within the pharmacy and how staff was treated in the aftermath of these incidents. According to the data, 82 percent of respondents felt that the staff in their pharmacy were treated fairly when they made mistakes and that the pharmacy helped staff to learn from their mistakes rather than punish them. Of the respondents, 85 percent felt that upper management reviewed staff actions and tried to understand why mistakes happen. On the other hand, 32 percent of respondents felt their mistakes were held against them. Another section of the AHRQ survey was directed toward staffing, work pressure and pace. Feeling rushed when processing prescriptions was reported by 79 percent of respondents, while 42 percent felt they lacked the staff for their workload and 69 percent indicated that interruptions and/or distractions made it difficult for staff to work accurately. Table 1 below demonstrates these results.

Table 1: Item-Level Comparative Results—2015 Database Community Pharmacies

<table>
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<tr>
<th>Survey Items by Composite</th>
<th>Number of Pharmacies</th>
<th>Number of Respondents</th>
<th>( \leq 700 )</th>
<th>701-1,500</th>
<th>( \geq 1,501 )</th>
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<tr>
<td>Staff are treated fairly when they make mistakes</td>
<td>87%</td>
<td>80%</td>
<td>81%</td>
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<tr>
<td>Pharmacy helps staff learn from their mistakes rather than punish them</td>
<td>88%</td>
<td>83%</td>
<td>76%</td>
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<tr>
<td>Staff feel like their mistakes are held against them</td>
<td>73%</td>
<td>70%</td>
<td>63%</td>
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<tr>
<td>We look at staff actions and the way we do things to understand why mistakes happen in this pharmacy</td>
<td>89%</td>
<td>86%</td>
<td>81%</td>
<td></td>
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When a mistake reaches the patient, and could cause harm but does not, how often is it documented?

- Always documented | 75% | 82% | 80%
- Most of the time documented | 19% | 13% | 13%
- Sometimes documented | 4% | 3% | 5%
- Rarely documented | 1% | 1% | 1%
- Never documented | 2% | 0% | 1%

Following the completion of the AHRQ survey, community pharmacies were encouraged to conduct the survey amongst their own staff and compare the results from the established database. By examining comparative statistics, pharmacies have an opportunity to see how they differ from other community pharmacies with similar workloads. Large deviations from standard results offer a chance for pharmacies to develop necessary action plans for change.

Currently, there is no national regulatory body providing guidance on disciplinary measures for pharmacy professionals involved in medication errors. All regulations related to defining potential disciplinary actions are provided in the pharmacy or public health laws of each state. Although the national trend is to develop a non-punitive culture in healthcare settings, the
regulatory bodies and legislation in most states remain punitive in nature. In most instances, when medication errors are reported to the respective state’s Board of Pharmacy, the Board’s disciplinary subcommittee, or other state-sanctioned body, imposes a penalty on the pharmacist. This is also the case in Michigan, with the penalties stated in the Michigan Public Health Code as licenses being limited, denied, suspended or revoked. In addition, licensees can be rescinded, fined or placed on probation. These disciplinary actions are published as a public record and permanently remain on the individual’s license. The permanent record of penalties can have negative implications for pharmacists as they continue to practice. Medication errors are still publicly deemed as unacceptable in these states and blame is placed on the pharmacist who was responsible for dispensing the medication in error regardless of the situation. With that said, there need to be alternative options besides permanent actions imposed on an individual’s license.

As an alternative to a punitive culture, one of the last recommendations made in “To Err is Human” was to create a blame-free process that identifies system failures and prevents future errors rather than punishing the erring employee. The National Aeronautics and Space Administration (NASA) and the Federal Aviation Administration (FAA) were the first to trial a confidential reporting system called the Aviation Safety Reporting System (ASRS) as a method for pilots, air traffic controllers and other employees to communicate their errors and close-calls to safety specialists without fear of punitive action. This program is still in use today. In 2002, the Department of Veterans Affairs contracted with NASA to establish a similar program called the Patient Safety Reporting System (PSRS). The healthcare community later adopted this idea through passage of the Patient Safety and Quality Improvement Act (PSQIA) of 2005. The PSQIA established a voluntary reporting system which allowed healthcare workers to report medication errors under promise of confidentiality through Patient Safety Organizations (PSOs). The PSQIA was an improvement over the historical punitive culture; however, it still withheld important information from families affected by medical errors, managers with reporting employees and government regulators.

Recognizing the deficiencies of blame-free cultures, healthcare has been migrating toward a “just culture” which builds upon the blame-free culture by evaluating the reported medical errors and improving the process to prevent similar errors from occurring in the future. “Just culture” was developed by recognizing that “the majority of medical errors are the result of poorly designed systems, and sub-optimal processes and working conditions—not the “bad” behavior of staff.” “Just culture” is further defined by Eurocontrol as “[a] culture in which front-line operators and others are not punished for actions, omissions or decisions taken by them which are commensurate with their experience and training, but where gross negligence, willful violations and destructive acts are not tolerated.” As the definition states, “just culture” provides managers with an algorithm to determine whether an error was due to system failure or human negligence. If an employee, while following the standard of work, makes an error that would be repeated by another individual of similar experience also following the standard of work, the fault is not with the individual worker but with the process. In these cases, there would
be no punitive action toward the employee, as reporting of the error can facilitate restructuring of a process and prevention of future errors. The organization would be accountable to change the work process for all.

As part of “just culture,” there are three types of behaviors determined by AHRQ that we must learn to expect and manage:

- **Human error**: inadvertently doing differently than what should have been done
- **At-risk behavior**: choices that increase risk where risk is either not recognized or mistakenly believed to be justified
- **Reckless behavior**: conscious disregard of substantial and unjustifiable risk

Each of these behaviors should result in differing responses from managers as shown below:

- **Human error**: console the individual and evaluate the system; errors are often the result of risky system design or choices made that increase likelihood of error
- **At-risk behavior**: coach the individual and examine the system; look for incentives that may have contributed to at-risk behavior and remove incentives, if possible
- **Reckless behavior**: punish the individual to send a punitive deterrent signal to others displaying the behavior

Today, “just culture” has become a standard accepted at many healthcare institutions as a method to decrease medication errors and improve safety while promoting a culture that encourages reporting. Although “just culture” has been accepted at many healthcare organizations, it is not recognized in many states’ statutes and regulations. This gap in the advancement of patient safety endeavors led to the formation of the MPA Workplace Task Force. One subcommittee of this group sought to identify key challenges faced by practicing pharmacists in various settings across the state.

**Current State**

A survey administered by the MPA Workplace Task Force in August 2016 collected input from approximately three hundred Michigan pharmacy personnel. This survey sought to assess where errors occur in the workflow process and what factors are believed to contribute. The results identified trends in medication safety challenges faced throughout pharmacy practice today. Pharmacists, technicians, interns and other pharmacy employees responded to questions assessing barriers to optimal medication safety and current practices in place to minimize errors.

Among the key work environment challenges identified were interruptions, understaffing and lack of relevant experience/training of new employees. When analyzing these issues, it was apparent that the deficit in quality and quantity of trained assistance significantly contributed to interruptions. Each of these leading factors clearly poses an increased risk of medication errors.

Respondents were asked to rank the likelihood of an error occurring in each of the four main workflow areas common to most pharmacy settings: order entry/intake, fill processing/production, order review/quality assurance and patient interface/point-of-sale. Of these, order entry/intake was the area most frequently identified as both “likely” and “very likely” for an error to occur. There was a succeeding trend between progression in the workflow
process and likelihood of an error occurring, such that fill processing production was second most likely and so forth. This data enabled us to identify that process improvement efforts should first target the area of order entry/intake. Specific types of error potential in this workflow point may vary by practice area and site, warranting individual companies and facilities to evaluate specifics going forward.

When asked what safeguards and quality improvement practices were already in place at their practice sites, responses reflected that the following are prevalent (>70 percent): barcode identification, drug utilization review, standardized processes and internal safety reporting. Other options for quality improvement showed lower utilization including root cause analysis (54.3 percent) and LEAN systems (28 percent). These strategies could be potential solutions to implement in areas not already utilizing them to assist in enhancing medication safety.

Efforts to determine barriers to error reporting revealed issues due to workload constraints (43.5 percent), fear of employer discipline (25.4 percent) or litigation (13 percent), lack of formal/standardized reporting (12.4 percent) and reporting processes that are complex/time consuming/lacking access (2.8 percent). Of note, 39.9 percent reported no barriers. In regards to fear of consequences, the survey did not assess if respondents’ practice areas purported a culture of blame or "just culture." Of the 74 respondents that listed “fear of employer discipline” as a barrier to error reporting in their current workplace, 31 were retail-large chain employees and 24 were institutional employees, showing no substantial dissimilarity in this regard. In the current state, however, there is significant discrepancy across practice areas and specific sites in how error reporting is viewed and conducted. Hospital settings are more likely to have one or more medication safety officers whose primary purpose is analyzing error occurrences and potential and then instituting process improvement initiatives. Open dialogue on minimizing medication errors and enhancing patient safety is an integral part of many institutional settings.

But the retail/community setting appears less likely to hold to these ideals. This is evidenced by the 26 percent to 42 percent difference between institutional respondents and retail-large chain respondents reporting utilization of each of various quality improvement tools listed in the survey. For example, of the 153 respondents who listed implementation of a root cause analysis in their practice area, 40 were retail-large chain employees and 73 were institutional employees. There is a definite opportunity for improvement here, especially in the community setting where employing such strategies could lead to great strides in upholding patient safety.

Soliciting final comments provided substantial insight into the current state across pharmacy practice areas. Common themes identified included increasing staff awareness of safety reporting and analysis, increasing dialogue around medication safety, improving/standardizing of technician training, labor allowances that truly match the demands of the pharmacy and minimizing the business pressures such as meeting mandated times on tasks and requirements to work excessive hours/days without relief. Changing several of these would require significant corporate mentality and operational shifts that may not be immediately feasible. However, considering the cost of the medication errors that these workplace conditions
are prone to, employers may look to reassess some of these aspects that are worth some investment in the long run. Additionally, as some of the comments suggested, opening dialogue and encouraging the mindset that error reporting is critical to improvement should help to minimize the fear of repercussions that some respondents reported. In terms of the more corporate-controlled, business-driven aspects, while it is understood that a business must be successful to operate, it is also an important consideration that patient safety should never be sacrificed for business reasons. The approximately three hundred Michigan pharmacists, technicians, interns and other pharmacy staff that responded to the survey helped to provide significant insight into the current state of pharmacy and opportunities for improvement going forward.

Based on the information gathered from the literature and other information, the Workplace Task Force is recommending proposed changes that are expected to improve patient and medication safety. The recommendations fall into two separate categories, a) recommendations for pharmacy practice and b) recommendations for pharmacy organizations/associations:

**Recommendations for Pharmacy Practice:**

1. Encourage leadership to use a “just culture” approach to the review process of a medication safety event.
2. Advocate for legislation that should be reflective of a “just culture” to allow Boards of Pharmacy members other options outside of existing license sanctions that can be utilized in response to medication errors that come before them.
3. Identify strategies to establish a culture of reporting in community practice that analyzes medication errors and captures close-calls to prevent future errors by instituting process improvement initiatives.
4. Establish quick and easy reporting systems to encourage frequent reporting that does not detract from the individual’s daily work load.
5. Designate a medication safety champion in the community pharmacy setting.
6. Conduct an annual review of medication safety with employees that details what the pharmacist/pharmacy technician should do when an error happens.
7. Promote best practices through peer-review processes and benchmarking to other pharmacies in the community pharmacy setting.
8. Evaluate order entry/intake processes and elicit definitive feedback to address specific instances of error potential and implement process improvement strategies accordingly.
9. Allow adequate quality and quantity of standardized pharmacy personnel training for the employee to safely and successfully participate in daily pharmacy processes.
10. Establish strategies for dealing with behaviors that undermine a culture of safety.\(^\text{15}\)
11. Encourage “Stop the Line” (cause the dispensing process to halt until the problem is resolved) initiatives that promote speaking up for patient safety.\(^\text{16}\)
12. Notify employees that various survey results identified interruptions as the number one challenge reported for all practice areas. Awareness of this should help employees to consider in their daily activities.

13. Promote best practices for the management of high risk drug interactions and high alert medications.¹⁷,¹⁸

14. Engage patients in their care to assist in enhancing their own safety.

15. Develop a process for communication with the patient and family in a contemporary model when there is a medication safety event.

16. Develop a process for communicating to the patient and provider the safety considerations of filling a prescription. This should help minimize impractical time expectations, therefore minimizing pressure on the pharmacist to sacrifice safety for time.

17. Promote United States Pharmacopeia (USP) Chapter <1066> Physical Environments that Promote Safe Medication Use, recognizing that the employer has responsibility for ensuring a safe environment.

18. Invite legislators to visit the pharmacy on occasion to provide insight on pharmacy activities.

19. Continue the advancement of health information sharing.

20. Promote the use of medication reconciliation.


**Recommendations for Pharmacy Associations/Organizations**

1. Develop statements encouraging organizations to embrace a “just culture,” outlining principles to facilitate the implementation of this model.

2. Promote the value of involvement with a Patient Safety Organization (PSO).

3. Promote national patient safety resources to pharmacists – such as Alliance for Medication Safety (AMS), Institute for Safe Medication Practices (ISMP) and Joint Commission.

4. Lead an effort with other healthcare organizations to enact a change in the pharmacy practice act to recognize re-education as an option for the Board of Pharmacy and some record keeping exemption that prevents certain circumstances from remaining in the licensee’s permanent record.

5. Work with legislators to do a press conference on changing the disciplinary process and the benefits of enhanced patient safety.

6. Establish a formal relationship with the Board of Pharmacy on patient safety.

7. Continue to seek evidence that an alternative approach of education is more successful than punishment in some circumstances.

8. Collaborate with corporate pharmacy to promote a “just culture” and patient safety awareness.

9. Create a toolkit of patient safety resources for pharmacists and patients.
10. Discuss joint patient safety continuing education (CE) opportunities with other organizations.

11. Consider running a medication safety track of continuing education (CE) programs at meetings.

12. Promote the value in having the pharmacist conduct an annual review on medication safety within their workplace.

Conclusion

“To Err is Human” emphasized the importance of creating an environment that encourages organizations to identify errors, evaluate causes and take appropriate actions to reduce patient harm caused by medical errors. In addition, the article specifically recommended a national agenda of implementing mandatory and voluntary reporting systems at all healthcare entities as a databank of medical errors. Following these recommendations, “just culture” has become an accepted standard method at many healthcare institutions to create a culture where no one individual is unjustly blamed for a medical error and where the process of evaluating the reported medical errors and improving the process to prevent the same errors from occurring again in the future is well established.

Recognizing these philosophies may not be universally accepted and implemented in our state, the Workplace Task Force was formed to examine opportunities for improvements in patient safety across practice areas in Michigan. Our findings led to recommendations that advocate for acceptance of a “just culture” approach to dealing with errors regardless of practice setting.
References


Appendix

Michigan Pharmacists Association (MPA) was established Nov. 14, 1883. MPA is the state professional society serving Michigan’s pharmacists, pharmacy technicians and student pharmacists in all settings of practices. For more than 130 years, MPA has strived to provide its members with the tools, resources and support needed to advance the profession of pharmacy and provide quality patient care.

The MPA Workplace Task Force is composed of MPA members, representing pharmacists and pharmacy technicians from MPA’s practice sections of pharmacy, including community, health-systems, health plans and consultants. The goal of the Task Force is to identify and recommend best practices and other strategies that can be implemented to minimize the potential for workplace environments contributing to medication errors.

MPA would like to recognize and thank the members of the MPA Workplace Task Force for their contributions to this white paper and continued collaboration in support of patient safety initiatives.

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