Medication Safety: Who's Accountable?

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Despite our best efforts to safely manage all the new drugs on the market, and the complex therapies for the burgeoning elderly population and chronically ill, mistakes occur each day in every kind of health care setting. The extent of this problem was revealed in the Institute of Medicine's (IOM) report *To Err is Human*, which estimated that at least 7,000 patients were dying each year from *preventable* medication errors.[1]

For 30 years, the USP-ISMP Medication Errors Reporting Program, operated jointly by the United States Pharmacopeia and the Institute for Safe Medication Practices, has provided compelling evidence of medication-use system failures through analysis of voluntary reports. The program has alerted the health care industry to hazardous conditions that have frequently linked ordering, dispensing, and administration errors to ambiguous and illegible handwritten prescriptions; look- and sound-alike drug names; and poorly designed labeling. Despite these and other well-known system-related issues, the majority of the public, media, regulatory boards, and even some health care leaders continue to believe that accountability for error prevention lies solely with front-line practitioners, where the caregiver/patient interactions occur.

James Reason, the "grandfather" of human errors and architect of the "Swiss cheese model" of error, believed that errors are never the result of a single failure but, instead, a series of system breakdowns, most of which are outside the control of the individual.[2] The Reason model also rejects naming, blaming, and training the practitioner closest to an error since this allows other key stakeholders to inappropriately delegate responsibility for the error back to that individual. A safe medication-use system requires early identification of problems, initiation of practical safety solutions, and universal acceptance of shared accountability among all stakeholders.[3] It is paramount that health care professionals, organizations, product vendors, academic professionals, regulatory authorities, the media, health policy leaders, and even patients do their part to ensure a safe medication-use system.

The IOM's recent report, *Preventing Medication Errors* outlines the actions that stakeholders should take, including a comprehensive examination of problems within the system and important safety strategies and policies needed for prevention.[4] Listed below are a just a few of the essential actions for which stakeholders should be held accountable.

Practitioners

Individual must speak out about patient safety issues, voluntarily report errors, near misses, and hazardous situations to internal and external programs, and share personal knowledge of what went wrong when an error occurs. Further, practitioners need to maintain competencies, stay abreast of current medication safety literature, and make the necessary changes in practice when safety recommendations are offered.

Health Care Leaders and Organizations

Organizations need to incorporate patient safety into their mission statement and uphold practice issues. The affirmation that patient safety is "Job #1" must be accompanied by genuine action and financial commitment to a safe medication-use system. Leaders must use clear communication techniques that allow discussions to flow freely at all levels of the organization. Front-line practitioners must be included in all discussions on strategies designed to improve safety.

Organizations need to completely eliminate professional silos in which each discipline works independently, providing episodic care without coordination across providers. "Silo" thinking has hindered the development of a team approach and has, thus, been at the root of many medication errors. The inability to reconcile medications across the continuum of healthcare continues to result in patient harm and death.

External Health Care Stakeholders

Regulatory, accrediting, and licensing bodies need to adopt safety standards as identified by scientific research and expert committees, and provide oversight to healthcare organization to ensure that they are fully implementing those safety standards.

The pharmaceutical industry should be held accountable for conducting pre-market testing, using proactive risk management strategies such as failure mode and effects analysis to detect potential labeling, packaging, or nomenclature problems. Post-marketing surveillance is also needed to detect adverse drug reactions and medication error-related product problems. When errors are reported to the manufacturer, problems should be fully disclosed to practitioners and changes should voluntarily be made to ensure safety.

The manufacturers of medical devices and software should also be held accountable for performing safety evaluations and for seeking expert advice about new products. They must also freely disseminate information to healthcare providers (and consumers, when appropriate) when design flaws in previously launched products are newly discovered.

Academia

On the academic front, educators should be accountable for weaving current medication safety concepts throughout the entire curriculum so students can develop the critical thinking skills necessary to manage patient safety.

Consumers

Patients can no longer be passive about their health care. They must see themselves as active partners and not be intimidated by their practitioner's disposition to ask questions about their drug therapy. They should be informed that they are the last line of defense from harm and must be proactive by providiing an accurate list of their medical history, allergies, chronic conditions, medications, and other important medical information to their healthcare providers.

Conclusion

Since no single stakeholder can sufficiently change a system, all health care stakeholders must unite to prevent patient harm by sharing accountability for providing a safe medication-use system. As Einstein stated, "Insanity is doing the same things the same way and expecting different results." Thus, significant improvements in medication safety will not be make unless we change the way accountability is view and begin to work together to finally design a medication-use system that is truly safe.

References

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