Drug Misfills−the Dependability of Medication Delivery

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The Problem

Prescription drug usage is common, particularly in the United States. Almost half of all Americans take at least one prescription drug and it increases in the elderly to 3 or more[1]. As the population ages, and perhaps because of a shift away from herbal medicines in developed nations, more and more prescriptions are written and filled each year. According to the report "Health, United States 2010" by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics[2] expenditure on prescription drugs in the U.S. has almost doubled between 2000 and 2008.

It is common sense that the filling of drug prescriptions needs to be reliable and dependable. The impact of receiving incorrect medicines or incorrect dosages can be catastrophic. Obviously, incorrect medicines or "misfills" can cause people to become sick and even die. In a well publicized incident, actor Dennis Quaid's newborn twins received overdoses of a blood thinning drug. These babies survived, however in a similar incident at a hospital where 17 babies received overdoses of the same drug, two died. Sadly, misfills happen all too frequently. A report by the National Foundation of Academies estimated in 2006 that medication errors injured 1.5 million people at a cost of 3.5 billion dollars from in-patient care alone[3]. This does not include the cascade of lost work productivity and health care costs for additional treatments that result.

The Factors

Of course there is no single or simple reason for medication misfills. The correct medication and dosage must be physically located, prepared and given to the patient. In a typical hospital this may include 1) order entry, getting the order from doctor into the system; 2) medication preparation; 3) delivery from the preparer to the patient location, and 4) administering the drug. As with any system, improvement starts with visibility into the errors. Then, the gambit of sources of error must be considered including human error, procedure, and physical factors (i.e. machinery and the drugs themselves). This is both a pharmacy and industry problem. And because of the wide range of possible factors, a solution with a reasonable chance of high sigma success must cover all considerations.

Medication misfill data has not always been made available for the benefit of industry improvement or patient awareness. As a result, the term "never event" for serious medical errors was coined by Ken Kizer, MD, former CEO of the National Quality Forum (NQF). There are cultural and practical reasons why this data has not always been forthcoming. Possible litigation or loss of business could make hospitals or pharmacies reluctant to release incident reports publically. They have traditionally resolved incidents individually and privately with the patient. Additionally, privacy regulations prevent releasing patient information. To improve the disclosure process, congress passed the Patient Safety and Quality Improvement Act of 2005[4]. This law encourages, but does not require, hospitals to report incidents to a

[1]Robert Longley, "Almost Half of Americans Take At Least One Prescription Drug", Government Info, About.com Guide (http://usgovinfo.about.com/od/healthcare/a/usmedicated.htm)
[2]Health, United States, 2010, (http:/www.cdc.gov/nchs/hus.htm), National Health Expenditures, Table 125
[3]Committee on Identifying and Preventing Medication Errors (Philip Aspden, Julie Wolcott, J. Lyle Bootman, Linda R. Cronenwett, Editors), "Preventing Medication Errors", National Academies Press
[4]Patient Safety and Quality Improvement Act of 2005, Public Law 109-41, 109th Congress

patient safety organization (PSO), which ensures sanitization of patient information. The incident information is shared with the system of other PSOs through a national database. Additionally, states themselves also collect misfill information, such as through a board of pharmacy, department of public health, or other named patient safety organizations. These organizations may also be responsible for disciplining pharmacists as a result of errors. Regardless, in many cases these function as a database but not as a corrective action system.

The drugs and systems associated with dispensing them play a key role in the cause and prevention of misfills. The physical factors, either in the drugs, containers, storage, distribution and dispensing system, are associated with several of the medicine preparation and dispensing process steps. Improvements have been made to systems in recent years toward making this process error proof. Dispensing machines have drugs loaded in specific bins which only open when the needed drug is requested, limiting the possibility of selecting an incorrect drug. Most hospitals now use a bed-side scanning process which matches the drug and patient in the system to ensure that medication is intended for that patient. Retail pharmacies can have a similar scanning system prior to dispensing. A weakness in the system appears to be the drug labeling and packaging. Drugs can be classified "look-alike/sound-alike" because their names and packaging are very similar. This was a contributing factor in the incorrect dosage given to the Quaid twins. Pills can have distinctive shapes and colors, but available options are limited. Vial size and packaging can be very similar because of dosage amount and manufacturer. Labels can look exactly the same except for the dose value. While names and dosages can be read on the label and pill shape/color/marking can be looked up in reference manuals, similarity contributes to the probability of human error. Overall, machine aspects have improved but still could be further changed to mitigate the opportunity for human error in the process.

Despite the increasing use of machine checks in the process, many steps still involve human interaction to ensure accuracy. The processes described herein may not be applicable at every hospital but are used as a case in point.

a) It starts with order entry. In many cases drug orders are manually transcribed from the patient chart into the order system. The administering nurse then becomes the backup check to ensure it is the same as ordered. Of course this may be a different nurse than when the drug was ordered so it is not necessarily a strong check. Electronic order systems are being implemented but process change is slow.

b) The pharmacy prepares the medicine and loads automated dispensing machines. Sources of error include selecting the correct drug and dosages, mixtures and dilution solutions, etc. This is where the physical drug packaging and labeling becomes a factor. Sources of error can be associated with co-location of look-alike/sound-alike stock, lack of special labeling and handling, use of compounding when ready-to-use products are available and insufficient training. One initiative to reduce sources of error is the High 5s project[5] on Managing Concentrated Injectable Medicines Standard Operating Protocol Fact Sheet. It is applicable to the injectibles most subject to error.

c) Even with bed-side scanning, errors in administration of medications can occur. The nurse delivering the medication must ensure that the drug is appropriate for the patient. If the scan indicates a warning, this must be investigated. The labels must be read at all applicable points of the process.

   An example of a human error incident involved a nurse administering the incorrect dosage drug. It had previously been given as three 25mg doses but was changed to one 75mg dose. The dispense machine correctly provided the bin with the 75mg vials but the nurse took three instead

[5]High 5s Project (https://www.high5s.org/bin/view/Main/WebHome)

of one because three vials had been previously administered. The bed-side scanner alerted on the second and third vials but the nurse, based on prior three vial dose, ignored the alerts. Local corrective action included eliminating the 75mg dose option to reduce opportunity for error.

The Improvement Process

Historically, medical errors have been resolved through causal analysis and feedback. Much of the effort is conducted at the hospital or pharmacy level with local analysis, feedback for training purpose and local corrective actions if possible. Databases for the collection of medication errors are becoming increasingly available. The inclusion of cause with the error data provides the opportunity to share feedback, in addition to error statistics, throughout the industry. Although the databases provide ample opportunity for training personnel, it is not apparent that all aspects of the industry are encompassed.

Traditional reliability improvement processes have been used successfully with equipment and in other industries. While the subject of this article does not deal with equipment reliability, those improvement processes could be useful to the medication industry. A strong industry organization focused on a failure reporting and corrective action system (FRACAS) would form the backbone of this process. A basis of reporting exists, however, an organization is needed to identify and document corrective actions through methodologies such as brainstorming, cause and effect (fishbone) analysis, matrix weighting, causal loop diagramming, 5 why's, pareto analysis, process mapping, etc. These methodologies would establish the cause and corrective actions necessary to successfully resolve the source of medication errors.

Of course, implementing corrective action is necessary to prevent recurrence of errors. Only through a rigorous closed loop process of implementing and verifying corrective action can all areas of cause be resolved. Not all areas of the industry appear to be fully involved in the current corrective action process. For instance, drug companies have not embraced a solution for the look-alike/sound-alike problem. They are standing on the position that the labels are correct, perhaps because of the threat of litigation or even the cost of change. It will take an industry forcing function for change at this breadth.

The medication industry needs an organization to champion the FRACAS process. Commercial air incidents are investigated by the National Transportation Safety Board (NTSB) who issue findings and recommendations. Although not bound by the recommendations, the airline industry and FAA have implemented many. The NTSB is publically recognizable and their recommendations carry both political and public weight for change. Additionally, a relationship exists across the industry, from airplane manufacturers to airlines, that facilitates a need for change despite these same concerns. This same wide-spread rigorous corrective action process and strong central organization to drive it is not available for the medicine industry.

Conclusion

The prescription medication industry has widespread interaction with a large percentage of the population. Unfortunately, incidents of medication errors such as misfills have a significant probability of occurring. Additionally, these errors have the potential for disastrous safety consequences. Although there are databases of incidents and feedback is available to use in training, primarily at the local level, broad processes for closed loop corrective action across the industry remain weak. Traditional reliability failure reporting and corrective action (FRACA) methods would benefit the establishment of a closed loop system. A strong central organization, possibly governmental, would be a key enabler for industry action. Other high reliability industries, such as commercial air, could contribute a resolution process model. The potential scope and impact of medication misfills demand a corrective action system and highly dependable outcome worthy of this safety critical industry.