

Medication Errors -- A Threat to Patient Safety

Mitigating Errors with Tablet Appearance

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THE PROBLEM

Medical prescription drug errors by doctors, pharmacists and patients account for 1.5 million incidences of sickness, injuries or deaths in the U.S. each year. Thirty percent of these unnecessary adverse events are attributed to human errors in identifying drugs and dosages. In fact, more people die from adverse drug events each year than from highway accidents, breast cancer, or complications from HIV.¹

Medical advancements and continued efforts to improve the quality of healthcare have only increased the demand for medications. Thus more medications will likely increase the scope for adverse drug events.

THE HIGH COST OF PREVENTABLE MEDICATION ERRORS

According to a report by the Institute of Medicine, approximately 7,000 deaths² are caused each year in the U.S. by medication errors. Different groups of healthcare providers in the U.S. have reported drug related injuries. Approximately 400,000 drug-related injuries occur each year in hospitals. Apparently this problem is not unique to hospitals; approximately 800,000 drug-related injuries occur in long-term care settings, such as nursing homes. Not to paint a grim picture, this all comes down to approximately one medication error per patient, per day. Pharmacies are not spared either. In fact, it is estimated that 51.5 million medication errors occur during the filling of 3 billion prescriptions each year. In addition, approximately 530,000 medication errors occur just among Medicare recipients in outpatient clinics.³

These numbers are alarming considering most; if not all medication errors could be prevented. Further, these statistics only include those medication errors that have actually been reported.

The costs of medication errors can have an enormous impact on the delivery of safe and effective patient care. The dollar value impact of preventable medication errors is roughly \$21 billion:

- Inpatient preventable medication errors cost approximately \$16.4 billion annually
- Outpatient preventable medication errors cost approximately \$4.2 billion annually⁴

This extra cost in healthcare spending is still only a conservative estimate of the real cost of preventable medication errors.

FDA RECOMMENDATION

The alarming numbers have not gone unnoticed. The FDA recently proposed a safety initiative and published a Draft Guidance document which advocates a systemic approach to medication error prevention. In the “FDA Guidance for Industry: Safety Considerations for Product Design to Minimize Medication Errors,” they maintain that predicting or pre-empting all medication errors is not possible, however, errors can be minimized by assessing, prior to marketing, how users interact with the drug product within the medication use system or environment of use.

Product design, as described by the FDA, comprises the active ingredient, strength, dosage form, product appearance, color, size, shape, palatability, etc. The goal is to design a drug product that enables safe and correct use minimizing the chances for health care practitioners, patients, and caregivers to make mistakes. The FDA advises that older adults who take more than one medicine need to be able to tell them apart by size, shape, color, number or name imprint, form (tablet or capsule), or container.⁵

ADOPTING A CULTURE OF PATIENT SAFETY

A medication can be readily identified if it has a distinctive appearance. So, clearly, pill appearance including size, shape, color or imprint can make that difference!

Color distinction of a medication can offer mental comfort, particularly to the older population whose waning eyesight may make it difficult to read labels on pill packages. Pill color is also especially important in situations where drug products have similarly spelled names. In fact, pharmacists, as dispensers, attest that the older population is the group contacting them most frequently to help identify their medicines. According to these professionals nearly 40% of identification requests are from people ages 65-84, and 36% from ages 45-64.⁶

For many, not just the elderly and their caregivers, color alone can serve as that great safety net, a simple protection against medication errors. For those who take multiple medications throughout the day, the drugs can be safely commingled in a pill sorting container where patients or caregivers rely on color or other visual clues to help them differentiate one medication from the other. Familiar colors, shape and size also help patients remember proper dosing.

Single or multiple visual cues are a defence against swallowing the wrong pills. A distinctive pill shape and color combination is also useful for patients, caregivers and emergency responders to tell the difference between co-medications or dosage sizes. Time is often a critical factor and ready drug identification can be particularly important in emergency situations.⁷

Research has unearthed that people also respond differently to different colors, and this psychology holds good everywhere, including the world of pharmaceuticals. From a medical perspective, anything that will positively reinforce taking necessary medications can impact recovery. Since physical health and emotional

health are highly interlinked, the patient who believes a specific pleasant-looking pill will achieve the results that it conjures up in his/her mind is much more likely to take the medication consistently and receive greater benefits from it. Aside from adding to the aesthetics and visual appeal of a pill, color has contributed more meaningfully to consumers as well as the pharmaceutical companies.⁸

COLORCON SOLUTION TO MITIGATE MEDICATION ERRORS

The markings of pills, color and shape, deserve the status of “a must-have” rather than “a nice-to-have” as their value can be perceived beyond aesthetics and branding. It is, therefore, critical that visual differentiation should be part of the strategy to reduce medication errors through improved product recognition.

Reducing medication errors should be a unified goal for pharmaceutical companies. For payers, namely insurance companies and the government who are trying to control spending on healthcare, pill differentiation can provide best solutions by improving compliance, reducing errors and ultimately saving treatment costs while improving patient outcomes. Last, but not the least for the patient population, pill differentiation can positively influence patient compliance and result in better health outcomes. The apparent reduction of medication errors requires a multipronged approach, ranging from financial incentives to organizational and care delivery improvements that address the root causes of these errors.

Differentiating tablets does not have to be costly; however, it does require the right resources at the right time. Selecting a development partner that can provide tablet design options based on research into currently marketed products by therapeutic category, as well as studying color, shape, logo, or special coating options offers key advantages for a manufacturer of solid oral dosages.

Colorcon, as a trusted specialty excipient supplier to leading pharmaceutical and nutraceutical manufacturers worldwide, provides just such a tablet design service, helping accelerate development timelines for formulators.

As an internationally-recognized expert in the field of film coatings, the company leverages its long-standing expertise in assisting pharmaceutical companies early in the development process. In addition to researching color, shape, logo, special coating options, Colorcon’s research and regulatory assistance helps determine the regulatory acceptance for colorant materials used in the final product design, and to evaluate the designs of currently marketed products by therapeutic category. Data on consumer medication color preferences for any region of the world is also available to customers.

The advantages this service brings significantly increase the likelihood that a prescription or over-the-counter medication will be easily recognized by patients, pharmacists, and caregivers.

Further information is available at <http://www.colorcon.com/products/brand-enhancement>.

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REFERENCES

- ¹ “Medication Error Stats & Examples;” Andrea Cook & Associates
<http://www.alcooklaw.com/practice-areas/medication-error-injury/medication-error-stats-examples/>
- ² FDA Guidance for Industry: Safety Considerations for Product Design to Minimize Medication Errors;” Food and Drug Administration: Drug Safety; December 2012
www.fda.gov
- ³ “Medication Error Stats & Examples;” Andrea Cook & Associates
<http://www.alcooklaw.com/practice-areas/medication-error-injury/medication-error-stats-examples/>
- ⁴ “Preventing Medication Errors: A \$21 Billion Opportunity;” National Priorities Partnership and National Quality Forum; December 2010
www.qualityforum.org
- ⁵ FDA Guidance for Industry: Safety Considerations for Product Design to Minimize Medication Errors;” Food and Drug Administration: Drug Safety; December 2012
www.fda.gov
- ⁶ “Survey Shows Pharmacists Believe Distinctive Tablet Appearance Reduces Dispensing and Patient Medication Errors;” Colorcon Inc.; June 2006
<http://globenewswire.com/news-release/2006/06/28/345128/101405/en/Survey-Shows-Pharmacists-Believe-Distinctive-Tablet-Appearance-Reduces-Dispensing-and-Patient-Medication-Errors.html>
- ⁷ “What is the Significance of the Color of a Pill;” Wallcur; April 2011
<http://www.wallcur.com/whitepaper-pill-color.aspx>
- ⁸ “What is the Significance of the Color of a Pill;” Wallcur; April 2011
<http://www.wallcur.com/whitepaper-pill-color.aspx>

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