

Packaging and Labeling Are at Root of Many Medication Errors

Problem: Designed Environment

On June 24 and 25, the Food and Drug Administration (FDA) held a workshop called Developing Guidance on Naming, Labeling, and Packaging Practices to Reduce Medication Errors.

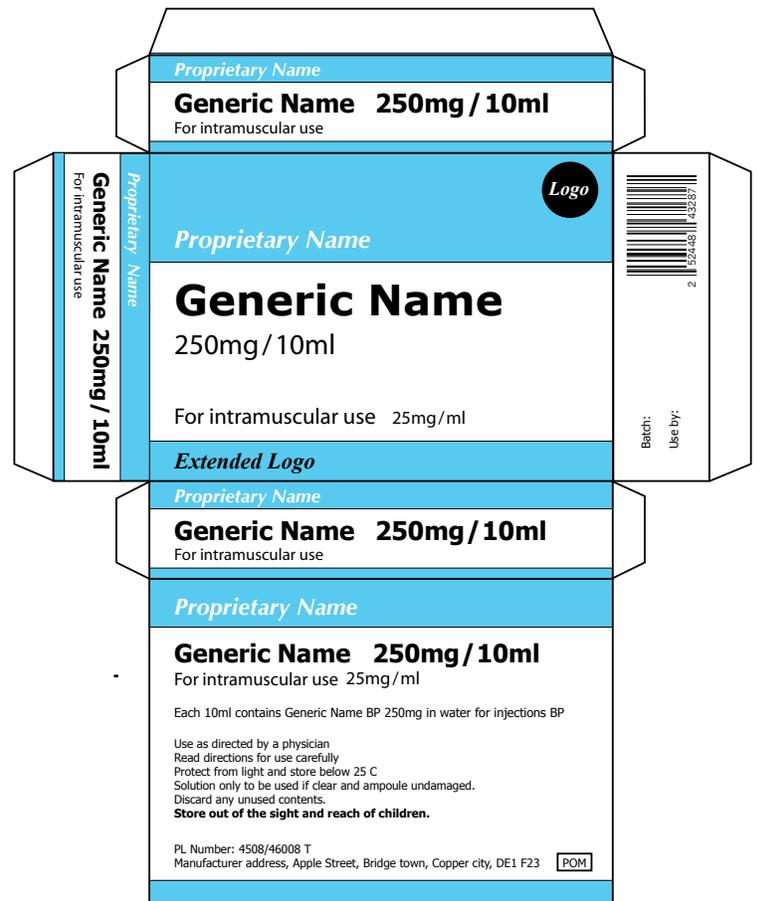
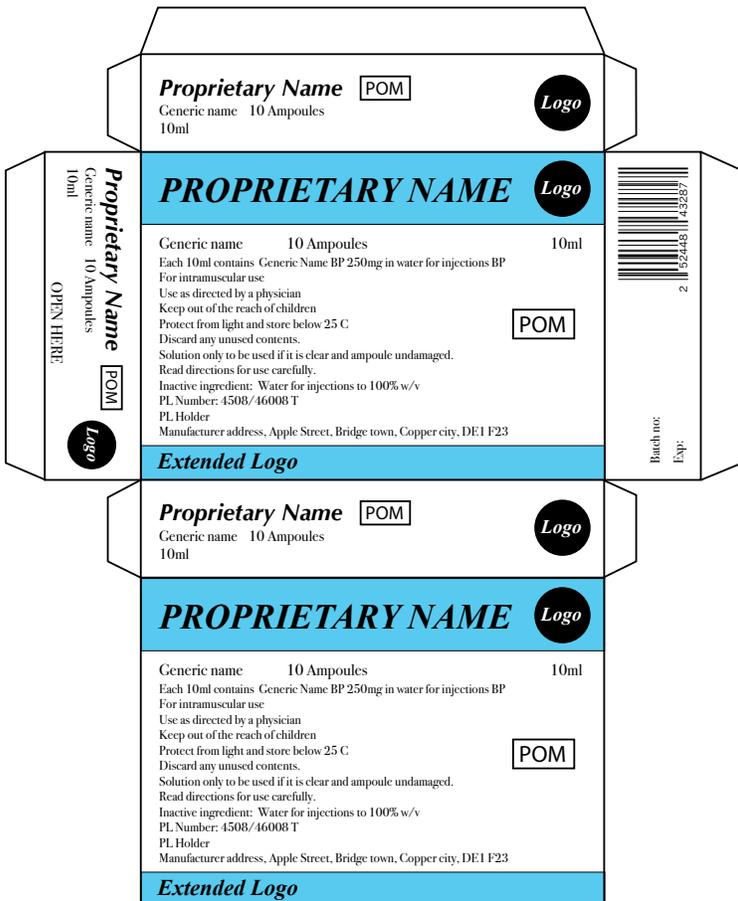
The FDA Division of Medication Error Prevention and Analysis (DMEPA) described problems with current medication packaging and labeling. One-third of all medication errors may be attributed to the packaging and labeling of drug products, including 30 percent of fatal errors.

Testimony from the DMEPA pointed out some of the issues with packaging and labeling. Taking these issues into account in purchasing decisions can help reduce the risk of medication errors.

Unfortunately, supply-chain constraints (e.g., single source drugs, shortages requiring switching manufactures) hampers a facility's ability to optimize safety. It ultimately will be up to the FDA and manufacturers to develop and implement safer packaging standards.

Labeling problems

- Inadequate differentiation between different drugs or strengths.
- Confusing statements.
- Missing or excessive information.
- Distracting images.
- Small font size or illegible information.
- Error-prone abbreviations or symbols.
- Confusing expression of strength, name or dosage form.



Application of the UK National Health Service guidance on safer packaging, before and after.

Packaging problems

Packaging a drug product in a container/closure system that implies or affords a route of administration other than intended.

Oral drug products packaged in injectable vial containers.

Oral inhalation products packaged in capsules.

Topical products packaged with closures that look similar to nasal, eye, or ear products.

Providing an amount of drug in a commercial container that is incongruent with recommended doses.

Vial overfill.

Excess drug in transdermal patches.

Multiple units required to achieve usual dose.

Configuration of solid oral dosage forms in blister packaging.

Presentation and sequencing of doses: using a fixed-dose configuration for a variable dosage regimen, grouping of tablets, etc.

Drug-device combination products (such as inhalers, prefilled pens).

Unusual or unexpected device operation.

Lack of protection against incorrect use.

Confusing or complex controls, labeling, operation.

Defeatable or ignorable safety features.

UK NHS recommendations

The UK National Health Service (NHS), in its [guide for labeling and packaging injectable medicines](#), has many recommendations for safer packages, including:

Emphasize generic name and emphasize the difference between look-alike or sound-alike medicine names.

Differentiate between strengths of the same medicine.

Orient text in the same direction, using a font that is a minimum 12 point for body text, upper and lower case, sans-serif and bold or semi-bold. Do not use condensed typefaces.

Create strong contrast between type and background color.

Put critical information in the same field of vision on at least three non-opposing faces.

Use blank space to emphasize critical information and allocate blank space for a dispensing label.

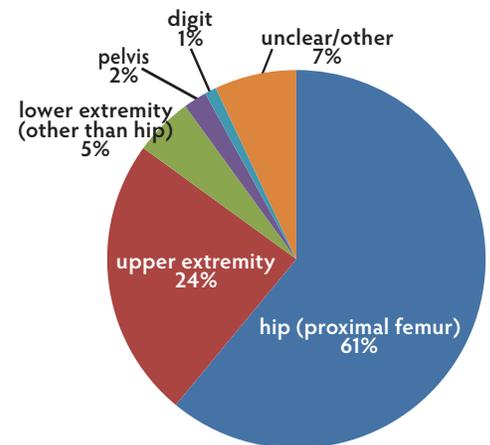
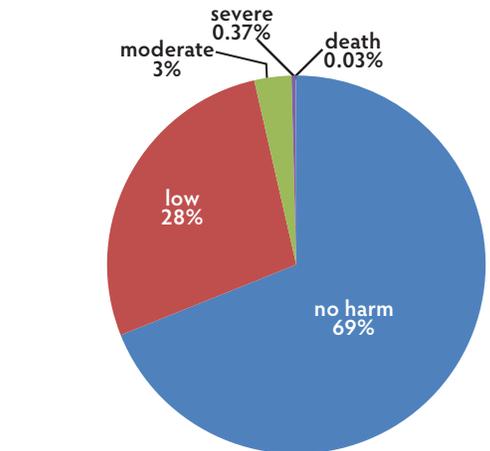
Other recommendations

Witnesses at the hearing had other recommendations as well. “De-clutter” labels by removing unnecessary text. Use positive language for correct administration route, telling users what to do instead of what *not* to do (e.g., “Vincristine: For intravenous use only. Fatal if given by other routes.” rather than “Vincristine: Not for intrathecal use.”)

— Rory Jaffe, MD MBA rjaffe@calhospital.org

UK NHS Slips, Trips and Falls Update

In the latest [Slips, Trips and Falls Update](#), the National Health Service (NHS) describes the severity of the harm in acute care hospitals and proportion of fracture types (all care settings).



NHS recommends that a falls prevention group work on both clinical and environmental risk factors and, if using a falls risk score, understand the degree to which it under- or over-predicts the chances of a patient falling.

— Rory Jaffe, MD MBA rjaffe@calhospital.org

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Eliminate Elective Deliveries prior to 39(+0) Weeks

Even though pregnancies at 37 and 38 weeks gestational age are often described as “term,” elective delivery of early term infants is associated with increased maternal and neonatal morbidity and mortality, even when fetal lung maturity criteria are met. The Regional Hospital Association collaboratives are working to eliminate elective delivery before 39 weeks. As part of its service to hospitals and the collaboratives, CHPSO is developing materials and resources on its web site to support change efforts.

CHPSO has prepared a [slide set describing the case for eliminating elective deliveries prior to 39 weeks](#). The slides briefly describe eight large studies illustrating the hazards of early term delivery. CHPSO members can [request a PowerPoint version](#) that the hospital can then customize.

Over the past year there has been a rapidly increasing number of publications addressing the issue. Many of those are available to journal non-subscribers without charge, and are so noted on the web site.

The California Maternal Quality Care Collaborative (CMQCC) is, in coordination with the March of Dimes, preparing a <39 Week Toolkit.

These resources and more are available on the CHPSO web site. The page is www.chpsso.org/perinatal/, and it will be regularly updated. Significant updates are planned in the upcoming weeks, including information on successful models for change.

— Rory Jaffe, MD MBA rjaffe@calhospital.org

What Are We Really Teaching?

As I write this, new residents are 11 days into their internship at academic medical centers across the country. They’re overwhelmed with new knowledge and beginning to wonder if they’ll ever master the complexities of delivering care and cure in today’s healthcare environment. All other clinicians are scrambling to ensure that this very necessary part of physician’s learning doesn’t result in patient harm. To everyone who is a part of this drama, my hat is off to you. I really am awestruck when I consider how well you manage this balancing act.

So, what is it that these new physicians are expected to learn? Clearly expanding their practical clinical knowledge is something we would expect. Successfully managing the patient, and not just the disease or injury, is another expectation. What’s interesting when we look at the priorities that have been articulated by the Accreditation Council for Graduate Medical Education (ACGME) is that in addition to these competencies, they’ve added some other skills that should be mastered. Among these are more subtle, even soft, skills like “system-based practice,” and “interpersonal skills and communication.” So who’s responsible for teaching these physicians, who may very well care for our loved ones or us in the future, these critical skills?

The first, and most obvious, answer is physician faculty. The key to this learning is no different than it is for clinical skills. If we don’t expect physicians to be able to intubate a patient, or place a stent, or diagnose a complex illness simply by reading a book, or by a more senior physician telling them what to do, then why would we expect these “soft” skills to develop merely through

seminars, lectures, or by reading a few articles tossed their way? Best practices in these skills must be demonstrated and practiced with constructive feedback for continuous improvement.

The teaching doesn’t stop there however. The truth is that every clinician, every member of the healthcare team, serves as a role model for shaping the norms of the healthcare environment. The fact is that every one of us serves as a teacher, a mentor and a leader; not only to those within our specific profession, but to all of those with whom we interact in a clinical setting. The phlebotomist who requests a readback of critical information, the respiratory therapist who diligently completes every step of the ECMO checklist and the RN who respectfully questions a pediatric dosage are all doing their part to teach these vital competencies. Gandhi said, “Be the change in the world that you wish to see.” So are you “Being the clinician that you wish to see?”

— Steven Montague, Vice President, [LifeWings, lifewings@verizon.net](mailto:lifewings@verizon.net).

Dirty Hands Cost Money

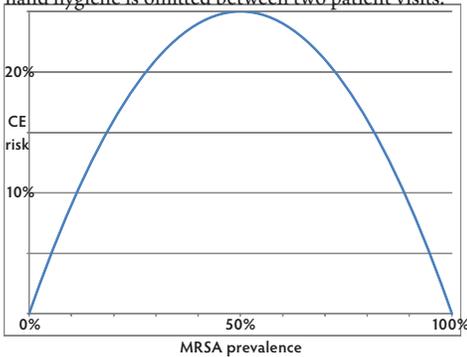
A recent study estimated the cost of hospital-acquired methicillin-resistant *Staphylococcus aureus* (MRSA) infections due to hand hygiene non-compliance. The authors used an estimated cost of about \$50,000 per hospital-acquired MRSA infection and total hospital MRSA prevalence of 4.63 percent, reflecting 2006 estimates of a typical hospital’s MRSA colonization rate.

Each non-compliance event cost \$1.60–\$2.00. If the patient were known MRSA+, a non-compliance event cost \$53.00. For a 200-bed hospital at 85 percent average occupancy, a 1 percent increase in hand hygiene compliance reduced costs by \$39,650 per year.

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The risk of a contaminated encounter (CE) (that is, patient 1 is MRSA+ and patient 2 is MRSA-) when hand hygiene is omitted between two patient visits.



If MRSA prevalence is higher now than in 2006, that would raise the cost of non-compliance. For example, raising the prevalence from 4.6 percent to 5.6 percent increases the cost of non-compliance by about 20 percent.

As high as these figures are, the calculations were solely for MRSA infections and did not attempt to estimate the expenses for other nosocomial infections. In addition, adverse effects on the affected patients and the patients' families were not quantified.

— Rory Jaffe, MD MBA rjaffe@calhospital.org

Cummings KL, Anderson DJ, Kaye KS. Hand hygiene noncompliance and the cost of hospital-acquired methicillin-resistant *Staphylococcus aureus* infection. *Infection control and hospital epidemiology*. 2010;31(4):357-64.

Calendar

The following upcoming events are still open for enrollment. For more information or to enroll, use the contacts listed below.

August

10: SCPC (Southern California Patient Safety Collaborative): Track I: Surgical Care Improvement Project, Sepsis, Hospital-Acquired Infections in the ICU Setting. City of Industry.

12: HASD&IC (Hospital Association of San Diego & Imperial Counties): San Diego Patient Safety Council; Sepsis. San Diego.

13: BEACON: Excel for Quality Improvement: Basics for Beginners. Fremont.

18: BEACON: Practical Skills for Quality Improvement. Oakland.

30: (Date change — was August 11) BEACON: Key Contacts Meeting. Location to be determined.

September

1: BEACON: Leadership Council Meeting. San Francisco.

1: BEACON: Compass Series 1 of 4. South San Francisco.

10: CAPSAC: California Patient Safety Action Coalition Meeting. Napa.

16: BEACON: Excel for Quality Improvement: Beyond the Basics. Fremont.

21: (Date change — was September 1) SCPC: Track II: Pressure Ulcers. City of Industry.

23: BEACON: Physician Leadership Meeting. Location to be determined.

24: BEACON: CNE Meeting. Location to be determined.

October

6: BEACON: Compass Series 2 of 4. South San Francisco.

6: HASD&IC: San Diego Patient Safety Council; Sepsis. San Diego.

26: BEACON: Quarterly Meeting. Fremont.

November

9: BEACON: Compass Series 3 of 4. Redwood City.

16: SCPC: Track I: Surgical Care Improvement Project, Sepsis, Hospital-Acquired Infections in the ICU Setting. City of Industry.

19: BEACON: Practical Skills for Quality Improvement. Fremont.

December

2: SCPC: Track II: Pressure Ulcers. City of Industry.

3: CAPSAC: California Patient Safety Action Coalition Meeting. Torrance.

15: HASD&IC: San Diego Patient Safety Council; Sepsis. San Diego.

15: BEACON: Compass Series 4 of 4. South San Francisco.

16: (Date change — was December 15) BEACON: Practical Skills for Quality Improvement. Redwood City.

For further information on these events:

BEACON: Petrina Aiello paiello@hospitalcouncil.net or www.beaconcollaborative.org

CAPSAC: Theresa Manley manleyt1@pamf.org or www.capsac.org

HASD&IC: Lindsey Wade lwade@hasdic.org

SCPC: Catherine Carson ccarson@hasc.org