

Managing pharmaceutical package labels with color to reduce medication errors

FDA Part 15 Hearing on use of color on pharmaceutical labeling and packaging

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Pennsylvania Patient Safety Reporting Program

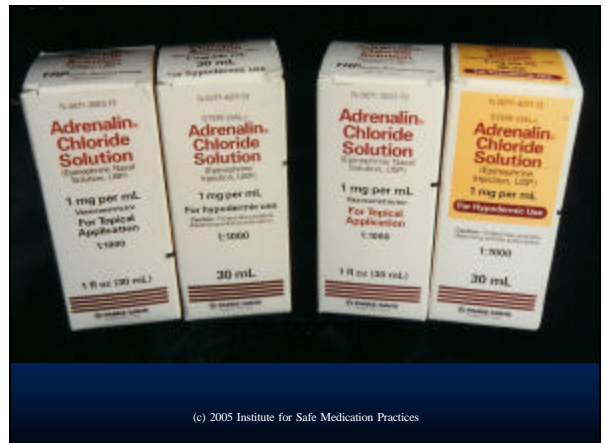


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Color Differentiation

- Can be helpful if carefully thought through
 - e.g. using color coding to differentiate three concentrations of sodium chloride injection
- Can be helpful in drawing attention to certain portions of a label
 - dosage concentration of a product (50% dextrose vs. 5% dextrose)
 - differences between similar names
 - warnings (e.g. must be diluted)

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Color matching

- A medical device may have a blue plug that attaches to a blue receptacle and yellow plug that attaches to a yellow receptacle. However, the colors have no special meaning beyond matching one item with another.

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Color coding

- Systematic application of a color system to identify specific information
 - Use of color-coding of caps and labels for ophthalmic products (e.g. tan = anti-infectives, pink = anti-inflammatory agents)

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Color coding

- Research-based evidence regarding use of color coding and reduction of medication errors is essentially lacking at this time
- Although color coding may help to differentiate drug classes, it may increase intra-class medication errors
 - Example 1: Color code by drug class and various drugs within a class may be confused with one another.
 - Example 2: Color code by drug and various strengths or concentrations for that drug may be confused

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Induction agents	
Propofol _____ mg/ml	Rofexane _____ mg/ml
Muscle relaxants	
Succinylcholine _____ mg/ml	Venomban _____ mg/ml
Narcotics	
Morphine _____ mg/ml	Fentanyl _____ mg/ml
Vasopressors	
Epinephrine _____ mg/ml	Epinephrine _____ mg/ml
Anticholinergic agents	
Atropine _____ mg/ml	Diprivate _____ mg/ml

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Read labels carefully - 3 times!

- When obtaining package
- When using package
- When discarding package or returning to storage

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Considerations with color on labels

- Never rely on a single variable such as color. One must always take into account amount and size of text, “corporate dress” including fonts, shape, size, logos, backgrounds, the manner in which corporate identity is expressed, similar strengths, etc., etc.
- Highly stylized labels distract and are more prone to mix-ups

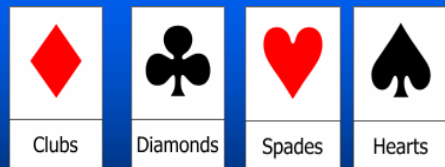
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Clubs Diamonds Spades Hearts

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Considerations with color on labels

- Potential for mix-ups within the class must be considered

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Considerations with color on labels

- Prototype testing with front-line practitioners and expert panels is essential
 - Environment of use and work processes must be considered:
 - » What works well in an ophthalmologist's office may not work well in a pharmacy or short procedure unit
 - » What works well in an OR may not work well in an ICU or an ER
 - What will be stored nearby?
 - What other drugs within the color class might it be confused with?
 - Etc., etc.

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Failure analysis

- A systematic assessment of how and where pharmaceutical trademarks may be vulnerable to confusion
- Set up process flow diagram
- Determine failure modes
- Rank likelihood of occurrence, severity of outcome
- Where effects of errors are judged unacceptable, action may be taken to minimize potential for errors

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Consider Process Flow:

- Entry into inventory
- Drug storage environment
 - Light, space, relation to other items
- Drug delivery system
- Who are the users?
 - Level of experience
- Environment of use
 - Storage
 - Dispensing
 - Administration

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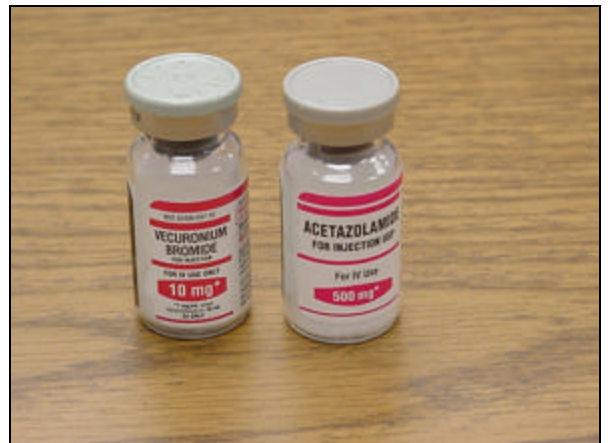
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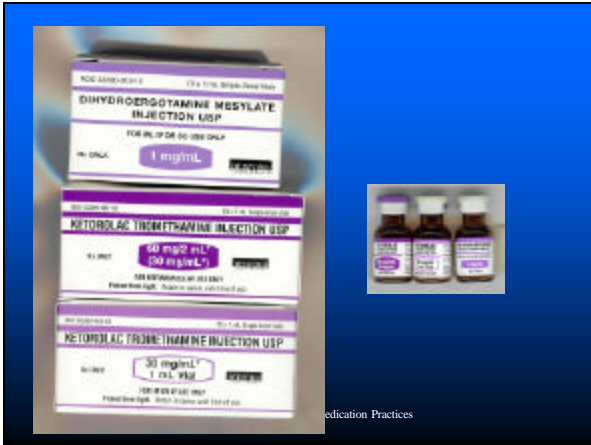


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Medication Practices



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PATIENT SAFETY PROGRAM

DOD PATIENT SAFETY CENTER ALERT

(2-04)

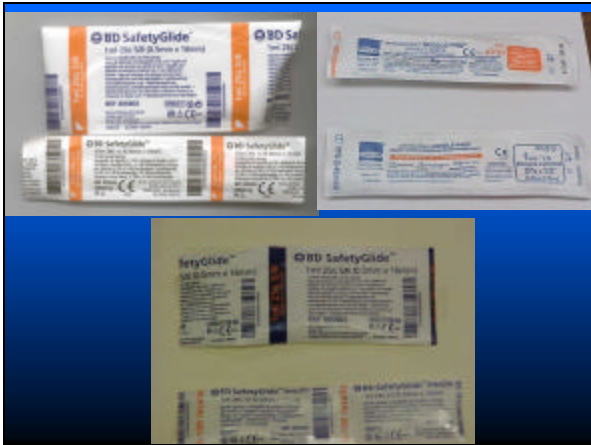
Similar Packaging and Labeling of Insulin and Tuberculin Syringes May Lead to Errors

The Naval Medical Center San Diego recently identified a potential for error due to similar packaging of insulin and tuberculin syringes by manufacturers. The specific products involved are the 1 cc (0.4 L) 25-gauge tuberculin syringe and the 1 cc (0.4 L) 25-gauge insulin syringe. Both syringes contain orange in various degrees on the product labels and the syringes themselves. A similar alert was recently issued by the Institute for Safe Medication Practices (ISMP) in their November 2003 Community/Outpatient Care Newsletter.

The issues are:

1. Both syringes have similar labeling. The packages and syringes look virtually identical.
2. Although the package for the insulin syringe contains more orange, orange is used on both packages.
3. The color orange is also used on both syringes.
4. 10:58 insulin over-doses are possible if the 10:58 mark on the tuberculin syringe is mistaken for units.

The bottom of the slide contains two images. The left image shows the packaging for insulin syringes, and the right image shows the packaging for tuberculin syringes. Both images show the syringes and their respective boxes.



Considerations with color on labels

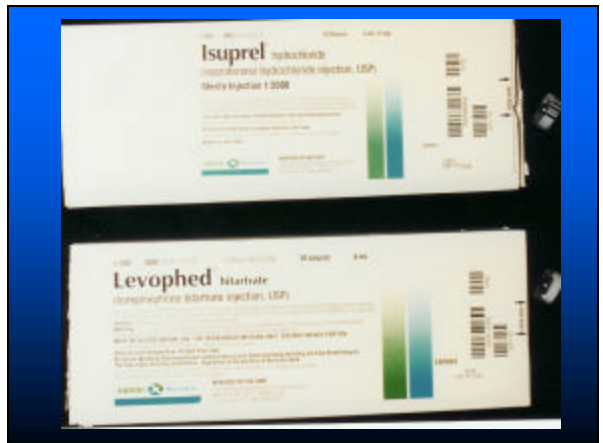
- Haphazard application of multiple colors to differentiate products must be avoided
- Again, take into account amount and size of text, “corporate dress” including fonts, shape, size, logos, backgrounds, the manner in which corporate identity is expressed, similar strengths, etc., etc.

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Caution
Look alike packaging
Proceed with care

Color “coding” causes mass confusion

Worth Repeating...
Tetanus toxoid vaccines again used for PPD
The Centers for Disease Control and Prevention (CDC) has published a warning. Standardized intradermal administration of tetanus, toxoid-containing vaccines instead of tuberculin skin tests, 2007-2008, 2007-2008, 2007-2008 about potential misadministration of tetanus toxoid-containing vaccines instead of tuberculin purified protein derivative (PPD). Vaccines previously authorized for PPD include tetanus toxoid and diphtheria and tetanus toxoids. In April 2008, 100 patients in 17 states had been identified as receiving a tetanus toxoid vaccine product instead of PPD. In April 2008, the additional cases were identified, some patients had localized responses that were interpreted as positive PPDs, which resulted in unnecessary treatment for tuberculosis with isoniazid (INH).



Considerations with color on labels

- Color should primarily draw attention to drug name and dose
- Ask, where is user's attention drawn?

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Color draws attention AWAY from important information



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Color blocks view of drug name



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Color memory helps to recall item incorrectly



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Considerations with color on labels

- Color (including use in reverse print) can be used successfully to
 - Differentiate products
 - Draw attention to important information such as warnings
 - Enhance recognition of unique letter characters of drug names

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differentiate



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Differentiate ("tall man" emphasizes)



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Warn



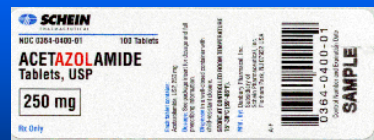
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Warn, inform, differentiate



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emphasize



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Final Recommendations

- Practitioner input, expert analysis is essential
 - FMEA methods
 - Large scale scientific studies should NOT be required
- Label consults with ODS DMETS with final decision-making authority
- Support for error reporting and more rapid response by FDA for serious problems
- Reserve color coding for “high alert” drugs such as insulin, neuromuscular blockers, concentrated electrolytes, etc. **BUT ONLY AFTER TESTING AND FEEDBACK ABOUT PROTOTYPES**
 - Use portion of package for color scheme and not associated with label information such that it draws attention away from identifying drug and strength

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Final Recommendations

- Color coding must be uniform throughout the industry not just one company brand
- Understand that actual color code schemes require simultaneous and ongoing education of health care professionals as to meaning
 - color code for user applied labels in anesthesia well known to anesthesia; ophthalmics to ophthalmologists but NOT by staff outside the OR which may contribute to user error
 - has staff education taken place?
- Bar coding will help
- Support scientific research for use of color but only as one of many variables, not by itself or in an isolated health care environment

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Are safety recommendations evidence-based?

Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon C S Smith, Jill P Pell



“Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials”

Ref: BMJ Vol 327, 20-27 December 2003



“Aviation safety was not built on evidence that certain practices reduced the frequency of crashes. Instead it relied on the widespread implementation of hundreds of small changes in procedures, equipment, training, and organization that aggregated to establish an incredibly strong safety culture and amazingly effective practices.”

In health care, the progress in anesthesia safety is a comparable example.

Leape LL, Berwick DM, Bates DW. What practices will most improve safety? *JAMA* 2002;288:5017

Enhanced text differentiates



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