MED SAFETY BOARD

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A CALL TO ACTION:

Pharmaceutical Manufacturers Must Ensure Injectable Medication Labels are Well-Differentiated to Prevent Patient Harm

A White Paper

About Med Safety Board

Med Safety Board is a wholly owned subsidiary of the Institute for Safe Medication Practices (ISMP), the only 501c (3) nonprofit organization devoted entirely to preventing medication errors, and an affiliate of ECRI, one of the foremost independent healthcare patient safety experts, dedicated to advancing evidence-based healthcare globally.

Built upon its heritage of decades of expertise in medication and device safety and its unparalleled breadth and depth of medication safety knowledge, Med Safety Board is uniquely positioned to assist the pharmaceutical and medication-related device industry in proactively identifying and addressing product risks for safe use in the clinical environment.

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About This White Paper

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Manufacturer anonymity: Medication labeling issues, particularly related to design and the potential for mix-ups, have been cited with products from multiple different pharmaceutical manufacturers throughout the years. This White Paper is intended as a call to action and to educate the greater healthcare community about the problem as a whole. As such, brand and manufacturer names, as well as identifying label elements, have been redacted in the examples of error-prone medication label designs illustrated in this document. The examples, though, are representative of actual events that have been reported through the ***ISMP National Medication Errors Reporting Program*** (ISMP MERP).

Scope: Numerous unsafe medication labeling and packaging conditions can exist, such as the use of certain abbreviations or symbols; error-prone expressions of the concentration, strength, or quantity; statements that do not clearly convey important messages; confusing formats for expiration dates and lot numbers; and packaging that does not match the intended route (e.g., supplying an oral product in a vial that is typically used for parenteral medications). However, the scope of this White Paper is limited to the concern with products, particularly those by the same manufacturer, that can easily be mixed up due to their look-alike appearance and lack of differentiation. Med Safety Board recommends pharmaceutical manufacturers not only consider the recommendations provided in this White Paper but also proactively evaluate their product labeling and packaging for other safety concerns by following US Food and Drug Administration (FDA) guidance documents[1-2] and based on lessons learned from events published by ISMP. Similarly, Med Safety Board encourages healthcare organizations to also consider these other error-prone aspects of product labeling and packaging when determining which products to purchase or add to their formulary. Additionally, the examples shared in this document refer to injectable medications, primarily those supplied in bags and vials; however, ISMP also receives numerous reports of mix-ups involving look-alike products in other presentations, such as bottles containing oral-solid medications. Many of the same issues and recommendations noted in this White Paper can also be applied to other dosage forms and types of packaging.

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Introduction

One of the most frequently reported issues with injectable products received by the Institute for Safe Medication Practices (ISMP) through the ***ISMP National Medication Errors Reporting Program*** (ISMP MERP) involves look-alike medication labels.[3-4] This includes look-alike similarities between different medications, different strengths or concentrations of the same medication, and different routes of administration of the same product.

While look-alike confusion can occur between products from different manufacturers, by far mix-ups reported to ISMP most often occur between medications supplied by the same pharmaceutical company. Manufacturers frequently want to create a corporate trade dress (the manner in which a company labels their products to create a commercial image or identity) across the various medication labels within their portfolio of products by using similar or the exact same colors, designs, graphics, and font styles. However, this approach often inadequately distinguishes between different products, resulting in labels that look too similar, which can contribute to mix-ups. Unfortunately, while ISMP has published events involving look-alike products for decades, in the hopes that lessons can be learned, mix-ups between different products by the same manufacturer continue to be reported to ISMP due to the lack of differentiation, resulting in patient harm.

Reasons Mix-ups Occur

Mix-ups involving look-alike medication label designs are more likely to occur when there are other overlapping product similarities, including the following:

Same or similar label content	Same or similar container packaging	Same product storage locations
— Same/similar medication name — Same infusion bag base solution — Same or overlapping numbers in the strength/concentration	— Same/similar container type and shape — Same/similar container size (e.g., both are 100 mL bags) — Same or similar vial cap color — Same type of overwrap or carton — Both are amber vials versus clear vials	— Stored near each other alphabetically — Same storage requirements, such as refrigeration — Overlapping clinical use (e.g., both stocked in anesthesia carts)

Errors in which similar-looking products are mixed up may involve the label on the container (e.g., bag, vial) or the outer packaging (e.g., overwrap, carton, cardboard shipping box). Mix-ups can also occur at various points throughout the medication-use process including from placing the product into storage, selecting products from storage for preparation or dispensing, stocking patient care locations (e.g., in automated dispensing cabinets [ADCs]), and retrieving medications from storage for administration.

Impact on Patient Safety

Patient events involving mix-ups of high-alert medications (defined by ISMP as drugs that bear a heightened risk of causing significant patient harm when used in error[5]), such as neuromuscular blocking agents, anticoagulants, opioids, insulin, vasopressors, and concentrated electrolytes, have led to adverse patient outcomes, including severe harm and even fatalities. In addition, poorly designed labels can burden healthcare organizations by requiring them to expend additional financial and staff resources to address the safety risks.

For example, organizations may need to add signage or other warnings, such as auxiliary labels, on the look-alike medication containers and storage locations to highlight the differences in the products, and ensure the products are well-segregated in all storage areas or stored in a certain configuration (e.g., with the vial label facing up, instead of the cap). Although not always possible with drug shortages, facilities may also need to identify alternative products from other manufacturers that are more distinguished in appearance and limit the purchasing of one of the products in a problematic pair. Additionally, to facilitate barcode scanning at the various steps in the medication-use process to catch a possible mix-up, if there is not a readable manufacturer barcode, the pharmacy may need to repackage or apply scannable auxiliary barcodes to each individual product. This all takes staff time, diverting valuable resources from other patient care activities, and may introduce errors due to manual processes involved in trying to "fix" a manufacturer's poor label design.

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Contributing Factors

When a product mix-up occurs, the look-alike similarity between the involved manufacturer product labels is often identified as just one of several contributing factors. Other latent failures may also be embedded within the system, such as barcode scanning process flaws in which the end user is only required to scan one bag or vial when multiple bags or vials are required for compounding or stocking. Active failures by individuals, such as human error and at-risk behaviors, also will have likely occurred, including human error arising from personal or environmental performance shaping factors (e.g., anxiety, stress, fatigue, low lighting, interruptions). Perceptual biases also contribute to human error, including confirmation bias, which is a phenomenon that leads individuals to "see" information that confirms their expectations, rather than information that contradicts their expectations, such as similar-looking medications that have been accidentally mixed together in the same storage bin.

While healthcare organizations need to safeguard the medication-use system, particularly for high-alert drugs, by implementing various strategies throughout each step in the process, manufacturers also play an important role in adding layers to the system to defend against errors. Using James Reason's "Swiss cheese" model, each layer or slice of cheese represents a part of the system intended to protect patients from errors, with each hole in the slices of cheese representing a latent failure that can possibly allow an active failure to get through. Adding more defense layers into the system, particularly high-leverage strategies, by both healthcare organizations and manufacturers, lessens the risk that the holes will perfectly align and that an error will reach and harm a patient.

More careful label design is needed by manufacturers to better differentiate the products within their own portfolios, in order to create an additional defense layer in the system to shield patients against errors. While the US Food and Drug Administration (FDA) Division of Medication Error Prevention and Analysis (DMEPA I and II) recommends safe label design and does evaluate labeling and packaging of products submitted for approval, ISMP has called for a more robust, standard, and proactive evaluation process that requires and enforces safe labeling and packaging practices for brand and generic products.[4] Other professional organizations have also recognized and addressed the issue of manufacturer look-alike medication labeling and packaging and its impact on patient safety.[6-9]

Pharmaceutical companies should take note of the critical role that they can play in minimizing harm to patients and act with a sense of urgency to produce safer product label designs by adhering to the following key labeling considerations, which are supported by actual examples that have been reported to ISMP. Until manufacturers can improve their label designs, healthcare facilities should also evaluate products before adding them to their formulary[10] and, when possible, select products with safe label designs that incorporate attributes found in the following recommendations.

Key Labeling Considerations

1 Prominently display critical information on the principal display panel of the container label, as well as the carton or overwrap labeling, allowing end users to readily identify products.

Critical information is the essential information that is necessary for end users to correctly select and use a medication. How prominently this information appears on the label depends on several factors.

Critical product information includes the following:

- Product name and dosage form
- Strength or concentration
- Route of administration
- Important warning or cautionary statements (e.g., such as for paralyzing agents)

Prominence depends on the following:

- Font size, particularly compared to the other label content and size of the container
- Readability of the font style and type selected
- Color contrast between the text and the background color
- Inclusion of distracting graphics or overshadowing logos
- Position or placement (e.g., visibility when viewing a vial head on)

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When this key information does not prominently stand out, mix-ups can occur as the labels may look too similar or healthcare practitioners may not be able to immediately distinguish between the different products. In one such example (**Figure 1**), the critical information (drug name and concentration) appears in a font size that is much too small, making it difficult to tell the two different concentrations apart.

*A pharmacist was checking a premixed bag of lev**ETIRA**cetam and identified that the wrong concentration had been selected, avoiding a dispensing error. The two different concentrations of lev**ETIRA**cetam by the same manufacturer (1,000 mg/100 mL and 500 mg/100 mL) had accidentally been mixed together in the same storage bin in the pharmacy.*[11]

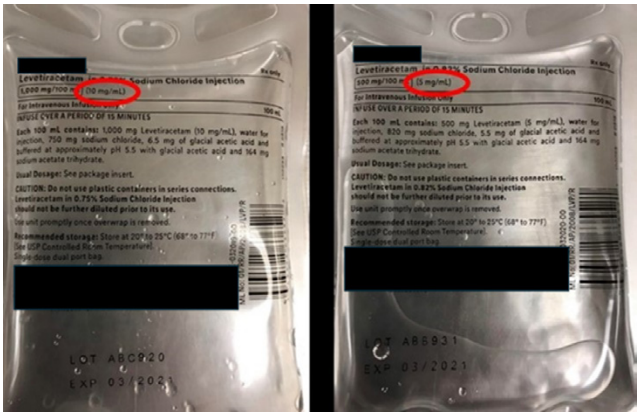

Figure 1. Two different concentrations of lev**ETIRA**cetam (1,000 mg/100 mL [left] and 500 mg/100 mL [right]) with small print for the drug name and concentration, making the labels look nearly identical.

In another example (**Figure 2**), a serious event occurred involving two different infusions. The critical information on both medication labels appears in an orange color that has poor contrast against the background of the clear bag, making it difficult to read and identify the difference between the two containers.

A nurse retrieved what was believed to be two 100 mL bags of magnesium sulfate 1 g from an ADC that had been ordered for a patient with hypomagnesemia. The nurse scanned the barcode on the first bag and started the infusion. Once the first 1 g dose of magnesium sulfate had finished infusing, the nurse hung the second bag and administered the infusion. However, instead of scanning the barcode on the second bag, the nurse scanned the barcode on the first bag that had finished infusing.

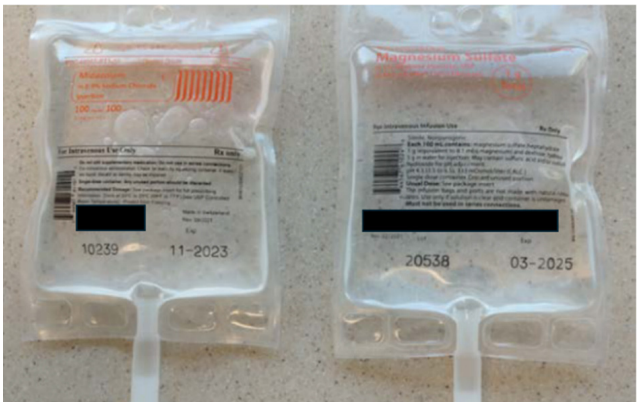

Figure 2. Midazolam 100 mg/100 mL (left) and magnesium sulfate 1 g/100 mL (right) labels appear similar once removed from the overwrap, with the drug name and concentration displayed in an orange font with poor contrast against the clear background.

The patient experienced respiratory depression, which was initially thought to be related to their illness. When later discarding the bags from the intravenous (IV) pole, the nurse identified that the second bag that had infused was actually midazolam 100 mg/100 mL, not magnesium sulfate, at which point several doses of flumazenil were administered. Following an investigation, it was determined that a pharmacy technician had accidentally stocked the midazolam bag in the ADC bin intended for magnesium sulfate. Once the overwrap had been removed from both products, it made it more difficult to distinguish between the two and to see that they contained different medications.[12]

End users should also be able to view the critical information without having to rotate the container, no matter the orientation of the container; otherwise, this key information could be missed.

Recommendations

- Critical product information should be the most prominent information and appear on the principal display panel of the label.[1] See example bag and vial labels that illustrate these recommendations in **Figures 3** and **4** (**page 6**).
- To ensure the critical information stands out:
  - Maximize the font size.
  - Use a readable font (e.g., sans serif).
  - Use tall man (mixed-case) lettering for the medication name when applicable.
  - Select a text color that has high contrast with the background color or container/packaging material.
  - Utilize other means to draw practitioners' eyes to this key information, such as through the use of bolding, color, reverse print, and/or boxing or other design features to highlight critical pieces of information.
  - Minimize crowding by providing space surrounding the critical information, and avoid the use of distracting designs and logos.

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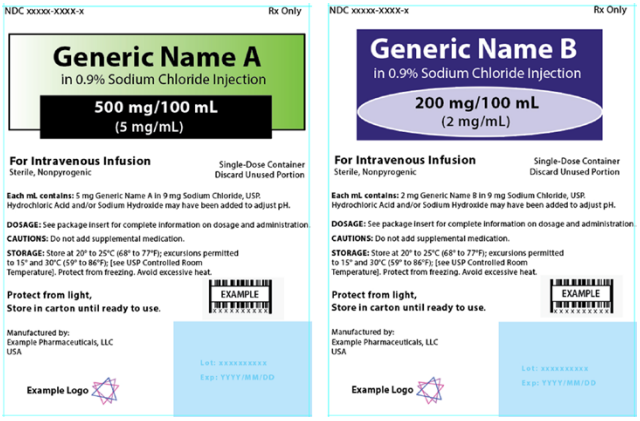

Figure 3. Example bag labels of two different medications (Generic Name A and Generic Name B) in which the critical information appears prominently, different colors and designs are used to make them each appear distinct and readable, and the barcode is printed using dark black lines.

Figure 4. Example vial labels of two different strengths of Generic Drug C in which the critical information appears prominently, different colors are used to highlight the key difference (the strength), and the barcode is positioned vertically.

— Place the critical information in a location on the label that will allow the end user to see it immediately and that is within their field of vision without requiring rotation of the container, no matter the orientation of the container. This may necessitate certain pieces of critical information be repeated, for example, so that practitioners can read the label on a vial both when it is stored upright and when it is hung upside down during administration, or when an infusion bag is placed face down.

2 Utilize color and design elements to differentiate container labels, as well as carton or overwrap labeling, to ensure products appear distinct.

While it is crucial to ensure that the critical product information appears prominently on the label, if the same or similar design elements and colors are used for multiple products, errors can still result. It is imperative that the essential information, such as the product name and concentration, stand out, but also that the labels appear sufficiently distinct in their design with the use of color to ensure that practitioners can readily recognize the difference and affirm that they have the correct product in hand.

When manufacturers create product labels by using the exact same design elements and colors, placed in the exact same locations on the labels, products can easily be confused with one another as the following example illustrates.

*A pharmacy technician mistakenly placed a bag of magnesium sulfate injection (4 g/100 mL) in the dexmede**TOMID**ine injection (400 mcg/100 mL) bin in an ADC during the refill process. Fortunately, the nurse who retrieved what she thought was dexmede**TOMID**ine scanned the barcode prior to administration and identified that she instead had a bag of magnesium sulfate* (**Figure 5**).[13]

A mix-up between these two high-alert medications, due to the nearly identical design and colors being used on the overwrap labeling, could result in serious patient harm if the wrong product is administered.

Figure 5. Nearly identical overwrap label design of magnesium sulfate (left) and dexmede**TOMID**ine (right) by the same manufacturer.

Similar errors have been reported with vials, particularly those used by practitioners in the perioperative and emergency settings, and when the vial cap color and vial size and type (e.g., amber versus clear) are also the same or similar. In these areas, the vials may be stored in an open matrix configuration tray, cart, or box with the cap up, increasing the similar appearance and ease with which the wrong vial can be selected, often in a fast-paced and stressful environment. Also in these settings, barcode scanning may not be available. Thus, there are even fewer barriers in place to prevent the patient from receiving the wrong medication.

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For example, a close call (i.e., near miss, good catch) was reported related to two products made by the same manufacturer that are typically stored in emergency carts. Not only do the labels appear nearly identical with similar colors and designs, but the vial size is similar, and the cap color is the same (**Figure 6**). For this particular medication pair, administering the wrong drug could have critical cardiac implications for patients.

In yet another event, almost identical vials that share a similar label design and colors, along with similar vial cap colors and sizes, were mixed up (**Figure 7**).

Verapamil 5 mg/2 mL was stocked in the anesthesia tray location intended for glycopyrrolate 0.2 mg/mL. When the anesthesiologist selected a vial of what they believed to be glycopyrrolate and drew up the entire vial contents, they noticed that it was more volume than normal and at that point realized that they had drawn up verapamil instead. As the patient was already bradycardic, it could have resulted in a serious outcome had the error reached the patient.[14]

Mix-ups can also occur when products are being compounded in the pharmacy. The potential for mix-ups with different potassium salts, which are both high-alert medications, has been reported due to the similarity in appearance once the vial caps have been removed, since the same label design and colors are used (**Figure 8**).

Even when different design features are utilized on labels of different products, if the labels contain the same colors, even if the placement of the colors differs, the medication labels can still appear similar and be mixed up. The following example demonstrates how such confusion can occur (**Figure 9**).

A nurse caring for a patient receiving a continuous infusion of Drug A was urgently called away to assist with another patient. Anticipating that the patient's continuous infusion was going to run out soon, the nurse first retrieved a replacement bag from the ADC. In her rush to leave to care for the other patient, though, the nurse did not scan the barcode on the bag before hanging it. When the nurse returned an hour later, she scanned the barcode on the infusing medication and discovered that Drug B, a high-alert medication, had been administered instead. It was later determined that a pharmacy technician had placed the wrong product in the ADC bin during the stocking process, scanning one correct product and inadvertently placing the wrong product along with it in the bin. The patient required intervention as a precaution but was luckily unharmed. However, had the wrong medication continued infusing, the patient may have experienced a much more serious outcome.

Figure 6. Similar-looking vials (left) that may both be stored near each other in a code cart (right), increasing the risk of mix-ups when stocking or selecting for administration.

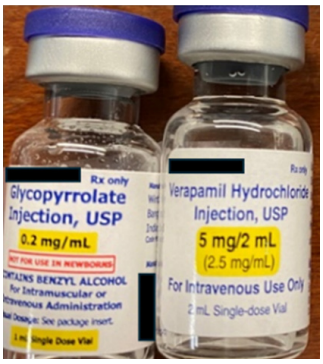

Figure 7. Similar vials of glycopyrrolate (left) and verapamil (right) by the same manufacturer have been mixed up due to the same label design.

Figure 8. Potassium chloride for injection concentrate (left) and potassium phosphates (right) vials with the caps removed share a similar yellow label background and black band highlighting the drug name.

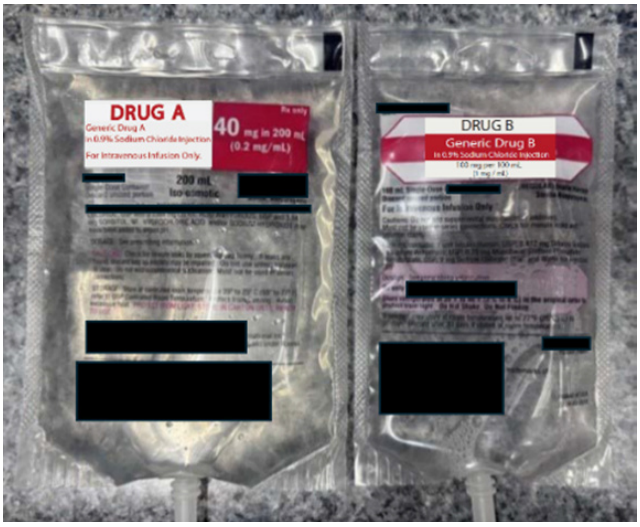

Figure 9. Two different high-alert medication infusion bags (Drug A [left] and Drug B [right]) with different label designs can still be mixed up when the same colors are used.

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In another case, similar-looking vials were mixed up and almost reached the patient (**Figure 10**). While each label uses slightly different geometric shapes, both have the same blue and white label colors and blue caps.

A few vials of etomidate were mixed in with pantoprazole vials in an ADC. Luckily, a nurse identified the error when retrieving a dose of pantoprazole. Otherwise, serious harm to the patient could have occurred had etomidate been given instead.

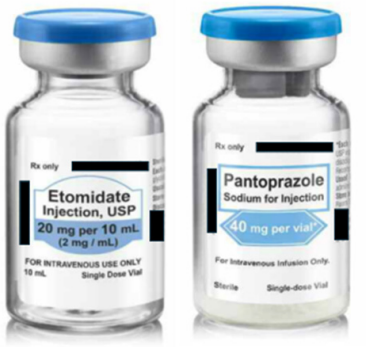

Figure 10. Look-alike etomidate (left) and pantoprazole (right) vials by the same manufacturer.

Recommendations:

- As recommended by the FDA, *"Sponsors should create a container label and carton labeling design that is sufficiently distinct from that of their other products so that the end user is able to correctly identify, select, dispense, and administer the appropriate medication, strength, and dose."*[1]
- To accomplish this, first identify the products that are most likely to be mixed up by considering overlapping similarities (e.g., container size, locations where they will be stored and used, medications that come in multiple concentrations) and determine the key information that differs between the products that should be highlighted.
- Incorporate different colors and/or bolding, boxing, reverse print, or other design features, on both the immediate container label (e.g., bag, vial) and any overwrap or carton labeling, to highlight the key differences between products and to draw end users' attention to the important piece of information. Avoid using the same colors and only changing a design feature or shape (e.g., using a circle versus triangle to highlight the strength/concentration), as this will likely be insufficient to make the labels distinct. See example bag and vial labels that illustrate these recommendations in **Figures 3** and **4** (**page 6**).
- Validate the use of additional colors and the ability to increase the number of colors that can be printed on each label, particularly for bags, which will provide more options for differentiating products.
- Print the label design on a white label, at least for the critical information, instead of printing the text on a clear background, to improve readability with different color choices and color contrast.

3 Ensure the label contains a readable barcode that can be scanned at each step in the medication-use process.

While barcode scanning may not always catch an error due to scanning process flaws or workarounds in the system (e.g., scanning after administration, only scanning one container prior to stocking multiple containers, overriding an alert, scanning a proxy label), in order for this safety technology to be effective and to facilitate compliance, it is imperative that labels are designed such that the barcode can be easily scanned at each step of the medication-use process from stocking, selecting, and preparation in the pharmacy, to stocking on patient care units and prior to administration.

Numerous reports have been shared with ISMP of vials in which the barcode is wrapped around the curvature of the container, rather than placed vertically, making it difficult or nearly impossible to scan. In one such case (**Figure 11**), nurses mistakenly thought that the product label had been scanned, but the scan had actually failed as the barcode could not be completely read by the scanner due to how it is printed horizontally on the curve of the vial.

Figure 11. Barcode wraps around the curvature of the vial, not allowing it to be captured by a barcode scanner.

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Reported barcode issues with bags have included white barcodes printed on a clear bag that are difficult to scan, as well as overwrap seams that interfere with the ability to scan the bag through the overwrap. This is particularly concerning when large-volume bags from the same company use the same colors (red and blue) in similar locations on a transparent bag, making it difficult to read the text (**Figure 12**).

In yet another similar example, concerns for mix-ups have also been shared with ISMP regarding bags containing different heparin concentrations (**Figure 13**) from the same manufacturer as the bag labels utilize the same red and black font with similar boxing of the concentration. This is again especially problematic as it has been reported that the barcode on the 1,000 units/500 mL bag is difficult to scan.

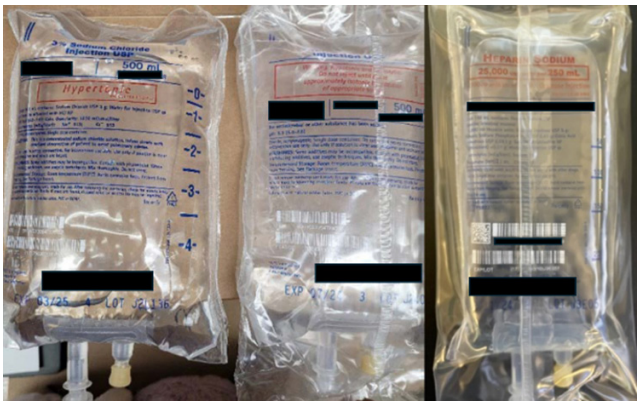

Figure 12. Bags of 3% sodium chloride (left), sterile water for injection (middle), and heparin (right) look similar with blue and red text. All have white barcodes that are difficult to scan, and the overwrap seam of the heparin bag also interferes with barcode scanning.

Recommendations:

- Print the barcode on the label using dark black lines on an opaque white background. See example bag labels that illustrate this recommendation in **Figure 3** (**page 6**).
- Test the barcode printed on the actual container and in a variety of settings (e.g., low-level lighting similar to an intensive care unit) to ensure practitioners can successfully scan the barcode in any environment.
- Position the barcode so that it does NOT wrap around the curvature of the container. See example vial labels that illustrate this recommendation in **Figure 4** (**page 6**).
- Ensure that a readable barcode is present on the immediate drug container and that a barcode can be scanned either on the overwrap or carton, or the container barcode can be scanned through a clear overwrap without interference of the overwrap seam.

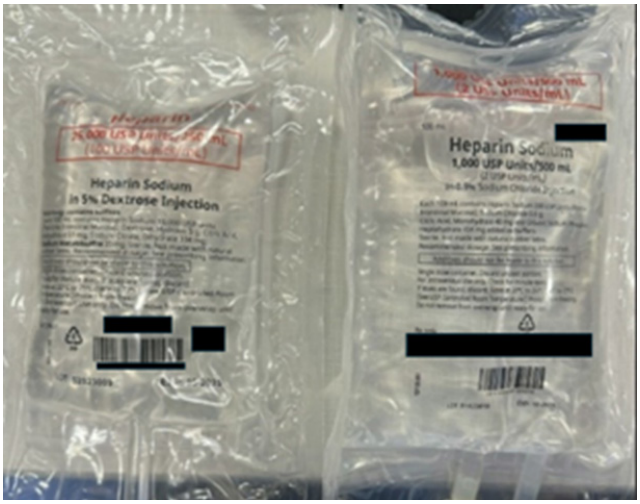

Figure 13. Different heparin concentrations by the same manufacturer appear similar, with the barcode on the right bag being difficult to scan.

Call to Action

Evidenced by the continued events that practitioners have reported to ISMP involving mix-ups between look-alike products, particularly those from the same manufacturer, urgent action is needed to address this long-standing safety issue. Pharmaceutical manufacturers can play a critical role in improving patient safety through the design of product labels that are well-differentiated to prevent product mix-ups. The above recommendations, together with FDA guidance documents, are great starting points toward the path to safety.

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