Selected medication safety risks to manage in 2016 that might otherwise fall off the radar screen—Part II

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. We thought it would be useful to describe selected medication safety risks for organizations to manage in 2016 that might otherwise fall off the radar screen. In Part I, published in our February newsletter, we described one risk for five of ISMP's Key Elements of the Medication Use System. These risks were related to:

1. Patient Information: Placing orders on the wrong patient's electronic health record
2. Drug Information: Nursing references that promote unnecessary dilution of IV push medications
3. Communication about Drug Therapy: In electronic records, confusing the available concentration as the patient's dose
4. Manufacturer Drug Labeling, Packaging, Nomenclature: Per liter electrolyte content on the labels of various sizes of manufacturers' IV bags
5. Practitioner Drug Labeling, Packaging, Nomenclature: Drawing more than one dose into a syringe
6. Patient Education: Discharging patients who do not understand their discharge medications

Part II in this newsletter covers one risk in each of the five remaining Key Elements associated with medication storage, the environment, medication devices, staff competency and education, and culture.

Drug Storage, Standardization, and Distribution—Improper and unsafe vaccine storage

The proper storage and handling of vaccines is vitally important because their stability and efficacy are dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold—even a single exposure in some instances—can reduce vaccine potency. These temperature deviations are often due to inadequate refrigeration or freezer units, faulty thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and consistent temperatures.

Improper and unsafe storage can also result in serious errors due to selecting the wrong vaccine, diluent, or other medication with a look-alike name and/or labeling and packaging. Unsegregated storage of vaccines has led to dispensing and administering the wrong vaccine, diluent, or other medication with a look-alike name and/or labeling and packaging. For example, vials of insulin have been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as hepatitis B or influenza vaccine.

The organization should store vaccines in stand-alone refrigerators or pharmacy grade/purpose-built refrigeration units (and freezers in the pharmacy), not in dormitory...
Safety Risks—continued from page 1

Style or combination units that both refrigerate and freeze. Regular temperature monitoring is necessary. Technology is available to enable continuous temperature monitoring that can alert staff via electronic messages (e.g., email, pager) and audible alarms if a unit is outside of the specified range. Separate vaccines into labeled bins or other containers according to vaccine type and formulation, keeping vaccines with their corresponding diluents. Never store different vaccines in the same bin/container. Do not store vaccines with similar labels, names, or abbreviations, or vaccines with overlapping components, immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct, age-specific selection and to remind staff that some vaccines have two components in separate vials that need to be combined before administration. Our June 2015 newsletter contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from the Centers for Disease Control and Prevention.

Environmental Factors, Workflow, and Staffing Patterns—Poor quality lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety. Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient’s room, infusion pumps that have been misprogrammed due to dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in healthcare, it’s been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been taken to increase staff awareness of the problem or improve the lighting. This is largely because the tasks associated with medication use are varied, carried out under diverse physical conditions and in differing locations, and because there are differences in an individual’s light requirements based on their visual acuity and age. With an ever-increasing population of older healthcare providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool-white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients’ rooms for nighttime administration of medications. Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity or task lights are recommended when difficult-to-read prescriptions and product labels are encountered. Illumination levels for computer order entry areas need to be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders. Medication preparation areas, medication verification areas, and patient counseling areas need to have illumination levels between 90-150 fc. Medication rooms should provide illumination at 100 fc. Lighting levels need to be increased if the workforce has an average age above 45 years. Additionally, the use of a magnifying glass and task light together can also significantly improve accuracy and should be used on mobile medication carts (including those used with barcode medication verification systems) and near ADCs.

Safe administration of Aggrastat loading doses. Aggrastat (tirofiban) is a platelet aggregation inhibitor indicated for patients with non-ST elevation acute coronary syndrome. The drug has been available for some time in a premixed bag. Figure 1, on page 3. Package sizes and dosing of the drug have also changed in recent years. A vial that was formerly available was withdrawn from the market in 2007. The drug requires a loading dose prior to a maintenance infusion.

The Aggrastat premixed bag only has an exit port, probably to avoid the inappropriate addition of additives. However, the loading dose should not be withdrawn from the premixed bag using this exit port. Instead, product label instructions should be followed. As a result of the interaction between the two products, the patient required intubation and admission to an intensive care unit. ISMP Canada points out that it is not widely known that methylene blue is a MAOI that can react with selective serotonin reuptake inhibitors (e.g., Paroxetine) and serotonin norepinephrine reuptake inhibitors (e.g., venlafaxine). The elevated levels of serotonin can result in serotonin syndrome. ISMP Canada cautioned facilities and practitioners to treat methylene blue as a medication, specifically by writing orders for its use and entering these orders into the pharmacy computer system to allow potential drug interactions to be identified.

In addition, operating room staff and other practitioners without order entry systems or traditional pharmacy support should incorporate drug interaction checks for methylene blue within their existing processes. Ultimately, it is critical that all patients receiving methylene blue have a complete and up-to-date medication history for use in assessing the risk for serotonin syndrome as well as a process for treating patients who might develop the condition. In 2011, the US Food and Drug Administration (FDA) issued a Drug Safety Communication, “Serious CNS reactions possible when methylene blue is given to patients taking certain psychiatric medications,” which includes a list of drugs with serotonergic activity. More recently, the Anesthesia Patient Safety Foundation published an analysis of this issue.

Handling ToolKit

Two seemingly harmless practice habits that breach aseptic technique might lead to contamination of sterile injection equipment and increase the risk of a healthcare-associated infection. As a result of the interaction between the two products, the patient required intubation and admission to an intensive care unit. ISMP Canada points out that it is not widely known that methylene blue is a MAOI that can react with selective serotonin reuptake inhibitors (e.g., Paroxetine) and serotonin norepinephrine reuptake inhibitors (e.g., venlafaxine). The elevated levels of serotonin can result in serotonin syndrome. ISMP Canada cautioned facilities and practitioners to treat methylene blue as a medication, specifically by writing orders for its use and entering these orders into the pharmacy computer system to allow potential drug interactions to be identified.

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infection (HAI) of the bloodstream or tissues: 1) failing to place a sterile cap on the end of a reusable intravenous (IV) administration set that has been removed from a primary administration set, saline lock, or catheter hub, and left hanging between use; and 2) failing to properly disinfect the port when accessing needleless valves on an IV set. In the first instance, the tip of the IV administration set is exposed to potential contaminants, which could lead to infection if the contaminated IV set is reconnected to the patient’s IV access. In the second instance, the port is exposed to potential contaminants that can be pushed into the patient’s IV line once the port has been accessed by tubing or a syringe.

These risks may be unintended consequences of needleless IV system implementation. Before needleless systems, practitioners typically replaced the needle used to connect the infusion to the IV tubing with a new sterile, capped needle to prevent contamination when the tubing was hanging between uses. Now it appears that practitioners are not considering the risk of contamination and are not placing a sterile cap on the exposed tubing. Some have speculated that the lack of a needle or cannula on a syringe, or at the end of the tubing, may suggest that protection and disinfection are not required.

It is imperative that facilities develop procedures that incorporate manufacturer recommended disinfection protocols for their needleless connectors, and to place a sterile cap on the end of the IV tubing between intermittent infusions. This disinfection process should specify the disinfecting agent, the method for disinfection (e.g., scrub the access surface), and the duration. “Looping”—attaching the exposed end of IV tubing to a port on the same tubing—is not recommended. Both processes (disinfection, capping) should be observed during competency assessments related to medication administration for new and existing practitioners. At-risk behaviors that breach aseptic technique require coaching and education, as well as continued monitoring by organizational leadership.

Parenteral drug administration often poses risks because of its complexity and the multiple steps required to prepare, measure, and administer medications. A systematic review determined an overall probability of 73% for a practitioner to make at least one clinical error during IV preparation and administration. While the causes of these errors are diverse, one contributing factor is that pharmacists and nurses are ill prepared to take on these tasks upon graduation from schools of pharmacy and nursing.

In recent years, pharmacy practice has moved into a more clinical realm. Partly as a result, core practices such as sterile compounding and IV admixture do not receive as much attention as that given to clinical pharmacy roles during training. Schools of pharmacy often do not adequately teach students sterile compounding nor prepare them to verify compounded sterile preparations and oversee processes they have never carried out themselves. Instead, sterile compounding procedures are typically handed down from one pharmacist to another, who may or may not carry out the procedures safely, depending on how they were taught.

It is much the same for graduate nurses, although for different reasons. Oftentimes, student nurses are not permitted to administer IV infusions or IV push medications during clinical rotations. Even if they are allowed, the experiences are few and far between. New graduate nurses need to quickly get up to speed and learn these skills. But again, the procedures are handed down from one nurse to another. Most training is prefaced with, “Here’s how I do it,” resulting in wide variability due to individual preferences. Furthermore, nurses receive little feedback on performance in this area due to lack of defined policies and procedures to outline expectations.

Training of all pharmacists and nurses new to the organization should follow a document-based competency module that includes education and simulation practice. The documentation should be maintained in the nurse’s record for future reference.

Some hospitals are questioning the safety of administering a loading dose from the bag, given that not every organization has smart infusion devices that can automatically switch from the loading dose rate to the proper maintenance infusion rate. It is also possible that this feature could be set improperly. If a pump doesn’t have a loading dose feature, it could still be set to administer the loading dose via the volume to be infused (VTBI) feature, then shut off. However, the nurse might become interrupted and forget to immediately change the rate to begin the maintenance infusion. A worst case scenario would be realized if a pump without a VTBI feature was manually set to administer a loading dose, relying on a nurse to reprogram the device once the loading dose has been infused. Obviously, if the reprogramming step is missed, it could lead to the entire volume running at 999 mL per hour until the medication was exhausted.

Instead of risking a serious medication event, for the loading dose, the manufacturer told ISMP that hanging the bag with an infusion set that is primed is recommended. The required bolus dose should then be drawn from a port on the infusion set tubing with a syringe. A syringe large enough to accommodate the volume based on patient weight (e.g., 96 to 104 kg = 50 mL volume) should be used. The bag tubing should then be clamped off. The loading dose can then be administered via the first port of the hub. Once the loading dose has been administered, the rate can be adjusted as needed. For the maintenance infusion, the bag can be hung with the fluid rate programmed to the desired rate. A pump that can automatically switch from the loading dose to the maintenance infusion rate is preferred, but not required.
> Safety Risks — continued from page 3

mented standard process outlining steps associated with sterile compounding (including IV admixture) and IV drug administration according to well-designed, evidence-based protocols. Variability in practice and individual preferences must be discouraged. Specific training modules need to be developed and standardized with competency evaluation via observation occurring at least annually. All practitioners must carry out all processes the same way with consistency every time to ensure safety and minimize errors.

As healthcare organizations move towards a Just Culture, one of the areas potentially overlooked is the organization’s human resource-related policies and procedures. Because these policies and procedures typically describe staff expectations, individual accountability, and disciplinary processes, they must be reviewed and often revised to ensure alignment with the tenets of a Just Culture. Otherwise, the journey will be long and unsuccessful if the policies are in conflict with a Just Culture.

In a Just Culture, human resource-related policies and procedures regarding safety should hold all individuals equally accountable for the quality of their behavioral choices and should not focus on errors (which are not a behavioral choice) except for the expectation to report them. The policies and procedures should reflect a tone that is proactive toward risk identification rather than reactive to errors and adverse outcomes. They should define human error as inadvertent, with a response of consoling individuals and conducting an investigation to determine how to redesign systems to prevent the errors or detect them before reaching the patient. Policies and procedures need to describe how to investigate a procedural violation to determine its causes and scope, and how to coach staff who have engaged in at-risk behaviors under the mistaken, but good faith, belief that the risks were insignificant or justified. For outcome-based duties related to a business code of conduct, such as arriving to work on time and wearing identification badges, policies should be clear about expectations and the actions that will be taken when they are not met. When describing reckless behavior (actions involving a conscious disregard of what an individual knows is a substantial and unjustifiable risk), remove any reference to “negligent” or “criminal” conduct as the basis for disciplinary action. Regrettably, mere human error can result in legal action (criminal negligence), but human error is never reckless behavior. Also, ensure that event reporting and investigation policies and procedures support the tenets of a Just Culture.

While human resource-related policies and procedures cannot guarantee that the desired actions will be realized in practice, they are a critical step for building an organizational foundation for success. Old punitive policies put the organization at risk of slipping back into an unjust culture. As organizations align actual practice with a Just Culture, they also need to align supporting policies and procedures.

References
2) CDC. Vaccine storage & handling toolkit. May 2014. www.ismp.org/Revised-1663
5) Graves K. Nurses’ decision making processes about lighting during medication administration. A dissertation submitted to Texas Woman’s University College of Nursing. May 2014.

SAFETY wires continued from page 3

and the bolus given over 5 minutes via a Y site close to the patient’s access site. The maintenance infusion should then follow.

Will patients ever be free from iatrogenic harm? A report from an expert panel convened by the National Patient Safety Foundation (NPSF) looks at patient safety 15 years after the Institute of Medicine published To Err Is Human. The report makes it clear that patient safety concerns remain a serious public health issue that must have a more pervasive response. The NPSF panel is calling for action by government, regulators, health professionals, and others to place higher priority on patient safety science and implementation. The content has been endorsed by a number of related organizations, including ISMP, which participated on the panel. Each of the following recommendations is expanded in the full report:

1. Ensure that leaders establish and sustain a safety culture
2. Create centralized and coordinated oversight of patient safety
3. Create a common set of safety metrics that reflect meaningful outcomes
4. Increase funding for research in patient safety and implementation science
5. Address safety across the entire care continuum
6. Support the health care workforce
7. Partner with patients and families for the safest care
8. Ensure that technology is safe and optimized to improve patient safety

The complete report is worthwhile reading and can be accessed at www.npsf.org/free-from-harm.

IV fat emulsion needs a filter. A change in the package insert for intravenous fat emulsions used in nutrition indicates a 1.2 micron filter should be used when administering these products (e.g., INTRALIPID, NUTRILIPID, LIPOSYN III [currently out of stock]). This is also a change from some product labeling that stated filters are not recommended, or if filtration is used, then a filter of less than 1.2 micron pore size must not be used. Newer fat emulsion labeling states: “Use a 1.2 micron filter with Intralipid (strength). Filters of less than 1.2 micron pore size must not be used.” There may be continuation on page 5—SAFETY wires—continued from page 3.

Methylergonovine errors in obstetrics

A woman underwent a scheduled induction at 41 weeks gestation. Shortly following delivery, her newborn daughter was given methylergonovine maleate (discontinued brand METHERGINE) injection by mistake instead of phytonadione (vitamin K₁) injection. The infant developed seizures and altered mental status requiring a neonatal intensive care unit (NICU) admission for several days. Fortunately, the baby recovered and is developing normally. The methylergonovine had been brought into the delivery room in case it was needed, due to the patient’s history of post-partum hemorrhage.

In the past, we have published mix-ups involving methylergonovine injection and hepatitis B vaccine, both of which are available in obstetrical areas, and mix-ups between adult and neonatal ampules of phytonadione. We are also aware of an event in which a nurse administered methylergonovine to a newborn infant instead of the infant’s mother due to a series of verbal miscommunications. The error was not caused by a mix-up between methylergonovine and phytonadione, but rather confusion about who was supposed to receive the prescribed methylergonovine. Tragically, the infant died.

Separating newborn medications from those used for mothers in perinatal areas reduces error potential. If an automated dispensing cabinet (ADC) must be shared between units, a locked, lidded storage bin should be used for neonatal products, and the selection screen should highlight which medications are for the mother and which medications are for the infant. If possible, infant medications should be administered in an area that is separate from where medications are administered to the mother. This strategy may not be workable in hospitals where mothers and babies room together. However, many infants are initially evaluated in a newborn nursery setting, so administration of some medications after birth, including phytonadione injection, may be delayed until the baby is in the nursery. Bringing only the medications that are needed to the bedside is a strategy to limit unnecessary access to medications without a current order or identified need. Also, neonatal phytonadione is available in a prefilled syringe, which can help to differentiate it from ampules of methylergonovine. Finally, hospitals should implement processes in which infants are reliably banded with an identification bracelet immediately after birth. Then barcode scanning of drug containers can eliminate dangerous mix-ups like this one.

> Safety Risks — continued from page 4

ISMP survey on tall man lettering to reduce drug name confusion

In 2008, ISMP compiled a list of look-alike drug name pairs with suggested tall man letters to be used in healthcare organizations to differentiate these products on pharmacy-generated labels, documents, and computer screens. It’s been 5 years since we last updated the list in 2011, so **today we are seeking your input** regarding a few more drug name pairs we are considering for addition to the list. We are also interested in learning how useful you find tall man letters, and any additional name pairs you believe we should consider for the list. Please submit your survey responses by **April 15** at: www.ismp.org/sec?id=1670.

**Key: DK = Don’t Know/Uncertain**

<table>
<thead>
<tr>
<th>Question and Drug Name Pairs</th>
<th>Aware of Confusion with Name Pair?</th>
<th>Add to List?</th>
<th>Proposed Tall Man Lettering</th>
<th>Alternate Suggestions for Tall Man Lettering</th>
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<tbody>
<tr>
<td></td>
<td>Yes  No DK</td>
<td>Strongly Disagree</td>
<td>Disagree</td>
<td>Neutral/Don’t Know</td>
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<tr>
<td>methyMIAzole and metOLazone</td>
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<td>methyMIAzole and methazoIAMIDE</td>
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<td>eriBULin and epiRUBicin</td>
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<td>diAZEpam and dilitiaZEM</td>
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<td>PONATimib and PAZOPanib</td>
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<td>rilAMPin and rilAXIMin</td>
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<td>oxyMORphone (and HYDROMorphine, oxyCODONE and OxyCONTIN, already on list)</td>
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<td>dexameTHASONE and dexmede-TOMidine</td>
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<td>penicillAMINE and penicillin²</td>
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<td>LEVoleucovorin and leucovorin²</td>
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<td>oxyBUTynin (and oxyCODONE, already on list with HYDROcodone and OxyCONTIN)</td>
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<td>cloBAZam (and clonazePAM, already on list with cloNIDine, cloZAPine, and LORazepam)</td>
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<td>levoFLOXacin (and levETIRacetam, already on list with levOCARNitin)</td>
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<td>zolPIDEM (and ZOLMtriptan, already on list with SUMAtriptan)</td>
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<td>DEPO-Medrol and SOLU-Medrol³</td>
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<td>idaruCIZUmb and idaruBICIN⁴</td>
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<tr>
<td>SAXagliptin and SITagliptin⁵</td>
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¹To determine which letters to capitalize, we attempted to apply the CD3 rule. This methodology suggests working from the left of the word first by capitalizing all the characters to the right once two or more dissimilar letters are encountered, and then working from the right of the word back, returning two or more letters common to both words to lowercase letters. When the rule cannot be applied, because there are no common letters on the right side of the word, the methodology suggests capitalizing the central part of the word only.

²No tall man letters recommended for one of the drug names in the pair

³Solu-MEDROL is already on the list with Solu-CORTEF, suggest changing to SOLU-Medrol

⁴IDARubicin is already on the list with DOXORubicin, suggest changing to idaruBICIN

⁵sitaGLIPin is already on the list with SUMAtriptan; suggest changing to SITagliptin

continued on page 7—ISMP survey on tall man lettering >
In your facility, please tell us if tall man letters are used in conjunction with the stated items, and if you answer All-Most or Some, whether you feel this strategy is effective in reducing the risk of drug selection and drug identification errors.

<table>
<thead>
<tr>
<th>Question and Items</th>
<th>All or Most</th>
<th>Some</th>
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<th>Partly Effective</th>
<th>Neutral or DK</th>
<th>Effective</th>
<th>Very Effective</th>
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<td>Computer-generated pharmacy labels</td>
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<td>Automated dispensing cabinet screens</td>
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<td>Smart pump drug libraries</td>
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<td>Policies/protocols</td>
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Please review the name pairs listed in Question 1 and those found on our current list at: [www.ismp.org/tools/tallmanletters.pdf](http://www.ismp.org/tools/tallmanletters.pdf), and then let us know if there are any additional name pairs that you feel should be included (please specify):

_______________________________________________________________________________________________________________

Do you believe the use of tall man letters by the pharmaceutical industry on product labels helps to reduce drug selection errors?

☐ Yes  ☐ No  ☐ Not sure

Please select the category that best describes your profession (check one):

☐ Registered Nurse  ☐ Licensed Practical Nurse  ☐ Advanced Practice Nurse  ☐ Pharmacist
☐ Physician  ☐ Other Prescriber  ☐ Pharmacy Technician  ☐ Other:________________________

Answer questions 6-10 only if you use tall man letters in your facility.

What sources are used in your organization to determine which drug name pairs may benefit from tall man letters? (select all that apply)

☐ FDA-approved list of name pairs with tall man letters  ☐ Internal facility risk and error data
☐ ISMP list of name pairs with recommended tall man letters  ☐ Other:________________________  ☐ Not sure

For how many drug name pairs are you using tall man lettering differentiation? (each look-alike drug name pair counts as one)

☐ 1-10  ☐ 11-20  ☐ 21-30  ☐ > 30

Do you believe tall man lettering has prevented you from transcribing, dispensing, or administering the wrong medication?

☐ No  ☐ Not sure  ☐ Yes  If Yes, please describe: _______________________________________________________
_____________________________________________________________________________________________________