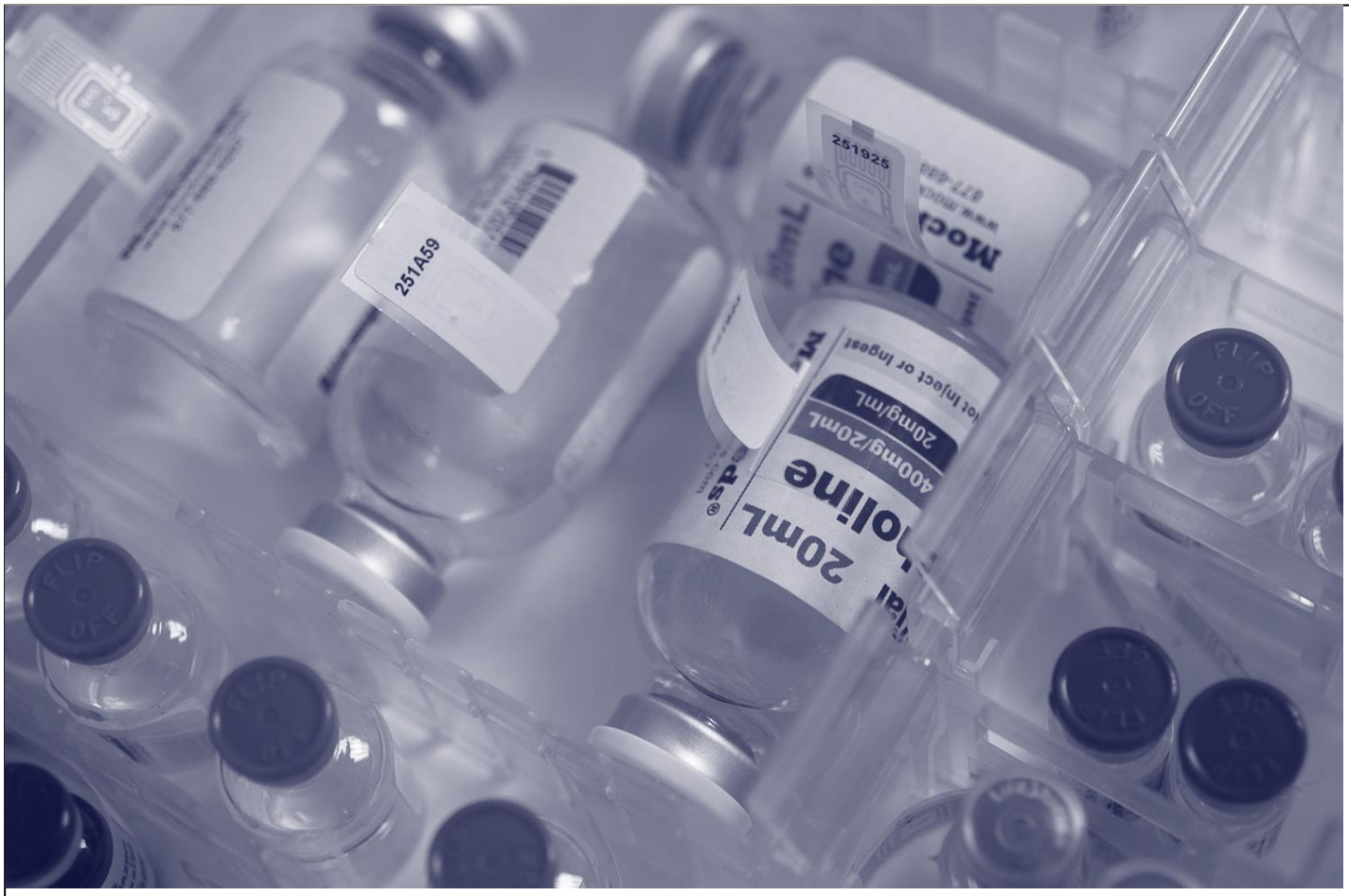

Radio Frequency Identification (RFID) Tag Encoding Best Practices for Hospital and Health System Inventory Control

An IntelliGuard® Intelligent Inventory Solutions whitepaper outlining vital safety implications and best practice guidelines for RFID encoding processes in hospital and health system inventory control solutions

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RADIO FREQUENCY IDENTIFICATION (RFID) TAG ENCODING BEST PRACTICES FOR HOSPITAL AND HEALTH SYSTEM INVENTORY CONTROL SOLUTIONS

Introduction

This whitepaper focuses on the vital safety considerations of radio frequency identification (RFID) tag encoding procedures in hospital and health systems pharmacies, specifically for use related to inventory storage, distribution, control and replenishment processes involving procedural and emergency drugs. It outlines published industry guidance on risks associated with pharmacy-applied drug relabeling and provides recommended best practices to ensure inventory control workflows do not introduce additional risk of medication error or patient harm.

When RFID-enabled kit and tray management systems were in initial design phases in 2010/2011, a Food and Drug Administration (FDA) Compliance Policy Guide (CPG Sec. 400.210, Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs) had been published representing the FDA's current thinking on the topic of RFID programs for drugs. The CPG was originally issued in November, 2004; revised in June 2013 and expired 12/31/2014. To date, these recommendations have not changed. You can view the full compliance policy guide here: CPG Sec. 400.210, Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs

From the perspective of IntelliGuard® our advisory board and our product team research, the footnote to this FDA Compliance Policy Guide served as a key point in shaping our IntelliGuard® Kit and Tray Management System product design principles.

"**Writing to a tag before it is affixed to a container increases the risk of product mix-ups**. We suggest that industry and other interested parties **explore the feasibility of writing to the tag after it is affixed to the container.**"

In addition to the FDA Compliance Policy Guide, the American Society of Health-System Pharmacists (ASHP) identifies relabeling as one of the significant points of error within the pharmaceutical chain of command. Additional pharmacy practice guidelines and references, including the Institute for Safe Medication Practices (ISMP) support the implication that relabeling is a common cause of medication errors and poses a safety risk at the point-of-use.

RFID-Enabled Pharmacy Inventory Management in Hospitals

In recent years, RFID technology has emerged as a reliable solution to improve both the efficiency and accuracy of hospital pharmacy workflows associated with medication inventory storage, purchasing, distribution and management. This includes the daily processing of anesthesia and emergency medication kit and trays as well the inventory control, tracking and security of high value, critical medications and controlled substances. RFID inventory management solutions are proven to reduce inventory costs; offer secure remote access to drugs at the point-of-use; support efficient management of drug expiry and effective stock rotation to reduce waste; enable fast and thorough handling of recalls and provide accurate usage data to optimize inventory levels and increase revenue through more accurate charge capture reconciliation.

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When designing IntelliGuard® Intelligent Inventory Solutions for hospitals and health systems, we set out to create both a reliable technical solution and workflow processes that are safe and user friendly. How RFID Smart Tags would be encoded and affixed to medication inventory was a key consideration.

IntelliGuard® RFID Smart Tag Encoding Process

Our patented techniques and processes facilitate a Smart Tag Processing™ method which uses Safe Tag Encoding™ and Smart Multi-Batch Approval™ workflows. The described methods follow best practice guidelines that support encoding RFID tags only after they are affixed to medication vials and do not add printed duplicate, human readable information on secondary labels (in this case, RFID tags) which poses a clinical safety risk at the point-of-use. Following these guidelines ensures hospitals and health systems are equipped to take advantage of RFID inventory control benefits and avoid the risk of product mix-up inherent in pharmacy-applied drug relabeling.

Pharmacy technician affixes drug containers with blank RFID Smart Tag. For tracking and control, each RFID tag contains a unique serial number identifier.

Pharmacy technician places tagged vials of like lot and expiration date in IntelliGuard® RFID encoding workstation.

Pharmacy technician scans barcode of one item in lot, confirms lot # and expiration date, and returns removed item to RFID encoding workstation.

Pharmacy technician initiates single RFID scan which simultaneously counts and programmatically associates each drug to a unique ID in the IntelliGuard® database. Pharmacist verification process provides concurrent, multi-batch processing to verify inventory for clinical use.

Unique Serial Number Provides Item-Level Drug Visibility Enterprise-Wide

The IntelliGuard® Intelligent Inventory Solutions software application utilizes a unique identifier on the RFID Smart Tag of each medication in a relational database to track and manage inventory at the item level. The inventory management software enables effective, efficient and safe pharmaceutical tracking, control and workflow automation processes and programmatically manages alerts, notifications, inventory verification and reporting on data such as expiration, location, unique storage requirements and usage. This item-level inventory tracking provides enterprise visibility to all RFID-tagged items - whether in picking station bins, bulk storage, deployed in anesthesia trays or crash cart kits, dispatched to point-of-use systems in the operating room, or stored in access-controlled refrigerators or controlled room temperature cabinets.

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RFID Tag Relabeling of Drug Information Not Recommended

In an alternative RFID tag encoding method described by other RFID solution providers for kit checking applications, RFID tag relabeling is promoted as the only way to assure an RFID tag is affixed to the correct medication vial. In the method described, medication data is entered into the kit checking software, which then prints an RFID label on a remotely located printer. This process then requires the technician to select a printed label from the remote printer, read that label, match it to the drug container, and then affix it to the correct medication package.

RFID label printed on remote printer

Printing to a tag before it is affixed to a container increases the risk of product mix-ups

Requires reading the RFID label and cross-matching it to the manufacturer's label

Introduces risk of human error in mismatching RFID label and medication container

Viewing this process, it's easy to see how human error could contribute to mismatching the RFID label and the medication vial. With this approach, there is an acknowledged risk of drug mix-up.

In the workflow as described above (where the RFID tag is printed before it is affixed to the drug container), relabeling is promoted as a "safety" feature. In fact, considerable research exists to confirm this type of relabeling causes a risk for medication error and patient harm.

More advanced RFID solutions negate the need for RFID relabeling with human-readable information by programmatically associating each RFID tag's unique serial number to each medication, and doing that only after the RFID tag is affixed to the medication container. Medication verification for inventory control purposes is managed through the software application, and does not rely on a visual match up.

How Mislabeling Can Lead to Medication Errors and Patient Harm

Sadly, there's no better example of the life-threatening risk of product mix-up than the case of Loretta Macpherson: Hospital medication error kills patient in Oregon. *"Macpherson, 65, died shortly after she was given a paralyzing agent typically used during surgeries instead of an anti-seizure medication."*

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Results of Medical Error Investigation:

Here are the key points of the root cause analysis detailing how mislabeling led to the medication error:

- *The label that printed from the system and was placed on the IV bag was for the drug that was ordered: fosphenytoin; although what was actually in the bag was rocuronium.*
- *The vials of rocuronium and the IV bag labeled "fosphenytoin" were reviewed without the error being noticed.*
- *The IV bag was scanned in the Emergency Department, but because the label on the bag was for the drug that had been ordered (fosphenytoin), the system did not know to sound an alarm.*
- *The bedside caregiving staff had no way of knowing the medication in the bag was not what had been ordered.*

In the ensuing investigation, it was discovered that the label on the bag was that for the drug that had been ordered, the staff (at the ER) had no way of knowing the drug that was actually in the bag was not the one that was ordered. "It is a human error," Robert Gomes, CEO at St. Charles Bend and Redmond, told reporters at a news conference.

Human Error Can Easily Cause Medication Product Mix-Ups

A printed pharmacy-generated label with human-readable drug information added to the drug container may be INCOMPLETE, or worse, as noted in the Macpherson case, provide INCORRECT DATA that is relied upon at the point-of-use. That mismatched pharmacy-generated label will follow the drug from pharmacy to point-of-use, increasing the risk of medication administration error and patient harm.

Although the Macpherson example did not involve secondary RFID labeling directly, it does highlight how human error can easily be the cause of a product mix-up. In this case, the wrong drug was filled in the IV bag but labeled with what was ordered. In the case of a secondary RFID label printed before it is affixed to a container, the same risk of human error and product mix-up exists, resulting in the same outcome: a label that incorrectly identifies the contents of the medication container.

IntelliGuard® RFID Smart Tags Include No Drug Information by Design

When used as an inventory control system, pharmacy-applied RFID tags do not require printed drug information. In fact, if human readable information is printed on a secondary, pharmacy-generated RFID label and that information is INCORRECT, not only is the RFID label inaccurately tracking inventory data; erroneous drug information is presented to clinical staff at the point-of-use (a potential medication administration error).

"No" to Relabeling is in the Best Interest of Patients

By design, the patented IntelliGuard® RFID Safe Tag Encoding process does not include any drug information that would be discernable to a clinician at the point-of-use and therefore, can never be the cause of a medication error at administration. Clinicians must continue to rely on the manufacturer's label to determine the contents of the medication package.

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Although IntelliGuard® Intelligent Inventory Solutions are capable of printing drug data on our RFID Smart Tag (Zebra printers do a fine job of that) and we could offer both printed and a non-printed options, we have designed certain resolute processes into our product and this is one that we don't compromise.

There have been misperceptions perpetuated to hospital and health system pharmacy teams who have been told the only way to assure an RFID tag is affixed to the correct medication vial is to create a secondary RFID label printed with drug information to enable a visual match.

In fact, the RFID Smart Tag unique identifier, patented Smart Tag Encoding™ process and inventory management software application used with any IntelliGuard® RFID Solution workstation, controlled temperature cabinet or point-of-use inventory station, provides the safest, most accurate level of correct medication inventory identification, management and control for hospital and health system pharmacies - without the risk of medication labeling error.

Summary

As documented in our whitepaper, The Risk of Relying on Human Perfection, safety cannot rely on human perfection, but should focus on designing systems, processes, and tasks that make it difficult for people to make mistakes at all. We are confident the evidence supports our position regarding RFID tag relabeling.

So while insight from customers has been, and will remain, a key part of our product enhancement strategy, nothing is more important than what we consider the safest approach – especially when patients are at risk.

In this case, we believe the risk of patient safety is just too great, and that is a risk we're not willing to take – for the sake of Mrs. Macpherson and all other patients like her.

Every human error contributor that you can design out of your process improves the safety and quality of care you deliver.

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