"Human beings have common failure modes and certain conditions make it more likely for a human operator to make a mistake. One of the advantages of technology is that it can enhance human performance to the extent that the human plus technology is more powerful than either is alone." (Shelton, 1999)

Conditions that create human errors:

- Human Reliability
- Information Crowding, Visual Clutter and Inconsistency
- Confused Drug Names
- Cognition and Brain Science
- Stress Effects
- Information feedback inadequate for determination of correctness of his or her actions
- For experienced staff, intuitive thinking can be risky

Quality improvement studies validate the efficacy of RFID-enabled kit and tray processing over manual methods that depend on human reliability.

intelliguard®
RFID Solutions for Critical Inventory
KIT AND TRAY MANAGEMENT SYSTEM

Quality Improvement Study Results
(MEPS Real-Time, Inc., 2014-2015)

- Using manual replenishment processes, **1 in 3-5 trays leave your pharmacy with one or more errors.**

- Using an **RFID**-enabled process, **100% of trays were accurate** with nothing missing and nothing expired

Technology can question the actions of operators, offer advice, and examine a range of factors that humans cannot possibly remember.

THE RISK OF RELYING ON HUMAN PERFECTION

A MEPS REAL-TIME, INC. WHITE PAPER

"There is often a myth ascribed to error prevention: If people try hard enough, they will not make any errors. However, saying that an accident is due to human error is not the same as assigning blame… humans commit errors for a variety of known and complicated reasons." (INSTITUTE OF MEDICINE, 1999)

The report *"To Err is Human: Building a Safer Health System"* was issued in November 1999 by the U.S. Institute of Medicine and has resulted in increased awareness of U.S. medical errors. The push for patient safety that followed its release continues. The report was based upon analysis of multiple studies by a variety of organizations and concluded that between 44,000 to 98,000 people die each year as a result of preventable medical errors. According to the report, "One of the greatest contributors to accidents in any industry, including healthcare, is human error."

This white paper focuses specifically on the human reliability challenges of procedural and emergency kit and tray processing in the inpatient pharmacy and explores the use of advanced RFID technology to automate, validate and ease the process to reduce the occurrence of human errors.

BACKGROUND

With a large variety of medications and patients needing a high degree of attention and care, health system staff pharmacists are charged with making sure those medications are delivered on time, accurately, and those medications are optimal for patients. Significant financial implications can be associated with inconsistent medication management processes as payers require accreditation for reimbursement. More importantly, patient safety concerns arise when emergency and procedural drug kits leave the pharmacy with missing, expired or recalled drugs.

For procedural and emergency kit management, Pharmacy Technicians, under the supervision of a licensed pharmacist, replenish medication inventory in every kit, tray or box before being deployed for clinical use. The same staff bear the responsibility of ensuring medication kit and tray inventories are complete and accurate at replenishment.

TECHNOLOGY REMOVES DEPENDENCE ON HUMAN RELIABILITY FROM ERROR-PRONE PROCESSES

The hospital pharmacy can provide a logical step in the journey to reduce regulatory exposure, improve patient safety, decrease clinical workflow interruptions and reduce pharmacy staff labor requirements. The challenge to achieving medication inventory goals is an objective that is nearly impossible to meet in an environment filled with manual processes, little visibility and few automation tools. Today's pharmacies have access to RFID solutions to provide fast, automated data capture of all elements of the kit and tray replenishment process including machine verification of approved formulary and PAR levels and associated medication data including name, concentration, dose, package volume, lot number and expiration.

MAINTAINING A STATE OF READINESS

If emergency equipment, drugs and supplies are not readily available when a patient experiences a life-threatening emergency, the consequences are often dire. The location of clinical emergencies varies, but there is a common theme: lack of the correct equipment and supplies hampers the ability to optimally manage the emergency. A report produced by ECRI Institute and the Institute for Safe Medication Practices (ISMP) identified 56 reports in a 12 month period that highlighted emergency or rapid response situations in which supplies or equipment were missing or outdated. Reports identified myriad issues including missing items and unstocked crash carts. (ECRI Institute and ISMP, 2010)

There are thousands of incidents of patient harm and even death associated with medication distribution mistakes. Many cases make the headlines.

Even if not headline worthy, preventable mistakes can and do cause harm to patients and create regulatory compliance challenges and associated financial implications for hospitals.

From the Headlines

Hospital Loses Appeal in Contaminated Drug Case
(CBS Miami, 2014)

There's a pending lawsuit that alleges a hospital had received notice of a recall of a blood thinner but failed to remove and return all of its supplies of the drug. The ruling said the contaminated drug caused a severe bacterial infection that led to the amputation of a patients left leg and right foot.

Joan Rivers Death: Crash Cart Failed to Carry Critical Lifesaving Drug
(Morgan, 2014)

River's family legal team believes the center failed to stock the drug Succinylcholine on the crash cart in the procedure room. Administration of the drug could have helped continue the flow of oxygen for Rivers when her vocal chords constricted and closed shut.

REGULATORY CHALLENGES

Being an accredited hospital not only demonstrates a commitment to quality and patient safety, it carries significant financial implications. In order to receive federal payments, an institution must be certified by the Centers for Medicare & Medicaid Services (CMS). The Joint Commission is the foremost hospital accrediting agency, accrediting over 80% of U.S. hospitals, and has "deemed status" in which their standards are at least the equivalent of CMS. (Department of Health and Human Services, 2011)

The Joint Commission's standards for Medication Management (MM) are among the most challenging for a hospital to implement. To maintain compliance, all stages of the medication use process must be integrated into a comprehensive medication management system. It is the pharmacist's responsibility to assure that outdated, recalled, or otherwise unusable drugs and biologicals must not be available for patient use.

In addition, to avoid shortages of supplies and equipment, the Joint Commission (in its Environment of Care standards) recommends a continual process to managing emergency / crash cart inventory. Ideally, nursing staff should check carts and kits daily to ensure seals are unbroken and all expiration dates are acceptable. This is often one of the first tasks to

be abandoned at change of shift, when staffing tends to be short. Further, the monotony of checking without finding problems day after day often leads to a lackluster approach, increasing the chance that problems will be missed.

DESIGNING SAFER SYSTEMS

Human beings have common failure modes and certain conditions will make it more likely for a human operator to make a mistake. (Shelton, 1999) Myriad studies and reports conclude that although good managerial decisions are required for safe and efficient production, they are not sufficient. As reported in *"To Err is Human: Building a Safer Health System",* designing safe systems means taking into account people's psychological limits and seeking ways to eliminate these preconditions or intervening to minimize their consequences.

The report concludes, "One of the advantages of technology is that it can enhance human performance to the extent that the human plus technology is more powerful than either is alone. Good machines can question the actions of operators, offer advice, and examine a range of factors that humans cannot possibly remember." (Institute of Medicine, 1999)

CONDITIONS THAT CREATE ERRORS

For routine, simple, work-related tasks, workers average 1:1,000 -10,000 errors. When a routine task requires more care (because it is more complicated), this error rate rises to 1:100, and for complicated tasks, can be as high as 1:10. Even if we consider kit and tray replenishment as a routine, simple task, the apparent low prevalence is misleading, because many jobs average 20,000 acts per day and some approach 100,000 (Smith, 2005).

HUMAN RELIABILITY

Humans are bound to make errors. Research in the area of human factors is just beginning to be applied to healthcare (Institute of Medicine, 1999). Technology solutions are designed with the understanding that human error mistakes are unavoidable with any process that depends solely on human reliability. The critical task of accurate procedural and emergency kit replenishment is also one of the most manual and tedious (requiring acute visual attention and text that is difficult to read because of font size or style, insufficient color contrast or other design elements).

INFORMATION CROWDING, VISUAL CLUTTER AND INCONSISTENCY (ISMP , 2009)

The FDA recommends the use of at least a 12-point font whenever a label size permits. (U.S. Department of Health and Human Services, 2013) For many vials and ampules used in procedural and emergency kits, the container label is too small for this to be practical. When labels are crowded, text size and prominence are generally decreased, and important information may be difficult to read and/or easily overlooked.

For expiration dates, the problem can be further intensified because various manufacturers use different ways to express the expiration date on a product label. Some express the expiration date with the month and day, while others use the month and year and most use abbreviations to express these dates (e.g., MA11). The use of abbreviations for expiration dates has led to confusion, misinterpretation, and sometimes delays in treatment because the abbreviation was interpreted incorrectly. For example: "MA" could mean March or May, whereas the number 11 could represent the day, month, or year.

(Actual Size)

CONFUSED DRUG NAMES (INSTITUTE FOR SAFE MEDICATION PRACTICES, 2015)

Medication names that look or sound similar have been identified as a potential source of error in health care systems. Medications in which packaging is visually similar to another medication falls in the category of look-alikes. Medications for which names of the product sound similar in the spoken or written word are categorized as sound-alike drugs. Look-alike and sound-alike drug names can lead to the unintended interchange of drugs that can result in patient injury or death. The Institute for Safe Medication Practices (ISMP) publishes as list of confused drug names, which includes look-alike and sound-alike name pairs.

As of the April 2014 publication of the *ISMP Medication Safety Alert, Community / Ambulatory Care Edition,* there are **more than 600 medications** on the list that have been involved in unanticipated clinical outcomes reported to ISMP.

EXAMPLES:

Drug Name	Confused Drug Name	
Ephedrine	Epinephrine	*Not only do these drug names look similar, but their use as vasopressors or vasoconstrictors makes storage near each other likely. Both products also may be packaged alike in 1 mL ampules or vials.*
Fentanyl	Sufentanil	*Sufentanil is approximately 5 to 10 times more potent than its parent drug, fentanyl, and 500 times as potent as morphine*
Heparin	Hespan	*Contributing to the errors, HESPAN and heparin share the characters "H-E," "P-A," and "N" in the same order and they are often stored near one another due to their similar spelling.*
Hydralazine	Hydroxyzine	*Because the first four letters of their names are identical, they are frequently stored next to one another on pharmacy shelves*
Hydromorphone	Morphine	*Many clinicians confuse hydromorphone with morphine because the names are similar. Although hydromorphone is a morphine derivative, it's much more potent than morphine*
Morphine – oral liquid concentrate	Morphine – non-concentrated oral liquid	*Deaths have resulted when oral morphine concentrate 20 mg/mL was confused with conventional morphine solution 20 mg/5 mL*
Naloxone	Lanoxin	*Lanoxin [a cardiac medication] and naloxone [an opiate antagonist] packages are made by the same manufacturer and are almost identical.*

COGNITION AND BRAIN SCIENCE

CAN YOU READ THIS?

Aoccdrnig to a rscheearch at Cmabrigde Uinervtisy, it deosn't mttaer in waht oredr the ltteers in a wrod are, the olny iprmoetnt tihng is taht the frist and lsat ltteer be at the rghit pclae. The rset can be a toatl mses and you can sitll raed it wouthit porbelm. Tihs is bcuseae the huamn mnid deos not raed ervey lteter by istlef, but the wrod as a wlohe.

According to a researcher (sic) at Cambridge University, it doesn't matter in what order the letters in a word are, the only important thing is that the first and last letter be at the right place. The rest can be a total mess and you can still read it without problem. This is because the human mind does not read every letter by itself but the word as a whole. (Davis, 2003)

The above text has been circulating on the internet since 2003: Although there remains controversy over this research and whether it was actually conducted at Cambridge University, scientists that study how the brain processes language do agree there are elements of truth. People do not ordinarily read each letter in a word individually (except in a relatively rare condition following brain injury known as letter-by-letter reading). What's striking is when these elements of truth are viewed in the context of confused drug names:
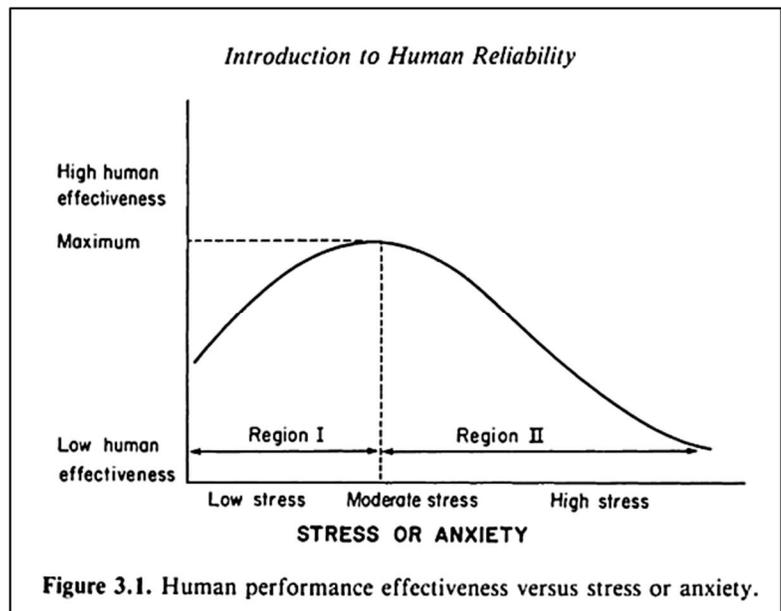
COGNITION AND BRAIN SCIENCE

- We know from research in which people read words presented very briefly that the exterior letters of words are easier to detect than middle letters. (e.g., **He**pari**n** read as **He**spa**n** or **Hydr**ala**zine** read as **Hydr**oxy**zine**)
- Additional research (Shillcock, 2000), shows another mechanism is in place: It seems that keeping letters in the appropriate half of the word, reduces the difficulty of reading jumbled text (e.g., Hydro**Morphone** read as **Morphine)**
- And, humans often attend to the sound of the words even when reading for meaning (Van-Orden, 1987) (e.g., **Fentanyl** read as **Sufentanil** or **Naloxone** read as **Lanoxin**)
- Tall man letters are uppercase letters that are used within a drug name to highlight its primary dissimilarities with look-alike drug names (e.g., oxy**CODONE** and Oxy**CONTIN)** (Institute for Safe Medication Practices, 2011)**.** Studies are mixed as to how effective tall man lettering is. And, although tall man lettering is gaining acceptance, confirmation bias is also in play in information processing tasks - whereby individuals see what they expect to see, rather than what is actually there.

STRESS EFFECTS ON HUMAN PERFORMANCE

Further, as reported in the American Pharmacists Association Career Pathway Evaluation Program for Pharmacy Professionals: "Workload and long hours are typically the least appealing aspect of inpatient pharmacy work. And concern with workflow issues and medication shortages are paramount."

Stress is another important area that affects human performance and its reliability. Obviously an overstressed person will have a higher probability of making human errors. Conversely, studies show that tasks that are unchallenging and dull also create human performance that is not at its peak (Dhillon, 2009). In fact, specific human operator stress characteristics are inherent in the manual process of kit and tray management in the inpatient pharmacy, including:

Figure 3.1. Human performance effectiveness versus stress or anxiety.

1. Information feedback to the operator is inadequate for the determination of correctness of his or her actions.
2. The operator is required to make comparisons of two or more displays quickly
3. The operator decision-making time is very short
4. To perform a task, the sequence of steps is very long

These challenges, and the associated errors caused by incorrect trays can have a direct impact on regulatory compliance and patient care.

EXPERIENCED STAFF: INTUITIVE THINKING CAN BE RISKY

Most medication errors are not caused by individual carelessness, but rather by faulty processes or conditions that lead people to make mistakes or fail to prevent them. In fact, even with extremely experienced staff, there are limits to the human attention span, especially in situations of fatigue, repetitive tasks and infrequently occurring events. There are abundant scholarly articles to confirm "intuitive behavior" as a well-known trap for experienced experts (Arnstein,

1997). A paper in the Journal of the Royal Colleges of Edinburgh and Ireland confirms: "Experts tend to commit errors when thinking intuitively (with overwork, tiredness and when doing repetitive tasks). These errors occur, not due to lack of skills, but due to relying on intuitive behavior when deviations from the norm are not recognized. In other words, it has been argued: "familiarity predisposes to oversight" – and it is something that all, including experienced experts, should be aware of." (ResearchGate, 2014)

QUALITY IMPROVEMENT STUDY: USING RFID FOR KIT AND TRAY MANAGEMENT

Automated RFID-enabled kit and tray solutions are proven to eliminate errors and improve processing time. MEPS Real-Time, Inc., a provider of RFID solutions for critical inventory management in hospital pharmacies, in conjunction with 5 hospitals, has conducted quality improvement studies to validate the efficacy of RFID-enabled kit and tray processing over manual processes that depend on human reliability. The purpose of these studies is to compare and record numbers and types of medication errors as well as time spent restocking and approving inventory using the manual replenishment method versus using the company's Intelliguard® Kit and Tray Management System.

STUDY DESIGN (MEPS REAL-TIME, INC., 2014-2015)

Studies were conducted in the inpatient pharmacies of five hospitals, using hospital staff pharmacy technician and pharmacist study subjects. Errors were embedded in the test trays and trays were configured to identically match trays in use at the hospital. Study subjects were informed that errors were specifically included. They were not told what the specific errors were.

Each study subject conducted the tray exchange process twice – once using the current manual method, and again using the RFID-enabled process. In each study, staff time and inventory accuracy were measured at completion of the tray replenishment process (pharmacy technician and pharmacist workflows), comparing the manual method against the RFID-enabled process.

Time Savings

The focus of this white paper is the quantifiable result in quality improvement through error mitigation. However, it should be noted that staff time savings was also observed in virtually every tray type processed using the automated RFID-enabled process (small, medium, large or extra-large based on the number of items located in the tray). For a full report on time savings results, contact MEPS Real-Time, Inc.

TRAY SIZES TESTED

Tray types were tested in specific size categories, based on the number of items in the tray:

	Size	Example
Small	Up to 15 items	e.g., RSI Kit
Medium	15-50 items	e.g., Pediatric Code Tray
Large	51-75 items	e.g., Crash Cart Tray
Extra Large	75+ items	e.g., Anesthesia Tray, Emergency Transport Box

TRAY ERRORS DATA COLLECTION KEY

Data Collection Key	Description
EX	Expired Med
MI	Missing Med
OP	Open/Used Med
OV	Overage
SALAD	Sound/Look Alike Drugs
SUB	Substitution

- Cumulatively, 100 tray cycles were processed
- Five hospitals were included in the study
- Total starting (embedded) error count was 247
- 20 different study subjects were involved

ERROR RATES: MANUAL WORKFLOW

As described, errors were embedded in the trays which needed to be replenished and study subjects were informed that errors were specifically included. The tables below indicate the ratio of inaccurate trays (trays that would have been deployed for clinical use with one or more errors) as well as the overall percentage of errors still remaining in the trays after using the manual replenishment and approval process: including missing, look alike/sound alike and expired medications.

TABLE 1: ERROR RATIOS USING MANUAL WORKFLOW

	Type	Beds	Error Ratio*	%
Hospital A	Pediatric	361	3:10	30%
Hospital B	Community Academic Acute + LTC	428 | 192	3:8	37.5%
Hospital C	Non-Profit IDN + Pediatric	462 | 373	4:10	40%
Hospital D	Acute Care / Trauma Canter	155	3:16	18.75%
Hospital E	Regional Acute Care	586	4:10	40%
				27.25%

*Error Ratio represents the number of trays completed using the manual replenishment process where one or more errors remained in the tray at the time of final approval for clinical use.

TABLE 2: ERROR PERCENTAGES USING MANUAL WORKFLOW

Tray	# of Trays Processed	Starting Errors	Ending Errors	Error Percentage**
Small	16	24	6	37.5%
Medium	32	69	16	50.0%
Large	38	73	4	10.5%
Extra Large	14	81	28	34.6%
				33.1%

**Error percentage represents the percentage of starting errors not detected using the manual replenishment process. In some cases, as many as 5 errors remained in a single tray.

ERROR ELIMINATION: RFID-ENABLED WORKFLOW

After the manual replenishment and approval process was complete, the MEPS® study proctor reset the identical tray errors. The same study subjects restocked and approved each tray using the RFID-enabled Intelliguard® Kit and Tray Management System.

Hospital A, B, C, D, E	Error Ratio
Error Ratio	Zero | All Trays were 100% Accurate
Error Percentage	Zero | 100% of errors were detected and corrected

When using the RFID-enabled workflow process, 100% of trays were completed with nothing missing and nothing expired.

Errors Using Manual Method

Using the manual replenishment method more than 1 in 3-5 trays would have left the pharmacy with one or more errors.

Errors Eliminated with RFID Enabled Process

100% of trays were complete with nothing missing and nothing expired.

SUMMARY

There are numerous things known to contribute to human error, making it easier to make a mistake.[i] 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. Advanced RFID technology automates, validates and eases the process to reduce the occurrence of human errors.

Accept that human beings make errors, and that the human plus technology is more powerful than either is alone. The main goal of machine verified workflows is to prevent the operator from making a mistake and causing a hazard. Today, RFID solutions provide fast, automated data capture of all elements of the kit and tray replenishment process, including machine verification of approved formulary and PAR levels and associated medication data including name, concentration, dose, package volume, lot number and expiration – removing dependence on human reliability from this error-prone process.

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

TERMS AND DEFINITIONS

- Human Factors: The study of interrelationships between humans, the tools they use and the environment in which they live and work.
- Human Reliability: The probability of accomplishing a job or task successfully by humans at any required stage in system operation within a specific minimum time limit (if the time requirement is specified).
- Human Error: The failure to carry out a specific task (or the performance of a forbidden action) that could lead to disruption of scheduled operations or a results to property and equipment

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