MedLite ID®
Illuminating Patient Safety™

Protect Your Patients and Caregivers Using MedLite ID

Significantly Improve Patient Safety and Staff Efficiency While Reducing Clinician Stress Associated with the Complexity of Multiple IV Infusions

Lighting the Primary / Emergency IV Medication Line to Help Prevent Adverse Events, Reduce "Infusion Confusion" and Medication Errors

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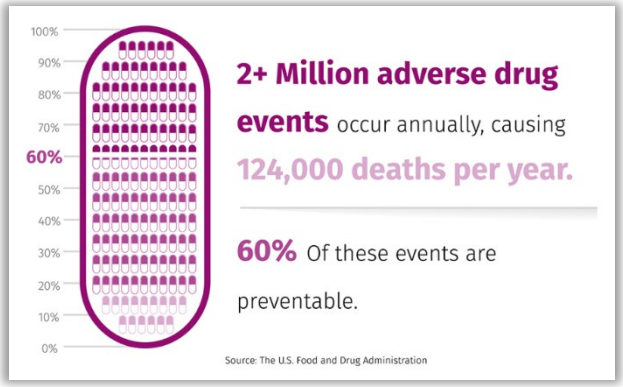
Executive Summary:

Using a unique medical device to improve patient safety, optimize efficiency and reduce clinician stress

According to the US Food and Drug Administration, there are over two million adverse drug events resulting in 124,000 deaths per year— and over 60% of these are preventable.

With over 440,000 medical error deaths each year, and 124,000 of those related to adverse drug events, healthcare providers are searching for solutions to prevent harm and protect their patients. Critically ill patients are often at a higher risk of errors due to the complexity of their care and the severity of their illnesses. Over 60% of all IV infusions contain one or more errors, with ***65% of those errors being related to IV tubing labeling.***



Researchers have suggested that industry solutions can help to reduce the incidence of infusion related errors, and some have even recommended a light linking solution. This is where MedLite ID® can help.

MedLite ID is a unique, simple-to-use medical device that enables clinicians to easily locate the primary medication infusion line in any light setting. MedLite ID significantly reduces "infusion confusion" by virtually eliminating line-tracing related to the primary line through utilization of robust visual indicators.

By making it easier to identify the primary medication line, MedLite ID can significantly improve patient safety and clinical efficiency while reducing the stress clinician experience when dealing with multiple intravenous (IV) infusions and trying to find the correct line in an urgent/ emergent situation.

Background: Why Focus on Multiple Infusion Safety?

Critically ill patients in the hospital often need several different medications at the same time. Many of these medications are administered via intravenous (IV) infusions. When more than one medication is given through IVs, mistakes can happen and cause harm to the patient.

Despite growing awareness of risks associated with multiple IV infusions, minimal research has been conducted into the environmental and human errors that can result from administering multiple IV infusions to a single patient.[1] A study by Kane-Gill found that each additional IV medication line increased the likelihood of an adverse drug event by 3%.[2]

Multiple Infusions Quick Facts

- 440,000 medical error deaths per year and 124,000 of those are ADEs
- 60% of all IV infusions contained one or more errors
- **65% of mistakes are related to IV tubing labeling**
- Each additional IV medication line increased the likelihood of an adverse drug event by 3%

Human Era Study on Multiple IV Infusions

Research was conducted by HumanEra, in collaboration with ISMP Canada, and supported by Health Quality Ontario, to better understand the risks associated with multiple IV infusions, with the goal of improving patient safety by reducing the hazards inherent to these processes. Supporting clinicians with targeted strategies and solutions to help clinicians do the right thing can reduce inherent hazards and improve safety.

HumanEra determined that technology could help to minimize the potential for infusion line identification errors by decreasing the complexity associated with multiple infusions. One such solution was a light-linking system.

- If an "emergency medication line" controlled by an infusion pump is set up, it is strongly suggested that the associated primary IV tubing be labelled as the emergency medication line at the injection port closest to the patient. The label should be prominent and visually distinct from all other labels in the environment.
- Always identify an emergency medication line with a unique label on both the pump and the drug tubing (near the IV push port).[1]

They believed so strongly that this could be a potential solution that they built a prototype for their lab study. For the purposes of this study, the light-linking system was intended to replace the need to manually trace infusions by illuminating the infusion pathway at discrete points, facilitating accurate line tracing.

Since there was no commercial light-linking system available at the time of this study (June 2012), HumanEra designed a simple prototype to help clinicians visually trace an infusion pathway. A prototype was developed that consisted of three discrete components per infusion. The light-linking system was designed so that it could be used only to trace the infusion pathway down from the IV container to the pump and patient access port;
it could not be used to trace the infusion pathway up from the patient access port to the pump and IV container.

Although all participants used the light-linking system to identify which patient access port an infusion was connected to, due to limitations of the prototype, some did not use it to identify which infusions were also connected to the same patient access port. Instead, these participants preferred to manually trace the infusion up from the multiport connector to the IV container; this limited the light-linking system's ability to reduce line tracing errors. When developing MedLite ID, the inventors used this knowledge to avoid the same problems with their system.

Complexity of Care: Risks Associated with Multiple IV Infusions

Infusion setup and programming risks may be compounded with multiple IV infusions. The number of infusions at a patient's bedside may increase both the physical complexity and the cognitive load. Medication errors are more common in clinical environments where patients are receiving multiple medications, such as ICUs; when more medications are prepared and administered, the likelihood of an error increases. Research shows that delivery of a single medication dose to an individual patient requires the correct execution of 80 to 200 individual steps[5].

Infusion Confusion: Current Challenges Associated with Multiple IVs

During shift handover, researchers observed nurses consistently exchanging information about patient medications, but inconsistently discussing IV-line set-up information, such as:

- Which IV line was assigned as an emergency medication line?
- Which pumps and associated IV access locations were associated with life-sustaining medications?

In addition to the number of infusions running, the following factors were observed to increase the challenges of monitoring and managing multiple IV infusions:

- IV tubing looks similar (i.e., they all contain a colorless or white fluid)
- IV tubing gets very tangled creating "infusion confusion" or "spaghetti syndrome"
- IV lines do not line up with their associated pump

Line Identification and Line Tracing

When managing multiple IV infusions, care providers must quickly identify the medication, location and infusion pump parameters for every IV line. Misidentifying an infusion or being unable to identify the right line quickly—can lead to administration of the incorrect infusion or medication, failing to perform the correct infusion, or a critical delay in administering a life-sustaining medication. Any of these errors may lead to patient harm or even death.

Line tracing is a critical task for managing multiple infusions. Most healthcare facilities require at least one nurse, and some require two nurses to trace an infusion from the IV container through the infusion pump to the patient access port before making connections or administering IV infusions.

Never Events (aka Sentinel Events)

In simple terms, “Never Events” are patient care events that should never happen if proper care is provided. The term "Never Event" was first introduced in 2001 by the former CEO of the National Quality Forum (NQF), in reference to particularly shocking medical errors—that should never occur. Over time, the term's use has expanded to signify adverse events that are unambiguous (clearly identifiable and measurable), serious (resulting in death or significant disability), and usually preventable.

When Never Events occur, they are devastating to patients– 71% of events reported to the Joint Commission over the past 12 years were fatal– and may indicate a fundamental safety problem within an organization.

The Joint Commission defines a sentinel event as “an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Sentinel events may include medication errors, adverse drug events, and medication misadventures. Sentinel events cause significant morbidity or mortality and are possibly preventable.

Since the initial never event list was developed in 2002, it has been revised multiple times, and now consists of 29 "serious reportable events" grouped into seven categories, one category being “Care Management Event”.

The first event listed in the Care Management Event category is “Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)”.

One of the major causes of medication errors is distraction. Nearly 75% of medication errors have been attributed to this cause. Physicians and nursing staff have many duties in a hospital. In the rush to be done with writing drug orders or administering medications, sometimes a lapse of judgment develops, and a medication error occurs. It can happen to the best physician and nurse. It is the unscheduled events in the life of a healthcare provider such as the constant pages, attendance at meetings, and answering telephone calls that disrupt patient care. These distractions are often the cause of medication errors. [6]

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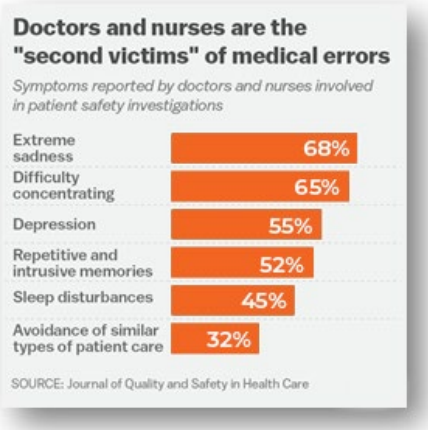
Wrong Route Errors

This error includes overdose, underdose, and an extra dose. An incorrect dose occurs when an inappropriate or different medication dose is given other than what was ordered, errors of omission when a scheduled dose of medication is not given, and when a drug is given via an incorrect route. Errors due to incorrect routes usually occur due to unclear labeling or tubing that is adaptive to multiple connectors/lines of access. Incorrect routes often result in result in significant morbidity and mortality.[7, 8, 9]

Second Victim: The Impact on Clinicians

The clinical personnel who make these errors often feel guilty, ostracized, and shunned— leading to physical and emotional tolls and sometimes results in the clinician leaving the profession. Over time, this culture of blame has shifted, and medication errors are believed to be a systemic problem. Errors in the system may be viewed as the result and not the cause. Thus, rather than focusing on changing the behavior of every healthcare worker, hospitals are now trying to understand how the system failed.



This approach is designed to introduce barriers and safeguards at every level so that a mistake can be caught before the drug is given to the patient. In many cases, mistakes are made by some of the well-trained healthcare professionals, and rather than blame them; one should try and understand why the error occurred. In many cases, errors occur in recurrent patterns, irrespective of the healthcare worker involved.[10]

The Financial Burden of Never Events

Because Never Events are devastating and preventable, health care organizations are under increasing pressure to eliminate them completely. The Centers for Medicare and Medicaid Services (CMS) announced in August 2007 that Medicare would no longer pay for additional costs associated with many preventable errors, including those considered Never Events. Since then, many states and private insurers have adopted similar policies. This means that the financial burden of these errors is absorbed by the healthcare facility.

Medication errors are a common issue in healthcare and cost billions of dollars nationwide while inflicting significant morbidity and mortality. While national attention has been paid to errors in medication dispensing issues, it remains a widespread problem.

Why MedLite ID?

Over 90% of hospitalized patients receive infusion therapy, yet today's smart pumps do little to reduce stress for caregivers or decrease the potential for error when working with multiple infusion lines. In 2017, ECRI Institute named infusion errors the #1 Healthcare Technology Hazard and in 2015 named line mix-ups as the 3rd Healthcare Technology Hazard and 4th biggest Patient Safety Hazard[3]. In addition to the human toll, infusion-related errors are estimated to add more than $2 billion annually to U.S. healthcare costs.[3]

MedLite ID can eliminate infusion confusion by ensuring the primary medication infusion line is prominent and visually distinct from all other lines in the environment. MedLite ID is a simple-to-use, disposable medical device that can significantly improve patient safety and staff efficiency while reducing clinician stress associated with the complexity of multiple IV infusions.

According to the Institute of Medicine, there are "three important strategies to address medical errors—preventing, recognizing, and mitigating harm from error—the first strategy (recognizing and implementing actions to prevent error) has the greatest potential effect, just as in preventive public health efforts." [11] MedLite ID is designed to prevent errors by making it easier, more efficient, and less stressful for the clinician to do the right thing.

MedLite ID: A Unique Solution Developed to Solve a Problem

In 2008 MedLite ID's founder, Dr. Wayne Provost's 16-year-old son, Dusty, was diagnosed with acute myelogenous leukemia. During Dusty's time in a children's hospital, infusion line confusion was a consistent problem in the ICU and during his normal hospital stays. On any average day, Dusty would have five IV lines attached to his ports and veins, and as many as eleven different infusion lines.

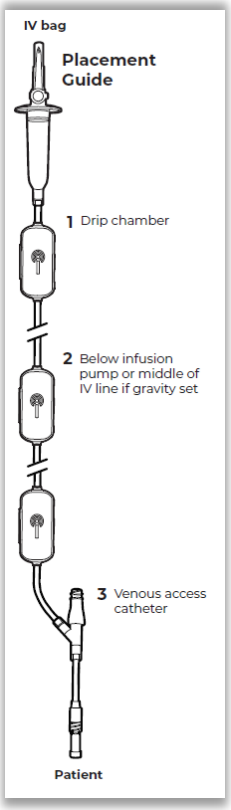
"In Memory of Dusty" is etched on every MedLite ID product

After watching clinician's frustration and stress in finding the right line, Dr. Provost knew there had to be a better, less stressful way to identify the proper line. He was extremely grateful to the clinician's caring for his son, and he was determined to find a way to help.

After his son died, Dr. Provost did significant research to find the best solution. He determined, and studies support, that lighting
the main medication line was the best approach— and MedLite ID was created.

Ease of Use: Simple Four-Step Installation Process

MedLite ID is simple to use, and training takes just minutes. You simply place a MedLite ID device just below the medication bag, one below the pump and one at the venous access catheter. As you pull the MedLite ID devices out of the packaging, they will light up automatically. This lets you know that the devices are working and ready for installation.



For patient safety, it is recommended that you install the MedLite ID devices before you connect the line to the patient. This ensures that you have the correct infusion line identified as the primary medication line (sometimes called the safe push line or saline line). Installation takes just minutes, and the device is ready for use immediately after you connect it to the patient.

MedLite ID is omnidirectional. Pressing any of the three devices will light all three lights—ensuring that there are no interruptions in patient care or any need to press a specific light. The lights remain on for about 50 seconds and is auto off- no need to worry about turning the device off when you have finished your task.

Simply put, MedLite ID makes it easier for nurses and clinical staff to do the right thing.

Current Industry Practices: Manual Line Tracing and Using Tape and a Sharpie

MedLite ID is a unique solution with no competitive products. MedLite ID replaces current practices – such as tape and a Sharpie® or pre-printed labels – with an easier, faster, and safer alternative.

As mentioned previously, line mix-ups are a serious patient safety issue and line tracing is a critical step in the setup process for administration of IV medications. This process is complicated when patients have multiple infusion lines that can become tangled and hidden by bedding or the patient's gown. MedLite ID lights the primary line and reduces the risk of line mix-ups related to the primary medication line, typically the saline line.

Studies suggest that when medical adhesive tape is placed in close contact with intravascular catheters for extended periods, it could theoretically contribute to localized infections. One study found that 74% of specimens of tape collected in one hospital were colonized by pathogenic bacteria.[12]

Hospital Acquired Infections (HAIs) Quick Facts

- HAIs cost U.S. hospitals $96-147 B annually in direct and indirect costs
- Central-line associated bloodstream infections added the most cost at $45,814 per case
- Nearly 1.7 M hospitalized patients acquire HAIs while being treated for other conditions
- More than 98,000 patients (1 in 17) die due to HAIs

Additionally, ongoing risks of healthcare-acquired infections (HAIs) are a significant patient safety concern prompting hospitals to seek new and innovative ways to reduce the risks of cross-contamination. HAI's cost U.S. hospitals $96-$147 billion annually in direct and indirect costs, with central-line associated bloodstream infections adding the most cost at $45,814 per case.[13] Nearly 1.7 million hospitalized patients annually acquire HAIs while being treated for other health issues and that more than 98,000 patients (one in 17) die due to these.[14]

MedLite ID Tape Study

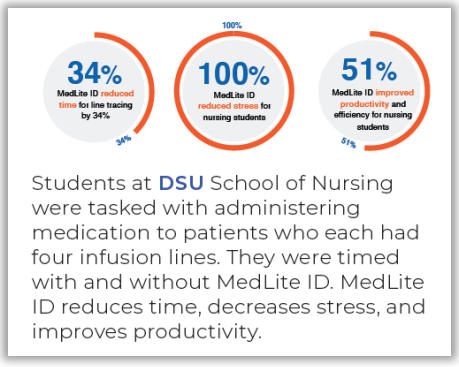
MedLite ID gathered five rolls of medical tape from a nurse's pocket and a brand-new roll from a local hospital and took them to a lab for testing. The results showed that 80% of the used rolls tested positive for pathogens and 16 of the 36 bacteria and fungus found were pathogenic.

Of the identified bacteria, one, Acinetobacter_ursingii, was identified by the World Health Organization as critical and the second, Enterococcus faecium, was listed as serious. Additionally, serious bacteria included Staphylococcus epidermis, a microorganism of the skin flor that can be extremely dangerous when it enters the bloodstream and cause potentially fatal complications.[15]

Benefits for Clinicians: Efficiency Gain, Stress Reduction

The benefits to clinicians using MedLite ID are numerous. Identification of the primary medication line is reduced by approximately 1-2 minutes. Over a 12-hour shift in a 16 bed ICU unit this would result in up to two hours of saved time. This time can now be dedicated to other necessary activities and patient care.

Of equal importance is the reduction in stress to the clinician while trying to identify the primary medication line. During an emergency, when time is of the essence MedLite ID makes the administration of potentially lifesaving drugs



Students at DSU School of Nursing were tasked with administering medication to patients who each had four infusion lines. They were timed with and without MedLite ID. MedLite ID reduces time, decreases stress, and improves productivity.

both quick and simple. Also, during patient transport and shift change the identification of the primary infusion line is easily determined when MedLite ID is incorporated.

MedLite ID Use During COVID-19

During a national pandemic, identifying new technologies and solutions is more important than ever. Many critically ill patients have multiple IV infusion lines, making the task of locating the correct injection port confusing, stressful, and time-consuming.

MedLite ID can drastically reduce the time it takes to perform line tracing, and subsequently lessens the risk of exposure to COVID-19 and the stress associated with infusion line management.

Hypothesis: A mid-sized hospital ICU unit has 16 beds. If 60% of those patients have an average of eight infusion lines, that would be 9.6 beds. Each patient's IV site is checked every two hours when the nurse enters the room to reposition the patient.

- 9.6 patients with four lines would reduce line tracing by approximately 57.6 minutes per unit, per 12-hour shift
- Line tracing for patients with eight lines would result in **approximately two hours' reduction in exposure to COVID-19 per unit, per 12-hour shift**

MedLite ID Health Economic Impact

MedLite ID benefits healthcare facilities in as little as 48-hours by:

- **Saving valuable nursing time** by making line tracing and medication administration more efficient and less disruptive to the patient
- **Significantly reducing risk of medication errors** via wrong route or drug interactions. The average payout for a verdict or settlement in a medical malpractice claim nationally is approximately $242,000.
- **Reducing impact of medical errors on clinicians.** By making it harder to make an error, MedLite ID can help keep nurses on the job. Nationwide, the cost of replacing a registered nurse ranges from $22,000 - $64,000[10], a sum reflecting expenses associated with filling temporary vacancies and hiring and training new staff
- **Medical errors can result in an Increased length of stay** (LOS) and the additional costs associated. These additional costs may not be covered by insurance or CMS if they are deemed a Sentinel Event

Sample Scenario of Facility ROI

In the DSU School of Nursing study, MedLite ID reduced the time it took to conduct line-tracing; the results showed MedLite ID improved efficiency by approximately one minute per task with four lines. The scenario below demonstrates how MedLite ID can give your facility a significant return on investment in as little as 48-hours.

Assumptions:

- Average ICU nurse salary is $100,000 / $48.08 per hour / $0.80 per minute

- Each nurse has two patients with four or more IV lines

Analysis		4-lines	8-lines	12-lines
Efficiency Gain (minutes saved every shift)		12	24	36
Efficiency Value per Minute (one shift)	$0.80	$9.62	$19.23	$28.85
Day 1 Value: two shifts, two patients		$19.23	$38.46	**$57.69***
Day 2 Value: two shifts, two patients		$38.46	**$76.92***	$115.38
Day 3 Value: two shifts, two patients		**$57.69***	$115.38	$173.08
Cost of MedLite ID Kit (two kits, two patients)		$49.00	$49.00	$49.00
Value Gain Above Kit MSRP Cost		$8.69	$66.38	$124.08

- Nurse checks IV lines six times in a twelve-hour shift

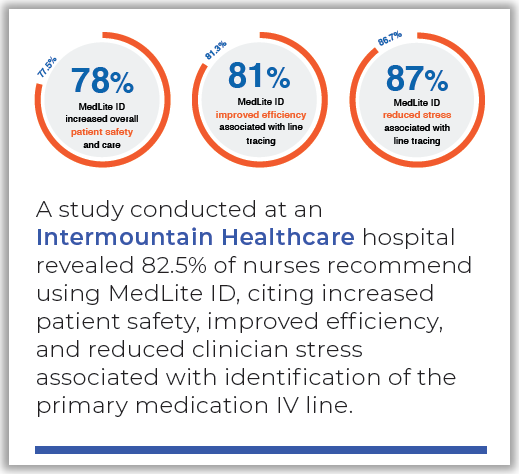
*Denotes point of profit

Quotes from Nurses Participating in a Recent Study with Intermountain Healthcare

When asked what they liked about MedLite ID or when they would use it, nurses from an Intermountain Healthcare hospital said:

"I liked that I could use it to identify the line I needed from the other side of the bed and had quicker access that way. Quicker access and detection of line in an emergent situation. When you have a lot of different meds running on a patient it made it so easy to identify."

"(I would use MedLite ID) When there are multiple lines on the patient and in a situation where there are rapid response events or codes being called needing immediate medications pushed. Also, would be beneficial for night nurses that are needing to push meds through the maintenance line to help identify without having to turn any lights on because they can verify the line before the lights go out. Then they know they're using the correct line on patients with multiple lines. Can be used in more scenarios than just emergent/rapid ones."



"It would more quickly identify an unlabeled line as so many meds can't go together or mix together. Having that knowledge would prevent you from delaying care by immediately knowing which line is which."

"I was able to trace line much easier because of MedLite ID"

"It helped me find the correct line faster in an emergency"

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