VIGILANT

WHITE PAPER

# INTRAVENOUS DEVICE LABELING

## A STRATEGY TO DECREASE PATIENT HARM

This white paper proposes a labeling strategy for intravenous devices to reduce patient harm caused by medication errors. The strategy aims to improve safety and increase efficiency in healthcare settings.

# Abstract


## BACKGROUND

The Institute for Safe Medication Practices (2021) reported a medication error in 2019 that resulted in the death of a patient. The mistake was made by the nursing staff where the patient was recovering from a stroke. The Fentanyl drip was not removed from the infusion pump, resulting in the patient receiving a dose 20 times higher than he had been previously prescribed. ISMP made recommendations to mitigate this kind of risk.

## OBJECTIVE

The objective of this white paper is to examine the impact of intravenous device labeling on reducing patient harm and promoting compliance and to provide a strategy for healthcare professionals to implement effective labeling practices in order to improve patient safety and ensure regulatory compliance.

## RESULTS

Vigilant Software solutions and feedback from end users enabled the company to customize medication labels with generic and brand names and more information about what the drugs do. This customization was done without any additional expense or requiring re-programming.

## CONCLUSION

The implementation of a standardized medical device labeling system, along with the use of advanced technology and proper training, can significantly decrease the risk of medication errors and patient harm. By ensuring that accurate and concise information is available on IV labels, healthcare providers can deliver safe and effective care to their patients.


# Overview

Intravenous (IV) devices are critical components in healthcare settings, used for the administration of medications and other therapeutic interventions. However, improper labeling of these devices can lead to patient harm, such as medication errors or infections. In this whitepaper, we will explore the importance of clear and standardized labeling of IV devices and outline a strategy for implementing effective labeling practices. By improving IV device labeling, healthcare providers can decrease the risk of patient harm and enhance overall patient safety.

# Introduction

Infusion tubing labeling, like medication labeling, is an important strategy used to mitigate medication errors and patient harm. Though medication and infusion tubing labeling are required by regulatory bodies, guidelines focused on medication safety, and many healthcare institutional policies, compliance with such has been shown to be low. Patient harm has occurred because of healthcare workers not following these recommendations for safe practice (Jeetu & Girish, 2010). The use of consistently formatted labels with content from the electronic infusion pump library on infusion tubing is a best practice for medication verification and patient safety (Gorski et.al., 2021).

# Problem Statement

Medical errors, specifically those related to medication administration, are a serious public health risk and are responsible for significant patient morbidity and mortality (Jeetu & Girish, 2010).

In the Unites States up to 9,000 patients die because of medication errors (Tariq, Georgiou, & Westbrook, 2019). Medication errors associated with infusion therapy are especially serious as intravenous medications were found to be associated with 54% of potential adverse events and 56% of medication errors (Summa-Sorgini, et.al., 2012). In their quality improvement initiative, Summa-Sorgini, et.al. (2012) found 5,641 errors associated with 1,882 infusions. Of those errors, 31.5% were related to incomplete infusion therapy tubing labeling. To comply with The Joint Commission's 2023 National Patient Safety Goals NPSG.13.04.01, "Improve the safety of using medications" that calls for the labeling of all medications, medication containers, and other solutions, healthcare workers need a simple and reliable solution to ensure they are following best practices (The Joint Commission, 2022).

# Background

The Institute for Safe Medication Practices (2021) reported a medication error that resulted in the death of a patient in 2019. The event was reported in the Indianapolis newspaper IndyStar October 30, 2020. An unfortunate mistake was made by the nursing staff where the patient was recovering from a stroke.

When the patient's Fentanyl drip was discontinued, it was not removed from the infusion pump. When his hydration fluid bag needed to be replaced and restarted, the nurse mistakenly re-started the idle fentanyl infusion. The mistake resulted in the patient receiving a dose 20 times higher than he had been previously prescribed. Fentanyl is an opioid medication that is 100 times stronger than morphine. Unfortunately, this patient did not survive this medical error.

The Fentanyl drip should have been taken down and discarded once it was discontinued, but had the tubing been labeled near the infusion pump and the pump channel been labeled, this medical error could have been avoided.

As a result of this reported event, ISMP made the following recommendations as a strategy to mitigate this kind of risk (Institute for Safe Medication Practices, 2021).

### Recommendation 1:

*"Label the tubing and pump channel. Labels with the name of the drug being infused and rout of administration should be affixed to each access line at the distal end of the tubing closest to the patient and on the tubing above the pump or channel."*

### Recommendation 2:

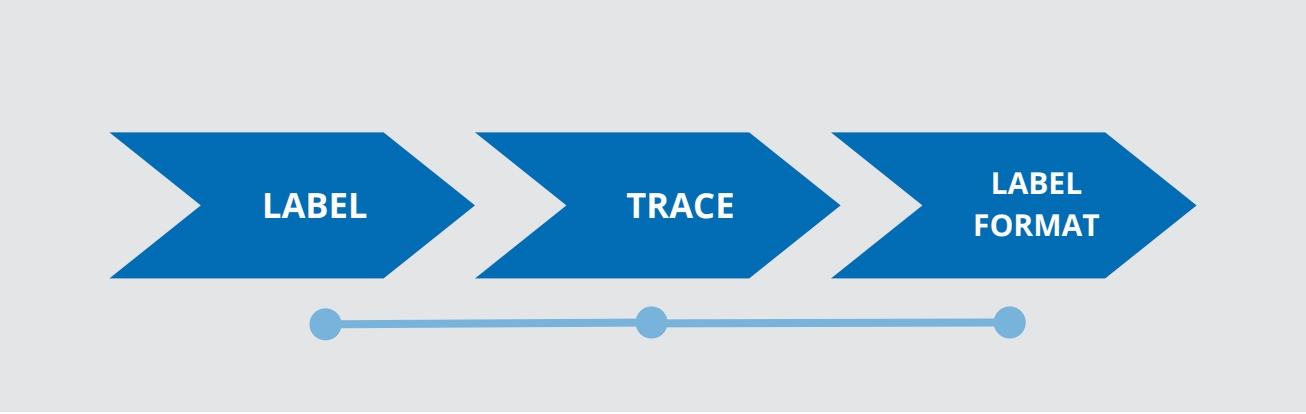
*"Trace the tubing. When parenteral infusions are started, reconnected, or changed, or the rate is adjusted, the tubing should be traced by hand from the solution container to the pump. And then to the patient for verification of the proper pump/channel and route of administration immediately prior to starting or changing the rate of the infusion."*

In an earlier Medication Safety Alert, ISMP, identified the risk associated with unlabeled medications and infusion tubing where they reported that medication errors from injectable medications are higher than those associated with medications administered via other routes. ISMP reported that 50% of harmful medication errors occur during the medication administration phase and two-thirds of those are associated with injectable medications (Institute for Safe Medication Practices, 2007). Their recommendation was as follows:

### Recommendation 3:

*"Provide labels. Commercially available labels for syringes should be provided and regularly restocked in all drug preparation areas. Offer nurses the opportunity to assess several label formats and select one standard format that best meets their needs. Tape is not suitable for labeling a syringe."*

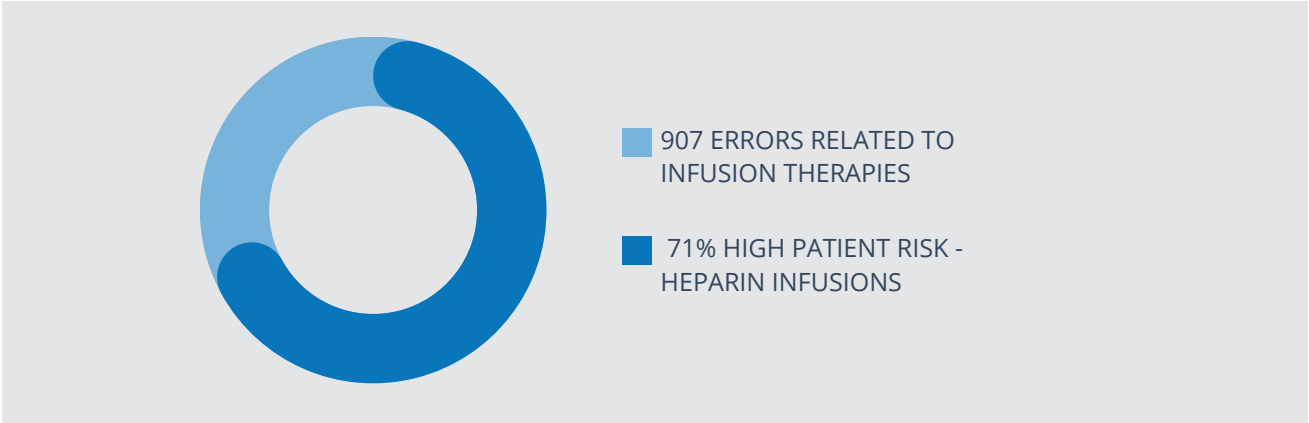
FIGURE 1: ISMP'S RECOMMENDATIONS



Intravenous infusion therapy in the Intensive Care Unit (ICU) is particularly complicated and high-risk. Frequent titration of medications, multiple simultaneous medication administration, and the administration of particularly dangerous medications makes safe practices particularly important. A recent meta-analysis, focused on medication errors in the ICU setting, relating errors to the identification of syringes, infusion pumps, solution bags, administration routes and intravenous administration tubing (Nunes, G, Campos, F., & Silva, R., 2022). Due to the high acuity of patients in the ICU, it is not unusual to see, what the authors of this study describe as, a "disarray and intertwining of IV lines" that makes it complicated and difficult for nurses to identify quickly and correctly what is being infused. This was also highlighted in the 2015 Top Ten Health Technology-related Hazards where errors from incorrect medication and infusion administrations occurred due to confusion when there were multiple intravenous infusions (ECRI, 2014).

They site a recent study from the United States where 907 errors were related the handling of infusion therapies with 71% associated with intravenous tubing where heparin infusions were the most common, a particularly high patient safety risk (Nunes, G, Campos, F., & Silva, R., 2022).

FIGURE 2: INTRAVENOUS TUBING RELATED ERRORS

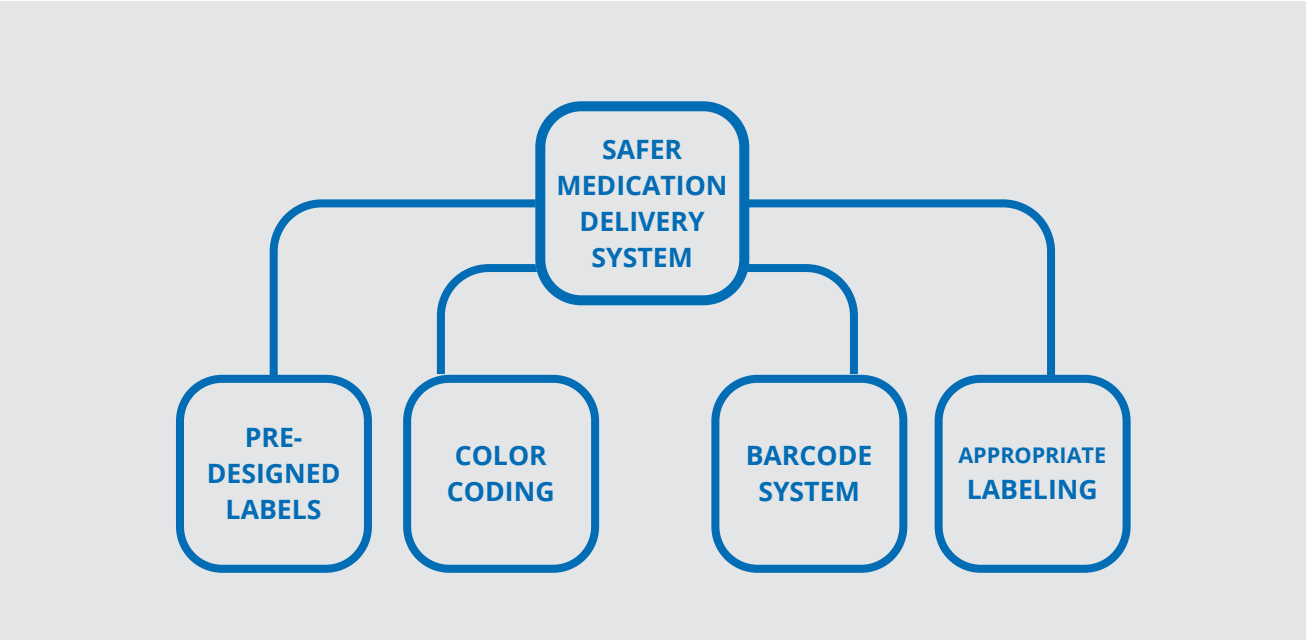



In their analysis of the literature, Nunes, G., Campos, F., & Silva, R. (2022), identified several opportunities for improvement. In one study, 31.5% of all errors were associated with incomplete intravenous tubing labelling and 26.8% of those represented a direct patient safety risk. Of 70 doses of medications prepared by nurses, 65.7% had no label indicating what the medication was and poorly labeled syringes were associated with a 2-fold increase in medication errors. Up to 95% of participants in one study reported they did not label intravenous tubing at all.

Nunes' group determined better performance among nurses when "pre-designed labels, with pre-defined colors and information" was part of a uniform pattern of structuring intravenous tubing and medication labels (Nunes, G, Campos, F., & Silva, R., 2022). To promote a safer medication delivery system, they call for utilizing pre-designed labels and color coding as important characteristics to reduce medication administration errors. In addition, they note that a barcode system for the generation of labels significantly reduced errors associated with syringe labeling. Their final determination was that appropriate labeling of intravenous administration sets, tubing or syringes, when done properly reduces medication errors and increases safe practice among nurses.

Furniss, et.al. (2018) performed a mixed methods study to understand the prevalence of procedural and documentation deviations in intravenous infusion administration across 16 hospitals in England's National Health Service. In their study, they found an overall deviation rate of 47.9%, ranging from 16.7 to 100%, associated with the administration, documentation of, or compliance with organizational policy in the administration of infusion therapy.

FIGURE 3: STUDY BY NUNES G., CAMPOS, F., & SILVA, R. (2022)




Deviations associated with intravenous tubing labeling were found at a rate of 26.8% with rates of deviation impacted by the level of detail of information required by hospital policy and the nurse's awareness of their policies. They also found a deviation of 10.9%, ranging from 3.3 to 74.0%, in the recording of details on additives to infusion labels.

During their data collection, a potentially significant deviation was found where an additive label was marked with "DEX" to indicate dexamethasone was added to the infusion. However, this could easily be confused with several other medications like dextrose. An unlabeled syringe of fentanyl was also identified in an infusion pump during data collection (Furniss, et.al., 2018).

This research study highlights the wide variability of practice across hospital settings as well as the gaps associated with safe handling of infusions. Nursing's lack of awareness of labeling content requirements further widens the gap of intravenous labeling compliance. As stated by Furniss, et.al. (2018) "If a deviation actively contributed to harm, it is obviously unsafe, but not contributing to harm in a given patient does not mean that it is safe".

In 2007, the American Nurses Association conducted an online survey of challenges nurses face when it comes to injectable medication labeling. In that survey, 97% of nurses reported being concerned about medication errors and 68% believed that injectable medication errors could be resolved with more consistent medication labeling.

Nearly half of the nurses reported giving injectable medications on each of their shifts but only a third reported always labeling the medication and alarmingly 28% said they never label injectable medications (American Nurses Association, 2007).

The 2021 Infusion Therapy Standards of Practice sets the standard of practice for medication labeling in multiple standards (Gorski et.al., 2021).

## Standard 13

Medication Verification recommends the use of supplementary labels as a safeguard to reduce the risk of medication errors and calls for medication labels to be consistent in format and content from the electronic infusion pump drug library.

## Standard 20

Compounding and Preparation of Parenteral Solutions and Medications recommends labelling all clinician-prepared medications at the location of preparation without any break in the procedure.

## Standard 43

Administration Set Management recommends labeling administration set tubing with the route and/or medication/solution near the connection to the solution container and near the patient's access site.

## Standard 59

Infusion Medication and Solution Administration recommends labeling administration set tubing with the route and/or medication/solution near the connection to the solution container and near the patient's access site using standardized labels that are consistent in format and that distinguish the injection site where intravenous push medications are administered with visually prominent labels that are formatted differently than other labels.

ISMP (2022) published the most recent recommendations for the safe handling of medications in the perioperative and procedural settings. While the ISMP guidelines are focused on safe medication handling in what are considered "procedural" areas, it makes sense that the recommended medication safe handling guidelines would be applicable to other patient care areas where medications are administered. ISMP made the following recommendations as key elements for drug labeling, packaging, and nomenclature:

## ISMP (2022) Statements

**4.3**

Eliminate the use of handwritten labels in perioperative/procedural areas by 2025.

**4.4**

Include a machine-readable code (e.g., barcode, radiofrequency identification on all syringes and infusion labels, including those that are practitioner-prepared, by 2025.

**4.5**

Label practitioner-prepared syringes of medications with, at a minimum, the full name, concentration/dose of the drug, name or initials of the preparing practitioner, as well as an expiration date (when not used in 24 hours) and time (if expiration occurs in less than 24 hours). Application of an anesthesia color-coded drug class label alone is not sufficient.

# Recommendations

To address proper medication and infusion administration set tubing a labeling solution is needed that supports the following:

- Automated label printing where content from a drug database accessed via barcode scanning
- The ability to print in a clear, understandable, consistent, and easy to identify format
- The inclusion of the drug being infused and the route of administration
- Labeling of the medication administration set tubing above the pump near the connection to the solution and near the patient access site
- Labels that are easily accessible and can be created at the point where the medication is prepared

In a recent product pilot, an on-demand infusion printer was trialed in a Critical Care Unit to determine if its use could increase compliance with intravenous administration set labeling, increase nursing satisfaction, reduce the amount of time required by nursing to follow appropriate labeling practice, and reduce central line associated bloodstream infections (Meister, 2017). In this pilot, the use of an automated, on-demand infusion printer solution increased nursing satisfaction and increased compliance with the administrative set labeling process. It also showed that nurses saved 1 to 2 minutes of work time on each administration set they were required to prime. The author determined these outcomes can reduce the risk of central line associated bloodstream infections.

# Conclusion

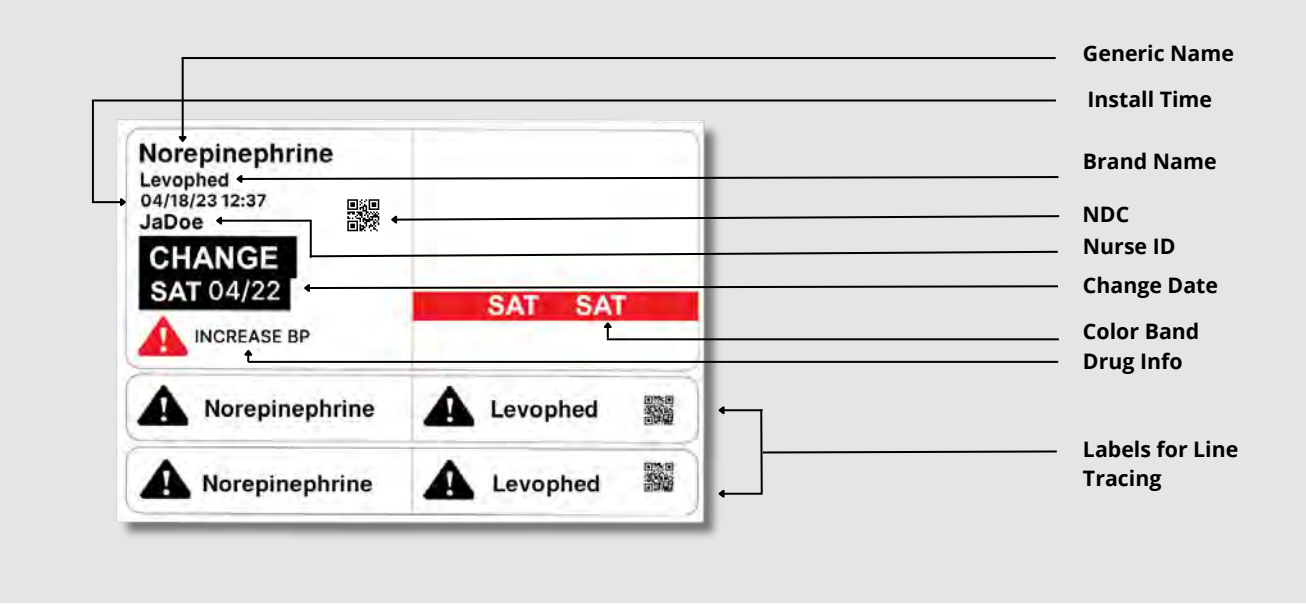
Infusion administration and medication syringe labeling is an important step in reducing medication errors. Whether the medication is administered intravenously or by another route, administration set, and syringe labeling provides safety information to ensure nurses and other healthcare providers have the information at their fingertips to administer medications safely.

Several strategies and recommendations to improve the safety of medication administration are reviewed above. Utilizing a unique, automated hardware and software system allows for a standardized approach to incorporate these recommendations in a solution supporting best practices.

Printing multiple labels for the syringe, infusion bag, and tubing allows for quick identification of infusions when there are multiple infusions that may be difficult to sort out in a high-acuity area. Multiple labels also make it easier for nurses to "trace" those medications from the bag through the infusion pump, to the infusion site. Customizing labels with "high alert" features for dangerous medications makes them highly visible and supports a safer medication administration system.

Vigilant Software offers a nimble printer and software solution to meet the outlined recommendations. With the ability to customize the output from barcode medication scanning to customized printed labels, Vigilant Software can meet the needs of the end user and support compliance with best practices.

FIGURE 4: VIGILANT SOFTWARE INTRAVENOUS LABEL SAMPLE




The ISMP (2022) recommendations for safe medication handling by the year 2025 are already included in the Vigilant Software solutions. As a progressive and adaptive thinking software solution, Vigilant is easy to use and implement in an organization's patient safety strategies.

As a result of trials of the Vigilant Software solutions during the COVID-19 pandemic, and based on feedback from end users, the company was able to further customize what nurses wanted to see on their medication labels. They wanted to see both generic and brand names of drugs on the labels and additional information about what the drugs does. Vigilant's flexibility allowed for this type of customization without any additional expense or requiring significant re-programming.

To ensure ongoing patient safety, organizations should consider solutions that allow them to customize medication labeling to meet their needs and seek out solutions that can robustly meet their ongoing needs. One way to determine what those needs are would be to understand their current compliance with intravenous administration set and medication labeling as well as medication errors associated with administration set and syringe labeling.

FIGURE 5: IMPROPER INTRAVENOUS LABEL VS. VIGILANT'S LABEL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