Anesthesia Patient Safety Foundation

Medication Safety:
Pre-Filled Syringes, Drug Labeling, and Infusion Pumps

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Objectives

Identify the differences between feedback and constraints in the perioperative environment

Analyze the multi factorial issues involving the labeling of syringes and vials in the perioperative environment and beyond

Develop a working knowledge regarding Smartpumps and DERS

Financial Disclosures: None

Criminalization of Medical Error

December 2017

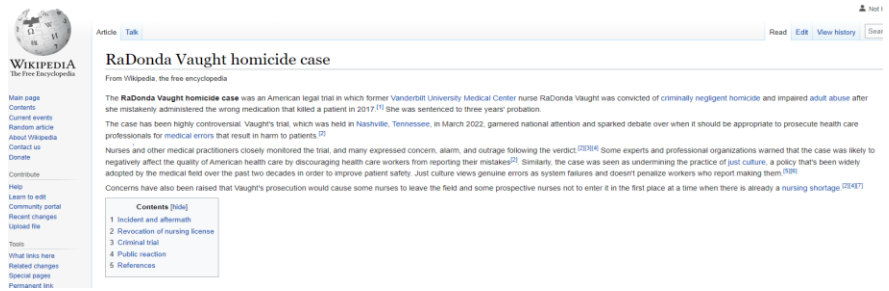
- RN Vaught administered vecuronium in place of midazolam in a NORA suite resulting in the death of 75 year-old patient Charlene Murphey

March 2022

- Vaught convicted of gross neglect of an impaired adult and negligent homicide

May 2022

- Vaught sentenced to three years' probation



WIKIPEDIA
The Free Encyclopedia

RaDonda Vaught homicide case

From Wikipedia, the free encyclopedia

The **RaDonda Vaught homicide case** was an American legal trial in which former Vanderbilt University Medical Center nurse RaDonda Vaught was convicted of criminally negligent homicide and impaired adult abuse after she mistakenly administered the wrong medication that killed a patient in 2017.[1] She was sentenced to three years' probation.

The case has been highly controversial. Vaught's trial, which was held in Nashville, Tennessee, in March 2022, garnered national attention and sparked debate over when it should be appropriate to prosecute health care professionals for medical errors that result in harm to patients.[2]

Nurses and other medical practitioners closely monitored the trial, and many expressed concern, alarm, and outrage following the verdict.[3][3][4] Some experts and professional organizations warned that the case was likely to negatively affect the quality of American health care by discouraging health care workers from reporting their mistakes[2]. Similarly, the case was seen as undermining the practice of just culture, a policy that's been widely adopted by the medical field over the past two decades in order to improve patient safety. Just culture views genuine errors as system failures and doesn't penalize workers who report making them.[5][6]

Concerns have also been raised that Vaught's prosecution would cause some nurses to leave the field and some prospective nurses not to enter it in the first place at a time when there is already a nursing shortage.[7][4][7]

Contents [hide]
1 Incident and aftermath
2 Revocation of nursing license
3 Criminal trial
4 Public reaction
5 References

NEWS

Elderly woman's family 'forgives' nurse accused of giving wrong medication

Photo by: Submitted

Posted at 1:47 PM, Feb 05, 2019 and last updated 1:47 PM, Feb 05, 2019

https://www.apsf.org/news-updates/position-statement-on-criminalization-of-medical-error-and-call-for-action-to-prevent-patient-harm-from-error/#:~:text=APSF%20believes%20that%20the%20criminal,prosecution%20of%20individual%20healthcare%20professionals.
https://en.wikipedia.org/wiki/RaDonda_Vaught_homicide_case

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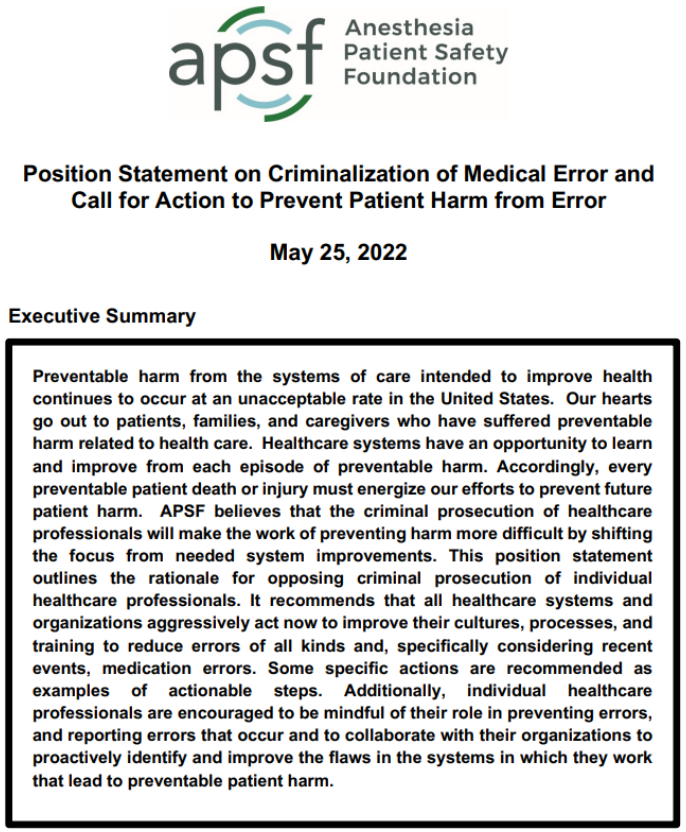
Criminalization of Medical Error



Anesthesia Patient Safety Foundation

Position Statement on Criminalization of Medical Error and Call for Action to Prevent Patient Harm from Error

May 25, 2022

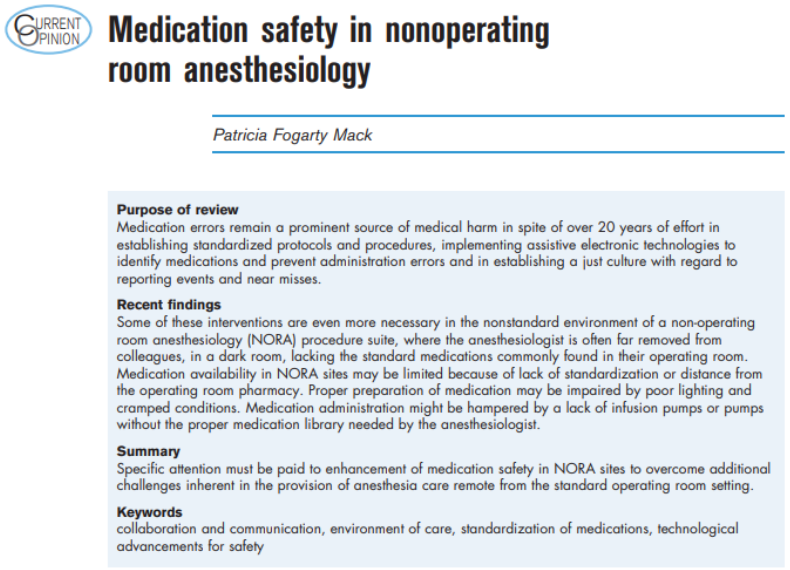
Executive Summary

Preventable harm from the systems of care intended to improve health continues to occur at an unacceptable rate in the United States. Our hearts go out to patients, families, and caregivers who have suffered preventable harm related to health care. Healthcare systems have an opportunity to learn and improve from each episode of preventable harm. Accordingly, every preventable patient death or injury must energize our efforts to prevent future patient harm. APSF believes that the criminal prosecution of healthcare professionals will make the work of preventing harm more difficult by shifting the focus from needed system improvements. This position statement outlines the rationale for opposing criminal prosecution of individual healthcare professionals. It recommends that all healthcare systems and organizations aggressively act now to improve their cultures, processes, and training to reduce errors of all kinds and, specifically considering recent events, medication errors. Some specific actions are recommended as examples of actionable steps. Additionally, individual healthcare professionals are encouraged to be mindful of their role in preventing errors, and reporting errors that occur and to collaborate with their organizations to proactively identify and improve the flaws in the systems in which they work that lead to preventable patient harm.

"APSF believes that the criminal prosecution of healthcare professionals will make the work of preventing harm more difficult by shifting the focus from needed system improvements."

https://www.apsf.org/news-updates/position-statement-on-criminalization-of-medical-error-and-call-for-action-to-prevent-patient-harm-from-error/#:~:text=APSF%20believes%20that%20the%20criminal,prosecution%20of%20individual%20healthcare%20professionals.
https://en.wikipedia.org/wiki/RaDonda_Vaught_homicide_case

Medication Safety and NORA



Medication safety in nonoperating room anesthesiology

Patricia Fogarty Mack

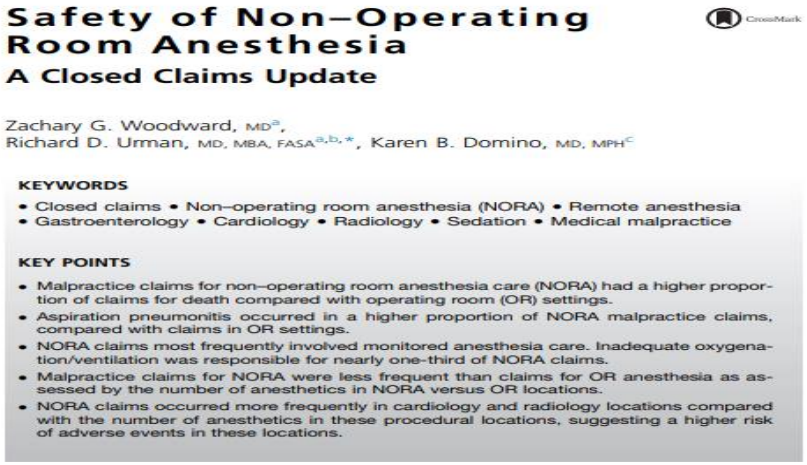
Purpose of review
Medication errors remain a prominent source of medical harm in spite of over 20 years of effort in establishing standardized protocols and procedures, implementing assistive electronic technologies to identify medications and prevent administration errors and in establishing a just culture with regard to reporting events and near misses.

Recent findings
Some of these interventions are even more necessary in the nonstandard environment of a non-operating room anesthesiology (NORA) procedure suite, where the anesthesiologist is often far removed from colleagues, in a dark room, lacking the standard medications commonly found in their operating room. Medication availability in NORA sites may be limited because of lack of standardization or distance from the operating room pharmacy. Proper preparation of medication may be impaired by poor lighting and cramped conditions. Medication administration might be hampered by a lack of infusion pumps or pumps without the proper medication library needed by the anesthesiologist.

Summary
Specific attention must be paid to enhancement of medication safety in NORA sites to overcome additional challenges inherent in the provision of anesthesia care remote from the standard operating room setting.

Keywords
collaboration and communication, environment of care, standardization of medications, technological advancements for safety

- **Distant location**
- **Limited availability of medications/supplies**
- **Physical and lighting limitations**
- **Challenges in monitoring**
- **Lack of familiarity with procedures and medications**



Safety of Non–Operating Room Anesthesia
A Closed Claims Update

Zachary G. Woodward, MD[a], Richard D. Urman, MD, MBA, FASA[a,b,*], Karen B. Domino, MD, MPH[c]

KEYWORDS
• Closed claims • Non–operating room anesthesia (NORA) • Remote anesthesia • Gastroenterology • Cardiology • Radiology • Sedation • Medical malpractice

KEY POINTS
- Malpractice claims for non–operating room anesthesia care (NORA) had a higher proportion of claims for death compared with operating room (OR) settings.
- Aspiration pneumonitis occurred in a higher proportion of NORA malpractice claims, compared with claims in OR settings.
- NORA claims most frequently involved monitored anesthesia care. Inadequate oxygenation/ventilation was responsible for nearly one-third of NORA claims.
- Malpractice claims for NORA were less frequent than claims for OR anesthesia as assessed by the number of anesthetics in NORA versus OR locations.
- NORA claims occurred more frequently in cardiology and radiology locations compared with the number of anesthetics in these procedural locations, suggesting a higher risk of adverse events in these locations.

Closed Claims (2002-2012): higher proportion of malpractice claims for death in NORA settings than in operating room settings

NORA Medication-related Claims: 6 %

Mack, Patricia Fogarty. Medication safety in nonoperating room anesthesiology. Current Opinion in Anaesthesiology: August 2021 - Volume 34 - Issue 4 - p 443-448 doi: 10.1097/ACO.0000000000001015
Woodward ZG, Urman RD, Domino KB. Safety of Non-Operating Room Anesthesia: A Closed Claims Update. Anesthesiol Clin. 2017 Dec;35(4):569-581. doi: 10.1016/j.anclin.2017.07.003. PMID: 29101947.

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Medication Errors

- Frequency of medication errors in the perioperative environment: 1 out of 20 administrations
- Observed error rates are higher than self-reported rates
- Types of Errors: 1) incorrect dosing
  2) substitution
  3) contraindicated drug administration
  4) timing errors

Nanji KC, Patel A, Shaikh S, Seger DL, Bates DW. Evaluation of Perioperative Medication Errors and Adverse Drug Events. Anesthesiology. 2016 Jan;124(1):25-34. doi: 10.1097/ALN.0000000000000904. PMID: 26501385; PMCID: PMC4681677.

Phases of Medication Process

SENSAR: 1970 MRE/7072 (28%) incidents

Administration phase most frequent (42%) and highest harm

Phase of medication process	1970	
Administration	835 (42)	Unintended epidural fentanyl administration instead of intravenous.
Prescription	425 (22)	Amoxicillin regimen prescription in a penicillin allergic patient.
Preparation	258 (13)	Incorrect epinephrine concentration labelling.
Dispensation	206 (11)	Incorrect medication (atropine vs adrenaline) given from one provider to the medication administering provider.
Monitoring	80 (4)	Absence of coagulation test in a patient under oral anticoagulant treatment.
Others	166 (8)	Preoperative medication administered is not registered in the clinical documentation of the patient, only oral information is recorded.
Type of MREs	**1970**	
Wrong treatment regimen	544 (28)	Continuous local epidural anaesthetic perfusion to 60 ml h^{-1} instead of 6 ml h^{-1}.
Wrong medication	534 (27)	Ceftazidime administration instead of the cefazolin prescribed.
No administration	184 (9)	Inadvertent loss of intravenous access during general anaesthesia, with a total intravenous anaesthesia impossible administration.
Wrong route of administration	112 (6)	Enteral nutrition connected to central intravenous access.
Wrong dosage	110 (6)	1000 μg ml^{-1} phenylephrine inadvertent administration instead of 100 μg ml^{-1}, with patient extreme bradycardia.
Expired medication	17 (1)	Expired epidural local anaesthetic bags storage in refrigerator.
Others	469 (24)	Anaphylaxis with amoxicillin.
Medication group involved	**1970**	
Medications that alter haemostasis	359 (18)	Low molecular weight heparin, sodium heparin, acetylsalicylic acid, acenocoumarin, protamine, clopidogrel, tranexamic, phytomethadione.
Vasoconstrictor agents	253 (13)	Atropine, noradrenaline, phenylephrine, adrenaline, ephedrine, dopamine, isoproterenol.
Opiates	204 (10)	Remifentanil, morphine chloride, fentanyl, tramadol, methadone, sulfentanil, alfentanil, meperidine.
Antimicrobial agents	163 (8)	Vancomycin, cefazolin, amoxicillin, clindamycin, gentamicin, teicoplanin, meropenem, ciprofloxacin.
Local anaesthetics	137 (7)	Bupivacaine, lidocaine, ropivacaine, levobupivacaine, mepivacaine, prilocaine.
Inhalation/intravenous anaesthetics	103 (5)	Sevoflurane, protoxide, desflurane, propofol, etomidate, dexmedetomidine, ketamine, thiopental.
Neuromuscular blocking agents	97 (5)	Rocuronium, cisatracurium, succinylcholine, atracurium.
Minor analgesics	93 (5)	Metamizole, dexketoprofen, paracetamol, diclofenac.
Reversal agents/ antidotes	67 (3)	Sugammadex, neostigmine, flumazenil, naloxone.

Sanduende-Otero Y, Villalón-Coca J, Romero-García E, Díaz-Cambronero Ó, Barach P, Arnal-Velasco D. Patterns in medication incidents: A 10-yr experience of a cross-national anaesthesia incident reporting system. Br J Anaesth. 2020 Feb;124(2):197-205. doi: 10.1016/j.bja.2019.10.013. Epub 2019 Nov 25. PMID: 31780140.

Anesthesia Safety Tools

Left (Medication) Side	Right (Machine) Side
No Dose Checking	Color-Coded Gases / Lines
No Alarms	Diameter and Pin-Index Safety Systems
No Way to Detect Errors	Oxygen-Nitrous Coupler
No "Exhaled" Propofol Monitor	Gas Monitors and Alarms
	Pressure and Flow Sensors and Alarms
	Keyed and Colored Vaporizer Fillers
	Patient Monitors: SpO_2, $ETCO_2$
	Flow Meter Assembly Order
	Oxygen Pressure Failure Device
	Vaporizer Transport Setting
	Machine Check

Grigg and Roesler. Anesth Analg 126(1): 346-50, 2018.

Feedback vs. Constraints

Feedback	Constraints
Color-coded syringes*	Smart pump guardrails
Barcode scanners	Standard pharmacy concentrations
Labels	Prefilled syringes
Two-provider checks / Checklists	Standard layouts
Alarms	(Machine examples…)

- Feedback requires compliance and engagement

30442240

Grigg EB, Litman RS. Feedback and constraints: rethinking medication safety countermeasures. Br J Anaesth. 2018 Dec;121(6):1188-1190. doi: 10.1016/j.bja.2018.08.003. Epub 2018 Sep 5. PMID: 30442240

Constraints

Eliminate steps / options

- Automate processes
- Physically prevent mistakes
- Types
  - Interfaces (pin-index, filler keys)
  - Coupling (O2-nitrous)
  - Standardization

Without impacting workflow / decision-making

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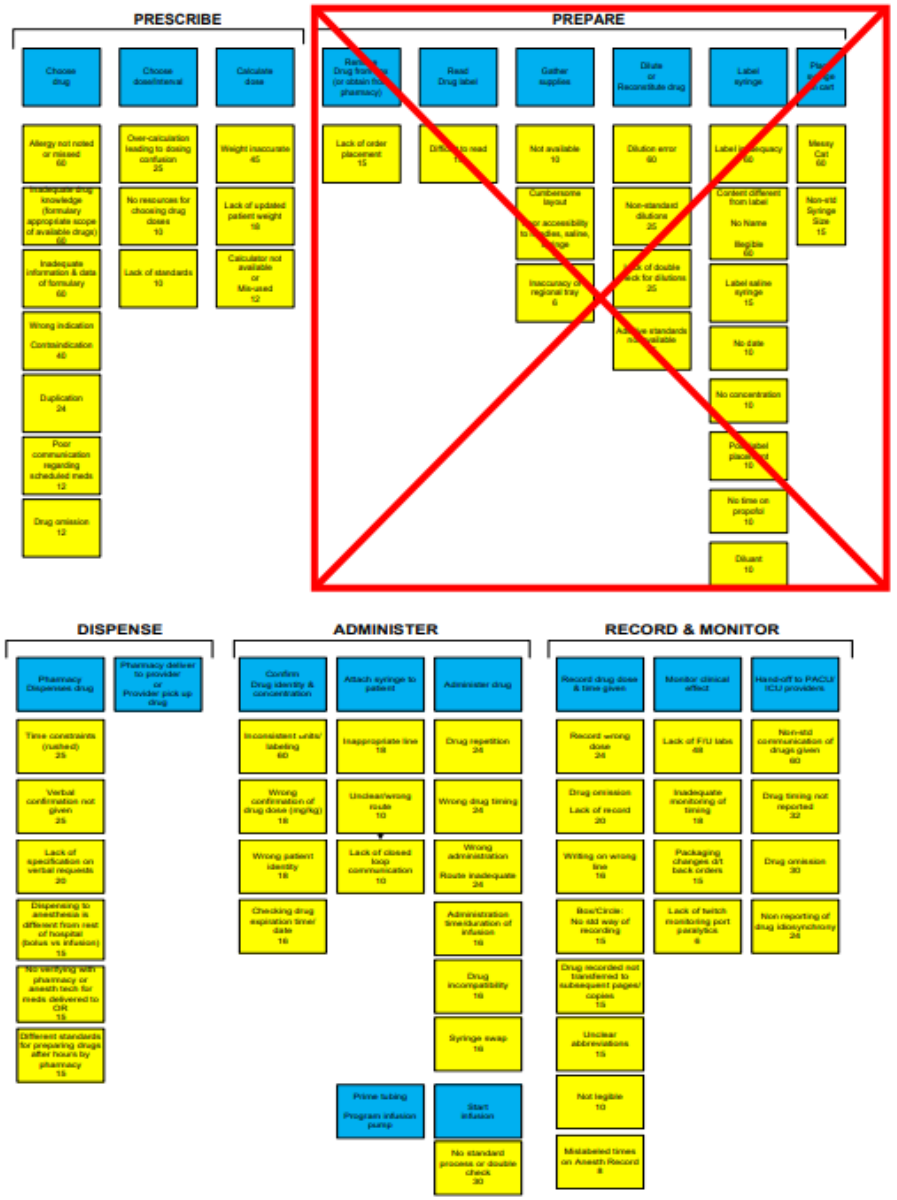
Failure Mode and Effects Analysis

- Failure Mode and Effects Analysis
- 5 steps
- 18 sub-steps (blue)
- 68 possible failure modes (yellow)

- Prefilled Syringes
- 6 sub steps eliminated
- 19 possible failure modes eliminated



Martin LD, Grigg EB, Verma S, Latham GJ, Rampersad SE, Martin LD. Outcomes of a Failure Mode and Effects Analysis for medication errors in pediatric anesthesia. Paediatr Anaesth. 2017 Jun;27(6):571-580. doi: 10.1111/pan.13136. Epub 2017 Mar 28. PMID: 28370645..

Labeling

American Society of Anesthesiologists

Statement on Labeling of Pharmaceuticals Used in the Practice of Anesthesiology

Committee of Origin: Equipment and Facilities

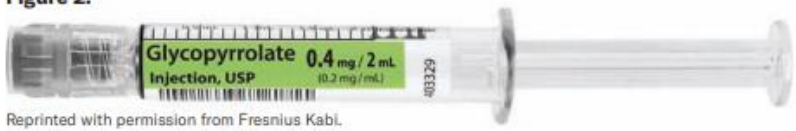
(Approved by the ASA House of Delegates on October 27, 2004, and last amended on December 13, 2020)

Statement: The primary consideration for the design and use of labels for syringes, drug infusion bags, and medication containers should be the reduction of medication errors and thus safer patient care. This is particularly true for the potent medications used in the practice of anesthesiology. Therefore, the ASA supports the manufacture and use of labels that meet the standards described below, which are consistent with those established by ASTM International (formerly the American Society for Testing and Materials), the International Organization for Standards (ISO), as well as recommendations and guidelines from the Food and Drug Administration (FDA) and the Institute

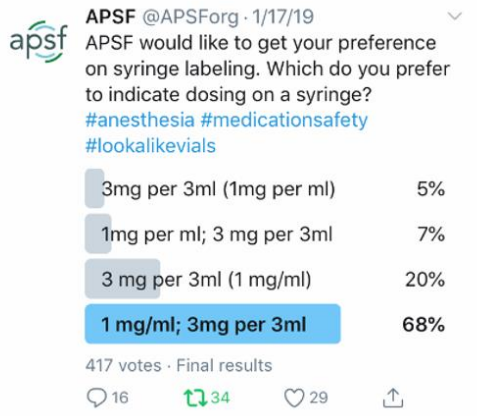
Figure 1:

Reprinted with permission from Fresnius Kabi.

Figure 2:



Reprinted with permission from Fresnius Kabi.



https://www.asahq.org/standards-and-guidelines/statement-on-labeling-of-pharmaceuticals-for-use-in-anesthesiology

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USP

General Chapters

⟨7⟩ LABELING

DEFINITION

The term *labeling* designates all labels and other written, printed, or graphic matter on an article's immediate container or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term *label* designates that part of the labeling on the immediate container.

A shipping container that contains a single article, unless the container also is essentially the immediate container or the outside of the consumer package, must be labeled with a minimum of product identification (except for controlled articles), lot number, expiration date, and conditions for storage and distribution.

LABELS AND LABELING FOR DRUG PRODUCTS EXPRESSED AS ACTIVE MOIETY IN NAME AND STRENGTH

The names and strengths of drug products and compounded preparations shall be expressed in terms of the active moiety and its corresponding strength on the label (see *Nomenclature* ⟨1121⟩, *Monograph Naming Policy for Salt Drug Substances in Drug Products and Compounded Preparations*).

Exceptions: In those rare cases in which the use of the specific salt form of the active moiety in the title provides vital information from a clinical perspective, an exception to this Policy may be considered. In such cases, where the monograph title contains the specific salt form of the active moiety, the strength of the product or preparation is also expressed in terms of the specific salt form.

Labeling: The labels and labeling shall clearly state the specific salt form of the active moiety that is present in the product/preparation, as this information may be useful to practitioners and patients. The names and strengths of both the active moiety and specific salt form (where applicable) are provided in the labeling.

LABELS AND LABELING FOR INJECTABLE PRODUCTS

and/or drug substance in a large-volume injection (LVI), the concentration of each active moiety and/or drug substance named in the official title is stated as if it were part of the official title (e.g., *5% Dextrose Injection*, or *5% Dextrose* and *0.2% Sodium Chloride Injection*).

Injections that are intended for veterinary use only should be labeled to that effect.

Vaccine labeling is not included in this general chapter.

Strength and Total Volume for Single- and Multiple-Dose Injectable Drug Products

For single- and multiple-dose injectable drug products, the strength per total volume should be the primary and prominent expression on the principal display panel of the label, followed in close proximity by strength/mL enclosed by parentheses. For containers that hold a volume of less than 1 mL, the strength per fraction of a mL should be the only expression of strength. Strength per single mL should be expressed as mg/mL, not mg/1 mL. The following formats are acceptable for contents greater than 1 mL:

Total strength/total volume: 500 mg/10 mL
Strength/mL: 50 mg/mL
or
Total strength/total volume: 25,000 Units/5 mL
Strength/mL: 5000 Units/mL.

The following format is acceptable for contents less than 1 mL:

12.5 mg/0.625 mL

There are some exceptions to expressing strength per total volume. In certain cases, the primary and prominent expression of the total drug content per container would not be effective in preventing medication errors (e.g., insulin). Another example is the use of lidocaine (or similar drugs for local anesthesia where the product is ordered and administered by percentage (e.g., 1% or 2%). In such cases, the total strength should be expressed: for example, 1% can be expressed as

(100 mg/10 mL) or
(10 mg/mL).

Dry solids that must be reconstituted should follow the same format with the exception that only the total strength of the

Infusion Pumps

- From 2002-2009, 56,000 adverse events and numerous deaths associated with infusion devices
- Smart infusion pumps are intended to ensure safe intravenous medication use by preventing over and under dosing
- REMEDI project was initiated in response to the national priority to improve patient safety for infusion pumps and to a request from the Indianapolis Coalition for Patient Safety

. **www.fda.gov/InfusionPumps**

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REMEDI database

"To be a vibrant, resourceful and collaborative community that advances and promotes infusion pump medication administration in the interest of patient safety and quality."

Regenstrief National Center for Medical Device Informatics (REMEDI)
https://www.purdue.edu/discoverypark/rche/REMEDI/REMEDI%20Overview.php
https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/infusion-pumps?_ga=2.51818473.158693613.1643124592-1816386686.1643124592

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REMEDI
Medical Device Informatics Overview
Awards
Events
Members
Join REMEDI
REMEDI Research

REMEDI Research

Researchers at Purdue University – and beyond – leverage the data and the community to improve patient and medication safety.

A representative sample of our publications

- DeLaurentis, Poching, Kang-Yu Hsu, and Yuval Bitan (2018). **Prevalence of wireless smart-pump drug library update delays**. *American Journal of Health-System Pharmacy*. June 2018. **https://doi.org/10.2146/ajhp170824**.
- Harris, P.R., S. Strickland, R. Zink, M.N. Flack, AAMI Ventilator Alarms Workgroup (2018). **The Mechanical Ventilator Alarm Default Setting Project**. *American Thoracic Society 2018 International Conference: Poster Session B53: Enhancing Practice Environments, Patient Safety, and Outcomes*. May 2018.
- Yu, Denny, Kang-Yu Hsu, Joon Hong Kim, and Poching DeLaurentis (2017). **Infusion pump informatics approach to quantify impact of alerts and alarms on healthcare delivery**. *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*. Vol 61, Issue 1, pp. 681-685. September 2017. **https://doi.org/10.1177%2F1541931213601657**.
- Giuliano, Karen, Wan-Ting Su, Daniel Degnan, Kristy Fitzgerald, Richard Zink, and Poching DeLaurentis (2017). **Intravenous Smart Pump Drug Library Compliance: A Descriptive Study of 44 Hospitals**. *Journal of Patient Safety*. June 2017. **https://doi.org/10.1097/PTS.0000000000000383**

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Team Effort

- Local facilities may seek to harmonize such concentrations with pharmacy services and other stakeholders and within their drug libraries
- Balance the objective of reducing the risk of patient harm with pragmatic considerations, such as strength and quality of evidence, feasibility and economic burden

Key Takeaways

- Utilize Constraints when available
  - ➢ Prefilled syringes, standardization, SMART pumps
- Understand the increased risk of the NORA environment
- Maintain vigilance

Patient Safety Resources

- COVID Perioperative Resource Center
- Anesthesia Patient Safety Podcast
- APSF Video Library
- News & Updates
- In the Literature
- Look-Alike Drug Vials
- Innovative Reports and Ideas
- Drug-Drug Interactions (DDI)
- Emergency Manuals Implementation Collaborative

LOOK-ALIKE DRUG VIALS: LATEST STORIES & GALLERY

The following alerts and photos show how look-alike drug vials and packaging can contribute to medication errors and impact patient safety.

QUICKLINKS:

- Latest Alerts
- Look-Alike Drug Vials Gallery
- APSF Articles and Media
- Submit a Look-Alike Drug Alert

Latest Alerts

Phenylephrine Hydrochloride Injection, Neostigmine Methylsulfate Injection

June 3, 2022

Concentrated phenylephrine and neostigmine vials and color schemes nearly identical.

Submitted by
Christopher Seiter, DO
Stony Brook Medicine

Phenylephrine Hydrochloride Injection, Neostigmine Methylsulfate Injection

https://www.apsf.org/look-alike-drugs/#gallery

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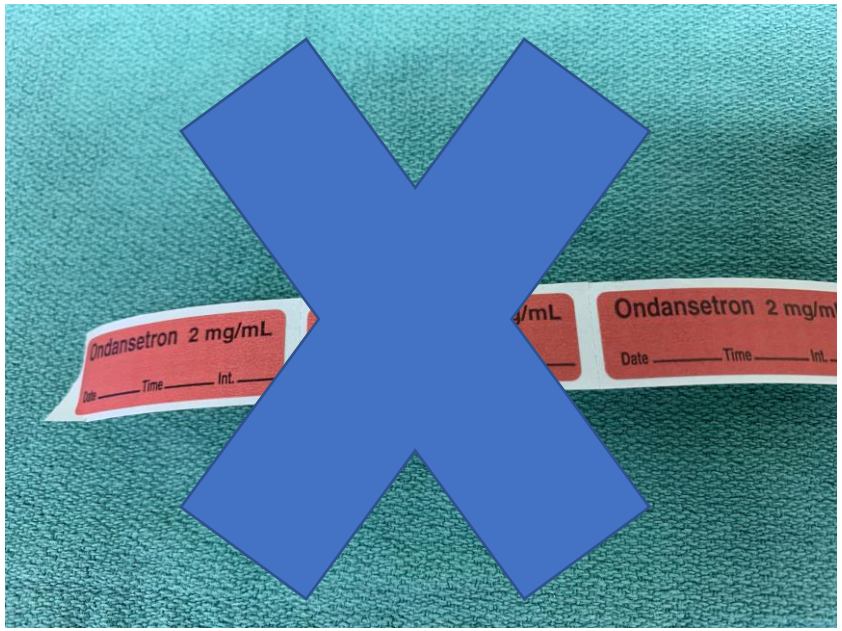
Medication Safety Begins with YOU!



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