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

- RN Vaught administered vecuronium in place of midazolam in a NORA suite resulting in the death of 75 year-old patient Charlene Murphey
  - December 2017

- Vaught convicted of gross neglect of an impaired adult and negligent homicide
  - March 2022

- Vaught sentenced to three years' probation
  - May 2022

https://en.wikipedia.org/wiki/RaDonda_Vaught_homicide_case
Criminalization of Medical Error

“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://en.wikipedia.org/wiki/RaDonda_Vaught_homicide_case
Medication Safety and NORA

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

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

NORA Medication-related Claims: 6%
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

Phases of Medication Process

SENSAR: 1970 MRE/7072 (28%) incidents

Administration phase most frequent (42%) and highest harm
## Anesthesia Safety Tools

<table>
<thead>
<tr>
<th>Left (Medication) Side</th>
<th>Right (Machine) Side</th>
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<tbody>
<tr>
<td><strong>No</strong> Dose Checking</td>
<td>Color-Coded Gases / Lines</td>
</tr>
<tr>
<td><strong>No</strong> Alarms</td>
<td>Diameter and Pin-Index Safety Systems</td>
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<tr>
<td><strong>No</strong> Way to Detect Errors</td>
<td>Oxygen-Nitrous Coupler</td>
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<tr>
<td><strong>No</strong> “Exhaled” Propofol Monitor</td>
<td>Gas Monitors and Alarms</td>
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<td></td>
<td>Pressure and Flow Sensors and Alarms</td>
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<td></td>
<td>Keyed and Colored Vaporizer Fillers</td>
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<td>Patient Monitors: SpO₂, ETCO₂</td>
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<tr>
<td></td>
<td>Flow Meter Assembly Order</td>
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<tr>
<td></td>
<td>Oxygen Pressure Failure Device</td>
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<tr>
<td></td>
<td>Vaporizer Transport Setting</td>
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<tr>
<td></td>
<td>Machine Check</td>
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Feedback vs. Constraints

<table>
<thead>
<tr>
<th>Feedback</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color-coded syringes*</td>
<td>Smart pump guardrails</td>
</tr>
<tr>
<td>Barcode scanners</td>
<td>Standard pharmacy concentrations</td>
</tr>
<tr>
<td>Labels</td>
<td>Prefilled syringes</td>
</tr>
<tr>
<td>Two-provider checks / Checklists</td>
<td>Standard layouts</td>
</tr>
<tr>
<td>Alarms</td>
<td>(Machine examples...)</td>
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</tbody>
</table>

- Feedback requires compliance and engagement
Constraints

Eliminate steps / options

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

Without impacting workflow / decision-making
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

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

(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 Numerator:1[12]), 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/0.25 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
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
REMEDEI 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


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
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-Alone Drug Vials Gallery
- APSF Articles and Media
- Submit a Look-Alone 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 Seiler, DO
Stony Brook Medicine

https://www.apsf.org/look-alike-drugs/#gallery
Medication Safety Begins with YOU!

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