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 for Safe Medication Practices (ISMP).

Label content: *Syringes:* The drug's generic name and concentration (in units per mL) should be the most prominent items displayed on the label of each syringe. The date and time of preparation, and the preparer's initials or name, should also be included. The patient's name and route of administration may also be printed on the label. *Infusions:* For infusion bags containing pharmaceuticals for use in the practice of anesthesiology, the total volume of the bag and the generic name and amount of each added pharmaceutical should be the most prominently displayed information. The final concentration of each pharmaceutical in units per mL should also be displayed, as well as the date and time of preparation, the preparer's name or initials, and the patient's name. *Vials and ampules:* Medication containers intended for use in the practice of anesthesiology should display the generic name and concentration (as the total amount of medication in the container divided by the total volume) most prominently. Preferably, the concentration in units per mL is also displayed. Syringes and containers of medications intended only for regional anesthesia shall be clearly marked as such.

Font and print characteristics: The text on the label should be designed to enhance the legibility of the drug name and concentration as recommended in ASTM D4267, *Standard Specification for Labels for Small-Volume* (100 ml or less) *Parenteral Drug Containers*, ASTM D6398, *Standard Practice to Enhance Identification of Drug Names on Labels*, ASTM D4774, *Standard Specification for User Applied Drug Labels in Anesthesiology, ASTM D4775*, *Standard specification for identification and configuration of prefilled syringes and delivery systems for drugs (excluding pharmacy bulk packages)*, and ISO 26825:2008, *Anaesthetic and respiratory equipment – User-applied labels for syringes containing drugs used during anaesthesia – Colour, design and performance.* These standards include recommendations for font size, extra space for separation around the drug name to improve readability, and the use of additional emphasis for the initial syllable, or a distinctive syllable, for drugs with similar names.

Text/Background contrast: Except as specified under "Reserved colors" below, maximum contrast between the text and background should be provided by the high-contrast color combinations specified in Section 6.3.1 of ASTM D6398-08, as shown in the table below. This reduces the impact of color blindness.

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TEXT	BACKGROUND
Black	White
Blue	Yellow
White	Blue
Blue	White

Reserved colors: Nine classes of drugs commonly used in the practice of anesthesiology have standard background/text colors established for user-applied syringe labels by ASTM D4774-11, *Standard Specifications for User Applied Drug Labels in Anesthesiology* and ISO 26825:2008, *Anaesthetic and respiratory equipment – User-applied labels for syringes containing drugs used during anaesthesia – Colour, design and performance* (which specifies only eight; beta-blockers are not included): (1) Induction agents; (2) Benzodiazepines and their antagonists; (3) Neuromuscular blockers and their antagonists; (4) Opioids and their antagonists; (5) Anti-emetics; (6) Vasopressors and hypotensive agents; (7) Local anesthetics; (8) Anti-cholinergic agents; and (9) Beta-blockers (see table, below). Text is black on the specified background color for most agonist agents, and is black on the white-striped specified background color for most antagonist agents. For two special medications, succinylcholine and epinephrine, text is the specified color on a black background bar at the top of the label.

	PMS [a]	ASTM [b] - RGB		ISO [c] - RGB
Induction Agents	Process Yellow C	255.255.0		255.255.0
Benzodiazepines and Tranquilizers	Orange 151	255.102.0		255.102.0
Benzodiazepine Antagonists	Orange 151 / White Diagonal Stripes	255.102.0		255.102.0
Muscle Relaxants	Florescent Red 805 [d]	255.114.118		
	Florescent Red 811 [e]			253.121.86
	Warm Red [f]			245.64.41
Muscle Relaxant Antagonists	Florescent Red / White Diagonal Stripes	255.114.118		253.121.86
Opioid/Narcotics	Blue 297	133.199.227		133.199.227
Opioid/Narcotic Antagonists	Blue 297 / White Diagonal Stripes	133.199.227		133.199.227
Major Tranquilizers and Anti-Emetics	Salmon 156	237.194.130		237.194.130
Vasopressors	Violet 256	222.191.217		222.191.217
Hypotensive Agents	Violet 256/White Diagonal Stripes	222.191.217		222.191.217
Local Anesthetics	Gray 401	194.184.171		194.184.171
Anticholinergic Agents	Green 367	163.217.99		163.217.99
Beta Blockers	Copper 876U	176.135.112		NA [g]
	White	255.255.255		255.255.255

a - Pantone Matching System
b - ASTM International; prior to 2001 it was the American Society for Testing and Materials
c - International Organization for Standardization
d - Designated by ASTM International
e - Designated by ISO
f - Designated by ISO as an alternative if Florescent Red cannot be printed
g - ISO has not designated a color for Beta Blockers

IMPORTANT: The colors represented in this electronic file are not intended to be used for color matching.

NOTE: RGB (Red, Green, Blue) is used only for digital (computer-based) designs. Any design created with an RGB color profile must be converted to CMYK (Cyan, Magenta, Yellow, blacK) or PMS color codes before printing. As a rule of thumb, RGB should only be used when designing for computer-based applications.

Label material: the material used for the label shall allow the user to write information on it using a ball-point pen or felt-tip marker without smudging or blurring as specified in Section 2.3 of ISO 26825:2008.

Rationale: Labeling of medications is an essential step in decreasing the risk of medication errors,[1-3] and influences selection of the correct medication, determining and then administering the correct dose, and ensuring that the medication chosen has not passed its expiration time or date. This is especially true for the practice of anesthesiology, which involves administration of a wide variety of potent medications. Medications with widely differing actions, for example, sedative/hypnotics, opiates, neuromuscular blockers, vasopressors, and vasodilators, are often used in the course of a single anesthetic, at times simultaneously. These medications are often given in high-acuity situations, in environments with high workload, poor visibility, and multiple distractions. It is recognized that perioperative medication errors are a significant source of morbidity and, rarely, mortality.[4-7] Concern about medication errors extends to regulatory agencies, the federal government, and the general public.

This document is intended to provide information to several different populations, for multiple purposes. Each has its own needs and requirements with regard to labeling. This statement can help clinicians to understand the importance of labeling, especially syringe labeling, as well as provide guidance on best practices for labeling. Furthermore, it can help to guide decisions about selection and purchase of labeling products. It can provide guidance to medication manufacturers, who usually print their own labels for medication containers, and suggest ways to better support clinicians who use their products. Producers of pre-printed labels, including those who make pre-filled syringes, or manufacturers of label printers intended for use at the point of care, can utilize the information in this statement to better align their products with recommended practices.

Labels may be applied in various circumstances. They are most commonly applied to syringes drawn up by anesthesia providers at the point of care. They may also be prepared and labeled in an on-site pharmacy. Additionally, it is increasingly common for pre-filled and pre-labeled syringes to be supplied by manufacturers. Infusion bags are labeled by the manufacturer, and additional labels are applied by the on-site pharmacy or by the provider at the point of care, when medications are added. Medication containers are labeled by drug manufacturers. Different standards apply for each of these situations, and they are currently not unified.

Medications are often identified and selected based upon their location as well as visual features of the container/syringe. The recognition and identification of such an object depends on shape, color, brightness, and contrast; as these elements become increasingly distinctive, identification of the object becomes faster and more accurate.[8-11] Identification of a medication is verified by reading the label. Therefore, although multiple factors contribute to medication errors, consistency and clarity of pharmaceutical and syringe labeling, in accordance with human factors principles, remain important elements of error prevention.

Additional Considerations:

Label enhancements: Bar coding on labels, required by the FDA for medication containers since 2004[12], can be utilized in several ways. The bar code contains the drug's National Drug Code (NDC) number, which is associated with the generic name and strength, at a location on the label which will not interfere with the label's legibility, as specified in Section 8 of ASTM D6398.[13] When medications are bar coded, there is an opportunity for reduction of a number of medical errors.

Electronic label printers can read the medication name and concentration from a medication vial and quickly print a syringe label that is more legible and complete (e.g., patient name, expiration time or date) than one written by hand. The electronic label printer can potentially verbally confirm the medication (adding a second-check that is often missing from anesthesia practice)[14]. Additionally, a bar code scanner or label printer might populate the electronic record, or apply a machine-readable element to the syringe label that can be scanned into the electronic record as the medication is administered, thereby decreasing workload and potentially reducing the risk of a medication error.[15]

Lettering: In 2001, the FDA Office of Generic Drugs requested manufacturers of sixteen look-alike name pairs to voluntarily revise the appearance of their established names in order to minimize medication errors resulting from look-alike confusion. Letters from the FDA encouraged manufacturers to revise labels and labeling, using TALL MAN lettering (TML) to visually differentiate their established names. Since then, the FDA and ISMP have expanded the list to include other easily confused generic and brand names. TML can be used along with color or bolding to draw attention to the dissimilarities. The following table, showing TML drug names of easily confused medication names that may be administered by the anesthesia care team during a procedure, is taken from lists compiled by the FDA and ISMP.[16,17]

ce**FAZ**olin	dexame**THASONE**	**DOBUT**amine	Huma**LOG***
cefo**TE**tan	dexmede**TOM**idine	**DOP**amine	Humu**LIN***
cef**OX**itin	diphenhydr**AMINE**	e**PHED**rine	hydr**ALAZINE**
cef**TAZ**idime	diaze**PAM**	**EPINEPH**rine	**HYDRO**morphone
cef**TRIAX**one	dil**TIAZ**em	fenta**NYL**	hydr**OXY**zine
chlorpro**MAZINE**	**LOR**azepam	**SUF**entanil	Solu-**CORTEF***
clo**NID**ine	ni**CAR**dipine	**PENT**obarbital	**SOLU**-Medrol*
qui**NID**ine	ni**FED**ipine	**PHEN**obarbital	

* Brand names, which always start with a capital letter

Regulatory requirements: National Patient Safety Goal (NPSG) 03.04.01, to improve the safety of using medications, was first introduced by The Joint Commission (TJC) in 2007.[18] It defines TJC Elements of Performance (EP) for labeling of medications and solutions in the perioperative setting, both on and off of the sterile field. Several requirements for compliance with this NPSG are relevant to this Statement. First, all medications and solutions that are not immediately administered must be labeled. A medication that is immediately administered is defined as one that is prepared or obtained, taken directly to a patient, and administered to that patient, without any break in the process. Second, each medication must be labeled as soon as it is prepared, which is when it is taken from its original packaging and transferred to another container. Third, the label must include the following information: medication or solution name, strength, amount of the medication or the solution containing the medication (if not apparent from the container), diluent name and volume (if not apparent from the container), and either expiration time (when expiration occurs in less than 24 hours) or date (when not used within 24 hours). However, the date and time are not necessary for short procedures, as defined by the organization. It can be inferred from the EP describing when a label is to be applied that syringes should be labeled and filled (in that order) one at a time. Finally, any medication or solution found unlabeled should be discarded.

Placement of syringe labels: While unlabeled syringes are known to be problematic, labels placed on syringes can also promote error. Consistent labeling practices, including how the label is applied to the syringe, may reduce medication errors. If the label is applied in such a way as to

not be visible at the time the medication is administered, or if the label covers the gradations on the syringe, a "syringe swap" (medication error where the wrong medication is administered) may occur or an incorrect dose may be given. Labels should therefore be placed in a way that avoids obstructing the view of gradations on the syringe barrel and its contents (e.g., a label at the top of the syringe barrel should not obscure the full extent of the solution in the syringe). It has been recommended that the label should be applied directly below the gradation lines so that the scale, name, strength, and dose of the drug are visible during administration.[19]

Readability and color recognition: ASTM[20] and ISO[21] standards specify color-coding for syringe labels. However, the use of color-coding for anesthesia syringe labels remains controversial.[22-24] The impact of color blindness may affect a clinician's ability to distinguish between different-colored labels. The use of laser goggles may also affect the ability to accurately discern syringe label colors.[25,26] Readability may also be affected by low light conditions. Further research into the effectiveness of color coding, especially given the advent of newer technologies that hold promise to reduce medication errors, seems warranted.[24] Given these considerations, it remains important for clinicians to use all available methods to ensure medication errors do not occur, including reading labels.

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Useful Websites:

For referenced ASTM International standards, visit the ASTM Website Reading Room at:
http://www.astm.org/READINGLIBRARY/ (Accessed December 29, 2019)
or, send an email to ASTM customer service at: service@astm.org

For referenced ISO standards, visit the ISO (International Organization for Standardization) Website at: http://www.iso.org/iso/home.html (Accessed December 29, 2019)

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http://www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm164587.htm
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