



Syringe Labeling Best Practices

INTRODUCTION

Labels printed for application to Compounded Sterile Products (CSPs) are intended to perform the following primary objectives:

- Permit a pharmacy technician or pharmacist to prepare the correct dose
- Permit the pharmacy to route the dose to the correct patient care location
- Permit the pharmacy to communicate administration instructions to the primary caregiver
- Permit the caregiver (usually a nurse) to ascertain that they do (or do not) have the correct dose of the correct drug intended for the correct patient
- Permit the caregiver to ascertain that the dose has not exceeded its beyond-use date

Pharmacy automation may dictate constraints on labeling capability. For example, the IntelliFill® i.v. automates the preparation of syringe-based CSPs, based on information in its formulary. The label applied to a syringe produced by IntelliFill i.v., therefore, needs to address only the last four objectives listed above.

Nurses work from a Medication Administration Record that also contains administration instructions. So the primary role for a label on a syringe is to permit the caregiver to verify that they have selected, and are using, the correct dose of the correct drug for the correct patient, and that they are administering it by the correct route.

For doses that are patient-specific, the key information on the IV syringe label includes:

- Two or more patient identifiers (including the name)
- The patient location
- The drug name as a generic name
- The dose
- The volume in which the dose is contained
- The beyond-use date of the dose
- Administration instructions

In specific jurisdictions, other information may be mandated by law.

Some customers may find benefit in including administration time on the label. Typically, however, syringes are prepared in a batch at one time and there is no practical advantage to preferring one particular syringe over another for use at any administration time. Nursing practice is generally driven by a Medication Administration Record and not by information on the label. Therefore, placing the administration time on the label may provide the nurse with another opportunity to make a mistake (using the syringe for the wrong time).

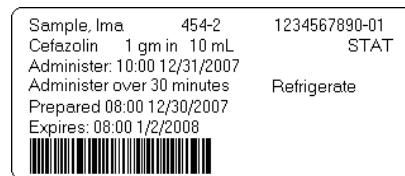
Given the relatively small label space within which most pharmacy automation must work, the way caregivers read labeling and caregiver work habits, it is important that labels produced on IV syringes be formatted to maximize the probability that key information can be readily and easily discerned.

PHARMACY AUTOMATION EXAMPLE: INTELLIFILL i.v. LABELS

Pharmacy automation can present a challenge for labeling in terms of complexity and clarity of communication. One example is the Baxa IntelliFill i.v. system for automated filling of sterile syringes. Syringes prepared by IntelliFill i.v. are banded together in a bandolier style, like machine-gun bullets. Its labels are applied to the transparent band between the syringes. The labels produced on IntelliFill i.v. syringes are 1.8125" x 0.875." This size is dictated by the length and width of the band between the syringes.

As a result, the information that can be contained on the label is limited and, as more information is placed on the label, each data point must be rendered in a smaller font. As the font gets smaller and the label more crowded, it becomes harder to read and the opportunity to provide clear visual distinction between drug names and other key data is reduced.

With the average age of caregivers increasing, it is critical that key information be printed in fonts large enough to be read easily.



Further, people read more effectively when the label contains large amounts of unformatted space (i.e., “white space”). The denser the printed information, the harder it is for someone to read and digest the information.

The result of this constraint is that label design for the IntelliFill i.v. must favor providing minimal key information rather than attempting to crowd large amounts of information onto the label. Other pharmacy automation equipment faces similar challenges.

THE WAY PEOPLE READ

THE EFFECT OF CULTURE

People in different cultures read differently. Western European cultures read left-to-right and top-to-bottom, while other cultures may read bottom-to-top or right-to-left. The following discussion presumes that labels are intended for use in a Western European culture.

READING INTENT

People read differently depending on their intent. When people read for pleasure, or for study, their primary goal is to read. Therefore, they organize their environment to be conducive to reading and focus on the task of reading. The material they read is probably in prose and they will consciously avoid concentrating on tables, graphs and other presentations that interrupt the flow of their reading.

When people read for reference, their primary goal is to obtain information they need to complete the performance of a task. The completion of their task is their primary goal. The purpose of their reading is to seek out and acquire specific items of information. Their reading tends to be cursory until they encounter the instructions or words of interest. Their eyes seek out key words and phrases that indicate the presence of the desired information. These readers prefer information that is highly structured, tabular or graphic, so they can easily scan it for the information needed to complete their task.

People reading labels are reading for reference. They are already in the role of performing a different task (administering medication), often under significant time constraints, so their reading habits focus on key information to ensure they are performing the task correctly.

Specifically, they are asking the following questions in sequence:

1. Is this the drug I intend to give?
2. Is this the dose I intend to give?
3. Is this intended for the correct patient (if patient-specific)?
4. Is this dose usable (has it expired)?
5. Is there anything about giving this dose that is important for me to know that I don't already know?

Referential readers develop reading habits around their reference information. This is a primary reason they prefer graphs and charts. They have developed habits around these known data organization schemes and those habits permit them to quickly locate the information they require.

In the case of labels, this means caregivers read labels more quickly and accurately if they can depend on the data organization to be similar in all cases. To the extent key information is always located in the same place, they can develop reading habits that permit them to rapidly identify key pieces of information. These habits form around gross visual presentation, as well as printed words.

Therefore, good label design presents information in a consistent fashion so a caregiver can readily locate the information they need more or less in the order in which they normally seek it. Labels that use widely variable presentation slow the reading down and increase the likelihood that the user will misread the label.

One of the habits that caregivers can adopt related to reading labels is to ignore information that is rarely valuable. This is especially true of warnings. To the extent that warnings convey information already well-known or failing to be relevant to the task at hand (medication administration), caregivers will tend to develop the habit of ignoring the warning text. As a result, warnings that really should demand the caregiver's attention may be ignored.

Therefore, good label design presents warnings and instructions only when they are exceptional so their presence represents a deviation from the routine, slows the reader's perusing of the label and causes them to direct additional attention.

USE OF WHITE SPACE AND BLOCK FORMAT

Labels are generally more readable when the printed material is surrounded by significant amounts of white space. This permits ready isolation of key information.

Use of a block style or presentation further assists in this regard; blocks of related information separated by white space allow the user to develop reading habits that rapidly and reliably locate and identify key information.

To the extent possible, the presentation of those blocks should follow the sequence of questions the user is asking. In the case of a drug label, the eyes should be drawn first to the drug identity, then to the dose, then to the patient information, then to expiration. Use of different fonts and font sizes can enforce this sequence even when the information on the label is not laid out in this sequence.

Good label design organizes key information into related blocks separated by enough white space that the blocks are easy to locate and read. The organization of those blocks should be in order of preference, either by physical location or by use of fonts that draw user attention to information in the order they normally require it. For a drug label, this means the eye should be drawn to the drug, then the dose, then the patient information.

ABILITY TO PERCEIVE DIFFERENCE – LOOK ALIKE/SOUND ALIKE NAMES

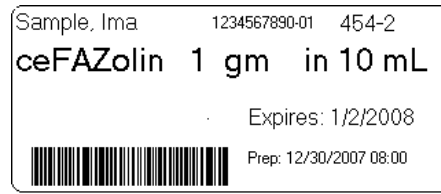
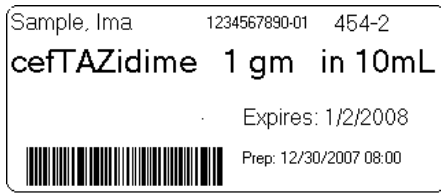
It must also be remembered that human perception is designed more to see similarity than difference, to see the familiar rather than the unusual. Given an incomplete picture, the mind will tend to supply detail to make the picture seem familiar. Given a picture that is nearly familiar but actually different, the mind will tend to interpret the picture as something familiar, even when it is not.

For reading labels, this means the human mind will tend to read an expected drug name or dose rather than the actual drug name or dose if it is sufficiently similar to what was expected. The Food and Drug Administration (FDA), in concert with the Institute for Safe Medication Practices (ISMP) has identified a scheme of “tall-man lettering” to increase the visual distinction between drug names that otherwise look and/or sound too much alike.

Tall-man lettering emphasizes the portion of a drug name that makes it unique from other drug names. Its original implementation was to use letters that were physically larger than the letters in the remainder of the drug name to provide that emphasis. A more practical implementation (as suggested by ISMP) is to print drug names entirely in lower case except for the tall-man lettering, which is printed in upper case.

For example, Epinephrine and Ephedrine are considered to look alike; to make the distinction between them clearer, they would be rendered in tall-man lettering as **EPIne**phrine and **ePHED**rine.

In order for these tall-man combinations to be safe and effective, any given set of tall-man characters can represent one, and only one drug. For example, if Epirubicin were also to be rendered as **EPIrubicin** it is possible, and even likely, that a very serious medication error would result.



It is therefore important that tall-man lettering be limited to officially recognized implementations.

Good label design limits the use of tall-man lettering to universally recognized and approved tall-man names.

COLOR

The use of color as a cue for identification is controversial. When color is supplied as a visual cue, users often become dependent on that color at the expense of reading label content. An error in the application of color can therefore result in medication errors.

The ability of individuals to perceive color is highly variable. For a color to be useful for identification and verification, the user must be able to readily identify it and distinguish it from other colors that may be used, even when that color is presented without comparison to other colors. Thus, if one expects the color blue to represent a specific drug, then it must always be perceived as blue by all users and must never be perceived to be another color that represents another drug.

This severely limits the number of colors that can be used to maintain distinction.

In the drug industry, several vendors use proprietary color schemes in which the application of color is consistent within their product line, but is not consistent across the same range of products produced by another vendor. As a result, switching vendors can result in color confusion.

There are over 5,000 different drug products in the United States; clearly there are not 5,000 different colors that can be readily distinguished when presented alone (that is, not in comparison to another color).

The production of a specific color at a specific hue requires considerable printing precision. The Pantone® color chart is considered to be the standard for ensuring a printed color always appears the same.

Color is poorly perceived when the amount of color on a label is small. Flooding the entire label with color, or producing labels with colored borders, makes the colors easier to discern.

Some colors interfere with barcode scanning; selection of colors for labels that are to contain bar codes (such as those used for bedside verification) must include determination that the bar code can be scanned when printed on a label of that color.

The American Society of Anesthesiologists has adopted an ASTM color standard that applies specific Pantone colors to the labeling of specific classes of drugs. This set of colors has been adopted by all vendors who provide medications for use in the anesthesia suite. The result is that this particular audience associates highly specific colors with classes of drugs rather than individual drugs. So the color provides a clue to the drug type, but still requires the user to read the label to know specifically which drug they are using.

For the Baxa IntelliFill i.v. and RapidFill™ systems, use of different colored labels requires physical changing of the label stock in the device printer. Care needs to be exercised to ensure the correct colored labels are installed in the IntelliFill i.v. or RapidFill printer at the beginning of every run.

Good label design makes minimal use of color. When colors are used, application should be made based on standards that can be applied across vendors to ensure they do not change. Care must be exercised to ensure color is not misapplied to incorrect drugs or drug categories. Color selection must include consideration regarding use of bar codes to ensure that any bar codes can be scanned.

SUMMARY

Best practices for label design incorporate appreciation for the primary use of the label, consideration of how people read labels and design for readability.

Good label design, therefore:

- Emphasizes delivery of small amounts of key information as opposed to large amounts of information that may be difficult to read
- Employs white space and block organization to maximize readability
- Provides consistent layout that permits users to rapidly locate and acquire desired information
- Draws user attention to the most important information in the order in which it is likely to be sought
- Provides warnings sparingly
- Provides cues, such as color and tall-man lettering, according to established standards to maintain consistency

IntelliFill i.v. is manufactured for Baxa Corporation by FHT, Inc.