

Improving Medication Label Readability and Functionality: The Children's Wisconsin Experience

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Medications errors cause 134 million adverse events annually, costing \$42 billion and contributing to 2.6 million deaths.¹ The Institute for Safe Medication Practices (ISMP) attributes 33% of all medication errors and 30% of fatalities from medication errors in the United States to poor medication labeling and packaging.² The ISMP has identified several factors related to medication labeling that contribute to medication errors. Such factors include small and illegible fonts, inconsistent label content and organization, and having multiple labels associated with a single medication.³

The ISMP developed key recommendations to prevent medication errors, reduce misinterpretation, and improve patient adherence. These recommendations include the inclusion of end-users in the design of the medication labeling. In the hospital setting, end-users would include pharmacy technicians, pharmacists, nurses, and other clinical practitioners.² It is recommended that medication labels use a sans serif font (common ones include Arial, Tahoma, and Calibri) and a minimum size of 12 points. All information should be printed in black ink on a white background in order to prevent restrictions for those with color blindness. The amount of white space on the label should also be maximized to increase readability. In organizing information on the label, conceptually related content should be placed together or in the same section. One section might include the provider or prescriber information, such as prescriber name, phone number, and dispense date. That information should be separated from patient-directed information, such as directions for use. Another section might

include the patient-specific information, such as patient name, location/unit, bed number, and identification number, such as the medical identification number (MRN). Another section might include the medication-related information, such as the drug name, strength, dose, route, frequency, and any medication bar codes or identification numbers.

One research manuscript seeking to improve intravenous medication labels for inpatient use identified several components for an ideal or improved inpatient label.⁴ Such items included emphasizing the patient name, drug, dose, and administration route; emphasizing internal information requirements of allergies, weight, drug concentration, and expiration dates; and expanding the use of color coding to differentiate information and drug types. Incorporation of these recommended best practices has the potential to improve medication safety and increase end-user satisfaction.

Objective

The primary objective of this project was to review the facility-generated medication labels at Children's Wisconsin with the goal of changing the label stock and design in order to ensure compliance with legal standards, align with best practices, enhance medication safety, and optimize pharmacy workflow.

Practice Description

Children's Wisconsin is an independent health system based in Milwaukee, Wisconsin, that provides primary care, specialty care, urgent care, emergency care, community health services, foster and adoption services, child and family counseling, child advocacy services, and family resource centers to pediatric patients in Milwaukee and throughout the state

of Wisconsin. Children's Wisconsin's flagship hospital located in Milwaukee is a 297-bed tertiary care teaching hospital with a Level 1 trauma center and a Level 4 neonatal intensive care unit (NICU). The pharmacy department provides centralized distributive services 24 hours a day and has decentralized pharmacists in acute care units, intensive care units, and ambulatory clinics. The Milwaukee hospital provides care to nearly 10,000 patient admissions and dispenses almost 1 million medication doses annually. The pediatric population necessitates a significant number of weight-based, patient-specific doses. The pharmacy department prepares approximately 300,000 patient-specific oral liquid syringes and 225,000 patient-specific injectable syringes annually. Children's Wisconsin uses the Epic electronic health record system, Intermec thermal label printers, and label stock supplied by Nev's Ink.

Assessment of Original Labels and Workflow:

Various medication product types are organized under "dispense codes" in the Epic electronic health record. Each pharmacy record has an Epic pharmacy label routing table that determines where labels print based on the dispense code and the action type (e.g. first dose, cart fill, redispense). Prior to this project, there were more than 50 Epic dispense codes and 8 pharmacy label routing tables used at Children's Wisconsin. Each Epic dispense code had a unique, corresponding label template that would need to be individually edited once a new, standardized label design was approved. Furthermore, each pharmacy label had a unique routing table that would also need to be manually updated to reflect the new label design.

The initial assessment of the medication labels at Children's Wisconsin

FIGURE 1. Concerns with the Original Label Design and Printing

a) Lack of Standardized Location For Information



b) Printing on Perforations



c) Force Re-Print Inversion



revealed significant variability among the medication label templates across Epic dispense codes. First, an assortment of different border colors were used on the label stock to differentiate different dispense codes and product types. The colors included white (no border) for oral solids, blue for oral liquids, orange for injectables, and pink for inhalation. Each border color came as a separate label stock and required a separate printer in the pharmacy. In addition, first doses and batch doses were routed to separate printers in the pharmacy as well. The colored borders on label stock, and differentiation between first dose and batch dose printers, were features the pharmacy staff wanted to keep.

The layout or location of information on the label templates was also highly variable across dispense codes. For example, a tablet label looked very different from an injectable label for a medication dispensed in a syringe (Figure 1a). There was a desire to create a standardized template or layout where important information would be available in the same location across all dispense codes. There were also concerns about the size of the label. For example, the injectable syringe and oral liquid syringe labels, specifically, were very short in height (0.64 inches) in order to allow the label to fit above the flange of the syringe without impeding the markings

on the syringe. The short label height made flagging the medication label on the syringe difficult. Alternatively, some of the pharmacy staff would wrap the medication label around the barrel of the syringe, often causing misalignment of the labels, and ultimately leaving portions of the sticky side of the label exposed. The exposed sticky labels would cause syringes to get stuck to one another or to the bag they were delivered in, creating issues for nurses on the inpatient units. The short label height also resulted in the use of a very small font size in order to fit in all of the required information. Furthermore, the injectable syringe and oral syringe dispense codes would first generate a “header” label, containing the patient-specific information, followed by additional labels containing the medication-specific information for each dose of the medication for that patient. While this system worked well for batches of doses for a given patient, it produced more medication waste for individual doses and first doses. More importantly, the header label created risk for bagging errors, whereby the header label for one patient could be placed in a bag for another patient’s syringes. Ideally, the syringe labels would contain both the patient-specific information and the medication-specific information in order to prevent these bagging errors.

There were also concerns about the effects of label size on printing. From a technology standpoint, the narrow label height often contributed to printer malfunction because the printer struggled to detect the label perforations or tear lines accurately. As a result, important information would often be printed on top of the perforations, making the information very difficult to read (Figure 1b). The printer misalignment would also frequently result in overall printer malfunction, whereby multiple batches would stop printing partway through or would not print at all. This printer malfunction would require a pharmacy staff member to manually force the printer to reprint the entire batch of labels. Reprinting labels is both costly and time intensive. Furthermore, the forced reprint resulted in other unintended safety consequences. When Epic was implemented at Children’s Wisconsin in 2012, the decision was made to request the labels print in an inverse format, which would allow pharmacy staff to read the labels as they scrolled off the printer. Unfortunately, this inverse setting in Epic proved to be a hindrance when batch labels required reprinting. When a batch of labels was reprinting, the inverse formatting was not retained, and the order of the labels, including the header labels, was shuffled. For example, where a header

FIGURE 2. Label Revision Project Objectives

Project Objectives:

- Invert the printing logic in Epic to ensure labels always print in the correct sequential order
- Increased label length
- Use a new, easier-to-read font
- Use a larger font size
- Standardize the location of information on medication labels across all Epic dispense codes
- Eliminate the header label and incorporate the patient-specific information on the label for each medication dose
- Design a new label stock with a perforated midline to guide folding in order to simplify flagging on medication syringes
- Incorporate two identical bar codes, one on each side of the syringe label, to assist with scanning
- Ensure labels for home-going medications, such as bulk products (e.g. inhalers, creams, ointments) contain all necessary items for compliance with state and federal laws
- Convert from using the Contact Serial Number (CSN) to the Medical Record Number (MRN) to help with looking up patients in Epic
- Create a new route of administration “Enteral - See MAR” to be used for PO, NJ, NG, GT, GJ administration routes, which will be indicated in the patient’s MAR
- Create a new label icon “DE,” or Discharge Expected, to indicate that a patient might be leaving the hospital that day in order to prevent preparing unnecessary doses

Abbreviations used in the figure include: contact serial number (CSN), medical record number (MRN), medication administration record (MAR), by mouth (PO), nasogastric (NG), nasoduodenal (ND), and nasojejunal (NJ)

label would customarily print first, followed by the dose labels, the reprint would cause the dose labels to print first followed by the patient-specific header label (Figure 1c). This deviation from standard practice caused confusion for pharmacy staff and ultimately led to errors where the doses prepared would be placed in a bag with a header label for a different patient.

Practice Innovation

Step 1: Exploring Opportunities For Improvement

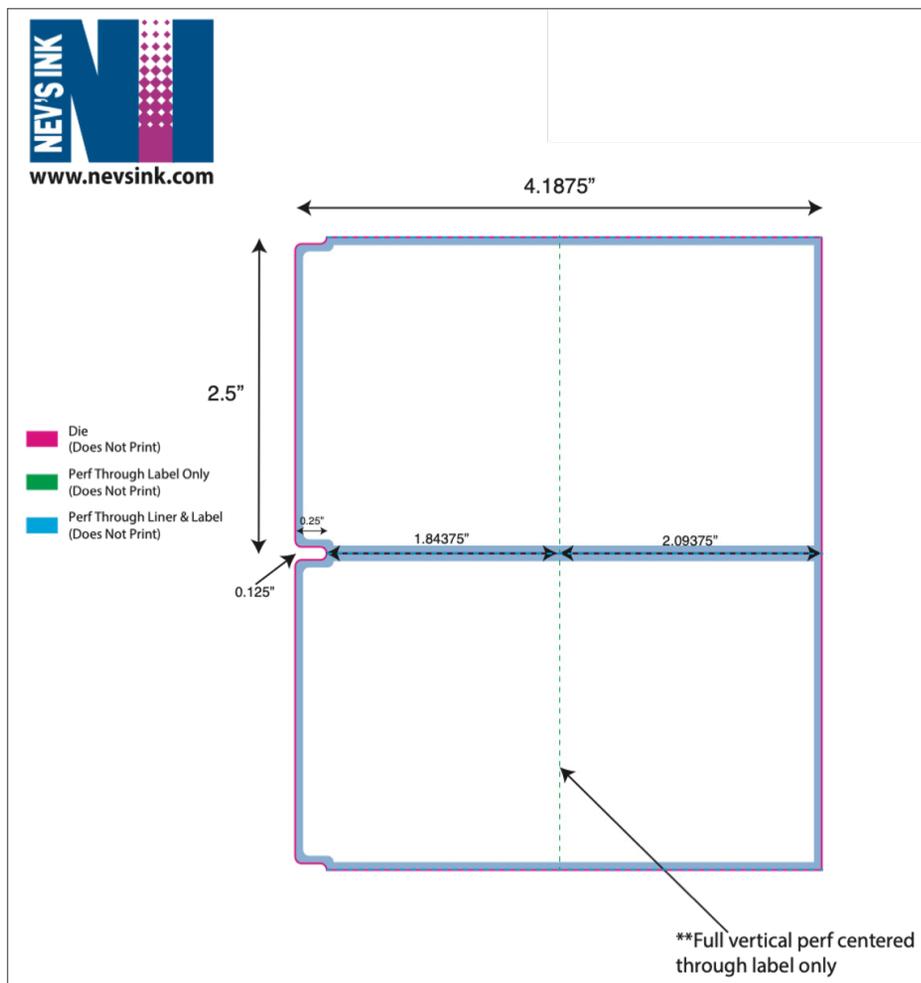
The pharmacy management team reviewed medication label designs from multiple pediatric hospitals across the United States and gathered input from Children’s Wisconsin staff on current labeling issues, readability, and workflow. In November 2018, the pharmacy management team asked pharmacists and technicians to provide feedback on current

labels, including what they liked, what they would change, and what an ideal label would look like. This was achieved through email requests to the entire department, individual conversations with pharmacists and technicians working in the main pharmacy, and an announcement on the pharmacy bulletin board soliciting anonymous comments or ideas. Initial mock label designs were created based on the first round of pharmacy feedback and focus groups. The mock designs were distributed to pharmacy staff a second time via email and were also posted on display in the main inpatient pharmacy. Pharmacy staff were encouraged to provide feedback on the proposed mock label designs either by email or by anonymous comments. The initial mock label designs were also shared with the clinical nurse specialist from each nursing unit in order to request feedback from nurses across the organization.

During the feedback gathering process, two additional label features were proposed that would potentially improve workflow and generate cost savings for the pharmacy department. As a pediatric hospital, Children’s Wisconsin prepares a large number of weight-based, patient-specific enteral liquid doses each day. Enteral liquid syringes are prepared in one large batch during the first shift at 0930. Enteral liquids can be given using several routes of administration, including by mouth (PO), nasogastric (NG), nasoduodenal (ND), and nasojejunal (NJ) delivery. There are many situations where the prescriber would desire to maintain the same enteral medication and dose, but would necessitate changing only the route of administration. For example, when a patient’s NG tube was removed, the patient could then begin taking medications orally by mouth. Each time the prescriber changed the route of administration in Epic, new medication labels would be generated in the pharmacy. The pharmacy would prepare new doses and send them to the nursing unit. Because the enteral liquids are weight-based and patient-specific, the previously prepared doses cannot be returned to stock for future use and would therefore be wasted. The first new feature proposed was the creation of a new route of administration for enteral medications that would print as “Enteral – See MAR” on the label, whereby the more specific route of administration (e.g. PO, NG, NJ) would be displayed on the Medication Administration Record (MAR) in Epic to provide administration instructions for nursing. This change would prevent medications from being wasted and remade, prevent delays in administering medication to patients, and ultimately create operational efficiency for both pharmacy and nursing.

The second new feature proposed was the development of a system for identifying patients likely to discharge from the hospital later that day and flag the medication labels for that patient to prevent preparing patient-specific doses, such as oral syringes and injectable syringes, during the morning batch that would later be wasted if the patient was discharged. The nursing units were already indicating the expected date of discharge for each patient in Epic. Creating a new Epic SmartLink

FIGURE 3. New Label Stock Design with Perforated Center



based on the existing date of discharge in Epic would then print “DE” (Discharge Expected) on the label for patients expected to discharge from the hospital in the next 12 hours. A new pharmacy workflow would need to be created to determine where the new discharge expected labels would be stored, along with when, how, and who would determine whether the patient was discharged or whether the doses ultimately needed to be prepared.

The alternative label designs from other hospitals, staff feedback, and new label feature ideas were compiled and reconciled against best practices, legal requirements, and the technical capabilities of the electronic health record and thermal printers at Children’s Wisconsin in order to create the project scope and objectives (Figure 2).

Step 2: Building & Testing

Willow is the pharmacy module within

the Epic EHR. The information systems department at Children’s Wisconsin employs several individuals, including several pharmacy technicians and pharmacists, who have become specially trained and certified to build and maintain the Willow pharmacy module within Epic. The first step undertaken by the pharmacy management team at Children’s Wisconsin was to submit a project intake form to request resources and support from the Epic Willow team. The information gathered during the initial assessment of the labels, along with the project scope and objectives, were essential to ensuring the project intake request form was accurate and thorough. The project intake request form was submitted on January 17, 2019.

Two Epic Willow analysts were assigned to the project to lead the building, testing, and implementation in Epic. Additional members of the project team included one pharmacist specializing in medication

quality and safety and three pharmacy managers: one to lead the project, one with Epic Willow training, and one with operational oversight of the inpatient pharmacies. Once assembled, the project team drafted a timeline and selected an implementation “go-live” date. The implementation required on-site support from the Children’s Wisconsin Epic team to manually adjust each printer across the organization, along with remote support from the Epic server team to invert the printing order of the labels. The project timeline was developed based on the anticipated go-live date when all necessary groups were available. The project team met once per week over a 10-month period to develop the new Epic medication label design based on the mock designs and project objectives. During the three months preceding go-live, the project team increased their meeting frequency to twice per week in order to maintain the implementation timeline.

One of the key project objectives was to change the label size and incorporate a perforate midline on the label stock, which would allow the label to be easily folded when flagging syringes. The project team decided to incorporate features from the medication label stock used at the University of Iowa Stead Family Children’s Hospital (UI SFCH). The label stock supplied to UI SFCH was also designed and distributed by Nev’s Ink, which also supplies label stock to Children’s Wisconsin. The project team consulted with Nev’s Ink to review the label stock options and the technical specifications of the thermal printers in order to develop the new label stock for Children’s Wisconsin (Figure 3).

The project team incorporated a perforated line, similar to the UI SFCH design. However, rather than using a perforated first inch in the center of the label stock, the project team opted for a fully perforated line down the center of the label for easier folding. The new label stock was increased in height from 0.64 inches to 2.5 inches, which was not to exceed the length of the 0.5 mL enteral syringes barrel used at Children’s Wisconsin. The label stock width was expanded to 4.1875 inches, which was just smaller than the printer’s maximum printable width. The

goal was to optimize the printable area while maintaining printer functionality and preventing printer errors. The project team considered reducing the number of color borders used to identify dispense codes when printing. During the feedback gathering process, nursing expressed consensus that they were not aware of what the colors indicated and, therefore, did not use the colors in any meaningful way. The pharmacy technicians, however, strongly favored maintaining the color borders to assist with their workflow and identifying product storage locations. The current border colors were retained, but the size of the border was reduced to maximize the printable area. The team also considered incorporating a solid black line on the back of the label stock to potentially increase printer alignment. This was determined to be unnecessary, as the increased label height would likely resolve the existing printer issues. The label stock retained the 0.25-inch notch used for printer alignment and to guide peeling the label from the label backing.

After the label stock specifications were finalized, the project team was ready to begin building the new label design in Epic. The resulting Epic label template included three columns. The two outer columns contained the SmartText links for medication information. The center column was only 0.25 inches and was left blank to prevent text from printing over the center perforation where the label would be folded.

The project team chose to build the label for the most difficult dispense code first, which was determined to be the investigational, hazardous, injectable medications, due to their high-risk nature; the presence of two label components (the compounding/production label and the medication label); the additional label fields/features needed; and the large amount of free text space required for instructions and warnings. The project team sought to standardize and reduce label comment length to prevent overflow onto multiple labels. To do this, they removed “hazardous” from the label comments in favor of creating a new banner at the top of the label for all of the hazardous dispense codes. Long label comments across other dispense codes were, and continue to be, an

issue with the new label design. Long label comments currently extend or overflow onto a second label.

The team continued to prioritize label build sequence based on the level of difficulty. Other notably difficult builds included: compounded injectables due to the presence of multiple components; hazardous medications due to the additional banners and warnings required; and bulk products that eventually go home with discharged patients due to the additional legal requirements for outpatient labels. These additional outpatient labeling requirements include the prescriber name, pharmacy address/phone, and quantity of refills, all of which are not otherwise required on inpatient medication labels. Each subsequent dispense code label design was built to mirror the previous label designs to ensure important information and key features were always in the same place across dispense codes. Each of the 50 dispense code labels had to be manually edited and converted to the new standardized design. Each of the 50 dispense code labels required several rounds of testing and reconfiguration to prevent overlapping text, prevent text being cut off during printing, and ensure overall printing alignment. Furthermore, the project team conducted several collective, side-by-side reviews of the label designs, followed by revisions and modifications to ensure consistency and standardization across dispense codes.

Step 3: Timing Trials

One of the primary concerns from technicians regarding the transition to the new perforated label stock was the transition to using the “flagging” method consistently on all medication syringes. The technicians expressed that they were concerned that the flagging method would be slower than the wrapping method they were using previously. One of the Longitudinal Advanced Pharmacy Practice Experience (LAPPE) students at Children’s Wisconsin was asked to develop a timing trial that would compare the amount of time required to label a syringe using the two different label stock designs. This was assigned as her longitudinal project.

The timing trials were performed twice, once with pharmacy students from

the Medical College of Wisconsin School of Pharmacy and once with pharmacy technicians from Children’s Wisconsin. The first timing trial was performed with pharmacy student volunteers because of their lack of previous experience or exposure to either label stock variety. The lack of experience would reduce the potential for bias or timing differences based on experience, which was more likely to occur among the pharmacy technicians who had weeks to years of experience using the original label stock.

Before students arrived for the timing trial, tables were set up with all of the necessary supplies and instructions for the timing trial. Tables were set up using one of four configurations based on the size of the syringe they would be using and which label type they performed first. One side of each table contained a large piece of paper marking the station for Label Type A (the original label stock) in red ink. The opposite side of the table contained a large piece of paper marking the station for Label Type B (the new label stock) in blue ink. Half of the groups used 1 mL syringes and the other half used 3 mL syringes. The appropriate syringes and medication label stocks (A or B) were provided at each of the respective stations on the table.

Two students were paired together and placed at a table. One student was identified as “Student 1” and their partner was identified as “Student 2” for recording purposes on the worksheet. No student identifiers were collected. Students were provided instructions and a brief tutorial on how to label the syringes with each label stock variety prior to the trial. Each student performed two trials with each label stock, for a total of eight trials completed by each table pairing. Each trial consisted of labeling five oral syringes and placing them into a basket. During the trial, one student would label while the other acted as the timer and recorder. Students used their smart phones for timing. The time it took to label each individual syringe was recorded on a color-coded worksheet provided to each pair of students. The same general protocol was used to perform timing trials with pharmacy technicians at Children’s Wisconsin. However, instead of having tables pre-configured with stations, syringes and baskets, the trials were

conducted in the inpatient pharmacy on a clean table. The LAPPE student performed the timing and recording of data for each technician.

Timing data was collected by the LAPPE student and transcribed from the paper worksheets into Microsoft Excel 2016 (Microsoft Corporation, Redmond, Washington, USA) for further analysis. Results from the timing trials demonstrated that the original label stock took longer on average to label compared to the new label stock, at 9.6 seconds and 7.6 seconds per syringe, respectively. Additionally, the average time to label syringes decreased by 0.2 seconds between the first trial and second trial using the new label stock. This improvement indicates that individuals will likely become more efficient with repetition as they gain experience working with the new label stock.

Step 4: Education

Educational documents for the pharmacy staff and the nursing staff were created by the project team in preparation for the new label go-live. The educational documents included photos comparing the old version to the new version (Figures

4-6), summarized the key changes, and provided the contact information for the project manager. The nursing-specific education document was shared with the Nursing Education Committee at Children’s Wisconsin to ensure the content would be easily understood by nurses. The Nursing Education Committee provided recommended edits to simplify the documents and improve readability. The final version of the nursing-specific educational document was distributed via email to the clinical nurse specialist representing each nursing unit for further distribution and discussion during the nursing unit huddle meetings. Members of the project team attended various nursing unit huddles as well to provide clarification and answer any questions regarding the new labels. Similarly, the pharmacy-specific educational document was distributed to all members of the pharmacy department via email and discussed during the monthly pharmacy all staff meeting.

Step 5: Implementation

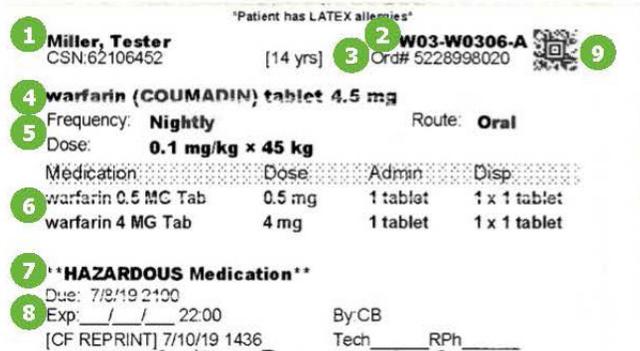
The pharmacy medication label redesign project at Children’s Wisconsin took approximately 16 months from the initial

assessment of labels to implementation. The new label changes were implemented in two phases. Phase I went live on October 16, 2019 and included implementation of the new label stock, the new label template, inversion of the printing direction, and addition of the “Discharge Expected” feature. Phase II went live on February 24, 2020 and included the implementation of the “Enteral – See MAR” feature on the medication label, which required additional nursing education and training, along with changes to pharmacy workflow.

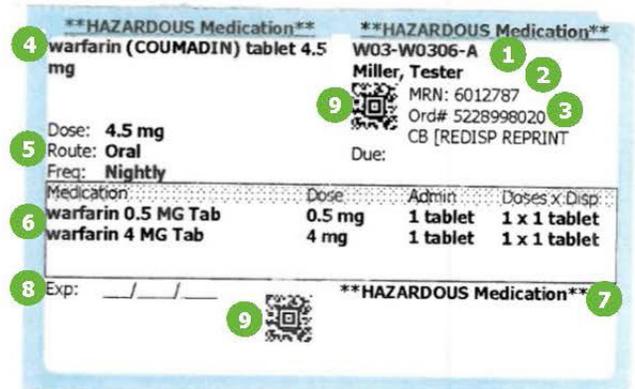
The Phase I implementation was scheduled to take place on October 16, 2019 from 0500 to 0700. The goal for implementation was to have all of the printers converted prior to the start of first shift when the labels for several large batches would be printed. The first step of implementation at 0500 involved the Epic server team inverting the printers. The printer inversion flipped the labels 180 degrees so the labels would print in the direction preferred or recommended by Epic. The second step at 0515 involved the Epic Willow team at Children’s Wisconsin moving the new label designs from the build environment

FIGURE 4. Education Explaining New Standardized Location of Information

a) Oral Solid BEFORE



b) Oral Solid AFTER



KEY

- 1 Patient Name
- 2 Patient Room Number
- 3 Medication Order Number
- 4 Medication Name, Strength, and Dosage Form
- 5 Medication Dose, Frequency, and Route
- 6 Medications and Quantities Needed
- 7 Auxiliary Warning Label
- 8 Expiration Date
- 9 Barcode

FIGURE 5. Oral Solid Medication Labels Before and After Redesign

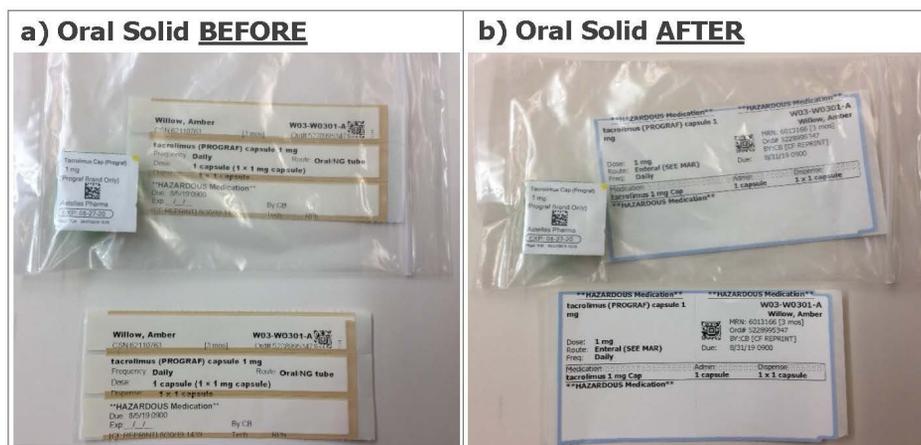
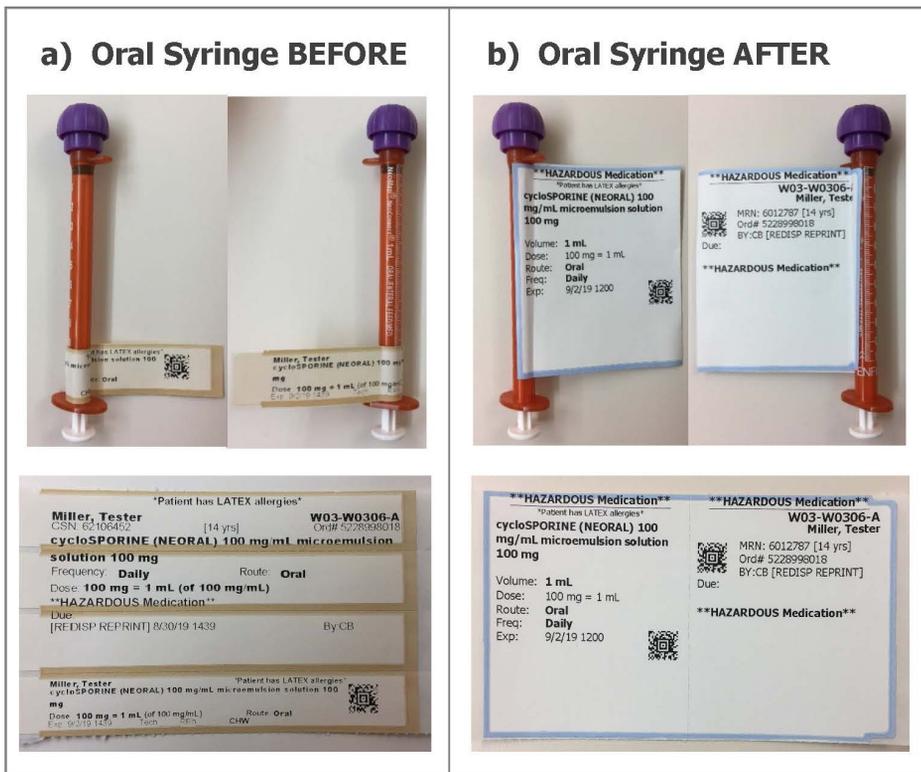


FIGURE 6. Oral Syringe Medication Labels Before and After Redesign



to the production environment in Epic. The third step involved changing out the old label stock with new label stock and manually reconfiguring each printer across the hospital. The central pharmacy printers were the first priority due to the large number of printers and the high volume of doses dispensed from the location. Subsequent printers would be temporarily re-routed to the inpatient pharmacy printers during the reconfiguration. Subsequent printers were the satellite pharmacy locations located

in the operating room, oncology, PICU and NICU. Unfortunately, several printers took significantly longer to reconfigure than anticipated. The implementation ultimately ended once all printers were successfully reconfigured and re-routed at approximately 1100.

Practice Implications

A retrospective analysis was conducted to estimate the potential cost savings from waste avoidance associated with implementing the “Discharge Expected”

feature on the labels. The retrospective analysis included the period of October 16, 2019 through November 17, 2019. During this period of time, 677 doses were set aside, never prepared, and ultimately not wasted when the patients discharged prior to needing the dose. The projected annual cost savings associated with the introduction of the “Discharge Expected” feature on the labels was approximately \$250,000 per year based on the cost of medications at the time of the analysis. The cost savings calculation included the cost of the medications, the cost of the containers or packaging, and the average technician hourly wage. The majority of the cost savings (71%) was attributed to enteral liquids prepared in oral syringes.

An additional retrospective analysis of delivery errors was also conducted for the period of March 26, 2019 through December 26, 2019. The analysis included a manual review of patient charts in Epic and the Children’s Wisconsin error-tracking system. The average delivery error rate prior to implementation of the new labels was 1.6 errors per day compared to 0.89 delivery errors per day following implementation. The average number of delivery errors decreased by 56% during the look back period.

Conclusions

Pharmacists and pharmacy departments have an important role to play in medication safety. While there are many legal requirements that dictate what is included on medication labels, opportunities for innovation and improvement exist. Applying best practices and incorporating innovative ideas have the potential to reduce medication waste, create operational efficiencies, reduce errors, and ultimately improve patient care.

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PR

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IRB: This quality improvement project was reviewed by the Institutional Review Board (IRB) at Children's Wisconsin on 1/27/20. The IRB determined it does NOT constitute research or human subjects research.

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