Pharmacy Labeling Can Cause, Rather Than Prevent, Drug Errors: An Unintended Consequence of Poor Design

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Introduction: Hospital pharmacies rely on printing software for labeling drugs. The software typically interfaces with the electronic medical record to reduce error by automation, producing an adhesive label. Pharmaceuticals that require dilution, doses prescribed to pediatric patients, and drugs administered by syringe pump all run a risk of labeling error because they must be dispensed to the user in containers that are not labeled by the manufacturer. We report a 10-fold drug overdose caused by a design and usage flaw in pharmacy labeling, and discuss the ergonomic issues related to labeling intravenous drug preparations in high intensity and acuity environments like the operating room.

Report of case: A 15-year-old healthy girl with scoliosis underwent thoracic posterior spinal instrumentation and fusion. Anesthesia was induced with sevoflurane and converted to total intravenous anesthesia with propofol and remifentanil infusions after establishing vascular access. Tranexamic acid was administered, first a loading dose of 10mg/kg over 20 minutes, followed by an infusion of 5mg/kg/h. This dose has been shown to maintain therapeutic levels in children, and was administered by a syringe pump (Medfusion 3500, Smiths Medical ASD Inc., St. Paul, MN, USA) from a 60ml syringe that was dispensed from the operating room pharmacy. Although these pumps have "drug libraries" which load preset parameters for each drug, the hospital has not implemented that software; instead the pumps are programmed manually by the user. After completion of the loading dose, the maintenance infusion was begun after confirming that the pump was programmed in accordance with the information on the syringe label, which depicted a concentration of 5mg/ml. Soon after starting surgery the pump alarmed, indicating a near empty syringe, which alerted the anesthesiologist that there was a problem, as the syringe should have lasted the entire case. Upon close inspection, it was noted that the label was ripped and stuck back on the syringe, obscuring the "0" in the drug concentration, which should properly have read "50mg/ml" rather than 5mg/ml. The infusion was stopped, and the patient suffered no consequences of the error.

Discussion: There are many regulations that stipulate how manufacturers must design drug vial labels, however despite numerous studies and advisories about optimal labeling of syringes

and infusions, there is no standardized labeling practice after dilution, reconstitution, or preparation of drugs for administration. Indeed, there is often no communication between the pharmacy and end-user (anesthesiologist or nurse) regarding the formatting or use of drug labels on these products to enhance safety and identification. Labels can emphasize data of little use to the clinician while obscuring the information that is critical for safe administration of the drug. Labels not specifically designed to fit on syringes further obscure these data, and orientation of print and international standardized color codes may be ignored.

Conclusions: Hospital pharmacies and anesthesiologists must work together to utilize drug labels that are designed to enhance readability and instantaneous recognition of clinically important drug information, especially when syringes are mounted in pumps. Labeling of syringes with stickers not optimized for this purpose compound the risk of drug errors. This is of greater importance as anesthesiologists rely on pharmacies to mix and prepare drugs. Standardized concentrations with pre-programmed pump drug libraries, use of barcodes or RFID may also be effective strategies to reduce errors.

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