Special Article

VEINROM: A possible solution for erroneous intravenous drug administration

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Abstract

Erroneous intravenous drug administration has a high probability of causing substantial financial consequences along with patient morbidity or mortality. Anesthesiologists and hospital administrators need to be cognizant of the problem. National and international anesthesiology bodies should be involved with the medical device manufacturing industry to alleviate this long standing enigma. We propose our concept Vassopressors, Emergency drugs, Induction agents, Reversal agents, Opioids and Miscellaneous (VEINROM) as a conceivable solution to this paradox.

Key words: Anesthesiology, innovation, intravenous drug errors, manifold, medical device, syringes

Introduction

Every anesthesiologist worth their salt is guilty of administering a wrong drug at least once in their career. Most of the time the consequences have been harmless (albeit not without feeling of guilt or remorse), but in some cases they have caused an undesired iatrogenic morbidity and/or mortality. The high duress milieu of an operation theatre (OT), intensive care unit (ICU) or emergency room (ER) predisposes flawed actions. Pediatric population in OT, ICU, or ER is at considerable hazard for medication blunders. Once injected into the blood stream, a drug cannot be retrieved, only countered.

Oxford English dictionary defines error as "something incorrectly done through ignorance or inadvertence; a mistake, e.g., in calculation, judgment, speech, writing, action, etc."[1] Kohn described it as "a failure to complete a planned action as intended, or the use of an incorrect plan of action to achieve a given aim."[2] A medication error can be defined as "a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient."[3] "Failure" here implies that the method used was beneath the usual realistic standards being practiced. While "treatment process" includes management of symptoms or their causes or investigation or prevention of disease or physiological changes.

The aviation industry has adopted a definitive safety culture, whereas anesthesia professionals exhibit an attitudinal barrier to safety. Both accidents and incidents in the aviation industry are reviewed and the risks are assessed, providing an opportunity for safety improvement and risk mitigation. Accidents during periods of anesthesia are often not reported due to the fear of being blamed for carelessness, forgetfulness and sometimes character weakness.[13]

The Institute for safe medication practices uses an index for categorizing medication errors written by The National Coordinating Council for Medication Error Reporting and Prevention. The Medication Error Index classifies errors according to the severity of the outcome.[4]

Incidence

For various reasons, all drug errors are not reported.[5] Stelfox *et al.* have reported that medication errors are the seventh most common cause of death in the health care system.[6] The drugs most frequently involved in errors were antibiotics and muscle relaxants.[7]

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A Canadian survey from 687 anesthesiologists (30% response rate) revealed that 85% of the participants had experienced at least one drug error or "near miss."[8] Although most errors (1,038) were of minor consequence (98%), four deaths were reported. The most common incident involved the administration of muscle relaxants instead of a reversal agent. "Syringe swaps" (70.4%) and the misidentification of the label (46.8%) were common contributing factors. 97.9% of anesthesiologists reported that they read the ampoule label "most of the time," although the label color was an important secondary cue. About 84% agreed that improved standards for drug labels would reduce the incidence of error.

In Norway, drug error was recorded in 63 cases (0.11%) in anesthesia-related information from all anesthetic cases for 36 months totaling 55,426 procedures.[9] There were 28 syringe swaps, nine ampoule swaps, 15 instances where muscle relaxants were erroneously given, eight "wrong drug" cases and 18 instances where a wrong dose of the correct drug was administered. Another study done in Australia identified 144 incidents in which the wrong drug was nearly or actually administered to a patient. Of these errors, the most common was actually giving the wrong drug from a correctly labeled syringe.[10] Interestingly, they found that communication failure was a significant factor in syringe incidents when two or more staff was involved.

In a critical care related study by Rothschild *et al.*, 120 adverse events were identified in 79 patients, including 66 (55%) non-preventable and 54 (45%) preventable adverse events. Two twenty three 223 serious errors were also noted during the study.[11] Most serious medical errors occurred during the ordering or execution of treatments, especially in administering medications (61%). Of 5744 observations in 851 patients, Calabrese *et al.* found 187 (3.3%) medication administration errors.[12] Therapeutic classes most commonly associated with those errors were vasoactive drugs 61 (32.6%) and sedative/analgesics 48 (25.7%).

The problem

We believe the key instigator of erroneous drug administration (EDA) is the adaptation of the universal Leur locking mechanism to intravenous drug delivery systems. All syringe ports on the fluid delivery system are able to interlock with any syringe nozzle by nature of the Leur design. This inherently provides the opportunity for an adverse event to occur especially in a situation of high duress.

Our solution

The development of a fluid intake manifold used for multiple intravenous drug delivery featuring specially designed syringe ports, which can only interlock with a predispositioned syringe. Hence we designed VEINROM.

VEINROM

An acronym which stands for Vassopressors, Emergency drugs, Induction agents, Reversal agents, Opioids, and Miscellaneous drugs. These seven categories encompass most of the intravenous drugs that are used frequently in anesthesia. The envisioned fluid delivery system, which we named VEINROM, shall harbor one syringe port for each of the seven drug class categories that are most commonly used drugs in anesthesiology and critical care.

Deterrents to prevent erroneous drug administration (EDA)

VEINROM is a unique drug delivery manifold and syringe assembly which has incorporated mechanical and electronic mechanisms that will make it very difficult to administer wrong drugs intravenously. These defense mechanisms are:

1. VEINROM manifold: The fluid intake manifold shall have seven differently designed syringe ports which feature a lock-and-key interaction between the port and designated syringe. Through the improvised VEINROM lock-and-key mechanism, it is impossible to incorrectly administer one category of drug into any one of the other six ports. Incompatible syringes will not be able to enter the manifold ports, and thus the drug administrator will not be able to inject the drug [Figures 1 and 2].
2. VEINROM syringes: Preloaded syringes will further decrease the potential for human error when administering drugs instead of loading-labeling them perioperatively. The VEINROM syringes shall have following features
   - Specific male ports: Each syringe shall have uniquely designed tips that can only mate with their destined manifold ports [Figure 3].
   - Engraved labels: Acting as a visual reinforcement to the user, each syringe shall display what category it belongs to by being boldly engraved on to the syringe

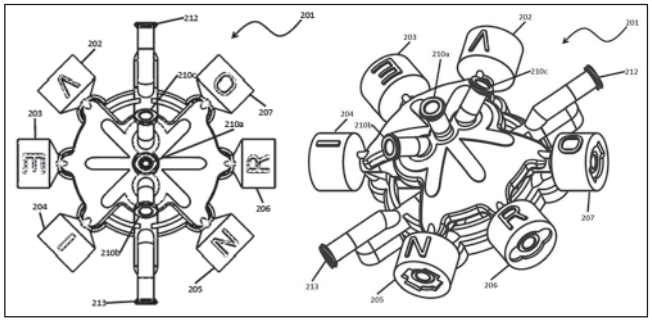

Figure 1: Ariel and lateral view of the dome shaped vassopressors, emergency drugs, induction agents, reversal agents, opioids and miscellaneous manifold. 202-207 are the specific ports with their acronyms displayed on the top. 212-213 is the connection with the intravenous line. 210 a, b, and c are the port for miscellaneous drugs (this will retain their universal port characteristics)

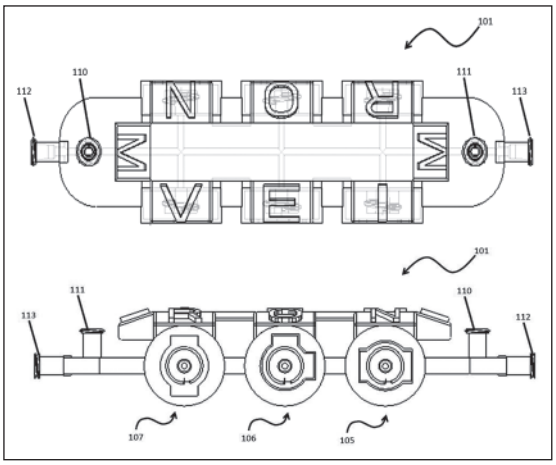

Figure 2: Ariel and side view of the liner Vassopressors, Emergency drugs, Induction agents, Reversal agents, Opioids and Miscellaneous manifold. 105-107 are specific ports that will take in only designated syringes. 110-111 are universal ports for miscellaneous drugs (universal syringes). 111-112 is for connection to the intravenous lines

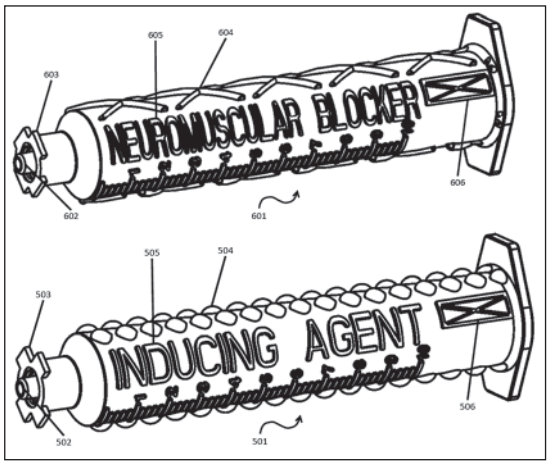

Figure 3: Vassopressors, Emergency drugs, Induction agents, Reversal agents, Opioids and Miscellaneous syringes prototypes with its unique physiognomies. 503, 603 are distinctive locking mechanisms for specified ports on the manifold. 504, 604 are the special texture, 506 and 606 are scan-able bar codes. Each syringe will have American Society for Testing and Materials specified colors

body, obviating the need for colored sticker labeling [Figure 3].

- Color coded: Syringe pistons and bodies for each drug class shall be color coded per American Society for Testing and Materials standards. This feature promotes visual memory and obliterates the need to manually label the syringes.
- Texture coded: Each syringe class shall have a specific external texture embedded within the syringe body, producing tactile stimuli which generates neurogenic memory rendering identification of syringes easier [Figure 3].
- Scan able bar codes: Each syringe shall have a barcode at its distal end that identifies drug class and lot number. Before delivery, the drug administrator swipes the syringe in front of a barcode scanner which in turn enters the drug information and delivery time into patient specific electronic medical records [Figure 3].
- Inherent electronic data collection: VEINROM shall incorporate a medical electrical system designed to identify and register the connection of a syringe to any port, thereby logging the port ID and time of delivery into the patient's medical records. Not only does this improve patient data logging practices, it implements practitioner accountability.

Conclusion

A time for change in the field of anesthesiology is inevitable. As indicated previously, medical errors are prevalent within this field and current safety protocol has not been changed in over 60 years. Not only will the implementation of a device like VEINROM increase practitioner's accountability, update patient records in real time and improve the overall health care system, it will most importantly save lives. It is an obligation for standards committee members and medical device manufacturers to implement safeguards that prevent human error. The Institute of medicine estimates that at least 1.5 million Americans are injured each year as a result of EDA, costing the US healthcare field more than 3.5 billion USD annually. The global health care system is in the process of implementing improved standards and regulations that require syringes to be pre-filled by outside pharmacies rather than medical practitioners during the pre-operation period. To support this claim, Transparency Market Research estimates that the global pre-filled syringe market will grow by a 13.3% compound annual rate, reaching a market value of 4.98 billion USD by the year 2019.[14] These trends point to an estimated 3 billion USD in profit opportunity within the next 7 years.

It is our moral and Hippocratic duty to continue risk management processes that decrease the probability of iatrogenic morbidities. For a device such as VEINROM, the time is right and future, bright. Medical device innovation is continuous and safety measures are continually updated. VEINROM is the next step in making the art of anesthesia safer for all involved.

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