

Are “High-alert Medication” Used Safely in Intensive Care Units?

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Adverse effects occurring due to medical errors are neither uncommon nor new. In 1995 Donchin Yoel, through 24-hour observers appointed in the ICU, found that 1.7 errors occur per patient per day in the ICU.¹ Institute of Medicine deemed medical errors as 7th common cause of death in 1999 resulting in the death of almost 98,000 patients per year. It also suggests that 78% of these medical errors are medication errors.² Critical Care Safety study done in 2005, a one-year observation study in Medical and Coronary ICU, revealed that 20% suffered medical errors, 45% of errors were preventable and 13% were fatal. Most serious medical errors occurred during the ordering or execution of treatments, especially medications (61%; 170/277).³ With the increasing complexity of care in the ICU and with an increasing number of machines and medicines in the ICU these errors are the same in frequency and harm caused by it despite modern methods of quality control.⁴ In a report published in BMJ in 2016 number of deaths due to medical errors has increased from 98,000 (1999, IOM report) to over 4 million in 2013.⁵ This makes medical errors as 3rd leading cause of death in the USA after Heart disease and cancer.⁶

Medication delivery in the ICU is a complex process involving multiple steps (discussion, determination of choice, dose, and route; ordering, dispensing, receiving, sorting, checking, diluting, injecting, regulating, monitoring, and stopping), by multiple people (consultants, registrars, house officers, nurses, pharmacist, assistants, bedside nurses) stationed at different locations in hospital (ICU nursing station, pharmacy, lift, ICU store, bedside). According to Dorman, the likelihood of error-free performance of a process is equal to $(X^n) \times 100$. Where 'X' is the percent likelihood of getting each step correct and 'n' is the number of independent steps.⁷ For example; If a process has a 95% likelihood of each step being correct and has 50 steps then $[(0.95^{50})] = 8$. The likelihood of error-free performance of the whole process is 8%. So the more complex the steps (error prone) and the more the number of steps, the more will be errors and less will be likely hood of completing it error-free. Thus, it is not difficult for one to understand that medication delivery in ICU is a process prone to errors.

Medication use in ICU is the cornerstone of care and many medications used have a low therapeutic window, i.e., the difference between a therapeutic dose and a toxic dose is narrow. The Institute of Safe Medical Practice (ISMP) defines “High-alert Medications” as drugs that bear a heightened risk of causing significant errors, the consequences of which are more devastating to patients.⁸ All of the medications in the ISMP high alert medication drug list; vasoactive agents, concentrated electrolyte solutions, antiarrhythmic medications, sedative and neuromuscular blockers, intrathecal infusions, opioids, insulin and oral hypoglycemic are commonly

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used in ICU patients. Thus errors in medication delivery are not only common but also of a serious nature due to the heavy use of high-alert medications in ICUs.

It is a norm that “you can improve only what you can measure”. To measure these errors in ICU multiple methods are used. Retrospective chart review have serious limitations due to dependency on chart availability and incomplete documentation. Prospective chart review still depends on documentation, the observer’s bias, and study period improvement due to the observer’s presence and knowledge about the ongoing study. Donchin’s study and critical care safety study involved the appointment of independent observers to study the medication errors prospectively for 4 and 12 months respectively.^{1,3} A critical care safety study found that performance level failures (slips and lapses) were more common (53%; 148/277) than rule-based or knowledge-based mistakes. However, study by Zirpe et al. in 6 monthly chart reviews, conclusions were at another extreme.⁹ They found transcription errors in 44%, prescription errors in 40%, and administrative errors in only 14% of cases. The extreme difference in conclusions can be due to the way medications were prescribed (Manual vs computerized), competency of the prescriber (Fellow vs House officer), level of supervision by senior team members, presence and implementation of protocols (e.g., drug dilutions and infusions for high-risk infusions). The method of study also matters. If one looks at the chart review, then one misses the more complex error-prone stages of drug delivery like dilution, loading infusions, dialing infusions, monitoring infusion alarms, infusion titrations to effects, monitoring compliance (aPTT for Heparin, MAP for Noradrenaline). If one appoints an observer to look at the whole process from ordering to delivery, more realistic conclusions can be arrived at. The observer-based study has the added advantage of creating awareness among staff, but is more cumbersome to do and prone to creating a litigious environment during the study period. The

qualification and competency of the observer will matter as well. Intensivists, anesthesiologists, or physicians will spot not only errors of commission but also errors of omissions and monitoring. The pharmacist as an observer will spot dilution, dose adjustment to renal function, compatibility, interactions, piggyback admixture, rate of infusion as well as post-dilution storage aspects.

In this issue of the journal, Aradhya et al., have published a six-month prospective study of errors in alert medication use in a 100-bed acute care setting (ICU) of a large Tertiary Care Hospital in India.^{10,11} Clinical pharmacists used predesigned forms to collect predefined errors. The observation included chart review, direct inspection of the injection process as well as interview of the healthcare providers. The inclusion of only 165 patients (on high-alert medications) in 100-bedded units over 6 months points to a high exclusion rate (DAMA and <24 hours, <18 years age) and possible selection bias. Out of 204 errors found, prescribing errors (45.1%) were the most common, followed by documentation errors (33.82%) and administration errors (21.08%). In both the Indian studies, one by Zirpe et al. and by Aradhya et al. found prescription errors more common than administrative errors. NCCMERP risk category B was most common in both and surprisingly none were fatal (category I). This is in sharp contrast to Western studies like one by Rothschild et al., where administrative errors account for over half of the errors (53%) and 13% were fatal. This extreme discrepancy in conclusions calls for a close look at the gaps in methodology before we compare and discuss its preventive aspects.

While all the efforts at the study of errors are welcome, variations in the method of patient selection (and exclusions), method of error detection (chart vs direct or both), multidisciplinary team (clinician and pharmacist) as an observer, inclusion of errors of omission as well as commission; and study design (prospective vs retrospective) makes it impossible to draw comparisons between studies. This calls for a standardized format for studies on medication errors. Doing the study itself increase awareness about these errors in the unit but a follow-up round of interview with healthcare workers and education sessions on ways and means of improvement (preventive solutions) will be highly beneficial to the system.

To develop a standardized format for such studies, we need collective multidisciplinary efforts of different specialties (intensive care, anesthesiology, nursing, pharmacy, and hospital administrators) coming under one roof for patient safety. Use of high-alert medications are not safe in the current era and we need more data from standardized studies in future to refine our protocols for its safe use in future.

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