

Features of Infusion Device Related Incidents Revealed by Systematic Analysis of an Incident Reporting Database

Mark E. Nunnally, M.D.; Valerie L. Brunetti, B.A.; John Gosbee, M.D.; John J. Crowley, Ph.D.; Richard I. Cook, M.D. Cognitive Technologies Laboratory, Department of Anesthesia and Critical Care, University of Chicago, Chicago, Illinois

Introduction : Microprocessor-based infusion pumps are ubiquitous in medical practice and errors during operation of these devices are common. Incidents involving these devices have been described in the literature 1. The FDA's MAUDE database (www.fda.gov/cdrh/maude.html) collects and analyzes reports of events involving the use of specific medical devices throughout the United States. As part of a research program on human error during operation of infusion devices, we examined MAUDE database reports for specific devices whose menu structure we studied previously to identify incident precursors and discover event evolution. Viable programming sequences consistent with the incident reports were identified.

Methods : Infusion device "A" and infusion device "B" infusion pumps were analyzed and finite state diagrams of their programming and operations developed. Incident reports involving these devices were extracted from the MAUDE database. Analysis of the factors involved examined the pathways used, alternative pathways available, and the impact of errant key presses at different stages of programming.

Data : The database contained 61 incidents involving device "A" and 36 involving device "B". Of these, mechanical problems were found in 7 (11.4%) and 1 (2.8%), respectively. Thirty-three (54.1%) of the "A" cases and 17 (47.2%) of the "B" cases described over infusion, and 11 (18.0%) and 1 (2.7 %), respectively, described the rapid administration of an entire bag or syringe of drug. Reports contained minimal data about the programming of the device; none of the "A" or "B" reports described the mode used for infusion. Recreation of a unique programming sequence based on the incident reports was not possible, although candidate sequences could be identified and critical fault locations are suggested.

Discussion : Incidents involving infusion devices fit the established model of complex system failures. A primary goal of

incident reporting systems is to permit analysis of etiologies of failure. The MAUDE database captures the occurrence of many events, but device complexity severely constrains inferences about the precise nature of failures related to programming and operation. Of particular note was the large proportion of over infusion incidents involving the administration of entire syringes or bags of drug.

The complexity of device programming and operation presents a significant barrier to the use of incident databases as a means for determining the causes of device malfunction. In the context of reporting systems, these limitations mean that deep insight into the sources of failures involving infusion devices cannot be obtained from incident databases alone.

1. Cook RI, et al. Unintentional delivery of vasoactive drugs with an electromechanical infusion device. *J Cardiothorac Vasc Anesth.* 6:238-44, 1992

This project was supported by grant number R18 HS11816 from the Agency for Healthcare Research and Quality.

Anesthesiology 2002; 96: A1073