
This study aimed to establish a hazard classification framework of medical devices and to apply it over practical adverse event data on infusion pumps" Gao et al (2019).

Abstract:

BACKGROUND: The adverse event report of medical devices is one of the postmarket surveillance tools used by regulators to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. However, with the development of the related technologies and market, the number of adverse events has also been on the rise, which in turn results in the need to develop efficient tools that help to analyze adverse events monitoring data and to identify risk signals.

OBJECTIVE: This study aimed to establish a hazard classification framework of medical devices and to apply it over practical adverse event data on infusion pumps. Subsequently, it aimed to analyze the risks of infusion pumps and to provide a reference for the risk management of this type of device.

METHODS: The authors define a general hierarchical classification of medical device hazards. This classification is combined with the Trace Intersecting Theory to form a human-machine-environment interaction model. Such a model was applied to the dataset of 2001 to 2017 class I infusion pump recalls extracted from the Food and Drug Administration (FDA) website. This dataset does not include cases involving illegal factors.

RESULTS: The proposed model was used for conducting hazard analysis on 70 cases of class I infusion pump recalls by the FDA. According to the analytical results, an important source of product technical risk was that the infusion pumps did not infuse accurate dosage (ie, over- or underdelivery of fluid). In addition, energy hazard and product component failure were identified as the major hazard form associated with infusion pump use and as the main direct cause for adverse events in the studied cases, respectively.

CONCLUSIONS: The proposed human-machine-environment interaction model, when applied to adverse event data, can help to identify the hazard forms and direct causes of adverse events associated with medical device use.

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Reference:
Gao, X., Wen, Q., Duan, X., Jin, W., Tang, X., Zhong, L., Xia, S., Feng, H. and Zhong, D. (2019) A Hazard Analysis of Class I Recalls of Infusion Pumps. JMIR Human Factors. 6(2), p.e10366. doi: 10.2196/10366.