



TRANSCULTURAL ANALYSIS OF MEDICAL DEVICE ALARM TREPIDATIONS: A NURSING PERSPECTIVE AND NEW THEORY PROPOSAL

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An exploratory review of the published literature sought to identify medical device alarm issue commonalities across countries and categories of devices. Categories were based on ECRI criteria for "alarming" medical devices. Following this review, consideration was given to the application of a new nursing theory entitled, "Medical device interaction theory". While medical device systems are intended to improve patient care by providing assistance with diagnosing, monitoring, and treating to alleviate disease and to support or sustain life, their effectiveness is compromised by the lack of device alarm differentiation (audio, visual, color, notifications, prioritization) and by the unpredictability of the sensitivity and specificity of alarms. Medical device use has been assumed to be consistent across countries because of the global nature of medical device manufacturers and their supply chain. Until the present review, however, no transcultural analysis of the published literature and relevant databases has been undertaken. This research aimed to understand transcultural alarm issues and human factor concerns, identify overlap, and propose collaborative approaches to improvement for healthcare organizations, clinicians, manufacturers, and end users. Variations of medical device alarm problems were analyzed following a review of medical device regulation databases for different countries available through the World Health Organization and application of a specific search strategy in PubMed. The review began with the assumption that patient care and patient safety related to medical device alarms are cross-cultural concerns without cross-cultural boundaries. While regulations vary between countries, the review found that the medical device alarm system constructs are similar transculturally. Issues can be categorized as related to People, Equipment, Local Practice, and Policy and Procedure. The categorization is the basis of the new "Medical Device Interaction Theory," which can be tested in future research and applied in practice and education. This theory views medical device alarms as a system rather than as individual medical devices. By focusing on general theoretical constructs rather than on individual products, manufacturers, clinicians, and human factors experts can work as a team to improve the development and use of medical devices with alarms.