

An Action-based Hierarchical Task Analysis for Evaluating Medical Device Safety

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Summary

Since the release of the Institute of Medicine medical error report in 1999, human errors in medicine and patient safety have become of great concern in the medical field. Device level incidents stemming from poorly designed interfaces are becoming particularly problematic, with advances in device technology. This is not, however, a new problem. The literature has long suggested that the number of injuries resulting from these types of problems far exceed that of injuries due to actual device failures (Cooper, Newbower, Long, & McPeek, 1978). Hence, the motivation for this effort was to apply existing cognitive theory to evaluate the safety of a simple yet pervasive medical device, the volumetric infusion pump.

The initial step in our evaluation methodology was to construct Hierarchical Task Analyses (HTA; Kirwan & Ainsworth, 1992) of three typical infusion tasks for six different pump models from three different manufacturers. In order to bring the relevant cognitive mechanisms into consideration, we conducted our analyses following Norman's Action cycle (Norman, 1986), which describes interaction between human and computer in seven basic stages of user activity (Figure 1).

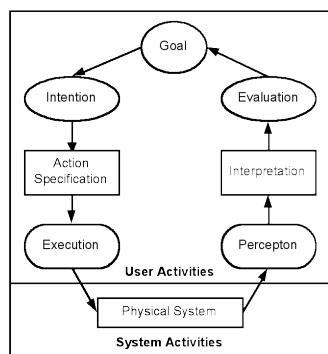


Figure 1. Norman's Action Cycle

Our most basic prediction from this theory was that interfaces requiring a greater number of internal operations

(less information on the interface) and more steps would generate higher frequencies of human error.

Compiling our HTAs in a tabular format facilitated counting of the number of tasks, subtasks, external representations, internal representations, error affordances, and basic operators. From these basic measures we were then able to generate general predictions of human error propensity given a pump interface.

For all six single and triple channel pumps, the overall trend for the number of affordances, task steps, and internal operations (representations) followed that of the number of actual user problems reported on the FDA's MAUDE database (FDA, 2003). Initial results from pump tests, currently in progress with human subjects, show a similar trend, although differences not captured by the proposed evaluation methodology were additionally reported (i.e. preference). These findings generally support our proposal and prediction that cognitive theories, such as Norman's Action theory, hold great value for deductive evaluations of medical device safety.

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