Using Clinical Workflows to Improve Device/System Development

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Medical technology innovations continue to provide improved ways to treat disease states that provide patients with longer life expectancies and thus an increased dependency on the healthcare system. As a result, healthcare providers are forced to compromise when providing these new, highly in-demand technologies to patients while controlling skyrocketing operational costs. Front-line healthcare providers find themselves with more patients and more technologies, but little increase in staff levels or workload-assisting technologies. This increased complexity of medical technology, designed with little consideration of the user environment, has only compounded the risk of adverse events because the medical community is too overburdened to practice medicine in a safe and efficient manner. Clinical staff are simply overwhelmed with new and changing technology that often lacks intuitive user interfaces and a fundamental understanding of the user’s environment. Integrated system design will only amplify these design flaws unless the approach to device design is altered. The implementation of this process in requirements gathering is going to become more and more crucial because the number of integrated systems is going to grow to 60-80% of all medical devices (IEEE 2006). Currently integrated medical devices are increasing the number of steps required to perform the same clinical function as a legacy device. Incorporating clinical work flow information will provide better understanding of the device requirements for developers and potentially decrease the number of steps required for clinical staff to perform their day to day tasks.

A clinical work flow is comprised of the sequential events that occur during a specific patient/clinician interaction. Clinical workflows track the human interactions involving equipment, staff, patients, supplies and other elements of the day-to-day environment. Understanding how these interactions work and translating this understanding into well-designed medical technology are vital to patient safety.

An analysis of these workflows will demonstrate that current healthcare systems still lack the efficiency or interoperability seen in traditional production and manufacturing systems (IOM, 2005). Integrated systems for industries such as automotive, aerospace and finance are more familiar to product developers because the role-based operational processes are fairly consistent and can be accurately modeled. The healthcare environment is more difficult to understand due to the increased number of unpredictable human interactions in the system. This is often related to culturally-inherited deviations from administrative standard procedures (work-arounds) with technology or processes. These work-arounds are often unidentified, misunderstood or ignored during new product development, as the traditional input specifications are derived from widespread market research or limited input from the product’s sales or technical support teams. A well-designed integrated system incorporates a thorough understanding of these work-arounds, based on analyzing the relevant clinical workflows and using these
workflows to inform a system’s use-case development. This approach can result in comprehensive design input specifications for use in building the technology.

A comprehensive workflow analysis needs to begin with understanding how and where technology could improve a clinical scenario in health care. Based on the scenario, a series of questions need to be asked of the clinical staff to understand their operational environment.

The appropriate questions to ask the clinical staff are related to what they are doing, why are they doing it and concerns they have about the process. Utilizing the lessons learned by clinical staff is the best resource available to understand the ways a medical device are utilized. By taking the answers from multiple sources (nurses, technicians, doctors) a complete and accurate workflow analysis.

The microcosms of clinical environments (outpatient clinic, radiology suite, inpatient unit) have different workflows, such that even when the intended use of the device is fundamentally the same, its placement and priority in the clinical workflow can be dramatically different. For example, a 12-lead electrocardiograph is usually located in both the emergency department and the general medicine outpatient clinic, but features like configuration, data-exchange capability, and portability are completely different.

Moreover, information carefully gathered by survey, direct interview, and direct observation is then utilized to develop the descriptive clinical workflow that, when used to create potential use cases for new technology, can identify the critical functional requirements essential for the new system design. Therefore, we intend to create a set of tools that system designer, whether clinical engineers, marketing professionals, or product developers, can use to analyze the clinical environment and accurately model the clinical workflow activity. These tools will be developed and validated in a modified product lifecycle as we measure the differences in features and functionality as described by the two sets of requirements, one using the old methodologies and the other using the new toolsets. Only by modifying the requirements-gathering process to include a comprehensive analysis of clinical workflows can systems be properly designed for patient safety through improved user interfaces and can device reliability be achieved.

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