ISO 16355 for Digital Health Records

Glenn Mazur
QFD Institute 1140 Morehead Ct. Ann Arbor MI USA

Increased access to health care combined with multiple foreign languages and cultures of both providers and patients has created a need for using digital records to communicate among different doctors treating the same patient for different conditions, as well as to communicate follow-up instructions to patients and care-givers. This project was part of a new study to "Cross the Healthcare Quality Chasm" where patients' experiences should be the fundamental source of the definition of quality. Among the fundamental changes recommended was that improvement should be bold, explicit, uniformly espoused, comprehensive, and patient centered. For healthcare organizations, suggested redesigns in six areas were summarized as:

1. Finding and standardizing best practices to replace historically protected or habitual ones.
2. Using information technology to improve access to information and to support clinical decision-making.
3. Improving workforce knowledge and skills.
4. Consistent development of effective teams.
5. Better coordination of care among services and settings, both within and among organizations, especially with respect to the care of people with chronic illnesses.
6. More informative measurement of performance and outcomes.

This paper will discuss the use of ISO 16355-1:2015, the new standard for quality function deployment (QFD), to better identify key customers and stakeholders in a pediatric hospital treating complex conditions such as spinabifida in a multidisciplinary clinical setting. Specifically, the needs of doctors, patients, and nursing staff will be obtained, analyzed, and prioritized in order to guide an agile development team creating a new communication application.

QFD is a quality assurance method used in new product development, to prioritize true customer needs and specify functional and non-functional design requirements to meet these needs. The presentation will show examples of the modern QFD tools described in the new series ISO 16355-1:2015, ISO 16355-2:2017, ISO 16355-4:2017, ISO 16355-5:2017, and ISO/TR 16355-8.