Six Sigma

Six Sigma is an innovative management- approach to reach practicable zero-defect quality in medical service processes. The Six Sigma principle utilizes strategies, which are based on quantitative measurements and which seek to optimize processes, limit deviations or dispersion from the target process. Hence, Six Sigma aims to eliminate errors or quality problems of all kinds. A pilot project to optimize the preparation for neurosurgery could now show that the Six Sigma method enhanced patient safety in medical care, while at the same time disturbances in the hospital processes and failure costs could be avoided. All six defined safety-relevant quality indicators were significantly improved by changes in the workflow by using a standardized process- and patient-oriented approach. Certain defined quality standards such as a 100% complete surgical preparation at the start of surgery and the required initial contact of the surgeon with the patient/ surgical record on the eve of surgery could be fulfilled within the range of practical zero-defect quality. Likewise, the degree of completion of the surgical record by 4 p.m. on the eve of surgery and their quality could be improved by a factor of 170 and 16, respectively, at sigma values of 4.43 and 4.38. The other two safety quality indicators “non-communicated changes in the OR- schedule” and the “completeness of the OR- schedule by 12:30 a.m. on the day before surgery” also show an impressive improvement by a factor of 2.8 and 7.7, respectively, corresponding with sigma values of 3.34 and 3.51. The results of this pilot project demonstrate that the Six Sigma method is eminently suitable for improving quality of medical processes. In our experience this methodology is suitable, even for complex clinical processes with a variety of stakeholders. In particular, in processes in which patient safety plays a key role, the objective of achieving a zero- defect quality is reasonable and should definitely be aspirated [1)].

Six Sigma, developed by Motorola in the 1980s [2)] is a widespread quality management concept to achieve a practicable zero defect quality in complex processes. Besides improvement cycles, i.e. DMAIC—Define, Measure, Analyze, Improve, Control, it includes an objective measurement concept to calculate the actual quality level of each process step. Based on standard normal distribution assumption, the sigma value is the key performance indicator of the Six Sigma concept. A Six Sigma process performance equals a quality level of 99.99966% or a max of 3.4 ‘defects per million opportunities’ (DPMO). Thereby, a defect is defined as a deviation of a self-determined standard. In some economic areas, like in the production of aircraft turbines or medical technology (particularly, in life support devices) such as a ‘zero-defect target’ as a self-selected standard is mandatory. In the medical field, such standards are linked to patient requests, so-called ‘critical to quality characteristics’ (CTQs), patient safety or the minimum requirements for patient outcome [3)].

A study showed that the Six Sigma concept is a suitable quality tool to analyze and improve the treatment quality of complex medical procedures such as lead positioning in DBS surgery in clinical routine. The results suggest that directional leads in subthalamic nucleus DBS may have a favorable impact on patients' outcome [4)].

1)
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