IQRO JURNALI / 2023
GUVOHNOMA № 060680
E-ISSN : 2181-4341
https://wordlyknowledge.uz
IMPACT FACTOR(SJIF) : 3,934
VOLUME 4, ISSUE 2, 2023

The penetration of Lean and Six Sigma techniques, practical methods of its application in clinical and translational research

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Annotation
Lean and *Six Sigma* are business management strategies commonly used in production industries to improve process efficiency and quality. During the past decade, these process improvement techniques increasingly have been applied outside of the manufacturing sector, for example, in health care and in software development. This article concerns the potential use of Lean and Six Sigma to improve the processes involved in clinical and translational research. Improving quality, avoiding delays and errors, and speeding up the time to implementation of biomedical discoveries are prime objectives of the NIH Roadmap for Biomedical Research and the NIH Clinical and Translational Science Award (CTSA) program.

Keywords
Lean, Six Sigma, process improvement, translational research, quality, TQM, CQI.

Various business management strategies have been developed to improve the performance of organizations by improving the processes by which they carry out their work. These strategies, which include *Lean* and *Six Sigma*, aim to implement process improvements through a coordinated set of principles and practices that promote greater efficiency and effectiveness, with fewer wasteful practices or errors. Evolving from their original application in manufacturing industries, these process improvement strategies have been extended to other settings including construction, software development, financial services, health care delivery, and laboratory sciences.

The creation of the Clinical and Translational Science Awards (CTSA) initiative as part of the National Institutes of Health (NIH) Roadmap for Medical Research is aimed at creating a clinical and translational research enterprise that assures maximal value is obtained from biomedical research investments. While the definition of *clinical and translational research* is still being debated, there is broad consensus that formal and sustained processes are needed to improve the timeliness and efficiency of research along the biomedical continuum. Reducing the time between biomedical research discoveries and their adoption into clinical practice requires increased coordination, systematic planning, and new types of connections within biomedical research organizations. This article suggests that better coordination, timeliness, efficiency and value of clinical and translational research can be achieved by applying the set of principles, practices and methods represented by Lean and Six Sigma.

Lean (also known as Lean Production, Lean Enterprise, and Lean Thinking) involves a set of principles, practices and methods for designing, improving and managing processes. The development of Lean is attributed to Taiichi Ohno's articulation of the Toyota Production System.[1] Ohno aimed to improve efficiency by eliminating particular kinds of waste (called *muda*, in Japanese) which absorb time and resources but do not add value. Examples include mistakes which need rectification, unneeded process steps, movement of materials or people without a purpose, unnecessary waiting because upstream activity was not delivered on time, and the creation of goods or services that are not really needed by end users.[2]

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A Lean process reflects the goal of continually reducing waste and improving work flow to efficiently produce a product or service that is perceived to be of high value to those who use it. Implementation of Lean involves systematic process assessment and analysis. The preliminary stages of Lean assessment include "value stream mapping" in which key people, resources, activities and information flows required to deliver a product or service are made explicit and depicted graphically. The value stream map is a key tool for identifying opportunities to reduce waste and more tightly integrate process steps, thus improving process efficiency.

Improvement approaches such as Lean and Six Sigma grow out of a long tradition of quality and process improvement efforts in manufacturing. For example, Frederick Winslow Taylor's scientific management and Frank Gilbreth's "time and motion" studies were among the earliest prescriptions for improving the quality and efficiency of production processes. Current thinking about process improvement draws heavily on the ideas of W. Edwards Deming, Joseph Juran and other statisticians whose data analysis tools and management philosophies were initially adopted by Japanese manufacturers, and have come to be known as Total Quality Management (TQM) or Continuous Quality Improvement (CQI).[3,4]

Six Sigma, like Lean, is a business management strategy used to improve the quality and efficiency of operational processes. While Lean focuses on identifying ways to streamline processes and reduce waste, Six Sigma aims predominantly to make processes more uniform and precise through the application of statistical methods.[5] Six Sigma was originally developed by Bill Smith of Motorola in 1986 as a way of eliminating defects in manufacturing, where a defect is understood to be a product or process that fails to meet customers' expectations and requirements. The name *Six Sigma* refers to a quality level defined as the near-perfect defect rate of 3.4 defects per million opportunities. As a process improvement strategy, Six Sigma gained much attention through its association with General Electric and its former CEO Jack Welsh.

A variety of systematic methodologies for identifying, assessing and improving processes have been developed as part of the Six Sigma approach. The Six Sigma improvement model, *Define, Measure, Analyze, Improve, and Control* (DMAIC) specifies the following sequence of steps for understanding and improving a process: 1) defining the project goals and customer (internal and external) requirements; 2) measuring the process to determine current performance; 3) analyzing and determining the root cause(s) of relevant defects; 4) improving the process by eliminating defect root causes, and 5) controlling future process performance. Another Six Sigma methodology, *Design for Six Sigma* (DFSS), is used to systematically design new products and services that meet customer expectations and can be produced at Six Sigma quality levels.[6]

Six Sigma also involves the training and certification of designated process specialists (called *black belts, green belts*, or other similar titles) within organizations to help guide Six Sigma improvement efforts. Other distinctive Six Sigma features include the expectation that process quality improvements be translated into financial metrics to assess value and the active involvement of top management in all Six Sigma initiatives.

Various combinations of Lean and Six Sigma techniques have been developed, which frequently are described as *Lean Six Sigma* approaches. The blended approach points to the common process-centered and data-driven foundations of both Lean and Six-Sigma. Proponents of a combined approach assert that organizations can benefit from utilizing both the customer-orientation and focus on eliminating waste inherent in Lean along with the statistical tools and systematic defect reduction strategies featured in Six Sigma.[7,8]

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Lean and Six Sigma are just two of numerous approaches that are in use for systematically analyzing and improving process flow and efficiency within industries. Other similar approaches include Business Process Modeling (BPM), Business Process Reengineering (BPR), and Workflow Mapping (WM), as well as a variety of TQM and CQI-oriented techniques such as management accounting systems, Kaizen, and Shewhart cycles (PDCA). The selection of a particular process improvement approach will depend upon the specific circumstances and needs existing in a working environment, including the type of processes, the improvement objectives, and the skills, knowledge, and resources available in that setting. For example, some approaches may b better suited to statistical analysis of defects (e.g., Six Sigma), some to layout planning and product flow (e.g., BPM and WM), and some to optimizing transitions between process steps (e.g., Lean). We chose to focus primarily on Lean and Six Sigma in this article because of literature suggesting their applicability to biomedical and research settings (reviewed below).

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