Commentary

Approaching Inpatient Glycemic Control Using Six Sigma Methodology

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Abstract
Process variation affects almost all healthcare processes. Wide fluctuation of blood glucose values is very common in hospitalized patients and may impact the outcome of care in negative way. The purpose of this article is to illustrate how to study the process variation using Six Sigma approach and how to use it teaching healthcare quality.

Keywords: Healthcare Six Sigma, glycemic variability

Introduction

To Err is Human: Building a Safer Health System [1] is a report issued by the U.S. Institute of Medicine (IOM) in November 1999 and has resulted in increasing awareness regarding high medical errors in healthcare industry. The report, which was based on an analysis of adverse health outcomes by a variety of organisations, concluded that between 44,000 and 98,000 people die each year as a result of preventable medical errors. Since its publication; there has been a significant enthusiasm to improve patient safety and to improve healthcare outcome. As a result of that, we have witnessed the introduction of many new innovations and reengineered processes. In spite of that medical error rate remains high, and possibly higher as shown by a more recent medical error analysis [2].

In other industries, any measurement falling outside of industry standards is regarded as a defect. This is how quality is defined, at least in companies that have adopted the Six Sigma approach which is a statistical approach for quality improvement. Processes that operate with "six sigma quality" over the short term are assumed to produce long-term defect levels below 3.4 defects per million opportunities (DPMO) [3]. Six Sigma's implicit goal is to improve all processes, but not to the 3.4 DPMO level necessarily. Its main philosophy it to reduce process variation to minimum level using a well-defined statistical approach. Many large companies use Six Sigma methodology to reduce the defect rate to its lowest possible value. The Six Sigma attempts to reduce the number of defects to below 3.4 per million opportunities; industries such as aviation target and achieve an even lower defect rate (less than 1 defect per 2 million opportunities).

Simply, the Six Sigma concept is a statistical approach to improving the quality and performance of a specific process by focusing on the “Critical to Quality Step” as identified by the “Voice of the Customer”. It aims to maintain the mean result within a target range (i.e., between upper and lower specification limits) and focuses on reducing the variation in the outcome to the lowest possible level. The variation in outcome is usually measured as the standard deviation around the mean (i.e., Sigma). The Six Sigma method aims to fit six standard deviations around the mean without crossing the lower or upper specification targets. This process yields high performance and high potential [3].

Healthcare processes have usually high defect rate and wide variations (low sigma level). Six Sigma approach can be used in healthcare to improve specific processes using the same methodology used by other industries. The purpose of this analysis is to illustrate how to use Six Sigma approach in healthcare processes to decrease variation, using inpatient glycemic control as an example.

Introducing this approach in medical education can help medical students, residents and other professionals to approach healthcare quality and patient safety in standardized way and can allow them to use recent advances in medical technology and artificial intelligence to achieve better healthcare outcomes.

Methods

Analysis of 9609 glucose data point done in non-ICU units from 2015 was done as part of the baseline data collected for a
quality improvement project that aimed to decrease glucose variation in non-ICU adults patients. These data were part of a quality improvement project that aimed to decrease glucose fluctuation across all medical units at a tertiary care center. It was agreed that the “industry standard” for glucose level in hospitalized non-critically ill patients should fall between 100 mg/dl and 180 mg/dl [4].

Using Six Sigma Methodology, the mean, standard deviation, Defect Per Million Opportunity (DPMO), sigma level and Process Performance indices were calculated. Statistical analysis was done using QI Macros 2011 software.

**Results**

Plotting glucose data against frequency was done to visualize the data distribution (Figure 1). Adding specification limits: 100 mg/dl (lower specification limit) and 180 mg/dl (upper specification limit), provided a visual estimation of process performance. The mean glucose value in the sample was 167.8 mg/dl with standard deviation of 69.1. As a process with a target of 100 mg/dl to 180 mg/dl, the glycemic control has a very high defect rate of 46.7% or Defect Per Million Opportunity (DPMO) of 467,478 ((only half of all glucose measurements fell within the target range). The Sigma level was 1.58. The Process performance (Pp) was 0.19.

The glycemic control data analysis showed high defect rate, and high variation. Sigma level of 1.58 reflects poor process performance and provides great opportunity for improvement.

![Histogram with process performance indices](image)

**Discussion**

Many large companies use Six Sigma methodology to reduce the defect rate to its lowest possible value. The Six Sigma attempts to reduce the number of defects to below 3.4 per million opportunities; industries such as aviation target and achieve an even lower defect rate (less than 1 defect per 2 million opportunities). Simply, the Six Sigma concept is a statistical approach to improving the quality and performance of a specific process by focusing on the “Critical to Quality Step” as identified by the “Voice of the Customer”. It aims to maintain the mean result within a target range (i.e., between upper and lower specification limits) and focuses on reducing the variation in the outcome to the lowest possible level. The variation in outcome (the killer in any industrial process) is usually measured as the standard deviation around the mean (i.e., Sigma). The Six Sigma method aims to fit six standard deviations around the mean without crossing the lower or upper specification targets. This process yields high performance and high potential. In our example of a mean glucose level of 167.8 mg/dl and a standard deviation of 69.1 mg/dl, we can calculate the Process Performance or Process Potential (Pp) for our data (Pp = (USL – LSL) / 6*s), where s is the standard deviation).

Using Six Sigma language to describe our data, we find that the number of defects is 467,478.41 per million opportunities (DPMO), with a Sigma level of 1.58. The current performance of this process has a process potential (Pp) of only 0.19, when ideally,
the Journal of Patient Safety estimated between 210,000 and 400,000 deaths from avoidable medical errors occur annually [2].

**Conclusion**

In summary, this example illustrates the need for innovation in the way that we evaluate healthcare processes and outcomes and in the way that we teach medicine. For inpatient glycemic control, regarding outlier glucose readings as defects and considering glucose variability in terms of Sigma level and process potential will help us to make progress towards the nearly defect-free industrial standards achieved in certain fields.

Our medical students and residents encounter a large number of defects every day (e.g., hypoglycemia or severe hyperglycemia) and often understand the root cause of the defect (i.e., not administering insulin on time, administering too much or too little insulin, and not adjusting for renal function or food intake) without much reaction most of the time.

I believe that we must radically change our approach to healthcare delivery, as well as our perception and attitude toward medical errors and adverse events. We need to introduce the concept of reducing process variability and defects by teaching medical, nursing and pharmacy students the industrial approach to quality, using concepts such as lean methodology, statistical process control and Six Sigma. Teaching medical quality through reducing process variation approach at the very early stages of the “process of making a physician” will help to create a new generation of physicians with completely different attitude and perception of medical errors and defects.

**Ethics approval and consent to participate**

Not applicable as the De-identified glucose data was obtained as part of the regular ongoing quarterly quality auditing.

**List of abbreviations**

- Institute of Medicine (IOM)
- Defects per million opportunities (DPMO)
- Process performance (Pp)
- USL: Upper Specification limit
- LSL: Lower Specification limit
- Mean Amplitude of Glycemic Excursions (MAGE)
- Standard Deviation (SD)
- Glucose variability (GV)
- Institute for Healthcare Improvement (IHA)
- The Agency for Healthcare Research and Quality (AHQR)

**Data Availability**

De-identified glucose data was obtained as part of the regular quarterly quality auditing by laboratory department and Diabetes committee at St. Mary’s Medical Center, Huntington, West Virginia, USA

**Conflicts of Interest**

The author declares that there is no conflict of interest regarding the publication of this paper.

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Not applicable
References

[1] Institute of Medicine (IOM). To Err is Human: Building a Safer Health System. Washington, DC: National Academy Press 1999.

[2] James JT. A new, evidence-based estimate of patient harms associated with hospital care. J Patient Saf 2013;9:122–8.

[3] Roderick A, Matthew J. Maio, Mohamed B. Nawaz, Govindarajan Ramu and Daniel J. Zrymiak. The Certified Six Sigma Green Belt Handbook. ASQ Quality Press 2007.

[4] Standards of medical care in Diabetes-2021. Diabetes Care. January 2021. Volume 44. Supplement 1

[5] Gorst C, Kwok CS, Aslam S, Buchan I, Kontopantelis E, Myint PK, Heatlie G, Loke Y, Rutter MK, Mamas MA. Long-term Glycemic Variability and Risk of Adverse Outcomes: A Systematic Review and Meta-analysis. Diabetes Care. 2015 Dec;38(12):2354-69

[6] Office of Inspector General reports: Medical Mistakes Plague Medicare Patientshttp://oig.hhs.gov/newsroom/news-releases/2010/plague.asp