Editorial

Are Perfusion Technology and Perfusionists Ready for Quality Reporting Employing Six-Sigma Performance Measurement?

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PERFUSIONISTS MUST REPORT THEIR PROCESS IMPROVEMENT

This editorial is the product of a recent communication with Journal Editor Stammers. Moss and Thompson, Editors of the journal Quality in Health Care adopted a new outline for quality improvement reports (1). They made the point that clinical quality reports (like case reports) do not fit the traditional scientific publication outline of introduction, method, results, and discussion.

Just as Moss and Thompson were encouraging those with practical experience in quality improvement to write about their success and failures, perfusionists must share their strategies and forays into process improvement. The Journal of Extra Corporeal Technology should facilitate perfusion technology quality improvement by adopting a report outline similar to the Quality in Health Care journal. A modified outline appropriate for perfusion technology adopted from Moss and Thompson is proposed (Figure 1).

Quality improvement and error-reduction strategies fit well into the perfusion practice and technology models. Perfusionists may communicate their process improvement successes and failures employing the proposed quality report outline.

SIX SIGMA PROCESS IMPROVEMENT METHODS

When it comes to the analysis part of quality reporting, perfusionists should adopt the Six Sigma methodology.

Six Sigma is about continuous quality improvement using the define, measure, analyze, improve, control (DMAIC) steps. Six Sigma provides a method to measure percent success (% yield) or defects (failures) per million opportunities (DPMO). The Six Sigma table (Table 1) outlines the standard normal distribution table where one sigma is one standard deviation (2).

Clinical administrators paying attention to the quality of health care today are focusing on improvement in professional performance not so much on organizational changes (3). Caregivers cannot adopt any one model for performance improvement, but need to employ components of many models to be effective in their discipline.

Woods illustrates how to bring Six Sigma DMAIC techniques into the design and adoption of services that have a high probability of success in a cardiac center. Woods also supports the premise that the next evolutionary step for cardiac centers designed for growth and innovation is to focus on clinical processes (4). Even mature patient care services and processes such as those found with cardiopulmonary bypass and cardiac surgery can benefit from Six Sigma methods and monitoring.

There are numerous improvements to cardiopulmonary bypass (CPB) yet to be identified, studied, and tried. The discipline of perfusion technology should re-examine our tried and true processes through the statistical lens of Six Sigma.

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THE MATHEMATICS OF EVENT REPORTING

Equations (1) and (2) relate the calculations of the rate or frequency of events, accidents, failures, or benign observations. DPMO is easily calculated from observation ratios (e.g., 1:10,000 = 100 DPMO and 1:200,000 = 5 DPMO).

\[
\text{Rate or Frequency} = \frac{\text{# of Accidents or Observations}}{\text{# of Procedures or Patients}} = \frac{\text{# of Failures}}{\text{# of Opportunities}} \tag{1}
\]

\[
\text{Defects per Million Opportunities} = \frac{\text{# of Failures or Defects}}{\text{One Million Opportunities}} = \text{DPMO} \tag{2}
\]

Applying these calculations to published cardiopulmonary bypass event data is useful to begin to apply Six Sigma methods to perfusion.

The most recent peer-reviewed survey for perfusion-related undesired accidents reports an incident rate of one occurrence per 138 patients (5). Mejak, et al. reported a rate of one serious injury per 1,454 procedures. This rate is an improvement over the frequency of one in about 1,000 patients reported in 1986 by Kurusz and coworkers (6).

These data are retrospective and collected by survey methods. There are no published reports of CPB accidents by prospective methods except what may be discovered at the US FDA MDR site [http://www.fda.gov/cdrh/maude.html], and these incidents are equipment-related only. Counting accidents or events reported to the FDA does not give us an accident rate. Calculating incident rate or frequency will still be a challenge because rates are relatively low and not all accidents would be captured. Most interesting, real caseload numbers (the denominator for a frequency calculation) are not readily available.

Perfusionists frequently call for a national database to collect and report perfusion-related events, equipment failure and accidents. The optimal method to measure perfusion-related accidents is a mandatory, prospective reporting protocol where clinicians are free to report incidents in a non-retributary environment where continuous process improvement is part of the culture. How many perfusionists work in an open-heart team that supports such a culture?

FAILURES IN OTHER INDUSTRIES

A company builds one million (10^7 or 1,000,000) computer microprocessor chips and during the testing of the final product only 22 of the chips do not meet performance specifications. The chip manufacturer has studied and improved their manufacturing processes to realize a yield of 999,978 or more successes in every million chips produced (DPMO = 22, sigma level = 5.6). Remember six (6.0) sigma is only about 3 or 4 DPMO, which is near perfection.

A major US tire manufacturer had to recall 6.5 million tires in 2001 after 192 related deaths and 500+ injuries. The defect rate for the tire manufacturer was estimated at 8:1,000,000.
A refrigerator manufacturer in England builds its own motors in an ancillary plant. The company builds 12,000 motors per year. In the final motor performance testing, 48 of the motors are rejected. Doing the math, the successful yield of refrigerator motors is 996,000 of 1,000,000 built (DPMO = 3,467, sigma level = 4.2).

In 1999 worldwide, about 486,000 major airline airplanes took off and only one did not make it safely to the ground. This is a yield of 99.9998% or about 2 DPMO (sigma level > 6.0).

Anesthesiologist in one multi-hospital system performed 12,600 general anesthetics one year in the late 1990s. In that year, 4 patients died as a consequence to anesthetic induction. Mathematically, 999,683 patients of one million survived anesthetic induction in this data set or the anesthesiologists realized a DPMO = 317 (sigma level = 4.9).

In the late 1990s, one group of perfusionists performed 33,267 on-bypass procedures with blood oxygenators in one year. As part of a quality monitoring process, the perfusionists prospectively reported that 11 oxygenators either failed or caused a disruption in the care to the patient in that year. Eleven failures in 33,267 opportunities rolls up to a DPMO rate = 0.000331 or 331 DPMO, which is a successful yield of 999,689 of 1,000,000 (sigma level = 4.9).

The concept of DPMO and the sigma level may be applied to the outcome measures of any major or minor process related to the application of cardiopulmonary bypass. Use of DPMO and sigma level allows perfusionists to use the same units of measure to report and compare clinical indicators such as the number of times an alarm condition is realized to the number of deaths due to CPB-related incidents.

ERROR REDUCTION IN PERFUSION

In 2001, the American Academy of Sciences’ Institute of Medicine called for substantial change to the quality of medical care in the United States to reduce the number of errors that result in negative patient outcomes (Institute of Medicine National Roundtable on Health Care Quality. Crossing the Quality Chasm: A New Health System for the 21st Century. Institute of Medicine, American Academy of Science. 2001). Error-reduction is a national healthcare imperative today.

As early as 1980, cardiothoracic surgeons and perfusionists worldwide have retrospectively surveyed their peers to discover the rates of specific CPB-related incidents during open-heart procedures (5–7).

Table 2 presents the results of three perfusion-related surveys in adult open-heart surgery. The rates of CPB incidents or events have been adjusted to DPMO to facilitate comparison and historical trending.

As the authors themselves point out, there are limitations in comparing the results of the three surveys. The DPMO statistics are useful for stimulating a more quantitative debate.

ARE PERFUSIONISTS READY TO REPORT PROCESS IMPROVEMENT EFFORTS?

Ready or not, the perfusion profession and open-heart teams must adopt the six-sigma DMAIC methodology as a guide to study and measure the improvement in their clinical processes. It is equally important for perfusion professionals to share the results of their process improvement strategies.

The proposed outline (Figure 1) for Journal of Extra-Corporeal Technology quality improvement reporting will give perfusionists the template to communicate the results of their process improvement successes and failures. Current national trends in reducing errors and improving processes in healthcare mandate that perfusionists become actively involved in local DMAIC efforts. The Journal editorial staff should encourage quality improvement reporting similar to case report and technique reporting by adopting the proposed template adopted from the Quality in Healthcare Journal. Our editorial staff should encourage the use of six sigma statistics as well.

ACKNOWLEDGMENT

The author wishes to acknowledge the support and input by Timothy Dickinson MS, Director, Research and Development, FMC-EA.

Table 2. Defects per million opportunities (DPMO): Survey experiences cited in the perfusion technology literature.

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<tr>
<td>OH Caseload</td>
<td>670,345</td>
<td>573,785</td>
<td>375,000</td>
</tr>
<tr>
<td>Country</td>
<td>United States</td>
<td>United States</td>
<td>United States</td>
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<tr>
<td>Aortic cannula dislodgement</td>
<td>244</td>
<td>489</td>
<td></td>
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<tr>
<td>Transfusion reaction</td>
<td>162</td>
<td>558</td>
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<tr>
<td>Protamine reaction</td>
<td>1,277</td>
<td>2,798</td>
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<tr>
<td>Post-op bleeding complication</td>
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<td>Medication error</td>
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<td>817</td>
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<td>Power interruption</td>
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<td>840</td>
<td>11</td>
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<td>Oxygenator failure</td>
<td>407</td>
<td>73</td>
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<td>Heater/cooler failure</td>
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<td>Pump mechanical failure</td>
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<td>289</td>
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<td>Air in CPB circuit</td>
<td>498</td>
<td>967</td>
<td>380</td>
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