Introducing Change (Science into the Operating Room): Quality Improvement versus Experimentation

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Abstract: Introducing change is sometimes vital on an individual, departmental, and institutional level to improve the quality of care of patients undergoing cardiopulmonary bypass. This review discussed the following areas: cost of poor quality, variation, knowledge, Deming’s red bead experiments and his conclusions, how do you try to improve, measurement, statistics, and quality improvement versus research. Successes and failures with regard to the introduction of change, and strategies to introduce change without creating conflict are discussed with reference to the hospital in which the author works. Keywords: change, quality, perfusion, cardiac surgery, JECT. 2009;41:P11–P15

Introducing change or quality improvement should be a goal of all teams involved in surgery to help translate current “best practice knowledge” into actual clinical practice. This article covers the following areas:

- Cost of poor quality
- Variation
- Knowledge
- Red Bead experiments
- How do you try to improve?
- Measurement
- Statistics
- Quality improvement or research
- Local success

For a more detailed account of quality improvement through planned experimentation, readers are referred to the work of Moen et al. (1).

COST OF POOR QUALITY

In the “iceberg model” the cost of poor quality in health care can be divided into the “obvious” and the “less obvious.” Obvious costs include those directly impacting upon the patient including mortality, morbidity, length of stay, and blood product usage. The less obvious costs of poor health care, those “beneath the surface” would include factors such as low morale, lost time, sickness, wasted effort, poor communication, and poor patient satisfaction (2).

VARIATION

Variation is the inability to maintain a constant performance, such that variation means that planning, which is based on predictability becomes difficult or impossible. Two types of variation exist, “natural” (normal) variation, due to biological variability, and “induced” (special) variation, due to a variable external influence (3).

KNOWLEDGE

Different types of knowledge exist. Subject Matter Knowledge is basic to the things we do in our job, e.g., professional knowledge. Profound Knowledge is the understanding of the theories of systems, variation, knowledge, and psychology (e.g., understanding how cardioplegia works, and not that it just does). In isolation neither subject matter nor profound knowledge will lead to improvements. For this, you need Knowledge for Improvement, which is the ability to combine subject matter knowledge and profound knowledge in creative ways to develop effective changes for improvement.

RED BEAD EXPERIMENTS

Deming is the father of quality improvement, and he developed classic experiments involving red and white beads to demonstrate his quality improvement points (4). In his famous red bead experiment he uses a scoop to draw small red and white colored beads from a bowl. Each draw
of the scoop gets 50 beads. Some are white and some are red (i.e., a random collection). The white beads symbolize the good things that we experience each day as we do our work and the red beads symbolize the problems or bad things that we experience. There are many teaching examples as you proceed. One example is that our lives experience different things each day some good and some bad. Workers most of the time have no control over their own experiences. The workers did not create the company, the bosses did and so the latter should be held responsible for most of the mistakes. Workers can control about four out each 100 problems but not the other 96; they are problems created by the system. If bosses want workers to do better work, they need to redesign improvements to the system to remove the problems (red beads) that we find each day.

Deming deduced that:

- If you want to improve performance, you must work on the system, not the workers.
- All the variation in number of red beads came from the system. There is no evidence that any one worker is better than another.
- Numerical goals and production standards can be meaningless. The number of red beads produced is determined by the process, not by the standard.
- Quality is made at the top. Quality is an outcome of the system. Top management owns the system.
- Rewarding or punishing the “willing workers” had no effect on the outcome (but possible negative side effects).
- Slogans, exhortations, and posters are at best useless to the “willing workers.”
- With rigid procedures, the “willing workers” have no chance to offer suggestions for improvement.
- Keeping the facility open with only the “best” workers was acting on “superstitious” knowledge.

Issues raised by the red bead experiments, relevant to medical care include:

- Over and under reaction by managers and teams and the impact on results, people, and customers.
- Problems with the use of measures and targets and individual reward or incentive schemes.
- The importance of measurement and the way data is displayed for decision making.
- The role of managers and others in the workplace in making decisions that focus on improving work processes.
- When run by a dynamic facilitator some insight to patterns of behavior in an organization can be provided.

**HOW DO YOU TRY TO IMPROVE?**

A large array of different theoretical strategies is available to assist clinicians to try to improve. Two such strategies are the Strength, Weakness, Opportunities, and Threats (SWOT), and Plan, Do, Study, Act (PDSA) that are commonly treated in isolation and are, however, actually inextricably linked together, as the outcome of the SWOT analysis will affect your PDSA design (5,6). A commonly overlooked point about the act part of a PDSA loop is that act can be adopt, adapt, or, abandon, and not “just carry on anyway”. In addition, multiple PDSA cycles may need to be implemented to result in an improvement.

Cause and effect diagrams, such as stem/leaf, fishbone, or Ishikawa, can be useful to help plan SWOT and PDSA loops (Figure 1). During planning of a PDSA cycle, three questions need to be asked and answered:

1. **What are we trying to accomplish?** The PDSA cycle needs a “Goal Statement,” such as a general description of the goal, a specific population, numerical goals, or a general description of spread.
2. **How will we know that a change is an improvement?** The “Measurement” step—measurement may need to be performed for each PDSA cycle, each monthly key measure, or each spread measure.
3. **What change can we make that will result in improvement?** What will be the “Improvement Strategies” that we invest in?

These can be identified through a change package, resident input/ideas, satisfaction surveys, chart audits, and brainstorming. Initially, use smaller scale tests to improve speed and reduce variance. This is called the power of “one” (i.e., conduct the initial test with one facility, one office, one doctor, and one nurse).

**MEASUREMENT**

Measurement is the key to success, otherwise how do we know a change is an improvement? Recent observations are more heavily weighted in our minds than old experiences. However, new observations depend on previous observations (e.g., if you are used to a room of 30 degrees, 60 degrees feels warm, but not if you are used to the room being 95 degrees). In addition, our minds automatically filter perceptions and sometimes we observe what we want or expect to observe, hence the need for measurement.

![Figure 1. Cause and effect diagram (stem/leaf, fishbone, Ishikawa).](image-url)
A number of different types of measures exist: “Outcome measures”—are the patients better? Are the patients having a better experience? “Process measures”—are we doing the work we are supposed to be doing to improve outcomes? “Balancing measures”—as we do our improvement work, what is our impact on the rest of the system?

STATISTICS

Statistical analysis needs to be considered prior to any PDSA implementation, as it is sometimes too late, or inefficient to collect data after an event. The type of variable being recorded will vary, making the statistical test that is appropriate alter as well. Data measurements can be classified as discrete (e.g., number of patients), applied to variables with specific outcomes (heads or tails, success or failures, conforming or non-conforming), dichotomous (dead or alive), or continuous, representing populations that can have infinitely many values usually within a finite range (e.g., height or weight). However, it is the distribution of the data that is the key to the decision as to which statistical test is used; for example, with discrete data, a binomial distribution applies to situations with just two possible outcomes (e.g., success or failure), a Poisson distribution is primarily directed at populations with rare events, and a hyper-geometric distribution occurs when sampling the population can alter the rate of a non-conformity.

Continuous data can have distribution described as: Normal or Gaussian, T-distribution, Chi-Square distribution, or F-distribution. Tables of numbers can make measurement interpretation difficult. Graphical representation via statistical control charts (Figure 2), dot frequency (Figure 3), cube design for factorial analysis (Figure 4), and a response plot (Figure 5) can ease interpretation of “a wall of numbers.”

QUALITY IMPROVEMENT OR RESEARCH

Sometimes the difference between quality improvement and research can be difficult to differentiate. Where any confusion or uncertainty exists, your ethics department should be involved in the process to avoid unnecessary action by regulatory bodies. This occurred to Pronovost et al. (7) who introduced a quality improvement program to reduce catheter related infections in intensive care. Their work was subsequently published in the New England Journal of Medicine, and they were then accused of performing a trial without ethics approval.

MEASURES IN IMPROVEMENT VS. RESEARCH

A number of differences exist between quality improvement and research measurements (see Table 1). Project conception differs between quality improvement programs.

<table>
<thead>
<tr>
<th>Variables Control Chart</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part Name: 0.187&quot; Skelp</td>
</tr>
<tr>
<td>Operation (Process): Hot Roll</td>
</tr>
<tr>
<td>Specification Limits: 0.187 ± 0.006</td>
</tr>
<tr>
<td>Operator: All</td>
</tr>
<tr>
<td>Machine: Rolling Mill</td>
</tr>
<tr>
<td>Gauge: 0.187 - 0.193</td>
</tr>
<tr>
<td>Unit of Measure: 0.001</td>
</tr>
<tr>
<td>Zero Equals: 100</td>
</tr>
<tr>
<td>Time</td>
</tr>
<tr>
<td>Sample Measurements</td>
</tr>
<tr>
<td>Sum</td>
</tr>
<tr>
<td>Average</td>
</tr>
<tr>
<td>Range</td>
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</tbody>
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Figure 2. Statistical control charts—these use process control data to monitor trends against pre-determined criteria.
In quality improvement programs, the use of stem and leaf diagrams, flow charts, frontline worker interviews, and PDSA cycles to improve an intervention are used. In research, theory, expert opinion, and pilot studies for intervention feasibility are used. However, a large gray area of overlap exists.

LOCAL SUCCESS

The Cardiothoracic Surgical Unit at Liverpool Heart and Chest Hospital has had some successes in improving quality and some failures. Our successes have included the introduction of retrograde autologous priming (see Figure 6) and quality markers in perfusion—blood pressure, glucose, lactate, lowest hematocrit, and maximum temperature. Local failures have included introduction of a sepsis care bundle involving prophylactic antibiotic administration to patients who meet defined criteria, an integrated care pathway to try and eliminate variation in patient treatments and assessments in patients undergoing cardiac surgery, and an antibiotic policy to standardize prophylactic antibiotic administration to patients undergoing cardiac surgery.

The changes that were successful involved the following key steps:

Step 1: Engagement
- Send out information on the topic to colleagues a few weeks prior to the planned group presentation with all accompanying supporting papers in pdf format.
- Ask colleagues for questions or queries.
- Ask colleagues to send you any opposing evidence.

Step 2: Adapt presentation in response to feedback from Step 1
- Present to colleagues and listen.

Step 3: Adapt presentation in response to feedback from Step 2
- Implement.

Step 4: Reassess

![Figure 3](image3.png)

**Figure 3.** Dot frequency diagram—this is designed to partition the variation in the original data among the factors in the study.

![Figure 4](image4.png)

**Figure 4.** Cube design for factorial analysis—a 3D representation of the effect of three variables A, B, and C on an outcome measure.

![Figure 5](image5.png)

**Figure 5.** Response plot—the effect of one or more factors on an outcome variable being studied.

<table>
<thead>
<tr>
<th>Table 1.</th>
<th>Measures in improvement vs. research.</th>
</tr>
</thead>
<tbody>
<tr>
<td>For Improvement</td>
<td>For Research</td>
</tr>
<tr>
<td>Biases are “stable” (this is real life)</td>
<td>Biases minimized by blinding, randomization (pure situation)</td>
</tr>
<tr>
<td>Run charts</td>
<td>Before and after</td>
</tr>
<tr>
<td>Just enough data</td>
<td>As much data as possible</td>
</tr>
<tr>
<td>Sequential testing to adapt a change to real-life situation</td>
<td>One big test</td>
</tr>
</tbody>
</table>

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Introducing change to clinical cardiac surgery can be extremely difficult with significant resistance often present within the existing structure. Common responses to change include:

- We tried that 10 years ago.
- We’re too busy to fix these problems.
- We don’t do things that way here.
- But those companies aren’t like us.
- We have different problems.
- We’ll change, but let’s do it very slowly.
- That won’t work here.

However, it is important not to let this usual resistance to change win. To successfully introduce change, it is essential that new ideas and techniques are introduced in a structured manner and using techniques such as those described above may be one way of achieving this.

REFERENCES