

# Seven Propositions of the Science of Improvement: Exploring Foundations

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**Context:** The phrase “Science of Improvement” or “Improvement Science” is commonly used today by a range of people and professions to mean different things, creating confusion to those trying to learn about improvement. In this article, we briefly define the concepts of improvement and science, and review the history of the consideration of “improvement” as a science. **Methods:** We trace key concepts and ideas in improvement to their philosophical and theoretical foundation with a focus on Deming’s System of Profound Knowledge. We suggest that Deming’s system has a firm association with many contemporary and historic philosophic and scientific debates and concepts. With reference to these debates and concepts, we identify 7 propositions that provide the scientific and philosophical foundation for the science of improvement. **Findings:** A standard view of the science of improvement does not presently exist that is grounded in the philosophical and theoretical basis of the field. The 7 propositions outlined here demonstrate the value of examining the underpinnings of improvement. This is needed to both advance the field and minimize confusion about what the phrase “science of improvement” represents. We argue that advanced scientists of improvement are those who like Deming and Shewhart can integrate ideas, concepts, and models between scientific disciplines for the purpose of developing more robust improvement models, tools, and techniques with a focus on application and problem solving in real world contexts.

**Conclusions:** The epistemological foundations and theoretical basis of the science of improvement and its reasoning methods need to be critically examined to ensure its continued development and relevance. If improvement efforts and projects in

health care are to be characterized under the canon of science, then health care professionals engaged in quality improvement work would benefit from a standard set of core principles, a standard lexicon, and an understanding of the evolution of the science of improvement.

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**Key words:** epistemology, improvement science, quality improvement, science of improvement

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Use of the phrase “science of improvement” (and its various morphologies) is becoming more common today, especially in health care where many are calling for a better understanding of this science.<sup>1,2</sup> It is obvious at times that people who use this phrase are referring to different ideas, concepts, and guiding principles. For example, in the health care literature, one can readily find current references to “*the science of improvement*,”<sup>3</sup> “*the science of safety improvement*,”<sup>4</sup> “*the science of patient safety*,”<sup>5</sup> “*the science and politics of quality improvement*,”<sup>6</sup> “*improvement science*,”<sup>2</sup> and “*scientific quality improvement*.”<sup>7</sup> Furthermore, some note strong similarities between the science of improvement and what is referred to as implementation science.<sup>2,8</sup> If improvement efforts and projects in health care are to be characterized under the canon of science, then health care professionals engaged in quality improvement work would benefit from a standard set of core principles, a standard lexicon, and an understanding of the evolution of the science of improvement. In the absence of such a shared understanding, the science of improvement is susceptible to a variety of interpretations.

As the history and philosophy of science teaches us, the roots of all confusions can be attributed to the vagaries of language and failure to understand the historical provenance of thought. The history behind the development of the science of improvement is rich and complex and needs to be understood, especially by those identifying themselves as improvement scientists or by those leading quality improvement programs. In this article, we identify 7 central propositions, grounded in the history and philosophy of science, that build on each other to define the nature of the science of improvement. We begin this process by describing the foundation for the science of improvement, based on Deming’s System of Profound Knowledge.<sup>9</sup> We suggest that Deming’s system has a firm association with many contemporary and historic philosophic and scientific debates and concepts. With reference to these debates and concepts, we identify 7 propositions that provide the building blocks of the science of improvement and

that have applicability to improvement efforts from leadership to the front lines. This article is for anyone interested in going below the surface of quality improvement to examine some of the “raw materials” and philosophic underpinnings of the science of improvement. It is especially geared to those who teach and lead improvement work, as well as those engaged in quality improvement research.

## BACKGROUND

### What is improvement?

Improvement has meaning only in terms of observation based on a given criteria. That is, improvement is useful and has meaning when it is defined by characteristics such as healthier, safer, more efficient, and so on. Because the concepts of improvement and change are connected so strongly, it is most useful to define them together. Although change will not always result in improvement, all improvement requires change. Langley et al<sup>10</sup> describe the principles to maximize the results of improvement efforts:

- Knowing why you need to improve (focused aim).
- Having a feedback mechanism to tell you if improvements are occurring.
- Developing effective ideas for changes that will result in improvement.
- Testing and adapting changes before attempting to implement.
- Knowing when and how to make changes sustainable through effective implementation to integrate the changes in the system of interest.

Of course, science involves these considerations as well and puts emphasis on observable phenomena capable of being tested and potentially falsified (see later discussion). The philosopher Kemeny argued that the task of science is “to record facts and form theories to explain and predict observations.”<sup>11</sup>(p122) Central to this activity is the language we use to describe our observations and interventions (linking them to our theories) and the way in which we operationally define concepts so that we can have a shared understanding of the phenomena under study. Improvement (as defined earlier to include

implementation) and science are cut from the same epistemic cloth—one that focuses on testable assertions of reality—and recognizing this similarity is critical to appreciating what the science of improvement is.

### Science of improvement: background on use of the term

Langley et al was the first to use the phrase “the science of improvement” in the first edition of *The Improvement Guide* in 1996.<sup>10</sup> The term was used to build on W. Edward Deming’s System of Profound Knowledge<sup>9</sup> composed of the following 4 interrelated parts:

- **Appreciation for a system:** A focus on how the parts of a process relate to one another to create a system with a specific aim.
- **Understanding variation:** A distinction between variation that is an inherent part of the process and variation that is not typically part of the process or cause system.
- **Theory of knowledge:** A concern for how people’s view of what meaningful knowledge is impacts their learning and decision making (epistemology).
- **Psychology:** Understanding how the interpersonal and social structures impact performance of a system or process.

Within Deming’s System of Profound Knowledge, Langley et al<sup>10</sup> stressed 2 critical ideas that helped define the science of improvement. First was the idea that all improvement comes from developing, testing, and implementing changes. The role of measurement is to create feedback (learning) loops to gauge the impact of these changes over time as conditions vary in the environment. The second focus of the science of improvement is a recognition that the subject matter expert plays the lead role in developing changes and establishing the conditions for testing that increase the degree of belief that the changes will lead to improvement. But the science of improvement goes beyond the specific subject matter. Langley et al ask the following question:

The science of improvement is concerned with how knowledge of specific subject matter is

applied in diverse situations. How are improvements made in hospitals, in grocery stores, in manufacturing plants, in insurance companies, in churches, or in communities? Is each application so specific that only specialized knowledge and expertise can be useful?<sup>10(p xxiv)</sup>

The answer to this question is no. Effective changes must be informed by the experience, knowledge, and intuitions of subject matter experts who are closest to the problems, but to be most effective, these insights must be framed scientifically and tested. Indeed, framing the change ideas suggested by subject matter experts using a scientific approach in a real world context is the essence of the science of improvement and will maximize learning about the ideas. Recognizing that testing ideas is the key to science, one can begin to understand that the problems encountered in various fields may be different and vary in complexity, but that all meaningful solutions must pass through a testing and learning phase. The science of improvement recognizes that the standards of applied science are often more exacting than those of pure science. As Shewhart noted:

Both pure and applied sciences have gradually pushed further and further the requirements for accuracy and precision. However, applied science, particularly in the mass production of interchangeable parts, is even more exacting than pure science in certain matters of accuracy and precision.<sup>12(p120)</sup>

In this quote from Shewhart, we see a strong commitment to the “primacy of practice”—a core feature of the pragmatist thesis—and the necessity of linking any scientific principle to actual practice. Theory is still critically important to science, but its ultimate test is in a temporal reality. In other words, vague predictions and boundaries in the real world are of more value than the perceived precise boundaries in a purely theoretical world.<sup>13</sup>

It is possible that much of the confusion and debate surrounding the nature of the science of improvement stems from what Wittgenstein<sup>14</sup> called language traps as well as the failure to understand what science is. By examining and understanding

the basis of science, one can appreciate what the science of improvement is at a foundational level. A key point to stress here is that much of science, especially the applied sciences, has an eye on improving something, yet not all attempts at improving something are scientific. Furthermore, all other sciences focus on a better understanding and improvement of specific phenomenon that fall within the scope of their discipline (eg, molecular biology, aviation, food production, education), but the science of improvement is focused on how improvement is done in general.

The remainder of the paper describes 7 propositions (see Table 1), many grounded in the history and philosophy of science, which come together to inform the nature of the science of improvement. These propositions provide a scientific foundation for Deming's System of Profound Knowledge, and critical examination of them could lead to the development of stronger improvement programs and provide a foundation for the preparation of improvement scientists.

## SEVEN PROPOSITIONS

A comprehensive review of the 7 propositions outlined in Table 1 would take multiple volumes. So, for each proposition, we provide a brief

**Table 1**

### SEVEN PROPOSITIONS OF THE SCIENCE OF IMPROVEMENT

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1. The science of improvement is grounded in testing and learning cycles.
  2. The philosophical foundation of the science of improvement is conceptualistic pragmatism.
  3. The science of improvement embraces a combination of psychology and logic (ie, a weak form of "psychologism").
  4. The science of improvement considers the contexts of justification *and* discovery.
  5. The science of improvement requires the use of operational definitions.
  6. The science of improvement employs Shewhart's theory of cause systems.
  7. Systems theory directly informs the science of improvement.
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summary, teaching implications, and a more detailed discussion of the foundational ideas. We refer people to the bibliography of this article and the following Web site for additional readings related to the topics addressed in this article (<http://www.apiweb.org/Bibliography.htm>).

## PROPOSITION 1: THE SCIENCE OF IMPROVEMENT IS GROUNDED IN TESTING AND LEARNING CYCLES

### Brief summary

Proposition 1 leads to the justification of Plan-Do-Study-Act (PDSA) cycles as an approach that is aligned with the scientific method.

### What this means to someone applying or teaching improvement methods

A PDSA cycle reflects the scientific method by requiring that a prediction (hypothesis) is described, data is collected to test the prediction, and the analysis of the data is used to determine whether the prediction was correct or not, the results of which generates learning and forms the basis for the next cycle.

### The foundations

For some, the tendency exists to argue that quality improvement methods that utilize PDSA approaches result in, scientifically, a lesser way of knowing. For example, the lack of a comparison group or randomization in some PDSA cycles is cited as problematic.

The nature and definition of science has been debated for thousands of years and such debates continue today. Throughout these debates, there is general consensus that science involves a process of testing claims, assertions, and theories and predicting the outputs of tests. More generally, science involves testable assertions of reality. An important principle established in the 20th century was the *falsification principle*, outlined by the philosopher Karl Popper. Specifically, Popper<sup>15</sup> in 1959 noted that any claim that cannot be tested (and therefore falsified) is not

a scientific claim.\* Here the term falsification means that if something is false, then it can be demonstrated by experiment and observation to be false. In other words, all scientific claims must be testable, which implies the need for appropriate data and a theoretical frame.

Reaching further into the history of science, many believe the pioneer of the modern scientific method was a physicist named Ibn al-Haytham (965-1040). His *Book of Optics* (1021) is seen as being important to the establishment of experiments as the norm of proof in this field.<sup>17</sup> Al-Haytham's studies were based on experimental evidence that was systematic and repeatable over time. Interestingly, his basic method included the following:

1. Explicit statement of a problem, linked to observation and proof by experiment.
2. Testing and/or criticism of a hypothesis using experimentation.
3. Interpretation of data and formulation of a conclusion, based on mathematics.
4. The publication of the findings.

Replacing the word “publish” with “act on the new knowledge,” these 4 elements are almost identical to the PDSA cycle of Deming and Shewhart<sup>18</sup> and anticipate the pragmatic philosophy of Lewis (see proposition 2).

The history of science shows us that this cycle of systematic activity and inquiry is core to science and seems to recapitulate itself over epochs of time. From the science of Aristotle (384 BC-322 BC) to the scientific revolution (eg, Copernicus, Galileo, Newton), all the way to modern times from Koch's<sup>19</sup> postulates to

Campbell and Stanley's<sup>20</sup> framework of experimental and quasi-experimental design for research in the social and educational sciences, this learning cycle is apparent and well described.

In summary, the strong links between the history and philosophy of science and the development and evolution of testing and learning cycles that form one part of the science of improvement have been made before.<sup>21</sup> However, this link is worth emphasizing to those working in improvement because it reinforces the idea that science—particularly applied science—is about testing and learning and not about waiting long periods of time for the perfectly designed experiment.

## **PROPOSITION 2: THE PHILOSOPHICAL FOUNDATION OF THE SCIENCE OF IMPROVEMENT IS CONCEPTUALISTIC PRAGMATISM**

### **Brief summary**

Proposition 2 leads us to the importance of using prior and existing knowledge to form theories or develop changes and make predictions of what will happen as these changes are applied. Furthermore, it supports the use of Shewhart charts as a tool to measure existing system performance and to guide future prediction of system performance.

### **What this means to someone applying or teaching improvement methods**

Conceptualistic pragmatism states that everyone's observations are informed by their past experiences (conceptualistic). These experiences in turn are used to predict a range of possible futures that will be acted on (pragmatic). Extrapolating from this underlines the importance of being able to form theories from existing knowledge and then predicting what will happen as these theories are applied in the form of change concepts in the future. Studying data over time through Shewhart's control chart methodology and theory of variation is central to improvement methods and reflects the pragmatism of Lewis.

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\*It should be stressed that Popper believed that unfalsifiable claims were still important in science and that many scientific ideas and theories must develop from ill-defined origins that eventually must reach a point of maturity and clarity to be tested and understood. Critics of the falsification principle, most notably Kuhn,<sup>16</sup> point out that if every failure were grounds for theory rejection, then all theories ought to be rejected at all times. We recognize these debates but focus on the usefulness of the falsifiability principle in improvement work as a means of learning through testing over time and do not assign any negative connotation to the term and concept of falsification.

## The foundations

Pragmatism is a philosophical attempt to shift from a focus on what is “true” to what is “useful.” For improvers, it signals the need to develop theoretical or conceptual frameworks to describe what lies behind existing best or promising practices and to then use this framework as a way to predict what will happen when the framework is applied in the future. In other words, it supports the use of theories or concepts as the basis for future change and that local settings will use their own experiences to tailor changes to their settings rather than try to implement a list of detailed tasks that are assumed to be generalizable to all settings. It also compliments the focus on testing and learning that defines the PDSA process. As Berwick<sup>22</sup> observed, the concept of spread is best understood as local reinvention, not as implementation of a magic bullet.

All science rests on the foundation of philosophy. The modern science of improvement is informed by the principles of *conceptualistic pragmatism* as developed by Lewis,<sup>23</sup> who extended the pragmatist theses of Peirce<sup>24</sup> and James;<sup>25</sup> indeed, it is difficult to understand the science of improvement without understanding the work of Lewis and his impact on Shewhart and Deming.<sup>26,27</sup> It should be stressed that it is impossible to fully address the contribution of Lewis to philosophy and quality improvement in passing and that readers interested in a more comprehensive account of Lewis’ philosophy should consult his original works.<sup>23</sup> For a review of the role of Lewis’s influence on quality improvement, see Peterson<sup>27</sup> and Wilcox.<sup>28</sup>

Lewis argued that only an active being can have knowledge, and the principal function of empirical knowledge “is that of an instrument enabling transition from the actual present to a future which is desired and which the present is believed to signalize.”<sup>29(p4)</sup>

In other words everyone makes observations from a base of experiences *from existing mental models* where the goal is to predict a future we know is coming but which we can only predict in very rough terms. Lewis also believed that our existing or “a

priori” mental models could change on the basis of intention or a mismatch between our expectations and experience—and that the degree of mismatch could vary. This cognitive interpretation of pragmatism Lewis termed *conceptualistic pragmatism*, and it was this philosophical position that both Shewhart and Deming embraced.<sup>†27</sup>

The aforementioned quote by Lewis could very well be the official mantra of the science of improvement. Indeed, Shewhart’s<sup>30</sup> theory of variation and control chart method is an attempt to define the “actual present” in terms of process limits and parameters based on experience and understanding of a process. Shewhart’s use of 3-sigma to define the limits of control charts is based on both statistical theory and experience. For example, the baseline data in the Figure are generated from past experience that can provide an approximate limit for the range of all possible observations from that system in the future, but one cannot know *precisely* where the observations (data points) will end up, or if a special cause will occur (eg, a point beyond the upper or lower limit).

Similarly, Deming’s<sup>9</sup> System of Profound Knowledge has Shewhart’s theory of variation as a key component. Deming’s<sup>31</sup> distinction between enumerative studies (descriptive) and analytic studies (predictive) is yet another attempt to articulate, in a statistical context, the “actual present” to a future state that the present signals are coming but cannot be known for certain (see proposition 6).

In summarizing proposition 2, the philosophical foundation of the science of improvement is conceptualistic pragmatism and it is foundational to the concepts of testing and learning through PDSA cycles. Studying the ideas of Lewis is helpful in developing a deep understanding of the science of improvement.

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†Deming and Shewhart both read Lewis’ *Mind and the World Order* together as Deming edited Shewhart’s 1939 book. Therefore, the theories developed by Shewhart in his 1931 book *Economic Control of Quality of Manufactured Product* came without benefit of Lewis.

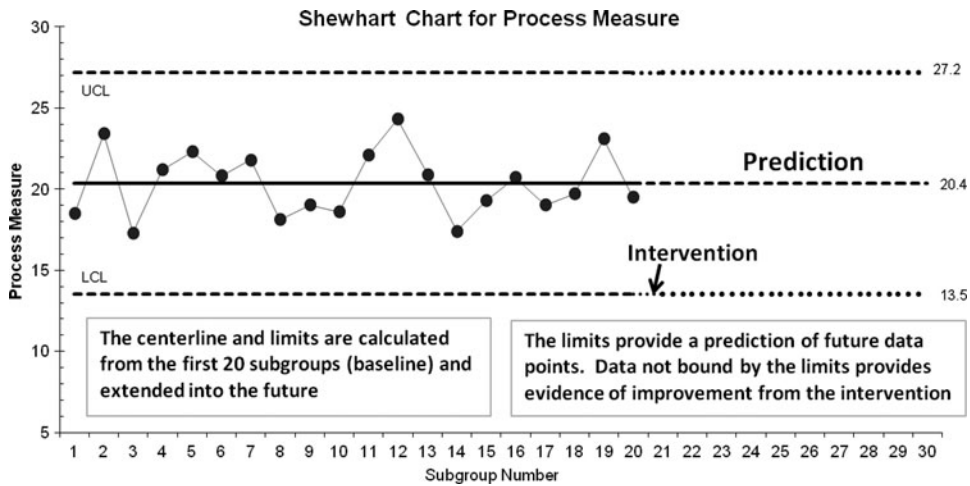


Figure. Use of Shewhart control chart for prediction.

**PROPOSITION 3: THE SCIENCE OF IMPROVEMENT EMBRACES A COMBINATION OF PSYCHOLOGY AND LOGIC (ie, A WEAK FORM OF “PSYCHOLOGISM”)**

**Brief summary**

Proposition 3 provides the basis for multidisciplinary collaboration and the value of addressing problems from different perspectives, which is one of the attributes of the System of Profound Knowledge. In particular, it underlines why it is important to use approaches from the social sciences in improvement methods and activities.

**What this means to someone applying or teaching improvement methods**

Psychologism is a view that acknowledges that both psychology and more formal ways of knowing (eg, analytical philosophy, logic, and mathematics) are important to understand human behavior and decision making. Historically, this idea was rejected by Western philosophers but is now considered a critical component to the science of improvement with its focus on understanding the multiple dimensions of thought and action.

**The foundations**

In simple terms, psychologism was an early precursor to multidisciplinary collaboration and thinking. If you were a proponent of psychologism, you would recognize the value of combining the study of psychology and philosophy or logic (hence the term *psychologism*). This was not always viewed as a good thing; in fact, psychologism was rejected as a sin by many Western philosophers such as Frege in favor of antipsychologism (see Table 2).

Psychology describes what inferences people do make, but logic is concerned with what inferences people should make. Similarly, epistemology is after only objective knowledge and truth—the kind of knowledge that is independent of individual belief systems. If there is no objective knowledge, then everything we think is relative to individuals, and no standards of thought (of how we should think and act) are possible. An epistemologist might ask whether this is the world you want to live in. From a health care perspective, do you want to go a hospital where the care you receive is based solely on a care provider’s belief system—and not on objective standards of knowledge and practice—standards of how providers should act and think in some situations, particularly situations where agreed upon clinical standards exist?<sup>34</sup>

Table 2

## DIFFERENT FORMS OF PSYCHOLOGISM

Psychologism is the epistemological view and position that knowledge is best understood through studying the cognitive structures and mechanisms that can be traced back to the empiricist John Locke and his concern for the limits of human understanding.<sup>32</sup> The main thesis of psychologism (as a way of knowing) incorporates the prescriptive aims and practices of philosophy and logic (ie, the types of inferences people should make) with the descriptive aims and practices of psychology (ie, the types of inferences people do make) in developing the most comprehensive and realistic views and models of knowledge, and in particular scientific knowledge.

There are different degrees or types of psychologism. The most useful model and description of the different types of psychologism is offered by Thagard<sup>33</sup> who, based on the work of Haack, defines 3 types of psychologism: weak psychologism, strong psychologism, and antipsychologism. Weak psychologism is the view that logic is prescriptive of mental processes. Strong psychologism is the view that logic is descriptive of how humans think, while antipsychologism is the view that logic has nothing to do with mental processes at all. Contemporary philosophers of science and cognitivists such as Thagard would not consider the latter approach tenable today. Thagard and others have convincingly argued that a weak version of psychologism is the epistemic framework of greatest potential because (a) it is a less extreme epistemology (compared to the strong and antipsychologism positions) and (b) it maximizes the gains that result from interdisciplinary collaboration (such as exposure to a wider and different range of concepts, theories, and views), while avoiding the charge of relativism.

Antipsychologism, championed by the likes of Husserl, Popper, and Frege, was a reaction against psychologism; it argued that philosophy and psychology should be kept separate and not combined or intermingled in the study of epistemology, for fear that the more descriptive (and less rigorous) claims and methods of psychology would dilute the formal logical rigor that defined 20th century Western philosophy.<sup>33</sup> As noted earlier, one of the major problems with accepting the descriptive epistemology of psychology, as argued by philosophers, was that it opened the door to relativism (the idea that all knowledge is relative and can change from person to person without an objective standard). On the surface, adopting the position of a strict antipsychologism might seem ideal to developing a standard-based world and care environment, but there happens to be one major problem with this position: people do not always act logically, nor is a “prescribed” logic necessarily conducive to innovative solutions to complex problems.

This problem with antipsychologism was recognized by philosophers, many of whom were quick to point out that in the real world we need to understand the psychology of behavior *and* logical forms of

thought—in other words, we need both, or what some have called the weak version of psychologism.<sup>35</sup> *Weak psychologism* says that logic can tell us how we should think, but it goes the additional step to determine whether our inferences are reasonable or normatively correct. This last step avoids the problem of all knowledge being subjective and relative. As Thagard points out “Knowledge is both private and public, inhabiting the brains of particular thinkers, but also subject to inter-subjective communication and assessment.”<sup>33(p8)</sup>

So, how does any of this relate to the science of improvement? First, the evidence-based care movement in health care has already embraced a weak version of psychologism by working to move the industry more toward objective standards of care and practice (recognizing there are things we should do consistently in specific care situations). The improvement movement is at the same time cultivating creativity, innovation, and problem solving (recognizing the psychology of change and that innovation does not always follow a formal calculus). These are not mutually exclusive positions, but rather necessary tensions—just as they are in the philosophy of science.



Second, from an improvement foundations perspective, weak psychologism supports Lewis' conceptualistic pragmatism and its focus on an individual actively constructing knowledge and Deming's System of Profound Knowledge. Because the System of Profound Knowledge fundamentally embraces psychologism, it opened the door to psychology and related disciplines that make up the science of improvement today. These include the psychology of change<sup>36-38</sup> and systems analysis.<sup>39,40</sup>

Third, today most people would recognize the most effective forms of inquiry and learning as multidisciplinary. Furthermore, as the fields of cognitive, educational, and social sciences have developed and are now considered requisite to understanding complex problems of industry and society, Deming's early acceptance of psychologism, through his System of Profound Knowledge, clearly positions him as an integrator of scientific disciplines.

#### **PROPOSITION 4: THE SCIENCE OF IMPROVEMENT CONSIDERS THE CONTEXTS OF JUSTIFICATION AND DISCOVERY**

##### **Brief summary**

Proposition 4 reinforces the idea that improvement efforts always involve an element of discovery and creativity in problem solving, but that these activities must be balanced by some form of justification such as using data to know if our tests of change worked, how well they worked, and what our next steps should be (eg, abandon the test, revise it, try it in another area).

##### **What this means to someone applying or teaching improvement methods**

The context of justification looks to answer the questions "what do we know" and "how do we know," while the context of discovery is focused on the processes of discovery and innovation, which are often more fluid and dynamic. Both justification and discovery are viewed as core (and complementary)

concepts in the science of improvement and its focus on rapidly testing ideas to determine if and to what degree they work.

##### **The foundations**

Once we allow for a weak version of psychologism as an epistemological frame of reference, we can explore the different contexts from which logic and psychology inform our work in health care and other fields. As mentioned in proposition 3, the term epistemology, as used by philosophers in a traditional sense, most often refers to the context of justification or the methods of rational reconstruction of knowledge that are *prescriptive* in that they dictate how *we should think*; the opposite (and complementary) side of this coin is the context of discovery, which was originally seen as a psychological concept and issue that is *descriptive* of how *we actually do think*, rarely with the 2 (intentionally) crossing intellectual paths.<sup>41</sup>

In developing his thesis in *Experience and Prediction*, Reichenbach,<sup>41</sup> who coined the expressions "context of discovery" and "context of justification," emphasized 2 important points. The first point was that the context of justification or rational reconstruction was never perfect and always subject to vagaries of human language and inexactitudes (hence the need for operational definitions). The second point was that scientific explorations and research often begin with certain choices (volitions), conventions, and heuristics that are not governed by logic as much as by axioms of choice. As Reichenbach points out:

Scientific method is not, in every step of its procedure, directed by the principle of validity; there are other steps that have the character of volitional decisions. It is this distinction which we must emphasize at the very beginning of epistemological investigations. That the idea of truth, or validity, has a directive influence in scientific thinking is obvious and has at all times been noticed by epistemologists. That there are certain elements of knowledge, however, which are not governed by the idea of truth, but which are due to volitional

resolutions, and though highly influencing the makeup of the whole system of knowledge, do not touch its truth character, is less known to philosophical investigators.<sup>41(p9)</sup>

Cronbach expresses a similar concern that science has largely discounted the context of discovery in favor of the context of justification:

“Design of experiments” has been a standard element in training for social scientists. This training has concentrated on formal tests of hypotheses—confirmatory studies—despite the fact that R. A. Fisher, the prime theorist of experimental design, demonstrated over and over again in his agricultural investigations that effective inquiry works back and forth between the heuristic and confirmatory. But since he could offer a formal theory only for the confirmatory studies, that part came to be taken for the whole.<sup>42(p25)</sup>

The fundamental contribution of the science of improvement is that it provides a scientific lens to bridge the context of discovery and human experience in the real world and the context of justification (using systematic methods and theories). Lewis, Shewhart, and Deming realized the gap between the context of discovery and experience and the context of justification—they were living in it, constantly trying to provide translations to each side (integrating and translating the disciplines). Deming hedged his bets in this complex zone of optimal learning and recognized that a multidimensional approach was needed to make sense of this space (hence his focus on a System of Profound Knowledge and the integration of different disciplines). The conceptual mistake people make is to think that the “rigorous” context of justification is “real science.” The real challenge is in the space and interplay between each context—between the knowledge, hunch, or intuition of the subject matter expert and the tests and methods that will guide their learning of a system. To argue that real science is restricted to the context of discovery only is to minimize the role of human experience and discovery in any form of exploration and learning. In-

tegration of these contexts is present today in health care research, as evidenced by the use of adaptive trials that use accumulating data to decide on how to modify aspects of the study as it continues without undermining the validity and integrity of the trial.<sup>43</sup> In the broadest sense, all improvement projects are types of adaptive trials.

In summary, improvers must always recognize if they are in the “justification” phase of work or the “creative and discovery” phase. Confusing these 2 phases can inhibit the creativity needed to solve problems or minimize the importance of data and measurement. It also reminds us that there is usually no single magic bullet solution to a problem and that the cycle of discovery and justification is best viewed as an iterative (and continuous) process, which is exactly what the PDSA cycle provides.

## **PROPOSITION 5: THE SCIENCE OF IMPROVEMENT REQUIRES THE USE OF OPERATIONAL DEFINITIONS**

### **Brief summary**

Proposition 5 stresses the need for improvers to develop clear and consistent definitions of the terms they use and to take care that others involved in improvement understand these definitions so they can have a shared understanding.

### **What this means to someone applying or teaching improvement methods**

Operational definitions are the only way to develop a shared meaning and understanding of concepts, ideas, goals, and measures. Without operational definitions, the meaning and intent of actions and words are known only by the individuals who use them. What exactly does it mean to be “better,” “more efficient,” “safer,” “cost efficient,” etc? Effective communication and collective action require that everyone is on the same page and operational definitions are designed to minimize confusion and move people toward shared understanding.

## The foundations

Deming believed operational definitions were so important to quality improvement that he dedicated an entire chapter to them in *Out of the Crisis* (Chapter 9). He defined an operational definition in the following terms:

An operational definition puts communicable meaning into a concept. Adjectives like good, reliable, uniform, round, tired, safe, unsafe, unemployed have no communicable meaning until they are expressed in operational terms of sampling, test, and criterion. The concept of a definition is ineffable: It cannot be communicated to someone else.<sup>44(p277)</sup>

This definition makes it clear that no 2 people could be assured a shared meaning of a concept by name alone and that a shared understanding of a concept must be expressed in the form of operational criteria. Although Deming introduced the use of operational definitions to improvement work, he was influenced by P. W. Bridgman, who established the use of operational definitions in physics (in the face of the revolution and theoretical crisis in physics during the early 20th century). Bridgman's philosophical orientation was toward operationalism and empiricism. According to the Stanford Encyclopedia of Philosophy, operationalism:

is based on the intuition that we do not know the meaning of a concept unless we have a method of measurement for it. It is commonly considered a theory of meaning which states that "we mean by any concept nothing more than a set of operations; the concept is synonymous with the corresponding set of operations."<sup>45(p5)</sup>

Operationalism provides further support to a pragmatic theory of knowledge and underpins a focus on prediction. As Towns points out, "scientific propositions are, roughly speaking, predictions and a prediction is an if-then proposition: If certain operations are performed, then certain phenomena having determinate properties will be observed."<sup>46(p2)</sup>

Although strict operationalism is considered an outmoded and extreme position today, Bridgman emphasized that clarity of language and meaning was critical to all who engaged in science. Deming would take this basic idea and frame it as a foundational and key functional element of management and the improvement of quality. Here again, we see Deming serving as master integrator between disciplines by borrowing an idea from physics (operationalism) and grafting it into the burgeoning science of improvement (in the form of an operational definition). Operational definitions are today a bedrock principle in the science of improvement, but the degree to which their importance is recognized as such is questionable. Indeed, as Towns notes:

Deming bemoaned the fact that one is more likely to learn about operational definitions and operationalism "in colleges of liberal arts, in courses in philosophy and theory of knowledge, but hardly ever in schools of business or engineering in the United States."<sup>46(p2)</sup>

## PROPOSITION 6: THE SCIENCE OF IMPROVEMENT EMPLOYS SHEWHART'S THEORY OF CAUSE SYSTEMS

### Brief summary

Understanding variation here means using tools (Shewhart charts) to understand whether a process is stable and to distinguish between special and common cause variation.

### What this means to someone applying or teaching improvement methods

Shewhart's control chart method is more than an applied statistical tool—it is a theory of variation. Its focus is on learning whether a process is stable and can be used to determine whether the changes we make to a system result in improvement. The idea of a chance-cause system says that a process will behave within certain normal (random) limits based on the

system. Failure to recognize this leads to the risk of tampering with a stable system, the effect of which is often increased variation and poorer performance.

### The foundations

The control chart was introduced at Western Electric by Walter Shewhart in 1924 and described in his 1931 book *Economic Control of Quality Manufactured Product*. The control chart is not simply a statistical stool but rather is grounded in a pragmatic philosophy that helps people distinguish between 2 types of variation: common or special cause variation. Distinguishing between these 2 basic types of variation has significant implications on decision making. Shewhart's focus was on the processes and systems that produced observable data. When a process displays common cause variation then its behavior is not discernible from a random or "chance" cause system and, as Deming points out, it makes little sense to try and determine the cause of any individual observation because the observations from a stable process will fluctuate naturally (eg, like flipping a coin). However, when a process displays special cause variation, it is economical to try and identify and remove the cause of this variation, which is markedly different from what would be expected by the random or chance process. Shewhart originally referred to these special causes as "assignable" because they were so different from what was expected to occur there must be a reason beyond chance for their appearance (note the distinction between a specific reason and chance occurrence as the distinguishing feature of variation). Shewhart charts are therefore tools for understanding the behavior of a process and to guide appropriate actions—to look for assignable causes when the data display special causes (or unpredictable variation) and to avoid looking for assignable causes when the process produces only common causes and is stable (producing only common cause or chance variation).

Of course, in this system, there are 2 specific mistakes one can make. As Nave and Wheeler point out:

The first mistake is to attribute an outcome to an assignable cause when it is simply the result

of common causes. The second mistake is to attribute an outcome to common causes when it is, in truth, the result of an assignable cause. It is impossible to avoid both of these mistakes. So this cannot be the objective. Instead, a realistic objective is *to minimize the overall economic loss* from making these two mistakes. To this end, Shewhart created the control chart with three-sigma limits. Shewhart's use of three-sigma limits, as opposed to any other multiple of sigma, did not stem from any specific mathematical computation. Rather, Shewhart said that 3.0 "seems to be an acceptable economic value," and that the choice of 3.0 was justified by "empirical evidence that it works." This pragmatic approach is markedly different from the more strictly mathematical approach commonly seen in the journals today. In fact, in order to have a practical and sensible approach to the construction of control charts, Shewhart deliberately avoided overdoing the mathematical detail.<sup>47(p2)</sup>

Shewhart charts are therefore used to determine if we are dealing with a well-defined and predictable process, where the past can predict the future within certain limits, or with a highly unpredictable process where the past gives little insight into future performance (Figure).

As Shewhart notes:

*a phenomenon will be said to be in control when, through the use of past experience, we can predict, at least within limits, how the phenomenon may be expected to vary in the future. Here it is understood that the prediction within limits means that we can state, at least approximately, the probability that the observed phenomenon will fall within given limits...*<sup>30(p6)</sup> (emphasis in original)

The idea that future performance can be predicted within limits sends a clear signal about the ontological view that Shewhart embraced: "We are not concerned with the functional form of the universe, but merely with the assumption that a universe exists." In other words, the goal in Shewhart's applied theory of variation is not to identify a precise model to

describe the process in question but rather to determine whether the process in question fits a general model of random (chance cause) behavior. In Shewhart’s theory, we can see a consistency of thought with Lewis’ pragmatism and its concern for using existing performance to predict future performance within certain limits.

The ability for management and those engaged in improvement work to recognize this specific and fundamental view of process behavior and variation is critical to effective decision making and quality improvement, and it sits at the heart of the science of improvement. Table 3 summarizes the appropriate management response to common and special cause variation.

**PROPOSITION 7: SYSTEMS THEORY DIRECTLY INFORMS THE SCIENCE OF IMPROVEMENT**

**Brief summary**

Proposition 7 provides the basis for the component of Profound Knowledge that Deming called *Appreciation for a system*. Systems thinking means viewing an organization as dynamic, adaptive to the needs of the customer, and composed of interdependent people, departments, equipment, facilities, processes, and products, all working toward a common purpose. The science of improvement is not being applied until systems thinking is incorporated into improvement methods and activities.

**What this means to someone applying or teaching improvement methods**

The language, thought processes, and methods of systems theory must be understood to lead improvement. Systems thinking combined with the pragmatism of proposition 2 and Shewhart’s theory of variation in proposition 3 leads to Deming’s concept of analytic studies.<sup>31,48</sup> Most methods of analysis and approaches to learning dissect a problem into pieces that can be understood and acted upon. But system thinking provides a focus on how the components relate to one another as a whole to create a system. Systems thinking is not a natural act and is not emphasized in our educational institutions. So, becoming comfortable with system thinking is necessary to keep the focus on how the parts of a system are connected, rather than just the performance of the parts.

**The foundations**

General Systems Theory<sup>39</sup> evolved in the early 1900s as existing analytic methods in a variety of the sciences proved inadequate to solve the complex problems arising as new technologies were introduced. Systems theory provided a unifying framework for the individual sciences as well as an overall framework applying to all disciplines. The aim of the theory was to apply conceptions, viewpoints, and mathematics (calculus, information theory, cybernetics, stochastic models, operations research, etc) to develop principles that

**Table 3**

APPROPRIATE MANAGEMENT RESPONSE TO COMMON AND SPECIAL CAUSE VARIATION

	<b>If the process is stable:</b>	<b>If the process is not stable:</b>
<i>Type of variation:</i>	Only Common	Special + Common
<i>Appropriate choice:</i>	Change the process	Investigate the origin of special cause
<i>Inappropriate choice:</i>	Treat normal variation as special cause (tampering)	Change the process
<i>Consequences of making the inappropriate choice:</i>	Increased variation	Wasted resources, complex learning

apply in general to all systems or classes of systems. An important classification is open and closed systems.

A closed system is often used in the physical sciences while the social sciences usually consider open systems. A closed system does not exchange any matter with its surroundings and is not subject to forces external to the system. An open system is one that can exchange material, energy, people, or knowledge with its environment or other systems. An open system can reach a steady state in different ways, and the state can be disrupted by the external environment. In improvement work, the focus is usually on social systems (an organization or group of work processes), which are always open systems that can change state and grow.

Change is fundamental to improvement and there are 2 basic types of change. First-order change occurs within a given system and the system remains the same. The occurrence of second-order change modifies the system. First-order changes are routine actions required to keep the organization running day to day, while second-order changes are required to improve the system. Changing the boundaries of the system is one example of a second-order change.

Ackoff<sup>49</sup> provided many of the practical applications of systems theory to improvement. Deming<sup>9</sup> focused his work on social systems and defined a system as a network of interdependent components that work together to try and accomplish the aim of the system. So, a system must have both an aim (purpose) and interdependence of its components. Management's job is to understand and manage the important interdependencies. Drucker<sup>50</sup> identified system thinking as one of the keys to understanding manufacturing organizations.

Given Deming's definition of a system, performance, or outcome measures becomes a property of a system. From Shewhart's theory of variation, if a system is stable, the performance is predictable. The performance is determined by the design of the system, and systems are perfectly designed to achieve the results they get. The infection rate for patients in a hospital is a property of the system(s) that have been designed or have evolved. If we are not satisfied

with the current infection rate, changing this system provides the mechanism to change the result.

Senge<sup>51</sup> popularized the use of "system archetypes" to gain insight into patterns of behavior from the underlying structure of the system being studied. The archetypes can be used to diagnose existing systems or predict the performance from proposed changes to a system. When we come to see that performance features are system properties, we come to realize that most problems in organizations do not come from individual workers.<sup>52</sup> They come from the structure of the systems themselves (policies, processes, organization structures, operating rules, culture), and people are only one of the parts of these systems. Because of the interdependence of the parts, cooperation follows as a key to improving performance. The system aim provides the focal point for this cooperation.

Learning about the performance of a system can be difficult and slow. The detailed and dynamic complexity of a system makes it difficult to discover the delayed impacts of interventions and their unintended consequences. In the 1950s, Forrester<sup>40</sup> developed a systems modeling methodology that he called systems dynamics. Using his methods, it became possible to explore systems with feedback loops and nonlinear interactions. Forrester pointed out that very often the existence of a dozen or so feedback loops created results, which were completely counterintuitive. Sometimes you got the opposite of what you intended (unintended consequences). A system dynamics model consists of a set of 10s or even 100s of differential and algebraic equations developed from an understanding of system interactions and calibrated with data from existing systems. Many complex challenges in improvement can be addressed with these methods, which involves development of causal diagrams and policy-oriented computer simulation models. A central principle of system dynamics is that the complex behaviors of social systems are the result of ongoing accumulations with both balancing and reinforcing feedback mechanisms. System dynamics allows different changes to the modeled systems to be tested

to understand the emerging outcomes and why these outcomes are obtained.

Systems theory is the basis for how the science of improvement engages the multidimensional complexity of improvement in a wide range of environments and situations over time. The complexity of different systems will certainly vary, but without approaching improvement from a systems perspective meaningful and sustainable change may be not possible.

## HEALTH CARE AND THE SCIENCE OF IMPROVEMENT

These 7 propositions are applicable as improvement principles to any field or discipline. The health care industry has generally embraced improvement as a core operating principle as a way to create or redesign a health care system that leads to improved care, lower costs, and better health of the population. Furthermore, the sacred relationship between patients and care providers makes continuously improving health systems a moral imperative, one requiring both knowledge of improvement and a fundamental desire to help others.

But we know improvement and change are not easy, especially second-order system changes. Changes in complex settings, such as health care, are often met with resistance and skepticism. In some situations, a negative test result is interpreted as a failure, not as information to guide the next test. In addition to knowledge of improvement science, successful improvers themselves need to embrace change, work effectively with difficult people and stakeholders, maneuver sensitive situations, keep teams focused and motivated, and interact with different levels of leadership. In health care, knowledge of improvement science is often seen as a way to drive the moral imperative to help others—in other words, knowledge of improvement science is a means to an end, not the end itself. Recognizing this aspect of improvement can help people persist during challenging times during the course of a project or initiative. As noted earlier, epistemology (nature of knowledge)

is central to the issues and debates around quality improvement, as well as representing 1 of the 4 pillars of Profound Knowledge. But epistemology is also linked to another branch of philosophy—ethics (also known as moral philosophy). Ethics involves identifying, defending, and recommending concepts of right and wrong behavior. It comes from the Greek word “ethos,” which means “character.” So, what is the character of the science of improvement as applied to health care? Is it important? Some will argue improvement is not about what is right or wrong, but is it right or wrong for surgeons not to wash their hands, for a patient to develop a stage 4 hospital-acquired pressure ulcer, for a health system to reward volume over value, or for leaders not to address deficiencies in patient safety? In many cases, especially in health care, there is a need to improve because improved systems are directly linked to safety through direct human contact and touch. In health care improvement, this dimension is rarely characterized under the rubric of ethics, but the tools of the science of improvement as they are applied to better patient outcomes, more efficient care, access to care, patient and family engagement, harm reduction and joy in work, are driven by a certain type of character and underlying motivation and energy to do what is right for people. Failure to explicitly link improvement science to its “fundamental character” makes it too easy to get lost in a sea of methods with no fundamental grounding. As Donabedian noted in a final interview before his death:

Systems awareness and systems design are important for health professionals but are not enough. They are enabling mechanisms only. It is the ethical dimension of individuals that is essential to a system’s success. Ultimately, the secret of quality is love. You have to love your patient, you have to love your profession, you have to love your God. If you have love, you can then work backward to monitor and improve the system.<sup>53(p140)</sup>

In health care, perhaps it is a shared ethic that brings people together to want to improve a system in the first place, and this coupled with knowledge of

the science of improvement can be a transformative combination.

## SUMMARY

In this article, we identified the history of the phrase “science of improvement.” We explored and outlined 7 philosophically based propositions that underpin Deming’s System of Profound Knowledge and the science of improvement. Those engaged in the science of improvement would benefit by examining these propositions to develop their knowledge bases. This is needed to both advance the field and minimize confusion about what the science of improvement actually is. Advanced practitioners of improvement are those who, like Deming and Shewhart, are able to integrate complex ideas, concepts, and models between scientific disciplines for the purpose of developing more robust improvement models, tools, and techniques where the focus is on application and problem solving in real world contexts. Finally, we addressed the idea that knowledge of the science of improvement in health care is best served by linking this knowledge to the underlying motivation of health care professionals to help others.

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## REFERENCES

1. Marshall M, Pronovost P, Dixon-Woods M. Promotion of improvement as a science. *The Lancet*. 2013;381(9864):419-421.
2. Health Foundation. *Improvement Science*. Research scan prepared by the Evidence Centre on behalf of the Health Foundation. [http://www.health.org.uk/public/cms/75/76/3763/2498/Research%20scan\\_Improvement%20science.pdf?realName=tYPIOS.pdf](http://www.health.org.uk/public/cms/75/76/3763/2498/Research%20scan_Improvement%20science.pdf?realName=tYPIOS.pdf). Published January 2011. Accessed August 2, 2011.
3. Berwick DM. The science of improvement. *JAMA*. 2008;299(10):1182-1184.
4. Clancy CM, Berwick DM. The science of safety improvement: learning while doing. *Ann Intern Med*. 2011;154(10):699-701.
5. Shekelle PG, Pronovost PJ, Wachter RM, et al. Advancing the science of patient safety. *Ann Intern Med*. 2011;154(10):693-696.
6. Curtis JR, Levy MM. Improving the science and politics of quality improvement. *JAMA*. 2011;305(4):363-372.
7. Goldmann D. Ten tips for incorporating scientific quality improvement into everyday work. *BMJ Qual Saf*. 2011;20(suppl 1):i69-i72.
8. May C. Toward a general theory of implementation. *Implementation Sci*. 2013;8:18.
9. Deming WE. *The New Economics for Industry, Government, Education*. 2nd ed. Boston, MA: MIT Press; 1994.
10. Langley GL, Moen R, Nolan KM, Nolan TW, Norman CL, Provost LP. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance*. San Francisco, CA: Jossey-Bass Publishers; 1996.
11. Kemeny JG. *A Philosopher Looks at Science*. Princeton, NJ: D. Van Nostrand Company, Inc; 1959.
12. Shewhart WA. *Statistical Method from the Viewpoint of Quality Control* [The Graduate School, Department of Agriculture, Washington DC, 1939]. Mineola, NY: Dover Publications; 1986.
13. Helmer-Hirschberg O, Rescher NH. On the epistemology of the inexact sciences (Rand Corporation Document No. R-353). <http://www.rand.org/pubs/reports/R353/>. Published 1960. Accessed November 24, 2008.
14. Wittgenstein L. *Philosophical Investigations*. New York, NY: Macmillan Company; 1965.
15. Popper K. *The Logic of Scientific Discovery*. English ed. Oxford, UK: Routledge; 2002. Originally published in 1959.
16. Kuhn TS. *The Structure of Scientific Revolutions*. Chicago, IL: University of Chicago Press; 1962.
17. Gorini R. *Al-Haytham the Man of Experience. First Steps in the Science of Vision*. Rome, Italy: International Society for the History of Islamic Medicine, Institute of Neurosciences, Laboratory of Psychobiology and Psychopharmacology; 2003.
18. Moen RD, Norman CL. Circling back: clearing up myths about the Deming cycle and seeing how it keeps evolving. *Qual Prog*. 2010;2010:22-28.
19. Koch R. An address on bacteriological research. Delivered before the international medical congress held in Berlin. *BMJ*. 1890;2:380-383.
20. Campbell DT, Stanley JC. *Experimental and Quasi-experimental Designs for Research*. Boston, MA: Houghton Mifflin; 1963.
21. Moen RD, Norman CL. Evolution of the PDSA cycle. Paper presented at: the 7th ANQ Congress; 2009; Tokyo, Japan.
22. Berwick DM. Disseminating innovations in healthcare. *JAMA*. 2003;289(15):1969-1975.
23. Lewis CI. *Mind and the World Order: Outline of a Theory of Knowledge*. Mineola, NY: Dover Publications; 1929.
24. Peirce CS. How to make our ideas clear. *Popular Sci Mon*. 1878;12:286-302.
25. James W. *Pragmatism: A New Name for Some Old Ways of Thinking*. Cambridge, MA: Harvard University Press; 1975. Originally published in 1907.
26. Strickland R. C. I. Lewis and Deming’s theory of knowledge. *Qual Manag Health Care*. 1995;3(3):40-49.
27. Peterson GT. The influence of C. I. Lewis on Shewhart and Deming. <http://www.learningsociety.org.uk/documents/CILewisShewhartandDemingbyGTPeterson.pdf>. Published 1998. Accessed July 29, 2011.



28. Wilcox M. Prediction and pragmatism in Shewhart's theory of statistical control. *J Manag Hist.* 2004;42(1/2):152-165.
29. Lewis CI. *An Analysis of Knowledge and Valuation.* La Salle, IL: Open Court; 1946.
30. Shewhart WA. *The Economic Control of Quality of Manufactured Product.* New York, NY: D Van Nostrand; 1931.
31. Deming WE. On probability as a basis for action. *Am Statistician.* 1975;29(4):146-152.
32. Locke J. *An Essay Concerning Human Understanding.* Abridged Version. Winkler K, ed. Indianapolis, IN: Hackett Publishing; 1996. Originally published in 1690.
33. Thagard P. *Computational Philosophy of Science.* Cambridge, MA: MIT Press; 1988.
34. Perla RJ, Parry GJ. The epistemology of quality improvement: it's all Greek. *BMJ Qual Saf.* 2011;20(suppl. 1):i24-i27.
35. Haack S. *Philosophy of Logics.* Cambridge, UK: Cambridge University Press; 1978.
36. Weisbord MR. *Productive Workplaces Revisited* (Chapters 3: Lewin: the Practical Theorist; Chapter 4: The Learning Organization: Lewin's Legacy to Management); San Francisco, CA: John Wiley & Sons/Jossey-Bass; 2004.
37. Trist E, Trist B, Murray H. *The Social Engagement of Social Science: A Tavistock Anthology: The Socio-Ecological Perspective (Tavistock Anthology).* Philadelphia, PA: University of Pennsylvania Press; 1997.
38. Herzberg F. *The Motivation to Work.* New York, NY: John Wiley & Sons; 1959.
39. Von Bertalanffy L. *General System Theory: Foundations, Development, Applications.* Rev ed. New York, NY: George Braziller; 1968.
40. Forrester J. *Principles of Systems.* Cambridge, MA: Productivity Press; 1986.
41. Reichenbach H. *Experience and Prediction.* Chicago, IL: University of Chicago Press; 1938.
42. Lincoln YS, Guba G. *Naturalistic Inquiry.* Thousand Oak, CA: Sage; 1985.
43. Gallo P, Chuang-Stein C, Dragalin V, et al., Adaptive designs in clinical drug development: an executive summary of the PhRMA working group. *J Biopharm Stat.* 2006;16:275-283.
44. Deming WE. *Out of the Crisis.* Cambridge, MA: MIT; 2000.
45. Bridgman PW. *The Logic of Modern Physics.* New York, NY: Macmillan; 1927.
46. Towns WC. Deming as pragmatist. Paper presented at: the Annual Fall Conference of the W. Edwards Deming Institute; October 11-12, 1997; Fordham University, New York, NY.
47. Neave HR, Wheeler DJ. *Shewhart Charts and the Probability Approach.* Knoxville, TN: SPC Press; 1996. [http://www.iienet.org/uploadedfiles/iie/Education/Six\\_Sigma\\_Green\\_Belt\\_Transition/Shewhart%20and%20Variation.pdf](http://www.iienet.org/uploadedfiles/iie/Education/Six_Sigma_Green_Belt_Transition/Shewhart%20and%20Variation.pdf). Accessed February 28, 2012.
48. Provost LP. Analytical studies: a framework for quality improvement design and analysis. *BMJ Qual Saf.* 2011;20(suppl 1):i92-i96.
49. Ackoff RL. *Creating the Corporate Future.* New York, NY: John Wiley & Sons; 1981.
50. Drucker PF. The emerging theory of manufacturing. *Harv Bus Rev.* 1990;3:94-102.
51. Senge PM. *The Fifth Discipline.* New York, NY: Currency Doubleday; 1990:170-171.
52. Weisbord MR. *Productive Workplaces.* San Francisco, CA: Jossey-Bass; 1987.
53. Mullen F. A founder of quality assessment encounters a troubled system firsthand. *Health Aff.* 2001;20(1):137-141.