### **Quality Improvement's 3 Premises**

W. Edwards Deming, a physicist and statistician born in 1900, is the father of quality improvement theory. He called his approach "a theory of profound knowledge." It includes 4 main elements:

- *Appreciation for a system* "systems thinking" describes how processes interact together to form systems.
- *Knowledge about variation* methods to separate signal from noise in measured results.
- *A theory of knowledge* tools for "data-based problem solving," and formal methods to reliably learn from experience.
- Understanding of psychology how humans interact and respond in work settings, an essential element for change leadership.

Any organized system of rational thought – a comprehensive theory – has a starting point. That starting point often takes the form of a set of initial premises, or axioms. An axiom is "a statement that is regarded as established, accepted, or self-evidently true." Initial axioms form a foundation. A series of proofs build up from that foundation, creating the system of rational thought. In mathematics, for example, a simple set of initial axioms leads to set theory, group theory, arithmetic, algebra, trigonometry, and finally the calculus, with its many subfields.

Deming's Theory of Profound Knowledge rests upon 3 axiomatic premises. Each has one or more derivative implications. The following paragraphs lay out those 3 fundamental premises with some of their most important implications.

#### Premise 1: All productive work happens through processes.

#### A "process" is

#### a series of linked steps, often but not necessarily sequential, designed to cause some set of outcomes to occur, to transform inputs into outputs (a change of state), to produce useful information, or in some other way add value.

Deming argued that the idea of "process" can describe any productive effort that humans undertake. For example, there are definable processes for changing the oil in a car, making burgers at a fast food restaurant, preparing a tax return, writing an academic paper, treating Type II diabetes mellitus, or performing a heart transplant operation. Processes are building blocks that, combined together, form systems. Deming's concept of process provides an effective, general infrastructure for designing, managing, analyzing, and systematically improving complex systems that produce useful results.

#### Technically, quality improvement is the science of process management.

In 1911, Frederick Taylor published *Principles of Scientific Management*.<sup>1</sup> That book broadly popularized standardized mass assembly production.<sup>a</sup> It represented the first wide-scale application of process

<sup>&</sup>lt;sup>a</sup> The idea of standardized mass assembly production was not new. For example, from the early 1100s to the late 1700s, the Venetian Arsenal used standardize mass assembly methods to build the ships that drove Venice's maritime power and economic success (ref: Wikipedia). In 1801, Eli Whitney, who had earlier invented the cotton

management theory in the modern era. Rapid uptake of standardized mass assembly production massively changed human society. Quality of goods and services improved. Not only did things work better, they failed less often. When things did fail, it took less time, effort, and resources to fix or replace them. The amount of human effort required to produce products and services dropped dramatically. As productivity increased, some of the resulting wealth found its way to workers' salaries. That created a swelling population with sufficient income to purchase the better, cheaper, products and services that Taylor's new approach created. Taylor is credited with creating society's middle class, and the economic engine upon which the modern world's prosperity rests.<sup>2</sup>

Beginning in the 1920s, Walter Shewhart developed statistical methods that greatly improved the efficiency and effectiveness of Taylor's approach.<sup>3,4</sup> Shewhart's contributions included statistical process control (SPC), a reliable method to separate signal from noise when measuring and managing front-line production. Shewhart also created and championed Plan-Do-Study-Act (PDSA) cycles. PDSA cycles allowed factory workers, often intelligent but usually with limited formal education, to apply scientific hypothesis testing to solve common front-line operations problems.

Deming generalized and extended Shewhart's work into a full process management system. He first applied it to mass assembly production during the 1930s and 1940s in the United States. He introduced his methods in Japan at the end of World War II, as Japanese manufacturing industries rebuilt from the devastation of the War.<sup>5</sup> Over the next 2 decades, that positioned Japan as a world-class economic competitor. During the 1980s and 1990s, Japanese competition forced American and European manufacturing industries back to Deming's concepts, which they had largely abandoned at the end of World War II.<sup>6,7,8</sup>

One key element in Deming's quality improvement theory applied a structured, data-based approach to understand and define operational problems, then applied Shewhart's PDSA method to test and prove possible solutions. Together, those are the tools that make up "data-based problem solving."

The idea that "all work is process-based" has an important direct implication. Deming's reasoning went like this:

- a) The core aim of any good organization is to satisfy customers. To the extent that customers have a choice of where to go for a product or service, and they choose a particular company to fill their need, then that company has succeeded. Such a company does not think of the payments it receives as "money." Instead, it thinks of them as the best measure of customer satisfaction ever conceived.
- b) The way that an organization satisfies customers is through products and services.
- c) It produces those products and services through "front line work processes."

gin, used a related method based on "interchangeable parts" to fill a contract for 10,000 muskets to the U.S. government (Encyclopedia Britannica).

#### d) Therefore, Deming argued

(Implication 1a)

# Any enterprise should organize literally *everything* around value-added front-line work processes, where "value-added" is defined by the organization's customers.

Deming called an organization structured upon this principle a "System of Production."

Process tools can model everything that happens in health care. From this vantage, care delivery is thousands of processes organized in complex interacting systems.

What form might a health care delivery system take, if it were designed as a System of Production? We will address that concept, in detail, in a later chapter. It will describe an optimal care delivery system that is radically different from almost all current care delivery organizations.

#### Premise 2: <u>All processes produce 3 parallel classes of outcomes</u>:

- (1) A "physical outcome" is the product, service, or experience that the process was designed to create. For clinical care delivery, "physical outcomes" are "clinical outcomes."
- (2) Every process also produces a "service outcome." Service describes the interaction between a producer and a consumer as a transaction takes place. In health care, it is "patient experience of care."
- (3) Deming's unique contribution to process theory had to do with inputs the buildings, equipment, raw materials, labor, management, marketing, and other expenses that any process consumes to create and deliver its physical and service outcomes. Deming analyzed process-associated resource consumption not as inputs, but as a "cost outcome."

Within formal quality theory, the term **"quality"** describes

#### the attributes and features of an outcome, regardless of its class.

For example, a clinical process scientist might address the quality of clinical outcomes, the quality of the patient care experience, or the quality of associated cost outcomes. "Quality" covers a continuum, ranging from negative attributes or performance up through positive attributes or performance. When used non-specifically in health care settings, the term "quality" usually means the positive aspects of a physical or service outcome. In such uses, context identifies the clinical or service outcomes subclass.

Figure 1 represents a fundamental truth that arises from this view of production. All operational change takes place at the level of process.



**Figure 1.** All processes produce 3 parallel sets of outcomes. Change always happens at the process level. That implies that any proposed change will simultaneously and unavoidably affect all 3 sets of outcomes.

(Implication 2a) Therefore,

#### any change made to modify one of the three classes of outcomes will necessarily also modify the other two outcome classes.

For example, imagine that a physician changes a care delivery process with an aim to improve a patient's clinical outcome. That will unavoidably affect the process's cost outcomes. The effect on costs could be large or small. It could be positive or negative. However, it *will* occur. Similarly a hospital administrator might adjust a process with an aim to reduce associated costs of operations. Unavoidably, that change will affect the process's clinical outcomes. The impact on clinical results could be large or small, it could be positive or negative, but it will always be present.

Deming spent much of his career studying how physical outcomes and cost outcomes interact. He identified a series of causal mechanisms that cover the full possible range of all such interactions. For some of those mechanisms, process changes designed primarily to improve physical outcomes, *cause* costs to fall. He labelled those specific circumstances "waste."

Within quality theory, "quality-associated waste" means

those circumstances in which process changes that produce better physical outcomes (higher quality), or hold physical outcomes stable (equivalent quality) <u>cause</u> operating costs to fall. Quality-associated waste contains 2 specific process-level causal mechanisms:

- (1) "Quality waste"<sup>b</sup> always starts with the failure of a process step. Some percentage of the time not necessarily all the time the process failure leads to a quality outcome failure. Deming noted that there are only 2 ways to address an outcome failure. The process operator could simply discard the faulty result (called "scrap" in the manufacturing literature) and start over. All of the material, time, and processing consumed to create the original, unusable product are wasted. Alternatively, the process operator could repair the faulty result ("rework"). But the repairs themselves consume additional resources. That means that the total cost to produce a usable final product goes up.
- (2) "Inefficiency waste" applies in those circumstances where quality (the physical outcomes) hold stable, but operating costs decrease. Imagine 2 processes, operating side by side. Both take identical inputs, and produce identical outputs. One uses substantially fewer resources to effect that transformation. In other words, it is more efficient in producing the desired outcome – the source of this category's name. Which one should you use?

To the extent that the term "quality" is commonly used to describe the features and attributes of physical outcomes, Deming demonstrated that

(Implication 2b)

#### quality controls cost.

More precisely, physical outcomes (traditional "quality") and cost outcomes are two sides of the same coin. It is impossible to manipulate one without affecting the other. That provides opportunity to increase value.

"Value" is a process's physical and service outcomes divided by its cost outcomes (Figure 2). Addressing quality-associated waste simultaneously increases the numerator and decreases the denominator of the value equation. In the manufacturing industries where Deming's approaches first saw wide use, that relationship became a truism: Do Deming, or die. Any organization that couldn't improve quality while reducing costs could not hope to compete with those that could.



Figure 2. The value equation

A subsequent chapter will explore the full range of interactions between physical and cost outcomes, with examples drawn from real care delivery settings. It will also extend Deming's initial definition of waste to more granular, directly actionable, categories. It will show that quality-associated waste in health care is huge – arguably, the dominant financial opportunity in all of health care delivery.

<sup>&</sup>lt;sup>b</sup> Admittedly, use of the terms "quality-associated waste" and "quality waste" can be confusing. Just remember that "quality waste" is a specific subunit of the broad concept of "quality-associated waste."

#### Premise 3: Theory is different from reality (fundamental knowledge).

Yogi Berra got it right. "In theory," he said, "practice follows theory. In practice, it don't."

Outside of pure mathematics, theory is always an abstraction and an oversimplification. Reality lives down at the process-level front lines, in the mud and the weeds, at the "sharp end" of health care delivery. The devil really is in the details. It's the kludges and work-arounds that define daily work. It's creative responses for circumstances that fall outside the standard pattern. It's people adjusting to a coworker who called in sick, or a new batch of a common supply with subtle but substantial differences from the old version.

(Implication 3a)

#### "Fundamental knowledge" is the idea that the person who routinely executes a process has the best functional understanding of its actual operation.

Fundamental knowledge is firmly rooted in front-line, operational reality. It has 2 immediate applications. The first has to do with organizing improvement teams for "data-based problem solving." Successful leaders know that such teams must be built around fundamental knowledge. That means that the team's primary membership will be front-line workers who deeply understand operational reality through routine exposure to and experience with the associated production processes, backed up by specialized support.

The second application of fundamental knowledge relates to leadership hierarchies.

Think of an organization as a group of people who are trying to cut a road through wild, uncharted forest across mountainous terrain, in competition with other teams trying to reach the same distant goal. Front-line workers deal with the details – things like trees, bushes, streams, rock outcroppings, steep-sided washes, and downed timber.

As a person rises in the organization's management hierarchy, that person gains increasingly broader views. At the top, senior managers soar with the eagles. They can't see individual rocks and trees, but they do see the forest. They map the strategic terrain into the far distance. They might send a message down the chain noting that there is a mountain with a large cliff directly ahead. That cliff is not visible to the front-line workers, just as the local rocks, trees, and bushes are not directly visible to the senior managers. The front-line road builders would do well, management instructs, to divert 15 degrees to the left, toward an open canyon that skirts around the mountain and its cliffs.

In theory, most modern organizations are meritocracies. While luck and relationships play some role (we tell ourselves), generally those who are smarter, better trained, more capable, and work harder rise through the ranks to positions of leadership. Higher rank is associated with more power, control, prestige, and financial reward.

That approach, in theory, produces an organization where those at the top are proven, capable thinkers. Those at the bottom can only do. From that viewpoint, effective management means addressing 3 questions:

How do we efficiently move the thinkers' ideas into the workers hands? How do we ensure that the front-line workers comply with the orders given to them? How do we motivate workers to contribute their best effort and stay on task?

This understanding of management's appropriate role defined standardized mass-assembly production when Fred Taylor first broadly popularized it at the turn of the 19<sup>th</sup> century. It is thus sometimes called "Taylorism." MIT Sloan School of Management Professor Douglas McGregor called it Theory X in his 1960 book, *The Human Side of Enterprise*.<sup>9</sup> A more functional name is "top-down management."

The concept of fundamental knowledge suggests that the climb to the top of an organization comes at a hefty price: Senior managers mostly live, work, and breathe the rarified air of strategy and theory, distant from front-line reality. But Premise 1 asserts that any organization's long term success comes primarily from front-line performance.

Dr. Deming regularly used this framing to challenge those in upper management. He would tell them that, because of their high positions and associated attitudes, they fundamentally didn't know what was going on in the daily front-line operations of their own organizations.

In his classic text *Good to Great*,<sup>10</sup> Jim Collins talks about getting the right seats on the bus, then the right people in those seats. Most senior leaders, because of their location at or near the top of organization's hierarchy, innately think in terms of "who." When faced with a challenge, their first reaction is to reorganize.<sup>c</sup> In contrast, front-line operations centers around work processes. Process operations necessarily focuses on "why, what, and how."

Somewhere along the continuum of top-level strategy moving into operational success, there must be a transition from "who" into "why, what, and how." Effective leaders do not leave that transition to chance.

In direct application of this principle, Lean (a relatively recent extension of Deming's quality improvement theory) demands that leaders "go to the gemba."<sup>d</sup> Gemba is a Japanese term meaning "the real place." The Australian version directs leaders to the "coalface." Some clinical groups implement regular "leadership walk-arounds" at the front lines of care delivery. Similar examples abound.

Deming stated the principle more directly. When faced with any operational problem, he advised that competent leaders would first closely observe the associated front-line work processes. They would engage those who knew them best – the front-line workers – in finding and testing solutions. Quality theory summarizes the 2 competing approaches as "judgment" versus "learning:"

<sup>&</sup>lt;sup>c</sup> "We trained hard, but it seemed that every time we were beginning to form up into teams we would be reorganized. I was to learn later in life that we tend to meet any new situation by reorganizing ... a wonderful method it can be for creating the illusion of progress while producing confusion, inefficiency, and demoralization."

<sup>-</sup> Petronius Arbitor, poet and philosopher, 210 BC (from who's name the word "arbitration" was derived) - courtesy of Dr. Larry Staker <sup>d</sup> Gemba (現場, also romanized as genba) is a Japanese term that means "the actual place." In business, gemba refers to the point where value is created. It can be any site where a service provider interacts directly with a customer, or a final product is produced (ref: Wikipedia).

#### Judgment-based approaches work top down. They focus on the performance of a person,<sup>e</sup> asking "who."

#### Learning-based approaches work bottom up. They focus on the performance of a process, asking "why, what, or how."

Clinical research, a central part of the healing professions and academic practice, is inherently learningbased. In recent years, the National Academy of Medicine defined and championed the Learning Health Care System.<sup>11</sup> That approach uses quality improvement to embed formal research methods into routine care delivery, so that it is possible to reliably learn from practice experience on a broad scale. It directly applies "a theory of knowledge," one element of Deming's 4 categories of Profound Knowledge, to clinical operations.

(Implication 3b)

### High quality, cost efficient (low waste) performance requires effective "bottom up" management.

A later chapter will address the psychology of human change within an organization. Judgment versus learning, linked to top down versus bottom up management, are key concepts that underlie effective change leadership.

Fundamental knowledge has a third implication. It centers around a question:

Who is best positioned within an organization to lead successful process management and improvement?

At this point, the answer should be obvious. A quality organization is made up of a set of defined processes. The people who make up the organization execute those processes to accomplish value-adding work in service to the organization's customers. The person (or people) who best understand a process is that person (or team) who routinely operates the process. That same person (or team) is best positioned to systematically improve it.

This suggests that everyone working within an organization has 2 jobs. Most of the time, they execute processes that produce value for the organization and its customers. That justifies their paycheck. But some of the time, they apply "data-based problem solving" to improve the processes that define their own primary work.

(Implication 3c)

# Within mature quality organizations, responsibility for quality is deployed to the level of front-line workers.

Such an approach redefines the role of clinical management. Competent leaders set a vision that aligns with the organization's quality culture. They understand that better clinical and service outcomes directly drive higher value. They supply the tools and related infrastructure, so that front-line workers can lead improvement. That includes training the entire workforce in process management science,

<sup>&</sup>lt;sup>e</sup> Under many accountability systems, "person" includes a legal entity such as a corporation or other organization.

backed up by readily-available specialized expertise. They create aligned data systems, that make process operations transparent and creates clear links to long-term goals.

Within this framework, consider Taylorism's first top-down mandate for effective management: How do we efficiently move the thinker's (management's) ideas into the workers hands? Akio Morita, chairman of Sony Corporation, took a very different view: "A company will get nowhere if all the thinking is left to management."<sup>12</sup>

This framing supplies a marker to judge the ability of any organization to deliver value to its customers. If responsibility for "quality" is delegated to a single administrative department – an organizational subunit – that means that the organization's leadership does not understand what quality means, and can't effectively use foundational quality tools to drive organizational success. Quality belongs to us all.

Summary of concepts from this section <yet to come>

Chapter references:

- 1. Taylor, Frederick. Principles of Scientific Management
- 2. Kanigel, Robert. The One Best Way
- 3. Shewhart, Walter. Economic Control of Quality of Manufactured Product.
- 4. Shewhart, Walter. Statistical Method From the Viewpoint of Quality Control.
- Deming, W. Edwards. Elementary Principles of the Statistical Control of Quality: A Series of Lectures. JUSE, 1950. (translation of Deming's lectures to Japanese business leaders, from this Japanese lecture tour in 1950)
- 6. Walton, Mary. The Deming Management Method. New York, NY: Dodd, Mead, & Company, 1986.
- 7. Scherkenbach, William W. The Deming Route to Quality & Productivity: Road Maps and Roadblocks. Washington, DC: CEEPress Books, 1986.
- 8. Matsushita, Konosuke. Quest for Prosperity: The Life of a Japanese Industrialist. Tokyo, Japan: The PHP Institute, 1988.
- 9. McGregor, Douglas. The Human Side of Enterprise. 1960.
- 10. Collins, Jim. Good to Great.
- 11. Olsen, LeighAnn; Aisner, Dara; McGinnis, J. Michael. The Learning Healthcare System. Washington, DC: The National Academies Press, 2007.
- 12. Morita, Akio. Made in Japan.