Society of Research Administrators International

Senior Executive Institute: Research Culture and Continuous Improvement

– virtual –

Tuesday, 9 November 2021 – 11:00a–12:30p EST

Optimal Organizational Culture

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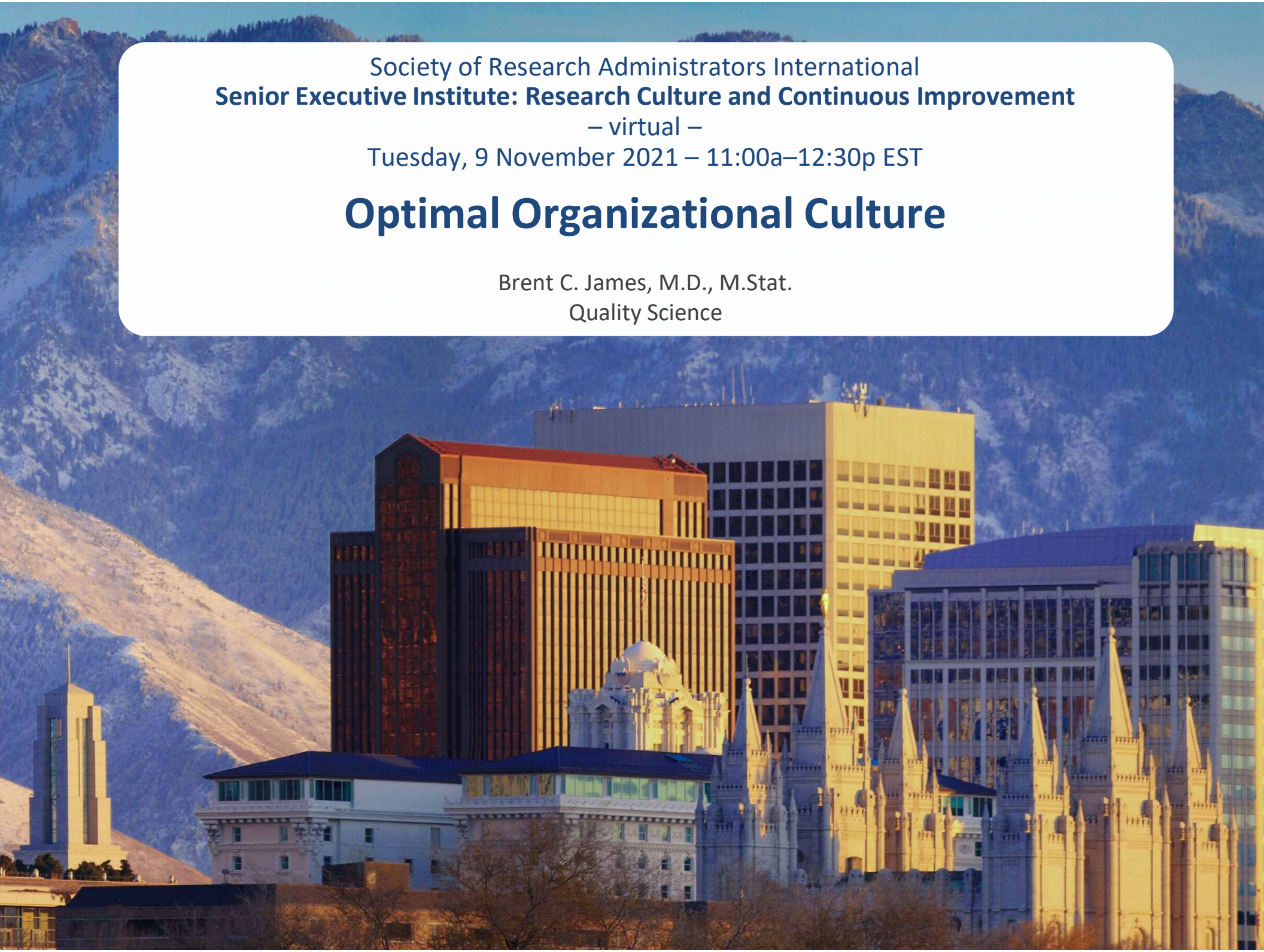
Quality Science



Video and slides

Disclosures

*I receive a monthly retainer as a part time (3 days / month) senior advisor for **Health Catalyst**.*
I also own (a small amount of) Health Catalyst stock.
*I serve on an advisory board for **Amplifire**,*
a privately-held company that provides computer-based health care education products.

Other than that, neither I nor any family members have any relevant financial relationships to be directly or indirectly discussed, referred to or illustrated within the presentation, with or without recognition.

Outline

1. ***What is organizational culture?***

2. ***The cultural values of quality improvement***

3. ***Building research into routine care delivery operations*** *(a two-way street)**:***

4. ***The Learning Healthcare System***

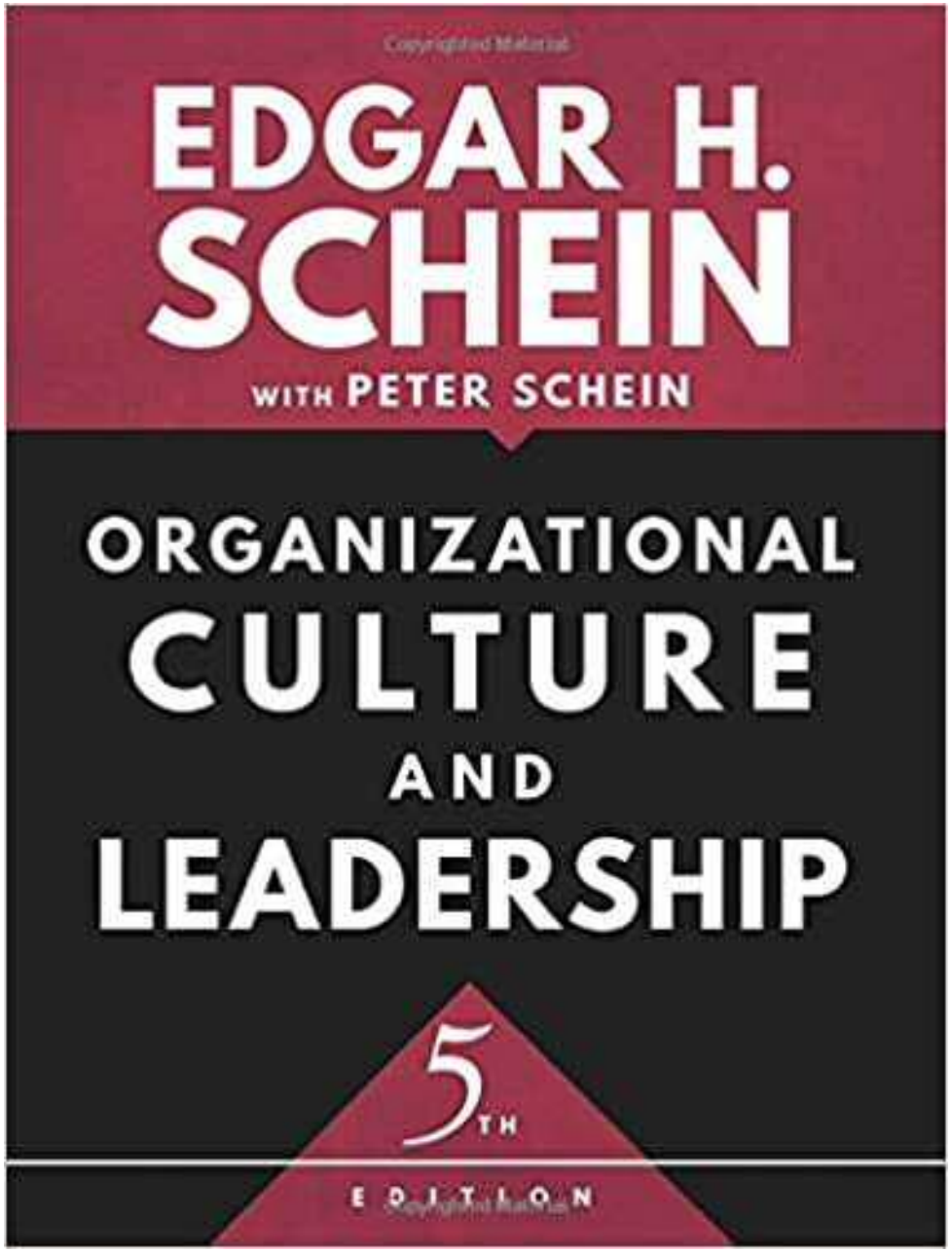
Part 1:

What is organizational culture?

Edgar H. Schein, PhD

Sloan Fellows Professor of Management,
Sloan School of Management
Massachusetts Institute of Technology

(now a professor emeritus at Stanford University)



Hoboken, NJ: John Wiley & Sons, 2017.

(first published in 1985)

Culture: the "people" side *of an organization*

A pattern of shared basic assumptions that was learned by a group as it solved its problem of external adaption and internal integration, that has worked well enough to be considered valid and, therefore, to be taught to new members as the correct way to perceive, think, and feel in relation to those problems. *(pg. 17)*

Non-negotiable; taken for granted; part of the identity of the group; taught to newcomers. *(pg. 16)*

Culture builds up through 3 levels

3. ***Artifacts*** *– explicit, visible organizational structures and processes; work climate, formal processes and policies, physical infrastructure, etc.*

2. ***Espoused beliefs and values*** *(justifications) – explicit strategies, goals, philosophies, and organizational value statements.*

1. ***Basic assumptions*** *– unconscious, implicit "taken for granted" beliefs, language, problem-solving approaches, etc.*

… non-discussable assumptions supported by articulated sets of beliefs, norms, and operational rules of behavior; an ideology; new members of the group are implicitly trained "how to behave." Those who fail to accept such beliefs and values run the risk of "excommunication" – being thrown out of the group. (pg. 29)

The bottom level is decisive

Real problems arise if leaders don't elicit and understand, then connect basic, unconscious organizational assumptions, beliefs, and methods through the upper 2 layers.

The power of culture comes about through the fact that the assumptions are shared and, therefore, mutually reinforced. (pg. 35)

… the test of whether they work or not is how comfortable and anxiety-free [group] members are when they abide by them. (pg. 29)

Once [a set of basic assumptions are] achieved, it is easier to distort new data [experience, challenges] by denial, projection, rationalization, and various other defense mechanisms than to change the basic assumptions. (pg. 36)

Leadership vs management

… leadership creates and changes cultures, while *management and administration act within a culture.* (pg. 11)

… the only thing of real importance that leaders do is to create and manage culture. (pg. 11)

The bottom line for leaders is that if they do not become conscious of the cultures in which they are embedded, those cultures will manage them. (pg. 23)

… an ultimate act of leadership is to destroy culture when it is … dysfunctional. (pg. 11)

Part 2:

The cultural values of quality improvement

William Edwards DEMING

Deming's Profound Knowledge

1. ***Appreciation for a system*** *– systems thinking describes how processes interact together*

2. ***A theory of knowledge*** *– (1) formal methods to apply "best evidence" to daily work execution, and (2) to learn from experience, including the tools of "data-based problem solving"*

3. ***Knowledge about variation*** *– methods to separate actionable signal from noise in measured results*

4. ***Understanding of psychology*** *– how humans interact and respond in work settings, a essential element for effective change leadership*

Quality improvement's 3 premises:

1. *all productive human activity can be described as* ***processes***

2. *every process produces*

   3 parallel sets of outcomes

3. ***Fundamental knowledge*** *–*

   there is a difference between theory and reality

Premise 1:

All productive human activity can be described as

processes

If you can't describe what you are doing as a process, you don't know what you are doing.

W. Edwards Deming

A process is …

A series of linked steps, often sequential, designed to

- *create a product or a service;*
- *generate data or knowledge;*
- *cause some set of desired outcomes to occur;*

or in some other way, create value

Organizations exist to serve customers

That money you get: Think of it as the best measure of customer satisfaction ever imagined …

You satisfy customers with a product or service

(the job to be done)

You create products and services with a value-added front-line work process

(where "value-added" is defined by the customer)

It will not suffice to have customers that are merely satisfied. Customers [who] are unhappy and some that are merely satisfied, switch. [Success] comes from repeat customers – those that boast about the product or service.

W. Edwards Deming

Implication: Therefore, you should

organize literally everything around

value-added front-line work process

- *management structure*
- *physical plant*
- *data systems*
- *financial accounting*
- *etc.*

Quality improvement is

the science of process management

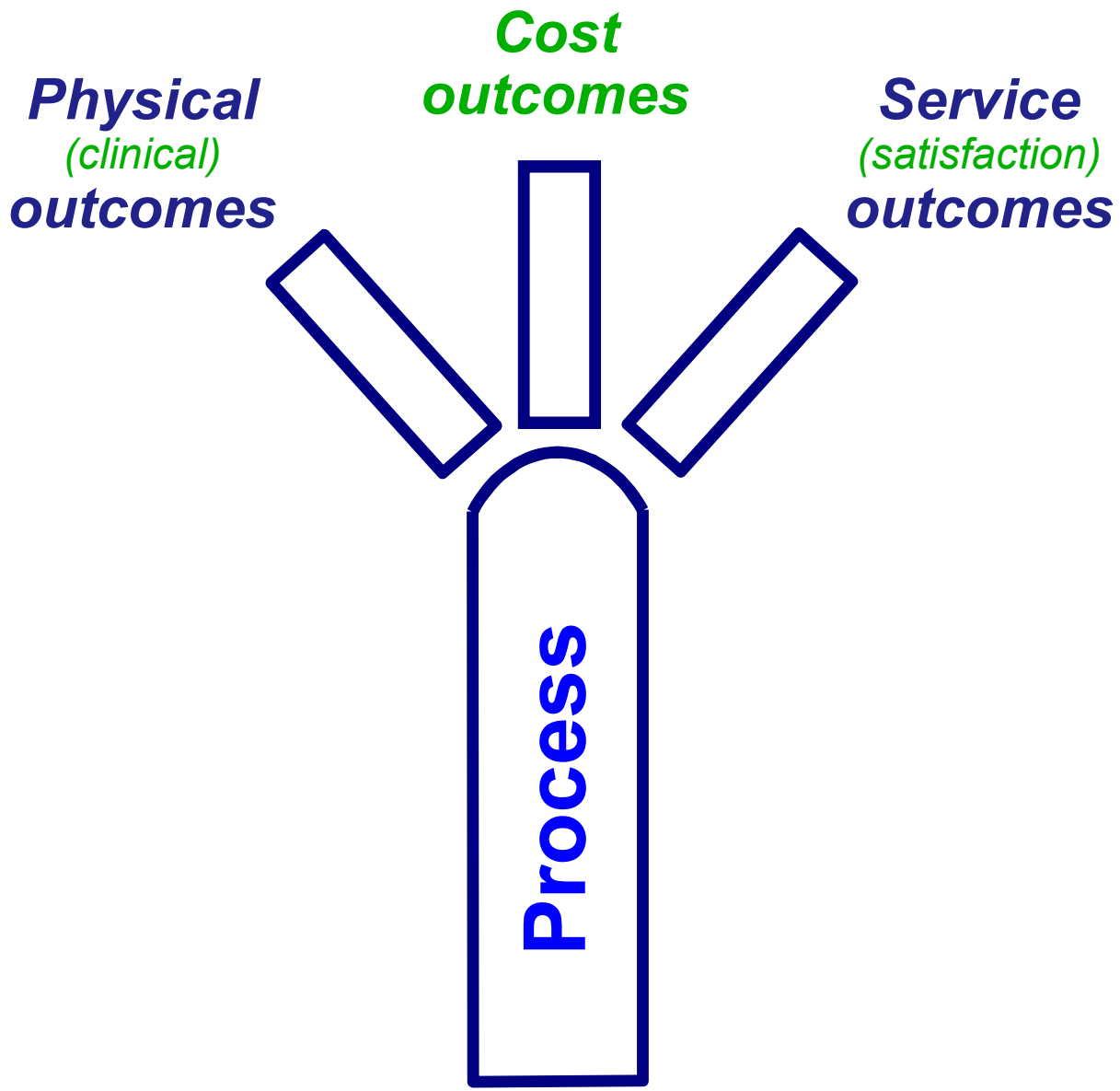
(in care delivery, sometimes called
"care delivery science")

Premise 2:

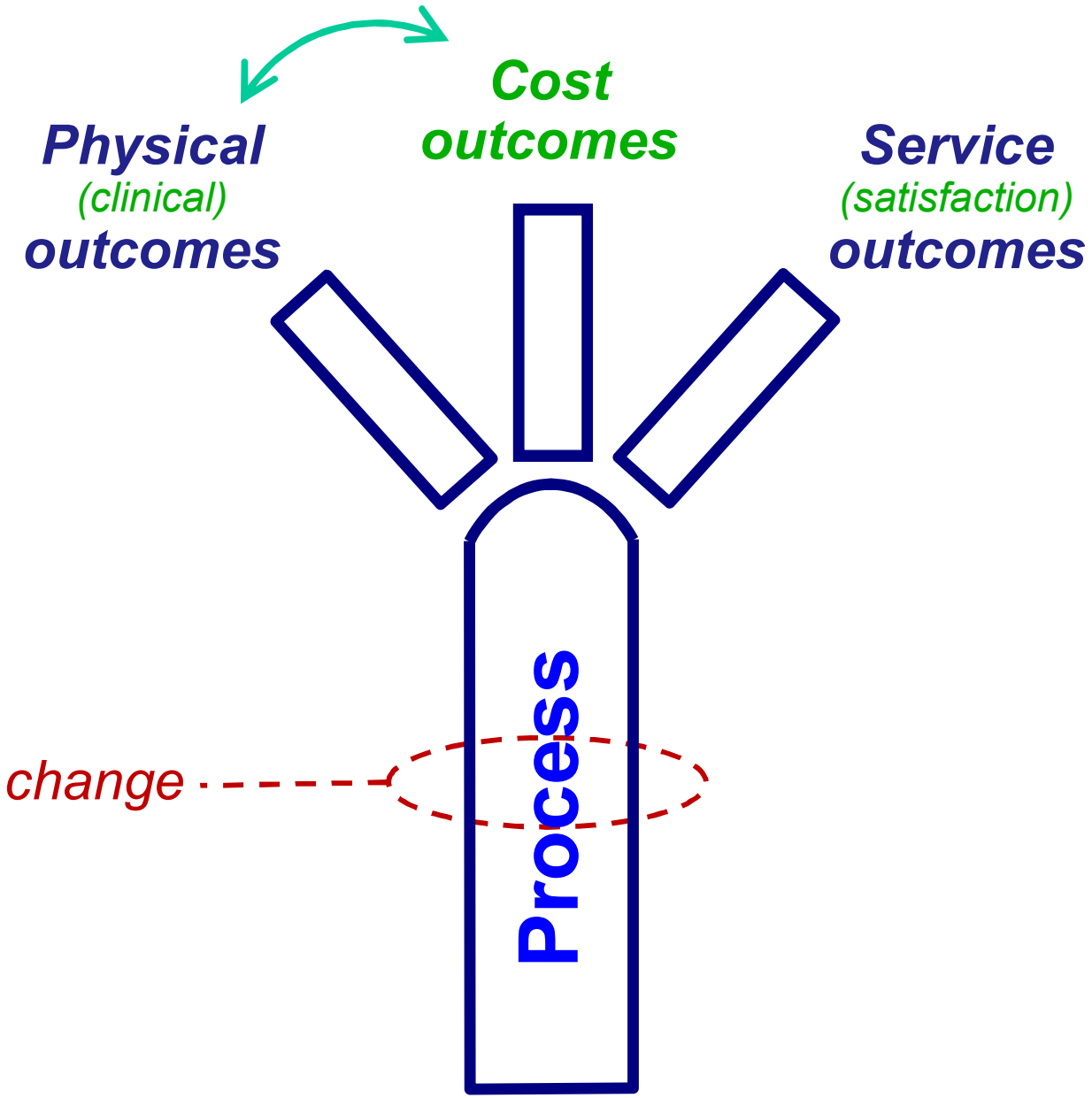
All processes always produce

3 parallel types of outcomes

Deming: Processes produce outcomes



Deming: Processes produce outcomes



Implication 1:

When you change a process

with an aim to change 1 of the 3 types of outcomes,
unavoidably,

you change them all

(all 3 classes of process outcomes)

Implication 2: Quality controls cost

1. ***Quality waste***
   - *a step in a process fails*
   - *sometimes that process failure causes an outcome failure*
   - *forcing either repair (rework) or discard ("throw it away" – scrap)*

   (manage the process so it doesn't fail in the first place: higher quality, lower cost)

2. ***Inefficiency waste***
   - *2 parallel processes*
   - *have identical outputs (same quality)*
   - *one consumes fewer resources (lower cost)*

3. ***Cost effectiveness***
   - *better physical outcomes (higher quality)*
   - *but legitimately consumes more resources (higher cost)*

Premise 3:

Fundamental knowledge –

there is a difference between theory and reality

Fundamental knowledge

- ***Theory is always an abstraction and an oversimplification***
- ***Reality lives down at the front lines****, in the mud and the weeds – the devil really is in the details*
- ***The only person who truly understands how a process operates is a front-line worker who executes it regularly***
- ***The higher you are in the management chain, the less you know what is going on***

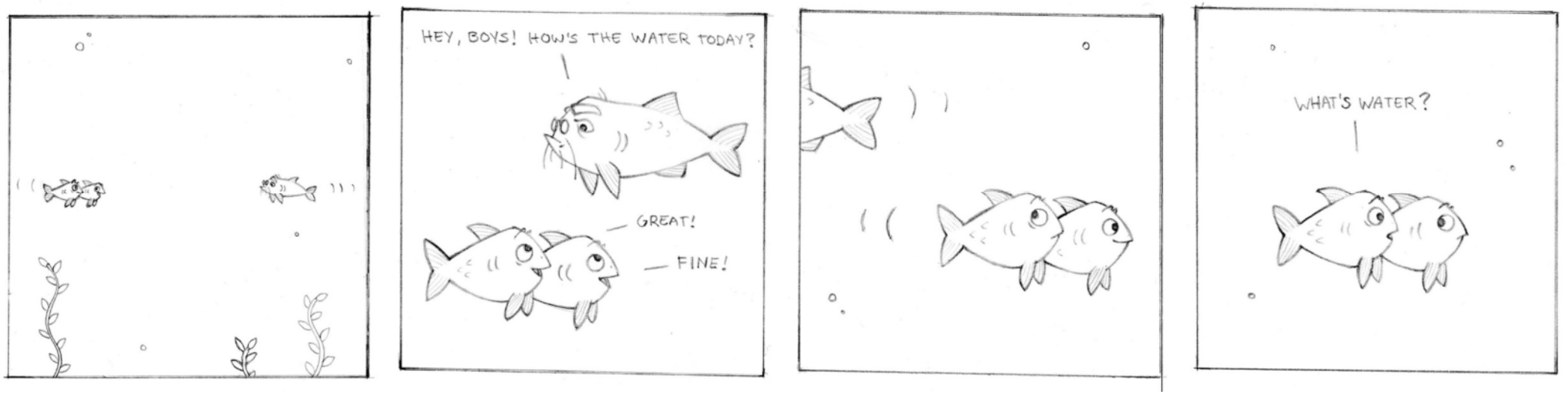
Implication:

Quality improvement is inherently

bottom-up

(as opposed to traditional "management in control" approaches, such as classic Taylorism)

- In 2005, David Foster Wallace, an American novelist, gave a commencement talk at Kenyon College
- Time Magazine called it “The greatest commencement speech ever given.”
- Foster’s talk started with a cartoon …



Quality Science

All from W. Edwards Deming

People work in the system. Management creates the system.

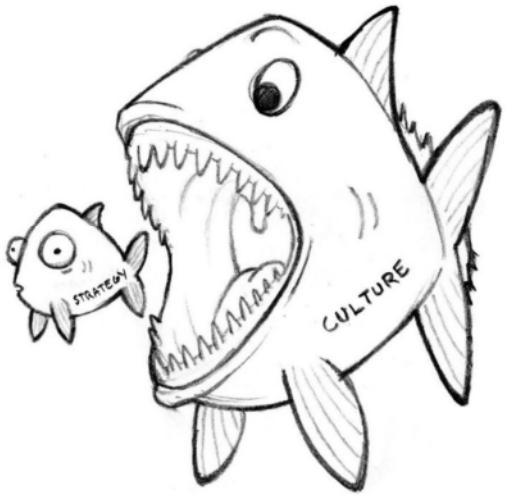
Eighty-five percent [95%] of the reasons for failure are deficiencies in the systems and process rather than the employee. The role of management is to change the process rather than badgering individuals to do better.

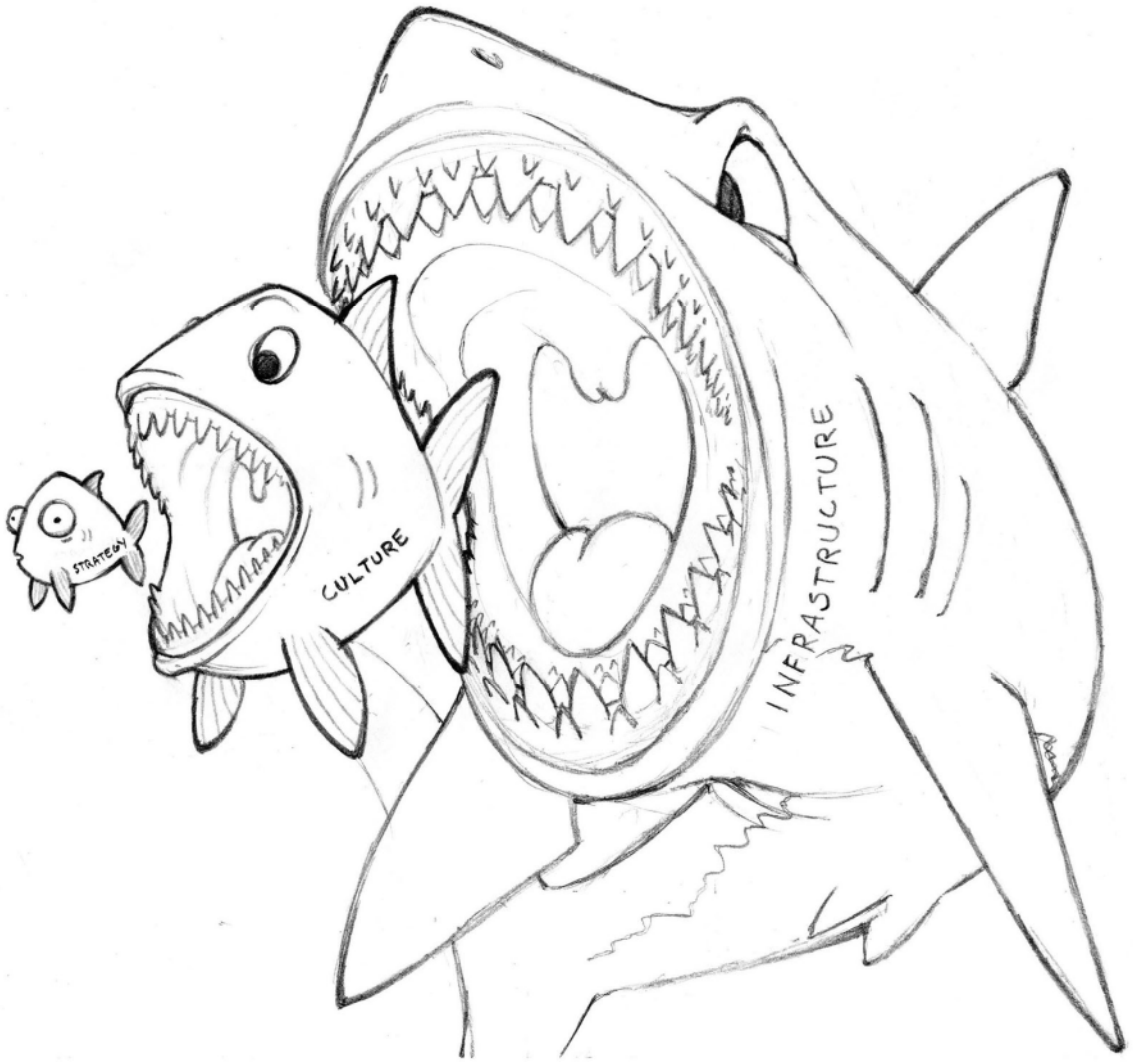
Any substantial improvement must come from action on the system, the responsibility of management. Wishing and pleading and begging the workers to do better is totally futile.

A bad system will beat a good person every time. Put a good person in a bad system and the bad system wins, no contest.

Every system is perfectly designed to get the result that it does.

The most valuable "currency" of any organization is the initiative and creativity of its members. Every leader has the solemn moral responsibility to develop these to the maximum in all of her/his people. This is the leader's highest priority [– joy in work].





Systems frame and shape
the work environment

at a subconscious level,

and thus

frame and shape culture.

Part 3:

Building Research Into Routine Care Delivery Operations

Two broad approaches to build a "culture of quality improvement" into the research enterprise:

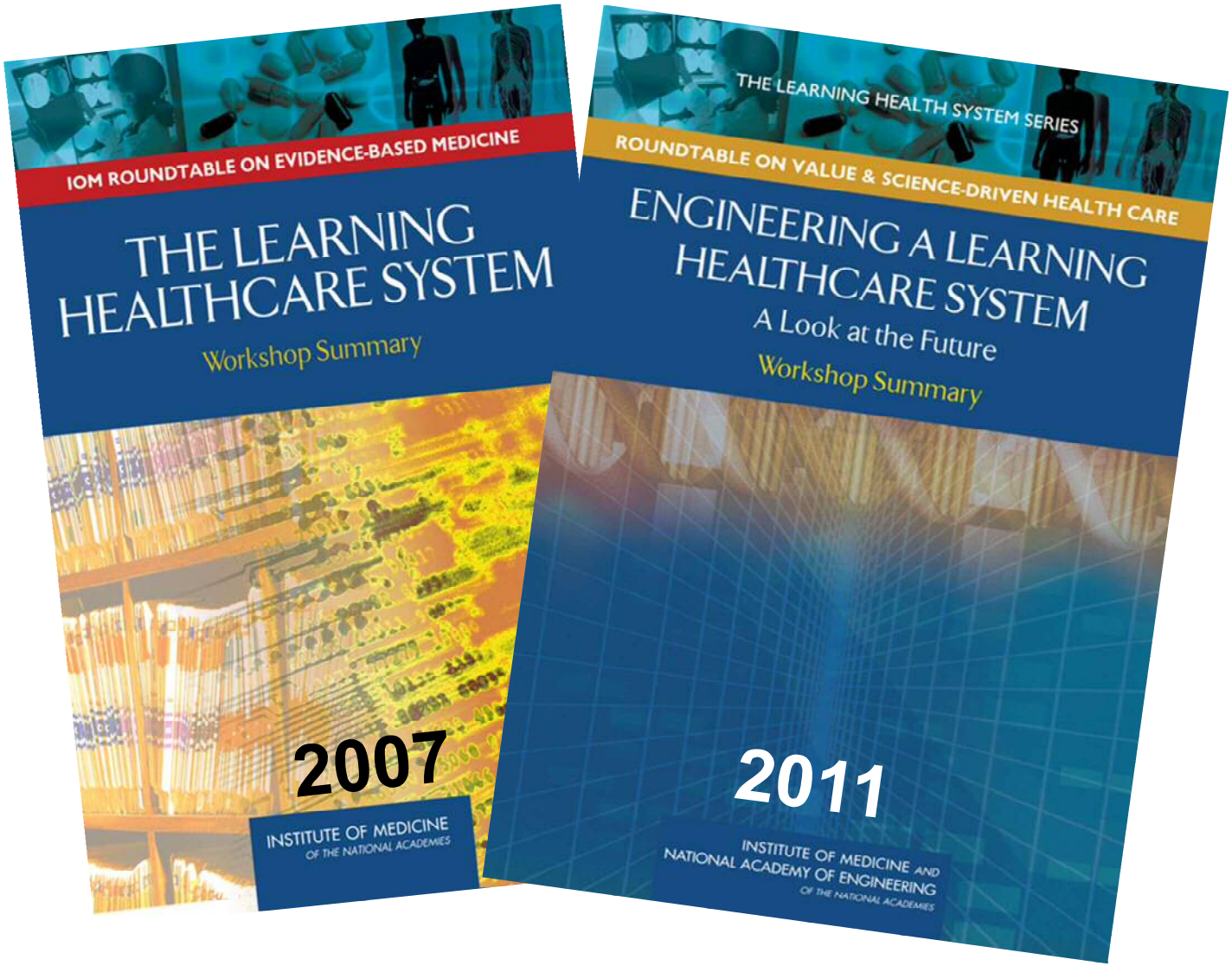
1) ***Use quality improvement tools and methods to execute and systematically improve routine research operations***

2) ***Embed reliable knowledge generation into routine care delivery practice –***
"every patient treated is automatically on a trial"

Improvement embedded in operations

- *Do you have a comprehensive, prioritized list of the processes / systems that make up your research operations?*
- *Have you deployed "standard work" (best practices) for each key process, embedded into operational workflows?*
- *Have you used formal methods to create data systems that embed into operational workflows, that (1) support front-line workers and (2) make research operations transparent?*
- *Have you trained all people in your organization in improvement principles, tools and methods?*
- *Can you show credible data demonstrating continuous improvement in your research operations?*

The Learning Healthcare System



The opportunity *(care falls short of its theoretic potential)*

1. ***Massive variation in clinical practices*** *(beyond even the remote possibility that all patients receive good care)*
2. ***High rates of inappropriate care*** *(where the risk of harm inherent in the treatment outweighs any potential benefit)*
3. ***Unacceptable rates of preventable care-associated patient injury and death***
4. ***Striking inability to "do what we know works"***

James, B.C. Testimony to the U.S. Senate Finance Committee, February 2009

Inappropriate variation causes waste

Definition of waste *under Deming's quality theory*

1. ***Quality improves***

which ***causes***

2. ***costs to fall***

How much "waste" opportunity?

30-50+% *of all health care resource expenditures are*

quality-associated waste:

- *recovering from preventable foul-ups*
- *building unusable products*
- *providing unnecessary treatments*
- *simple inefficiency*

Institute of Medicine Roundtable on Value and Science-Driven Healthcare. T*he Healthcare Imperative: Lowering Costs and Improving Outcomes*. Yong, Pierre L., Saunders, Robert S., and Olsen, LeighAnne, editors. Washington, DC: National Academy Press, 2010.

Quality Science

We know why clinical variation happens

Causes of clinical variation

1. ***Complexity*** *(clinical uncertainty) in the context of*
2. *continued, primary* ***Reliance on human memory***
   – the "craft of medicine" and
3. ***Low transparency*** *– poor data linking clinical choices to patient outcomes in routine practice*

Change strategies that fail to address these root causes will perform suboptimally or *(most often)* ***fail entirely***

"The complexity of modern medicine exceeds the capacity of the unaided expert mind."

David M. Eddy, MD, PhD

- ***Eddy is the "father" of evidence-based medicine***
  - *first used the term in the published literature in 1990*
  - *developed most of the formal methods still used today for evidence review and summation*
- ***He was based at Stanford University***
- ***Evidence-based medicine was popularized by Dr. David Sackett, et al.***
  - *first used the term in the published literature in 1995*
  - *Which is more important? Inventing it, or spreading it broadly?*

Quality Science

We then compound the problem

by attempting to load massively complex clinical knowledge into expert human minds,

("craft of medicine deployment methods, a.k.a. academic detailing: Grand Rounds, articles, published guidelines, and the like)

then expecting those experts to apply it correctly, consistently, and completely to each patient who seeks help …

but that demonstrably

DOES. NOT. RELIABLY. WORK.

We have found

proven solutions

(a clinical management method)

Two methods to manage complexity

Subspecialize *(analytic method; reductionism; 'divide and conquer')*

An old joke: ***Know more and more about less and less until you know everything about nothing***

Mass customize *– deploy "**standard work**" to "**make it easy to do it right**;" then vary based on individual customer need.*

An oxymoron?

The key to effective variation is standardization.

Dr. Alan Morris, LDS Hospital, 1991

- ***NIH-funded randomized controlled trial***
  assessing an Italian "artificial lung" vs. standard ventilator management for acute respiratory distress syndrome (ARDS)
- ***discovered large variations in ventilator settings***
  across and within expert pulmonologists
- ***created a protocol*** *for ventilator settings in the control arm of the trial*

James Brent C., Savitz Lucy A. How Intermountain trimmed health care costs through robust quality improvement efforts. *Health Affairs* 2011; 30(6):1185-91 (June).

Problems with "best care" protocols

- ***Lack of evidence for best practice***
  - *Level 1, 2, or 3 evidence available only about 15-25% of the time*

- ***Expert consensus is unreliable***
  - *experts can't accurately estimate rates relying on subjective recall*
    (produce guesses that range from 0 to 100%, with no discernable pattern of response)
  - *what you get depends on whom you invite (specialty level, individual level)*

- ***Guidelines don't guide practice***
  - *systems that rely on human memory execute correctly ~50% of the time (McGlynn: 55% for adults, 46% for children)*

- ***No two patients are the same;*** *therefore, no guideline perfectly fits any patient (with very rare exception)*

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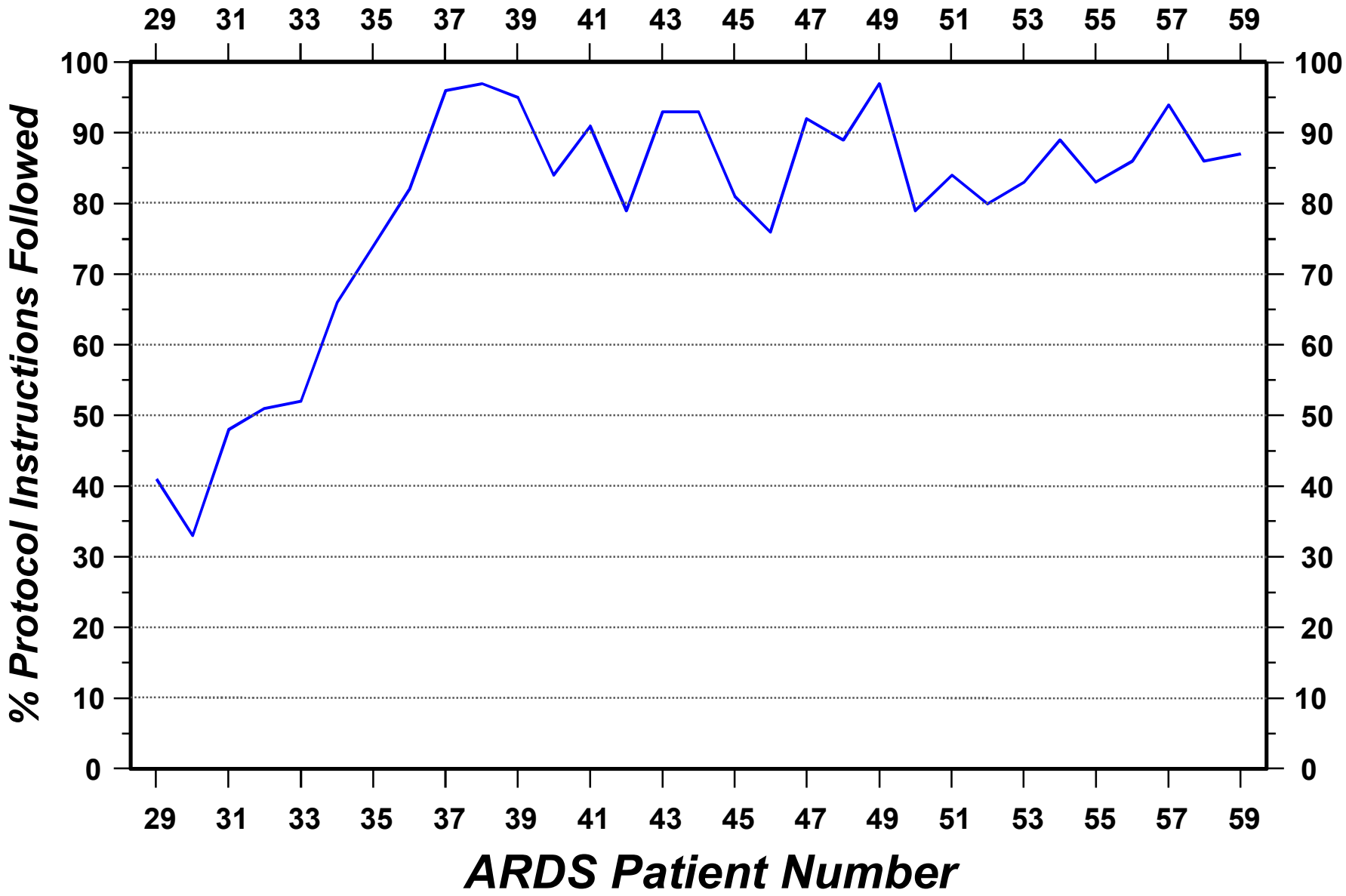
- ***created a protocol*** *for ventilator settings in the control arm of the trial*
- ***implemented the protocol using Lean principles***
  (Womack et al., 1990 - The Machine That Changed the World)
  - built into clinical workflows - automatic unless modified
  - clinicians encouraged to vary based on patient need
  - variances and patient outcomes fed back in a Lean Learning Loop

James Brent C., Savitz Lucy A. How Intermountain trimmed health care costs through robust quality improvement efforts. *Health Affairs* 2011; 30(6):1185-91 (June).

ARDS Protocol Compliance



East Thomas D, Morris Alan H, Clemmer T, Orme James F, Wallace C Jane, Henderson Susan, Sittig Dean F, gardner Reed M. Development of computerized critical care protocols – a strategy that really works! *Proceedings – The Fourteenth Annual Symposium on Computer Applications in Medical Care. Washington, DC: IEEE Computer, 564-8* (5-7Nov1990).

This “shift” happened every time

(across more than 100 Shared Baseline protocols –
we called them Care Process Models - CPMs*)*

You must have a** (formal, consistent) **method to

“tune” theory to reality

(fundamental knowledge – Deming’s 3rd premise)

Results

- ***Survival*** *(for ECMO entry criteria patients)* ***improved from 9.5%*** *to* ***44%***
- ***Costs fell by ~25%*** *(from ~$160,000 to ~$120,000 per case)*
- ***Physician time fell by ~50%*** *(a major increase in physician productivity)*

James Brent C., Savitz Lucy A. How Intermountain trimmed health care costs through robust quality improvement efforts. *Health Affairs* 2011; 30(6):1185-91 (June).

Quality Science

Shared Baseline "Lean" protocols *(bundles)*

1. ***Identify a high-priority clinical process*** *(key process analysis)*
2. ***Build an evidence-based best practice protocol*** *(always imperfect: poor evidence, unreliable consensus)*
3. ***Blend it into clinical workflow*** *(= clinical decision support; don't rely on human memory; make "best care" the lowest energy state, default choice that happens automatically unless someone must modify)*
4. ***Embed data systems to track (1) protocol variations*** *and* ***(2) short and long term patient results*** *(intermediate and final clinical and cost outcomes; you can profitably treat service quality as a separate system)*
5. ***Demand that clinicians vary based on patient need***
6. ***Feed those data back*** *(variations, outcomes)* ***in a Lean Learning Loop*** *- constantly update and improve the protocol*

James Brent C., Savitz Lucy A. How Intermountain trimmed health care costs through robust quality improvement efforts. *Health Affairs* 2011; 30(6):1185-91 (June).

Things to notice *in Shared Baseline approach*

1. ***No protocol perfectly fits any patient***
   - *solution:* ***mass customization*** *= "patient centered care" / "personalized medicine"*

2. ***Reliance on human memory*** *(craft of medicine) produces "50% execution"*
   - *solution:* ***embed protocols in workflows***

3. ***Serious limitations to protocol development***
   - *solution:* ***a Learning System*** *(embedded variance and outcomes tracking; continuous protocol review and tested improvement; a method to "map theory to reality")*

4. ***Embedded front-line transparency*** *– condition-specific clinical registries tracking intermediate and final clinical and cost outcomes*

Lesson 1

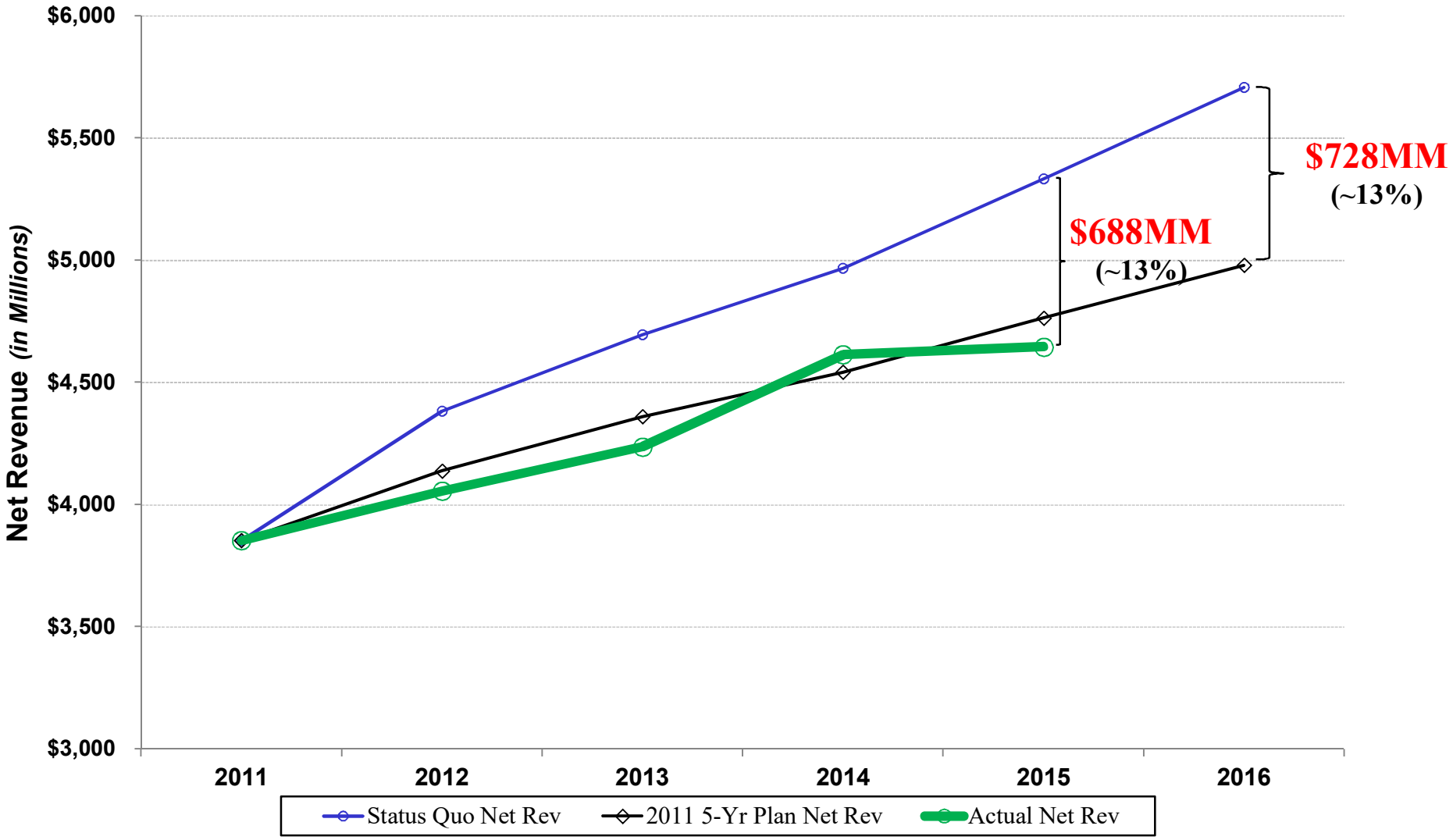
We count our successes in lives

Lesson 2

Nearly always *with proper clinical management*
better care is cheaper care *through waste elimination*
(quality controls cost – Deming's 2nd premise)

The path to financial success leads through clinical excellence

Financial impact of clinical quality improvement at one large system



James Brent C and Poulsen Gregory P. The case for capitation: It's the only way to cut waste while improving quality. *Harv Bus Rev* 2016; 94(7-8):102-11, 134 (Jul-Aug).

Part 4:

Building a Learning Healthcare System

A series of registries

(we had 57, which covered about 80% of all care delivered in the system)

- ***Disease specific*** *(e.g., Type II diabetes mellitus, heart failure, pregnancy/labor/delivery, acute myocardial infarction)*
- ***System wide*** *– captures data from all care delivery locations*
- ***Intermediate and final clinical and cost outcomes*** *– need both clinical and cost outcomes to measure "value"*
- ***Primary aim: care delivery execution***
- ***Secondary aim: generate reliable new knowledge***
- *(Tertiary aim: accountability – external reporting)*

The Learning Health Care System

1. ***Build a system to manage care***
2. ***Justify the required major financial investment on the basis of care delivery performance*** *-- "the best clinical result at the lowest necessary cost"*
3. ***Use the resulting clinical management data system to:***
   (a) Generate true transparency at the clinician-patient level, rolling up to the national level
   (b) "Learn from every patient" - integrate clinical effectiveness research into front-line care

4 “types” of clinical research

1. ***Rapid impact on care delivery performance***
   (best medical result at lowest necessary cost)
   - *internally funded - patient care dollars*
   - *publication, external grant funding = "icing on the cake"*

2. ***Investigator-initiated research***
   - *traditional academic model*
   - *external grant funding*

3. ***Collaborations with external investigators***
   - *multi-center trials*
   - *local universities*
   - *requires an internal "champion"*

4. ***Industry-based groups*** *(pharma, device manufacturers)*

2015 “Type 1" knowledge generation

- ***Women & Newborn: 84 peer-reviewed articles***
- ***Cardiovascular*** *(2013 data)**:***
  - ***64 peer-reviewed articles***
  - ***67 abstracts***
  - ***15 "other" - book chapters, editorials, etc.***
- ***Other Clinical Development Teams also published***
  *(just not as prolific as Women & Newborn and CV -- **399** total articles)*
- ***Cumulative impact on cost of operations: ~$688 million***

Better has no limit ...

an old Yiddish proverb