Quality Has No Limit

Brent C. James, M.D., M.Stat.
Quality Science
Disclosures

I receive a monthly retainer as a part time senior advisor for Health Catalyst. I also own (a small amount of) stock in Health Catalyst.

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.
Part 1

Current care delivery ...

- *is the best the world has ever seen; but*

- *it could be much better*
Framing:

- **Current care delivery is the best the world has ever seen**
  - we routinely achieve miracles (save lives under immediate threat)
  - care delivery adds between 3.5 and 7 years of life, on average, for every citizen
  - far better health care and health than any previous generation
  - care in the U.S. is better than in any other country (for rescue care, at least)
  - easy case to make on readily-available evidence

- **We have an ethical commitment to pass along** (to the next generation) **something better than we ourselves received**

- **The first step is to identify areas where we “fall short of our theoretic potential”**

- **Health care is not “broken”**
  - to be “broken,” somewhere, sometime, it has to have worked correctly: (1) it’s working; then (2) it breaks; after which (3) it’s broken
  - there is no example, across time or around the world, where health care delivery has consistently worked correctly
Sources of progress

Traditional biomedical and clinical research

Care delivery science
Starting in the 1950s and accelerating over time

We applied

the rigorous measurement tools developed for clinical research

to

daily care delivery performance

(that is, to quality of care)
Quality, Utilization, and Efficiency (QUE)

- Six clinical areas studied over 2 years:
  - transurethral prostatectomy (TURP)
  - open cholecystectomy
  - total hip arthroplasty
  - coronary artery bypass graft surgery (CABG)
  - permanent pacemaker implantation
  - community-acquired pneumonia

- Pulled all patients treated over a defined time period across all Intermountain inpatient facilities - typically 1 year

- Identified and staged (relative to changes in expected utilization)
  - severity of presenting primary condition
  - all comorbidities on admission
  - every complication
  - measures of long term outcomes

- Compared physicians with meaningful # of cases (low volume physicians included in parallel analysis, as a group)

Intermountain TURP QUE Study

Median Surgery Minutes vs Median Grams Tissue

Intermountain TURP QUE Study

Average true cost to hospital

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"

5. Huge amounts of waste, leading to spiraling prices that limit access to care

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

35-50+% of all health care resource expenditures are quality-associated waste:

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

Part 2

We know why this happens
(“this” = the 5 areas where care falls short of its theoretic potential)
Why? The collision of 2 forces:

1. Continued reliance on the "craft of medicine" (clinicians as stand-alone experts) encounters

2. Complexity; a.k.a. clinical uncertainty - the fruits of 100 years of clinical discovery

in the context of

3. Payment that encourages utilization

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

(Dr. David Eddy, Stanford University -- the father of evidence-based medicine)
The craft of medicine

An individual physician
- placing her patient's health care needs before any other end or goal,
- Drawing on extensive clinical knowledge gained through formal education and experience

can craft
- a unique diagnostic and treatment regimen customized for that particular patient.

Medicine's promise:

This approach guarantees the best result possible for each patient.
Clinical uncertainty (a hundred years of science … the primary sources of practice variation)

1. Lack of valid clinical knowledge regarding best treatment (poor evidence)

2. Exponentially increasing new medical knowledge (doubling time has decreased to <8 years; at current rates, a clinician will need to learn, unlearn, then relearn half of her medical knowledge base 5+ times during a typical career)

3. Continued reliance on subjective judgment (subjective recall is dominated by anecdotes, and notoriously unreliable when estimating results across groups or over time)

4. Limitations of the expert mind when making complex decisions (Miller, 1956: The magic number 7, plus or minus 2: some limits on our capacity for processing information)

Which, when combined with the craft of medicine, leads to:

Enthusiasm for unproven methods … Mark Chassin, MD
The maxim, "If it might work, try it" … David Eddy, MD, PhD
Quality means "spare no expense" … Brent James, MD, MStat

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Part 3

We have found proven solutions ...
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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- 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

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).
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).
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, cost, and satisfaction outcomes)

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).
Lesson 1

We count our successes in lives
Lesson 2

there is nothing new here

except the idea that

“it takes a team …”
(and, perhaps, better process-aligned data systems)

It started in medicine
(not Toyota Production System Lean)

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Team-Based Care
(3rd generation coordinated medical home)

An investment of $22 per-member-per year (PMPY) decreased medical expenses by $115 PMPY

Lesson 3

Most often
(but not always)

better care is cheaper care
# Financial incentive alignment under different payment mechanisms

<table>
<thead>
<tr>
<th>WASTE REMOVAL LEVEL</th>
<th>% of all waste</th>
<th>PAYMENT METHOD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Efficiency</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>FFS</td>
</tr>
<tr>
<td>2. Within-case utilization</td>
<td>50%</td>
<td>▼</td>
</tr>
<tr>
<td>(# and type of units per case)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Case-rate utilization</td>
<td>45%</td>
<td>▼</td>
</tr>
<tr>
<td>(# cases per population)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: For green arrows, savings from waste elimination accrue to the care delivery organization; for red arrows, savings go to payer organizations.

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).
Lesson 4

The long-term organizational viability of clinical quality improvement strategies requires aligned financial incentives.
Three levels of quality

1. Availability and competence of clinical staff
   - most common approach -- traditional
   - built on idea of “craft of medicine”
   - main method: credentialing and privileging

2. Regulatory compliance / external rankings
   - Joint Commission / NCQA reviews
   - CMS quality measures and star rankings
   - rankings from other external groups

3. Quality as a core business strategy
Clinicians managing clinical processes

**Education programs** (ATP) – creating a cadre of clinical and administrative leaders with shared vision and tools

*1996: (strategic) Key process analysis*

*1997: Integrated management information systems*  
(an outcomes tracking system)

*1997: Integrated clinical / operations management structure*

*1999: Integrated (aligned) incentives*

*2000: Full roll-out and administrative integration*
The Iron Triangle of health care delivery

Without access, “quality” is meaningless; 

**Accessible** means **Affordable**
Financial impact of clinical quality improvement at Intermountain

Net Revenue (in Millions)

- Status Quo Net Rev
- 2011 5-Yr Plan Net Rev
- Actual Net Rev


$728MM (~13%)
$688MM (~13%)

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“Pay for value” continues to grow

Forward looking indicators:

- **Kaiser Permanente**
- **Medicare Advantage**
- **ACOs** *(Leavitt Group; mostly commercial)*
- **Provider-payer consolidation**
  *by ownership or partnership*
Process management is the key

- **better clinical results produces lower costs**

- **aligned financials:** *under fee-for-value payment, savings drop to care groups’ bottom lines*

- **more than half of all cost savings will take the form of unused capacity** *(fixed costs: empty hospital beds, empty clinic patient appointments, reduced procedure, imaging, and testing rates)*

- **balanced by increasing demand:**
  - demographic shifts (Baby Boom); population growth; behavioral epidemics (e.g., obesity); technological advances

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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*
Electronic data warehouse – disease-specific registries

- 58 clinical registries aligned to specific conditions represented about 80% of all care delivered within one integrated system

- follow every patient longitudinally over time condition-specific clinical, cost, and service intermediate and final outcomes

- primary use: routine clinical management
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" learning production

- **Women & Newborn**: 84 peer-reviewed articles

- **Cardiovascular** (2103 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 -- 390 total articles)

- **Cumulative impact on cost of operations**: ~$688 million

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Better has no limit ...

an old Yiddish proverb