Welcome to Quality Assurance

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Gilbert Burnham

Outline
- Defining Quality
- The performance gap and "gap analysis"
- Quality can be measured
- Origins of the movement for Quality
  - Emphasis on variations
  - Plan-Do-Check-Act
- The Q words
- Institute of Medicine
- New approaches to Quality

Basic Quality Cycle

Define quality

Measure quality

Improve quality

Quality Improvement cycle

Re-assess quality

Defining Quality
- The degree of excellence (Latin Qualitas)
  - It is made of good materials
  - Meets expectations people have of it
  - It does what is intended of it
  - It is better than other similar things to which it is compared
  - The results are worth the investment (value for money)

In reality, quality can have different definitions depending on the context.
- Clinical procedures
- Patient management
- Public health programs
- Industrial processes

Judging quality

$20,000 or $2,500

1. Assumption that price = quality. But is it true?
Defining Quality another way...

- What is a service should an item be expected to do?
- How well were the expectations met?
  - Were they met reliably and consistently?
  - Did they exceed expectations?
- What resources were required to meet that expectation?
- Does the value to the user justify resources expended?

What Is an Item or Service Expected to Do?

- $20,000
  - Project your image
- $2,500
  - Provide a livelihood

What Is an Item or Service Expected to Do?

- Lasts 15 years
- $1330 per year

What Is an Item or Service Expected to Do?

- Provide a livelihood

What Is an Item or Service Expected to Do?

- $20,000
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Meeting customer expectations

<table>
<thead>
<tr>
<th></th>
<th>Met expectations</th>
<th>Less than expectations</th>
<th>Exceeded expectations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of waiting time</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Courtesy of health workers</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Thoroughness of health workers</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Explained my health problems</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Answered questions I had</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Explained the treatment</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Described the possible adverse reactions I might have</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Explained when I should return</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Asked if I had any questions</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>

Quality can be defined by the Voice of the Customer

Patient or user

Challenge with the user's voice

Over a century ago Sir William Osler, one of the founders of modern medicine, said: “Listen to your patient. He is telling you the diagnosis.”
4. Defining Quality by Outcomes

- Quality is achieved by “doing the right thing in the right way”

  Carrying out interventions according to pre-established standards and procedures to maximize the results

The right thing at the right time

- Quality comes from “doing the right thing at the right time”

<table>
<thead>
<tr>
<th>Wrong Things</th>
<th>Wrong</th>
<th>Right</th>
</tr>
</thead>
<tbody>
<tr>
<td>Times</td>
<td>Wrong time</td>
<td>Wrong thing</td>
</tr>
<tr>
<td>Right</td>
<td>Wrong thing</td>
<td>Right time</td>
</tr>
</tbody>
</table>

Right thing in the wrong way and wrong time

- Mortality rate among children admitted to Margret Marquart hospital in Ghana was 17.5/1000 admissions
- Hospital team began to study problem
  - Delays in coming to the hospitals
  - Delays in admission processing
  - Laboratory tests took a long time
  - The doctor saw the child late—and then did the Right Thing
- Multiple interventions to speed up time to treatment

Another way of looking at quality

- The “performance gap”
  - Where is the system or process failing?
  - The “gap analysis” looks at the things contributing

The Performance Gap

- Assessing the performance gap
  - What could be achieved
    - Our vision — where we could be
  - What is presently being achieved

Margret Marquart Catholic Hospital, Kpanido

Time From Registration Of Critically Ill Child To Initiation Of Treatment

- Median: 40
- Median: 20
- Time in Minutes
- Days

- Trage of OR/ICU, First track at Registration, Lab, Pharmacy
- Separate OR/ICU URGs
- No demand for payment for blood

Where we are now
Improving Efficiency and Effectiveness

- Assessing the performance gap
  - What could be achieved?

Gap Analysis: Why is the system not realizing full potential?

This gap is likely made up of many many small things

The Performance Gap

What is presently being achieved?

Getting here may require a different management approach

If you continue doing things the same way as you always have you will get _____

Getting here may require a different management approach

Gap analysis

- What steps need to be taken to move from the current state to a desired future state
- Commonly-listing of characteristic factors and performance of current state what is
- Listing of the factors required to achieve the future status what should be
- Identify gaps that need to be filled

The challenge: Close this gap with accessible resources

What could be achieved?

Gap Analysis: Why is the system not realizing full potential?

This gap is likely made up of many many small things

The Performance Gap

What is presently being achieved?

Search for new ways to address unmet needs

Not to create chaos or confusion

Secret team to "kill the old healthcare model" launches at Florida Hospital

Orlando-based Florida Hospital President and CEO Daryl Tol said during a recent talk that the hospital has created a secret team called Project Fulcrum to "kill the old healthcare model," according to the Orlando Sentinel (2018)
Simple example

<table>
<thead>
<tr>
<th>Future desired state</th>
<th>Current state</th>
<th>Action proposals</th>
</tr>
</thead>
</table>
| 90% of calls for appointments answered within in 2 minutes | 40% of calls for appointments answered within 2 minutes | 1. Develop a call-volume reporting system and ensure adequate staff in busy times  
2. Recruit additional people as required.  
3. System to book a automatic call back in busy times |

Bridging the gap

- In reality there may be a number of items contributing to the gap, some large and some small
- For major systems problems a problem solving process may be required
- This is where a “disruptive approach” may be appropriate—searching for a new or alternative model

Measurement according to standards

- Standards are common methods to measure quality
- Performance can be determined to exceed, meet or fall short of the standards
- Standards come in many forms
  - Guidelines
  - Pathways
  - Protocols
  - Best practices
  - Benchmarks
- Many sources for standards

Defining Quality by standards

- Measuring Quality
- Many definitions which often overlap, some qualitative
- A common approach is measured by performance against the applicable standard
  \[ Q = \frac{P}{S} \]
- “Quality is the conformity between actual care and pre-set criteria…”—Donabedian
- “Conformance to requirements”—Crosby
- Aim is to reduce performance variation from the standard

Origins of the Quality Movement

- Concern about quality started with industry in the 1920s
- Dissatisfaction with inspection
- Hiring more inspectors was not improving quality of manufactured goods
- But it was causing excessive...
  - Waste ➔ product was discarded
  - Rework ➔ product was sent back for correction
- These two words became part of the quality vocabulary

Costs of Correcting a Defect

\[ \begin{align*}
\text{Internal failure costs} & = 1x \text{ if found while being done} \\
\text{External failure costs} & = 10x \text{ if found on inspection} \\
& = 100x \text{ if found by customer}
\end{align*} \]
Enter W. Edwards Deming (1950s)
- Began his work with war industries
- Transferred to Japan to help with the national census post WW2
- Began to consult with Japanese industry
- Concepts of “customer” and “supplier”
- Emphasis on statistical control of production

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- Concepts of “customer” and “supplier”
- Emphasis on statistical control of production
- Promulgated 14 points
- Some became famous Deming phrases
  - “Cease dependence on inspection”
  - “Drive out fear”

Early Focus on “Variation”
- Looking for variations from the standard (Q = P/S)
- Reducing variation is an important part of the quality literature
- Reflects statistical origins of quality improvement
- Variation are classified and causes pursued
  - How frequent, how much variation?
  - In control? Out of (statistical) control?
- No American interest in quality assurance until 1960s when US automobile industry was in trouble from Japanese competition
- Now variation is of great interest for service industries
- Hospital outcomes research a common example

Variations from standard
- Common variations and consequences—leading to loss of effectiveness—here is an example from health care—

<table>
<thead>
<tr>
<th>Standard</th>
<th>Performance gap</th>
<th>Consequence</th>
</tr>
</thead>
<tbody>
<tr>
<td>All hypertensives will receive adequate treatment</td>
<td>25% did not get the adequate care</td>
<td>68,000 deaths per year</td>
</tr>
<tr>
<td>Patients with heart attacks will get appropriate hospital care</td>
<td>50% did not get appropriate hospital care</td>
<td>37,000 deaths annually</td>
</tr>
<tr>
<td>Older patients will receive pneumococcal vaccine</td>
<td>36% did not receive OPV</td>
<td>10,000 deaths annually</td>
</tr>
<tr>
<td>Persons at risk for colon cancer screened</td>
<td>62% not screened</td>
<td>5,000 deaths annually</td>
</tr>
</tbody>
</table>

Common and Special Cause Variations—creating performance gaps
- Common cause variation
  - Caused by everyday events in the process
    - Staff
    - Equipment
    - Supplies
  - These arise from problems with the process, so potential for statistical control is good if the process is improved
Common and Special Cause Variations

- **Special cause variation**
  - Caused by "one-off" events or due to specific events
  - A specific piece of equipment, or issues with a few people, or uncontrollable circumstances (flooding)
  - May not be so easy to control

The Shewhart Plan-Do-Check-Act Cycle (1931) PDCA

- A start at looking at improvement as a cyclic process

Quality is discovered by the U.S.

- Adopted by large manufacturing industries 1970s
  - Crosby: "Quality is free"
- Rising concerns about costs
- Realization that poor quality costs
  - Juran: "Costs of non-compliance"
- Concern about costs, competitiveness, client retention
  - It takes three times less effort to retain a user than get a new one

The term “Quality Assurance” appeared

- Arose out of the industrial concerns of loss of market share
- The original idea was to “assure” the customer that a product or service would always contain quality.
- The term “quality assurance” now includes many quality-related activities
  - Process control
  - Repair of existing systems
  - Creation of new systems with quality as a “built-in”
- Many “Q” words have evolved

Unpacking “Quality Assurance”
Parts of Quality Assurance: Quality Improvement

- Quality design
- Quality assurance
- Quality improvement
- Quality control

Trying to fix existing activities

What is commonly done when things are pointing down

Parts of Quality Assurance

- Quality design
- Quality assurance
- Quality improvement
- Quality control

Inspecting for compliance

Parts of Quality Assurance: Quality Assurance

- Quality design
- Quality assurance
- Quality improvement
- Quality control

Building quality in from the beginning

Quality Design

- Designing with quality from the beginning of a new process
- Full understanding of environment and background
- Find out the "voice of the customer"
- Include customer/user in the design process
- Flow chart out the entire process
- Standardizing the process
  - Establishing procedures or protocols
  - Benchmarking
  - Quality function deployment for industrial design

Quality Control

- The "little q" things
  - Inspection of the processes
  - Medical record reviews
  - Laboratory confirmation testing
  - Outcome standards
  - Drug utilization
  - Infection control
  - Safety inspections
  - Credentialing
  - Accreditation

Quality Improvement

- The "Big Q" things
  - Total quality management (TQM)
    - Term originated with Deming
    - Supply chain management and internal statistical control
    - Run charts, variation measures, and LOQAS examples
    - Strong emphasis on customer satisfaction
    - Emphasis on training and support of individual workers
Total Quality Management
- Everyone in an organization must be part of improving quality
  - Planning—Organizing—Implementing
- An organization must develop a problem-prevention mentality
- Every activity in an organization must be viewed through the lens of quality improvement
- The organization is totally committed to quality as the way of doing business—the creation of a Culture of Quality

The Culture of Quality
- The Culture of Quality is highly sought after
  - But organizational culture is hard to turn around—often said to take about 8-10 years—may require incentives
  - A culture of quality starts with the leadership of an organization
  - Behavior change is often the first evidence of take-off
    - This can be driven by new protocols, new expectations, and working methods—but driven by leadership
    - This is followed later by changes in attitudes

Quality Improvement
- The “Big Q” things
  - Continuous quality improvement (CQI)
    - Named this to indicate the continuous nature of improvements to quality—always looking to raise quality
    - Less of a systems-wide approach than TQM—suitable for departments and functional units
    - Has many of the features of TQM, but with a stronger emphasis on process improvement.
    - CQI stresses strengthening organizational structure and systems

Continuous Quality Improvement
- Less of a top-down approach and suitable for decentralized organizations with professional staff
- Encourages people in the processes to set their own standards
- “Threshold standards” not consistent with the idea of continuous quality improvement
- “Best practices” also not a good fit with the process-oriented philosophy
- Implies that there is a formula which will produce best results

Many Management Tools
- Quality improvement management approaches strive to bring together established management methods to focus on issues of improving quality
- They are built on a series of principles and use a variety of tools
  - These have many origins
  - Most came from industry, but increasingly from other service industries

“Quality Assurance”
- Quality assurance is a generic term used worldwide
- Other terms don’t include idea of “assurance”
  - Total Quality Management (TQM)
  - Continuous Quality Improvement (CQI)
- In some places quality assurance has a bad name because of long association with control and inspection activities and the “quality police”
- Quality improvement moves away from the ideas of inspection and control—emphasizing that everything can be improved
- But “assurance” remains especially relevant to health care
Quality moves into health care

- Quality remained an industrial idea until the 1970s
- Then picked up by the service industries
- In the 1980s Quality started being taken seriously by health care
- By this time Avedis Donabedian had already been thinking seriously about quality

Donabedian and quality in health care

- Introduced systems thinking
- Insisted quality could be defined
- And this it could be measured

Avedis Donabedian

- He defined quality as the “… provision of care in a way which is expected to maximize measures of patient welfare.”
- These were inclusive measures—measuring multiple components
- Not only could the process of care be measured
- But importantly outcomes could be measured
- But in measuring outcomes the variability of patients responding to a process would be considered

Measuring Quality

- Donabedian believed that once quality was defined it could be made “transparent”—in his words
- Monitoring and measurement is undertaken against a standard or “benchmark”
- Using this information, adjustments can be made in the process to improve quality
- Through this approach quality can be “assured.”

Components of quality

- Donabedian proposed that quality was composed of two groups of factors
  - The first was the science and technology of health care
  - The second was the application of that science and technology in actual practice—the process of applying quality
- Both of these were measurable, but by different approaches

Donald Berwick

- Early student of quality in health care
- Strong proponent of evidence-based medicine
- Established Institute for Healthcare Improvement
- Felt that 20-30% health care expenditure was waste
  - overtreatment
  - Uncoordinated care
  - Administrative waste and fraud
- Briefly the administrator of Centers for Medicare Medicaid
- Support for health care to the poor cost him his job
**Berwick’s triple aim**

- Strengthen the health status of populations
- Focus on individuals and families
- Redesign of primary care services and structures
- Population health management
- Cost control platform
- System integration and execution
- Stabilize or reduce per capita costs
- Improve patient satisfactions and outcomes

**The Institute of Medicine...**

- Noted that not all Americans got high quality medical care
- A large number of unnecessary deaths occurred
- Health care in the US is poorly organized to meet health needs
- A major redesign is needed to focus on primary care
- Making health insurance available and affordable
- Improved use of technology

**Crossing the Chasm**

The health care we could have

For quality, this is not a Gap
But a Chasm

The health care we now have

**IOM defines quality**

- Institute of Medicine definition
  - Healthcare quality is “…the degree to which health care services for individuals and populations increase the likelihood of desired outcomes and are consistent with current professional knowledge”
  
- This definition went on to say—
  - The care should be based on the strongest clinical evidence
    - Provided in a technically and culturally competent manner
  - With good communication and shared decision making

**IOM identified aims for the 21st Century**

- These are similar to the “Components of Quality” from the Quality Assurance project
- Effective
- Efficient
- Patient-centered
- Timely
- Equitable
- Safe

**1. Effectiveness**

- How well does an activity deliver what was intended?
- Effectiveness may be diluted by many things
1. Effectiveness

- How well does an activity deliver what was intended?
- Effectiveness may be diluted by many things
- The Tugwell formula
  - Community effectiveness = efficacy \times diagnostic accuracy \times provider compliance \times patient compliance \times coverage

1. Effectiveness

- Does a treatment or activity produce a better outcome than alternatives—which may include doing nothing?
- The right thing in the right way
  - Avoiding underuse or misuse of effective care
  - Avoiding overuse of ineffective care
- Builds on evidence from
  - Bench research
  - Clinical trials
  - Epidemiological research
  - Outcome research

Individual and Population based

2. Efficiency

- Reducing leaks in health system performance
- Unnecessary steps
- Duplication of effort
- Unnecessarily complex tasks
- Emphasis on the reduction in waste and rework
- Stabilizing or reduction in per capita costs of health care is a central tenet of quality improvement

This is a major quality improvement area

3. Patient centeredness

1. Focusing on the needs of the user or the external customers
- Users include families and communities
- Understanding expectation of the users (Voice of the Customer)
  - Below expectations, at expectations, exceeding expectations
  - What happens if expectations are unrealistic?
  - Collecting information from the users to inform services
  - Taking measures to ensure expectations are met
3. Patient Centeredness

2. Recognizing the Internal Customer
- Unless the internal customer is satisfied, the client or external customer will not have expectations met.
- Employee satisfaction is an important
  - "The patient will not be treated well unless we are treating each other well.
- Employee retention is important—the idea of continuity of care is a central Quality Assurance tenet.

Examples of using data
- Hospital addressing low satisfaction and retention of professional staff.
- Collected information for employees, addressed concerns.

3. Patient Centeredness

3. Access to services
- Can people physically access clinic services?
  - Individually and as population groups.
- Are there cultural, language or perceptions to services?
- Is there access to referrals?
- How important are costs as a barrier to accessing services?

Iraqi refugees in Syria
We can always afford medications we need.
We can always afford medical care.
We receive enough information to stay healthy.
We have access to the medical specialists we need.
We are able to get medical care when necessary.
- Strongly Agree
- Somewhat Agree
- Somewhat Disagree
- Strongly Disagree

3. Patient Centeredness

4. Recognizing the needs for basic patient amenities
- Waiting facilities
- Privacy
- Gender issues
- Environment for care.
7. Amenities
- Waiting facilities
- Toilets
- Personal comforts
- Environment

4. Timeliness
- This can be examined at different levels
- Awareness that services exist
- Delays in seeking services
- Transportation issues in utilizing services
- Delays within the health facilities in receiving care
- Common area for quality improvement activities

5. Equity in health services
- Providing health care that does not vary by
  - Gender
  - Ethnicity
  - Geographic location
  - Socioeconomic status

6. Safety
- This is another “assurance: part of health care
- Medical errors may kill from 44,000-98,000 hospital patients per year (IoM)
- Overall medical deaths may be 180,000 per year in USA
- Probably around a quarter are preventable
- Many of these have to do with poor communications, and poor hand-offs between services and providers
- Medications incorrectly given
- Lab tests never reaching the patient’s records
- Treatments accidentally discontinued
- Errors are have costs—human and financial
6. Safety

- To be safe, care must be seamless—supporting the ability of interdependent people and technologies to perform as a unified whole, especially at points of transition between and among caregivers, across sites of care, and through time. (IoM)
- Improving quality is a systems thing addressing—
  - Organization of health care must be improved
  - Accessibility and useful of clinical evidence
  - Methods of payments
  - Providing incentives to promote quality

Two levels

- Safety within the health facility
  - Hand washing, disposal of sharps and medical wastes
  - Hospital disaster plan
- Safe treatment for patients
  - Standards of care
  - “Best practices” in patient care

6. Safety

- The “assurance” part of quality assurance
- Can the patient trust the health services to provide the maximum benefit with minimal danger?
- The role of . . .
  - Standards and regulation
  - Guidelines
  - Procedures
  - Job aids
- The health workers
  - Initial training, continuing education
- The Gold Star or similar accreditation approaches

“Third generation” quality improvement methods

- Baldrige Criteria
- Six Sigma
- Balanced Score Card
- Lean Project Management
- 5S Kaizen—builds on TQM

Final thoughts

- There are more new quality improvement methods in the market place of ideas
- And more will come—and maybe you will invent the next!
- Increasingly these focus on specific areas or types of services, often expanding on more general or traditional quality improvement approaches
- Applying new methods to health services in developing countries remains a major challenge—but one which is very important indeed