An Engineering Perspective on Quality

or

How to design a quality improvement that works and avoid “6x9 error”

J. Geoffrey Chase and Geoffrey M. Shaw
**Who**: An engineer with experience in several failed companies over time

- General Motors, Xerox, Hughes Space and Communication, Reflectivity, ... , University of Canterbury (?)
- Yet another lesson on association and causality?

**What**: An experiential tour of how basic quality faults in process or design can kill your great new, actually good, idea ...

**Warning**: I will avoid all the “stock” charts, processes, and buzzwords (if I can), and try to talk more about the basics from an engineering perspective

- I.e. I promise not to solve your problem(s)
What is Quality?

- **Quality**: noun /kwälətē/: The standard of something as measured against other things of a similar kind; the degree of excellence of something

- Simple sense: does it perform well compared to similar things?
- Even simpler sense: is it good?

- **Main problem**: what do you compare against? How do you maintain quality? When do you compare? ...
  - Don’t we all have other jobs?
  - At Ford Motor Company “Quality is/was Job #1” ... But, is it really?

- **Other main problem**: how do you design an intervention that you are confident will perform better and stay that way?
- Attention to detail
- Focus on critical elements
- Willingness to revisit the data regularly

- ... OCD ... (?) ... Note that we haven’t seen anything about charts or methods

- I.e. Cultural not methodological, but ..., then anyone can do it
Assessing Quality

- Easy, and there about **8 Trillion** ways to do it ... (NB: statistic is entirely made up)
  - Process control charts, run diagrams, X (averages) and R (ranges) charts, p-charts (proportion defective) ... None to different to Bland-Altman (over time) or others ...

- **Problem**: These are all after the fact ... They capture deviation from desired performance and improvement after a change, but, ... They don't tell you whether a change is worth doing in the first place ..
The real goal

- Design interventions to minimise risk of failing to improve
  - Means you should know, truly know, the answer before you implement it fully!
  - Assumes you are designing an improvement in care in the first place

- Main elements:
  - **Right metric**: something easy and non-arbitrary to measure
  - **Right metric**: make sure it isn't biased by admissions or other factors outside the control of the quality change
    - Means you need to understand those elements and what they might be
  - **Right metric**: something of value and relevance to the unit
    - Not typically financial, but workload, consistency of care, patient outcome, patient burden...

- Outcome: you need to define expected (and realistic) desired performance in design phase
  - Areas where you can get big changes are important, and areas where changes may be small or hard/arbitrary to measure may be less so.
  - Identifying these areas is actually the hard part
Metrics: the good, the bad, and the just plain ...

- **Good:**
  - BG, platelets, FiO2, mortality ... Deterministic, low error (except in South Africa?), measured regularly, easily identified and stratified, patient-centered ...

- **Bad:**
  - LoMV, LoS, SMR, many agitation and acuity scores ... OK, but subject to uncontrolled bias in policy, cohort, admission process, time of day, patient type, ...
  - Cost, normally “good” but usually too broad a task. At GM we were always $800/car behind the Japanese and the constant demand to “reduce cost” wasn't helpful without a specific target. Note: “everywhere” is not a specific target.

- **The just plain ... :**
  - Effort (not related to countable tasks), perceived anything, in fact anything almost entirely subjective and based on personal feeling as it is very hard to get consistent results across a unit or cohort.
Where to live metric (WtL):

- WtL = Yearly_High_Temp – Yearly_Low_Temp
- Here are two places that look the same, but are clearly different by metric – showing good resolution! The “sheep” are bigger in one too...

North Dakota = 42 - (-45) = 87

Christchurch = 35 - (-4) = 39
Of course care must still be taken

- Care is needed with ideal values, so make sure you have all the necessary information in your metric

North Pole / Arctic = -5 - (-40) = 35
San Francisco = 33 - (-2) = 35

- Perhaps average temp should be included!
Quality should come from a significant and in-depth design process up front (i.e. Think the idea through first)

- There are actually very often only a few areas to improve quality and consistency in a realistic and sustainable manner (I could go on for hours ...)
- Far fewer than are usually undertaken
- Thus, as seen in my resume and a range of quality literature, many fail

In many complex engineered products the design phase can be as long as, or longer than, the product lifecycle

- Why should it be different in clinical cases?

The reason?

- Improving quality is easy, especially with extra resources available
- Sustaining it is not, especially if extra resources are not available

The solution ... design and careful targeting of quality improvements

- One sustained quality change is worth more than 1000 that are not ...
- A quote and statistic I just made up ... But reflective of the real outcomes
- For example, almost every TGC protocol ever published (vs SPRINT)
- All those charts and process management systems are about measuring whether quality is sustained

- There is actually very little about how to design or target them
- The biggest design improvements and game changers are at “leverage points” where big gains in cost/outcomes may be seen for relatively small changes in process, design or behaviour.

- GM designed a $125 ABS system when they cost $2500, where the big reduction leveraged ABS into 4x more cars (from top 20% to ~all).
- Ipods/Iphones: leveraged low cost touch screens and good interface design into $500M per day of sales and whole new ways of accessing information.
- Winglets reduced fuel consumption in aircraft for a small change in design.

- Note that all of these can be “defeated” by “poor” use of the device, or by poor construction.

- Similarly, in healthcare, variability in how you implement something can reduce efficacy ➔ **good design comes in here** to prevent that.
- Equally, variability in patient behaviour can defeat improvements targeted at the mean or median patient response. **Patients are variable too, the more conscious the more variable!**
3 Main Lessons

- **One Method** instead of **One Size** (fits all)
  - Most engineering areas design by a fixed “method” rather than a fixed answer or approach – they sound the same but ...

- Continual improvement is allowed, and in fact defines engineering ...
  - Where nothing is so good that it cannot be “improved”
    - A real quote: *There comes the time in the life of every project where it becomes necessary to shoot the engineers and begin production*

- Minimise your **6x9 error**
  - Design for easy assembly and for easy checking of mis-assembly
One Size

- Based on a fixed rule or set of rules
- Requires explicit calculations that are the same for the same inputs
- **Risk**: rigid design that doesn't account for variable conditions or use
- **Risk / Benefit?** Done once to get one answer, not iterative
- **Benefit**: Ensures a minimum documentable standard (6ml/kg anyone?)
- A “standard” in health care because easily documented and defended, and, to some, it removes the need for regular (every day) QC
I mentioned Civil Engineering

- Structural engineering codes are based on One Size approach to design and there is little QC in construction, despite some checking
  - *Each is unique as they are built just once, but design is not!*

Didn't account for parking garage next door

Built to same code and in similar style – 3-5 blocks away
One Method:

- A fixed approach using models or other means to adapt design to specific conditions. Calculations are therefore not explicit, but subject/product specific by method.
- **Risk**: incorrect implementation → poor result and failure, hard to document!
- **Benefit**: accounts for variability and changing conditions, individualised
- **Benefit**: Inherently iterative in nature, always a chance and basis to improve
- A “standard” in all arenas of engineering I have worked except Civil Eng, because you can use QC to check and easily ensure risks are minimised and benefits maximised.
8 zillion ways to do it, but the fundamentals are always the same

- Information
- Understanding
- Not “outsiders”

- Iterative development of solutions
- Time consuming ~ Patience + Planning
  - Cars = 3-5 years or more
  - Medical devices = up to 10 years
  - Planes = up to 20 years
  - Computer chips = 2-4 years but ongoing
  - Dedicated ongoing effort

- We spent 5 years developing SPRINT
- vs <6 months for other protocols (<1 week?)
Recently (re)discovered by the FDA!

- And given name Quality by Design (QbD)
  - For drug development primarily...

Recently (re)discovered by the FDA!

A note on design by committee

- Design does require leadership and focus
  - Preferably centered on end-users to avoid “strange perspectives”
  - Nothing is worse than the resulting paralysis in large group design
Columns define a building's strength and flexibility.

For steel reinforced concrete columns, it's the area or amount of steel, and the distance from the column center.

- More steel area and farther away is generally better.

Distance = \( L \) from center
Area = \( \pi \times \text{diameter}^2 / 4 \)
So, a young civil engineer is inspecting buildings in (city) in (recent year) and comes across ...

The difference is over 50% reduction in stiffness and strength.

PS: yes, this is bad ... Very (falling down) bad ...
Young 22 year old engineer vs 50+ year old Sr Foreman ...
  - What to do ?? ... Sound familiar?

Senior Foreman: *Six 9s or nine 6s, same difference, and the 9/16ths is really hard to get these days ...*

Young Engineer: *Ummmm ...*

**The Motto:** Never design something that isn't robust to how it might get built / implemented, your “6x9 error”
  - Never assume perfect implementation, especially if its complex
  - This limits a lot of otherwise feasible quality changes
  - An improvement that adds effort isn't an improvement these days
  - If you ask nicely I will tell you about “after lunch” cars ...
- Keep it simple, but not too simple – every engineer knows this... As do many other folks...
  - Yet, have you seen some of those protocol flow charts?!
As with the previous slide ... It helps to use good design to know the answer before you build it...

- It will save you lots of time and effort, and all sorts of other good stuff
- **Design, design, design ... and then implement**
  - One Method not one size
  - Know the answer before you implement it, yes I know it takes out all the fun and equipoise but ...

- **Simple counts ... A lot**
  - Added effort these days equals non-compliance and poor results, integrate with workflow and don't expect it to adapt to you

- **Robustness and 6x9 error**
  - If the change you expect is within the 6x9 error you might get it needs to be either simpler (more robust) or avoided
  - Don't fool yourself on how large 6x9 error actually is ...

- **All together, these are rare and hard to do, and require detailed on the ground insight and focused effort**
  - It's why evolution so often beats revolution! In medicine as in many areas of engineering
  - Or, **keep your eye out for revolution while ensuring constant evolution** – it’s how the biggest and best technology companies work (Truly! An iPhone is an iPod with a phone chip and an iPad is a large iPod!)
With special thanks to ...

- My occupational heroes...

- You’re never too old or experienced for a new take on gravity!