Why we need to learn standardisation

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Following 12 years of gradual transition from direct patient care to health care improvement, I still remain a novice. However, I have learned several important lessons including the importance of standardisation in which the 'what' is driven by evidence based medicine, the 'how' is customised but specified by small tests of change, and the way the two are linked.

Most improvement activities use elements of standardisation, but unfortunately standardisation is looked at as the end of the improvement process rather than as a start of the learning process. When standardisation lacks customisation and improvement methods are presented as the final word, standardisation may be seen as little more than loss of their autonomy in caring for the special needs of unique patients, and the victory of 'cookbook medicine'.

But as Deming noted in his book, *Out of the crisis*,[1] if we do not use standardisation voluntarily, we end up with regulation. It would be hard for even the most independent minded physician to disagree that regulation has now become commonplace in medicine, and that medicine is nearing a crossroad of public credibility. Consumers are rapidly becoming aware of the glaring deficiencies in our current health care system, and consequently are demanding safer and more reliable health care. In an effort to both conform to current regulations and respond to pressure to improve health care outcomes, quality organisations are standardising a variety of clinical care processes.

Why standardisation?

Although most clinicians agree that standardisation is warranted if only a single process has been conclusively shown to be both effective and safe, very few such clinical opportunities exist and when they do, standardisation attempts usually fail. For most medical tasks, no single 'right' process has been identified, but a number of possible actions are available, all of which are considered acceptable in light of the existing scientific evidence.

The difficulty with allowing any acceptable process within any given area of clinical practice is the lack of infrastructure to support the process. For example, multiple approaches will work for the practice of anticoagulation in the ambulatory setting. It is very likely impossible for a clinic or practice to train, test for competency, and follow outcomes for all nurses or possibly pharmacists working under such multiple approach conditions. For these reasons, the practice of anticoagulation is usually not standardised and remains the most common outpatient cause of serious adverse medication events. The multiple method approach makes the recognition of system defects difficult, and the correction of defects in a particular protocol even more challenging.

In contrast, a single standardised care process allows a group or institution to expect that all staff will be trained in that protocol, making follow up of the efficacy of care less arduous. More importantly, such standardisation facilitates detection of defects in care, and increases the ability to trace defects back to the cause. Each defect then becomes an opportunity to learn and improve the process. With multiple approaches, the ability to learn from defects of a care process is both more limited and more resource intensive, even when all approaches are consistent with acceptable practice.

Although the overall goal of a particular care process (eg. anticoagulation) should be similar between units, the details of each standardised process should be dependent on decisions by the local providers of the service. The creation of one care process that is universally appropriate across all care environments is nearly impossible. More importantly, imposing universal, 'one size fits all' requirements prevents front line providers from modifying the protocol to meet local demands and developing the sense of ownership needed to create acceptability in implementation. As front line personnel take ownership and develop and implement standards, they also acquire the new skills, attitudes and beliefs that are an integral part of continuous learning.

Method of standardisation

Planning and development of standards cannot succeed when experts try to develop the perfect protocol in an isolated environment without engaging front line care givers in testing those standards in the clinical environment. Unfortunately, in most

organisations standardised protocols or care processes are written by groups of experts in nonexperiential settings, all the while attempting to compromise and account *a priori* for all possible objections and contingencies. The resulting protocol is at worst completely unworkable; at best used only by a portion of clinical staff and has little staying power. Once clinicians and improvement staff have that type of experience most conclude that standardisation is almost impossible in the clinical environment. Successful standardisation methodology demands and expects local development and customisation, with the clear understanding that a given protocol is never being finished, but always in a state of modification and adjustment. This concept can be best described in a step by step process.

Steps to standardisation

Step 1 – define the situation

Establish the current state of affairs by observing, identifying problems and drilling for the root causes. Describe the ideal or target condition using evidence from the literature, knowledge of the local environment, and any available local data.

Step 2 – decide what and how to measure

Define and implement a practical measurement system for testing change and measuring long term outcomes.

Step 3 – write the protocol

The first draft of the protocol should be written by experts, taking a minimum of time and using out of organisation examples of protocols if necessary. The initial protocol should reflect the views of the experts willing to try the first version of the protocol with patients within the next day or so. It should be written in such a way that changes can be made within minutes. The smallest possible number of items in the protocol combined with solid evidence should be the primary goal for most organisations. Only the most mature organisations should attempt to write complex if/then type statements.

Step 4 – get rapid reviews

Begin the processes of 'buy in' and improvement in safety and robustness of the protocol or standardised process by sending early drafts out to stakeholders for comment (with short turn around time limits).

Step 5 – test it

The early draft of the protocol should be tested with a few patients. Immediately after these patients have been tested, the authors of the protocol, nurses, and other staff who will be using the protocol should meet to discuss what worked well and what needs to be changed. Agreed on changes resulting from that feedback information should immediately be incorporated into the protocol for the next series of tests.

Step 6 – spread it

Once the protocol has been initially tested and modified, it should be given out to all other clinicians and staff who will eventually be expected to use it, and they should be asked for input. That information should then be used to remodel the protocol, as appropriate. The remodelled protocol should be tested and repeatedly remodified as needed.

Step 7 – establish rules for use

Before the protocol is released for use, an understanding should be reached that all clinicians will either use the protocol or will provide an explanation whenever they opt out of using it. All clinical users of the protocol should understand the underlying rationale for this rule, namely, that their explanations for opting out provide information that is crucial for remodelling and improving the protocol.

Step 8 – identify an owner

The ability to sustain a protocol is dependent on an owner. The owner's responsibilities include continuously gathering new literature that would impact the protocol, gathering and analysing data on why the protocol is not being used, and monitoring compliance with protocol use. Changes to the protocol should not be made without 'buy in' by the protocol team and the consent of the process owner, who should then delegate the process of making the changes.

Step 9 – remodel it

Remodel the protocol based on knowledge from instances of nonuse and defects detected during its use. Modification and improvement should be an ongoing process. In essence, no protocol should ever be finished; it will always be in the design (or redesign) stage.

Conclusion

Standardisation of a care process need not be perfect. If an attempt is made in the initial design to deal with any and all possible clinical events that can occur, the initial product becomes far too complicated. It is better to start with the common, then use observed defects in the protocol to determine the redesigns that will ultimately, and continually, be needed.

It is also important to recognise that the methods of creating standardisation may be more important than the standardisation itself. When the process of testing, measuring and improving the protocol is inclusive, clinicians are more likely to feel reassured that the standards are safe and effective. Certainty, in turn, creates simplicity, acceptance, increased use, and better clinical outcomes.

The literature on standardisation is extensive[2,3] and no single method has proven to be consistently successful. However, the combination of the small test of change and involvement of the whole care team develops the culture necessary to sustain any change that is made.

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References

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