An Emerging Science of Improvement in Health Care

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An Emerging Science of Improvement in Health Care

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ABSTRACT The purpose of this article is to describe the emerging science of improvement in health care and to add a perspective from the industrial quality improvement movement, the use of data from quality registers, and to give some personal reflections and suggestions. Furthermore, we want to introduce to the broader quality management community what is happening in health care with respect to quality improvement. We will discuss some of the challenges of the health care system and the current status of a science of improvement and give some suggestions for further improvements to the area.

We discuss a possible extension of improvement knowledge and the theoretical and practical arsenal of a science of improvement, in particular, understanding variation and implications for the use of, for example control charts. In addition, the normative side of a science of improvement is discussed. The article ends with some brief reflections of use for future research agendas.

KEYWORDS health care, quality improvement, improvement science, science of improvement, profound knowledge

INTRODUCTION

Health care is increasingly facing a lot of challenges. The demands are increasing and reports about health care shortcomings have become increasingly common. Thus, there is a need to introduce new ways of working. Health care of today is said to be evidence driven with high requirements for data from randomized controlled trials and from careful observational studies. However, even though huge amounts of data are collected in quality registers and by other means, clinical practice is often not governed utilizing these data for learning, improvement, and innovation. Thus, even though individual health care workers are providing excellent and dedicated work, the health care system might be flawed and patient outcome might be less than optimal, perhaps unsatisfactory, or even unacceptable without anybody noticing it, more than individual patients.

During the last decades there has been a movement toward a view that clinics and health care systems should not only have a systematic way of improving
medical treatment and nursing utilizing evidence from research but also have a systematic way of improving how health care is delivered to the patients—how the health care system supports its patients to better health without risking any harm. An attempt to provide a basis for such initiatives is called improvement science or a science\(^1\) of improvement. The purpose of this article is to describe this emerging field and to add a perspective from the industrial quality improvement movement, the use of data from quality registers, and to give some reflections and suggestions. In this introductory section we will first discuss some challenges of the health care system and give a short outline of the rest of the article where the current status of a science of improvement is discussed as well as some suggestions for further developments of the area.

The increasing demand on the health care system is due to, first, the growing population of elderly people suffering from multiple diseases. At the same time, the productive part of the population has become relatively smaller and therefore health care funding may be jeopardized (Weisz et al. 2013). A second reason is the appearance of new and much improved possibilities to give life supporting cure and care. Some of these possibilities are very costly, and even if many may indeed reduce the total costs to society, the cost reductions do not always benefit those that have the cost burdens from new treatments. Systems handling this unbalance are not common. Furthermore, the rate of innovations in health care is increasing—it has been argued (Dixon-Woods, Alamberti et al. 2011; Sjohania et al. 2007) that the half-life of knowledge is 5.5 years. A third argument is an increased focus on health and well-being in the population—how does the health care system in a productive way take care of an increased health literacy and requirements on patient autonomy and patient empowerment? (Anderson and Funnell 2005; Reach 2014).

Another kind of challenge is the stream of reports on the shortcomings of health care systems. In the UK, for example, the Bristol heart scandal (Weick and Sutcliffe 2001) at the Bristol Royal Infirmary a number of years ago revealed unacceptable shortcomings and later the Mid Staffordshire scandal attracted a lot of attention, with many investigations and government reports—similar shortcomings were reported in these inquiries:

No clear visions and goals, no culture of patient centeredness, boards and top management not taking the lead on these questions, insufficient feedback loops on what is really going on in the organization with respect to quality and safety, etc. In a recent study (Dixon-Woods et al. 2014) of the National Health Service (NHS) many good things were reported, specifically the ambitions and goodwill of the health care professionals to provide good care; on the negative side, however, it reported that the above-mentioned shortcomings might be more widespread than so far revealed. We will return to this study later.

It is not only in the UK that these types of problems are frequent. In Swedish newspapers we read almost every day about mistreatments, long waiting times, and scarcity of personnel. Just to mention one recent story revealed by a Swedish TV program, the deteriorating screening procedures of cervix cancer samples may have caused malign tissue samples to remain undiscovered. Even though results were fed into a database, there was no feedback to the person performing the screening. In all work correct feedback is important—without correct feedback any work process may deteriorate.

The high cost of the U.S. health care system\(^2\) is, of course, also well known. For example, the U.S. health care expenditure in relation to the gross national product is almost double that of Sweden and the medical results are not better; in many respects, in fact, they are much worse. Furthermore, in a recent paper (James 2013) it was reported that as many as 200,000 and perhaps even 400,000 deaths per year in the United States may be caused by avoidable harm.

Of course, there are no silver bullets to solve these problems (Shjoania and Grimshaw 2004). However, as one part of a solution, a focus on quality and quality improvement seems necessary. As illustrated by the study of the NHS, a mindset, close to what in industrial settings has been known as total quality management (Bergman and Klefsjö 2010), should be strived for—perhaps a new management paradigm in health care. In this direction we find the emerging science of improvement in health care.

In this article, we will first discuss the findings of the NHS study mentioned above and relate these to

\(^1\)The concept science might be considered problematic; see, for example, Wilmott (1997).

\(^2\)Based on Organization for Economic Cooperation and Development data comparisons between the cost and medical outcomes were compared in a report from Swedish Association of Local Authorities and Regions (SALAR).
the early discussions on quality in health care by Ernest Amory Codman¹ and Avedis Donabedian (1992, 2002)² but also to the early discourse on quality improvement in industry. Based on these discussions we will inquire into the scope of a science of improvement. During the course of the article we will come back to the NHS study mentioned above for illustrative purposes. Illustrations from the Swedish health care will also be used. As part of a brief review, some earlier discussions on the emerging science of improvement will be given. Then, in the main part of the article, the core of a science of improvement will be discussed. It should, however, be emphasized that a science of improvement in health care really is in a preparadigmatic stage, to use the words of Kuhn (1962). Thus, many interpretations and outlines have been given, perhaps under different headings, and probably many more will come—and should come. Indeed, this article will give our interpretations and suggestions, which might go further in scope than many other alternatives.

A science of improvement must, of course, address how improvement issues are identified and elaborated upon, eventually leading to successful interventions with even better outcomes for the patients. It must also address how these improvements are evaluated and how lessons are learned from them. But it is equally important to foster an environment where improvements are seen as normal and inspiring parts of the daily life in an organization. This environment is a pivotal requirement for a transformed health care system. How is that achieved? These latter questions are much harder and more pressing than the operating work with improvements themselves, however important they are. Of course, these aspects—that is, the operational improvement interventions and the improvement of the organization’s readiness (capability and capacity) to improve and innovate—should go hand in hand, and no simple recipe can be expected.

THE SCOPE OF A SCIENCE OF IMPROVEMENT

The NHS study mentioned above was a multime-thod study of the NHS during the years 2010–2012 with interviews, surveys, board protocols, and direct observations together with data from 2007 to 2011 on staff experiences, patient experiences, and patient mortality rates. A large number of findings in this study corroborate our view of what is important in a science of improvement. Some findings were highly encouraging; for example, a consistent focus from front line people to do their best for their patients to create the best possible care.

However, in some organizations there were no clear goals, no vision, and no culture for continually refining patient quality and safety. In such organizations the front line staff observed severe system deficiencies but felt powerless to deal with them, whereas management perceived problems with quality and safety as caused by the front line people. That is, the staff and the management had no common understanding about how to solve their problems and to improve patient quality and safety. In addition, there was a lack of intelligence—that is, poor follow-up of both their own results and results from similar units—in order to find improvement opportunities. Interestingly, the researchers were able to observe that

... hospital standardised mortality ratios were inversely associated with positive and supportive organisational climates. Higher levels of staff engagement and health and wellbeing were associated with lower levels of mortality, as were staff reporting support from line managers, well structured appraisals (e.g., agreeing objectives, ensuring the individual feels valued, respected and supported), and opportunities to influence and contribute to improvements at work. NSS [NHS Staff Survey] data also showed that staff perceptions of the supportiveness of their immediate managers, the extent of staff positive feeling, staff satisfaction and staff commitment were associated with other important outcomes, including patient satisfaction. (Dixon-Woods et al. 2014, p. 112)

Let us compare these results with the simplified model of health care that was suggested by Avedis Donabedian, who observed that health care (1) outcomes are produced in (2) processes that are imbedded in systems and their (3) structures. According to Donabedian (2003), “structure” is meant “to design the conditions under which care is provided” (p. 46). Examples include material and human resources, the presence of teaching and research, performance reviews, etc. In our interpretation aspects like governance, leadership, learning mechanisms, organizational climate, organizational design, intelligence, attractors, incentives, norms, values, and similar “soft” issues should be included. Process signifies “the activities that constitute health care – including diagnosis, treatment,

¹For a short biography of Codman, see Neuhauser (2002).
²For a short biography about Donabedian, see Best and Neuhauser (2004).
prevention, and patient education. . .” (Bergman et al. 2011, p. 41). Finally, outcome measures are the resulting states from care processes, both technical (for instance, absence of complications) and interpersonal outcomes (for instance, patient satisfaction).

However, we also want to add how individuals in the organization would react to different change interventions; that is, individual predispositions. It should also be noted that we interpret the concept structure rather freely, not as it is often interpreted as something that is but rather as something that is in a constant becoming and flux; see, for example, Sztompka (1991). Indeed, this view on structure is pivotal to our view on the health care system.  

With a serious ambition to improve outcome for patients—that is, quality and safety—a science of improvement has to address improvements on all levels of the Donabedian model. It is not enough to make improvements on the process level only. In addition, soft aspects of the environment of the process (and its microsystems) have to be addressed: How is the climate for change generally and how are the individuals’ predispositions for change? How is patient centeredness supported? How is intrinsic motivation of the staff supported? What are the norms and values? How is reflection and learning supported? It is only at such levels that we can assure some sort of long-term survivability of improvement efforts, see e.g. Docherty et al. (2003) and Docherty and Shani (2008).

From this discussion, the following definition of quality improvement suggested by Batalden and Davidoff (2007, p. 2) is adequate; that is, quality improvement is seen

... as the combined and unceasing efforts of everyone—health care professionals, patients and their families, researchers, payers, planners and educators—to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning).

When talking about system performance in the above definition we should also include the predispositions for change (or readiness for change) of the individuals within the organization. Depending on past experiences, these predispositions could look very different in different organizations. The organization’s drive for change (i.e., improvements including innovations) should be a very important target of improvement efforts.

A SCIENCE OF IMPROVEMENT: A BRIEF REVIEW

An important starting point of the quality movement was the seminal books by Shewhart (1931, 1939); Shewhart was very much influenced by pragmatic philosophy (Lewis 1929), eventually leading to the much used Plan-Do-Study-Act (PDSA) cycle and his thoughts about predictability and corresponding criteria have been central. Later, the experiences from the Japanese wonder and the reawakening (Cole 1999) of the American industry were important. In health care, Ernest Amory Codman was already a pioneer in advocating the reporting of failures in order to encourage improvement before WWI. Later, after WWII, Avedis Donabedian developed the model referred to previously. However, inspiration from the industrial quality movement hit health care in the 1980s, first with quality circles and later in a much broader scope; see, for example, Berwick (1989), Berwick et al. (1990), and Batalden and Stoltz (1993). In the late 1980s, the Institute of Healthcare Improvement was founded by Don Berwick and a number of his colleagues. Many more initiatives started in the beginning of the 1990s.

Some important milestones were the roundtable around quality that was arranged by the Institute of Medicine; see Chassin and Garvin (1998) and the subsequent publications To Err Is Human: Building a Safer Health System (Institute of Medicine 1999) and Crossing the Quality Chasm: A New Health System for the 21st Century (Institute of Medicine 2001). These publications have had a great impact; for example, in Sweden they changed the earlier dominant punitive view on health care errors and quality dimensions of health care were identified as those suggested by the Institute of Medicine (Swedish National Board of Health and Welfare 2006).

In Sweden, Mölnndals Hospital (Alänge and Steiber 2011) was a forerunner focusing on quality improvement of its processes; a clinic at Linköping University...
Hospital (Bergman and Klefsjö 2010) was one of the first organizations, in competition with many otherwise successful manufacturing companies, to win the Swedish Quality Award; and in Jönköping County they initiated a journey on quality improvement that is still going on (Andersson-Gäre and Neuhauser 2007).

Deming (1994) identified that for leaders to work firmly in what he called the “New Economy” they have to have some understanding of a number of important interrelated knowledge areas. He emphasized “a system of profound knowledge” and “appreciation for a system; knowledge about variation; theory of knowledge; psychology” (p. 96). These knowledge areas and their extensions will be discussed more in the next section. Here we only mention that these areas were introduced to the health care community in a paper by Batalden and Stoltz (1993) under the concept improvement knowledge; see Figure 1. In a seminal book (Langley et al. 1996) on health care improvement the name improvement science seems to have been introduced for the first time (Perla et al. 2013; see also Berwick 2008).

They also suggested, as illustrated in Figure 2, how improvement of performance as experienced by patients (3) is achieved by the application of generalizable scientific knowledge (1) to the special context based on careful planning (4) and then a careful execution of the plan (5).

In Batalden and Stoltz’s approach, eight domains of interest with associated tools and methods are of importance. These domains are health care as processes within systems; variation and measurement; customer/beneﬁciary knowledge; leading, following, and making changes; collaboration; social context and accountability; and developing new knowledge. They are similar to but formulated differently than the principles for organizing we present in the section The Normative Side of a Science of Improvement. In Sweden, professional societies (nurses, doctors, nutritionists, physiotherapists, work therapists, etc.) have joined forces to create a common ground for professional education on improvement knowledge.

During April 12–16, 2010, a colloquium on the epistemology of improving quality convened at Clive-den (see, e.g., Batalden et al. 2011). One important outcome of this colloquium was the awareness and importance of taking many different perspectives on quality improvement in health care and to base training programs on multiple epistemologies informing health care improvement. Not only does traditional evidence-based medicine, resting on a natural science foundation, have to be called upon but also social science and deeper understandings of social change processes.

Recently, Perla et al. (2013) suggested some theoretical and philosophical foundations on which “the science of improvement” rests. For example, learning and the development of actionable knowledge is stressed and they refer back to philosophical pragmatism, especially that of Lewis (1929) and his conceptualistic pragmatism and subsequent interpretations and translations of Shewhart and Deming.

Concerns that improvement efforts too often are lacking in a thorough scientiﬁc basis has been aired by, for example, Marshall (2011) and Marshall et al. (2013). There is also a tendency that too much focus has been on implementation of solutions and on operational process improvement rather than on improvement and innovation of the health care system itself; that is, improvement of the organizational abilities and transformational changes of the health care system. Another striking observation is the relative lack of a patient’s perspective. Not that the patient is forgotten, but quite a lot of the literature is more operations focused than really patient focused. Works on the patient perspective (Bergman et al. 2011), patient empowerment (for a review, see Aujoulat et al. 2007), patient involvement in health care design and improvement (Bate and Robert 2006; Gustavsson 2013) should, we think, be much more in focus.

![Figure 1](http://qualitysafety.bmj.com/content/20/Suppl_1/i99.full.html#ref-list-1)
It is quite natural for an emerging field that its theories are discussed quite extensively and also that results close to the very aim of the field are discussed. Educational aspects are, of course, also very important. What would be needed, though, are more empirical papers contributing to our understanding of how an organization’s capability and capacity\(^9\) for improvement and innovation are enhanced.\(^10\) The NHS study described earlier is a good illustration. A Ph.D. thesis on a similar theme but limited to one hospital group including the surrounding municipalities and the primary care centers has been presented by Lifvergren (2013).

**IMPROVEMENT KNOWLEDGE**

As emphasized in Figure 1 based on Deming’s “profound knowledge,” improvement knowledge takes a central position in most descriptions of a science of improvement. However, the different knowledge domains have deepened since the days of Deming and the need to broaden these areas has become obvious. In the following we will discuss each one of the basic knowledge domains separately, emphasizing their deepening and possible ways to extend them. However, we will leave most of the “understanding variation” domain until the next section.

**Appreciation for a System**

Some basic features of the understanding that Deming drew on—for example the insight that enlarging the system boundary may give opportunities to better solutions to pressing issues—are still important and, unfortunately, in these respects health care still has a lot to do to integrate their different parts as well as to integrate with other organizations outside health care for the benefit of their patients (see the section Understanding Variation). This is also an important part of what Deming called *win–win solutions*.

However, our understanding of systems has increased substantially since the days of Deming. The theories of complexity (see, for example, Waldrop [1992] and Stacey [2003]) and complex systems had just started in the beginning of the 1990s. Recent knowledge from complex adaptive systems research shows that the complexity increases\(^11\) and thus the manageable and predictability decreases (e.g., Axelrod and Cohen 1999; Stacey 2003). In complex systems the concept of attractors—that is, what attracts the system to develop toward a certain set of states—is also important for our understanding of how change efforts may work. In order to try to understand social systems better we also have to draw much more on social sciences in our basic improvement knowledge—we will come back to that later in this section, giving the knowledge area *psychology* a much wider definition than in the original one suggested by Deming.

**Understanding Variation**

Deming emphasized reduction of variation (see also Bergman 2003); however, there is much more to it. We will come back to that later but let us first make a note on the control chart, suitable for finding assignable or (as Deming put it) special cause variation.\(^12\) Shewhart emphasized the need to have predictable processes, Shewhart’s (1939) definition of such processes is the same (see Bergman [2009] and references cited therein) as that of exchangeability used by de Finetti (1974). Shewhart (1931) gave five criteria for such processes.\(^13\) One of these is based on the control chart—the one that is most well known and for which Shewhart is the

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\(^{9}\)Note that an organization might have the capability to make improvements but due to resources restrictions their capacity is limited.

\(^{10}\)This is also emphasized by Marshall et al. (2013); see also Parry et al. (2013).

\(^{11}\)Interestingly, these have been graphically explained by Ishikawa (1982, 1985) in the seven quality control tools.
most famous. Violations of these criteria may be used to identify assignable causes. Specifically, if we have made an intervention hoping for an improvement, then that should result in an assignable cause indicating a positive result. That used to be one of the cornerstones in the philosophy of Joseph Juran.\textsuperscript{14} We will discuss variation more in the next section.

### Knowledge Theory

This theory originated in the conceptualistic pragmatic philosophy of Clarence I. Lewis, professor of philosophy at Harvard University. It provided a background for the PDSA cycle (see, for example, Mauleon and Bergman 2009; Peterson 1999; Wilcox 2004). In addition, it is emphasized that theory is the basis for prediction—prediction is the basis for action and if the action does not lead to the predicted result there is a need for reflection and revision of the theory (i.e., learning) in order to perform better actions in the future. Lewis emphasized that knowledge is for action (Lewis 1929). Indeed, this is what Dixon-Woods, Bosk et al. (2011) wrote in their reflections on the Michigan case. Furthermore, when different humans observe the same phenomenon, they may experience it very differently due to their \textit{a priori} understanding. This understanding sometimes leads to conflicts in a group if it is not understood that the differences depend on different mental models, as Peter Senge (1990) would state it.

Closely related is how we as individuals create meaning—and even more important how individuals transform their ways of creating meaning—something that is important in many quality improvement efforts, especially on the structural and system levels in the Donabedian model. When there is a need for second-order type of learning, how is that achieved? We have to call in much more from current research around meaning creation, transformative learning (Mezirow & Associates 2000), and learning to learn (Argyris 2003; Visser 2003). Note that first-order learning means that we learn something within our earlier understanding of reality, and second-order learning means to change our way of understanding reality, to get a new way of creating meaning. Third-order learning means achieving a way of reflecting on self and question the current way of creating meaning. In this learning, reflection is an important process: to use a statistical metaphor, the Bayesian learn more and more about the current model when the given likelihood function changes due to an increasing amount of data (single loop learning). However, to change the shape of the likelihood function or recognizing that no likelihood function exists due to assignable causes of variation (not in themselves under statistical control; see Bergman and Chakhunashvili 2007) is an illustration of a kind of second-order learning. Within this metaphor, third-order learning should mean to have a systematic approach to find out whether the current assumed likelihood function really is relevant for the problem at hand or not. Usually, the above forms of learning are taken as individual learning; however, in an organization it is important to attach these types of learning to the organization. Learning is the achievement of knowledge—knowledge is for action—and common knowledge is for common action.\textsuperscript{15}

### Psychology

What Deming emphasized here was the importance of intrinsic motivation. Currently, there is much more evidence about the importance of intrinsic motivation and how that has been put into systematic use in some organizations. A popular book by Dan Pink (2010) illustrates this nicely. Closely related to research results on intrinsic motivation and self-determination theory (see the introductory chapter of Deci and Ryan 2002) is the new research field called \textit{positive psychology} (see, for example, Csikszentmihalyi and Nakamura 2011) with an interesting forerunner, Mihaly Csikszentmihalyi (1990), and his research on creativity and the concept of \textit{optimal experiences}, also known as \textit{flow}.

Under the heading \textit{psychology}, Deming emphasized not only individual psychology but also interactions between people. This should lead us into a much broader research field to integrate into a science of improvement. Indeed, a lot of social science should be incorporated here; there might be a need for a new heading for this broad knowledge field, which has been proven to be of great interest to a science of improvement (see, e.g., Dixon-Woods, Bosk et al. 2011). For example, an important research tradition with much in common with the quality movement is action research;

\textsuperscript{14}This is called the Juran trilogy: design–control–improvement; see Juran (1986).

\textsuperscript{15}This is a reformulation of a comment in Lewis (1929); an interesting framework connecting the individual with the common is given by Crossan et al. (1999).
see, for example, Lewin (1948) and Coghlan and Brannick (2010). For some recent applications within health care see, for example, Lifvergren, Gremyr et al. (2010), Lifvergren, Docherty et al. (2010), Lifvergren et al. (2011), Lifvergren et al. (2012), Gustavsson (2014), and Lifvergren (2013).

A System of Knowledge

Deming emphasized that profound knowledge is a system of knowledge—the different parts are interrelated. Even though Dixon-Woods, Bosk et al. (2011) do not explicitly use this conceptualization in their study of the Michigan project, it is an excellent illustration.

Even though Deming’s profound knowledge serves well as a starting point, we now need a broader set of basic scientific knowledge—perhaps under different headings. Indeed, this is underway even if the headings have remained the same. However, it is important to understand that the theories we use in our interpretations are important for our continual learning how to better achieve our organizational goals; as Deming (1994) said, “Experience by itself teaches nothing. . . . Without theory, experience has no meaning. Without theory, one has no questions to ask. Hence, without theory, there is no learning” (p. 106).

UNDERSTANDING VARIATION

In the Beginning There Was Variation

Already with the Big Bang variation was there—if it had not, we would probably still have a homogenous universe—and no “we”! And so it goes on—heavier and heavier atoms, the creation of stars and galaxies, and eventually some things that replicate, vary, interact, and compete for energy—the organic life has begun. And eventually intelligent creatures who create ideas and thereby a new evolution starts. And here we are—the results of a long chain of results from variation, selection, and interaction. Indeed, variation is a central part of our lives.

In discussions of variation it is important to see differences and similarities between two different kinds of variation: variation between units when time is not in focus, or synchronic variation, and variation over time, or diachronic variation. Too often, only the synchronic variation is discussed, though in many cases diachronic variation is the most interesting—how is it possible to predict future outcomes given the data? Did an intervention give the intended result? Much medical research in terms of randomized controlled trials emphasizes synchronic variation. A stronger emphasis on diachronic variation would be an important contribution to medical research. And, of course, diachronic variation is of great importance for the improvement of health care. An illustration where a quality improvement intervention seems to have had a very important effect is illustrated in Figure 3. For some further reflections see the following subsection.

Variation in Health Care

We are all different—patients are all different. Most often health care professionals have a good sense for that—meeting each patient here and now on the conditions of this patient. Thus, on an individual level there is often a deep understanding of variation. However, when it comes to clinical research, variation has often been kept under the carpet—what have been counted are averages—mean values. At least, that has very often been the case in randomized controlled clinical studies, known as the golden standard of clinical research. Variation is used mostly through the standard error of the mean to judge whether mean values are statistically significant or not. If it is not mean values it is often percentages of individuals reaching a certain target; HbA1c is a typical case where changes have been made a
number of times—not only target values but also measurement methods. This is, of course, very problemati-
cic—target values change and thus operating definitions change and possibilities to compare with history are
lost. This may partly be due to a lack of insight concerning diachronic variation.

Nowadays, with the insights and the possibilities for
genetic testing, an increasing understanding for variation
and that randomized testing is not always the best
answer is emerging. But genetic variation is just one
source of variation—also important are epigenetic vari-
ation, behavioral variation, and perhaps even cultural
variation (Jablonka and Lamb 2005). These types of
variation must be taken into account. That is often not
done in the current clinical research paradigm. As
many interventions and improvement activities have to
be adopted in a social system, the variation in contexts
is very important and can explain sometimes confusing
results and large variations; see, for example, Pettigrew
and Whipp (1991), Bate (2014), and the Health Foun-
dation (2014). Today, there is quite a lot of focus on
quality registers and thereby a potential to evaluate
new interventions. From the registers random selec-
tions taking different factors into account—the use of
design of experiments based on registers and follow-up
through the registers and then subsequent analysis of
results—seems to be a very interesting possibility not
yet utilized.

Quality Registers

The world’s first national quality register was created
by Ove Gulberg Høegh to register patients suffering
from leprosy in Norway 1856. In the beginning of the
20th century, Ernest Amory Codman created a register
on shoulder surgery. However, it was not until the end
of the 20th century that registers for a large number of
diseases became common. In Sweden, we have around
100 such registers today—each recording a number of
different diagnoses and corresponding process and out-
come measures. They were first created by enthusiastic
physicians to get better hold of their specialties as well
as for research purposes. An illustration is the first regis-
ter in Sweden, a knee replacement register, initiated in
1975 and shortly after followed by a hip replacement
register. Due to the registers it has been possible to
increase reliability of these types of replacements with
great benefits both for patients and for replacement
costs. The situation in Sweden, where all citizens have
a unique personal number, is especially beneficial for
research. It is, for example, possible to combine results
from different types of registers. Of course, efforts are
needed to assure that integrity aspects are taken into
account.

Registers are increasingly thought of as a huge possi-
ability for improvement activities. However, it has still
very much stayed at a rhetoric level and much has to
be done to educate health care professionals to utilize
these registers in their daily improvement work (see,
e.g., Bergman 2013). Among the best registers to pro-
mote improvement work is the diabetes register, where
today it is possible to get information online concern-
ing different hospitals and their results with respect to
smoking cessation, blood pressure, HbA1c, patient
recorded outcome measures, etc.

Reflections on Variation, Statistics,
and the Theory of Probability

As we observed in an earlier section, variation is a
basic concept in our understanding of the universe. In
this section, we want to explore further some of the
basic aspects of knowledge theory and variation. When
observing the world we find variation, and that gives
rise to uncertainty when we try to make predictions
about the future—and, in a way, such predictions lie
behind our decisions and subsequent actions, even if
not always as rational as we would like to think; see, for
example, Kahneman (2011). In this way of looking at
things, which is very much in line with the ideas of C.
I. Lewis that influenced Deming and Shewhart, proba-
bilities describing our uncertainty exist in our theories
about the world, not in the world itself. In fact, that
leads us to a subjective (or Bayesian) interpretation of
probabilities as promoted early by Ramsay (1926), de
Finetti (1974), and Savage (1954). Bayesian statistics
has gained a lot of attention in medical statistics lately
(see, e.g., Ashby 2006).

The Subjectivist Interpretation of
Probabilities and Conceptualistic
Pragmatism

Lewis (1929), in his conceptualistic pragmatism,
emphasized that theories are a priori, which however,
we are free to choose. He also emphasized that it is
only in the light of this a priori that we experience what
happens in the world. According to Lewis, experiences are an interpretation of the sensuously given based on the a priori. It is indeed also a basic ingredient in our possibility to reflect upon and learn from our experiences. We find a striking similarity between the thinking of Lewis and that of Bayesians.

There is another interesting connection between Bayesian statistics and traditional quality improvement à la Shewhart and Deming. The control chart makes an interesting bridge investigated by Bergman (2009). When Shewhart (1939) made a formal definition of a process under statistical control—that is, about predictability—he used a criterion that in the Bayesian/subjectivist literature is called exchangeability. It was introduced by de Finetti (1974) as a prerequisite for a predictive distribution to exist. However, in the Bayesian/subjectivist literature the judgment of a process being exchangeable is left to the decision maker and no tools are provided. However, here the Shewhart control chart comes in handy. It is designed exactly as a tool for judging predictability of a process. We will come back to this in the next section. First, however, we will make an important note that is sometimes forgotten when discussing the contributions of Shewhart. He not only suggested the control chart to be used for judging if a process is under statistical control, but he also pointed to four more criteria to be fulfilled for a process to be free from assignable causes of variation. Four of these five criteria of Shewhart’s were later transformed into a graphical form by Kaoru Ishikawa (1982) to form some of the well-known seven QC tools: histogram, stratification, scatter diagram, and control chart.

### Control Charts

When Shewhart introduced the control chart in his seminal book from 1931 he recognized that not all processes were predictable in a statistical sense—sometimes assignable causes of variation interfered and predictability was lost. It is important to identify such assignable causes of variation and to eliminate them in order to get a predictable process. But not all predictable processes give an acceptable result. We have to make more drastic improvements in the process, not only to remove assignable causes of variation but to more radical changes in the process/system. This was illustrated in what Juran called the Juran quality trilogy (Juran 1986): planning a process, controlling it (and take away assignable causes of variation), and then improving the process. After a successful improvement we go into a control phase again; see Figure 4.

As seen in Figure 4, the control chart works in three different ways. First, to judge whether a process is predictable, take away assignable causes, estimate parameters, etc. (phase I); second, to survey the process (phase II) to guard against new assignable causes that hopefully will be eliminated to give a predictable process; and thirdly, to work as a confirmation that an intervention, a change of some kind, really was an improvement (phase III). It should be mentioned that phase III is usually not mentioned in a systematic way in the literature on control charts even though it should be regarded as a very important aspect of the use of control charts. In Figure 3 on sudden infant death syndrome we saw that a substantial improvement in the process had occurred. The occurrence of an assignable cause of variation of a positive kind could be taken as a strong indication that the intervention (in this case a campaign) really was successful. Of course, it is important to make sure that no other changes have been active that could have affected the process.

In health care today, both process measures and outcome measures are documented in quality registers. This provides us with an excellent possibility to evaluate improvement interventions—if the relevant measures come from a process under statistical control it is possible to conclude whether an intervention really is
an improvement or not because it should show up as a positive assignable cause. In many respects, such a strategy for evaluating an intervention has many advantages over the usual gold standard of clinical medical research; however, we will not go further into this debate here.

When reflecting on the ideas behind Figure 4 it becomes obvious that the usual phase I and phase II descriptions of the work with a control chart are not quite enough. A phase III should be added when improvements are in focus. The special assignable cause that might have occurred due to an intervention usually takes some time to mature (if positive as intended). How long do we need to run the process until we can judge predictability (and the new level)? A possible phase IV should be very similar to phase II. We will come back to this later in this section.

### A Bayesian Control Chart

In the literature on Bayesian control charts we do not see the type of control charts that Shewhart advocated; that is, a chart for judging whether a process is under statistical control or not. Rather, the state under statistical control is determined from the beginning and an out-of-control state is defined. The argument for the name Bayesian is because these states are given subjective probabilities and if the out-of-control state gets a high enough probability an out-of-control situation is declared. In fact, the out-of-control state is in itself assumed to be a process under statistical control. Depending on the purpose, this might be perfectly all right. However, we just want to determine whether the process is under statistical control or not; that is, whether it is reasonable to judge it predictable or not. Based on the nature of the process, some sort of model might be judged if the process is under statistical control.\(^\text{21}\)

When we observe the process, we also increase our knowledge about the process and increase our possibility to predict what will happen in the future of the process—at least if it is under statistical control; that is, still predictable. But how do we judge that? A simple way would be that the observation at time \(t + 1\) is within what could be called the predictive interval as judged from observations up to time \(t\). And that should also be the case for all of the past observations due to the fact that the process under statistical control is exchangeable.\(^\text{22}\) The only thing to find out is how the predictive interval should be calculated. In the spirit of Shewhart it may be taken as the 3\(\sigma\) limits of the predictive distribution. However, just as Shewhart indicated, another choice could be relevant depending on the situation. It should be noted that it is necessary to go back also to old observations because in the beginning of the observation period the knowledge about the process is not as strong as later on. That means that an observation at time \(s\) might be within the predictive interval based on observations up to time \(s - 1\) but when time has passed to time \(t \gg s\) we know much more and therefore the observation at time \(s\) may be outside the new predictive interval and judged to be due to an assignable cause of variation. This is an interpretation of what Lewis (1934) meant by “[…] knowing begins and ends in experience; but it does not end in the experience in which it begins” (p. 134). Based on more knowledge, we may reinterpret the history that gave us the knowledge we have.

We still have a task to think about how the process should be handled after an improvement has been made and found effective as described by the Juran trilogy. In fact, we could proceed just as before—we have an improvement and we have to reformulate \(a\) \(\text{priori}\) in order to predict the future. When starting to observe the process it was natural to assume a noninformative \(a\) \(\text{priori}\) distribution. However, after observing a positive effect of an intervention it is not quite clear how a renewed \(a\) \(\text{priori}\) would look like. A pessimistic choice would probably be to use a noninformative \(a\) \(\text{priori}\) before the observation that has just been seen to be outside the predictive limits—most probably due to the intervention made—and then start anew from there. As is often the case, the process has not yet reached a steady state and thus it would be natural to find the next point outside its predictive interval. The procedure goes on until a new steady state may be concluded.

\(^{22}\)A small problem is that the prediction interval for an observation at time \(s < t\) is based on all observations including the one we want to have a predictive interval for. If a recalculation should be made for the predictive interval for the observation at time \(s\), utilizing all observations but that at time \(s\) is a matter of being purist or not.
Evidence-Based Medicine

The gold standard of clinical research has been the randomized controlled trial for a long time. However, some problems are surfacing. Too much focus has been on differences in averages (or median), though of course variation is also very important, as well as factors underlying that variation. The Plavix case is an interesting illustration—due to genomics, 30% of patients do not have the possibility to transform the drug into its active component. Emphasis is also almost always on one-factor-at-a-time experimentation. Furthermore, the population used for the test was different from the one in which the results will be utilized, and the controls may be different and not adequate for the application area. For a long time treatments that have been shown to have efficacy for one type of population have been used for a very different population (for example, the elderly or small children). Thus, much more emphasis should be put on methods utilized in industrial settings: design of experiments, control charts, data taken from the treatment processes, etc.

Control charts are an excellent illustration: Assume that an intervention to a process under statistical control has been performed (after Phase II in Figure 4), and that after the intervention the process again is under statistical control but on a better level (better mean, lower standard deviation etc.). Then there are good reasons to assume that the intervention had a positive effect on the process, at least if no other changes to the process are found.

We will not go further into these interesting areas here, but there is a great potential in letting improvement methodologies stimulate the development of complementary medical research methodology.

THE NORMATIVE SIDE OF A SCIENCE OF IMPROVEMENT

A science of improvement is not a science that is purely objective and without a purpose; on the contrary, its purpose is quite clear. The knowledge needs that a science of improvement has to fulfill are how improvements are achieved and sustained. In a health care context, it should be understood that improvements are directed toward health in society: For patients here and now and in the future and, more generally, for the health of the citizens here and now and in the future. In the quality movement this has been formulated as a value or a principle for organizing. As a support to this main principle some other principles have been promoted (see, e.g., Anderson et al. 1994; Bergman and Klefsjö 2010; Cole and Scott 2010; Dean and Bowen 1994; Hackman and Wageman 1995; ISO-9000, International Organization for Standardisation (ISO) 2000). As we emphasized earlier, it has to address operational improvements not only at the operational process level but on the organization as well as on the overall health system level. An illustration is given in Figure 5. The different principles are related to those presented in Bergman and Klefsjö (2010) but with a slightly different wording. These and similar principles have been suggested in many other publications, in research papers on the quality movement, and in more popular books as well as in ISO-9000. Sometimes these principles are formulated as values. Here we prefer to talk about principles for organizing—principles that should be possible to test for when decisions and other kinds of actions are taken in the organization. Do they follow or are they breaking against these principles? In the next section we will discuss these principles. Then we will discuss the relations between principles, practices, and tools.

Principles for Organizing

In Figure 5 the principles advocated in Bergman and Klefsjö (2010) are displayed but with slightly different formulations. Below, we only give a very brief description—more detailed descriptions are found in textbooks like Bergman and Klefsjö (2010).

*Patients or citizens/stakeholders that health care wants to create value for.
Take a Customer Perspective

This means that we always should try to understand things from the patient’s point of view and also to support the empowerment\(^{23}\) of the patient. We judge this to be a huge revolution in health care because better informed patients are able to be equal partners in the curing and caring processes, resulting in higher quality and lower costs. Of course, not all patients have the possibility, but the lower the resource needs for capable patients, the more there is for those who are not as capable and therefore in need of more support. It is also worth considering that health care in a strict meaning seldom create direct value to the patients—the value is created in the life world of the person who is, has been, or is close to the current or former patient. Health care’s contribution is of cause very important, but it is only one of the components in the creation of value.

As observed by Normann (2001), it seems to be a general trend in different industries to change the way customers are looked upon. First, customers are looked upon as only consumers on a market, mass production is in focus and the decisive competence is production competence. Later on, customers are seen as a source of information (i.e., what is quality from a customer point of view), a customer basis becomes important and the decisive competence is the ability to build relations with the customers. In the final stage, the customer is seen as a co-producer and even as a co-creator of the value creation process. Value creation networks are in focus and the creation of such networks becomes a decisive competence.

Patient empowerment, co-production of care, and even in some cases codesign of care are currently discussed.\(^{24}\) A case of the last kind has been performed as an action research project on the rebuilding of neonatal care at the Skaraborg Hospital Group (SkaS). The method applied has been that of experienced based co-design developed by Bate and Robert (2006) based on concepts from the design industry. The method is based on four key steps: capturing experiences from patients and staff, understanding these experiences, improving based on these experiences, and finally measuring the results. In all of these steps patients are actively working first in their own group (the first and part of the second step) and then together with the staff. The experiences from the project at SkaS led to a number of changes—experiences from the patients indicated improvement possibilities of not only trivial kinds but regarding quite complex issues such as the cooperation between different wards, which showed new ways to coordinate work. Interestingly, the issues noted by the patients differed markedly from those of the staff (for a discussion of this and similar projects see Gustavsson 2013).

Use Intelligence for Decisions about Future Actions

How do we know about our customers preferences and needs and wants—how are our decisions in line with the life situation of the patient? Understanding the situation of the patient is an important starting point even though in decisions regarding treatment many other factors have to be taken into account. It is also important to understand the value creation processes and their functioning. How do we measure and with which results? But also intelligence concerning the processes and results of providers that are similar to us. From whom is it possible to learn? How do we keep track of new research results of importance to our activities? Earlier (Bergman and Klefsjö 2010) we called this “base decisions on facts”; however, replacing this with “intelligence” is a quest for an active process for gathering necessary information of importance for decisions. In addition, a focus on a high degree of intelligence is pivotal for learning in the organization.

Focus on the Value Creation Processes

The value creation processes in a system is all of those activities that repetitively create value. These activities may be value streams as emphasized in Lean manufacturing, more complex networks of activities, or shop solutions.\(^{25}\) Value is more and more created in networks of individuals—it has to be emphasized that these networks not only consist of the patient and other patients and health care personnel but also of others in society. For

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\(^{23}\)Patient empowerment has grown to a very intense area of both practical applications and theoretical research; see, for example, Nordgren (2008), Ekman et al. (2012), and Gustavsson (2013).

\(^{24}\)For illustrations of how patients have been involved in the creation of new health care solutions, see, for example, Bate and Robert (2007), Iedema et al. (2010), and Maher and Baxter (2009).

\(^{25}\)Unfortunately, the concepts here have become blurred—in many treatises processes are thought of as linear streams of activities; that is, value streams. Here it is interpreted as all of those arrangements that repetitively create value.
further discussions on processes see e.g. Hellström (2007), and Hellström et al. (2010).

**Improve Continuously**

Improvement is, of course, at the heart of a science of improvement but is also very demanding for an organization that has to be able to, at the same time, exploit the knowledge, capabilities, and capacities to deliver value to its customers. Simultaneously, the organization must explore new ways of working both in small incremental improvement steps but also in more innovative ways. Improvement in many cases means innovation—it is important for health care to rethink its capability and capacity for innovation; see also Dixon-Woods, Alamberti et al. (2011). Continual improvement is also very close to organisational learning. From a management point of view it is important to understand and help the organization to build learning mechanisms of different kinds: cognitive, structural, and procedural learning mechanisms (see Shani and Docherty 2003).

**Support Employee Intrinsic Motivation**

Earlier we discussed the importance of intrinsic motivation. As described by Dixon-Woods et al. (2014), most people in health care really want to help their patients—they have a strong intrinsic motivation. However, this is not always a principle that has been used for organizing, which is a serious waste.

**Take a Systems Perspective**

Everything goes on in systems—today’s health care is a very complex system that might sometimes make it unpredictable. System understanding should be utilized as a basis for decision making.

**Lead According to All of the Other Principles**

Good management and visionary leadership are important assets in all organizations. The support of employees’ inner motivation is an art. It is also a radical shift from many contemporary leadership and management ideals.

It should be noted that these principles are close to those advocated in ISO-9000 (2000) and not very far from what Anderson et al. (1994) described as concepts in a theory underlying the Deming management method.

**Improvement Domains**

It is easy to see that the principles described above are closely related to the domains described in the brief review above. The reason we have chosen to describe similar things as principles rather than domains is to clearly show the normative side of a science of improvement. Of course, the selection of domains is also governed by a normative will. However, it is not very clearly expressed.

**Principles, Practices, and Tools**

A large number of practices and tools are related to the principles and are necessary for the principles to be applied in everyday work. In many treatises on quality management, practices are not as clearly stated as opposed to principles and tools. One reason for this may be that practices have to be tailored to the context of the organization and its operation. On the high level of principles it is easy to give these principles a near-universal applicability. The same goes for the precise tools, whether quantitative or qualitative. However, when it comes to practices—the actual work processes applied in an organization—they have to be tailored to the specific situation and the tasks to be performed in the organization. To give universally valid descriptions of work practices would be hard even though recommendations could be given.

**REFLECTIONS**

When reflecting upon an emerging science of improvement in health care, a number of issues arise. Some of these reflections are very practical with respect to the development of health care in the future and some more philosophical. Only a few points will be given an initial reflection and some important questions and agendas for future research will be raised.
Practical Reflections

Reflecting on the challenges that health care faces, it could be asked whether it is really enough with a science of improvement. Will the use of improvement activities alone solve the problem or perhaps only lock health care even stronger in the current dead-end trajectory? Probably not. But technologies exist that could provide us with a completely different health care, but there seems to be no strong pull for these new technologies—health care is the last industry taking information technology solutions to heart. With a stronger focus on improvement issues—areas for reflection and an awareness of the possibility to find better ways—we believe that the ability to adopt new ways of working utilizing new technologies will be improved. Transformative learning is needed at all levels of health care and sometimes even on the patient side. But how is transformative learning supported in a health care system that is fully occupied with today’s problem (and sometimes yesterday’s omissions)?

As emphasized by Walker et al. (2007), working with improvements makes it easier to adopt more improvements and even disruptive innovations (see also Moore and Buchanan 2013). Today, skilful people work so hard that they have no time to find solutions just around the corner. “Best efforts are not enough” (Deming 1986, p. 19).

Philosophical Questions on an Improvement Science

Is a science of improvement really a science? What is a science? What is its ontology? What about its epistemology? How is it related to other kinds of sciences? What about its universality? As a combination of different knowledge areas, it could possibly be characterized by what Gibbons and collaborators (1994) called Mode 2 research. Many of its methods have been inspired by statistical improvement from other areas of application, but it is also about social change. How are these different ontologies and epistemologies combined in noncontradictory ways?

If we look upon health care as a service industry, we should perhaps learn more from the knowledge area of service management. It is often emphasized that value is not created by the deliverer only but together with the customer and in the customer’s own processes.

This seems to be very much related to issues in the patient empowerment movement. How far can we go in that direction?

What about fashions and fads? Many researchers of the critical management school are talking about the problems with what they call “new public management.” Is there something to take care of and be worried about from their critique? How is that done in a constructive way? And whatever theories and sciences we come up with, they are in a sense socially constructed—they cannot be otherwise (Hacking 1999). But the real test is their usefulness—still a science of improvement is only in an initial phase, but it is important that its usefulness is proven not only on local scales but on more universal ones!

... and the world moves on—who wants to be left behind?

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