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Quality Improvement from the Viewpoint of Statistical Method‡

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With the purpose of guiding professionals in conducting improvement projects in industry, several quality improvement strategies have been proposed which strongly rely on statistical methods. Examples are the Six Sigma programme, the Shainin System and Taguchi's methods. This paper seeks to make a rational reconstruction of these types of improvement strategies, which results in a methodological framework. The paper gives a demarcation of the subject of study and proposes a reconstruction research approach. Thereupon, the elements of the methodological framework are listed and briefly discussed. Finally, the effectiveness of the framework is illustrated by showing to what extent it reconstructs Six Sigma's Breakthrough Cookbook. Copyright © 2003 John Wiley & Sons, Ltd.

KEY WORDS: quality improvement; Six Sigma; improvement strategies; methodology; methodological framework; reconstruction

QUALITY IMPROVEMENT FROM THE VIEWPOINT OF STATISTICAL METHOD

In the course of the twentieth century statistical methods have come to play an ever more important role in quality improvement in industry. In this context, statistical methods were made operational in the form of statistical improvement strategies. It is the purpose of this paper to develop a methodological framework for statistical improvement strategies. Such a framework should provide definitions of relevant concepts, methodological rules and heuristics, both to help the practitioner carry out an improvement project, and as a paradigm for the researcher.

In the section below I give a precise statement of the objective of this paper. In the succeeding section I enumerate the elements of the proposed methodological framework. Thereupon, I discuss how the proposed framework can be corroborated and demonstrate to what extent it manages to reconstruct Six Sigma's Breakthrough Cookbook.

PROBLEM STATEMENT

Clarifying the words in the title of this paper, I work in this section towards a definition of the objective of this research.

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Quality improvement

According to Juran[1] the activities in companies that assure quality can be grouped in three processes: quality planning, quality control and quality improvement. In this paper I focus on the last process, quality improvement. It consists of the systematic and proactive pursuit of improvement opportunities in production processes to increase the quality to unprecedented levels ('breakthrough'). Typically, quality improvement activities are conducted in projects. Its proactive and project wise nature distinguishes quality improvement from quality control, which is an on-line process that is reactive in nature. Compare as well Ishikawa[2] (p. 201) and Taguchi's[3] distinction between on-line and off-line quality control.

Statistical method

Statistics offers a range of methods for the collection, presentation and analysis of data[4]. Underlying these methods is the framework of mathematics and mathematical modelling. Typically in statistical methods, a major role is played by the notion of uncertainty and the mathematical solution to deal with it, namely: probability, and—closely linked—the concept of random variation. This uncertainty arises when one realizes that an actual data set is just a specimen of a set of possible outcomes that one might have obtained in the given situation just as well. As a consequence, inferences that are made from data should take into consideration not only the data themselves, but also the alternative outcomes that would have been possible. Statistical methods do this—and by doing so enable an assessment of the reliability of a certain inference—by regarding observed data as realizations of random variables.

From the viewpoint of...

The link between quality improvement and statistics is formed by *empirical inquiry*. Namely, quality improvement projects can be regarded as empirical inquiry and it is in this context that statistical methods are applied in quality improvement. Statistical method as part of scientific method for empirical inquiry is described in, for instance, Good[5] and Mayo[6]. In quality improvement, the suggestion to consider statistical method in the context of empirical inquiry was supported by, for example, Box and Liu[7], who refer to statistics as 'a catalyst to learning by scientific method'.

The function of empirical inquiry is to *explain* empirical phenomena and, as a consequence, *predict* and *control* such phenomena (e.g. De Groot[8], p. 19; Kerlinger and Lee[9], p. 11). Explanations of empirical phenomena provide understanding by showing that the phenomenon to be explained should be expected as a consequence of certain causal influence factors[10,11]. Grounding explanation in causal relations is also consistent with Shewhart's views[12] (pp. 364–368).

Predictions have the same structure as explanations: where explanations show that *observed* phenomena follow from the laws underlying their behaviour, predictions show which *unobserved* phenomena would follow from these laws if conditions changed. Control consists of the application of explanations and predictions for one's benefit, in that conditions are changed in a way that has a positive predicted result.

The method of empirical inquiry is based on testing conjectures to empirical evidence. These tests provide feedback as to what extent the conjecture gives a useful explanation of a phenomenon. The rationale behind this method is that empirical evidence is based on real things, which are independent of our opinions about them. As a result, testing ensures that empirical inquiry is self-corrective and objective (this is C.S. Peirce's error-correcting doctrine; Mayo[6] (ch. 12) provides a recent discussion).

Objective of this research

Taking together the description of quality improvement and statistical method, and the proposed link between the two, I can define the subject of study. I define a *quality improvement strategy* as a coherent series of concepts, steps (phases), methodological rules and tools, that guide a quality professional in bringing the quality of a process or product to unprecedented levels.

The subject of this paper is formed by statistical improvement strategies. I call a quality improvement strategy *statistical* if:

1. it is aimed at the discovery of relations between the quality characteristic under study and influence factors in the process; improvement actions are derived from these relations;
2. conjectured relations are tested against empirical data before they are accepted as true.

In effect this definition states that in order for a quality improvement strategy to qualify as *statistical* it should be based on empirical inquiry. The definition rejects such improvement approaches as acceptance sampling, feedback control and mistake proofing, although they can be successfully exploited as part of a statistical improvement strategy. The definition specifically rejects 'problem fixing' in favour of explain → predict → control. Approaches that comply with the definition are the Six Sigma Breakthrough Cookbook[13], the Shainin System[14] and Taguchi's methods[15].

The study of quality improvement strategies as prescriptions for quality improvement projects can be seen as *reconstruction research*. This type of research studies systems of rules and seeks to formulate a rational reconstruction of these rules. A rational reconstruction presents a given complex system—such as a system of rules—in a similar but more precise and more consistent formulation. Rational reconstructions can have a purely descriptive impetus, but often have a prescriptive objective as well. Primitive reconstructions have the form of recipes or protocols; they are based on a systematization of instructions. True reconstructions have the form of a grammar. They should provide:

- definitions of relevant concepts;
- heuristics;
- methodological rules.

It is the objective of this paper to make a rational reconstruction of statistical improvement strategies.

A METHODOLOGICAL FRAMEWORK

The literature on empirical inquiry (methodology, philosophy of science) was taken as a starting point to formulate a methodological framework for statistical improvement strategies. Translating themes in this literature to the context of quality improvement resulted in elements $E1$ through $E7$. This process is described in more detail in De Mast[16]. Below I confine myself to listing the elements and giving basic explanation and some references.

E1. Explanatory networks and their structure

Empirical inquiry aims to result in an 'explanatory network' or 'theory'. A theory consists of a set of definitions of factors and—most important—*relations* among these factors. By specifying which factors are related to which factors and how they are related, empirical inquiry explains phenomena (for introductory discussions about the structure of scientific theories, see, e.g., Kerlinger and Lee[9] and Losee[17]).

The result of a quality improvement project has the form of an explanatory network that specifies causal relations between factors in the production process and the quality characteristic under study. Thus, it lists the causes of the problem, which is the basis for improvement actions. The knots in the explanatory network are of two types:

- *CTQs* (critical to quality) are the quality characteristics which are the subject of the improvement project (in the sense that the quality problem can be translated in this form: one or a few CTQs do not meet their requirements);
- *Influence factors* are factors in the process that causally affect the probabilistic properties of a CTQ.

E2. Types of influence factors

Based on the role they play in an improvement project, influence factors could be distinguished in three categories.

1. Control variables: continuous, discrete or even binary variables which are the experimenter's instrument to manipulate the CTQ. This implies that it is possible and feasible to set a control variable to a desired value.
2. Nuisance variables: continuous, discrete or even binary variables which are sources of unwanted variation that have to be eliminated or compensated for. It is not necessarily impossible for the experimenter to exert influence on their value, but especially during production it is either not feasible or unwanted to control their value.
3. Disturbances: events that have an undesired consequence for the CTQ.

The type of an influence factor determines to a large extent how it should be discovered, its effect tested and which role it plays in improvement actions. Control variables, for example, often do not vary during regular production and consequently they do not leave their fingerprints in passively collected data. This means that brainstorming techniques are likely to be more effective for their identification than analysis of passively collected data. Nuisance variables, however, can often be identified from passively collected data. The role of the types of influence factors in improvement actions is demonstrated briefly under *E*7.

E3. Phases in improvement projects

The activities in improvement projects can be grouped in five phases.

1. Operationalization: operational definition of the problem.
2. Exploration: identification of potential influence factors.
3. Elaboration: ordering and explicitation of potential influence factors.
4. Confirmation: experimental confirmation of the effects of influence factors.
5. Conclusion: exploit discovered relations to define improvement actions and update the quality control system.

The phases are based on the hypothetico-deductive method from philosophy of science, especially in the form of Dewey[18]. The core is formed by the alternation of the Exploration and the Confirmation phase. In the Exploration phase, potential (conjectured) influence factors are identified. This work has a speculative and non-methodical nature. In the Confirmation phase the effects of the potential influence factors are experimentally verified. This phase ensures objectivity. The iteration between exploration and confirmation (or discovery and justification, creative thinking and critical thinking, inductive and deductive thinking) is at the heart of many descriptions of scientific method.

In the Operationalization phase the experimenter makes the problem under study operational. In the Elaboration phase the identified potential influence factors are defined operationally. In the Conclusion phase the discovered relations between influence factors and CTQs are exploited to arrive at improvement actions. In De Mast[16] the relationship between these phases and Box's inductive-deductive model[19] and the PDCA cycle[20] is explicated.

The identification of these phases serves two purposes:

- as concepts they can be used to group related activities;
- as a heuristic these phases and their proposed order guide activities in improvement projects.

E4. Rules for the operational definition of a quality problem

In the Operationalization phase the experimenter makes his problem definition operational (see Hempel[21], ch. 7, for an introduction to operational definitions), resulting in the following.

1. The unit that is measured (that is, the 'thing' of which the CTQ is a property) is specified. The collection of all units is called the population. The population can be defined by describing the process that generates the units.
2. The CTQ is associated with a (reliable) measurement procedure, which attributes to each unit a value.
3. The requirements on the CTQ are stated (in terms of the defined measurement scale).
4. The current magnitude of the problem is assessed. The experimenter collects a sample of units, determines their CTQ value and compares it to the stated requirements. The result can be expressed as a percentage of defective units, in the form of a capability index, or as a mean and a short- and long-term spread.
5. It is specified when the problem is considered solved.

In industrial statistics the importance of operational definitions was emphasized by Shewhart[22] and Deming[23].

E5. Heuristics for the discovery of potential influence factors

In the Exploration phase the experimenter identifies factors that might affect the CTQ. For this purpose, he can study empirical data, systematize convictions that involved persons have, or consult accepted technical knowledge. The activities in this phase are not methodical, but literature provides heuristics that make these activities more effective[24,25].

- Zooming-in strategy: the space of possible influence factors is subdivided into classes (e.g. classes of types of variation). Identifying characteristic behaviour of the CTQ the experimenter eliminates entire classes of influence factors, thus zooming-in on the relevant classes.
- Thinking in standard categories: influence factors could be searched in standard categories, such as Man, Machine, Material, Method, Measurement and Environment.
- Assignable causes in data: the experimenter searches for patterns in data, thus identifying potential influence factors.
- Thinking in analogies: influence factors that play a role in comparable problems could be translated to the problem at hand.

E6. Iterative nature of improvement projects

A naïve portrayal of the work in improvement projects is: knowledge/data $\rightarrow$ logical and mathematical derivations $\rightarrow$ conclusion. This approach can only work if the solution is indeed logically implied in the data that were taken as a starting point. This is typically not the situation that an experimenter finds himself in. Empirical inquiry means that the experimenter takes his 'conclusion' as an intelligent guess (or 'hypothesis') and confronts it with empirical evidence. Based on the feedback, he again makes logical and mathematical derivations, which yield a refined hypothesis. This process continues ad infinitum or until a satisfactory result has emerged.

Inquiry means learning, and learning means that the experimenter starts out with incomplete knowledge and has to make assumptions. The learning process consists of refining and adjusting one's assumptions on the basis of confrontations with empirical evidence. Effective improvement projects exploit this interaction between assumptions and observations. Popper[26] depicts this process as a sequence of conjectures and refutations, or, in other words, 'trial and error'. A modern framework for learning from error is Mayo[6]. Compare as well Box and Liu[7] and Box[27], who distinguish between one-shot testing procedures and iterative discovery.

E7. Improvement patterns

Upon arriving in the Conclusion phase, the experimenter has discovered and modelled relations between influence factors and CTQs. Based on these relations improvement actions are defined. These actions follow standard patterns.

- Adjustment of the mean: one or more control variables are adjusted to bring the CTQ's mean closer to its desired value.

- Robust design: one or more control variables are adjusted to make the process less sensitive to sources of variation such as nuisance variables.
- Tolerance design: the variation in a nuisance variable is reduced or eliminated.
- Feedforward control: a control variable is continuously adjusted to compensate for the variation of a nuisance variable.
- Feedback control: a control variable is continuously adjusted to compensate for unexplained drifts in the process.
- Mistake proofing: the occurrence of disturbances is prevented or their effect on the CTQ reduced.

See MacKay and Steiner[28] for a similar discussion.

CORROBORATION OF THE PROPOSED FRAMEWORK

Before the proposed methodological framework can be accepted it should prove its value in a confrontation with the praxis of quality improvement. The acceptability of the framework has the following two aspects.

1. Is the approach that the framework generates for given improvement projects 'correct'?
2. Can the framework reconstruct approaches for improvement projects which are accepted to be 'correct'?

Two improvement projects were conducted along the lines of the proposed framework. The approaches are described in two case studies[16], which are open for criticism from researchers and quality professionals. In De Mast[29] the framework is used to compare three generally accepted statistical improvement strategies, namely, the Six Sigma Breakthrough Cookbook (DMAIC), the Shainin System and Taguchi's method. In this paper I limit myself to presenting how the framework reconstructs the Six Sigma Breakthrough Cookbook.

The Six Sigma programme

Six Sigma is a philosophy for company-wide quality improvement. It was developed by Motorola and popularized by General Electric. Several variants are current (compare, for example, the approaches described in Harry[13], Breyfogle[30] and Pyzdek[31]). For the strategical and methodological aspects I discuss the variant as presented by Harry[13] which was introduced at General Electric. For a description of the tools and techniques I consulted Breyfogle[30].

The programme is characterized by its customer driven approach, by its emphasis on decision-making based on quantitative data and by its priority on saving money. The selection of projects is based on these three aspects. Part of the Six Sigma programme is a 12-step 'Breakthrough Cookbook' (Inner MAIC-loop), a problem solving method '(...) specifically designed to lead a Six Sigma Black Belt to significant improvement within a defined process' (Harry[13], pp. 21.18–19). It tackles problems in four phases: Measure, Analyze, Improve and Control. The Breakthrough Cookbook is part of an embracing strategy—the Outer MAIC-loop—which comprises the strategical coordination of improvement projects (Harry[13], pp. 21.21–22). The 12-step Breakthrough Cookbook is studied here as a statistical improvement strategy.

Reconstruction of the Six Sigma Breakthrough Cookbook

It can be shown that the Six Sigma Breakthrough Cookbook meets the given definition of statistical improvement strategies.

1. The search for causal relations is omnipresent. Compare, for example, Harry[13] (p. 21.2): 'Supporting the approach is the central belief that the product is a function of the design and the manufacturing process which must produce it'. This is symbolized as $Y = f(X)$, where Y is characterized as dependent, output, effect, symptom, and its role as 'to be monitored' (Harry[13], p. 3.9). The X is described as independent, input, cause, problem, and its role as 'to be controlled'. The view is that the emphasis should shift from monitoring Y to controlling the relevant Xs (Harry[13], p. 12.24).

Table I. Phases proposed in the methodological framework and the Six Sigma Breakthrough Cookbook

Framework	Breakthrough cookbook	Six Sigma phases
Operationalization	1. Select CTQ characteristic	Measure
Operationalization	2. Define performance standards	Measure
Operationalization	3. Validate measurement system	Measure
Operationalization	4. Establish product capability	Analyse
Operationalization	5. Define performance objectives	Analyse
Exploration	6. Identify variation sources	Analyse
Elaboration		
Confirmation	7. Screen potential causes	Improve
Confirmation	8. Discover variable relationships	Improve
Conclusion	9. Establish operating tolerances	Improve
Conclusion	10. Validate measurement system (Xs)	Control
Conclusion	11. Determine process capability	Control
Conclusion	12. Implement process controls	Control

2. Six Sigma's maxim is 'Show me the data'. It provides statistical hypothesis testing and experimentation as means of testing hypothesized improvement opportunities.

I enumerate the elements $E1$ through $E7$ of the framework and apply them to the Six Sigma Breakthrough Cookbook.

$E1$. Explanatory networks and their structure
$E2$. Types of influence factors
In the Six Sigma programme, the needs of the customer are translated into critical-to-satisfaction (CTS) characteristics. These are associated with characteristics which are critical to quality, delivery or cost (CTQ, CTD, CTC) (Harry[13], p. 12.20). Influence factors are referred to under a variety of names, such as 'causes', 'Xs', 'leverage variables' and 'sources of variation'. Breyfogle[30] introduces the terms Key Process Output Variable (KPOV) and Key Process Input Variable (KPIV) for CTQ and influence factor. Copying Taguchi's[15] approach to parameter design, Breyfogle[30] (ch. 32) introduces the distinction between control and nuisance variables ('controllable' and 'uncontrollable factors' in his terminology). Disturbances are not explicitly distinguished in the Six Sigma literature.

$E3$. Phases in improvement projects
Table I compares the phases and steps in the Six Sigma Breakthrough Cookbook and the methodological framework. The 12 steps of the Breakthrough Cookbook are grouped in four phases (Harry[13], pp. 21.18–19).

1. Measure: a product related CTQ characteristic is targeted and its performance on the 'sigma scale' of quality defined.
2. Analyse: the principal sources of variation in the CTQ are identified.
3. Improve: the 'vital few' variables which govern the CTQ's performance are surfaced and with this knowledge operating limits for the leverage variables can be established.
4. Control: a control scheme is identified and deployed for the vital few variables.

These descriptions match to a large extent the functions of the phases Operationalization, Exploration, Confirmation and Conclusion respectively. However, the division of the 12 steps of the Breakthrough Cookbook over Harry's four phases deviates from the grouping in the table, in that steps 4 and 5 are grouped under Analyse, and step 9 under Improve. This seems to be dictated more by the desire to have three steps in each phase than by methodological arguments.

The Elaboration phase cannot be clearly distinguished in the Breakthrough Cookbook: it does not list explicitly steps in which potential influence factors are organized, defined operationally, and the possibilities for the experimental verification of their effect studied.

E4. Rules for the operational definition of the problem
Six Sigma pays adequate attention to the operational definition of CTQs and the problem under study. CTQs are made operational in the Measurement phase. An opportunity for non-conformance requires (Harry[13], pp. 12.9–10):

- a characteristic: the attribute, trait, property or quality to be measured;
- a scale: the relative basis for measuring a characteristic;
- a standard: the criterion state or condition specifying non-conformance;
- a density: the empirical distribution of the observations made on this characteristic.

The objective of the project—in terms of the chosen metric—is stated in step 5 of the Breakthrough Cookbook. These demands conform closely to the requirements that were stated in the methodological framework.

E5. Heuristics for the discovery of potential influence factors
The Six Sigma programme suggests a vast collection of tools and techniques for the discovery of potential influence factors (flowcharting, brainstorming, cause and effect diagrams, run charts, control charts, multi-vari charts, etc. See, e.g., Breyfogle[30], chs. 4, 5 and 15). However, these tools are not placed in a strategy or heuristic. When compared to, for instance, the Shainin System (see De Mast[29] for a comparison), it can be concluded that the guidance that the Breakthrough Cookbook gives for the work in the Exploration phase lacks a clear structure and coherence.

E6. Iterative nature of improvement projects
The notions of learning from error and that hypotheses and even the problem definition can be modified when insight advances are completely absent. The method is presented as a 'recipe' that guides the experimenter in a straight line to a solution (the designation Breakthrough *Cookbook* is telling in this context). It is not pointed out to the experimenter that many of his decisions (concerning, e.g., the problem definition, specification limits, objectives, potential influence factors) are intelligent guesses at best. The suggestion is aroused that the experimenter's decisions should be perfect at once, whereas experimenters should be taught a fallible and adventurous attitude that is open for new insights.

E7. Improvement patterns
The Six Sigma method focuses on experimentation. Among the suggested improvement actions are adjustment of the mean, robust design (Breyfogle[30], ch. 32), feedback control (briefly discussed in ch. 36), mistake proofing (ch. 38), and tolerance design (step 9 in the Breakthrough Cookbook). Feedforward and feedback control are underemphasized in the approach.

CONCLUDING REMARKS

Strategies like the Six Sigma programme introduce statistical methodology for empirical inquiry in an easily accessible manner in industry. Typically, strategies like this are presented in the form of a stepwise method. Although this format might be suitable for teaching research methodology to practitioners, it is important that researchers in the field of industrial statistics have a more profound understanding of strategies like Six Sigma. This paper seeks to provide clear definitions of the concepts that are used and of the foundations of the approach.

Furthermore, it is in my view important to link on to the literature of other disciplines like methodology and philosophy of science. These disciplines have long studied subjects that are relevant for understanding improvement strategies. The proposed framework was formulated with the literature in the mentioned disciplines as a starting point.

The title of this paper paraphrases Shewhart's[22] 1939 book *Statistical Method from the Viewpoint of Quality Control*. Studying Shewhart's books more and more thoroughly, I realized how much my research links on to his line of thought. Where I understand quality improvement projects as empirical inquiry, Shewhart[22] models quality control as scientific inquiry (pp. 23, 45). I also found myself following him in seeking guidance from the literature on a wide range of disciplines; see his bibliography[12], appendix III, which lists tens of books on diverse subjects such as physics, mathematical statistics, economics, logic and philosophy of science.

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