

Systematic Literature Review – Variation in Quality Management

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Abstracts

This paper aims to present a systematic literature review within the field of quality management (QM), focusing specifically on the concept of variation. Variation is a foundational topic in QM, initially defined by Walter Shewhart and later expanded upon by leaders such as W. Edwards Deming. This concept, closely associated with statistical process control (SPC), emerged in the first half of the 20th century and has remained central to quality improvement efforts. This review is intended to explore the latest research on variation and SPC, identify prevailing trends, and highlight gaps in the current body of knowledge.

This study's methodology employs a systematic literature review to explore the concept of variation and SPC within the field of QM. The Scopus and Web of Science databases were selected as primary sources. A structured search was conducted using the following keywords and logic combinations: (variation OR "Statistical process control") NEAR/1 (interpret* OR understand* OR knowledge) AND ("Quality Management"). One hundred and ten articles were identified. Nonrelevant articles were excluded, and the remaining 20 were read completely and analysed.

Findings: Research on understanding variation is gaining momentum in health care and medicine, particularly in the context of applying SPC in quality improvement initiatives. The primary emphasis is on analysing continuous data through run and control charts, highlighting the methodological importance of avoiding comparisons between two datasets. Interestingly, despite its foundational roots in engineering and production, current research in these fields appears to be comparatively limited.

One significant gap identified in the reviewed literature is the lack of analysis concerning data normality, application, and interpretation of the bell curve. Many of the studies reviewed rely on limited sample sizes, which calls into question the robustness of their statistical foundations.

Keywords: Variation, Quality Management, Statistical Process Control, Review.

Paper type: Review

1. Introduction

Variation forms the core foundation of quality management (QM); thus, conducting a systematic review of variation within the research field is of significant interest. Knowledge about variation in this field is well-established, yet older insights risk being overlooked. It is important to provide a comprehensive overview of the current state of research, highlighting active areas of investigation and the tools commonly used by researchers today.

1.1 Understanding Variation in Quality Management

Understanding variation is an essential element of QM. Walter Shewhart is considered the father of QM. His seminal work, *Economic Control of Quality Manufactured Product* from 1931, primarily describes statistical process control (SPC) (Shewart, 1931). SPC is a mathematical method for describing variation. W. Edwards Deming expanded on Shewhart's knowledge and developed a management system called *Profound Knowledge*, where knowledge about variation is one of four key elements (Deming 2018a, 2018b). Other quality pioneers, such as Juran, Taguchi, Ishikawa, and Feigenbaum, also consider variation a central topic in their work, sharing the same foundational knowledge that can be traced back to Shewhart (Bergman et al. 2022). In the postwar period, Japan rebuilt its industry and emerged as a world leader over the past decades (Bergman et al. 2022; Boaden, 1997). Total quality control (TQC) and company-wide quality control (CWQC) describe quality management systems in Japan. Control refers to SPC; Japanese management was taught this theory of controlling variation by Deming and Juran (ibid.). Western countries have studied Japanese success and adopted the tools and theories of the SPC. Six Sigma is a Western adaptation of this knowledge of variation that became widely implemented during the 1990s (Andersson et al., 2006; Bergman et al., 2022; Magnusson et al., 2003).

Shewhart (1931) describes the outcome of a production process as a probability density function called the bell curve or the normally distributed function. It is a statistical distribution based on numerous data points that form a bell curve, which is the same as the Gaussian distribution. Each data point is random or occurs by chance, as Shewhart noted. If the process is under statistical control, all variation is due to chance causes (ibid). Deming (2018b) referred to the causes of this variation as common causes. The process is not under statistical control if there is a special cause for the variation. Deming (2018b) uses the term special causes, whereas Shewhart (1931) refers to assignable causes. The outcome of a process can also be illustrated in a control chart, where each data point is plotted in a time series. The data will vary or be left

to chance between the 3-sigma limits within 99.7% of the population (ibid.). Learning from this theory, the SPC describes the system, not the individual data. The aim is that the system should be under control.

1.2 Systematic literature review

In doing research, searching for knowledge is important. Conducting a literature review on a topic is one method to find knowledge. First, we must know “what is known” to find new knowledge (Gough et al., 2017). “Reviews can inform us about what is known, how it is known, how this varies across studies, and thus also what is not known from previous research. It can therefore provide a basis for planning and interpreting new primary research.” (Gough et al. 2017 p.3). In the Oxford English Dictionary (2025), the word *review* is defined as *inspection or examination*.

Grant and Booth (2009) identify 14 distinct types of review methodologies, one of which is *overview*. This term broadly refers to any summary that surveys the literature and describes its general characteristics (ibid.). Given the holistic nature of this research, it adopts a combined approach, integrating an overview with a systematic review. The emphasis is on synthesizing overall knowledge and drawing broad conclusions within the scientific domain rather than delving into narrowly defined specifics. As articulated by Gough et al. (2017), this reflects the balance between *breadth*, the scope of the research question, and *depth*, the level of detail in addressing it. Breadth has a similar meaning to overview. In this context, the current study is best described as an *overview systematic review*.

2. Search Methods

This review examines research published between 1986 and 2024. This topic of variation traces back to the first half of the 20th century (Shewhart, 1931). Therefore, the timelines of the past 38 years represent the most recent research in this scientific field. Ultimately, the studies span several decades and provide an analysis of differences over this period.

The identified keywords—variation and statistical process control—stem from early research titled Review of Quality Management and Modern Physics - Possible Parallels between these two research areas (Gavelin Andersson et al. 2025). This study recognizes two key parallels between these fields: variation and systems thinking. To conduct the literature review, "variation" was chosen as a central keyword. Given its broad usage across various contexts, it is analysed alongside interpretation, understanding, and knowledge. Rather than focusing on

direct applications, this study explores the conceptual interpretation and understanding of variation and SPC. The terms “understanding variation” and “knowledge about variation” are widely used in quality management (Deming 2018a, 2018b; Bergman et al., 2022). Accordingly, "variation" is incorporated into the search string for this research. With help from a librarian, a structured search was conducted using the following keywords and Boolean operators for Scopus:

(TITLE-ABS-KEY ((variation OR "Statistical process control") W/1 (knowledge OR interpret* OR understand*)) AND TITLE-ABS-KEY ("Quality Management"))

The same search string was used for the Web of Science but was modified to fit the database:

TS = ((variation OR "Statistical process control") NEAR/1 (interpret* OR understand* OR knowledge)) AND TS= ("Quality Management")

The search methods followed the PRISMA (2025) flow diagram. Searches in Scopus and Web of Science identified 110 articles, including 18 duplicates. After the titles and abstracts of the remaining 92 articles were reviewed, 62 were excluded because of irrelevance. Among the 30 remaining articles, 10, mostly conference articles, were inaccessible. They were probably not published and were presented only at a conference. The full texts of the remaining 20 articles were examined in detail.

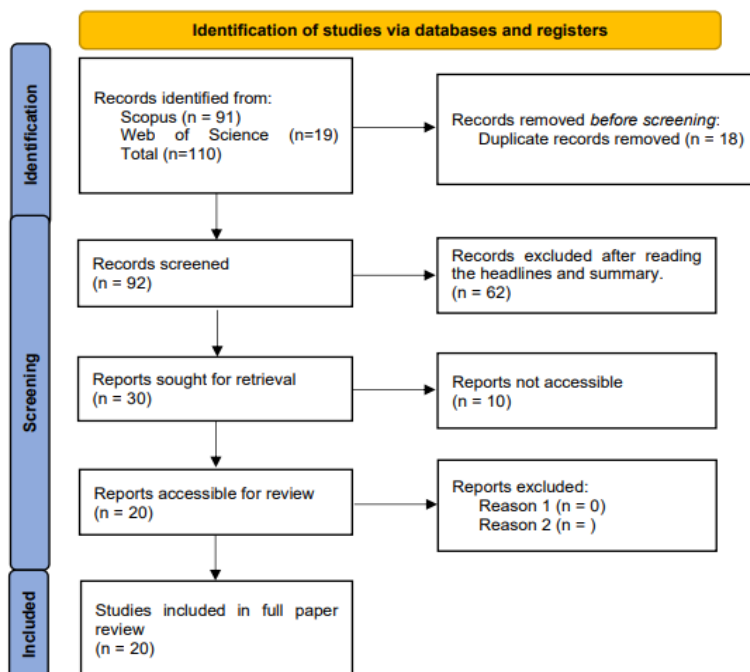


Figure 1. PRISMA 2020 flow diagram of the steps in this systematic literature review (PRISMA, 2025).

The search for relevant articles was conducted using two major academic databases: Scopus and Web of Science. These databases were selected for their complementary strengths. Scopus is widely used among QM researchers because of its extensive indexing of scientific literature in this field. Moreover, Web of Science was included for its broad coverage across disciplines, ensuring a diverse and comprehensive selection of research articles. By leveraging both databases, this study aimed to identify a wide range of literature that aligns with the research focus, providing a well-rounded foundation for analysis.

3. Results and discussion

This review resulted in an in-depth study of 20 articles, with 14 (70%) referring to medicine or health care. Three articles (15%) refer only to industry or engineering. This is somewhat surprising, as variation and SPC in QM are based on industry and the production process. This study started with 110 articles from Scopus and Web of Science that showed similar patterns. The three articles from engineering and industry did not provide deep research on this topic or had other focuses, and two were old (Lagrosen, 2002; Kraft, 2022; Rahman, 1998). There appears to be no active research on variation and SPC in the engineering research field. Research on this topic is ongoing in the fields of medicine and health care.

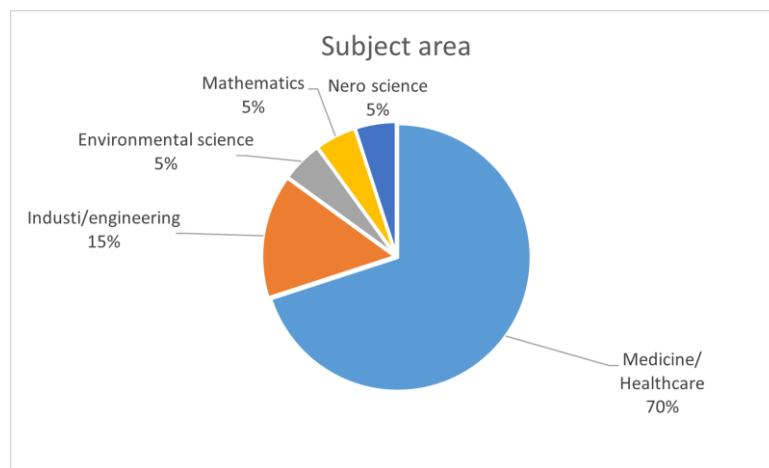


Figure 2. Original subject areas of the 20 fully reviewed articles.

An examination of the country's original data revealed that 9 articles (45%) originated in the U.S. Articles from other countries are distributed, with only a few from each country, primarily from Western nations. It is not surprising that most articles come from the U.S., given their dominance in academic research across various fields. One notable observation is that there is

only one article from China and none from the rest of Asia. SPC was one of the effective tools utilized in Japan when it became a world leader in manufacturing.

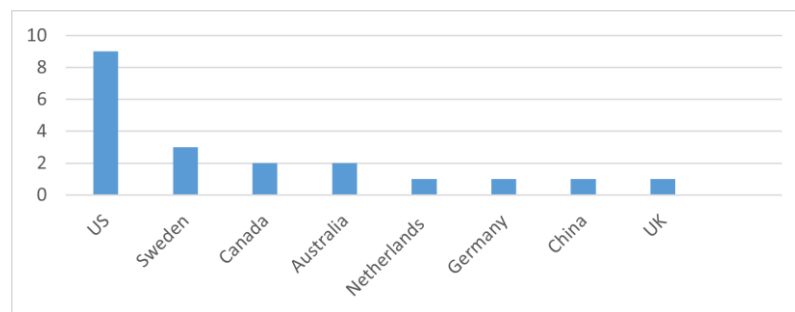


Figure 3. Histogram of the countries of origin of 20 articles.

3.1 Review of Articles

Berwick (1991) wrote an article titled "Controlling Variation in Health Care: A Consultation from Walter Shewhart." The author has deep knowledge and understanding of Shewhart's work and refers directly to the original book. Berwick argues that health care should use this knowledge to reduce unwanted variation. Health care comprises complex systems that produce outcomes with natural variations resembling a production process in which Shewhart's work is grounded (ibid). Bergman et al. (2015) is also a well-grounded article based on Deming's Profound Knowledge, where variation is one of the four elements. This article provides deep knowledge of Shewhart's basic theoretical foundation and Lewis's pragmatic philosophy (ibid). Grossman (1998) provides an overview of quality improvement in health care. The article offers a good description of variation from the original works of Shewhart and Deming (ibid).

Profound Knowledge, the management philosophy developed by Deming, has been widely employed to increase quality in health care settings (Bergman et al., 2015; MacDonald, 2021; Ma & Thull-Freedman, 2024; Roehrs, 2018; Wong & Headrick, 2021). Given that hospitals and health care organizations are typically large and complex systems, Deming's framework offers a particularly suitable lens for quality improvement. The system of Profound Knowledge comprises four interrelated elements, one of which is understanding variation (ibid). Among the 20 studies reviewed in this analysis, Deming is the most frequently cited author.

Understanding variation in QM is used in some articles when the author highlights differences between different departments or countries (MacDonald 2021; Liu et al. 2025; Lagrosen 2002). It is essential to recognize that managers cannot apply the same intervention in different

situations. MacDonald (2021) bases the theoretical component of variation on the differentiation between departments and various wounds. Liu et al. (2025) studied indoor ventilation and seasonal variation. Lagrosen (2002) examined cultural differences in several European countries where one international company has production sites. These articles use the expression “understanding variation” to understand the differences. This is important to highlight, but it is not what Deming or Shewhart meant by understanding variation; their understanding of variation is rooted in statistical process control. Variation is based on the statistical theoretical foundation of processes. This systematic literature review identified 62 articles that were not relevant, including those that used variation to signify a difference but not in a statistical context.

The control chart and the run chart are used to study quality improvement before and after an intervention (Aung et al., 2025; Gupta & Kaplan, 2020; Jones & Fleming, 2022; Nofal et al., 2023; Wong & Headrick, 2021). If a quality improvement program has been performed, it is often questioned whether the change is truly an improvement. The authors argued that studies often compared one data point before with one data point after. Quality improvement is time-oriented, and performance must be examined over time using continuous variables. Run charts and control charts can be utilized to investigate change over time (ibid). Jones & Fleming (2022) argue for using continuous variables instead of binary data in “The problem with dichotomizing quality improvement measures.” Binary data consists of two attributes: “performance met” or “performance not met.” Continuous variables over time facilitate the analysis of change and provide more information regarding distribution and mean values. Continuous data can be illustrated in a run chart or control chart (ibid.). Wong & Headrick (2021) argued that quality improvement should utilize continuous variables to analyse continuous change. Their illustration effectively shows three scenarios where performance shows identical results before and after, with 30% before and 70% after in all three scenarios, indicating significant improvement. When the same data are plotted in a time series, three different scenarios emerge. One scenario depicts continuous improvement, whereas the other illustrates a large step and holds the same level before and after improvement. The last scenario portrays a significant improvement step, followed by a negative performance trend (ibid). These articles highlight the importance of using continuous variables over time rather than merely comparing two data points, which appear to be common in health care (Wong & Headrick, 2021; Gupta & Kaplan, 2020; Jones & Fleming, 2022; Aung et al., 2025; Nofal et al., 2023). This knowledge is valuable, but it is not new. Shewhart (1931) established a control chart based on continuous

data over time. The bell curve is derived from numerous metric data on a ratio scale (decimals), which can be used to calculate mean values and statistical distributions. This knowledge was further expanded by Deming (2018a, 2018b). Continuous data over time, diachronic, can be illustrated in scatter plots and control charts, which are two of the seven quality control tools that have long been utilized in the industry (Bergman et al., 2022).

Williams (2018a, 2018b) and Gupta & Kaplan (2020) provide informative and educational insights into tools for quality improvement. Their objective is to equip practitioners with methods to assess whether an intervention produces meaningful change within a system. These articles describe and illustrate the use of run charts and control charts, visual tools designed to track data trends over time and detect potential shifts in process behaviour. A control chart builds upon the foundational structure of a run chart by incorporating control limits. Once an adequate volume of data is collected and the data are normally distributed, the standard deviation can be calculated, allowing for the establishment of control limits typically set at the mean ± 3 sigma. Certain rules or pattern-recognition criteria are commonly used to detect changes in run and control charts. For example, a “shift” is typically identified when six or more consecutive data points fall above or below the median, whereas a “trend” is defined by five or more data points progressing in the same direction (*ibid.*). These methodological conventions are widely acknowledged across the studies included in this review. Roehrs (2018) refers directly to Williams (2018a, 2018b). According to Gupta and Kaplan (2020), a run chart may be initiated with only a few data points; however, at least ten data points are required to establish a statistically reliable median. In contrast, control charts generally necessitate a minimum of twenty data points to calculate meaningful control limits (*ibid.*).

A run chart with up to 20 data points may provide a visual indication of trends within a given subgroup; however, this sample size is generally insufficient for conducting robust statistical analysis. Although this limitation is noted in the literature, the run chart is considered an SPC tool (Williams, 2018a; Williams, 2018b; Gupta & Kaplan, 2020). Without a sound statistical foundation, it becomes challenging to draw generalizable conclusions from such data. While SPC involves formal statistical analysis of process behaviour, the run chart lacks the statistical underpinnings required for SPC classification. Nonetheless, it remains a valuable quality improvement tool, comparable to a scatterplot, and is recognized as one of the seven quality control (QC) tools (Bergman et al., 2022). Ma and Thull-Freedman (2024) conducted a study examining the waiting time from the decision to the execution of pelvic ultrasound in the emergency department. The analysis included nine subgroups categorized by sex, age, and work

shift. The results were presented using a control chart with control limits, specifically employing an individual (I) chart based on only eight data points collected over one year. However, the construction of each data point remains unclear, whether representing individual observations or aggregated subgroup means is not specified (ibid.). This ambiguity, combined with the limited dataset, raises concerns regarding the appropriateness of statistical analysis. Applying SPC under such conditions may be misleading, given its reliance on sufficient data for valid interpretation. Despite this limitation, this study effectively demonstrates the use of stratification, a key principle in quality improvement and one of the seven quality control (QC) tools, as it identifies notable differences among subgroups.

The three educational articles describe some rules on how to interpret different patterns in a control chart (Williams 2018a, Williams 2018b, and Gupta & Kaplan 2020). These guidelines can be traced back to the Western Electric Handbook from 1956 (Bergman et al., 2022), which provided early operational instructions for identifying special-cause variation. Notably, such rules were not articulated by Shewhart or Deming themselves; rather, they represent a later interpretation and operational simplification intended for industrial practitioners. In 1956, statistical software capable of computing and visualizing data did not yet exist. As such, the rules developed during that era, while practical at the time, may no longer be adequate for analysing the complexity and variability inherent in modern health care data. For example, the definition of a system *shift* as six consecutive data points falling either above or below the mean, as cited in all three articles (Williams 2018a, Williams 2018b, and Gupta & Kaplan 2020), lacks contextual nuance and may not adequately reflect the dynamics of modern health care processes. The scale and structure of the underlying system are rarely considered. Similarly, experiencing six consecutive days of warm weather does not necessarily indicate a shift in climate. Similarly, interviewing six individuals who share an unexpected opinion does not provide sufficient grounds to claim a national change in public sentiment. Without contextual framing and statistical rigor, such rules risk overinterpretation and misguidance in data analysis.

The bell curve, or normal distribution, attributed to Walter Shewhart, is derived from Brownian motion. While individual movements are random, the aggregate behaviour conforms to a well-defined probabilistic structure, namely, the bell curve. In a stable system under statistical control, process variation is expected to fall within three sigma limits, encompassing 99.7% of all outcomes (Shewhart, 1931). Given that each data point arises by chance, drawing conclusions from a single observation is inappropriate and may lead to erroneous adjustments. Deming referred to this reactive behaviour as "tampering", illustrated through his funnel

experiment (Deming, 2018b). However, this raises a practical question: if each data point is governed by randomness, can meaningful patterns still emerge from as few as six observations?

3.1.1 Other studies

Bakir (2015) provides a tool for a control chart for an ordinal scale, not an interval scale, using a limited amount of data. Deming did not describe how to construct a control chart using an ordinal scale (1,2,3,4...). The control chart for the ordinal scale includes control limits to help distinguish special causes from common causes (ibid). Although there are solid mathematical insights, it remains unclear how much data are needed.

Nofal et al. (2023) conducted a large survey in which a checklist was used to improve the quality of surgery in Ethiopia. An improvement program was conducted with education. The result was a significant improvement, but the authors' limitation mentioned the Hawthorne effect, where people tend to produce better results when observed. The study has solid statistical grounding (n=2767), (ibid.)

Lagrosen & Travis (2015) explored the connection between QM and brain function. A conceptual article aims to explore and understand the connections between brain function and Profound Knowledge and the element of knowledge about variation. The coherence between different parts of the brain is closely related to appreciation for a system. The principles of homeostatic feedback loops are related to knowledge about variation (ibid.). This article distinguishes itself from the other. This study highlights an interesting field of research: how the human brain understands and interprets variation and holistic thinking. This systematic review shows that the interpretation of variation from Shewhart and Deming is different and adopted in different ways, which has some bias from the original theory. Human brains likely have difficulties adopting the full potential of the original theory of variation.

3.2. Gap and trends

One significant gap identified in the reviewed literature is the lack of analysis concerning data normality, application, and interpretation of the bell curve. As all the statistical methods are predicated on some underlying data distributions, this oversight is significant. SPC is fundamentally based on the assumption of a normal (Gaussian) distribution. While this is acknowledged by Gupta and Kaplan (2020) and Bakir (2015), neither source provides a practical explanation of its application. Furthermore, none of the empirical studies conducted a formal analysis of normality. The bell curve, together with control charts, serves as a powerful tool for process analysis: the bell curve reflects the overall distribution of outcomes,

whereas the control chart tracks individual data points over time. While the latter reveals variation within a sequence, the former captures the broader statistical pattern across the overall dataset.

A distinction can be observed between earlier publications (Berwick, 1991; Bergman et al., 2015; Grossman, 1998) and more recent studies. Notably, Bo Bergman, the lead author of Bergman et al. (2015), is a professor and pioneer in Scandinavia who established the first academic program in quality management during the 1980s; for this reason, the work is considered part of the earlier literature in this review. These earlier articles demonstrate a deeper engagement with the foundational theories, referencing the original works of Shewhart and Deming directly. In contrast, more recent publications often lack a thorough understanding of variation from a statistical perspective, despite continuing to cite Shewhart and Deming. Crucially, they tend to overlook the concept of total distribution, relying instead on specific rules to detect changes in systems, an approach that may be questionable when applied within the framework of SPC.

4. Conclusion

Research on variation is gaining momentum in health care and medicine, particularly through the application of statistical process control (SPC) in quality improvement initiatives. Interestingly, despite variation being a foundational concept in engineering and production, active research in these fields appears limited. In health care, the focus lies in analysing continuous data using run and control charts, emphasizing the importance of not comparing different datasets.

A noticeable distinction exists between earlier publications (Berwick, 1991; Bergman et al., 2015; Grossman, 1998) and more recent literature. The former aligns more closely with the foundational principles established by Shewhart and Deming, reflecting a deeper adherence to their original conceptualization of variation and quality management than what is typically observed in contemporary works.

This review identifies a critical gap in the absence of analysis related to the bell curve, a foundational element of the SPC. As a result, assessments of process capability, directly derived from bell curve analysis, are likewise underrepresented. The normal distribution curve is particularly well suited for application in health care, given that it effectively models a wide range of biological phenomena, including molecular motion, body weight, and human life expectancy.

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Appendix

Literature Review

Authors	Location	Subject area	Summary
Ma & Thull-Freedman, 2024	Canada	Medicine	A study of understanding variation in time to ultrasonic. Use SPC over time for different subgroups. Result of differences between subgroups, sex, age, and shifts. It is not clear how much data is used. Ref. Deming and profound knowledge.
Williams, 2018a	US	Medicine	A guide on how to use a Run chart to determine if a change is an improvement. Explaining trends and shifts, five or six points in a row. Ref, Wheeler.
Williams, 2018b	US	Medicine	See above. Focus on the Control chart, an extension of the Run chart when more data is available. It is missing the bell curve and statistical interpretation of small amounts of data.
Atsma et al., 2020	Nether lands	Medicine	Conceptual article on how to decrease unwarranted variation in clinical practice. Suggest networking and feedback.
Jones & Fleming, 2022	US	Medicine	The authors argue that binary (yes/no) data analyses are not good enough and suggest using continuous variables.
Kraft, 2022	Germany	Engineering	Conference article on how to use statistical software to analyse variation in QM.
Lagrosen, 2002	Sweden	Industri	Understanding variation in culture between four countries in the EU.
Aung et al., 2025	Australia	Medicine	A survey of a workshop on SPC in health care. More reliable results than comparing two-point comparisons.
Gupta & Kaplan, 2020	US	Medicine	A well-grounded article from Harvard on interpreting data, based on Deming and Shewart. Use the <i>rules</i> to detect special signals.
Lagrosen & Travis, 2015	Sweden	Other	Article on our brain function and connection to Profound knowledge.
Berwick, 1991	US	Medicine	Article on variation in health care using Shewhart's theory. Fundamental knowledge of the basic theory of Shewhart.
Liu et al., 2025	China	Environment. science	Study indoor ventilation and variation in season.
Roehrs, 2018	US	Medicine	A short article on Building of profound knowledge for health care. A summary. Reference Williams (2018a; b) above.
Wong & Headrick, 2021	Canada	Medicine	An article about using Profound Knowledge as the <i>mindset</i> for QI in health care. An example of variation is

			comparing the same before and after the intervention, but having different development in a run chart. Time dependent.
Bergman et al., 2015	Sweden	Medicine	Solid article on Profound Knowledge and basics from Shewhart and Levis. Probably predictions.
MacDonald, 2021	UK	Medicine	A short paper on using the lens of profound knowledge for health care. Variation between apartments and different wounds and patients.
Nofal et al., 2023	US	Medicine	A large survey (n=2767) of using a checklist to improve quality in surgery in Ethiopia. Improvement program with a very good outcome.
Bakir, 2005	US	Mathematics	Provides a tool for a control chart for an ordinal scale, not an interval scale.
Rahman, 1998	Australia	Engineering	A conceptual framework for variation reduction, using Taguchi, QFD, and SPC. Statistical thinking involves system thinking and understanding variation.
Grossman, 1998	US	Medicine	An overview of quality improvement in health care. A TQM approach, based on Shewhart and Deming, PDCA.