International Journal for Quality in Health Care 2010; **Volume 22, Number 5:** pp. 402–407
Advance Access Publication: 30 July 2010
10.1093/intqhc/mzq037

The *p*-control chart: a tool for care improvement

ANTOINE DUCLOS[1,2] AND NICOLAS VOIRIN[3,4]

[1]Pôle Information Médicale Évaluation Recherche, Hospices Civils de Lyon, Lyon F-69003, France, [2]Université de Lyon, EA Santé-Individu-Société 4129, Lyon F-69002, France, [3]Laboratoire de Biométrie et Biologie Évolutive, Université de Lyon, Université Lyon 1, CNRS, UMR 5558, Lyon F-69373, France, and [4]Hospices Civils de Lyon, Hôpital Édouard Herriot, Service d'Hygiène, Épidémiologie et Prévention, Lyon F-69437, France

Address reprint requests to: Antoine Duclos, Hospices Civils de Lyon, Pôle d'Information Médicale Évaluation Recherche, Unité d'Étude des Pratiques Professionnelles, 162 avenue Lacassagne, F-69424 Lyon Cedex 03, France. Tel: +33-4-72-11-57-25; Fax: +33-4-72-11-57-20; E-mail: antoineduclos@yahoo.fr

Accepted for publication 5 July 2010

Abstract

Background. The *p*-chart is a user-friendly tool for monitoring adverse events. By converting data into knowledge, it is helpful in interpreting and reducing sources of variability in care. Certain basics for developing expertise to use *p*-charts correctly are necessary.

Purpose. This paper provides key elements on how to develop and interpret a *p*-chart for clinical practice, how to successfully integrate this tool within a comprehensive approach, and how to report a study based on *p*-chart utilization.

***P*-chart building**. The *p*-chart combines time series analysis with a graphical presentation of data by plotting successive indicator measurements in chronological order. The pragmatic choice of well-defined indicators to be monitored is essential. Exact control limits based on the binomial distribution and the incorporation of risk adjustment represent important contributions for further improving the tool's performance in health-care settings.

***P*-chart implementation**. The solution needed to reduce adverse events is not available from measurement alone. The success of routine introduction of the *p*-chart requires investigation of the causes of indicator variations and the trying out of quality improvement initiatives. It must be supported by strong management leadership within an atmosphere of constructive evaluation.

Perspectives. The implementation of the *p*-chart into clinical practice encourages practitioners to continuously undertake a critical examination of the care delivered. Nearly a century after it was created in the manufacturing industry, the control chart now contributes to improving the quality of health-care processes and patient safety.

Keywords: safety management, quality control, quality indicators, outcome assessment

Introduction

The *p*-control chart is a graphical tool developed in industry to interpret and reduce sources of variability in manufacturing processes. It is now increasingly applied in health care for continuous quality control and quality improvement research. There is strong interest in implementing *p*-charts in clinical practice to monitor adverse events and guide initiatives for the improvement of patient safety. Although the *p*-chart is easy to use, its design requires certain precautions and it must be interpreted carefully in order to avoid erroneous conclusions. This paper provides key elements to physicians, nurses, managers, students or researchers of quality on how to develop and interpret a *p*-chart for clinical practice, how to successfully integrate this tool within a comprehensive control chart programme, and how to report a study based on *p*-chart utilization. In order to help non-experts in designing the *p*-control chart correctly, additional material is appended to help the non-experts in designing the *p*-control chart correctly, including a statistical appendix and an online spreadsheet with formulas for plotting the *p*-chart.

Basic principles of the control chart

The statistical control chart concept was first developed in the 1920s by Shewhart [1] in order to improve the reliability of telephone transmission systems. The concept resulted from the observation that operators often overreact and make inappropriate changes in settings in response to

indicator variations that are simply random [2]. Such decisions are wasteful and introduce more variation in the process, making the system less reliable. Shewhart's theory of variation states that quality is inversely proportional to variability and that understanding the variability of some indicators could teach the operator about when and how to reduce it.

The implementation of control charts in health services to monitor adverse events was advocated by Deming [3]. It has since been used in a wide range of settings and specialties, which suggests a broad applicability in the health-care context [4]. On the basis of the monitoring of patients' health outcome indicators, the control chart detects significant changes over time in patient safety. In the field of quality control, the routine use of control charts is helpful in interpreting and reducing sources of variability in care [5]. By converting data into knowledge, it guides multidisciplinary teams towards the most appropriate action(s) for continuous improvement [6]. In health services research, the control chart represents a low-cost and robust method for rapidly assessing change initiatives in care [7]. It can be viewed as a quasi-experimental study design, which is complementary to randomized controlled trials in providing evidence on the impact of safety improvement interventions [8]. Control charts have also been successfully used in other areas such as public health surveillance in communities [9] or in hospitals [10], benchmarking of hospital performance [6, 11] or monitoring of clinical variables at an individual patient level [12].

Although relatively simple, the control chart is a powerful tool for decision support. It combines time series analysis with a graphical presentation of data by plotting successive indicator measurements in chronological order. By distinguishing special causes from common causes of variation, the control chart categorizes variation according to the action needed to reduce it [13]. Special causes are supposed to reflect substantial variation in care that deserves further investigation, whereas variation related to common causes is expected to arise due to other misleading factors, including random events. Three horizontal lines are drawn on the chart to determine whether or not care is in statistical control; they are termed the central line, the upper control limit (UCL) and the lower control limit (LCL). An indicator data point lying outside of the control limits suggests that some special cause of variation has been detected and that care is out of control. This requires finding and acting on one or more assignable causes to reduce variation. After controlling all special causes of variation, care should be subject only to common-cause variation related to unknown or unmeasured factors. In this case, if the level of performance is still regarded as unsatisfactory, the classical way to further improve care is to reorganize the whole process. This implies choosing simplicity in the restructuring of care, considering that simple systems would be more reliable than complex ones [2].

How to build a *p*-control chart

The *p*-chart, where *p* stands for proportion, is useful for the routine monitoring of a binary outcome, such as the occurrence of an adverse event (e.g. postoperative complications). Although the *p*-chart was conceived to be user-friendly for non-experts, previous knowledge is required for design. In creating a *p*-chart, both the sample size and the frequency of sampling must first be specified before plotting the observed proportion of adverse events in each successive sample [14]. A choice should be made between large samples at wider intervals (aimed at detecting small shifts in the monitoring of rare adverse events) and small samples at shorter intervals (aimed at detecting shifts as soon as possible for real-time monitoring). In practice, *p*-charts are usually displayed with at least 20 consecutive samples that can be of variable size, as it is relatively common to examine samples based on every patient cared for over some convenient period of time (e.g. the number of patients operated on each month). Second, a central line is drawn, which corresponds to the overall proportion of adverse events across all samples, $\bar{p}$ (e.g. the mean proportion of postoperative complications). Third, the control limits are traditionally positioned at a distance of three standard deviations (SD) around the central line and the detection of special-cause variation depends on finding a single point outside the control limits. This decision rule ensures an optimal balance between the tool's sensitivity in detecting signals (i.e. avoid mistaking a special cause for a common cause) and its specificity in avoiding false alarms (i.e. avoid mistaking a common cause for a special cause). Accordingly, 99.73% of all points are expected to fall within 3 SD from the mean if the process is stable (common-cause variation), with the remaining 0.27% falling >3 SD away from the mean (special-cause variation) [15].

There are three main approaches in setting control limits on a *p*-chart with a variable sample size (see supplementary material, Appendix for detailed formulas). The first one consists in calculating constant control limits based on the average of the sample sizes. This assumes that the sizes of successive samples do not vary greatly. However, in the case of an unusually large variation in the size of a particular sample or if an indicator is positioned close to the approximate limits, then interpretation must be conducted cautiously [16]. To avoid such pitfalls, there is a second approach, which consists in determining variable control limits for each sample i based on its specific size n_i. In this case, the control limits will be drawn in stair-steps to reflect the changes in sample size over time. The more the sample size increases, the closer to the central line the limits will be. Generally, calculations of the *p*-chart limits are based on a normal approximation of the binomial distribution. This approximation is acceptable as long as $n_i\bar{p}(1-\bar{p}) > 5$ and $0.1 \leq \bar{p} \leq 0.9$. If these conditions are not satisfied, a third approach based on the calculation of exact control limits should be adopted, directly using the binomial distribution [13].

The modalities for setting the control limits may have a great influence on the tool's performance, as shown in Fig. 1. The *p*-charts displaying the three types of control limits described above were designed using Microsoft Office Excel®, so that the reader can replicate the

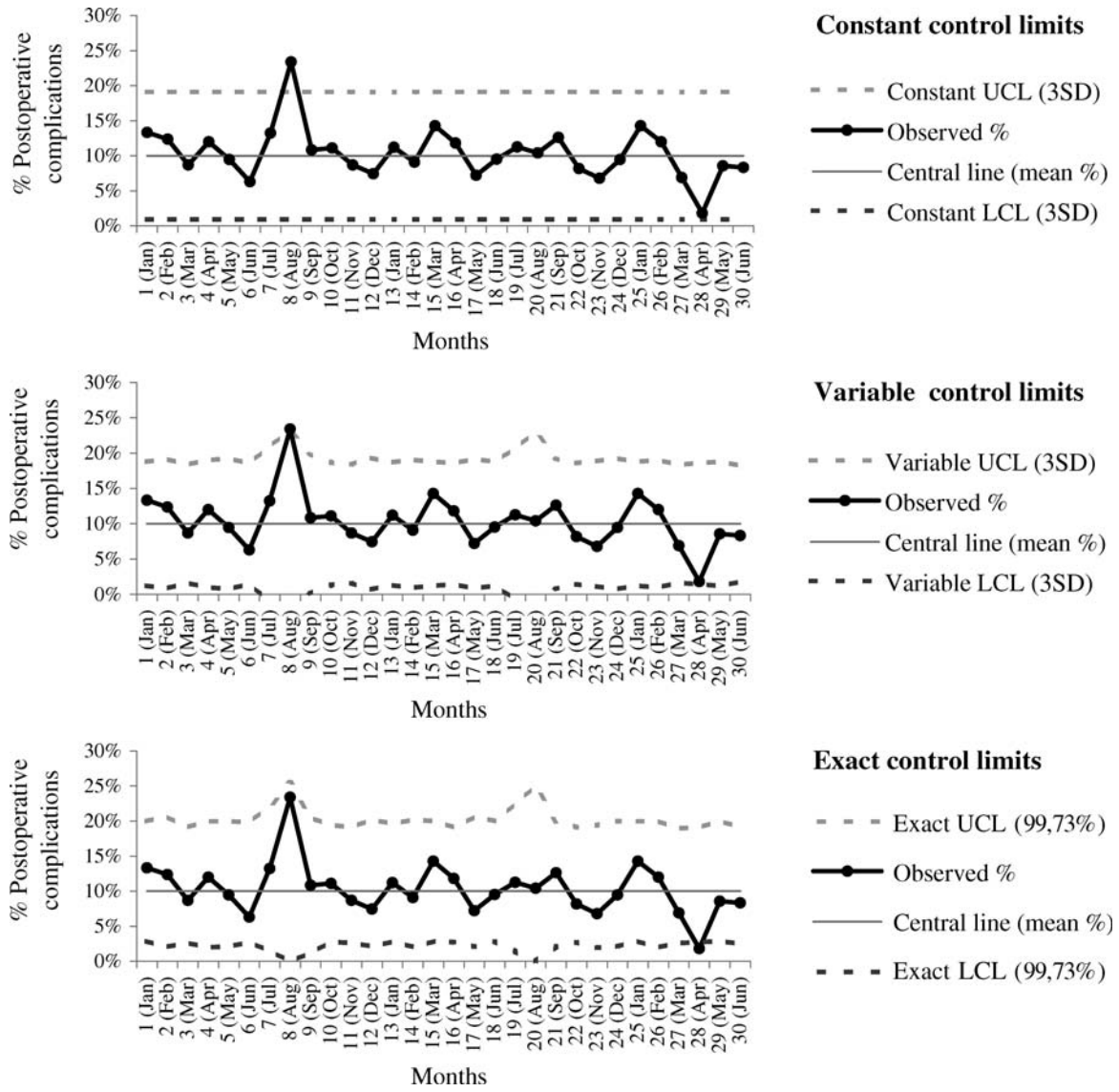

Figure 1 Three *p*-charts with different settings of LCL and UCL (see online supplementary material for a colour version of this figure).

method by accessing the online supplementary material containing fictive data, parameter calculations and chart plotting. Many other popular spreadsheets or statistical software can also be used to build control charts easily [17]. Each data point expresses the observed proportion of postoperative complications per month for 30 successive samples (Table 1). The central line is positioned at 10% (i.e. the mean proportion of complications) and control limits are set at 3 SD from the central line. The conditions for a normal approximation were not satisfied for several points (see supplementary material, samples 8 and 20), making the control chart based on exact limits more reliable. When comparing the three charts, two points should be discussed specifically. No special-cause variation was detected at month 8 by the *p*-chart based on exact limits, whereas it was erroneously detected by the *p*-charts based on constant and variable approximate limits. The single special-cause variation needing to be investigated was detected at month 28 only by the *p*-chart based on exact limits, but not by the other two charts. In the end, if sample sizes vary, one should always prefer interpretation with variable limits rather than constant limits. Furthermore, if the conditions for normal approximation of the binomial distribution are not satisfied, it is recommended to base interpretation on the exact limits. Nevertheless, the key to success in using the control chart should be to strike a balance between statistical correctness and special attention to every change occurring in the delivery of care. The pragmatic use of the control chart implies to interpret rigorously the indicator variations as well as to know what happens in the practical field, before and after measurement.

Table I Data set for plotting *p*-charts

Month	No. of complications	No. of surgical procedures
1	14	105
2	12	97
3	10	115
4	12	100
5	9	95
6	7	111
7	9	68
8	11	47
9	9	83
10	12	108
11	10	115
12	7	94
13	12	107
14	9	99
15	15	105
16	13	110
17	7	97
18	10	105
19	8	71
20	5	48
21	12	95
22	9	110
23	7	103
24	9	95
25	15	105
26	12	100
27	8	116
28	2	110
29	9	105
30	10	120
Total	294	2939

How to develop a *p*-chart programme

Box 1 provides the essential points that should be considered in a protocol aimed at implementing a *p*-chart programme. To be successful, the use of *p*-charts must be supported by strong management leadership and by mechanisms for communicating results throughout the organization. It should be integrated within a multidisciplinary team approach focusing on a strategic process of care [14]. High-frequency and standardized care in relatively homogeneous patient groups should be primarily selected for *p*-chart control. The organization should have a high potential for quality improvement and changes in care should be proposed in order to be tested. Another prerequisite implies the pragmatic choice of well-defined indicators to be monitored, with the ultimate goal of reducing their variability over time and achieving better outcomes.

Box 1 Implementing a *p*-chart programme

(1) Appointment of a motivated project head within the team that owns the process under observation.
(2) Choice of care process to be put under control (high-volume procedure with critical outcome and great potential for improvement).
(3) Setting quality improvement objectives to be accomplished (reduction of outcome variability, performance level to achieve or maintain).
(4) Selection of indicator to be monitored (based on its clinical relevance, construction feasibility and validity) and its calculation formula (ratio with monitored event as the numerator and exposed population as the denominator).
(5) Selection of computerized data collection (standardized, continuous and exhaustive cases registration) and extraction systems (automatic data processing based on user-friendly software).
(6) Setting control chart parameters (sample sizes and sampling frequency, central line position and width of control limits) and explaining interpretation rules.
(7) Selection of modalities for identification of special causes (logbook, chart restitution meetings or other quality control tools).
(8) Detailing specific actions that could be tested with the aim of improving patient safety.
(9) Planning the periodicity and modalities of chart restitution within the organization.
(10) Editing the timetable and assigning tasks among the different actors involved.

Appropriate logistic support is necessary for developing a *p*-chart programme, which may quickly yield cost savings by avoiding adverse events. Ideally, *p*-chart development requires a computerized system for data management and it must be implemented within a sustainable approach based on the Plan-Do-Check-Act cycle [14]. Indeed, the solution needed to reduce adverse events is not available from measurement alone and requires local action to systematically explore the core reasons for the specific pattern of outcomes [18]. If special causes of variation are detected by the *p*-chart, they must be investigated by 'detective work' on the process. This involves appropriate methods or quality control tools [17], such as using a logbook in which all changes in care are continually reported. The holding of periodic meetings, during which control charts are interpreted by health-care workers, may also be useful to generate knowledge about the root causes of the observed variations of indicators. Once special causes have been identified, some suitable actions must be conducted with the aim of conserving or eliminating these unusual sources of variability according to the observed improvement or impairment, respectively, in care safety. Then, after obtaining a stable process, concrete interventions aimed at care improvement must be successively

implemented and tested. Furthermore, to implement a *p*-chart programme most effectively, it is essential to have an atmosphere of constructive evaluation rather than to judge the individual performance of the professionals whose outcomes are being assessed [19].

How to report a study based on *p*-chart utilization

When reporting a study based on the use of a *p*-chart, authors must clearly state certain information to help the reader in judging the rigour of the employed methodology (Box 2). Special attention should be paid to describing the modalities of identification and actions taken against special causes of variation, as well as to detailing quality improvement interventions that have been assessed. Benefits and limitations should also be reported, along with barriers and facilitating factors related to the implementation of a *p*-chart programme.

Box 2 Checklist for reporting a *p*-chart programme [4, 12, 20, 21]

(1) Study objective (tutorial, quality control, assessing the impact of interventions on care, individual patient monitoring, public health surveillance or performance monitoring).
(2) Study design (retrospective or prospective, observational or quasi-experimental controlled before-and-after study).
(3) Study setting (country, health-care sector, medical or surgical specialty) and units under observation (hospital ward, primary care centre, surgical team, single clinician or patient).
(4) Process of care under control.
(5) Monitoring period and number of samples examined.
(6) Modalities of construction of monitored indicators.
(7) Modalities of data collection and extraction systems (data sources, type of software used, data quality and exhaustiveness).
(8) Control chart parameters (sample sizes and sampling frequency, central line and limit settings, adjustment for case-mix or other confounding factors) and rules of interpretation.
(9) Complementary methods and quality control tools for identifying special causes.
(10) Specific safety improvement actions that have been tested.

Conclusions

Monitoring a health-care process is different from monitoring a manufacturing process. The rarity of events and confounding factors such as patient case-mix represent fundamental differences. Considering that the probability of adverse events may vary considerably across patients undergoing particular care interventions, risk adjustment or stratification is useful to enable correct analysis of data from heterogeneous populations. Accordingly, the use of adjusted *p*-charts seems to be a valuable approach to improving the tool's reliability in health-care settings [22, 23]. Warning limits (2 SD around the central line) can also be added to improve the sensitivity of the control chart [15], but this tends to increase the risk of false alarms in detecting special-cause variation [13]. Furthermore, the cumulative sum chart (CUSUM) may be helpful in overcoming the limitations of *p*-chart sensitivity in clinical practice, as it performs fairly well in detecting small changes when monitoring rare adverse events [11, 19].

The implementation of the *p*-chart in clinical practice encourages practitioners to continuously undertake a critical examination of the care delivered. Deming predicted in the 1980s that 'another half-century may pass before the full spectrum of Dr. Shewhart's contributions has been revealed in liberal education, science, and industry' [24]. Nearly a century after it was created in the manufacturing industry, the control chart now contributes to improving the quality of health-care processes and patient safety.

Supplementary material

Supplementary material is available at *International Journal for Quality in Health Care* online.

References

1. Shewhart WA. *Economic Control of Quality of Manufactured Product*. New York: Van Nostrand, 1931.
2. Berwick DM. Controlling variation in health care: a consultation from Walter Shewhart. *Med Care* 1991;**29**:1212–25.
3. Deming WE. On a classification of the problems of statistical inference. *J Am Stat Assoc* 1942;**37**:173–85.
4. Thor J, Lundberg J, Ask J *et al*. Application of statistical process control in healthcare improvement: systematic review. *Qual Saf Health Care* 2007;**16**:387–99.
5. Duclos A, Touzet S, Soardo P *et al*. Quality monitoring in thyroid surgery using the Shewhart control chart. *Brit J Surg* 2009;**96**:171–4.
6. Mohammed MA, Cheng KK, Rouse A *et al*. Bristol, Shipman, and clinical governance: Shewhart's forgotten lessons. *Lancet* 2001;**357**:463–7.
7. Norberg A, Christopher NC, Ramundo ML *et al*. Contamination rates of blood cultures obtained by dedicated phlebotomy vs intravenous catheter. *J Am Med Assoc* 2003;**289**:726–9.
8. Diaz M, Neuhauser D. Pasteur and parachutes: when statistical process control is better than a randomized controlled trial. *Qual Saf Health Care* 2005;**14**:140–3.
9. Hanslik T, Boelle PY, Flahault A. The control chart: an epidemiological tool for public health monitoring. *Public Health* 2001;**115**:277–81.

10. Morton AP, Whitby M, McLaws ML *et al*. The application of statistical process control charts to the detection and monitoring of hospital-acquired infections. *J Qual Clin Pract* 2001;**21**: 112–7.

11. Woodall WH. The use of control charts in health-care and public-health surveillance. *J Qual Technol* 2006;**38**:89–104.

12. Tennant R, Mohammed MA, Coleman JJ *et al*. Monitoring patients using control charts: a systematic review. *Int J Qual Health Care* 2007;**19**:187–94.

13. Mohammed MA, Worthington P, Woodall WH. Plotting basic control charts: tutorial notes for healthcare practitioners. *Qual Saf Health Care* 2008;**17**:137–45.

14. Montgomery DC. *Statistical Quality Control: A Modern Introduction, International Student Version*, 6th edn. Hoboken, NJ: Wiley, 2008.

15. Benneyan JC, Lloyd RC, Plsek PE. Statistical process control as a tool for research and healthcare improvement. *Qual Saf Health Care* 2003;**12**:458–64.

16. Ryan Thomas P. *Statistical Methods for Quality Improvement*, 2nd edn. New York: Wiley, 2000.

17. Lighter D. *Advanced Performance Improvement in Health Care: Principles and Methods*. Sudbury, MA: Jones and Bartlett Publishers, 2010.

18. Werner RM, McNutt R. A new strategy to improve quality: rewarding actions rather than measures. *J Am Med Assoc* 2009;**301**:1375–7.

19. Rogers CA, Reeves BC, Caputo M *et al*. Control chart methods for monitoring cardiac surgical performance and their interpretation. *J Thorac Cardiovasc Surg* 2004;**128**:811–9.

20. Biau DJ, Resche-Rigon M, Godiris-Petit G *et al*. Quality control of surgical and interventional procedures: a review of the CUSUM. *Qual Saf Health Care* 2007;**16**:203–7.

21. Ogrinc G, Mooney SE, Estrada C *et al*. The SQUIRE (Standards for Quality Improvement Reporting Excellence) guidelines for quality improvement reporting: explanation and elaboration. *Qual Saf Health Care* 2008;**17**(Suppl 1):i13–32.

22. Duclos A, Voirin N, Touzet S *et al*. Crude versus case-mix-adjusted control charts for safety monitoring in thyroid surgery. *Qual Saf Health Care* 2010; April 8 [Epub ahead of print].

23. Amin SG. Control charts 101: a guide to health care applications. *Qual Manag Health Care* 2001;**9**:1–27.

24. Shewhart WA. *Statistical Method from the Viewpoint of Quality Control*. Washington, DC: Graduate School of the Department of Agriculture, 1939.