Statistical Process Analysis of Medical Incidents

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Abstract

Personnel engaged in the medical field have implemented continual improvement by team activities in an effort to construct a system that reduces the risks involved in medical care. Knowledge in total quality management (TQM), especially statistical quality control (SQC) developed for industry, seems to be applicable to medical care. This paper describes the application of SQC to continual improvement in medical care.

Key Words: incident analysis, c control chart, Pareto diagram, CART

1. Introduction

Over the past several years, personnel engaged in medical care have continually striven to improve the occurrence rate of incidents; an incident being defined as an error that does not result in personal injury. We have supported these activities in our capacity as members of an improvement team responsible for performing data analysis by applying the concept of TQM and statistical methods for SQC. We describe an analytical approach minimizing risk. In particular, we discuss the advantages of using SQC as the foundation of integrated medical risk management, through analysis and examination of an incident report data set based on QC story.

2. Step of continual improvement

Berwick (2000), who in the 1980's became the first to introduce TQM to medical care, suggested the existence of three types of improvement, which, as shown in Figure 1, can be combined to form a hierarchical structure for the development of a TQM process.

The first level in Figure 1 is the lowest level of improvement and is used for reducing defects experienced by the customer. After this first level, Type 2 improvement is introduced on the second level, in order to reduce costs while maintaining or improving the experience of the customer. Finally, Type 3 improvement is implemented: improvements on the third level create and meet a new demand and satisfy pre-existing demands at an unprecedented level of performance. Judging from this structure, we consider the current state of the improvement process at the hospital concerned to fall between Type 1 and Type 2, but to be very close to Type 1, because the improvement activities are performed solely by QC circle activities of nurse groups in proximity to the patients and the hospital does not attempt to construct a prevention system such as a quality management system based on the ISO 9000 series. We started our evaluation by preparing and analyzing a data set under the above-mentioned phase of the improvement process.

3. Law of Heinrich

Figure 2 illustrates the foundation of a major incident proposed by Heinrich (1959).

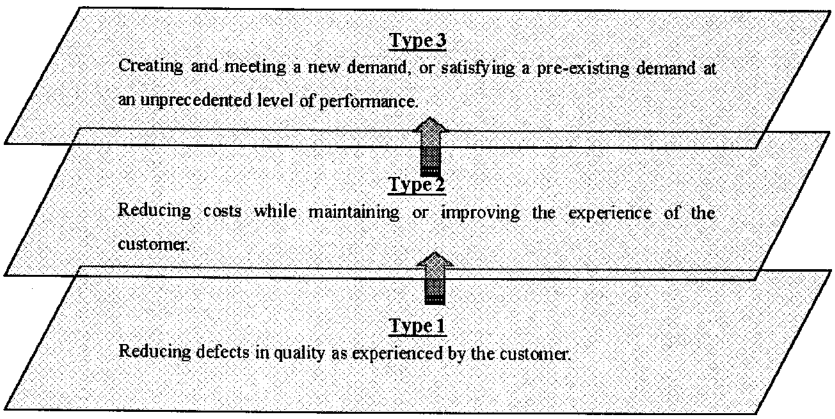

Figure 1. Structure of the improvement process.

He suggested that the ratio 1-29-300 shows that in a unit group of 330 similar accidents occurring to the same person, 300 will result in no incident, 29 will produce minor incidents, and 1 will cause a serious incident. We analyzed data pertaining to minor incidents that, following Heinrich's law, did not result in injury, because we consider the improvement activities for the hospital under investigation to be of Type 1, and analysis of such incidents results in reducing and preventing the recurrence of injuries.

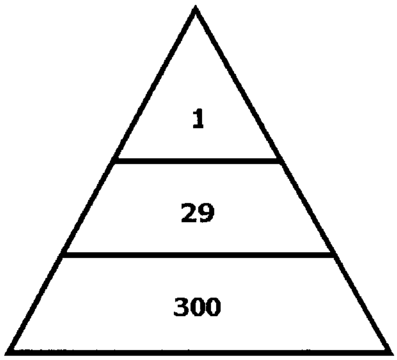

Figure 2. Structure of the Law of Heinrich.

4. Analyses of incident data set

The data set consists of 845 cases arranged on the basis of incident reports whose format is shown in Table 1, and was constructed according to the classification code table shown in Table 2. The reports, which were written by the person who made the error, were collected from January to June, 2001 in the hospital. "01. INCIDEN T," "02. ACCIDENT," and "03. FIND" in the report refer to a minor incident, a serious incident directly connected with injury, and an event found and prevented by someone before commission of an error, respectively.

We apply QC story to incidents analyses as follows:

(1) We examine whether the incident data fit a Poisson distribution, because the number of incidents is widely understood to follow such a distribution.
(2) We use a c chart to examine whether the medical error are statistically stable, because error counts are known to follow Poisson distribution.
(3) We then use Pareto diagrams to identify kinds of critical incidents from the data.
(4) Finally, we apply classification and regression trees, or CART (Breiman, 1984), to perform cause route analysis according to influence level.

4.1 Distribution of incident counts

Figure 3 shows a histogram for data consisting of 845 cases arranged on the basis of incident reports showing Poisson distribution. The outline bars represent the actual frequency distribution showing an

Table 1. Incident report.

01. INCIDENT		02. ACCIDENT		03. FIND			
Patient	※Name			※Sex		※Age	
	※Distinction		Others( )	※Section		Others( )	
	※Disease						
Reporter	※Job		Others( )	In find, also enter partner's occupational description.			
	※Assignment		Others( )	※Job		Others( )	
	Experience (Present)		Y	Experience (Present, Post)			Y
	Condition						
	※Generating day	D/M/Y (A.D)		※Generating time			

Table 2. Classification code table.

Distinction	Distinction	01. Visitor 02. Hospitalization 99. Others	Gender	01. Male 02.Female
	The department of medical care	01. Internal medicine 02.Inside of nerve 03. Neuroscience 04. Pediatrics 05. Obstetrics and gynecology 06. Surgery 07. Esthetic surgery 08. Urological section 09. Ophthalmology 10. Otolaryngology 11. Dermatology 12. Radiology 13. Anesthesiology 99. Others		
	Type of job	01. Doctor 02. Nurse 03. Midwife 04. Pharmacist 05. Inspection engineer 06. Radiation engineer 07. Physiotherapist 08. Clinical engineer 09. Dietitian 10. Licensed cook 11. Assistant nurse 12. Clerical employee 99. Other		

average incident count of 4.5 per day, and the black bars represent the theoretical frequency having the same average Poisson distribution. The black line is the theoretical cumulative curve. The distribution of the actual incident data differs slightly from the theoretical curve, suggesting variation of some assignable causes in addition to variation of chance cause. Therefore, we apply the data set to a Schewhart control chart for examination.

4.2 Analysis by c control chart

We created a c control chart having a subgroup composed of the number of incidents per day, and examined whether or not the daily incidents were controlled statistically. The chart is shown in Figure 4. The average of daily incidents is 4.5, and

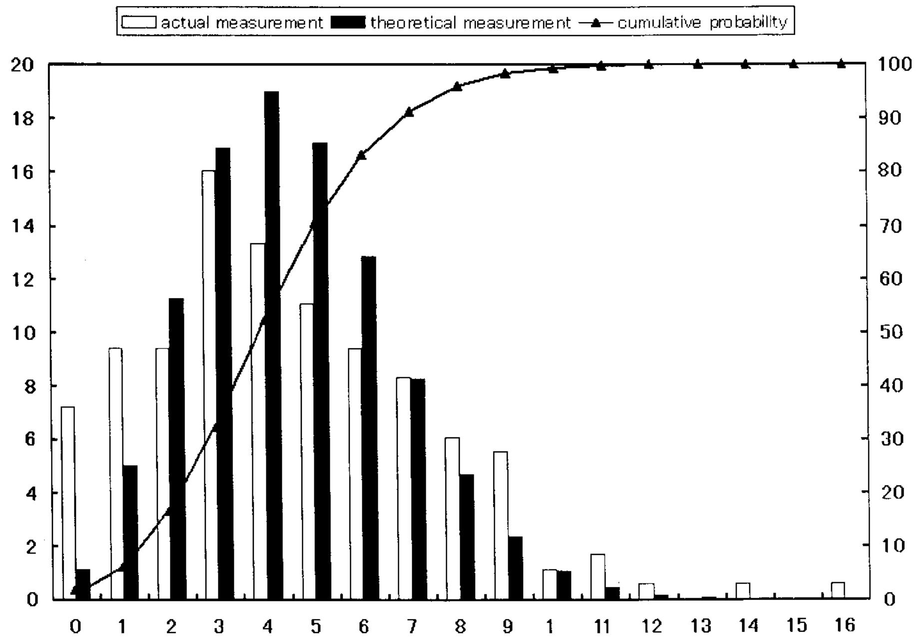

Figure 3. Distribution of incident counts.

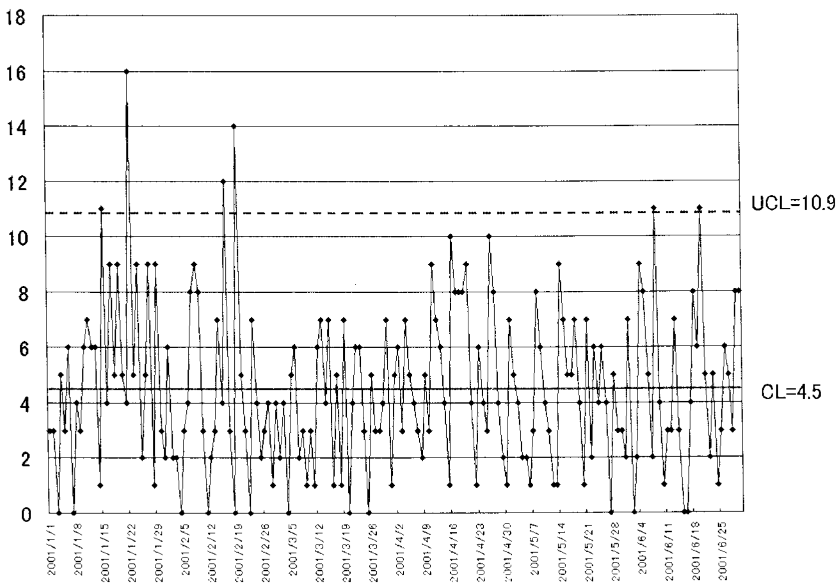

Figure 4. c control chart of daily incident cases.

the upper control limit is 10.9. Six days yield out-of-control points exceeding the upper control limit, and some run lengths are abnormally long. Identifying assignable causes in the care process requires analysis of the unstable state.

4.3 Analysis by Pareto diagrams

Figure 5 shows a Pareto diagram in which the incident cases are arranged by job classification. The rate of incidents attributable to nurses is the highest, at about 80%. Examining the cases attributable to nurses is the best approach to consider how to reduce this problem. Figure 6 shows the classification of incidents attributable to nurse's tasks, and analysis suggests that a problem exists in the administration of medication and nursing care provided after tests or operations. Incidents in the administration of medication occur with the greatest frequency and account for 40% of all cases, and nursing care after medical tests or operations accounts for approximately 25% of cases.

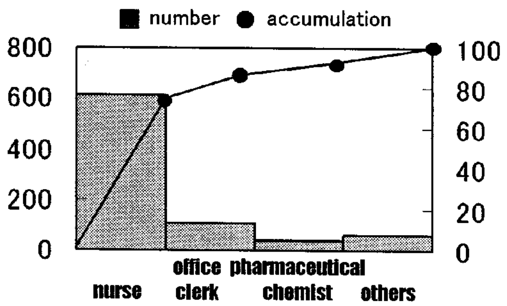

Figure 5. Pareto diagram by job classification.

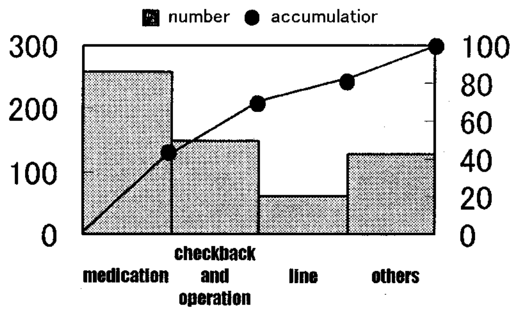

Figure 6. Pareto diagram by causes of incident by nursing.

4.4 Incident process analysis by CART

In the next stage, we apply CART to analyze the process of administering medication (classification A). Table 3 shows the response variable and predictors. INFLUENCE to a patient is set as the response variable. The greater the level, the greater the severity of the effect. Variables P_SEX to MONEY are set as predictors.
Figure 7 shows the results of the CART analysis. A split variable is defined as a variable for which the data are divided into two subsets so as to maintain the maximum reduction in impurity, which is defined as a probability of incorrectly classifying a case. The identified class of a terminal node differs from the class of plurality rule according to the breakdown probabilities

Table 3. Response variable and predictors.

	Variable name	levels	Explanation	
Response	INFLUEN	4	0	There was no influence to a patient
			1	There was no actual harm to a patient
			2	The necessity for medical treatment and the increase in hospitalization days are predicted (reversible)
			3	Extension of hospitalization days, leave an obstacle, concerned with life and death are predicted (irreversible)
Predictors	P_SEX	2	Patient's sex	
	DISTINCT	3	Inpatient wards and outpatient department	
	SECTION	14	The department of medical examination which the incident generated	
	ASSIGNME	17	In-charge of-nursing station	
	EXP_TOTA		Years-of-experience	
	CONDITIO	7	Health condition at the time of incident generating	
	WEEK	3	Generating day	
	PLACE	10	Generating place	
	TIME		Working-hours were employed	
	MANUAL	4	Existence of nursing manual	
	A_KIND	7	The kind of administration	
	A_STATE	11	The state of administration	
	A_C_1-19	19	The cause of administration	
	CONFIDEN	3	The degree of reliance loss	
	MONEY	2	The degree of money loss	

shown in the table of a terminal node in the figure, because the prior probabilities of a class are set as the probabilities derived from the rate of incident class in the actual data set. Besides, misclassification costs are set as shown in Table 4. As seen in this figure, the cases where the risk becomes high are terminal nodes No.5 and No.8.

Table 4. Table of misclassification costs.

	Miss class				
True class	-	0	1	2	3
	0	-	1	1	1
	1	2	-	1	1
	2	6	3	-	1
	3	10	5	1.67	-

The route to the terminal node No.5 is: The split variable of the root node is ASSIGNME; a case goes to the right if a value of the variable is either level in the bracket in Node 1; predictor EXP_TOTA splits the second branch from the root node; a case goes to the left if the value of the variable is more than 10.5. The last split variable is TIME, which leads to the terminal node if working hours are after 21:30. When terminal node No.5 was compared with terminal node No.6, the degrees of influence become level 2 and level 3 by the variable TIME split at 21:30. Meanwhile, the route to terminal node No.8 is: the same route as that of the terminal node No.6 up to node No.5, but if EXP_TOTA is more than ten years of experience and CONDITION is not good, then a case reaches the high-risk terminal node No.8.

The attribute of terminal nodes along the

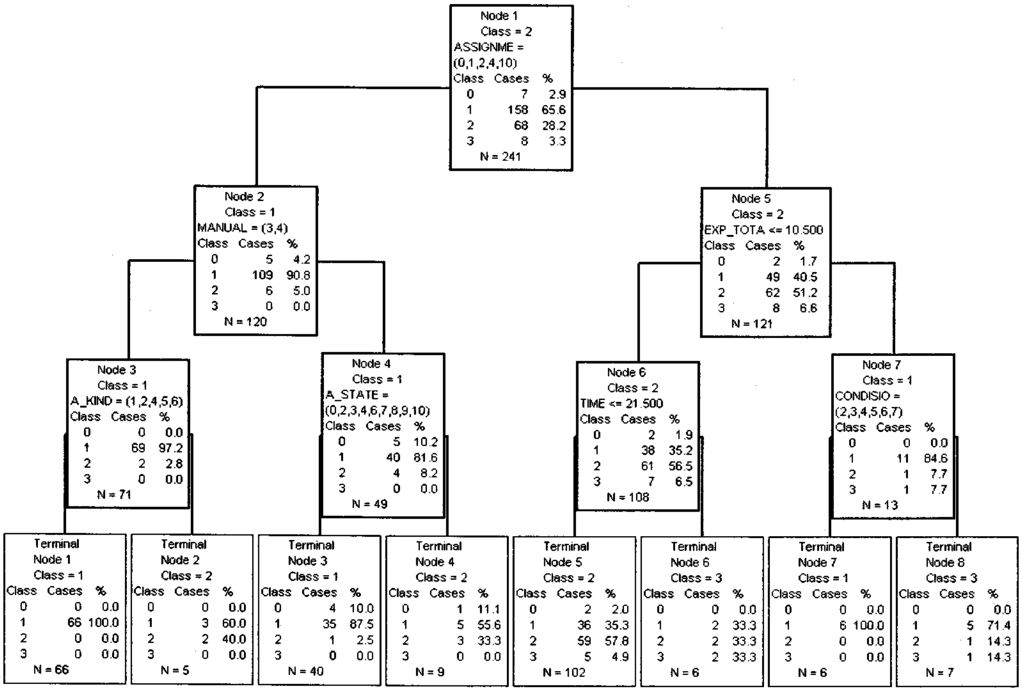

Figure 7. Incident classification tree.

routes that go to the left from the first branch is outpatient; in contrast, the attribute of the terminal nodes on the right side is inpatient. Although the conditions of split variable allowing cases to go to the left side have slight influence on fatal incident of the cases, those on the right side involve higher risk than those on the left side, because the number of the breakdown influence level in the terminal nodes on the right side is greater than that in the terminal nodes on the left side. These causes are EXP_TOTA, TIME, and CONDITION, which are assignable factors and controllable. This shows the importance of promoting standardization of the assignable causes by introducing manuals such as standard operating procedures. In future work, we will examine countermeasures to reduce the number of incidents within the nursing process.

5. Conclusions

This paper describes the progress of application of the concepts and methods developed in SQC to reducing medical incidents. Current progress is summarized as follows:

(1) The current level of quality improvement approximates Type 1 improvement, because the nursing tasks are not always standardized. The hospital concerned makes efforts to improve medical care process while recognizing the present state and studying best practices in the hospital.
(2) Medical incident path analysis by CART is useful for determining the routes to reducing medical errors. At present, we are working towards designing the measures.
(3) The basic concepts of statistical quality control developed for industrial applications are useful in the analysis of nursing process.

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