Method for Observation of Processes in Invasive Medical Techniques

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Abstract:
At hospitals, invasive medical techniques such as insertion of a central venous catheter are basic and common techniques for medical doctors. Since invasive techniques have impact on patient's body, standardization for quality assurance through prevention of any problems is important. In activities of standardization, not only preparation of operating procedure but also observation of process with operating procedure are required. In this paper, “observation of processes” is defined as an action to follow processes with operating procedures accurately. The purpose of this study is to develop a practical method for observation of processes with operation procedures and demonstrate efficiency of observation for invasive medical techniques. In this paper, we develop a method to observe processes using checklists in invasive medical techniques. In this method, processes are observed practically through implementation of checklists in daily operation of invasive medical techniques. In a verification for central venous catheter insertion process in hospital A, higher rate of observation have been achieved and improved outcomes of process performance have implied.

Keywords
Quality of healthcare, Quality of Conformance, Checklist, Central Venous Catheter, Quality Function Deployment

1. Introduction

1.1 Backgrounds

In order to assure quality of medical invasive techniques in hospitals, healthcare staffs have to achieve techniques without any problems to patients. Since invasive medical techniques accompany with heavy invasion to patient’s body, problem occurrence in techniques involve critical impact on patients such as bloodstream infections (Bion J et al., 2012) and artery puncture (Oliver WC Jr et al., 1997). Therefore, safety of implementing techniques are desired (Ishikawa, T., et al., 2012; Tsueshita, T., 2012). For example, “Central venous catheter (CVC) insertion” is one of the most invasive techniques and CVC insertion requires special license or special facilities for implementation in some hospitals in Japan (Masugata, H., et al., 2014). This means that invasive techniques are recognized as dangerous actions in clinical sites.

Invasive medical techniques are usually implemented at hospitals and some processes have been distributed among medical doctors (Charles A et al., 2013). For continuous quality assurance, each healthcare facility has to develop and improve processes through specifying common processes due to each facility’s characteristics about patients and resources. Though each organization has to implement PDCA cycles, an accurate method for evaluation in invasive medical techniques has not yet established (Lilford R et al., 2004; Leigh VE et al., 2010).

Shimono et al. (2013) have proposed a method for problem analysis in invasive medical techniques. Figure 1 shows an example of analysis of a problem which the incorrect order occurred the chain of problematic events and generated arrhythmia (cardiac complications). The developed method contributes to standardization. This method, however, has not sufficient for quality assurance because medical doctors have not always observe processes with operating procedure. Therefore, not only preparation of operating procedure but also observations of process with operating procedure is required for accurate performance of invasive techniques.

1.2 Purpose

In this study, we aim at clarifying effectiveness of observation of processes for quality assurance in...
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invasive medical techniques. The purpose of this paper is to develop practical methods for observation of processes and demonstrate efficiency of observation for invasive medical techniques.

This paper targets on CVC insertion process as one of the most invasive techniques. CVC insertion is a process which inserts special catheters to patient’s central venous from a needle point: neck (internal jugular vein), shoulder (subclavian vein) or inguinal (femoral vein) points for the purpose such as medication and nutrition.

Our research system is a joint research among researcher of quality management and medical staffs of Hospital A (University Hospital in Tokyo, about 1100 beds) who are medical doctors, nurses and so on. Authors develop the research projects through data investigation and discussions in Hospital A.

Figure 1: Problem Occurrence as a Chain of Dysfunctional Modules in the CVC Insertion Process
(Shimono et al., 2013)

2. Approach

In general, there are two types of quality: 1) quality of design, 2) quality of conformance. In healthcare industry, 1) quality of design means a degree of sufficiency of healthcare operation design to requirements for healthcare by patients (Iida et al., 2005). Therefore, 1) quality of design relies on a degree of standardization of healthcare operation which are ways to achieve quality target. On the other hands, 2) quality of conformance relies on a degree of observation by healthcare staffs as shown in figure 2. In this paper, “observation of processes” is defined as an action to follow processes with operating procedures accurately.

In order to evaluate medical doctors for implementing invasive medical techniques, Shimono et al. (2015) proposed a method to evaluate competences of medical doctors. However, the effectiveness of the proposed method is not clarified for quality assurance. In order to elucidate contribution to quality of healthcare by achieving quality of conformance, actual situation of observation of processes has to be revealed.

In this study, we illustrate the effectiveness of observation of processes based on standardization for quality assurance in invasive medical techniques. In Chapter 3, we propose a method to observe processes by checklists, which composed of two steps; step 1) Preparation of checklists using evaluation items for checklists through quality target deployment and step 2) Implementation of checklists for observation of processes. In Chapter 4, we validate the developed method through application in actual cases.
3. Development of a method to observe processes in invasive medical techniques

3.1 Preparation of checklists using evaluation items through quality target deployment (Step 1)

In order to observe processes of invasive medical techniques by medical doctors, checklists are effective. Since checklists require implementation of components of process one by one, medical staffs who implement processes are guided to observe. Therefore, results of checklist implementation show the situation of observation in actual works.

In order to construct an accurate checklist to observe process, we have to derive evaluation items to be monitored through implementation of the process. As regards evaluation items, quality targets in the technique have to be clarified. Thus we construct evaluation items for quality evaluation of invasive techniques by quality function deployment (QFD).

Since processes of invasive medical techniques accompanies with invasion, the targets require not only achievement of techniques but also prevention of defects from techniques as shown in the large classification of Table 1. This deployment is a result of application of the framework which Kato et al. (2015) proposed. Table 1 shows 34 items to evaluate quality target in CVC insertion and the structure which explains a relationships between them. Several items to evaluate in the middle category of prevention of complication are derived through investigation of potential complications (Yagnik L et al., 2016; Lai NM et al., 2016; Gunther SC et al., 2016). In invasive medical techniques, goals are to insert and set accurate medical devices at an accurate site in-body through punctuation and insertion of the devices. It is not easy to construct items for quality evaluation for invasive techniques because accurate invasive techniques relies on particular patient and requires complicated consideration by invasion.

Items shown in Table 1 are quality targets necessary for invasive medical techniques in the small classification and items to evaluate quality target for CVC insertion process. It is difficult to confirm all items in daily works because of its botherations for medical staffs. A part of items for quality targets have to be selected for installing on a checklist. The right low of Table 1 indicates whether each item is selected or not for a checklist.

3.2 Implementation of checklists for observation of processes (Step 2)

In order to enhance observation of processes of invasive medical techniques, implemented checklists have to be monitored. We developed a procedure to implement checklist actually. In this procedure, 1) filled-in checklists are submitted to safety management office in a hospital, 2) data of checklists is collected, 3) collected data is analyzed, 4) results of analysis are provided to special committee, and 5) results of analysis are provided to each department.

Though this procedure is general, implementation is not easy as organizational actions. Authors have focused on steps of 3) collected data is analyzed, and 4) results of analysis are provided to special committee, in order to enhance the procedure and accelerate an improvement activity for quality management by the committee and each department.
4. Verification

4.1 Application of the developed method for CVC insertion process in hospital A

In order to verify efficiency of the developed method to observe processes for quality assurance in invasive medical techniques, we applied the developed method consists of two steps. Authors verified in CVC insertion process at hospital A, university hospital has about 1100 beds.

Firstly, we confirmed checklists for CVC insertion process at hospital A. As a result, the checklist at hospital
A covers almost all items to evaluate achievement of process (upper half of Table 1) and covers a part of items to evaluate prevention of defects (lower half of Table 1).

Secondly, checklists for CVC insertion process are implemented at hospital A for a certain period. Since hospital A has already implemented the checklists, we updated the several items of the checklist. Therefore, accumulated data from the checklist implementation can be analyzed and comparison of the data before updating with after updating of the checklist. In this verification, this checklist update means the start of enhancing the step 2. Therefore, we verified the developed method by comparison data between before update and after update.

4.2 Results of verification

4.2.1 Verification in rate of observation

As a result of checklist implementation at hospital A, several types of data are collected. From the viewpoints of verifying the observation of processes, comparison of the results between before and after enhancing observation through checklist update. This observation enhancement through checklist update was performed July 2014 at hospital A. The average number per month of CVC insertion cases using checklists is 23 cases. The following results show changes of rate month by month.

In figure 3, one of the examples for rate of observation are shown. The blue line graph shows the rate of cases performed with echocardiographic guidance which is suggested for accurate recognition of vessels under layer of patient’s skin (Denys BG et al. 1993; Karakitsos D., et al, 2006; Tokumine, J., 2012). The other red line graph shows the rate of cases performed a particular method “Seldinger technique”, is more safe technique using guide wire for CVC insertion. These two rates have trends of increasing especially after checklist update. This means high rate of observation is achieved after observation enhancement through checklist update.

![Figure 3: Rate of Process Observation](image)

4.2.2 Verification in outcomes

Figure 4 and Figure 5 show the outcomes of CVC insertion by analysis of checklist data. In Figure 4, the rates by the number of needle for CVC insertion. If the performance by 1 time means the CVC insertion for one patient’s case was performed successfully for one time. Since the operating procedure limits the number of needle less than three times, a rate of the number less than three times (parts of blue and red bars in graphs) means that implemented process is observed. In hospital A, the rate of the number less than three times has a trend of increasing after the checklist update. This results are also shown in Table 2.
Table 2: Outcome Transition through Checklist Update

|                | Before n=786 | After n=528 | p Value (chi-squared test) |
|----------------|-------------|-------------|---------------------------|
| Artery Damage  | Occurred n (%) | 64 (8)      | 22 (4)                    | 0.004 **            |
| Number of Needle | ≥ 3 times n (%) | 179 (23)   | 94 (18)                  | 0.029 *            |

Figure 4: Number of Needle

Figure 5 shows the rate of artery damage occurrence by CVC insertion. Artery damage is a major complication of CVC insertion by puncturing wrong blood vessels. As shown in Figure 5, the rate of occurrence has decreased after checklist update. This means outcome of CVC insertion at hospital A has been improved in the point of complication occurrence. These results are also shown in Table 2.

Figure 5: Occurrence Rate of Artery Damage after CVC Insertion
Table 3 shows outcomes in cases of CVC insertion with and without ultrasonic guide. CVC insertion under ultrasonic guide is succeeded in higher rate compared with insertion without ultrasonic guide. On the other hand, artery damages are occurred regardless of whether insertion is proceeded under ultrasonic guide.

Table 3: Outcome with/without Ultrasonic Guide

|                          | with echo guide | without echo guide | p Value (chi-squared test) |
|--------------------------|----------------|-------------------|---------------------------|
|                         | n = 1,100      | n = 214           |                           |
| Number of Needle         |                |                   |                           |
| ≤ 2 times                | 857 (78%)      | 184 (86%)         | 0.008 **                  |
| ≥ 3 times                | 243 (22%)      | 30 (14%)          |                           |
| Artery Damage            |                |                   |                           |
| Not Occurred             | 1029 (94%)     | 199 (93%)         | 0.764                     |
| Occurred                 | 71 (6%)        | 15 (7%)           |                           |

5. Discussions

The verification results imply an improvement of outcome that is the degree of achievement of quality targets partially. Since invasive medical techniques damage patient’s body in a case of problem occurrence, these trends deliver quality improvement in some viewpoints at hospital A.

In this study, application of the developed method to observe, and the improved rates for observation of standardized CVC insertion processes have acquired. These results show the efficiency of the developed method for observation in invasive medical techniques. Moreover, the results imply an efficiency of learning through observation of processes by medical doctors.

Though the verification has performed in a particular hospital A, authors developed generic procedure for development of standardization and observation. Thus, the developed method can be applied for other invasive medical techniques in hospitals.

As future issues, a method for developing standard is required in order to observation gets more efficiency. In this paper, we only make evidences for quality assurance by processes observation. In future, explanation of the most efficient degrees of standardization and observation is required.

6. Conclusion

In this study, we developed a method to observe processes of invasive medical techniques. The developed method is consists of two steps:
step 1) Preparation of checklists using evaluation items through quality target deployment
step 2) Implementation of checklists for observation of processes

As a result of application in CVC insertion process at Hospital A, several rates of observation and outcome have achieved higher. The results implies effectiveness of the developed method for process observation. However, since some outcome have improved without relation to observation, application results have to be analyzed more precisely.

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Dr. Yoshinori Iizuka is emeritus professor of the University of Tokyo, having retired from the position of professor. He has played important roles, including President of JSQC for 2003-2005, Chair of Deming Application Prize Committee for 2008-2011, and Vice President of International Academy for Quality. He was awarded Deming Prize for Individuals in 2006, and ASQ Freund-Marquardt Medal in 2011.

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