นิพนธ์ต้นฉบับ

Analysis of incident reports according to the laboratory service risk management program of King Chulalongkorn Memorial Hospital[@]

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Abstract:

Analysis of incident reports according to the laboratory service risk management program of King Chulalongkorn Memorial Hospital[@]

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Risk management is an important item for all pathology laboratories. One consideration is the laboratory quality system. The author reports the results from an analysis of incident reports of the risk management program laboratory service, King Chulalongkorn Memorial Hospital, from October 2000 to March 2001. This program is a part of the ISO 9002 quality system of the laboratory. All workers in the laboratory monitored the risks, accident and service/environment in the laboratory. During the study period, 14 incidents, 11 service/environment items and 3 accident items were reported. The venipuncture clinic is the place where most incidents occurred. The results from analysis were collected and used as baseline data for improvement of the laboratory process. The author recommends the incident report system for improvement of the quality of all laboratories.

Key words: *incident report*

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บทคัดย่อ:

การบริหารความเสี่ยงเป็นสิ่งที่สำคัญสำหรับทุกห้องปฏิบัติการ เนื่องจากมีความเสี่ยงหลายชนิดในห้องปฏิบัติการ ดังนั้น การบริหารความเสี่ยงที่ดีจึงเป็นข้อสำคัญในระบบคุณภาพของห้องปฏิบัติการ ในบทความนี้ผู้นิพนธ์ได้รายงานผลการวิเคราะห์รายงานเหตุการณ์พิเศษตามโปรแกรมบริหารความเสี่ยงของห้องปฏิบัติการ โรงพยาบาลจุฬาลงกรณ์ ในช่วงเดือนตุลาคม พ.ศ. 2544 ถึงมีนาคม พ.ศ. 2545 ซึ่งเป็นไปตามระบบคุณภาพ ISO 9002 ของห้องปฏิบัติการ ในระหว่างช่วงที่ศึกษาพบว่ามีเหตุการณ์พิเศษเกิดขึ้น 14 เหตุการณ์ โดยตัดเป็นกลุ่มอุบัติเหตุ 3 เหตุการณ์และกลุ่มการบริการ/สิ่งแวดล้อม 11 เหตุการณ์ โดยสถานที่ที่มีเหตุการณ์เกิดขึ้นบ่อยที่สุด คือ คลินิกเจาะเลือด ผลจากการวิเคราะห์ได้ถูกนำมาใช้เป็นข้อมูลพื้นฐานในการพัฒนาคุณภาพของห้องปฏิบัติการต่อไป ผู้นิพนธ์ได้แนะนำให้ใช้ระบบการรายงานพิเศษเพื่อเป็นเครื่องมือในการธำรงคุณภาพของห้องปฏิบัติการทางการแพทย์

คำสำคัญ: *เหตุการณ์พิเศษ*

Introduction

Risk management is an important item for all pathology laboratories. One consideration is the laboratory quality system. This paper reports the results from an analysis of incident reports of the risk management program laboratory service, King Chulalongkorn Memorial Hospital, from October 2000 to March 2001. This program is a part of the ISO 9002 quality system at this laboratory. An "incident report" was defined as any report of any situation during the entire process that influenced in any way the quality of the laboratory service. Recommendations to improve the laboratory service and reduce incident reports are also given.

Materials and methods

1. ISO 9002 : 1994 system

ISO 9002 : 1994[1], a quality system in the ISO 9000 series, is a model for quality assurance in production, installation and servicing, which includes a number of sections providing guidance for the implementation of the quality system. This quality system starts from general quality and documentation plans followed by an internal audit plan and the launch of the quality system. Finally, an assessment by an external team from an accredited third-party organization and final certification for compliance to ISO 9002 must be performed. The main topics according to ISO 9002 standards include management responsibility, organization, quality system, control of nonconforming products, statistical techniques, etc. Like certain other processes, the clinical laboratory process is a type of service, therefore the ISO 9002 can be applied[1-2]. This quality system, which must be maintained and undergo external audit at regular intervals so that certification is renewed, assures clinicians that the product (laboratory analysis service) conforms to predefined levels of quality[2].

In Thailand, the ISO 9002 : 1994 quality system has also been implemented for the clinical laboratory. The laboratory at King Chulalongkorn Memorial Hospital, the largest Thai Red Cross Society hospital, is the first clinical laboratory in Thailand with ISO 9002 : 1994 certification for the whole unit, including structures, processes, and so on. Monitoring of incident reports is one commitment of our quality plan[4].

2. Determination of the incident report

Based on the recommendations for ISO 9002 system for the hospital by the Technology Promotion Association (Thailand-Japan)[3], the laboratory quality committee decided that the incident report is a quality indicator of our laboratory. The other quality indicators were client satisfaction, complaint, turnaround time etc. According to the documentation plans, the specific quality system procedure, which provides the details on monitoring of preanalytical mistakes as a quality indicator according to the statistical technique prescribed by the ISO 9002 standard, was set. Furthermore, specific work instructions, which provide stepwise descriptions of the activities, and the specific data record forms for data collection and storage, were also set.[3].

As previously described, the definition of "incident report" is any situation during the entire process, that influenced in any way the quality of the laboratory service[4]. The two main items for incidences are A) accident such as falling down, needle-stick injury, blood contact and B) service/environment such as patient complaint, automatic analyzer error, nosocomial infection. All workers in the laboratory participated in monitoring of the risks, accident and service/environment in the laboratory. The incident report forms were distributed to each unit of the laboratory. For each incident, the following actions are processed: A) primary management by the workers at site, B) sending the incident report to the group quality manager for secondary management, C) the laboratory management quality committee finds the preventive action and D) in emergency case, early management is ensured.

Data record forms from all units were collected monthly and transferred to the laboratory quality committee for further statistical analysis. After review of the monthly data, the laboratory quality committee sets the corrective strategy for the identified problems.

3. Management review

According to the ISO 9002 system of the laboratory, the management review of the laboratory was performed every three months. During the study period, there was a management review in January 2001. At to this meeting, the incident reports during October to December 2000 were reviewed. The root cause analysis for each incident report was performed. The preventive action was set as well. The following continuous quality improvement (CQI) after this management review was shown by the monitoring of the incident reports in the following three months (January 2001 to March 2001).

Results

During the study period, 14 incidents, 11 service/environment items and 3 accident items were reported. Incident reports classified by month are shown in Table 1. Incident reports classified by unit are shown in Table 2. There were 12 incident reports, 11 service/environment items and 1 accident item, before the management review on January 2001. According to this management review, we set the preventive action to the incident reports in the CQI program for improvement of the service behavior of the workers. As a result, there were only 2 incident reports, both accident items, in following three months after the CQI.

Overall the accident reports comprised blood contact (3 cases) while service/environment reports comprised patient complaint (6 cases), automatic analyzer error (2 cases), nosocomial infection (3 cases).

Table 1 Incident reports classified by month: 2000-2001

Items	Before management review (2000)			After management review (2001)		
	October	November	December	January	February	March
Accident	1	0	0	2	0	0
Service/environment	4	6	1	0	0	0

* During management review, root-cause analysis and finding of the preventative action was performed for each incident.

Table 2 Incident reports classified by unit

Unit	Service/environment	Accident
Clinical Chemistry I	0	0
Clinical Chemistry II	0	0
Clinical Chemistry III	3	2
Clinical hematology I	0	0
Clinical hematology II	0	0
Urinalysis I	4	0
Specimen collection	4	1
Special analysis	0	0
Quality control	0	0

Discussion

In modern times, the quality system for clinical laboratories must include promotion of accuracy in the analytical phase as well as assurance of the reliability of preanalytical and postanalytical activities. Reliability cannot be achieved in a clinical laboratory through the control of accuracy in the analytical phase of the testing process alone. Indeed an "incident" can be defined as any defect occuring during the testing process[4]. The incident report can be a valuable tool for risk monitoring in the laboratory.

During this study, there were several incident reports. Most of them were classified as service/environment reports. Patient complaint became the most common type of incident report. Indeed, the medical service can be classified as a type of service business; therefore, the clients or patients' satisfaction is one of the most important items for consideration in laboratory management[5-6].

Concerning the preventive action, these results were analyzed and used as baseline information to improve the quality of the laboratory. The two main points for consideration are patient complaints, for which the preventive action is service behavior promotion[5], and nosocomial infection for which the preventive action is infectious control. According to our study, the first phase before the CQI, during service/environment items were the important risks, which required preventive action. After the CQI concerning service behavior promotion, there was no incident report on this item in the following three months. This finding can represent the success of using the incident report system as the quality indicator of the laboratory for risk management. Therefore, the incident report is a good tool for finding the risk and providing the baseline data for planning for the preventive action.

The detection of these incidents was aided by both the ISO system of the laboratory and the Laboratory Information System (LIS), which is another useful system for laboratory management. The backup program can notify the workers in case there is disparity between previous and present results[7].

Table 3 Common pitfalls and preventive actions in the laboratory analysis

Pitfall	Corrective action	Preventive action
1. Accident		
❑ Blood contact and needle stick injuries	❑ Post-exposure management	❑ Universal precautions, pre-exposure vaccination
❑ Falls	❑ Primary care	❑ Primary care protocol
❑ Fire	❑ Fire fighting program	❑ Fire safety program
2. Service/environment		
❑ Patient complaint	❑ Response to complaint	❑ Service behavior promotion
❑ Nosocomial infection	❑ Treatment, infection control	❑ Infection control
❑ Automatic analyzer error	❑ Sparing machine, reanalysis	❑ Routine automated care program

Table 4 Comparison of the quality manual and incident report system between the ISO system and the Thai HA system

Point	ISO system	Thai HA system
1. Quality manual (QM) or procedural manual (PM)	■ Must be written for all works ■ According to ISO standards ■ Can be used in any service ■ International standard	■ Should be written for important works ■ Combining between medical standard, patient right and ethics ■ Specific for the hospital ■ The Thai HA is issued within Thailand
2. Incident report system	■ For control of the non-conforming product ■ No mention of continuous quality improvement	■ For risk management ■ Continuous quality improvement is necessary
3. Advantage	■ Well document control ■ International standards	■ Specific for Thailand ■ Has standards covering the medical service especially for the patient rights
4. Disadvantage	■ Difficult to interpret the standards	■ Not the international standards ■ The document control is not strict

However, both incident reports and LIS are based on human participation, and is subject to errors from carelessness and unawareness of the workers. In this case, the root problem is honesty of the hospital personnel. Common pitfalls and the corresponding corrective and preventive actions in the laboratory analysis are shown in Table 3. In addition, the comparison of the quality manual and incident report system between the ISO system and the Thai HA system is shown in Table 4.

Conclusion

The incident reports in a 6-month period of the Laboratory Medicine Division, King Chulalongkorn Memorial Hospital were analyzed. Most of the incident reports were service/environment items. It is suggested that incident reports be used as a risk monitoring system for medical laboratory quality management. In conclusion, the incident report system can be a useful indicator in risk management. It can be used for any other medical services in the hospital as well.

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