Development of Quality Indicators for Sterilization Practices of the Central Sterile Supply Department

Kwanjit Sangthong MNS*, Poonsap Soparat MSc**,
Wanchai Moongtui PhD**, Somwang Danchaivijitr MD***

*Somdej Prachaotaksin Maharaj Hospital,Tak,
**Faculty of Nursing, Chiang Mai University, Chiang Mai,
***Department of Medicine Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok

Objective : *To develop quality indicators for assessing the performance of central sterile supply department. (CSSD).*
Material and Method : *Quality indicators for sterilization in CSSD were searched by literature review and by current situation analysis by 79 infection control nurses (ICNs) and 83 heads of CSSD. Quality indicators were drafted and subsequently validated by 5 experts. The feasibility and applicability of the quality indicators were tested in 37 ICNs and 34 heads of CSSD. The quality indicators were finally refined by a forum of 5 experts and 5 representatives from CSSD.*
Results : *A total of 30 quality indicators were developed. These include 9 indicators for structure, 12 for process and 9 for output of CSSD. The quality indicators were deemed appropriate for the assessment of the quality of CSSD in Thailand.*
Conclusion : *Thirty indicators were developed for assessing the quality of CSSD.*

Keywords : *Quality indicators, Sterilization practice, Central sterile supply department*

J Med Assoc Thai 2005; 88 (Suppl 10): S128-32
Full text. e-Journal: *http://www.medassocthai.org/journal*

The central sterile supply department provides a hospital with services in the areas of supply processing and distribution. The department is responsible for cleaning, decontamination and sterilization of all reusable instruments and supplies. Defects in sterilization can lead to catastrophic consequences and economic burden[1,2]. The quality of sterilized products must be assessed by certain quality indicators. These should include not only the products, but also the structure and work process in CSSD[3]. The development process of quality indicators should stem from literature review and situation analysis, followed by expert opinion and feasibility study[4]. In Thailand, each CSSD has its own job description and job instruction. Certain quality indicators for the process of sterilization, for example, tape test, pack test, and for the products, for example, spore test, have been used[5]. A set of quality indicators for overall assessment of the quality of CSSD is thus needed. These indicators must be scientifically sound and practical for the country. A study on the development of comprehensive quality indicators for CSSD was carried out from 2003 to 2004.

Correspondence to : Danchaivijitr S, Department of Medicine, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand. E-mail: sisdc@ mahidol.ac.th

Material and Method

A study on the development of quality indicators for sterilization practices was done during November 2003 and March 2004. The study was divided into 4 phases. Phase 1 was literature review and situation analysis involving 79 ICNs and 83 heads of CSSD. They were selected from university and Ministry of Public Health hospitals across the county. The second phase was the drafting of quality indications subsequently validated by 5 specialists in infection control including 2 physicians and 3 ICNs. Phase 3 was the feasibility study by 37 ICNs and 34 heads of CSSD. The fourth phase was for the refinement of quality indicators by a forum of 5 specialists and 5 CSSD personnel.

Data was analysed by using descriptive statistics.

Results

A set of questionnaire on quality indicators were sent to 1 ICN and 1 head of CSSD of each of 110 hospitals across the country in November 2003. As shown in Table 1, 79 ICNs and 83 heads of CSSD responded, with an average of 73.6%. They were from 5 university, 16 regional, 53 provincial and 5 district hospitals. The indicators on structure of CSSD was shown in Table 2. There were small discrepancies between the written quality indicators and those in practice except assignment of duties for CSSD personnel. Human resource development and budget plan were among the least implemented quality indicators. There were 4 quality indicators that did not exist at the time of the survey : retrieval of defective products, channel for communication between CSSD and users, a fully structured CSSD and the imposition of head of CSSD as a member of infection control committee (ICC). There were 5 quality indicators available for sterilization process (Table 3). Less than 3 quarters of CSSD where personnel complied fully with sterilization guidelines and validated sterilization instrument. Missing important quality indicators include the complying with guidelines on : cleaning, packaging, loading, unloading, distribution of sterilized products, maintenance of sterilization instrument and proper use of sterilized instrument.

Table 4 demonstrates the presence and implementation of quality indicators for sterilized products. Application of indicators for steam sterilization by tape test, adequate steam penetration by Bowie-Dict test were as low as 25.9% to 47.5%. The most important biological (spore) test was applied in only 83.3%. The level of satisfaction by users was only at 3.1%. The following quality indicators were not used : percentage of retrieved products, mechanical failure of instru-

Table1. Infection control nurses (ICNs) and heads of central sterile supply department (CSSS) participated in situation analysis of in-use quality indicators

Types of Hospitals	ICNs		Heads CSSD	
	No	%	No	%
University	5	6.3	3	3.6
Regional	16	20.3	16	19.3
Proviacial	53	67.1	57	68.7
District	5	6.3	7	8.4
Total	79	100	83	100

Table 2. Presence and implementation of quality indicators (%) for structure of CSSD (N=162)

Quality Indicators	Presence	Implementation
Written policy	76.5	72.8
Work flow chart	97.5	89.5
Job assignment	92.6	92.6
Practice manual	79.6	76.5
Human resource development plan	63.6	56.8
Annual health check Up	97.5	86.4
Budget plan	74.1	71.0

Table 3. Presence and implementation of quality indicators for sterilization process (%) (N=162)

Quality Indicators	Presence	Implementation
Complying to sterilization guideline	97.5	74.1
Validation of sterilization instrument	72.8	72.8
Use of chemical indicator	98.2	97.5
Use of biological indicator	96.3	95.7
Precautions of sharp injury	95.1	93.2

Table 4. Presence and implementation of quality indicators for sterilized products (%) (N=162)

Quality Indicators	Presence	Implementation
Percentage of :		
Negative chemical test	30.3	25.9
Negative Bowie Dict test	47.5	47.5
Negative biological test	84.6	83.3
Satisfaction of custumers	3.1	3.1

Currently not available
- Percentage of retrieved products
- Percentage of undelivered sterilized products
- Percentage of wet packs
- Percentage of technical failure of sterilizer
- Incidence of accidents at work.
- Percentage of expired products in stock

ment, percentage of undelivered sterile products, percentage of wet packs, percentage of inappropriate packaging, accidents, and percentage of expired products in stocks.

The feasibility study was participated by 37 ICNs and 34 heads of CSSD (Table 5). They were among the subjects enrolled in phase 1. The results of the feasibility study on structure of CSSD are given in Table 6. Most of the quality indicators in-use were feasible. Retrieval of defective products were considered feasible by 71.8% of personnel and imposition of head of CSSD as a member of ICC was 84.5%. The applicability of a channel of communication between CSSD personnel and users, a well-planned structured CSSD were not included in the feasibility study.

The quality indicators for process in CSSD were all feasible, including indicators not present at the time of the present study.

The results of the feasibility study on products of CSSD are shown in Table 7. The Bowie-Dict test, as an indicator was deemed feasible in only one-third. Other indicators, not available at the time of survey, were considered feasible at a high percentage. These included retrieval of defective products, technical failure of sterilizer, wet packs, expired products in stocks and undelivered products.

Discussion

The present study on the development of indicator to assess the quality of CSSD was done to include structure, process and output.[3] The practices were reported by ICNs and heads of CSSD from governmental hospitals in Thailand (Table 1). The common practices included the setting of a work flow chart and job assignment. However, the written policy, practice manuals, and budget plan were not incorporated into the structure of CSSD in many hospitals. This could lead to improper practices in a developing country where automated machines are lacking[6]. A policy and practice in human resource development were as low as 63.6% and 56.8% respectively. The personnel in CSSD need continuing professional development through education otherwise they will be left behind in the advancement of knowledge and technology of new machines. The calling-back of sterilized products that do not meet the standard was also lacking in all hospitals. The heads of CSSD were not automatically selected as a member of ICC. This widens the gaps between CSSD and ICC and costumers.

Five indicators were used to assess the quality of sterilization process in the hospitals surveyed (Table 3). It is to be noted that validation of sterilization instrument was done in only 72.8%. Even though it was validated, it was done by CSSD personnel who were not engineers. Defects of the instrument could easily occur and are not easily detected in daily practice leading to unsterile products[7]. The use of process and outcome indicators were satisfactory (93.2%-

Table 5. Infection control nurses and heads of CSSD participated in feasibility study

Types of Hospitals	ICNs No	ICNs %	Heads CSSD No	Heads CSSD %
University	1	2.7	1	2.9
Regional	9	24.3	8	23.5
Provincial	22	59.5	21	61.8
District	5	13.5	4	11.8
Total	37	100	34	100

Table 6. Feasible quality indicators for structure of CSSD by 37 ICNs and 34 heads of CSSD

Quality Indicators	Feasible (%)
Written policy	97.2
Work flow chart	90.1
Job assignement	98.6
Practice manual	100.0
Human resource development	91.6
Annual health check-up	93.0
Budget plan	97.2
Retrieval of defective products	71.8
Head of CSSD as a member of infection control committee	84.5

Table 7. Feasible quality indicators for sterilized products by 37 ICNs and 34 heads of CSSD (%)

Quality Indicators	Feasible (%)
Percentage of :	
- negative chemical test	84.5
- negative Bowie-Dict test	64.9
- negative biological test	94.3
- satisfaction of customers	67.6
- retrieved products	71.8
- technical failure of sterilizer	84.3
- wet packs	74.7
- expired products in stock	73.2
- undelivered products	70.4

98.2%). These monitoring processes provide quality assurance to healthcare workers and patients that the instruments have been properly processed[8]. Certain important guidelines were not available in the hospitals ; these included guidelines on : cleaning, packaging, loading, unloading, delivery of sterilized products and maintenance of sterilized instruments.

The quality indicators for sterilized products were very limited (Table 4). The result of biological (spore) test was the major indicator. Process indicators were less recognized. Positive feedbacks from users were almost absent. Many useful indicators were to be introduced, for example, the proportion of retrieved products, defective products, undelivered products, wet packs, expired products in stocks, incidence of technical failure of sterilizer and events of work-related accidents. The feasibility of application of quality indicators was studied in 37 ICNs and 34 heads of CSSD (Table 5). They were enrolled from governmental hospitals. Quality indicators for structure of CSSD were highly feasible (Table 6). Two indicators not present in practice were also assessed. The feasibility of retrieval of defective product and of assigning the head of CSSD as a member of ICC were 71.8% and 84.5% respectively.

The quality indicators for process of sterilization were also studied. All indicators in Table 3 and all essential indicators not implemented in the hospitals were all 100% feasible. The quality indicators for output of CSSD, as shown in Table 7, were less feasible except the biological test. This reflected the infrequent use of process indicators such as chemical test (84.5%), Bowie-Dict test (64.9%) in the hospitals. Proposed indicators to be incorporated into quality indicators for output were considered feasible in 70.4%-84.3%.

The quality indicators were finally refined by a panel of 5 specialists and 5 CSSD personnel. Wording in the draft, details of sub-topics were corrected as appropriate.

Conclusion

The development of quality indicators for assessing the performance of CSSD by literature review, situation analysis, feasibility study and final refinement yielded a set of indicators for structure, process and output of CSSD. It is hoped that these indicators be applicable in hospitals in Thailand.

Acknowledgement

The authors wish to thank the participating ICNs and heads of CSSD. The research was supported by a Mahidol University Research Grant.

References

1. Centers for Disease Control and Prevention (CDC). Corneal decompensation after intraocular ophthalmic surgery. MMWR 1998; 47: 306-9.
2. Babeock HM, Caroll C, Matava M, L'ecuyer P, Fraser V. Surgical site infections after arthroscopy, investigation and case control study. Arthroscopy 2003; 19: 172-81.
3. Donabedian A. Exploration in quality assessment and monitoring. Michigan: Health Administration 1980.
4. Hofer TP, Benstein SJ, Hayward RA, De Monner S. Validating quality indicators for hospital care. J Quality Improvement. 1997; 23: 455-67.
5. Ayliffe GAJ, Lowbury EJL, Geddes AM, William JD. Control of hospital infection - a practical handbook. 3rd ed. London, Glasgow, New York, Tokyo, Melbourne, Madras: Chapman and Hall Medical, 1992: 47-64.
6. Alfa MJ, Nemes R. Inadequacy of manual cleaning for reprocessing single-use, triple-lumen sphincter tomes: simulated-use testing comparing manual with automated cleaning methods. AJIC 2003; 31: 193-207.
7. Van Doornmalen JPCM, Dankert J. A validation survey of 197 hospital steam sterilizers in the Netherland in 2001 and 2002. J Hosp Infect 2005; 59: 126-30.
8. Miller CH. Sterilization disciplined microbial control. Dent Clin North Am 1991; 35: 339-55.

การพัฒนาดัชนีคุณภาพการปฏิบัติการทำให้ปราศจากเชื้อในหน่วยจ่ายกลาง

ขวัญจิตร สังข์ทอง, พูนทรัพย์ โสภารัตน์, วันชัย มุ้งตุ้ย, สมหวัง ด่านชัยวิจิตร

วัตถุประสงค์ *: พัฒนาดัชนีคุณภาพการปฏิบัติการทำให้ปราศจากเชื้อของหน่วยจ่ายกลาง*

วัสดุและวิธีการ *: สรรหาดัชนีคุณภาพการปฏิบัติการทำให้ปราศจากเชื้อของหน่วยจ่ายกลางโดยการทบทวนวรรณกรรมและสำรวจสถานการณ์ใช้ดัชนีจากพยาบาลควบคุมโรคติดเชื้อ 79 คน และหัวหน้าหน่วยจ่ายกลาง 83 คน ร่างดัชนีคุณภาพและตรวจสอบโดยผู้เชี่ยวชาญ 5 คน ทดสอบความเป็นไปได้ของดัชนีโดยพยาบาลควบคุมโรคติดเชื้อและหัวหน้าหน่วยจ่ายกลาง 37 และ 34 คนตามลำดับ ดัชนีขั้นสุดท้ายได้จากการนำข้อมูลมาเสวนากลั่นกรองโดยผู้เชี่ยวชาญ 5 คนและผู้เกี่ยวข้องกับงานหน่วยจ่ายกลาง 5 คน*

ผลการศึกษา *: ได้พัฒนาดัชนีคุณภาพการปฏิบัติการทำให้ปราศจากเชื้อในหน่วยจ่ายกลาง 30 ดัชนี ประกอบด้วยดัชนี 9 ตัว สำหรับด้านโครงสร้าง 12 ตัวสำหรับด้านขบวนการและ 9 ตัวสำหรับด้านผลลัพธ์ ดัชนีที่พัฒนาขึ้นนี้น่าจะเหมาะสมสำหรับการประเมินการปฏิบัติการทำให้ปราศจากเชื้อของหน่วยจ่ายกลางในประเทศไทย*

สรุป *: ได้ดัชนีคุณภาพ 30 ดัชนีสำหรับประเมินคุณภาพของหน่วยจ่ายกลาง*