



Developing the Use of Quality Indicators in Sterilization Practices

H Jabbari^{1,2}, H Alikhah³, N Sahebkar Alamdari⁴, M Naghavi Behzad⁴, E Mehrabi⁵, L Borzui⁶, *F Bakhshian⁷

1. *Dept. of Community Medicine & Health Administration, Medical Faculty, Tabriz University of Medical Science, Tabriz, Iran*
2. *National Public Health Management Center (NPMC), Tabriz University of Medical Sciences, Tabriz, Iran*
3. *Researcher, Tabriz University of Medical Sciences, Tabriz, Iran*
4. *Student Research Committee, Medical Faculty, Tabriz University of Medical Science, Tabriz, Iran*
5. *Dept. of Midwifery, Tabriz Branch, Islamic Azad University, Tabriz, Iran*
6. *Health Administration Section, Health Faculty, Tabriz University of Medical Science, Tabriz, Iran*
7. *Chancellor Dept., Tabriz University of Medical Sciences, Tabriz, Iran*

(Received 11 Jan 2012; accepted 18 May 2012)

Abstract

Background: Health-care-associated infections are a major threat to the safety of patient care. Control of such problem is a major criterion for hospital accreditation. This study was aimed to determine the developing use of chemical (class 6 products) and biological indicators in Tabriz district hospitals since 1997 to 2011.

Methods: We conducted this time-trend interventional study with all of the public and private hospitals, which counted to 21 in Tabriz district as a sample. The situations of indicator use were presented for each time in the base of indicator groups. Furthermore, the results were showed in the base of hospital groups.

Results: All of district hospital (n=21) with 74 autoclave machine and 22 central sterilization room were studied. The result of second time study in 2008 showed a markedly improvement in the control of sterilization processes. Furthermore, we continued our intervention results 6 month later in 2009 and 2 years later in 2011. The most striking result were use of chemical indicator in 100% of hospitals. However, there are defects in the use of biological indicators (63.65%).

Conclusion: The most obvious finding was significant improvement in sterilization control especially in development the use of chemical indicators. The finding of this study has a number of important implications for hospital managers and infection control practitioners such as continuous practical training of CSSD personnel in hospitals and mandating of indicator using in all sterilization process with controlling of this subject in evaluation and accreditation of hospital programs.

Keywords: Health Care, Education, Quality control, Chemical indicators, Hospital sterilization, Biological indicators

Introduction

Health care-associated infections are among major threats to the safety of patient's care. It affects millions of people worldwide and acts as a rising problem (1). Because millions of surgical procedure was conducted in hospital and other health care –setting involves contact by a medical device

or surgical instrument with a patient's sterile tissue or mucous membranes. One of the major risks of these procedures is transmission of pathogens that can lead to infection not only to host barriers but also person-to-person transmission (2).

Previous studies suggested that risks of health-care-associated infection are significantly higher in developing countries (2). Similarly last World Health Organization reporting indicates health care-associated infection in Iran is 8.8% (3). Controlling this problem is a major criterion for hospital accreditation (4). Both of central sterile supply department (CSSD) and nurses in office of surgical facilities are responsible for cleaning, decontamination, and sterilization of all reusable instruments and items (5). Proper sterilization of instruments between patients is an essential action in removing all of microbes and prevention of catastrophic consequences (6).

The most common method for sterilization of medical instruments worldwide is steam sterilization. However, steam sterilization or autoclaving may not be 100% effective at killing all microorganisms under all circumstances (7). Therefore, the quality of sterilized products should be assessed by physical, chemical, and biological indicators (4). The formulation of class 6 chemical indicators is sensitive to the sufficient combination of the three factors necessary for sterilization: time, temperature, and saturated steam (7). According to CDC and other medical associations, to ensure heat penetration to all instruments during each cycle, a chemical indicator should be placed inside and in the center of a load of unwrapped instruments, routinely in every sterilization process. Finally, biological indicators are used periodically for monitoring of the quality of sterilization processes (8).

Most of studies using chemical and biological indicators have only been carried out in a small number of developing countries during the recent decades. Two studies just attempted to determine the quality of sterilization processes in Poland hospitals (1997 and 2000) which showed need for improvement in the sterilization process (9,10). In addition, 30 indicators were developed in 2005, following the assessment of the performance of CSSD in Thailand hospitals (6). Similar studies in Brazil (8), Hong Kong (7), Libya (11) and China (12) in outpatient and inpatient departments demonstrated that sterilization monitoring are less attention paid and there is urgent need for ade-

quately trained personnel and defined national guidelines.

Our previous research finding in monitoring of sterilization processes in Tabriz- Iran district hospitals (13), outpatient clinics and physician office (14-17) during recent 14 years demonstrated unacceptable situation in use of chemical and biological indicators.

The objectives of this interventional study were determining the developing use of chemical (class 6 products) and biological indicators in Tabriz district hospitals since 1997 to 2011.

Materials & Methods

In order to identify the effectiveness of researches and interventions on the improvement of sterilization process control since 1997 until 2011, we conducted this time-trend study with all of the public and private hospitals, which count to 21 in Tabriz district as a sample.

At the first stages of study, a descriptive cross-sectional study was conducted to determine the situation of controlling the sterilization process in all local hospitals (n = 21; Tabriz, Iran) in 1997. Data were gathered in base of an approved checklist. The checklist was developed by research team (1997), and its validity and reliability were confirmed by expert reviewers and Ethics Committee of Tabriz University of Medical Sciences (TUMS). The second study was conducted in 2007 with the same materials and methods. Status of hospitals in controlling of sterilization process was classified into three levels; acceptable, unacceptable, and relatively acceptable, based on the expert opinions of the research team (through site visits, observations, and conversations). The research team included one assistant professors of hospital management, one associated professor of environmental health, two M.S.-level hospital management researchers.

Results of two last studies demonstrated that there was not any improvement in controlling the sterilization process so we conducted an intervention through seminar and training the hospital representatives about importance of indicator use in

2008. In addition to training the participations in seminar we gave 50 chemical indicators to each hospital with practical education of users in the site of CSRs. Otherwise in this intervention we were studied the knowledge of participations (head nurses of CSR and the nurses of infection control program) before and after seminar through questionnaire who developed by research team (2008), and its validity confirmed with expert opinions. In addition, we assessed the reliability of each component of questionnaire using Cronbach's Alpha coefficient. The Cronbach's Alpha values for knowledge (0.702) reasonable reliability (internal consistency).

After six month data gathering process repeated in all hospitals (n=21) in 2009. As a final time study the situation of indicator use was surveyed in 2011. The results were presented for each time in the base of indicator groups. Furthermore, the results were showed in the base of hospital groups. Data were collected using same checklist in the all times.

Ethical consideration of this study and the study protocol was approved by the Ethics Committee of Tabriz University of Medical Sciences (TUMS), which complied with Helsinki Declaration.

Results

In order to determine time trend development on sterilization process control with current indicators, all of district hospital (n=21) with 74 autoclave machine and 22 central sterilization room were studied. Fifty percent (n=11) of them were in educational hospitals and other were belonging to private, armed force, social security organization and charity.

There are 3 types of indicators in the world which are using to control of sterilization process in the final step. Table 1 presents the results of 6 times study on the indicator uses.

Table 1: Indicator uses by hospitals in study times (%)

Time Indicator type	1997	2007	2008	2008	2009	2011
Test - tape indicator	76	80	90	100	100	95.5
Chemical indicator	4.8	4.8	10	40	80	100
Biological indicator	0	0	15	25	25	63.6
Number of studied CSRs	21	10	20	20	20	22

Following the first and second time study, we conducted a training program (intervention) in two stages:

Training of head nurses of CSR and the nurses of infection control program of hospitals in one-day's seminar (70 people) as a first stage. Table 2 demonstrates the knowledge differences of participations before and after training program. Education of indicators using in practically form in the site as a second stages.

Of all participations in seminar, 35% were male and 65% were female. Thirty percent of them were head of CSR, 52.5% were infection control nurse, and others were head nurse or supervisor of hospital. Of them, 62.5% never had been participated in the similar training program and so

there did not have any familiar with sterilization indicators.

Table 2: The knowledge of participations in seminar (before and after)

Subject	Before		After	
	True	False	True	False
The necessity of biological indicators using	57.5	42.5	70	30
The necessity of chemical indicators using	57.5	42.5	41.5	57.5
The best temperature for autoclave Machines	45	55	80	20
The necessity of autoclave machines calibration	55	45	67.5	32.5
The necessity dry heat machines calibrations	42.	57.5	65	35

After training program two educated person were sent to hospitals and gave 50 chemical indicators for use as a pilot with practical education on the using method of them. The results of 50 sample indicators in each hospital indicated the importance of Problem in sterilization processes because only one CSR units performance were correct. Meanwhile hospitals were encouraged to use of indicators by medical university managers.

The result of second time study in 2008 showed a markedly improvement in the control of sterilization processes. Furthermore, we continued our intervention results 6 month later in 2009 and 2 years later in 2011. The most striking result were use of chemical indicator in 100% of hospitals. However, there are defects in the use of biological indicators (63.65%).

Table 3 shows the performance of hospital groups in this subject.

Table 3: Use of indicators by hospital groups in 2011

	Tape – test	Chemical indicator	Biological indicators	Number of hospitals	% of hospitals
Educational hospitals	100	100	91	11	40
Private hospitals	100	100	20	5	22.72
Governmental hospitals (arm force, social security organization)	75	100	50	4	18.18
Charity and Azad university hospitals	100	100	50	2	9.09

According to Table 3, the use of biological indicators in non-educational hospitals, especially Private hospitals, is need to urgent attentions.

Discussion

The present study was designed to determine the effects of educational interventions in controlling of sterilization process with current indicators since 1997 to 2011. Steam sterilization processes are validating with indicators in many countries (18).

Our finding indicated that marked increases in the controlling of sterilization process with use of chemical and biological indicators in the past 15 years. We focus on improving the sterilization process throw to detect and learn from experiences are consistent with World Alliance for Patient Safety (1).

The proportion of hospitals which using chemical indicators reached 100% (all of Tabriz district

hospitals) whiles the using of biological indicators increased to 68%.

The important reason for these achievements is that continuity of efforts by researches and conducting practical training program. Because while we start the first survey in 1997, the almost hospitals were not familiar with necessity and instruction of the working with indicators so that they did not monitor autoclaves effectiveness routinely witch similar to a survey in UK in years of 2000 (19).

The surveys in other developing countries indicated noticeable deficiencies in the use of physical, chemical, and biological indicators. For example hospitals of FUJIAN province in China (n=70) have had seriously problems in sterilization (12). Furthermore, Autoclaves in private dental practice in Hong Kong were not cheeked routinely by indicators so that only 4% of them used biological and 62% used chemical indicators according with recommendations (7). In addition, in Brazil, use of

test strip was not routinely and use of biological indicators neglected in most dental medicine colleges (8). Unfortunately, Libyan hospitals rely on traditional process indicators such as tapes (11). All of these findings are consistent with our findings. In contrast to earlier findings of our study and mentioned evidences there are important and clear experiences in countries such as Thailand (4, 6) and Poland (9, 10) that both of them were improved infection control and sterilization manners in hospitals in the short time-trend. These results are completely consistent with our improvements. However, there are failures in the use of biological indicators. Because they are ideal monitors of sterilization process (20) and the results of all indicators (chemical, biological and physical), should be used to assure the effectiveness of the sterilization process (21). We didn't find any valid documents or formal reports about the rate of health-care-associated infections in Tabriz district hospitals in the years of this study. Hence, we cannot exactly claim that our intervention had decreased the rate of hospital infections. However there are a great deal of evidence and guideline in all of the world that emphasize the necessity of indicator use in the control of sterilization process in order the control of hospital infection controls. Finally, mandate of preventive maintenance practices on sterilizers and recording of gauges according recommendations seriously are recommending (22). In conclusion, health-care-associated infection is the most frequent result of unsafe patient care worldwide, but few data are available from the developing world. The most obvious finding of this time trend study was significant improvement in sterilization control especially in development the use of chemical indicators. The current findings of this study have a number of important implications for hospital managers and infection control practitioners such as continuous practical training of CSSD personnel in hospitals and mandating of indicator using in all sterilization process with controlling of this subject in evaluation and accreditation of hospital programs.

Ethical considerations

Ethical issues (Including plagiarism, Informed Consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc) have been completely observed by the authors.

Acknowledgments

This study was supported by a grant from National Public Health research Management Center (NPMC) of Tabriz University of Medical Sciences. The authors wish to thank Student Research Committee for their help and Dr. Nezami for editing of this manuscript. The authors declare that there is no conflict of interests.

References

1. Pittet D, Donaldson L (2006). Challenging the world: patient safety and health care-associated infection. *Int J Qual Health Care*, 18(1):4-8.
2. Allegranzi B, Bagheri Nejad S, Combescure C, Graafmans W, Attar H, Donaldson L, et al. (2011). Burden of endemic health-care-associated infection in developing countries: systematic review and meta-analysis. *Lancet*, 2011; 377: 228-41.
3. World Health Organization (2011). Report on the Burden of Endemic Health Care-Associated Infection Worldwide, World Health Organization Report.
4. Danchaiwijitr S, Rongrungruang Y, Pakaworawuth S, Jintanothaitavom D, Naksawas K (2005). Development of Quality Indicators of Nosocomial Infection Control. *J Med Assoc Thai*, 88(10): S75-82.
5. Springer R (2002). Sterilization/disinfection: correcting common misconceptions in the office setting. *Plast Surg Nurs*, 22(1):19-22.
6. Sangthong K, Soparat P, Moongtui W, Danchaiwijitr S (2005). Development of Quality Indicators for Sterilization Practices of the Central Sterile Supply Department. *J Med Assoc Thai*, 88 Suppl 10:S128-32.
7. Wai-Kwok A, Chi-Ming N (2007). Autoclave performance in private dental Practices in Hong Kong. *HongKongDental Journal*, 4:102-12.

8. Sasamoto SA, Tipple AF, Silva e Souza AC, Paiva EM, Paula e Souza C, Pimenta FC (2004). Evaluation of Central Supply Units in Public Dental Medicine Colleges in Brazil. *The Braz J Infect Dis*, 8(6):445-53.
9. Jakimiak B, Röhm-Rodowald E (1997). Evaluation of medical supplies sterilization at health care institutions in Poland. *Przegł Epidemiol*, 51(3):247-54.
10. Röhm-Rodowald E, Jakimiak B (2004). Assessment of the sterilization of medical devices--an important challenge to health care in Poland. *Przegł Epidemiol*, 58(3):501-10.
11. Abdulaziz Z, Mohamed E (2009). Steam sterilization: are we applying recent advances in control and validation process? *The Libyan Journal of Infectious Diseases*, 3(2):3-6.
12. Chen J, Zhan R (2009). Survey of the status of central sterile supply department in 70 hospital of FUJIAN province. *Chinese Journal of Disinfection*, 3:0-26.
13. Jabbari H, Bakhshian F, Mohammadpoor Asl (2007) A. The comparison of CSSDs section performance in Tabriz -Iran hospitals in 1997 and 2007. *Research Journal of Biological Science*, 2(7):740-742.
14. Jabbari H (1997). Surveys on performance of central supply sterilization departments (CSSD) in Tabriz -Iran hospitals [Ms thesis]. School of Health Administration. Tehran University of Medical Sciences, Iran; 1997. [In Persian]
15. Jabbari H, Bakhshian F, Mohammadpoor Asl A (2007). Effectiveness of training on performance of public and private gynecologic service providers in infection control in Tabriz-Iran. *Res J Biol Sci*, 2(7):736-739.
16. Jabbari H, Bakhshian F (2009). Preventing nosocomial infection transmission in gynecology and midwifery Service providers in Tabriz (experience of educational interventions). *Medical Sciences Journal of Islamic Azad University*, 18(4 (54)):259-264.
17. Bakhshian F, Jabbari H (2008). Function of family health workers of Comprehensive Network in preventing of infection in IUD volunteers. *Iranian Journal of Infectious Diseases and Tropical Medicine*, 13:31-35.
18. Van Doormalen J, Kopinga K (2008). Review of surface steam sterilization for validation purposes. *Am J Infect Control*, 36(2):86-92.
19. Coulter WA, Chew-Graham CA, Cheung SW, Burke FJ. Autoclave performance and operator knowledge of autoclave use in primary care: a survey of UK practices. *Journal of Hospital Infection* 2001; 48(3):180-185.
20. Kelkar U, Bal AM, Kulkarni S. Monitoring of steam sterilization process by biologic indicators- a necessary surveillance tool. *Am J Infect Control*. 2004 Dec;32(8):512-3.
21. Schneider PM, Reich RR, Kirckof SS, Foltz WG (2005). Performance of various steam sterilization indicators under optimum and sub-optimum exposure conditions. *Am J Infect Control*, 33(5 Suppl 2):55-67.
22. AORN Recommended Practices Committee (2006). Recommended practices sterilization in the perioperative practice setting. *AORN J*, 83(3):700-716.