

Health technology assessment: Off-site sterilization

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Abstract

Background: Every year millions of dollars are expended to equip and maintain the hospital sterilization centers, and our country is not an exception of this matter. According to this, it is important to use more effective technologies and methods in health system in order to reach more effectiveness and saving in costs. This study was conducted with the aim of evaluating the technology of regional sterilization centers.

Methods: This study was done in four steps. At the first step, safety and effectiveness of technology was studied via systematic study of evidence. The next step was done to evaluate the economical aspect of off-site sterilization technology using gathered data from systematic review of the texts which were related to the technology and costs of off-site and in-site hospital sterilization. Third step was conducted to collect experiences of using technology in some selected hospitals around the world. And in the last step different aspects of acceptance and use of this technology in Iran were evaluated.

Results: Review of the selected articles indicated that efficacy and effectiveness of this technology is Confirmed. The results also showed that using this method is not economical in Iran.

Conclusion: According to the revealed evidences and also cost analysis, due to shortage of necessary substructures and economical aspect, installing the off-site sterilization health technology in hospitals is not possible currently. But this method can be used to provide sterilization services for clinics and outpatients centers.

Keywords: Health technology assessment, Off-site sterilization, In-house sterilization.

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Introduction

Hospital infections have been always one of the most important problems of health centers. Due to increasing number of hospitals, the rise of new and emerging diseases, increasing microbial resistance and need

for various medical services, incidence of health care associated infections has become inevitable (1). In addition to death and complications, hospital infections increase the hospitalization period and consequently increase the cost of medical services and

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patients' dissatisfaction. Of course applying effective methods of sterilization will decline hospital infections and consequently the infections caused by it (2). In fact, sterilization means applying physical and chemical methods to destruction and disruption of all germs Endospore-resistant microbes (3).

Every year millions of dollars are expended to equip and maintain the hospital sterilization centers in the world. The hospital's Central Sterilization Room, which is called CSR, is placed in the vicinity of the operating rooms or near the surgical ward. This place is the center of preparation and distribution of sterilized medical and surgical supplies for the diagnosis, treatment and patient care (4).

Recently, hospital managers, in the process of hospitals' development and progress, have been faced with numerous challenges which are caused by advances in technology, converting the diseases' appearance, the growing demand for hospital services, and consequently increasing the cost of maintenance and equipping or reconstruction of the sterilizations centers. In response to these pressures, especially financial shortages and to reach high effectiveness, hospital managers are looking for new solutions and some changes to design and apply in their own sterilizations' services (5).

Sterilization of the medical instrument out of the hospital which is called in some scientific resources as off-site sterilization center or outsourcing the sterilization tasks is one of the methods which are applied in some hospitals to face above mentioned problems. There are so many discussions about applying this method such as: costs reduction, quality increase, and effectiveness of medical instrument sterilization. For the first time, off-site sterilization center was used in Glasgow, Scotland. In this way, a company, as an "off-site sterilizing company", is responsible to deliver sterilization services to several hospitals (6).

In 2012, in the wake of demographic change, technology growth and increasing

demand for surgical services, Ipswich hospital in England, reviewed its sterilization unit available options to deliver efficient sterilization services and access to the last quality standards. Off-site sterilization was one of the considered options (7). Also, in 2013, National Health Service (NHS) was reviewed the off-site sterilization method among other considered options. The examining factors in this survey were the initial investment, flexibility, Speed and continuity of sterilization services (8).

Recently, some Iranian hospitals are faced with proposals by domestic and foreign companies about construction of off-site sterilization center focusing on the reasons of workload and costs reduction and increasing the sterilization quality. Consequently, some questions have been raised for officials. These questions are about efficacy, efficacy costs and possibility of applying this method for instrument sterilization in the service provider centers in Iran. Health technology assessment is a technique which can help to answer the raised questions about off-site sterilization centers and to provide scientific evidence based on evidences related to this technology for policy maker to decision making. In this study of health technology assessment, researchers tried to compare new off-site sterilization technology with the common in-house sterilization method.

Methods

This study was done in four steps. At the first step, consequences of using off-site sterilization centers was identified via systematic study of evidence, and in the next step by combining the information provided by systematic review of literature and local data, economic evaluation was done via costs minimization approach. In the third step the experiences of using off-site sterilization methods in some selected hospitals in the world were gathered and in the fourth step possibility of using off-site sterilization technology in Iran was surveyed via interviews with experts.

Systematic review of research question

What consequences have been off-site sterilization centers in terms of efficacy, effectiveness and costs for the hospitals applying this technology?

Data Sources and Search Strategy

We searched for relevant English language articles, based on keywords in title, abstract and MeSH terms. We performed searches (in June 2015) of the literature indexed in PubMed, Scopus and Science Direct using a broad set of terms to maximize sensitivity. We also searched the Cochrane library as the most important systematic reviews database, and the Google Scholar for other unpublished literatures; Searching was supplemented by scanning bibliographies from identified articles; and mined hand-searching personal libraries by project staff and experts. We asked experts to identify unpublished literature. The following search strategies were used in PubMed:

Search Strategy (PubMed):

1. "outsourcing of sterile services"
2. "outsourcing of sterile"
3. "off-site sterilization"
4. "Decentralized sterile services"
5. (1 or 2 or 3 or 4)
6. "cost effectiveness"
7. "Efficacy"
8. (6 or 7)
9. (5 AND 8)

Inclusion and exclusion criteria for studies

Inclusion criteria included of studies conducted about consequences of using off-site sterilization compared with in-house sterilization and also studies in English. The exclusion criteria were studies conducted about other sterilizations methods, the function of sterilization devices, and improving ways for sterilization methods.

Selection of studies

At first, the specifications of articles and reports which were gathered from data

banks and other resources were entered into the Endnote software. Then using the software, the duplicate cases were deleted and in the next step two people of research team individually reviewed the topics and abstracts of the articles and deleted irrelevant cases. Then researchers studied the articles completely and carefully and selected the relevant articles and deleted the irrelevant ones.

Assessing the information quality and extraction and analysis of information

A checklist includes of 6 questions was prepared in order to select the articles. The questions were about the exact definition of research aim, exact definition of variables studied, the exact definition of research time and place, selecting a prepare method to analyze data, appropriateness of data collection and analysis tools with the research aim and reliability of data collection tool. Each of the criteria was categorized as clearly yes or clearly no. The articles quality was examined via complete review over them. Since we didn't aim to perform Meta-analysis of evidences, to reduce the risk of subjective quality judgment, we decided not to exclude nor weigh studies based on quality rating or scales. "While study quality assessment is important to judge the effectiveness, the usefulness of excluding studies based on quality has been contested" (9). We used the results of quality assessment to identify potential gaps in the evidence on the off-site sterilization technology and analyzed their results descriptively.

Every article's data were extracted based on article's topic, the first author, year of conducting the research, research method and consequences of using off-site sterilization method and in-house sterilization. Analyzing the results of the study was done in the form of quantitative summarizing of data in terms of efficacy and effectiveness variables.

Economic evaluation

Cost minimization analysis (CMA) was

used in order to economic evaluation of off-site sterilization technology. The CMA is used in case of the same outcomes and results of applying different services and technologies in a field. In simple terms, the aim of CMA is to find technology and services which have the same quality and consequences but impose fewer costs to the service delivery system (10,11). From health care system perspective costs include of personnel costs, special and general consumable costs, equipment costs, power costs, capital cost and amortization cost separated according to the cost centers during a year (12).

To calculate CMA, first of all, the cost of CSR was extracted from a study which was done in the Flushing hospital of New York, in 1990 (6). After applying a discount rate of 5%, the cost of CSR changed to current value. Counting 34600 Rials for every dollar, the annual cost of off-site sterilization method was found. After that, with considering 4500 sterile bags for every year, the cost of every sterile bag was calculated. In-house sterilization cost was extracted from a study which was done in 2007 in Iran, and its current value was calculated with discount rate of 5%. Then, with considering 20605 sterile bags for every year, the cost of every sterile bag was calculated.

Qualitative method

A qualitative case-study approach was used to explore understand cons and pros of off-site sterilization technology from the experts' point of view and frontline healthcare professionals under public settings. A case study is a research methodology that focuses on the circumstances, dynamics and complexity of a single case or small number of cases (13). Semi-structured interviews were used for qualitative data generating.

Identification of experts

The inclusion criteria were: being a hospital manager or sterilisation ward supervisor for at least 5 years in public hospitals or being a Health Technology Assessment ex-

pert. Participants with expertise in Health Technology Assessment, Health Services Management and Health Economics were identified through contact with Standardization and Tariff Management in Deputy of curative affairs of Ministry of Health. Hospital managers and sterilisation ward supervisors were identified in public hospitals and recruitment continued through snowball sampling. All identified informants accepted to participant in the study.

Totally 14 interviews were conducted with informants; 5 interviews with health economics and Health Technology Assessment experts and 9 interviews with hospital managers and supervisors and the interviews continued until the point of saturation, in which no new relevant data seemed to emerge. Eligible participants were approached for written consent and there were no concerns related to authority relationship between interviewer and interviewee.

Semi-structured interview Guide

A guided set of open-ended questions was developed based on literature review and expert opinion. The questions have been covered the following: (i) current hospital sterilization system, (ii) their knowledge about off-site sterilization technology, (iii) cons and pros of off-site sterilization technology in Iran.

Data Collection Procedure

The semi-structured group interviews were conducted at the interviewee's work place. Each interview took approximately 30-40 minutes, and the proceedings were audio-recorded with the interviewee's consent. Interviews were transcribed and subsequently sent back to participants for verification.

Data Analysis

A framework analytical approach, which is appropriate for health policymaking studies (14), was used for data analysis. Initial analysis was conducted by NM and SG using Framework Analysis independently

(15) supported by the Atlas.ti 6 Software package. These initial concepts were reviewed and revised by the chief investigator (RD) and subsequently applied to the remaining transcripts. Interview transcripts from informants were read and re-read and multiple emerging themes and subthemes framework were designed by the researchers and each interview transcript was coded using this framework (16).

Ethical Approval

The purpose of the present study was explained for all interviewees and written informed consents were taken. All discussions were recorded as anonymous and kept confidential.

Results

Systematic review

Totally 287 studies were found in the systematic review. After excluding irrelevant topics and repeated ones, 19 relevant studies were found and surveyed in detail for further evaluation. 7 out of 19 studies were removed due to lack of abstract or complete texts and also 7 other studies were removed because they didn't have the entrance criteria (including 3 studies in languages other than English, two studies about various off-site sterilization methods, and two studies in calculating the cost of in-house sterilization method.). Finally only 5 studies were found completely relevant to the aims of the study (6,7,8,17,18) (Table 1). All of 5 selected studies were in accordance with the 6 quality assessment criteria proposed by research team. Figure 1 presents the re-

sults of the search and review strategy for Systematic Reviews flow diagram.

Because of the long-time differences between studies, their results were so different. Only one study was done in 1988, which has been compared off-site and in-house sterilization methods in terms of efficacy and effectiveness. The authors has mentioned that after three years, using this technology has been ceased because of some management concerns including not suitable weather conditions such as storms and delay in delivering equipment to the hospital (6).

Two studies in 2012 and 2013 compared the available options to do sterilization services in terms of costs and benefits. The results has shown that total cost of off-site sterilization was more than other options and in other hand had the minimum score (7,8) while the results of two older studies done in 1988 and 1990 have showed that off-site sterilization method results in cost saving and is a suitable option to do sterilization services (6,17). Some positive and negative consequences of off-site sterilization method compared with in-house sterilization method which were extracted from each study were expressed in two variables of efficacy and effectiveness (6-8,17,18) (Table 2).

Two main criteria to compare these two technologies are efficacy and effectiveness. Effectiveness of the technology means the technology's ability to convert infected tools and equipment into sterile, safe and secure ones. Review of the results of studies shows that the possibility of providing

Table 1. Features of the studies included in systematic review

Reference	Study Title	First author	Year of publication	Kind of study
6	Off-Site Instrument Sterilizing: A New Concept	Dorsey R	1988	Case study
12	In-house versus off-site sterilization.	Giarraputo D	1990	Costing
13	A two-phased approach for the centralization versus decentralization of the hospital sterili- zation service department	Tlahig H	2009	Modeling
7	Compliant Sterilization Services Department (SSD)	Business Development Planning	2012	Economical assessment record
8	Sterile Services Department Option Appraisal.	Grimwood J	2013	Sectional report

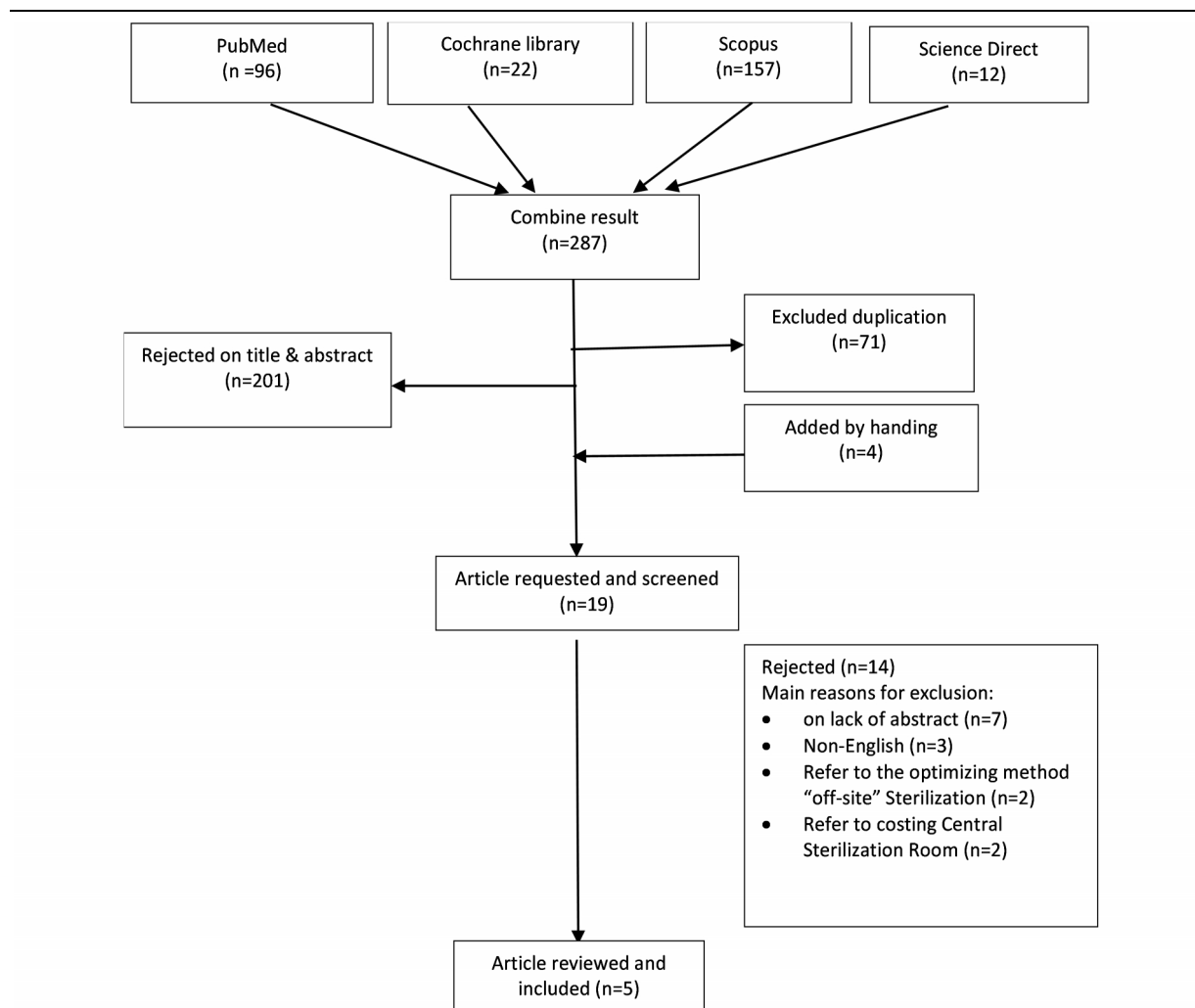


Fig. 1. Selection process of included studies in the systematic review

safe and sterile tools in both methods is the same. Efficacy means doing sterilization services with a minimum of resources and in the minimum time.

In the other hand negative and positive

mentioned consequences of off-site sterilization such as more total cost, less need for staff training, more possibility of delay in delivering equipment to the surgery room in critical conditions, more need for in-

Table 2. Off-site and in-house sterilization consequences in terms of efficacy and effectiveness criteria

Study Title	Efficacy Criteria	Options	Effectiveness Criteria
off-Site Instrument Sterilizing: A New Concept (1988)	possibility of delay in delivering equipment to the surgery room in critical conditions need to the personnel in the hospital	Off-site S In-house S	Same in Both
In-house versus off-site sterilization. Hospital Material Management Quarterly (1990)	Save in hospital costs	Off-site S	
A two-phased approach for the centralization versus decentralization of the hospital sterilization service department (2009)	Save in hospital costs	Off-site S	
The Ipswich Hospital Compliant Sterilization Services Department (SSD) (2012)	Administrative and control problems Final cost	Off-site S	
Sterile Services Department Option Appraisal. West Suffolk NHS Foundation Trust (2013)	need for staff training need for investment	In-house S Off-site S	

vestment, less need for personnel in the hospital and saving in fuel and supporting costs of hospital, all are considered as effective factors in the hospital efficacy.

Economic evaluation

In order to calculate CMA, first of all total cost of CSR was extracted from the study which was done in Flushing hospital of New York in 1990. Then considering discount rate of 5%, the total cost of CSR converted to the current value of 47137384 dollars. Considering the dollar rate of 34600, annual cost of off-site sterilization method was calculated equal to 16309 million Rials and considering 4500 sterile bags in every year, the cost of each sterile bag was calculated equal to 362434. In-house sterilization cost was extracted equal to 461 million Rials from a study which was done in Iran in 2007, and with discount rate of 5% converted to current value of 682 million Rials and considering 20605 sterile bags for every year, the sterilization cost for each bag were calculated equal to 33116. Finally, it can be mentioned that for each sterile bag, new technology (off-site sterilization) imposes 329318 Rials more than the other method.

The experience of using Off-site Sterilisation technology in selected hospitals

After sending emails to the approved hospitals and receiving emails, analysing some of the received emails showed that using these methods is not common in these hospitals. But some hospitals such as Mediclinic hospital in Dubai (Emirates) have limited use of this method in order to support the city's clinics by the sterilization unit which is near the hospital.

Possibility of using Off-site Sterilisation technology from interviewee's point of view

After analysing the experts' interviews, effective factors for possibility of using each sterilization technology were clustered in 3 main themes: hospital related factors, employer related factors, and contractor related factors.

A: The scope of hospital related factors

In this scope interviewers pointed to some cases which directly affect the bargaining power of hospital such as the extent of hospital, possibility of coordinated action between the region hospitals, the number of hospital in the city, available resource and equipment in the hospital, the extent of hospital's budget flexibility to provide the contractor's costs and the situation of technically competent human resources in the hospital. One of the hospital managers mentioned:

"Given the fact that in off-site technology hospitals will lose all of their sterilization's equipment and skilled staffs, hospitals will be at a disadvantage because they couldn't bargain with contractors over the forms of contracts or its price, but will be faced with a "take-it-or-leave-it" choice."

They also mentioned economic aspects of the technology, for example a health economic expert stated that:

"Nowadays our hospitals have significant investment to equip their central sterilization units and ceasing them and outsourcing sterilization services to out of hospital contractors is not economical."

B: The scope of employer related factors

In this scope some factors such as technical competence and the managers' point of view about the outsourcing strategy were focused. Manager should have necessary knowledge, experience, competence and ability for outsourcing the sterilization services and could find the appropriate providers. From interviewer's view, management changes, some managers' weaknesses to find the program deviation and hospital services sensitivity in unexpected disasters all points out the difficulty of outsourcing sensitive services such as sterilization. Here is one of the comments:

"Another reason is that there are lots of activities in the hospitals and hospital managers have to find shortest path for critical process like sterilisation. Furthermore, most of them don't have skills and Knowledge for outsourced services quality control."

C: The scope of contractor related factors

In this scope the view and the satisfaction's extent of clinical teams with the contractors' performance, mutual trust, and the existence of valid institute with technical knowledge were the main considered subjects by the interviewers. In the case of identifying unacceptable performance for the off-site sterilization centres by the hospital's clinical team, it is not possible to have an appropriate working relationship. Need for too much investment and the importance of security for the investors were other concerns mentioned by the experts. Sometime medical science universities cannot participate in such an investment and there is a need for intersectional investment that it is not possible at least in small towns. One participant commented the following:

"The problem is that we cannot rely on these contractors, they may suddenly stop cooperating with hospital or ask for more money."

Discussion

The subject of outsourcing hospital services has been under consideration of many managers and policymakers. Sometimes successful experiences in order to increase efficacy and effectiveness of services, and consequently increasing the customers' satisfaction with the quality of hospital services have recorded (19-21). In this study off-site sterilization technology, that recently some contractor companies in Iran have made widespread propaganda about its benefits and it has used in some hospitals of other countries, was evaluated. At the first chapter of research's findings, efficacy and effectiveness of this technology were analysed in comparison with central in-house sterilization technology via assessing the result of systematic review of evidence. Findings of economical assessment were presented in the second chapter by the minimization of costs method. In the third chapter, the qualitative views of experts, about possibility of applying this technology in Iran, were analysed.

The systematic review of the available evidences revealed that limited studies about off-site sterilization method have been published. The evidence of effectiveness, cost of effectiveness and effects of this method on equipment's sterilization process and also its final consequences are so limited and sometimes they are in contrast with each other and also have been changed during the time.

Analysing the result of selected articles revealed that typically older articles have been reported more efficacy, affectivity and economical saving for off-site sterilization method (6). In contrast newer articles have showed opposite results. While effectiveness, which means providing safe and sterile equipment, is reported the same in both methods, efficacy criteria such as capital and current costs, time and access are mainly reported in favour of in-house sterilization method (7, 8,18).

In health technology studies which are done on the group of management or supportive technologies, the result are significantly affected by social, cultural and organizational conditions (22,23). In this study, according to the experts' point of view, the possibility of applying off-site sterilization method is different in various conditions whereas it is only possible to apply off-site sterilization technology in big cities that have many hospitals and it is more possible to change the contractor. In small cities hospitals cannot rely on contractors in order to providing sterile equipment and tools. If this technology is approved as an applicable technology in Iran, it is necessary to identify which cities can apply it and new hospitals which are going to be established in these cities should equip with the assumption of applying off-site sterilization method.

Reducing hospital costs, access to the new sterilization technology, time saving, the possibility of employing professional staff and providing continues training for them are some cases the mentioned about the benefits of using off-site sterilization method. In this regard, managers and uni-

versity experts should propound the standards, procedures and policies that the contractor should perform and provide mechanism to enforce them (24,25,26).

There are also some limitations on outsourcing the hospital services. For example, contractors may not be able to understand the organization's culture and the hospital's conditions (27). Always there is a risk of contractors' entrance to the market as the organization's competitor (28). Some studies have reported that delivering vital services out of the hospitals reduces the hospital's ability to meet urgent needs in times of crisis. If the contractor does not adhere to its obligations on the quantity and quality of services, due to the specialized nature of services and need for considerable investment, changing the contractor will be really difficult for the hospitals (29). So, monopoly on the important issue of providing hospital sterile equipment of a city in the hands of a company can be a serious threat (30).

Limitations

This review revealed severe shortage in the published studies to assess off-site sterilization technology. The main methodological weaknesses identified in these studies were the use of largely invalidated instruments to assess off-site sterilization technology efficacy and effectiveness, and lack of details regarding the data analysis methods.

Another limitation for this study was that there were no study regarding off-site sterilization technology in Iran, therefore, some participants had not heard anything about this technology. To reduce the effect of this limitation, we had to explain off-site sterilization technology characteristics to them. Since most of health technology assessment studies carried out before rising a new technology, many experts do not have much experience of the performance of the technology (31-34).

Moreover, although we performed a wide search of the literature to identify studies which estimates cost of sterilization in Iran's public hospitals, we couldn't find

any related study to compare our results with other studies results.

Nonetheless, emerged themes show consistencies in the health managers and health technology assessment and health economic expert opinions about main pros and cons of off-site sterilization technology in Iranian public hospitals.

Conclusion

Analysing the results of this study suggests that considering the investments made in the sterilization wards of Iranian hospitals and shortage of necessary infrastructures for hospitals, nowadays, delivering off-site sterilization services is not economically possible. It is obvious that after entrance of newer technologies and equipment to reduce the sterilization costs, facilitation of transporting the sterile equipment to the hospitals, appropriate training for the staff, and foundation of sterilization major in medical science universities in the future, off-site sterilization method can be revised. However, off-site sterilization method is acceptable for clinics and outpatient centres.

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