Journal of Infection and Public Health 10 (2017) 685–687

Contents lists available at ScienceDirect

Journal of Infection and Public Health

journal homepage: http://www.elsevier.com/locate/jiph

The importance of paper records and their preservation period in a Central Sterile Supply Department: An experience from a oncology center in eastern India

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ARTICLE INFO

Article history:
Received 10 June 2016
Received in revised form 3 October 2016
Accepted 11 October 2016

Keywords:
Purpose of recordkeeping
Functions of CSSD
Types of CSSD records
Preservation period
Consequence of unnecessary documentation

ABSTRACT

Everywhere recordkeeping is very essential for future need. This may be required for any audit purposes, legal issues and forgetting any incident. Record keeping is a specialized area in every hospital that is handled by specialized medical records officer for proper management of all important documents for long time preservation purposes.

In this article there are various important healthcare sterilization related paper records have been discussed for documentation and preservation purposes. Though several articles on 'retention of medical records' have already been published worldwide but exclusively sterilization related records and their cause of preservation have not been discussed as such.

The purpose of the article is to highlight only the essential CSSD paper records and their preservation policy so that this certainly guides to every CSSD in-charge and hospital authority for making a standard guideline of retaining sterilization records in their institution.

Introduction

Universally, recordkeeping is an essential component for a variety of purposes, such as audits, legal issues and for preservation purposes also. But maintaining the huge number of records within a medical institution, in a proper manner is a fairly challenging exercise where human lives are involved.

Recordkeeping system can be carried out either as paper-based (manual) or computerized. Presently computerized documentation is more effective than paper based system for long-term preservation purposes. This is also better for easy recovery or access to any records, limited workspace or manpower and relatively saves on a variety of costs. But some documents may need to store in paper format, especially where authorization is required [1,5,9].

In this article there are important healthcare sterilization related papers records have been discussed for documentation and preservation purposes. Though several articles on preservation of medical records have already been published worldwide but specifically sterilization related medical records and their cause of preservation has not been discussed as such.

Record keeping in a Central Sterile Supply Department is essential for patient safety, future documentation, as well as infection control purposes. Though CSSD is not directly involved in patient services but they also maintain various important documents connected with the process of sterilizing items. Good quality sterilization practices can reduce the rate of infection and therefore decrease the infection risks to patients, which in turn helps patients both physically and financially. Besides, in case of an incident, the incriminating items can be easily traced out. Moreover nowadays controlling the rate of infection is really very challenging and such sterilization records helps to the hospital authority to avoid any future implications related to sterilization.

Role of Central Sterile Supply Department in infection control

The central sterile supply department (CSSD) plays a critical role in ensuring that costly medical devices are sterilized and delivered to various users in the hospital in a quality-assured environment.

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http://dx.doi.org/10.1016/j.jiph.2016.10.004

The physical infrastructure of the CSSD consists of several separate work areas, including decontamination room, packaging room, linen preparation room, and sterile storage area. The workflow in the CSSD is unidirectional, and materials to be sterilized move from dirty area (decontamination room) to semi-clean area (preparation zone) to clean area (sterile storage) after proper disinfection and sterilization process.

The equipments that are essential in CSSD includes automated washer disinfector, ultrasonic cleaner, air and water jet spray guns, thermal drying cabinet, rotary sealing machine, steam sterilizers, ethylene oxide (ETO) sterilizer and plasma sterilizer [4].

There are various types of instruments that have been disinfected and sterilized by these equipments are surgical instruments, laparoscopic and robotic instruments for minimal invasive procedures, powered instruments, gastrological instruments like endoscopes, bronchoscopes and hysteroscopy and such other instruments that are used in radio-diagnostic purposes. Moreover laundered linens and dressing materials are also products that the CSSD sterilizes.

The consumables are specially used in CSSD such as; various chemical solutions for cleaning and disinfection of medical instruments, packaging materials for wrapping the medical devices prior to sterilization and various kinds of indicators for ensuring the sterilization efficacy of a sterilizer. Moreover some office items like registers, printing papers, pens, markers are also used as consumable in daily basis [7,8].

Therefore, when good quality sterilization practices are performed there should be maintained some evidence based record keeping system that ensures sterility of medical devices and also redress the legal issues in future [5].

Recordkeeping in Central Sterile Supply Department

In our 180 bed oncology center in eastern India we are maintaining several CSSD records for documentation purposes. But on the basis of priority, only seven varieties of records (e.g.: sterilizer log book, washer and sterilizer printout, dispatch register, records of Biological indicator and Bowie-Dick test records) have been retained in the CSSD for first 6 months and then they are sent to the medical records department (MRD) for a further retention period of 3 years (Table 1). The rest of the records (e.g.: recall file, seal test report, seropositive records, loan instrument file, various audit report) from CSSD are destroyed directly over a period of time as per hospital record retention policy, because keeping redundant files is an extra cost and loss of space for management [1,2,10].

Though records like procedure manual has never been destroyed to any extent and need to be upgraded as or when required.

Reason behind retaining all sterilizer registers in CSSD for 6 months is because;

i) In our hospital shelf life (expiry) of a sterilized items are maintained for 6 months on the basis of frequent sterility testing in microbiology. For the reason this has been observed that within six months period of time almost all reusable medical devices are used for patient services and very few expired materials are returned to CSSD for re-sterilization purposes. So, after six months this assures that previous sterilization related issues like; wet pack, improperly expose of internal chemical indicators and instruments misplaced are outdated (expired) and therefore no chance of claiming from internal customer (ex: doctor, staff nurse) [3].
ii) As per infection control audit report maximum surgical site infections (SSI records preserve for six months to one year) recur within this period of time and if any claim registered, then CSSD

Table 1
Name of important sterilization related paper records and their specialization areas (preserved for 3 years in MRD).

Sl. No.	Name of different files	Specialty areas
1	Bowie-Dick test file with batch label system	Empty sterilizer chamber air removal test prior to medical device sterilization
2	Biological indicator file (Steam/EO/Plasma)	Check the integrity of sterilizer by sporocidal effect
3	Sterilizer cycle print out (Steam/EO/Plasma)	Physical parameter that calibrate sterilizer in every minute interval
4	Washer disinfector cycle record	To monitor the disinfection system properly prior to sterilization
5	Sterilizer register (Stem/EO/Plasma) (Including implantable materials)	Records of all pre-sterilized materials including loaner instruments (Implants cannot be sterilized by plasma processes)
6	Sterile product dispatch register	Sterile materials issued with evidence for traceability
7	Equipment preventive maintenance by 3rd party and calibration report	Approval and validation of sterilizers as per international standard

can show their supportive documents immediately according to need or demand [3].

iii) For surgery related to prosthetic implants or loaner instruments, these sterilization records are important even after a prolonged period from date of surgery where the chances of infection can be aggravated [2,10].

iv) Sometimes special care or treatment of instruments is required for decontaminating the instruments which are seropositive or infected with any organisms like HBV, HCV, HIV, Creutzfeldt–Jakob disease (CJD), Mycobacterium. For CJD, special cleaning and disinfection program (prion cycle) is required in washer disinfector and specially equipped sterilization time (holding time 18 min in pre-vacuum sterilizer) is required for sterilization purposes as per standard. The record is essential for CSSD personnel who clean and disinfect such surgical instruments (to track incident like sharp injury) and the following patient for next surgery [6].

Reason behind preserving the most valued CSSD records in MRD for 3 years is because;

i) In case of highly poisonous gas used as a sterilizing agent in ethylene oxide sterilizer there may be required some specific documentation like sterilization time, aeration time, report of Biological indicator results because such toxicity may be recurred after long days of procedure specially for children due to sensitivity [1].

ii) During audit, auditor wants to verify the previous sterilization records (log book) for justification. The main scrutiny areas are daily or yearly equipment validation or calibration report, preventive maintenance report, sterilizer registers for load configuration, specific procedure (surgery) to sterilization ratio [9].

Finally all out dated (discarded) records have to be signed by respective personnel and then records have to be incinerated to destroy completely.

Conclusion

Record keeping is a legal responsibility for every institution and should be maintained in a proper manner. An ideal record keeping should be correct, complete and consistent with date and signature, so that it meets customer satisfaction effectively. This should be approved by hospital authority or any national regulatory body.

But unnecessary recordkeeping can make an awful impact on work practices and also consumes time and cost.

So, a well defined recordkeeping can make it easy to understand what quality work practices have been performed on a daily basis with their quality of manpower that are associated with this work.

Conflict of interest

None.

Financial support

None.

Acknowledgement

None.

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