



## Study on criterion of continuous quality improvement management of loaner instrumentation and implants in central sterile supply department

Chunyan Chen<sup>1</sup>, Lian Zhang<sup>2\*</sup>, Xiuyue Zeng<sup>3</sup>, Haohui Yu<sup>4</sup>, Huantian Zhang<sup>5</sup>

The First Affiliated Hospital of Jinan University, Jinan University College, Guangzhou, China

### Abstract

**Objective:** To investigate the influence of continuous quality improvement on Criterion of management of loaner instrument and implants in central sterile supply department.

**Methods:** By optimizing the processing flow of loaner instrument and implants, the first data after optimizing the advance release rate and the eligibility rate of disassembly of instruments were compared with those after optimizing year by year. In order to implement the management of cleaning and disinfection of loaner instrument and implants and the first sterilization verification, the accuracy rate of knee joint surface replacement kits was compared before and after implementation.

**Results:** After continuous quality improvement persistently, the first data after optimizing the early release rate, instrument disassembly and the accuracy rate of knee joint surface replacement kits were increase/decrease significantly ( $P < 0.05$ ). After operation, the cleaning and disinfection management and first sterilization effect verification achieved expected efficiency.

**Conclusion:** The application of continuous quality improvement in the management of loaner instrument and implants has achieved satisfactory results and improved the management level of loaner instrument and implants.

**Keywords:** criterion management, loaner instrument and implants, continuous quality improvement

### 1. Introduction

Loaner instrument to the devices were leased by the equipment supplier to the hospital for reusing, mainly for implant-related surgery. Implants refer to implantable medical devices were placed in the body cavity caused by surgical operation or in physiological presence for 30 days or more <sup>[1]</sup>. Loaner instrument and implants had the characteristics of strong application pertinence, complex varieties, high price, rapid update, high frequency of use and frequent flow between hospitals. Thus, there was a potential risk of infection. In order to reduce the risk of infection caused by loaner instrument and implants, the Standard of Hospital Central Sterile Supply Department (WS 310-2016) emphasized the importance of strengthening the management of loaner instrument and implants <sup>[2]</sup>. The Central Sterile Supply Department (hereinafter referred to as CSSD) of our hospital got remarkable achievement in continuous quality improvement management of loaner instrument and implants from 2014 to 2018. The report is as follows.

### 2. Materials and Methods

#### 2.1 General data

General data were retrospectively analyzed for the continuous quality improvement of CSSD loaner instrument and implants in our hospital from 2014 to 2018. To compare and study the results of advance release, precise package matching, post-operative cleaning and disinfection management and first sterilization effect verification of loaner instrument and implants in continuous quality improvement management were evaluated disassembly.

#### 2.2 Methods

After optimizing the process of loaner instrument and

implants, the first data after optimizing the release rate and dismantling eligibility rate of loaner instrument were compared with those after optimizing year by year. The accuracy rate of knee joint surface replacement kits was compared before and after implementation; Implementing the management of cleaning and disinfection of loaner instrument and implants and first sterilization verification after operation, the details are as follows.

#### 2.2.1 Reduce the advance release rate of loaner instrument and implants

To reduce the advance release rate of loaner instrument and implants, the nursing improvement project of CSSD in our hospital in 2014. By collecting the data of advance release of loaner instrument and implants from May to July of 2014 for "Reducing the advance release rate of loaner instrument and implants", and analyzed the reasons and formulated countermeasures. After the implementation of the countermeasures, the data of advance release from August to October of 2014 were counted, and the results were compared before and after the improvement. It was concluded that the advance release rate decreased from 31.82% to 8.78% after improvement. Moreover, the hospital had established a standardized management system, clarified the responsibilities of various departments, standardized the definition of emergency surgery, determined the time of release implants to CSSD, and established the process of receiving, cleaning, disinfection, inspection, packaging, sterilization and distribution of loaner instrument and implants. Since 2014, a spare kit for external medical devices has been established for upper limb and lower limb trauma surgery to prepare for emergency operation. Since 2015, there have been spare kits for loaner instrument such as spine and joint replacement

surgery, which reduces the advance release rate of loaner instrument and implants for external medical devices year by year.

**2.2.2 Improve the qualified rate of cleaning loaner instrument**

Many effective methods were used to improve the eligibility rate of dismantling loaner instrument in our hospital CSSD 2017 for standardized management of dismantling loaner instrument, by inviting suppliers to train the methods of dismantling and cleaning, establishing dismantling manual, using unified list template, standardizing the handover of loaner instrument and cleaning pretreatment, implementing dismantling and cleaning quality inspection, etc. Cleaning quality management.

**2.2.3 Improve the accuracy of knee joint surface replacement kit of loaner instruments**

From July to December 2018, CSSD were used in our hospital to control circle management quality and to improve the accuracy of knee joint surface replacement kit. This paper reviewed and analyzed the management problems of knee joint surface replacement loaner instrument in CSSD from January to June 2018. The improvement schemes were as follows: training and evaluating CSSD personnel to identify knee joint surface replacement loaner instrument, and making loaner instrument atlas as work guidelines; standardizing the way doctors inform loaner instrument manufacturers of operation information; Standard instrument vendors strictly allocate packages according to the operation notification, and distributing the standard instruments in left, right knee and both knees. After the implementation of the scheme, the accuracy of loaner instrument configuration for knee joint surface replacement was improved, resulting in higher work efficiency of operation room, CSSD and orthopedic surgeon.

**2.2.4 Standardize the management of cleaning and disinfection in loaner instruments after operation**

CSSD of our hospital began to implement the cleaning and disinfection management of loaner instrument after operation in the second half of 2017. Up to now, it has fully implemented the cleaning and disinfection of loaner instrument after operation and returned them according to the requirements of WS 310.1-2016, so that they can be cleaned and disinfected in time, and the chance of biofilm formation will be lowest [3]. Firstly, CSSD appointed people to manage loaner instrument, responsible for cleaning, disinfection and return of loaner instrument after operation. Secondly, the operating room should ensure that there was no obvious residual blood, tissue, bone debris, etc. of loaner instrument after operation, and no one-time medical residues, and filled in the handover contents of the devices, and the devices were loaded and transported to CSSD in closed condition. CSSD personnel clean and disinfect the

instruments according to the instrument handover order, and record relevant information. After the instrument was cleaned and disinfected, it was placed at a designated place. Finally, the instrument manufacturer took the instrument according to the handover list and signed the instrument on the record sheet for CSSD archive inquiry.

**2.2.5 Implementing First Sterilization Verification**

According to the requirement of WS 310.3-2016 4.4.1.8, CSSD of our hospital carried out the first sterilization validity test for loaner instrument and implants in the second half of 2017 [1]. It is confirmed that the first reception of loaner instrument and implants has been put on record in the hospital and should be delivered to CSSD 24 hours before use [2]. According to the manufacturer's instructions, evaluate whether CSSD possesses the conditions and abilities of cleaning, disinfecting and sterilizing this set of instruments, and formulate the test plan [3]. Cleaning and disinfection, sterilization methods, sterilization parameters and monitoring of sterilization effect were selected according to the instructions; validity test of sterilization parameters and wet package inspection were carried out to confirm the results. The standard of wet package inspection and judgment refers to GB 8599 dryness test: after sterilization, the weight load of metal instrument package does not exceed 0.2% before sterilization. Sterilization effect monitoring procedures were implemented in accordance with WS 310.3-2016 requirements and equipment manufacturer's instructions. Confirm that physical, chemical and biological monitoring was qualified [4]. Record the qualified test parameters and file the instructions of loaner instrument and implants as the routine treatment of the loaner instrument and implants [5]. According to the need of operation, it can be used only after the physical, chemical and biological monitoring was confirmed to be qualified.

**2.3 Statistical analysis**

SPSS 19.0 software was used for statistical analysis. Among them, t-test or variance analysis were used to compare the measurement data, and X<sup>2</sup>-test or Fisher's exact probability method was used to compare the counting data. P < 0.05 showed significant difference.

**3. Results**

**3.1 Advance release of loaned instruments and implants**

The continuous quality improvement management after the implementation of the project "Reducing the advance release rate of loaner instrument and implants" had reduced the advance release rate of surgical implants for loaner instrument year by year. There was a significant difference in the advance release rate of loaner instrument and implants between the years (X<sup>2</sup>= 99.997, P = 0.000), indicating the effectiveness of continuous improvement measures. (Table 1).

**Table 1:** Advance release of loaned instruments and implants in 2015-2018

Particular year	Total number of cases	Advance release number	Advance release rate (%)	X <sup>2</sup>	P
2015	1360	27	1.99%	99.997	0.000
2016	1584	1	0.06%		
2017	2294	2	0.09%		
2018	2604	4	0.15%		

### 3.2 Disassembles Loaner Instruments

After implementing the standard management of disassembles and cleaning of loaned instruments, the eligible rate of disassembles increased from 95.94% after project improvement to 98.72% after continuous

improvement in 2018. The eligible rate of disassembles of continuously improved loaned instruments was significantly different ( $X^2=96.156$ ,  $P=0.000$ ), indicating that the continuous improvement measures were effective (Table 2).

**Table 2:** Comparisons of Qualified Implementation of Standardizing Disassembles Management of Loaner Instruments

Time	Total number of disassembles items	Number of disassembles	Eligible rate of disassembles	$X^2$	$P$
Oct-Dec 2017	2511	2409	95.94%	96.156	0.000
Jan-Dec 2018	13189	13020	98.72%		

### 3.3 Accuracy of loaner instruments allocation for knee joint surface replacement

Quality control circle management was used to improve the accuracy of loaner instruments allocation for knee joint surface replacement from 10.42% to 96.72% after implementation, which is 86.30% higher than that pre-implementation. There was a significant difference in the accuracy of loaner instrument allocation after continuous

improvement ( $X^2=112.781$ ,  $P=0.000$ ), indicating that continuous improvement measures were effective. Under the cooperation of many parties, the equipment vendors were equipped with spare bags, and the supply of emergency surgical instruments is guaranteed, so as to better guarantee the safety of patients (Table 3).

instruments was 12 minutes per case. The 500L cleaner saves 1/3 of the cleaning machine space before and after operation, and the 0.8 L sterilizer saved 1/6 of the space. It was shown that reasonable package allocation<sup>[9, 10]</sup> was conducive to the efficient utilization of CSSD human resources, water, electricity, appliances and so on, and improves economic benefits.

### 4.4 Standardize the management of cleaning and disinfection in loaner instruments after operation

According to the requirements of WS 310-2016, CSSD in our hospital began to carry out cleaning and disinfection of loaner instruments and implants after operation at the end of 2017. In 2018, the retrospective management of cleaning and disinfection of loaner instruments after operation has been fully implemented<sup>[11]</sup>.

**Table 3:** Comparison of the accuracy rate of knee joint surface replacement loaner instruments before and after implementation

Implementation time	Precise allocation	Unprecise configuration	Accuracy rate	$X^2$	$P$
Before	10	86	10.42%	112.781	0.000
After	59	2	96.72%		

### 4.5 Implementing the first sterilization verification

At present, high pressure steam sterilization is the preferred sterilization method for loaner instruments in CSSD of our hospital. There were many, heavy and bulky instruments, and the specifications of the packages often exceed the requirements of the industry standards for the packages. There were too many condensate water produced by sterilization, and the incidence of wet packages was high. It was easy to lead to sterilization failure. Strict implementation of measures to verify the effectiveness of the first sterilization can guarantee the safe supply of instruments and ensure the smooth operation<sup>[12]</sup>.

## 4. Discussion

### 4.1 Reduce early release rate to ensure medical quality and safety

Through multi-sectoral communication, clear conditions for early release<sup>[4]</sup>, optimize the process of loaner instrument<sup>[5]</sup>. To reduce the occurrence of early release rate, it standardized that implants must be used only when the results of biological monitoring were qualified, ensures the health and life safety of patients, improved the management level and sterilization quality of implants, and ensured the safety of medical quality.

## 5. Summary

During continuous quality improvement and strict management of key links in several years, CSSD in our hospital tends to standardize the management of loaner instruments and implants, improves the quality of treatment of loaner instruments and implants, and plays an important role in promoting the control of nosocomial infection. This is not only the guarantee of quality control, but also the basis for continuous improvement of quality.

### 4.2 Enhance the qualified rate of dismantling loaner instrument to ensure the effectiveness of sterilization

With the efforts of CSSD and the cooperation of instrument manufacturers, drawing lessons from foreign management experience<sup>[6, 7]</sup>, we had completed the disassembly and cleaning data and operation guidelines of loaner instrument, realized the thorough cleaning of instruments, and improved the cleaning quality of instruments<sup>[8]</sup>.

## 6. References

### 4.3 Accuracy of knee joint surface replacement kit and improvement of economic benefit

Through the communication and cooperation of various departments, CSSD standardized the configuration process of loaner instrument for knee joint surface replacement. By comparing before and after the implementation of the scheme, the average time saved for each case of unilateral knee surgical instruments was 5 minutes, Packing time 2 min/case, the time of counting and arranging loaner

1. National Health and Family Planning Commission. Health Industry Standards of the People's Republic of China [S]. Hospital Sterilization Supply Center Part 1: Management Standards, 2016, 12.
2. Feng Xiulan. Interpretation of the revised contents of the three standards of disinfection supply center and Its Enlightenment to nursing management [J]. China Nursing Management. 2017; 17(6):725-729.
3. Mittelman MW. Bacterial biofilms in pharmaceutical water systems [J]. Drugs Pharmaceut Sci. 2008; 174:699.
4. Wang Hongmei, Zhong Liping, Xiangping, *et al.*

- Quality control circle to improve the punctual delivery rate of loaner instrumentation in orthopaedic surgery [J]. *Chinese Journal of Hospital Infectiology*. 2016; 26(21):5007-5009.
5. Song Yanping. Application of Quality Control Circle Activities in Standardized Management of External Instruments in Disinfection Supply Room [J]. *Contemporary Nurses*. 2017; 10(10):177-178.
  6. Seavey R. Reducing the risks associated with loaner instrumentation and implants [J]. *Aorn J*. 2012; 92(3):322-331.
  7. Winthorp TG, Sion BA, Ganines C. Loaner instrumentation: processing the unknown [J]. *Aorn J*. 2007; 85(3):566-573.
  8. Zeng Xiuyue, Shiyu, Chen Chunyan, *et al*. Study on the application of standardizing dismantling and cleaning management of loaner instrumentation in disinfection supply room [J]. *Journal of Nurses' Further Education*. 2019; 34(8):719-720.
  9. Hong Ying, Huang Wenxia, Wang Hui. Comparison of the effects of two different configurations of spinal surgical instrument kit [J]. *Journal of Nurses' Further Education*. 2009; 21:1943-1944.
  10. Zhou Xiaoli, Xie Zimao, Li Xiuying. Discussion on Effective Equipments of Surgical Instrument Package [J]. *Journal of Nurses' Advanced Studies*. 2004; 10:934.
  11. Zhang Qing, Gao Haiyan, Zhu Tianyu, *et al*. [J] *China Nursing Management*. 2019; 19(1):119-122.
  12. Xu Juanfang, Zhu Ziyang. Domestic and international status of quality management requirements for loaner instrumentation [J]. *Chinese Journal of Infection Control*. 2019; 18(5):455-460.