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ORIGINAL RESEARCH

Incidence of Adverse Events in Central Sterile Supply Department: A Single-Center Retrospective Study

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Purpose: Adverse events bring pain to patients, prolong hospitalization, and may even endanger life, it is necessary to effectively identify and manage adverse events. However, in Chinese mainland, there are few studies on adverse events in Central Sterile Supply Department. The purpose of this study was to investigate the prevalence of adverse events in Central Sterile Supply Department and offer suggestions for enhanced quality management.

Materials and Methods: A retrospective study was conducted to assess the prevalence of adverse events in a tertiary hospital from January 2020 to December 2022, employing a convenient sampling approach. The occurrence of adverse events of CSSD shall be collected for the basic information of the principal person of adverse events and the information of the adverse event. Descriptive statistics are described by frequency (percentage) and are analyzed by using X^2 test.

Results: A total of 101 adverse events were reported, with the majority being attributed to substandard cleaning quality (34, 33.66%), followed by faulty instrument assembly (25, 24.75%) and defective marking (7, 6.93%). Additionally, incorrectly sterilized items (6, 5.94%), occupational exposures (3, 2.97%) and late distribution (5, 4.95%) were also observed, accidents (8, 7.92%) and other types of adverse events (13, 12.87%). The highest risk chain for adverse events was identified as inspection and packaging (49, 48.51%) and device cleaning (32, 31.68%), with the majority of adverse events occurring on a scale of three (30, 29.7%) and four (70, 69.31%), respectively. Furthermore, it was determined that the type of person responsible, education, years of work and the structure of the device, the number of instruments in the operating kit, and the size of the kit may be factors in the occurrence of adverse events ($P < 0.05$).

Conclusion: Adverse events occur frequently in central sterile supply department, thus necessitating strict supervision during cleaning and inspection of packaging. Managers should pay special attention to staff with low working life and education. Furthermore, a grading system, in line with the central sterile supply department, should be implemented to ensure the management of adverse events and the quality of services provided is harmonized.

Keywords: central sterile supply department, surgical instruments, adverse events, sterilization, nurse

Introduction

Due to the rapid development of science and technology, all kinds of sophisticated surgical instruments came into being, and most of the surgical instruments are reused in China. Reused medical devices may be used in hundreds of operations, and today, there is no clear standard for the safe service life of reusable medical devices. Therefore, the device is recycled and reprocessed until its integrity and functional status are severely destroyed. The reused medical devices as specified in the health industry standards of the People's Republic of China shall be returned to central sterile supply department (CSSD) for centralized management.[1] CSSD provides the clinical departments with reliable sterile articles with sterilization quality through professional and standardized effective treatment, which is the core work of the CSSD. Under centralized management, surgical instruments are diverse, complex and fast turnover.[2–4] In addition, hospitals have sought to improve the quality of their services, taking into account cost concerns, leading to the emergence of medical equipment rental companies and increasing demands for the expertise of staff in CSSD.[5,6] The vast majority of

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those working in the CSSD are nurses, technicians or general workers, the complexity of the equipment, the variety of reprocessing processes, the variance in staff organization, and the significant differences in educational structure, professional background, and personal abilities leading to the occurrence of adverse events in the CSSD[7].

The term "adverse event of the CSSD" refers to a situation[8] that occurs during the disinfection supply work and may have an impact on the regular operation of the hospital, the outcomes of patient diagnosis and treatment, the workload of the same department, and the safety of the staff. According to the severity of adverse events and their impact on patients, CSSD adverse events were classified into four grades by the Nursing Society of Shanxi Province in China,[8] Grade I: An outbreak of infection in the hospital led by irregularities activity, improper sterilization and sanitation, occupational exposure, etc. Grade II: Rather than the condition itself, the patient's body and functions were harmed by irregularities operation, improper cleaning and sterilization, and workplace exposure. Grade III: Despite the irregularities operation, subpar cleaning and sterilization, occupational exposure, and the delay in diagnosis and treatment activities, the patient made a full recovery without the need for any further medical care. Class IV: Although there were irregularities operations and unqualified sterilization and disinfection, mistakes were discovered in a timely manner, and no facts were established.

Adverse events are the third leading cause of patient death in the US.[9] Adverse events not only bring economic costs but also bring high social costs. Adverse events during device reprocessing increase medical costs delay the start of surgery, prolong anesthesia, and cause pain to patients. Errors during instrument processing may also distract members of the surgical team, potentially affecting the surgical procedure. Finally, it is possible to contaminate the patient's wound surface, and may even endanger life.[10,11] In 2017, the Emergency Care Institute (ECRI) listed improper device processing as one of the top 10 health technology hazards. Studies showed that the defect rate of packaging inspection was 1.43 ‰ ~1.67 ‰.[7] Ye et al[12] found that the qualified rate of manual cleaning and mechanical cleaning were 70.59% and 84.97%, respectively. Costa et al[13] still found biofilm and bone fragments by scanning electron microscope after sterilization, which is not surprising given the number of surgical instruments processed. For example, about 40,000 reusable surgical instruments are processed each day in a large hospital in the US alone.[14]

For serious medical injury, adverse events reduce and avoid the occurrence of adverse events focus on prevention. However, to the best of our knowledge, research on adverse events in CSSD has focused on implementing comprehensive intervention strategies to reduce their frequency, Zhou et al[15] through the procedural management of CSSD adverse events decreased by 12.51%, Yang et al[6] through defect management of adverse events decreased by 18.3%, but there is no unified definition in the CSSD article, and the key links, specific contents, grades and factors of adverse events are rarely reported. A comprehensive and systematic investigation of the prevalence of adverse events in CSSD has not found, and scientific standard investigation is the key to promote the prevention of adverse events. Therefore, this study aimed to investigate the prevalence and associated factors of adverse events in CSSD. From the two key aspects of personnel and device, uncover and identify potential risk factors for adverse events, to formulate a systematic and comprehensive management plan for people with potential safety hazards or medical devices.

Methods

Study Design

This study generated a retrospective study to analyze the adverse events between January 2020 and December 2022 in CSSD.

Ethics

All procedures were carried out in accordance with relevant guidelines and regulations in accordance with the Declaration of Helsinki. This study has been approved by the Biomedical Ethics Review Committee, West China Hospital, Sichuan University (batch number: 2022 Trial (1893)). All participants provided written informed consent before they can respond to the questionnaires.

Study Setting

Data collection in Chengdu, Sichuan province, a tertiary hospital CSSD, the center construction area of 2000m^2, service more than 100 clinical departments and more than 50 other hospitals, is a medical research as one of the large tertiary first-class hospital, daily surgical instruments 10 thousands of chunks, with 4 long dragon cleaning machine, 23 large pressure steam sterilizer, ethylene oxide sterilizer 8 sets, low-temperature plasma sterilizer 12 units. There are 256 employees, including 40 nurses, 14 technicians and 202 general workers.

Survey Tools

Through a review of the relevant literature and combination with the Adverse Event Classification Standard of Care,[16] the Adverse Event Classification Standard of CSSD of Shanxi Province[8] and (Part 2: Standard for Operating Procedure of Cleaning, Disinfection and sterilization (WS 310.2–2016)),[17] the Adverse Event and Factor Questionnaire of CSSD were designed and refined prior to the start of the formal investigation. The adverse event survey form of the CSSD was preliminarily prepared. Through the expert meeting method, 11 group leaders were invited (with the title of supervisor nurse or above, engaged in management work for more than 8 years, and worked in CSSD for more than 10 years) to score the feasibility and importance of each item, and the deletion score was less than 3 points. The final questionnaire consists of 13 entries in three parts.

Part I: The Occurrence of Adverse Events

It mainly consists of four problems, including the natural day of adverse events, the chain of adverse events, the types of adverse events and the grade of adverse events. The chain of adverse events shall follow the ten major procedures of device reprocessing in the CSSD, including recycling, classification, cleaning, disinfection, inspection and packaging, sterilization and monitoring, storage and distribution links. The types of adverse events include: (1) unqualified cleaning quality: (2) device assembly errors: (3) identification defects: (4) sterilization mode errors: (5) supply delay: (6) occupational exposure: (7) accidents: (8) other types of adverse events.

Part II: The Background Information of the Principal Responsible for the Adverse Event

It is mainly composed of five questions, including the gender, age, educational background, type, and working years, which are used to analyze the impact of the general data of the main responsible person on the occurrence of adverse events.

Part III: Adverse Event Surgical Instruments Data

The questionnaire consists of four questions including the period of time from the surgical instrument to the CSSD, the number of surgical instrument kits, the size of the surgical instrument kits, and the structural characteristics of the problem instruments.

Data Collection

Department leaders organize area leaders to actively report adverse events within the area in the traceability system, and the non-punishment reward mechanism is adopted for reporting adverse events. The collection of data officially began in January 2020. Two scientific nurses (1 scientific research nurses with more than 6 years of working experience in CSSD and 2 years of scientific research work experience and 1 with more than 5 years of scientific research experience and 3 years of working experience in CSSD) independently exported adverse event data from the traceability system, and separately checked the accuracy and completeness of the data. If the data collection was not consistent between the two parties, a third party (chief manager with 15 years of working experience in the CSSD and more than 10 years of scientific research experience) was asked to discuss the data and decide jointly.

Sample

Typically, 5 to 10 times the survey factors were selected, depending on the method of sample size calculation. A total of 13 factors were collected in this study, and the sample size was 65–130 adverse events, and a total of 101 adverse events were collected by December 2022.

Statistical methods

In this study, SPSS 23.0 statistical software was used for statistical analysis of the data, frequency and percentage of categorical variables were used for statistical description, and bar chart and pie chart were used for representation. X^2 test was used for statistical analysis. The test level was set at 0.05.

Results

The Occurrence Type and Frequency of Adverse Events

CSSD of a tertiary hospital 2020.01—2022.12, 141,480 packages of reuse surgical instruments. There were 101 device-related adverse events, among, 34 (33.66%) substandard cleaning quality, 25 (24.75%) device assembly error, 7 (6.93%) defective marking, 6 (5.94%) sterilization mode error, 3 (2.97%) occupational exposures, 5 (4.95%) delivery delays, 8 (7.92%) unexpected events, 13 (12.87%) other type of adverse events.

The Chain of Adverse Events

One hundred and one adverse events were classified according to the disinfection supply process, including 49 inspection packaging inspection (48.51%),32 cleaning (31.68%), 8 recovery (7.92%), 7 sterilization monitoring (6.93%), and 4 storage and distribution (3.96%),1 disinfection (0.99%), see Figure 1.

Grade of the Adverse Events

According to the four-level adverse event classification system of Shanxi Provincial CSSD,[8] in this survey: with 1 adverse event occurring in level II (0.99%), 30 adverse events occurring in level III (29.7%), and 70 adverse events occurring in level IV (69.31%), as shown in Figure 2.

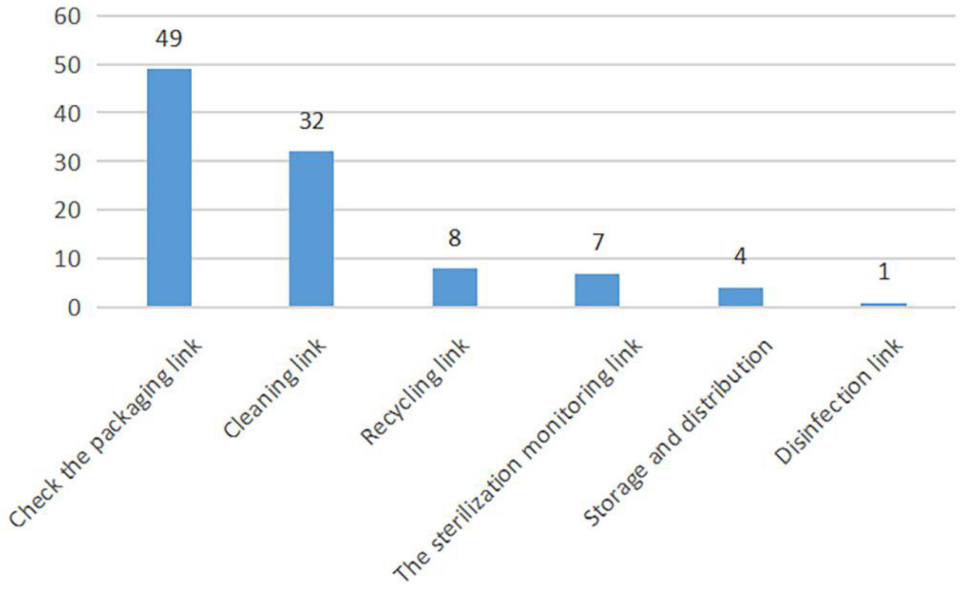

Figure 1 Distribution of adverse events in each link of CSSD.

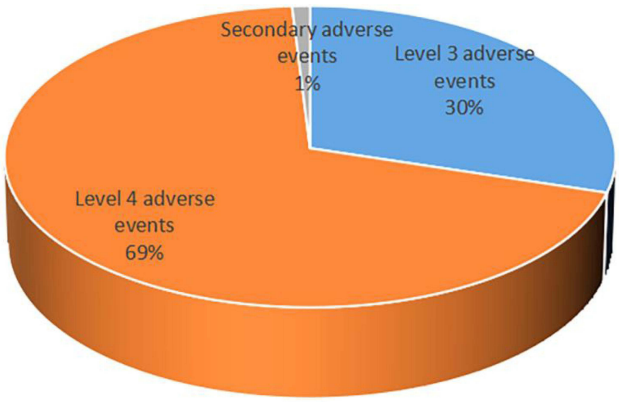

Figure 2 Grade distribution of adverse events in CSSD.

Analysis of the Occurrence of Adverse Events

Compared with the group with no adverse events, the responsible person was a general worker, and the education and working years of the responsible person were lower, and the higher the frequency of adverse events. In the adverse event group, the medical device structure was more complex, more numerous and larger in the surgical device package, with a statistically significant difference ($P < 0.05$), as shown in Table 1.

Table 1 Comparison of the Occurrence of Adverse Events in the CSSD

Project	Class	Total	Adverse Events	No Adverse Events	X^2	P
Gender of the Person Responsible	Man	132	58	74	2.296	0.159
	Woman	124	43	81		
Age (year)	<25	22	8	14	6.939	0.139
	25–35	88	30	58		
	35–45	96	38	58		
	45–55	34	20	14		
	>55	16	5	11		
Type Of personnel	Nurse	40	5	35	15.997	<0.001
	Skilled worker	14	4	10		
	General Worker	202	92	110		
Educational background	Junior high school and below	33	16	17	83.738	<0.001
	High school or technical secondary school	64	51	13		
	Junior college	80	30	50		
	Undergraduate course	79	4	75		
Working life (year)	<2	46	39	7	83.716	<0.001
	2–5	74	42	32		
	5–9	83	12	71		
	>9	53	8	45		
The type of natural day	Day	136,808	97	136,711	0.137	0.578
	Festival and holiday	4672	4	4668		
Time period of device handling	8–11	26,580	19	26,561	0.751	0.861
	12–16	43,883	30	43,853		
	17–20	45,370	36	45,334		
	20–0	25,647	16	25,631		

(*Continued*)

Table 1 (Continued).

Project	Class	Total	Adverse Events	No Adverse Events	X^2	P
The size of the surgical package	Small bag	31,796	18	31,778	8.438	0.038
	Medium package	48,567	25	48,542		
	Big bag	41,647	39	41,608		
	Jumbo bag	19,470	19	19,451		
Number of instruments in the surgical package (piece)	<10	16,478	8	16,470	16.613	0.002
	10–20	44,920	18	44,902		
	20–30	34,675	26	34,649		
	30–40	25,647	30	25,617		
	>40	19,760	19	19,741		
Structure of the surgical instrument	Routine surgical instruments	67,628	39	67,589	84.906	<0.001
	Electrical power system operating equipment	9870	4	9866		
	Tubular surgical instruments	12,640	11	12,629		
	Jointed or grooved surgical instruments	34,864	8	34,856		
	Precision and complexity of the surgical instruments	9108	26	9082		
	Other	7370	13	7357		

Discussion

The CSSD is one of the important units to maintain the stable operation of the hospital. Its management level will directly affect the clinical and surgical treatment. If medical equipment is not cleaned properly, sterilized thoroughly and supplied in a timely manner, it may cause adverse reactions, affect the smooth operation of the hospital and threaten the life of the patient.[6,18]

Number and Type of Adverse Events in the CSSD

The survey results indicated that a total of 101 (0.714‰) adverse events occurred. Among them, unqualified equipment cleaning quality and equipment assembly error account for respectively 33.66% and 24.75%. The unqualified cleaning quality is mainly concentrated in foreign medical instruments, which may be due to the complex structure of foreign medical instruments, which are often used in implant-related operations, incomplete pretreatment, and greater difficulty in manual or mechanical cleaning in the later stage, which are more likely to contain residual blood and stains. In addition, due to complex structure, heavy pollution, precision instruments mostly using manual cleaning, manual cleaning to avoid aerosols in the underwater, it is inevitable to see clearly.

Instrument assembly errors include few, many and missing parts. Under the health system reform of the regional CSSD in mainland China not only provides instrument services for the local institution but also provides instrument services for the local primary medical institutions, resulting in a wide variety of instruments in the CSSD. In an instrument package with the same name, different configurations of instruments are required to meet the requirements of different institutions (for example, 3 instruments in mechanism A, 8 instruments in mechanism B, and 12 instruments in mechanism C), leading to a high risk of instrument assembly errors.

For the above situation, prompt CSSD manager when introducing new surgical equipment, facilities, and instruments, it is suggested that hospital managers focus on strengthening relevant training in cleaning and inspection of packing staff, and they may only take up the position after passing the exam. Through professional training for the staff of the center, the division of labor is clear to ensure that the work of all links meets the standard and is qualified, comprehensively improving the quality of medical devices. At the same time, the strict implementation of the inspection system, for the surgical equipment package, rescue package, must be double-check signature confirmation, can be packaged.

The Chain of of Adverse Events

Surgical instruments cleaning and sterilization work gradually get the attention and medical field and related work also gradually specialized, scientific, standardized, surgical instrument reprocessing including: recycling, cleaning, disinfection, packaging, sterilization, storage, transportation, and other links, any link problems will have a significant impact on the overall quality of work.[19] The results of this survey showed that the frequency of adverse events in the cleaning process (32, 31.68%) and in the inspection process of packaging (49, 48.51%) was relatively high. The procedure of instrument cleaning is the basis, and the instrument should be thoroughly cleaned after use. Removing blood stains, pus stains, dry excrement and secretions attached to the instrument is an important step to prevent hospital infection and ensure the safety of surgery. Only the correct washing and maintenance method can ensure the sterilization effect of medical instruments. If the cleaning is not thorough, any organic matter remaining on the instruments will form a protective film on the surface of microorganisms, affecting the disinfection and sterilization effect,[20] proper cleaning can remove up to 99% of microorganisms, and may extend device life and save medical costs.[12,21] Using the proper cleaning method to sanitize surgical instruments and strictly monitor their quality. Therefore, it is suggested that the standardized cleaning process: for special and complicated medical equipment, should be classified by a special person, cleaning separately, reasonable selection of cleaning agent, while the cleaning personnel are required to strictly regulate the operating procedures to prevent cross-infection.

The inspection and packaging process of the CSSD is a key link for the inspection, assembly, packaging and marking of the decontaminated medical instruments, utensils and articles,[4] as well as an important part of the quality control of the CSSD. Xiaolian et al[22] studies found that the error rate in the packaging link was 1.18%, which was higher than that in this study. The analysis reason may be due to the study on the defects in the packaging link, which is consistent with the conclusion of this study on the high incidence of adverse events in the packaging link. Check the packaging link is the last barrier to directly observe the quality and type of instruments in the operating kit during the CSSD. However, due to the large amount of surgery, complicated instruments and uneven education level of staff, Incomplete professional expertise. At the beginning of the work, the memory of the type, quantity, structure, specification and packaging materials in the device package is not reliable, easy to be confused, the handover is unclear to mix the equipment of different hospitals, the boring work repeated every day makes some people appear slack off. These factors are easy to lead to various packaging errors. Therefore, the manager of the CSSD should strictly check the quality requirements of inspection packaging personnel. Nurses are the core and soul of the CSSD. It is suggested that the manager of the CSSD match the number of nurses reasonably according to the complexity of the instruments or the sterilization method. At the same time, a visual system or paper map is introduced in the assembly process of devices to package the reference map to reduce the memory errors of staff and avoid the occurrence of adverse events in the packaging process.

Factors of Adverse Events

Managing key linkages and key drivers of adverse events, and controlling the frequency of adverse events. The study found that the risk of adverse events increased with ordinary worker, lower education or years of service, more sophisticated surgical instruments, more instruments in the surgical package, and larger surgical kits.

Currently, there is a severe shortage of nursing staff. With the aim of better controlling medical costs and saving human resources, the hospital introduces a large number of workers to work in the CSSD, with a zero medical foundation. The CSSD has a complex staff structure, with nurses acting as the primary team leader, information gatherer, promoter of scientific research, instructional manager, cost controller, and controller of equipment and facility operations.[23] However, the number of frontline nurses in the CSSD is low, and primarily with low-seniority nurses, and overall work capacity is low. Cao et al[24] investigated CSSD personnel in Shanghai and found that their professional knowledge was not good and their awareness of occupational protection needed to be further improved. CSSD nursing human resources shortage,[25] human resources shortage reasons are the CSSD is the department that is most easily overlooked, not only the closed environment, low income, low promotion, heavy work, and highly repetitive and mechanized operating processes, leading to poor immersion in nursing work, loneliness in the workplace, professional identity and work enthusiasm are also poor, the quality of equipment management in the CSSD is not ideal.[26] Therefore, standardizing the management of the CSSD and improving the enthusiasm of the department staff are also the key

contents of the current construction of the CSSD. At the same time, the establishment of general workers admittance system (such as: educational requirements, work experience, professional quality, family stability). After becoming a regular employee, the training and assessment system (head nurse—nurse—general workers) will be established according to different personnel structures, so as to promote the skill level of the staff to better serve the surgical department and ensure the surgical safety of patients.

Furthermore, with the rapid development of the technical level of the medical industry, the medical equipment constantly updated, its varieties are becoming more complicated, complex devices often require multi-step cleaning, disassembly, and assembly. The management difficulty is increasing, especially overweight, super bag, the equipment is relatively special, Super-large and overweight bags are mostly foreign medical equipment, Tipple et al[27] in Brazil and Australia found that the external medical devices reached CSSD less than 24h before the expected operation, causing insufficient time for proper cleaning, inspection, inventory, packaging, the disinfection management difficulty is relatively large. Therefore, perioperative professionals must ensure that surgical supplies are not contaminated in use, they should be proficient in the hospital policies and procedures for leased devices and implants management, and when arranging medical devices, inform CSSD personnel of any specific treatment required, including but not limited to: the number of instrument trays and/or items; the surgical procedure requiring the surgeon; date and time of intended use; mode of transportation, time of estimated arrival, etc., to ensure safe and effective reprocessing of surgical devices.

As a logistics support department, CSSD has no right to decide the number of instruments in the surgical package, but it can effectively communicate and feedback with the operating room and equipment department. The department nurses are assigned to the operating room to learn and understand the use of the doctor team during the operation. Not commonly used in the device packs, a single package can be used to reduce the weight and number of devices in the surgical package, reduce the sterilization process of the devices and save the medical cost.

In addition, a traceability system should be established for foreign medical devices, from the entry of foreign medical devices into the hospital as the starting point to the termination of the device life as the end point, so as to realize the traceability of the whole process and the whole life cycle of foreign medical devices.

Grade of Adverse Events

The results of this survey showed that mainly level three and level four adverse events, and the impact on patients was low. However, there are still deficiencies according to the existing classification criteria for adverse events. Prior studies have shown that approximately 5% of incorrect device assembly adverse events typically do not result in infection or safety concerns, but can cause delays in the operating room, cancellation, additional processing, and loss and damage to the device causing significant quality and cost issues.[22] Thus, there is a need to build a multidimensional grading system for adverse events of the CSSD based on the actual situation of cost, patients, equipment, and facilities, as well as the nosocomial infection, in order to better guide clinical practice.

Limitations

This study has the following limitations. First, the single-center study design and potential selective bias limit the generalizability of the conclusions. Secondly, the adverse events in this study were voluntarily reported systematically. Due to the inherent thinking of the staff, they may have a certain impact on the number and severity of the adverse events reported, although we have traced the source of the adverse events as far as possible. Lastly, since the quality of surgery not only depends on the high quality of surgical instruments, but also includes the doctor's skills, teamwork, facilities, and the patient itself and other factors, the long-term outcome of patients is not tracked, and a large sample matching design can be conducted in the future to explore the impact of adverse events on the long-term outcomes of patients.

Conclusion

Adverse events are common and hindering to the development of high-quality surgical procedures, but less attention has been paid to adverse events in CSSD. The frequency of adverse events in the CSSD is high, the main cleaning quality is unqualified and instrument assembly error. Device cleaning and inspection and packaging are the key links of adverse events. Managers should reinforce management of low seniority, low academic qualifications, precision equipment, and

overweight bags management, In addition, we observed that the existing adverse event classification criteria are not combined with the actual situation of CSSD, which cannot clearly divide the grade of adverse events. In the future, based on considering the impact on patients, combining the corresponding important indicators of CSSD (such as cost, hospital awareness, equipment and facilities, etc.) to construct an adverse event classification system suitable for CSSD specialty, so as to make the management of adverse events more scientific and accurate. Overall, these results identify the high-risk links, risk groups, key devices of adverse events in CSSD, to cause the attention of medical experts to CSSD adverse events. In addition, the relevant functional departments in the hospital also more attention to CSSD and cooperation (example: the increase of personnel and the adjustment of configuration; the control of device super overweight package, etc.) to strengthen the implementation of relevant specifications. At the same time, it provides evidence for CSSD decision-makers and develops more accurate and scientific adverse event management strategies.

Ethics Approval and Consent to Participate

This study was approved ethically by the Biomedical Ethics Review Committee, West China Hospital, Sichuan University under the number 2022 Trial (1893).

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that they have no competing interests in this work.

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