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Study on the Current Status of Standardized Initial-use Processing Technology and Management of New Stainless Steel Instruments in Central Sterile Supply Departments in Shaanxi Province

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ABSTRACT: Objective To investigate the current implementation of initial-use pre-treatment of new stainless steel instruments in Central Sterile Supply Departments (CSSDs) of medical institutions in Shaanxi Province; identify deficiencies in current clinical management; establish a standardized pre-treatment procedure based on authoritative national and international standards; and develop feasible, tiered optimization measures to ensure sterilization safety and prolong instrument service life. **Methods** CSSD staff members from 107 medical institutions in the province qualified to process surgical stainless steel instruments were selected as study participants. A self-developed five-dimension questionnaire was used. Following expert evaluation of content validity and reliability testing in a pilot survey, an electronic questionnaire survey was conducted via the Wenjuanxing online platform, with quality control implemented throughout the entire process. A total of 107 valid questionnaires were collected, and descriptive statistics were performed using SPSS 26.0. Relevant national and international standards were systematically reviewed, and standardized procedures and tiered corrective strategies were developed based on the literature. **Results** Only 23.4% of institutions fully implemented the complete degreasing + passivation process, while 29.9% sterilized the instruments directly without pre-treatment. The utilization rates of dedicated degreasing agents and passivating agents were 32.7% and 8.4%, respectively. Only 33.6% of personnel were able to distinguish between degreasing and passivation, 34.6% of institutions had established dedicated management procedures, and only 14.0% had incorporated pre-treatment into monthly quality control. Deficiencies existed across multiple aspects, including staff awareness, system development, operational implementation, consumable supplies, and quality control, resulting in a vicious cycle of management. **Conclusion** The level of standardization of pre-treatment for new stainless steel instruments in CSSDs in Shaanxi Province is relatively low. Medical institutions should implement corrective measures according to tiered priorities, strictly follow the standardized "degreasing-cleaning-passivation-lubrication and drying-sterilization" process, ensure adequate provision of dedicated reagents, improve management systems and tiered training, establish continuous quality control, and correct the misconception that "new instruments do not require pre-treatment", thereby preventing instrument corrosion and staining at the source and ensuring the safety of aseptic clinical diagnosis and treatment.

KEY WORDS: Central Sterile Supply Department (CSSD); stainless steel surgical instruments; pre-treatment of new instruments; quality management

1 Introduction

Central Sterile Supply Departments (CSSDs) are responsible for the cleaning, disinfection, sterilization, and distribution of reusable medical instruments in hospitals. Stainless steel surgical instruments are the most commonly used type of instrument in clinical surgical practice. A common misconception in clinical

practice is that newly manufactured stainless steel instruments are visibly clean and can be sterilized and used directly after routine cleaning alone. However, clinical practice has shown that if new instruments do not undergo standardized initial-use processing, yellow spots, black or gray spots, and early corrosion are highly likely to develop after the first sterilization. This not only shortens the service life of the instruments and increases procurement costs, but also means that residual polishing paste and industrial rust-preventive oil on instrument surfaces may impede steam penetration, posing potential risks of sterilization failure and cross-infection among patients[1-2].

Stainless steel instruments undergo passivation by the manufacturer before leaving the factory. However, residual polishing paste from manufacturing, rust-preventive protective oil applied during transportation, and friction during storage can all result in the retention of contaminants on instrument surfaces and damage to the passivation film[3-4]. International standards ASTM A967/A967M and ANSI/AAMI ST79, as well as the Chinese national standard GB/T 2766—2022 and the group standard T/NAHIEM 142—2025, specify corresponding technical requirements for the in-hospital pre-treatment of new instruments[5-8]. Most existing studies in this area are single-center, small-sample surveys, and province-wide cross-sectional survey data are lacking. Differences in the implementation of pre-treatment and management weaknesses among medical institutions at different levels within the region have not yet been systematically elucidated[9]. Therefore, this study conducted a cross-sectional survey of the current status of initial-use pre-treatment of new stainless steel instruments in CSSDs in Shaanxi Province to identify gaps in regional implementation, establish a standardized pre-treatment procedure based on national and international standards, and propose tiered improvement measures, thereby providing data to support instrument quality control in CSSDs in China.

2 Participants and methods

2.1 Study design

A cross-sectional survey design was used in this study.

2.2 Study participants

The CSSDs of all 107 medical institutions in Shaanxi Province that were qualified to independently perform the cleaning and sterilization of stainless steel surgical instruments were included in the study.

Inclusion criteria: (1) head nurses or quality control officers of CSSDs in medical institutions at all levels in Shaanxi Province; (2) having been engaged in work related to instrument cleaning, disinfection, and sterilization for ⩾6 months; (3) being aware of the purpose of the survey and voluntarily participating in the study.

Exclusion criteria: (1) interns, staff undergoing further training, and staff on temporary rotation; (2) staff who were on leave or otherwise not on duty during the survey period; (3) individuals who declined to complete the questionnaire or withdrew from the survey before completion.

In this survey, “new stainless steel instruments” specifically refers to brand-new surgical instruments being put into use for the first time at a medical institution that have not previously undergone processing through a CSSD, excluding rented and externally supplied instruments. This study surveyed all eligible medical institutions in the target population; no sampling was performed.

2.3 Survey instrument

Based on the research objectives, national and international standards for instrument management, and practical challenges encountered in CSSD operations, a self-developed Questionnaire on the Current Status of Pre-treatment of New Stainless Steel Instruments in Medical Institution CSSDs was developed. The questionnaire comprised five dimensions: (1) processing procedures; (2) reagent selection; (3) staff awareness; (4) management systems and training; (5) implementation of quality control. The questionnaire included single-choice questions, multiple-choice questions, and five-point Likert-scale items (1 point = completely unaware, 2 points = slightly aware, 3 points = moderately aware, 4 points = relatively knowledgeable, and 5 points =

fully proficient). The total score ranged from 7 to 35 points, with higher scores indicating a higher level of professional knowledge and awareness. Seven experts at the associate-senior level or above in the fields of healthcare-associated infection management, CSSD nursing management, and instrument quality management were invited to participate in two rounds of Delphi expert consultation. Based on expert feedback, ambiguous items were deleted or revised. Using the four-point Likert rating method, the overall content validity index (CVI) of the questionnaire was 0.92, with item-level CVIs ranging from 0.86 to 1.00. According to the evaluation criteria for the Delphi method, these results indicate that the questionnaire content was well aligned with the research topic and demonstrated good professional relevance and representativeness. Reliability testing: Before the formal survey, a pilot survey was conducted to assess the reliability of the questionnaire. The overall Cronbach's α coefficient was 0.872, while the Cronbach's α coefficients for the five dimensions ranged from 0.741 to 0.835, all exceeding 0.7. These results indicated good internal consistency and reliability, supporting the use of the questionnaire in the formal cross-sectional survey.

2.4 Survey implementation

The questionnaire was administered online in combination with on-site quality control supervision. Questionnaires were distributed to the head nurses or quality control officers of CSSDs in 107 medical institutions, with one-on-one assistance provided throughout the survey to clarify any questions and ensure that the information reported was accurate and complete. A total of 107 questionnaires were distributed, and all 107 valid questionnaires were returned, yielding a valid response rate of 100%.

Quality control measures: (1) During the pilot survey, all ambiguous items were revised and optimized, and the questionnaire completion process was simplified; (2) The online platform was configured to allow only one questionnaire submission from each IP address, thereby preventing duplicate submissions from the same institution; (3) All items were set as mandatory, and the system automatically prevented submission of questionnaires with missing responses; (4) A minimum completion time was set, and questionnaires completed in less than 3 min were automatically excluded as invalid; (5) Before the survey, an online briefing session was conducted for all participants, and questions regarding questionnaire completion were addressed on a one-to-one basis; (6) After the questionnaires were collected, two researchers independently exported the data, cross-checked the datasets, and excluded logically inconsistent data to ensure data accuracy and reliability. System verification confirmed that there were no missing responses for any questionnaire items. The data completeness rate of the 107 questionnaires ultimately included in the analysis was 100%.

2.5 Retrieval of standards and reference documents

The international standards ASTM A967/A967M and ANSI/AAMI ST79 were systematically reviewed[7]; the Chinese national standard GB/T 2766—2022[8]; the group standard T/NAHIEM 142—2025 Specification for Reusable Surgical Instruments Management in Hospitals[5]; the Post Training Textbook for Hospital Central Sterile Supply Departments (2022 Edition)[9], and the Shaanxi Province Central Sterile Supply Department Quality Control Manual were reviewed to identify the technical requirements related to the pre-treatment of new instruments.

2.6 Statistical methods

Data were analyzed using SPSS 26.0 statistical software. Categorical data were expressed as frequencies and percentages (%). Descriptive statistics were used to calculate the percentages, implementation rates, and utilization rates of indicators in each module.

3 Results

3.1 Basic information on the study participants

This survey covered all 107 medical institutions in Shaanxi Province qualified to handle surgical stainless steel instruments. The valid questionnaire response rate was 100%. The participating institutions included grade A tertiary general hospitals, grade A secondary hospitals, primary specialized hospitals, and private medical institutions, reflecting

the actual implementation of new-instrument pre-treatment across CSSDs at different levels in the province.

3.2 Implementation of indicators for new-instrument pre-treatment

Only 23.4% of institutions fully implemented the entire degreasing + passivation process, whereas 29.9% directly sterilized new instruments without any pre-treatment; The rates of provision and use of dedicated degreasers and passivating agents were low; Significant deficiencies were identified in staff understanding, the establishment of dedicated management systems, and the implementation of monthly quality control, as shown in Table 1.

3.3 Objective description of implementation across key areas

Process implementation: 76.6% of medical institutions had incomplete pre-treatment procedures, 45.8% performed only simple degreasing and omitted passivation, and 29.9% proceeded directly to routine cleaning and sterilization. Consumable provision: 67.3% of institutions used conventional multi-enzyme detergents instead of dedicated degreasers, and only a small number (8.4%) had dedicated medical passivating agents. Staff awareness: Most staff (66.4%) could not distinguish between the degreasing and passivation steps or clearly understand the respective responsibilities for manufacturer-performed passivation before shipment and in-hospital passivation before first use. Management systems and quality control: More than half of the institutions (65.4%) had no dedicated management system, and only 14.0% had incorporated pre-treatment into monthly quality control. These problems were interrelated, forming a vicious management cycle of "insufficient awareness-lack of management systems-simplified procedures-inappropriate consumables-inadequate quality control-recurrent instrument staining and corrosion".

4 Discussion

4.1 Current status of standardized initial-use treatment of new instruments

A province-wide cross-sectional survey of CSSDs in 107 medical institutions in Shaanxi Province showed that the overall implementation of initial-use pre-treatment for new stainless steel instruments was suboptimal. Prominent deficiencies were identified across five dimensions: implementation of operating procedures, provision of dedicated consumables, staff professional knowledge, establishment of dedicated management systems, and routine quality control. Deficiencies across these areas were interrelated, forming a vicious management cycle.

4.2 Analysis of the technical and management factors underlying the current status

From a technical perspective, polishing paste and industrial anti-rust oil remaining on new instruments after manufacture cannot be removed using conventional multi-enzyme detergents. The passivation film applied by the manufacturer provides protection primarily during transportation, but friction during handling and transit can readily damage the film. Medical institutions therefore need to perform passivation again after degreasing to restore the protective film and reduce the risk of yellow staining and corrosion[1-4]. International ASTM/AAMI stan-

Table 1 Implementation of Indicators for New-Instrument Pre-treatment in CSSDs of 107 Medical Institutions in Shaanxi Province

Survey indicator	Number of institutions meeting the criterion (N=107)	Percentage (%)
Full implementation of the complete degreasing-plus-passivation process	25	23. 4
Simple degreasing only, with the passivation step omitted	49	45. 8
No pre-treatment; direct sterilization	32	29. 9
Provision of dedicated alkaline degreasers	35	32. 7
Provision of dedicated medical passivating agents	9	8. 4
Staff can clearly distinguish between degreasing and passivation	36	33. 6
Medical institution has established a dedicated management system for pre-treatment	37	34. 6
Pre-treatment is incorporated into routine monthly quality control assessment	15	14. 0

dards have established technical requirements for the degreasing and passivation of new instruments, whereas the Chinese national standard GB/T 2766—2022 primarily addresses manufacturers' quality control before products leave the factory and does not address damage to the passivation film after instruments arrive at hospitals[6-8].

At present, some medical institutions still use the traditional "three-wash, three-disinfection" approach (i.e., repeated cleaning with a conventional multi-enzyme detergent followed by thermal disinfection, which is the routine process for reusable instruments) to process new stainless steel instruments. This process can remove only ordinary organic contaminants from instrument surfaces; it cannot completely remove polishing paste and industrial antirust oil remaining from manufacturing, nor can it repair and restore the stainless steel passivation film damaged by friction during transportation and handling. Existing comparative studies have shown that, compared with the traditional "three-wash, three-disinfection" approach, passivation with a medical-grade dedicated passivating agent following thorough degreasing and cleaning can regenerate a dense, chromium-rich oxide passivation film on the stainless steel surface, significantly reduce the incidence of yellow staining and corrosion of instruments, improve their corrosion resistance, and effectively extend the service life of surgical instruments[3-4]. It should be noted, however, that thorough prior degreasing and cleaning is a prerequisite for the protective effect of the dedicated passivating agent. If industrial oil contaminants or polishing paste residues remain on the instrument surface, the passivating agent cannot react sufficiently with the underlying metal, substantially reducing the protective effect of passivation.

From a management perspective, the current Chinese group standard T/NAHIEM 142—2025 is a recommended standard and lacks mandatory enforcement mechanisms for implementation[5]. Although the job training manual clearly specifies key operating requirements, dedicated training coverage remains inadequate in medical institutions. Many departments lack SOPs and quality control oversight, making it difficult to translate standard requirements into routine clinical practice. Standardized pre-treatment can not only reduce instrument disposal and hospital costs, but also mitigate the risk of sterilization failure associated with residual oils, enhance patient safety during surgery, and align with the concept of life-cycle management of medical devices[6-7].

Based on the findings of this survey and relevant national and international standards and literature, a five-step standardized pre-treatment process for new stainless steel instruments in hospitals is proposed: "degreasing-cleaning-passivation-lubrication and drying-sterilization": (1) Dedicated degreasing: Soak the instruments in a dedicated alkaline degreasing agent and thoroughly brush them to remove industrial oil contaminants; (2) Routine cleaning: Use softened water/purified water to complete standard CSSD cleaning; (3) Passivation: After degreasing and cleaning, use a medical-grade passivating agent to repair the passivation film; (4) Lubrication and drying: Apply a water-soluble lubricant to hinged instruments and thoroughly dry lumened instruments with hot air; (5) Sterilization and visual inspection: After steam sterilization, inspect the instruments for any abnormalities in appearance. In addition, the causes and management measures for common clinical findings, including yellow stains, black spots, corrosion, and white water marks, are summarized (see Table 2).

Based on the problems identified in the survey, graded management improvement measures were proposed according to three priority levels: urgent, important, and basic. (1) Urgent corrective measures (reagents and quality control): Promptly ensure adequate supplies of dedicated degreasing and passivating agents, incorporate pre-treatment into monthly quality control, and establish a closed-loop tracking log for verification-feedback-corrective action; (2) Important corrective measures (systems and procedures): Develop a dedicated SOP for the pre-treatment of new instruments, formalize the five-step operating process, and specify key parameters, including temperature, time, and reagent ratios; (3) Basic correc-

Table 2 Common Defects, Contributing Factors, and Corrective Measures After First Sterilization of New Instruments

Instrument surface defects	Contributing factors	Standardized corrective measures
Large-area yellow staining or mottling after sterilization	Incomplete removal of anti-rust protective oil and polishing paste	Before first use, strictly perform alkaline degreasing by soaking and manual brushing, use a dedicated degreasing agent throughout the process, and do not omit the degreasing step[1-2], in accordance with industry specifications for instrument management[5]
Stubborn black or gray spots on the instrument surface	Residual industrial polishing paste	Extend the degreasing soaking time, with particular attention to brushing gaps and joints, and rinse until no black contaminants remain on the wiping gauz[1]
Corrosion and rust spots occurring shortly after use	Damage to the factory-applied passivation film and failure to perform passivation before first use	Establish a fixed passivation step, procure dedicated medical-grade passivating agents, incorporate passivation into the mandatory pre-treatment process[3-4], and perform passivation with reference to the ASTM series of standards[6]
White water stains and water-mark spots after sterilization	Excessive hardness of cleaning water and substandard water quality of sterilization steam	Use purified water/softened water for cleaning, regularly inspect and maintain the steam generator, monitor water quality parameters, and follow the Comprehensive Management Guidelines for Steam Sterilization[7]

tive measures (staff training): Conduct tiered training on the principles of pre-treatment, the allocation of responsibilities for each process step, and key points of practical operation, supplemented by theoretical and practical assessments, to correct the misconception that "new instruments do not require pre-treatment".

4.3 Limitations of this study

(1) This study was a cross-sectional questionnaire survey and could only reflect the implementation status at the time of the survey. It could not capture changes over time or establish a causal relationship between pre-treatment deficiencies and adverse outcomes such as instrument corrosion and sterilization failure, but only describe the associated phenomena. (2) The survey was limited to Shaanxi Province. Economic conditions and the intensity of quality control management vary across regions; therefore, when applying the findings to other provinces, appropriate adjustments should be made in light of local conditions. (3) The questionnaire was completed by the head nurse or quality control lead of the CSSD at each institution. Their ratings reflected a subjective assessment of the overall training effectiveness of the department rather than the results of a knowledge assessment administered to randomly selected frontline staff; therefore, social desirability bias may have resulted in an overestimation of the actual level of staff awareness. At the same time, this survey was conducted through the provincial quality control network, resulting in a 100% valid response rate. This response rate was facilitated by administrative coordination through the quality control system and may be difficult to replicate in routine voluntary questionnaire surveys; therefore, response bias cannot be completely excluded.

5 Conclusion

The overall level of standardization of initial-use pre-treatment of new stainless steel instruments in CSSDs of medical institutions in Shaanxi Province is relatively low, with multiple deficiencies, including inadequate implementation of pre-treatment procedures, insufficient dedicated consumables, limited staff awareness, lack of dedicated management systems, and inadequate quality control and supervision. Medical institutions should implement corrective measures according to the three priority levels of urgent, important, and basic; strictly follow the standardized pre-treatment process of "degreasing-cleaning-passivation-lubrication and drying-sterilization"; ensure the availability of dedicated reagents; improve management systems and SOPs; implement tiered training and routine quality control; and correct misconceptions, thereby reducing the risk of instrument corrosion and staining at the source and ensuring the safety of

reusable medical instruments in clinical use.

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