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The Role of Endoscope Diagnosis and Treatment Center Traceability System in Quality Control of Endoscope Cleaning

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Abstract: As the cornerstone of sterile instrument maintenance in endoscopy centers, the quality of endoscope cleaning directly impacts hospital infection control effectiveness. The traceability system for endoscopy centers utilizes digital means to document the entire cleaning process, enabling real-time monitoring and precise quality control. This paper analyzes current quality control practices in endoscope cleaning and addresses existing challenges. It explores how traceability systems standardize procedures, enhance monitoring, and improve management efficiency. The study proposes optimization strategies for traceability system implementation, clarifying its core value in endoscope cleaning quality control. These findings provide theoretical foundations and practical guidance for hospitals to refine management of endoscopy centers, ensure diagnostic safety, and reduce infection risks, ultimately advancing endoscope cleaning quality control toward standardized and informatized development.

Keywords: Endoscopic diagnosis and treatment center; Traceability system; Endoscope cleaning; Quality control; Hospital infection prevention and control

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1. Introduction

Endoscopes, as critical diagnostic and therapeutic instruments for gastrointestinal and respiratory diseases, pose significant challenges in hospital infection control due to their complex structures and high usage frequency. Endoscopy centers are responsible for endoscope cleaning and disinfection. Non-compliant procedures during cleaning or inadequate monitoring can lead to pathogen residues and cross-infections. Traditional quality control methods relying on manual documentation and random inspections suffer from incomplete data records, difficulties in tracing, and delayed supervision, failing to meet the demands of precision management. The digital traceability system in endoscopy centers collects real-time data throughout the cleaning process, enabling "one

item, one code" and full-process traceability. This system provides robust support for quality control, making its analysis clinically valuable and significantly manageable.

2. Current situation and existing problems of quality control in endoscope cleaning

2.1. Current status of quality control in endoscope cleaning

As a sophisticated optical instrument, flexible endoscopes are primarily used for diagnosis and treatment in medical practice. Their flexibility allows access to various natural body cavities and organs for observation, biopsy, and therapeutic procedures. However, frequent disinfection and potential physical damage during operation make leakage a major maintenance challenge and safety hazard. Given their frequent use with patient bodily fluids and tissues, combined with structural features like long tubes and high precision, these endoscopes are susceptible to microbial contamination. Most hospitals establish cleaning protocols specifying operational requirements, provide dedicated equipment and consumables, conduct regular inspections focusing on tube patency and leakage detection, and implement staff training and assessments. However, information management systems remain inadequate, some hospitals still use paper-based records, while electronic systems in a few only record basic data without enabling full-process monitoring. This results in difficulties in real-time process control and precise risk management of endoscope contamination [1].

2.3. Problems existing in quality control of endoscope cleaning

Quality control in endoscope cleaning procedures faces multifaceted challenges. While operators are familiar with the cleaning protocols, they often simplify steps during implementation, such as delayed pretreatment or inappropriate brush selection leading to incomplete pipeline cleaning. Manual documentation frequently contains missing or incorrect entries, failing to accurately reflect operational realities. When quality issues occur, it becomes difficult to trace specific responsible parties or identify operational deviations. Quality monitoring demonstrates sluggish efficiency, traditional methods relying on periodic spot checks cannot provide real-time insights into each endoscope's cleaning standards. If an endoscope fails to meet cleanliness requirements, it may already be deployed clinically, increasing infection risks. Limited sampling capacity makes it impossible to cover all endoscopes, potentially overlooking quality risks. Management efficiency remains suboptimal, as paper-based or basic digital records require manual organization and archiving. Data retrieval and statistical analysis are time-consuming, making it difficult to generate timely cleaning quality reports. Managers struggle to adjust control strategies based on data, ultimately hindering continuous improvement in quality control.

3. The role of endoscopic diagnosis and treatment center traceability system in quality control of endoscopic cleaning

3.1. Standardize operation process and reduce human error

Each endoscope is assigned a unique identification code. Before cleaning, operators scan this code to automatically trigger the corresponding cleaning procedure guidelines, which specify operational requirements, timelines, and parameter standards for each step, such as completing pre-treatment within 30 minutes after use and maintaining detergent concentration at specified levels. These guidelines ensure standardized operations. During cleaning, operators must scan the workstation code or device code after completing each step to input operation time, equipment parameters, and consumable usage data. The system only permits proceeding to the next step if all

required information is entered, preventing skipped critical procedures or simplified operations. Failure to enter data as required triggers system alerts, forcing operators to supplement information to ensure full traceability of every operational phase [2].

3.2. Strengthen quality monitoring to achieve whole-process control

The traceability system achieves "full-process control" of endoscope cleaning quality through real-time data collection and multi-dimensional monitoring. During cleaning operations, the system integrates with cleaning equipment to automatically collect operational parameters such as water temperature, chemical concentration, and processing duration. When parameters exceed standard thresholds, the system immediately triggers audible-visual alerts to prompt operators to make adjustments, preventing abnormal equipment conditions from compromising cleaning efficacy. Operators must upload post-cleaning endoscope images and chemical analysis results, which are automatically stored and linked to the device's unique identification code to create comprehensive quality records. After cleaning completion, managers can review real-time data including procedural compliance, parameter adherence, and quality metrics for each endoscope, eliminating manual spot checks to monitor overall cleaning standards. When quality issues arise, the system enables traceability to specific cleaning procedures, operator identities, and equipment status, allowing rapid identification of root causes. For instance, if an endoscope fails to meet cleaning standards, the system identifies potential issues like insufficient chemical concentration or inadequate processing time, providing actionable insights for targeted improvements. This approach transforms traditional "post-facto inspections" into proactive "in-process intervention and pre-event prevention".

3.3. Improve management efficiency and promote continuous improvement

The retrospective system, powered by digital data management, significantly enhances the efficiency of endoscope cleaning quality control. By automatically integrating all cleaning data, it generates multidimensional analytical reports covering key metrics like qualification rates across different timeframes, operator compliance rates, and equipment failure frequency. This eliminates manual data compilation for administrators, enabling them to swiftly grasp overall quality control status and identify weak points. For instance, operators with low compliance rates receive targeted retraining, while frequently malfunctioning equipment requires immediate maintenance or replacement [3]. The system also supports historical data queries and comparisons, allowing managers to analyze quality trends across quarters and teams while evaluating control measures effectiveness. For example, after introducing new cleaning agents, operators can compare pre-and post-implementation qualification rates to determine if the agents improve cleaning efficacy.

Furthermore, the system facilitates data sharing with hospital infection control departments and clinical departments. Infection control teams can access real-time endoscope cleaning data for risk assessments, while clinical departments review cleaning records to enhance diagnostic safety confidence. This establishes a multi-department collaborative management mechanism that drives continuous improvement in endoscope cleaning quality control.

4. Strategies for optimizing the application of the tracing system in endoscopic diagnosis and treatment centers in the cleaning process of endoscopes

4.1. Improve the functional design of the traceability system

Hospitals should optimize traceability system functions by integrating endoscope cleaning process characteristics

to enhance system adaptability. At the foundational level, the system must strengthen coordination with cleaning equipment and monitoring instruments, enabling automatic data collection and quality monitoring results transmission to reduce manual input and minimize human errors. An "abnormal process interception" feature should be implemented, such as locking the interface when operators proceed to cleaning without completing pre-treatment, ensuring workflow integrity. For extended functionality, a quality alert module should be added with historical data-based thresholds. When endoscope cleaning qualification rates fall below specified thresholds consecutively, the system should automatically trigger alerts to management for timely intervention. Additionally, mobile operation terminals supporting QR code scanning and data upload via smartphones or tablets could be developed to accommodate multi-station scenarios in endoscopy centers, improving operational convenience [4]. Furthermore, secure data storage must be ensured through encryption technology and regular backups to prevent information loss or leakage, guaranteeing stable system operation.

4.2. Strengthen systematic application training for operators

Operators' proficiency in the traceability system directly impacts its effectiveness. Targeted training programs should be implemented with tiered approaches. New employees must complete specialized system operation training covering core functions like barcode scanning, data entry, and alert handling, supplemented by simulated scenario drills to ensure independent operation. Current staff should regularly participate in system update training. For instance, when a new quality alert module is added, they should promptly learn to identify and address warning messages to avoid operational difficulties caused by unfamiliarity. The training adopts a "theory + practice + assessment" model, theoretical lectures explain system design principles and operational standards, practical exercises are conducted in real work environments with technical guidance, and assessments combine written tests with hands-on evaluations to ensure operators meet competency requirements before independent use. Additionally, a system support mechanism should be established. Select experienced operators as "technical experts" to assist colleagues with operational issues in daily work, fostering a collaborative learning environment to enhance overall system proficiency.

4.3. Establishing a quality assessment mechanism for system applications

Hospitals should establish a quality assessment mechanism for traceability system applications, conducting regular evaluations of the system's effectiveness in endoscope cleaning quality control to facilitate continuous optimization. The evaluation team, comprising the head of the Endoscopy Diagnosis and Treatment Center, infection control department staff, and system technicians, must define clear assessment criteria covering data entry completeness, early warning response timeliness, and quality improvement outcomes. Data entry accuracy must exceed 95%, with response times strictly controlled within 30 minutes. The evaluation combines quarterly inspections and random spot checks. During routine inspections, system data is analyzed to assess indicator compliance. Random spot checks involve randomly selecting endoscopes to compare system records with actual cleaning conditions, verifying data authenticity. Based on evaluation results, system implementation strategies are adjusted: when data entry accuracy falls below standards, simplify procedures due to cumbersome operations; if quality improvements show limited effectiveness, verify system functionality aligns with quality control requirements and make necessary enhancements. Collect operator and management feedback on system usability, including interface convenience and functional practicality, to inform optimization strategies and ensure the traceability system consistently meets endoscope cleaning quality control needs.

5. Conclusion

The Endoscopy Diagnosis and Treatment Center Traceability System provide an information-based, intelligent solution for endoscope cleaning quality control. By standardizing operational procedures, enhancing quality monitoring, and improving management efficiency, it addresses the shortcomings of traditional quality control methods. This system serves as a critical technical support to ensure endoscope cleaning quality and reduce hospital infection risks. Existing issues such as non-standard operations and delayed supervision in endoscope cleaning quality control can be gradually addressed through optimized application of the traceability system. Hospitals should continue to enhance system functionalities, strengthen staff training, and establish evaluation mechanisms to fully leverage the technical value of the traceability system. This will elevate endoscope cleaning quality control to higher standards, solidify the foundation for endoscopic diagnosis and treatment safety, and contribute to the continuous improvement of hospital infection prevention systems.

Disclosure statement

The authors declare no conflict of interest.

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