Healthcare Risk Management and Countermeasures of Clinical Medical Laboratory Testing

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Abstract: Clinical laboratory test-data report is not only an important basis for clinical diagnosis and treatment, but also an important medical evidence. However, at present, in clinical practice, there is a general situation that the medical test-data report have no pay necessary attention in medicine evidence. As a result, in cases of medical malpractise disputes, the medical test-data report often becomes the evidence of litigation against the hospital. This study aims to analyze the healthcare risks in clinical medical laboratory testing and propose effective risk management strategies. The article first identifies key risk points in clinical medical laboratory testing, including risks before, during, and after testing, as well as other related risks. It then discusses existing issues in healthcare risk management, such as non-standardized testing processes, inadequate risk warning mechanisms, and insufficient credibility of test results. Based on these analyses, the article puts forward targeted management strategies, including standardizing testing processes, improving warning mechanisms, and enhancing the credibility of test results. The purpose of this study is to enhance the safety and accuracy of clinical medical laboratory testing, reduce healthcare risks, and ensure patient safety.

Keywords: Clinical Medical Laboratory Testing; Healthcare Risk Management; Risk Prevention; Quality Mangement to Test

1. Introduction

In the current healthcare system, clinical medical laboratory testing plays a crucial role, but issues related to risk management during the process still require significant attention. The accuracy of medical testing directly affects the effectiveness of clinical diagnosis and treatment decisions; thus, ensuring the safety and reliability of the testing process is a core aspect of healthcare quality management. This study focuses on the analysis of risk factors and management strategies in clinical medical laboratory testing, aiming to provide theoretical support for risk control and quality improvement in medical practice. By analyzing potential risk points in the testing process and proposing corresponding management strategies, this article aims to contribute to the overall level of clinical medical laboratory testing and patient safety.

2. Risk Factors in Clinical Medical Laboratory Testing

2.1 Risks Before Testing

In chronological order, the pre-test procedure begins with the clinician's application and ends at the initiation of the test application, patient preparation, original sample collection, transfer of the specimen to the laboratory, delivery within the laboratory and pretreatment of the specimen. The risks primarily arise from sample collection, processing, and transportation in the pre-testing phase, example: (1) Error collectong information about patient to be test. Therefore, it is necessary to strictly check the object information sucha as the name, gender, age, bed number, hospitalization number, test item, sample type, sampling time and method ect. (2) Standardize and correctly take testing samples and submit for inspections. The accuracy of sample collection is fundamental to ensuring the quality of testing, and improper collection methods may lead to sample contamination or deterioration, affecting the accuracy of test results. For example, if the aseptic operation principles are not followed during the collection of blood samples, bacterial contamination may occur. Incorrect labels or identification information can lead to sample confusion, while inappropriate storage conditions may cause biochemical changes or cell rupture. Similarly, sample transportation is critical, as unstable transportation conditions, such as temperature fluctuations and vibrations, may pose a threat to the stability of sensitive samples (such as certain cells and enzymes). Additionally, patient

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preparation is an important component of pre-testing risks. Insufficient patient preparation, such as improper dietary and medication restrictions, can significantly impact test results. (3) Time of inspection. In clinical practice, testing specimens have the timeliness requirements of emergency detection and routine time testing. Because test results are the important basis for clinicians to make diagnosis and treatment decisions, and emergency test is in the first line of emergency diagnosis and treatment, which is an important link to rescue urgent, critical and severe patients. If emergency examination is treat with a general test or routine test, Serious medical damage results of patient should to be occuence by a significant delay in clinical diagnosis and treatment. In general, the specimens should be transferred to the laboratory within 2h after sampling, and special specimens such as cerebrospinal fluid specimens should be tested within 1h. Some specimens cannot be tested in time due to special reasons, and should be properly preserved. Delayed processing of blood samples for glucose testing may result in sugar decomposition, affecting the results. (4) Handover and pretreatment of the inspection laboratory . The key issue is how to control and prevent specimen contamination and confusion. Therefore received laboratory samples shall be pretreated and mixed, and the analytical samples shall be obtained by appropriate shrinkage. The quantity of analytical samples should generally meet the needs of testing, re-examination or confirmation and sample retention. If the sample for measurement uncertainty evaluation is required, the number of analyzed samples shall be increased. Preparation of analytical samples should be performed in independent regions. Use clean sample preparation tools and containers to avoid leakage and contamination. Analytical samples and samples are sealed in clean plastic bags or inert containers. Add the sample identification and keep them in the specified temperature environment. In a few words, strengthening management in the pre-testing phase, from technical operations to patient guidance, is crucial for ensuring the quality of testing [1].

2.2 Risks During Testing

Risks during testing mainly involve the accuracy of equipment, the selection of testing methods, and the skills and experience of operators. The performance of equipment directly affects the accuracy and reliability of test results, and regular maintenance and calibration of equipment are crucial to ensuring its proper operation. Lack of appropriate maintenance may lead to incorrect instrument readings, affecting result accuracy. The selection of testing methods is also crucial, as different methods may result in differences in result interpretation due to variations in sensitivity, specificity, and applicability. Choosing methods suitable for specific samples and testing purposes is the foundation for ensuring the accuracy of test results. Furthermore, the professional skills and experience of operators are essential for ensuring the correctness of the testing process. Non-standardized technical operations, such as errors in operating procedures or inadequate contamination control, may lead to result deviations or errors. Ensuring standardized operations and continuous training of personnel during the testing process are key to reducing risks and enhancing the quality of testing.

The core of the above content is the quality control and quality management of the inspection laboratory. How to reduce the relevant risks in the testing process, Firstly, The Laboratory personnel should strictly abide by the operating procedures, strictly implement the inspection system and the review system, and have a scientific style of seeking truth from facts. Secondly, Strengthen the study of basic theories, basic skills and basic operations. In particular, the working principle of various analytical instruments and the selected methodology principles and their influencing factors should be understood thoroughly. The parameters of the instrument correctly, the calibrate the sensitivity of the instrument and grasp the reaction linear relationship is the key to good quality control. Thirdly, implement a three-level (daily, first-level, two-level) maintenance system for inspection instruments, with s pecial personnel regularly, check and correct to improve accuracy and precision and reduce system errors. Fourthly, Strictly grasp the quality of reagents, calibration fluid and quality control products. Reagent quality: Before use, the reagent, paper, dye, antiserum, and identification cards (bacteria) must be checked; the sterility of each batch and its ability to support microbial growth when used the finished medium supplied by the manufacturer. Control (calibrator): Control (calibrator) must be measured as in the patient specimen; when using new controls, repeat testing to determine the statistical parameters of each batch in the room (such as mean, standard deviation, coefficient of variation, etc.). Fively, the experimental methods with good linear relationship, high sensitivity, strong specificity and good stability are selected. After methodology changes, standard product (or quality control product) must be used to verify: qualitative test, negative and positive control test shall be done; quantitative test, quality control test at least once per batch operation shall include at least two different control product or standard. Sixth, Establish the system of critical value reinspection and reporting. Pay close attention to the critical value of the test results, and check and verify it immediately once it occurs. After indeed, we should mat and report with clinicians as soon as possible to remind clinicians to pay attention to and extract specimens again for review.

2.3 Risks After Testing

Risks after testing mainly involve the interpretation, reporting, and subsequent communication and archiving of

test results. Accurate interpretation of test results is crucial to ensuring appropriate treatment for patients, as incorrect interpretations may lead to misdiagnosis or missed diagnosis. For the readings of specific biochemical indicators, the overall clinical situation of the patient, including medical history, symptoms, and other relevant test results, must be considered. Furthermore, the timeliness and accuracy of test reports are critical to clinical decision-making, and any delays or errors may impact the timeliness and appropriateness of patient treatment. Report formats should be clear and understandable, avoiding terms or abbreviations that may cause misunderstandings. Regarding the communication of test results, ensuring accurate and error-free information is conveyed to relevant healthcare professionals is crucial, as communication barriers may lead to treatment delays or errors. Finally, the management of archived test results is a key aspect. A robust and reliable archiving system is essential not only for the subsequent treatment and tracking of patients but also as a part of legal and quality control requirements. Therefore, establishing a sound data management and archiving system to ensure the security, integrity, and traceability of information is an important measure to reduce risks after testing.

Finally, general specimens should be retained for 24 hours, and special specimens should be retained for 72 hours. The report requires no alteration and no pollution, and the inspector, the reporter and the auditor have their own responsibilities.

2.4 Other Risks

In addition to risks before, during, and after testing, there are other risks in clinical medical laboratory testing that may involve ethical, legal, and quality control aspects. For instance, patient privacy and data protection are crucial ethical and legal issues. Strict privacy protection regulations must be followed when handling and transmitting test data to prevent the leakage of patient information. Additionally, the quality control of reagents and materials used in testing is also an important factor in ensuring test accuracy. The use of expired or substandard reagents may result in inaccurate test results, impacting clinical judgment. In terms of quality control, regular quality assessments and calibration of testing equipment, reagents, and methods are the foundation for ensuring test quality. Faced with the increasing demand for testing and the challenges of technological advancements, continuous education and training are crucial for testing personnel to update their knowledge and skills, enabling them to adapt to emerging testing technologies and methods and effectively reduce the risks associated with outdated technology or improper operation.

3. Clinical Medical Laboratory Testing Healthcare Risk Management Issues

3.1 Lack of Standardization system in Medical Testing Practices

It should be noted that in recent years, the national health administration has issued a series of documents and standards regulating the laboratory inspection capacity and improving the quality management level. For instance, Basic Standard and Management Specification of Medical Laboratory (Trial,2016), Administrative Measures for Clinical Gene Amplification Test Laboratory in Medical Institutions(2020), Expert consensus on the standardization of the transport and preservation of clinical test samples(2023), However, clinical laboratory laboratories still lack the technical standard system to ensure the accuracy of the test data in nation.

In the field of clinical medical laboratory testing, non-standard practices in actual operations manifest in several ways: (1) Standard Operating Procedures (SOP) in the testing process may be incomplete or not strictly enforced. For instance, some laboratories may overlook crucial steps in the operation process, such as the proper handling and storage of samples, leading to reduced sample quality or distorted test results. (2) Calibration and maintenance of testing equipment may not meet prescribed standards, directly affecting the reliability of test results. Uncalibrated instruments may introduce errors, leading to diagnostic mistakes. (3) Issues exist in the training and qualification certification of testing personnel; some may lack sufficient professional training or fail to regularly update their knowledge and skills, impacting their operational accuracy and judgment. (4) Insufficient quality control of testing materials and reagents is also a critical issue, as the use of substandard or non-compliant reagents directly affects the accuracy of test results.

3.2 Need for Improvement in Risk Warning Mechanisms

Firstly, the risk monitoring and assessment system is insufficient; many medical testing institutions lack effective risk assessment tools and methods, unable to promptly identify and respond to potential risk factors, such as equipment malfunctions, operational errors, or changes in the external environment. Secondly, information feedback and communication mechanisms are not smooth; in certain situations, testing personnel may fail to promptly report abnormal conditions or potential risks, or senior management may not effectively respond to and address this information. Additionally, cross-departmental collaboration in risk warning mechanisms is not effective enough; insufficient information exchange between the testing department and clinical departments may lead to misunderstandings or delayed handling of test results. Finally,

continuous risk education and training are lacking, resulting in testing personnel having inadequate awareness of the importance of risk identification and management, and a lack of necessary risk awareness and coping abilities[2].

3.3 Strengthening the Credibility of Test Results

The credibility of clinical medical laboratory test results currently faces challenges in several aspects. Firstly, there is an issue of accuracy and consistency in test results. Due to differences in instrument standardization, operating procedures, and personnel technical proficiency, the same test item in different laboratories may yield varying results, reducing trust in test results by patients and clinical physicians. Secondly, different testing personnel may interpret the same result differently, especially in certain subjective judgment-required test items, such as pathological examinations. Additionally, delayed reporting of test results may result in delayed clinical decisions, affecting the timeliness of patient treatment. Finally, transparency and traceability of test results are crucial factors. A lack of transparent and traceable testing processes raises doubts among patients and healthcare professionals regarding the credibility of test results.

4. Strategies for Healthcare Risk Management in Clinical Medical Laboratory Testing

4.1 Standardizing Clinical Medical Laboratory Testing Practices

Standardizing clinical medical laboratory testing practices requires ensuring that all operational processes follow strict Standard Operating Procedures (SOPs). This means that every step, from sample collection and processing to final analysis and reporting, should be strictly executed according to established standards. In the sample collection stage, emphasis should be placed on using correct techniques and equipment to ensure sample quality. For example, during blood collection, attention must be given to the aseptic operation of the blood collection needle, the accuracy of blood volume collection, and appropriate specimen storage conditions. In the processing phase, special attention should be paid to cross-contamination and proper storage methods to ensure the biological integrity and analytical suitability of the samples. During the testing process, the key is to use accurately calibrated instruments and validated reagents. This includes regular maintenance and calibration of all instruments to prevent reading errors caused by aging instruments. Additionally, the use of high-quality reagents and consumables is crucial for ensuring the accuracy of experimental results. For instance, using standardized and validated chemical reagents can significantly reduce the impact of chemical composition variations on test results. Lastly, regular technical and theoretical training should be conducted to ensure that testing personnel can accurately and effectively execute testing processes and adapt to the introduction of new technologies and methods. For example, employees should receive specialized training in the operation and maintenance of newly introduced automated testing equipment to ensure their effective use [3].

4.2 Improving Risk Warning Mechanisms

To enhance the risk warning mechanisms in clinical medical laboratory testing, a series of comprehensive measures must be taken to strengthen the identification, assessment, and response capabilities to potential risks. Firstly, establishing a comprehensive risk assessment system is crucial. This involves continuous monitoring and evaluation of potential risks at each stage of the testing process. For example, regular assessments of instrument performance, sample processing procedures, and data management systems can help identify risk factors that may lead to errors or inaccurate test results. Secondly, developing an efficient risk reporting and feedback mechanism is essential for timely identification and handling of risks. This includes encouraging testing personnel to promptly report any abnormal situations and ensuring that management can take appropriate measures quickly to mitigate risks. For instance, establishing a clear and concise online reporting system can facilitate the rapid circulation and handling of risk information. Additionally, utilizing advanced data analysis tools to enhance risk prediction capabilities is a key aspect of improving warning mechanisms. Analyzing historical test data can help identify risk patterns and predict potential issues, allowing for preventive measures to be taken. For example, applying machine learning algorithms to analyze large amounts of test data can help discover abnormal patterns that may lead to inaccurate results. Lastly, regular training and education of testing personnel in risk management are essential to enhance their abilities in risk identification, reporting, and response.

4.3 Enhancing the Credibility of Test Results

Ensuring transparency and traceability in the testing process can be achieved through the implementation of a comprehensive recording and reporting system. This includes detailed documentation of every step of the testing process, including operations and the use of reagents and instruments. Transparent operational processes and comprehensive records facilitate not only auditing and quality control but also provide credible evidence for test results. Secondly, regular validation

and quality control checks of testing equipment and methods are essential to ensure the accuracy and consistency of the testing process. Participating in external quality assessment programs and implementing internal quality control measures can effectively monitor and maintain the standardized level of the testing process. Additionally, strengthening professional training and continuous education for testing personnel ensures their ability to accurately interpret and report test results. Improving professional knowledge and skills helps reduce operational errors and misunderstandings, ultimately enhancing the accuracy of test results. Effective communication with clinical physicians is a key aspect of boosting the credibility of test results. Through efficient communication, testing personnel can provide necessary explanations and recommendations, aiding clinical physicians in correctly understanding and applying test results. Furthermore, building and maintaining trust from patients and the public regarding testing services is crucial for enhancing the credibility of test results. This requires continuous improvement in service quality, ensuring the timeliness and accuracy of test results, and enhancing public understanding and trust through open and transparent communication strategies [4]. Implementing these comprehensive strategies can effectively enhance the credibility of test results, fostering trust from both patients and clinical physicians in testing services.

At present, internal quality control (IQC) and external quality control (EQC) have been became an important measure and quality assurance for testing data management. IQC is to detect the patient sample, while the known results or already calibrated quality control test, through the quality control results to know whether the patient sample results are accurate. Interventricular quality control is established on the basis of IQC, EQC is to rely on the clinical laboratory outside the ministry of health clinical inspection center and provinces, city, unified to the hospital laboratory quality control test, and report the test results to the organizer, the ministry of health clinical inspection center and provincial, municipal clinical inspection center for unified analysis of the quality of the laboratory. On the basis of routine work, IQC and EQC are conducted to monitor the stability of the system. Through the quality control system, the precision of the test results, the combined capability comparison (PT) experiment can indirectly evaluate the accuracy of the test results. Therefore, the development of IQC and EQC has strongly promoted and greatly promoted the quality improvement of the hospital laboratory, which fully shows the importance of carrying out quality control and ensuring the quality of the laboratory.

5. Conclusion

By delving into the healthcare risk management of clinical medical laboratory testing, this paper emphasizes the importance of establishing a comprehensive risk management framework to improve testing quality and ensure patient safety. Core strategies include standardizing operational processes, strengthening risk warning mechanisms, and enhancing the credibility of test results. Implementing these measures not only relies on the optimization of technology and equipment but also necessitates professional training and effective communication and collaboration among personnel. In the future, risk management in the field of clinical medical laboratory testing will continue to face new challenges. However, through continuous efforts and improvements, significant advancements can be made in the quality of medical services, safeguarding the health and well-being of patients.

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