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Analysis of Blind Sample Testing Results in Beijing-Tianjin-Hebei-Shandong Medical Testing Recognition and Implications for Baoding's Testing Recognition Work

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Abstract: This study conducts a systematic analysis of blind sample testing for medical testing result recognition in the Beijing-Tianjin-Hebei-Shandong region during 2022-2024. Through comprehensive data collection from Baoding and Xiong'an New Area, statistical analysis of testing results reveals an overall pass rate of 92.5%. Non-conforming items were primarily concentrated in biochemical testing and immunological testing. The study identifies testing equipment precision, reagent quality, and operational standardization as main factors contributing to non-conformance. Based on the analysis results, improvements are suggested in quality control system construction and testing result standardization, providing reference for advancing regional testing result recognition work.

Keywords: Testing result recognition; Blind sample testing; Quality control; Homogenization; Regional cooperation

Introduction

The Beijing-Tianjin-Hebei-Shandong region, as an important area for China's economic and social development, faces increasingly prominent issues such as uneven distribution of medical resources and heavy burden of cross-regional medical treatment. To achieve efficient integration of medical resources and improve the efficiency of medical insurance fund utilization, the region actively promotes clinical testing result recognition among medical institutions. Baoding and Xiong'an New Area, as important components of this region, actively participate in and promote this process. Through in-depth analysis of recent blind sample testing results in the region, this study aims to provide scientific basis and practical suggestions for Baoding's testing result recognition work.

1. Analysis of Blind Sample Testing Results in Beijing-Tianjin-Hebei-Shandong Region

1.1 Data Collection and Organization

This study employed systematic data collection methods to comprehensively gather basic information from medical institutions participating in testing result recognition work in Baoding and Xiong'an New Area from 2022 to 2024. The collected content covered important parameters including testing equipment manufacturers, model specifications, reagent types, batch numbers, and calibrator information. Detailed records were kept of specific methodologies used for testing items, laying a solid foundation for subsequent data analysis[1].

During data organization, the research team, leveraging the professional advantages of Baoding Clinical Laboratory Quality Management and Control Center, systematically organized and classified blind sample testing results, establishing complete data archives. Through classification of testing results, conforming and non-conforming items were grouped, with in-depth analysis conducted on specific causes of each non-conforming item[1]. Special attention was paid to improvement measures proposed by medical institutions for non-conforming items, summarizing these measures to provide important reference for subsequent improvement work.

1.2 Analysis of Testing Results

Based on blind sample testing data statistics from 2022-2024, medical institutions in Baoding and Xiong'an New Area achieved an overall pass rate of 92.5% in testing result recognition work, reflecting significant progress in laboratory quality control.

Classification analysis of non-conforming items shows: biochemical testing items accounted for 35.2% of total non-conformance, mainly involving routine testing indicators such as liver function, kidney function, and electrolytes, with coefficients of variation exceeding allowable ranges for items like ALT, creatinine, potassium ions, and total calcium; immunological testing items accounted for 28.6%, primarily in thyroid function and tumor marker testing, showing high dispersion in external quality assessment results; blood

cell analysis items accounted for 21.3%, mainly reflecting systematic errors in white blood cell differential counting and platelet counting; coagulation test items accounted for 14.9%, with significant fluctuations in indicators such as prothrombin time and activated partial thromboplastin time.

Longitudinal comparison analysis of testing data between 2022 and 2023 shows that after active improvement by medical institutions, the number of non-conforming items showed a clear downward trend, decreasing from 7.8% in 2022 to 5.2% in 2023. This improvement trend was particularly evident in biochemical and immunological testing items, indicating that quality improvement measures adopted by medical institutions in these areas have achieved positive results.

Regional distribution analysis of testing results shows that tertiary hospitals in urban areas generally have higher pass rates than county-level hospitals, reflecting a clear correlation between medical institution grade and testing quality level. For various non-conforming items detected, the research team and quality control center expert group jointly developed targeted improvement plans, including equipment performance optimization, reagent quality control, and operational procedure revision, providing feasible suggestions for continuous improvement of testing quality.

1.3 Analysis of Non-conforming Item Causes

Through systematic analysis of non-conforming testing results in Baoding and Xiong'an New Area during 2022-2024, causes of abnormal results show multiple characteristics. Testing equipment accuracy and precision issues accounted for 32.5% of non-conformance causes, manifesting as non-standardized equipment calibration and performance verification, poor measurement repeatability, and inadequate equipment maintenance, leading to unreliable testing data.

Reagent quality issues accounted for 28.7% of non-conformance causes, mainly involving large batch-to-batch variations, reagent performance degradation due to improper storage conditions, and improper temperature control during reagent transportation, causing systematic bias in testing results. Improper calibrator use accounted for 21.3%, specifically manifesting as lack of traceability in project calibration (different manufacturers for equipment, reagents, and calibrators), insufficient calibration curve verification, and poor control of calibration cycles, directly affecting testing accuracy.

Operational standardization issues among testing personnel accounted for 17.5%, specifically including improper sample handling, non-strict execution of operational procedures, and errors in quality control result interpretation, reflecting shortcomings in personnel training and assessment at some medical institutions. Notably, data shows these issues are more prominent in primary healthcare institutions, accounting for approximately 65% of such problems.

Assessment of quality management systems at various medical institutions revealed issues such as weak quality control awareness, incomplete management systems, and inadequate implementation of quality monitoring measures. These management-level deficiencies show significant positive correlation with non-conformance rates in testing results, indicating that institutional management level has important influence on testing quality.

2. Implications for Baoding's Testing Result Recognition Work

2.1 Strengthening Quality Control System Construction

Based on identified issues, quality control system construction in Baoding medical institutions should focus on optimization and upgrading from multiple dimensions. It is recommended that medical institutions construct layered, comprehensive quality control networks, establishing dedicated quality management positions within laboratory departments responsible for daily quality monitoring and assessment work, ensuring effective implementation of quality control measures[2].

Regarding equipment management, a complete equipment performance assessment system should be established, implementing equipment performance verification after installation, replacement of key components, and equipment relocation, evaluating key indicators such as precision, accuracy, and linear range, and establishing equipment maintenance archives. For reagent and calibrator management, reagent acceptance systems should be established, performing performance verification on new batch reagents, strictly controlling reagent storage conditions, and standardizing calibrator usage procedures[3].

Professional capability improvement of testing personnel is particularly important. It is recommended to develop systematic training plans, regularly organize technical operation training, quality control knowledge training and assessment, and establish training archives to achieve traceability of training effects. Quality control record management should be informatized, establishing quality control data analysis systems for real-time monitoring and statistical analysis of quality control results, promptly identifying and resolving issues.

2.2 Promoting Testing Result Standardization and Homogenization

Standardization and homogenization of testing results are core foundations for achieving regional testing result recognition, requir-

ing standardized construction throughout the testing process. Regarding methodology selection, medical institutions are recommended to adopt internationally recognized standard testing methods, with method validation required for non-standard methods to ensure result comparability[4].

In reference interval establishment, traceability of reference intervals should be ensured, with intervals sourced from industry standards, expert consensus, testing operation procedures, or reagent instructions, prioritizing industry standards or expert consensus recommended intervals, and conducting reference interval verification. Expression of testing results should be unified, including measurement units, decimal places, and reference interval representation methods, avoiding understanding deviations caused by inconsistent expression.

Standardization of reporting systems is equally important. It is recommended to develop unified testing report templates, standardizing presentation of report content, including display methods for key information such as item names, testing methods, equipment information, and reference intervals. Through information systems, testing data should be standardized to achieve data interoperability and sharing, providing technical support for regional testing result recognition.

2.3 Strengthening Regional Cooperation and Information Sharing

Construction of regional cooperation and information sharing mechanisms is an important guarantee for advancing testing result recognition work. Currently, Baoding has initiated internal quality control and external comparison work for biochemical projects, and on this basis, can establish regular cooperation and exchange mechanisms across the four regions, regularly organizing professional technical seminars to exchange quality control experiences and jointly solve technical difficulties encountered in testing result recognition.

Regarding information platform construction, regional testing information sharing networks should be constructed to achieve testing data interconnection and interoperability. Platform functions should cover core functions such as testing result upload, query, and statistical analysis, establishing data quality monitoring mechanisms to ensure accuracy and reliability of shared data. Meanwhile, platforms should have real-time warning capabilities for prompt notification and handling of abnormal data[5].

In cooperation mechanisms, regional testing quality control expert groups can be established to regularly conduct regional external quality assessment activities, organize technical training and experience exchange, promoting overall improvement of regional testing quality. Through establishing mutual assistance relationships, promotion of quality medical resource sharing can be achieved, realizing balanced development of regional testing medical standards.

2.4 Improving Policy Support and Incentive Mechanisms

Policy support and incentive mechanisms are important driving forces for sustainable development of testing result recognition work. It is recommended that local governments incorporate testing result recognition work into key medical reform work, developing specific policies that clarify work objectives, implementation steps, and safeguard measures, providing institutional guarantees for recognition work.

Regarding funding support, special funds should be established to support medical institutions in improving testing equipment conditions, conducting personnel training, and participating in external quality assessment activities. Scientific assessment and evaluation systems should be established, incorporating testing result recognition work completion into medical institution performance assessment indicators, linking with medical insurance payment and grade evaluation to form effective incentive and constraint mechanisms[6].

In talent cultivation, it is recommended to establish special reward funds to recognize and reward medical institutions and individuals with outstanding performance in testing result recognition work, stimulating medical staff's enthusiasm for participation in recognition work. Meanwhile, establish testing talent training bases to provide further education opportunities for primary healthcare institutions, promoting construction of professional testing talent teams.

3. Conclusion

Through systematic blind sample testing and analysis, testing result recognition work in the Beijing-Tianjin-Hebei-Shandong region reveals problems and shortcomings in laboratory quality control among regional medical institutions. Research shows significant correlation between medical institution grade and testing quality level, with operational standardization issues particularly prominent in primary healthcare institutions. Technical factors such as testing equipment precision and reagent quality management, along with systematic factors including quality control awareness and management systems, jointly affect testing result accuracy. Strengthening quality control system construction, promoting testing result standardization, and deepening regional cooperation will effectively improve testing result recognition work quality, promoting medical resource sharing and balanced development. Through establishing and improving policy support and incentive mechanisms, continuous advancement of testing result recognition work can be promoted.

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