RESEARCH PAPER

Effect Of A Structured Educational Intervention On Reducing False-Positive Hepatitis C Virus Screening Results: A Multi-Center Quasi-Experimental Study In Saudi Arabia

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Abstract

Background: False-positive results in hepatitis c virus (hcv) screening remain a critical challenge, particularly in low-prevalence settings where the positive predictive value of serological assays is reduced. These inaccuracies can lead to unnecessary confirmatory testing, increased healthcare costs, and psychological distress.

Methods: A multi-center quasi-experimental pre–post study was conducted across five healthcare institutions in arar city. Laboratory technicians underwent a six-month structured educational program focusing on diagnostic techniques, quality control, and result interpretation. False-positive cases were extracted from laboratory records before and after the intervention. Chi-square analysis was used.

Results: False-positive cases decreased from 22 pre-intervention to 9 post-intervention, representing a 59% reduction. The reduction was statistically significant ($p < 0.05$), indicating improved diagnostic accuracy.

Conclusion: Structured training significantly improves diagnostic performance. Workforce development and quality systems are essential for optimizing hcv screening accuracy.

Keywords: Hepatitis C Virus, False-Positive Results, Diagnostic Accuracy, Laboratory Training, Quality Control.

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Introduction:

Hepatitis C Virus (HCV) infection remains a major global public health concern, contributing significantly to chronic liver disease, cirrhosis, and hepatocellular carcinoma (Manns & Maasoumy, 2022). Despite substantial advances in antiviral therapy, early and accurate diagnosis remains essential for effective disease control, prevention of transmission, and achievement of global elimination targets (WHO, 2023).

Serological screening assays, including enzyme immunoassays (EIA) and chemiluminescent immunoassays (CLIA), are widely used for the initial detection of HCV infection due to their high sensitivity and operational feasibility (Li et al., 2021). However, these assays are associated with false-positive results, particularly in low-prevalence settings, where the positive predictive value of screening tests is reduced (Geretti et al., 2021). In such contexts, the positive predictive value declines despite high test specificity, resulting in a disproportionately higher proportion of false-positive results. These inaccuracies may lead to unnecessary confirmatory testing, increased healthcare costs, delays in clinical decision-making, and psychological distress among patients.

In Saudi Arabia, the epidemiology of HCV has shown a declining trend in recent years, reflecting improvements in public health interventions and screening programs (Almajid et al., 2024). While this decline represents a positive public health achievement, it also amplifies the relative impact of false-positive results within screening programs. In low-prevalence populations, even a small number of false-positive results can significantly affect the efficiency, cost-effectiveness, and credibility of diagnostic services. Therefore, improving diagnostic accuracy has become a critical priority within the national healthcare system.

Laboratory-related factors play a central role in determining the accuracy and reliability of HCV diagnostic testing. These include technician competency, adherence to standard operating procedures, and the implementation of internal quality control (IQC) and external quality assurance (EQA)

systems (Aleman et al., 2020). Previous studies have identified variability in laboratory practices and highlighted the need for strengthening quality management systems. However, there remains limited empirical evidence evaluating the direct impact of structured educational and training interventions on reducing diagnostic errors, particularly false-positive results, in real-world clinical settings.

Therefore, this study aims to evaluate the effect of a structured educational and training intervention on the false-positive rate of HCV screening tests in Arar City, Saudi Arabia. By focusing on laboratory workforce development and quality improvement, this study provides practical evidence to enhance diagnostic accuracy and supports national and global efforts toward the elimination of HCV as a public health threat by 2030.

Literature Review:

Hepatitis C Virus (HCV) infection remains a significant global health challenge, despite major advances in antiviral therapy and diagnostic technologies. The World Health Organization (WHO, 2023) estimates that millions of individuals are living with chronic HCV infection, with a substantial proportion remaining undiagnosed. Early detection through accurate screening is essential for effective disease control and for achieving global elimination targets.

Serological assays, including enzyme immunoassays (EIA) and chemiluminescent immunoassays (CLIA), are widely used as first-line screening tools due to their high sensitivity and operational feasibility (Li et al., 2021). However, these assays are associated with false-positive results, particularly in low-prevalence settings where the positive predictive value of screening tests is inherently reduced (Geretti et al., 2021). In such contexts, even highly specific tests may yield a considerable proportion of false-positive results, leading to unnecessary confirmatory testing and inefficient use of healthcare resources.

Several studies have highlighted that false-positive HCV results are influenced by both analytical and non-analytical factors. Analytical factors include assay characteristics, cross-reactivity, and technical variability, while non-analytical factors include laboratory practices, sample handling, and operator proficiency (Huang et al., 2021). Importantly, laboratory personnel play a critical role in ensuring diagnostic accuracy, particularly in the interpretation of borderline or weakly reactive results.

In low-prevalence countries such as Saudi Arabia, the impact of false-positive results is more pronounced. Epidemiological studies have reported declining HCV prevalence rates in the region, reflecting successful public health interventions (Almajid et al., 2024). However, as prevalence decreases, the proportion of false-positive results relative to true-positive cases increases, which may compromise the efficiency and credibility of screening programs.

To address these challenges, international guidelines emphasize the importance of confirmatory testing using nucleic acid amplification techniques, such as reverse transcription polymerase chain reaction (RT-PCR), to distinguish true infection from false-positive serological results (WHO, 2023). While confirmatory testing improves diagnostic accuracy, it also increases costs and delays in clinical decision-making, highlighting the need to minimize false-positive results at the screening stage.

Quality management systems, including internal quality control (IQC) and external quality assurance (EQA), are essential components of reliable laboratory diagnostics. Previous studies have demonstrated that adherence to standardized protocols and participation in EQA programs significantly improve laboratory performance and reduce diagnostic errors (Aleman et al., 2020). However, variability in the implementation of these systems remains a persistent challenge, particularly in resource-limited or decentralized healthcare settings.

Educational and training interventions have been proposed as effective strategies to enhance laboratory performance. Training programs that focus on technical skills, quality assurance practices, and result interpretation have been shown to improve diagnostic accuracy and reduce error rates in laboratory settings (O'Donnell et al., 2022). Despite this, there is limited empirical evidence specifically evaluating the impact of such interventions on reducing false-positive HCV screening results.

Most existing studies have focused on test performance characteristics or epidemiological outcomes, with relatively few addressing the role of human factors, such as technician competency and training, in influencing diagnostic accuracy. This represents a critical gap in the literature, as laboratory errors are often linked to operational and procedural factors rather than inherent test limitations.

Therefore, this study contributes to the existing body of knowledge by evaluating the effectiveness of a structured educational and training intervention in reducing false-positive HCV screening

results in a real-world clinical setting. By focusing on both laboratory practices and diagnostic outcomes, the study provides practical insights into improving screening accuracy, particularly in low-prevalence environments. These findings are highly relevant for optimizing laboratory performance and supporting national and global HCV elimination strategies.

Methodology:

Research Design and Setting

A multi-center quasi-experimental pre–post study design was employed to evaluate the impact of a structured educational and training intervention on the false-positive rate of Hepatitis C Virus (HCV) screening tests. This design enabled direct comparison of diagnostic performance before and after the intervention, allowing assessment of its effectiveness in improving laboratory accuracy under real-world conditions.

The study was conducted in Arar City, located in the Northern Borders Region of Saudi Arabia, a key healthcare hub serving the surrounding population. The research setting comprised five major public healthcare institutions actively involved in HCV screening and diagnostic services: Prince Abdulaziz Bin Musaed Hospital, Northern Medical Tower Hospital, Maternity and Children Hospital, the Northern Border Regional Laboratory, and the Central Blood Bank. These institutions represent the primary centers responsible for HCV testing, blood safety, and disease surveillance in the region.

All participating facilities utilize standardized HCV diagnostic protocols, including serological screening using enzyme-linked immunosorbent assays (ELISA) and chemiluminescent immunoassays (CLIA), followed by confirmatory testing using reverse transcription polymerase chain reaction (RT-PCR). Laboratory practices are supported by internal quality control (IQC) procedures and varying levels of participation in external quality assurance (EQA) programs.

Educational and Training Intervention

A structured six-month educational and training intervention was implemented to enhance laboratory diagnostic accuracy. The program was designed and delivered by the principal investigator in collaboration with a senior laboratory quality specialist.

The intervention consisted of multiple components:

Theoretical sessions: Covering HCV epidemiology, diagnostic principles, sensitivity and specificity, and sources of false-positive results

Hands-on laboratory training: Focused on proper test execution, sample handling, and adherence to standard operating procedures

Workshops on quality management: Emphasizing internal quality control (IQC) and external quality assurance (EQA) practices

Result interpretation training: Targeting the identification and management of weakly reactive or borderline results

Continuous feedback and supervision: Provided throughout the intervention period to reinforce best practices

Participants were laboratory technicians directly involved in HCV testing across the five participating institutions. The intervention aimed to improve technical competency, standardize laboratory practices, and reduce diagnostic errors, particularly false-positive results.

Research Instrument

Data were collected using a structured data extraction tool specifically designed to evaluate the false-positive rate of HCV screening tests and assess the impact of the intervention on diagnostic accuracy.

The instrument captured laboratory-based diagnostic data during both pre- and post-intervention phases and included key variables such as:

- Total number of HCV screening tests performed
- Number of reactive (positive) screening results
- Number of confirmed positive cases based on RT-PCR
- Number of false-positive cases

False-positive results were defined as reactive serological test results not confirmed by nucleic acid testing (RT-PCR), in accordance with international diagnostic standards.

Data Collection

Data were collected using a structured pre–post approach. Laboratory records were retrospectively reviewed for two defined phases: the pre-intervention period, representing baseline diagnostic practices, and the post-intervention period following completion of the six-month training program.

Data were obtained from laboratory information systems, including serological screening records and confirmatory molecular testing reports. Only records with complete linkage between screening and confirmatory results were included to ensure accurate classification of false-positive cases.

Data analysis

All data were cleaned and validated prior to analysis to ensure accuracy and consistency. Records were reviewed for completeness, duplication, and logical errors. Data were initially organized using Microsoft Excel and subsequently analyzed using SPSS version 26 (IBM Corp., Armonk, NY, USA).

The primary outcome variable was the proportion of false-positive HCV screening results. Descriptive statistics were used to summarize the data, including frequencies and percentages.

To evaluate the effectiveness of the intervention, a Chi-square test was used to compare the proportion of false-positive results between pre- and post-intervention phases. This test was appropriate due to the categorical nature of the outcome variable. Statistical significance was set at $p < 0.05$.

Results:

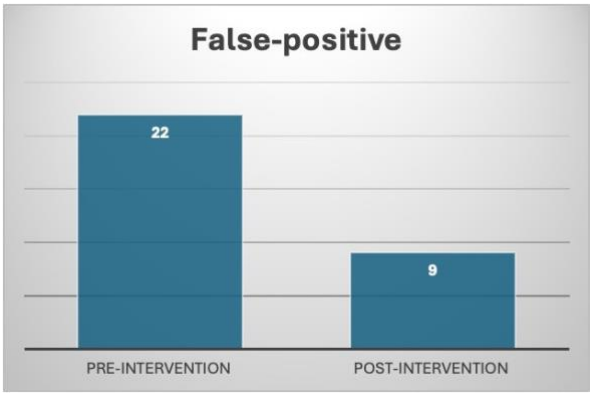

Figure 1: Reduction in False-Positive HCV Screening Results Before and After Educational Intervention

Figure 1 presents a comparison of false-positive Hepatitis C Virus (HCV) screening results before and after the implementation of the educational and training intervention. In the pre-intervention phase, a total of 22 false-positive cases were recorded across the participating laboratories. Following the intervention, the number of false-positive cases decreased to 9.

This corresponds to a **59% relative reduction** in false-positive results, indicating a substantial improvement in diagnostic accuracy. The reduction was statistically significant based on Chi-square analysis ($p < 0.05$), demonstrating the effectiveness of the intervention in minimizing diagnostic errors.

Table 1: False-Positive HCV Cases Before and After Intervention

Phase	False-Positive Cases	Reduction (%)
Pre-intervention	22	—
Post-intervention	9	59%

A marked decrease in false-positive HCV screening results was observed following the intervention. The proportion of false-positive cases declined substantially between the pre-intervention and post-intervention phases, reflecting improved diagnostic performance across all participating laboratories.

The statistically significant reduction ($p < 0.05$) suggests that the educational and training program effectively enhanced laboratory practices, particularly in test execution, quality control adherence, and result interpretation. These improvements contributed to minimizing false-positive outcomes, which is particularly critical in low-prevalence settings where diagnostic accuracy directly impacts the efficiency and reliability of screening programs.

Discussion

This study demonstrates that a structured educational and training intervention significantly reduced false-positive Hepatitis C Virus (HCV) screening results in a real-world laboratory setting. The observed 59% reduction represents a meaningful improvement in diagnostic accuracy and underscores the critical role of laboratory workforce competency in minimizing diagnostic errors.

These findings are consistent with existing evidence indicating that false-positive results are more prevalent in low-prevalence settings due to the reduced positive predictive value of serological screening assays (Geretti et al., 2021). In such contexts, even small improvements in test specificity and result interpretation can lead to disproportionately large gains in overall screening efficiency. The present study extends this understanding by demonstrating that targeted training interventions can effectively address this challenge through improvements in laboratory practice rather than changes in diagnostic technology.

The observed reduction in false-positive results is likely multifactorial. First, the intervention enhanced laboratory technicians' understanding of diagnostic principles, including sensitivity, specificity, and the interpretation of borderline or weakly reactive results. Misclassification of such results is a well-documented contributor to false positives, and improved interpretive competency likely played a key

role in reducing these errors. Second, the emphasis on internal quality control (IQC) and external quality assurance (EQA) contributed to greater consistency and standardization across participating laboratories. Strengthening these quality systems is essential for minimizing both random and systematic errors. Third, the hands-on component of the training reinforced adherence to standardized operating procedures, thereby reducing technical variability in test execution.

Importantly, the magnitude of reduction observed in this study (59%) suggests that combined theoretical and practical training approaches may have a substantial impact on diagnostic performance. This finding supports previous research emphasizing the importance of continuous professional development and competency-based training in laboratory medicine (O'Donnell et al., 2022). It also highlights that improvements in human and operational factors can complement technological advancements in diagnostic testing.

The implications of these findings are particularly relevant in the context of Saudi Arabia's low HCV prevalence (approximately 0.3%). In low-prevalence settings, false-positive results disproportionately affect screening outcomes by reducing the positive predictive value and increasing unnecessary confirmatory testing. This not only places an additional burden on healthcare systems but may also lead to patient anxiety and delays in appropriate clinical management. By reducing false-positive rates, the intervention enhances both the clinical effectiveness and cost-efficiency of HCV screening programs.

From a public health perspective, improving diagnostic accuracy is a critical component of efforts to achieve the World Health Organization's target of eliminating HCV as a public health threat by 2030. Accurate laboratory results are essential for reliable surveillance, timely case identification, and effective linkage to care. Reducing false-positive results also helps maintain public trust in screening programs, which is vital for sustained participation and program success.

This study contributes to the existing literature by providing empirical evidence on the effectiveness of structured training interventions in improving diagnostic accuracy within routine clinical practice. Unlike previous studies that have primarily focused on assay performance characteristics, this research highlights the importance of human and system-level factors in laboratory diagnostics. It demonstrates that targeted, context-specific interventions can produce measurable improvements in diagnostic outcomes.

However, several limitations should be considered. The quasi-experimental design without a control group limits the ability to establish causal relationships definitively. Additionally, the study was conducted within a single geographic region, which may affect the generalizability of the findings. Variations in laboratory infrastructure and baseline competency levels across institutions may also have influenced the observed outcomes. Future research should consider multi-center randomized designs and longer follow-up periods to further validate and sustain these findings.

Conclusion

This study demonstrates that a structured educational and training intervention can significantly enhance the accuracy of Hepatitis C Virus (HCV) screening by reducing false-positive results in routine laboratory practice. The observed decrease in false-positive cases from 22 in the pre-intervention phase to 9 post-intervention, representing a 59% reduction, provides strong evidence of the effectiveness of targeted training in improving diagnostic performance.

These findings highlight the pivotal role of laboratory personnel competency and adherence to standardized quality control practices in minimizing diagnostic errors. In low-prevalence settings, where false-positive results disproportionately affect screening efficiency and resource utilization, such improvements are particularly critical. Strengthening continuous professional development, alongside robust internal quality control (IQC) and external quality assurance (EQA) systems, is essential to ensure sustained gains in diagnostic accuracy.

From a broader perspective, this study underscores that workforce-focused interventions are a practical and scalable strategy for optimizing laboratory performance without requiring changes in diagnostic technology. Integrating structured training programs into routine laboratory practice can enhance the reliability of HCV screening, reduce unnecessary confirmatory testing, and support cost-effective healthcare delivery.

In conclusion, enhancing laboratory capacity through targeted educational interventions represents a key component of effective HCV control strategies and contributes meaningfully to national and global efforts toward the elimination of HCV as a public health threat.

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