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“BRIDGING THE GAP BETWEEN HEALTHCARE AND IT: ROLE OF QMS AND HIS IN INDIAN HEALTHCARE”

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ABSTRACT:

The rapid digitalization of healthcare has increased the adoption of Hospital Information Systems (HIS) to enhance efficiency, data management, and patient care. However, many healthcare facilities, particularly small and medium-sized hospitals, struggle with effective implementation and sustained use of these systems due to operational, financial, and organizational challenges. This study examines the role of Quality Management Systems (QMS) in supporting successful HIS adoption and bridging the gap between technology and practice in Indian healthcare settings.

A mixed-methods research design was used, combining primary data collected from 25 healthcare facilities with secondary literature on technology adoption and healthcare quality standards. Statistical analysis, including Chi-square and ANOVA tests, was conducted to assess relationships between facility characteristics, IT budgets, and system integration levels. The findings reveal a significant digital divide, with tertiary hospitals demonstrating higher levels of HIS integration compared to primary and secondary facilities. Financial constraints, lack of training, poor system integration, and workflow misalignment were identified as key barriers to adoption.

The study highlights that aligning QMS practices—such as standard operating procedures, training, audits, and risk management—with the HIS lifecycle significantly improves adoption outcomes and operational stability. Based on these insights, a structured framework is proposed to guide healthcare organizations in implementing HIS more effectively. The study contributes to both theory and practice by integrating quality management principles with technology adoption models and offers actionable recommendations for policymakers, healthcare administrators, and solution providers to enable scalable, affordable, and sustainable digital transformation.

Keywords: Hospital Information Systems (HIS), Quality Management Systems (QMS), eQMS, Healthcare Digital Transformation

1. INTRODUCTION:

The rapid digital transformation of healthcare systems has increased the adoption of **Hospital Information Systems (HIS)** to improve efficiency, data management, and patient care outcomes. HIS integrates clinical, administrative, and financial functions, enabling hospitals to streamline workflows and support evidence-based decision-making. However, despite significant investments in digital health technologies, many healthcare facilities struggle to achieve effective and sustained utilization of these systems. Common challenges include poor data quality, user resistance, inadequate training, workflow mismatches, and lack of standardized processes, which ultimately limit the expected benefits of digitalization.

A critical yet often overlooked factor in successful HIS adoption is the role of **Quality Management Systems (QMS)**. QMS provides a structured framework encompassing standard operating procedures (SOPs), training and competency management, internal audits, corrective and preventive actions (CAPA), and risk management. When aligned with digital systems, QMS ensures consistency, accountability, and continuous improvement in healthcare processes. In the absence of such governance mechanisms, HIS implementations often remain fragmented, leading to operational inefficiencies and increased risk during and after system deployment.

The importance of aligning QMS with HIS is particularly relevant in the Indian healthcare context, where national initiatives such as the **Ayushman Bharat Digital Mission (ABDM)** are accelerating the adoption of interoperable digital health infrastructure. While these initiatives create opportunities for improved data exchange and healthcare delivery, they also impose new requirements for standardization, compliance, and process readiness. Many hospitals, especially small and medium-sized facilities, adopt HIS modules in isolation without adequately preparing workflows, training staff, or establishing governance structures, thereby widening the gap between technological capability and practical implementation.

This study addresses this gap by examining how QMS practices can support the effective adoption and sustained use of HIS across different stages of the system lifecycle, including selection, configuration, testing, go-live, and monitoring. Drawing on established technology adoption frameworks, the research investigates key factors influencing user acceptance and organizational readiness while incorporating contextual elements such as resource availability, regulatory environment, and vendor support.

The study aims to develop a structured understanding of the relationship between quality management practices and HIS adoption outcomes, with a focus on real-world healthcare settings. By identifying key barriers and enablers, it seeks to provide practical insights and actionable recommendations for healthcare administrators, quality managers, and policymakers to improve digital adoption, reduce implementation risks, and enhance the overall quality and reliability of healthcare service.

2. LITERATURE REVIEW:

The adoption of digital technologies in healthcare, particularly **Hospital Information Systems (HIS)** and electronic Quality Management Systems (eQMS), has accelerated globally as part of broader digital health transformation efforts. International studies highlight that HIS improves efficiency, data accessibility, and coordination of care, while eQMS supports compliance, patient safety, and continuous quality improvement (World Health Organization, 2019; Markets and Markets, 2024). However, successful implementation depends not only on technology availability but also on organizational readiness and user acceptance.

Technology adoption in healthcare is commonly explained using models such as the **Technology Acceptance Model (TAM)** and the **Unified Theory of Acceptance and Use of Technology (UTAUT)**. These models emphasize that perceived usefulness, ease of use, social influence, and facilitating conditions significantly influence user intention and actual system usage (Venkatesh et al., 2025). In hospital settings, these factors are further shaped by workflow complexity, clinical risk, and the need for coordination across departments. Therefore, user acceptance alone is insufficient without strong organizational support and governance mechanisms.

To address organizational and environmental influences, the **Technology–Organization–Environment (TOE)** framework is widely used. TOE explains that adoption is determined by technological characteristics, organizational readiness (such as resources, leadership, and training), and external factors including regulation and vendor support (Press Information Bureau, 2024). In the Indian context, national initiatives such as the Ayushman Bharat Digital Mission (ABDM) have strengthened the regulatory and infrastructural environment, encouraging healthcare providers to adopt interoperable digital systems. However, these developments also increase the need for standardized processes, data governance, and compliance mechanisms.

Despite policy support, several studies highlight persistent barriers to HIS adoption, particularly in low- and middle-income settings. Common challenges include high implementation costs, lack of technical expertise, resistance to change, workflow disruptions, and concerns related to data privacy and security (Ahmed et al., 2023; Sharma & Gupta, 2022). Fragmented systems and poor interoperability further limit the effectiveness of digital solutions, resulting in manual workarounds, data duplication, and inefficiencies in service delivery.

Quality Management Systems (QMS) play a critical role in addressing these challenges by providing structured governance for healthcare processes. QMS frameworks formalize key practices such as standard operating procedures (SOPs), training and competency management, internal audits, corrective and preventive actions (CAPA), and risk management. Studies show that well-implemented QMS is associated with improved patient safety, process consistency, and organizational performance (RINA, 2023). In digital environments, these practices help ensure data quality, accountability, and compliance.

The adaptation of ISO 9001 to healthcare through EN 15224 further strengthens the relevance of QMS by incorporating clinical risk, patient safety, continuity of care, and evidence-based practice into quality standards. These principles align closely with digital workflows in HIS, including clinical documentation, diagnostics, medication management, and discharge processes. Integrating QMS with HIS implementation can therefore reduce risks during system deployment and support stable, long-term use (TÜV NORD, 2024).

Change management literature also emphasizes the importance of structured implementation strategies for HIS adoption. Effective approaches include stakeholder engagement, workflow redesign, phased implementation, and continuous training (HealthIT.gov, 2014). Without these elements, digital systems may introduce new risks such as documentation burden, workflow disruption, and user dissatisfaction. Governance mechanisms, supported by QMS practices, are essential to mitigate these risks and ensure sustainable adoption.

In addition, concerns related to data security and trust play a significant role in adoption decisions. Standards such as ISO/IEC 27001 and frameworks like SOC 2 provide guidance on managing data security, confidentiality, and system reliability. Integrating these standards with QMS enhances organizational confidence in digital systems and supports compliance with regulatory requirements.

3. RESEARCH GAP:

Although existing literature extensively discusses technology adoption models and quality management practices independently, there is limited research examining their **integrated role in HIS adoption**, particularly in the Indian healthcare context. Most studies focus on user perceptions or technological factors, with less attention to governance mechanisms and their timing across the HIS lifecycle.

Furthermore, evidence on how QMS practices can be systematically aligned with different stages of HIS implementation—such as selection, configuration, testing, and monitoring—remains limited, especially in resource-constrained settings. This gap is more pronounced in small and medium-sized healthcare facilities, where adoption challenges are more severe.

4. OBJECTIVE OF THE STUDY:

The primary objective of this study is to examine the gap between healthcare operations and digital system adoption, and to evaluate the role of Quality Management Systems (QMS) in improving the adoption and effective use of Hospital Information Systems (HIS).

Specific Objectives:

1. To identify key challenges and barriers affecting the adoption of HIS and eQMS in small and medium-sized healthcare facilities.
2. To analyze the mismatch between existing healthcare workflows and available digital system functionalities.
3. To assess the influence of organizational, financial, and operational factors on HIS adoption.
4. To evaluate how QMS practices—such as standard operating procedures, training, audits, and risk management—impact system adoption and usage.
5. To develop practical, scalable recommendations and a structured framework to support effective and sustainable HIS implementation in resource-constrained settings.

5. PROBLEM STATEMENT:

Small and medium-sized healthcare facilities, including Primary and Secondary Healthcare Centers, face significant challenges in adopting and effectively using Hospital Information Systems (HIS) and electronic Quality Management Systems (eQMS). Despite the availability of digital solutions, these institutions continue to rely on fragmented systems and manual processes, resulting in incomplete documentation, inefficient workflows, delayed decision-making, and poor audit readiness.

The core issue lies in the mismatch between available technology solutions and the practical needs of resource-constrained settings. High implementation costs, lack of structured training, limited technical support, connectivity issues, and absence of standardized processes hinder successful adoption. Additionally, inadequate alignment between Quality Management System (QMS) practices and HIS implementation further reduces system effectiveness and sustainability.

This creates a persistent gap between digital capability and real-world utilization, particularly in smaller healthcare settings, limiting the overall impact of digital transformation initiatives.

6. METHODOLOGY:

6.1 Research Design

This study adopts a **mixed-methods research design**, combining both quantitative and qualitative approaches to examine the adoption of Hospital Information Systems (HIS) and the role of Quality Management Systems (QMS) in healthcare settings. The approach enables a comprehensive understanding of both measurable trends and real-world operational challenges.

6.2 Study Setting and Scope

The study focuses on **Primary Healthcare Centers (PHCs), Secondary Healthcare Centers (SHCs), and small hospitals**, particularly those with limited financial and technical resources. The scope includes key operational departments such as registration/ADT, laboratory services (LIS), pharmacy, and billing, along with associated QMS practices like document control, training, audits, and risk management.

6.3 Data Collection Methods

6.3.1 Primary Data

Primary data was collected through:

- **Structured questionnaires** (10–15 items)

- **Short interviews** with healthcare staff and managers

The survey captured:

- Perceived usefulness and ease of use of systems
- Training and support availability
- System usage and integration levels
- Key operational challenges

A sample of **25 respondents** from different healthcare facilities participated in the study.

6.3.2 Secondary Data

Secondary data was gathered from:

- Government reports (digital health policies)
- Quality standards (EN 15224, ISO guidelines)
- Published research on HIS adoption and healthcare IT

This helped in validating findings and building a theoretical foundation.

6.4 Sampling Technique

A **purposive sampling method** was used to select respondents who are directly involved in healthcare operations and digital system usage, ensuring relevant and practical insights.

6.5 Data Analysis Techniques

Quantitative data was analyzed using **SPSS software**, applying:

- **Descriptive Statistics** (frequencies, percentages)
→ To understand respondent profile and system usage patterns
- **Chi-Square Test**
→ To examine the relationship between level of care and system integration
- **ANOVA (Analysis of Variance)**
→ To assess differences based on IT budget and facility type

Qualitative responses from interviews were analyzed using **thematic analysis** to identify common patterns and key issues.

6.6 Variables and Indicators

- **Dependent Variables:**
 - HIS adoption and system integration level
- **Independent Variables:**
 - IT budget
 - Facility type and level of care
 - Training and support availability
 - QMS practices (SOPs, audits, risk management)

6.7 Ethical Considerations

- Participation was **voluntary and anonymous**
- No patient data was collected
- Responses were used strictly for academic purposes

6.8 Limitations of the Study

- Small sample size (25 respondents)
- Limited to specific geographic region
- Short study duration

7. DATA ANALYSIS AND DISCUSSION:

Phase 1: Descriptive Statistics (The "What"):

This phase profiles your sample and provides a high-level overview, addressing your objective to identify the current gap and pain points.

Test Name	SPSS Menu Path	Purpose & Variables
Frequencies	Analyze > Descriptive Statistics > Frequencies	To understand the profile of your respondents. Generate frequency tables and bar charts for: -Type of Facility -Level of Care provided by the Hospital -Estimated IT budget

Type of Facility:

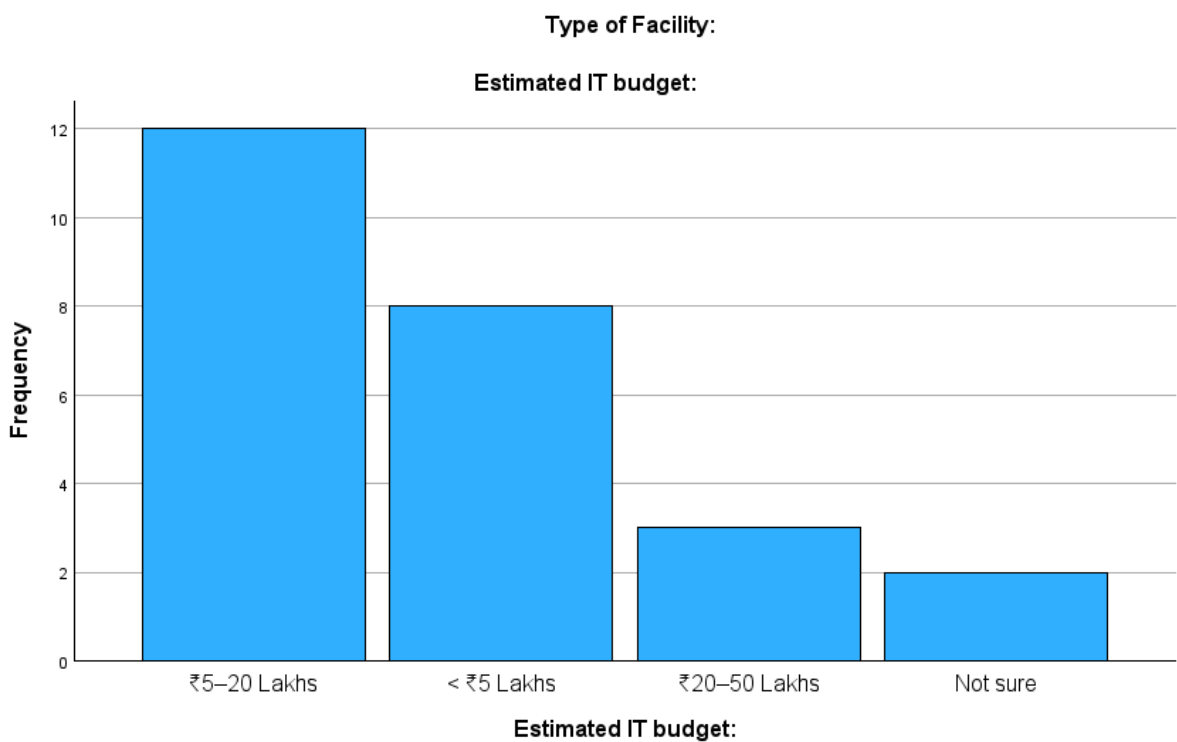
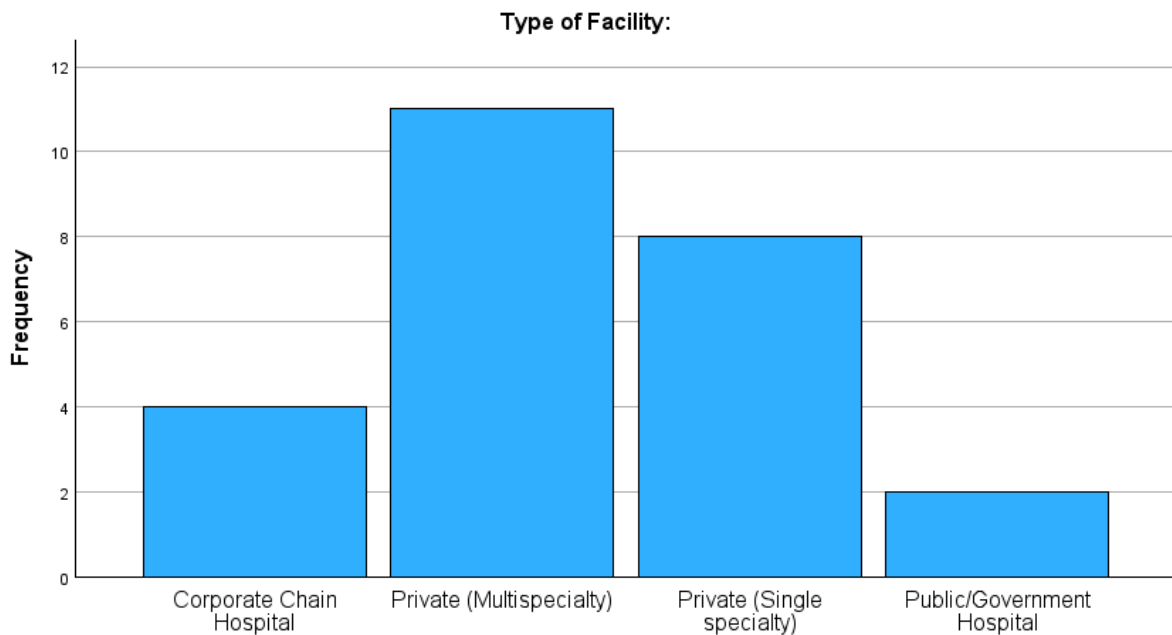
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Corporate Chain Hospital	4	16.0	16.0	16.0
	Private (Multispecialty)	11	44.0	44.0	60.0
	Private (Single specialty)	8	32.0	32.0	92.0
	Public/Government Hospital	2	8.0	8.0	100.0
	Total	25	100.0	100.0	

Level of Care provided by the Hospital:

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Primary Healthcare Centre (PHC: ~6 beds)	10	40.0	40.0	40.0
	Secondary Healthcare Centre (SHC: ~30 beds)	9	36.0	36.0	76.0
	Tertiary Healthcare Centre (THC:100+ beds, often >500)	6	24.0	24.0	100.0
	Total	25	100.0	100.0	

Estimated IT budget:

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	₹5–20 Lakhs	12	48.0	48.0	48.0
	< ₹5 Lakhs	8	32.0	32.0	80.0
	₹20–50 Lakhs	3	12.0	12.0	92.0
	Not sure	2	8.0	8.0	100.0
	Total	25	100.0	100.0	



Phase 2: Bivariate Analysis (Exploring "Relationships"):

This phase tests for significant associations between different variables, addressing your objective to understand why small centres struggle with adoption.

Test Name	SPSS Menu Path	Purpose & Variables
Crosstabs with Chi-Square Test	Analyze > Descriptive Statistics > Crosstabs	<p>To determine if there is a statistically significant association between two categorical variables. This is the core of your analysis. Test key hypotheses such as:</p> <p>Hypothesis 1: Smaller facilities have lower levels of system integration. - Variables: Level of Care (Rows) vs Are these systems integrated... (Columns).</p> <p>Hypothesis 2: Facilities with lower budgets report more issues related to "Lack of support/training." -Variables: Estimated IT budget (Rows) vs. a dummy variable for the "Lack of support/training" issue (Columns).</p> <p>Hypothesis 3: The type of integration barrier is related to the facility type. - Variables: Type of Facility (Rows) vs. a dummy variable for "Budget" as a barrier (Columns).</p>

Case Processing Summary:

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Level of Care provided by the Hospital: * Are these systems integrated with your core HIS?	25	100.0%	0	0.0%	25	100.0%

Level of Care provided by the Hospital: Are these systems integrated with your core HIS? Crosstabulation

Count

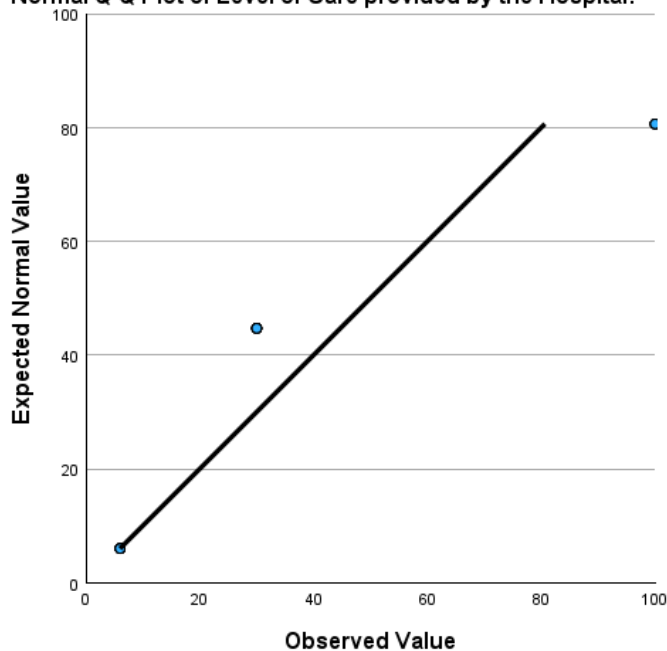
		Are these systems integrated with your core HIS?				Total
		All are standalone	Not sure	Some are integrated; some are standalone	Yes – All major systems are integrated	
Level of Care provided by the Hospital:	Primary Healthcare Centre (PHC: ~6 beds)	2	2	5	1	10
	Secondary Healthcare Centre (SHC: ~30 beds)	0	2	5	2	9
	Tertiary Healthcare Centre (THC:100+ beds, often >500)	0	0	0	6	6
Total		2	4	10	9	25

Chi-Square Test:

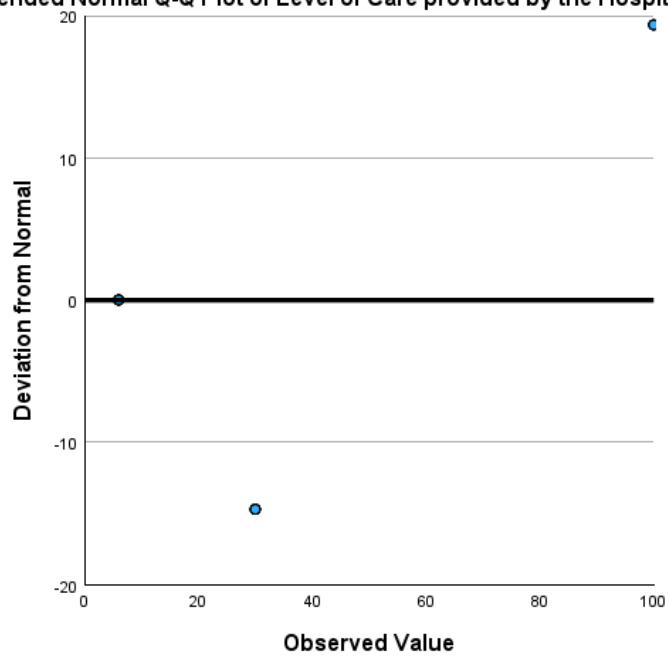
	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	16.651 ^a	6	.011
Likelihood Ratio	19.156	6	.004
N of Valid Cases	25		

a. 12 cells (100.0%) have expected count less than 5. The minimum expected count is .48.

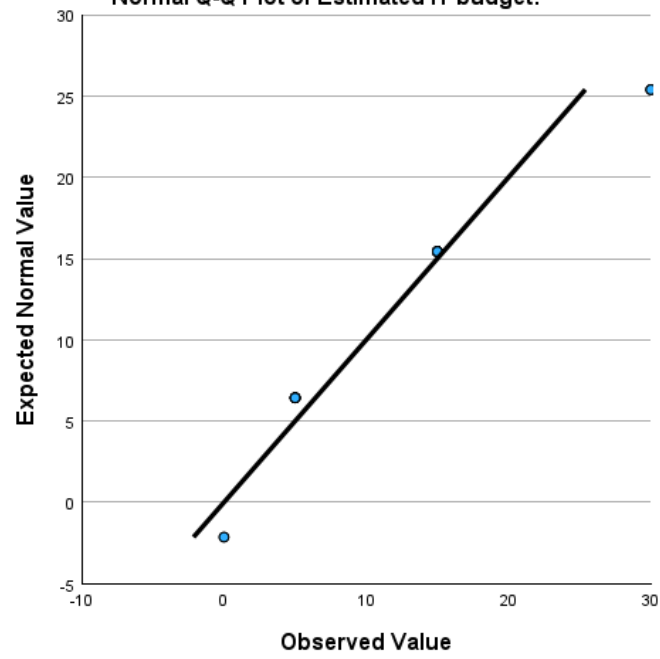
Normal Q-Q Plot of Level of Care provided by the Hospital:

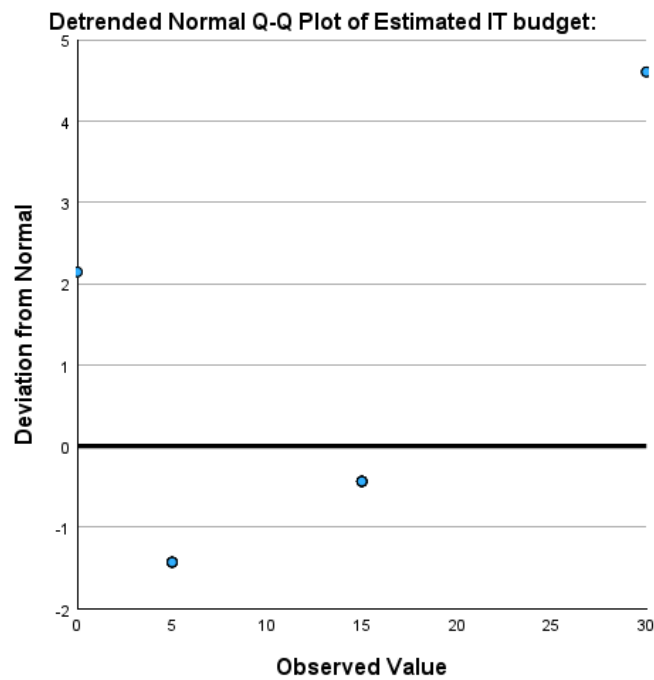


Detrended Normal Q-Q Plot of Level of Care provided by the Hospital:



Normal Q-Q Plot of Estimated IT budget:





ANNOVA TEST
Dependent List: Level Of Care
Factor Affecting: It Budget

ANOVA

Level of Care provided by the Hospital:					
	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	17154.833	3	5718.278	7.187	.002
Within Groups	16709.167	21	795.675		
Total	33864.000	24			

ANOVA Effect Sizes^{a,b}

		Point Estimate	95% Confidence Interval	
			Lower	Upper
Level of Care provided by the Hospital:	Eta-squared	.507	.117	.652
	Epsilon-squared	.436	-.009	.603
	Omega-squared Fixed-effect	.426	-.009	.593
	Omega-squared Random-effect	.198	-.003	.327

a. Eta-squared and Epsilon-squared are estimated based on the fixed-effect model.

b. Negative but less biased estimates are retained, not rounded to zero.

8. MAJOR LEARNING AND CONTRIBUTION:

8.1 Major Learning

This study provided key insights into the practical challenges associated with the adoption of Hospital Information Systems (HIS) in resource-constrained healthcare settings. One of the primary learnings is that **technology implementation alone is insufficient** to achieve effective digital transformation. The success of HIS depends significantly on the alignment between system functionalities and existing healthcare workflows.

The findings highlight that **financial limitations, lack of structured training, and inadequate technical support** are major barriers, particularly in primary and secondary healthcare facilities. Additionally, the study reveals that **fragmented system adoption**, where different modules operate independently, leads to inefficiencies such as duplication of work, poor data flow, and reduced operational effectiveness.

A critical learning from this research is the importance of **Quality Management Systems (QMS)** in supporting digital adoption. Practices such as standard operating procedures (SOPs), training, internal audits, and risk management play a vital role in ensuring consistency, accountability, and system reliability. The absence of these governance mechanisms contributes to implementation failures and limits the long-term sustainability of digital systems.

The study also underscores the existence of a **digital divide across levels of care**, with tertiary hospitals demonstrating higher levels of system integration compared to smaller healthcare facilities. This disparity is largely influenced by differences in financial capacity, infrastructure, and organizational readiness.

8.2 Contributions of the Study

This study makes both **theoretical and practical contributions** to the field of healthcare management and digital health adoption.

8.2.1. Theoretical Contribution

The research extends existing technology adoption literature by integrating **Quality Management Systems (QMS)** with established frameworks such as the Technology Acceptance Model (TAM) and the Technology–Organization–Environment (TOE) framework. While prior studies have examined technological and user-related factors, this study emphasizes the role of **governance mechanisms and process standardization** in influencing HIS adoption outcomes.

8.2.2. Empirical Contribution

The study provides **primary evidence from Indian healthcare settings**, particularly focusing on small and medium-sized facilities that are often underrepresented in research. It highlights real-world challenges such as limited IT budgets, system fragmentation, and operational constraints, thereby contributing context-specific insights to the literature.

8.2.3. Practical Contribution

The research offers **actionable recommendations** for healthcare administrators and policymakers, including the need for:

- Affordable and modular HIS solutions
- Structured training programs
- Integration of QMS practices during system implementation

- Improved technical and vendor support

These recommendations can support more effective and sustainable digital transformation in healthcare institutions.

8.2.4. Conceptual Contribution

A key contribution of this study is the proposal of a **structured approach to integrating QMS practices across the HIS lifecycle**, including stages such as system selection, configuration, testing, implementation, and monitoring. This approach provides a practical roadmap for aligning quality management with digital system adoption.

9. CONCLUSION AND RECOMMENDATION:

This study examined the adoption of Hospital Information Systems (HIS) in resource-constrained healthcare settings, with a particular focus on the role of Quality Management Systems (QMS) in improving implementation and usage outcomes. The findings highlight that while digital health technologies are increasingly available, their effective utilization remains uneven across different levels of healthcare delivery.

A significant digital divide was observed, with tertiary healthcare centers demonstrating higher levels of system integration compared to primary and secondary facilities. This disparity is largely influenced by differences in financial capacity, infrastructure, and organizational readiness. Limited IT budgets, lack of structured training, and inadequate technical support were identified as major barriers to adoption, resulting in fragmented systems and inefficient workflows in smaller healthcare institutions.

The study emphasizes that successful HIS adoption extends beyond technological deployment and requires strong governance mechanisms. The integration of QMS practices—such as standard operating procedures, training, audits, and risk management—plays a crucial role in ensuring system reliability, process standardization, and sustainable use. Facilities that align these practices with digital implementation are better positioned to achieve improved operational efficiency and data quality.

By linking empirical findings with established technology adoption frameworks, this study contributes to a more comprehensive understanding of digital transformation in healthcare. It highlights the need for a structured and integrated approach that combines technology, organizational readiness, and quality management practices.

Overall, the study underscores the importance of developing scalable, affordable, and well-governed digital solutions tailored to the needs of small and medium-sized healthcare facilities. Strengthening alignment between QMS and HIS implementation can help reduce operational risks, enhance system adoption, and ultimately improve the quality and consistency of healthcare delivery.

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