Systematic Review of Challenges to ISO 9001 Adoption in Low- and Middle-Income Countries (LIMCs) of Asia

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***Abstract*—ISO 9001:2015 is standard developed by International Organization for Standardization (ISO) for establishing Quality Management System. This system is globally recognized for increasing organizational performance and customer satisfaction. However, the adoption of ISO 9001 is limited within Low- and Middle-Income countries (LIMCs). This paper based on PRISMA systematic review of 21 empirical and conceptual studies focused on finding out the challenges to ISO adoption within LIMCs of Asia published between 2000 to 2025. Nine themes were generated to categorized the challenges pointed out in the studies. The themes are 1) Knowledge and Awareness barriers, 2) Human Capital and Competency constraints, 3) Financial Constraints, 4) Organizational culture and resistance to change, 5) Symbolic Adoption and Superficial implementation of standards,6) Documentation and system formalization challenges, 7) Deficit of Leadership and commitment of top management, 8) Lack of Market and customer demand of certified products, 9) Absence of institutional and Regulatory environment. The findings reveal that the organizational culture and resistance to change was the most common among LIMCs of Asia.**

***Keywords*— ISO 9001:2015, Quality Management System, PRISMA systematic review, Low- and Middle-Income Countries, Adoption challenges**

I. BACKGROUND

ISO 9001 is globally accepted international standard developed by International Organization of Standardization (ISO), a worldwide federation of national standards bodies for Quality Management Systems. It offers a systematic model that allows organizations to consistently produce products and services that satisfy the needs of the customers and regulatory authorities and improve customer satisfaction by continually improvement, risk based thinking and process approach [1]. The standard has seven Quality Management Principles: customer focus, leadership, people engagement, process approach, improvement, evidence-based decision making, and relationship management that a combination of them, enables organizations to attain sustainable performance excellence[2].

ISO 9001:2015 standard specifies the requirements for establishing, implementing and maintaining of Quality Management System (QMS) through continual improvement. This requires organization to meet the customer and regulatory requirement. It focusses on leadership commitment, planning for addressing risk and opportunity, identification and documentation of external and internal context of organization, establishment of Quality policy with well aligned objectives, availability of resources for operation, performance evaluation through internal audit and planning for continual improvement [1]

This standard is generic in nature and could be applied to any organizations regardless of size, sector or type. This universally recognized framework for establishing Quality Management System has demonstrated its remarkable benefits across wider contexts including Customer Satisfaction[3],Competitive Advantages[4], Improving efficiency and Productivity [5], [6],employee engagement, supplier management, better documentation and knowledge and overall organizational performance [7].

This diverse, collective benefits of these standards support organizations in strengthening their performance whilst positioning themselves in frontline in global markets showcasing their commitment to international quality standards. More the guideline, framework also serve as an essential tool for Government, industry and consumers in

achieving United Nation Sustainable development goals[8].

Low- and middle-income countries (LIMCs) are the nations classified by World Bank based on their Gross National Income (GNI) per capita. For the fiscal year 2026 World Bank based on the calculation using World Bank Atlas method has identified low economies countries with GNI $1,135 or less in 2024, and middle-income economies with GNI per capita between $1,136 and $4,495[9]. This includes countries like Afghanistan, Yemen, Bangladesh, Bhutan ,India, Nepal, Pakistan, Sri Lanka, Cambodia, Laos, Myanmar, Philippines, Timor-Leste, Vietnam, Kyrgyz Republic, Tajikistan, Uzbekistan, Jordan, Lebanon of Asia [9].

The change in nature of trade, emergence of global value chain in trade has supported producers from such countries to be integrated in global economics dynamics. Among various supporting factors, a study on role of Volunteer Standards on sustainability and better trade has highlighted the role of voluntary standards like ISO 9001 to enhance the credibility, safety reliability of their products with reduction in information symmetries and to overcome the traditional market barriers [10]. However, adoption of such standard can represent a significant compliance burden for small and resource constraints enterprises of LIMCs. The cost associated of implementation, monitoring, certification, limited technical capacity, weak support system may hinder the small producers from competing with firms in developed countries.

ISO 9001 as driver for global competitiveness suggests that business from developing countries (the South) can progressively narrow down the gap with the developed countries (the north) by advancing their technology and management system. Here ISO 9001 could serve as a form of self-regulation to comply with international standards and increase an organization's effectiveness to drive into global competition. Evidences supports that ISO 9001 positively influences global trade by increasing the export performance of developing countries [11]. Research from developing countries has also suggested that policymakers from developing nations need to prioritize ISO adoption as it will facilitate to enter into global value chain and ultimately contribute to broader economic growth [12].

Despite of the huge potential of QMS for the organizational development, LIMCs countries have their own unique struggle in terms of social, economic, cultural, regulatory, infrastructural and so on. These challenges can undermine the potential of QMS on economic growth. Further there is gap in comprehensive analysis that integrates multifaceted challenges specific to LIMCs countries. By systematically identifying and analysing these challenges this study aims to provide evidence-based insights and practical recommendation to enhance QMS in LIMCs context. The finding of the study will support policymakers, organizations, national as well as international agencies in preparing strategic quality improvement plan for enhancing trade and competitiveness. Ultimately this study aims to bridge the knowledge gaps and contribute in finding out the practical barriers that may be common to LIMCs.

II. OBJECTIVES

The primary objective if this systematic review are:

1. To determine the major challenges that impact the adoption and implementation of ISO 9001 in low- and middle-income countries (LIMCs) of Asia.
2. To categorize and group these challenges into broad thematic groups and establish their rankings within industries and nations.
3. To formulate evidence-based recommendations to aid policymakers and organizations to enhance the success of the adoption of ISO 9001 in the socio-economic environment of Asian LIMCs.

III. RESEARCH METHODOLOGY

a. Review Design

This method adopted a systematic review method to analyze and integrate the critical issues and obstacles involved in the implementation of ISO 9001 in different sectors in low- and middle-income nations (LIMCs) in Asia. The review process was well-structured and transparent and was conducted in line with the Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

b. Information Sources:

Peer-reviewed journal articles, conference proceedings, theses, and trustworthy organizational reports dated between 2000 and 2025 were taken into consideration. Research articles were included

provided that they directly studied the issues about the adoption or implementation of ISO 9001 in Asian LIMCs. Non-Asian studies that were not related to ISO 9001, were not full-text accessible, and did not show adequate methodological clarity were declined. Scopus, Web of Science, and Google Scholar were all used as sources of databases to conduct a literature search. The search strategy involved the use of combinations, such as keywords and Boolean operators, such as: ISO 9001, quality management system, adoption challenges, LMICs, and the names of certain Asian countries. Grey literature was also examined to increase the completeness of evidence base.

c. Eligibility Criteria

The information was systematically analysed and condensed in tabular, where the variables such as authorship, publication, country of study, sector, research methodology, critical challenges to the ISO 9001 adoption, and major findings were obtained. In order to assure methodological rigor, the quality of qualitative studies was evaluated with the help of Critical Appraisal Skills Programme (CASP) checklist, whereas the quality of quantitative studies was evaluated with the help of Joanna Briggs Institute (JBI) appraisal tools. Only those studies that had reached a certain quality burden were incorporated in the final synthesis.

After extraction of Challenges from the reviewed literature, it was categorized to certain theme. The themes were generated using an inductive thematic synthesis approach.

d. Study Selection

56 articles which were focused on identification of challenges or Barriers to implementation of ISO 9001 globally were selected After applying the inclusion and exclusion area and focusing on only to the studies conducted on Low- and middle-income countries in Asia 21articles that met all the requirements were included in final synthesis.

The selection process of the study is shown in a PRISMA flow diagram (Figure 1), which provides the steps of identifying, screening, and eligibility of the studies, and, finally, the inclusion of the studies.

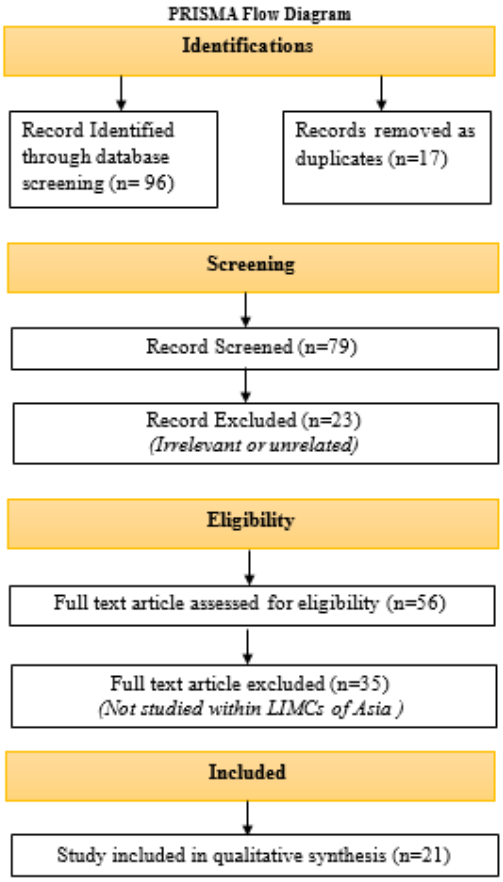

Figure 1: Prisma Flow Diagram

e. Data Extraction and synthesis:

The information with alignment to the objectives of the study were selected and coded out of the chosen study. Systematic method of data extraction was applied for consistency and comparability. The extracted data were analyzed using thematic synthesis method. Based on the similarity of the patterns nine themes were generated as barriers of Quality Management System Implementation in LIMCs country. They were Knowledge and Awareness barriers, Human Capital and Competency constraints, Financial Constraints, Organizational culture and resistance to change, Symbolic Adoption and Superficial implementation of standards, Documentation and system formalization challenges, Deficit of Leadership and commitment of top management, Lack of Market and customer demand of certified products, Absence of institutional and Regulatory environment.

IV. RESULT

The thematic review of the 21 articles finds out the common challenge on ISO adoption among LIMCs

countries. Based on the similarities these challenges were categorized in 9 themes. Among the studies the most frequent challenges that were common was Organizational culture and resistance to change [13], [14], [23]–[27], [15]–[22].

Lack of qualified person, training, technical understanding of QMS requirement was reported as another major challenges in more than 50 % of the studies which were themed under Human Capital and Competency Constraints [13], [15], [29]–[31], [17], [18], [20]–[23], [27], [28]

Similarly Financial Constraints [13], [16], [20]–[22], [25], [30], [32], Lack of Knowledge and Awareness on QMS [14], [16], [17], [19]–[22], [31]–[33], Documentation and System formalization [15], [19], [21], [23], [26], [29], [32], [33]were another challenges reported among LIMCs countries.

Symbolic Adoption and superficial implementation of Standards i.e. gap in real implementation versus the requirement of standards [16], [26], [27], [31], [34], [35], Deficit of Leadership and Commitment from top management [13], [15]–[17], [20], [21], [27], [31] were also reported as challenges in some of the countries.

Also lack of Market and customer demand of certified products resulting in no difference in value of certified and uncertified products were reported in wooden based industries of Malaysia [30] and also Absence of Institutional and Regulatory environment for enforcing quality was reported as challenges over there [30].

V. DISCUSSION

This paper has systematically reviewed 21 peer-reviewed articles to understand the challenges and barriers to adoption of ISO 9001 (Quality Management System) in LIMCSs of Asia.

The findings underscore the co-existence of multiple, interrelated barriers. However, the cultural and resistant to change emerged to be the most frequent one among LIMCs of Asia. This clearly reflects the deeper structural and socio organizational characteristics where certification is perceived as externally imposed requirement in most of the developing countries. Inadequate systematization knowledge and weak participatory management have similarly constrained other developing countries too [36].

Likewise, financial constraints remain other barriers despite of QMS doesn't demand substantial investment; rather reduce operational cost in long run. Implementation cost in less developing countries arises from weak institutional support, limited testing facilities, skilled workers and technology[37]. Orientation of SMEs in LIMCs in short term financial gain [38]but QMS needs certain time for its maturity[39] so do the financial benefits appear gradually [38]. This wrong perception discourages resources allocation towards compliance and continuous improvement.

Lack of proper awareness and understanding of QMS principle is the root for all the reported challenges with respect to knowledge, awareness, documentation competency. Preference of traditional informal mode of working and taking systematization as unnecessarily complex and burdensome linked with cultural traits [40] could be also related to the knowledge gap. And the other major challenges that may be either related with finance, documentation or superficial implementation of QMS is due to lack of its integration in organizational process. The possibility of success of QMS adoption is only when it's fully embedded to existing process rather than viewing it as separate or parallel unit [13].

Hence seamless integration of QMS into organization will reduce the challenges of documentation, system formalization, extra cost and so on [41]. Such symbolic implementation also reflects the absence of value driven leadership. Lack of commitment from leadership emerges a critical mediating factor for all the documented challenges. Besides Absence of Institutional and Regulatory environment was reported in only one article this needs further exploration. Studies like case of Japan [42], Institutional theory [43], adoption of technology[44] , UK Food safety Act (1990) shows shown a significant role of regulatory compliance. The challenges of lack of value of certified products reported within wood industries of Malaysia and Vietnam[30]clearly undermines the lacking regulatory framework to enforce quality and absence of incentives for certification within LIMCs

From a theoretical perspective, these findings illustrate how deeply embedded cultural norms in LMICs can hinder both the adoption and operationalization of international management standards. Practically the results highlight the need of integration of QMS within organizational process. This requires massive awareness on the requirements

as well as benefits of standards, increase competency, promotion of leadership engagement and coordinated effort to address these interrelated barriers.

VI. CONCLUSIONS

A systemic review of 21 empirical and theoretical studies was undertaken with an objective of finding out the major challenges on adoption of ISO 9001:2015 (Quality Management System) within LIMCs of Asia. The thematic analysis generated nine categories of barriers: Knowledge and Awareness barriers, Human Capital and Competency constraints, Financial Constraints, Organizational culture and resistance to change, Symbolic Adoption and Superficial implementation of standards, Documentation and system formalization challenges, Deficit of Leadership and commitment of top management, Lack of Market and customer demand of certified products, Absence of institutional and Regulatory environment. The findings reveal that the organizational culture and resistance to change was the most common among LIMCs of Asia and there are several interconnected and common challenges among diverse sector of LIMCs in Asia.

VII. LIMITATIONS

Despite of the contributions this study has several limitations. Firstly, there is dearth in empirical researches focusing on ISO 9001 adoption in LIMCs of Asia. So, all the country specific research with LIMCs of Asia was not included like there were no Nepal based studies. Second the research was confined within the Peer reviewed articles publish after 2000 to 2025. Third, generation of themes may allow for organizational and institutional dynamics but it doesn't cover the causal inference. This suggests the need of quantitative or mixed method studies to validate and extend these findings.

VIII. RECOMMENDATIONS

Based on the summarized evidence several recommendations are provided to enhance the effective adoption of ISO 9001 in context of LIMCs of Asia. This study urges the need of coordinated interventions. Firstly, policymakers and organization need to prioritize sustainability and quality standards within national economic development strategies. Awareness campaigns at all levels are required for creating value of QMS. Supporting SMEs through training, competency development could help them to integrate QMS in organizational process to increase the effectiveness as well as for overcoming the challenges identified. Investment in local training institution, certification auditors, advisor can reduce dependency on external experts. Finally, regional cooperation among Asian LIMCs will help to overcome the barrier.

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