

Examining the impact of total quality management and regulation on blood production

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CHRONICLE

Article history:

Received: October 15, 2025

Received in revised format: November 15, 2025

Accepted: December 20, 2025

Available online:

December 20, 2025

Keywords:

Total quality management

Regulation

Blood production

Blood Bank

Uganda

ABSTRACT

This study aims to examine total quality management, regulation, and blood production relationships of blood banks in Uganda. A structured questionnaire was used to collect data from 146 randomly selected respondents. The model was validated using Smart PLS-SEM analysis. The findings indicate that both total quality management and regulation have a significant and positive influence on blood production, accounting for a 17.8% variation at a 95% confidence interval. Regulation exhibited no mediation effect in the relationship between total quality management and blood production. Total quality management and regulation are essential factors enhancing blood production. Prioritizing total quality management practices in areas such as determining and meeting customer needs; customer and employee satisfaction surveys; and market research can optimize blood production. This study contributes to the blood bank management knowledge body and identifies areas to support blood production. Blood bank managers can apply these insights to improve operational performance.

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1. Introduction

Blood production plays a vital role in delivering life-saving therapy to patients in need of blood and blood products. In both developed and developing countries, it remains a cornerstone of healthcare, significantly contributing to the survival of patients. However, the increasing complexity of blood production processes has challenged the ability of many countries, especially developing ones to consistently meet blood demand. Patients and healthcare providers alike require easily accessed safe, high-quality blood and blood products, yet persistent uncertainties continue to threaten the stability of blood supply chain systems.

With liminal total quality management and robust regulatory frameworks implementation, blood banks struggle to fulfill their life-saving mandate. Many studies have examined how total quality management and regulatory measures influence blood production, however there remains a knowledge gap particularly concerning their contributions in Uganda.

This study aims to examine total quality management, regulation, and blood production relationships of blood banks in Uganda. The findings will help blood bank managers and policymakers identify key areas for operations improvement within their increasingly complex environment.

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ISSN 3115-8269 (Online) - ISSN 3115-8250 (Print)

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doi: 10.5267/j.he.2026.1.001

2. Theoretical foundations and research hypotheses

2.1 Dynamic capability theory

Dynamic capability theory is a prominent framework in strategic management across various operations (Bititci et al., 2011; Forkmann et al., 2018). It emphasizes the importance of how organizations adapt to rapidly changing environments (Forkmann et al., 2018; Tran et al., 2019; Zaefarian et al., 2017). Dynamic capability theory has been applied by business firms to enhance supplier - customers relationships in an evolving environment (Mitrega & Pfajfar, 2015). Following the discussion, it can be concluded that dynamic capabilities are instrumental in management of blood bank uncertain operations.

2.2 Regulation and blood production

Blood and blood products are essential components of modern medical treatments. Their regulation ensures an adequate and reliable supply, maintains quality and safety standards, addresses emerging threats, and supports the development of new products and technologies. These regulations encompass legal, ethical, and procedural frameworks that guide blood production and use. Effective regulation promotes continuous blood production improvement and helps achieve the best outcomes for both patients and communities (Asamoah, 2025). A coordinated approach, particularly involving legal experts, is crucial for effective oversight of blood production (Gonnade et al., 2017). Following the discussion, this study examines regulation and blood production association, and proposes that:

H₁: *There is a significant and positive association between regulation and blood production.*

2.3 Total quality management in blood production

Total quality management is a comprehensive approach to improving the quality and performance of an organization to meet or exceed customer expectations. It involves continuous improvement in all aspects of the business, with a strong focus on customer satisfaction, employee involvement, and process optimization. In blood production, total quality management is essential for maintaining and improving safety and quality of blood and blood products. Blood production process encompasses several critical stages, including collecting, screening, storing and distributing.

Total quality management implementation through use of digital timelines and regular, repetitive training significantly reduce blood production waste (Paganini et al., 2021). Additionally, total quality management contributes to shorter waiting times for blood collection, increases patient satisfaction, and improves patient experience, thereby supporting the goals of efficient blood production (Fu et al., 2021).

Furthermore, total quality management enhances visibility across the blood supply chain allowing blood production processes to adapt effectively to fluctuations in demand or supply (Hamadneh et al., 2021). Total quality management improves laboratory diagnostic accuracy, reduces turnaround time, and enhances patient safety by minimizing errors (Akase & Kpera, 2024; Shaikh, 2025). Following the discussion, this study proposes the following hypothesis:

H₂: *There is a significant and positive association between total quality management and blood production.*

2.4 Mediating role of regulation in the relationship between total quality management and blood production

Mediation perspective proposes that no single variable is universally optimal across all organizational and environmental settings (Venkatraman, 1989). Instead, it emphasizes the importance of intermediary variables (mediators) that influence independent and dependent variables relationships. Mediation explains the transitive or indirect effect between variables (Boyd et al., 2012).

Regulation encompasses the degree to standard operating procedures implementation. Regulation has been acknowledged by scholars as a critical factor in enhancing blood production. When properly integrated, regulation serves as a bridge, aligning total quality management initiatives with blood production processes. This integration ensures that quality standards are upheld and operational benefits of blood production are maximized. Therefore, regulation may play a mediating role between total quality management and blood production.

Regulation plays a vital role in streamlining blood production by minimizing procedural risks, boosting compliance with transfusion protocols, enhancing safety and quality of blood and blood products, and improving administrative efficiency. Regulation in blood production improves coordination of internal functions, transportation, stock management, and information sharing related to blood inventory. Following the aforementioned discussion, this study examines total quality management impact on blood production with regulation mediating effect, and suggests the following hypotheses:

H₃: *There is a significant and positive association between total quality management and regulation.*

H4: Regulation mediates relationship between total quality management and blood production.

3. Research methodology

3.1 Instrument

Primary data was collected through a Five-Point Likert scale (1 = strongly disagree to 5 = strongly agree) questionnaire given to randomly selected blood bank respondents. The questionnaire indicators for the variables, adapted from established tools used in previous studies, are presented in Table 1.

3.2 Data collection

Data was gathered through a structured self-administered questionnaire, with respondents selected using a simple random sampling technique to ensure impartiality in targeting the population. A total of 146 usable out of 215 questionnaires distributed were completed and returned for further analysis, showing a response rate of 67.9%; providing enough data to support the reliability of the results and draw valid conclusions (Kothari, 2014). A written informed consent was obtained from all respondents that voluntarily participated in the study. Respondents were also assured of their anonymity, so no information that identified individuals was collected.

3.3 Data analysis

Smart PLS-SEM version 4, a powerful tool widely recognized for advanced data analysis in business and social science research, was used to analyze the gathered primary data. PLS-SEM is more effective than other methods for estimating results and establishing variable validity, particularly when dealing with small sample sizes, non-normal data distributions, complex models with multiple interrelated hypotheses, or underdeveloped theoretical frameworks. (Hair et al., 2017). PLS-SEM process involves two main stages: first, specifying the measurement model: content validity, convergent validity, and discriminant validity, and evaluating the structural model to determine path coefficients and their significance (Ringle et al., 2020; Wong, 2013). All data cleaning, measurement and structural model assessment methods were carried out in accordance with relevant guidelines and regulations.

4. Results

4.1 Common methods bias

Prior to evaluating the measurement model, data was cleaned, and measures implemented to eliminate common method bias, which was assessed through a full collinearity test using the Variance Inflation Factor (VIF). VIF values were below the threshold of 3.333, indicating that the model is not influenced by common method bias (Kock, 2015). Table 1 gives a summary of study constructs, sources, measurement items and collinearity statistics (VIF).

Table 1

Study constructs, sources, measurement items, and collinearity statistics (VIF)

Construct / Source	Indicator	VIF
Blood Production (BP) (Noor Haslina Mohd Noor, 2021)	BP2: Transport requirements during blood collection are carefully planned by our blood bank	1.281
	BP4: The stock management practice applied in our blood bank is designed based on the purpose of blood products	1.417
	BP5: Availability of blood products is improved through the sharing of blood stock status	1.418
Regulation (RE) (Chejor, 2018; Dei-Adomakoh et al., 2021)	RE11: Regulation is essential in managing complex setups such as the blood transfusion services	1.316
	RE2: Regulation reduce procedural risks associated with blood transfusions	1.540
	RE4: Regulation enhance (clinician and patient) compliance to blood transfusion services	1.671
	RE5: Regulation enhance blood administration processes	1.739
	RE7: Regulation boost the quality and safety of blood products	1.763
Total quality management (TQM) (Gonnade et al., 2017; Romon & Lozano, 2017)	TQM2: Regular and systematic customer satisfaction surveys are carried out by our blood bank	1.849
	TQM3: Our blood bank engages in market research to gather suggestions for improving transfusion services.	1.589
	TQM4: Initiatives are taken by our blood bank to determine customer needs and enhance transfusion services.	1.515
	TQM6: Employee satisfaction is routinely gauged by our blood bank.	1.357

4.2 Measurement model assessment

The measurement model was assessed to determine factor loadings, composite reliability (CR), and average variance extracted (AVE), and the results are presented in Table 2. Factor loadings were used to evaluate content validity, which refers to the extent to which items designed to measure specific variables show stronger associations with their intended variable than with other variables within a given model framework (Hair et al., 2020). The factor loadings exceeded the acceptable threshold of 0.500 (Hair et al., 2011).

Table 2
Reliability and validity results

Variable	Item	Loadings	Cronbach's alpha	Composite reliability (rho_a)	Composite reliability (rho_c)	Average variance extracted (AVE)
Blood Production (BP)			0.698	0.705	0.831	0.621
	BP2	0.791				
	BP4	0.810				
	BP5	0.762				
Regulation (RE)			0.795	0.814	0.855	0.541
	RE11	0.738				
	RE2	0.742				
	RE4	0.723				
	RE5	0.761				
Total Quality Management (TQM)			0.779	0.812	0.853	0.592
	TQM2	0.815				
	TQM3	0.719				
	TQM4	0.744				
	TQM6	0.797				

Note: CR: Composite Reliability, AVE: Average Variance Extracted

Convergent validity measures how strongly two assessments of the same variable are positively related (Hair et al., 2014), ensuring that the items accurately reflect their corresponding factor. Model convergent validity is assessed through loadings, average variance extracted (AVE), and composite reliability (CR), with the best-quality items retained. Convergent validity was evaluated using AVE (Hair et al., 2017). The AVE values ranged from 0.541 to 0.621, surpassing the minimum threshold of 0.500 (Hair et al., 2017), which confirms their adequacy. The composite reliability values ranged from 0.705 to 0.814, well exceeding the recommended threshold of 0.700 (Hair et al., 2020).

Cronbach's alpha, rho_a, and composite reliability were employed to evaluate reliability (Wasko & Faraj, 2013). The retained rho_a values fell within the range of Cronbach's alpha and composite reliability (CR), indicating robust reliability (Henseler et al., 2015; Sarstedt et al., 2017).

Discriminant validity measures the extent to which one variable differs from another based on empirical evidence, requiring that variable items exhibit greater variance than those of other constructs. Discriminant validity was evaluated using the Fornell-Larcker Criterion and the Heterotrait-Monotrait Ratio (HTMT). The HTMT ratio was employed because, according to Hair et al., (2020), it is more effective than other measures. HTMT values were below the conservative threshold of 0.85, as recommended by (Henseler et al., (2015). Furthermore, discriminant validity was assessed by comparing the correlations among latent variables with the square root of the AVE, following (Fornell & Larcker, 1981). The square root of the AVE (presented in bold on the diagonal) exceeded all off-diagonal correlations for the reflective constructs. Therefore, discriminant validity is confirmed, as shown in Table 3.

Table 3
Fornell Larcker criterion and HTMT ratio results

	Blood Production (BP)	Regulation (RE)	Total Quality Management (TQM)
Blood Production (BP)	0.788	0.394	0.426
Regulation (RE)	0.326	0.735	0.237
Total Quality Management (TQM)	0.334	0.220	0.770

Note: Diagonal and bold are the square root of AVE. Below the diagonal elements are the correlations between the construct's values. Above the diagonal elements are the HTMT values.

4.3 Structural model assessment

The structural model was evaluated to determine the statistical path coefficients (β), their significance levels (p-values), and the model's coefficient of determination (R-squared), in accordance with (Hair et al., 2020). The results of the structural model analysis are presented in Tables 4 and 5.

The findings revealed a significant and positive relationship between regulation (RE) and blood production (BP) ($\beta = 0.265$, $t = 3.157$, $p = 0.002$), thereby supporting H1. Additionally, the results demonstrated a significant and positive relationship between total quality management (TQM) and blood production (BP) ($\beta = 0.275$, $t = 3.586$, $p < 0.001$), supporting H2. The analysis also indicated a significant and positive relationship between total quality management (TQM) and regulation (RE) ($\beta = 0.220$, $t = 3.223$, $p = 0.001$), supporting H3. Notably, the direct effect of total quality management on blood production was found stronger than that of regulation.

Table 4
Direct relationships results

Hypothesis	β coefficient	Sample mean (M)	Standard deviation (STDEV)	T statistics (O/STDEV)	P values	Results
H1: RE \rightarrow BP	0.265	0.282	0.084	3.157	0.002	Supported
H2: TQM \rightarrow BP	0.275	0.282	0.077	3.586	0.000	Supported
H3: TQM \rightarrow RE	0.220	0.239	0.068	3.223	0.001	Supported

Note: β : beta coefficient, T: t-statistic, p: probability value, TQM: total quality management, BP: blood production, RE: regulation

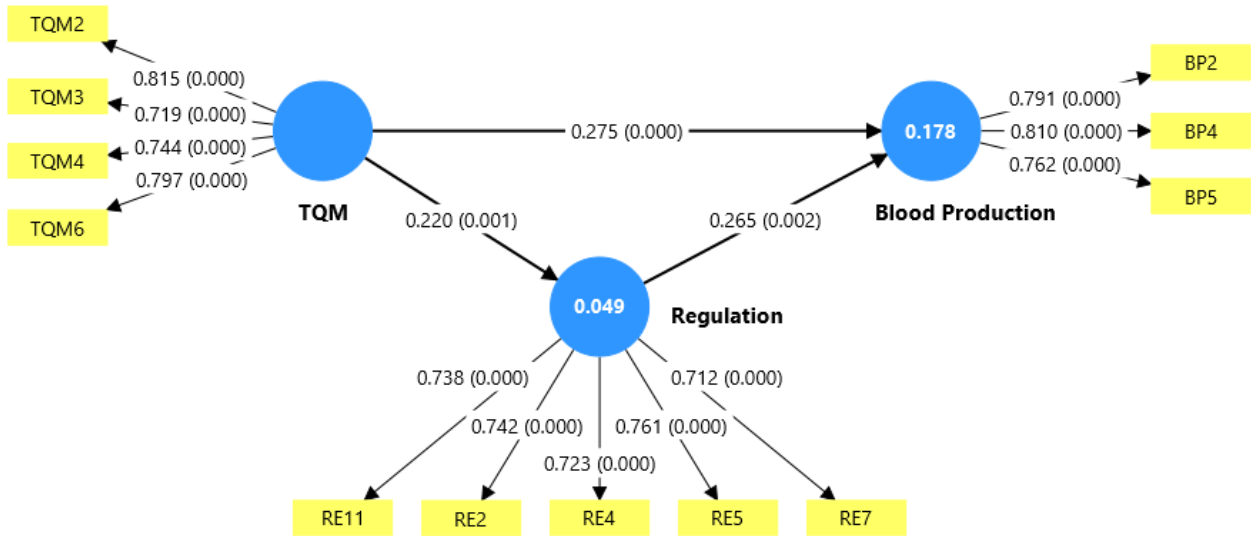


Fig. 1. Structural model results

H₄ aimed to assess the mediating effect of regulation. As shown in Table 5, the bootstrapping results indicated that the indirect effect of total quality management (TQM) on blood production (BP) was not significant ($\beta = 0.058$; $t = 1.899$; $p = 0.058$), thus providing no support for H₄. This suggests that regulation does not mediate the relationship between TQM and BP.

Table 5
Indirect relationship results

Hypothesis	Total effect	Indirect effect		Sample mean (M)	Standard deviation (STDEV)	T statistics (O/STDEV)	P value	Results
		Direct effect	β coefficient					
H4: TQM \rightarrow RE \rightarrow BP	$\beta = 0.334$ $p = 0.000$	$\beta = 0.275$ $p = 0.000$	0.058	0.068	0.031	1.899	0.058	Not supported (No Mediation)

The coefficient of determination (R-squared) assesses the goodness of fit of the structural model by indicating the proportion of variance in the dependent variable explained by the independent variable(s) (Henseler et al., 2009). It reflects the model's in-sample predictive power (Rigdon, 2016), with R-squared values ranging from 0 to 1. According to Cohen, (1988), an R-squared value of 0.26 or higher indicates substantial explanatory power, 0.13 suggests moderate power, and 0.02 is considered weak. As shown in Figure 1, the R-squared value of 0.178 reflects a moderate influence of the independent variables (total quality management and regulation) on the dependent variable (blood production).

5. Discussion

The results revealed that total quality management and regulation significantly and positively impact blood production. However, regulation did not mediate the relationship as hypothesized.

Blood banks encounter problems in matching blood products supply and demand. These challenges stem from stringent blood production standard operating procedures, and weak enforcement of transfusion regulations. The study's results show

R-square of 0.178, meaning that total quality management and regulation account for 17.8% of the total variance in blood production revealing that they are part of the broader factors.

Hypothesis (H1): regulation was found to have a significant positive relationship with blood production ($\beta = 0.265$, $p = 0.002$), consistent with findings from previous studies (Booth et al., 2021; Gupta & Popli, 2018; Samukange et al., 2023) which identifies regulation as a critical factor in promoting positive impacts in blood production. Ensuring optimal adherence to regulations enhances the safety of blood and blood products (Obeagu et al., 2024). Strict regulatory framework enhances positive blood production (Booth et al., 2021). Regulation enhances audit, follow up of adverse events, and administration process (Gupta & Popli, 2018). In Africa, regulatory measures play a crucial role in enhancing access to safe blood and blood products (Samukange et al., 2023). Guidelines for safe blood production and accreditation of blood bank operations leads to improved performance (Chandrashekar & Kantharaj, 2014). Regulation in complex operations such as blood banks improves performance (Sibinga, 2017). The findings suggest that regulation helps reduce procedural risks, improve compliance and administrative processes, and enhance the quality and safety of blood and blood products, thereby promoting positive blood production outcomes.

Hypothesis (H2): total quality management was found to have a significant positive relationship with blood production ($\beta = 0.275$, $p = 0.000$), aligning with the results of previous studies (Bolcato et al., 2020; Sibinga & Hasan, 2020). Total quality management culture created in transfusion medicine enhances blood production positive outcomes (Sibinga & Hasan, 2020). Total quality management practices in blood bank management maximizes patient safety (Bolcato et al., 2020). A study on blood bank programs and transfusion sustainability in Uganda found that total quality management had a significant impact on blood production (Kaconco et al., 2024). The findings show that total quality management with focus on customer satisfaction achieved through regular surveys, market research, and employee surveys enhance blood production.

Hypothesis (H3) total quality management demonstrated a relationship that is significant and positive ($\beta = 0.220$, $p = 0.001$) with regulation, in agreement with former studies (Bolcato et al., 2020; Sibinga & Hasan, 2020). Total quality management (TQM) plays a key role in achieving optimal outcomes, and its effectiveness is further enhanced when there is strict compliance with regulatory standards, particularly those focused on the principles of fitness for purpose (Sibinga & Hasan, 2020). This relationship underscores the importance of integrating TQM practices with regulatory frameworks to ensure both quality and compliance. The findings show that total quality management with focus on customer satisfaction and employee involvement enhance regulation, an essential factor in attainment of quality and safe blood products, reduction of procedural risks, administration and management of blood bank operations.

Hypothesis (H4) the mediating effect of regulation on the relationship between total quality management and blood production showed an insignificant relationship ($\beta = 0.058$, $p = 0.058$). This may be due to laxity of regulation implementation. Blood and blood products obtained under regulated guidelines improve safety and patient outcomes (Irving et al., 2020). According to Hervig et al., (2021), improvement in total quality management and regulation enhance blood production, especially use of whole blood as an attractive alternative to multi-component therapy. There is limited literature on regulation mediation effect in transfusion medicine; the empirical finding of this study contributes to this knowledge gap. Thus this study suggests that regulation should be assessed as an independent variable.

6. Implications

6.1 Theoretical implications

This research examined the connections between total quality management, regulatory practices, and blood production in Uganda. It investigated how both total quality management and regulatory measures influence blood production, contributing to the body of literature and informing future studies. While existing research primarily focuses on other regions, studies specifically examining Ugandan blood banks are scarce. Additionally, the study provided an empirical analysis of the effects of total quality management and regulation on blood production. This study adds to existing literature by investigating the mediating effect of regulation to achieve improved blood production.

6.2 Managerial implications

This study explains how total quality management and regulation can improve blood production. It informs managers and policymakers about key priorities for better blood production, identifying transport requirements, stock management, and stock status sharing as critical factors. The study assists in understanding total quality management, and regulation potential benefits enhancing blood production. Complying with regulations enhances results and builds public trust. The findings and contextual analysis of the study affirm the relevance of each construct.

6.3 Limitations

Due to the wide dispersion of hospital blood banks, the study involved regional and blood collection centers, limiting the sample size. The study used a cross-sectional design, lacking a longitudinal view of total quality management's impact on

blood production, so generalizing results to other countries should be done cautiously. However, identifying, testing, and validating the hypothesized relationships supported by extensive literature can help researchers develop comparative studies for broader findings. Total quality management and regulation moderately explain variation in blood production. Future studies should examine moderating factors like stakeholder engagement, policymakers, and blood products patients. Lastly, the study utilized a closed-ended questionnaire; future research could develop an open-ended questionnaire to further explore managerial perspectives on the impacts of total quality management and regulation on blood production.

7. Conclusion

This study examined the relationships among total quality management, regulation, and blood production. Using a validated PLS path model, the results revealed that both total quality management and regulation have significant and positive direct effects on blood production. However, regulation mediation impact was found to be insignificant. These findings offer empirical support that effective blood production rely on both total quality management and regulatory frameworks, with total quality management emerging the strongest predictor. The study concludes that total quality management and regulation independently and significantly influence blood production in Uganda. Though limited by a cross-sectional design, the validated relationships and comprehensive literature review offer a basis for future comparative research.

Ethics approval and consent to participate

Ethics approval and a waiver of consent from all subjects was granted by Mulago Hospital Research Ethics Committee (MHREC REC) under the protocol number MHREC-2022-081 dated 24/2/2023, and from Uganda National Council of Science and Technology under the protocol number SIR244ES dated 21/9/2023. Written informed consent was obtained from all subjects. The privacy of subjects was protected, and the intended use of the collected data was clearly communicated and assured.

Consent for publication

All authors have critically reviewed and approved the final draft and are responsible for the content and similarity index of the manuscript.

Data availability

Reasonable requests to access de-identified data can be made in writing to the corresponding author and are subject to further ethics and organizational approvals.

Competing interests

The authors have no conflict of interest to declare.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Acknowledgement

The authors acknowledge the participating respondents from blood banks, and Mulago Hospital Research Ethics Committee.

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