

A Comprehensive Framework for Developing and Implementing Standard Operating Procedures in Tertiary Care Hospitals a Practice-Based Approach to Operational Standardization, Quality Management and Patient Safety

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ABSTRACT

Background

Hospitals are complex organizations in which clinical, nursing, diagnostic, administrative, technical and support functions must operate in an integrated manner. Variability in processes, unclear responsibilities, inadequate documentation and inconsistent communication can affect operational efficiency, service quality and patient safety. Standard Operating Procedures (SOPs) provide an important mechanism for translating organizational expectations into standardized operational practices.

Objective

This paper develops and presents a comprehensive, practice-based framework for designing, implementing, governing and continuously improving hospital SOPs, with particular emphasis on tertiary-care hospital environments.

Methodology

The paper uses a qualitative, practice-based conceptual methodology. The framework was developed through systematic organization and synthesis of practical hospital SOP-development experience across clinical, nursing, patient-service, diagnostic, pharmacy, facility, administrative and support functions, complemented by a narrative review of relevant healthcare quality, patient-safety, standardization, implementation and quality-improvement literature. The framework was structured around the principles of process standardization, accountability, competency, monitoring, audit and continuous improvement.

Results

The proposed framework identifies seven interconnected dimensions of SOP management: governance, process ownership, standardized procedures, competency development, implementation, measurement and continuous improvement. A hospital SOP lifecycle is proposed consisting of need identification, process mapping, risk assessment, drafting, multidisciplinary review, approval, training, implementation, monitoring, audit, corrective action and revision. A five-level SOP maturity model is also proposed, ranging from informal processes to continuously improving systems.

Conclusion

Hospital SOPs should be treated not as isolated documents but as components of an integrated management and quality system. Their effectiveness depends on leadership commitment, clear ownership, staff competency, implementation discipline, monitoring and continuous improvement. The framework provides a practical



foundation for hospitals seeking to strengthen operational consistency, accountability, quality management and patient safety.

Keywords: Standard Operating Procedures, Hospital Management, Healthcare Operations, Patient Safety, Quality Management, Process Standardization, SOP Governance, Healthcare Quality, Hospital Administration

INTRODUCTION

Healthcare organizations operate in environments characterized by clinical complexity, high professional specialization, continuous service delivery and significant operational risk. Unlike many conventional service organizations, hospitals must coordinate numerous interdependent activities while simultaneously protecting patients from preventable harm.

The delivery of healthcare involves multiple transitions and interfaces. A patient may move from registration to consultation, diagnostic services, pharmacy, admission, nursing care, surgery, intensive care, discharge and follow-up. Each transition creates opportunities for communication failure, process variation and error.

Standardization is therefore an important component of healthcare quality and safety.

The World Health Organization's High 5s initiative specifically examined the development, implementation and evaluation of Standard Operating Procedures to achieve measurable and sustainable reductions in patient-safety problems. The initiative included standardized procedures for areas such as medication reconciliation, correct-site surgery and safe management of concentrated injectable medicines.

WHO also identifies standardized patient-safety solutions, education and training as important components of safe and high-quality healthcare.

However, the presence of an SOP does not necessarily mean that a process is standardized in practice. An SOP may remain ineffective if employees are not trained, managers do not monitor implementation, responsibilities are unclear, documentation is weak or procedures are not periodically reviewed.

Consequently, hospital SOP management should be understood as a **system rather than a document-production exercise**.

This paper proposes such a system based on practical hospital-management experience and relevant literature.

Problem Statement

A common challenge in hospital management is the gap between **documented policy and actual practice**.

Hospitals may have policies and procedures but still experience:

- variation in service delivery;
- unclear process ownership;
- inconsistent documentation;
- communication gaps;
- inadequate staff orientation;
- weak monitoring;
- outdated procedures;
- duplication of activities;

- ineffective escalation mechanisms;
- poor integration between departments; and
- limited use of process data for improvement.

The problem can therefore be expressed as follows:

How can hospitals transform SOPs from static administrative documents into actively managed systems that support reliable processes, employee accountability, quality improvement and patient safety?

RESEARCH QUESTIONS

This conceptual paper addresses the following research questions:

RQ1

What are the essential components of an effective hospital SOP management framework?

RQ2

How can hospital SOPs be systematically developed across clinical, nursing, administrative and support functions?

RQ3

What organizational mechanisms are required to ensure that SOPs are implemented rather than merely documented?

RQ4

How can SOP compliance be integrated with hospital quality management, performance measurement and continuous improvement?

RQ5

How can the maturity of a hospital's SOP management system be assessed?

RQ6

What areas require empirical investigation to determine the relationship between SOP maturity and hospital outcomes?

Objectives

The overall objective is to develop a practical framework for comprehensive hospital SOP management.

Specific objectives are to:

1. identify the core components of hospital SOP governance;
2. establish a standardized SOP development methodology;
3. define an SOP lifecycle;
4. identify mechanisms for implementation and employee competency;
5. establish a monitoring and audit framework;
6. integrate SOPs with KPIs and performance management;
7. develop an SOP maturity model; and
8. identify future research opportunities.

LITERATURE REVIEW

Standardization and Healthcare Quality

Standardization has long been associated with reliability and safety in high-risk industries. Healthcare, however, presents particular challenges because patient conditions vary and professional judgment is necessary.

Standardization should therefore not eliminate clinical judgment. Instead, it should create reliable processes around activities that can and should be standardized.

Care pathways represent one related form of standardization. Kinsman et al. (2010) described care pathways as structured multidisciplinary plans designed to translate evidence into local structures and standardize care for specific patient populations.

Recent research continues to show that standardized care pathways can support patient safety, although implementation is influenced by local culture, patient complexity and organizational context.

SOPs and Patient Safety

The WHO High 5s project provides one of the clearest international examples of using SOPs as patient-safety interventions. The initiative sought to develop, implement and evaluate standardized processes addressing major safety problems.

The underlying principle is that some errors arise not simply from individual incompetence but from weaknesses in systems and processes.

For example, wrong-site surgery can be associated with failures in patient identification, information verification, communication and preoperative processes. WHO's correct-site-surgery SOP therefore incorporates multiple standardized verification steps.

This supports a broader systems perspective: **reliable outcomes require reliable processes.**

Standardization, Checklists and Structured Processes

Checklists are another important form of process standardization.

Gawande (2009) argued that checklists can help professionals manage complexity by ensuring that critical steps are not omitted.

In healthcare, the WHO Surgical Safety Checklist demonstrated that a relatively simple standardized communication and verification process could be integrated into surgical practice.

However, checklist effectiveness depends on implementation quality and organizational culture. A checklist that is completed mechanically without meaningful verification may provide limited safety value.

The same principle applies to SOPs.

Documentation alone is insufficient; implementation quality matters.

SOPs and Implementation Science

Implementation research emphasizes the difference between an intervention's design and its actual adoption.

Damschroder et al. (2009) developed the Consolidated Framework for Implementation Research (CFIR), which identifies multiple domains affecting implementation, including intervention characteristics, organizational context, individual characteristics and implementation processes.



This perspective is particularly relevant to hospital SOPs.

A technically excellent SOP may fail if:

- staff perceive it as impractical;
- leadership does not support it;
- required resources are unavailable;
- responsibilities are unclear;
- the process conflicts with existing workflows; or
- compliance is not monitored.

Therefore, SOP implementation should be managed as an organizational change process.

Organizational Culture and Patient Safety

Patient safety is strongly influenced by organizational culture.

Reason (2000) argued that organizational accidents often result from multiple system weaknesses rather than a single individual's action.

Similarly, safety culture literature emphasizes leadership, communication, teamwork, learning and organizational commitment.

A hospital may therefore have excellent SOPs but poor safety outcomes if employees fear reporting errors, supervisors tolerate deviations or management does not act on identified risks.

SOP governance must consequently operate within a broader culture of learning and safety.

Quality Improvement and Measurement

Quality improvement requires measurement.

Donabedian's (1988) structure-process-outcome framework provides a useful conceptual foundation.

In the context of hospital SOPs:

Structure

- staffing;
- equipment;
- facilities;
- technology;
- governance.

Process

- SOP compliance;
- documentation;
- communication;
- turnaround time;
- adherence to defined procedures.

Outcome

- patient safety;

- patient experience;
- clinical outcomes;
- efficiency;
- cost;
- staff outcomes.

This suggests that SOP compliance represents an important **process measure**, but it should not automatically be treated as an outcome measure.

SOPs and Quality Improvement Reporting

Quality-improvement interventions should distinguish between implementation and outcomes.

SQUIRE 2.0 provides guidance for reporting healthcare improvement initiatives and emphasizes the description of the problem, available knowledge, rationale, context, intervention, measures, analysis, results and ethical considerations.

This paper follows the spirit of that framework while recognizing that the present work is a conceptual/practice-based framework rather than a controlled intervention study.

Patient Safety Monitoring

Recent evidence further emphasizes the importance of systematic patient-safety monitoring.

A 2025 systematic review of hospital patient-safety monitoring systems identified applications across emergency departments, intensive care, radiology, operating rooms and other settings and reported positive contributions to safety practices and safety culture.

This supports the argument that SOPs should be connected with broader monitoring and learning systems rather than maintained as independent documents.

CONCEPTUAL FRAMEWORK

The proposed framework integrates six theoretical perspectives:

1. Process standardization
2. Patient safety
3. Implementation science
4. Quality management
5. Performance measurement
6. Continuous improvement

The central proposition is:

Hospital SOP maturity → better process standardization → improved compliance and reliability → stronger quality and safety management → improved organizational performance

However, the framework does not assume that SOP maturity automatically causes better clinical outcomes. Empirical research is required to establish those relationships.

CONCEPTUAL MODEL

Figure 1. Proposed Hospital SOP Management and Performance Model

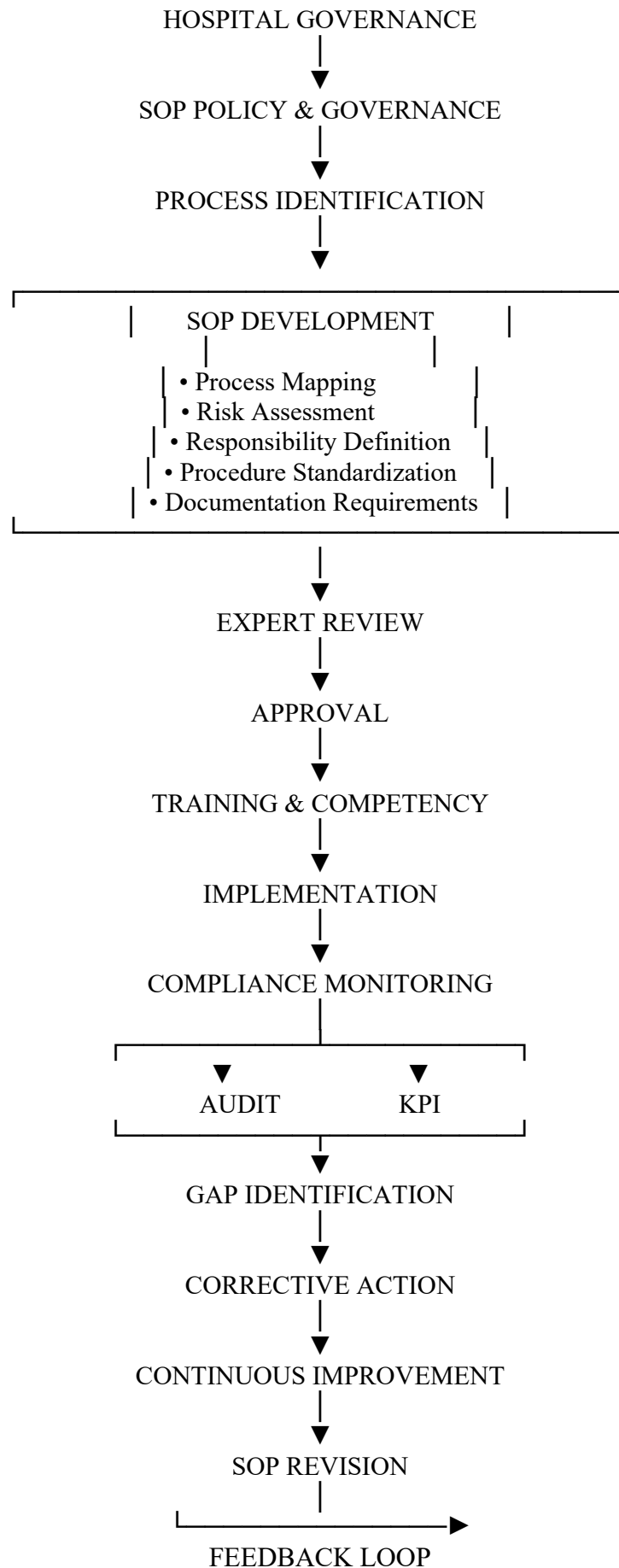


Figure Interpretation



The model presents SOP management as a **closed-loop system** rather than a linear document-development process.

The feedback loop is particularly important. Hospital processes change because of technology, regulations, staffing, clinical evidence, incidents, patient feedback and organizational learning. SOPs must therefore evolve accordingly.

METHODOLOGY

Research Design

This study uses a **qualitative practice-based conceptual design**.

It does not claim to be a randomized controlled study, observational outcome study or systematic review.

The purpose is to develop a structured conceptual framework from practical hospital SOP-development experience and relevant scholarly literature.

Practice-Based Source

The practical component was derived from the author's experience in developing and organizing hospital SOPs across multiple hospital functions, including:

- nursing;
- OPD;
- IPD;
- patient services;
- clinical support;
- diagnostics;
- pharmacy;
- infection prevention;
- facility management;
- engineering and maintenance;
- housekeeping;
- security;
- administration;
- human resources;
- procurement;
- finance; and
- information technology.



Confidential institutional information, patient information and proprietary operational details are intentionally excluded from this framework.

Literature Review Approach

A narrative literature review approach was used to identify concepts relevant to:

- healthcare standardization;
- SOPs;
- patient safety;
- quality management;
- implementation science;
- care pathways;
- checklists;
- organizational culture;
- healthcare quality measurement; and
- continuous improvement.

The literature was synthesized conceptually rather than statistically.

Analytical Approach

The analysis followed four stages:

Stage 1 — Process Categorization

Hospital activities were grouped into clinical, nursing, diagnostic, administrative, technical and support functions.

Stage 2 — Common SOP Elements

Common elements were identified across processes, including:

- purpose;
- scope;
- responsibility;
- procedure;
- documentation;
- safety;
- monitoring;
- escalation; and
- approval.



Stage 3 — Governance Integration

The individual SOP components were connected to organizational governance, training, monitoring and audit.

Stage 4 — Framework Development

The components were integrated into the proposed SOP lifecycle and maturity model.

Ethical Considerations

This paper does not present identifiable patient information or confidential clinical data.

Because the framework is based primarily on professional practice and conceptual synthesis, it does not claim to constitute human-subject research.

Before publication of any organization-specific SOPs or institutional data, appropriate organizational authorization should be obtained.

Proposed Hospital Sop Framework

The framework consists of ten major components.

Governance

The organization should establish:

- SOP policy;
- approval authority;
- document-control mechanism;
- review schedule;
- process ownership; and
- escalation mechanisms.

Process Ownership

Every SOP should have an accountable process owner.

Ownership should not be ambiguous.

Standard SOP Format

A common organizational format should be used.

Risk-Based Prioritization

High-risk processes should receive priority for SOP development and monitoring.

Training

Employees should be trained before or during implementation.

Implementation

Approved SOPs should be incorporated into daily workflows.



Monitoring

Compliance should be periodically measured.

Audit

Independent or quality-function audits should identify gaps.

Corrective Action

Identified deviations should result in appropriate corrective and preventive action.

Review

SOPs should be periodically reviewed and revised.

Proposed Sop Lifecycle

Phase 1 — Identification

Identify a process requiring standardization.

Phase 2 — Analysis

Map the process and identify risks.

Phase 3 — Development

Draft the SOP.

Phase 4 — Validation

Obtain multidisciplinary review.

Phase 5 — Approval

Obtain formal authorization.

Phase 6 — Communication

Distribute the approved SOP.

Phase 7 — Training

Train relevant employees.

Phase 8 — Implementation

Integrate the SOP into routine operations.

Phase 9 — Monitoring

Measure compliance.

Phase 10 — Audit

Evaluate effectiveness and gaps.

Phase 11 — Corrective Action

Address deviations.

Phase 12 — Revision

Update the SOP based on evidence and experience.

Sop Maturity Model

A five-level maturity model is proposed.

Level	Description	Characteristics
1	Informal	Processes depend on individual experience
2	Documented	SOPs exist but implementation is inconsistent
3	Implemented	Staff are trained and procedures are routinely followed
4	Measured	Compliance, audits and KPIs are established
5	Continuously Improved	Data and learning systematically improve processes

Level 1 — Informal

The organization relies heavily on individual knowledge.

Level 2 — Documented

Policies and SOPs are created but may not be consistently implemented.

Level 3 — Implemented

Training, supervision and communication support implementation.

Level 4 — Measured

The organization monitors compliance and process performance.

Level 5 — Continuously Improved

SOPs are routinely updated using data, incidents, patient feedback, staff feedback and emerging evidence.

Sop Compliance And Performance Measurement

SOP compliance can be measured through structured audits.

Example indicator

SOP Compliance Rate (%)

$$\text{SOP Compliance Rate (\%)} = \frac{\text{Number of Compliant Observations}}{\text{Total Number of Observations}} \times 100$$

Other indicators may include:

- documentation completeness;
- training completion;
- process turnaround time;
- incident frequency;
- deviation rate;
- corrective-action closure;
- audit score;
- patient complaint rate; and
- patient experience measures.

Importantly, organizations should avoid assuming that a high SOP compliance score automatically means high-quality clinical outcomes.

Integration With Hospital Performance Management

The proposed model links SOPs with organizational performance.



This creates a line of sight between:

Strategy → Process → People → Performance → Improvement

This is particularly relevant to hospitals seeking to establish integrated performance-management systems.

DISCUSSION

The central finding of this conceptual analysis is that hospital SOPs should be viewed as an **organizational control and learning mechanism**, rather than merely as written instructions.



This position is supported by several strands of literature.

First, WHO's High 5s initiative demonstrates that standardized procedures can be designed specifically around patient-safety risks.

Second, care-pathway literature indicates that structured multidisciplinary processes can help translate evidence into standardized local practice.

Third, implementation-science literature indicates that organizational context influences whether interventions become embedded in practice.

Fourth, quality-improvement reporting standards emphasize the importance of context, implementation, measurement and analysis rather than simply describing an intervention.

Therefore, the effectiveness of an SOP should be considered a function of several interacting factors:

SOP Quality × Leadership × Training × Resources × Implementation × Monitoring × Organizational Culture

If any major component is weak, the overall system may underperform.

The Role of Leadership

Leadership is fundamental to SOP implementation.

Senior management should:

- communicate the importance of standardization;
- assign clear process ownership;
- allocate required resources;
- monitor critical SOPs;
- review significant deviations;
- support staff training;
- encourage reporting;
- avoid blame-oriented responses to system failures; and
- use data for improvement.

A safety-management perspective similarly emphasizes leadership commitment, risk management, safety assurance and safety culture as important components of healthcare safety systems.

The Role of Employees

Employees are not simply recipients of SOPs.

They are also important sources of operational knowledge.

Frontline staff often understand:

- process bottlenecks;

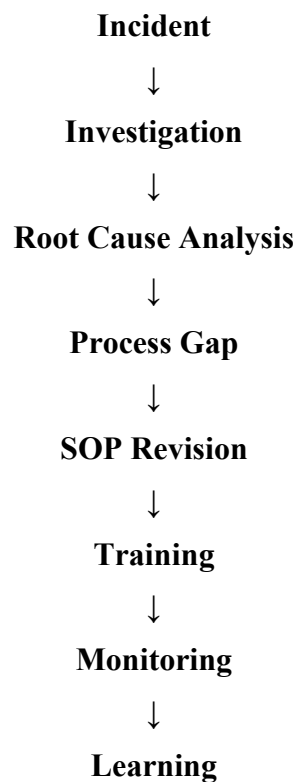
- unnecessary steps;
- communication failures;
- equipment limitations;
- patient difficulties; and
- practical barriers to implementation.

Consequently, SOP development should include frontline participation whenever feasible.

This can increase practicality, ownership and acceptance.

Sops And Organizational Learning

An effective SOP system should create a learning cycle:



This prevents the organization from repeatedly solving the same problem through isolated corrective actions.

SOPs and Patient-Centred Care

Standardization should not make healthcare impersonal.

A patient-centred SOP should ensure that standardized processes support:

- dignity;
- communication;
- informed participation;
- privacy;

- timely information;
- complaint resolution;
- continuity of care; and
- respect for patient preferences.

Standardization should therefore focus on **reliable processes while preserving appropriate individualized care**.

Implications for Developing-Country Healthcare Systems

The proposed framework may be particularly relevant to developing healthcare systems where hospitals may face:

- rapid expansion;
- staff turnover;
- variable competency;
- resource constraints;
- inconsistent documentation;
- fragmented processes; and
- limited quality-management infrastructure.

In such environments, SOPs can provide a relatively low-cost management mechanism for clarifying responsibilities and establishing consistent processes.

However, SOPs should be realistic and adapted to available resources.

An SOP requiring resources that the hospital cannot reliably provide is unlikely to be sustainable.

Practical Implementation Roadmap

A hospital implementing this framework could follow the following sequence.

Phase 1 — Foundation

- Establish SOP governance.
- Identify process owners.
- Create document-control standards.
- Develop a master SOP register.

Phase 2 — Prioritization

Prioritize high-risk and high-volume processes.

Phase 3 — Development

Develop and validate SOPs.



Phase 4 — Training

Train managers, supervisors and frontline staff.

Phase 5 — Implementation

Introduce SOPs into operational workflows.

Phase 6 — Monitoring

Establish compliance measures.

Phase 7 — Audit

Conduct periodic departmental and quality audits.

Phase 8 — Improvement

Use audit findings, incidents and feedback to revise processes.

Proposed Research Model for Future Empirical Testing

The conceptual framework generates several testable propositions.

Proposition 1

Higher SOP maturity is positively associated with higher SOP compliance.

Proposition 2

Leadership commitment positively influences SOP implementation.

Proposition 3

Employee training mediates the relationship between SOP availability and SOP compliance.

Proposition 4

SOP compliance is positively associated with process reliability.

Proposition 5

A stronger SOP governance system is positively associated with continuous improvement capability.

Proposition 6

Organizational safety culture moderates the relationship between SOP implementation and patient-safety performance.

These propositions should be tested through empirical research rather than presented as established causal relationships.

FUTURE RESEARCH METHODOLOGY

Future researchers could test this framework using a mixed-methods design.

Quantitative component



Potential variables:

- SOP maturity;
- SOP compliance;
- training completion;
- incident rate;
- patient satisfaction;
- turnaround time;
- employee performance.

Qualitative component

Interviews could explore:

- leadership commitment;
- implementation barriers;
- staff perceptions;
- organizational culture;
- resource constraints;
- process ownership.

Potential statistical analysis

Depending on sample size and research design:

- descriptive statistics;
- correlation;
- multiple regression;
- mediation analysis;
- moderation analysis;
- structural equation modelling.

Longitudinal studies would be particularly useful because quality improvement is dynamic.

LIMITATIONS

This paper has several limitations.

First, the framework is based substantially on practical experience and conceptual synthesis rather than primary empirical outcome data.

Second, the framework has not yet been validated across multiple hospitals.

Third, the proposed maturity model has not undergone psychometric validation.

Fourth, the relationship between SOP compliance and patient outcomes cannot be established from this paper.

Fifth, hospital context may influence implementation significantly.

Accordingly, the framework should be considered a **proposed model requiring empirical validation**.

CONCLUSION

Hospital SOPs have the potential to serve as a powerful mechanism for operational standardization, quality management and patient safety.

However, their value does not come from documentation alone.

A mature SOP system requires:

Governance → Process Ownership → Standardization → Training → Implementation → Monitoring → Audit → Corrective Action → Continuous Improvement

The proposed framework therefore moves the concept of SOPs:

From: “Documents that describe work”

To: “A managed organizational system that standardizes work, develops employee capability, measures compliance, and drives continuous improvement.”

The practical significance of this framework lies in its potential to provide hospital leaders with a structured approach for connecting everyday operational processes with organizational quality and performance objectives.

Future empirical research should validate the proposed maturity model and investigate whether higher levels of SOP maturity and compliance are associated with measurable improvements in process reliability, patient experience, safety and organizational performance.

SUGGESTED AUTHOR DECLARATION

Author Contribution: The author conceptualized the framework, organized the practice-based material, developed the conceptual model, conducted the narrative literature synthesis and prepared the manuscript.

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Ethical Statement: This manuscript is based on professional practice and conceptual analysis and does not report identifiable human-subject research.

Institutional Confidentiality: No confidential institutional information, patient information or proprietary hospital documents should be included in the publicly available version without appropriate authorization.

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