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## Systems based medication governance: Empowering pharmacists in strategic policy, compliance and health outcomes leadership

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### Abstract

The dynamic landscape of healthcare demands a transformative approach to medication governance—one that repositions pharmacists as integral leaders in shaping policy, ensuring compliance, and driving improved health outcomes. Systems-based medication governance offers a holistic and structured framework in which medication management is embedded within the broader context of health system performance, regulatory oversight, and clinical accountability. This paradigm empowers pharmacists not merely as dispensers of medication but as architects of therapeutic strategy, quality assurance, and population health interventions. This study explores the evolution and operationalization of systems-based medication governance, highlighting how pharmacists can lead within multidisciplinary care teams to influence national formularies, medication safety protocols, and real-time clinical decision support systems. Emphasis is placed on the intersection between policy-making, digital health integration, and performance-based compliance, where pharmacists act as stewards of both public health and institutional accountability. Through comparative case studies, stakeholder interviews, and policy analysis, the research investigates best practices in countries where pharmacist-led governance models have successfully contributed to reduced medication errors, cost containment, and improved therapeutic outcomes. The paper also examines challenges such as regulatory constraints, interprofessional resistance, and gaps in leadership training among pharmacists. Findings support a shift towards systems-oriented thinking in pharmaceutical services, advocating for strategic capacity-building, regulatory reform, and digital infrastructure that enables pharmacists to proactively manage clinical and policy-level medication risks. This work underscores the untapped leadership potential of pharmacists and calls for a systemic recalibration of their role within integrated health governance models.

**Keywords:** Medication Governance; Pharmacist Leadership; Health Policy Compliance; Systems-Based Care; Clinical Outcomes; Strategic Pharmacy Practice

## 1. Introduction

### 1.1. Evolution of Medication Governance

Medication governance has historically centered on compliance frameworks aimed at ensuring pharmaceutical practices adhered to regulatory mandates, safety protocols, and documentation standards. While such compliance-based models provided a necessary foundation for legal accountability, they often emphasized control mechanisms over proactive improvement and clinical alignment [1]. As health systems became increasingly complex, the limitations of

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isolated, transactional pharmacy models became evident—particularly in contexts where rapid technological innovation and interdisciplinary care are the norm.

In recent years, the transition from compliance-focused governance to systems-based medication governance has gained momentum. This paradigm shift positions pharmacy services not just as support functions but as integral components of healthcare strategy and patient outcomes [2]. It recognizes that medication use does not occur in isolation but is deeply embedded in a network of clinical, logistical, financial, and societal systems. Therefore, governance structures must evolve to reflect this interdependence.

A systems-thinking approach encourages the integration of pharmacy into broader healthcare delivery mechanisms. It considers the interplay of medication policy, digital infrastructure, data analytics, supply chain coordination, and human capital in shaping therapeutic outcomes [3]. Rather than reacting to incidents or regulatory audits, systems-based governance anticipates risk, supports continuous quality improvement, and embeds accountability across the medication lifecycle.

This transformation also necessitates a multidisciplinary collaboration framework, where pharmacists work alongside clinicians, informaticians, policy advisors, and administrators to influence decisions on formulary management, procurement, and medication optimization strategies [4]. In this model, governance extends beyond documentation and into strategic foresight, performance monitoring, and dynamic response mechanisms that safeguard both individual patient safety and population health.

Ultimately, systems-based medication governance fosters a resilient, learning-oriented pharmaceutical environment—essential for navigating modern health challenges such as chronic disease burdens, antimicrobial resistance, and health system digitization [5].

## **1.2. Pharmacists as Strategic Leaders in Health Systems**

As medication governance evolves, so too does the role of pharmacists—from operational technicians to strategic health system leaders. Increasingly, pharmacists are being called upon to drive initiatives related to medication safety, performance measurement, quality assurance, and policy formulation. This transformation is underpinned by their unique positioning at the intersection of clinical practice, pharmaceutical knowledge, and health systems design [6].

One of the most impactful areas of pharmacist-led leadership is in medication safety governance. Pharmacists are now integral to multidisciplinary safety committees, where they analyze medication-related incidents, implement corrective strategies, and track performance metrics. Their oversight ensures compliance with national safety standards and accreditation benchmarks while fostering a culture of continuous learning [7].

In parallel, pharmacists are assuming leadership in healthcare quality improvement, developing and managing formularies, therapeutic guidelines, and audit frameworks. Their influence on medication selection, de-prescribing strategies, and antimicrobial stewardship programs has a direct bearing on treatment effectiveness, patient outcomes, and healthcare cost containment [8].

Moreover, pharmacists are strategically positioned to engage with digital health ecosystems. They contribute to the design and deployment of clinical decision support systems (CDSS), electronic prescribing platforms, and digital surveillance tools. Through these platforms, pharmacists help operationalize performance-based care models by aligning medication decisions with value-based outcome measures [9].

In population health, pharmacists collaborate with epidemiologists and public health professionals to address health disparities, enhance medication access, and support immunization campaigns. Their involvement in chronic disease management initiatives—especially those leveraging AI and big data—cements their relevance as proactive healthcare architects [10].

The elevation of pharmacists into leadership roles reflects a broader health system recognition of their value not only as medication experts but as key contributors to governance, innovation, and strategic healthcare transformation [11].

## **1.3. Purpose and Scope of the Study**

This study explores the critical role of systems-based medication governance and the growing leadership responsibilities of pharmacists within that framework. As healthcare systems pivot toward integrated, value-based, and

digitally enabled care, there is an urgent need to reposition pharmacists not merely as process enforcers but as architects of safety, efficiency, and therapeutic optimization [12].

The central purpose of this article is to articulate the strategic imperative for pharmacist-driven governance models that encompass clinical, operational, and policy dimensions of medication use. By examining key drivers, frameworks, and case studies, the study underscores the necessity of equipping pharmacists with the authority, data access, and institutional support to influence system-level decisions.

The scope includes a review of governance evolution, assessment of pharmacist leadership in health systems, and the design of scalable governance models that promote interdisciplinary collaboration and performance transparency. Through this lens, the study contributes to emerging discourse on sustainable and resilient medication governance systems [13].

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## **2. Conceptual and theoretical frameworks**

### **2.1. Understanding Systems-Based Governance in Healthcare**

Systems-based governance is a strategic approach to healthcare management that emphasizes integration, feedback, and adaptability. Unlike fragmented or siloed models, systems-based governance treats the healthcare system as an interconnected web of functions and stakeholders, where changes in one area influence outcomes across the entire continuum of care [5]. The key characteristic of this model is its ability to coordinate policy, operations, and outcomes through continuous information exchange and cross-functional accountability.

At the heart of systems governance is the integration of clinical, operational, and financial data. This integration enables real-time performance monitoring, risk identification, and course correction, which are vital in environments as complex and variable as healthcare [6]. Systems thinking encourages organizations to track not just endpoint outcomes, but also the processes, behaviors, and contextual variables that shape those outcomes. This fosters a learning environment where governance evolves based on evidence and feedback rather than static rule adherence.

Feedback loops are essential in such systems, as they provide a mechanism for learning, adjustment, and shared insight. In medication governance, these loops might include adverse drug event (ADE) tracking, prescription audit results, or antimicrobial resistance data that inform future formulary decisions [7]. Systems-based governance therefore avoids reactive strategies and instead builds resilience into medication use processes.

Adaptability is another pillar of this model. In the face of emerging challenges—such as drug shortages, new treatment protocols, or AI integration—systems-based governance provides a flexible yet controlled mechanism for response and mitigation [8]. Rather than relying solely on top-down mandates, it supports frontline decision-making within a structured oversight framework.

Applied to medication management, systems-based governance ensures that policies are not only enforced but continuously improved upon, promoting clinical alignment, operational consistency, and sustainable innovation [9].

### **2.2. Governance and Compliance Models**

Effective medication governance requires a robust foundation in compliance and quality management frameworks, many of which have been adapted from broader organizational governance principles. One of the most widely recognized models in healthcare is ISO 9001, a quality management standard that emphasizes customer satisfaction, leadership commitment, process optimization, and continual improvement [10]. When applied to medication systems, ISO 9001 promotes clear documentation, measurable objectives, and structured review processes—attributes that strengthen regulatory compliance and accountability.

Lean healthcare systems, inspired by manufacturing efficiency models, are another governance tool that supports medication management. Lean emphasizes waste elimination, streamlined processes, and value creation from the patient's perspective. In pharmaceutical services, Lean principles guide process mapping, error reduction, and throughput improvements, ensuring that governance mechanisms do not become bottlenecks but rather enablers of safety and efficiency [11].

Beyond these industrially inspired frameworks, specialized safety governance structures have emerged to address the complex nature of medication-related harm. These include centralized medication safety committees, multidisciplinary

review boards, and sentinel event tracking systems. These entities foster shared responsibility and continuous surveillance, creating governance ecosystems that are both proactive and responsive [12].

In pharmaceutical compliance, frameworks such as the Good Pharmacy Practice (GPP) standards issued by the International Pharmaceutical Federation (FIP), and regulatory compliance models enforced by national drug authorities, form the backbone of policy implementation. These models define the minimum acceptable thresholds for procurement, storage, dispensing, and documentation, and are increasingly being embedded into digital systems for real-time monitoring [13].

As healthcare systems move toward value-based and risk-adjusted models, governance structures must evolve to align compliance with strategic goals. This requires the fusion of operational standards, clinical evidence, and stakeholder accountability to deliver safe, effective, and efficient medication services.

**Table 1** Comparison of Medication Governance Models Across Healthcare Systems

Model	Key Features	Scope	Integration Level
ISO 9001	Quality management principles, process orientation, continuous improvement	Organization-wide (including pharmacy)	High (cross-departmental standard)
Lean Systems	Waste reduction, value stream mapping, workflow optimization	Operational pharmacy and medication use	Moderate to high (varies by site)
GPP (Good Pharmacy Practice)	Standards for ethical, safe, and effective pharmacy services	Professional pharmacy conduct	High (globally recognized, regulated)
Medication Safety Boards	Multidisciplinary safety oversight, adverse event review, protocol updates	Institutional level (clinical governance)	Moderate to high (depends on structure)
P&T Committees	Formulary management, therapeutic policy, drug utilization review	Clinical governance and therapeutic policy	High (core to system medication strategy)
Antimicrobial Stewardship Committees	Surveillance, restrictive formulary, prescriber education	Focused clinical programs	Moderate (specialized scope)

### 2.3. Leadership in Medication Systems

Leadership within medication governance systems has become increasingly multi-dimensional, requiring a blend of clinical insight, policy understanding, and system navigation. One of the core domains where leadership manifests is clinical governance, which involves setting and enforcing standards of practice, evaluating outcomes, and fostering a culture of learning. In the context of medication management, clinical governance supports initiatives like therapeutic audits, formulary decisions, and adverse event reviews—all of which require coordinated leadership [14].

Effective governance also requires stewardship, particularly in high-risk areas such as antimicrobial use, high-alert medications, and oncology. Pharmacists, clinicians, and health administrators play shared roles in managing therapeutic access, tracking usage patterns, and adjusting policies based on evidence. Stewardship programs function not only to improve outcomes but to align medication use with health system sustainability, especially in settings challenged by resource limitations or public health crises [15].

Leadership in medication systems must further promote shared accountability. Gone are the days when pharmacy oversight was confined to departmental boundaries. Today, governance requires cooperation across departments—from prescribing physicians and nursing teams to informaticians and quality officers. Medication-related outcomes, including safety incidents and financial performance, are collective responsibilities supported by transparent data flows and multidisciplinary decision-making forums [16].

Importantly, leadership must embrace innovation, including the integration of AI, real-time analytics, and predictive modeling into governance tools. Leaders must be fluent in translating digital intelligence into clinical relevance, ensuring that governance structures are not static but responsive and forward-thinking [17].

Ultimately, leadership in medication governance is about orchestrating complexity—aligning clinical, operational, and technological resources to protect patients, optimize outcomes, and create resilient systems that adapt to evolving healthcare landscapes.

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### **3. Core domains of pharmacist-led medication governance**

#### **3.1. Policy Development and Health System Planning**

Pharmacists play an increasingly strategic role in the formulation and implementation of healthcare policies, especially in medication-related domains that affect population health, cost management, and quality assurance. One of the most critical contributions lies in shaping national formularies—standardized lists of medications deemed essential for quality care across public health systems. Pharmacists, through evidence synthesis and cost-benefit evaluations, guide therapeutic selections and ensure that formularies reflect both clinical relevance and economic sustainability [6].

The inclusion and regular updating of Essential Medicines Lists (EMLs) is another domain where pharmacists contribute to health system planning. These lists, developed under frameworks such as those established by the World Health Organization (WHO), aim to ensure equitable access to safe, effective, and affordable medicines. Pharmacists involved in policy development help evaluate emerging therapies, biosimilars, and generic equivalents, ensuring the EMLs stay aligned with epidemiological shifts and evolving clinical evidence [7].

A particularly urgent area of policy engagement involves the formulation of antimicrobial stewardship policies. Given the rise of antimicrobial resistance (AMR), pharmacists have been integral in designing prescribing protocols, monitoring resistance trends, and guiding formulary restrictions that promote rational antibiotic use [8]. These policies not only support public health but also reduce unnecessary pharmaceutical expenditures and safeguard drug efficacy for future use.

Additionally, pharmacists contribute to health system planning through their involvement in forecasting drug demand, advising on procurement logistics, and designing digital infrastructure that supports real-time decision-making. Their input ensures that planning processes are both clinically sound and operationally feasible, particularly in decentralized and resource-constrained environments [9].

By actively shaping policy at national and institutional levels, pharmacists elevate medication governance beyond routine compliance, embedding it into broader strategic objectives such as universal health coverage, sustainability, and quality enhancement [10].

#### **3.2. Regulatory Compliance and Risk Mitigation**

A robust medication governance system must ensure not only efficiency and clinical efficacy but also unwavering regulatory compliance. Pharmacists serve as frontline custodians of compliance, applying their expertise to mitigate risk while maintaining operational readiness for audits, inspections, and accreditation reviews. One key area is audit preparedness, where pharmacists help design and maintain documentation systems that demonstrate adherence to drug storage, dispensing, and record-keeping regulations [11].

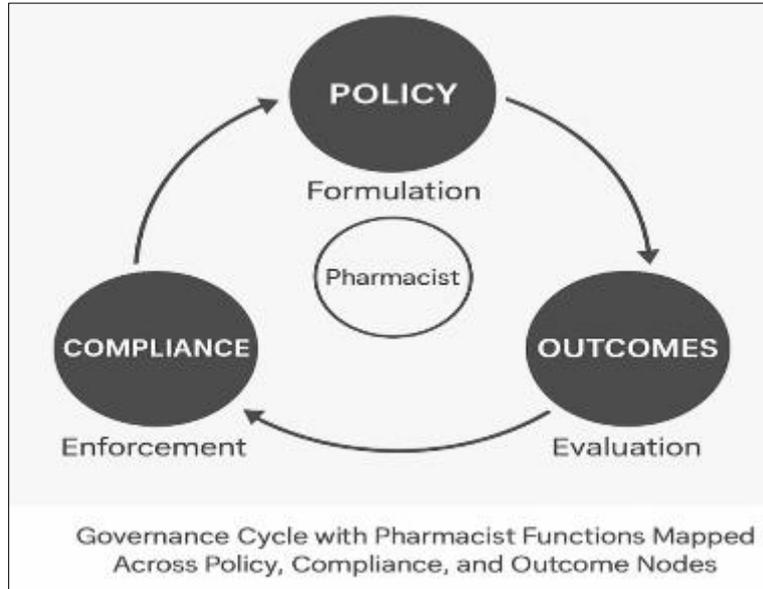
This involves overseeing real-time monitoring dashboards, conducting internal compliance checks, and ensuring proper traceability of pharmaceutical transactions across both digital and manual systems. Pharmacists also guide teams on best practices for inventory control, temperature monitoring, and handling of expired or recalled products—activities crucial for inspection readiness [12].

Pharmacovigilance—the ongoing monitoring of medication safety—is another central responsibility in compliance-oriented governance. Pharmacists contribute by collecting, analyzing, and reporting adverse drug events (ADEs), thus ensuring continuous evaluation of benefit-risk profiles for marketed medications. Their role extends to training clinicians and allied staff in recognizing and documenting ADRs using standardized reporting formats, which supports national and global pharmacovigilance networks [13].

Regulations surrounding controlled substances demand an even higher level of precision and vigilance. Pharmacists are entrusted with managing Schedule I-V medications, maintaining narcotic registers, conducting reconciliations, and reporting discrepancies in accordance with federal and local laws. Errors in this domain can lead to severe legal consequences, making pharmacist-led oversight a critical risk mitigation strategy [14].

Moreover, regulatory compliance increasingly involves digital traceability and alignment with data protection regulations. Pharmacists are key in configuring pharmacy information systems to meet audit standards, safeguard patient information, and ensure compliance with privacy laws such as GDPR or HIPAA [15].

Through these functions, pharmacists enable organizations to move beyond minimum compliance toward proactive, risk-informed governance models that balance safety, accountability, and clinical efficacy [16].



**Figure 1** Governance Cycle with Pharmacist Functions Mapped Across Policy, Compliance, and Outcome Nodes

### 3.3. Health Outcomes Leadership and Accountability

Pharmacists are increasingly recognized as leaders in defining and achieving key health outcome measures related to medication use. Their role in governance extends into the territory of performance monitoring and accountability, ensuring that pharmaceutical services are aligned with system-wide goals of safety, effectiveness, and patient satisfaction.

A core area of pharmacist-led outcome monitoring is the reduction of hospital readmissions due to medication-related causes. Pharmacists contribute through medication reconciliation at discharge, education on adherence, and post-discharge follow-up, thereby closing the loop between acute care and long-term therapy management [17]. Their participation in readmission prevention teams demonstrates the value of pharmacist insight in minimizing transitions-of-care failures.

Another critical outcome is medication adherence, especially for patients with chronic diseases such as hypertension, diabetes, and asthma. Pharmacists utilize digital tools, personalized counseling, and data analytics to track and improve adherence rates. Their interventions—ranging from mobile health messaging to smart pill technology—have been proven to reduce treatment abandonment and enhance therapeutic success [18].

Equally important is the prevention and monitoring of adverse drug events (ADEs). Through stewardship programs and decision-support tools, pharmacists reduce inappropriate prescribing and enhance early detection of ADRs. They often lead root cause analyses following serious ADEs, translating findings into improved protocols and staff training [19].

Pharmacists also collaborate with administrators and clinicians to define Key Performance Indicators (KPIs) for pharmaceutical services. These may include average dispensing times, stock-out frequency, formulary compliance, and patient-reported outcomes. The presence of pharmacists in strategic planning teams ensures these KPIs reflect meaningful, measurable dimensions of health system performance [20].

In these leadership roles, pharmacists help define what success looks like in pharmaceutical care—grounding governance not only in compliance but in measurable contributions to population health.

## **4. Operationalizing systems-based governance in pharmacy practice**

### **4.1. Structuring Pharmacy Governance Committees**

A central element of systems-based medication governance is the establishment of structured pharmacy governance committees that provide strategic, clinical, and operational oversight. These bodies institutionalize accountability, promote interprofessional collaboration, and facilitate informed decision-making aligned with health system goals. Among the most prominent are hospital medication safety committees, which oversee medication use processes, adverse event analysis, and implementation of quality improvement initiatives [10].

Medication safety committees typically include pharmacists, physicians, nurses, and quality assurance professionals. Their mandate extends from evaluating medication error reports to developing corrective action plans and tracking implementation effectiveness. By serving as central hubs for incident review, policy refinement, and staff education, these committees embed a culture of safety within the organization [11].

Therapeutic policy boards, also known as pharmacy and therapeutics (P&T) committees, are another cornerstone of governance infrastructure. These committees focus on formulary management, therapeutic protocol development, drug utilization reviews, and health technology assessment. Pharmacists play a leading role by presenting evidence-based reviews of new drugs, therapeutic alternatives, and economic evaluations [12]. Their contributions ensure that formulary decisions balance clinical efficacy, patient needs, and budgetary constraints.

Effective governance committees also operate within a performance management framework, tracking adherence to medication-related KPIs, compliance metrics, and pharmaco-economic indicators. Routine reporting mechanisms support transparency and enable leadership to make data-informed adjustments to strategy or resource allocation [13].

Importantly, these committees must reflect multidisciplinary representation and hierarchical balance to ensure broad accountability. Structures where pharmacists hold co-chair or lead analytical roles have been associated with stronger implementation fidelity and cross-functional alignment [14].

Overall, governance committees serve as institutional anchors for medication oversight. When well-structured, they bridge policy and practice, enabling a responsive, data-driven governance system that evolves with emerging clinical, technological, and regulatory developments.

### **4.2. Leveraging Health IT and Clinical Decision Support**

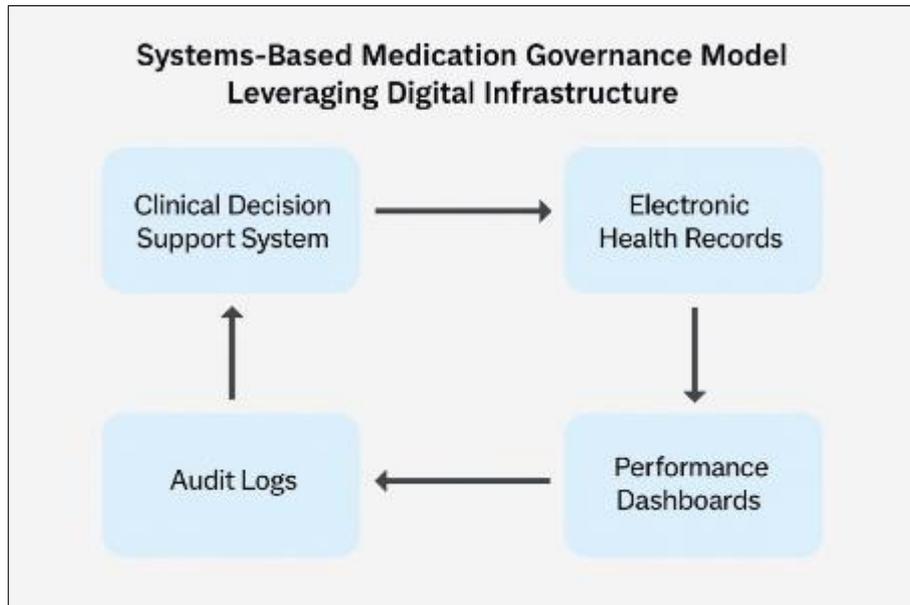
The digital transformation of healthcare provides new opportunities to strengthen pharmacy governance through Health Information Technology (Health IT) and Clinical Decision Support Systems (CDSS). These technologies support real-time monitoring, informed decision-making, and regulatory compliance by integrating medication data into broader clinical workflows. A foundational component is the integration of Electronic Health Records (EHRs), which centralize patient histories, lab results, and medication profiles, enabling pharmacists to review comprehensive data during verification and counselling [15].

By embedding CDSS into EHRs, pharmacists can access real-time alerts for drug interactions, allergy risks, duplications, and inappropriate dosing. AI-powered systems enhance traditional rule-based alerts by factoring in lab trends, pharmacogenomic data, and patient-specific variables to minimize alert fatigue while increasing clinical precision [16]. These intelligent systems foster timely interventions, reduce prescribing errors, and improve documentation consistency.

Another key digital feature is the use of automated audit trail logs, which capture every system interaction—such as medication orders, approvals, overrides, and verifications. These logs provide essential traceability for regulatory compliance and forensic analysis, especially in high-risk or litigation-prone environments. Pharmacists are often responsible for configuring system permissions, establishing override protocols, and reviewing deviation patterns in collaboration with IT and compliance teams [17].

Barcode medication administration (BCMA) and automated dispensing cabinets (ADCs) further integrate with Health IT to prevent wrong-patient and wrong-drug errors. Pharmacists contribute to configuring these systems with formulary-aligned data and ensuring synchronization with EHRs to maintain real-time accuracy [18].

Additionally, health IT platforms support performance dashboards that visualize prescribing trends, adherence rates, and medication-related incidents. Pharmacists use these dashboards for benchmarking, root cause analysis, and feedback loops within governance committees.



**Figure 2** Systems-Based Medication Governance Model Leveraging Digital Infrastructure

Digital integration not only improves safety and efficiency but reinforces pharmacists' leadership in governance by positioning them as stewards of intelligent medication systems.

#### 4.3. Data Analytics for Medication Use Evaluation (MUE)

As healthcare systems strive for greater efficiency and clinical effectiveness, data analytics has emerged as a vital tool in medication governance, particularly through Medication Use Evaluation (MUE). MUE involves systematic analysis of prescribing patterns, patient outcomes, and medication-related resource utilization to assess the appropriateness, safety, and cost-effectiveness of drug therapies [19].

One powerful application of MUE is population-level surveillance. Pharmacists and data scientists collaborate to analyze high-risk medication usage, monitor trends in chronic disease management, and evaluate the impact of formulary changes across patient cohorts. These analyses help identify prescribing outliers, optimize treatment algorithms, and assess adherence to clinical guidelines [20].

Another key use of analytics is in identifying prescribing trends and utilization variation. By stratifying data across service lines, demographics, and diagnoses, governance teams can detect overuse or underuse of medications and target interventions accordingly. For example, real-time dashboards may reveal unusually high opioid prescribing in certain departments, prompting audits or provider education [21].

Analytics also supports cost-effectiveness studies by correlating medication utilization with clinical outcomes such as readmission rates, adverse events, and quality-adjusted life years (QALYs). Pharmacists use these findings to justify formulary decisions, negotiate supply contracts, or propose alternative therapies that offer better value without compromising care [22].

Emerging technologies like predictive analytics and machine learning now enable proactive risk identification. These tools forecast patients at high risk for ADEs, medication non-adherence, or therapeutic failure, allowing pharmacists to intervene earlier in the care cycle. When integrated into governance dashboards, predictive insights align medication oversight with broader value-based care goals [23].

Ultimately, MUE analytics equips pharmacy governance structures with actionable intelligence that bridges performance data, clinical quality, and operational decision-making. As health systems shift toward outcome-driven

care, data literacy and analytical capabilities become core competencies for pharmacist leaders driving medication governance transformation [24].

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## 5. Strategic impact on quality, safety, and performance

### 5.1. Patient Safety and Medication Error Reduction

Patient safety is the cornerstone of healthcare delivery, and within the scope of systems-based medication governance, pharmacists have emerged as key leaders in error reduction and safety enhancement initiatives. Their expertise plays a central role in managing high-alert medications, which include drugs with heightened risk of causing significant harm if used in error—such as insulin, anticoagulants, and chemotherapy agents [15]. Governance structures that embed pharmacist oversight of these agents—via formulary restrictions, color-coded labelling, or protocol standardization—have significantly reduced error rates in high-risk scenarios [16].

Technological safeguards like barcode medication administration (BCMA) further reinforce safety. Pharmacists contribute by ensuring that barcode libraries are accurate, continuously updated, and aligned with drug inventory systems. By integrating barcoding into dispensing and administration workflows, organizations create an additional verification layer that intercepts wrong-patient or wrong-dose incidents before they reach the bedside [17].

Equally critical is the pharmacist-led implementation of medication reconciliation frameworks, particularly during patient transitions across care settings. Errors due to incomplete medication histories or duplicative therapies are common during admissions and discharges. Pharmacists mitigate these risks by conducting structured reconciliation, validating prescribed therapies, and flagging inconsistencies before they manifest as clinical harm [18].

Beyond these interventions, pharmacists participate in root cause analysis (RCA) of medication incidents, helping translate findings into institutional learning and system redesign. Their involvement in incident reporting systems and participation in hospital safety committees ensures that safety intelligence leads to sustained improvements rather than isolated fixes [19].

Thus, by combining technological integration, clinical insight, and systems-level leadership, pharmacists substantially contribute to a culture of safety. Their governance role not only reduces harm but also reinforces a proactive, data-informed approach to medication risk management [20].

### 5.2. Driving Clinical and Fiscal Performance

Pharmacists' involvement in governance directly influences both clinical quality and fiscal performance. A central strategy is the use of cost avoidance metrics, which quantify the financial savings associated with pharmacist-led interventions—such as preventing adverse drug events (ADEs), optimizing therapeutic substitutions, and implementing dosage adjustments based on renal function or lab data [21]. These metrics form a persuasive basis for demonstrating return on investment (ROI) in clinical pharmacy services.

In formulary management, pharmacists apply pharmacoeconomic principles to assess the cost-effectiveness of medications. Governance frameworks often require clinical and economic justifications for new drug inclusions, therapeutic switches, or off-label use protocols. These activities not only standardize prescribing but help institutions align with value-based purchasing models, where reimbursement is linked to outcomes rather than service volume [22].

Pharmacists also play a central role in reducing readmissions and length of stay (LOS) by participating in multidisciplinary rounds, counseling on chronic medications, and initiating deprescribing strategies. These interventions yield measurable gains in both patient outcomes and resource utilization, reinforcing the idea that clinical pharmacy is not a cost center but a performance lever [23].

Governance structures enable these contributions to be tracked via metrics-based accountability systems. Key indicators include medication error rates, adherence to formulary protocols, documentation completeness, and patient satisfaction scores. By participating in performance dashboard development and audit committees, pharmacists ensure that quality metrics are both meaningful and actionable [24].

In financial terms, the savings associated with pharmacist-led governance can extend beyond drug costs to include reduced litigation, fewer emergency interventions, and improved insurer incentives under bundled payment models.

As institutions seek to reconcile cost containment with clinical excellence, pharmacist-driven governance offers a scalable, sustainable path toward both goals [25].

**Table 2** Metrics Used to Assess Pharmacist-Led Governance Impact on Quality and Cost

Metric	Definition / Focus	Indicative Use
Medication Error Rate Reduction (%)	Percentage decrease in reported prescribing, dispensing, or administration errors	Safety performance tracking
Adverse Drug Event (ADE) Prevention Savings	Financial value of prevented hospitalizations or complications due to avoided ADEs	Cost avoidance justification
Medication Adherence Improvement (%)	Increase in patients adhering to prescribed regimens over time	Clinical effectiveness, chronic disease control
Formulary Compliance Rate (%)	Proportion of medications prescribed from the approved institutional/national formulary	Policy adherence and therapeutic consistency
Cost per Adjusted Discharge (\$)	Average medication-related expenditure per inpatient discharge, adjusted for complexity	Financial benchmarking, efficiency assessment
Average Time to Reconciliation (hrs)	Time from patient admission or discharge to completed medication reconciliation	Workflow optimization and transition safety
High-Risk Medication Audit Closure Rate (%)	Proportion of identified high-alert drug issues addressed within defined timelines	Risk mitigation responsiveness

### 5.3. Institutional Trust and Public Confidence

Medication governance extends beyond clinical walls to influence institutional reputation and public trust. As patients and caregivers become more engaged in their health decisions, the visibility and transparency of medication policies become essential. Pharmacists, as public-facing and data-informed professionals, play a vital role in building this trust through transparent governance and structured communication.

One avenue is through clear communication channels between the pharmacy department and the public. This includes publishing formulary decisions, medication safety bulletins, and patient-friendly drug education materials. When institutions openly share how and why certain medications are prioritized—or restricted—it fosters a perception of fairness, evidence-based practice, and accountability [26].

Pharmacists also contribute to community engagement efforts, such as hosting medication safety forums, participating in health literacy programs, and addressing concerns about new therapies or drug shortages. Their ability to demystify pharmaceutical policies positions them as accessible sources of credible health information, especially in times of uncertainty or regulatory change [27].

Within institutional settings, pharmacists support transparency in governance structures by leading reporting mechanisms for adverse events, chairing medication safety committees, and documenting corrective actions. These efforts are crucial for maintaining compliance with external accreditation standards while reinforcing public assurance that health systems prioritize safety and integrity [28].

Moreover, in crises—such as pandemics, drug recalls, or vaccine rollouts—pharmacists act as trusted spokespersons and operational leaders. Their engagement in risk communication and logistical execution strengthens the institution's ability to respond credibly and effectively to public health challenges [29].

In sum, pharmacist-led governance contributes not only to clinical and operational gains but also to the social license under which healthcare institutions operate. Through transparency, responsiveness, and advocacy, pharmacists play a foundational role in earning and maintaining public confidence [30].

## **6. Challenges in governance and leadership implementation**

### **6.1. Regulatory Fragmentation and Bureaucratic Hurdles**

Despite the growing evidence supporting pharmacist-led governance models, implementation often stalls due to regulatory fragmentation and bureaucratic barriers. These challenges manifest in various ways, including inconsistent policies across jurisdictions, sectoral overlaps, and administrative inertia that hinders agile reform [19].

One of the most pressing issues is the lack of harmonization between regulatory frameworks governing pharmacy practice, hospital operations, and public health systems. For instance, medication safety protocols may differ between primary care, hospital, and community pharmacy settings, making it difficult to implement unified governance strategies [20]. Such inconsistencies force pharmacists to navigate conflicting directives, creating uncertainty and operational inefficiencies.

In addition, licensing bodies and health authorities often impose redundant or overlapping requirements on pharmacists. The coexistence of state-level, national, and organizational credentialing processes can delay the recognition of pharmacist-led programs, complicating cross-border collaboration or the scaling of innovative governance frameworks [21].

Administrative burdens also play a significant role. Many institutions rely on outdated approval chains and slow policy cycles that limit timely updates to medication formularies, safety protocols, or data-sharing agreements. These bureaucratic lags reduce the responsiveness of pharmacy governance teams and undermine the iterative nature of systems-based models, which rely on continuous feedback and adaptation [22].

Moreover, pharmacists are frequently underrepresented in national and regional policymaking bodies, despite their expertise in medication systems. Without formal inclusion, governance decisions may overlook pharmacist input or delay the adoption of practice-enabling legislation [23].

These regulatory and administrative hurdles create a fragmented ecosystem where pharmacist-led governance remains underleveraged, despite its proven potential. Addressing this fragmentation requires coordinated advocacy, streamlined policy frameworks, and recognition of pharmacists as co-leaders in healthcare governance and reform [24].

### **6.2. Workforce Capacity and Professional Recognition**

Another critical barrier to pharmacist-led governance adoption is the mismatch between workforce capacity and expanding responsibilities. As the governance role of pharmacists grows—encompassing safety oversight, policy development, data analysis, and digital infrastructure—there is increasing concern about whether the existing workforce is sufficiently trained and recognized to fulfill these expectations [25].

One of the primary gaps lies in education and professional training. Many pharmacy curricula continue to emphasize clinical pharmacology and dispensing workflows, with limited focus on leadership, governance frameworks, or systems thinking. Graduates may lack exposure to quality management tools, health policy analysis, or collaborative governance models—skills essential for effective participation in strategic planning [26].

In-service training opportunities are often fragmented or optional, leading to uneven distribution of governance competencies across institutions and regions. While some pharmacists receive advanced training in regulatory science or health informatics, others remain confined to traditional scopes of practice, limiting their ability to lead or contribute meaningfully to interdisciplinary committees [27].

Ambiguity around the scope of practice further complicates governance participation. In many jurisdictions, pharmacists face legal or institutional constraints that prevent them from initiating policy, signing off on therapeutic decisions, or auditing prescriber behavior—even when they possess the requisite expertise. This uncertainty affects both their perceived authority and willingness to engage proactively in governance roles [28].

Moreover, the lack of formal recognition and incentivization for governance contributions discourages pharmacist involvement. While clinical metrics may be rewarded in performance evaluations, contributions to formulary development, safety protocol design, or audit processes often go unacknowledged, creating a misalignment between effort and institutional value [29].

To build governance-ready pharmacy workforces, there is a need for system-wide alignment between educational standards, regulatory frameworks, and organizational expectations. Empowering pharmacists to function as governance leaders will require structural reforms and sustained investment in professional development [30].



**Figure 3** Intersecting Barriers to Pharmacist-Led Governance Adoption

### 6.3. Data Integrity and Interoperability Gaps

In the digital era, the effectiveness of pharmacy governance increasingly hinges on the quality, availability, and interoperability of medication-related data. However, many healthcare systems remain burdened by legacy infrastructures and fragmented platforms that undermine real-time, data-driven governance [31].

A major challenge is the continued reliance on legacy systems, which were designed primarily for transactional functions like billing or dispensing rather than for dynamic, analytics-enabled governance. These systems often lack the flexibility to support real-time decision support, audit trail documentation, or predictive analytics, thereby constraining pharmacists' ability to engage in proactive governance [32].

Even in organizations that have adopted modern electronic health records (EHRs) or enterprise pharmacy systems, platform misalignment remains a problem. Poor interoperability between pharmacy, clinical, and administrative systems can lead to duplicated records, mismatched medication histories, and incomplete decision support alerts. These discrepancies not only compromise patient safety but erode trust in the governance infrastructure [33].

Another persistent issue is the lack of standardized data-sharing frameworks across institutions and regions. Without robust data governance protocols—such as those defined by HL7 or FHIR standards—pharmacists face difficulty aggregating or comparing prescribing trends, adverse event rates, or compliance metrics across populations. This inhibits system-wide learning and weakens accountability mechanisms [34].

Furthermore, data quality issues—such as incomplete documentation, outdated formularies, or inconsistent terminology—introduce noise into analytics dashboards, reducing the accuracy of governance decisions. Pharmacists often spend considerable time validating or cleaning data rather than focusing on strategic oversight [35].

To overcome these challenges, healthcare systems must prioritize digital modernization, interoperability standards, and pharmacist access to integrated data streams. Doing so will enable governance models that are agile, evidence-informed, and capable of improving outcomes at scale.

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## 7. Case studies of successful systems-based pharmacy governance

### 7.1. Singapore's Integrated Medication Management Framework

Singapore has become a leading example of how pharmacist-led governance can be embedded in national healthcare infrastructure through a technology-enabled, policy-driven framework. The country's Integrated Medication Management (IMM) model links national drug policy, electronic systems, and cross-sector collaboration to support safe, effective, and accountable pharmaceutical practices [25].

At the heart of Singapore's framework is a centralized formulary system, maintained through coordinated oversight by pharmacists, clinicians, and Ministry of Health (MOH) authorities. Medications approved for use within public hospitals must meet criteria on safety, cost-effectiveness, and therapeutic need. Pharmacists participate in regular formulary reviews and health technology assessments, ensuring the system remains responsive to epidemiological trends and financial constraints [26].

In addition, Singapore employs tech-enabled medication audits across its public hospitals. These audits are powered by integrated health IT systems that generate real-time alerts, track prescription-to-dispensation workflows, and automatically flag discrepancies or deviations from national guidelines. Pharmacists are responsible for interpreting audit data, conducting root cause analyses, and coordinating with medical teams to close performance gaps [27].

The IMM framework also features pharmacist-driven initiatives in medication reconciliation and patient education, particularly during admission and discharge transitions. These efforts are aligned with national performance indicators and feed into institutional accreditation processes. Furthermore, a strong emphasis on e-learning and continuous professional development has created a digitally competent pharmacy workforce ready to lead governance activities [28].

Singapore's model demonstrates that with the right mix of policy support, IT infrastructure, and workforce investment, pharmacists can anchor medication governance across a national system. The scalability of its approach provides a blueprint for other high-income countries seeking to integrate medication oversight with broader health policy objectives [29].

## **7.2. UK's NICE Guidance and Pharmacy Practice Integration**

The United Kingdom (UK) offers a strong institutionalized model for pharmacist-led medication governance, driven by the integration of National Institute for Health and Care Excellence (NICE) guidance into clinical pharmacy practice. NICE produces evidence-based recommendations for therapeutic interventions, public health strategies, and cost-effectiveness thresholds, which are then operationalized by pharmacists within the National Health Service (NHS) [30].

A key feature of the UK system is its emphasis on stakeholder engagement in guideline development. Pharmacists actively participate in NICE advisory groups, contributing expertise on pharmacology, patient adherence, and formulary optimization. Their involvement ensures that the resulting guidance is not only clinically sound but also implementable in pharmacy-led workflows [31].

Pharmacists are instrumental in translating NICE guidance into local therapeutic protocols and clinical decision support tools. In many NHS Trusts, medicines optimization teams led by pharmacists oversee guideline dissemination, audit implementation, and prescriber education. These efforts reinforce adherence to evidence-based practices and reduce variability in care delivery [32].

Another important mechanism is the use of Formulary Interface Groups (FIGs)—interdisciplinary committees where pharmacists, general practitioners, and commissioning managers collaborate to align primary and secondary care formularies. These groups ensure seamless transitions between care settings and prevent duplication, under-prescribing, or unsafe medication switches [33].

UK pharmacists also engage in data-driven quality improvement projects, supported by NHS Business Services Authority dashboards and prescribing analytics platforms. These tools enable pharmacists to monitor prescribing trends, benchmark against national averages, and identify areas for targeted intervention.

The UK's alignment of pharmacist practice with NICE's evidence and NHS accountability structures offers a robust model of integrated governance. It illustrates how guideline-driven, collaborative frameworks can elevate the pharmacist's role in strategic decision-making and improve system-level outcomes [34].

## **7.3. Rwanda's National Pharmaceutical Strategic Plan**

In contrast to high-income settings, Rwanda presents a compelling case for pharmacist-led governance in a low-resource, decentralized health system. The country's National Pharmaceutical Strategic Plan (NPSP) prioritizes medication access, accountability, and sustainability, with pharmacists positioned as key governance agents across all healthcare levels [35].

One of Rwanda's most innovative approaches lies in its district-level pharmaceutical governance committees, which decentralize oversight and promote local problem-solving. Pharmacists chair these committees, coordinating drug procurement, formulary adherence, and community-level medication audits. This model ensures that governance is responsive to local disease patterns, supply chain disruptions, and health system capacity [36].

The NPSP also incorporates pharmacists into national policy formulation, including the design of essential medicines lists (EMLs) and procurement strategies. Their responsibilities include evaluating supplier performance, advising on budget allocation, and ensuring that procurement aligns with national treatment guidelines. In doing so, pharmacists balance clinical priorities with financial stewardship—a critical skill in low-resource environments [37].

In addition, Rwanda has embraced performance-based financing (PBF) mechanisms, which reward health facilities for achieving quality indicators, including those tied to pharmaceutical governance. Pharmacists play a monitoring role, validating performance data and supporting compliance with medication management protocols. This links governance activities directly to institutional incentives and patient care outcomes [38].

Rwanda's use of digital tools—though more limited than in higher-income contexts—is expanding. Pharmacists are involved in piloting open-source inventory management platforms and digital prescription tracking, enabling basic analytics to support oversight and reporting. These platforms help prevent stock-outs and minimize wastage, critical issues in resource-constrained health systems [39].

Perhaps most notably, Rwanda's governance framework demonstrates how professional empowerment and decentralization can compensate for limited resources. By embedding pharmacists in both policy and operational structures, Rwanda has cultivated a resilient, responsive pharmaceutical system that offers valuable lessons for other low-income countries navigating similar challenges [40].

**Table 3** Snapshot Comparison of Case Study Systems and Pharmacist Roles

Country	System Type	Governance Model	Pharmacist Involvement	Key Innovations	Outcomes Tracked
Singapore	Centralized, Tech-Enabled	Integrated Medication Management (IMM)	Formulary design, medication audits, reconciliation leadership	Real-time audit dashboards, centralized e-formulary	Medication discrepancies, safety incidents, adherence
United Kingdom	Public, Guideline-Driven	NICE-Aligned, Committee-Based Governance	Protocol implementation, P&T committees, interface coordination	Formulary Interface Groups, prescribing analytics	Formulary compliance, prescribing variation, patient outcomes
Rwanda	Decentralized, Low-Resource	National Pharmaceutical Strategic Plan (NPSP)	District-level committees, procurement oversight, audit roles	Performance-based financing, community audit loops	Stock-outs, essential drug access, compliance with EML

## 8. Strategic recommendations for policymakers and administrators

### 8.1. Building Enabling Policy and Legal Frameworks

A critical enabler of pharmacist-led medication governance is the establishment of coherent policy and legal frameworks that support standardized practice and cross-sector alignment. In many jurisdictions, pharmacists remain underutilized in governance roles due to outdated professional acts or fragmented health policies that do not clearly define their authority in oversight, analytics, or decision-making [29]. Without legal recognition, even well-trained pharmacists may be excluded from key forums or lack the authority to implement systemic interventions.

To address this, countries must prioritize the revision and harmonization of pharmacy acts and practice standards, ensuring they reflect contemporary clinical roles, digital capabilities, and governance expectations. These revisions

should clearly delineate pharmacist responsibilities in areas such as therapeutic protocol development, quality assurance, digital system governance, and pharmacovigilance reporting [30].

Standardizing governance structures across regions and health systems is equally important. Currently, the scope and composition of governance committees vary widely, limiting scalability and comparability of interventions. National-level guidance—detailing the required functions, membership, and reporting obligations of governance structures—would provide a blueprint for consistent implementation [31].

Additionally, legislative updates should address interprofessional governance, enabling shared accountability between pharmacists, physicians, nurses, and administrators. Legal support for collaborative practice agreements, data-sharing protocols, and protected whistleblower roles can further solidify pharmacist participation in governance processes.

Finally, regulatory agencies should support these frameworks by aligning licensure, inspection, and accreditation standards with pharmacist-led governance objectives. When supported by law, pharmacists can confidently lead medication oversight activities, enhance transparency, and promote the safe, equitable distribution of health resources [32]. Institutionalizing these frameworks is not merely a procedural upgrade—it is foundational for sustaining integrated, outcome-driven pharmacy governance across all levels of care.

## **8.2. Investing in Governance Capacity and Training**

Pharmacist-led governance cannot thrive without deliberate investment in the capacity and competencies of the workforce. Traditional pharmacy education, while strong in clinical and scientific foundations, often lacks structured content on leadership, quality systems, informatics, and health policy. To meet governance expectations, curricula must evolve to include systems thinking, data analytics, and strategic planning [33].

Educational institutions should embed clinical leadership training into undergraduate and postgraduate programs, emphasizing skills in communication, conflict resolution, and decision-making. These capabilities are vital for leading multidisciplinary teams and influencing institutional priorities. Simulation-based governance modules—such as mock formulary reviews, safety committee exercises, and compliance audits—can prepare students for real-world scenarios [34].

Professional development pathways also require transformation. Continuing education offerings should move beyond therapeutics and into regulatory science, digital health systems, and health economics. Credentialing bodies could create specializations in governance leadership, ensuring pharmacists have recognized qualifications to pursue these roles in hospitals, regulatory agencies, and ministries of health [35].

Capacity-building efforts must also target mid-career and senior pharmacists, enabling them to upskill and mentor the next generation. Structured fellowships, leadership residencies, and joint degree programs (e.g., PharmD-MPH or PharmD-MBA) can accelerate readiness for complex governance functions.

In addition to formal education, access to decision-support technologies and real-time data tools is essential. Pharmacists must be equipped with dashboards, audit platforms, and analytics training to monitor performance indicators and make evidence-based interventions [36].

Ultimately, governance readiness is not just about increasing numbers—it's about fostering a resilient, analytically fluent pharmacy workforce with the confidence and tools to drive sustainable change within medication systems.

## **8.3. Encouraging Multisectoral Collaboration and Accountability**

Pharmacy governance does not operate in isolation; its success depends on multisectoral collaboration that aligns stakeholders, leverages diverse expertise, and holds institutions accountable to shared goals. A systems-based approach requires cooperation between ministries of health, education, finance, and information technology—as well as private sector actors such as pharmaceutical suppliers, academia, and civil society [37].

One of the most effective strategies is aligning national health priorities with pharmacy governance mandates. For instance, if a country prioritizes reducing antimicrobial resistance (AMR), pharmacists should be positioned as leaders in stewardship committees, policy design, and educational outreach. Similarly, in contexts where access to essential medicines is a national concern, pharmacists should be part of procurement task forces, forecasting teams, and pricing negotiations [38].

Formal coordination platforms can facilitate this collaboration. Examples include national pharmaceutical councils, interagency governance boards, and donor-aligned working groups where pharmacists engage alongside economists, legal advisors, and public health officials. These platforms support collective decision-making and transparent accountability structures [39].

Public-private partnerships also offer untapped opportunities. Collaborating with technology firms on digital inventory systems or with insurers on medication adherence incentives allows pharmacy governance to innovate while addressing real-world system constraints.

Additionally, external oversight and citizen engagement can reinforce trust. Publishing medication governance dashboards, involving patient groups in policy reviews, and enabling open forums for community feedback ensures that pharmacists remain responsive to those they serve.

By embedding pharmacy governance within a broader ecosystem of actors and priorities, countries can ensure coherence, legitimacy, and long-term sustainability. Pharmacists, in turn, become not only medication stewards but strategic collaborators in advancing population health [40].

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## **9. Conclusion and future directions**

### **9.1. Summary of Key Messages**

This article has demonstrated that pharmacist-led medication governance is no longer a conceptual ambition but a practical necessity within evolving health systems. As healthcare grows more complex, data-driven, and patient-centered, the role of the pharmacist has transformed from transactional dispensing to strategic leadership. Pharmacists now contribute meaningfully to the architecture of safety, efficiency, and accountability in both policy and practice.

Empowering pharmacists in governance enables a more structured, evidence-informed approach to medication oversight. Whether through leading formulary reviews, designing adverse event mitigation protocols, or analyzing real-time prescribing trends, pharmacists are proving indispensable to organizational safety and performance. These contributions help not only in reducing medication errors but also in improving adherence, minimizing waste, and ensuring the fiscal sustainability of health systems.

The article highlighted a systems-based approach to medication governance—one that relies on integration, continuous learning, and adaptability. This paradigm recognizes medication use as a shared responsibility and embeds governance into daily workflows rather than relegating it to top-down policy enforcement. Through structured committees, interoperable technologies, and performance dashboards, governance becomes a living system that evolves alongside clinical practice and technological advancement.

Crucially, the elevation of pharmacists into governance roles aligns with broader trends toward decentralization, value-based care, and digital transformation. National strategies in high- and low-income countries alike are beginning to institutionalize pharmacist participation in strategic decision-making, illustrating both the scalability and impact of this approach.

The call to action is clear: governance models must formally recognize pharmacists as system architects, not just system operators. By equipping them with the legal authority, analytic tools, and interprofessional platforms to lead, health systems can unlock a deeper layer of operational intelligence and patient-centered care. Pharmacist-led governance, when fully realized, becomes a cornerstone of resilient, equitable, and high-performing healthcare systems.

### **9.2. Roadmap for Future Research and Global Alignment**

While significant progress has been made in integrating pharmacists into governance structures, several frontiers remain ripe for exploration and standardization. A key area for future research is the intersection of pharmacy governance with emerging digital health innovations. As AI, predictive analytics, and automation reshape healthcare, understanding how pharmacists can govern, interpret, and ethically deploy these technologies will be essential. Studies examining the impact of these tools on governance quality, data accuracy, and patient outcomes are particularly needed.

Additionally, there is a growing need to explore unified regulatory systems that standardize pharmacy governance roles across jurisdictions. At present, wide disparities exist in pharmacist authority, governance participation, and data access

across countries and even within regions. Comparative policy studies that assess the effect of harmonized regulatory frameworks on system performance could provide valuable insights for national and global stakeholders.

Another promising avenue lies in the benchmarking of cross-country models. By creating platforms for international knowledge exchange, countries can compare governance outcomes, identify best practices, and adapt scalable models to local contexts. These benchmarks could include indicators such as governance structure effectiveness, pharmacist leadership representation, medication safety outcomes, and health system responsiveness.

The future of pharmacist-led governance depends not only on national will but on a shared global vision. Aligning education, regulation, digital infrastructure, and funding mechanisms will be key to realizing the full strategic potential of pharmacists in every health system. Research and policy communities must work together to support this vision—building a governance architecture that is adaptive, inclusive, and deeply rooted in the goal of better care for all.

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## Compliance with ethical standards

### *Disclosure of conflict of interest*

No conflict of interest to be disclosed.

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