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Original article

Transforming the Patient-Pharmacist Relationship in Libya: A Perspective on Digital Health and AI Integration

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ABSTRACT

The Libyan health sector faces structural challenges in regulating the patient-pharmacist relationship, most remarkably the overlapping roles in prescribing and dispensing medications, and the weak implementation of drug scheduling systems, which could pay attention to patients' quality of life. This study aims to propose an integrated framework for regulating this relationship, grounded in recent technological developments and international standards, while respecting local specificities. The study employed a descriptive-analytical approach by reviewing the literature, previous studies, and media on the realities of pharmacy practice in Libya, analyzing recent national initiatives (such as the electronic insulin dispensing system), and aligning these initiatives with World Health Organization guidelines and pharmaceutical regulations in Arab, European, and American contexts. An integrated "Safe Dispensing" framework (Sarif Aaman integrated system) was established, built on five pillars: (1) Separation of prescribing and dispensing roles of the caregiver, (2) Implementation of a national drug scheduling system, (3) Expansion of the electronic system to cover all medications, (4) Legislation of an obligatory or commitment charter on the rights and duties of patients and pharmacists, (5) Incorporation of AI tools. Conclusions: The proposed framework is a viable solution that addresses current regulatory gaps, enhances patient safety, consolidates the pharmacist's professional role, and aligns with international standards, including those of the FDA, EMA, and WHO. Recommendations: It is recommended that the framework be adopted gradually, beginning with a pilot phase in the possible three main regions in Libya focused on high-risk medications, while developing digital infrastructure and continuous training programs for pharmaceutical personnel.

Introduction

The regulation of the relationship between patients and pharmaceutical service providers establishes a fundamental pillar in the construction of any advanced health system. In Libya, despite the availability of qualified pharmaceutical personnel [(1). Pharmaceutical practice continues to face structural challenges that limit the pharmacist's role and threaten patient safety. Among the most prominent challenges is the persistent phenomenon of community pharmacists (CPs) in the private sector engaging in both prescribing and dispensing medications, which studies have recognized as a primary cause of the spread of medication errors and the excessive use of other medications, such as antibiotics [(2, 3). This issue has assumed growing significance, particularly following the adoption of the Libyan Essential Medicines List (LEML) by the Libyan Ministry of Health, which constitutes a strategic milestone in advancing the rational use of medicines and optimizing prescribing and dispensing practices in accordance with evidence-based principles and harmonized national standards [(4, 5).

This practice contradicts international principles that distinguish between the physician's competence in diagnosis and prescribing, and the pharmacist's competence in review, dispensing, and patient education [(2)]. The absence of a clear separation of roles, coupled with weak implementation of drug scheduling systems (classifying medications into prescription and non-prescription categories), has created a regulatory gap that undermines oversight and exposes patients to serious risks [(2).

In contrast, recent years have witnessed positive developments, most notably the Libyan Ministry of Health's launch of an advanced electronic system for dispensing and tracking insulin medications, linking the dispensing process to the citizen's national ID number to prevent duplication and leakage [(1, 6, 7). This initiative represents a solid foundation upon which a comprehensive framework for regulating the entire pharmaceutical relationship can be built.

This study addresses a central research question: How can an integrated framework for regulating the patient-pharmacist relationship in Libya be constructed, one that benefits from international experiences

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and local technological developments while remaining consistent with local, Arab, and international regulations? It aims to present a proposed model (the "Safe Dispensing" framework) that answers this question through four interconnected pillars, while analyzing its alignment with international standards issued by the World Health Organization (WHO), the US Food and Drug Administration (FDA), and the European Medicines Agency (EMA).

In parallel with regulatory and technological reforms, the integration of artificial intelligence (AI) and health information technologies represents a transformative opportunity to enhance the safety, efficiency, and accountability of pharmaceutical care. AI-driven clinical decision support systems (CDSS) have demonstrated significant potential in identifying drug–drug interactions, predicting adverse drug events, optimizing dosing, and supporting medication verification processes, thereby reducing medication-related harm and improving therapeutic outcomes [(8, 9, 10).

In addition, health information technology (HIT) systems—including electronic prescribing (e-prescribing), integrated patient registries, and automated reminder systems—can enhance continuity of care and patient adherence [(11). These systems can notify patients or their caregivers regarding prescription renewals, scheduled clinical visits, and medication administration, thereby reducing treatment interruptions and minimizing inappropriate self-medication practices [(12, 13). Importantly, recent evidence indicates that community pharmacists demonstrate increasing readiness and positive perceptions toward adopting AI-based technologies for drug interaction assessment, highlighting the feasibility of integrating such systems into routine pharmacy practice [(14, 15, 16).

Methodology

This study adopts a descriptive–analytical approach based on qualitative content analysis to diagnose the reality of pharmaceutical practice in Libya, and a developmental approach to construct the proposed model. Information was gathered through:

- Literature Review and Previous Studies: Analyzing academic content published in peer-reviewed journals on the reality of pharmacy in Libya, most notably studies by Atia (2018) on prescribing errors and the need for prescription separation [(2) Sherif (2023) on the future of pharmacy and continuing education [(17, 18), and Ali and Benkorah (2021) on evaluating pharmacists' competencies against international standards [(19).
- Analysis of Official Documents and Reports: Monitoring and analyzing verified media reports on the launch of the electronic insulin dispensing system [(1, 6, 7, 20).
- Alignment with International Standards: Comparing the components of the proposed model with the joint guidelines of the International Pharmaceutical Federation (FIP) and the World Health Organization (WHO) for good pharmacy practice [(19), and with data integrity requirements in global Good Manufacturing Practice (GMP) systems such as European Annex 11 and US 21 CFR Part 11.
- Assessment of Digital Transformation and AI Integration in Pharmacy Practice: Reviewing recent international developments in AI-powered pharmaceutical systems and digital health technologies. This includes analysis of newly launched AI-driven dispensing platforms in real-world settings, such as the Australian model reported by MobiHealthNews (2021)[(21), which highlights the role of automation and artificial intelligence in improving dispensing accuracy and workflow efficiency. Additionally, insights were drawn from recent scholarly discussions on intelligent pharmacy systems and the integration of AI and automation in enhancing patient care and expanding pharmacists' clinical roles [(22).

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Results

Presentation of the Integrated "Safe Dispensing" Framework. Based on the analysis of regulatory gaps and recent trends, the integrated "Safe Dispensing" (Sarif Aaman) framework was developed, built on five interconnected fundamental pillars:

Pillar One: Separation of Prescribing and Dispensing Roles

The framework proposes the gradual implementation of the principle of "separation of prescribing and dispensing," whereby the physician's role is limited to diagnosis and writing the prescription. At the same time, the pharmacist assumes responsibility for reviewing the prescription, verifying its safety, dispensing the medication, and providing patient counseling. This principle addresses the conflict of interest arising from linking the pharmacist's profit to the quantity of medications dispensed [(2). It also enhances quality through role specialization, allowing both physicians and pharmacists to focus on their respective areas of expertise [(2).

Pillar Two: Implementation of a National Drug Scheduling System

The framework proposes establishing an independent scientific committee under the National Medicines and Poisons Board to develop a national drug classification system (National Drug Scheduling) that precisely defines medication categories. This classification fills a significant gap identified in previous research [(2) and includes (i) Prescription Drugs (Rx): Dispensed only with a physician's prescription following diagnosis, (ii) Over-the-Counter Drugs (OTC): Can be dispensed without a prescription following pharmacist consultation and appropriate counseling, and (iii) Specially Controlled Drugs: Including psychotropic medications and those for rare chronic disease, subject to strict monitoring within the electronic system.

Pillar Three: Expansion of the Electronic System Scope

Based on the success of the electronic insulin system experience [(1, 6, 7, 20)]. The framework proposes its expansion to cover all medications through (i) Unified Electronic Prescription: Issued by the physician with a secure code, containing all necessary data (medication name, dosage, duration), (ii) Linkage with National ID Number: Ensures the patient receives only the prescribed doses and prevents duplication across different pharmacies, and (iii) Centralized Database: Tracks medication movement from importation to patient receipt, enhancing national inventory management efficiency [(1).

Pillar Four: Charter of Patient and Pharmacist Rights and Duties

This charter is enacted within the regulations governing professional practice and includes: (i) Patient Rights and Duties, Patient Rights: The right to effective, safe, and standards-compliant medication [(18); the right to a clear explanation from the pharmacist regarding usage and side effects [(17, 18); the right to privacy and confidentiality of health data; the right to refuse generic substitution with a clear explanation of the differences. Patient Duties: Commitment not to purchase prescription medications without a prescription; informing the pharmacist of all medications being taken; adherence to prescribed doses and not sharing medications; reporting adverse effects, (ii) Pharmacist Rights and Duties, Pharmacist Rights: The right to dispense only prescribed medications according to scheduling; the right to refuse dispensing if potential harm is identified (after consulting the physician); the right to a safe working environment. Pharmacist Duties: Verifying identity and electronic prescription; providing pharmaceutical counseling and ensuring patient understanding [(17, 18); immediate reporting of adverse effects and counterfeit medications through the platform.

Pillar Five: AI-Driven Pharmaceutical Governance

As part of the proposed regulatory framework, artificial intelligence is integrated into national pharmaceutical systems to strengthen regulatory oversight and patient safety. AI-based clinical decision support can detect drug interactions, prescribing errors, and inappropriate dispensing in real time. Additionally, data-driven monitoring enables early identification of misuse patterns, particularly for high-risk medications. Integration with digital platforms also supports automated patient reminders for prescription renewal and follow-up, enhancing adherence and continuity of care.

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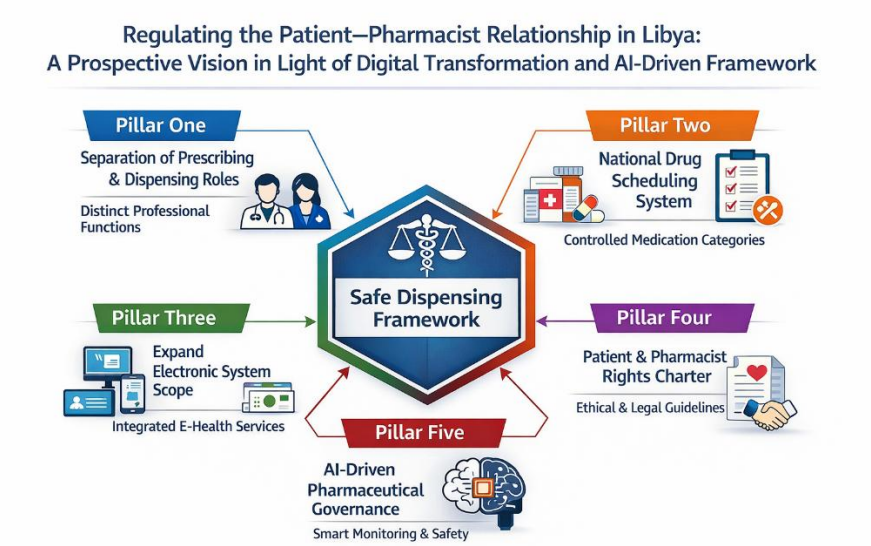

Discussion

The proposed framework represents a qualitative leap in regulating pharmaceutical practice in Libya. The results indicate that the main challenge is not a shortage of qualified personnel, as Libya has enough pharmacy graduates [(2), but rather a regulatory and legislative challenge at its core.

The study conducted by Ali and Benkorah (2021) showed that pharmaceutical practice in Libya remains more system-focused than patient-focused [(19). The fourth pillar of the framework (the Rights and Duties Charter) directly addresses this issue by establishing clear obligations toward the patient. Furthermore, Sherif (2023) emphasized the importance of continuous professional development for pharmacists to enable them to perform advanced clinical roles [(17, 18), which aligns with the requirements of the first pillar (role separation) that needs qualified pharmacists to provide counseling and review prescriptions.

The experience of the electronic insulin system, launched in 73 centers [(7, 20)]. This demonstrates the government's seriousness in adopting digital solutions. Expanding this experience to cover all medications, as proposed in the third pillar, aligns with international trends toward e-Health and Clinical Decision Support Systems.

Regarding alignment with international standards: Arab and International Levels: The framework aligns with the directions of Arab drug authorities in unifying registration and control procedures. It is also consistent with World Health Organization (WHO) standards for rational drug use and patient safety [(2, 19). Rigorous Regulatory Systems (FDA - EMA): The separation of prescribing and dispensing is fundamental to the system in the United States and Europe. Additionally, the data integrity requirements in the proposed electronic system (data integration, prevention of tampering) align with Good Manufacturing Practice (GMP) requirements such as European Annex 11 and US 21 CFR Part 11.

Furthermore, embedding AI and digital health infrastructure within pharmaceutical regulatory frameworks is essential for achieving a safe, transparent, and patient-centered healthcare system, aligned with global trends in intelligent and data-driven healthcare delivery [(9, 10).

Conclusions and Recommendations

Pharmaceutical practice in Libya continues to face a significant regulatory gap, reflected in role overlap and insufficient drug scheduling control. However, the existing electronic insulin system provides a practical and scalable foundation for improvement. Building on this, the proposed “Safe Dispensing” framework offers a context-sensitive, integrated model aligned with international standards and adaptable to local healthcare realities. The incorporation of artificial intelligence may further strengthen medication safety through early detection of potential drug interactions and adverse effects. To operationalize this framework, a phased implementation strategy is recommended. Initial efforts should focus on establishing a formal drug scheduling system or law and preparing healthcare professionals (physicians and pharmacists) through targeted training on electronic platforms. This can be followed by pilot implementation involving high-risk medications (such as psychiatric and rare chronic disease medications), alongside the introduction of a clear rights and duties charter. Gradual nationwide rollout should then ensure integration across public and private pharmacies, with enforcement of role delineation. Sustained impact will depend on parallel reforms in pharmacy education, including curriculum updates and mandatory continuing professional development

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programs. Finally, institutional oversight—particularly through an empowered pharmacy syndicate—will be essential to monitor adherence and ensure long-term system effectiveness.

Conflict of interest

The authors declare that there is no conflict of interest

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