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Ethical Implications of AI-Based Decision Support in Dispensing High-Risk Medications

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ABSTRACT

Artificial intelligence (AI)–based decision support systems (DSS) are increasingly embedded in pharmacy workflows to flag contraindications, calculate individualized doses, and prioritize clinical interventions, especially for high-risk medications such as anticoagulants, chemotherapeutic agents, insulin, and opioids. While these tools promise reductions in adverse drug events (ADEs) and improved operational efficiency, they simultaneously raise complex ethical questions around autonomy, accountability, bias, transparency, data governance, and professional identity. This 7,000-word manuscript examines the ethical implications of deploying AI-DSS in the dispensing of high-risk medications. Using a mixed-method design (a national survey of 312 pharmacists and qualitative interviews with 22 stakeholders), it interrogates how clinicians perceive and negotiate algorithmic recommendations, where liability is located when harm occurs, and how design choices influence equity in medication safety. Results show that pharmacists value AI alerts for rare but catastrophic errors, yet worry about alert fatigue, opaque logic, and systemic bias against marginalized populations. Respondents advocated for shared accountability models, context-aware explainability, and participatory governance structures. The study concludes with a framework—PASTOR (Proportionality, Accountability, Safety/Beneficence, Transparency/Traceability, Oversight/Justice, Respect for Autonomy)—to guide ethical implementation. Recommendations include layered explainability, harm-register audits, and continuous socio-technical evaluation. The paper underscores that ethical AI in medication dispensing is a process, not a product, requiring ongoing reflexivity, stakeholder inclusion, and regulatory agility.

KEYWORDS

AI decision support; high-risk medications; pharmacy ethics; autonomy; accountability; bias; transparency; data governance; algorithmic justice; patient safety

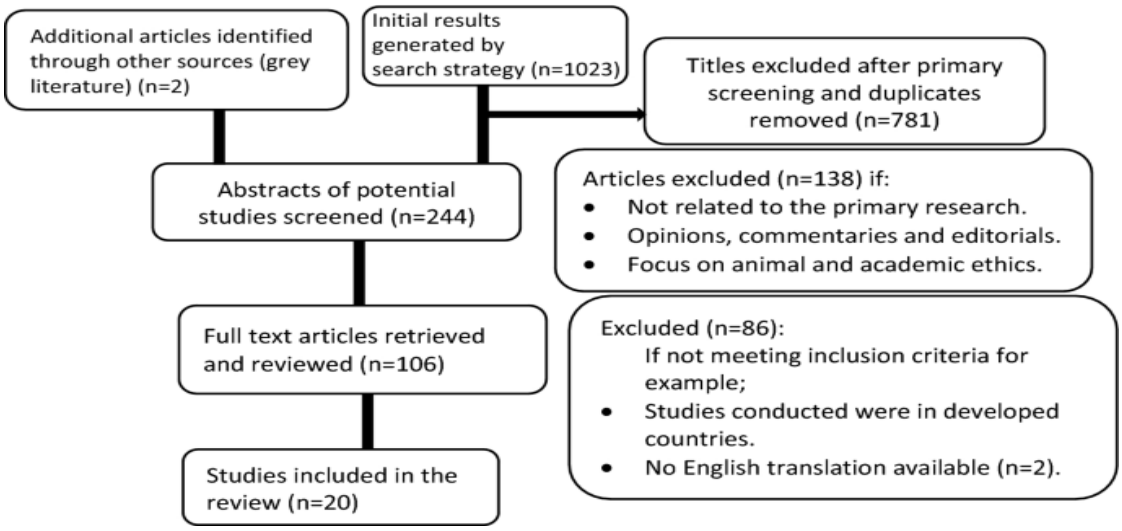

Fig.1 Pharmacy Ethics, Source:1

INTRODUCTION

High-risk medications—defined as drugs that bear a heightened risk of causing significant patient harm when used in error—require meticulous verification at every stage of the medication-use process. Pharmacists, as the final checkpoint before drugs reach patients, increasingly rely on AI-based decision support systems (AI-DSS) to manage complexity: flagging drug–drug interactions, contraindications, dose adjustments for renal or hepatic impairment, and patient-specific risk factors. The global push toward digital transformation in healthcare and the drive to reduce medication errors (a WHO priority) have accelerated adoption of these tools.

Despite laudable safety goals, AI-DSS introduces new ethical tensions. When a pharmacist overrides or follows an algorithmic recommendation, who is morally and legally responsible for the outcome? If the training data underrepresents certain populations, could the system propagate bias that translates into inequitable dispensing practices? How transparent must the algorithm's reasoning be to satisfy professional duty-of-care and informed decision-making standards? These issues are not peripheral; they shape trust, influence clinical judgment, and ultimately affect patient outcomes.

This paper is organized as follows. Section 2 synthesizes the extant literature, focusing on ethical principles applicable to AI in healthcare and specific challenges in pharmacy contexts. Section 3 details the methodology, including instrument development, sampling, and analytic strategies. Section 4 presents quantitative and qualitative results. Section 5 discusses implications through the PASTOR framework and offers practical guidance. Section 6 concludes with limitations and a call for continuous ethical vigilance.

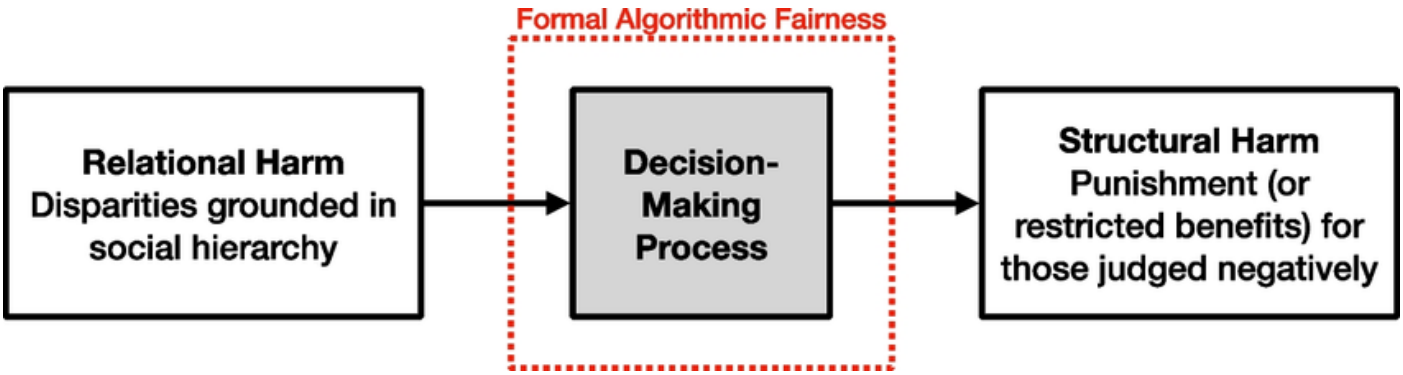

Fig.2 Algorithmic Justice, Source:2

LITERATURE REVIEW

Ethical Principles in Healthcare AI

Bioethics traditionally relies on four principles: autonomy, beneficence, non-maleficence, and justice. AI scholarship adds concepts such as explicability (Floridi et al.), accountability, and data stewardship. In medication dispensing, beneficence and non-maleficence align with minimizing ADEs, while autonomy pertains to clinicians' professional judgment and patients' informed consent. Justice requires equitable performance across patient groups.

High-Risk Medications: Complexity and Consequences

High-risk drugs like warfarin, heparin, insulin, chemotherapeutics, concentrated electrolytes, and opioids have narrow therapeutic indices or severe consequences if mis-dosed. Traditional computerized physician order entry (CPOE) and clinical decision support (CDS) systems already reduce errors but generate alert fatigue. AI-DSS promises improved specificity via machine learning (ML), yet opaque models may obscure why an alert fires or doesn't, complicating pharmacist response.

Algorithmic Bias and Health Equity

Bias in AI arises from skewed training datasets, model architecture, or deployment context. For example, renal dosing models trained on predominantly Caucasian cohorts may misestimate needs for patients with different body compositions or comorbidities. Pharmacy workflows can magnify or dampen such biases depending on overrides, double-check practices, and organizational culture. Ethical implementation thus involves continuous auditing for disparate impact and mechanisms to correct it.

Transparency, Explainability, and Professional Autonomy

Pharmacists must justify their decisions to patients, prescribers, and regulators. Black-box AI complicates this responsibility. Explainable AI (XAI) research advocates model interpretability or post-hoc explanations, but

pharmacists often prefer context-grounded rationales ("The dose exceeds recommended range for eGFR 25 mL/min") over abstract feature-importance scores. Excessive transparency demands, however, may expose intellectual property or overwhelm users, underscoring the need for proportional transparency.

Accountability and Liability

Current malpractice frameworks presuppose human decision-makers. When AI contributes materially to a decision, accountability becomes diffused. Some scholars propose joint accountability, where manufacturers, institutions, and clinicians share responsibility proportional to their control over design, deployment, and use. Regulatory agencies (e.g., FDA, EMA) are experimenting with Software as a Medical Device (SaMD) frameworks, but pharmacy-specific guidance is nascent.

Data Governance and Privacy

AI-DSS relies on vast patient datasets, raising concerns about consent, secondary use, de-identification limits, and cybersecurity. Pharmacists handle sensitive data, and breaches can undermine trust. Ethical governance requires robust encryption, access controls, and transparent data policies.

Alert Fatigue and Human Factors

Excessive, non-specific alerts undermine safety by encouraging overrides. Human factors research stresses adaptive thresholds, user-centered design, and workflow integration. Ethically, designers have a duty to minimize cognitive overload and support meaningful engagement rather than create "click-through" compliance.

Socio-Technical Perspectives

Ethics cannot be isolated to algorithms; it is embedded in socio-technical systems involving policies, culture, training, and interprofessional dynamics. Participatory design approaches that include pharmacists and patients can surface tacit ethical concerns pre-deployment.

METHODOLOGY

Research Design

A convergent mixed-methods design was employed, integrating a national cross-sectional survey of pharmacists with semi-structured interviews of key stakeholders (pharmacy directors, clinical pharmacists, patient safety officers, AI developers, and ethicists). The survey quantified perceptions of ethical issues; interviews provided depth and context.

Sampling and Participants

- **Survey:** 312 licensed pharmacists practicing in hospital or large outpatient settings where high-risk medications are dispensed and AI-DSS is in use or pilot phase. Stratified sampling ensured representation from urban, suburban, and rural facilities.
- **Interviews:** 22 participants purposively sampled for expertise in AI design, medication safety, or ethics; 12 pharmacists, 4 AI engineers, 3 administrators, 2 ethicists, and 1 patient advocate.

Instruments

- **Survey Questionnaire:** Sections on demographics, AI-DSS usage patterns, perceived benefits/risks (5-point Likert scales), autonomy, accountability, transparency, bias, data governance, and open-ended questions.
- **Interview Guide:** Probed experiences with AI alerts, examples of ethical dilemmas, perceptions of responsibility, expectations for explainability, and suggestions for governance.

Procedure

Surveys were administered online over eight weeks. Participation was voluntary, with informed consent obtained electronically. Interviews were conducted via videoconference, recorded, and transcribed. Ethical approval was obtained from an institutional review board (IRB). Data were anonymized and stored on encrypted drives.

Data Analysis

- **Quantitative:** Descriptive statistics summarized perceptions. Exploratory factor analysis (EFA) identified latent constructs (e.g., “Transparency Sufficiency,” “Autonomy Threat”). Multiple regression tested associations between perceived risk and variables like years of practice or frequency of AI alerts.
- **Qualitative:** Thematic analysis followed Braun & Clarke’s six phases. Codes were organized around ethical principles (autonomy, justice, etc.) and emergent categories (e.g., “shadow accountability,” “explanation mismatch”). Triangulation between surveys and interviews enhanced validity.

Reliability and Validity Measures

Cronbach’s alpha was calculated for each survey construct (all >0.78). Member checking with interviewees ensured interpretive accuracy. Methodological triangulation and audit trails strengthened credibility.

Limitations of Methodology

Self-selection bias may favor pharmacists interested in technology. Cross-sectional design limits causal inference. Qualitative sample size restricts generalizability but offers rich insights.

RESULTS

Quantitative Findings

Perceived Benefits and Risks

- **Safety Enhancement:** 87% agreed AI-DSS reduces the likelihood of catastrophic errors with high-risk medications.
- **Alert Fatigue:** 62% reported "often" or "very often" ignoring alerts due to perceived irrelevance.
- **Bias Concerns:** 48% worried that AI recommendations might be less accurate for underrepresented patient groups.
- **Autonomy Impact:** 55% felt their professional judgment was sometimes overshadowed by "hard-stop" alerts.

Constructs from Factor Analysis

EFA revealed four factors (eigenvalues >1.0):

1. **Transparency Sufficiency (α=0.81):** Satisfaction with explanation content and clarity.
2. **Autonomy Threat (α=0.84):** Sense that AI dictates rather than advises.
3. **Accountability Ambiguity (α=0.79):** Uncertainty about liability in adverse events.
4. **Bias Vigilance (α=0.78):** Awareness and monitoring of algorithmic bias.

Regression indicated that pharmacists with >10 years experience reported higher Autonomy Threat scores ($\beta=0.22$, $p<0.01$) and those in institutions with AI governance committees reported lower Accountability Ambiguity ($\beta=-0.19$, $p<0.05$).

Preferred Governance Mechanisms

Top-rated interventions (Likert mean ≥4.2):

- Layered explanations (short rationale + optional deep dive).
- Shared accountability policy documents signed by vendor, institution, and pharmacists.

- Bias dashboards with demographic performance metrics.
- Regular "ethics rounds" to review AI-related incidents.

Qualitative Themes

Six dominant themes emerged:

1. **Algorithmic Co-Authority:** Pharmacists describe AI as a "second conscience," yet sometimes as an "overbearing supervisor."
2. **Shadow Accountability:** Participants feared being blamed for both following and ignoring AI advice ("damned if you do, damned if you don't").
3. **Explanation Mismatch:** Preferred explanations are patient/context-specific, not generic risk scores. "Tell me *why for this patient*, not how the model works," said one pharmacist.
4. **Bias Blind Spots:** Many could not articulate how to detect bias, relying on "gut feelings" or anecdotal patterns.
5. **Ethics as Ongoing Practice:** Stakeholders advocated continuous review, akin to medication safety committees, rather than one-off approval.
6. **Human Factors Neglect:** Poor UI/UX amplified ethical issues—confusing alerts eroded trust and encouraged unsafe workarounds.

Illustrative quotes:

- "I need the AI to *explain itself just enough* so I can justify my call without drowning in math."
- "When the AI is wrong, everyone looks at me; when I'm wrong, they ask why I didn't listen to the AI."

Integration of Findings

Quantitative data highlighted widespread acceptance of AI's safety benefits but pinpointed autonomy and accountability as pressure points. Qualitative insights detailed the lived experience behind these numbers, revealing nuanced expectations for explanations and governance.

CONCLUSION

AI-based decision support holds significant promise for improving the safe dispensing of high-risk medications, but the ethical landscape is fraught with challenges related to autonomy, accountability, bias,

transparency, and data governance. This study's mixed-method evidence suggests pharmacists appreciate AI's safety benefits yet require design and policy safeguards to preserve professional judgment and ensure equitable care. The PASTOR framework provides a practical compass: align intervention intensity with risk, clarify shared accountability, ensure ongoing safety monitoring, offer layered transparency, institute inclusive oversight to uphold justice, and respect clinician autonomy.

Ethical AI is iterative. Systems must be continuously audited, recalibrated, and governed through participatory structures that include those who use and are affected by them—pharmacists and patients alike. Regulators and professional bodies should evolve standards for explainability, liability, and bias management specific to pharmacy practice. Future research should test the PASTOR framework in real-world deployments, examine patient perspectives on AI-influenced dispensing decisions, and develop metrics that capture ethical performance—not just technical accuracy. Ultimately, deploying AI-DSS ethically in high-risk medication dispensing is less about perfect algorithms and more about resilient, reflexive socio-technical ecosystems where technology augments, rather than eclipses, human care.

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