

Who Governs the Digital Pharmacy Algorithm? An Integrative Review of Accountability, Regulation, and Professional Practice

Elena Fedorova^{1*}, Alexey Volkov¹, Irina Morozova², Dmitry Kuznetsov³

¹Department of Digital Pharmacy Governance and Accountability, Faculty of Pharmacy, Novosibirsk State University, Novosibirsk, Russia.

²Department of AI Regulation and Professional Practice, Faculty of Pharmacy, Ural Federal University, Yekaterinburg, Russia. ³Department of Algorithm Governance in Pharmacy, Faculty of Pharmacy, Kazan Federal University, Kazan, Russia.

Abstract

Digital pharmacy algorithms are governed through legal, regulatory, organizational, commercial, professional, and patient-facing arrangements. These arrangements distribute authority unevenly and often separate formal accountability from practical control. To integrate evidence on who governs medication-related algorithms, where responsibilities arise across the lifecycle, and how monitoring, challenge, correction, and redress are allocated. An integrative review combined health, pharmacy, informatics, policy, ethical, and legal scholarship published from 2017 through 2026. Searches covered MEDLINE, Scopus, Web of Science Core Collection, International Pharmaceutical Abstracts, HeinOnline, and citation searching. Eligible peer-reviewed reports had to identify a governance actor, authority, responsibility, mechanism, or lifecycle stage relevant to digital pharmacy or medication-related algorithms. Records were deduplicated, screened, retrieved, appraised by source type, extracted into a structured governance framework, and synthesized through comparative thematic analysis. The search identified 556 records; 214 duplicates were removed, 342 records were screened, 68 reports were sought, 3 were not retrieved, and 65 full texts were assessed. Thirty reports representing 30 studies or scholarly analyses were included. Governance was distributed across regulators, healthcare organizations, vendors, developers, pharmacists, and patients, but the allocation of monitoring, incident investigation, correction, and redress was inconsistent. Formal regulatory authority did not reliably correspond to operational control. Pharmacists retained professional duties, while vendors and organizations controlled many technical and workflow conditions. Patient participation and contestability remained underdeveloped. Digital pharmacy algorithm governance is multilevel, fragmented, and lifecycle-dependent. Clearer allocation of authority, documentation, surveillance, escalation, and redress is needed before governance arrangements can be considered dependable.

Keywords: Integrative review, Digital pharmacy, Artificial intelligence, Pharmacy practice, Medication safety, Evidence synthesis

INTRODUCTION

Digital pharmacy algorithms increasingly influence medication selection, prescription verification, risk detection, prioritization, counselling, and monitoring. Yet no single actor governs these systems from conception to retirement. Regulatory agencies may classify and authorize selected products; healthcare organizations choose procurement, configuration, access, and workflow integration; vendors and developers determine architecture, training data, updates, and technical documentation; pharmacists remain answerable for professional decisions; and patients experience the consequences while possessing variable opportunities to question automated influence. A healthcare governance model therefore requires attention to distributed authority rather than a simple search for one accountable owner [1].

This distribution creates a recurring divergence between formal authority and practical control. A regulator may possess legal oversight without access to local configuration, a hospital may control deployment without understanding

proprietary model behaviour, and a pharmacist may bear professional responsibility without authority to inspect training data or alter update schedules. Ethical analysis of machine learning in medicine has emphasized that responsibility, transparency, privacy, and fairness cannot be

Address for correspondence: Elena Fedorova, Department of Digital Pharmacy Governance and Accountability, Faculty of Pharmacy, Novosibirsk State University, Novosibirsk, Russia. elena.fedorova@nsu.ru

Received: 30 March 2026; **Accepted:** 27 July 2026

This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-Share Alike 4.0 License, which allows others to remix, tweak, and build upon the work non commercially, as long as the author is credited and the new creations are licensed under the identical terms.

How to cite this article: Fedorova E, Volkov A, Morozova I, Kuznetsov D. Who Governs the Digital Pharmacy Algorithm? An Integrative Review of Accountability, Regulation, and Professional Practice. Arch Pharm Pract. 2026;17(3):19-27. <https://doi.org/10.51847/RjpvOQ1Q1>

reduced to technical performance alone [2]. Governance must consequently be examined across the algorithm lifecycle and across the institutional boundaries through which medication decisions are produced.

The problem is especially consequential in pharmacy because algorithmic outputs can shape high-frequency, safety-critical work while remaining embedded within ordinary software, clinical decision support, vendor platforms, or generative systems. Responsible machine-learning scholarship has called for rigorous design, evaluation, documentation, and monitoring, but these functions are often distributed among parties with different incentives and capabilities [3]. Safety may therefore depend less on the existence of a nominal overseer than on whether authority, information, resources, and escalation duties align at each stage.

Accountability also extends beyond prospective approval. Systems may drift, encounter new populations, produce unanticipated interactions, or become unsafe through local workflow changes. Analyses of healthcare artificial intelligence have accordingly linked accountability to safety management, institutional responsibility, and the capacity to investigate failures [4]. For digital pharmacy, this raises questions about who detects harm, who can suspend use, who communicates with patients, and who provides correction or redress.

An integrative review is appropriate because these questions are addressed across empirical studies, professional research, legal commentary, policy analysis, ethics, informatics, and implementation scholarship. No single evidence type can establish the complete governance picture. This review therefore asks how governance is distributed among regulators, organizations, vendors, developers, pharmacists, and patients; where formal authority diverges from operational control; which duties apply before and after deployment; how monitoring, challenge, correction, incident investigation, and redress are handled; and where responsibilities overlap or disappear. Its objective is to

develop an evidence-bounded multilevel account of digital pharmacy algorithm governance while preserving distinctions among formal rules, observed practice, normative argument, and original synthesis. Rather than treating governance proposals as proof of effective implementation.

Review Design, Questions, and Protocol

This integrative review examined authority, control, responsibility, oversight, and redress in digital pharmacy algorithms. It followed transparent searching, appraisal, synthesis, and limitation reporting [5]. Six questions addressed governance distribution, authority–control gaps, lifecycle duties, monitoring, redress, and the design of a multilevel governance model.

Pilot searches refined terms and exclusions. Final searches followed PRISMA 2020 [6] and PRISMA-S reporting principles [7]. Evidence was appraised according to source type, and protocol deviations were documented.

Eligibility and Evidence Extraction

Eligible studies were English-language, peer-reviewed articles published from 2017 to 2026 that addressed governance of medication-related algorithms and identified relevant actors, duties, mechanisms, or lifecycle stages. Purely technical studies and general AI-governance papers without health relevance were excluded.

Screening included deduplication, title-and-abstract review, and full-text assessment. Empirical evidence was distinguished from normative recommendations. Ethical mapping, responsibility, explainability, and trustworthiness literature informed the framework without being treated as evidence of clinical effectiveness or safety [8–10].

Extraction covered actors, authority, control, responsibility, validation, monitoring, contestability, correction, redress, and evidential status. **Table 1** summarizes the eligibility, definitions, and extraction framework.

Table 1. Eligibility, definitions, and evidence-extraction framework for the review Who Governs the Digital Pharmacy Algorithm? An Integrative Review of Accountability, Regulation, and Professional Practice.

Review element	Operational definition	Eligibility or decision rule	Data field	Rationale	Bias or ambiguity risk	Planned synthesis use
Digital pharmacy algorithm	A computational system materially informing medication-related prioritization, verification, recommendation, communication, surveillance, or professional action	Include when the system has a direct medication, pharmacy-workflow, prescribing, dispensing, or pharmacotherapy relationship	System type; medication task; intended user; setting	Prevents general healthcare artificial intelligence from being treated automatically as pharmacy evidence	Pharmacy relevance may be indirect or incompletely reported	Classify systems by medication function and decision proximity
Governance	Formal or practical arrangements assigning authority, control, responsibility, oversight, participation, accountability, or remedy	Include when at least one governance actor, mechanism, or lifecycle duty is identifiable	Authority; practical control; responsibility; mechanism	Governance is distributed and cannot be represented solely by product authorization [1]	Normative language may be mistaken for implemented practice	Compare formal authority with operational control

Governance actor	Regulator, organization, vendor, developer, pharmacist, patient, payer, professional body, or other identifiable participant	Record every actor explicitly assigned a decision, duty, power, or consequence	Actor; role; institutional level	Ethical responsibility may be distributed among multiple parties [2]	Actor labels may obscure subcontractors or shared control	Construct actor-by-lifecycle governance map
Lifecycle stage	Development, procurement, validation, deployment, use, updating, monitoring, suspension, retirement, or redress	Code the stage at which authority or responsibility applies	Lifecycle stage; triggering condition	Responsible development requires attention beyond model creation [3]	Reports may discuss “implementation” without defining its stage	Identify predeployment and postdeployment duties
Accountability mechanism	A process connecting conduct or outcomes to explanation, review, correction, sanction, compensation, or remedy	Include only when the mechanism, responsible actor, and affected stage can be identified	Documentation; audit; escalation; investigation; correction; redress	Accountability requires operational safety and investigation capacity [4]	Responsibility statements may lack enforceable mechanisms	Distinguish nominal accountability from actionable accountability
Patient participation and contestability	Patient access to information, explanation, challenge, review, correction, appeal, or redress	Record whether patients can recognize algorithmic involvement and initiate review	Disclosure; challenge route; correction; remedy	Ethical governance includes effects on autonomy, fairness, and justified reliance [8]	Absence of reporting may not prove absence of a mechanism	Compare proposed and observed participation arrangements
Evidence type	Empirical, review, legal, regulatory, ethical, policy-analytic, methodological, or professional scholarship	Retain heterogeneous evidence but appraise it according to source type	Design; jurisdiction; data source; analytic method	Integrative reviews require transparent handling of different knowledge forms [5]	Incomparable evidence may be combined into a false hierarchy	Separate observation, interpretation, and original synthesis
Publication and language limits	Peer-reviewed English-language journal article published from 2017 through 2026	Exclude sources outside the frozen date, language, or publication criteria	Year; language; publication type	Supports reproducible eligibility decisions and stable accounting	English-only inclusion may omit jurisdictionally relevant evidence	Define review scope and limitation
Full-text exclusion	One mutually exclusive primary reason assigned after assessment	Apply the highest applicable reason in the prespecified hierarchy	Exclusion decision; primary reason	Ensures that exclusion subtotals reconcile with assessed reports [6]	Complex reports may satisfy several exclusion reasons	Support transparent flow reporting
Search documentation	Complete source, platform, strategy, limits, date, displayed result count, and captured count	A final search is valid only when its full retrieval pathway is recorded	Source; query; date; filters; count	Reproducible search reporting requires source-level transparency [7]	Platform changes and indexing variation may affect replication	Link every identified record to its originating search
Technical governance condition	Transparency, explainability, usability, trustworthiness, documentation, validation, or human interaction feature	Extract only when connected to a governance actor, decision, or responsibility	Technical condition; responsible actor; stated consequence	Technical properties influence governance but do not establish safety independently [10]	Desirable properties may be presented as evidence of effectiveness	Analyse relationships between technical design and institutional duty
Interpretive boundary	Statement limiting claims to the evidence type and context from which they were derived	Every synthesis theme must retain jurisdictional, methodological, and applicability qualifications	Evidence status; limitation; applicability	Ethical and governance claims require distinctions among explanation, reliance, and responsibility [9]	Review synthesis may appear more authoritative than its components	Prevent unsupported claims of validation, safety, or universal applicability

Eligibility decisions were retained in the master ledger, with identifiers, duplicate families, screening outcomes, retrieval status, exclusion reasons, study-family links, and synthesis membership recorded for traceability. Uncertain classifications were resolved through comparative review.

Search, Selection, Extraction, Appraisal, and Synthesis

Included reports were summarized in an evidence table and mapped by actor and lifecycle stage. Extraction covered authority, control, responsibility, monitoring, incident

response, challenge, correction, and redress from development through retirement.

Appraisal was matched to study type and informed by MMAT, CONSORT-AI, and SPIRIT-AI principles [11–13]. Findings were grouped by actor, lifecycle stage, mechanism, and evidential status. Observed findings were distinguished from normative proposals, and themes were checked against source records, negative cases, jurisdictional limits, and study-family links. The resulting model was treated as a

review-derived synthesis, not a validated governance instrument or deployment standard.

Search and Selection Results

The search identified 556 records. After removing 214 duplicates, 342 records were screened and 68 reports sought. Three were unavailable, leaving 65 full texts. Thirty-five were excluded for insufficient pharmacy relevance, absence of governance analysis, unclear responsibility mechanisms,

ineligible publication type or date, or duplicate reporting. Thirty reports were included in the synthesis.

Figure 1 presents the completed review-selection pathway in a black-and-white prisma-style flow diagram for evidence selection, documenting identification, deduplication, screening, eligibility, exclusions with reasons, and final inclusion using the values approved in PRISMA Record-Accounting Audit.

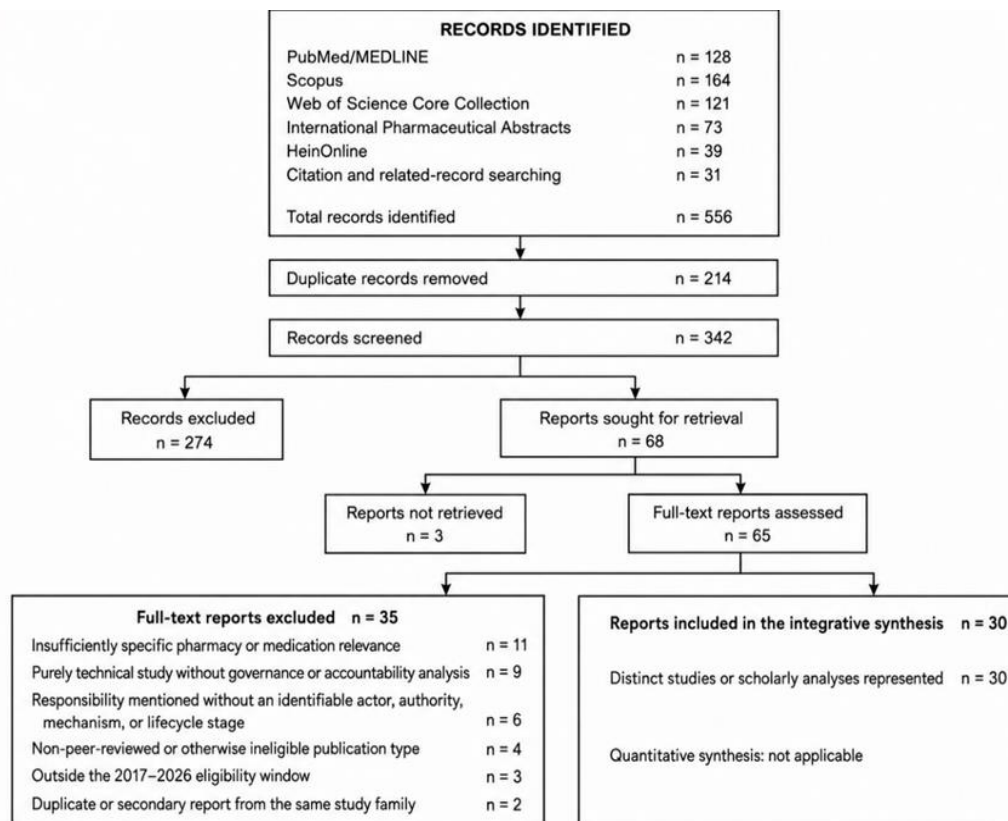


Figure 1. PRISMA-Style Flow Diagram for Evidence Selection

The pharmacy-focused literature covered multiple algorithmic functions but provided uneven governance detail. A scoping review identified expanding applications alongside heterogeneity in purpose, evaluation, and implementation maturity [14]. Regulatory oversight was clearest for systems classified as medical devices, for which authorization pathways and public listings created visible decision points [15]. Comparative analysis of United States and European approvals nevertheless demonstrated jurisdictional differences in how artificial intelligence and machine-learning devices were reviewed and described [16]. Regulatory authority was therefore selective rather than comprehensive. Product authorization could permit market access, but it did not by itself allocate local validation, workflow supervision, update control, incident investigation, patient communication, or redress. In practice, systems embedded in general software, local decision support, or

generative platforms remained especially difficult to locate within a single regulatory pathway.

Evidence-Base Characteristics

The evidence base combined empirical evaluations, reviews, surveys, qualitative studies, ethical analyses, legal commentary, policy scholarship, and reporting guidance. It provided neither a common outcome measure nor a uniform standard for judging governance effectiveness. Most sources examined one lifecycle segment, such as design, validation, professional use, regulation, or monitoring, rather than tracing responsibility from development through retirement.

Organizational governance was most visible where algorithms were embedded in clinical decision support. A machine-learning system designed to identify prescriptions at high risk of medication error illustrated how outputs become consequential through local data pipelines, alert thresholds,

professional review, and workflow response [17]. Healthcare organizations therefore controlled procurement, configuration, access, staffing, escalation, and continued use, although not necessarily proprietary training data, source code, or update logic.

Vendor and developer responsibilities concerned robustness, documentation, validation, transparency, and maintenance. Cross-sectional analysis of digital health companies found variation in clinical robustness supporting marketed products [18]. Purchasers and pharmacists may consequently depend on vendor-generated evidence when independent evaluation is unavailable. Qualitative evidence from clinicians also

identified concerns about explainability, professional displacement, liability, and redistributed expertise [19]. These concerns were relevant when professionals remained responsible for decisions mediated by opaque tools.

Table 2 organizes the evidence, constructs, relationships, uncertainties, and boundary conditions required for characteristics and classification of the evidence included in the review *Who Governs the Digital Pharmacy Algorithm? An Integrative Review of Accountability, Regulation, and Professional Practice*.

Table 2. Characteristics and classification of the evidence included in the review *Who Governs the Digital Pharmacy Algorithm? An Integrative Review of Accountability, Regulation, and Professional Practice*.

Evidence category	Study or source design	Population or setting	AI system or intervention	Comparator or reference standard	Outcome or construct	Validation level	Key limitation
Pharmacy-application landscape	Scoping review [14]	Pharmacy practice across reported settings	Artificial-intelligence applications relevant to pharmacy	Not applicable; descriptive evidence mapping	Application types, evaluation approaches, implementation maturity, and reported barriers	Review-level descriptive synthesis	Heterogeneous technologies, tasks, designs, and outcome reporting limit conclusions about effectiveness or governance
Regulatory product landscape	Cross-sectional analysis of a public regulatory database [15]	Artificial-intelligence and machine-learning medical devices authorized in the United States	Regulated medical-device algorithms	Public authorization records and device descriptions	Product availability, specialty distribution, and regulatory visibility	Regulatory-record characterization; not independent clinical validation	Public authorization data do not capture all software functions, local configurations, updates, or postdeployment performance
Cross-jurisdictional regulation	Comparative regulatory analysis [16]	Artificial-intelligence and machine-learning medical devices in the United States and Europe	Products entering different authorization systems	Comparison between regulatory jurisdictions	Approval characteristics and differences in regulatory description	Comparative policy and regulatory analysis	Findings apply to classified medical devices and cannot represent every digital pharmacy algorithm
Medication-error risk identification	Retrospective machine-learning clinical decision-support evaluation [17]	Hospital prescriptions and medication-review workflow	Model identifying prescriptions with elevated medication-error risk	Historical classifications and medication-review reference processes	Risk prioritization and support for pharmacist review	Retrospective model evaluation within the reported environment	Local data, thresholds, workflow integration, and transferability constrain broader applicability
Commercial clinical robustness	Cross-sectional observational analysis [18]	Digital health companies and marketed products	Diverse digital health technologies and company claims	Prespecified indicators of clinical robustness	Availability and strength of clinical evidence supporting products	Public-evidence assessment rather than direct product validation	Publicly available evidence may be incomplete; products and companies are heterogeneous
Professional expectations and concerns	Exploratory qualitative study [19]	United Kingdom general practitioners	Prospective use of artificial intelligence in primary care	Participant experience and qualitative thematic interpretation	Explainability, professional role, liability, trust, and expertise	Perception evidence; no clinical validation	Conducted outside pharmacy and does not establish actual governance arrangements or patient outcomes

Across categories, claims about responsibility were more developed than operational mechanisms. Few sources specified who could halt a system, demand correction, inspect vendor logs, notify patients, or verify that an update remained

suitable locally. The synthesis therefore classified governance functions instead of ranking actors. Organizations held workflow authority; vendors and developers controlled technical conditions; regulators

exercised selective legal authority; professionals retained judgment; and patients possessed the least defined control.

Pharmacist Professional Accountability

Pharmacist accountability appeared central but constrained. Pharmacists remained responsible for interpreting prescriptions, resolving medication-related problems, communicating with patients, and deciding whether an algorithmic output was usable. A national survey showed that pharmacists perceived benefits from artificial intelligence while reporting concerns about accuracy, privacy, professional roles, and preparedness [20]. These findings support professional engagement but do not establish that pharmacists can compensate for deficiencies originating in design, procurement, data quality, or organizational configuration.

Ethical concerns in pharmacy practice included transparency, confidentiality, bias, responsibility, and preservation of professional judgment [21]. The review therefore distinguished responsibility for using an output from responsibility for creating the conditions under which it was produced. A pharmacist may be accountable for checking a recommendation within information and authority, whereas organizations and vendors may remain responsible for inaccessible model behaviour, update management, or defective documentation. Assigning all downstream responsibility to the pharmacist would obscure upstream control.

Medication-alert research showed that governance decisions are embedded in threshold selection, prioritization, and alert suppression. A review of artificial intelligence used to optimize medication alerts found promising approaches but heterogeneous methods and limited evidence concerning clinical outcomes [22]. Pharmacists may manage alert consequences, yet organizations and developers determine parameters shaping which cases become visible.

Patient participation and contestability were less developed than professional oversight. Pharmacy studies discussed acceptance, trust, ethics, or workflow but seldom explained how patients would be informed that an algorithm influenced care, obtain an explanation, correct relevant data, request human reconsideration, or pursue remedy. Absence of reporting did not prove that no mechanism existed, but it prevented a conclusion that contestability was secured. Review-derived synthesis therefore treated patient participation as a governance function. Meaningful contestability requires disclosure, a route to challenge, an authorized reviewer, correction of erroneous information, documentation of the response, and escalation when harm or disagreement remains.

Postdeployment Monitoring

Predeployment testing cannot ensure performance after changes in populations, workflows, interfaces, or model

versions. External validation findings support local evaluation after implementation [23].

Algorithmic vigilance extends monitoring to effectiveness, inequity, drift, and unintended consequences [24]. Pharmacy systems therefore require defined indicators, review intervals, responsible personnel, version tracking, and thresholds for investigation or suspension.

Incident processes should include harm containment, record preservation, impact assessment, notification, case finding, correction or withdrawal, patient communication, and redress. Liability alone does not provide these functions [25].

Responsibility remained fragmented among pharmacists, organizations, vendors, and regulators. Effective governance requires named ownership from detection through investigation, correction, learning, and patient redress.

Jurisdictional and Governance Gaps

Jurisdictional gaps arose because digital pharmacy algorithms can be regulated partially or not at all as medical devices, professional tools, organizational systems, data-processing services, or components of practice. Liability scholarship indicates that clinicians may remain exposed when using artificial intelligence even where developers, institutions, and regulators influence use [26]. No single rule resolved responsibility across system types, jurisdictions, and lifecycle stages.

Governance gaps also appeared when technical flexibility conflicted with professional values. Value-flexibility analysis argues that medical artificial intelligence must accommodate relevant variation rather than encode one fixed conception of care [27]. In pharmacy, this matters when algorithms rank medication risks, prioritize adherence, infer preferences, or recommend action under uncertainty. Control over settings may carry normative consequences without formal regulatory authority.

Implementation scholarship emphasizes that ethical risks arise through data selection, design, validation, integration, and use, not only through isolated outputs [28]. The review-derived model assigns functions rather than one universal governor. Regulators define pathways and reporting duties. Vendors and developers document intended use, limitations, versions, changes, data provenance, validation, and incidents. Organizations evaluate procurement, applicability, access, workflow fit, monitoring, suspension, and investigation. Pharmacists exercise judgment, verify medication relevance, communicate uncertainty, report problems, and decline unsafe reliance. Patients require notice, information, correction routes, human review, and redress.

Responsibility overlaps can protect against failure, but become problematic when every actor assumes another is accountable. The model separates authority, control, duty,

information access, and remedy across stages. A party should not receive a duty it lacks power to perform; decisive control should carry documentation and cooperation duties.

This model is review synthesis, not a validated legal framework, regulatory classification, professional standard, or deployment protocol. It reveals unassigned functions, responsibility-control mismatches, and transitions where monitoring, challenge, correction, investigation, or redress can fail. Applicability requires examination against technologies, organizations, jurisdictions, patients, and medication-use contexts.

Discussion

The principal finding is that digital pharmacy algorithms are governed through a distributed arrangement in which legal authority, technical control, organizational power, professional judgment, and patient consequence rarely reside with the same actor. This distribution is not inherently defective. Oversight, local supervision, professional checking, and vendor maintenance can create useful redundancy. Fragmentation becomes hazardous when responsibilities are described abstractly, actors cannot access the information required to perform their duties, or no mechanism connects detection of a problem to corrective authority. These mismatches were recurrent across sources.

Formal regulation covered only part of the field. Device-oriented pathways created identifiable authorization and reporting points, but many medication-related systems were embedded in broader software, locally configured decision support, or services whose functions could change through updates. Healthcare organizations consequently became de facto governors through procurement, configuration, access, staffing, workflow design, monitoring, and suspension decisions. Vendors and developers retained control over model architecture, documentation, technical logs, and updates. Pharmacists were expected to preserve professional judgment at the point of care, yet their ability to do so depended on usable information, time, escalation routes, and organizational support. Patients bore consequences while receiving the least described rights to information, challenge, correction, or remedy.

Responsibility overlap was most defensible when it created independent checks. A vendor's validation did not remove the organization's duty to evaluate local applicability; organizational authorization did not remove the pharmacist's duty to assess a medication-specific output; and professional review did not remove developer responsibility for defective design or misleading documentation. Overlap became an accountability gap when each participant interpreted another actor's involvement as relieving its own duty. Governance should therefore specify primary ownership, supporting duties, information-sharing requirements, and escalation authority for each lifecycle function.

Fairness illustrates why responsibility cannot be confined to technical developers. Evidence of racial bias in a widely used population-health algorithm showed how apparently neutral targets can reproduce inequity when they serve as proxies for clinical need [29]. For pharmacy organizations, this means that procurement and monitoring must examine the relationship among training data, target definitions, access patterns, workflow decisions, and consequences for patient groups. Technical performance averaged across a population cannot establish equitable operation.

Fairness scholarship further argues that advancing health equity requires attention to data, labels, objectives, evaluation, deployment, and institutional context [30]. Accordingly, responsibility for inequity may be distributed across those selecting the problem, building the model, purchasing the system, defining workflow responses, and monitoring outcomes. A fairness metric does not replace governance. Ethical analysis has also warned that algorithmic fairness solutions can obscure structural causes, value conflicts, and limits of formal optimization [31]. The review therefore interprets equity as a continuing governance obligation requiring patient-relevant outcomes, subgroup analysis, participatory scrutiny, and authority to intervene.

For pharmacy organizations, the findings support a lifecycle governance register. Each algorithm should have a named owner, intended use, version, evidence basis, local validation status, accountable professional lead, monitoring plan, incident pathway, patient communication process, and suspension or retirement rule. Procurement contracts should provide access to documentation, change notices, relevant logs, investigation cooperation, and corrective responsibilities. Professional bodies can define minimum competencies for evaluating algorithmic outputs, documenting disagreement, reporting incidents, and communicating uncertainty without implying that education alone resolves structural deficiencies.

The synthesis does not establish that any single governance model improves clinical outcomes or medication safety. The reviewed evidence was heterogeneous, often normative, and frequently indirect for pharmacy. The multilevel model should therefore be used as an analytic framework for identifying responsibilities and gaps, not as proof of regulatory compliance or operational readiness. Its value lies in making governance functions visible and testable within particular organizations, technologies, jurisdictions, and patient populations.

Implications, Strengths, and Limitations

Research should move from responsibility statements to evaluations of governance mechanisms. Priorities include whether organizations can detect drift and inequity, whether vendors provide documentation and investigation support, whether pharmacists can challenge outputs without workflow penalty, and whether patients can obtain review and correction. Explainability research offers a multidisciplinary

account of technical, clinical, legal, and patient needs, indicating that explanations must suit users and decisions [32]. Explanation is not a universal remedy. Critiques of explainable artificial-intelligence approaches show that plausible explanations may fail to reveal model reasoning, establish validity, or support safe reliance [33].

Prospective studies should specify governance before deployment and report human-system interaction, errors, modifications, and context. DECIDE-AI provides expectations for clinical evaluation, including intended use, participants, workflow, safety, performance, and human factors [34]. Pharmacy research should extend reporting to ownership, version control, monitoring thresholds, escalation, incident investigation, patient notification, and redress. Comparative work is needed across community, hospital, and platform-mediated settings across jurisdictions.

The review's strength was integration of heterogeneous evidence through an actor, lifecycle, mechanism, and evidential-status framework. Source-sensitive appraisal prevented empirical findings, legal interpretation, ethical argument, and original synthesis from being presented as interchangeable. Record-level accounting distinguished records, reports, and studies and preserved one exclusion reason per full text. The multilevel analysis exposed relationships that a technical or profession-specific review could miss.

Limitations remained. English-language journal inclusion may have omitted jurisdiction-specific scholarship, regulatory documents, case law, and nonindexed professional evidence. The publication window restricted historical legal development. Much literature addressed healthcare artificial intelligence broadly rather than pharmacy directly, so conclusions were transferred cautiously to medication contexts. Heterogeneity precluded pooled effect estimation or a unified certainty rating. Sparse reporting of incidents, patient challenge, contractual duties, and retirement may reflect governance gaps or publication practices.

The proposed model requires empirical testing and jurisdiction-specific legal analysis. It should guide questions, documentation, and gap identification, not certify compliance, safety, effectiveness, equity, or readiness.

CONCLUSION

Digital pharmacy algorithms are governed by regulators, organizations, vendors, developers, pharmacists, professional bodies, and patients rather than one dominant authority. Across the reviewed evidence, formal authority frequently diverged from control. Regulators governed products and reporting pathways; organizations controlled procurement, configuration, workflow integration, access, monitoring, and suspension; vendors and developers controlled technical design, documentation, updates, and logs; pharmacists retained judgment; and patients encountered consequences

without consistently described routes for information, challenge, correction, or redress.

This distribution can provide safeguards, but only when responsibilities, information access, decision rights, and escalation powers are explicit. Overlap becomes a gap when each actor assumes another party owns validation, surveillance, investigation, communication, or remedy. Governance must therefore extend across the lifecycle, from problem definition and development through procurement, deployment, updating, incident response, suspension, and retirement.

The review-derived multilevel model separates authority, control, duty, monitoring, contestability, and redress so that unassigned functions and responsibility-control mismatches can be identified. It does not establish a validated legal framework, regulatory standard, professional mandate, or deployment protocol. The evidence was heterogeneous, limited, and often indirect for pharmacy, with sparse evaluation of patient participation, incident pathways, and postdeployment outcomes.

Future governance should be assessed empirically within medication-use settings and jurisdictions. Dependable arrangements require traceable versions, local applicability assessment, surveillance, vendor cooperation, pharmacist escalation authority, patient-accessible challenge mechanisms, incident investigation, and documented correction and redress. Until these functions are demonstrated, governance claims should remain bounded and should not be interpreted as evidence of effectiveness, safety, equity, legal compliance, or readiness for unrestricted use.

ACKNOWLEDGMENTS: None

CONFLICT OF INTEREST: None

FINANCIAL SUPPORT: None

ETHICS STATEMENT: None

REFERENCES

1. Reddy S, Allan S, Coghlan S, Cooper P. A governance model for the application of AI in health care. *J Am Med Inform Assoc.* 2020;27(3):491-7. doi:10.1093/jamia/ocz192
2. Vayena E, Blasimme A, Cohen IG. Machine learning in medicine: Addressing ethical challenges. *PLoS Med.* 2018;15(11). doi:10.1371/journal.pmed.1002689
3. Wiens J, Saria S, Sendak M, Ghassemi M, Liu VX, Doshi-Velez F, et al. Do no harm: A roadmap for responsible machine learning for health care. *Nat Med.* 2019;25(9):1337-40. doi:10.1038/s41591-019-0548-6
4. Habli I, Lawton T, Porter Z. Artificial intelligence in health care: Accountability and safety. *Bull World Health Organ.* 2020;98(4):251-6. doi:10.2471/BLT.19.237487
5. Snyder H. Literature review as a research methodology: An overview and guidelines. *J Bus Res.* 2019;104:333-9. doi:10.1016/j.jbusres.2019.07.039
6. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. *BMJ.* 2021;372. doi:10.1136/bmj.n71
7. Rethlefsen ML, Kirtley S, Waffenschmidt S, Ayala AP, Moher D, Page MJ, et al. PRISMA-S: An extension to the PRISMA statement for reporting literature searches in systematic reviews. *Syst Rev.* 2021;10(1):39. doi:10.1186/s13643-020-01542-z

8. Morley J, Machado CCV, Burr C, Cowls J, Joshi I, Taddeo M, et al. The ethics of AI in health care: A mapping review. *Soc Sci Med*. 2020;260:113172. doi:10.1016/j.socscimed.2020.113172
9. Grote T, Berens P. On the ethics of algorithmic decision-making in healthcare. *J Med Ethics*. 2020;46(3):205-11. doi:10.1136/medethics-2019-105586
10. Cutillo CM, Sharma KR, Foschini L, Kundu S, Mackintosh M, Mandl KD, et al. Machine intelligence in healthcare—perspectives on trustworthiness, explainability, usability, and transparency. *NPJ Digit Med*. 2020;3:47. doi:10.1038/s41746-020-0254-2
11. Hong QN, Pluye P, Fàbregues S, Bartlett G, Boardman F, Cargo M, et al. Improving the content validity of the mixed methods appraisal tool: A modified e-Delphi study. *J Clin Epidemiol*. 2019;111:49-59.e1. doi:10.1016/j.jclinepi.2019.03.008
12. Liu X, Cruz Rivera S, Moher D, Calvert MJ, Denniston AK, Chan AW, et al. Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: The CONSORT-AI extension. *Nat Med*. 2020;26(9):1364-74. doi:10.1038/s41591-020-1034-x
13. Cruz Rivera S, Liu X, Chan AW, Denniston AK, Calvert MJ, Ashrafian H, et al. Guidelines for clinical trial protocols for interventions involving artificial intelligence: The SPIRIT-AI extension. *Nat Med*. 2020;26(9):1351-63. doi:10.1038/s41591-020-1037-7
14. Hatzimanolis J, Riley B, El-Den S, Aslani P, Zhou J, Chaar B. Applications of artificial intelligence in current pharmacy practice: A scoping review. *Res Social Adm Pharm*. 2025;21(3):134-41. doi:10.1016/j.sapharm.2024.12.007
15. Benjamens S, Dhunoo P, Meskó B. The state of artificial intelligence-based FDA-approved medical devices and algorithms: An online database. *NPJ Digit Med*. 2020;3:118. doi:10.1038/s41746-020-00324-0
16. Muehlematter UJ, Daniore P, Vokinger KN. Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015-20): A comparative analysis. *Lancet Digit Health*. 2021;3(3). doi:10.1016/S2589-7500(20)30292-2
17. Corny J, Rajkumar A, Martin O, Dode X, Lajonchère JP, Billuart O, et al. A machine learning-based clinical decision support system to identify prescriptions with a high risk of medication error. *J Am Med Inform Assoc*. 2020;27(11):1688-94. doi:10.1093/jamia/ocaa154
18. Day S, Shah V, Kaganoff S, Powelson S, Mathews SC. Assessing the clinical robustness of digital health startups: Cross-sectional observational analysis. *J Med Internet Res*. 2022;24(6). doi:10.2196/37677
19. Blease C, Kaptchuk TJ, Bernstein MH, Mandl KD, Halamka JD, DesRoches CM. Artificial intelligence and the future of primary care: Exploratory qualitative study of UK general practitioners' views. *J Med Internet Res*. 2019;21(3). doi:10.2196/12802
20. Gustafson KA, Rowe C, Gavaza P, Bernknopf A, Nogid A, Hoffman A, et al. Pharmacists' perceptions of artificial intelligence: A national survey. *J Am Pharm Assoc* (2003). 2025;65(1):102306. doi:10.1016/j.japh.2024.102306
21. Hasan HE, Jaber D, Khabour OF, Alzoubi KH. Ethical considerations and concerns in the implementation of AI in pharmacy practice: A cross-sectional study. *BMC Med Ethics*. 2024;25(1):55. doi:10.1186/s12910-024-01062-8
22. Graafsma J, Murphy RM, van de Garde EMW, Karapinar-Çarkit F, Derijks HJ, Hoge RHL, et al. The use of artificial intelligence to optimize medication alerts generated by clinical decision support systems: A scoping review. *J Am Med Inform Assoc*. 2024;31(6):1411-22. doi:10.1093/jamia/ocae076
23. Wong A, Otles E, Donnelly JP, Krumm A, McCullough J, DeTroyer-Cooley O, et al. External validation of a widely implemented proprietary sepsis prediction model in hospitalized patients. *JAMA Intern Med*. 2021;181(8):1065-70. doi:10.1001/jamainternmed.2021.2626
24. Embi PJ. Algorithmic vigilance—advancing methods to analyze and monitor artificial intelligence-driven health care for effectiveness and equity. *JAMA Netw Open*. 2021;4(4). doi:10.1001/jamanetworkopen.2021.4622
25. Duffourc M, Gerke S. Generative AI in health care and liability risks for physicians and safety concerns for patients. *JAMA*. 2023;330(4):313-4. doi:10.1001/jama.2023.9630
26. Price WN 2nd, Gerke S, Cohen IG. Potential liability for physicians using artificial intelligence. *JAMA*. 2019;322(18):1765-6. doi:10.1001/jama.2019.15064
27. McDougall RJ. Computer knows best? The need for value-flexibility in medical AI. *J Med Ethics*. 2019;45(3):156-60. doi:10.1136/medethics-2018-105118
28. Char DS, Shah NH, Magnus D. Implementing machine learning in health care—addressing ethical challenges. *N Engl J Med*. 2018;378(11):981-3. doi:10.1056/NEJMp1714229
29. Obermeyer Z, Powers B, Vogeli C, Mullainathan S. Dissecting racial bias in an algorithm used to manage the health of populations. *Science*. 2019;366(6464):447-53. doi:10.1126/science.aax2342
30. Rajkomar A, Hardt M, Howell MD, Corrado G, Chin MH. Ensuring fairness in machine learning to advance health equity. *Ann Intern Med*. 2018;169(12):866-72. doi:10.7326/M18-1990
31. McCradden MD, Joshi S, Mazwi M, Anderson JA. Ethical limitations of algorithmic fairness solutions in health care machine learning. *Lancet Digit Health*. 2020;2(5). doi:10.1016/S2589-7500(20)30065-0
32. Amann J, Blasimme A, Vayena E, Frey D, Madai VI, Precise4Q Consortium. Explainability for artificial intelligence in healthcare: A multidisciplinary perspective. *BMC Med Inform Decis Mak*. 2020;20(1):310. doi:10.1186/s12911-020-01332-6
33. Ghassemi M, Oakden-Rayner L, Beam AL. The false hope of current approaches to explainable artificial intelligence in health care. *Lancet Digit Health*. 2021;3(11). doi:10.1016/S2589-7500(21)00208-9
34. Vasey B, Nagendran M, Campbell B, Clifton DA, Collins GS, Denaxas S, et al. Reporting guideline for the early-stage clinical evaluation of decision support systems driven by artificial intelligence: DECIDE-AI. *Nat Med*. 2022;28(5):924-33. doi:10.1038/s41591-022-01772-9