House of Delegates

Board of Directors Report: Policy Recommendations for the November 2024 Virtual House of Delegates

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COUNCIL ON PHARMACY PRACTICE POLICY RECOMMENDATIONS

The Council on Pharmacy Practice is concerned with ASHP professional policies related to the responsibilities of pharmacy practitioners. Within the Council's purview are (1) practitioner care for individual patients, (2) practitioner activities in public health, (3) pharmacy practice standards and quality, (4) professional ethics, (5) interprofessional and public relations, and (6) related matters.

Vickie Powell, *Board Liaison*

1. Pharmacist's Leadership Role in Anticoagulation Therapy Management

To discontinue ASHP policy 2006, Pharmacist's Leadership Role in Anticoagulation Therapy Management, which reads:

To advocate that pharmacists provide leadership in caring for patients receiving drug products for anticoagulant therapy management; further,

To advocate that pharmacists be responsible for coordinating the individualized care of patients receiving drug products for anticoagulation therapy management; further,

To encourage pharmacists who participate in anticoagulation therapy management to educate patients, caregivers, prescribers, and other members of the interprofessional healthcare team about anticoagulant drug product uses, drug interactions, reversal therapies and strategies, adverse effects, the importance of adhering to therapy, access to care, and recommended laboratory testing and other monitoring.

Background

The Council concluded that caring for patients receiving anticoagulant medications is routine pharmacy practice and no longer requires a policy distinguishing it from other comprehensive,

patient-centered care delivery. In addition, the Council noted that the policy is redundant with other ASHP policies.

2. Use of Two Patient Identifiers in the Provision of Patient Care

1 To encourage the use of two unique identifiers during the provision of patient care.

Note: This policy would supersede ASHP policy 2010.

Rationale

Errors caused by dispensing or administering medications to the wrong patient are largely preventable. The Institute for Safe Medication Practices reports that dispensing a correctly prepared prescription to the wrong patient in community pharmacies is the most common complaint reported to the National Consumer Medication Errors Reporting Program, with approximately 25% of events resulting in patient ingestion of the wrong medication. The Joint Commission (TJC) recognizes that wrong-patient errors occur in all stages of diagnosis and treatment in hospitals and health systems. Both organizations call for a standard approach to verify a patient's identity using at least two patient identifiers.

TJC defines a patient identifier as "Information directly associated with an individual that reliably identifies the individual as the person for whom the service or treatment is intended. Acceptable identifiers may be the individual's name, an assigned identification number, telephone number, date of birth, or other person-specific identifier." ASHP supports the consistent use of two patient identifiers in the dispensing and administration of medications during the provision of care in all care settings. ASHP also believes that bar code medication administration is important for verification of medication use, however, should not be a replacement for verifying a patient's identity with two patient identifiers.

Background

The Council reviewed ASHP policy 2010, Use of Two Patient Identifiers in the Outpatient Setting, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> To encourage the use of two unique identifiers during the provision of patient care. ~~to confirm patient identity when transferring filled prescriptions to the possession of the patient or patient's agent for outpatient use.~~

The Council suggested revisions to ASHP policy 2010 that acknowledge the importance of using two patient identifiers to confirm patient identity in medication dispensing and administration across all settings of care. They identified standards from The Joint Commission National Patient Safety Goals and the Institute for Safe Medication Practices Targeted Best Practices in community pharmacy settings as two standard setting organizations committed to ensuring patient safety. The Council considered advancements with bar code medication administration (BCMA) since the original policy approval in 2010 (then ASHP policy 1024). However, the

council quickly emphasized that BCMA should not replace a standardized and consistent process for using two patient identifiers prior to medication dispensing and administration.

COUNCIL ON THERAPEUTICS
POLICY RECOMMENDATIONS

The Council on Therapeutics is concerned with ASHP professional policies related to medication therapy. Within the Council's purview are (1) the benefits and risks of drug products, (2) evidence-based use of medicines, (3) the application of drug information in practice, and (4) related matters.

Douglas Slain, *Board Liaison*

1. Clinical Significance of Accurate and Timely Height and Weight Measurements

To encourage pharmacists to participate in interprofessional efforts to ensure accurate and timely patient height and weight measurements are recorded in the patient medical record to provide safe and effective drug therapy; further,

To encourage drug product manufacturers to conduct and publicly report pharmacokinetic and pharmacodynamic research in pediatric, adult, and geriatric patients at the extremes of weight and weight changes to facilitate safe and effective dosing of drugs in these patient populations, especially for drugs most likely to be affected by weight; further,

To encourage independent research on the clinical significance of extremes of weight and weight changes on drug use, as well as the reporting and dissemination of this information via published literature, patient registries, and other mechanisms; further,

To advocate that clinical decision support systems and other information technologies be structured to facilitate prescribing and dispensing of drugs most likely to be affected by extremes of weight and weight changes; further,

To advocate for federal and state laws and regulations to include weight, height, and date obtained as a required component of prescriptions for medications that are dosed based on height and weight.

Note: This policy would supersede ASHP policy 1721.

Rationale

Patients who have clinically significant changes in weight during an admission or between physician visits, or who are at an extreme high or low weight, have a higher risk of medication dosing errors that depend on weight body surface area. Accurate heights and weights in SI units (i.e., kilograms, grams, meters, and centimeters) are an integral part of a physical examination for pharmacists to ensure proper dosing of medications. Certain medications require dosing based on body surface area, and there is a need for healthcare organizations to consistently record patients' height, as estimation of height or weight can contribute to potential over- or underdosing.

Factors such as clinically significant changes in weight due to fluid overload and subsequent diuresis, patient growth, and weight changes due to changes in caloric consumption complicate the picture of an appropriate weight to record for dosing certain medications. Some healthcare organizations default to a dosing weight that is used for dosing medications alone, while other weight fluctuations recorded on a daily basis are not used to dose medications, whereas other organizations alert pharmacists to a clinically significant change in weight. Leveraging technology to ensure such safeguards are in place is essential, and providing interoperability between the patient's recorded dosing weight and smart pumps is ideal.

Pharmacists are also seeing an increase in the number of patients at both extremes of weight, and there is a lack of information regarding dosing medications for these populations. ASHP advocates that the Food and Drug Administration develop guidance for voluntary drug dosing studies in these populations, as the need for this guidance is supported by the complexity of drug dosing that can vary based on drug and patient characteristics. Drug product manufacturers should be encouraged to complete pharmacokinetic and pharmacodynamic dosing studies, and to publicly report the results, especially for drugs for which significant weight extremes may have clinical impact.

Dosing medications based on height and weight presents important concerns, particularly for pediatric patients, whose variables can change often, but also for oncology patients and aging populations, for whom toxicities or adverse events are a concern (Lubsch L et al. Patient Weight Should Be Included on All Medication Prescriptions. *J Pediatr Pharmacol Ther.* 2023;28:380–1). Therefore, regulations that mandate recording of height and weight on orders for medications that are dosed based on height and weight would enhance patient safety.

Background

The Council reviewed ASHP policy 1721, Clinical Significance of Accurate and Timely Height and

Weight Measurements, as part of a discussion of mandatory recording of pediatric weights on all prescriptions. The Council believed that while most weight-based dosing for medications is for the pediatric population, it is not the only population for which weight-based dosing is used. The Council therefore recommended amending policy 1721 with language that would include all patients for whom medication doses are based on height and weight, as follows (underscore indicates new text):

> To encourage pharmacists to participate in interprofessional efforts to ensure accurate and timely patient height and weight measurements are recorded in the patient medical record to provide safe and effective drug therapy; further,
>
> To encourage drug product manufacturers to conduct and publicly report pharmacokinetic and pharmacodynamic research in pediatric, adult, and geriatric patients at the extremes of weight and weight changes to facilitate safe and effective dosing of drugs in these patient populations, especially for drugs most likely to be affected by weight; further,
>
> To encourage independent research on the clinical significance of extremes of weight and weight changes on drug use, as well as the reporting and dissemination of this information via published literature, patient registries, and other mechanisms; further,
>
> To advocate that clinical decision support systems and other information technologies be structured to facilitate prescribing and dispensing of drugs most likely to be affected by extremes of weight and weight changes; further,
>
> To advocate for federal and state laws and regulations to include weight, height, and date obtained as a required component of prescriptions for medications that are dosed based on height and weight.

2. Safety of Intranasal Route as an Alternative Route of Administration

To encourage research on the pharmacokinetic and pharmacodynamic characteristics of drugs not approved for intranasal administration; further,

To encourage the development of institutional guidance and resources on the safe and effective use of drugs not approved for intranasal administration; further,

To encourage manufacturers to develop intranasal formulations in accordance with current regulatory standards to minimize the risk of medication errors, including ready-to-use devices.

Note: This policy would supersede ASHP policy 2041.

Rationale

Intranasal administration has gained more attention in the recent past as a means of administering both systemic and topical medications. The well-vascularized tissues of the nasal cavity provide a direct route of absorption that avoids gastrointestinal destruction and first-pass metabolism in the liver. Bioavailability of intranasal medications, therefore, is predictable, and absorption can be comparable to intravenous administration. Intranasal administration is often the route of choice in the emergency department due to access issues, safety concerns, and the characteristics of specific patient populations (e.g., children). The intranasal route is frequently used to treat pain when oral and intravenous routes are not optimal, and several medications have been approved for intranasal use in the recent past. Certain rescue medications, such as naloxone, have been approved for the intranasal route, and others, such as epinephrine, are being studied. Intranasal midazolam and ketamine are often used for sedation in the pediatric population, but have not been approved for that indication. The intranasal formulations of these medications have, however, recently been approved for the short-term treatment of seizure clusters and treatment-resistant depression, respectively. Vaccines are also commonly administered via the intranasal route.

Because many of these drugs are not approved for intranasal administration for the specific indications for which they are often used, there are varying degrees of evidence for use in specific cases. There is also varying evidence regarding the degree of systemic absorption of intranasally administered drugs that are not formulated for that route. Many characteristics may affect systemic distribution from the intranasal route, such as the presence of preservatives, viscosity of the agents, lipophilicity, molecular weight, and volume administered. Given the interest in and potential benefits of intranasal administration, further research on the pharmacokinetics and pharmacodynamics of that route is needed.

In recent years, intranasal administration has become a routine part of practice, but pre-made, ready-to-administer devices are still not universally available. Therefore, medications are often administered through an ancillary device such as an atomizer to optimize delivery, but these devices are not always available and have been on backorder in the past. Several medications have been approved by the Food and Drug Administration (FDA) for intranasal use, including esketamine, lorazepam, diazepam, naloxone, and zavegepant, and all are supplied by the manufacturer in ready-to-use administration devices. By encouraging manufacturers to continue to develop intranasal formulations in ready-to-use devices, patient-specific doses could be administered, allowing patients or caregivers to administer medications in a less-invasive or labor-intensive method. The FDA has developed guidance documents relating to the development of combination products (consisting of a medication and its delivery device) to optimize the efficacy and safety of such devices.

Background

The Council reviewed ASHP policy 2041, Safety of Intranasal Route as an Alternative Route of Administration, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> To encourage ~~the development of institutional guidance and advocate for further~~ research on the pharmacokinetic and pharmacodynamic characteristics of drugs not approved for intranasal administration; further,

To encourage the development of institutional guidance and resources on the safe and effective use of drugs not approved for intranasal administration; further,

~~To foster the development of educational resources on the safety of intranasal administration of drugs not approved for that route; further,~~

To encourage manufacturers to develop intranasal formulations in accordance with current regulatory standards to minimize the risk of medication errors, including ready-to-use devices.

COUNCIL ON PHARMACY MANAGEMENT POLICY RECOMMENDATION

The Council on Pharmacy Management is concerned with ASHP professional policies related to the leadership and management of pharmacy practice. Within the Council's purview are (1) development and deployment of resources, (2) fostering cost-effective use of medicines, (3) payment for services and products, (4) applications of technology in the medication-use process, (5) efficiency and safety of medication-use systems, (6) continuity of care, and (7) related matters.

Vivian Bradley Johnson, *Board Liaison*

1. Pharmacy Drug Theft

To discontinue ASHP policy 0303, Pharmacy Drug Theft, which reads:

To support the development of policies and guidelines for health-system pharmacists designed to deter drug product theft and thereby enhance both the integrity of the drug distribution chain and the safety of the workplace; further,

To encourage the development of systems that limit the diversion and abuse potential of medications, including high-cost drugs and controlled substances, and thereby reduce the likelihood that these products will be targets of theft.

Background

The Council found the ASHP Guidelines on Preventing Diversion of Controlled Substances and ASHP policy 2335, Pharmaceutical Distribution Systems, adequately cover all aspects of this policy, making it redundant.

SECTION OF PHARMACY INFORMATICS AND TECHNOLOGY POLICY RECOMMENDATION

The mission of the ASHP Section of Pharmacy Informatics and Technology is to provide a collective voice on best practices and issues related to the use of health information technology for medication use processes across the continuum of care, and the advancement of pharmacy informatics as a specialty practice.

1. ASHP Statement on Artificial Intelligence in Pharmacy

1 To approve the ASHP Statement on Artificial Intelligence in Pharmacy (Appendix).

DRAFT ASHP Statement on Artificial Intelligence in Pharmacy

Position

Artificial intelligence (AI) has the potential to improve patient care and the medication-use process by offering innovative methods to gather clinical, operational, and economic knowledge; assist end users; enhance educational experiences; and streamline administrative processes within pharmacy practice.[1] The pharmacy workforce is uniquely positioned to serve as key contributors and domain experts in the advancement of AI in healthcare. They should lead in decision-making, design, validation, implementation, and ongoing evaluation of AI-related applications and technologies that affect medication-use processes and related tasks.[1] Pharmacy leaders should use scientific approaches to define appropriate medication-related use cases for AI-enabled technology and determine which aspects of the medication-use process are best handled by the pharmacy workforce, by AI, or by the pharmacy workforce who receive information or support from AI-based systems.

The pharmacy workforce must assist in validating AI for clinical and operational uses and identify strategies to mitigate unintended consequences of AI, especially recognizing the ethical considerations that must guide the development and use in pharmacy practice.[1] Pharmacists should engage in research efforts to generate data to support additional AI use cases and identify potential risks. At a minimum, AI should be evaluated for accuracy, transparency, and interpretability, with policies adopted for AI utilization and ongoing surveillance of AI-related applications.[1] Additionally, the pharmacy workforce should actively pursue ongoing education and training in AI, given its rapidly growing adoption.

Fully automated AI should be reserved for algorithmic tasks where AI performance is comparable to that of its human counterpart. AI of proven value, particularly AI with proven safety and efficacy, should be adopted and used so that the pharmacy workforce can make informed and efficient decisions and focus their expertise on solving new and confounding problems for patients, families, and healthcare professionals and organizations.[1]

Background

In 2020, the American Society of Health-System Pharmacists (ASHP) released a statement on the use of AI in pharmacy.[2] Given the rapid advancements in AI technology,[3] this statement has been developed to expand the scope to include generative AI, large language models (LLMs), natural language processing (NLP), AI agents, and deep learning within the context of pharmacy practice.

AI is the theory and development of computer systems to perform tasks previously thought to require human intelligence, such as visual perception, language processing, learning, and problem solving, by using machine learning to extrapolate from large collections of data.[4] Deep learning, a form of machine learning, allows a network to understand concepts quickly, learning from examples, similar to the way the human brain does.[5] LLMs use deep-learning methods to process large data sets to construct natural-sounding text.[6] To put these concepts together, generative AI is a type of AI trained using deep learning that can create content such as text, images, and sound. As a result, text-based generative AI is a type of AI LLM that can generate human-like text responses to written or spoken prompts, based on identified patterns.[7]

AI-based technologies are being adopted by industries worldwide to improve efficiency and outcomes. Healthcare has an opportunity to leverage AI to improve all aspects of the value equation – outcomes, cost, and access. By increasing automation and improving workflow efficiencies, AI has the potential to reduce time spent on manual and routine tasks, allowing healthcare practitioners to optimize their scope of practice and improving clinician satisfaction, both of which are vital in the context of ongoing clinician workforce shortages. AI adoption in the healthcare system can also create new roles for the pharmacy workforce and alter the scope of pharmacist patient care.[8] Therefore, pharmacy teams must be prepared to embrace and lead efforts in selecting, implementing, safely using, and assessing AI technology use in the medication-use process.

At its June 2024 meeting, the ASHP House of Delegates approved ASHP policy 2413, Role of Artificial Intelligence in Pharmacy Practice.[1] The policy recognizes the potential for AI to improve patient care, acknowledges the risks and ethical challenges associated with the use of AI in healthcare settings, and supports the adoption of policies and procedures related to the use of AI. This statement expands upon the ideals described in that policy and further defines the roles and positions of the pharmacy workforce in the advancement of AI in the care of patients. This statement was developed not simply to consider potential applications of AI within the current practice of pharmacy but also to plan for how this technology will need to be developed and implemented in coming years. Although this statement is similar to positions held by other organizations of health professionals, it is uniquely focused on identifying opportunities for AI to drive change specific to the practice of pharmacy. This statement is

based on consensus opinion and professional judgment among experts on AI in pharmacy and is applicable to all pharmacy practice settings.

Role of the pharmacy workforce in AI

The pharmacy workforce serves in crucial roles in AI, including developing and validating models, ensuring data quality, educating about implementation and use, and identifying enhancement needs. As subject matter experts in medication-use processes, they bear significant responsibility to ensure that AI contributes to safe, effective, and efficient outcomes. In the same way they apply scientific rigor to medication formulary decision-making, they should evaluate the deployment of AI capabilities and contribute to experimental design when research gaps are identified.

The pharmacy workforce can support the development of new AI models or the implementation of prebuilt AI models, depending on the scope of the need. Pharmacy informaticists, operations pharmacists, and clinical pharmacists possess diverse clinical and technical skills, equipping them to collaborate with computer scientists to build or adjust existing models. They can ensure data used in AI models are accurate and minimize bias, which can impact outputs.[9] Among the 2023 ASHP Pharmacy Forecast panelists, 73% predicted that health systems will be required to validate the safety and effectiveness of AI tools, while only 37% reported that they were prepared to perform the validation.[10] The pharmacy workforce must be aware of pharmacy data sources, data classification, data quality and lineage, intellectual property, and privacy management during model development and validation stages. Once a model is established, the pharmacy workforce is responsible for testing it to

ensure it serves its intended function without errors.[11] Because it is important to define the quality assurance and quality engineering processes that must occur to test AI accuracy as part of the validation process, the pharmacy workforce will need to be trained on the evaluation and validation of AI solutions, including failure modes and effects analysis.

The pharmacy workforce must also educate AI users, informing them of the AI model's focus, scope, and boundaries. Generative AI models may require engineering to ensure that prompts are crafted with the optimal textual inputs (i.e., appropriate words, phrases, sentence structure, and punctuation). To be reliable and efficient, a generative AI tool will require a clearly defined problem with a formulated prompt. Prompts can be built and standardized for use. However, proper user education is required to ensure reliable outputs. Furthermore, superusers can be designated among the pharmacy workforce to build credibility and advocate for technology.

Role of pharmacy informaticists. Pharmacy informaticists play a vital role in creating, supporting, and interfacing clinical information and technology to improve medication safety, efficiency, and patient care.[12] Because that role typically includes oversight of data and analytics, pharmacy informaticists should also have a robust understanding of AI, especially as it pertains to medication-related applications. Pharmacy informaticists should have a deep understanding of AI model types and variables.[13] They should assess models to align with organizational policies to safeguard sensitive information, including protected health information, personally identifiable information, and financial data. These individuals should be responsible for ensuring models are trained, evaluated, corrected, and applied to data that match clinical practice prior to implementation. Additionally, pharmacy informaticists should

also perform routine maintenance and monitoring of deployed AI models, as clinical practice, data inputs, or data distributions change over time.[14] Pharmacists who have knowledge and experience in informatics are well-suited for designing, implementing, and researching AI applications in the future. As healthcare professionals, pharmacists can focus on AI and data science as a specialty, going beyond the supportive role with data scientists and industry.

AI education and training

Education on AI is necessary across all pharmacy practice domains.[3,15] Pharmacy curricula should introduce students to the essential concepts of data science, including the fundamentals of AI, ethical use of generative AI, AI e-iatrogenesis, and AI model safety and efficacy validation.[16,17] The pharmacy workforce must also be given the chance to expand their understanding of AI through continuing education. Data science courses or pharmacy residencies with a focus on AI topics should be available to pharmacists seeking advanced training in these fields. Existing residencies could explore how to incorporate foundational AI concepts into their learning experiences (e.g., pharmacy administration or informatics electives).

Role of AI in pharmacy practice

Informatics. Pharmacy information systems, automation, and technology have been key sources of data and analytics within health systems. These data should not only be an output but should also be considered an agent to troubleshoot, enhance, and optimize pharmacy technology to better suit the needs of end users.[18] Given the differing levels of data complexity

and organization, AI may aid pharmacy personnel in mining the vast amount of healthcare data for actionable trends or patterns. Informaticists must also partner with their medical technology vendors, advocating for continual, ethical advancement of AI applications to provide the best possible patient outcomes.

Clinical applications. Historically, AI has been used in pharmacy to perform repetitive tasks and translate large quantities of data into easily digestible patterns or trends.[18] More recent literature has emerged describing clinical applications of AI. For example, AI has proven useful in interpreting diagnostic imaging,[19] conducting pharmacovigilance,[20] and designing treatment plans.[18] Generative AI has the potential to offer additional benefits, including clinical documentation, patient chart analysis, patient education, drug information, clinical protocol development, and publication support. Future clinical applications of AI may intersect with other growing fields in pharmacy, including pharmacogenomics, population health, drug development, and telehealth pharmacy practice. A common feature of current and future use cases is that they are designed to augment clinical pharmacy services, not replace the pharmacy workforce. Pharmacists should be open to changing traditional clinical workflows to include AI and AI-enabled clinical decision support systems that improve patient care. Pharmacy departments should support efforts to integrate emerging AI-enabled tools to evaluate models, improve care, improve access, lower costs, and provide comprehensive medication management for patients.

Pharmacy practice. From an operational standpoint, AI platforms can improve inventory management, facilitate product verification, assess medication adherence, and help pharmacists perform at the top of their skill set.[20,21] Generative AI can assist with pharmacy

administration documentation requirements, such as staffing memos, human resource management tasks, and medication safety event analysis.[22,23] As AI becomes more reliable, standard pharmacy operations will become increasingly automated, allowing pharmacists to focus more on high-value patient-care activities. Furthermore, it may also enable pharmacy technicians to assume operational tasks historically performed by pharmacists (e.g., medication optimization, medication safety and quality surveillance, and drug diversion monitoring), supporting pharmacists' ability to provide direct patient care.

Rather than just adopting AI, pharmacy executives should lead the effort to define the future of pharmacy and educate their healthcare colleagues and administrators on the role of the pharmacy workforce in an environment in which AI is pervasive.

Educational applications. Generative AI has been used in various settings to provide patient education.[7,24,25] Because pharmacists are often the most accessible healthcare professionals, they must be willing and able to address concerns and comprehension challenges when AI technologies are used for primary patient education. Ultimately, as technologies rapidly evolve, the pharmacy education system must remain agile to ensure our profession is equipped to steward these transformations of care, including educating patients on safe use of generative AI drug information.

In addition to patient education, AI capabilities may be leveraged to support education of the pharmacy workforce, including students and residents. AI applications have already been used in the pharmacy curriculum, including in skills-based courses, exam writing, and school admissions decision support, among other use cases.[26-28] These capabilities may allow for pharmacy instructors to streamline administrative tasks and optimize their time with pharmacy

trainees. Pharmacy educators should evaluate AI capabilities to determine which are most appropriate to deploy within the classroom, skills laboratory, and experiential training environments.

Ethical considerations and unintended consequences of AI

While AI is poised to bring significant benefits to patient care, it also has its limitations. An effective AI system relies on a repository of high-quality data. In the absence of high-quality data, AI systems can easily perpetuate bias due to limited training data, population size, or human bias. Medicine is vulnerable to those risks, as evidence-based clinical practice and measures are often based on data from study populations skewed towards certain groups.[29] Healthcare organizations must ensure that AI models are based on high-quality and expansive data sets that include other objective measures to minimize perpetuating biases.

Generative AI also poses the risk of creating content that is false or misleading. These models should be developed to minimize the probability of creating misleading content, such as setting constraints on possible responses.[30] Operating these tools with human oversight is crucial; AI should serve as a valuable aid to support the pharmacy workforce, rather than as a proxy for them.[31]

These risks have been well recognized nationally. Recently, an executive order outlined the risks, requirements, responsibilities, and accountability measures for the "safe, secure, and trustworthy development of artificial intelligence."[32] One outcome of this executive order was designating the National Institute of Standards and Technology (NIST) as the lead organization for development of guidelines, standards, and best practices for AI safety and security. NIST has

already constructed an AI risk management framework, which includes guidelines on general AI risk management and a companion framework on generative AI risk management.[33] Within these frameworks, NIST tackles many common unintended consequences of AI, including harmful bias, homogenization, data privacy, information integrity, and transparency.[33] Organizations should establish AI governance committees to evaluate and ensure compliance with these guidelines, standards, and best practices.

Having educated, competent staff using these models helps organizations mitigate potential liability. Generally, individuals or groups are not found liable when the standard of care is followed.[34] However, there are two scenarios in which liability may occur: when the AI tool makes a recommendation that aligns with the standard of care, or optimal care, but is dismissed, or when it erroneously makes a recommendation that is not the standard of care and is accepted. In both situations, staff using the AI model must be educated and competent, not only in the current subject in which AI is being applied, but also in the strengths and weaknesses of the model itself.

As with any technology used to assist the practice of pharmacy, contingency plans must be developed in the event of unexpected downtimes, breaches, or recalls.[35] Organizations should answer such questions as: How are patient safety risks identified and handled? If the model is unavailable, what processes should staff fall back to in its absence? Mitigation strategies for unintended consequences of AI must be proactively identified and included within an organization's AI policies and procedures.

In 2021, the World Health Organization published a set of ethical considerations that should be observed in the application of healthcare AI.[36] These considerations include the

preservation of human autonomy within AI-supported medical decision-making and uses of protected health information, the avoidance of harm, and the responsibility to provide the maximum possible unbiased benefit across diverse patient populations. Pharmacy leaders should address these considerations when AI is implemented.

AI regulation

Rapid expansion of AI use in health information technology has highlighted the need for federal agency standards and policy to support safe use, encourage responsible development, improve trust, and promote adoption. In January 2021, the FDA released its first AI/ML-Based Software as a Medical Device (SaMD) Action Plan, outlining the agency's plans to develop a SaMD regulatory framework for AI while also establishing best practices for development, implementation, and monitoring of AI capabilities.[37] In December 2023, the Office of the National Coordinator for Health Information Technology (ONC) issued the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule.[38] This rule established new standards for algorithm transparency and risk management expectations for AI-enabled decision support interventions. Additionally, it advanced interoperability standards designed to promote health equity and established interoperability-focused reporting metrics.

Interoperability and AI are uniquely related. A common barrier to health information exchange is the lack of standardized documentation or use of data standards. AI and machine learning can improve interoperability by allowing the use of streamlined data standards to provide for semantic exchange of health information. Given the fundamental role of data sets

and LLMs in AI, improving health information exchange will be a key goal of AI technology development and optimization. In December 2023, the ONC also announced that the Trusted Exchange Framework and Common Agreement (TEFCA) had become operational.[39] TEFCA is a new interoperability framework supporting nationwide exchange of health information that may support the facilitation of AI in healthcare due to simplification of connectivity and increased flexibility for the exchange of data[40].

As AI and interoperable exchange of information continue to rapidly evolve, pharmacy leaders are uniquely positioned to contribute to the regulatory efforts and ethical considerations for applications related to medication use. Pharmacy leaders must embed themselves in all arenas (organizational, regional, and national) of AI policymaking, governance, and data stewardship to promote personalized, continuous, and preventive care.[15]

Conclusion

Advances in AI technologies will continue at a rapid pace, as will the opportunities to leverage AI in all aspects of pharmacy practice. This evolving landscape presents pharmacy professionals with the opportunity to embed themselves in processes to investigate, implement, maintain, and optimize the use of AI technologies within their respective organizations. Pharmacy workforce engagement in these processes is necessary to ensure that the use of AI technologies results in safe and effective tools for improved patient care. To see this vision come to fruition, pharmacy leaders must ensure sufficient education regarding AI technologies is available to current and future pharmacy professionals. The incorporation of AI technologies within

pharmacy practice is inevitable, and pharmacists have the potential to significantly impact patient care and the profession's future.

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Disclosures
The authors have declared no potential conflicts of interest.

Additional information
Developed through the ASHP Section of Pharmacy Informatics and Technology and approved by the ASHP Board of Directors on DATE, 2024, and by the ASHP House of Delegates on DATE, 2024. Supersedes the ASHP Statement on the Use of Artificial Intelligence in Pharmacy dated May 20, 2020.

Acknowledgements
ASHP gratefully acknowledges Andrew Tang, PharmD Candidate, University of Colorado Skaggs School of Pharmacy, for his contributions to this statement. ASHP also gratefully acknowledges the following organizations and individuals for their review of draft versions of this statement (review does not imply endorsement): Baxter Healthcare Corporation; LogicStream Health; Mount Sinai Health System; QuVa Pharma; Ghalib Abbasi, PharmD, MS, MBA; Thomas Achey,

PharmD, MS, BCPS; Nicole M. Acquisto, PharmD; Ellena Anagnostis, PharmD, MS, BCPS; Samantha Burton, PharmD, FISMP, CPHQ (Baxter); Hanh Chu, PharmD, MBA; Tony Dao, PharmD, EMBA, CPHIMS, CSSBB, LSSBB, PMC HI, FCPhA; Lynn Eschenbacher, PharmD, MBA, FASHP (LogicStream Health, QuVa Pharma); Jenny Lo-Ciganic, MSPharm, MS, PhD; Georgia Luchen, PharmD; Benjamin Michaels, Pharm D, 340B-ACE; Hesham Mourad, PharmD, EMBA, BCPS, BCCCP, CPHIMS, FASHP; Scott Nelson, PharmD, MS; Casey Olsen, PharmD; Ellen Revak, PharmD, MBA, BCPS; Grant Sivley, PharmD, BCPS; Tyler A. Vest, PharmD, MS, BCPS, BCSCP, FNCAP; Kong Kit Wong, PharmD, BCACP; Sawyer Wylie, PharmD, CSPI; and Kimberly Zammit, PharmD, MPH, BCPS, BCCCP, FASHP (Mount Sinai).

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