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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Additional information

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