Artificial Intelligence Considerations for Pharmacy

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PHiT
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We encourage the pharmacy profession to assure there is transparency, safety, effectiveness, trusworthiness, and no population bias for all CDS algorithms using AI.

1. INTRODUCTION

The purpose of this document is to identify how artificial intelligence (AI) and machine learning (ML) are applied in pharmacy dispensing and clinical workflows, including the high and low risk to patient care. The development of software applications building algorithms using ML for AI to drive an automated process must be safe, effective, trustworthy, and void of population bias to optimize patient care and clinical outcomes. The designed artificial intelligence workflow (AI algorithm) uses simple computer-generated steps that lead to standardized clinical processes. Once these AI simple steps become a need, clinical judgment is the point where augmented human intelligence needs to take over and a new AI algorithm can occur, depending on population bias, medication safety, or other clinical judgment needs. Other areas in pharmacy (e.g., supply chain, clinical trials, manufacturing) will also utilize AI, but we will focus on pharmacy dispensing and clinical services.

WHAT IS AI AND ML?

AI is a way for a machine to simulate human intelligence, and ML is a way for a computer system to learn without following instructions using clinical decision support (CDS) algorithms.[1]

APPLICATIONS OF AI AND ML IN PHARMACY

Applications of AI and ML in pharmacy are available today. The initial application of the use of AI and ML should focus on pharmacy's repetitive processes[2] and medication access (e.g., dispensing verification, inventory management, drug shortages) and not necessarily more complex clinical decisions (e.g., choice of medication, CDS, patient assessment). For complex clinical decisions, we encourage the use of augmented human intelligence. "Augmented intelligence is the use of artificial intelligence (AI) technologies to enhance human cognitive capabilities, decision-making processes, and productivity. The label 'augmented' is meant to focus attention on AI's assistive role and emphasize the important role humans play in unlocking the complete potential of AI technologies." [3]

2. RECOMMENDATIONS

The following are reccomendations for pharmacy:

- Since AI is newer technology, and there is limited testing and evaluation of the AI concepts within pharmacy workflow, augmented human intelligence should be used when the pharmacist deems it appropriate and when pharmacist clinical interventions are warranted.
- More research specific to the United States policies and workflow should be conducted because global research is demonstrating potential safety issues for medication management services.[4]

1. Kathryn Marchesini, Jeff Smith, and Jordan Everson, "Two Sides of the AI/ML Coin in Health Care," HealthITbuzz, October 19, 2022. https://www.healthit.gov/buzz-blog/blog-series-artificial-intelligence-machine-learning/ai-ml-in-health-care
2. Reema Hammoud, PharmD, BCPS, "AI and Pharma: Creating Improved Outcomes for Patients and Practitioners," Pharmacy Times, February 27, 2023. https://www.pharmacytimes.com/view/ai-and-pharma-creating-improved-outcomes-for-patients-and-practitioners
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- Clinicians should understand the steps in the workflow process to ensure the correct clinical steps are employed by the AI algorithm.
- Initially apply AI to support pharmacists in the care of their high-risk patients for access to medications (e.g., drug shortages, price transparency, privacy, consent for services, prior authorization).

CALL TO ACTION

With the fast moving evolution of AI, it is important for pharmacists to be aware of the benefits and risks of AI tools (e.g., Chat GPT, BARD, and newer tools). We encourage the pharmacy profession to assure there is transparency, safety, effectiveness, trusworthiness, and no population bias for all CDS algorithms using AI. This requires clinician participation with CDS development and assessment to assure decision making is at the right point in the workflow.

As AI and ML become more available to health care, it is important for pharmacists to understand the benefits and risks when system vendors adopt tools using AI driven algorithms.

3. DISCUSSION

Although AI tools are not currently widely adopted, identifying how AI and ML are applied in pharmacy dispensing and clinical workflows, including the high and low risk to patient care, is vital. As AI and ML become more available to health care, it is important for pharmacists to understand the benefits and risks when system vendors adopt tools using AI driven algorithms.

GUIDING PRINCIPLES

In order to develop the algorithms for ML, vendors need to use codified data to ensure reliable AI. If standardized codified data is not used, the data lead to inaccurate AI algorithms. Principles and policies need to be created by the pharmacy profession related to ethical decisions to mitigate risk and leverage benefits of AI utilization. Privacy and security should be evaluated in order to mitigate malicious intent. Repetitive processes can be automated through the use of AI as the machine continues to learn. More complex decisions should include human interventions in CDS algorithms (augmented intelligence).

BENEFITS

When the CDS algorithms are built correctly, patient care workflow can be efficiently prioritized and can help to triage high risk events.

When the CDS algorithms are built correctly, patient care workflow can be efficiently prioritized and can help to triage high risk events. This can result in reducing provider burden and improving patient outcomes. By using pharmacogenomic data (e.g., PGx) alongside other patient factors, machine learning can apply the data to support personalized drug selection, dose optimization, prevent adverse events (e.g., choosing the right hypertension therapy). Reducing administrative and repetitive functions will allow more time for essential patient care services.

Artificial intelligence clinical decision support (AI-CDS) is an example of the benefit that would be gained in a clinical workflow. Data are entered into the system (structured and unstructured) and the AI-CDS system generates predictions using ML algorithms that become actionable recommendations to health care providers.[5]

Since drug information is highly codified, there are several uses of ML and AI that can be beneficial to pharmacy. Drug development and drug inventory management (using a combination of block chain and/or AI) are beneficial uses for applying AI. As an example, the development of new medications (e.g., new compounds for antibiotic resistant infections) have been used.

5. Sriram Ramgopal, L. Nelson Sanchez-Pinto, Christopher M. Horvat, et al, "Artificial intelligence-based clinical decision support in pediatrics," Pediatric Research, July 29, 2022. https://www.nature.com/articles/s41390-022-02226-1

In pharmacy, applying AI and ML solutions offer numerous benefits pertaining to prior authorization for medications, medical devices, and medical services helps to reduce clinician burden. "The use of AI in prior authorization can be a positive step toward reducing the use of valuable practice resources to conduct these manual, time-consuming processes."

Solutions such as these may also reduce clinical burden and create time efficiencies allowing for more meaningful patient interactions[6]

AI in pharmacies can help to ensure patients receive consistent and effective pharmacy care by helping to prevent them from "falling through the cracks" in our health care system.[7] Examples, such as, scheduling patient visits, triaging patient interventions, processing prescription refills, managing inventory, enhancing CDS, etc., would help to enhance the overall quality and continuity of pharmacy care.

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RISKS

When applying AI algorithms, clinicians should be aware of several challenges and risks associated with AI implementation and use. Examples of AI risks include biases in data, biases in population health, and errors in data.

Errors in data manifest when there is an over-reliance on algorithms. When applying AI to clinical workflows, it is important to assure the data points are codified. The workflow of clinical documentation also needs to be standardized in order to prevent errors and ensure the machine does not include incorrect information. We must ensure the ML algorithms have access to information outside the workflow (e.g., PDFs containing notes, care plans, results, etc.)

Two ways to encourage this are to build trust through an authoritative organization, like the FDA, with regulations that encourage vendors to use codified data for ML. Moreover, it is essential to involve relevant stakeholders, particularly medication experts such as pharmacists, in the development of these algorithms. For example, CDS algorithms should be collaboratively developed with pharmacists input prior to integration into physician processes. Government initiatives[8] will play a critical role in identifying and mitigating the risks associated with AI algorithms and AI implementation in health care processes.

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In pharmacy, regulatory requirements should adhere to FAVES principles[9] to ensure that pharmacy practices that use AI applications are Fair, Appropriate, Valid, Effective, and Safe (FAVES). These practices and regulations should also prioritize preventing population bias and ensuring the safety and effectiveness of AI-driven pharmacy practices.

The FDA is concerned when new medications and biologics are being developed at a faster rate. Using AI can affect the current regulatory clinical trials timeline.[10] Because of the accelerated medication and biologics development, evidence-based research may be unavailable at the time the CDS algorithm is being written. This can affect FAVES documentation.

There are some use cases, such as pharmacogenomic use in precision medicine, population health

6. AMA adopts policy calling for more oversight of AI in prior authorization, American Medical Association. https://www.ama-assn.org/press-center/press-releases/ama-adopts-policy-calling-more-oversight-ai-prior-authorization#:~:text=The%20new%20AMA%20policy%20calls,manual%2C%20time%2Dconsuming%20processes.
7. Mark Haglan, "In Houston, Enterprise-Wide Innovation Is On the Agenda," healthcareinnovation, October 12, 2023. https://www.hcinnovationgroup.com/population-health-management/patient-engagement/article/53075096/in-houston-enterprise-wide-innovation-is-on-the-agenda?utm_source=HI+Daily+NL&utm_medium=email&utm_campaign=CPS231013027&o_eid=3326G3739001D8X&rdx.ident[pull]=omeda|3326G3739001D8X&oly_enc_id=3326G3739001D8X
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When applying AI algorithms, clinicians should be aware of several challenges and risks associated with AI implementation and use.

issues related to social determinants of health, electronic prior authorization, and medication reconciliation processes, that can be affected if the data lack standardized codification or incomplete evidence-based research.

Another risk when applying AI algorithms is biases in data, specifically with how use of AI affects clinician workflow. The workflow must be designed in a way that makes data usable. When information is received from a source external to the EHR or clinical documentation module, the data are usually in a "read-only" format and not editable. Typically, the barrier for interoperable sharing of eCare plans, for example, are on the receiving end (the EHR.) Vendors might perceive eCare plan data as erratic or possibly corrupt and, therefore, only allow the viewing of that data. As a result, the eCare plan becomes a PDF or some other read-only file that is stored outside of the system and must be referenced from the clinician's workflow. If the content of the eCare plan is not included in the algorithm, it impacts clinical judgment, as the clinician may not have all the necessary information at the point of care.

There are many unexplored areas related to the integration of AI and ML within pharmacy workflows. In the future of pharmacy: How AI is revolutionizing the industry article, figure 2 highlights the need for further research into how AI can be used to enhance patient care in the pharmacy setting. Technical challenges include data integration, system maintenance, usability of algorithms, and affordability and return on investment within pharmacy systems and workflows. There are also key unexplored areas related to the use of AI and ML to support therapeutics, including patient adherence. Perhaps most importantly, the use of AI in pharmacy workflows and systems necessitate the need for research into the ethical implications of using these as tools in patient care.

AI in health care, use of AI tools in pharmacies, and future AI developments all bring about important areas of research, some overlapping and some disparate. In the future of pharmacy: How AI is revolutionizing the industry article, figure 1 depicts the dearth of research at the intersection of these three areas, identifying the need for further investigation. Keeping these three areas of research in mind when developing and improving AI tools for use into existing pharmacy systems will be important. Highlighting these various factors will help to enhance the functionality and the usefulness of AI solutions in the pharmacy setting.

The novelty approach is one way to account for advantages, limitations, especially related to ethics, and challenges associated with the integration of AI tools in the pharmacy setting. In the future of pharmacy: How AI is revolutionizing the industry article, figure 3 shows the unique potential that

AI tools can have. The integration of an AI tool such as this could lead to better personalized care, early detection of adverse drug reactions (ADRs), and has the potential for improved medication adherence. However, it is important to mitigate limitations and ensure that all intelligence outputs from the integration of these types of AI tools serve as augmented human intelligence and that there is not an overreliance on technology. Furthermore, it is important to consider the potential of bias in algorithms and accuracy issues. Longer term, if carefully and thoughtfully implemented, AI implementation could ultimately lead to improved patient outcomes, increased efficiency, and evolving roles for pharmacists in the health care ecosystem, leading to an overall improved population-level health. It will be important to take into consideration the potential for good and the ethical challenges that these transformative interventions will bring.

4. CONCLUSION

Recommendations to the pharmacy profession related to the use of CDS, ML, and AI are important to understand the impact of these technology solutions moving forward. Since AI is a newer technology, and there is limited testing and evaluation of the AI concepts within pharmacy workflow, we recommend the review and critical analysis of augmented human intelligence when pharmacist clinical interventions are warranted.

Globally, there is research and potential engineering pharmacy workflows and CDS algorithms. These tools can demonstrate potential safety issues for medication management services. More research specific to the United States policies and efficient adoption in pharmacy systems is recommended. Clinicians should understand the steps in the workflow processes to ensure the correct clinical steps are employed by ML to limit concept drift and generation of accurate AI functionality. Initially applying AI to support pharmacists in the care of their patients for access to medications (e.g., drug shortages, price transparency, prescription claims, privacy, consent for services, prior authorization) that yields precise results desired outcomes is also recommended.

Perhaps most importantly, the use of AI in pharmacy workflows and systems necessitate the need for research into the ethical implications of using these as tools in patient care.

5. RESOURCES

A deep-learning algorithm helped identify new compounds that are effective against antibiotic-resistant infections in mice, opening the door to AI-guided drug discovery. https://www.scientificamerican.com/article/new-class-of-antibiotics-discovered-using-ai/

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AI ushers in next-gen prior authorization in healthcare https://www.mckinsey.com/industries/healthcare/our-insights/ai-ushers-in-next-gen-prior-authorization-in-healthcare

it is important to consider the potential of bias in algorithms and accuracy issues.

Artificial intelligence-based clinical decision support in pediatrics https://www.nature.com/articles/s41390-022-02226-1

Artificial Intelligence at CMS https://ai.cms.gov.

Artificial Intelligence in Healthcare: Peter Lee on Empathy, Empowerment, and Equity https://www.ihi.org/insights/artificial-intelligence-health-care-peter-lee-empathy-empowerment-and-equity?utm_campaign=tw&utm_medium=email&_hsmi=280334513&_hsenc=p2ANqtz-80Rru64fFKmHq-eXawQIWJTCR-Kq2UnJMPSXMGWMlPCQo0lPMn8oaHZKwazaB-nrx7WED0oAMTL5_15A-OCKpRAIWxbA&utm_content=280167929&utm_source=hs_email

Artificial Intelligence in Medicine https://www.nejm.org/doi/full/10.1056/NEJMe2206291

Artificial Intelligence (AI) in Pharmacy: An Overview of Innovations https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9836757/

Artificial intelligence in the field of pharmacy practice: A literature review https://pmc.ncbi.nlm.nih.gov/articles/PMC10598710/#s0025

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ASHP Artificial Intelligence https://www.ashp.org/pharmacy-practice/resource-centers/informatics/artificial-intelligence?loginreturnUrl=SSOCheckOnly

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ASHP Pharmacy Forecast 2023 (includes info on AI) https://academic.oup.com/ajhp/article/80/2/10/6854799

ASHP Report ASHP Statement on the Use of Artificial Intelligence in Pharmacy https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/artificial-intelligence-in-pharmacy.pdf

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FDA Guidance on Artificial Intelligence and Machine Learning in Software as a Medical Device https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device

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How Machine Learning And AI Could Solve Drug Shortages https://www.forbes.com/sites/forbestechcouncil/2023/09/12/how-machine-learning-and-ai-could-solve-drug-shortages/?sh=3ca22fe43ea2

https://www.bd.com/en-us/products-and-solutions/products/product-brands/healthsight

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https://www.sciencedirect.com/science/article/pii/S0002945923001420

Laboratory Automation Reaches Every Stage of Drug Development https://www.genengnews.com/topics/artificial-intelligence/laboratory-automation-reaches-every-stage-of-drug-development/

New Class of Antibiotics Discovered Using AI https://www.scientificamerican.com/article/new-class-of-antibiotics-discovered-using-ai/

ONC HTI-1 Proposed Rule – Decision Support Interventions (DSI) and Predictive Models (Algorithmic Transparency) 5-4-23 https://www.healthit.gov/news/events/hti-1-proposed-rule-information-sessions

Podcast Your Undivided Attention (by The Center for Humane Technology Tristan Harris) https://openai.com/dall-e-3.

Plenful picks up $17M to automate administrative tasks for pharmacists https://www.fiercehealthcare.com/health-tech/plenful-picks-17m-automate-administrative-tasks-pharmacists

Predicting drug shortages using pharmacy data and machine learning https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10009839/

Regulatory considerations on artificial intelligence for health https://iris.who.int/bitstream/handle/10665/373421/9789240078871-eng.pdf?sequence=1&isAllowed=y

Remedi Chain https://www.donatemymeds.org/ how you can donate or receive unused medication. This is an example of using the block chain technology.

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What Pharma Fears Most About AI https://www.pharmexec.com/view/what-pharma-fears-most-about-ai

6. GLOSSARY

AI - Artificial Intelligence

AHI - Augmented Human Intelligence: a design pattern for a human-centered partnership model of people and artificial intelligence (AI) working together to enhance cognitive performance, including learning, decision making and new experiences.[11]

CDC - Centers for Disease Control and Prevention Population Health: CDC views population health as an interdisciplinary, customizable approach that allows health departments to connect practice to policy for change to happen locally. This approach utilizes non-traditional partnerships among different sectors of the community – public health, industry, academia, health care, local government entities, etc. – to achieve positive health outcomes. Population health "brings significant health concerns into focus and addresses ways that resources can be allocated to overcome the problems that drive poor health conditions in the population."[12]

CDS - Clinical Decision Support

EHR - Electronic Health Record

ePA - electronic Prior Authorization

FAVES - Predictive decision support interventions is - Fair, Appropriate, Valid, Effective, and Safe

FDA - Food and Drug Administration

FHIR - Fast Healthcare Interoperability Resource

IG - Implementation Guide

ML - Machine Learning

MR - Medication Reconciliation

PGx - Pharmacogenomics

SDOH - Social Determinants of Health

SMP - Standardized Medication Profile

11. Augmented Intelligence, Gartner. https://www.gartner.com/en/information-technology/glossary/augmented-intelligence

12. What is Population Health, Centers for Disease Control, https://archive.cdc.gov/#/details?url=https://www.cdc.gov/pophealthtraining/whatis.html

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