

CANCEAL = Artificial intelligence in the pharmaceutical galenic field: A useful instrument and risk consideration= CANCEAL

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Abstract: It is undeniable that artificial intelligence technology helps humans in many fields; however, it is necessary to consider the risks associated with unprofessional use. Today, in the healthcare system, the use of artificial intelligence is widely disseminated, and it is likely to increase in the future. Literature reports the accuracy of the various artificial intelligence tools like chatbots in some medical fields. This article aims to verify some relevant literature about this field and to test one famous provider of artificial intelligence Chatbots: Based on the results of this test some crucial considerations are submitted to the researcher. A rigorous evaluation of the benefits and risks must be considered at this level of technology and today available.

Introduction

Machine learning (ML), artificial neural networks (ANNs), and deep learning (DL) are all topics that fall under the heading of artificial intelligence (AI) and have gained popularity in recent times. ML involves the application of algorithms to automate decision-making processes using models that have not been manually programmed but have been trained on data. ANNs that are a part of ML aim to simulate the structure and function of the human brain. DL uses multiple layers of interconnected neurons. This enables the processing and analysis of large and complex databases (**Figure 1**). In the medical field, these techniques are being introduced to improve the speed and efficiency of disease diagnosis and treatment (**Figure 2**) [1]. The impact of AI on pharmaceutical laboratories and explore AI applications in analytical processes, regulatory compliance, and quality control. AI is transforming pharmaceutical labs by enhancing automation, data interpretation, and compliance monitoring. With the rise of ML, DL, and big data analytics, AI enables predictive analytics, anomaly detection, and process optimization, reducing human error and increasing efficiency. Regulatory authorities are increasingly focusing on these innovations to ensure AI implementation aligns with GLP and GMP guidelines [2]. According to the International Pharmacist Federation (FIP), an AI for pharmacy (launched in 2020), the FIP Development Goals seek to direct the transformation of the pharmacy profession globally by 2030 (**Figure 3**). Aligning with the UN Sustainable Development Goals, the FIP Development Goals specifically focus on enhancing pharmacy practice, education, and the pharmaceutical sciences. The One FIP Development Goals enable the identification of commonalities and inter-sectoral collaboration within a transformative framework for the pharmacy profession. The FIP Development Goal on Digital Health is structured around three elements: education and workforce, practice, and science [3].

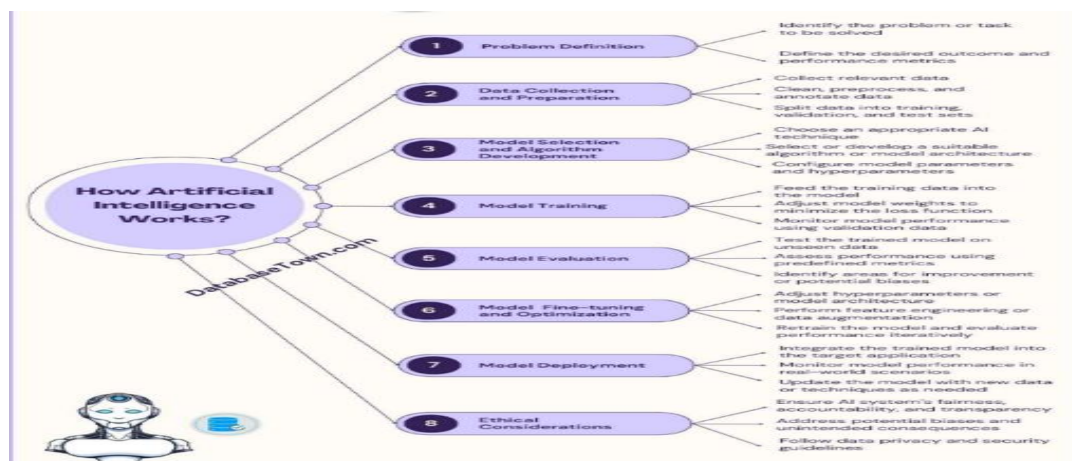


Figure 1: How does work Artificial Intelligence?

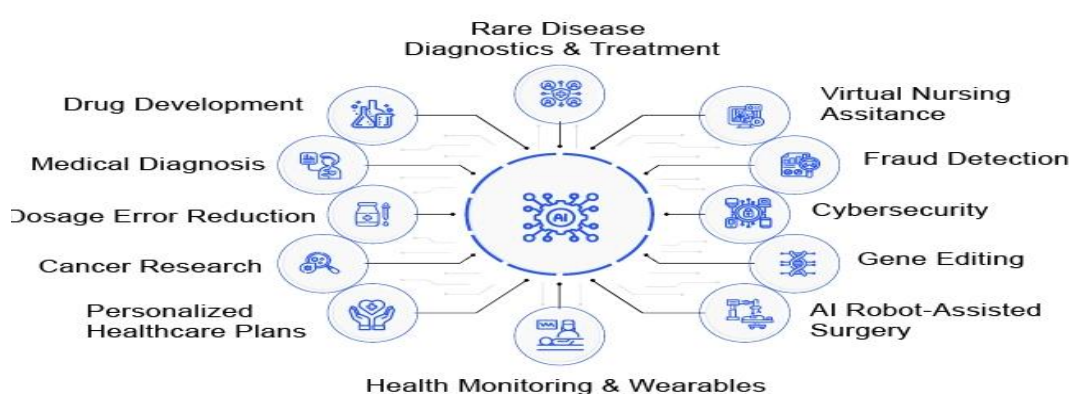


Figure 2: Applications of Artificial Intelligence in Healthcare Segment

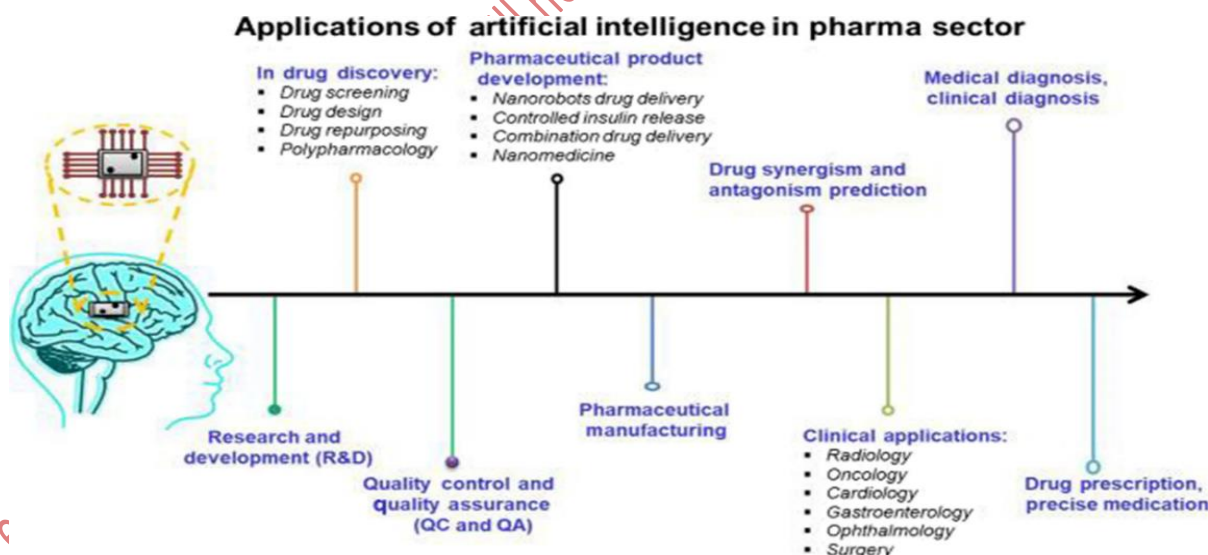


Figure 3: Applications of Artificial Intelligence in the Pharmacy sector

Machine learning is a subset of AI that uses algorithms to analyze and “learn” from massive amounts of data. The algorithms can include: DL algorithms that specialize in image and speech recognition. Natural Language Processing algorithms that work to comprehend and generate language. Computer vision algorithms that interpret data to analyze objects, recognize faces, or other visual tasks. Reinforcement learning algorithms are used to train agents (or autonomous systems) in making sequential decision tasks. AI systems are powering the future of healthcare in multiple fields like: Telemedicine and Remote Monitoring, Diagnosis and Disease

Detection, and analysis of medical images (MRIs, CT scans). Drug Discovery and Development: AI analyzes massive data sets to identify potential new drug candidates and improve drug discovery. AI-driven simulations additionally predict the drug efficacy or interactions to enhance the safety profile, save resources, and speed up development. Treatment personalization: applications that analyze genetic, clinical, and lifestyle data. Predictive analytics and risk assessment, increased administrative efficiency robots. Among the advantages: saving time, eliminating biases, increasing diagnostic accuracy, advanced data management, processing higher volumes of complex data, making it usable for analysis, increasing predictive medicine, reducing global costs, increasing surgery precision, reducing automating repetitive tasks, and others [4]. The design and study of machines that can perform tasks that would previously have required human (or biological) brainpower to accomplish. AI is a broad field that incorporates many different aspects of intelligence, like reasoning, making decisions, learning from mistakes, communicating, solving problems, and moving around the physical world. AI was founded as an academic discipline in the mid-1950s and is now found in many everyday applications, including virtual assistants, search engines, navigation apps, and online banking. This scoping review has three main areas of focus, (a) identification and classification of atypical or inappropriate medication orders, (b) improving efficiency of mass screening services, and (c) improving adherence and quality use of medicines [5]. It also identified gaps in AI's current utility within the profession and its potential for day-to-day practice, as our understanding of general AI techniques continues to advance. AI is transforming compounding pharmacy operations by streamlining workflows, enhancing compliance, and saving valuable time. This white paper analyzes 997 questions posed by compounding pharmacist clients to two specialized AI tools-compounding AI and policy AI developed to operate in a closed system with validated sources. These tools, designed to provide accurate answers without speculation, saved an estimated 15 238 minutes (254 hours) of the pharmacist's time. With time savings averaging over 11 minutes per question. AI is proving to be a game-changer in compliance, calculations, documentation, and operational efficiency. This report explores the data, highlights real-world applications, and addresses the risks and rewards of AI adoption in compounding pharmacies [6]. According to the Royal Pharmaceutical Society, AI in pharmacy education and training: Pharmacists must familiarise themselves with AI to ensure they have a level of awareness that allows them to contribute to the digital advancement of pharmacy practice (PP). With AI tools already integrated into everyday devices and some clinical practices, we must emphasise the importance of awareness and informed decision-making among pharmacists to navigate the benefits/risks of AI deployment in PP [7].

The development and implementation of an AI-driven chatbot for Master Formulation Record represents a significant advancement in pharmacy education. By leveraging the power of AI, educators can provide students with a dynamic and immersive learning experience that prepares them for the complexities of real-world pharmacy practice. Looking ahead, the AI-driven chatbot holds immense potential to further transform pharmacy education and elevate the standard of care in PP. As the technology continues to evolve, future iterations of the chatbot will incorporate additional features such as voice recognition and natural language understanding, further enhancing the authenticity and interactivity of the learning experience. Through collaboration, innovation, and a commitment to excellence, the future of pharmacy education is bright and full of possibilities [8]. The application of decision-making tools such as expert systems and ANNs to the development of optimal formulations for hard gelatin capsules. Although AI has a hugely beneficial impact on medical science, it is followed by several significant risks and dangers. It is strongly suggested for medical organizations to monitor the changes which are associated with the giant steps of AI development, and modify accordingly medical education and practice. The major risks might emerge when AI becomes more powerful than the human brain, thus it is of paramount importance to develop solid and safe mechanisms to keep AI under control. The establishment of an ethical pathway could be one of the safe ways for AI to remain human-friendly in the future [9]. AI is not a high-precision technology, and this has profound implications for the world of work, AI, by contrast, operates on probabilities and approximations. Even with vast amounts of data and processing power, AI cannot guarantee exact outcomes because they are trained on historical data and

predict future behaviours based on patterns [10]. Error analysis in production processes with an AI-based root cause analysis: In modern, digital production facilities, vast amounts of data are recorded, which can no longer be analyzed with simple means. AI can help when it comes to finding clues about possible causes of errors in these large datasets [11]. In compounding, computer vision technologies are being explored to map pharmacist movements and provide double-checking mechanisms, ensuring precision and reducing human error. AI offers increased accuracy, reduced costs, and time savings while minimizing human errors. It can revolutionize personalized medicine, optimize medication dosages, enhance population health management, establish guidelines, provide virtual health assistants, support mental health care, improve patient education, and influence patient-physician trust [12].

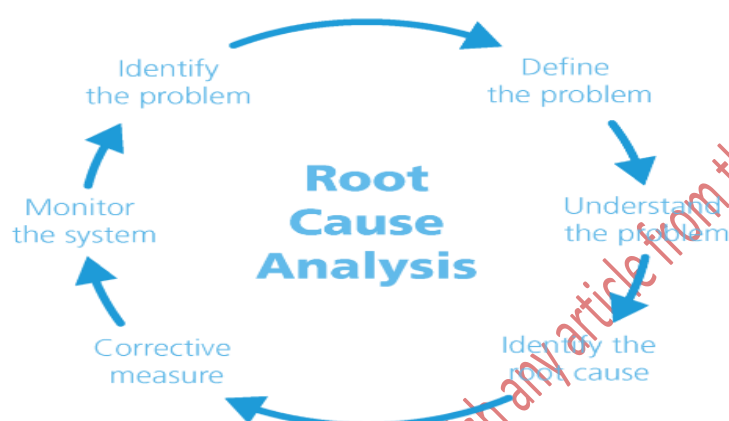


Figure 4: Error analysis in production processes with an AI-based root cause analysis

Materials and methods

From an observational point of view, some scientific literature related to the topics of this work is reported. **Figures 1 - 5** help in showing the general meaning. A specific practical experience is provided: A test of simple or more complex queries to a famous chatbot. After all this, a global conclusion is submitted to the researcher.

Results

The human mind has several obstacles and limitations to remember and apply the thousands of medical information learned at medical school quickly. Knowledge of medicine is proliferating. The analysis of hundreds of papers and textbooks is impossible for a clinician. In evidence-based medicine (EBM) practice, physicians must use recent guidelines and papers. According to a report, most diagnostic errors in medical care are related to the wrong cognition by healthcare workers. Also, medical errors are one of the significant causes of death in the US most related to human errors [13]. AI is a transformative technology used in various industrial sectors including healthcare. In PP, AI has the potential to significantly improve medication management and patient care. By using AI algorithms and ML, pharmacists can analyze a large volume of patient data, including medical records, laboratory results, and medication profiles, aiding them in identifying potential drug-drug interactions (DDIs), assessing the safety and efficacy of medicines, and making informed recommendations tailored to individual patient requirements [14]. Personalized medicine approaches can be facilitated through AI algorithms that analyze real-world patient data, leading to more effective treatment outcomes and improved patient adherence. This explores the wide-ranging applications of AI in drug discovery, drug delivery dosage form designs, process optimization, testing, and PK/PD studies [15]. AI

technology for the pharmacy field, otherwise known as pharmacointelligence, can help streamline processes for clinical pharmacists, including making more accurate and EB clinical decisions through analyzing a large amount of patient data, medical records, laboratories, and medication profiles [16]. Pharmacists are highly concerned about patient safety and AI may help in this area. The integration of AI technologies in PP can help detect and prevent medication errors, such as incorrect dosages or potential DDIs, thereby minimizing adverse drug reactions and hospital readmissions [17]. This also discusses the AI concepts and their applications, particularly in developing solid dosage forms. Advanced algorithms optimize formulation processes, predict PK profiles, and assess drug toxicity profiles, facilitating a more efficient pathway from pilot study to market. This highlights the advancements in 3D printing technologies of dosage forms that can provide personalized treatment PT to different individuals [18]. Excipient compatibility assessment using AI offers tremendous promise and potential for enhancing pharmaceutical development and manufacturing procedures [19]. The use of AI in predicting drug toxicity offers several advantages. This enables the analysis of large data sets, allowing for a more complete understanding of the complex interactions between drugs and biological systems [20].

Drug formulation, design, and development: AI algorithms evaluate data to predict the stability and compatibility of pharmaceutical ingredients (PI). This technology can improve formulations for controlled release, optimize bioavailability, and minimize side effects, enhancing the entire lifecycle of pharmaceutical products [21]. The aim is to assist pediatricians in determining appropriate treatment doses for children based on various parameters like age, weight, and other significant factors [22]. AI involves the combination of human knowledge and resources with AI. As research into AI continues, with many interesting applications of it in progress, one may consider it a necessary evil even for those that see it as an enemy. It is recommended that pharmacists should acquire the relevant hard skills that promote AI augmentation. Education about and exposure to AI is necessary throughout all domains of PP. Pharmacy students should be introduced to the essentials of data science and the fundamentals of AI through a health informatics curriculum during their PharmD education. Pharmacists must also be allowed to develop an understanding of AI through continuing education. Data science courses or pharmacy residencies with a focus on AI topics should be made available for pharmacists seeking more hands-on involvement in AI development, governance, and use. As these technologies rapidly evolve, the pharmacy education system must remain agile to ensure our profession is equipped to steward these transformations of care [23].

The literature search yielded 8796 articles. After removing duplicates and applying the inclusion and exclusion criteria, 44 studies were included in the qualitative synthesis. This highlights the significant promise that AI holds in healthcare, like enhancing healthcare delivery by providing more accurate diagnoses, personalized treatment plans, and efficient resource allocation, persistent concerns remain, including biases ingrained in AI algorithms, a lack of transparency in decision-making, potential compromises of patient data privacy, and safety risks associated with AI implementation in the clinical settings [24]. The results highlighted the usefulness of AI not only for risk prevention in clinical practice but also in improving the use of an essential risk identification tool, which is incident reporting. Used judiciously, AI has immense potential to advance toxicology into a more predictive, mechanism-based, and evidence-integrated scientific discipline to better safeguard human and environmental well-being across diverse populations [25].

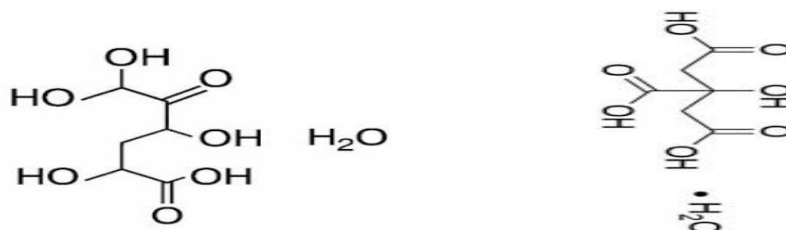
One of the main risks associated with AI in the chemical industry is the possibility of human error. As AI systems become increasingly sophisticated, they can become more difficult to understand and operate, increasing the risk of errors and accidents. AI systems may also malfunction, leading to unexpected results and potential hazards [26]. The multifaceted ethical considerations surrounding the use of AI and ML in health care, include privacy and data security, algorithmic bias, transparency, clinical validation, and professional responsibility. By critically examining these ethical dimensions, stakeholders can navigate the ethical complexities of AI and ML integration in healthcare, while safeguarding patient welfare and upholding ethical principles [27]. 3D printing technology is very versatile in that a wide range of release profiles can be created

by controlling tablet structure. Customized appearance, size, dose, and other characteristics of the dosage forms can be achieved by 3D printing, resulting in patient-centric designs. In early-stage development, 3D printing technology can accelerate formulation development for pre-clinical studies and allows the production of small batches, including flexible dose adjustment, to facilitate pilot clinical studies [28]. The application is based on the interconnection of prescription-related aspects (patients' and prescriber's details and prescription information). The prescription name is linked to the list of substances, which allows for monitoring of the stock levels. Inserting the daily dosage into the system, our personnel can calculate the monthly supply of medicine. Each prescription contains specific warnings on printable labels. A printed sheet, inclusive of labels and checks on final preparation, is produced for each prescription [29].

Artificial Intelligence systems can fail (a) if there are problems with its inputs comprising various representations of data, sensor hardware, etc., and/or (b) if the processing logic is deficient in some way, and/or (c) if the repertoire of actions available to the AI system is inadequate, i.e. if the output is inappropriate. These problems/deficiencies/inadequacies originate from two kinds of errors-commission and omission errors in the design, development, and deployment of an AI system. These errors are: Error of commission: doing something that should not have been done. It is not doing something that should have been done [30]. This identified and clarified seven main risks of AI in medicine and healthcare: a) patient harm due to AI errors, b) the misuse of medical AI tools, c) bias in AI and the perpetuation of existing inequities, d) lack of transparency, e) privacy and security issues, f) gaps in accountability, and g) obstacles in implementation. Each section, as summarised below, not only describes the risk at hand but also proposes potential mitigation measures [31].

The work evaluated the suitability of Chat-GPT versions 3.5 and 4 for healthcare professionals seeking up-to-date evidence and recommendations for resuscitation by comparing the key messages of the resuscitation guidelines, which methodically set the gold standard of current evidence/recommendations, with the statements of the AI chatbots on this topic. In response to inquiries about the five chapters, ChatGPT-3.5 generated a total of 60 statements, whereas ChatGPT-4 produced 32 statements. ChatGPT-3.5 did not address 123 key messages, and ChatGPT-4 did not address 132 of the 172 key messages of the ERC guideline chapters. A total of 77.0% of the ChatGPT-3.5 statements and 84.0% of the ChatGPT-4 statements were fully in line with the ERC guidelines. The main reason for the nonconformity was superficial and incorrect AI statements [32]. Occasionally, ChatGPT provided 2 completely different responses to the same question. Overall, ChatGPT provided more accurate responses (8 out of 12) to the "what" questions with less reliable performance to the "why" and the "how" questions. It has identified errors in calculation, unit of measurement, and misuse of protocols by ChatGPT. Some of these errors could result in clinical decisions leading to harm. It also identified citations and references shown by ChatGPT that did not exist in the literature [33]. A total of 600 consecutive questions were inputted into ChatGPT. ChatGPT 40 answered 72.2% of questions correctly, whereas 3.5 answered 53.8% of questions correctly. There was a significant difference in performance by question category. ChatGPT performed poorer concerning knowledge of landmark studies and treatment recommendations and planning. ChatGPT is a promising technology, with the latest version showing a marked improvement. Although it still has limitations, with further evolution, it may be considered a reliable resource for medical training and decision-making in the oncology space [34].

Experimental project: In this section, various query (simple or more complex) was submitted to a famous AI tool (Chatbot) available for free on the web: the response is then reported: 1) Digoxin is water soluble? Response: it is poorly soluble in water and more soluble in alcohol, 2) What is the molecular weight of NaCl? Response: 58.44 g/mol. 3), The Colliria must be sterile: Response Yes it is fundamental to avoid eye infections, 4) Is it compatible propranolol with Cellulose microcrystalline? responde Yes, 5) Is omeprazole gastro sensible acid label?: Response Yes, it is inactivated in the gastric (acid) environment, 6) What is the chemical structure of the acid citric monohydrate? Response:

**Figure 5:** Response received

(Expected right formula with 3-COOH groups)

7) Question: Lidocaine cloridrate is considered a poison by Italian Pharmacopeia n. 3 tab? Response received: yes, 8) Aceton in inflammable? Response: yes, 9) What is the galenic use of NIPAGIN? Response: preservative,

10) What is the water solubility of amoxicillin? Response: the water solubility is not so extremely high so is needed specific formulation to improve body absorption, 11) How does increase the solubility of water-insoluble active principles in galenic oral drops? Response: various strategies like: to be used for cosolvents like ethanol, glycerin, propylene glycol or surfactants, or cyclodextrin complexation, solubility enhancers (PEG), pH adjustment, formulation of suspension, 12) How to increase the solubilization of a solute in a solution?: response: Increase temperature, use a solvent, agitation, increase the surface area of the solute, use surfactants, change the pH of the solution, use co-solvents, apply pressure (for gases), use complexants, 13) How many grams of KOH are to be weighed to prepare 100 ml solution at 30.0%? Response To be dissolved 30 gm total volume of 100 ml of solution, 14) How do administrate drugs in children with difficulty swallowing? Response: liquid suspension, chewable tablets, dissolved forms, powders or orally disintegrating tablets, other liquid forms, or suppositories, and 15) What is the time needed to adequately mix Apis and excipients in the galenic field using ana semi-automatic powder mixer to prepare capsules?: response.

Summary (Galenic Lab Semi-Automatic Mixer):

Type of Blend	Minimum Time	Notes
Simple, high-dose API	5–10 minutes	Similar particle size, good flow
Low-dose/ potent API	10–15 minutes	Use geometric dilution
Difficult/ cohesive powders	15–20 minutes	May need intensification
Visual/ manual mixing	Add 2–3 min	Common in small batches

Figure 5: Response from an Artificial Intelligence Chatbot

Discussion

Today many applications of AI can be used in the galenic field: from robots for the oncologic labs to the software for the management of the laboratory, the algorithms to verify incompatibility or the posology of toxicity but there are many other topics of interest. As in other disciplines like medicine or technology, AI tools will be introduced to help humans and healthcare professionals (like in the pharmaceutical fields). Because in the pharma world, it is needed for regulatory and safety rules to follow strict requirements it is crucial to observe the kind of results that can be obtained by the various AI instruments (robots, software chatbots, and others available). But in the pharma world is needed certainty for drug production and use. AI operates on probabilities and approximations. Even with vast amounts of data and processing power, AI models cannot guarantee exact outcomes because they are trained on historical data and predict future

behaviours based on the patterns. For this reason is needed to know the algorithm used or followed and the kind and percentage of possible errors of this new technology. In the healthcare field, some concepts are fundamental: continuous updating activity, digital competencies and innovations, accuracy of the information. According to FIP, the integration of AI in pharmacy requires the pharmacist to understand not only the capacity of the new technology but also the limits, the quality of the data, the normative conformity, the ethical consideration, and the infrastructural investments needed. The FIP guide on AI use in PP contributes to holding responsible pharmacists to provide patients with safe assistance tailored without compromising their critical thinking or professional judgment. The response of the AI used in the experimental project reported in this work provided a unique response and not as the classic Search engine: various responses from various sources reporting various points of view. Related to the experimental project: between 15 scientific technical questions 14 responses were substantially acceptable, one with some peculiarity error: In the chemical structure of acid citric monohydrate, the AI instrument did not provide a formula with three carboxylic acids. Between the disadvantages of AI is possible to see: A lack of AI transparency and explainability: AI and DL models can be difficult to understand, even for those who work directly with this new technology. Bias and fairness concerns in training data may result in unequal treatment, misdiagnosis, or underdiagnosis of certain kind of demographic groups. New regulatory and legal challenges that require navigating complex regulatory frameworks. Possibility of manipulation through AI algorithms, and increased control systems (face recognition). Lack of data privacy (due to explicit law that protects this), racial biases; loss of human influence; interoperability problems between existing healthcare systems and the emerging data platforms; accountability concerns: to identify what or who is responsible in the event of an error; resistance to adoption by the healthcare professionals; lack of trust in AI-generated recommendations; high costs of development and implementation of AI; lack of emotions and creativity; the possibility that this technology can reduce the critical thinking and judgment of healthcare professionals; ethical concerns: AI decisions that may conflict with the patient or family preferences; data quality problems related to incomplete or inaccurate data; and potential cybersecurity risks: ransomware, malware, data breaches, or privacy violations and related malfunctions.

Conclusion: Artificial intelligence tools can be useful in orientating in galenic practice but the findings of the query using chatbot must be strictly verified under a specific pharmaceutical requirement. Related to the practical experience performed, 15 queries only 14 responses were found acceptable: a result of 6.7% not acceptable is a sinificative percentage. This is because the safety and efficacy of the galenic product must follow strictly normative rules for the health needs of the patients. The human verification of the results obtained from a chatbot today is mandatory for a field like galenic activity.

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