

# Lean Management and use of AI in healthcare: living in the present

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## ABSTRACT

This study explores the possible relationship between Lean Management and generative artificial intelligence (Generative AI), which are seemingly distant but with common objectives namely to reduce waste and increase efficiency. Our analysis reveals that Generative AI models can support “lean” principles by facilitating just-in-time manufacturing, increasing flexibility, promoting waste reduction, and rapid prototyping. However, solutions are needed for the technological challenges and the quality of the content generated. Effective implementation requires a focus on optimizing operations and automating data analysis, as well as aligning goals between stakeholders. The joint use of cross-functional teams can maximize resource utilization and drive informed decisions. Generative AI is therefore a powerful complement to Lean Management in business processes. A focus was then placed on the impact that AI and technological advancement may have in various areas of the pharmaceutical sector. The state of the art was assessed by referring to publications in the literature and by interviewing experts not only with a corporate profile, but also community pharmacists, students, and professionals in the pharmaceutical sector.

## INTRODUCTION

Lean Management, originally developed in Japan under the influence of Toyota’s production management model, represents a corporate philosophy aimed at improving the quality of production, personnel, and the entire supply chain through the adoption of functional decision-making strategies and innovative models. This approach aims to make company management more “lean” with benefits for the company in terms of time and costs. A key concept

in Lean Management is the Japanese word “kaizen”, which conveys continuous improvement and encourages employees and managers to constantly seek more efficient and innovative pathways, with the aim of getting closer to perfection. Lean Management embraces several aspects, including involving employees in identifying and proposing improvements, followed by their implementation in small and continuous steps rather than sudden changes. The focus, therefore, is on the gradual and constant improvement of processes, the elimination of waste in all phases of company

operations, and the involvement of all levels of the company with a view towards continuous improvement.

At the same time, generative artificial intelligence (Generative AI) has attracted growing interest in business applications. This technology allows one to generate content such as text, images, audio, or video on demand, quickly and economically, following customer or user specifications. At first glance, Lean Management and Generative AI may seem like distant concepts, although an interesting potential relationship between the two emerges. Generative AI models can, in fact, support the principles of Lean Management, facilitating just-in-time production, while promoting flexibility in adapting to customer needs, waste reduction, and rapid prototyping. Despite the technological and quality challenges of the content generated, the integration of Generative AI can help streamline workflows and reduce time-to-market, and is proving to be a valuable ally of “lean” principles in multiple business processes.

The effective implementation of Lean Management and Generative AI is based on three key factors:

- optimizing operations and reducing waste in Lean Management,
- automating data analysis,
- organization of information in Generative AI.

Building cross-functional teams with complementary skills and aligning goals between stakeholders are critical to maximizing resource utilization and driving informed decisions.<sup>1</sup> Furthermore, the use of cloud computing offers additional opportunities to optimize production processes. Through services such as Amazon Web Services (AWS), companies can access computing resources on demand, enabling more efficient and scalable management of production, with significant impact on cost optimization and process traceability.<sup>2,3</sup>

In this context, Generative AI emerges as a powerful, complementary tool to Lean Management in production and technological processes, offering new perspectives to improve business efficiency and innovation.

The use of AI, including Lean Management, extends well beyond the corporate context, and has also found

applications in crucial sectors such as clinical trials and drug discovery and design. Traditionally, this process has been characterized by a long and sometimes cumbersome approach, often based on experiment and error. However, in recent years, the introduction of Machine Learning and data analysis techniques has revolutionized these efforts, allowing large quantities of data to be analyzed automatically and significantly accelerating drug design and testing.<sup>4-8</sup>

This progress is of fundamental importance, especially in the introduction of new therapeutic drug classes, where it is essential to evaluate how the molecule designed can interact with specific targets, taking into account multiple variables. AI is able to automate this process and predict, albeit with some uncertainty given the randomness, potential side effects and toxicity. However, it is important to consider that AI can identify patterns and relationships that are not always obvious, including the ability to identify effective therapies for patients with complex diseases.<sup>9</sup>

One of the main challenges in this context is the validity of available sources, which can influence the effectiveness of the algorithms used. Careful selection of sources is therefore essential to obtain optimal and reliable results.<sup>10</sup> Furthermore, the ethical aspect raises important questions. In particular, the following problems are discussed herein: the reliability of AI in the management of human health, including diagnosis and prescription of drugs; the influence of available sources and biases on algorithms, which could compromise the principle of fairness and justice in the treatment of patients; and the migration of sensitive data, since the use of large datasets may raise concerns about privacy<sup>11</sup> and data security. Adequately addressing these ethical challenges is critical to ensure that the adoption of AI in the pharmaceutical field is responsible and respectful of patient rights and safety. In this regard, previous studies have raised these issues and the Italian medicines agency (AIFA) is expressing its opinion on the subject.<sup>12-14</sup>

## **METHODS AND RESULTS**

The present analysis involved experts from different sectors, including information technology (IT) services, medicine, clinical research, pharmacies, and scientific



**Fig. 1. Interviewed individuals**

drug information. People with practical experience in the pharmaceutical sector, such as pharmacists and employees of pharmaceutical companies, were also consulted (**Fig. 1**). Interviews were conducted via online meetings and a total of 31 interviews were conducted, which included:

- 6 experts in IT services,
- 2 medical experts,
- 2 professors for in-depth clinical research,
- 10 students in Pharmacy school,
- 3 pharmacists,
- A medical scientific representative,
- A corporate team of about 7 people.

The interdisciplinary discussions allowed for comprehensive evaluation of the implications and challenges related to the integration between Lean Management and Generative AI, and allowed for identification of common themes and key questions for in-depth reflection.

#### *Clinical research*

AI is revolutionizing the process of designing and discovering new drugs, making it possible to significantly accelerate the research and optimization of candidate molecules. Thanks to advanced algorithms, large amounts of data can be analyzed to identify molecular structures that are optimized considering several pharmaceutical, pharmacokinetic, and pharmacodynamic aspects, which has brought about significant progress in medicinal chemistry and pharmaceutical technology.<sup>1</sup> However, the

application of AI in pharmacology and toxicology presents unique challenges, especially regarding the preclinical and clinical experimental phases. Although AI can help predict the interaction with specific targets and suggest optimal therapies, it is still necessary to carefully evaluate its impact in clinical trials, considering the complexity of the variables involved while ensuring patient safety. The regulation of the use of AI in the clinical field represents another critical issue, which involves regulatory authorities such as AIFA.<sup>12</sup> It is essential to establish clear guidelines for the validation of algorithms, reliability of datasets, and transparency in decision-making processes.<sup>10</sup> Furthermore, protecting patient privacy and standardizing processes are crucial aspects to ensure the safety and effectiveness of AI in a clinical setting.

The current use of AI in scientific research carries some risks, including the limited ability to consider a large number of variables in decision-making processes. This problem is not unique to AI but is also present in the work of human researchers. However, the evolution towards more complex systems can reduce this risk, allowing a larger amount of data to be processed and interpreted more accurately. A tangible risk is the proliferation of incorrect data, which could compromise the effectiveness of AI algorithms. It is essential to ensure the quality and reliability of the data used to train and operate the algorithms, in order to avoid biases in the results and evaluation of patterns.<sup>10</sup> Going forward, it will be essential to address these challenges through continued research and development of advanced methodologies for data management and analysis, as

well as in the implementation of rigorous quality control processes. These measures will maximize the benefits of AI in scientific research, while reducing the risks associated with its use.

### *Pharmacies*

At present, the use of AI and Machine Learning is limited in pharmacies, but some rudimentary applications are already in place. For example, AI-based management systems are able to analyze daily and monthly income/expenses and offer suggestions on specific purchases. However, there is a significant difference between traditional AI and Generative AI. The latter could revolutionize pharmacy management, offering more rational purchasing advice based on multiple variables in addition to accounting.

Generative AI could also solve the problem of “missing” drugs, by identifying patterns that are not immediately obvious and provide personalized solutions for each pharmacy. This potential development could pave the way for a “second rebirth” of the pharmacist; the first was generated by the advent of services, streamlining procedures, and improving overall efficiency. Automating processes like booking appointments and managing medications could free up time for more patient-focused tasks.

However, the implementation of AI and Machine Learning requires close collaboration with regulatory institutions to ensure that access to medicines remains controlled and that patients receive the necessary care. It is also crucial to consider the ethical and legal issues related to the use of AI in pharmaceutical practice and ensure transparency and accountability in decision-making processes.

Studies conducted on the perception of Pharmacy students<sup>15</sup> highlight a growing interest in AI in the medical-health sector, but also a concern for the lack of preparation to deal with its use in professional practice. There is a clear need for more in-depth training on AI in educational curriculum, along with greater awareness of the ethical and legal implications. The potential of Generative AI in optimizing medical therapies and increasing patient safety and adherence may suggest a promising future

for the integration of AI and Machine Learning into pharmaceutical and clinical practice.<sup>16</sup>

Below is the questionnaire (**Table 1**) administered to students and healthcare professionals, with the corresponding percentages of responses:

- Question 1: Is there concern about the lack of trust and/or reluctance towards IT systems and professional figures due to possible dehumanization?
- Question 2: Would you be afraid of sharing your data due to possible cyber-attacks?
- Question 3: Are you aware of the possibility of creating systems that are capable of encrypting data?
- Question 4: Can automation be a starting point for the sector you are involved in?
- Question 5: Does the use of Generative AI carry a risk?
- Question 6: Do you know what Generative AI is?
- Question 7: Would you trust sharing your personal data to create more efficient analytic systems?

**Table 1. Percentages of responses to the questionnaire administered**

	Yes (%)	No (%)
Question 1	60.00	40.00
Question 2	60.00	40.00
Question 3	100.00	
Question 4	100.00	
Question 5	40.00	60.00
Question 6	33.30	66.70
Question 7	46.70	53.30

### *Pharmaceutical drug representatives*

The integration of Generative AI into drug information offers opportunities to improve the analysis and translation of scientific articles and facilitate more efficient and global communication in the pharmaceutical industry. AI can analyze large amounts of data to identify emerging trends and evidence in the vast scientific literature. Furthermore, it can be used to translate scientific articles from one language to another quickly and efficiently, enabling smooth communication between researchers from different parts of the world.

### *Companies and supply chains*

In today's business environment, optimization of the supply chain has become a crucial goal to improve the efficiency and effectiveness of operations, especially in the pharmaceutical industry. The introduction of innovative technologies, such as AI and blockchain, offers unprecedented opportunities to reduce delivery times, improve the quality of service, and reduce waste.

Data analytics is a key element of supply chain optimization, allowing one to identify trends, forecast demand, and improve planning of resources. Leading companies have already implemented intelligent systems in their production lines, which monitor production in real time and timely identify any deviation from normal parameters. Using models such as "Residence Time Distribution" allows for quick identification of defective products and eliminate them from the production line, reducing waste to a minimum.

Furthermore, robotic process automation (RPA)<sup>17</sup> is revolutionizing the way companies manage their daily activities. In the field of pharmaceutical production, the introduction of automated robots that are capable of adapting to the different needs of the production process is making the entire production chain more efficient, thereby reducing delivery times and improving the quality of the final product.

The integration of blockchain technology offers transparency and traceability across the entire supply chain, enabling responsible sourcing practices and fair trade. Furthermore, using AI to optimize resource allocation and reduce waste can contribute to more sustainable resource management and reduced environmental impact.<sup>18-20</sup>

### *Hospitals and healthcare systems*

Data integration in healthcare has revolutionized operational efficiency and the quality of care provided to patients. Through advanced data management and analysis systems (e.g. Palantir Foundry),<sup>21,22</sup> healthcare organizations have been able to more efficiently organize clinical information, accelerate decision-making processes, and improve access to medical services.<sup>23</sup>

These systems enable centralization of patient data, waiting lists, and medical resources, and facilitate sharing of information between healthcare providers and ensure better coordination of care. Furthermore, advanced data analysis has identified significant trends and patterns, allowing healthcare organizations to anticipate patient needs and adopt preventative interventions.<sup>24-26</sup>

During the COVID-19 pandemic, the use of data management systems<sup>27</sup> played a crucial role in managing the supply chain of vaccines and personal protective equipment, enabling rapid and efficient distribution of needed resources.

Furthermore, data integration has significantly improved healthcare research and development, accelerating drug discovery processes and facilitating clinical trials. Thanks to centralized access to real-world evidence (RWE), researchers have been able to conduct more sophisticated analyses on the effectiveness of therapies and support the planning of randomized clinical trials.<sup>1</sup>

## **DISCUSSION**

From the analysis conducted, it is evident that AI and cloud computing in the healthcare sector can have a significant impact on existing professions by guaranteeing privacy, with improvements in productivity and secure data management, without however completely replacing human figures. We suggest the creation of a platform common to different geographic regions that is accessible to all healthcare facilities, which will improve collaboration and efficiency in patient management.

### *Privacy*

The issue of privacy was deemed crucial, with an emphasis on the transparency of platforms and the protection of sensitive data. The use of advanced encryption techniques and the organization of data via the cloud have been suggested to be effective measures to ensure data security and accessibility, while reducing the risk of leaking sensitive information.

We have recently witnessed the introduction of innovative systems for data analysis based on the emerging architectural principles of “DataMesh”. These systems offer a new approach to organize data according to specific business domains, and facilitate more targeted and efficient analyses. DataMesh acts as an online cloud platform where suppliers and manufacturers make software products available that contain “depersonalized” and anonymous data, divided into specific categories. These data packages are accessible to any facility that needs to analyze a particular set of information, ranging from data on endemic disease to financial data.

“Clean Rooms” or fully automated environments that allow organizations and their partners to collaborate securely on their collective datasets, without having to directly share or copy the underlying data, are particularly interesting. A Clean Room can perform analyses on data made available by manufacturers, without giving direct access to the original data. For example, a pharmaceutical company can request an analysis of a drug’s effectiveness using hospital datasets without directly accessing patient data.

The implementation of systems such as DataMesh and Clean Rooms is crucial to preserve data privacy through anonymization and controlled access. These tools allow organizations to analyze data without compromising the confidentiality of information, opening up new perspectives in data analysis and collaboration between different organizations.<sup>28,29</sup>

It should be remembered that regulations have already been put in place at both the European and national levels to protect patient data. Every medical intervention, clinical trial, or other activity requires the informed consent of the patient, who authorizes any data profiling for research or business purposes. However, this data is protected, and patients remain anonymous. The use of AI and Machine Learning in data analysis does not raise particular privacy issues, since they are based on the processing of already anonymized data. Transparency is another fundamental aspect, and we must work to clearly communicate the sources of the data used, the

processes used for data preparation and processing, and any limitations or problems. This ensures that patients are informed about the use of their data and can fully understand the implications.

#### *Comparing sectors - risks*

The widespread adoption of AI systems in healthcare and the pharmaceutical industry has the potential to revolutionize business processes, improve patient care, and accelerate innovation. However, it is essential to carefully consider the risks associated with this transition. A distinction between different professions reveals contrasting perspectives regarding the risks and benefits of implementing AI.

In the business context, the implementation of AI systems for data analysis and quality control could further improve production processes and the quality and efficiency of the final product. However, the implications of human-machine collaboration need to be carefully considered to ensure a smooth transition.

In the hospital sector, the adoption of AI can help improve the management of healthcare facilities, as well as patients and staff, and increase the general compliance of patients and speed up processes within facilities. However, it is essential to maintain a close human-machine collaboration to maximize the benefits and mitigate the risks associated with AI.

In medical research, the use of AI can significantly improve the patient-physician relationship and accelerate the process of scientific discovery. However, there are risks related to the evaluation of patterns and the proliferation of incorrect data, which could compromise the efficiency of the algorithms used.

As far as the pharmaceutical sector is concerned, AI could revolutionize economic management, but replacing pharmacists would be complex, given the importance of human relationships in patient consultation. Therefore, it is essential to balance technological innovation with the preservation of fundamental human values in the pharmaceutical sector.

### *Comparing sectors - future prospects*

In the near future, the generation of representative virtual patient models could revolutionize clinical trials, offering a more efficient and safer approach to evaluation of drug safety. However, addressing regulatory challenges and ensuring responsible adoption of intelligent systems require coordinated action between research and legislation. One promising strategy is to integrate intelligent systems in the early stages of research alongside existing standards rather than replacing them. This approach can not only demonstrate the safety of systems, but also accelerate scientific and legislative progress. Similar to the implementation of intelligent systems in corporate quality control, where the gradual introduction of new technologies has improved efficiency without compromising standards, scientific research must take a similar approach. The use of AI and Machine Learning requires an openness towards a more collaborative and accessible research model. Promoting more ergonomic data management can reduce analytical errors and maximize the value of data used to make decisions.<sup>11,14,30</sup>

Regarding the integration of AI in pharmacies, there are several obstacles to address. First, comprehensive training regarding the potential of AI is required, which requires investments in terms of time and resources. Furthermore, to ensure effective adoption, it is essential to involve the entire pharmaceutical system, from government regulations to wholesale structures and software management. The lack of knowledge represents a further problem, resulting from the novelty of AI systems in this context. One strategy to address this challenge could be to integrate training on the basics of AI into the curricula of future professionals in the sector.

While implementation of AI in some areas, such as management of diagnostic tests and appointments, can proceed without legislative complications, other areas, such as electronic health records and prescription management, require thorough legislative review. This is essential to ensure patient safety and compliance with current regulations. Furthermore, it must be remembered that the patients' search for human contact could represent an obstacle to the

adoption of AI in pharmacies. It is important to consider how to adequately integrate the human element into new systems to ensure an effective and acceptable transition for all the players involved.

In addition to optimizing data analytics, the use of AI can lead to tangible economic benefits. Automating complex analysis processes can reduce time and associated costs. Furthermore, AI in scientific drug information can positively influence market choices. Thanks to its ability to analyze data from different sources and monitor industry trends in real time, it can provide strategic information to pharmaceutical companies. This can help companies identify market opportunities, adapt their marketing strategies, and make more informed business decisions. Therefore, the use of AI in scientific drug information offers significant advantages on multiple fronts. This approach can generate a positive economic impact by reducing costs and optimizing decision-making processes, while at the same time it can improve market choices by providing companies with strategic and timely information. In this sector, the ability to quickly assess the impact of disruptions in the supply chain and adopt reallocation strategies thanks to AI provides a real-time end-to-end view of operations, allowing companies to quickly understand the situation and make informed decisions.<sup>30,31</sup>

### *Reluctance towards innovation*

The ambivalence towards technological progress, which is common in society, is also reflected in the pharmaceutical sector. While modern medicine has produced exceptional results, the world of medications can be dark and intimidating for many. Elderly people may feel especially overwhelmed by new pharmaceutical technologies and practices, often preferring to rely on the pharmacist for guidance and advice. However, as generations evolve and there is greater exposure to technology, this perception is likely to change. Continuous education and transparent communication can play a key role in fostering greater understanding and acceptance of pharmaceutical innovations. Pharmacists, in particular, can play a vital role in providing clear information and support to patients in

adopting new technologies. Ultimately, while the idea of embracing technological progress may raise uncertainty, it is possible to overcome these barriers through education and an open approach to change. Over time, greater integration of technology into the pharmaceutical industry can be expected, with consequent improvements in the quality of healthcare and contribute to the overall well-being of society.

*Is it possible to replace healthcare providers?*

The advent of AI has raised concerns about the possibility to render many professions obsolete. However, it is crucial to recognize that, despite technological advances, there are areas where collaboration between humans and machines remains crucial, especially for ethics, effectiveness, and safety. While AI can handle repetitive and analytical tasks more efficiently than humans in many sectors, there are still areas where human intervention is indispensable. For example, in the pharmaceutical industry, personalized advice and understanding patients' individual needs still require the human touch.

From an ethical perspective, the use of AI raises important questions regarding responsibility and moral decision-making. While intelligent systems can be programmed to follow certain ethical principles, it is essential that there is human oversight to evaluate the ethical implications of decisions made by AI and to intervene when necessary. While it is possible that increasingly sophisticated technologies will make some human-machine collaborations obsolete in the future, this does not mean that the professions involved

will disappear. Rather, they must adapt and innovate to remain relevant. For example, pharmacists could focus on personalized counseling, patient education, and additional services that go beyond simply dispensing medications. Professions must be ready to be reinvented and adapt to technological changes, leveraging unique skills and finding new ways to add value in an increasingly automated world.

## CONCLUSIONS

The process of adapting to the present and the digital transition is an imperative that involves multiple sectors, from healthcare to pharmacy, from legislation to academic training. Although the Italian panorama may show resistance and delays in the modernization of practices and systems, it is clear that innovation is essential to improve the efficiency, quality, and accessibility of the services offered. The complexity of healthcare management and legislative processes requires a revolution that involves all the players involved, with a particular emphasis on the importance of professional training and constant updates. In this context, the pharmacy emerges as a crucial point of contact between professionals and patients, where automation can lead to a second life of the profession, strengthening the bond between the pharmacist and patient. However, addressing this transformation will require a joint commitment from regulatory institutions, companies, and academic institutions to ensure that the professionals of the future are adequately prepared to face the challenges and exploit the opportunities offered by recent technological advancements.



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