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Smart Dosage Optimization using Machine Learning and Biomedical Engineering for Personalized Drug Therapy: A Review

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ABSTRACT:

Background: Personalized medicine is revolutionizing modern medicine by customizing medicine for the individual patient based on their genetic, physiological and clinical profile. The problem of choosing the right dose, i.e., the maximum benefit versus minimum toxicity, is still one of the most important in clinical pharmacology, and conventional "population based" dosing recommendations for drugs do not account for significant inter-patient variability.

Objective: This review investigates the architectures, algorithms, clinical application and open challenges of the field and proposes ways to integrate this with machine learning (ML) to facilitate intelligent, patient specific dosage optimization.

Methods: The literature was systematically reviewed to highlight the effects and recent developments of ML-driven dosing and the enabling of biomedical-sensing technologies, categorizing the evidence based on the system architecture, algorithmic paradigms, biomedical-engineering enablers and comparative clinical outcomes.

Findings: In the studies reviewed, several electronic health record-based, genomic-based, laboratory-based, and continuous physiological signal-based ML dosing systems have been found to outperform traditional dosing systems in terms of dosing accuracy, reduction of drug-related toxicity, and increased patient adherence. Supervised models can be used to guide interpretable pharmacokinetic/pharmacodynamic predictions, deep learning can extract high dimensional, time-series physiological data, and reinforcement learning can provide closed-loop dosing for chronic and evolving disease states. These systems rely on wearable biosensors, smart drug delivery devices and Internet of Medical Things (IoMT) platforms to provide the real-time data streams.

Conclusion: The combination of ML and real time biomedical monitoring provides a viable avenue to safer, more effective and more individual drug therapy. To make this happen at scale, work needs to be done on data heterogeneity, model interpretability, clinical validation, regulatory acceptance, and on the performance of the models in different patient cohorts.

1. INTRODUCTION

Precision medicine is a new paradigm in health care that aims to tailor treatment to the individual variability of people's genetic makeup, environmental exposure, physiological traits, and lifestyles. Precision medicine aims to optimize the benefits of medicine by taking into account the individual biological and clinical profile of the patient, as compared to traditional treatment with doses based on dosage recommendations from population-based trials. However, the traditional dosing methods often do not account for patient to patient variability, potentially leading to under- or over-therapeutic doses, drug toxicity or adverse drug reactions. There is clinical evidence that the response a patient has to a given drug is determined by a combination of factors including pharmacogenomic variation, age, organ function, metabolism, severity of the disease and comorbidities [1].

This has led to the use of ML in recent years as a promising approach to overcome these challenges in biomedical engineering technologies. High-dimensional health data can be leveraged by ML to uncover new patterns that are hidden in the data and are correlated with drug response and pharmacokinetic behavior. Alongside, developments in the field of biomedical engineering make it possible to measure physiological and biochemical parameters continuously at real-time using wearable biosensors, smart monitoring devices and Internet of Medical Things (IoMT) platforms. These technologies can work in concert to enable intelligent clinical decision support systems that can predict the best dose of a single drug for each patient.

Smart dosage optimization systems use massive amounts of biomedical data including electronic health records, genomic information, clinical lab data and real-time physiological data to make personalized dosing recommendations. These systems can dynamically adapt treatment plans based on predictive analytics and adaptive learning as patients' conditions change, thereby fine-tuning treatment, minimizing drug side effects, and ensuring patient safety [2].

The paper summarizes recent developments at the intersection of machine learning (ML) models and biomedical sensing and monitoring devices, and discusses the design of intelligent systems for personalized drug therapy. Specifically, it addresses the following research questions:

RQ1: What system architectures underpin ML-based dosage optimization?

RQ2: What methods do researchers use to ensure that ML models accurately represent real-world conditions?

RQ3: How is the quality and performance of ML-based dosage optimization measured?

RQ4: What are the most appropriate modelling paradigms for different types of data and tasks in dosage optimization?

RQ5: How can real-time adaptive dosing be enabled through biomedical engineering technologies?

RQ6: What are the advantages, challenges, and future research directions associated with ML-based personalized and adaptive dosing?

This work provides a comprehensive collation of architectures, algorithms, and enabling technologies, together with a critical synthesis of the available clinical evidence and the factors that impede the translation of ML-based dosage optimization into clinical practice

2. REVIEW METHODOLOGY

This article is a systematic review of the literature. The literature was searched from peer-reviewed scientific journals and scientific databases, focusing on recent works on the intersections of machine learning, pharmacokinetic/pharmacodynamic (PK/PD) modeling, and biomedical sensing. The search terms that were used included elements of “machine learning,” “deep learning,” “reinforcement learning,” “dose individualization,” “precision dosing,” “pharmacokinetics,” and “clinical decision support,” as well as other terms. Only studies focused on dosage optimization with models, model-informed precision dosing or on the biomedical-sensing infrastructure that supports these models were included, as studies which addressed only non-

clinical or non-dosing aspects were omitted. The evidence is presented narratively and thematically across four dimensions: system architecture, algorithmic paradigms, biomedical-engineering enablers, and comparative clinical outcomes, with the aim of offering a holistic perspective of the field and identifying common themes and areas for exploration.

3. BACKGROUND: PK/PD MODELING AND THE CASE FOR MACHINE LEARNING

Artificial Intelligence (AI) and data-driven healthcare have been driving the growth of research in PK and PD modelling. These are the basic models for drug absorption, distribution, metabolism and elimination and the mechanisms of interactions between drugs and biological systems that lead to therapeutic responses. Traditional PK/PD models are based on mean estimates and are often simplified, and do not necessarily reflect inter-patient variability. Hence, the research in the last few years focused on the application of ML techniques to increase the accuracy of prediction and to enable personalized treatment.

There are many examples of the potential of ML algorithms in the field of pharmacological research and practice. They have been applied to modelling the complex relationship between clinical, genomic, and observed phenotypes, as a means to predicting personal drug responses. In addition to using ML for predicting patient outcomes, it is being utilized in therapeutic drug monitoring to adjust dosages as patient information and treatment results change. The advantage of a dose–response model based on artificial intelligence is that it can effectively capture high-dimensional interactions and nonlinear relationships between patient-specific parameters [4].

As the number of ML-driven clinical decision support systems grows, they are increasingly being used to guide clinicians in determining optimal treatment plans. These systems incorporate medical history, lab test results and physiological data to provide evidence-based dosing recommendations. Another application that is crucial is drug-toxicity prediction, where ML models can predict potential adverse drug interactions before or during treatment, enhancing patient safety and adherence. The real-time health monitoring and data collection has been made possible by the help of biomedical engineering. Continuous monitoring of physiological parameters like heart rate, glucose level, blood pressure, oxygen saturation and others, are possible using wearable biosensors, implantable medical devices, and IoMT platforms. Incorporating these sensing technologies together with AI models leads to more high-resolution patient data, which has a significant impact on the performance and reliability of the predictive dosing systems [1–3, 7]. AI based dosing has been shown to be valuable in various therapeutic areas in recent clinical and computational studies. AI algorithms for chemotherapy dosing have also helped to enhance the personalization of the treatment and minimize toxicity; ML has been used for insulin therapy to optimize dose adjustments based on real-time glucose monitoring, which has also been linked to better glycemic control; and finally, AI drug dosing algorithms for anticoagulants have been shown to reduce the risk of complications, such as bleeding. Overall, this growing body of evidence indicates that intelligent dosing systems may be useful in decreasing ADEs in specific clinical situations, with some studies reporting a relative reduction of as much as 30-40% (which would require further validation in larger, prospective trials). Yet, the use of AI in dosing is still under investigation for clinical use. However, the use of these data remains limited by data heterogeneity, lack of interpretability of the model, regulatory acceptance and clinical validation. Current research is thus focused on powerful, interpretable and clinically-validated ML models appropriate to precision medicine and customized drug therapy.

Table 1: Comparison of machine learning techniques used in dosage optimization.

ML Technique	Key Characteristics	Advantages	Limitations	Typical Clinical Use
Linear Regression	Statistical predictive model for continuous outcomes	Simple, interpretable, low computational cost	Limited ability to capture nonlinear relationships	Pharmacokinetic modeling
Random Forest	Ensemble of multiple decision trees	High accuracy; handles complex datasets	Computationally intensive for large datasets	Toxicity and adverse-drug-reaction prediction
Support Vector Machine (SVM)	Margin-based classifier/regressor	Effective in high-dimensional data	Requires careful parameter tuning	Pharmacogenomic dose prediction

Neural Networks	Multi-layered learning architecture	Captures nonlinear relationships	Requires large datasets	Disease-specific dosage prediction
Deep Learning	Advanced neural-network models	Suited to large-scale biomedical data	High computational requirements	Medical imaging and real-time monitoring
Reinforcement Learning	Feedback-driven decision making	Adaptive treatment optimization	Complex training process	Chronic-disease treatment planning

4. ARCHITECTURE OF MACHINE LEARNING–BASED DOSAGE OPTIMIZATION SYSTEMS

A standard ML based dosage optimization system consists of a multi-layered system that combines heterogeneous biomedical data, powerful analysis and clinical decision support. It aims to convert huge amounts of individual patient data for the benefit of the clinician in order to find the right dosage of a drug for an individual patient. The principle components are outlined below [3].

Table 2: Data sources used in intelligent dosage optimization systems

Data Source	Type of Data	Role in Dosage Prediction	Example Applications
Electronic health records	Clinical history, demographics, prescriptions	Provides baseline patient information	Hospital decision support systems
Genomic data	Genetic mutations, biomarkers	Predicts drug-metabolism variability	Pharmacogenomics-based therapy
Wearable devices	Continuous physiological signals	Real-time monitoring	Diabetes and cardiac disease management
Clinical laboratory data	Blood tests, metabolic markers	Supports pharmacokinetic modeling	Chemotherapy dosage planning
Medical imaging	CT, MRI, diagnostic imaging	Disease-severity analysis	Oncology treatment optimization

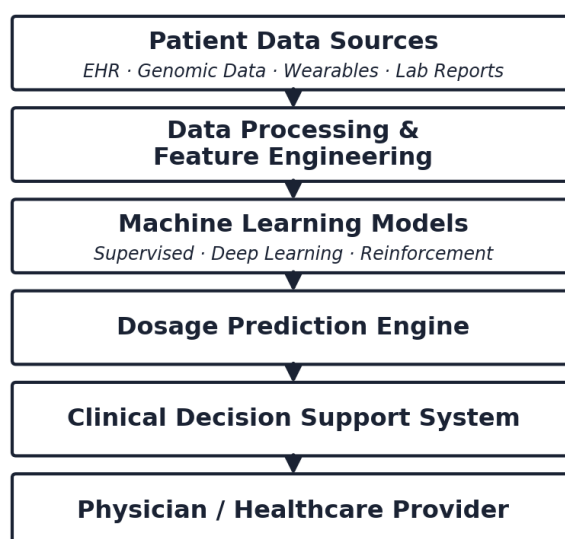


Figure 1: Smart dosage optimization framework.

Figure 1 shows a smart healthcare system where patient information is collected, analysed with ML models to determine the optimal dosage of drugs, and the resulting recommendations are used for clinical decision making and providing personalized and accurate treatment.

4.1 Data Acquisition Layer

The data acquisition layer gathers various, high-dimensional clinical and biomedical data, which will be used to make predictions and enable personalized treatment. Typical sources include:

- Electronic health records (EHRs): Patient demographics, diagnostic history, medication history and treatment outcomes.
- Genomic and pharmacogenomic databases: genetic variation and drug metabolism and therapeutic response.
- Wearable and remote monitoring sensors: continuous vital signs like heart rate, blood glucose, blood pressure and physical activity.
- Biochemical indices, blood tests relevant to pharmacokinetic analysis.
- Medications: previous treatments, allergies, medications, lifestyle.

These are all merged to create a complete patient profile that is needed to calculate patient-specific doses.

4.2 Data Processing and Feature Engineering

After being acquired, biomedical data is pre-processed and transformed to guarantee quality, consistency and relevance for analysis, which is crucial to the success of the model and its prediction accuracy. Important operations involved are missing data handling, noise reduction, clinical variable standardization, clinical variable normalization, physiological signal temporal synchronization and dimensionality reduction through feature extraction. Processed data then becomes clinically relevant information such as drug metabolism markers (liver enzyme activity, etc.), physiological markers, genetic markers that affect the PK/PD, drug–drug interaction markers and markers of disease progression. By designing these features, the strength of the model in representing the complex relationships between patient characteristics and drug-response patterns was enhanced.

4.3 Machine Learning Model Layer

Analytical core of the system is the ML model layer. In this case, historical clinical information is used to train predictive algorithms to learn patterns that correlate with efficacy of treatment and dosage. Common techniques used are:

- Random Forest: useful for high dimensional clinical data, and for the identification of influential predictors.
- Support Vector Machine (SVM): Useful for the classification and regression problems in the context of dose–response prediction.
- Artificial Neural Networks (ANNs): able to model the non-linear relationships between physiological variables and drug effect.
- Deep learning models: Convolutional and Recurrent networks for complex biomedical and time-series data.
- Adaptive dosing strategies: in which treatment policies change based on the patient's response, are better suited to reinforcement learning approaches.

These models can estimate an optimal dose level based on patient-specific inputs and can be used to aid in treatment planning.

4.4 Clinical Decision Support Interface

The final component is providing the clinical actionability of the predicted output through an intelligent clinical decision support system (CDSS) that transforms the predictions from ML into actionable, real-time suggestions for health care professionals. This part is usually used to deliver dashboards for clinicians that allow them to interact with; integration with hospital systems and EHRs; visualization of patient risk profiles and treatment outcomes; real-time dosing recommendations and alerts; and explainable-AI modules that show how the model is making predictions, improving accountability and trust. The interface does so, connecting the world of advanced analytics with the practice of care, and thereby making dosage optimization systems feasible, understandable and in clinical use.

5. MACHINE LEARNING TECHNIQUES FOR DOSAGE OPTIMIZATION

In Precision Medicine, machine learning serves as the backbone for intelligent dosage optimization, allowing for predictive modeling of a drug's response based on the patient's specific attributes, clinical variables, and outcomes, while learning complex relationships between them. Various paradigms of learning such as supervised learning, deep learning and reinforcement learning are utilized to enhance treatment efficacy and dosing accuracy based on the type of data and clinical goal. Figure 2 [4] shows the ML workflow to predict dosage.

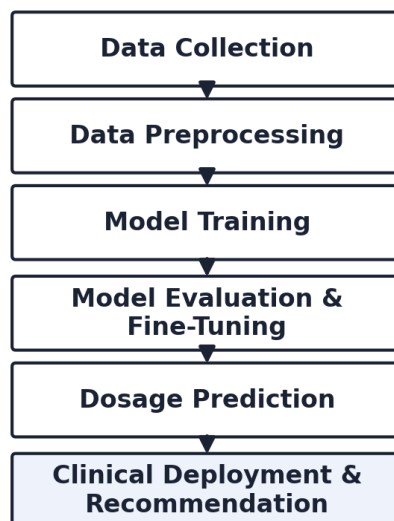


Figure 2: Machine learning workflow for dosage prediction.

Table 3: Performance metrics used in ML-based dosage prediction studies.

Metric	Description	Importance in Clinical Studies
Accuracy	Percentage of correct predictions	Evaluates overall model performance
Precision	Correct positive predictions	Important for drug-toxicity detection
Recall (sensitivity)	Ability to identify true positive cases	Critical in disease-treatment optimization
F1-score	Harmonic mean of precision and recall	Balanced evaluation of models
Mean absolute error (MAE)	Average prediction error	Used in dosage-prediction models
Area under the curve (AUC)	Model discrimination ability	Used in classification problems

5.1 Supervised Learning Models

Supervised learning is one of the most popular methods for dosage prediction and pharmacologic-outcome analysis. They are trained on labelled data sets that match patients' clinical parameters with their observed therapeutic response and, after training on historical data, they can predict optimal doses of the medication for new patients with similar characteristics. A number of supervised approaches have proved to be effective in drug discovery and clinical practice. In pharmacokinetics, linear regression is frequently used to model relationships between physiological parameters, time and the concentration of a drug. Random forests are suitable to incorporate high-dimensional clinical data for toxicity prediction and adverse-drug-reaction detection, and gradient boosting algorithms have been used to model complex interactions among clinical factors to increase the prediction accuracy of individual dosing. Supervised techniques have a major benefit of being easily interpretable and robust, thus enabling integration into clinical decision support systems.

5.2 Deep Learning Approaches

Deep learning's capabilities of learning complex, nonlinear interactions and hierarchical representations from large-scale data has resulted in a great deal of interest in the biomedical data analysis field. With now increasingly available healthcare data that is heterogeneous – such as medical imaging data, genomic data and physiological time series – deep neural networks can be used to optimise drug dosages. Structured biomedical data and medical images that have an impact on treatment are particularly well suited for convolutional neural networks (CNNs), while sequential, time-dependent physiological data collected with wearables and monitoring devices are well suited to recurrent networks, such as long short term memory (LSTM) models. These models have been used in multiple clinical field, such as the chemotherapy dose-optimization models (which trade off efficacy against risk of toxicity); deep learning models that forecast the outcome of antibiotic therapy based on patterns of infection and patient response; and intelligent insulin-dosing systems that analyse continuous glucose-monitoring (CGM) data to make recommendations for insulin doses in diabetes management. In the broadest sense, deep learning can significantly enhance a health system's ability to manage complex cases and patient information—all of which is constantly shifting.

5.3 Reinforcement Learning for Adaptive Dosing

The reinforcement learning (RL) method is a potential solution for adaptive drug-dosage optimization, which is especially suitable for dynamic, long-term drug therapy. In contrast to supervised learning that uses a set of labeled data, the RL models learn optimal treatment strategies by continually interacting with data from patient responses. For RL-based models, the algorithm is an intelligent agent that assesses the efficacy of the treatment, and alters the dose selection based on that evaluation, with the feedback coming as a reward or penalty based on the therapeutic effect, side effects, or clinical stability of the treatment. Over time, a system evolves a dosing policy which is designed to maximize health gains and minimize harm. Chronic diseases, such as diabetes, hypertension, and cancer, require treatment plans that need to change based on the physiological state, in which RL has been shown to be an encouraging therapy for personalized medicine and monitoring long-term therapy.

6. BIOMEDICAL ENGINEERING IN PERSONALIZED DRUG THERAPY

Advanced sensors, smart medical devices, and real-time health-monitoring systems are integral to making intelligent drug-therapy systems a reality, a role that biomedical engineering is playing. These technologies provide the continuous, high-quality data needed for ML models to accurately predict an individual patient's response to a drug and its dose [5]. Incorporating biomedical engineering is shown in Fig. 3.

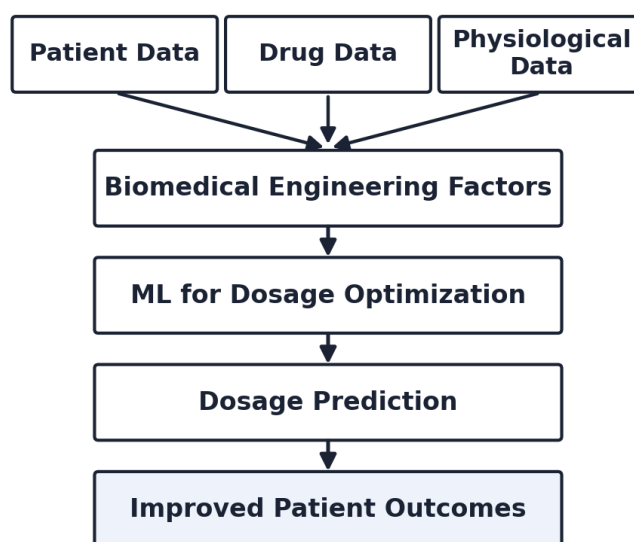


Figure 3: Biomedical engineering integration.

6.1 Wearable Health Monitoring Devices

Wearable medical monitoring devices have completely revolutionised the way patients' data is collected, allowing continual monitoring of physiological parameters outside of the clinic. Smartwatches, biosensors, and portable medical monitors can collect real-time health information, which can be fed into ML-based therapeutic systems. These devices usually measure heart-rate variability, blood-glucose readings, blood pressure, oxygen saturation (SpO₂) and physical activity and sleep. The benefit of the continuous data stream is that it enables ML models to make continual adjustments in dosing recommendations based on a patient's current condition, which is particularly useful for chronic conditions and for those with a high risk of needing adjustment to their treatment.

6.2 Smart Drug Delivery Systems

Biomedical engineering also has made intelligent drug delivery systems that enable targeted therapeutic delivery and controlled release of the drug which increases the precision and efficiency of the drug delivery process. Some examples of representative technologies involve implantable infusion pumps for delivering continuous medication, nanocarrier-based medicine delivery systems for controlled release, and automated insulin-delivery systems for diabetes. Closed loop-therapy models, where the dosage is predicted, and the drug is administered in a closed loop with patient monitoring, will be supported by such systems coupled with ML algorithms.

6.3 Internet of Medical Things (IoMT) Integration

The IoMT is playing an important role in the future of healthcare, creating a new era of inter-connected medical devices, patients, and providers. IoMT platforms provide capabilities for the transmission and analysis of patient data in real-time from wearable sensors, diagnostic devices and hospital systems. IoMT integration enables ML models to have real-time patient data for better predictive accuracy and timely clinical responses, while also supporting remote patient monitoring, telemedicine, and distributed healthcare delivery. This integration of IoMT, ML, and biomedical engineering thus paves the way for intelligent data-driven healthcare ecosystems that can provide highly personalized and efficient drug therapy.

7. COMPARATIVE ANALYSIS OF EXISTING STUDIES

AI-based dosage optimization strategies have been increasingly adopted in healthcare to enhance therapeutic outcomes and minimize risks. With the rapid progress in machine learning and biomedical engineering, the field of dosage optimization has seen significant innovation, particularly in the context of medical treatment and the prevention of adverse effects.

Table 4: Comparative analysis of machine-learning–based dosage optimization studies [6, 7].

Study	ML Technique	Clinical Application	Key Outcome
AI-based anticoagulant dosing model	Random Forest	Cardiovascular disease management	Reduced risk of bleeding complications
Deep-learning insulin prediction system	Neural Networks	Diabetes management	Improved glucose control and dosing accuracy
Reinforcement-learning chemotherapy optimization	Reinforcement Learning	Cancer therapy	Adaptive, patient-specific dosing strategies
Pharmacogenomic ML prediction model	Support Vector Machine	Precision medicine	Enhanced personalized dose prediction from genetic data
IoMT-integrated intelligent dosing platform	Hybrid ML models	Remote patient monitoring	Real-time dose optimization and improved monitoring

The comparative analysis shows that each type of ML approach is suitable to a specific clinical context, which depends on the nature of the data and the dynamics of treatment. Ensemble methods, such as random forests, could perform well with a heterogeneous clinical dataset, and predicting adverse outcomes. High-dimensional physiological and time-series data are suitable for deep learning models, making them suitable for managing chronic-diseases like diabetes. Reinforcement learning is

a viable approach to adaptive treatment plan in dynamic drug response, such as chemotherapy. Genetic data can be used in pharmacogenomics-based ML models for more precise and personalized dosing, and a combination of ML with IoMT technologies yields hybrid systems for enhanced remote patient monitoring and therapeutic optimization.

AI vs Traditional Systems

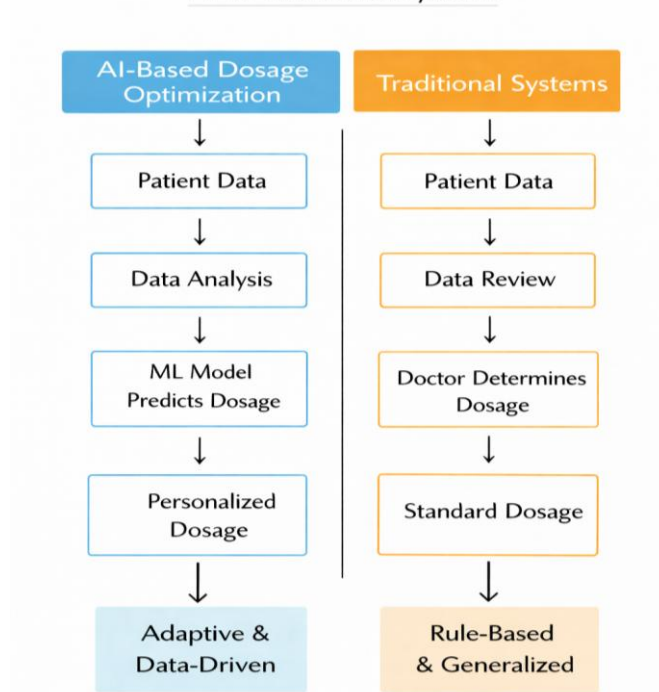


Figure 4: AI-based versus traditional dosage optimization

Table 5: Comparison of traditional and AI-based dosage optimization

Parameter	Traditional Methods	AI-Based Methods
Data usage	Population-based guidelines	Patient-specific large-scale datasets
Accuracy	Moderate	High
Adaptability	Limited	Dynamic and adaptive
Monitoring	Periodic clinical visits	Real-time monitoring
Risk of adverse drug reactions	Higher	Reduced
Decision support	Manual clinical judgment	Automated clinical decision systems

Overall, the literature indicates that combining machine learning with real-time health-monitoring technologies can substantially improve the efficacy, safety, and individualization of drug therapy.

8. BENEFITS OF SMART DOSAGE OPTIMIZATION

Combining machine learning and biomedical engineering for drug-dosage optimization brings a range of significant advantages to modern healthcare systems. Smart dosing systems use predictive analytics and vast amounts of patient information to guide clinicians in making more precise and personalized treatment decisions [8].

One of the major benefits is that treatments will work better. By analyzing patient data, ML algorithms can uncover patterns that are not observable in clinical analysis and thus enable more effective therapeutic interventions, with optimization of the dose based on the specific characteristics of the patient and improvements in the clinical result. The second advantage is the

decrease in negative effects from drugs: standard prescriptions might not take individual variability into account, leading to drug toxicity or under-response, whereas AI-driven systems can foresee potential drug feedback and adjust doses to enhance patient safety.

Intelligent dosing structures also help to support patient individualization. The broader aim of precision medicine and patient-centred care can be achieved by the use of ML models for recommending individual patient treatment options based on their health history, physiological-monitoring data and genomic information. Further, these systems can aid in the speeding up and streamlining of clinical decision making: predictive modelling and automatic analysis of data allow clinicians to interpret complex patient information more quickly, and to respond more rapidly to shifting circumstances.

Another benefit of continuous monitoring and adaptive therapy is the use of biomedical engineering technologies like wearable sensors and IoMT devices that enable real-time data capture and treatment adjustments. This is particularly useful for chronic conditions and chronic treatments. As a whole, AI-powered optimization models for dosage have shown to be effective for improving patient outcomes, optimizing treatments, and utilizing hospital resources, and will likely become increasingly important in the future of personalized and data-driven healthcare.

9. CHALLENGES AND LIMITATIONS

While ML-based dosage optimization systems have demonstrated promising results in personalized drug therapy, there are several technical, clinical and regulatory hurdles that stand in the way of incorporating these systems into everyday healthcare [4]. One of the major concerns is data privacy and security. Secure data sharing, which meets healthcare regulations and privacy requirements, is a critical problem in smart dosing systems, and the use of large amounts of sensitive patient data (clinical records, genomic data, and real-time physiological measurements) is a constant challenge. Another challenge is the lack of standardized, high-quality medical datasets: Healthcare data are often siloed in different hospital systems, medical devices, and EHRs, and inconsistencies in data formats, missing information, and quality can negatively impact model performance and generalizability. There is also a major challenge regarding the clinical validation and reliability. The effectiveness of the dosing models developed and trained in controlled clinical studies may differ based on patient populations, treatment regimens, and healthcare infrastructure in other specific clinical contexts, so broad clinical trials and validation studies will be required for widespread hospital adoption. Regulatory approval and compliance are another challenge: AI-powered medical technologies need to adhere to strict regulations and standards for safety, transparency, and accountability, and getting approval often involves extensive testing, documentation, and explainability of algorithmic decisions. Other concerns are model bias and model fairness. Biases in training datasets can lead to models that generate incorrect or biased predictions for specific patient populations, posing ethical and clinical concerns and requiring responsible practices in the development of AI. Lastly, integration with current hospital systems might be tough as many establishments are still working with legacy systems that could not easily integrate other AI-based tools; seamless integration with EHRs, clinical workflows and hospital information management systems is essential for success. Solving these problems will be pivotal for the widespread clinical implementation of intelligent dosage optimization systems in the future of healthcare.

Table 6.: Research gaps identified in existing studies

Research Area	Current Limitation	Future Research Direction
Clinical data integration	Fragmented healthcare data systems	Unified healthcare data platforms
Model interpretability	Black-box AI models	Explainable AI in healthcare
Real-time deployment	Limited real-world implementation	Integration with hospital infrastructure
Regulatory approval	Lack of standardized evaluation protocols	Policy development for AI in medicine
Data privacy	Patient-data security concerns	Federated learning and secure AI models

10. FUTURE RESEARCH DIRECTIONS

The future of this smart dosage optimization research is likely to be on creating more robust, transparent, and clinically viable AI-assisted healthcare systems. Personalized drug-therapy systems will be influenced by several emerging technologies and research areas [9]. The envisioned future healthcare ecosystem is described in Figure 5.

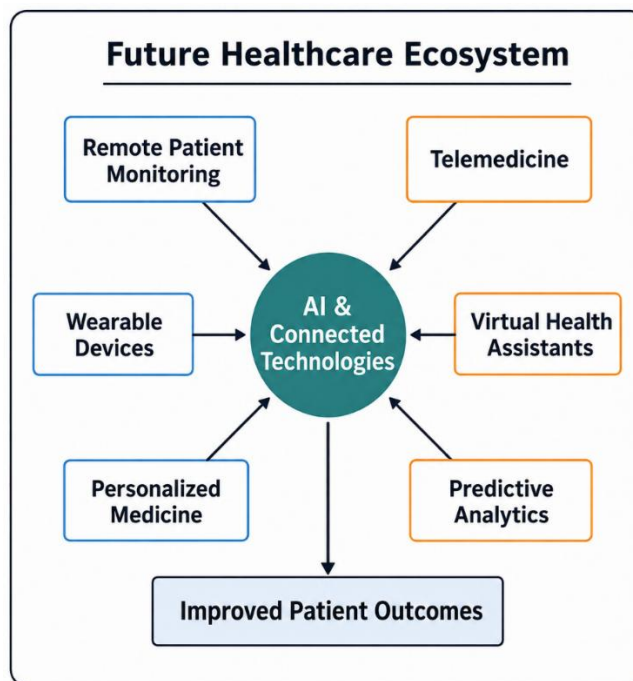


Figure 5: Future healthcare ecosystem.

Personalized drug-response prediction and dose optimization that could be significantly improved by integration—combining genomic, proteomic and metabolomic data with clinical and physiological data—which could substantially improve the precision of personalized drug-response prediction and dose optimization.

Healthcare is another field that is garnering interest for digital twins. They leverage digital-twin models, which simulate individual patients using real-time health data, biological characteristics and medical history to determine how therapy will impact a patient before it is administered, in order to guide the administration of "dose optimization. Aside from that, the research of explainable AI (XAI) for medical decision-making will continue to be vital: explainable models can give clear rationales for dosages, a crucial requirement for the trust of clinicians and regulatory adherence.

Another growing area is the autonomous, closed-loop drug delivery, which includes continuously and actively monitoring the patient, predictive analytics, and drug delivery automation, all of which are combined in fully adaptive drug delivery platforms to adapt treatment on the fly. All together, these developments can improve the reliability, scalability and acceptability of personalized-medicine systems based on AI.

11. LIMITATIONS OF THIS REVIEW

This is not a systematic review, nor is it a protocol-driven review because it is a narrative. There is no protocol, no screening, and no quantitative meta-analysis; the synthesized evidence comes from a purposive sample of recent literature. The reported performance improvements come from various study designs, participants, and outcomes, making direct comparisons and generalizations difficult. The reader is reminded of these limitations when interpreting the comparative results presented here, and provides a motivation for future systematic reviews reporting outcomes in a standard manner.

12. CONCLUSION

Biomedical engineering and machine learning enable smart dosage optimization to contribute to personalized medicine. Intelligent dosing systems that integrate the use of large-scale healthcare information, predictive analytics and advanced

biomedical sensing can provide patient-specific treatment recommendations, thereby improving therapeutic results and mitigating potential side effects from drug administration.

By combining ML algorithms with wearable health monitoring devices, smart drug delivery systems, and IoMT platforms, healthcare providers can now continuously monitor patients and tailor treatment plans to their specific needs, leading to more effective data-driven clinical decision-making and further progress in precision medicine and personalized care.

Despite significant advances, however, there are still remaining issues that need to be addressed to allow for the widespread adoption of these systems in clinical practice: data privacy, non-standardized datasets, clinical validation and regulatory barriers. These challenges will be met through further research into federated learning, multi-omics integration, digital twins, and explainable AI. Overall, the combination of machine learning, biomedical engineering, and intelligent healthcare systems has a great potential to revolutionize drug therapy and enhance patient outcomes. Future healthcare generation will be smart, and the potential to harness the benefits of such smart dosage optimization will lie in sustained interdisciplinary collaboration between clinicians, engineers and policymakers.

DECLARATIONS

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CONFLICT OF INTEREST: The authors declare that they have no competing interests.

DATA AVAILABILITY: All data supporting the findings of this study are included within the article.

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