



Pharmacokinetic–Pharmacodynamic Modeling of Personalized Medicine Approaches: Integrating AI-Driven Dose Optimization in Chronic Disease Management

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Abstract

The therapeutic management of chronic diseases—including diabetes, cardiovascular disorders, oncology, and autoimmune conditions—remains constrained by conventional fixed-dosing regimens that fail to account for substantial interindividual pharmacokinetic and pharmacodynamic variability. Pharmacometric modeling provides a quantitative framework for characterizing drug exposure–response relationships and optimizing individualized therapy. The integration of artificial intelligence with pharmacokinetic–pharmacodynamic modeling represents a transformative paradigm shift toward model-informed precision dosing. This review examines the mechanistic foundations of pharmacokinetic–pharmacodynamic modeling, including compartmental analysis, population approaches, Emax models, and indirect response models, as foundations for personalized dose individualization. Artificial intelligence-driven strategies—encompassing supervised learning algorithms, neural networks, reinforcement learning, and hybrid mechanistic-machine learning architectures—enhance predictive accuracy by capturing nonlinear relationships and processing multimodal patient data. Bayesian forecasting frameworks augmented with machine learning enable adaptive dosing algorithms that incorporate therapeutic drug monitoring data in real time. Clinical applications across chronic disease domains demonstrate improved outcomes: insulin optimization in diabetes through glucose–insulin dynamic modeling, anticoagulant dose individualization in cardiovascular disease, and targeted therapy optimization in oncology and autoimmune disorders where narrow therapeutic indices demand precise exposure control. Comparative evaluation reveals that artificial intelligence-augmented approaches achieve superior predictive accuracy and safety outcomes compared to traditional methods, though challenges including data heterogeneity, model validation requirements, and regulatory acceptance persist. Future directions include hybrid mechanistic-artificial intelligence architectures that preserve physiological interpretability while leveraging data-driven flexibility, real-time clinical decision support system integration, and personalized digital twin platforms. The convergence of pharmacometrics and artificial intelligence holds substantial promise for transitioning chronic disease management from empirical dosing to precision pharmacotherapy.

Keywords: PK–PD modeling; artificial intelligence; precision dosing; chronic disease; pharmacometrics; machine learning

1. Introduction

Chronic diseases represent the predominant global health burden, accounting for approximately 71% of annual mortality worldwide. Diabetes mellitus affects over 500 million individuals, cardiovascular diseases remain the leading cause of death, cancer incidence continues to rise, and autoimmune disorders impose lifelong morbidity on millions of patients ^[1]. These conditions typically require long-term pharmacotherapy, often with medications characterized by narrow therapeutic indices, significant interindividual pharmacokinetic (PK) variability, and complex exposure–response relationships.

Conventional fixed-dose regimens, derived from population-average clinical trial data, inadequately address the substantial heterogeneity in drug disposition and response among patients. Genetic polymorphisms in drug-metabolizing enzymes and transporters, variability in organ function, drug–drug interactions, and disease-related pathophysiological changes contribute to

Unpredictable drug exposure that may result in therapeutic failure or toxicity [2]. The limitations of one-size-fits-all dosing are particularly evident for drugs with narrow therapeutic windows, including anticoagulants, immunosuppressants, and chemotherapeutic agents.

Pharmacokinetic–pharmacodynamic (PK–PD) modeling provides a quantitative framework for characterizing the time course of drug concentration and the relationship between exposure and pharmacological effect. These models enable prediction of individualized dose requirements based on patient characteristics and facilitate rational dose adjustment guided by therapeutic drug monitoring [3]. Population PK–PD approaches quantify interindividual variability and identify covariates that explain observed differences in drug disposition and response.

The emergence of artificial intelligence (AI) and machine learning (ML) in clinical pharmacology has created unprecedented opportunities to enhance PK–PD modeling and dose optimization. AI techniques can process high-dimensional data, capture nonlinear relationships that traditional models may miss, and enable real-time adaptive dosing strategies [4]. The integration of mechanistic PK–PD models with data-driven ML approaches—termed hybrid modeling—leverages the physiological interpretability of pharmacometrics with the flexibility and pattern recognition capabilities of AI.

This review provides a comprehensive examination of PK–PD modeling frameworks and AI-driven dose optimization strategies for personalized medicine in chronic disease management. The mechanistic foundations of PK–PD modeling are presented, followed by analysis of AI methodologies for precision dosing. Clinical applications across major chronic disease domains are evaluated, and future directions for integrating these approaches into routine practice are discussed.

2. Fundamentals of Pharmacokinetic–Pharmacodynamic Modeling

2.1. Pharmacokinetic Modeling

Pharmacokinetic modeling characterizes the time course of drug absorption, distribution, metabolism, and excretion. Compartmental models represent the body as one or more compartments with defined volumes and rate constants for drug transfer between compartments [5]. The one-compartment model with first-order elimination describes drug concentration (C) as $C = (\text{Dose}/V) \times e^{-(kt)}$, where V is volume of distribution and k is elimination rate constant. Multi-compartment models incorporate peripheral compartments to capture distribution phases observed for many drugs.

Non-compartmental analysis provides model-independent estimates of PK parameters including area under the concentration–time curve (AUC), maximum concentration (C_{max}), clearance (CL), and volume of distribution at steady state (V_{ss}). While computationally simpler, non-compartmental methods offer limited mechanistic insight and cannot predict concentrations beyond observed time points [6].

Population pharmacokinetic modeling using nonlinear mixed-effects modeling (NONMEM, Monolix, Phoenix NLME) represents the gold standard for characterizing interindividual variability. These approaches partition total variability into fixed effects (typical population parameters influenced by covariates) and random effects (interindividual

and residual variability) [7]. Covariate analysis identifies patient characteristics—age, body weight, renal function, genetic polymorphisms—that explain variability in PK parameters, enabling dose individualization based on these factors.

2.2. Pharmacodynamic Modeling

Pharmacodynamic models quantify the relationship between drug concentration and pharmacological effect. The E_{max} model, derived from receptor theory, describes effect (E) as

$$E = (E_{\text{max}} \times C) / (EC_{50} + C)$$

where E_{max} is maximum effect and EC₅₀ is concentration producing half-maximal effect [8]. The sigmoidal E_{max} model incorporates a Hill coefficient (γ) to account for steepness of the concentration–response relationship.

Indirect response models, developed by Jusko and colleagues, describe effects mediated through inhibition or stimulation of production or loss of endogenous substances [9]. These models are particularly relevant for biomarkers and physiological responses where drug effect is not directly proportional to concentration but involves turnover processes. Four basic indirect response models account for inhibition of production, inhibition of loss, stimulation of production, and stimulation of loss.

For biologics and drugs with specific molecular targets, target-mediated drug disposition models incorporate binding of drug to its pharmacological target, affecting both disposition and response [10]. These mechanism-based models provide deeper physiological insight and improved extrapolation beyond observed data.

2.3. Integrated PK–PD Frameworks

Integrated PK–PD modeling links the time course of drug concentration to the time course of pharmacological effect, enabling prediction of entire effect profiles following dose administration [11]. Exposure–response relationships characterize how different measures of exposure (AUC, C_{max}, trough concentration) relate to therapeutic outcomes or toxicity. Dose–response modeling integrates PK information to predict effect magnitude for any given dose regimen.

Time-dependent therapeutic windows recognize that optimal concentration ranges may vary during the dosing interval or treatment course. For antibiotics, the ratio of AUC to minimum inhibitory concentration (MIC) predicts efficacy, while for immunosuppressants, trough concentration monitoring guides dose adjustment [12]. Understanding these relationships is essential for designing rational individualized dosing regimens.

3. AI-Driven Dose Optimization Strategies

3.1. Machine Learning in Pharmacometric Modeling

Machine learning techniques have emerged as powerful complements to traditional pharmacometric approaches. Supervised learning algorithms—including random forests, gradient boosting machines, and support vector machines—can predict drug exposure or response from patient characteristics without requiring predefined structural models [13]. These methods excel at capturing nonlinear relationships and interactions among covariates that may be missed in conventional covariate analysis.

Neural networks and deep learning architectures offer enhanced capability for modeling complex PK–PD relationships. Recurrent neural networks and long short-term memory networks are particularly suited for time-series data such as concentration-time profiles ^[4]. Neural ordinary differential equations (NeuralODEs) combine the mechanistic structure of differential equations with neural network flexibility, enabling learning of unknown system dynamics from data ^[14].

Reinforcement learning provides a framework for adaptive dosing optimization, where an algorithm learns optimal dosing policies through interaction with an environment (patient) to maximize cumulative reward (therapeutic outcome) while minimizing penalties (toxicity) ^[15]. This approach is particularly promising for chronic diseases requiring long-term dose titration.

3.2. Model-Informed Precision Dosing (MIPD)

Model-informed precision dosing integrates population PK–PD models with individual patient data to generate personalized dose recommendations. Bayesian forecasting represents the cornerstone of MIPD, combining prior information from population models with individual therapeutic drug monitoring (TDM) measurements to obtain maximum a posteriori (MAP) estimates of individual PK parameters ^[16]. These estimates then inform dose adjustment to achieve target exposure.

Adaptive dosing algorithms continuously update dose recommendations as new patient data become available. The integration of TDM with Bayesian forecasting enables real-time dose individualization that accounts for changes in patient status over time ^[17]. Clinical decision support systems incorporating these algorithms are increasingly embedded within electronic health records to provide point-of-care dosing guidance.

Recent advances have explored hybrid approaches combining ML with Bayesian forecasting. Hughes and Keizer demonstrated that ML models can predict when flattened priors—reducing the influence of population priors during Bayesian estimation—improve predictive performance compared to conventional MAP estimation ^[18]. This hybrid ML/PK approach maintains mechanistic interpretability while leveraging ML's ability to learn from large datasets and extract information from rich feature sets.

3.3. Digital Health and Clinical Decision Support Systems

Integration of AI-driven dose optimization with digital health technologies enables continuous, real-time therapeutic management. Electronic health record integration allows automated extraction of patient data—demographics, laboratory values, concomitant medications—for input into dosing algorithms ^[19]. Predictive analytics identify patients at risk of sub therapeutic exposure or toxicity before adverse outcomes occur.

Automated dose recommendation systems provide clinicians with evidence-based, patient-specific dosing guidance at the point of care. These systems must balance accuracy with interpretability to gain clinical acceptance. Symbolic regression approaches, which generate explicit mathematical expressions relating inputs to dose recommendations, offer transparency while maintaining predictive accuracy comparable to black-box models ^[20].

4. Applications in Chronic Disease Management

4.1. Diabetes and Endocrine Disorders

Diabetes management represents one of the most advanced applications of PK–PD modeling and AI-driven dose optimization. Physiologically-based PK–PD models of glucose–insulin dynamics incorporate multiple interacting systems—insulin secretion, glucose production and utilization, incretin effects, and counter-regulatory hormones ^[21]. These models enable simulation of patient response to various insulin regimens and oral antidiabetic agents.

The artificial pancreas systems for type 1 diabetes integrate continuous glucose monitoring with insulin pump delivery controlled by algorithms that predict future glucose concentrations and adjust insulin infusion rates accordingly. Model predictive control algorithms, grounded in PK–PD models of insulin action, achieve glycemic control superior to conventional therapy ^[22]. Machine learning enhancement of these algorithms enables adaptation to individual patient patterns and improves hypoglycemia prevention.

4.2. Cardiovascular Diseases

Cardiovascular pharmacotherapy includes numerous drugs with narrow therapeutic indices requiring precise dose individualization. Anticoagulants—warfarin, direct oral anticoagulants, heparins—exhibit substantial PK variability and narrow therapeutic windows where underdosing risks thrombosis and overdosing causes bleeding ^[23]. Pharmacogenetic-guided warfarin dosing algorithms incorporating CYP2C9 and VKORC1 genotypes represent early examples of personalized cardiovascular therapy.

Machine learning models for warfarin dose prediction have demonstrated improved accuracy compared to clinical algorithms or pharmacogenetic equations alone. Random forest and neural network approaches incorporating clinical and genetic factors achieve higher percentage of patients reaching target international normalized ratio (INR) ^[24]. For direct oral anticoagulants, population PK models with Bayesian forecasting enable dose adjustment based on renal function and concomitant medications.

Antihypertensive therapy optimization benefits from PK–PD modeling of blood pressure response and AI analysis of ambulatory blood pressure monitoring data. Reinforcement learning approaches can identify optimal combination therapy and dosing schedules that account for circadian blood pressure patterns and individual patient response profiles.

4.3. Oncology and Autoimmune Disorders

Oncology pharmacotherapy presents unique challenges for dose individualization due to the narrow therapeutic index of cytotoxic agents and the increasing complexity of targeted therapies and immunomodulators. Chemotherapeutic agents such as busulfan, methotrexate, and fluorouracil exhibit substantial PK variability, and TDM-guided dosing improves outcomes while reducing toxicity ^[25].

Population PK models for targeted anticancer agents—tyrosine kinase inhibitors, monoclonal antibodies—enable characterization of exposure–response relationships and identification of optimal dose based on individual patient characteristics. Model-informed dose individualization for imatinib in chronic myeloid leukemia has demonstrated improved molecular response rates compared to fixed dosing ^[26].

Autoimmune diseases—rheumatoid arthritis, inflammatory bowel disease, psoriasis—increasingly employ biologic agents with complex PK and immunogenicity concerns. Pharmacometric modeling of biologic disposition, including target-mediated drug disposition and anti-drug antibody effects, enables prediction of individual response and optimization of dosing regimens [27]. AI-enhanced models integrating clinical biomarkers and genetic factors improve prediction of therapeutic response and guide treatment selection.

Immunosuppressant therapy in transplantation and autoimmune disorders exemplifies the critical need for precision dosing. Tacrolimus, mycophenolate, and cyclosporine exhibit narrow therapeutic indices and extensive PK variability. Population PK models with Bayesian forecasting guide dose adjustment based on TDM, improving graft survival and reducing toxicity [28]. Machine learning approaches, including symbolic regression for mycophenolic acid dosing, have demonstrated clinically acceptable accuracy while providing transparent, interpretable decision logic applicable in resource-limited settings [20].

5. Comparative Evaluation of Traditional vs AI-Augmented PK–PD Approaches

5.1. Predictive Accuracy

AI-augmented approaches consistently demonstrate improved predictive accuracy compared to traditional methods alone. Neural networks and gradient boosting machines achieve lower prediction errors for drug exposure metrics (AUC, C_{min}, C_{max}) when validated against external datasets [13]. Hybrid ML/PK approaches combining mechanistic models with machine learning outperform either approach individually, leveraging the strengths of both paradigms [18].

5.2. Clinical Outcomes

The ultimate measure of any dosing strategy is improvement in clinical outcomes. Studies comparing AI-guided dosing to conventional care demonstrate reduced time to therapeutic target, decreased incidence of toxicity, and improved efficacy endpoints [19]. In antibiotic therapy, AI-optimized dosing increases target attainment rates from 30–43% with standard dosing to 70–80% with model-informed precision dosing [12].

5.3. Safety Improvement

Adverse drug reactions represent a major cause of morbidity and healthcare utilization. AI-driven dose optimization reduces toxicity by maintaining drug exposure within therapeutic windows and identifying patients at risk before toxicity manifests. Machine learning models predicting vancomycin-associated nephrotoxicity achieve superior sensitivity compared to conventional AUC-guided monitoring, identifying cases missed by standard approaches [1].

5.4. Economic Implications

Precision dosing reduces healthcare costs through multiple mechanisms: decreased toxicity requiring intervention, reduced therapeutic failures necessitating additional treatment, shortened hospital stays, and optimized utilization of expensive biologic agents [16]. Economic analyses demonstrate favorable cost-effectiveness ratios for MIPD

implementation, particularly for drugs with narrow therapeutic indices and high toxicity burdens.

6. Challenges and Future Perspectives

6.1. Data Heterogeneity and Quality

AI model performance depends critically on training data quality and representativeness. Heterogeneity in data sources—electronic health records, clinical trials, TDM databases—introduces variability that may limit model generalizability [4]. Standardization of data collection and reporting, combined with rigorous external validation across diverse populations, is essential for developing robust models suitable for widespread clinical implementation.

6.2. Model Validation and Regulatory Acceptance

Regulatory acceptance of AI-driven dosing algorithms requires demonstration of safety, efficacy, and reliability through appropriate validation frameworks. The U.S. Food and Drug Administration and European Medicines Agency have issued guidance on AI/ML in drug development, emphasizing the need for clearly defined intended use, validation on independent datasets, and ongoing performance monitoring [29]. Prospective clinical trials comparing AI-guided dosing to standard care provide the highest level of evidence for regulatory approval and clinical adoption.

6.3. Ethical and Data Privacy Concerns

Implementation of AI-driven dosing raises ethical considerations regarding algorithmic bias, transparency, and patient privacy. Models trained on datasets lacking diversity may perform poorly in underrepresented populations, potentially exacerbating healthcare disparities [15]. Explainable AI approaches—including symbolic regression, feature importance analysis, and model visualization—address transparency concerns by revealing decision logic. Robust data governance frameworks ensuring patient privacy and data security are essential for maintaining trust in AI-enabled healthcare.

6.4. Integration into Routine Clinical Practice

Successful translation of AI-driven dosing from research to clinical practice requires seamless integration into clinical workflows. Clinical decision support systems must present recommendations in intuitive formats, provide clear rationale for suggested doses, and allow clinician override when clinically indicated [19]. User-centered design, involving clinicians in development and testing, improves adoption and sustained use. Integration with electronic health records enables automated data extraction and reduces documentation burden.

6.5. Future Hybrid Mechanistic-AI Models

The future of pharmacometric modeling lies in synergistic integration of mechanistic and data-driven approaches. Hybrid models that embed machine learning components within physiologically-based PK–PD frameworks offer the interpretability and extrapolation capability of mechanistic models with the flexibility and pattern recognition of AI [18]. These architectures can learn unknown system components from data while maintaining structural constraints that ensure physiological plausibility.

Digital twin platforms—computational replicas of individual patients continuously updated with multimodal data—

represent an emerging paradigm for personalized pharmacotherapy^[15]. These virtual patients enable simulation of therapeutic interventions before clinical application, identification of optimal dosing strategies, and prediction of long-term outcomes. Integration of PK–PD models, AI algorithms, and real-time patient monitoring within digital twin frameworks promises to transform chronic disease management from reactive to predictive and personalized.

7. Conclusion

The integration of pharmacokinetic–pharmacodynamic modeling with artificial intelligence-driven dose optimization represents a fundamental advance in personalized medicine for chronic disease management. Mechanistic PK–PD frameworks—compartmental models, population approaches, Emax and indirect response models—provide quantitative understanding of drug exposure–response relationships and sources of interindividual variability. AI methodologies—machine learning, neural networks, reinforcement learning, and hybrid approaches—enhance predictive accuracy, enable real-time adaptation, and extract insights from complex multimodal patient data.

Clinical applications across diabetes, cardiovascular disease, oncology, and autoimmune disorders demonstrate improved therapeutic outcomes, reduced toxicity, and favorable economic impact through AI-augmented precision dosing. While challenges in data quality, model validation, regulatory acceptance, and clinical integration remain, ongoing advances in hybrid mechanistic-AI architectures and digital twin platforms hold promise for addressing these limitations. The convergence of pharmacometrics and artificial intelligence enables transition from empirical, population-based dosing paradigms toward truly individualized pharmacotherapy. As these approaches mature and evidence accumulates, model-informed precision dosing will become standard of care for an expanding range of chronic diseases, improving patient outcomes and advancing the principles of precision medicine.

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