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Model-Informed Precision Dosing (MIPD): The Evolution and Role of Pharmacists in Clinical Practice

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Abstract- ***A new paradigm in personalized medicine called Model-Informed Precision Dosing (MIPD) uses patient-specific data and statistical and mathematical models (pharmacokinetic, pharmacodynamic, population PK/PD, physiologically based PK, and Bayesian forecasting) to optimize drug dosage. By taking into consideration inter-individual differences in drug absorption, distribution, metabolism, excretion, and response, it seeks to optimize effectiveness while minimizing toxicity. With their knowledge of therapeutic drug monitoring, pharmacokinetics, drug therapy, and patient care, pharmacists are in a unique position to take the lead in the development, application, and use of MIPD in clinical settings. The history of MIPD is traced, the roles pharmacists play (and could play) in its implementation are examined, clinical evidence of its benefits is surveyed, important obstacles and enablers are discussed, and future directions for integrating MIPD more widely in healthcare are suggested.***

I. INTRODUCTION

Standardized regimens based on average responses in clinical trials have historically been used for drug do sing in clinical practice. Patient-level variations like age, weight, organ function (parti cularly renal/hepatic), genetic variation, disease sever ity, comorbidities, drug interactions, and intra- and in ter-occasion variability are not sufficiently taken into acc ount by such "one-size-fits-all" dosing.

Many patients consequently receive doses that are eit her too high, running the risk of toxicity, or too low, for therapeutic effect.

A method called Model-Informed Precision Dosing (MIPD) forecasts drug exposure and response by combining mathematical modeling with patient data, allowing for customized dose prescription. Physiologically based pharmacokinetic (PBPK) modeling, Bayesian estimation/feedback, population pharmacokinetic/pharmacodynamic (popPK/PD) modeling, therapeutic drug monitoring (TDM), and, more and more, pharmacogenomics and real-time biomarkers are all components of MIPD.

With training in pharmacokinetics, pharmacodynamics, drug interactions, and patient counseling, pharmacists are experts in medications. They are in a good position to close the gap between patient care and model outputs. In addition to interpreting TDM results, their evolving role involves developing dosing algorithms, taking part in model validation, managing clinical decision support tools, training other clinicians, and directly influencing patient outcomes through customized dosing.

The development of MIPD, evidence of its clinical impact, pharmacists' roles and challenges, and potential future developments are all covered in this review.

II. EVOLUTION AND FOUNDATIONS OF MIPD

2.1 Historical Perspective

- Dose individualization has historically begun with Therapeutic Drug Monitoring (TDM), particularly for medications with limited therapeutic windows (e.g., aminoglycosides, vancomycin, immunosuppressants). It entails determining drug concentrations (typically troughs) and modifying subsequent dosages.
- Population PK models, which use covariates (age, weight, kidney function, etc.) to explain variability, were developed as a result of recent decades' advancements in computing and statistical methodologies. Pharmacometrics now uses tools like Phoenix NLME, Monolix, and NONMEM as standard practice.
- By simulating drug behavior using physiological parameters (e.g., organ sizes, blood flows, enzyme expression, etc.), physiologically based pharmacokinetic (PBPK) modeling has increased the ability to predict dosing in populations that are

underrepresented in clinical trials (e.g., pediatrics, pregnancy, hepatic/renal impairment).

2.2 Components of MIPD

- PK/PD models for populations, which measure the influence of covariates on drug behavior.
- Bayesian forecasting/Bayesian feedback, which enhances dose prediction by combining previous population data with patient-specific data (often sparse).
- Integration with TDM, in which estimates of individual parameters are improved by using measured concentrations as input into the model.
- Clinical Decision Support Systems (CDSS) (also known as decision support tools, or DSTs) that incorporate models into workflows so that physicians, including pharmacists, can enter patient information and receive recommendations for dosage.
- Pharmacogenomics and biomarkers: models can be informed by genetic polymorphisms (e.g., in transporters, drug-metabolizing enzymes) and biomarker measures (e.g., toxicity markers, therapeutic effect biomarkers).

III. CLINICAL EVIDENCE AND APPLICATIONS

3.1 Antimicrobials & Infectious Disease
Antimicrobials (such as beta-lactams and vancomycin) have been extensively studied in MIPD, particularly in critical care settings where patient variability is high. The goal of MIPD tools (and Bayesian dosing, such as AUC-based vancomycin dosing) is to attain target exposure.

3.2 Oncology & Immunosuppressants
MIPD has proven useful for medications such as tacrolimus (transplantation), busulfan (in pediatric transplantation), and cytotoxic agents with limited therapeutic windows. MIPD reduces PK variability in oncology.
Individualized dosing arms, as opposed to fixed doses, have been used in oncology trials in recent years.
Antimicrobial dosing tools are increasingly being integrated into software tools and hospital systems.

3.3 Chronic Diseases & Other Settings
Pharmacist-led individualized management (dose adjustments, close monitoring) in chronic diseases has associated benefits, even though it isn't always referred to as "MIPD" in studies.

Pharmacists use medication reviews, counseling, and follow-ups to improve lipids, blood pressure, and glycemic control in patients with type 2 diabetes mellitus.

Pharmacist interventions that improve medication adherence in COPD, asthma, and chronic therapies.

Pharmacist involvement in antimicrobial stewardship lowers mortality, inappropriate antimicrobial use, treatment duration, cost, and other factors.

These demonstrate how pharmacists can affect results by tailoring dosage (or therapy management) to patient-specific parameters.

IV. THE ROLE OF PHARMACISTS IN MIPD (CURRENT AND POTENTIAL)

4.1 Current Roles
Therapeutic Drug Monitoring & Dose Adjustment: Pharmacists frequently use Bayesian tools or dosing nomograms, order or interpret drug concentration assays, and suggest adjustments.

Participation in Multidisciplinary Teams: To guarantee that dosage is customized, pharmacists work with doctors, clinical pharmacologists, nurses, and oncologists in intensive care units, transplants, and infectious disease services.

Model and Software Tool Selection and Validation: In certain centers, pharmacists assist in assessing popPK models, selecting suitable software, and verifying tool functionality for the local populace.

Workflow & Implementation Integration: Integrating CDSS/DSTs into hospital information systems and electronic health records (EHRs); guaranteeing that necessary data (drug levels, patient covariates, and lab values) are available.

Education, Advocacy, and Training: educating other members of the healthcare team; creating policies and

procedures; providing training in Bayesian or pharmacometric techniques.

4.2 Potential / Emerging Roles

Model Development & Continuous Learning: Using local patient data, pharmacists with research training can create or improve models, assisting in "learning models" or "adaptive" frameworks that get better with time.

Integrating genetic data (enzyme polymorphism, etc.) into dosing models is known as pharmacogenomics integration.

The oversight of regulatory and quality assurance involves making sure that software and dosing tools adhere to legal requirements (such as being deemed medical devices and following CE/FDA regulations), that maintenance and updates are carried out, and that safety inspections are conducted.

Explaining specific dosage schedules, risks and benefits, and involving patients in monitoring are all examples of patient-centric communication and shared decision making.

V. BARRIERS AND FACILITATORS TO IMPLEMENTATION

5.1 Barriers

Model validation and data limitations: A lot of popPK or PD models are created using limited trial populations, which may make them not generalizable. Predictions are made more difficult by intra-occasion variability, sparse sampling, and a lack of covariate data.

Obstacles related to software-device classification and regulations: Software used for dose calculation is frequently regarded as a medical device, which results in requirements for regulatory compliance (validation, risk management, documentation). This may slow adoption and raise costs.

Clinician acceptance and workflow integration: Tools need to be easy to use; fragmented patient data or a lack of EHR integration can be major roadblocks. If clinicians are not aware of the underlying assumptions, they might not trust model recommendations.

Lack of formal training in pharmacometrics, Bayesian methods, or advanced PK/PD limits the ability of many pharmacists (and doctors) to confidently evaluate or use tools.

Software licensing, lab assays (drug levels), staffing, and IT support are among the expenses and resource limitations. Lower-income areas or small hospitals may face difficulties.

Reimbursement and incentive structure: Adoption may be constrained if software expenses, lab monitoring, and pharmacist time are not financially supported or reimbursed.

5.2 Facilitators

Accessibility of validated, user-friendly CDSS tools: Systems with clear visualization, feedback, minimal manual data entry, integration with EHRs, and good interfaces.

Professional society protocols and regulatory guidance: Standardized dosing guidelines, such as vancomycin AUC targets, promote uniform practice.

Strong interdisciplinary cooperation: pharmacists collaborating with doctors, IT, laboratory medicine, clinical pharmacologists, and institutional leadership.

Programs for training and education: These include workshops, continuing education, and the inclusion of MIPD in pharmacy curricula.

Clinical and financial benefit demonstration: Research demonstrating that MIPD increases target achievement, lowers adverse events, or lowers hospital stays or expenses will encourage adoption.

VI. RECOMMENDATIONS & BEST PRACTICES FOR IMPLEMENTATION

Some useful suggestions to more extensively and successfully integrate MIPD into clinical practice are as follows:

Validation and adaptation of local models

Validate population PK/PD models using local patient data whenever feasible, and make adjustments as needed (taking into consideration distributions of renal or hepatic function, ethnicity, etc.).

Appropriate software tools and integration
Select tools with interfaces appropriate for the clinical setting, that are certified or regulatory compliant, and that have undergone extensive validation. Reduce the burden of manual data entry by integrating with an EHR to automatically access necessary data.

Clearly define roles and workflows.
Make it clear who enters data, who runs the model, who decides on dosage, and how feedback (drug levels, etc.) is taken into account. This process can frequently be led or co-led by pharmacists.

Building capacity and providing training
Pharmacy education should include instruction in pharmacometrics, Bayesian techniques, and software tools. Current pharmacists should also have access to ongoing professional development opportunities.

Supervision of regulations and quality assurance
Make sure the software or design complies with local regulations; incorporate audit trails, model versioning, performance monitoring, and adverse events.

Observation, evaluation, and ongoing education
To evaluate efficacy, gather data on clinical, safety, and cost outcomes; modify models and tools over time ("learning healthcare systems") to increase precision and generalizability.

Strategies for reimbursement and economic assessment
Evaluate the cost-benefit ratio, show value or savings (such as fewer adverse events or shorter hospital stays), and push for payment for pharmacist time, software, and cost monitoring.

VII. DISCUSSION

MIPD holds great potential for enhancing patient outcomes, particularly for medications with highly variable pharmacokinetics or limited therapeutic windows. The knowledge, attitude, and clinical role of pharmacists enable them to take the lead in converting model predictions into safe and efficient dosage.

Although increasing, the clinical evidence is still rather small as many applications are still only found in specialized facilities with funding for research. To more accurately measure the impact (on morbidity, mortality, cost, and patient-reported outcomes), more extensive prospective randomized controlled trials or pragmatic trials comparing MIPD vs. standard dosing in various clinical settings are required.

Implementing MIPD is not risk-free, though; errors may arise from bad model selection or inappropriate application (e.g., using a model outside of its domain of validity), delays in drug assays or lab results, or a lack of real-time data. Strong safeguards and quality assurance are crucial.

Equity is another crucial concern, which includes making sure that MIPD is available in environments with limited resources and that models are appropriate for a range of age groups, ethnic groups, and comorbid conditions. Transparency in model assumptions, patient consent when genetic or biomarker data is used, and data privacy are additional ethical considerations.

Mastering MIPD may necessitate further training, cooperation with pharmacometricians, and potentially new positions or certifications from the standpoint of a pharmacist's career and professional practice. Policymakers and institutional leadership need to acknowledge and encourage the expanded roles of pharmacists in this field.

VIII. CONCLUSION

Since they are knowledgeable about pharmacokinetics, drug interactions, and patient care, pharmacists are at the forefront of the evolution of Model-Informed Precision Dosing (MIPD), which has the potential to improve efficacy, reduce toxicity, and optimize resource use. However, in order to fully realize MIPD's potential, obstacles like regulatory complexity, data limitations, training gaps, and software integration must be addressed. Facilitators include validated CDSS tools, institutional buy-in,

multidisciplinary collaboration, and evidence of clinical and economic benefit.

The pharmacist's role is expected to grow as healthcare continues its transition to precision medicine, evolving from a traditional dispenser and monitor to a model developer, decision support leader, and customized dose architect. Future research should focus on developing policies that allow pharmacists to practice at the highest level permitted by their license in MIPD, integrating pharmacogenomics, adapting to a variety of environments, including low-resource contexts, and conducting prospective clinical trials.

REFERENCES

[1] Model-Informed Precision Dosing at the Bedside: Scientific Challenges and Opportunities https://pubmed.ncbi.nlm.nih.gov/30255663/

[2] Berezowska A, Weiss J, Ulrich C, et al. Recommended approaches for integration of population pharmacokinetic modelling with precision dosing in clinical practice. British Journal of Clinical Pharmacology. https://pubmed.ncbi.nlm.nih.gov/39568428/

[3] Kluwe J, Keiser MJ, Caudle KE, et al. Perspectives on Model-Informed Precision Dosing in the Digital Health Era: Challenges, Opportunities, and Recommendations. Clinical Pharmacology & Therapeutics. 2021. https://pubmed.ncbi.nlm.nih.gov/33068303/

[4] Recent Advances Addressing the Challenges of Precision Dosing. Clinical Pharmacology & Therapeutics. 2024. https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.3365?af=R

[5] From Prospective Evaluation to Practice: Model-Informed Dose Optimization in Oncology. Drugs. 2025. https://pubmed.ncbi.nlm.nih.gov/39939511/

[6] Dose Individualisation of Antimicrobials from a Pharmacometric Standpoint: The Current Landscape. Drugs. 2024. https://pubmed.ncbi.nlm.nih.gov/39240531/

[7] Barriers and Facilitators for Bringing Model-Informed Precision Dosing to the Patient's Bedside: A Systematic Review. https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.3510

[8] Model-informed precision dosing: State of the art and future perspectives https://www.sciencedirect.com/science/article/pii/S0169409X24002436

[9] Editorial: Model-informed drug development and precision dosing in clinical pharmacology practice https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2023.1224980/full

[10] A continued learning approach for model-informed precision dosing: Updating models in clinical practice https://pubmed.ncbi.nlm.nih.gov/34779144/

[11] Model-Informed Precision Dosing for Personalized Ustekinumab Treatment in Plaque Psoriasis https://www.mdpi.com/1999-4923/16/10/1295

[12] Model-informed precision dosing of vancomycin in clinical practice: an intervention development study https://link.springer.com/article/10.1007/s11096-024-01822-x