Journal of Young Pharmacists, 2026; 18(1):80-85.
https://www.jyoungpharm.org

Review Article

Therapeutic Drug Monitoring: Impact on Efficacy and Safety in Narrow Therapeutic Index Drug Management

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ABSTRACT

By keeping medication concentrations within a specific therapeutic window, Therapeutic Medication Monitoring (TDM), a crucial part of precision medicine, guarantees the best possible therapeutic results. It is essential for the management of medications with a Narrow Therapeutic Index (NTI), in which even little variations in plasma levels can have serious toxicity or subtherapeutic effects. The research analyzed PubMed alongside Scopus and Web of Science databases for articles between 2000 and 2025 under keywords that included "Therapeutic drug monitoring, Narrow therapeutic index drugs, Pharmacokinetic-pharmacodynamic modelling, Model informed precision dosing." Through the integration of pharmacokinetic, pharmacodynamic, and pharmacogenomic data, TDM enables customized dosage to maximize effectiveness and reduce unfavorable drug effects. Because of their limited safety margins and interindividual variability, NTI medications such phenytoin, digoxin, lithium, tacrolimus, and aminoglycosides necessitate cautious dose titration and frequent monitoring. Accurate drug quantification is supported by sophisticated analytical methods such as immunoassays, Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS), and High-Performance Liquid Chromatography (HPLC). Real-time decision-making and customized treatment have been further reinforced by recent advancements like Point-of-Care Testing (POCT), Model-Informed Precision Dosing (MIPD), and artificial intelligence-driven algorithms. Combining TDM with wearable sensor technology and pharmacogenomics opens up new possibilities for ongoing monitoring and enhanced patient safety. Clinical pharmacists are essential in analyzing TDM data, spotting drug-related issues, and directing the right course of treatment. All things considered, TDM is essential to the safe and efficient administration of NTI medications, guaranteeing therapeutic accuracy, reducing toxicity, and encouraging individualized pharmacotherapy for a range of patient demographics.

Keywords: Therapeutic Drug Monitoring, Narrow Therapeutic Index, Pharmacokinetics–Pharmacodynamics, Model-Informed Precision Dosing, Personalized Medicine, Drug Safety, Clinical Pharmacology, Pharmacogenomics.

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Received: 16-12-2025;
Revised: 29-01-2026;
Accepted: 06-03-2026.

INTRODUCTION

Therapeutic Drug Monitoring (TDM) is a key clinical service and laboratory test that analyzes drug content in biological fluids, primarily blood. Its primary purpose is to optimize and alter drug dosages so that it remains within a therapeutic window, where effectiveness and safety are maximized (Kim *et al*., 2022). TDM offers precision dosing customized to specific patient demands, as drug concentration can change due to demographics and inter- or intra-Pharmacokinetic/Pharmacodynamic (PK/PD) characteristics (Lee *et al*., 2022). TDM proves advantageous when treatment is ineffective or causes Adverse Drug Reactions (ADRs), allowing doctors to evaluate potential concerns by evaluating drug levels (Choi *et al*., 2021). Additionally, TDM can proactively alter doses based on the existing levels of the drug within the body. Overall, TDM strives to sustain drug levels within the therapeutic range, therefore reducing toxicity and ADRs while boosting therapeutic efficacy (Yamaguchi *et al*., 2023).

TDM is particularly relevant for medications with a Narrow Therapeutic Index (NTI), immunosuppressants, and antiepileptic therapies where correct dosing is crucial to improve efficacy and reduce the toxicity of these treatments (Lai *et al* ., 2024). In clinical practice, NTI medicines require careful dose titration and quantitative monitoring of drug concentrations due to their susceptibility to elicit dose-dependent toxicity at or near the therapeutic dose (Habet, 2021). Examples of such pharmaceuticals are ciclosporin, aminoglycosides, warfarin,

DOI: 10.5530/jyp.20260253

digoxin, digitoxin, carbamazepine, lithium, phenytoin, rifampicin, and phenobarbital; these treatments have small therapeutic windows, necessitating careful dosage adjustments and effective monitoring (Blix *et al*., 2010).

Treatment complexity further increase when NTI pharmaceuticals interact with concomitant medications, particularly those impacting the cytochrome P450 enzyme system, which can alter drug concentrations. The effectiveness of NTI medicines may also be modified by patient age, medical condition, and genetic differences (Blix *et al*., 2010). Therefore, TDM is vital for correctly measuring medication concentrations, thereby ensuring the safety and efficacy of patients. This paper will review the effects of TDM on the efficacy and safety of NTI medication management (McCudden, 2018).

MATERIALS AND METHODS

This is a comprehensive review. A literature search was conducted using PubMed, Scopus, and Web of Science (2000-2025) with keywords: Therapeutic drug monitoring, Narrow therapeutic index drugs, Pharmacokinetic-pharmacodynamic modelling, Model informed precision dosing. This review included peer-reviewed English-language articles focusing on mechanistic and preclinical or clinical aspects of biased agonists. The research excluded studies written in non-English languages together with preprints and non-peer-reviewed literature. This review was not registered in PROSPERO because it fails to meet systematic review criteria

Pharmacokinetic and pharmacodynamic challenges of NTI drugs

NTI medications have a small difference between the drug's therapeutic and hazardous levels, therefore the pharmacokinetic factors, such as ADME, considerably influence the features of these drugs. Any changes in ADME might readily boost the medication's concentration above its therapeutic range, resulting in treatment failure or other adverse drug reactions. Considering ADME features is critical for risk groups, such as older patients and persons with comorbid diseases, including age, pre-existing medical conditions, and genetic variations, as these factors can alter the metabolism and action of NTI medicines in individual patients (Sane and Sinz, 2017). Population Pharmacokinetics (popPK) modelling greatly enhances the precision of personalized dosage for NTI medicines. This method promotes tailored treatment by combining high-quality precision-dosing solutions into routine clinical procedures across multiple patient groups, typically necessitating Therapeutic Drug Monitoring (TDM) and dose adjustment based on patient-specific features (Berezowska *et al*., 2025).

Cytochrome P450 enzymes play a crucial role in drug metabolism, and genetic variations of these enzymes greatly alter medication responsiveness. Around 80% of medicines are metabolized by CYP2D6, CYP2C19, and CYP2C9, and their polymorphisms are the most common causes of differences in phase I metabolism (Zhou *et al*., 2009). For medications with a narrow therapeutic index, CYP polymorphisms can dramatically effect therapeutic outcomes. To address concerns associated with these medicines, therapeutic drug monitoring, investigation of pharmacokinetic interactions, and pharmacogenetic testing are indicated (Khaitovych, 2019). However, medications with a NTI are more prone to drug-drug and drug-food interactions. These interactions can affect medication plasma concentrations, potentially causing lower efficacy or increased toxicity (Vranckx *et al*., 2018). Risk factors for these drug-related disorders include polypharmacy, lengthy hospital stays, and concomitant diseases. Patient safety can be enhanced by early detection of drug-related problems by the assessment of risk factors and ongoing patient monitoring (Chhatrala *et al*., 2023; Iyer *et al*., 2018).

Principles and Methods of TDM

TDM is the technique of measuring and evaluating medication concentrations in biological fluids to inform treatment decisions. By integrating principles of pharmaceutics, pharmacokinetics, and pharmacodynamics, TDM guarantees that drug levels remain within the therapeutic range, enhancing both safety and effectiveness while tailoring treatment for each patient (Kang and Lee, 2009). Common analytical techniques used for TDM are High-Performance Liquid Chromatography (HPLC), Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) and immunoassays. HPLC-based approaches are crucial for evaluating medication identity, potency, purity, bioavailability, and efficiently monitoring pharmacokinetics. The LC-MS/MS platform offers simultaneous assessment of numerous medicines with excellent precision and consistency, making it appropriate for ICU patients receiving combination therapy and facilitating personalized dosage (Liu *et al*., 2023). Enzyme Linked Immunoassay (ELISA) based immunoassays quantify multi-domain biotherapeutics, detect interference from anti-drug antibodies, and enable quick total drug exposure measurement during early drug development (Pöhler *et al*., 2024). Sampling strategies in TDM include trough sampling (before the next dose to assess minimum levels), peak sampling (at maximum concentration to evaluate efficacy and toxicity), random sampling, Limited Sampling Strategies (LSS), and population pharmacokinetic modeling to support individualized dosing (Tang and Carlson,2020; Aronoff *et al*., 2018). Proper timing involves collecting samples after 4-5 half-lives to achieve steady-state, maintaining consistent dosing schedules, and considering patient-specific factors such as age, weight, organ function, and comorbidities. These approaches optimize therapy, enhance safety, and improve clinical outcomes (Sawchuk and Kelly, 2017; St John and Price, 2014). Point-of-Care Testing (POCT) in (TDM) is a diagnostic technique that determines drug concentrations at or close to the patient's location. It gives speedy results, enabling timely, personalized dose modifications

and enhanced therapeutic outcomes. Unlike central laboratory testing, POCT substantially shortens turnaround time. This strategy is especially advantageous for medications with narrow therapeutic indices, such as biologics and immunosuppressants, where accurate maintenance of drug levels is crucial for both treatment success and patient safety (Koster and Alffenaar, 2020). POCT provides quick dose modifications in both critical care and outpatient settings, enhancing patient safety, therapeutic effectiveness, and medication adherence while minimizing hospital stays and associated consequences (Aronoff *et al*., 2018; Sawchuk and Kelly, 2017).

Efficacy and Safety of Therapeutic Drug Monitoring in Narrow Therapeutic Index Drug

Personalized dosing solutions based on TDM are becoming acknowledged across varied medication classes. In transplantation, tacrolimus is a paradigmatic case where trough concentration monitoring substantially corresponds with graft survival and lower rejection rates (Lennernäs *et al*., 2025). Population pharmacokinetic research in Chinese lung transplant recipients indicated that genetic polymorphisms, hematocrit, and medication interactions significantly impacted tacrolimus exposure, underlining the necessity for dose adjustment guided by TDM. Similarly, in neurology, classic antiepileptics such as phenytoin and carbamazepine require close monitoring due to non-linear pharmacokinetics and potential of toxicity at high plasma levels (Liang *et al*., 2024). In infectious illness, aminoglycosides and vancomycin remain key options for TDM, where dosage modification maintains appropriate bactericidal action while limiting nephrotoxicity and ototoxicity (Liang *et al*., 2024). Oncology has also adopted TDM, as exemplified with imatinib, where higher plasma exposure is associated with superior tumor control but also increased toxicity, needing careful balancing through customized dose.

Special populations further underline the significance of TDM in NTI drug treatment. Pediatric patients generally display unexpected pharmacokinetics due to immature enzyme systems, varying body composition, and altered clearance, rendering routine dosing inaccurate (Liang *et al*., 2024). In contrast, older individuals may develop drug buildup due to diminishing renal and hepatic function, polypharmacy, and diminished protein binding. Similarly, TDM is especially relevant in pregnancy and obesity, where alterations in volume of distribution and clearance might complicate dosage (Liang *et al*., 2024; Liang *et al*., 2024). These groups benefit greatly from TDM-directed changes, ensuring efficacy without compromising safety.

For antibiotics such as vancomycin, elevated trough concentrations are intimately related with nephrotoxicity, and TDM allows doctors to pre-emptively alter dosages in high-risk patients. The rising amount of data currently supports integration of advanced technology and Model-Informed Precision Dosing (MIPD) into normal practice. MIPD provides a revolutionary technique that integrates population pharmacokinetic and pharmacodynamic modelling with TDM and patient-specific clinical factors to individualize medication therapy. This method tries to maximize therapeutic effectiveness while lowering the likelihood of unwanted consequences. In contrast to typical fixed or weight-based dosing regimens, MIPD offers real-time, personalized dose decisions, making it particularly suitable for pharmaceuticals with a narrow therapeutic index, such as antibacterial agents, immunosuppressants, and anticancer treatments (Van Wynsberge *et al*., 2024). MIPD combines TDM with Bayesian forecasting and pharmacogenomic data to individualize medicine more accurately, notably, in critical care and infectious disease situations.

Therefore, TDM remains the cornerstone of NTI medication management by optimizing efficacy, avoiding toxicity, and supporting individualized dose across varied therapeutic areas and populations. Advances in precision dosage models and real-time monitoring technology are projected to significantly enhance its significance in modern pharmacotherapy.

Clinical Applications and Guidelines for TDM of NTI Drugs

TDM of NTI medications is being considerably advanced by contemporary technology and precision medicine. Some of the novel solutions include point-of-care assays, sophisticated bioanalytical approaches, digital analytics, and model-informed dosage that permit precise and rapid monitoring, facilitating customized treatment, reduced toxicity, and increased efficacy (Liang *et al*., 2024). As much as there exist concerns with drug-level monitoring in a timely manner, general TDM is prescribed for anti-infectives such as vancomycin, aminoglycosides, voriconazole, and parconazole. Trough levels or the area under the curve is the basis of monitoring (Li *et al*., 2024; Balakrishnan and Shorten, 2016). Although accumulating evidence favors TDM in critically ill or organ-failure patients, most hospitals are unable to use it owing to the absence of onsite assays or infrastructure (Sandaradura *et al*., 2022; Choi *et al*., 2025).

Clinical pharmacists and pharmacologists play a significant role in TDM services across varied clinical settings. In the treatment of Non-Tubercular Mycobacterial (NTM) infections, clinical pharmacists have been found to identify many drug therapy difficulties, such as improper dose, side effects, and drug-drug interactions. They are also crucial to carrying out and evaluating TDM data, with more than 50% of monitored instances leading to dosage changes (Dara, 2024). Within hospital environments, pharmacist-led TDM programs for vancomycin and aminoglycosides have improved initial dosage, monitoring, and laboratory follow-up. Reviews of drug-related difficulties employing narrow therapeutic index drugs reveal a high prevalence of incorrect dose and unnecessary management.

These concerns are frequently connected with prolonged hospital stays, underscoring the necessity of clinical pharmacists in diagnosing and preventing such problems (Vohra *et al.*, 2024). Recommendations include establishing nodal centres, capacity development, compilation of national guidelines, and enhancing the role of clinical pharmacists and pharmacologists in strengthening TDM services (Pattanaik *et al.*, 2023).

Implementation Challenges and Limitations of TDM

Despite breakthroughs in medical science, major gaps remain in our understanding of the functional dynamics of TDM. The lack of defined procedures and heterogeneity in the inclusion criteria for their use provide substantial obstacles for healthcare professionals. Other challenges, including the unavailability of assays, delays in result interpretation, cost-effectiveness, and clinical effectiveness, need to be overcome before it can be adopted in clinical settings (Abdulla *et al.*, 2022). Tim M. J. Ewoldt *et al.*, performed a nationwide survey among Healthcare Professionals (HCPs) regarding the implementation of TDM in the administration of beta-lactam antibiotics in intensive care units. These antibiotics are extensively utilized, and their dose often does not depend on pharmacokinetic qualities; that results in therapeutic failure for critically ill patients. They identified 11 potential impediments and offered measures, including focusing on assay availability, establishing clear working instructions, educating HCPs, agreeing on pharmacodynamic breakpoints, and organizational support, to address these barriers (Ewoldt *et al.*, 2022). The use of TDM in oncology necessitates the in-house creation of bioanalytical procedures rather than relying on standardized, commercially available pathological toolkits. This technique is linked with high expenses and demands an advanced level of technical competence (Menz *et al.*, 2021).

The primary difficulty in implementing TDM is that it is quite expensive. In developing nations, the expenses play a large role in medical care, which limits the adoption of TDM. Delayed TDM data diminish the possibility of adjusting drug dosages by physicians, and these timing concerns cause practical restrictions in the value of TDM results. These are numerous important restrictions that hinder the application of TDM internationally. The other major constraints that need to be overcome to ensure optimal implementation of TDM include logistics, availability of equipment, methodological issues, and educational gaps.

Future Directions and Emerging Concepts in TDM

Model-Informed Precision Dosing (MIPD) is the future of TDM, which offers a substantial development in the evaluation of TDM differently than standard TDM approaches, which enable personalized dose using mathematical predictions and patient-related factors (Minichmayr *et al.*, 2024). Additionally, clinical evidence shows MIPD's superior performance in setting target drug concentrations, in which both TDM and MIPD have shown beneficial for various drug classes, including aminoglycosides, beta-lactams, glycopeptides, and linezolid. Recent technical breakthroughs make it feasible to tailor pharmacological treatments more accurately for specific patients. However, these approaches are not commonly employed in clinical practice yet, as further randomized clinical trials are needed to verify their therapeutic benefits (Li *et al.*, 2025).

Pharmacogenomics and TDM are emerging as supportive techniques for customized medication therapy and improved results for patients. In psychiatry, the inclusion of TDM with pharmacogenomic findings promotes the safety and efficacy of medicine; nevertheless, doctors must be able to discern between the statistical results and clinical findings (Crettol *et al.*, 2014; Jannetto and Bratanow, 2011). Both TDM and pharmacogenetics play a vital role in Pharmacovigilance by decreasing the adverse medication effects (Jaquenoud Sirot *et al.*, 2006). Artificial intelligence and machine learning are mostly applied to TDM and MIPD to improve patient care. These techniques can handle multidimensional data from electronic medical records and have been examined for concentration prediction, dose optimization, and population pharmacokinetics. Both AI and ML approaches are advanced above the traditional population pharmacokinetic model, which extends medication safety and toxicity prediction by addressing issues in pharmacovigilance through the study of databases (Basile *et al.*, 2019).

Digital health technology and wearable sensors are enhancing Therapeutic Drug Monitoring (TDM) by overcoming significant drawbacks of older approaches, including patient discomfort and insufficient monitoring of drug level fluctuations. These technologies establish real-time, continuous detection of medication concentrations in the body (Liu *et al.*, 2023). Additionally, these wearable devices have the potential to improve treatment outcomes while decreasing side effects and saving healthcare expenditures by enabling customized dosing and enhancing medication adherence (Teymourian *et al.*, 2020).

CONCLUSION

To address the growing issue of heterogeneity in treatment outcomes, Therapeutic Drug Monitoring (TDM) acts as an excellent tool for developing personalized medicine and lowering the risk of unwanted effects and therapeutic failures. Although recent breakthroughs like as Model-Informed Precision Dosing (MIPD) and Point-of-Care Testing (POCT) offer potential opportunities for improved patient-centered care, financial restrictions remain a key obstacle to the broad application of TDM. Moreover, bioanalytical procedures utilized in TDM are time-consuming and require a high level of professional skill to operate properly.

TDM has established itself as an integral component of modern pharmacology, enabling customized treatment and promoting reasonable drug usage. Moving forward, healthcare education should prioritize increasing the competencies of

future professionals by blending TDM-focused instruction with real-time clinical exposure across varied healthcare settings. The future research on TDM must focus upon incorporating AI-driven analytics into TDM that could streamline workflow efficiency, reduce turnaround time, and strengthen precision medicine practices in real-world clinical settings.

ACKNOWLEDGEMENT

We thank the all the pharmacists, study participants for the support provided during the conduct of the study.

ACKNOWLEDGEMENT OF AI USE

Editage Paperpal and Quillbot supported the preparation of this manuscript by providing assistance for structural editing and language refinement. The authors have verified all scientific content. No AI-generated figures were used.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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Cite this article: Sankar T, Elango D, Farook MJJ, Kattuva MIK, Manivannan K, Meeran PSN, *et al*. Therapeutic Drug Monitoring: Impact on Efficacy and Safety in Narrow Therapeutic Index Drug Management. J Young Pharm. 2026;18(1):80-5.