

From Precision Pharmacotherapy to Pharmacoequity: Why Therapeutic Benefit Depends on Affordability, Medicine Availability, Health Literacy, Monitoring Access, and Feasible Treatment Alternatives

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ABSTRACT

Precision pharmacotherapy seeks to improve treatment selection and dosing by matching therapy more closely to biological characteristics, drug response, and individual risk. Yet biological appropriateness does not ensure that a patient can obtain, understand, monitor, sustain, or replace the recommended treatment. This Perspective argues that clinical pharmacology therefore requires a complementary concept of pharmacoequity: the condition in which biologically appropriate therapy can plausibly become realized therapeutic benefit because critical access and feasibility requirements are sufficiently aligned. The analysis integrates five clinically distinct domains—affordability, medicine availability, health literacy and treatment interpretability, monitoring access, and feasible treatment alternatives. Evidence across pharmacogenomics, medication-cost research, medicine shortages, health-literacy interventions, therapeutic drug monitoring, and shared decision-making indicates that each can modify the pathway between a technically appropriate prescription and its practical realization. These domains should not be treated as interchangeable, equally weighted, or uniformly causal. Their relevance depends on the medicine, disease, therapeutic window, duration and urgency of treatment, patient circumstances, local supply and financing arrangements, and the availability of clinically acceptable alternatives. The proposed pharmacoequity framework consequently extends precision pharmacotherapy without replacing biological criteria. It treats efficacy and safety requirements as noncompensatory clinical boundaries while asking whether an otherwise appropriate strategy is realistically deliverable and sustainable. The framework remains conceptual rather than validated and should initially be used to organize questions, expose hidden feasibility assumptions, and motivate prospective measurement rather than to generate scores or prescriptive thresholds.

Keywords: Precision pharmacotherapy, Pharmacoequity, Medication affordability, Medicine availability, Health literacy, Monitoring access

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Introduction

Precision pharmacotherapy has strengthened the proposition that treatment quality depends not merely on selecting a generally effective medicine but on selecting and dosing therapy appropriately for a particular patient. Pharmacogenomics illustrates the clinical importance of this shift. In the PREPARE implementation study, genotype-guided prescribing across actionable gene–drug pairs reduced clinically relevant adverse drug reactions under defined implementation conditions [1]. Such findings establish that greater biological specificity can matter clinically; they do not establish that a biologically optimized treatment will be equally obtainable, sustainable, or useful for every patient or health system.

The potential reach of precision approaches is substantial. National US prescribing data indicate that diverse patient populations are exposed to medications carrying evidence-based pharmacogenomic information, making

the infrastructure for translating such information relevant beyond a narrow specialist population [2]. Yet the clinical existence of actionable information and its practical use are different states. Contemporary US implementation experience continues to identify barriers involving testing, reimbursement, electronic health-record integration, clinician education, decision support, and equitable access [3]. The precision problem is therefore partly biological and partly translational.

This Perspective advances a complementary concept: pharmacoequity, proposed here as the condition under which an appropriately selected treatment has a realistic pathway to realized therapeutic benefit because affordability, medicine availability, treatment interpretability, monitoring access, and feasible alternatives are sufficiently aligned. These domains are not proposed as a validated causal score, nor as five universally necessary prerequisites. A short-course treatment with little follow-up may be minimally monitoring-dependent, whereas a narrow or dynamically dosed regimen can fail operationally if timely measurement and interpretation are unavailable. Similarly, affordability may dominate one decision while local supply instability or treatment complexity dominates another.

The purpose is therefore not to displace pharmacokinetics, pharmacodynamics, pharmacogenomics, exposure–response reasoning, or conventional efficacy and safety criteria. It is to expose a hidden assumption often embedded within them: that the biologically preferred treatment can actually be obtained, understood, monitored, continued, and—when necessary—replaced by another clinically acceptable strategy.

Why biologically precise therapy can still be clinically inaccessible

Biological actionability must be translated through infrastructure. The Ubiquitous Pharmacogenomics Consortium illustrated this requirement by linking genotyping with prescribing guidance, clinical decision support, and multicountry implementation processes rather than treating a genetic result as a self-executing therapeutic decision [4]. This distinction generalizes beyond pharmacogenomics: a theoretically optimal dose or treatment may remain clinically inert when the system cannot generate the required information, deliver it at the point of prescribing, or support the resulting action.

Precision is also conditioned by the therapeutic environment in which recommendations are expected to operate. Analysis of actionable pharmacogenomics against World Health Organization and African essential-medicine lists shows that the relevance of genomic guidance intersects with which medicines are actually embedded in a health system [5]. A recommendation for a preferred medicine has a different practical meaning when that medicine is routinely stocked, intermittently available, unaffordable, or absent from the locally usable treatment set.

Access to the precision technology itself may also be patterned. Real-world evidence from a large health system examining psychiatry-focused pharmacogenomic testing found differences in who received testing and showed that changes in prescribing after testing did not translate into uniform improvement in acute-care utilization [6]. The implication is not that pharmacogenomics lacks value. Rather, precision interventions have multiple transitions—identification, testing, interpretation, prescribing, access, adherence, monitoring, and response—and loss of feasibility at any transition can separate technical precision from realized benefit.

Pharmacoequity therefore begins where biological appropriateness ends: not by weakening the standard of biological appropriateness, but by asking whether a clinically defensible recommendation possesses a viable route through the patient and health-system conditions required for its use.

Affordability as a determinant of realized therapeutic benefit

A prescription can be pharmacologically appropriate while remaining economically unusable. Cost-related nonadherence captures part of this gap because it concerns medication behaviors altered specifically by financial burden rather than by pharmacological unsuitability. Following implementation of provisions of the US Inflation Reduction Act, cost-related medication nonadherence among Medicare beneficiaries declined relative to a privately insured comparison group, supporting the relevance of financial exposure to realized medication use within that policy context [7]. The finding does not imply that cost is the sole determinant of adherence or that similar policies will produce identical effects elsewhere.

Patient experience also indicates that cost information can itself be clinically relevant. In a national survey of US adults aged 65 years and older, cost-related medication nonadherence occurred alongside substantial interest in receiving information about medication costs [8]. When costs are unknown to prescribers, patients, or both, treatment selection can therefore occur using an incomplete description of feasibility.

Randomized evidence strengthens the distinction between price as background context and affordability as a modifiable treatment condition. In the CLEAN Meds trial, providing essential medicines at no charge improved treatment adherence among eligible primary-care patients who had reported cost-related barriers [9]. Across observational, policy, and randomized evidence, medication cost can influence whether prescribed treatment is actually taken, although the magnitude and mechanism are context dependent [7–9].

The pharmacoequity implication is narrower than a claim that cheaper treatment is inherently better. Affordability should enter decision-making only after clinically unacceptable options have been excluded. When two or more treatments remain clinically defensible, however, substantial differences in out-of-pocket burden, coverage stability, administrative complexity, or the likelihood of treatment interruption may affect which option is most capable of producing sustained real-world exposure.

Medicine availability and supply-sensitive precision

Affordability is irrelevant if the medicine cannot be obtained. Medicine availability should therefore be treated as a dynamic property rather than a static attribute of a formulary. A multinational network cohort analysis of drugs with reported shortages between 2010 and 2024 found changes in medicine utilization around shortage periods, indicating that supply disruption can alter what treatment is actually used [10]. These shifts matter for precision pharmacotherapy because the clinically preferred option at one point in time may not remain physically accessible throughout treatment.

Shortage risk is also health-system dependent. A comparison of matched drug supply issues in the United States and Canada found differences in whether disruptions developed into shortages, demonstrating that the translation of a supply disturbance into clinical scarcity varies across national systems [11]. Availability is therefore not simply a molecular or manufacturer-level property; it is partly produced by procurement, regulatory, distribution, inventory, substitution, and institutional responses.

Patient consequences are similarly heterogeneous. A framework applied to medicine shortages in the Netherlands emphasized that impact depends on factors including the clinical condition, patient susceptibility, cost consequences, and whether acceptable substitutes exist [12]. The important distinction is between nominal substitution and therapeutically feasible substitution. A medicine may have alternatives on paper while none are equivalent for a particular patient because of previous intolerance, contraindications, dosing burden, interactions, monitoring requirements, or expected loss of disease control.

This motivates the concept of supply-sensitive precision: the precision of a recommendation is partly conditional on whether its intended therapy remains obtainable over the clinically relevant time horizon. Supply instability should not justify indiscriminate substitution, but neither should treatment models assume uninterrupted access when real-world supply can change.

Health literacy and the interpretability of complex treatment plans

Precision can increase informational demands. Genotype-dependent recommendations, dose adjustments, titration schedules, laboratory targets, food or drug interactions, contingency instructions, and alternative plans may all be pharmacologically sound yet difficult to enact when information is poorly communicated. Health literacy is therefore relevant not because some patients can be categorized simply as deficient, but because treatment comprehension is produced through an interaction between individual capabilities and the demands imposed by health information and health systems. Contemporary health-literacy theory explicitly supports this relational interpretation [13].

Medication communication is also modifiable. In a randomized trial of hospitalized children and their caregivers, a health-literacy-informed discharge communication intervention improved medication-related understanding and reduced dosing errors in that defined setting [14]. The study does not establish identical effects for adult chronic pharmacotherapy, but it demonstrates that interpretability is partly a property of how medication information is designed and delivered rather than a fixed patient characteristic.

At the same time, health literacy should not be elevated into a universal explanation for medication behavior. A systematic review among adults from ethnic-minority backgrounds with type 2 diabetes found limited and inconsistent evidence for a strong relationship between health literacy and medication adherence [15]. Adherence may instead reflect affordability, beliefs, adverse effects, regimen burden, competing responsibilities, trust, availability, disease experience, or combinations of these influences.

For pharmacoequity, the relevant question is consequently not “Does this patient have adequate health literacy?” but “Can this treatment plan be understood and enacted under the communication conditions actually available?” That reframing places responsibility partly on regimen design, clinicians, pharmacists, care teams, written and digital information, language access, and the responsiveness of the health system.

Monitoring access and the feasibility of safe optimization

Some precision strategies depend on continuing information after the prescription is written. Model-informed precision dosing is an example: its bedside implementation requires data capture, appropriate models, workflow integration, professional expertise, interpretation, and the ability to act on an updated dose recommendation. A systematic review of model-informed precision dosing implementation identified numerous barriers and facilitators distributed across technical, organizational, professional, and workflow domains [16]. The existence of a dosing model therefore does not establish that model-guided optimization is operationally available.

Therapeutic drug monitoring makes the access problem especially visible. An international assessment of antimicrobial TDM in critically ill adults showed substantial variation in access, utilization, and reported barriers across countries and clinical settings [17]. The implication is not that greater monitoring availability invariably improves outcomes; rather, patients can differ in whether the measurement infrastructure required by a monitoring-dependent strategy is reachable at all.

Oncology provides a related implementation boundary. Analysis of barriers and opportunities for therapeutic drug monitoring in oncology emphasizes that useful monitoring requires more than an assay: analytical capability, interpretable exposure targets, clinical evidence, sampling logistics, turnaround, and integration into prescribing decisions all condition implementation [18]. Across MIPD and TDM settings, safe optimization therefore depends on operational capacity extending beyond the pharmacological rationale itself [16–18].

Monitoring access should consequently be conceptualized as a chain: the required sample or clinical measurement must be obtainable at the appropriate time, processed with adequate quality and turnaround, interpreted against a clinically meaningful target or model, communicated to a decision-maker, and followed by an actionable treatment response. Failure at different links produces different consequences. Missing a routine measurement may delay optimization; inability to monitor a high-risk regimen may make that treatment practically unsuitable; and a measurement that arrives too late to influence treatment provides technical data without timely clinical actionability.

Table 1 identifies how monitoring dependency can convert an otherwise appropriate treatment option into an access-sensitive decision and where proposed adaptations still leave residual inequity.

Table 1. When monitoring requirements become access constraints on an otherwise appropriate treatment

Therapy	Monitoring dependency	Access barrier	Consequence if monitoring is missing	Feasible adaptation*	Residual inequity
Model-informed precision dosing–supported treatment	Timely patient data, model execution, interpretation, dose revision	Missing software, expertise, workflow, or serial measurements	Precision recommendation cannot be updated reliably	Use a clinically acceptable strategy requiring less model-dependent adjustment when available	Patients at resource-rich sites retain greater access to individualized dosing
Antimicrobial regimen managed with TDM	Concentration measurement with clinically useful turnaround	Limited assay access, delayed sampling or reporting, insufficient specialist support	Exposure-guided optimization may be delayed or unavailable	Refer to a monitoring-capable pathway or select a clinically acceptable less monitoring-dependent regimen	Referral distance, laboratory capacity, and turnaround remain uneven
Oncology treatment considered for TDM	Valid assay, interpretable exposure target, coordinated sampling and prescribing response	Weak evidence-to-workflow integration or inaccessible testing	Measurement may be absent or fail to change management	Restrict monitoring to clinically justified settings and use an acceptable alternative where monitoring is indispensable but unavailable	Availability of specialized monitoring can remain institution dependent

*Feasible adaptations are proposed clinical responses derived from the preceding evidence and should not be interpreted as validated outcome-improving substitutions. Biological efficacy and safety remain noncompensatory boundaries; an easier-to-monitor option is not preferable if it is clinically unacceptable.

Feasible treatment alternatives and the meaning of choice

Treatment choice is meaningful only when more than one clinically acceptable option is realistically usable. Shared decision-making provides the clearest starting point: treatment decisions should incorporate evidence alongside patient goals, values, and preferences rather than assuming that technical superiority alone determines the best choice [19]. Yet preference-sensitive care still operates inside pharmacological boundaries. A patient cannot meaningfully choose an option that is unavailable, unaffordable, incomprehensible in practice, or dependent on monitoring that cannot be obtained.

Choice architecture also matters. In a randomized study of primary care physicians, presenting multiple suggested care alternatives changed clinical decision-making [20]. The finding does not show that more options necessarily improve patient outcomes, but it demonstrates that the composition of the visible option set can influence what clinicians select. Pharmacoequity extends this observation by distinguishing the nominal choice set from the feasible choice set. An option should remain inside the latter only if it is clinically defensible and realistically obtainable, understandable, sustainable, and monitorable for the patient in question.

A nominal alternative may therefore disappear after feasibility is considered, while another may become more relevant because its biological disadvantage is small and its practical sustainability substantially greater. This is a proposed decision distinction, not an instruction to prefer convenience over efficacy or safety. The resulting contraction and expansion of usable choice is shown in **Figure 1**.

Feasibility is also dynamic. Insurance status, stock availability, caregiver support, travel capacity, and laboratory access may change during a treatment course, so the usable choice set should be reconsidered when these conditions change. A strategy that is feasible at initiation can become fragile later, while a previously inaccessible alternative may become usable. This temporal feature argues against treating the original prescription as a one-time optimization problem.

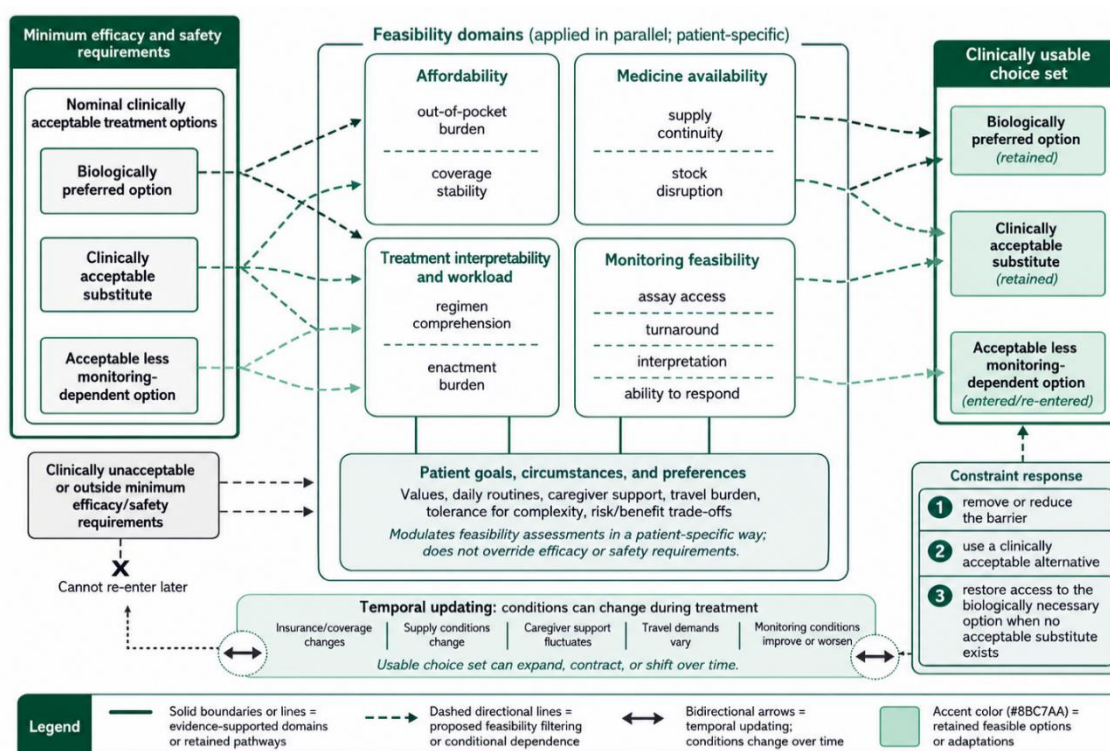


Figure 1. When nominal treatment options become a clinically usable choice set

The proposed pharmacoequity framework

Access to medicines is multidimensional rather than reducible to whether a product is formally listed or physically present. A systematic review of access to essential medicines in low- and middle-income countries identified interacting barriers and facilitators spanning availability, affordability, and appropriate use [21]. Qualitative evidence among people facing social disadvantage likewise indicates that access to health care and access to

medicines are not interchangeable: contact with services can coexist with difficulty obtaining or using the prescribed treatment [22].

On this foundation, pharmacoequity is proposed here as the condition under which a biologically appropriate therapeutic strategy has a realistic pathway to realized benefit because the access and feasibility requirements relevant to that strategy are sufficiently aligned. Five domains are foregrounded: affordability, medicine availability, health literacy and treatment interpretability, monitoring access, and feasible alternatives. Their importance is conditional rather than additive. A medicine requiring no laboratory follow-up does not become inequitable because advanced monitoring is absent; conversely, a narrow therapeutic strategy may become impracticable when essential monitoring cannot be obtained.

The domains also sit at different levels of analysis. Affordability may arise from payer design and household resources; availability from supply and procurement; interpretability from regimen demands and communication systems; monitoring from laboratory and workforce capacity; and alternatives from the interaction between the patient's clinical state and the local therapeutic repertoire. Pharmacoequity therefore concerns alignment across levels, not attribution of failure to a single patient characteristic.

The framework therefore uses biological appropriateness as an entry boundary rather than one interchangeable dimension among many. Options that fail minimum efficacy or safety requirements cannot acquire acceptability merely because they are cheap, available, or simple. Among clinically defensible options, however, feasibility conditions may influence which strategy is most likely to be initiated, sustained, interpreted correctly, and adjusted when necessary. **Figure 2** organizes this nested relationship while keeping evidence-supported domains separate from the proposed integrative synthesis.

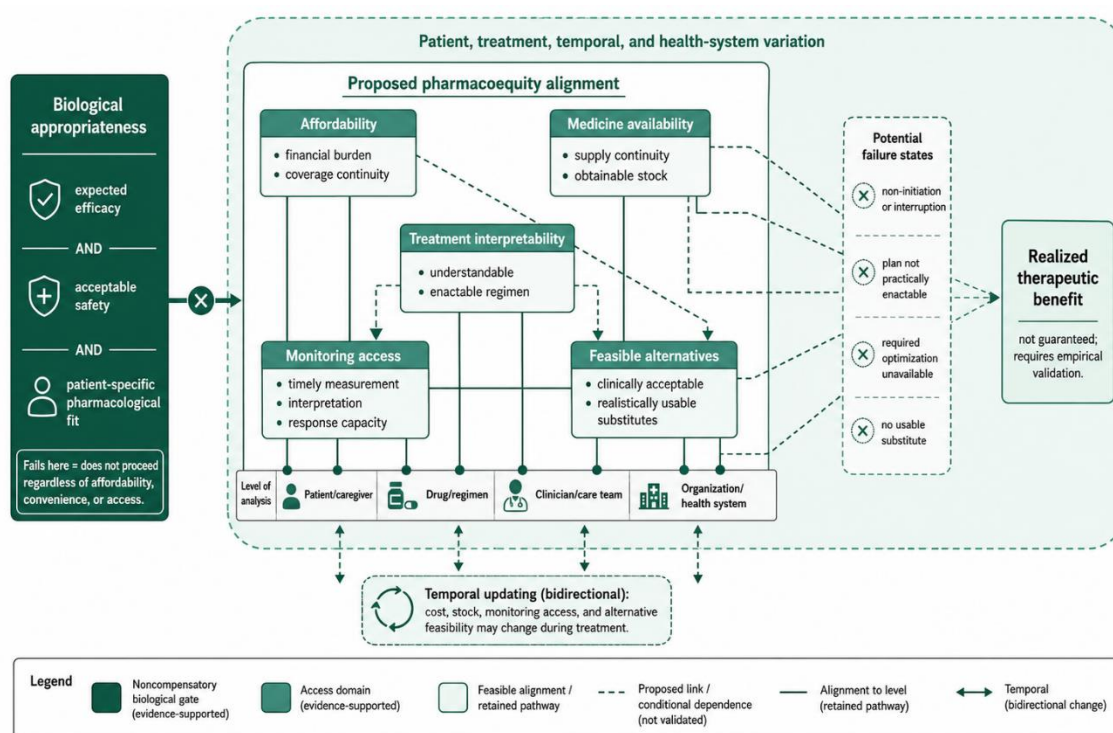


Figure 2. Access filters that determine whether biological precision can become realized therapeutic benefit

Trade-offs between biological precision and real-world feasibility

Pharmacoequity becomes most useful when biological precision and practical feasibility point toward different choices. Shared decision-making evidence illustrates why a uniformly patient-centered process cannot be assumed to improve every endpoint: a systematic review and meta-analysis of cardiovascular risk-factor interventions found heterogeneous effects across outcomes and approaches [23]. Feasibility-aware prescribing should therefore not be converted into a simple rule that the easier option is better.

Cost constraints show the same problem from another direction. Strategies for navigating high prescription-drug costs include substitution, benefit optimization, assistance programs, and other routes, but each can carry eligibility, administrative, clinical, or continuity constraints [24]. A less expensive option may be more sustainable

yet clinically inferior; a biologically preferred medicine may justify greater burden when alternatives materially reduce expected efficacy or safety. The decisive question is therefore whether a less precise option remains clinically acceptable while materially improving the probability that treatment can actually be obtained and sustained.

A feasibility-aware comparison should also distinguish reversible from structural constraints. A temporary shortage may justify bridging or delayed switching, whereas persistent unaffordability can repeatedly threaten continuity. Likewise, a monitoring barrier may be removable through referral, remote sampling, or workflow redesign, while no clinically acceptable substitute may exist for a patient with a specific contraindication profile. These distinctions matter because the same observed failure to receive a preferred treatment can imply very different responses. The proposed framework therefore asks whether a constraint can be reduced, whether an alternative remains inside the efficacy and safety boundary, and whether the resulting treatment is sustainable over the relevant time horizon.

The framework is intentionally noncompensatory at its clinical boundary and flexible within it. No affordability advantage offsets a contraindication, and no convenience advantage justifies inadequate efficacy. Once unacceptable options are excluded, however, modest differences in biological precision may reasonably be considered alongside major differences in access and workload. **Table 2** makes these trade-offs explicit without assigning scores or universal weights.

Table 2. Clinical choice when biological precision and treatment realizability diverge

Treatment-choice trade-off	Biological precision	Affordability / availability	Literacy / work burden	Monitoring feasibility	Feasible alternative	Equity-sensitive decision question
Preferred option is financially fragile	Higher	Unstable	Manageable	Feasible	Slightly less precise but affordable	Is the expected biological gain large enough to justify interruption risk?
Preferred option is supply-unstable	Higher	Intermittent	Similar	Similar	Clinically acceptable stocked option	Would continuity outweigh a modest precision advantage?
Preferred option requires inaccessible monitoring	Higher	Available	Higher logistical burden	Poor	Acceptable less monitoring-dependent option	Can safe use be sustained without the required monitoring chain?
Simpler option reduces treatment work	Similar or modestly lower	Similar	Lower	Similar	Simpler acceptable regimen	Does reduced complexity improve realizability without crossing efficacy or safety boundaries?

Note: Entries are proposed decision patterns synthesized from the preceding evidence. They are not validated rankings, thresholds, or treatment recommendations.

Implications for clinical pharmacology and therapeutics

Clinical translational pharmacology is increasingly positioned to address equity across the therapeutic lifecycle, including discovery, development, regulation, and use [25]. Pharmacoequity gives that aspiration a treatment-level question: after identifying what should work biologically, what conditions must be present for the patient to receive a clinically meaningful opportunity to benefit? This shifts part of clinical pharmacology's evaluative focus from technical actionability alone toward actionability under real delivery conditions.

Future clinical translational pharmacology has also been framed around broader integration of data, quantitative methods, implementation, and multidisciplinary decision-making [26]. Within that trajectory, pharmacoequity could influence several activities without becoming a substitute for established pharmacological evaluation. Early development could identify monitoring or administration demands likely to create later access barriers. Precision-dosing programs could document who can reach required assays and follow-up. Clinical decision support could distinguish a theoretically preferred option from one rendered impracticable by current supply or cost. Comparative evaluations could report treatment burden and feasibility alongside exposure, response, and safety.

These are proposed applications, not implementation-ready recommendations. Their value depends on whether the relevant constructs can be measured without excessive burden and whether incorporating them improves decisions rather than merely adding documentation. Clinical pharmacologists should also resist collapsing inequity into a single patient-level variable. Cost, supply, communication demands, laboratory capacity, and alternative availability are produced at different levels and may require different interventions.

Evaluation should preserve these levels rather than reporting a single access endpoint. Patient-level measures can capture treatment burden and out-of-pocket exposure; regimen-level measures can capture dosing and monitoring demands; organizational measures can assess turnaround and service capacity; and system-level measures can capture coverage and supply continuity. Linking these measurements to pharmacological outcomes would allow clinical pharmacology to test where loss of realizability actually occurs instead of presuming that every access barrier acts through adherence.

Boundary conditions and research priorities

The proposed framework should be expected to behave differently across populations, treatments, diseases, and health systems. Real-world pharmacogenomic testing can show selective uptake without uniform downstream utilization effects; health literacy may have inconsistent associations with adherence; and shared decision-making interventions produce heterogeneous outcomes [6, 15, 23]. These findings caution against treating any pharmacoequity domain as a universally dominant mechanism.

Several boundaries are especially important. Urgent treatment may allow little deliberation. A life-saving therapy with no acceptable substitute may make the appropriate response improved access rather than selection of an easier option. Short treatment courses may be minimally sensitive to long-term monitoring capacity, whereas chronic or narrow-therapeutic-index regimens may be highly sensitive to it. Supply and affordability can change during treatment, making pharmacoequity temporally unstable. The same regimen may therefore move into or out of feasibility without any change in its intrinsic pharmacology.

Empirical development should begin by measuring the domains separately rather than creating a composite score. Studies should test whether affordability, availability, interpretability, monitoring access, and alternative feasibility add clinically useful information beyond biological appropriateness; whether their effects interact; and whether relationships persist across payer, formulary, geographic, and health-system contexts. Longitudinal designs are needed because several domains vary over time, while pragmatic and multisystem evaluations could test whether feasibility-aware decisions improve initiation, persistence, exposure, safety, patient burden, or disease control.

The framework should also be falsifiable. It would require revision if its domains cannot be distinguished reliably, if feasibility information fails to improve explanation or decision quality, or if feasibility-aware choices systematically reduce net clinical benefit. Its purpose is to expose assumptions for testing, not to convert inequity into an unvalidated bedside score.

Conclusion

Precision pharmacotherapy has made treatment selection increasingly sensitive to biological variation, but biological precision alone does not determine whether therapy becomes usable care. This Perspective proposes pharmacoequity as a complementary concept focused on the conditions that allow an appropriate therapeutic strategy to be obtained, understood, monitored, sustained, and replaced when necessary.

Affordability, medicine availability, treatment interpretability, monitoring access, and feasible alternatives should not be treated as equivalent causes or universal requirements. Their relevance varies with the medicine, disease, therapeutic window, urgency and duration of treatment, patient circumstances, and health-system environment. Biological efficacy and safety remain noncompensatory boundaries: a convenient or inexpensive option cannot become acceptable merely because it is easier to deliver.

The practical contribution of pharmacoequity is therefore diagnostic rather than prescriptive. It asks where the pathway between an appropriate recommendation and realized therapeutic benefit may fail, which level produces the constraint, and whether a clinically acceptable adaptation exists. Before pharmacoequity can support decision tools or implementation strategies, its domains, interactions, temporal behavior, and transferability require prospective study. Precision pharmacotherapy becomes more complete when the question is not only what

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treatment best fits the patient biologically, but whether that treatment can realistically become sustained therapeutic benefit.

It also changes the interpretation of therapeutic optimization: optimization is incomplete when its assumptions about access, comprehension, monitoring, or substitution are invisible. Making those assumptions explicit creates hypotheses that can be challenged rather than a new guarantee of equitable care.

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