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Medicines Access Without Treatment Continuity Is a Policy Failure Driven by Stockouts, Product Switching, Fragmented Records, and Burden Transferred to Patients

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ABSTRACT

Medicines-access policy is commonly assessed through formulary inclusion, procurement, outlet availability, price or successful dispensing. These indicators are important, yet they can classify a medicine as accessible while an individual treatment episode is repeatedly disrupted. Stockouts may force patients to search across facilities or sectors; substitutions may preserve treatment or destabilize it depending on therapeutic fit and how the change is managed; medication information may fail to accompany the patient; and monitoring responsibilities may become disconnected from prescribing and dispensing. When health systems do not absorb these disruptions, patients and caregivers frequently perform the repair work. This commentary develops a longitudinal interpretation of medicines access centred on treatment continuity. Continuity is defined as preservation over time of access to a clinically appropriate medicine, including appropriately managed substitution where necessary, adequate medication-information transfer, required monitoring and follow-up, and a level of patient repair work that does not itself become a material access barrier. The argument does not assume that every shortage causes interruption or that every switch is harmful. Evidence from drug shortages, biosimilar switching, medication reconciliation and treatment-burden research instead indicates that the consequences of disruption depend on available alternatives, health-system organization, communication, information continuity, monitoring and patient capacity. Policy evaluation should therefore supplement point availability indicators with longitudinal measures capable of detecting whether treatment remains practically and clinically viable across repeated episodes of care.

Keywords: Medicines access, Treatment continuity, Drug shortages, Therapeutic substitution, Medication information, Treatment burden

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Introduction

Essential medicines policy has progressively moved beyond the idea that access can be secured through selection alone. The broader policy agenda encompasses financing, procurement, quality assurance, affordability and appropriate use, because a medicine that exists on a national list may still fail to reach the patient in usable form [1]. Yet even this multidimensional understanding often remains temporally thin. Cross-national analyses still commonly assess whether medicines are present at surveyed outlets and whether their prices are affordable at the time of observation. Recent evidence from low- and middle-income countries (LMICs), including analyses of adult medicines and systematic evidence for asthma and chronic obstructive pulmonary disease, continues to show

substantial gaps in measured availability and affordability [2, 3]. Those findings identify serious access deficits, but the underlying indicators usually answer whether a medicine can be obtained at an observed moment more readily than whether treatment can remain viable over weeks, months or years.

The difference becomes important for chronic treatment and other therapies requiring repeated dispensing, monitoring or coordinated follow-up. Qualitative evidence from Uganda illustrates that access to medicines for hypertension and diabetes involves repeated navigation across public and private facilities, constrained by medicine availability, affordability, information and health-system organization [4]. A patient may therefore satisfy a conventional access criterion on one occasion while subsequently encountering a stockout, being directed toward a different product, losing continuity of medication information, or being required to make additional visits and payments to keep treatment going.

This commentary uses nominal access to describe a policy or measurement state in which a medicine is formally covered, listed, available at a particular observation, or dispensed successfully once without demonstrating whether an appropriate treatment episode remains sustainable. Treatment continuity refers to preservation over repeated episodes of timely access to a clinically appropriate medicine, including appropriately managed substitution when necessary, medication-information continuity, clinically required monitoring or follow-up, and a level of repair work that does not itself become a material access barrier. This definition does not require uninterrupted receipt of an identical manufacturer, brand or formulation. Its concern is whether the therapeutic course remains clinically and operationally connected.

The policy question is consequently narrower than the general question of why medicines become inaccessible. It asks why nominal access indicators can overstate effective access when stockouts, product changes, fragmented records and transferred patient work intervene over time. The central contention is conditional: a disruption constitutes a continuity failure when the health system cannot preserve or restore an appropriate treatment episode without clinically important gaps, unmanaged therapeutic change, information loss, monitoring failure or disproportionate work being transferred to the patient.

Availability at one moment is not continuity over a treatment episode

Availability is an indispensable access measure because treatment cannot occur when the required medicine is absent. Its limitation is temporal resolution. Outlet surveys typically identify whether a medicine is stocked when data are collected, while affordability measures estimate whether specified quantities can be purchased under defined assumptions. These indicators are valuable for comparing markets and identifying structural deficits, but they cannot by themselves establish what happens between observations, during refill cycles or after an unexpected change in supply [2].

The same distinction applies to disease-specific access assessments. Persistent deficiencies in asthma and chronic obstructive pulmonary disease medicine availability demonstrate that basic access remains unresolved in many LMIC settings [3]. For a patient already receiving treatment, however, the relevant policy problem is not exhausted by whether the recommended product appears on a list or was present during the last visit. Continuity depends on whether the next clinically necessary treatment episode can be completed without an avoidable interruption, unsafe workaround or unsustainable transfer of effort and cost.

This longitudinal interpretation also changes the meaning of substitution. Continuity cannot reasonably require permanent product constancy in health systems where generics, biosimilars or therapeutically appropriate alternatives are routinely used. The more discriminating question is whether a change preserves the intended treatment under conditions appropriate to the medicine and patient. A switch may therefore represent successful continuity recovery, whereas the inability to identify, obtain, communicate or monitor a suitable alternative may convert a supply disturbance into treatment failure.

For policy analysis, five dimensions should remain analytically separate: timely availability, therapeutic substitutability, medication-information continuity, monitoring and follow-up continuity, and patient repair burden. They are not proposed as a validated score and should not be collapsed into an untested composite index. Their value is diagnostic. Two health systems with similar measured product availability may perform differently if one reliably manages substitutions, information transfer and follow-up while the other depends on patients to reconnect those functions themselves.

A stockout becomes a continuity failure through its downstream response

Drug shortages arise through heterogeneous manufacturing, supply, demand, commercial and regulatory processes [5]. Definitions also vary according to whether the perspective is that of the manufacturer, regulator, wholesaler, facility or clinician [6]. For continuity analysis, this upstream complexity matters because a warning of supply difficulty, a national shortage and an empty shelf at one facility are related states but do not identify the same patient-level outcome. The policy-relevant transition occurs when a supply disturbance changes the feasibility of maintaining treatment.

Recent US evidence reinforces this distinction. Not every reported pharmaceutical supply-chain problem developed into a substantial shortage, indicating that upstream vulnerability can sometimes be absorbed before a large supply reduction becomes clinically visible [7]. Comparative US–Canadian evidence goes further: supply-chain issues affecting the same medicines were less likely to become shortages in Canada than in the United States, a finding consistent with a role for national regulatory and market organization in how upstream disturbances propagate, without isolating those mechanisms [8]. The relevant policy question is therefore partly one of buffering capacity.

When buffering fails, consequences may spread beyond the facility reporting the stockout. Evidence from the Ugandan antimalarial market showed that public-sector stockouts increased private-sector prices and reduced access among vulnerable consumers, illustrating how a public supply failure can shift both financial and search burdens downstream. Broader shortage literature similarly identifies clinical, economic and humanistic consequences while also reporting settings in which outcomes were equivalent or occasionally improved after alternative management [9, 10]. The heterogeneous findings are important: shortage status should not be used as a universal proxy for treatment harm.

Product and therapeutic context also shape the response. A recent systematic review of antibiotic shortages found diverse causes and management strategies and emphasized that robust evidence concerning downstream clinical outcomes, antimicrobial resistance and economic effects remains limited [11]. Governments likewise deploy heterogeneous measures, including early notification, reserve mechanisms, alternative sourcing, regulatory flexibility and coordination policies, but cross-country mapping does not establish that each measure produces equivalent protection [12]. Shortage policy therefore needs to evaluate how a particular response preserves treatment, not simply whether a mitigation measure exists.

Supply-side investigations show that immediate disruption can reflect deeper manufacturing, commercial, market or regulatory conditions [13]. At the point of care, however, these upstream causes often appear as a requirement to change therapy. During the cefazolin shortage in Japan, hospital antibiotic utilization shifted substantially toward alternative parenteral agents [14]. Such evidence documents a forced change in prescribing patterns; it does not demonstrate that every substitution was clinically inappropriate. Conflating utilization change with harm would obscure the distinction between a disruption successfully managed through an alternative and one that destabilizes treatment.

The most useful counterexample is provided by the large US angiotensin receptor blocker recall and shortage episode. Although switching increased markedly, overall adherence and spending did not show a correspondingly large deterioration, indicating that many patients were able to move to alternatives without losing medication continuity [15]. The ability to switch nevertheless differed by insurance context. This finding directly challenges a simple shortage-equals-nonadherence assumption. A more defensible interpretation is that the continuity consequence of a shortage depends on whether an appropriate alternative can be identified, obtained and sustained under the patient's actual payment and care arrangements.

These distinctions separate the initiating disruption from the downstream condition that ultimately matters for an ongoing treatment episode.

Table 1. Distinguishing medicine-supply disruption from treatment-continuity failure

Continuity-failure class	Initiating condition	What must remain preserved for continuity	Signature that continuity has failed	Patient work that may be transferred downstream
Stockout-related disruption	Required medicine is unavailable at the usual dispensing point or within the normal supply pathway	Timely access to the same medicine or a clinically appropriate alternative	Missed or delayed treatment because no viable recovery pathway is available	Searching other facilities, repeated travel, additional payment, contacting clinicians or pharmacies

Forced product change	Usual product cannot be supplied and another product must be considered	Therapeutic appropriateness of the alternative and a workable transition	Change occurs without adequate assessment of therapeutic fit or without a sustainable supply route	Locating alternatives, clarifying instructions, negotiating coverage or resolving inconsistent advice
Medication-information discontinuity	Treatment changes but current medication information does not move reliably across settings or providers	Accurate current treatment information accompanies prescribing, dispensing and follow-up	Different actors act on incomplete, outdated or conflicting medication information	Reconstructing medication history, carrying documents, repeatedly explaining changes
Monitoring discontinuity	Treatment continues or changes without the clinically required follow-up process	Relevant clinical or laboratory review remains connected to the treatment episode	Therapy proceeds without required reassessment, dose review or safety follow-up	Scheduling extra visits, identifying responsibility for monitoring, chasing results
Repair-work transfer	Formal access remains nominally present while recovery depends on patient or caregiver effort	System absorbs a reasonable share of coordination, navigation and recovery tasks	Treatment is practically maintainable only through substantial patient work or resources	Time, travel, administrative work, cognitive load, financial outlay and coordination across providers

Product switching is conditional on therapeutic fit, communication and monitoring

The distinction between forced change and harmful change is especially important because policies that treat every switch as evidence of discontinuity can misclassify successful substitution. Biosimilar research provides the clearest counterweight. A systematic review encompassing a large body of reference-biologic–biosimilar switching studies found no consistent evidence of major loss of efficacy, safety or immunogenicity after switching, although study quality and open-label designs varied and discontinuation in some settings was associated with nocebo phenomena [16]. These findings support a conditional view: product identity can change while therapeutic continuity is maintained.

Evidence concerning biosimilar-to-biosimilar switching points in the same direction. A systematic review did not find a consistent reduction in effectiveness or increase in adverse outcomes after switching between biosimilars sharing the same reference product [17]. A separate meta-analysis of switching between reference biologics and biosimilars found similar aggregate safety and immunogenicity outcomes in switched and non-switched populations [18]. These results do not justify universal interchangeability claims across medicines. They do show why "product switching" is too broad to function as a stand-alone marker of continuity failure.

Management conditions can matter even where pharmacological comparability is well supported. Nocebo research in biosimilar switching indicates that expectations, communication practices and the organization of the switch can influence symptoms, acceptance and persistence. A systematic review identified multiple mitigation approaches, including structured communication and education, while also emphasizing that direct evidence for the effectiveness of individual mitigation strategies remains limited [19]. The policy implication is narrower than prescribing a standardized communication package: treatment continuity can be affected by how a clinically reasonable switch is introduced and supported.

Therapeutic context remains the final constraint. Evidence from psoriasis biologic switching demonstrates that outcomes vary according to the type of switch and therapeutic context; some switching strategies preserve or improve effectiveness while others may alter adverse-event or discontinuation patterns [20]. Likewise, the ARB shortage experience shows that alternatives can maintain adherence without establishing that every patient can switch equally easily [15]. Managed substitution should therefore be defined by clinical appropriateness, access to the substitute, understandable communication and any monitoring required by the medicine or patient. Where those conditions are absent, a supply-restoring product change can still represent a treatment-continuity failure.

The evidence supports a contextual classification of switching instead of a binary switched/not-switched indicator.

Table 2. Treatment-continuity interpretation of medicine switching under different clinical and system conditions

Switching context	Therapeutic relationship	Conditions that favor continuity	Conditions that can destabilize continuity	Appropriate policy interpretation

Reference biologic ↔ biosimilar	Products evaluated against the same reference biological medicine	Evidence-supported comparability, clear communication, continued access and appropriate follow-up	Negative expectations, poor communication, fragmented follow-up or product-specific clinical concerns	Switching alone should not be counted as failure
Biosimilar ↔ biosimilar sharing the same reference product	Alternative biosimilars anchored to the same reference medicine	Reliable product identification, supply continuity and clinically appropriate use	Weak evidence for a particular product/context, confusion over product identity or inadequate monitoring	Assess the managed transition, not merely the change in manufacturer
Biologic switch across therapeutic classes or mechanisms	Therapeutic alternatives may differ in mechanism, efficacy or safety profile	Explicit clinical rationale and indication-specific assessment	Assuming equivalence because both medicines treat the same condition	Requires stronger clinical justification than a same-reference biosimilar switch
ARB substitution during recall or shortage	Alternative medicine can preserve antihypertensive therapy	Accessible alternative product and workable insurance/payment pathway	Coverage barriers, inability to identify a substitute or prolonged treatment gap	Successful switching can indicate continuity recovery
Antibiotic substitution during a shortage	Alternative agent may differ in spectrum, stewardship implications or other clinical properties	Patient- and indication-specific selection with stewardship oversight	Substitution driven by availability without adequate clinical fit	Utilization change is evidence of disruption; harm cannot be inferred from the switch alone

Medication information must travel with the treatment

A medicine can remain physically obtainable while treatment continuity fails because the information needed to use it safely does not move with the patient. Pharmacist-led medication reconciliation in hospital settings can identify discrepancies and improve medication-information processes, although intervention content and reported outcomes vary substantially [21]. Community reconciliation after discharge likewise improves the identification and resolution of discrepancies, while effects on readmission and other downstream utilization outcomes are less consistent [22]. Information repair is therefore a continuity function in its own right; its success should not be inferred solely from later service-use outcomes.

Electronic tools can strengthen this function. Reviews of advanced and electronic medication reconciliation report reductions in discrepancies and, in some settings, medication-related harm [23]. More recent evidence nevertheless shows that improvements in medication records do not consistently translate into fewer emergency visits or readmissions [24]. Digital availability of a medication list should consequently be distinguished from information continuity: the clinically relevant question is whether current, comprehensible information is available to the person making the next prescribing, dispensing or monitoring decision.

This distinction becomes particularly visible when care crosses organizational boundaries. Nationwide German pharmacy surveys conducted after new discharge requirements found continuing problems in medication-information transfer and continuous medication supply between hospital and home [25]. The finding joins two domains that access indicators often separate: having a medicine available and having sufficient information to continue it safely can fail together.

Care fragmentation should also be specified rather than inferred from the number of clinicians involved. Fragmentation, continuity and coordination describe related but different features of care [26]. Observational evidence linking continuity with polypharmacy and medication appropriateness is suggestive, but confounding by illness complexity and service use prevents simple causal interpretation [27]. For medicines access, the practical concern is whether responsibility, medication history and the current therapeutic plan remain connected across actors.

Monitoring is part of the same longitudinal problem. Medication-review evidence indicates that collaboration, patient involvement, action planning and follow-up occur in differing combinations across successful interventions, without establishing that any single component independently causes better outcomes [28]. A treatment episode is incompletely restored when supply and information have been re-established but clinically required reassessment has no clear owner.

The informational distinctions relevant to longitudinal access can be compared directly.

Table 3. Medication-information functions that preserve continuity across repeated treatment episodes

Information function	Continuity question	Failure that may remain invisible to availability measures	System responsibility
Current prescription record	Is the intended regimen current and accessible to the next decision-maker?	Medicine is stocked but prescribing instructions are outdated or conflicting	Maintain an authoritative, updated medication plan
Dispensing history	Can recent supply, product changes and refill timing be reconstructed?	Repeated dispensing or switching cannot be interpreted across pharmacies	Preserve accessible dispensing history where governance permits
Cross-provider exchange	Do prescribers, pharmacists and monitoring teams receive the same relevant treatment information?	Each service has a partial record while the patient appears formally "in care"	Enable timely transfer and clarify responsibility
Patient-held information	Can the patient identify the current medicine, dose and recent changes when systems do not interoperate?	Patient is asked to reconstruct treatment from memory or disconnected documents	Provide usable, current information without making the patient the sole record carrier
Monitoring linkage	Is required clinical or laboratory follow-up connected to the current treatment?	Medicine continues after a switch or discharge without assigned reassessment	Attach monitoring responsibility and timing to the treatment plan

When systems fail to reconnect care, patients become the continuity buffer

Continuity failures are often repaired through patient and caregiver work. System-level changes can alter treatment burden, but randomized evidence has measured that burden inconsistently and has not shown that organizational redesign uniformly reduces it [29]. Measurement is itself incomplete: a scoping review identified multiple treatment-burden instruments but important gaps in content validity, responsiveness, interpretability and application in lower-resource settings [30].

The underlying construct is broader than adherence. An integrative review describes treatment burden as healthcare work combined with social, emotional and financial impacts, conditioned by the resources available to the patient [31]. In Ethiopia, greater measured treatment burden among people with multimorbidity was associated with poorer health-related quality of life, although the cross-sectional design does not establish causal direction [32]. For access policy, the relevant subset is repair work generated by discontinuity: searching for stock, travelling between facilities, arranging payment, reconciling conflicting instructions, obtaining replacement prescriptions, locating monitoring services, or repeatedly explaining a medication history.

Patient participation in self-management is not itself evidence of policy failure. The distinction is whether clinically necessary treatment remains feasible only because patients absorb coordination and recovery functions that could have been prevented or organized by the health system. Successful substitution during the ARB disruption shows that a system can preserve medication use despite a major supply shock [15]. Conversely, hospital-to-home evidence shows that formal discharge requirements can coexist with continuing supply and information gaps [25]. These cases place the burden of recovery, rather than the initiating disruption alone, at the centre of continuity assessment.

Figure 1 shows how disruptions can resolve, persist or accumulate across repeated treatment episodes, producing different continuity trajectories.

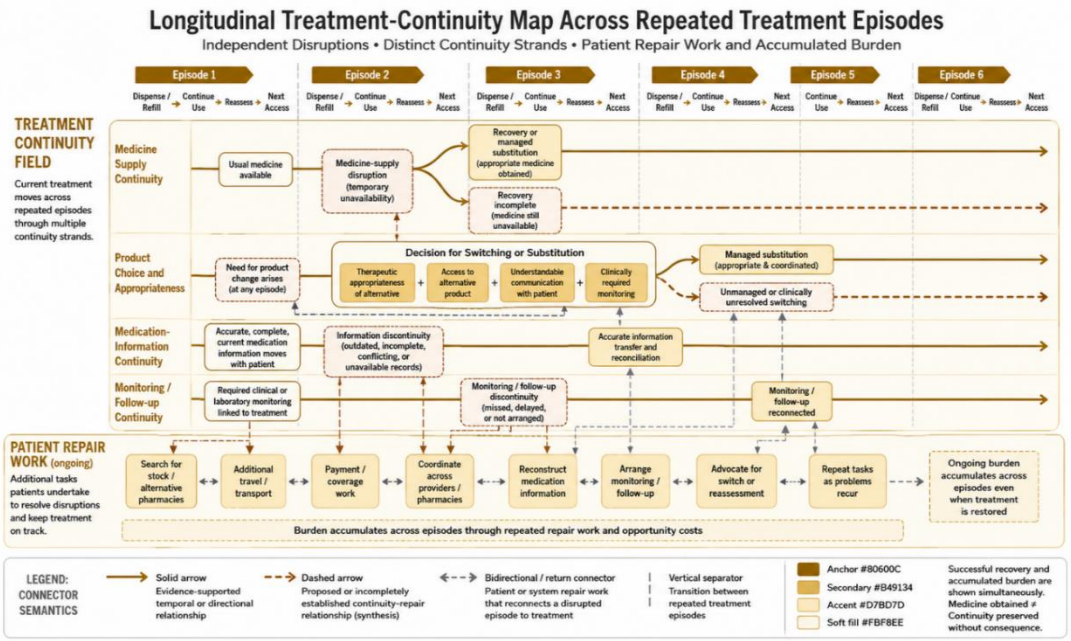

Figure 1. Longitudinal continuity of medicine treatment under repeated disruption and repair

Policy implications

Medicines-access monitoring should retain conventional indicators of listing, availability, price and affordability while adding measures that observe what happens across treatment time. The purpose is not to replace established access metrics but to detect failures they cannot resolve: whether an expected refill was obtained, whether a shortage required a change, whether that change was clinically appropriate, whether current medication information followed the patient, and whether required monitoring occurred. Point availability remains informative, but it should not be interpreted as proof of longitudinal continuity [2].

Shortage policy should similarly evaluate recovery quality. Cross-country evidence shows that the same type of supply problem can propagate differently under different market and regulatory arrangements [8], while national responses use varied notification, reserve, sourcing and coordination measures [12]. Performance assessment should ask whether disruption was absorbed before treatment was affected and, when it was not, whether patients obtained an appropriate alternative without disproportionate delay, cost or clinical uncertainty. Information systems belong in this assessment because digital reconciliation can improve proximal medication safety without guaranteeing downstream outcomes [24], and transfer rules can coexist with residual supply and information gaps [25].

A continuity perspective also exposes distributional effects hidden by national averages. Public-sector stockouts can redirect patients toward private markets, where prices and access conditions differ [9]. The ARB experience likewise showed that the capacity to switch was not identical across insurance arrangements [15]. Continuity indicators should consequently be stratified by financing pathway, sector, geography and patient resource constraints when data permit. A national system may appear resilient because aggregate adherence or supply recovers while particular groups experience longer gaps, higher out-of-pocket costs or more intensive navigation. Equity assessment should examine who absorbs the disruption, who receives a clinically suitable alternative promptly, and who must supply the time, information or money needed to restore treatment. This prevents successful average recovery from concealing unequal continuity within the same shortage response.

Patient repair work is a further candidate policy outcome, although existing measures require adaptation and validation for this specific purpose. Treatment-burden research demonstrates both the multidimensional nature of patient work and limitations of present instruments [30]. The policy objective is not zero patient involvement. It is to identify when formal access is sustained only through repeated search, coordination, travel, payment or monitoring effort that the system has shifted downstream.

These differences separate conventional point indicators from the additional observations required for continuity-sensitive policy.

Table 4. What point medicines-access indicators reveal—and what longitudinal continuity assessment must add

Policy observation	What it can establish	Continuity information still required	Example longitudinal question
Formulary or essential-medicine listing	Formal policy inclusion	Whether an appropriate product remains obtainable over the treatment period	Could the patient continue the indicated treatment at the next required episode?
Outlet availability	Stock at an observed place and time	Refill reliability, duration of disruption and recovery pathway	Was treatment maintained when the usual outlet lacked stock?
Price or affordability estimate	Financial accessibility under specified assumptions	Additional costs created by switching, travel or repeated search	What did continuity cost after a disruption occurred?
Successful dispensing	A medicine was supplied on one occasion	Therapeutic fit of substitutions and subsequent persistence	Was the supplied medicine an appropriate and sustainable continuation?
Medication-record availability	Some treatment information exists	Currency, cross-provider consistency and linkage to monitoring	Did the next decision-maker receive the correct current regimen?
Patient-reported burden	Work and impact experienced by the patient	Whether burden arose specifically from restoring disrupted access	How much additional work was required to keep treatment connected?

Conclusion

Medicines access can be present on paper, at an outlet and at one dispensing encounter while still failing across the life of a treatment. The evidence does not support treating every stockout as an interruption or every product switch as harmful. It instead points to the quality of the downstream response. Continuity is preserved when an appropriate medicine remains obtainable, clinically suitable substitution is managed when required, current medication information reaches the next decision-maker, necessary monitoring remains connected, and recovery does not depend on excessive patient work. Policy systems that measure only whether a medicine was listed or available at a particular moment can overstate effective access. Adding longitudinal observations of disruption, recovery and transferred burden would make medicines-access policy more sensitive to whether treatment is actually maintained.

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