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The Same Medicine in a Different Package Can Become a Different Task for the Patient: Recognition Disruption and Medication Error Prevention During Product Substitution

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Abstract

Product substitution is usually evaluated through pharmacological equivalence, economic consequences, policy acceptance, and adherence. These perspectives incompletely represent what substitution may change for a person who has learned to recognize and use a medicine through recurring visual, textual, tactile, contextual, and routine cues. A pharmaceutically equivalent replacement can preserve therapeutic intent while altering the recognition work required before the next dose is taken. This conceptual article develops a Human-Factors Recognition-Disruption Model to explain that transition. The model distinguishes cue change from recognition mismatch, mismatch from error, and error vulnerability from actual harm. It proposes that substitution becomes safety-relevant when altered product cues conflict with an existing recognition schema and require cognitive reconciliation through memory, written information, pharmacy communication, medication records, or other verification resources. Successful reconciliation can restore confident and correct use; unresolved uncertainty can instead produce hesitation, additional checking, inappropriate rejection, or conditions in which omission, duplication, or misselection becomes more plausible. The model therefore rejects both visual determinism and the assumption that pharmacological equivalence makes presentation changes behaviorally irrelevant. Its central implication is that safe substitution depends partly on how product change is made recognizable, interpretable, and verifiable within the patient's medication-use system. Research should consequently measure recognition disruption and reconciliation directly rather than infer them from adherence or switching outcomes alone.

Keywords: Product substitution, Medication recognition, Medication packaging, Human factors, Generic substitution, Medication errors

Introduction

Medication use is a form of human work performed within a wider sociotechnical system. Patients identify products, interpret instructions, organize regimens, coordinate medicines with daily routines, detect anomalies, and decide when additional checking is necessary. Human-factors and ergonomics approaches are useful precisely because they examine how such tasks arise from interactions among people, tools, information, environments, and system design rather than treating safety solely as a property of individual vigilance [1]. Medication errors likewise emerge from combinations of contributory conditions rather than from a single universal failure mechanism [2].

Product substitution creates a particularly instructive case. At the pharmacological level, an interchangeable medicine may retain the active ingredient, strength, dosage form, and intended therapeutic effect. At the level of everyday medication use, however, the patient's object of recognition may change. A different manufacturer, package design, tablet colour, shape, imprint, name presentation, or device can alter cues that have become embedded in routine use. A systematic review of

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variation in pill and package appearance found evidence that such changes can influence medication-taking behavior, although effects were heterogeneous and did not support a deterministic relationship between visual change and unsafe use [3]. The distinction matters: a changed cue is an exposure; recognition disruption is a possible cognitive response; an error is a further and contingent outcome.

Implementation research on automatic substitution similarly indicates that medication safety may depend on information transfer, traceability, communication, and the organization of medication-use processes in addition to pharmaceutical interchangeability [4]. These observations motivate a human-factors question that is narrower than asking whether generic or other product substitution is broadly safe. The question is how a familiar medicine becomes a different recognition task when its observable presentation changes, how the user reconciles the mismatch, and which external signals can support accurate recovery. The article therefore treats substitution neither as inherently hazardous nor as perceptually neutral. Its analytical focus is the intermediate work between noticing that something looks or seems different and deciding what medicine the product is and what action should follow.

Product substitution as a human-factors problem

Community-pharmacy substitution is not merely an inventory event. It also produces a communication episode in which the patient may need to understand why a product differs from the one expected and whether the difference is therapeutically meaningful. Survey evidence from Finnish community pharmacies shows that counseling about interchangeable medicines accompanies the substitution process, although the content delivered is not perfectly uniform [5]. From a human-factors perspective, this encounter can alter the information available for later recognition: a patient who has been told to expect a different package or tablet approaches that change with a different cognitive starting point from a patient who discovers it only when opening the medicine at home.

Patient choice also demonstrates that familiarity is only one component of substitution behavior. Among Finnish pharmacy customers, decisions about interchangeable medicines reflected several considerations, including price, availability, and previous familiarity [6]. Familiarity therefore should not be treated as a proxy for safety or as evidence that patients simply prefer branded appearance. Its theoretical relevance lies in the possibility that repeated exposure creates expectations about what a medicine should look like, where particular information should appear, and which cues normally confirm its identity.

Substitution policy can alter these expectations before the product is encountered. In a discrete-choice experiment, patient preferences for generic-substitution arrangements changed with characteristics of the policy and information environment [7]. Such findings indicate that acceptance is configured by more than the physical product. The informational conditions surrounding substitution help determine whether the replacement is interpreted as expected variation, an unexplained anomaly, or a potential medication problem.

Contemporary experience with biological-medicine substitution makes this informational component especially visible. Patients preparing for automatic substitution have reported variable knowledge and explicit information needs, showing that implementation requires active explanation rather than passive product exchange [8]. Insulin substitution further illustrates that the magnitude of task change is product-specific: concerns can involve not only medicine identity but also handling, delivery systems, and the practical meaning of an apparently equivalent replacement [9]. These examples should not be generalized indiscriminately to conventional oral generics. Their importance is conceptual. A substitution can change little about the user's task, or it can alter several elements that must be reinterpreted before routine use resumes.

A human-factors account therefore begins by asking what work was previously unnecessary. Before substitution, a highly familiar product may be taken with little conscious verification because recognition has become efficient through repetition. After substitution, additional operations may become necessary: inspecting the label, comparing the active ingredient or strength, remembering what the pharmacist said, consulting a medication list, or seeking clarification. The safety significance of substitution lies partly in this change in required work. Equivalence at the level of formulation does not guarantee equivalence in the cognitive effort required to establish identity.

Recognition cues in medication use

Recognition ordinarily depends on combinations of cues rather than a single definitive signal. Patients report noticing pill colour, shape, size, markings, and other

appearance characteristics, and many consider changes in these features meaningful enough to question [10]. Such observations do not establish that visual appearance dominates medication identification. They show that repeated perceptual features can become incorporated into a recognition schema: an internal expectation of what a familiar medicine typically looks like and how it is encountered.

The reliability of any cue depends on whether the user knows what it signifies. Research on pharmaceutical pictograms demonstrates that familiar visual representations can facilitate interpretation, while poorly understood symbols may produce incorrect interpretation or even unwarranted confidence [11]. The same principle applies more broadly to medication recognition. A visible difference becomes useful only when it can be interpreted. Conversely, a familiar appearance may become unsafe if it is trusted despite conflicting textual or contextual information.

Systematic evidence concerning pharmaceutical pictograms also shows that visual supplementation can improve textual comprehension in some circumstances, but its effect varies with design and user context [12]. Recognition should consequently be understood as multimodal. Printed medicine names, active ingredients, strength, packaging structure, tablet appearance, pharmacy labels, routine storage location, and prior explanation can converge to identify a medicine. Redundancy can increase confidence when signals agree; disagreement creates a demand for reconciliation. This distinction separates recognition cues from medication knowledge. A patient may understand what a medicine is for yet still be uncertain whether a newly supplied tablet is that medicine. Another may immediately recognize a familiar appearance without being able to state the active ingredient. Safe use therefore cannot be reduced either to visual familiarity or to factual knowledge. What matters is how available signals are combined at the moment an identity judgment is required.

Packaging, shape, colour, naming and familiarity

Observable product features differ in both stability and diagnostic value. A tablet's colour or shape can become highly familiar while remaining manufacturer-dependent. A package can preserve the same active ingredient while changing typography, branding, layout, quantity, or visual hierarchy. Product naming may remain stable at the generic level while a brand or manufacturer name changes. Pharmacy-applied labels may preserve prescription-specific information across products even when the manufacturer's presentation differs. These cues form an overlapping recognition environment rather than a hierarchy in which one feature is always authoritative.

Evidence linking appearance changes with adherence illustrates why this environment deserves attention. In a retrospective cohort of patients receiving angiotensin receptor blockers, changes in pill appearance were associated with differences in adherence [13]. That association does not establish that the appearance change caused nonadherence through recognition failure. It does establish that product presentation can coincide with behaviorally meaningful disruption and therefore warrants consideration as more than cosmetic variation.

Switching behavior provides a second caution against single-mechanism interpretation. Cohort evidence comparing switches involving branded, authorized-generic, and generic products found differences in subsequent switchback behavior [14]. A switchback can reflect dissatisfaction, expectations, cost, availability, clinical preference, administrative factors, or other influences; it is not itself an error. For the present model, such ambiguity is instructive. Behavioral endpoints observed after substitution cannot reveal whether a recognition mismatch occurred unless the recognition process is measured directly.

Visual communication is nevertheless modifiable. Randomized evidence shows that pictograms can be introduced experimentally to alter comprehension of prescription medication information [15]. This does not mean that pictograms solve product-recognition problems. It establishes a broader design principle: visual information can be intentionally structured and evaluated rather than treated as an incidental surface property.

Recent evidence on prescription medication information similarly emphasizes layout, organization, patient involvement, and other design characteristics that influence usability [16]. Earlier systematic work reached a related conclusion while also identifying important evidence gaps and variation in outcomes [17]. Digital medication labels extend the issue into another channel, where content structure and presentation can influence comprehension but do not simply reproduce the functions of physical packaging [18].

The substitution problem therefore concerns cue configuration rather than appearance alone. A change in

one familiar feature may be inconsequential when several stable cues confirm identity. The same change may be disruptive when it occurs alongside altered branding, unfamiliar package architecture, weak labeling, multiple medicines with similar presentations, or poor recollection of the pharmacy explanation.

The recognition consequences of several recurring cue configurations are differentiated in **Table 1**. The table does not rank cues by universal importance; it specifies why the same physical change can demand very different amounts of reconciliation work depending on what remains stable.

Table 1. Recognition configurations created when a familiar medicine is supplied in a changed product presentation

Product-cue configuration	What remains available to recognition	What changes at substitution	Likely mismatch signature	Reconciliation work created	Principal ambiguity to control
Peripheral package change with stable medicine identity cues	Medicine name, strength, dosage form, pharmacy label, familiar tablet	Manufacturer graphics, package colour, layout, branding	"The box is different, but the medicine inside appears familiar"	Brief confirmation that packaging rather than therapy changed	Assuming any packaging difference signals a different medicine
Changed tablet appearance with stable textual identity	Generic name, strength, dispensing label, indication/routine	Tablet colour, shape, size, imprint, manufacturer	"The label matches, but the tablet does not look like mine"	Cross-check tablet against authoritative textual or pharmacy information	Rejecting a correct substitute or trusting appearance over conflicting text
Changed manufacturer or brand naming with otherwise stable use task	Active ingredient, strength, dosage instructions, route	Manufacturer/brand identifier and associated visual identity	"The name I normally recognize is missing or secondary"	Translate between brand/manufacturer identity and active-ingredient identity	Treating naming difference as therapeutic difference
Several cues change simultaneously	Prescription-level information may remain stable	Package, branding, tablet appearance, layout and manufacturer change together	"Very little of the familiar presentation is preserved"	Active comparison across label, medicine list, prior instruction and/or pharmacy confirmation	Greater cognitive load and uncertainty without implying inevitable error
Familiar-looking product with weak confirmatory information	Strong perceptual familiarity	Text may be difficult to locate, poorly understood or insufficiently checked	"It looks right, so verification feels unnecessary"	Deliberate confirmation despite perceptual fluency	False reassurance from appearance similarity
Substitution that changes practical handling as well as presentation	Therapeutic purpose may remain stable	Presentation plus device, preparation or administration features	"The medicine may be equivalent, but the use procedure is not fully familiar"	Reconcile identity and technique as separate tasks	Correct identification paired with incorrect use procedure

Table note: Cue configurations are conceptual syntheses derived from the manuscript's recognition-disruption logic. They describe conditions requiring different forms of verification; they do not assign probabilities of adherence, error, or harm.

What changes when a familiar product is replaced

The immediate consequence of substitution is not necessarily confusion. It is a change in the correspondence between the product encountered and the product expected. When the new presentation remains sufficiently compatible with the user's recognition schema—or when the change has been anticipated through counseling—the substitution may be absorbed with little additional effort. When salient expectations are violated, the patient encounters a mismatch that must be interpreted.

Appearance research is consistent with such heterogeneity. The systematic evidence does not show that every visual change generates a behavioral problem [3]. Instead, it suggests that effects depend on the medicine, patient, setting, and nature of the change. Recognition disruption should therefore be defined narrowly as a state in which the cue pattern presented by

a medicine no longer provides the user with the expected degree of confidence about its identity or correct relation to the existing regimen. It does not require a subsequent mistake.

Prospective evidence on generic medicines reinforces this separation. Among patients followed after percutaneous coronary intervention, perceptions of generic medicines changed over time and did not translate into a simple relationship with adherence [19]. Patients can therefore encounter unfamiliarity or hold reservations without necessarily using medicines incorrectly. Familiarity may also grow after repeated exposure, converting what was initially an anomalous product into the new expected presentation.

Several transitions are consequently possible after substitution. A user may notice no meaningful mismatch. A mismatch may be noticed and immediately resolved from the dispensing label. It may prompt recollection of prior pharmacy counseling. It may lead to comparison with a medication list, packaging information, an electronic record, or another trusted source. It may remain unresolved but cause the patient to delay taking the dose and seek clarification. Alternatively, an apparently familiar cue may suppress additional checking even when another identifier differs. These transitions cannot be recovered reliably from adherence, switchback, or dispensing data alone because the same observable behavior can result from different cognitive processes.

The theoretical significance of the substitution episode is thus temporal as well as perceptual. Before replacement, recognition may be fast and largely habitual. During the first encounters with the new product, recognition can become deliberate. After successful reconciliation and repeated correct use, the new cue pattern may itself become familiar. The same substitution may therefore impose substantial recognition work initially and almost none later.

Recognition disruption and cognitive reconciliation

Recognition disruption begins when expected and encountered cues fail to align sufficiently for confident identification. Similarity-based medication research provides an adjacent mechanism: look-alike and sound-alike names can create medication-selection problems because perceptual or linguistic resemblance affects identification and differentiation [20]. Product substitution presents a different configuration—the problem may be excessive difference from a known medicine rather than excessive similarity to another—but both illustrate that medication identity is mediated by how signals are perceived and interpreted.

Look-alike medication incidents in perioperative environments provide further evidence that presentation characteristics can participate in medication errors, while also showing that risk depends on workflow, storage, labeling, checking practices, and other system conditions [21]. These findings cannot be transferred as incidence estimates to self-managed substitution. Their theoretical value is to demonstrate that perceptual information becomes safety-relevant through the surrounding task system.

Recognition is also fallible even when sophisticated visual-processing technology is used. Experimental assessment of image-based medication recognition has shown that medication identification can vary with visual input conditions [22]. Human recognition cannot be inferred from artificial-intelligence performance, but the comparison illustrates an important boundary: appearance is informative without being a self-authenticating identifier.

The model therefore introduces cognitive reconciliation as the work performed after a mismatch is detected. Reconciliation asks whether the changed product can be brought into correspondence with the medicine already represented in the patient's regimen. It may involve reading the active ingredient or strength, comparing the pharmacy label with an existing list, recalling counseling, checking an image or electronic source, inspecting an imprint, or contacting the pharmacy.

Mismatch detection and reconciliation are analytically separate. A patient can detect that the product looks different yet resolve the discrepancy correctly. Another patient may detect no mismatch because the new presentation is sufficiently similar or because the relevant cue is not routinely used. A third may notice a difference but rely on an unreliable signal. These distinctions explain why visual change should neither be dismissed nor equated with error.

Cognitive reconciliation also has a stopping condition: the user reaches enough confidence to act, decides that uncertainty remains too high and seeks assistance, or proceeds despite unresolved uncertainty. Human factors enters at this point because the burden of reconciliation is partly designed by the system. Information visibility, consistency across records, pharmacy communication, packaging legibility, medication-list accuracy, and access to clarification alter how much work is necessary

and what resources are available when expectation and presentation diverge.

Development of the human-factors model

The Human-Factors Recognition-Disruption Model integrates these distinctions around a conditional sequence rather than a deterministic error chain. Its starting state is a pre-existing recognition schema: the learned combination of product features, names, routines, contextual cues, and expectations through which a person ordinarily recognizes a medicine. Substitution creates an encountered cue configuration that may preserve, alter, remove, or add familiar signals. The comparison between the schema and the encountered product can produce sufficient correspondence, a detectable mismatch, or ambiguous partial correspondence.

Pharmacy counseling is one resource that can modify this comparison before the new product is encountered. Contemporary pharmacy scholarship has questioned whether greater standardization of medication counseling could reduce variation in what patients receive and understand [23]. Within this model, counseling is not assumed to prevent errors. Its role is more specific: it can alter expectation, making a forthcoming change recognizable as an intended substitution rather than an unexplained anomaly.

The next stage depends on reconciliation resources. A detected mismatch can initiate checking of textual identity, strength, records, package information, prior instructions, or pharmacy advice. These resources are not equally available or reliable, and their effectiveness cannot be assumed to persist simply because an intervention initially worked. Evidence from pharmacy-based safety redesign demonstrates that intervention effects may attenuate over time, underscoring the importance of sustainability and implementation rather than one-time exposure [24].

The model also accommodates interacting system conditions. Analysis of medication incidents involving high-alert medicines shows that error-producing circumstances can span tasks, technologies, work processes, and contextual factors rather than residing within one isolated cognitive failure [25]. Applied to substitution, this means that recognition disruption becomes consequential through configurations. An altered cue may remain harmless when authoritative confirmation is visible and understandable. The same altered cue may be more difficult to reconcile when several medicines are present, labels are hard to interpret, records disagree, prior counseling was absent or forgotten, or the user lacks timely access to clarification. The resulting theoretical proposition is intentionally bounded: product substitution creates additional medication-safety vulnerability when the encountered cue configuration generates a recognition mismatch and the available reconciliation resources are insufficient, inaccessible, misunderstood, or bypassed before medication-use action occurs. This statement does not predict that error must follow. It identifies where the patient's task changes and where system design can influence recovery.

Figure 1 represents this logic as a field rather than a pipeline. The central feature is the comparison between a pre-existing recognition schema and the cue configuration presented by the substituted product. From that comparison, correspondence, mismatch, and ambiguity remain possible; mismatch can trigger iterative reconciliation using several external resources before an action is selected. The model preserves a direct route to correct use, a route through successful verification, and unresolved states that remain vulnerable without being labeled as errors.

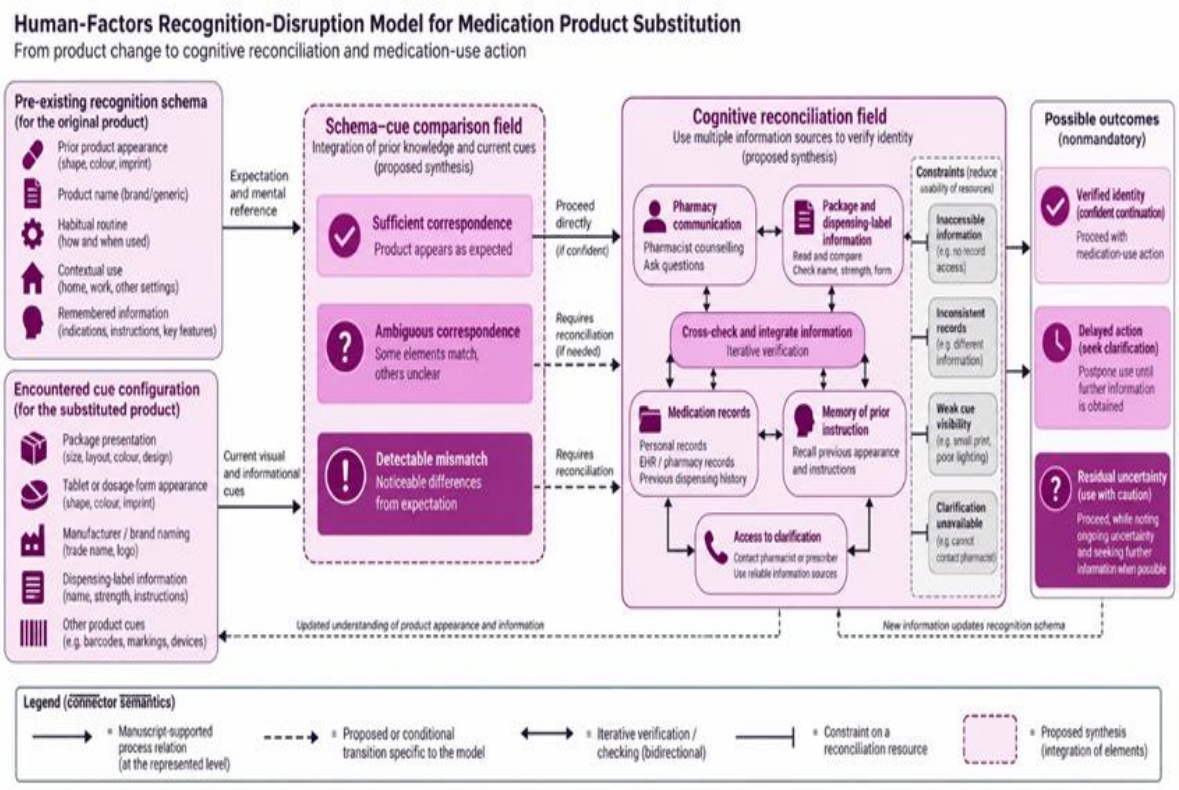


Figure 1. Recognition-disruption field linking changed product cues with cognitive reconciliation and medication-use action

Error pathways after substitution

Recognition disruption does not specify a single downstream outcome. Community-pharmacy incident data show that medication-use problems can involve both customer- and professional-originating errors, while counseling and assessment may function as protective interruptions before unsafe use proceeds [26]. Within the present model, this supports a branching account. A person who notices a mismatch may verify the medicine correctly, postpone use while seeking clarification, reject a correct substitute, or proceed with residual uncertainty. Only some of these states create conditions in which omission, duplication, or selection of the wrong product becomes more plausible.

Verification can also intercept an emerging error. Clinical decision-support research shows that appropriately targeted checking systems can identify wrong-drug and look-alike/sound-alike problems before completion of the medication-use process [27]. The setting differs from self-managed product substitution, but the principle is relevant: uncertainty does not become harm automatically when a usable verification layer remains available.

The protective value of verification is nevertheless conditional. Longitudinal evidence from barcode medication administration shows that safety technology depends on actual use, workflow integration, and adherence to the checking process [28]. A verification resource that is unavailable, ignored, difficult to use, or treated as optional cannot be assumed to protect simply because it exists. **Figure 2** therefore distinguishes recognition disruption from both unsafe action and successful recovery.

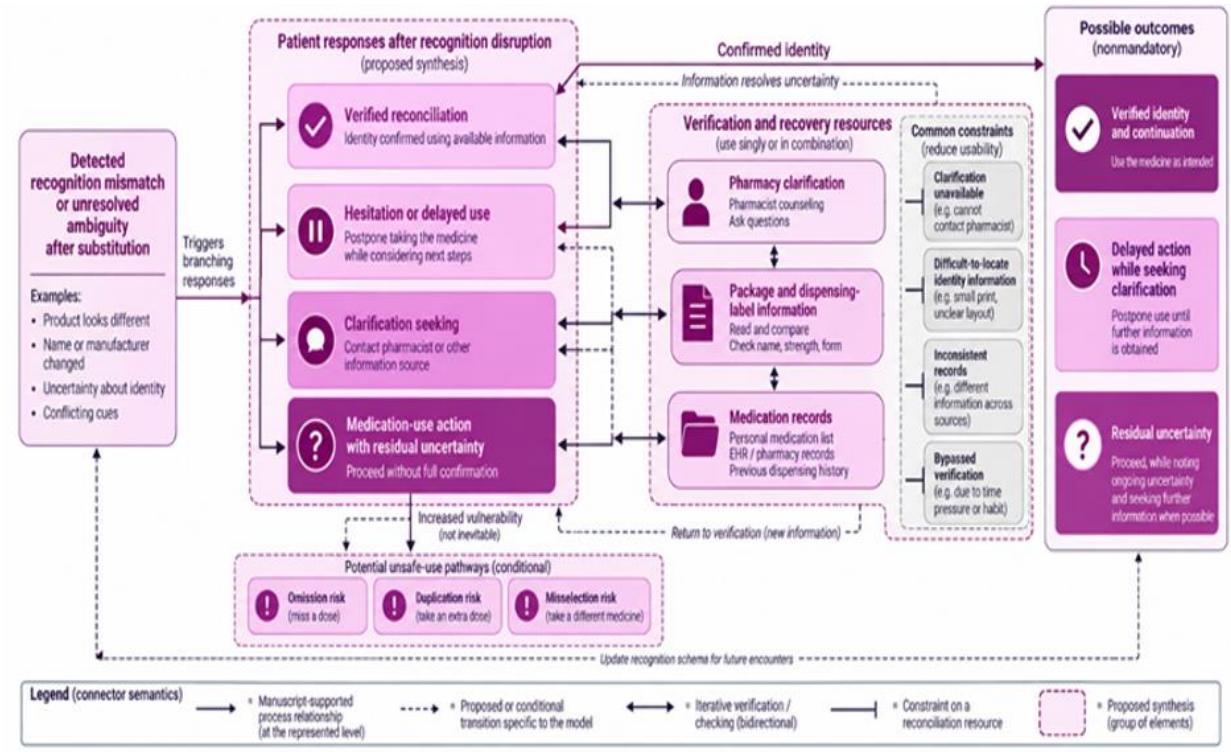


Figure 2. Conditional error and recovery routes after medication-recognition disruption

Compensatory signals from pharmacy, packaging and records

A recognition mismatch becomes easier to resolve when an external source supplies identity information that is both authoritative and usable. Pharmacy communication can prepare patients for an appearance change before the first encounter with the substitute, while package and dispensing-label information can support later checking. These resources operate as compensatory signals because they reduce reliance on memory or appearance alone.

Medication records provide another verification route, but they are not infallible. After hospital discharge, discrepancies can occur between documented medication lists and what patients actually use [29]. A record should therefore function as one source within reconciliation rather than as unquestioned ground truth. Structured medication documentation can improve the organization of review and problem identification, as demonstrated in randomized evaluation of a drug-related-problem-oriented record [30]. Its relevance here is procedural: verification is strengthened when relevant information is organized so that conflicting signals can be detected and resolved.

The most robust reconciliation environment is consequently redundant rather than singular. Packaging, pharmacy communication, and records should reinforce one another while retaining mechanisms for detecting disagreement. When one source is weak or inconsistent, another may allow recovery before the patient acts on an uncertain identification.

Design countermeasures

The model suggests that countermeasures should target the work created by substitution, not merely preserve visual sameness. One strategy is anticipatory communication: tell the patient that a change will occur and identify which features may differ while emphasizing stable authoritative identifiers. A second is cue design: make medicine name, strength, dosage form, and other critical information sufficiently visible that a changed appearance can be reconciled without extensive search. A third is verification support: ensure that medication records, dispensing labels, and clarification channels can be used when confidence remains low.

Countermeasures also need to acknowledge implementation durability. Pharmacy-based human-factors redesign can change medication-selection behavior, but intervention effects should be evaluated

over time rather than assumed from initial uptake [31]. Verification technologies likewise require integration into actual workflow. The practical objective is not to eliminate all variation in product appearance; it is to prevent variation from becoming an unexplained and difficult-to-resolve identity problem.

Table 2 translates these principles into article-specific intervention positions along the recognition-disruption process.

Table 2. Countermeasure positions within the recognition-disruption and reconciliation process

Countermeasure position	Recognition problem addressed	Intended human-factors function	Example implementation form	Failure condition requiring attention
Before substitution is encountered	Unexpected change in familiar cues	Modify expectation before mismatch occurs	Explicit pharmacy explanation that appearance/manufacturer may change while medicine identity remains stable	Explanation absent, forgotten, too generic, or delivered without identifying the actual change
At first visual/product encounter	Familiarity disrupted by new packaging or dosage-form appearance	Make authoritative identity cues easier to locate than incidental visual differences	Clear prominence of medicine name, strength, dosage form, and dispensing-label information	Critical identifiers visually weak, cluttered, or difficult to interpret
During detected mismatch	Patient recognizes that the product differs but cannot resolve why	Support rapid cognitive reconciliation	Comparison with pharmacy label, package information, medication list, or verified digital record	Sources disagree or the patient cannot determine which source is authoritative
During unresolved uncertainty	Identity remains uncertain after initial checking	Interrupt action and enable clarification	Accessible pharmacy contact, pharmacist counseling, structured clarification pathway	Clarification unavailable, delayed, or treated as excessive patient burden
During repeated substitutions	Recurrent cue change continually resets familiarity	Reduce cumulative recognition burden while preserving traceability	Consistent explanation practices and continuity of accessible medicine records	Repeated unexplained changes produce reliance on ad hoc recognition strategies
After verification or correction	New cue configuration remains unfamiliar	Update the patient's recognition schema for future encounters	Reinforcement of the new appearance/name relationship during correct use	Correct reconciliation is not consolidated, leaving the next encounter equally uncertain

Table note: Countermeasure positions are proposed applications of the Human-Factors Recognition-Disruption Model. They do not imply that any single intervention has established effectiveness across all medicines, patients, or substitution systems.

Research and practice implications

Research should measure the intermediate states that the model distinguishes. Studies that record only adherence, discontinuation, switchback, or error cannot determine whether recognition disruption occurred. Future designs should assess which cues changed, whether the patient detected a mismatch, what checking behavior followed, which external resources were used, whether identity was successfully verified, and only then what medication-use action occurred.

A particularly discriminating test would manipulate both cue discontinuity and reconciliation support. If the model is correct, the effect of changed appearance should depend partly on whether the new presentation is anticipated and whether usable verification resources are available. Contemporary substitution studies already show substantial information needs across different patient groups [8, 9]. The next step is to connect such information conditions directly to recognition and reconciliation behavior rather than treating knowledge, acceptance, and adherence as interchangeable endpoints. Practice implications are similarly distributed. Pharmacists can reduce unexpectedness and provide clarification; manufacturers can improve the accessibility of authoritative product identifiers; medication-record systems can support cross-checking; and healthcare organizations can design substitution policies that recognize the patient's role in verification. Medication safety is best treated as an interconnected

pathway involving several actors and transitions rather than a single act of correct dispensing [32].

Results and Discussion

This article proposes that product substitution can alter the cognitive task required to identify and use a medicine even when therapeutic intent remains unchanged. Its principal contribution is the separation of four events that are often collapsed: cue change, recognition mismatch, cognitive reconciliation, and medication-use outcome. The distinction prevents two opposite errors of interpretation. One is to regard presentation changes as clinically irrelevant because the medicine is pharmaceutically equivalent. The other is to assume that unfamiliar appearance itself produces medication error.

The evidence supports a more conditional account. Research on pill and package appearance shows that visual change can influence behavior, but effects are heterogeneous [3]. Individual cohort studies linking appearance changes with adherence and switching outcomes further demonstrate that an observed post-substitution behavior does not identify its mechanism [13, 14]. Price, availability, prior beliefs, dissatisfaction, nocebo expectations, counseling quality, and administrative features can all provide alternative explanations.

The Recognition-Disruption Model therefore makes a narrower claim. A substitution becomes human-factors relevant when it alters cues used for recognition sufficiently to create mismatch or ambiguity. Whether that state becomes consequential depends on reconciliation resources, task conditions, and what action occurs before uncertainty is resolved. The model is strongest where patients actively use appearance, naming, packaging, or routine context as part of medicine identification. It should be weaker where substitution is anticipated, authoritative identifiers remain prominent, or verification is immediate and easy.

Several limitations follow from the evidence base. Much of the direct substitution literature measures adherence, preferences, acceptance, switching, or counseling rather than recognition itself. Evidence from look-alike medicines, barcode systems, decision support, medication reconciliation, and other safety domains therefore informs mechanism plausibility and design reasoning but cannot be treated as direct validation. The model is consequently a proposed theoretical synthesis, not a validated causal pathway.

Its usefulness depends on whether it generates findings that competing explanations would not. A study that directly measures cue change, detected mismatch, reconciliation behavior, verification success, and subsequent action could show that recognition disruption adds explanatory value beyond cost, beliefs, or preference. Equally, repeated failure to observe such mediation where salient product cues change would weaken the account. The model is intended to be testable in that sense.

The practical implication is not a demand for identical medicines or permanently standardized appearance. Product availability, manufacturing, regulation, procurement, and cost all make variation unavoidable and sometimes desirable. The more defensible safety objective is to ensure that variation remains interpretable: when a product changes, the medication-use system should make the change recognizable, the stable identity verifiable, and unresolved uncertainty recoverable before action.

Conclusion

The same medicine in a different package can become a different task for the patient when substitution changes cues that previously supported rapid recognition. That task difference does not itself constitute an error. It creates a need for reconciliation between what the patient expects and what is encountered.

The Human-Factors Recognition-Disruption Model locates medication-safety vulnerability in the interaction between cue change, mismatch detection, available verification resources, and medication-use action. Product substitution is therefore most likely to become safety-relevant when a meaningful recognition mismatch occurs and the patient cannot readily reconcile it before acting. Safe substitution depends less on preserving every familiar visual feature than on making change expected, identity information usable, and uncertainty recoverable.

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