Annals of Pharmacy Practice and Pharmacotherapy
ISSN: 3062-4436
2023, Volume 3, Issue 2, Page No: 42-50

Available online at: www.galaxypub.co/page/journals

Galaxy Publication

From Latent System Conditions to Patient Injury: How Medication-Process Deviations Become Harm and Where Recovery Remains Possible

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Received: 19 May 2023; **Revised:** 25 August 2023; **Accepted:** 29 August 2023

ABSTRACT

Medication-process deviations are frequently treated as interchangeable indicators of medication harm, although many never alter drug exposure and many exposure changes are detected or corrected before injury occurs. The clinically important question is therefore not simply whether an error occurred, but how a deviation interacts with the work system, the resulting exposure, patient susceptibility, detection timing, and remaining opportunities for recovery. This Current Opinion separates process failure from harm realization across prescribing, dispensing, administration, monitoring, communication, and subsequent patient response. It argues that latent conditions configure which deviations arise and whether they propagate; altered or omitted medication exposure provides a critical link between process failure and clinical consequence; and recovery remains possible only while a deviation is detectable and its consequences remain reversible or mitigable. Human-factors adaptations and technologies can both strengthen and weaken safety depending on how they alter workload, information flow, attention, and coordination. The proposed synthesis therefore treats medication harm as a conditional trajectory rather than the inevitable endpoint of a process deviation. This distinction has implications for measurement, intervention evaluation, safety-system design, and attribution of medication-related injury.

Keywords: Medication safety, Medication errors, Medication-related harm, Patient safety, Human factors, Medication-use process

How to Cite This Article: Lin M, Thompson D, Haddad N. From Latent System Conditions to Patient Injury: How Medication-Process Deviations Become Harm and Where Recovery Remains PossibleAnn Pharm Pract Pharmacother. 2023;3(2):42-50. https://doi.org/10.51847/0ENPu55Ovu

Introduction

Preventable medication harm remains a substantial safety problem across healthcare settings, but pooled estimates combine events arising through very different medication-use pathways and show marked heterogeneity in severity, setting, and stage of the medication process [1, 2]. A prevalence estimate can therefore establish burden without revealing why one medication-process deviation remains clinically inconsequential while another culminates in injury. This distinction matters because a medication error may be intercepted before exposure changes, an altered exposure may be clinically trivial, or a potentially serious deviation may be corrected before measurable injury develops.

Empirical work that separates potential severity from actual patient harm illustrates the importance of this distinction. In paediatric inpatient medication use, structured assessment of medication errors and subsequent harm required more than identifying a prescribing or administration deviation; clinical plausibility and realized

injury had to be assessed separately [3]. The same logic should apply more broadly. Error occurrence, exposure consequence, injury, and preventability represent related but non-equivalent observations.

The central question is consequently conditional: which combinations of latent system conditions, process deviations, exposure consequences, patient vulnerability, and failed recovery convert a medication-process problem into actual injury? The answer cannot be reduced to a single "defence layer," medication-error count, or high-risk label. It requires attention to severity, timing, detectability, reversibility, and the capacity of professionals, technologies, organizations, and patients to interrupt a developing harmful trajectory.

A deviation is not yet an injury

Medication safety begins with the medication-use process, but a departure from intended practice does not by itself establish patient harm. Deviations can originate upstream, including in the interpretation or application of clinical guidance. Analysis of national patient-safety incident reports has shown that guideline-related activities can themselves contribute to medication errors through problems in locating, interpreting, reconciling, or implementing recommendations [4]. Such reports identify failure mechanisms, although they cannot establish population incidence or demonstrate that every reported deviation reached the patient.

The same distinction is visible at administration. Direct observation in paediatric inpatients showed that medication-administration error risk varied with clinical and medication-related circumstances rather than occurring at a constant rate across administrations [5]. An administration error is therefore better understood as a process event whose importance depends on what was administered or omitted, by how much, at what time, to whom, and whether the deviation was recognized before a consequential exposure developed.

Outpatient and ambulatory evidence reinforces the problem of treating "medication error" as a unitary outcome. Reported prevalence varies substantially across settings, definitions, medication-use stages, and methods of ascertainment [6]. These differences reflect true variation as well as measurement variation. They also indicate why medication-safety evaluation should distinguish four observations: the process deviation, the resulting exposure consequence, the clinical injury, and whether that injury was preventable.

For this article, a *process deviation* is an observed departure from the intended or clinically appropriate medication-use process. An *exposure consequence* is a downstream alteration in medication exposure, including inappropriate receipt, omission, delay, continuation, dose, route, or timing. Monitoring failures may permit such exposure to persist or delay recognition of its consequences. *Harm realization* refers to clinical injury for which the medication-process trajectory is a plausible contributor after competing explanations are considered. These definitions are analytical tools rather than a new universal taxonomy.

Latent conditions configure which deviations matter

Process deviations occur within work systems. Human-factors guidance emphasizes that safety cannot depend exclusively on individual vigilance: work should be designed to reduce opportunities for failure, support detection, and mitigate consequences when failure occurs [7]. Latent conditions are therefore relevant not because every system imperfection directly causes harm, but because staffing, workflow, information availability, task design, technology, and coordination can change the probability that a deviation occurs and the likelihood that it will propagate.

Studies comparing *work as imagined* with *work as done* show why simple compliance models are inadequate. Community-pharmacy dispensing involves adaptations to real workload, delegation, interruptions, and resource constraints that may differ from formal procedures [8]. Medication reconciliation at discharge similarly exhibits performance variability because information flows, professional responsibilities, timing, and available resources are coupled rather than independent [9]. High-risk intravenous insulin processes also contain practical adaptations absent from written procedures [10]. These findings should not be interpreted as evidence that adaptation is inherently unsafe. Some adaptations enable work to succeed; others remove checks, increase ambiguity, or create conditions under which a subsequent deviation becomes harder to detect.

Technology changes the same system rather than standing outside it. Automated dispensing cabinets, barcode medication administration, and closed-loop electronic medication-management systems can strengthen access control, documentation, and verification, yet their effects depend on implementation and may be accompanied by workarounds or new dependencies [11]. A systematic review of barcode medication administration similarly found that adoption and safe use depend on alignment among technical design, clinical workflow, infrastructure,

and users [12]. Technology can therefore alter several points in the harm trajectory simultaneously: occurrence of the initial deviation, detectability, response latency, and the possibility of recovery.

Medication alerts illustrate this conditionality particularly clearly. Artificial-intelligence approaches are increasingly used to suppress or reprioritize alerts, but the literature remains dominated by algorithmic or process performance rather than demonstrated reductions in medication-related injury [13]. Alert fatigue is likewise sensitive to interaction design, clinical role, specificity, and workflow [14]. An alert is consequently not a safety benefit merely because it exists. Its value depends on whether it appears for a clinically meaningful condition, reaches an appropriate decision-maker, is interpretable in context, and triggers action before the underlying exposure becomes consequential.

Exposure is the hinge between process failure and patient harm

The crucial transition between process deviation and patient injury is a clinically meaningful change in medication exposure. A prescribing error that is corrected before dispensing, a dispensing discrepancy intercepted before administration, or an administration-recording problem that never changes what the patient receives may remain process failures without becoming exposure failures. Conversely, an omission, excessive dose, wrong route, clinically important delay, or inappropriate continuation can alter the patient's pharmacological state; failure to perform necessary monitoring can allow such changes to persist undetected even when the original deviation appears superficially similar to other errors.

This exposure-centered distinction helps explain why potential severity and actual injury diverge. The same nominal deviation can have different implications depending on medicine, dose, route, duration, therapeutic index, timing relative to disease state, and whether compensating actions occur. The system also shapes how long that altered exposure persists. A barcode warning, pharmacist intervention, laboratory result, nurse observation, clinician review, or patient report may interrupt the trajectory. A poorly aligned workflow or ignored low-specificity alert may instead allow it to continue.

Accordingly, three transitions should remain separate. First, latent conditions and immediate actions produce or permit a process deviation. Second, the deviation may or may not generate a clinically relevant exposure consequence. Third, that exposure may or may not become injury, depending on patient susceptibility and whether recovery occurs before the consequence becomes irreversible or no longer meaningfully modifiable. None of these transitions should be assumed to have a fixed probability across medicines or settings.

The evidence reviewed so far also argues against viewing defences as independent slices that simply accumulate protection. The same staffing shortage can affect prescribing review, barcode compliance, alert response, and monitoring; the same fragmented information flow can impair medication reconciliation and later detection. A technology that strengthens one point may create a new dependency elsewhere. The clinically relevant unit is therefore the evolving trajectory and its recoverability, not the number of nominal controls surrounding an error.

The relationships established in these sections can now be organized according to whether a process deviation changes exposure, whether meaningful detection remains possible, and whether the trajectory has already crossed into patient injury.

Table 1. Conditions determining whether medication-process deviations remain process events or progress toward patient harm

Medication-process situation	Immediate process failure	Possible exposure consequence	Detection opportunity before injury	Factors affecting recoverability	Permitted interpretation of patient outcome
Guideline interpretation or application problem	Incorrect, conflicting, inaccessible, or misapplied instruction	Inappropriate medicine choice, dose, timing, monitoring plan, or no exposure change if intercepted	Prescriber review, pharmacist clarification, multidisciplinary discussion, decision support	Clarity of guidance, access to expertise, time before treatment, ability to revise order	A guideline-related deviation is a potential upstream contributor; injury requires evidence of downstream exposure and clinical consequence
Dispensing workflow deviation	Selection, preparation, labelling, verification, or communication departs from intended process	Wrong product/strength/instructions, delayed supply, or no patient exposure if detected	Pharmacy checking, barcode/product verification, patient or clinician query	Workload, task design, interruptions, delegation, information completeness	A dispensing deviation may be adaptive, erroneous, or clinically neutral depending on whether exposure changes

Medication-administration deviation	Dose, route, timing, omission, preparation, or administration procedure differs from intended care	Direct alteration of delivered medication exposure	Bedside checking, barcode systems, observation, rapid clinical recognition	Drug characteristics, timing, detectability, ability to stop/reverse treatment	Administration error establishes a process event; severity and actual injury remain separate determinations
High-risk medication process under operational pressure	Local adaptation or workaround modifies prescribed sequence	Potentially substantial exposure change if adaptation fails	Continuous monitoring, laboratory data, staff cross-checks, escalation	Therapeutic window, monitoring frequency, workload, expertise, reversibility	High-risk context increases potential consequence but does not make every adaptation harmful
Barcode, automated dispensing, or closed-loop technology use	Design-workflow mismatch, bypass, workaround, incorrect configuration, or dependency failure	May prevent exposure errors or create/preserve unintended exposure	Automated verification plus human review	System usability, infrastructure, alert quality, data integrity, fallback procedures	Technology modifies the trajectory; implementation cannot be equated automatically with reduced injury
Medication-alert or decision-support signal	Relevant warning absent, excessive low-value warnings, poor prioritization, or inappropriate override	Unsafe exposure may proceed, or a benign deviation may be interrupted	Alert review, pharmacist interpretation, clinician reassessment	Specificity, clinical role, timing, cognitive load, actionability	Alert generation or model performance is a process measure; patient benefit requires timely clinically appropriate action

Note: The table separates process deviation, medication exposure, detection, and recoverability. These categories are analytical distinctions used in this article and do not imply a validated numerical risk score.

Figure 1 depicts the nonlinear trajectory: interacting system conditions can converge on a deviation, several recovery openings may appear or disappear over time, and a harmful exposure can sometimes be corrected before injury becomes fixed.

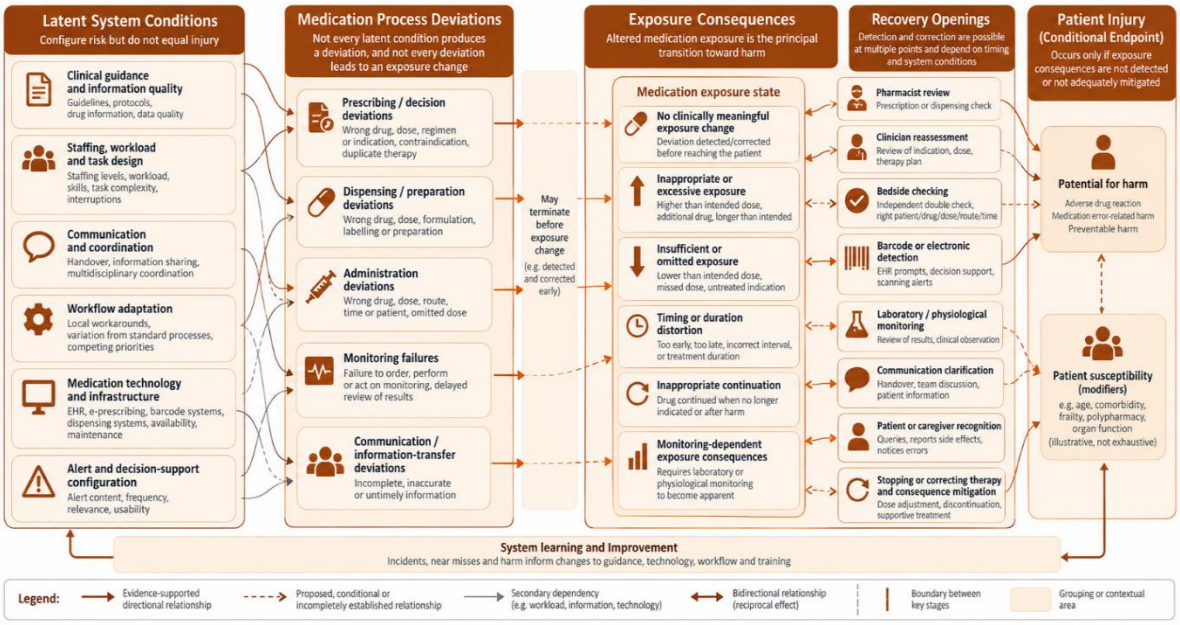

Figure 1. Diverging medication-safety trajectories around exposure change and recoverability

Patient vulnerability changes the consequence of the same exposure

Medication exposure does not have a uniform clinical consequence. In older adults, medication-related harm reflects physiological reserve, multimorbidity, treatment complexity, cognition, function, and the feasibility of monitoring and self-management; medication count alone is therefore an incomplete representation of susceptibility [15]. Prospective post-discharge evidence confirms that medication-related harm can be common and potentially preventable in older patients [16]. Frailty further modifies the likelihood that harm generates healthcare use, although the size of this association depends partly on how frailty is operationalized [17].

Interaction burden provides another example of the distinction between potential hazard and realized injury. Potentially clinically important drug–drug interactions are frequent in community-dwelling older adults, but identification of an interaction does not establish that exposure changed sufficiently to produce an adverse outcome [18]. Prescribing cascades illustrate a different pathway: an unrecognized medication effect may be interpreted as a new condition and treated with another medicine, extending exposure and potentially increasing vulnerability [19].

Downstream outcomes require the same caution. Drug-related readmissions occur in older adults, yet attribution methods vary substantially across studies [20]. Vulnerability should therefore be treated as a modifier of what follows a medication-process deviation, not as proof that the deviation caused a subsequent event.

Recovery remains possible, but only while time and detectability permit it

A harmful trajectory can be interrupted only while there remains something clinically meaningful to detect, correct, compensate for, or mitigate. Analysis of older patients with potentially preventable drug-related admissions showed that some medication errors were detectable during an earlier medication review, whereas others developed afterwards or persisted because recommendations were not implemented [21]. Recovery opportunity is consequently time-dependent.

Recognition is also imperfect. Doctors did not reliably identify which older patients would subsequently experience medication-related harm in one multicentre cohort [22]. Pharmacists considering a medication-harm prediction tool nevertheless emphasized that useful risk information must fit workflow, remain interpretable, and support rather than displace professional judgement [23]. Detection capacity therefore depends on both information and the ability to act on it.

Evidence for common safety interventions further demonstrates that adding a nominal defence does not guarantee patient benefit. A systematic review of medicines optimisation in frail primary-care populations found extremely limited eligible evidence [24]. Medication reconciliation at admission did not reduce 30-day hospital returns in a randomized trial [25], while evidence that double checking reduces medication-administration errors remains inconsistent and does not establish a reduction in medication-related patient harm [26].

Enhanced medication reconciliation more consistently affects discrepancies and other proximal process outcomes than downstream adverse-drug-event outcomes [27]. In a cluster randomized trial, electronic medication reconciliation markedly reduced medication discrepancies without significantly reducing adverse drug events [28]. Video telemedicine consultation likewise did not significantly reduce prescribing errors compared with telephone consultation in the studied paediatric emergency-care network [29]. These findings make process success and clinical recovery analytically separable.

The evidence therefore supports several different recovery functions: designing hazards out of work, trapping deviations before exposure changes, detecting altered exposure, correcting treatment, mitigating consequences, and learning from preceding failure [30]. Healthcare-resilience research similarly describes anticipatory, responsive, recovery, and learning capacities distributed across different system levels [31]. A transition-of-care medication-safety service for patients using monitored dosage systems illustrates the same distinction: transfer activity can improve while the downstream effect on discrepancies or adverse events remains uncertain [32].

Recovery opportunities can consequently be compared by where they intervene and by what must remain true for them to prevent injury.

Table 2. Where medication-harm trajectories can still be interrupted

Recovery position	What must be detected	Typical corrective function	Dependency that can defeat recovery	Clinical interpretation
Before altered exposure	Incorrect order, product, instruction, preparation, or intended administration	Clarify, cancel, correct, substitute, or reissue	Missing information, workload, unclear responsibility, delayed review	Interception can prevent exposure altogether
After exposure begins but before injury	Dose, route, timing, duration, omission, interaction, or monitoring abnormality	Stop, modify, replace, monitor, or reverse treatment	Delayed recognition, weak monitoring, poor escalation, limited reversibility	Recovery remains possible if exposure consequences are still modifiable
During emerging clinical deterioration	Plausible medication contribution to symptoms, physiology, or laboratory change	Diagnose, withdraw or modify treatment, provide supportive or antidotal care where appropriate	Competing diagnoses, attribution error, fragmented information	Recovery may attenuate rather than completely prevent harm

During transitions of care	Unresolved discrepancy, changed therapeutic intent, missing monitoring plan, or communication failure	Reconcile information and transfer responsibility	Recommendation not implemented, poor handover, inaccessible community follow-up	Process correction does not guarantee fewer adverse events
Across the work system	Recurrent pattern of deviations, workarounds, alert burden, or failed detection	Redesign workflow, technology, staffing, information, or escalation processes	Shared dependencies across nominal safety controls	Resilience depends on coordinated capacities rather than the number of defences

Note: Recovery position describes when interruption remains clinically plausible; it is not a validated severity scale or quantitative risk score.

Figure 2 shows how recovery capacity can contract over time and is distributed across people, information systems, organizations, monitoring processes, and patients rather than residing in a single safety barrier.

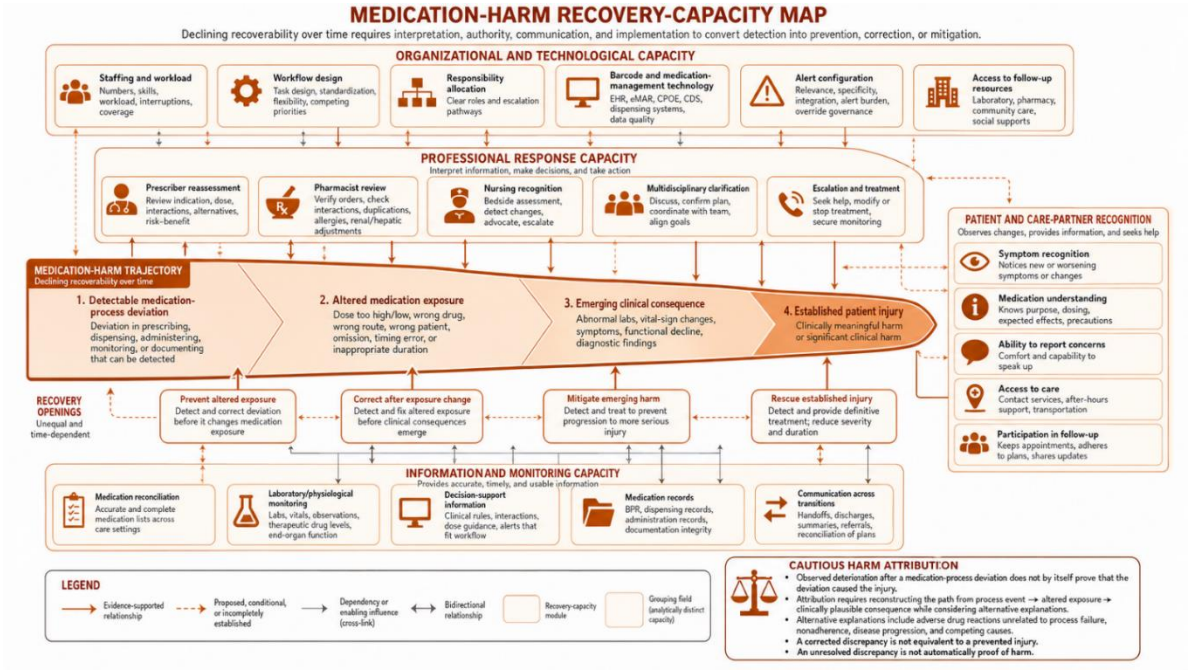

Figure 2. Recovery capacity contracts as medication exposure becomes harder to detect or reverse

Attributing harm and making the synthesis testable

Observed deterioration after a medication-process deviation does not by itself establish that the deviation caused the injury. Estimates of medication-related hospital admission vary substantially according to whether investigators use detailed chart review, administrative data, or other attribution approaches [33]. Attribution therefore requires reconstruction of the sequence from the process event to altered exposure and then to a clinically plausible consequence, while considering adverse drug reactions unrelated to process failure, nonadherence, disease progression, and other competing causes.

The distinction is particularly important when an intervention changes a process measure. Medication reconciliation can reduce discrepancies without producing a detectable reduction in adverse drug events [25, 28]. A corrected discrepancy is therefore not equivalent to a prevented injury, and an unresolved discrepancy is not automatically proof of harm.

Table 3 sets out questions for distinguishing a plausible medication-process contribution from competing causes of injury.

Table 3. Attribution tests for linking a medication-process deviation to observed patient harm

Attribution question	Evidence strengthening medication-process contribution	Evidence weakening attribution	Competing explanation that must remain possible
Did the process deviation alter clinically relevant medication exposure?	Documented wrong, omitted, delayed, excessive, insufficient, or inappropriately continued exposure	Deviation corrected before exposure or no plausible exposure change	Documentation-only or operational deviation

Is the timing compatible with the observed clinical event?	Exposure precedes an effect within a clinically plausible interval	Event predates exposure change or occurs outside plausible timing	Disease progression or unrelated event
Does patient susceptibility make the consequence plausible?	Relevant frailty, organ dysfunction, interaction burden, treatment complexity, or reduced physiological reserve	No credible susceptibility or pharmacological link	Background morbidity
Was a recovery opportunity missed or ineffective?	Detectable abnormality, unresolved recommendation, failed monitoring, delayed correction, or failed escalation	Timely correction before consequential exposure	Injury not preventable by the identified process
Are competing causes adequately considered?	Medication-process explanation fits better after structured review	Stronger alternative cause or weak medication linkage	ADR without process error, disease evolution, independent clinical event

Note: These questions support structured attribution; they do not establish a validated causality algorithm.

Three propositions follow from this synthesis. **First**, among broadly comparable deviation classes, realized injury should be better discriminated when exposure magnitude or duration, timing, susceptibility, and recovery latency are considered than when deviation counts alone are used. This proposition would be weakened if those variables add no predictive or explanatory information once deviation type is known.

Second, interventions should have greater effects on actual harm when they operate before clinically consequential exposure becomes difficult to reverse and when detection latency is short relative to the onset of injury. The proposition would be challenged if intervention timing and detectability consistently fail to explain differences between proximal process improvement and patient outcomes.

Third, safety mechanisms sharing information, staffing, workflow, or technological dependencies should not be assumed to behave as independent protective layers. Evidence that such controls retain stable, separable effects across markedly different resource and workflow conditions would weaken this proposition.

Conclusion

Medication-process deviations become patient injury through conditional trajectories, not through an automatic progression from error to harm. Latent system conditions influence whether deviations arise and whether they are visible; clinically meaningful alterations in medication exposure connect process failure to potential consequence; patient susceptibility modifies the significance of that exposure; and recovery depends on detection, timing, reversibility, communication, and the capacity to act.

This interpretation changes what should be measured. Counting errors alone cannot show how much patient injury has occurred, while counting corrected discrepancies cannot show how much harm was prevented. Safety evaluation should reconstruct where exposure changed, whether injury was pharmacologically and temporally plausible, which competing explanations remain credible, and where an opportunity for recovery existed or failed. The approach emphasizes mechanisms of injury and recovery. Its value will depend on whether future studies show that exposure, susceptibility, detection latency, and recoverability explain patient outcomes more effectively than process-deviation counts or nominal defence inventories alone.

Acknowledgments: None

Conflict of Interest: None

Financial Support: None

Ethics Statement: None

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