

A Near Miss Is Not a Uniform Safety Signal When Opportunities for Interception and Reporting Differ Across Pharmacy Work: Implications for Quality Improvement

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Abstract

Near-miss reporting is widely used in medication-safety improvement because events intercepted before patient harm can reveal vulnerabilities while preserving opportunities for organizational learning. Yet the observed number of near misses is not generated solely by the underlying frequency of unsafe events. It also depends on how often pharmacy work creates opportunities for error, whether an error encounters an available point of interception, whether it is detectable at that point, and whether a detected event is subsequently reported. These processes can vary across dispensing tasks, medicines, technologies, staffing arrangements, reporting systems, and organizations. Consequently, two pharmacies or two time periods can produce similar recorded near-miss counts through materially different safety configurations, while different counts can arise without corresponding differences in latent error generation. This methodological/conceptual article develops an Opportunity-Adjusted Near-Miss Framework that separates exposure to error opportunity, event occurrence, interception opportunity, detectability, reporting propensity, and the observed near-miss record. It specifies comparison conditions, classification requirements, interpretation constraints, and a validation agenda without proposing a universal adjustment coefficient. The central implication is that near-miss data become comparison-informative only when the opportunity base and observation process are sufficiently characterized for the inference being attempted. Near-miss counts remain valuable for learning, but their meaning depends on how pharmacy work makes errors possible, visible, interceptable, and reportable.

Keywords: Near miss, Medication errors, Community pharmacy, Incident reporting, Interception, Safety measurement

Introduction

Medication errors remain a persistent concern in community pharmacy, yet the empirical literature does not describe a single, stable phenomenon that can be counted identically across settings. A recent systematic review of medication errors in community pharmacies identified substantial variation in definitions,

medication-use stages, study designs, and methods of event identification, illustrating that an observed error frequency is partly a property of how safety events are operationalized and captured [1]. This variation matters especially for near misses, because a near miss requires more than the occurrence of an error: the event must also be stopped before the relevant harm-producing consequence occurs.

The denominator used to express error frequency is similarly consequential. Reviews of dispensing and community-care medication errors have used prescriptions, items, doses, opportunities for error, patients, or other process units, and have employed markedly different detection methods [1-3]. A pooled estimate may therefore combine studies whose numerators and denominators represent different

Access this article online

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Received: 21 March 2026; Accepted: 12 June 2026

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How to cite this article: Mokoena N, Novak P, Mendes S. A Near Miss Is Not a Uniform Safety Signal When Opportunities for Interception and Reporting Differ Across Pharmacy Work: Implications for Quality Improvement. Ann Pharm Educ Saf Public Health Advocacy. 2026;6(1):164-74. <https://doi.org/10.51847/nccoUoXHkY>

underlying opportunities. Apparent differences between pharmacies, tasks, or periods can reflect actual differences in unsafe-event generation, but they can also arise because the opportunity base, detection process, or reporting process has changed.

Near misses must also remain analytically distinct from preventable patient harm. Preventable-harm research shows that the occurrence, severity, and preventability of patient injury are separate dimensions of safety measurement [4]. An intercepted event may be valuable precisely because harm was avoided, yet the frequency of such events cannot be interpreted as if it were a direct measure of injury. The methodological problem is therefore not whether near misses are useful. It is determining what an observed near-miss count permits a safety investigator to infer.

This article addresses that problem by separating the processes that precede an observed near-miss record. The central question is: How should pharmacy near-miss data be interpreted when exposure to error opportunities, opportunities for interception, detectability, and reporting propensity differ across tasks and settings? The objective is to develop measurement and interpretation rules that preserve the learning value of near-miss data while preventing unsupported comparisons between counts generated under different conditions.

Why raw near-miss counts are not direct measures of safety

A raw near-miss count is the endpoint of an observation process. It does not reveal, by itself, how many error-producing opportunities existed, how many errors actually occurred, how many could have been intercepted, how many were detectable, or how many detected events were reported. Evidence comparing incident-reporting systems with active detection methods illustrates this problem. Studies using incident reports and trigger-based methods can identify substantially different numbers and types of safety events from the same broad care environment [5]. Such discordance does not mean one source is useless; it means that the recorded dataset is conditional on the mechanism used to observe events.

This distinction is consistent with broader safety-measurement research, which treats safety as a multidimensional construct requiring complementary sources of information rather than a single definitive indicator [6]. Near-miss counts can reveal emerging vulnerabilities, recurring task failures, or changes in

reporting behavior, but their interpretation depends on which part of the safety system generated the signal. A rise in reports might accompany worsening underlying error generation, improved interception, greater detectability, stronger willingness to report, or several changes occurring together.

Incident-reporting systems are also designed primarily to support learning and signal detection rather than to provide complete epidemiologic enumeration. International recommendations for reporting systems emphasize their role in identifying hazards and supporting learning while recognizing dependence on system design, participation, feedback, and governance [7]. Raw counts become especially problematic when they are transformed into league tables or performance rankings without establishing that the events could have been generated, detected, and reported in comparable ways.

The resulting measurement problem is one of non-identifiability. Multiple underlying configurations can yield the same observed count. A pharmacy with many opportunities for error and strong interception may produce the same number of reported near misses as a lower-volume pharmacy with fewer error opportunities but poorer interception. Likewise, two pharmacies with similar underlying errors and interception opportunities may report different counts because one has stronger detection or reporting systems. The count is real, but its causal and evaluative meaning is not self-identifying.

Exposure to opportunities for error

Interpretation begins with the process that creates opportunities for an error to occur. In a national analysis of dispensing errors reported by Finnish community pharmacies, thousands of reports accumulated within a defined reporting infrastructure over multiple years, allowing patterns in reported dispensing errors to be described [8]. Such data are informative about what entered the reporting system, yet the numerator does not alone specify how many prescriptions, items, clinical decisions, dispensing steps, checks, or other error-producing opportunities were encountered during the same period.

The appropriate opportunity unit depends on the error process under study. A wrong-product selection may relate most naturally to dispensing items or selection acts; a dosing or prescribing error may require a different process denominator; and an error linked to counselling may arise only when a particular counselling task is

indicated and performed. Treating these units as interchangeable assumes that equal workload volume corresponds to equal exposure to the relevant failure opportunity.

Incident-reporting studies reinforce the importance of retaining process context. Community-pharmacy incident reports can provide information on the nature, causes, and severity of medication incidents that a simple event count cannot capture [9]. This contextual information helps identify whether the observed events arose from prescription interpretation, product selection, labelling, checking, communication, workload, or other aspects of the medication-use process.

Accordingly, exposure to opportunities for error is defined here as the number or configuration of occasions on which the specific error type under analysis could plausibly arise. It is not synonymous with total prescription volume. A valid opportunity base must correspond to the process generating the numerator. When this correspondence is absent, an apparently standardized rate can remain conceptually mismatched.

Opportunity for interception

Once an error exists, a separate question is whether pharmacy work provides a usable opportunity to intercept it before the relevant consequence occurs. This opportunity can arise through pharmacist verification, technician checking, clinical decision support, barcode scanning, patient questioning, reconciliation, prescription clarification, handoff review, or another process capable of stopping the error. The availability of an interception point is therefore a property of work design as well as individual action.

Interruptions and distractions illustrate why interception cannot be assumed constant. A recent scoping review of pharmacy dispensing found that interruptions and distractions influence pharmacy work and have implications for error risk and safety interventions [10]. Their importance is not limited to whether an interruption initiates an error. They may also alter attention, task-state preservation, timing of checks, or the ability to recognize that a correction is required.

Human-factors research similarly shows that medication errors emerge through interactions among people, tasks, technologies, organizational arrangements, and environments [11]. Interception capacity should consequently not be reduced to pharmacist vigilance. A system may formally include an independent check while making that check less effective through workload,

interface design, information fragmentation, role ambiguity, or poorly timed interruptions.

The availability and usefulness of interception also vary by medication and task. Longitudinal medication-error analyses show that error types and medication characteristics can be associated with different error patterns [12]. In community pharmacy, some self-medication errors are detected and corrected before reaching the customer, demonstrating how an event can become a recorded near miss because an interception opportunity was successfully used [13]. Other contexts, including high-alert medication use, involve combinations of contributory factors that can alter whether an error reaches a recoverable point [14].

For measurement purposes, opportunity for interception therefore means the presence of a practicable recovery point after an error has arisen but before the outcome defining successful interception has been crossed. It must remain distinct from actual interception. A checking step can exist without detecting the error, and an error can sometimes be detected even when no formal check was designed for that purpose.

Detectability

An interception point is useful only when the relevant error can produce a signal that someone or something can recognize. Detectability refers to that observational property. An error may be present and pass through a checking opportunity without being detectable under the information, interface, knowledge, timing, or technology available at the moment of review.

National incident data illustrate how the recognition and classification of contributory conditions influence what becomes visible in safety records. Analysis of incidents involving guideline-related factors, for example, shows that recorded events can reflect how safety problems are recognized and coded within reporting systems [15]. The reported category is therefore partly the result of an observational and classificatory process.

This process is inherently sociotechnical. The Systems Engineering Initiative for Patient Safety framework locates safety outcomes within interactions between persons, tasks, tools and technologies, organizational conditions, and the physical environment [16]. Applied to near misses, this means that detectability may depend on whether relevant information is present, whether it is displayed at the appropriate moment, whether the workflow brings discrepant information together, and

whether the observer has enough contextual knowledge to recognize the discrepancy.

Evidence from trigger tools makes the measurement consequence particularly clear. A systematic review and meta-analysis of trigger tools for detecting adverse drug events found substantial variation in the tools used and in their performance [17]. Active detection methods can therefore alter the set of events that becomes observable. A trigger tool developed for home healthcare was able to identify both adverse events and no-harm incidents from record review, demonstrating that non-harm events can be systematically sought rather than waiting for voluntary reports [18].

The same principle applies to harm ascertainment. Work developing explicit processes for identifying actual harm from medication errors in pediatric inpatients shows that even downstream outcomes require structured measurement rules and data sources [19]. Near-miss measurement cannot plausibly assume that detection occurs automatically when an error exists.

In this article, detectability is therefore the conditional capacity of the active observation process to recognize an extant error or its trace. Detectability may vary by error type, information source, technology, observer, timing, and setting. It is distinct from the presence of an interception opportunity and from the later decision to report.

Reporting propensity

A detected event still does not necessarily become a recorded near miss. Reporting introduces another selection process. A systematic review of near-miss reporting identified individual and organizational influences on whether healthcare workers report detected events [20]. Broader evidence on incident reporting likewise identifies fear of blame, knowledge, perceptions of usefulness, managerial support, reporting-system characteristics, and organizational culture as determinants of reporting behavior, while national safety-culture research demonstrates meaningful variation in reporting environments across organizations and practitioner groups [20-22].

These influences make reporting propensity analytically different from detectability. Detectability asks whether the event can be recognized; reporting propensity asks whether a recognized event enters the formal dataset. A pharmacy may improve its reporting interface, introduce protected reporting time, strengthen non-punitive feedback, or begin actively encouraging documentation

without changing the underlying generation of medication errors. An increase in recorded near misses following such a change may therefore be evidence of improved observation rather than deterioration in latent safety.

Reporting infrastructure also varies among care sectors and organizations. A systematic review of safety incidents and reporting processes in care homes found heterogeneity in both the types of incidents recorded and the systems through which they were reported [23]. A scoping review of reporting-and-learning guidelines similarly showed that implementation involves more than event submission; feedback, learning processes, and organizational structures influence whether reporting contributes to improvement [24].

The practical implication is that near-miss datasets are selected datasets. The selection does not invalidate them, but it affects the questions they can answer. Comparisons across pharmacies, teams, or periods require consideration of whether reporting expectations, technologies, governance, psychological safety, and feedback arrangements were sufficiently stable or equivalent. Where they were not, raw differences in reported counts cannot be attributed to underlying safety performance without additional evidence.

The denominator problem

A denominator can improve interpretation only when it corresponds to the process that generated the numerator. Standardization of event classification is one prerequisite. Work on medication-error harm classification has shown why explicit, reproducible definitions are needed before safety events can be compared or aggregated [25]. A numerator labelled “near miss” is therefore not automatically comparable across datasets if the underlying event class, interception endpoint, or harm boundary differs.

Even a well-matched exposure denominator cannot correct all forms of incomparability. Dividing reported near misses by prescriptions dispensed, for example, may account for workload volume while leaving differences in interception opportunity, detectability, and reporting propensity untouched. Two pharmacies can have the same prescriptions-per-report rate while operating very different checking systems or reporting cultures. Conversely, a pharmacy can experience a rise in near misses per prescription because it introduced more sensitive detection or a more accessible reporting process.

This limitation explains why triangulation across safety sources can be useful. Patient-level linkage of incident reports, adverse-event data, and complaints has shown that different safety-information streams provide overlapping but non-identical perspectives [26]. No single stream necessarily captures the complete underlying event population. For near-miss analysis, the appropriate denominator is therefore necessary but insufficient: comparison also requires attention to how events became observable and reportable.

The denominator problem can be stated as two linked tests. First, opportunity-base comparability asks whether the denominator measures equivalent chances for the relevant error to arise. Second, observation-process

comparability asks whether errors had sufficiently equivalent opportunities to be intercepted, detected, and reported. Only when both tests are reasonably satisfied can a rate difference be interpreted primarily as evidence about differences in the underlying event-generating process. When one or both tests fail, the comparison must remain conditional.

This distinction changes the practical interpretation of commonly encountered near-miss patterns. The same observed count can support different conclusions depending on the configuration that produced it, while different counts can be compatible with similar underlying safety performance.

Table 1. Comparison validity under alternative opportunity-base and observation-process configurations

Observed near-miss pattern	Error-opportunity base	Interception opportunity	Detectability / reporting state	What the comparison can support	What the comparison cannot support	Quality-improvement interpretation
Similar counts across two periods with stable workload and unchanged measurement system	Comparable and stable	Comparable	Stable	Reasonable descriptive comparison of reported event frequency	Proof that latent error generation is identical	Examine event type and mechanism before concluding stability
Similar counts across pharmacies with substantially different task volume or complexity	Not equivalent	May differ	Unknown or partly comparable	Description of absolute reporting burden	Direct claim of equivalent safety performance	Identify task-specific opportunity units before comparison
Higher count after additional checking or recovery steps are introduced	Comparable or measurable	Increased	Potentially increased	Evidence that more events are being intercepted and/or observed	Automatic inference of deteriorating safety	Determine whether latent errors, interception, or observation changed
Higher count after reporting access, feedback, or non-punitive reporting is strengthened	Comparable	Comparable	Reporting propensity likely increased	Evidence of greater recorded-event capture	Automatic inference that more errors are occurring	Treat the count change as partly measurement-system dependent
Lower count after an automated or manual detection process is removed	Comparable	Reduced or altered	Detectability reduced	Evidence that the observable event stream changed	Automatic inference of improved safety	Investigate whether events became less visible
Similar rate per prescription across tasks with different error-generating steps	Nominally standardized but process-mismatched	Different	Potentially different	Broad workload-normalized description	Task-level equivalence of risk or interception performance	Replace generic volume denominator with task-relevant opportunity base
Different counts when event definitions or interception endpoints differ	Potentially comparable	Unclear	Classification differs	Within-system description under each local definition	Cross-system ranking	Harmonize event classification before comparison
Different counts despite matched opportunity	Comparable	Comparable	Sufficiently stable	Stronger basis for investigating differences in	Causal attribution to a specific	Use contextual and mechanism data to

units and stable
observation process

underlying event
generation

mechanism
without further
evidence

explain the remaining
difference

Note: The configurations are methodological synthesis developed in this article. They represent comparison states, not empirical effect estimates, thresholds, or validated adjustment coefficients.

Development of the opportunity-adjusted near-miss framework

The recorded near miss is a downstream observation, not a direct reading of underlying safety. Incident-report narratives can reveal system conditions and resilience mechanisms omitted by counts [27], while reported-event characteristics can relate differently to harm [28]. Pharmacy-safety programmes also show that reporting capability itself can change over time [29].

The Opportunity-Adjusted Near-Miss Framework therefore separates: exposure to a relevant error opportunity; error occurrence; availability of an interception opportunity; detectability at that point; and

reporting of the detected event. It is not a multiplicative score. Its function is to identify which parts of the data-generating process must be sufficiently comparable before a count or rate can support a performance inference.

When exposure differs, the question becomes whether a suitable opportunity denominator exists. When detectability or reporting differs, the question becomes whether capture changed. When interception opportunities differ, underlying event generation must be distinguished from recovery capacity. **Figure 1** summarizes this conditional measurement logic.

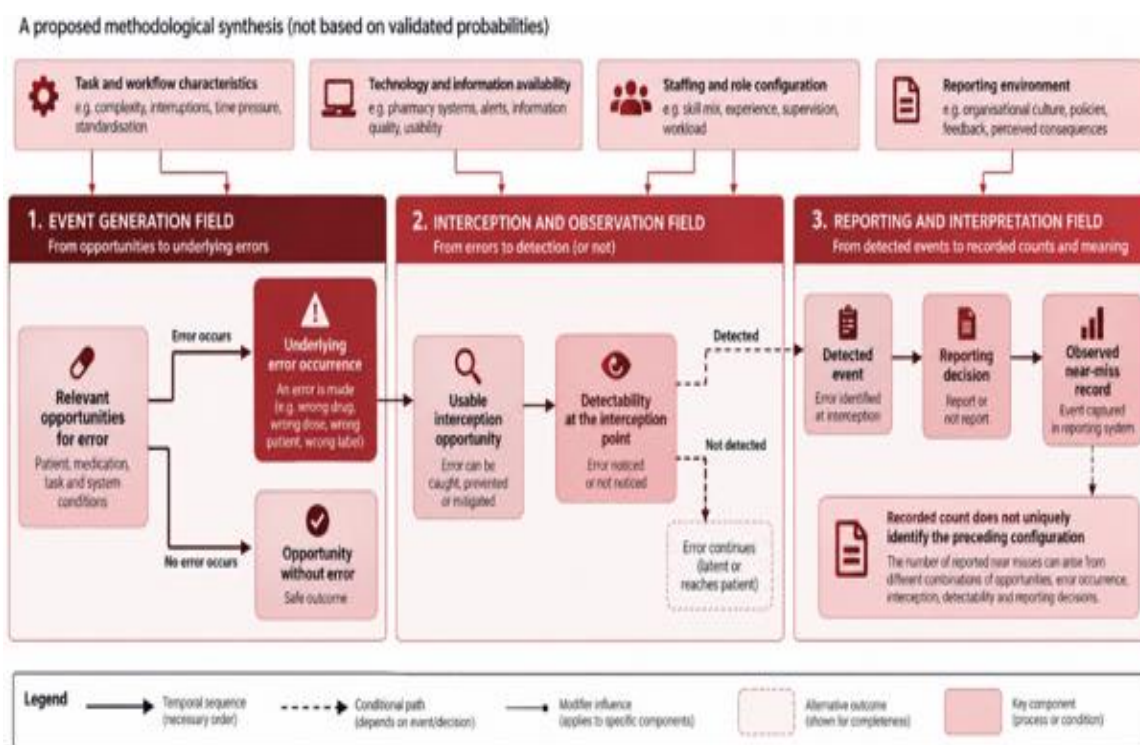


Figure 1. Opportunity-adjusted measurement architecture for pharmacy near-miss interpretation

Classification and measurement rules

A comparison requires a minimum measurement record. Explicit classification systems can be formally developed and validated [30], yet community-pharmacy evidence shows substantial heterogeneity in identification, classification, and documentation [31]. Root-cause

analysis adds contextual explanation but should not be treated as a substitute for measurement structure [32].

Each near-miss record should therefore distinguish event class, eligible opportunity unit, interception point, detection route, reporting route, and relevant context. Missing fields should remain missing. Comparisons can

then be classified according to whether exposure and observation processes are sufficiently characterized.

Table 2. Minimum measurement states for interpretable pharmacy near-miss comparison

Measurement state	Required information	Permissible inference	Inference withheld
Opportunity and capture characterized	Event class, opportunity base, interception, detection and reporting routes	Strongest comparative interpretation	Causal attribution without additional evidence
Opportunity characterized; capture uncertain	Opportunity base known; detection/reporting unstable	Exposure-normalized description	Performance ranking
Capture characterized; opportunity uncertain	Detection/reporting stable; opportunity base unclear	Within-system signal tracking	Cross-task rate comparison
Interception or detectability altered	Recovery point or observation process changed	Change in recovery/visibility	Direction of latent error-rate change
Reporting pathway altered	Reporting access, expectations, feedback or culture changed	Change in reporting capture	Safety improvement or deterioration from count direction alone

Note: These are proposed measurement states, not validated categories.

Worked measurement scenarios

Equal observed counts need not imply equal safety. If two pharmacies record similar counts but differ substantially in relevant opportunity volume, the equal numerator is not equivalent. If opportunity bases are comparable but one pharmacy introduces more sensitive checking or easier reporting, a higher count may reflect

improved capture. Detection-method research supports the first distinction [5], and evidence on reporting propensity supports the second [20]. Triangulation can help when competing explanations remain plausible because different safety sources provide partly distinct information [26].

Table 3. Worked opportunity-observability configurations

Configuration	Observed pattern	Plausible explanation	Priority quality-improvement question
Unequal exposure	Similar counts	Different opportunity volumes	What opportunity denominator matches the event class?
Added interception	Higher count	More errors recovered before consequence	Did underlying event generation also change?
Improved detectability	Higher count	More extant errors recognized	Which previously invisible events became observable?
Stronger reporting system	Higher count	More detected events documented	Did reporting conditions change?
Reduced detection capacity	Lower count	Fewer errors recognized	Was a checking or information source lost?
Stable opportunity and capture	Different counts	Underlying event generation becomes a stronger candidate	Which error-generating process changed?

Interpretation for quality improvement

Quality improvement should begin with a comparability check rather than the direction of the count. Multidimensional safety monitoring supports this approach [6], and incident-reporting guidance cautions against treating voluntary reports as complete epidemiologic measures [7]. A rising count should prompt questions about event generation, new checks,

detection technology, reporting expectations, and feedback systems. Reporting-and-learning evidence also shows that event submission alone is not learning [24]. Near-miss trends should therefore be accompanied by a description of opportunity base, detection route, reporting conditions, and relevant workflow change. Pharmacy-safety programme evidence confirms that reporting structures and safety roles can evolve during

improvement work [29]. A changed observation system should be treated as part of the explanation for a changed series.

Organizational learning without naïve rate comparison

Near-miss reports remain valuable when cross-setting rate comparison is inappropriate because they can reveal recurring mechanisms, weak controls, successful recoveries, and conditions requiring investigation. Their value depends on what happens after reporting.

Recent analyses show substantial variability in investigation quality and in the systems orientation of contributory-factor analyses and recommendations [33, 34]. Report volume therefore does not establish learning quality. Learning depends on whether reports are examined for system conditions, linked with other safety information, translated into credible corrective action, and revisited after change. **Figure 2** separates the observed signal from the learning response.

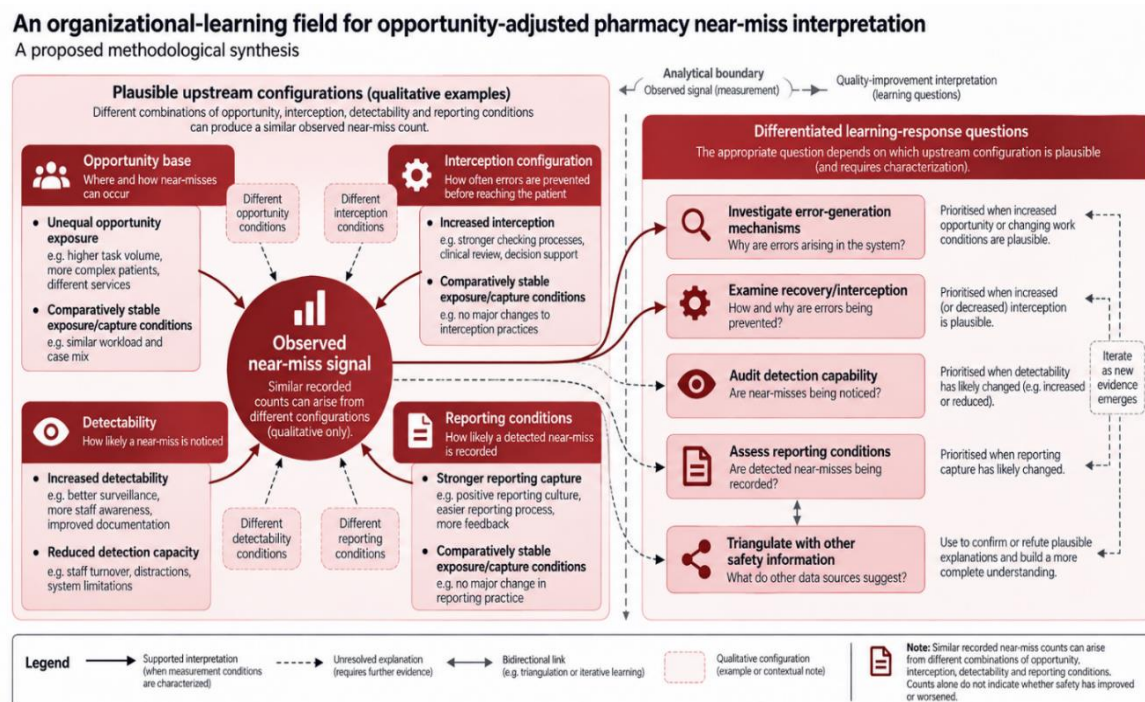


Figure 2. Branching interpretation field for organizational learning from similar near-miss counts

Validation agenda

Prospective validation is required before standardized benchmarking. The proposed measurement states need reliability and content-validity testing comparable to other medication-safety classifications [30]. Denominator fidelity must then establish whether selected opportunity units correspond to the error process. Medication-error burden modelling shows that opportunities can be defined at process stages, but those definitions remain assumption-dependent [35]. Construct validity should also be tested with interventions expected to affect one component more than others. A new trigger should principally alter detectability; a reporting intervention should alter reporting propensity; a redesigned checking step should

alter interception opportunity. Trigger-tool evidence [17] and reporting research [20] provide candidate test settings. Cross-setting and longitudinal measurement invariance should precede any adjustment score or benchmark.

A useful validation design should also compare the framework against simpler alternatives. If a prescription-normalized rate performs as well as the full classification when capture conditions are deliberately changed, the added structure would have limited methodological value. Conversely, if the framework correctly identifies apparent safety changes produced by altered detection or reporting while a simple rate misclassifies them, that would support discriminant validity.

Results and Discussion

The framework locates the observed near-miss count at the end of a measurement process. Its contribution is inferential discipline: investigators should establish what opportunities generated the numerator and how interception, detection, and reporting shaped entry into the dataset before making comparative claims.

A count difference may still reflect a genuine difference in underlying error generation. Opportunity adjustment must not explain away deterioration; it structures competing explanations. Where exposure and observation processes are stable, count differences provide stronger grounds for investigating underlying risk. Where those conditions are unstable, the difference is less identifiable.

For practice, the framework also changes what should be documented during improvement interventions. Changes to checking sequence, staffing, software alerts, reporting interfaces, feedback expectations, or event definitions should be treated as measurement-relevant interventions because each can alter the pathway from underlying error to recorded near miss. This documentation is essential for interpreting discontinuities over time and for deciding whether a pre-intervention baseline remains comparable. Important limitations remain. The framework cannot recover information never recorded; its components may interact rather than operate independently; and measurement behaviour may differ across sectors and institutions. It is a methodological synthesis, not a validated numerical adjustment procedure. Its practical value is therefore to improve the questions attached to near-miss data and to preserve learning without unsupported ranking.

Conclusion

A pharmacy near miss is not a uniform safety signal because exposure to error opportunities, interception, detectability, and reporting all shape what becomes visible. Counts become comparison-informative only when those processes are sufficiently characterized for the inference attempted. Where they are not, the appropriate response is a narrower quality-improvement question about the configuration that generated the observation, not a forced adjusted ranking.

Acknowledgments: None

Conflict of Interest: None

Financial Support: None

Ethics Statement: None

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