

Patient Safety Hazard Analysis

Artifact 4 | NorthStar Health Network

NorthStar Health Network is a fictional regional health system comprising 12 hospitals, 70 outpatient facilities, approximately 18,000 employees, and roughly 3 million annual patient encounters. All systems, metrics, incidents, vendors, and findings in this portfolio are simulated.

Patient-Safety Hazard Analysis

This FMEA-style analysis identifies how AI failure can translate into clinical harm and assigns preventive, detective, and recovery controls.

Hazard	Cause	Potential effect	Severity	Likelihood	Controls	Residual
False-negative sepsis score	Data missingness; distribution shift; model limitation	Delayed assessment or treatment	Critical	Possible	Sensitivity threshold; chart review; nurse concern pathway; drift alerts	High
False-positive overload	Threshold too low; local prevalence shift	Alert fatigue; delayed response to true alerts	High	Likely	Alert-rate cap; PPV monitoring; unit-level review	Moderate
Automation bias	Clinician over-trusts score	Other causes of deterioration overlooked	High	Possible	Training; "support only" label; independent assessment; override reason capture	Moderate
Site mismatch	Model underperforms at a hospital with different population/workflow	Unequal safety performance	High	Possible	Site validation; phased rollout; minimum-data gate	Moderate
Stale input data	Interface latency / lab feed outage	Incorrect score	High	Possible	Freshness indicator; interface-health monitor; fail-safe suppression	Low-Moderate
Unannounced model change	Vendor or internal update bypasses review	Unknown performance / changed behavior	Critical	Unlikely	Change freeze; version control; revalidation gate; rollback image	Moderate

Safety Controls by Layer

Layer	Control examples
Prevent	Approved intended use; validation; site readiness; version control; threshold governance; clinician training; privacy/security review
Detect	Performance dashboard; subgroup monitoring; data-quality checks; alert-response metrics; complaints / safety reports; vendor-change alerts
Respond	Clinical escalation; temporary suppression; rollback; patient chart review; incident command; corrective action; revalidation

No-Automation Rule

The sepsis model may **trigger attention** but may not autonomously diagnose sepsis, order treatment, suppress clinician concern, or prevent escalation when a clinician identifies deterioration.

Safety ownership

Role	Accountability
Clinical AI Safety Lead	Owns safety-case review and pause recommendation
Service-line Medical Director	Approves clinical workflow and intended use
Model / Analytics Owner	Owns performance evidence and versioning
Nursing Leadership	Owns alert workflow and escalation usability
Patient Safety / Quality	Owns incident review and harm analysis
Privacy / Security	Owns PHI, access, and security controls