Op-ed article

The confused epistemology of a safety incident, are we in the realm of justified belief or opinion?

DOI: 10.5377/alerta.v8i4.21203

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La confusa epistemología de un incidente de seguridad: ¿nos encontramos en el ámbito de la creencia justificada o de la opinión?

Suggested citation:
Hybinette K. The confused epistemology of a safety incident, are we in the realm of justified belief or opinion? Alerta. 2025;8(4):452-456. DOI: 10.5377/alerta.v8i4.21203

Editor:
David Rivera.

Received:
August 20, 2025.

Accepted:
September 05, 2025.

Published:
October 31, 2025.

Author contribution:
KH: writing, revising and editing.

Conflicts de interest:
No conflicts of interest.

Introduction

The global patient safety movement have seen a surge of research over the past 20 years, with the emergence of primarily two schools of thought regarding safety management, Safety-1 and Safety-2. A simplified description of these views would state that Safety-1 focuses on the absence of adverse outcomes (accidents, incidents, harm), while Safety-2 focuses on the presence of adaptive capacity to ensure that things go right under varying conditions.[i,ii] These contrasting (and complimentary) views introduces several underlying epistemological assumptions concerning causality, determinism, and the notion that complex processes can be decomposed into discrete elements. Assumptions that warrant critical examination and further scientific deliberation.[iii]

The purpose of this philosophical position paper is to introduce and problematize these foundational issues, particularly given their implications for the governance of healthcare organizations. When the operational reality involves highly sophisticated and interdependent processes, strategic decisions are at risk of being based on anecdotal knowledge or popular beliefs rather than on robust theoretical or empirical foundations.

Table 1 introduces a condensed list of the main differences between the two safety views. The paper discusses these views through the lens of the most significant patient safety incident in Sweden during the 19th century, the Lex Maria incident of 1939. The Sorites paradox will be used to structure the comparison between the safety views and the incident.[iv,v]

The chain of events – August 1936

The following section is a narrative synthesis of the 1936 documents regarding the Maria Hospital incident in Stockholm. The references regarding the Lex Maria incident in 1936 originals can be found at the Stockholm City Archives, Swedish National Archives, The Swedish Tax Agency and the Royal Library (Table 2).

On Thursday, August 20, 1936, two patients, Karl Eriksson (25), a welder, and Stig Tärnholm (15), a messenger boy, were treated at the surgical outpatient clinic of Maria Hospital in Stockholm. Eriksson presented with a neck abscess, while Tärnholm had an infected corn. Both were scheduled for minor surgical procedures requiring local anesthesia (Patient journals and Estate inventory for Eriksson & Tärnholm). The intended agent was a 1 % solution of ethocaine; however, the syringe used in both procedures had been mistakenly filled with the highly toxic antiseptic compound mercury oxycyanide (News articles. DN, SvD, Stockholms-Tidningen August-September, 1936).

Following their procedures, both patients were discharged, only to return shortly thereafter with acute symptoms including nausea, abdominal pain, and vomiting. Their conditions rapidly deteriorated. The following day, two additional patients, Mrs. Elsa Berglund, who had undergone removal of a skin lesion, and a hospitalized surgical patient, Engineer Nils Nilsson, were also injected with the same contaminated syringe in conjunction with a hernia operation (Patient journal). All four patients

Table 1. A synthesis of the main differences between Safety-1 and Safety-2.

Aspect	Safety-1	Safety-2
Definition of Safety	The absence of adverse outcomes (accidents, incidents, harm)	The presence of adaptive capacity that ensures things go right under varying conditions
Focus	Focuses on what goes wrong and preventing failures	Focuses on what goes right and sustaining successful performance
Assumption about System Behaviour	Systems are assumed to be linear and decomposable; errors are due to failures or deviations	Systems are complex and adaptive; variability and performance adjustments are normal and necessary
Role of Human Operators	Humans are seen as a source of error that must be controlled	Humans are viewed as a resource for flexibility and resilience
Primary Strategy	Reduce risk by constraining behaviour, increasing control, and eliminating variability	Enhance resilience by supporting learning, monitoring, anticipation, and adaptation
Incident Investigation Approach	Investigate failures and incidents to find root causes	Understand and learn from everyday performance and how people adapt to ensure success.
Goal	Minimize the number of things that go wrong	Maximize the number of things that go right

Source: Hollnagel E. Safety-I and Safety-II. Safety-I and Safety-II. CRC Press; 2018. and Cooper MD. The Emperor has no clothes: A critique of Safety-II. Vol. 152, Safety Science. Elsevier; 2022.

Table 2. Chain of Events of the Lex Maria Incident, August 1936.

Source archive	Document(s)
Stockholm City Archives	Patient journals. August 1936, Surgical policlinic
Stockholm City Archives	Board of directors' diary, Maria Hospital 1936
Stockholm City Archives / Swedish National Archives	Estate inventory for Eriksson & Tärnholm
Stockholm City Archives	Nurses and doctors' testimonies. Volume E1:128, Case 322 (1936)
Swedish National Archives	Judgment and police interrogation and protocols from the board of medication.
Royal Library	News articles. DN, SvD, Stockholms-Tidningen (aug–sep 1936)
Swedish National Archives / The Swedish Tax Agency	Diseased persons logbook, Death certificate

Source: Physical documents in 1936 originals can be found at the Stockholm City Archives, Swedish National Archives, The Swedish Tax Agency and the Royal Library. All accessed between 2025-07-01 and 2025-07-11.

developed acute renal failure and died between August 27 and 29 (Nurses and doctors' testimonies).

initial discovery and institutional response

As early as August 22, an on-call physician noted the strikingly similar acute symptomatology in Eriksson and Berglund, prompting contact with the acting chief physician, Professor Einar Key, the hospital director, who was on vacation at the time. A sample vial was immediately dispatched to the State Pharmaceutical Laboratory, which swiftly confirmed the presence of mercury oxycyanide. That same evening, the National Board of Health and Welfare (Medicinalstyrelsen) was notified, though the police report from the hospital pharmacy was not filed until August 26 (Judgment and police interrogation and protocols from the board of medication).

Investigations, accountability, and institutional failures

The subsequent investigation revealed systemic deficiencies in medication handling: toxic and non-toxic substances were stored side by side without clear labelling (Figure 1), and the syringe had been filled without proper verification or dual control (double check by two people, usually nurses) (Judgment and police interrogation and protocols from the board of medication). Criminal charges were brought against five individuals, including Professor Key, a nursing student suspected of having filled the

syringe with the wrong substance, and several nurses responsible for medication preparation and oversight. Ultimately, no convictions were reached, as the causal chain could not be established with sufficient certainty. However, the hospital's deficient routines were subject to strong official criticism (News articles. DN, SvD, Stockholms-Tidningen August-September, 1936).

Discussion

The Emergence of Lex Maria

The intensity of media scrutiny, coupled with demands from the National Board of Health and Welfare for improved clinical practices, led the Swedish government to enact new legislation in January 1937. Known as Lex Maria, this regulation mandated the immediate reporting of serious care-related injuries to public authorities. It marked the first legally binding requirement for healthcare providers in Sweden to report adverse events, a system that remains in place to this day under the same name.

Contemporary significance

The Lex Maria incident demonstrated how ostensibly routine medical interventions, such as the treatment of an abscess or a corn, could result in fatal outcomes due to organizational shortcomings. At the same time, it stands as a historical example of how rapid responses, both clinical and political, can catalyse systemic change and regulatory reform with the purpose of enhancing patient safety. However, incident reporting systems and accident investigations does not seem to equate an actual reduction in patient harm.[vi]

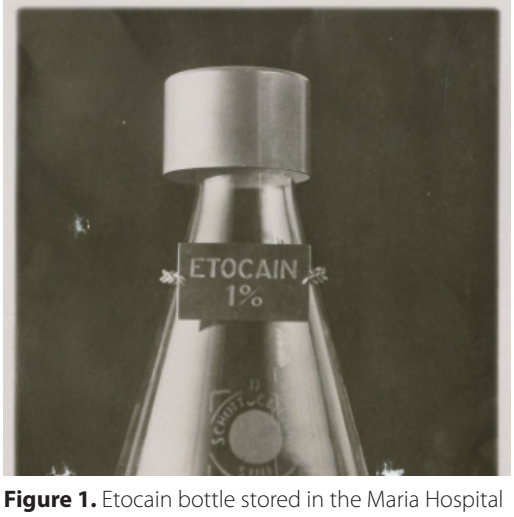

Figure 1. Etocain bottle stored in the Maria Hospital medicine cupboard.

Source. Image from the criminal investigation, Stockholm city archives SE/SSA/0140/06/2.

The transition from Safety-1 to Safety-2 can be framed through the lens of the Sorites paradox, recast here as an n – 1 problem.[v] In the classic paradox, successively removing single grains of sand from a heap eventually, without any clear boundary, turns it into "notaheap".[iv] Analogously, Safety-2 treat a system's accident profile as a finite set n of identifiable errors; safety improves by removing these errors one by one. Yet as the tally approaches n – 1, the conceptual footing begins to erode: at what residual error count does a system cease to be "unsafe" and instead qualify as "safe"? This vagueness exposes a logical gap that Safety-2 fills by redefining safety not as the nearzero presence of adverse events but as the continuous capacity of the system to function as intended under variable conditions. Thus, the "last grain" is never simply the final preventable error; rather, its removal signals a qualitative shift, from a strategy of deficit reduction (error hunting) to one of capability assurance (supporting adaptive performance). In other words, when incremental error counting can no longer meaningfully discriminate between safe and unsafe, the safety construct inevitably migrates from a subtractive Safety-1 paradigm to an additive Safety-2 paradigm, where the operative question is no longer "How many errors remain?" but "How robustly can the system keep things going right?"

Consequences of a confused epistemology

Ineffective interventions due to poor theoretical grounding

The Lex Maria incident brings to light how an apparently simple fix (segregating toxic from non-toxic solutions) proved inadequate because the hospital's safety model was restricted to linear, Safety-1 error elimination. By focusing on the countable event—the wrong fluid in a syringe—policy makers overlooked deeper sociotechnical couplings (staff rotations, weak verification rituals, supply-chain pressures) that most likely made the error more or less inevitable. The Sorites metaphor explains why: once "n – 1" errors remain, we have no principled criterion for declaring the system safe, so we keep adding micro-rules that ultimately produce little new insight or resilience.[vii] Interventions derived from such shaky logic may suppress specific failure modes while leaving the adaptive capacities of the system unchanged or even eroded—hence the now frequent observation that new checklists or labels usually show diminishing returns in terms of accident and in-

cident reduction and sometimes even create fresh pathways to failure.

Difficulty in achieving consensus on best practices

A logic that equates safety with "as few grains of error as possible" permits wildly different interpretations of what actually counts as a grain. For some, the decisive unit is a recorded adverse event; for others, it is any deviation from protocol; for yet others, it is a latent system weakness.[viii] Because the epistemic frame is unsettled, attempts at consensus guidelines drift into semantic debate ("Is this incident severe enough to classify?") rather than converging on functional markers of system robustness.[ix,x] The Lex Maria legislation itself illustrates this dilemma: while the duty to report serious harm events became law in 1937, Swedish hospitals still diverge on thresholds for Lex Maria-level reporting, precisely because the underlying theory does not specify where the "heap" of errors stops and normal variability begins.

Fragmentation of patient-safety efforts across organizations

When safety is operationalised as isolated error counts, each hospital or ward tailors its own surveillance apparatus to local incidents, and therefore develops idiosyncratic taxonomies, metrics, and dashboards. The result is a patchwork of partially incompatible datasets, making supra-organizational learning slow and costly. In resilience-engineering terms, weak synoptic coupling arises: each node optimizes for its own error heap without an integrative view of how everyday performance succeeds across the wider care continuum.[xi,xii] The Lex Maria mandate was intended to centralize learning, yet a confused epistemology means the centralized archive still aggregates heterogeneous, often incomparable, entries. Consequently, federated interventions (national training, procurement standards, shared protocols) struggle to gain traction.

Resistance to change because of competing interpretations of safety problems

Finally, the "n – 1" mindset embeds a tacit promise: once the last few errors are squeezed out, our job is done. When clinicians or managers are asked to shift toward Safety-2, investing in monitoring, adaptation, and proactive capacity building—they can legitimately object that their dashboards already show record-low error counts. The Lex Maria case did provoke rapid regulatory change, but it also entrenched a reactive view of safety: compliance equals prompt reporting and root-cause analysis, not necessarily the cultivation of foresight, slack, and cross-boundary coordination. Competing factions thus advance mutually exclusive narratives: one side calls for tighter controls to chase the remaining grains, the other for looser structures to foster flexibility. As long as the underlying epistemic frame oscillates between those poles, ambitious reforms are met with scepticism, incrementalism, or outright push-back.

Conclusion

The Sorites paradox reveals an inherent vagueness in incremental error-counting logics, while the Lex Maria episode shows how that vagueness materializes in real-world governance. Unless patient-safety science grounds itself in a clearer ontology of system performance under variability, rather than in the ever-shrinking enumeration of discrete mishaps, these four pathologies will continue to blunt the impact of well-intentioned safety programs.

Addressing this confusion requires greater interdisciplinary collaboration, improved research methodologies, and clearer epistemological foundations in patient safety science.

Funding

No external funds were received for this work.

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