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Introducing a novel epidemiologic category to move beyond the outbreak centered paradigm

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Abstract

This Perspective introduces the concept of Epidemiologically Relevant Event (ERE), a novel operational category designed to enhance the early detection, documentation, and response to public health signals that fall outside conventional classifications such as clusters or outbreaks. While current frameworks are largely shaped by binary outbreak-centered logic, many events that trigger significant public health action remain unclassified, inconsistently documented, and difficult to evaluate retrospectively. EREs are defined as early-warning signals that warrant a public health response based on their potential for harm or escalation, even if they do not meet formal outbreak criteria. By integrating EREs into surveillance systems, health authorities can improve risk assessment, resource prioritization, and accountability. The ERE framework is applicable to infectious and non-infectious hazards—whether community-based, nosocomial, or environmental—and is particularly valuable in contexts of uncertainty or limited surveillance capacity. The concept aims not to replace existing categories, but to fill a definitional and operational gap—stimulating expert dialogue and supporting a more flexible, responsive, and transparent public health system.

1 Foreword

1.1 Context and rationale

The timely detection and management of epidemiologic occurrences is a cornerstone of public health practice. Yet, not all events requiring substantial response efforts can be neatly classified within existing epidemiological categories such as incidents, clusters, or outbreaks. This gap in classification poses significant challenges for surveillance, resource allocation, reporting, and accountability. Despite advancements in data systems and analytical tools, there remains no coherent framework capable of capturing the full range of signals that prompt public health action but fall short of conventional definitional thresholds.

The prevailing outbreak-centered paradigm—often rooted in rigid dichotomies—can constrain the ability of health authorities to describe and quantify the continuum of

epidemiologic signals [1–4]. To address this limitation, we advocate for the development of clearer, consensus-based definitions of epidemiological events. Terms such as event, incident, cluster, and outbreak should not be used interchangeably without a shared framework. In this context, we propose a novel term to serve as an entry point for formal classification: the Epidemiologically Relevant Event (ERE).

This proposal goes beyond semantics. While the detection and management of such events already take place in many systems, their inconsistent classification limits systematic documentation, hinders retrospective evaluation, and undermines international comparability. The ERE framework addresses to this gap by providing a structured operational framework that enables public health authorities to consistently record, analyze, and learn from response-triggering occurrences that currently fall outside formal categorization.

1.2 Illustrative scenarios

To exemplify these limitations, we present two real-life inspired events that triggered substantial public health responses but remain difficult to classify using existing epidemiological categories.

In the first case, rabies was confirmed in a dog that had spent approximately three months in a country where the disease is endemic. The diagnosis was established in Spain, which had been rabies-free for almost four decades, following multiple human exposures due to bites. The animal, which had incomplete immunization against rabies, had traveled across various regions within the country. Once identified, authorities initiated a comprehensive public health response, including risk-area delineation, contact tracing of exposed individuals and animals, examination of carcasses, mandatory vaccination of susceptible species, and restrictions on the movement of domestic animals [5].

In a second scenario, a person experiencing nonspecific symptoms spent nearly two weeks traveling in Europe before returning to their country of residence, Nigeria. A few days after returning, the individual died and was subsequently diagnosed with a highly fatal, contact-transmissible viral hemorrhagic disease—eventually identified as Lassa fever—for which no proven specific treatment exists. Upon notification, public health authorities launched immediate contact tracing and health monitoring efforts to ensure timely medical interventions if required [6].

In both scenarios, mass media were utilized to disseminate risk communication, and formal notifications were issued through the International Health Regulations (2005) (IHR) framework [1]. Despite the absence of secondary transmission, each event necessitated a high level of preparedness, intersectoral coordination, and deployment of human and material resources. Yet, both would be difficult to classify unambiguously within current epidemiological terminology. While both scenarios resulted in effective and timely responses, the absence of a formal category to describe and document such events poses challenges for accountability, performance assessment, and knowledge sharing across jurisdictions. Labeling them as EREs *ex post* would allow for their systematic inclusion in surveillance reporting frameworks, enabling data-driven insights on the frequency, triggers, and outcomes of early-stage responses.

1.3 Limits of the outbreak-centered paradigm in epidemiologic classification

Public health professionals engaged in the management of atypical or complex events are aware of the significant demands such situations impose—ranging from the rapid mobilization of human and material resources to the intense operational pressure sustained over time. Yet, despite the scale of the response they require, it remains unclear how these events should be formally classified within existing epidemiological frameworks [2–4].

As highlighted in a recent review, the difficulty in accurately classifying emerging clusters stems from the inherent complexity of detecting novel or unexpected pathogens amidst the background noise of endemic conditions. This diagnostic uncertainty—particularly in discerning which atypical clusters merit exceptional response efforts—remains a persistent challenge for public health systems worldwide [7]. Moreover, the absence of standardized terminology to describe intermediate or atypical events hampers the systematic registration, reporting and evaluation of these occurrences, resulting in data gaps and inefficiencies in public health decision-making. How, for example, should such events be reflected in annual epidemiologic reports when they do not meet standard definitional thresholds?

While modern epidemiology has evolved rapidly—leveraging real-time data, digital surveillance tools, and interdisciplinary inputs including genomics and environmental indicators—it continues to grapple with foundational conceptual limitations. Chief among these is the entrenched, outbreak-centered view that dominates epidemiologic reasoning and reporting.

Two key issues underlie this gap. First, the prevailing framework tends to operate within a binary logic: events are either classified as outbreaks or not. This dichotomy drives efforts to fit epidemiologic signals into predefined criteria, often through complex algorithms or stepwise classifications. A substantial body of literature is devoted to refining these thresholds. However, this rigid approach fails to accommodate a wide range of scenarios that, while not classified as outbreaks, still carry significant implications for public health and require intensive responses. In many instances, such "non-outbreak" events can demand equal or greater resources than events that formally meet outbreak criteria.

Second, the lack of a universally accepted definition of "outbreak" further compounds this problem. Terminology such as "event", "incident", and "outbreak" is often used interchangeably [2, 3], particularly when only a small number of cases are involved. Leading public health agencies offer inconsistent definitions of what constitutes an outbreak. Some, such as the WHO and CDC, emphasize a rise in case numbers beyond expected levels in a defined population and time period [1, 8]. Others, including national bodies such as the Health Protection Surveillance Centre (Ireland) and the Public Health Agency (Northern Ireland), define outbreaks based on thresholds of confirmed cases or incorporate specific criteria related to pathogen characteristics or settings [2, 3]. Even well-established outbreak classification algorithms may fail to adequately capture the nuances of real-world epidemiologic occurrences [9]. As a result, practitioners often struggle to assign a clear designation to complex events, undermining both clarity and comparability in public health reporting. This definitional fluidity underscores the need for a preliminary, standardized operational alert—such as the ERE—that can guide early-stage decision-making without requiring full consensus on outbreak thresholds.

We define an ERE as a structured early-warning signal—an occurrence that warrants a public health response based on its potential for harm or escalation, even if it does not (yet) meet formal definitions of outbreak, cluster, or incident. Rather than adding a new classification tier, the ERE concept formalizes a space already occupied by informal signals and uncertain events, providing a consistent operational trigger for early investigation and preparedness. By capturing events that signal potential disease threats—in line with the IHR (2005) [1]—the ERE framework offers a structured designation for situations that demand attention and intervention but defy traditional classification schemes.

1.4 Why ERE is essential

EREs function as early warning signals, enabling public health systems to initiate a response before an event's characteristics are fully defined or the situation escalates. In this sense, EREs serve as early-stage risk assessment tools, allowing for timely, proactive interventions in the face of potential threats—regardless of whether the event ultimately fits within conventional epidemiologic categories. By analogy, an ERE can be likened to a fire alarm that detects smoke, prompting action before it becomes clear whether the source is a cigarette or a full-blown fire.

Importantly, while an ERE may represent the first step in the escalation toward a more clearly defined public health threat, it can also be the final classification when an event does not align with existing categories such as isolated case, cluster, or outbreak. Recognizing and documenting EREs as distinct occurrences allows public health agencies to better quantify their activities and resource deployment. It also enables the collection of measurable data to support improved reporting, evaluation, and accountability.

Similar to the concept of a care cascade in chronic disease management, a system built around measurable stages—such as signal detection, ERE classification, and defined epidemiologic outcomes—could serve as a proxy for assessing the performance and responsiveness of surveillance systems. For example, if only 5% of EREs evolve into outbreaks, or if 70% remain unclassified after investigation, what might that imply? A robust early-warning system? A conservative outbreak definition? Or something else entirely? At present, public health systems lack the data infrastructure to answer such questions.

By formalizing EREs within surveillance frameworks, we can improve the granularity and responsiveness of public health monitoring. Identifying and categorizing EREs facilitates more targeted, adaptive responses and more rational allocation of resources. Ultimately, EREs may guide local, regional, and national systems in prioritizing investigations, containment measures, and preparedness efforts—enhancing both the efficiency and effectiveness of public health responses.

The concept of ERE can be positioned as a structured operational signal — a pre-notification alert category — intended to enhance the early detection of public health threats. Much like the decision instrument outlined in Annex 2 of the IHR (2005) [10], which requires national authorities to assess events based on four key criteria (seriousness, unusualness, risk of international spread, and potential trade/travel restrictions), EREs offer an upstream classification tool that can trigger preliminary investigation and mobilization before formal notification thresholds are met. Complementing the IHR (2005) Annex 2 framework, EREs serve as an intermediate layer, offering a structured designation for events that warrant immediate attention and preliminary public health action, even when they do not (yet) fulfill at least two of the four notification criteria

outlined in Annex 2 (notably, certain diseases—such as smallpox, poliomyelitis due to wild-type poliovirus, human influenza caused by a new subtype, and severe acute respiratory syndrome (SARS)—require immediate notification under the IHR (2005), regardless of whether the two-criteria rule is met) [10]. By doing so, EREs can help reinforce the early warning function of surveillance systems, particularly in contexts of uncertainty or incomplete information, and act as a trigger for internal escalation, risk assessment, and intersectoral coordination. Integrating EREs into surveillance systems would therefore serve as a precursor stage to IHR (2005) Annex 2 assessments, supporting timely detection and better preparedness. Importantly, EREs could be especially useful in resource-constrained settings, where structured tools to identify unusual, locally impactful events may be lacking.

1.5 EREs in practice

The relevance of EREs is also consistent with how we define the term "event"—not only as the manifestation of disease but also as an occurrence that creates the potential for disease. This implies that even in the absence of consolidated health damage, the mere possibility of harm may justify a substantial public health response. Many of these possibilities do not fit neatly within the standard epidemiologic taxonomy we are accustomed to. The range of events that could fall under the proposed category of ERE is broad, encompassing occurrences that merit public health attention yet fall outside traditional classifications. These include but are not limited to sentinel cases of emerging or re-emerging infectious diseases, imported cases involving high-impact pathogens, unusual clusters or disease patterns, seasonal anomalies, geographic expansion of vector-borne diseases, and the emergence of novel antimicrobial resistances.

Beyond the illustrative scenarios presented earlier, the detection of a single human case of highly pathogenic avian influenza A (H5N1) in a European country could serve as a paradigmatic example of an ERE. Although such a case may not immediately fulfill outbreak criteria, it would undoubtedly require urgent investigation to assess risks—including those related to zoonotic spillover—and to implement precautionary measures, including public communication through mass media. The potential for progression to human-to-human transmission further elevates its importance.

Classifying such cases as EREs within existing influenza surveillance systems could significantly enhance risk assessment, guide resource prioritization, and improve overall response effectiveness. From a clinical standpoint, recognizing such cases as EREs is equally crucial: the management of H5N1 infections has already demonstrated substantial resource demands—including extracorporeal membrane oxygenation (ECMO), continuous dialysis, and advanced antiviral treatments [11, 12]—many of which are not readily available in most healthcare settings. Formal ERE classification would therefore support more structured and strategic deployment of clinical and public health resources, ultimately strengthening preparedness.

Building on the IHR (2005) Annex 2 framework, it is important to acknowledge that several types of public health events may not initially meet at least two of the four notification criteria and therefore may not require immediate notification under the IHR (2005) [10]. Nevertheless, such events can still warrant prompt attention and early public health action. In these cases, the classification of an event as an ERE can support

structured internal risk assessment, timely mobilization of resources, and systematic documentation.

For instance, environmental surveillance may detect anomalies—such as hepatitis E virus in wastewater [13]—even in the absence of reported clinical cases, prompting preventive measures despite not fulfilling Annex 2 thresholds. Similarly, signals from digital epidemiology—such as unexpected spikes in syndromic presentations (e.g., fever and rash) in emergency departments, or surges in online searches and social media content related to specific symptoms—may indicate the early onset of a public health threat before traditional criteria are met.

The increasing availability of advanced surveillance modalities, including wastewater monitoring, syndromic surveillance, and digital signal tracking, enables earlier detection of atypical health events. EREs provide a conceptual and operational framework to act upon such signals in a structured manner.

Importantly, this framework also applies to non-infectious events, such as the detection of toxic or radioactive contaminants in the environment, or clusters of unexplained symptoms potentially linked to environmental exposures (e.g., industrial chemical spills, air pollution peaks, or hazardous consumer products). Although such situations may not trigger immediate international notification, their early recognition and structured classification as EREs can enhance the responsiveness of surveillance systems, enable targeted escalation, and ultimately strengthen preparedness and accountability.

Moreover, the concept of EREs is highly applicable to one of the domains most frequently affected by localized outbreaks with significant health and economic burden: the social and healthcare assistance sector. Within long-term care facilities, hospitals, and broader healthcare environments, events involving potential transmission of infections, the emergence of antimicrobial resistance, or combinations of both, often arise in complex clinical and organizational settings. An illustrative example is a case of colonization due to *Candida auris* identified within a healthcare facility located in a region where no previous cases had been reported [14]. While these may not always meet traditional outbreak criteria, their consequences can be far-reaching. The early identification and structured classification of such events as EREs would enable timely containment strategies, better protection for vulnerable populations, and improved coordination across institutional care systems.

The ERE framework may be intentionally designed to be adaptable across different levels of the health system. It can be applied at subnational, national, and even facility levels to support timely detection, prioritization, and escalation of public health signals. In high-resource settings, EREs may integrate with digital surveillance platforms, while in low-resource contexts, ERE classification may rely on sentinel networks, frontline clinical reports, or simple checklists. By standardizing the early recognition of relevant events—before they reach formal notification thresholds—EREs can enhance accountability and responsiveness, particularly in settings with limited capacity to perform rapid laboratory confirmation or complex epidemiological investigations. The framework's flexibility allows it to complement existing protocols without requiring major structural changes, making it suitable for phased or pilot implementation within routine surveillance systems.

Additionally, the ERE framework could enhance communication across agencies, policymakers, and the public, aligning with international efforts—such as those under the

IHR (2005)—to reinforce early warning systems and build resilience to emerging health threats. It may also help navigate the turmoil caused by the rapid dissemination of unvalidated information that often accompanies illness emergence events [7].

2 Conclusion

The formal introduction of "Epidemiologically Relevant Events" as a distinct category in epidemiology may present a valuable opportunity to enhance public health practice. It recognizes the nuanced continuum of disease emergence and provides a structured framework for identifying and managing events that fall outside conventional classifications such as clusters or outbreaks. Introducing the ERE category allows for greater flexibility in the evaluation of events that pose public health concerns, helping to avoid both overestimation and underestimation of their relevance. This contributes to overcoming the prevailing dichotomous and restrictive approach in the field. By serving as a trigger for earlier interventions, the ERE concept can improve the efficiency of resource utilization and strengthen the accountability of public health systems.

We encourage the broader epidemiologic and public health community to engage in a collaborative effort to establish a consensus-based framework for defining and operationalizing EREs. As global health threats become increasingly complex and unpredictable, the adoption of innovative and flexible approaches like this one will be essential to improving preparedness, response, and resilience in the 21st century.

We recognize that several of the dynamics highlighted in this paper—early signal detection, multi-agency response coordination, and proactive communication—are already part of best practice in many public health systems. However, we argue that the absence of a formalized and generalizable category for such precursor events results in missed opportunities for learning and accountability. Establishing the ERE concept is therefore not about introducing a new term, but about proposing a framework that enables structured documentation, fosters dialogue, and supports evaluation of the public health response continuum.

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