ADVERSE DRUG REACTİON REPORTİNG: BEYOND REPORTİNG / A STATE OF THE ART

Marilyn Deleon Castro[1]
0000_0003_0453_5240

Sofia Hazel Esperanza Ángel[1]

Ana Aida Hernández[1]

Jorge Manuel Molina Aguilar[2]
0000_0001_7288_9740

1. Sanitary Surveillance Unit
Superintendency of Health Regulation
2. Unidad Integral de Servicios de Clínica del Dolor y Psicología Oncológica del Instituto del Cáncer de El Salvador "Dr. Narciso Díaz Bazán", Co-director del Observatorio del Comportamiento de Automedicación de la Universidad del Rosario (Bogotá)
revista@srs.gob.sv

Literary Review

Received:
March 20, 2026

Accepted:
April 23, 2026

Published:
August 07, 2026

Abstract

Adverse drug reaction reporting constitutes a central component of pharmacovigilance systems; however, its implementation in real-world settings does not follow a linear correspondence with the normative frameworks that underpin it. From both health sciences and social sciences perspectives, this field has been progressively problematized as a situated practice shaped by organizational dynamics, working conditions, institutional arrangements, and diverse professional rationalities.

This state-of-the-art review examines how reporting has been addressed in the literature, shifting its understanding from a purely technical act to a complex sociotechnical practice. The study was conducted as a non-systematic, theoretically informed review, employing a data triangulation approach that integrated empirical, normative, and institutional sources. Analysis was carried out through thematic coding and interpretive synthesis, enabling the identification of patterns, tensions, and gaps within the field. Findings indicate that underreporting cannot be explained solely by individual deficits but emerges from structural misalignments between system requirements and the concrete conditions of clinical work. Recurrent tensions were identified between regulation and practice, institutional design and effective use, as well as procedural demands and care dynamics. In this sense, the review provides an analytical reconstruction of the field, enabling a deeper understanding of reporting beyond its procedural dimension, situating it at the intersection of institutional arrangements, professional practices, and organizational contexts, and offering an interpretive basis for further analysis.

Keywords: pharmacovigilance; adverse drug reactions; underreporting; reporting systems; professional practice

Introduction

This state of the art defines its scope around the reporting of adverse drug reactions (ADRs) from a perspective that goes beyond its understanding as a mere technical procedure, positioning it as a complex health phenomenon and, at the same time, as a multi-dimensional social process. Within this framework, reporting is situated within the field of patient safety and health surveillance, but also within the concrete dynamics of clinical practice, where organizational conditions, professional rationales, technological devices, and regulatory frameworks interact.

The reporting of ADRs can be understood as a point of articulation between various levels of analysis that have been previously explored: the alignment—or mismatch—between system requirements and actual workflows; procedural demands and the administrative burden associated

the tensions between clinical and institutional timelines; and professional perceptions regarding the adequacy and feasibility of the system in specific contexts. Added to this, as an emerging element, is the citizen dimension as an epistemic actor within pharmacovigilance, expanding the field toward forms of experiential knowledge, relationships of institutional trust, and conditions of access to reporting systems.

From this perspective, reporting cannot be reduced to a regulated technical act; rather, it is shaped as a situated practice in which healthcare professionals operate under conditions of high clinical demand, fragmented workflows, and time pressure. The tension between ideal regulations—which presuppose a standardized, systematic, and timely process—and actual practice—marked by immediate clinical priorities and structural limitations—constitutes a central axis for understanding the phenomenon of underreporting.

In methodological terms, the present review is developed under a non-systematic approach, understood as a narrative review with a systematized approach. According to Codina (2024), traditional or narrative reviews can constitute "works of thought" of high conceptual value, whose quality depends on the author's experience, critical capacity, and relevance in the selection of sources; nevertheless, the same author recommends incorporating systematization strategies—such as database verification—in order to mitigate biases and strengthen the consistency of the analysis (Codina, 2024).

In this work, this recommendation is adopted as a methodological principle, articulating a review that, without aiming for exhaustiveness or total replicability, is oriented toward constructing a solid interpretive framework. This approach makes it possible to integrate evidence from various traditions—epidemiological, clinical, and sociotechnical—and to situate ADR reporting in relation to the actual conditions of its practice. Under this logic, pharmacovigilance is understood not only as a regulatory system, but as a field of practices where institutional structures, organizational cultures, and professional experiences converge, shaping the concrete possibilities for reporting.

Definition and evolution of pharmacovigilance

In the contemporary field of public health, pharmacovigilance is configured as a structural mechanism oriented toward the detection, assessment, understanding, and prevention of adverse effects associated with the use of medicines—particularly those that have not been identified during pre-marketing phases due to methodological restrictions such as sample size, follow-up duration, or the controlled selection of participants. Its fundamental purpose lies in ensuring that, under real-world conditions of use, the benefit-risk ratio of medicines remains favorable, thereby establishing itself as a central articulating axis of therapeutic safety in modern healthcare systems (World Health Organization [WHO], 2002; European Medicines Agency [EMA], 2017).

From a historical perspective, the development of modern pharmacovigilance found a decisive turning point in the thalidomide tragedy of the 1960s—an event that not only exposed the structural limitations of pre-marketing evaluation processes, but also ushered in a new regulatory sensitivity surrounding the risks associated with medicines (WHO, 2002). In response to this crisis, the World Health Organization's International Drug Monitoring Programme was established in 1968, currently coordinated by the Uppsala Monitoring Centre, creating a global network destined for the collection, systematization, and analysis of suspected adverse reaction reports from multiple national contexts (WHO, 2002; Edwards, 2017).

Within the framework of the drug life cycle, Phase IV or post-marketing surveillance acquires a unique relevance, as it constitutes the space where spontaneous reporting systems operate as the primary mechanism for detecting emerging risks. This centrality is largely due to the inherent limitations of clinical trials, which, even under rigorous methodological conditions, fail to capture the complexity of real-world clinical practice characterized by polypharmacy, comorbidity, and population diversity (Hauben & Aronson, 2007). In this sense, pharmacovigilance progressively shifts from a model centered on experimental validation toward a model oriented toward continuous observation in everyday contexts of use.

From the second decade of the 21st century onward—and particularly within the European context following the legislative reform in pharmacovigilance—a substantive reconfiguration of the model can be observed, transitioning from a predominantly reactive logic toward a comprehensive risk management approach. This shift incorporates tools such as Risk Management Plans, post-authorization safety studies, and

the strengthening of active pharmacovigilance mechanisms, while simultaneously promoting greater transparency and openness to the participation of non-traditional actors, including patients and citizens (EMA, 2017). This process not only expands the technical scope of the system but also redefines its epistemological boundaries by recognizing the relevance of multiple forms of knowledge in the construction of drug safety.

Currently, pharmacovigilance is recognized as an essential public health activity whose contribution transcends the identification of adverse events to impact the reduction of morbidity and mortality, the optimization of the benefit-risk ratio, the improvement in the quality of medicine use, and the strengthening of confidence in regulatory systems (FDA, 2020; EMA, 2017). However, this evolution cannot be understood solely in terms of technical or regulatory sophistication. From an expanded reading, pharmacovigilance is configured as a sociotechnical framework in which regulatory frameworks, technological devices, clinical practices, and organizational cultures converge. This implies that its effective functioning depends as much on its institutional design as on its appropriation in the daily practice of healthcare professionals. This perspective makes it possible to problematize the apparent neutrality of the system and position its analysis at the intersection of structure, practice, and experience.

Adverse Drug Reactions (ADRs)

Adverse drug reactions constitute the analytical core around which pharmacovigilance is structured, as they represent the events that trigger surveillance, analysis, and regulatory mechanisms. The World Health Organization defines them as any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease (WHO, 2002). This operational definition delineates the scope of action of pharmacovigilance by distinguishing ADRs from other drug-related events, while establishing a criterion of clinical and sanitary relevance.

From a classificatory standpoint, ADRs have been traditionally organized based on their mechanism and predictability. The typology proposed by Rawlins and Thompson distinguishes between Type A reactions—which are predictable and dose-dependent—and Type B reactions, which are idiosyncratic and unpredictable, thereby establishing a fundamental distinction between events derived from the known pharmacological properties of the drug and those emerging from complex, not yet fully understood interactions (Rawlins & Thompson, 1977). Subsequently, this classification was expanded to incorporate categories that consider dimensions such as chronicity, latency, or treatment withdrawal, reflecting a growing complexity in the understanding of adverse events (Edwards & Aronson, 2000).

On the clinical level, the evaluation of ADRs is carried out based on criteria such as severity, frequency, and the causal relationship with the suspected drug. Tools such as the Naranjo algorithm have been developed with the purpose of systematizing causality assessment; however, its application in real-world contexts is limited by the heterogeneity of clinical scenarios, the coexistence of multiple factors, and the uncertainty inherent to medical practice (Naranjo et al., 1981). This tension between standardization and contingency evidences that the understanding of ADRs cannot be reduced to a technical operation; rather, it needs to be situated within the framework of clinical and social complexity.

Beyond their formal categorization, ADRs constitute experiences that directly impact patients' lives, affecting their well-being, therapeutic adherence, and trust in their treatments. Likewise, they generate a significant burden for healthcare systems, both in terms of costs and clinical demand. In this sense, ADRs must be understood not only as biomedical events, but as phenomena that articulate clinical, social, and subjective dimensions, which justifies addressing them from a comprehensive perspective.

ADR reporting as a healthcare practice

The reporting of adverse drug reactions constitutes the central operational mechanism of pharmacovigilance, as it enables the generation of safety signals and evidence-based regulatory decision-making. In regulatory terms, it is defined as the procedure through which healthcare professionals report suspected ADRs to national or international surveillance systems, thereby contributing to the collective construction of knowledge regarding the risks associated with medicines (EMA, 2017; FDA, 2020).

However, conceiving reporting exclusively as a technical act is insufficient to account for its complexity. In practice, reporting is shaped as a situated healthcare practice, intersected by multiple

dimensions that extend beyond the procedural level. Various studies have shown that factors such as clinical workload, work organization, the perceived relevance of the event, knowledge of reporting systems, and institutional dynamics significantly influence the decision to report. This creates scenarios where underreporting emerges as a structural phenomenon rather than an individual failure (López-González, Herdeiro, & Figueiras, 2009).

Within this framework, reporting can be understood as a space of constant negotiation between immediate clinical demands and the requirements of the pharmacovigilance system. In their daily practice, healthcare professionals find themselves needing to prioritize direct patient care over tasks that, although relevant to collective safety, are perceived as additional or disconnected from clinical urgency. Added to this is a lack of institutional feedback, the perceived ineffectiveness of reporting, and, in some cases, fear of legal implications, which contributes to making the process even more complex.

From an ethical perspective, reporting implies a commitment to patient safety and to the collective responsibility of improving knowledge about medicines (EMA, 2017). However, this commitment is embedded within actual working conditions that do not always favor its practice, highlighting the need to analyze pharmacovigilance not only from its regulatory design, but from the concrete conditions in which it is implemented.

Consequently, ADR reporting must be understood as a sociotechnical practice in which technological devices, regulatory frameworks, professional knowledge, and organizational conditions converge. This understanding allows for a shift in analysis from compliance-centered approaches toward a broader interpretation that recognizes the tensions, limitations, and potential of the system in its interaction with daily practice. Thus, reporting—or the lack thereof—ceases to be interpreted exclusively as a problem of knowledge or attitude, and is instead understood as the result of structural mismatches between system requirements and actual workflows within clinical settings.
In coherence with the conceptual elements developed, the present review aligns with an integrating approach that articulates epidemiological, clinical, and, centrally, sociotechnical dimensions of pharmacovigilance. While the contributions of the biomedical paradigm in the identification, classification, and analysis of ADRs are acknowledged, the approach adopted transcends the descriptive and quantitative to position reporting as a complex healthcare practice, embedded within specific institutional, cultural, and organizational contexts.

This positioning allows for the understanding that reporting does not respond solely to knowledge deficits or system failures, but rather to structural tensions between clinical logic and regulatory demands, as well as to the actual conditions of professional practice. Added to this is the public's experience with medicines, which not only shapes perceptions regarding risk and effectiveness, but also gives rise to communication and reporting practices outside of institutional channels. In this sense, a culture of formal underreporting emerges, coexisting with informal circuits of information circulation—particularly on social networks and digital spaces—where adverse events are narrated, interpreted, and shared without necessarily translating into reports within pharmacovigilance systems. This dynamic expands the field of analysis by incorporating citizens as epistemic actors, highlighting the coexistence of multiple rationalities and reporting channels that challenge the centrality of formal mechanisms. In this way, the disciplinary plurality adopted in this study is not only pertinent but necessary, as it enables a thicker understanding of the phenomenon. It articulates empirical evidence with the dynamics of daily practice, opening up the discussion toward the need to rethink pharmacovigilance not merely as a surveillance system, but as a situated field of action where knowledge, practices, and structures converge, ultimately shaping the concrete possibilities for reporting.

Methodology

To achieve the proposed analysis, a methodological strategy was developed based on a non-systematic state of the art with an analytical and interpretive orientation, drawing primarily on the framework of Codina (2020). This author recognizes this type of review as particularly relevant for complex, heterogeneous fields of study in the process of consolidation, where phenomena cannot be reduced to rigid protocols or exclusively quantifiable criteria. In this case, ADR reporting is approached as a complex healthcare phenomenon that goes beyond its definition as a technical procedure, positioning itself at the intersection of patient safety, health surveillance, and the actual dynamics of clinical practice, which are intersected by organizational, temporal, and sociotechnical conditioning factors.

From this perspective, the review is configured as a narrative review with an integrative purpose, in the sense proposed by Grant and Booth (2009), who distinguish this type of approach as one that allows for mapping, synthesizing, and interpreting diverse bodies of literature without being restricted to the criteria of exhaustiveness and reproducibility characteristic of systematic reviews. This approach is especially pertinent when the interest does not lie in the estimation of effects, but rather in understanding complex configurations of practices, discourses, and structures, enabling an expanded reading of pharmacovigilance as a situated practice.

Search strategy and corpus delimitation

In operational terms, the search strategy was carried out by consulting specialized databases such as PubMed, Scopus, Web of Science, SciELO, and Google Scholar, as well as institutional repositories of international organizations and regulatory agencies. Keywords were used in combinations of Spanish and English related to "pharmacovigilance," "adverse reaction reporting," "patient safety," "underreporting," and "clinical workflows." Inclusion criteria prioritized documents published within the last fifteen years, while also incorporating classic texts relevant to the conceptual development of the field. Empirical studies, reviews, technical documents, and regulatory frameworks were included, while those lacking methodological rigor or thematic relevance were excluded.

The conformation of the corpus did not follow a logic of exhaustive accumulation or a merely quantitative inclusion criterion; instead, it responded to a theoretically informed selection process—an analytical process guided by conceptual frameworks that direct the selection, organization, and interpretation of evidence, allowing for the prioritization of analytical relevance over descriptive exhaustiveness (Dixon-Woods et al., 2006). In that direction, the study aimed to capture the diversity of approaches, disciplinary traditions, and levels of analysis from which ADR reporting has been addressed. This selection was based on the conceptual relevance of the studies, their explanatory capacity regarding the phenomenon, and their contribution to understanding the tensions between the regulatory design of pharmacovigilance and the actual conditions of its implementation.

In this sense, the research was configured based on the potential of the studies to illustrate different dimensions of the problem, including clinical, organizational, institutional, and sociotechnical aspects, as well as professional rationalities and the material conditions of healthcare work. Rather than aiming for a totalizing representation of the literature, priority was given to the inclusion of studies that allowed for problematizing the phenomenon, identifying recurrent patterns, making divergences visible, and recognizing analytical gaps. In this way, the conformation of the corpus aligns with a logic of theoretical saturation and interpretive density, in which the selection of sources responds to their capacity to contribute to the construction of a robust comprehensive framework, capable of articulating empirical evidence with the concrete dynamics of healthcare practice.

Analytical organization of the corpus and interpretive frameworks

In a complementary manner, contributions from organizational sociology and social studies of health make it possible to problematize the tensions between institutional mechanisms and professional practices. They bring to light processes of reinterpretation, adjustment, negotiation, or resistance that emerge within concrete contexts of implementation. Various studies have shown that health policies, protocols, and technologies do not integrate linearly into practice; instead, they are appropriated, reconfigured, or even partially dismantled by actors based on their own rationalities, working conditions, and frameworks of meaning (Waring & Bishop, 2010; Berg, 1997; Timmermans & Berg, 2003).

From this perspective, regulatory mechanisms—including pharmacovigilance systems—can be understood as forms of standardization that, far from imposing themselves homogeneously, interact with situated practices, generating frictions, adjustments, and displacements. As Timmermans and Berg (2003) argue, health standards do not eliminate the variability of practice; rather, they coexist with it, producing local arrangements that reveal the gap between formal design and effective use. In a convergent line of thought, Berg (1997) cautions that information systems and organizational tools do not merely support clinical practice, but also reconfigure it, introducing new forms of work that may be accepted, adapted, or resisted.

In the specific realm of organizational reforms in healthcare, Waring and Bishop (2010) have documented how initiatives oriented toward improving quality and efficiency can be reinterpreted by professionals as organizational

rituals or additional burdens, generating responses that oscillate between strategic adherence and tacit resistance. This type of analysis allows for a shift in the understanding of the gaps between regulation and practice—moving from a logic of individual non-compliance toward a structural reading, in which these gaps emerge as an expression of the coexistence of multiple rationalities: institutional, clinical, administrative, and that of daily practice.

This perspective contributes to a thicker reading of the corpus, as it allows for the analysis of the frictions between pharmacovigilance regulations and their implementation not as isolated deviations, but as manifestations of structural mismatches between system requirements and the actual conditions of healthcare work. Within this framework, reference points from organizational sociology do not operate as direct empirical evidence of the phenomenon under study, but rather as frameworks of intelligibility. These frameworks make it possible to interpret the literature's findings through a relational lens, thereby strengthening the analytical coherence of the state of the art and expanding its explanatory possibilities.

Systematization matrices and analytical tools

The review was structured through the design and use of systematization matrices, conceived as analytical tools that allowed for the rigorous organization, comparison, and discussion of evidence prior to its narrative integration. These types of tools align with qualitative traditions of document analysis that seek to transform bibliographic material into comparable units, thereby fostering processes of coding, categorization, and interpretive synthesis (Bowen, 2009; Miles et al., 2014).

The first matrix corresponded to a technical datasheet of the studies, designed to record baseline information such as authorship, year, context, study type, and source, thereby guaranteeing the traceability of the corpus and providing an overview of the analyzed material. This initial level operated as an ordering tool that facilitated the identification of general trends and the precise location of sources.

The second matrix constituted the analytical core of the process, breaking down each study into substantive dimensions such as the research problem, objectives, theoretical framework, methodology, population, results, and factors associated with reporting. The incorporation of categories such as professional role, institutional framework, citizenship, and the communicational dimension made it possible to expand the field of observation and capture the complexity of the phenomenon from multiple perspectives, avoiding a reductionist reading focused exclusively on technical or clinical variables. This type of breakdown aligns with qualitative analysis approaches that prioritize the identification of relationships between categories and the progressive construction of meaning (Miles et al., 2014).

The third matrix introduced a level of configurational analysis aligned with the study's theoretical cartographies, allowing for the interpretation of evidence based on previously defined analytical axes and the establishment of relevance levels according to the density or recurrence of the findings. This tool made it possible to identify patterns, regularities, and tensions in the literature, moving from a descriptive logic toward a relational reading of the phenomenon.

The fourth matrix was oriented toward synthesis, condensing each study into key elements such as its central idea, the most relevant findings, the predominant types of barriers and facilitators, and its relevance to the context of analysis. This level made it possible to articulate individual results into a coherent narrative, facilitating cross-comparisons between studies and the identification of convergences and divergences.

Finally, the fifth matrix compiled relevant textual extracts, including definitions, findings, and recommendations, along with their precise location within the original documents. This matrix served as a support function for the drafting process, ensuring conceptual precision, traceability, and fidelity to the sources—fundamental aspects in document analysis processes (Bowen, 2009).

The articulated use of these matrices not only made it possible to systematize the information, but also to generate spaces for discussion among the researchers, wherein interpretations were contrasted, categories were adjusted, and analytical gaps were identified.

This iterative process, characteristic of qualitative analysis, contributed to consolidating the interpretive character of the review and strengthening the internal coherence of the constructed analytical framework.

Triangulation and interpretive construction

The analysis process was structured based on a logic of qualitative triangulation, understood not merely as a validation mechanism, but

as an analytical deepening strategy aimed at contrasting, complementing, and bringing into tension different sources, approaches, and levels of interpretation. In this sense, triangulation made it possible to shift the reading of the phenomenon from a descriptive logic toward a relational and situated understanding, coherent with advanced qualitative approaches (Denzin, 1978; Flick, 2018). This triangulation operated across three articulated levels.

In the first place, the triangulation of sources involved the systematic cross-referencing of empirical, regulatory, and institutional literature, which made it possible to identify both convergences and dissonances in the way ADR reporting is conceptualized and operationalized.

This cross-referencing proved key to highlighting the gaps between regulatory frameworks, technical recommendations, and actual practices within care contexts. In the second place, interpretive triangulation materialized through discussion spaces among the researchers, wherein readings were contrasted, assumptions were problematized, and meanings were negotiated. This collective process strengthened the internal consistency of the analysis and contributed to reducing individual biases by incorporating multiple perspectives into the construction of the interpretations.

Based on this strategy, the analysis was carried out through a process of thematic coding and interpretive synthesis. In the first phase, units of meaning linked to barriers, facilitators, organizational conditions, and professional perceptions were identified, operating as the initial nodes of analysis. In the second phase, these units were grouped into patterns that allowed for the recognition of recurrent configurations and structural tensions within the literature. Subsequently, the analysis moved toward a relational interpretation aimed at understanding the interdependence among the various factors that shape reporting practice, situating it within broader organizational, regulatory, and sociotechnical frameworks.

Scope and limitations

The described process made it possible to transform a heterogeneous set of studies into an intelligible corpus, capable of being examined through a relational lens. The articulation among searching, matrix-based systematization, discussion, and triangulation not only facilitated the organization of evidence, but also enabled a critical reading capable of identifying regularities, tensions, discontinuities, and gaps within the field of pharmacovigilance, particularly regarding ADR reporting. The state of the art presented below is offered as an analytical reconstruction of the field, aimed at showing how this phenomenon has been conceptualized, operationalized, and problematized across different disciplinary frameworks and practice contexts. Rather than a cumulative synthesis, it proposes a configurational reading that organizes the evidence around patterns and relationships, paying special attention to the tensions between regulation and practice, between institutional design and effective use, and between system requirements and the concrete conditions of clinical work.

In this sense, the review is not limited to describing the state of available knowledge; rather, it seeks to contribute to its problematizing, bringing to light the structural mismatches that run through reporting practice and the multiple rationalities that shape it. In this way, the state of the art provides a solid interpretive basis for understanding underreporting not as an individual deficit, but as the result of the interaction among institutional mechanisms, organizational conditions, and situated professional practices, thus paving the way for the development of the analytical cartographies that structure this study.

However, it is necessary to acknowledge that the non-systematic nature of the review entails certain limitations. In the first place, the selection of the corpus responded to criteria of analytical relevance rather than exhaustiveness, which may have left out relevant studies from other traditions or contexts. In the second place, the interpretive emphasis, guided by specific conceptual frameworks, implies a tailoring of the phenomenon that privileges certain readings—particularly those linked to organizational, sociotechnical, and professional dimensions—to the detriment of clinical approaches. Likewise, the heterogeneity of the included studies and their contexts of production limits the possibility of making generalizations, placing the findings on an analytical rather than a representative plane.

However, these limitations do not constitute weaknesses in a strict sense, but rather conditions inherent to the adopted approach, which privileges a relational understanding and the problematization of the phenomenon over its exhaustive measurement. Within this framework, the value of the review lies in its capacity to reorganize the

field, identify tensions, and open new research questions. Based on this positioning, the state of the art presented below is organized around the main analytical configurations identified in the literature, allowing for an examination of how ADR reporting has been constructed, tensioned, and reinterpreted at different levels—regulatory, organizational, and practical. This organization does not follow a cumulative logic, but a relational one, oriented toward making visible the patterns, discontinuities, and points of friction that structure the field.

Discussion

The study of adverse drug reaction reporting: A state of the art

The state of the art developed below is oriented toward examining how ADR reporting has been addressed in the literature, taking into account the diversity of approaches, levels of analysis, and contexts in which this phenomenon is embedded. Rather than organizing the background information according to a chronological sequence or traditional hierarchies of evidence, preference is given to an analytical reading that allows for the identification of patterns, recurrences, and tensions in the way reporting has been conceptualized and problematized. This approach responds to the need to understand reporting not as a homogeneous procedure, but as a practice whose configuration varies according to organizational conditions, institutional frameworks, and the dynamics of clinical work.

In this way, the reviewed studies are incorporated based on their capacity to contribute to the understanding of the conditions that favor or limit reporting, as well as the meanings that actors attribute to it within concrete contexts of practice. This approach makes it possible to move toward an analytical reconstruction of the field, in which different contributions engage in dialogue with one another, bringing to light both convergences and divergences, and progressively paving the way for the identification of gaps and areas of problematization that will be taken up again later on.

The study by Burbano Valdés, Caicedo Eraso, Cerón Burgos, Jacho Caicedo, and Yépez Chamorro aligns with a line of research oriented toward understanding the causes of non-reporting of adverse events in hospital contexts, providing relevant evidence to problematize reporting as an institutionally situated practice. Utilizing a mixed-methods design that coordinates surveys, interviews, and focus groups, the study demonstrates a significant gap between the occurrence of adverse events and their formal reporting, showing that underreporting is not solely due to knowledge deficits, but rather to organizational and cultural conditions that mediate the decision to report. In this sense, the work identifies a distance between regulatory knowledge and effective practice, wherein the recognition of the importance of reporting coexists with its omission in daily healthcare delivery (Burbano Valdés et al., 2013).

Among the most relevant findings, the fear of retaliation, the association of reporting with blame or punishment, and the absence of institutional feedback stand out as factors that shape ambivalent dispositions toward reporting. These elements make it possible to understand reporting not as an automatic technical act, but as a practice intersected by professional rationalities, hierarchical relationships, and specific organizational climates. From this perspective, the study contributes to the understanding of underreporting as an expression of structural mismatches between institutional mechanisms and the actual conditions of healthcare work, reinforcing the need to approach pharmacovigilance—and the reporting of adverse events—from a sociotechnical lens that integrates organizational, cultural, and practical dimensions (Burbano Valdés et al., 2013).

The study by Katusiime, Semakula, and Lubinga (2015) analyzes ADR reporting in African hospital contexts, situating pharmacovigilance as a practice conditioned by cognitive and institutional factors. Utilizing a cross-sectional quantitative design based on the administration of questionnaires to healthcare professionals at a national referral hospital in Uganda, the research demonstrates a low proportion of effective reporting, in which only a minority of respondents had ever reported an ADR. This finding identifies a significant gap between the occurrence of adverse events and their formal registration, showing that reporting is not systematically integrated into clinical practice. Likewise, it is observed that although some professionals recognize the importance of reporting, limitations persist regarding practical knowledge of institutional procedures and channels, which highlights a gap between the existence of the pharmacovigilance system and its effective appropriation (Katusiime, Semakula, & Lubinga, 2015).

Among the most relevant findings, insufficient training in pharmacovigilance stands out as one of the primary barriers to reporting, alongside a lack of knowledge regarding where and how to report ADRs. Added to this are factors such as workload and a lack of continuous awareness-raising, which shape an environment that is poorly conducive to active reporting. These elements make it possible to understand reporting not as an automatic technical act, but as a situated practice intersected by organizational conditions and professional dispositions that affect the decision to report. In this sense, underreporting emerges as an expression of structural weaknesses in the implementation of the pharmacovigilance system, reinforcing the need for interventions oriented both toward strengthening knowledge and consolidating institutional strategies that favor the integration of reporting into routine clinical care (Katusiime, Semakula, & Lubinga, 2015).

The study by Pérez-Ricart, Gea-Rodríguez, Roca-Montañana, Gil-Máñez, and Pérez-Feliu (2019) analyzes the operational integration of pharmacovigilance in hospital contexts, situating ADR reporting as a practice that depends on organizational design and its embedding within routine clinical workflows. Utilizing an observational, descriptive, and retrospective design carried out in a hospital pharmacy department, the research examines the implementation of a pharmacovigilance program over a nine-year period, combining prospective, retrospective, and intensive detection strategies. The results show that incorporating the system into healthcare dynamics led to an increase in the identification and registration of ADRs, demonstrating that reporting can be effectively integrated into clinical practice when it forms part of the tools and processes used daily by professionals. This finding allows for the problematization of underreporting not as an absence of events, but as an effect of the low structural integration of reporting systems within clinical work (Pérez-Ricart et al., 2019).

Among the most relevant elements, the study highlights that the efficacy of the pharmacovigilance system does not depend exclusively on the individual willingness to report, but on its degree of articulation with the organization of healthcare work. The evidence suggests that systems operating in parallel with or disconnected from clinical workflows tend to capture only a fraction of adverse events, especially in highly complex contexts such as intensive care units. Likewise, barriers associated with workload and the perceived normalization of certain events are identified, along with facilitators such as the simplification of reporting systems, anonymity, and the visibility of the reporting effects on improving patient safety. These findings make it possible to understand reporting as a situated practice, whose viability depends on concrete organizational conditions, and reinforce the need to design pharmacovigilance systems that integrate seamlessly into the clinical routine, favoring their sustainability and appropriation over time (Pérez-Ricart et al., 2019).

The systematic review by Hazell and Shakir (2006) broadens the analysis by situating ADR underreporting as a global phenomenon, the magnitude and persistence of which cannot be explained solely by specific local or institutional contexts. Based on the synthesis of 37 international studies, the authors estimate an average underreporting rate of nearly 94%, demonstrating that pharmacovigilance systems, even when formally established, capture only a minimal fraction of the adverse events that occur in clinical practice. This finding consolidates underreporting as a structural problem within the field, revealing a systematic gap between the occurrence of events and their formal registration, and reinforcing the idea that reporting is not organically integrated into the daily dynamics of professional practice (Hazell & Shakir, 2006).

In analytical terms, the review identifies a set of recurrent barriers that transcend different healthcare contexts and systems, among which the lack of knowledge regarding reporting mechanisms, uncertainty regarding ADR causality, the perceived futility of individual reporting, and the workload associated with its completion stand out. Added to this are cultural and communicational dimensions, such as skepticism about the impact of reporting and the absence of institutional feedback, which shape environments that are poorly conducive to active reporting. However, key facilitators are also recognized, such as continuous education in pharmacovigilance, the simplification of reporting systems, and the integration of electronic tools into clinical practice. In this sense, the study reinforces the understanding of underreporting as an expression of structural and sociotechnical mismatches, while providing a robust epidemiological foundation to guide systemic interventions that favor the appropriation and sustainability of reporting within healthcare systems (Hazell & Shakir, 2006).

The study by López-González, Herdeiro, and Figueiras is oriented toward identifying and systematizing the determinants of ADR underreporting, proposing an analytical reading that transcends approaches focused exclusively on operational flaws within the system (2009).

Based on a systematic review of international literature, the authors construct a typology of explanatory factors that coordinates cognitive, cultural, and professional dimensions, demonstrating that the decision to report is mediated by interpretive frameworks that professionals develop in their daily practice. Within this framework, they introduce the notion of the "seven deadly sins" of underreporting—among which ignorance, insecurity, and indifference stand out—which help explain why, in practice, only events perceived as severe or unequivocal are reported, leaving out a broad spectrum of clinically relevant ADRs (López-González, Herdeiro, & Figueiras, 2009).
This approach complicates the understanding of reporting by incorporating the psychosocial dimension of professional practice, showing that underreporting is also shaped by subjective dispositions and rationalities constructed throughout training and work experience. Uncertainty regarding causality, the fear of being wrong, and the perception of insufficient technical knowledge emerge as central barriers that inhibit reporting, while professional culture may discourage reporting by penalizing uncertainty. In this way, the study provides a robust theoretical framework to analyze underreporting beyond structural deficits, suggesting that interventions should be oriented not only toward optimizing pharmacovigilance systems, but also toward transforming the frameworks of meaning through which professionals value, prioritize, and decide to report (López-González, Herdeiro, & Figueiras, 2009).

The study by Vincent, Stanhope, and Crowley-Murphy (1999) analyzes the reasons why healthcare staff do not report adverse incidents, even when formal notification systems are established. Utilizing a descriptive quantitative design based on surveys administered within the UK hospital context, the research demonstrates a notable variability in the criteria by which professionals decide which events to report, showing that even incidents formally considered reportable are not always notified. This finding identifies a significant gap between the regulatory definition of reporting and its interpretation in clinical practice, suggesting that notification does not operate as an automatic procedure, but rather as an action mediated by situated professional judgments (Vincent, Stanhope, & Crowley-Murphy, 1999).

The results highlight that barriers to reporting are shaped at the intersection of cultural and organizational factors, where staff perceptions, fear of sanctions, and a lack of clarity regarding reporting criteria decisively influence the act of reporting. Likewise, facilitators associated with the simplification of systems, the provision of feedback, and training processes are identified, all of which contribute to strengthening the willingness to report. In analytical terms, evidence is provided that allows for the understanding of underreporting as a multifactorial phenomenon, in which the decision to report depends more on subjective and contextual interpretations than on the mere existence of regulations or institutional systems. In this way, the study reinforces the need to approach reporting from a perspective that integrates organizational, cultural, and professional dimensions, recognizing the centrality of clinical judgment in the configuration of this practice (Vincent, Stanhope, & Crowley-Murphy, 1999).

Correa, Jauregui, Frangella, Peuchot, Otero, and Luna (2019) examine the impact of implementing an adverse event reporting system integrated into the electronic health record, situating pharmacovigilance at the intersection of technological design and daily clinical practice. Based on an empirical study conducted within a hospital setting, the research demonstrates an increase in reporting rates following the incorporation of the system, showing that integrating reporting into routinely used tools reduces operational barriers and favors its embedding within the clinical workflow. This finding highlights that underreporting is not solely due to individual factors, but also to the manner in which reporting systems articulate—or fail to articulate—with healthcare dynamics (Correa, Jauregui, Frangella, Peuchot, Otero, & Luna, 2019).

The results make it possible to identify that technological limitations—such as system fragmentation or the duplication of tasks—constitute relevant obstacles to reporting, whereas data automation, interoperability, and user-centered design emerge as key facilitators. In analytical terms, this reinforces the understanding of reporting as a sociotechnical practice, the viability of which depends on the alignment between technological mechanisms and the

actual conditions of clinical work. In this way, the evidence suggests that the effective integration of pharmacovigilance into information systems not only increases reporting volume, but also contributes to improving registration quality and patient safety, consolidating the need for approaches that link technological design, work organization, and professional practice (Correa, Jauregui, Frangella, Peuchot, Otero, & Luna, 2019).

From an approach centered on the operational actors of the healthcare system, Hussain, Hassali, Rehman, Muneswarao, Atif, and Babar analyze ADR reporting based on the experience of nursing staff in a Pakistani hospital context (2020). Through a qualitative lens, the research explores the perceptions and practices associated with reporting, demonstrating that although nurses frequently identify ADRs in their daily practice, these do not systematically translate into formal notifications. This discrepancy makes it possible to problematize the relationship between clinical detection and institutional registration, showing that the existence of pharmacovigilance systems does not guarantee their effective appropriation at the practical level (Hussain, Hassali, Rehman, Muneswarao, Atif, & Babar, 2020).

Within this framework, the findings highlight that the predominant barriers are located at the structural and organizational level, particularly in the lack of clarity regarding procedures, limited accessibility to reporting mechanisms, and institutional weaknesses in channeling information. In parallel, it is recognized that insufficient training and scarce awareness-raising affect how the role of nursing staff within the pharmacovigilance system is understood. Nevertheless, relevant facilitators are identified, such as continuous training, institutional backing, and the incorporation of strategies that integrate reporting into routine clinical care. In analytical terms, these results reinforce the understanding of underreporting as a systemic and relational phenomenon, in which the participation of actors depends on concrete organizational conditions. Thus, the study underlines the need to design systems that recognize and strengthen the role of nursing staff as a key agent in the detection and reporting of ADRs (Hussain, Hassali, Rehman, Muneswarao, Atif, & Babar, 2020).
Within the context of hospital systems in developing countries, Malik, Alam, Mir, Malik, and Abbas analyze the attitudes and barriers perceived by healthcare professionals regarding incident reporting, situating the phenomenon at the intersection of organizational culture and professional dispositions (2010). Utilizing a quantitative design based on surveys administered at a tertiary care hospital in Pakistan, the research demonstrates that although there is general recognition of the importance of reporting for patient safety, this does not translate into systematic practice. The results show a low frequency of reporting, which identifies a gap between the normative valuation of reporting and its effective incorporation into clinical practice (Malik, Alam, Mir, Malik, & Abbas, 2010).

In explanatory terms, barriers associated with the fear of punitive consequences, the lack of confidentiality in reporting systems, and the perception that reporting can generate professional conflicts are identified. Likewise, the absence of an institutional culture oriented toward safety and the limited feedback on submitted reports emerge as factors that discourage participation. Complementarily, it is observed that a lack of knowledge regarding procedures and the absence of specific training in reporting contribute to the persistence of underreporting. These elements make it possible to understand reporting as a practice conditioned by cultural and organizational frameworks, in which institutional trust and the perception of safety play a central role. Consequently, the evidence suggests that strengthening reporting systems requires not only technical adjustments, but also transformations in organizational culture that promote non-punitive environments and favor the active participation of healthcare personnel (Malik, Alam, Mir, Malik, & Abbas, 2010).

From an approach centered on surgical practice, Kreckler, Catchpole, McCulloch, and Handa (2009) examine the factors that influence incident reporting in highly complex clinical environments, situating the analysis within the specific dynamics of surgical work. Based on an empirical study conducted in surgical departments, the authors demonstrate that reporting is heavily conditioned by the professional culture and the hierarchies inherent to the surgical environment, where decision-making and error management are inscribed within frameworks of individual and collective responsibility. The results show that while there is recognition of the importance of reporting, this does not systematically translate into practice, identifying a gap between institutional safety policies and their implementation in highly demanding clinical contexts (Kreckler, Catchpole, McCulloch, & Handa, 2009).

The analysis highlights that barriers to reporting include cultural factors—such as the fear of blame or finger-pointing—as well as organizational elements related to workload, lack of time, and the perception of reporting as having little utility. In particular, the influence of professional hierarchies stands out, as they can inhibit open communication regarding incidents, especially among lower-ranking members. In contrast, facilitators associated with the promotion of a safety culture, the creation of non-punitive spaces for discussion, and the implementation of systems that allow for effective feedback are identified. In analytical terms, these findings reinforce the understanding of reporting as a practice situated within specific organizational contexts, where power relations, team dynamics, and the conditions of clinical work shape the possibilities of reporting. Thus, the study underlines the need for interventions that address not only formal systems, but also the professional cultures that mediate their use (Kreckler, Catchpole, McCulloch, & Handa, 2009).

Within the scope of nursing practice in Latin American hospital contexts, Juárez-Pérez and Durán-Muñoz (2018) address the reporting of sentinel events as a critical component of patient safety, situating the analysis within the responsibilities and experiences of nursing staff. Based on an empirical study, the authors demonstrate that although staff recognize the relevance of reporting serious adverse events, notification is not performed systematically, thereby identifying a gap between institutional regulations and their implementation in daily practice. This discrepancy highlights that reporting is not shaped solely as a technical act, but as a practice mediated by organizational and cultural conditions that influence the decision-making of healthcare personnel (Juárez-Pérez & Durán-Muñoz, 2018).

The findings highlight that barriers to reporting are related to the fear of sanctions, workload, and a lack of clarity regarding procedures, as well as the perception that reporting can generate negative consequences in the professional sphere. At the same time, facilitating elements linked to training, patient safety awareness-raising, and the strengthening of an institutional culture oriented toward learning rather than punishment are identified. In analytical terms, the study reinforces the understanding of underreporting as a phenomenon conditioned by structural and cultural factors, in which the participation of nursing staff depends on the concrete conditions of the work environment. In this way, the study underlines the need to promote institutional strategies that favor environments of trust, clarify reporting processes, and integrate notification into routine clinical care, thereby strengthening its sustainability and effectiveness (Juárez-Pérez & Durán-Muñoz, 2018).

From a perspective oriented toward the measurement of professional attitudes, Wilson, Bekker, and Fylan (2008) develop and validate a scale to evaluate the perceptions of doctors and nurses regarding adverse event reporting, providing an analytical instrument to understand the subjective determinants of reporting. Based on an empirical study in a hospital context, the authors demonstrate that attitudes toward reporting vary significantly between professional groups, identifying differences in the willingness to report and in the perceived utility of the system. This finding makes it possible to recognize that reporting depends not only on structural conditions, but also on attitudinal dispositions that shape practice at individual and collective levels (Wilson, Bekker, & Fylan, 2008).

The analysis highlights that factors such as risk perception, fear of negative consequences, and trust in the system directly influence the decision to report, while simultaneously demonstrating the importance of having tools to measure and monitor these dimensions. Furthermore, the validation of the scale offers a methodological resource to identify critical areas for intervention, particularly regarding the construction of safety cultures and the improvement of organizational communication. In analytical terms, the study contributes to consolidating the understanding of reporting as a practice intersected by cognitive and attitudinal components, complementing structural and organizational approaches. In this way, it reinforces the need to integrate strategies that address both system conditions and the perceptions and dispositions of professionals, favoring a more comprehensive approach to the problem of underreporting (Wilson, Bekker, & Fylan, 2008).

From an approach centered on the reporting intention of nursing staff, Throckmorton and Etchegaray (2007) analyze the factors that influence the decision to report errors, coordinating individual, normative, and contextual dimensions of the hospital environment. Based on a quantitative study, the authors examine the relationship between the perception of the reporting environment, knowledge of professional regulations, and demographic variables,

demonstrating that the willingness to report does not depend exclusively on the occurrence of the event, but rather on how professionals interpret the organizational and regulatory conditions in which they develop their practice. This approach makes it possible to identify that reporting is configured as an intentional action mediated by perceptions of the environment, rather than as an automatic response to error (Throckmorton & Etchegaray, 2007).

The results show that an environment perceived as safe, non-punitive, and learning-oriented significantly increases reporting intention, whereas contexts characterized by fear of sanctions or normative ambiguity tend to inhibit it. Likewise, knowledge of professional legislation and the obligations associated with reporting emerges as a relevant factor, though not sufficient on its own to guarantee notification. In analytical terms, these findings reinforce the understanding of underreporting as a relational phenomenon in which structural, cultural, and cognitive factors converge to shape professional action. In this way, the study underlines the need for interventions that not only strengthen regulatory knowledge but also transform perceptions of the organizational environment, promoting conditions that favor trust and active participation in reporting systems (Throckmorton & Etchegaray, 2007).

From a perspective oriented toward the implementation of patient safety systems, Harper and Helmreich (2005) analyze the barriers that limit the success of reporting systems, situating the problem within the interaction between organizational, cultural, and human factors. Based on a conceptual review framed within health safety studies, the authors demonstrate that the effectiveness of reporting systems does not depend solely on their technical design, but rather on the conditions in which they are implemented and utilized in practice. In particular, it is identified that reporting is hindered by punitive organizational cultures, a lack of trust in the systems, and the perception of reporting as having little utility, all of which limit the active participation of professionals (Harper & Helmreich, 2005).

The analysis highlights that barriers include the fear of sanctions, ambiguity in the definition of what should be reported, a lack of feedback, and workload overruns—factors that collectively shape environments that are poorly conducive to systematic reporting. Likewise, it is noted that the absence of institutional leadership and clear implementation strategies hinders the integration of these systems into organizational routines. In contrast, facilitating elements associated with the promotion of a non-punitive safety culture, the simplification of reporting processes, and the generation of organizational learning mechanisms from reported events are identified. In analytical terms, this approach makes it possible to understand reporting as a sociotechnical process whose effectiveness depends on the alignment between design, organizational culture, and professional practices, underlining the need for comprehensive interventions that transcend the mere introduction of formal tools (Harper & Helmreich, 2005).

Fung, Koh, and Chow (2012) examine the attitudes and perceived barriers that influence incident reporting by nursing staff, integrating international evidence from a systematic review. Based on the analysis of multiple studies, the authors demonstrate that the willingness to report is closely linked to perceptual and contextual factors, highlighting that reporting does not depend solely on the occurrence of events, but on how these are interpreted by professionals in their daily practice. The results show that, even when nurses identify adverse incidents, the decision to report them is conditioned by the perceived utility of the system, workload, and organizational culture, which reveals a persistent gap between detection and formal notification (Fung, Koh, & Chow, 2012).

The analysis identifies the predominant barriers as the fear of negative consequences, the lack of feedback, the perception that reporting does not generate change, and insufficient clarity in reporting processes. In turn, facilitators associated with continuous education, patient safety training, and the promotion of non-punitive environments that foster institutional trust are highlighted. In analytical terms, the findings reinforce the understanding of underreporting as a multifactorial and systemic phenomenon, in which cognitive, cultural, and organizational dimensions converge. In this way, the study underlines the need for comprehensive interventions that not only optimize reporting systems, but also transform the perceptions and dispositions of nursing staff, thereby strengthening their active participation in pharmacovigilance and patient safety processes (Fung, Koh, & Chow, 2012).

Within the Latin American context, Mira, Cho, Montserrat, Rodríguez, and Santacruz (2013) address the key elements for the implementation of

hospital adverse event reporting systems, situating the analysis within the institutional conditions necessary for their effective operation. Based on a study oriented toward reviewing experiences in the region, the authors identify that the implementation of these systems faces structural challenges linked to the organization of health services, the availability of resources, and institutional culture. In this regard, it is demonstrated that the mere introduction of reporting mechanisms does not guarantee their sustained use, highlighting the importance of adaptation processes to the local context and alignment with the dynamics of clinical work (Mira, Cho, Montserrat, Rodríguez, & Santacruz, 2013).

On the other hand, the analysis highlights that the consolidation of reporting systems requires the development of a safety culture based on trust, non-punitive approaches, and organizational learning, along with training and awareness-raising strategies for healthcare personnel. Likewise, it underlines the need for institutional leadership, effective feedback, and mechanisms that integrate reporting into daily practice. In analytical terms, these findings make it possible to understand pharmacovigilance and reporting systems as processes dependent on specific structural and cultural conditions, in which the sustainability of the system is closely linked to its appropriation by the actors involved. In this way, the study reinforces the importance of situated approaches that consider the particularities of healthcare systems in Latin America to strengthen the reporting of adverse events (Mira, Cho, Montserrat, Rodríguez, & Santacruz, 2013).

In the Mexican case, Suárez, Varela, Fajardo Dolci, and Torres (2012) examine the lessons learned from the implementation of incident reporting and registration systems, situating the analysis within the processes of institutional development and organizational adaptation of these devices. Based on a review of national experiences, the authors show that the introduction of reporting systems has been progressive and heterogeneous, demonstrating advances in the formalization of reporting mechanisms, but also limitations in their effective use within daily practice. This overview makes it possible to identify that the existence of regulatory frameworks and formal structures does not automatically translate into a consolidated culture of reporting, revealing tensions between institutional design and practical appropriation (Suárez, Varela, Fajardo Dolci, & Torres, 2012).

In this context, challenges associated with the fragmentation of the health system, variability in institutional capacities, and the insufficient integration of reporting systems into clinical care processes are highlighted. At the same time, advances linked to the generation of public policies oriented toward patient safety, as well as the gradual incorporation of training and awareness-raising strategies, are recognized.

From an analytical perspective, these findings make it possible to understand reporting as a process under construction, conditioned by structural, organizational, and cultural factors that shape its development within specific national contexts. In this manner, the study reinforces the need to strengthen the coordination among regulations, institutional capacities, and professional practices, favoring the consolidation of sustainable and contextualized reporting systems (Suárez, Varela, Fajardo Dolci, & Torres, 2012).

Moumztoglou (2010) examines the factors that hinder the reporting of adverse events from the perspective of nursing staff, emphasizing the organizational and cultural conditions that affect this practice. Through an empirical study in a hospital context, it is demonstrated that although nurses participate actively in direct patient care and in the identification of incidents, their involvement in formal reporting is limited by multiple obstacles that transcend the individual sphere. Among the most relevant findings, it is highlighted that workload, clinical pressure, and lack of time significantly reduce the possibilities of reporting, shaping an environment where reporting competes with other immediate clinical priorities (Moumztoglou, 2010).

In a complementary manner, barriers associated with the fear of negative consequences, the perception of a lack of institutional support, and scarce feedback regarding the reports made are identified, all of which weaken the motivation to participate in the system. Likewise, the lack of clarity in procedures and insufficient training in reporting contribute to reinforcing these limitations. In analytical terms, the study makes it possible to understand underreporting as the result of structural conditions that affect the practical viability of reporting, rather than as a deliberate omission on the part of the staff. Consequently, the study highlights the importance of generating organizational environments that facilitate reporting, integrating it into clinical routines and promoting an institutional culture based on trust, learning, and continuous improvement (Moumztoglou, 2010).

Gómez Ramírez, Arenas Gutiérrez, González Vega, Garzón Salamanca, Mateus Galeano, and Soto Gámez (2011) examine the patient safety culture from the perspective of nursing staff, situating the analysis within the perceptions and practices that shape adverse event reporting in hospital contexts. Based on an empirical study, the authors demonstrate that, although there is a positive assessment of patient safety, weaknesses persist within the organizational culture that limit reporting, particularly regarding the fear of sanctions, internal communication, and trust in institutional systems. This scenario makes it possible to identify that reporting is conditioned by the organizational climate, where the perception of institutional support and openness to learning directly influence the willingness to report (Gómez Ramírez et al., 2011).

In this sense, it is observed that barriers are not restricted to technical aspects, but are anchored in cultural dynamics that can inhibit transparency and error reporting. Limited feedback, together with the perception of punitive responses, shapes environments in which staff choose not to report.

Faced with this, the promotion of a non-punitive safety culture, the strengthening of teamwork, and the improvement of communication channels stand out as facilitators. From an analytical perspective, these findings make it possible to understand underreporting as a phenomenon deeply linked to organizational culture, underlining the need for interventions that transform institutional environments to favor sustained reporting practices (Gómez Ramírez et al., 2011).

Kousgaard, Joensen, and Thorsen (2012) address patient safety incident reporting in primary care using a qualitative approach centered on the reasons explaining non-reporting in daily practice. Through interviews with general practitioners, the study shows that the decision to report is mediated by the perceived relevance of the incident, the clinical context, and the demands of daily work, demonstrating that many events are not considered significant enough to be reported. This finding highlights that reporting does not depend solely on the existence of systems, but rather on interpretive processes that prioritize events based on their immediate impact (Kousgaard, Joensen, & Thorsen, 2012).

Additionally, factors such as a lack of time, the complexity of reporting systems, and the perception of scarce utility are identified as elements that discourage reporting. It is also observed that professionals prioritize continuity of care over the formal recording of incidents, which contributes to the omission of reporting in contexts with a high clinical workload. In analytical terms, the study allows for a deeper understanding of underreporting as a situated practice, in which decisions are constructed based on pragmatic and contextual criteria. In this way, it reinforces the need to design reporting systems that adapt to the actual dynamics of clinical work, facilitating their integration into daily practice and reducing the frictions that limit their use (Kousgaard, Joensen, & Thorsen, 2012).

Heard, Sanderson, and Thomas (2012) examine the barriers to reporting adverse events in the field of anesthesia, situating the analysis within a clinical environment characterized by high complexity and risk. Based on an empirical study, the authors demonstrate that, despite the existence of reporting systems, their utilization is limited by factors that combine individual and organizational dimensions. Among the findings, it is highlighted that a lack of time, the complexity of notification procedures, and the perception of reporting as having little utility act as significant obstacles. Likewise, the fear of professional consequences and concern over reputation influence the decision not to report, particularly in contexts where the organizational culture does not favor openness toward error. These elements make it possible to understand that reporting in highly specialized environments is not automatically integrated into practice, but rather depends on conditions that facilitate its operational and symbolic viability (Heard, Sanderson, & Thomas, 2012).

From another perspective, Ocaña Poveda and Bustamante (2012) analyze the relationship between quality management and adverse event reporting, situating notification as a key indicator within continuous improvement systems in healthcare. Based on an applied study, the authors demonstrate that the consolidation of quality management processes is associated with higher levels of reporting, insofar as it promotes organizational structures, protocols, and practices oriented toward patient safety. However, they also identify limitations linked to the effective implementation of these systems, particularly regarding institutional culture and appropriation by staff. In this way, it is highlighted that reporting depends not only on the existence of formal tools, but on their alignment with management strategies that favor the active participation of professionals. In analytical terms, these findings position underreporting at the intersection of

organizational management and clinical practice, highlighting the need to strengthen comprehensive approaches that link quality, safety culture, and the effective use of reporting systems (Ocaña Poveda & Bustamante, 2012).

Poorolajal, Rezaie, and Aghighi (2015) analyze the barriers associated with medical error reporting, addressing the phenomenon from a perspective that integrates individual, organizational, and systemic factors. Based on a review of the available evidence, the authors identify that underreporting is heavily influenced by the fear of legal and professional consequences, the lack of confidentiality, and the perception that reporting may result in sanctions. To this are added limitations related to the lack of knowledge regarding procedures and the perceived complexity of reporting systems. These findings make it possible to understand that the decision to report takes shape within an environment of uncertainty and perceived risk, where professionals evaluate not only the relevance of the event but also the personal implications of its notification (Poorolajal, Rezaie, & Aghighi, 2015).

Within this framework, it is highlighted that the absence of feedback and the perception of the report's scarce utility reinforce low participation in pharmacovigilance systems. At the same time, the promotion of non-punitive environments, the simplification of processes, and the implementation of training strategies that strengthen trust in the system are identified as facilitators. In analytical terms, the study reinforces the idea that underreporting constitutes a multifactorial phenomenon, where cognitive, cultural, and organizational dimensions converge to condition professional practice.
Dorgham examines the personal preferences and perceived barriers surrounding error disclosure and reporting by healthcare personnel, situating the analysis at the intersection of individual dispositions and organizational conditions (2012). Based on an empirical approach, it is demonstrated that the decision to report does not depend exclusively on technical knowledge, but rather on subjective factors such as risk perception, trust in the system's confidentiality, and the evaluation of possible professional consequences. Within this framework, the fear of sanctions, concern over reputation, and the absence of clear incentives emerge as elements that discourage reporting. At the same time, it is observed that the willingness to report increases in environments where there are guarantees of anonymity and institutional cultures oriented toward learning rather than penalization, which makes it possible to understand reporting as a practice mediated by the perception of organizational justice (Dorgham, 2012).

Along a converging line, Badiveymaje Jahromi, Parandavar, and Rahmanian address the factors associated with the non-reporting of medical errors from the perspective of the healthcare team in Iran, delving into the cultural and structural dimensions that condition this practice (2014).

Based on an applied study, barriers linked to the fear of legal consequences, the lack of clarity in reporting processes, and the perceived futility of reporting in the absence of visible changes are identified. Additionally, the influence of professional hierarchies and organizational dynamics that limit open communication regarding errors is recognized.

These elements allow for the interpretation of underreporting as the result of institutional configurations that fail to align formal systems with the daily practices of personnel. In analytical terms, both studies reinforce the understanding of reporting as a socially mediated process, involving perceptions, implicit norms, and organizational structures that directly affect its viability.

Pfeiffer, Briner, Wehner, and Manser (2013) explore the motivational antecedents of incident reporting, emphasizing the interaction between individual and contextual factors in the decision to notify. Based on a study utilizing surveys administered to physicians and nurses, it is observed that the motivation to report is closely linked to perceptions of system efficacy, expectations of feedback, and a sense of professional responsibility. The evidence suggests that professionals are more inclined to report when they anticipate that their action will have a concrete impact on improving patient safety. In contrast, the perceived futility of reporting or the absence of institutional responses tends to weaken this motivation. Likewise, differences between professional groups are identified, highlighting the need to consider occupational dimensions when designing pharmacovigilance strategies. This approach makes it possible to understand reporting as an intentional behavior, mediated by motivational processes that transcend regulatory compliance (Pfeiffer, Briner, Wehner, & Manser, 2013).

On the other hand, Ferreira Umpiérrez and Chimelli Tomás (2014) address the experience of professionals who have been involved in adverse events, incorporating an experiential dimension that adds complexity to the understanding of reporting. Based on a qualitative study, it is demonstrated that involvement in adverse events generates significant emotional responses—such as guilt, anxiety, and fear—which influence the willingness

to report. These experiences shape processes of individual and collective reflection that can lead to either learning or avoidance mechanisms. In this sense, reporting appears to be shot through with affective dimensions that are usually left out of technical pharmacovigilance models. Incorporating this perspective allows the analysis to expand toward subjective aspects of professional practice, highlighting that the construction of safe environments for reporting requires not only formal devices, but also the recognition of the emotional implications associated with error in clinical practice.

Paiva, Popim, Melleiro, Tronchim, Lima, and Juliani (2014) analyze the motives that influence adverse event reporting by nursing staff, focusing on the specific conditions of professional practice and the perceptions associated with the act of reporting. Based on an empirical study, it is identified that the decision to report is conditioned by factors such as workload, lack of time, and the complexity of reporting systems, as well as the perception that certain events do not require notification. Elements linked to organizational culture also emerge, particularly the fear of sanctions and the absence of effective feedback. These findings make it possible to understand that, even within professional groups highly involved in direct patient care, reporting is configured as a secondary practice, subordinated to clinical demands and the subjective interpretation of the event's relevance (Paiva et al., 2014).

For their part, Varallo, Guimarães, Abjaude, and Mastroianni (2014) examine the causes of underreporting of adverse drug events through a systematic review, providing an integrative overview of the factors that limit reporting across different contexts. In this analysis, recurrent barriers of a cognitive nature are identified—such as a lack of knowledge regarding what and how to report—as well as cultural dimensions associated with fear, insecurity, and the perception of guilt. Added to this are organizational factors, among which a lack of time, insufficient resources, and the absence of accessible and functional systems stand out.

The compiled evidence allows for the recognition that underreporting stems from a multifactorial configuration in which individual, institutional, and systemic elements converge. In analytical terms, this work reinforces the need to approach pharmacovigilance through comprehensive frameworks that simultaneously consider training, safety culture, and the design of reporting systems, thereby avoiding reductionist interpretations centered exclusively on individual performance.

Rashed and Hamdan (2019) examine the perceptions and attitudes of physicians and nurses toward incident reporting in Palestinian hospitals, providing evidence regarding the interprofessional differences that permeate this practice. Based on a quantitative study, it is observed that, although there is general recognition of the importance of reporting for patient safety, varying levels of willingness to report persist.

Nurses tend to display a greater inclination toward reporting compared to physicians, who express higher levels of skepticism regarding the utility of the system. Among the factors conditioning this behavior, a lack of feedback, the perception that reporting does not generate concrete changes, and the fear of negative consequences are identified. These results make it possible to note that reporting is mediated by differentiated professional dynamics, as well as by trust in the institutional structures that sustain the system (Rashed & Hamdan, 2019).

Along a line that delves into contexts of high clinical complexity, Zárate-Grajales (2016) et al. analyze the factors associated with adverse events reported by nursing staff in intensive care units, based on a multicenter study. The findings demonstrate that reporting is concentrated within certain types of events, particularly those that are more visible or carry immediate consequences, while others remain underreported. Likewise, conditioning factors linked to workload, the complexity of the clinical environment, and the organizational dynamics characteristic of critical care units are identified. This approach allows for the recognition that reporting depends not only on individual dispositions, but also on the nature of the clinical context in which it is embedded. In analytical terms, both studies reinforce the understanding of underreporting as a differentiated phenomenon according to professional roles and clinical environments, underlining the need for strategies sensitive to these variations in order to strengthen pharmacovigilance systems.

Achury Saldaña (2016) et al. examine the occurrence of adverse events in intensive care units, incorporating both their frequency and the factors associated with their appearance in hospitalized patients. Based on an empirical study, it is demonstrated that these events occur with significant regularity in contexts of high clinical complexity, where the severity of the patients' conditions and the intensity of interventions increase the risk. The results show that factors such as clinical overload, the complexity of procedures, and organizational conditions affect both the

occurrence of events and their recording. Likewise, it is observed that reporting does not always match the magnitude of the phenomenon, suggesting the persistence of gaps between clinical experience and its formalization within reporting systems. This approach makes it possible to position pharmacovigilance in critical care environments as a process conditioned by structural dynamics that exceed the individual level (Achury Saldaña et al., 2016).

From a perspective more focused on institutional implementation, Centeno (2007) analyzes adverse event reporting in a national hospital in Lima, highlighting the challenges associated with the effective incorporation of these systems into daily practice. The study demonstrates that, despite the existence of formal reporting mechanisms, their utilization is limited by factors such as a weak safety culture, a lack of training, and the perception that reporting does not generate concrete changes within the organization. Obstacles related to workload and the prioritization of clinical activities over administrative tasks are also identified. These elements make it possible to understand that reporting takes shape as a practice dependent on institutional conditions that favor its integration, rather than on the mere availability of formal tools. In analytical terms, both studies converge in pointing out that underreporting is embedded within specific organizational contexts, where the articulation between management, safety culture, and working conditions proves to be a determining factor for the effective functioning of reporting systems.

Adams (2009) et al. examine the occurrence of adverse events based on self-reported data from the population, shifting the analytical focus from institutional systems to the direct experience of patients. Through a population survey, it is demonstrated that a significant proportion of people report having experienced adverse events associated with healthcare, many of which are not captured by formal systems. This finding introduces a critical dimension to the field of pharmacovigilance by showing that a pool of events exists outside institutional channels. The evidence suggests that reporting is not limited to the clinical-professional sphere, but is also configured within the interaction between users and healthcare systems, opening up the possibility of considering alternative forms of recording and surveillance that integrate the citizen's perspective (Adams et al., 2009).

Barach and Small (2000) address incident reporting systems from a learning-oriented organizational perspective, analyzing the contributions of near-miss reporting systems in the prevention of adverse events. Based on a conceptual review, they argue that reporting systems only become effective when embedded within institutional cultures that promote transparency, trust, and continuous learning. It is highlighted that the identification and reporting of no-harm incidents constitute a strategic opportunity to anticipate risks and improve patient safety. However, they also warn that these systems face limitations when perceived as mechanisms of control or sanction, which reduces the willingness to report. This approach makes it possible to understand reporting as a component of broader organizational systems, in which safety culture and knowledge management prove to be determining factors for their functioning (Barach & Small, 2000).

Lawton and Parker (2002) address the barriers to incident reporting from an organizational perspective, emphasizing how the perceptions of healthcare staff influence the decision to report.

Based on an empirical analysis, it is identified that underreporting cannot be attributed solely to technical limitations, but is instead deeply linked to cultural and structural factors. Conspicuous among these are the ambiguity in defining what constitutes a reportable incident, the lack of clarity in procedures, and the perception that reporting does not yield tangible benefits.

Likewise, it is demonstrated that hierarchical dynamics and concern over professional consequences condition the willingness to report, especially in environments where a punitive culture predominates. Within this framework, reporting is configured as a negotiated practice, in which professionals weigh risks, utilities, and institutional expectations before deciding to report (Lawton & Parker, 2002).

In a complementary manner, the authors underline that the simplification of reporting systems, effective feedback, and the consolidation of learning-oriented organizational cultures constitute key conditions for improving participation in these

systems. This approach reinforces the idea that the efficacy of pharmacovigilance does not depend exclusively on the technical design of the devices, but rather on their articulation with organizational environments that foster trust and ownership among professionals.

Taken together, the state of the art allows for the identification of a series of recurrent patterns that crosscut the various studies analyzed. Underreporting consistently emerges as a multifactorial phenomenon, where cognitive, cultural, organizational, and technological dimensions converge. Throughout the corpus, it is observed that factors such as a lack of time, unfamiliarity with procedures, the complexity of systems, the absence of feedback, and the fear of sanctions shape persistent barriers to reporting. At the same time, facilitators associated with the simplification of processes, technological integration, continuous training, and the strengthening of learning-oriented safety cultures are identified.

Likewise, the studies highlight the existence of structural tensions between institutional requirements and the actual conditions of clinical work, as well as significant differences according to professional roles and healthcare contexts. The evidence also suggests the presence of underreporting circuits that exceed formal systems, including experiences not captured by institutional mechanisms and emerging forms of communication surrounding adverse events.

Within this framework, the collective findings allow for a shift in the understanding of reporting from a logic centered on individual compliance toward a relational perspective, involving institutional mechanisms, professional practices, and organizational contexts. This shift not only expands the field of analysis but also enables the identification of gaps in the literature, particularly regarding situated studies, qualitative approaches, and integrated analyses between systems and clinical practice. Such gaps do not merely constitute limitations of the available knowledge; rather, they delineate analytical opportunities to deepen the understanding of the phenomenon, paving the way toward the construction of cartographies that allow for a denser examination of the configurations and tensions that permeate ADR reporting.

Critical synthesis of the state of the art

The analytical trajectory developed here makes it possible to go beyond a cumulative reading of the evidence, shaping an articulation that interrelates the findings, approaches, and levels of analysis present in the literature on adverse event reporting. Within this framework, consistent convergences are identified around the multifactorial nature of underreporting, where cognitive, cultural, organizational, and technological dimensions converge to condition the practice of reporting. At the same time, persistent tensions emerge between the regulatory designs of pharmacovigilance systems and the actual conditions of clinical work, evidencing misalignments between institutional demands and the effective possibilities for implementation within healthcare contexts.

In a complementary manner, the review highlights relevant contradictions in the development of the field. While some studies emphasize the need to strengthen individual competencies and technical knowledge, others underscore the weight of structural factors—such as organizational culture, workload, or the absence of feedback. This heterogeneity reflects a field in consolidation, wherein different levels of problematization coexist, ranging from approaches centered on individual behavior to perspectives that position reporting as a sociotechnical practice embedded within broader institutional assemblages.

Likewise, an unequal distribution in methodological approaches is observed, with a predominance of quantitative studies and systematic reviews, in contrast to a lesser presence of qualitative and situated investigations that could allow for a deep understanding of the daily dynamics of reporting.

This limitation restricts the possibility of capturing the complexity of the phenomenon within specific contexts, particularly regarding the interaction among actors, technologies, and organizational environments. At this juncture, the problem of ADR reporting positions itself as a field crossed by multiple rationalities in tension, the understanding of which requires analytical frameworks capable of integrating micro, meso, and macro levels. This synthesis does not close the analysis, but rather delimits a problematic space from which it becomes necessary to advance toward a more precise identification of research gaps, shifts, and opportunities, which are developed in the following section.

Final reflections: gaps and opportunities

Within this analytical shift, the review supports the argument that ADR reporting cannot be approached through a linear explanatory logic, nor can it be reduced to the aggregation of individual factors.

The examined evidence converges to show that it is a relational phenomenon, configured at the intersection of organizational structures, institutional mechanisms, professional rationalities, and material working conditions. In this sense, the persistence of underreporting does not appear as an anomaly in relation to an ideal normative model, but rather as a consistent effect of misalignments between the formal logic of the pharmacovigilance system and the actual architecture of clinical work, which is characterized by time pressure, task fragmentation, and the overlapping of clinical and administrative demands (Sinsky et al., 2016; Arndt et al., 2017; Westbrook et al., 2010).

As one delves deeper into the literature, it becomes apparent that these misalignments do not operate homogeneously; rather, they are configured across different dimensions that, while analytically distinguishable, are empirically intertwined. On one hand, the evidence shows that pharmacovigilance tends to integrate in a partial and peripheral manner into the actual workflows of clinical work, depending on the possibility of being incorporated into practical sequences that are already saturated and highly regulated by healthcare urgency (Carayon et al., 2006; Pérez-Ricart et al., 2019). On the other hand, the daily organization of work reveals structural conditions of overload and fragmentation that reconfigure the prioritization of tasks, displacing those activities that do not produce immediate effects on the patient's clinical resolution (Sinsky et al., 2016; Evans et al., 2006). In this scenario, reporting is situated in an ambiguous position: recognized in normative terms, yet subordinated in practical terms.

In a complementary manner, the review identifies that the decision to report is mediated by situated professional rationalities, in which clinical judgment, accumulated experience, and a pragmatic assessment of the reporting's utility operate as activation filters for the pharmacovigilance system (Freidson, 2001; López-González, Herdeiro & Figueiras, 2009).

This dimension introduces a level of variability that cannot be captured by exclusively normative approaches, insofar as the act of reporting does not derive automatically from knowledge of the procedure, but rather from interpretive processes that consider the perceived severity, diagnostic certainty, and clinical relevance of the event. To this are added professional imaginaries regarding risk, responsibility, and institutional recognition, as well as educational trajectories that define the place pharmacovigilance occupies within professional identity (Vincent, Stanhope & Crowley-Murphy, 1999; Burbano Valdés et al., 2013).

At an additional level, the literature highlights the existence of persistent gaps between system requirements and the actual conditions of their implementation, expressed in procedural demands, administrative burdens, and limitations in institutional support. The absence of feedback, the complexity of reporting systems, and the lack of integration with routine clinical tools have been consistently identified as factors that weaken the professionals' ownership of the system (Evans et al., 2006; Hazell & Shakir, 2006). From this perspective, underreporting can be understood as an implementation problem, in which the distance between normative design and effective use generates conditions of low operational viability, in line with the arguments raised by Pressman and Wildavsky (1973) regarding the inherent tensions in the execution of public policies.

In a particularly significant manner, the review also allows for an expansion of the analytical focus toward traditionally sub-explored dimensions linked to communicational ecologies in health and citizen participation.

The evidence suggests that patients' experiences with adverse reactions do not necessarily translate into institutional reports; instead, they circulate through informal channels, including social networks, everyday interactions, and community-based risk management practices. These forms of circulation, traversed by linguistic barriers, asymmetries of knowledge, and processes that delegitimize citizen knowledge, shape what can be understood as zones of invisibilization of the phenomenon—where the experience exists but is not captured by formal pharmacovigilance mechanisms. This finding opens a relevant line of problematization, insofar as it shifts the discussion from the absence of reporting toward the insufficiency of systems to incorporate heterogeneous forms of experience and knowledge.

Holistically, these findings make it possible to identify a set of analytical gaps that transcend the mere absence of studies and are linked to limitations within the predominant approaches.

Conspicuous among them are the scarce production of situated studies that address reporting within actual contexts of practice, the weak incorporation of qualitative methodologies aimed at understanding the rationalities and experiences of the actors involved, and the limited integration among the organizational, professional, and sociocultural levels of the phenomenon. Likewise, there is an insufficient problematization of the citizen dimension and informal communication circuits, which restricts the understanding of pharmacovigilance strictly to its formal institutional mechanisms.

Far from constituting mere limitations, these gaps shape analytical opportunities that allow for the reorientation of the field of study toward more integrative and situated perspectives. Within this framework, the need to articulate the various identified dimensions opens the possibility of developing analytical cartographies, understood as theoretical-methodological mechanisms oriented toward exploring the configurations of the phenomenon in its complexity.

These cartographies do not emerge as a prior classificatory schema; rather, they serve as an analytical response to the limitations of available knowledge, making it possible to organize evidence around the relationships, tensions, and mediations that make the practice of reporting intelligible within real-world contexts. From this perspective, their development not only contributes to thickening the understanding of the phenomenon but also opens possibilities for designing interventions that are better tailored to the concrete conditions of clinical work, thereby strengthening the articulation among pharmacovigilance systems, professional practices, and social experiences.

References

Abbott, A. (1988). The system of professions: An essay on the division of expert labor. University of Chicago Press.

Achury Saldaña, D., Rodríguez, S. M., Díaz, J. C., Cavallo, E., Zárate Grajales, R., Vargas Tolosa, R., y de las Salas, R. (2016). Estudio de eventos adversos, factores y periodicidad en pacientes hospitalizados en unidades de cuidado intensivo. Enfermería Global, 15(42), 324–340. http://scielo.isciii.es/scielo.php?script=sci_arttext&pid=S1695-61412016000200011

Adams, R. J., Tucker, G., Price, K., Hill, C. L., Appleton, S. L., Wilson, D. H., Taylor, A. W., y Ruffin, R. E. (2009). Self-reported adverse events in health care that cause harm: A population-based survey. The Medical Journal of Australia, 190(9), 484–488. https://doi.org/10.5694/j.1326-5377.2009.tb02523.x

Arndt, B. G., Beasley, J. W., Watkinson, M. D., Temte, J. L., Tuan, W.-J., Sinsky, C. A., y Gilchrist, V. J. (2017). Tethered to the EHR: Primary care physician workload assessment using EHR event log data. The Annals of Family Medicine, 15(5), 419–426. https://doi.org/10.1370/afm.2121

Badiveymaje Jahromi, Z., Parandavar, N., y Rahmanian, S. (2014). Investigating factors associated with not reporting medical errors from the medical team's point of view in Jahrom, Iran. Global Journal of Health Science, 6(6), 96–104. https://doi.org/10.5539/gjhs.v6n6p96

Barach, P., y Small, S. D. (2000). Reporting and preventing medical mishaps: Lessons from non-medical near miss reporting systems. BMJ, 320(7237), 759–763. https://doi.org/10.1136/bmj.320.7237.759

Burbano Valdés, H. M., Caicedo Eraso, M. E., Cerón Burgos, A., Jacho Caicedo, C., y Yépez Chamorro, M. C. (2013). Causas del no reporte de eventos adversos en una institución prestadora de servicios de salud en Pasto-Nariño, Colombia. Universidad y Salud, 15(2), 187–195. https://revistas.udenar.edu.co/index.php/usalud/article/view/2362

Carayon, P., Schoofs Hundt, A., Karsh, B.-T., Gurses, A. P., Alvarado, C. J., Smith, M., y Brennan, P. F. (2006). Work system design for patient safety: The SEIPS model. Quality and Safety in Health Care, 15(Suppl. 1), i50–i58. https://doi.org/10.1136/qshc.2005.015842

Centeno, R. (2007). Notificación de eventos adversos en un hospital nacional en Lima. Revista de Calidad Asistencial, 22(3). https://doi.org/10.1016/S1134-282X(07)71242-3

Correa, E., Jauregui, O. I., Frangella, J., Peuchot, V., Otero, C., y Luna, D. (2019). Adverse Drug Event Reporting Rates After the Implementation of an EHR Integrated Reporting System. Studies in Health Technology and Informatics, 264, 1652–1653. https://doi.org/10.3233/SHTI190580

Denzin, N. K. (1978). The research act: A theoretical introduction to sociological methods (2nd ed.). McGraw-Hill.

Dixon-Woods, M., Cavers, D., Agarwal, S., Annandale, E., Arthur, A., Harvey, J., Kelly, M., Katbamna, S., Olsen, R., Smith, L., Riley, R., y Sutton, A. J. (2006). Conducting a critical interpretive synthesis of the

literature on access to healthcare by vulnerable groups. BMC Medical Research Methodology, 6, 35. https://doi.org/10.1186/1471-2288-6-35

Dorgham, S. (2012). Personal preference and perceived barriers toward disclosure and report of incident errors among healthcare personnel. Life Science Journal, 9, 4869–4880. https://www.researchgate.net/publication/244988387_Personal_Preference_and_Perceived_Barriers_toward_Disclosure_and_Report_of_Incident_Errors_among_Healthcare_Personnel

Elnitsky, C., Nichols, B., y Palmer, K. (1997). Are hospital incidents being reported? Journal of Nursing Administration, 27(11), 40–46. https://pubmed.ncbi.nlm.nih.gov/9372807

Evans, S. M., Berry, J. G., Smith, B. J., Esterman, A., Selim, P., O'Shaughnessy, J., y DeWit, M. (2006). Attitudes and barriers to incident reporting: A collaborative hospital study. Quality and Safety in Health Care, 15(1), 39–43. https://doi.org/10.1136/qshc.2004.012559

Ferreira Umpiérrez, A. H., y Chimelli Tomás, V. (2014). Aspectos significativos surgidos de la experiencia de haber sido responsable de un evento adverso en salud. Aquichan, 14(3), 294–302. https://aquichan.unisabana.edu.co/index.php/aquichan/article/view/2919

Flick, U. (2018). An introduction to qualitative research (6th ed.). SAGE.

Freidson, E. (2001). Professionalism: The third logic. University of Chicago Press.

Fung, W. M., Koh, S. S., y Chow, Y. L. (2012). Attitudes and perceived barriers influencing incident reporting by nurses and their correlation with reported incidents: A systematic review. JBI Library of Systematic Reviews, 10(1), 1–65. https://doi.org/10.11124/jbisrir-2012-44

Gómez Ramírez, O., Arenas Gutiérrez, W., González Vega, L., Garzón Salamanca, J., Mateus Galeano, E., y Soto Gámez, A. (2011). Cultura de seguridad del paciente por personal de enfermería en Bogotá, Colombia. Ciencia y Enfermería, 17(3), 97–111. https://dx.doi.org/10.4067/S0717-95532011000300009

González, J. C., Arango, V. E., y Einarson, T. R. (2006). Contribution of Latin America to pharmacovigilance. The Annals of Pharmacotherapy, 40(7–8), 1394–1399. https://doi.org/10.1345/aph.1H052

Grant, M. J., y Booth, A. (2009). A typology of reviews: An analysis of 14 review types and associated methodologies. Health Information and Libraries Journal, 26(2), 91–108. https://doi.org/10.1111/j.1471-1842.2009.00848.x

Greenhalgh, T., Robert, G., Macfarlane, F., Bate, P., y Kyriakidou, O. (2005). Storylines of research in diffusion of innovation: A meta-narrative approach to systematic review. Social Science and Medicine, 61(2), 417–430. https://doi.org/10.1016/j.socscimed.2004.12.001

Harper, M. L., y Helmreich, R. L. (2005). Identifying barriers to the success of a reporting system. En K. Henriksen, J. B. Battles, E. S. Marks y D. I. Lewin (Eds.), Advances in patient safety: From research to implementation (Vol. 3: Implementation issues). Agency for Healthcare Research and Quality. https://www.ncbi.nlm.nih.gov/books/NBK20544/

Hazell, L., y Shakir, S. A. W. (2006). Under-reporting of adverse drug reactions: A systematic review. Drug Safety, 29(5), 385–396. https://doi.org/10.2165/00002018-200629050-00003

Heard, G. C., Sanderson, P. M., y Thomas, R. D. (2012). Barriers to adverse event and error reporting in anaesthesia. Anaesthesia and Analgesia, 114(3), 604–614. https://doi.org/10.1213/ANE.0b013e31822649e8

Hussain, R., Hassali, M. A., Rehman, A., Muneswarao, J., Atif, M., y Babar, Z. U. (2020). A qualitative evaluation of adverse drug reaction reporting system in Pakistan: Findings from the nurses' perspective. International Journal of Environmental Research and Public Health, 17(9), 3039. https://doi.org/10.3390/ijerph17093039

Juárez-Pérez, H., y Durán-Muñoz, C. (2018). Eventos centinela y la notificación por el personal de enfermería. Revista de Enfermería del Instituto Mexicano del Seguro Social, 17(1), 39–44. https://revistaenfermeria.imss.gob.mx/index.php/revista_enfermeria/article/view/475

Katusiime, B., Semakula, D., y Lubinga, S. J. (2015). Adverse drug reaction reporting among health care workers at Mulago National Referral and Teaching hospital in Uganda. African Health Sciences, 15(4), 1308–1317. https://doi.org/10.4314/ahs.v15i4.34

Kousgaard, M. B., Joensen, A. S., y Thorsen, T. (2012). Reasons for not reporting patient safety incidents in general practice: A qualitative study. Scandinavian Journal of Primary Health Care, 30(4), 199–205. https://doi.org/10.3109/02813432.2012.732469

Kreckler, S., Catchpole, K., McCulloch, P., y Handa, A. (2009). Factors influencing incident reporting in surgical care. Quality and Safety in Health Care, 18(2), 116–120. https://doi.org/10.1136/qshc.2008.026534

Lawton, R., y Parker, D. (2002). Barriers to incident reporting in a healthcare system. Quality & Safety in

Health Care, 11(1), 15–18. https://doi.org/10.1136/qhc.11.1.15
Lipsky, M. (1980). Street-level bureaucracy: Dilemmas of the individual in public services. Russell Sage Foundation.
Lopez-Gonzalez, E., Herdeiro, M. T., y Figueiras, A. (2009). Determinants of under-reporting of adverse drug reactions: A systematic review. Drug Safety, 32(1), 19–31. https://doi.org/10.2165/00002018-200932010-00002
Malik, M. R., Alam, A. Y., Mir, A. S., Malik, G. M., y Abbas, S. M. (2010). Attitudes and perceived barriers of tertiary level health professionals towards incident reporting in Pakistan. North American Journal of Medical Sciences, 2(2), 100–105. https://doi.org/10.4297/najms.2010.2100
Miles, M. B., Huberman, A. M., y Saldaña, J. (2014). Qualitative data analysis: A methods sourcebook (3rd ed.). SAGE.
Mira, J. J., Cho, M., Montserrat, D., Rodríguez, J., y Santacruz, J. (2013). Elementos clave en la implantación de sistemas de notificación de eventos adversos hospitalarios en América Latina. Revista Panamericana de Salud Pública. https://iris.paho.org/items/a00f8954-b7e0-4996-bf94-47c28670f255
Moumztoglou, A. (2010). Factors impeding nurses from reporting adverse events. Journal of Nursing Management, 18(5), 542–547. https://doi.org/10.1111/j.1365-2834.2010.01049.x
Ocaña Poveda, C., y Bustamante, L. (2012). Relación entre la gestión de la calidad y el reporte de ocurrencia de eventos adversos en la atención del paciente. SIGNOS - Investigación en sistemas de gestión, 4(15). https://doi.org/10.15332/s2145-1389.2012.0001.03
Paiva, M. C. M. da S., Popim, R. C., Melleiro, M. M., Tronchim, D. M. R., Lima, S. A. M., y Juliani, C. M. C. M. (2014). Motivos del equipo de enfermería para la notificación de eventos adversos. Revista Latino-Americana de Enfermagem, 22(5), 747–754. https://doi.org/10.1590/0104-1169.3556.2476
Pérez-Ricart, A., Gea-Rodríguez, E., Roca-Montañana, A., Gil-Máñez, E., y Pérez-Feliu, A. (2019). Integrating pharmacovigilance into the routine of pharmacy department: Experience of nine years. Farmacia Hospitalaria, 43(4), 128–133. https://doi.org/10.7399/fh.11169
Pfeiffer, Y., Briner, M., Wehner, T., y Manser, T. (2013). Motivational antecedents of incident reporting: Evidence from a survey of nurses and physicians. Swiss Medical Weekly, 143, w13881. https://doi.org/10.4414/smw.2013.13881
Poorolajal, J., Rezaie, S., y Aghighi, N. (2015). Barriers to medical error reporting. International Journal of Preventive Medicine, 6, 97. https://doi.org/10.4103/2008-7802.166680
Pressman, J. L., y Wildavsky, A. (1973). Implementation: How great expectations in Washington are dashed in Oakland. University of California Press.
Rashed, A., y Hamdan, M. (2019). Physicians' and nurses' perceptions of and attitudes toward incident reporting in Palestinian hospitals. Journal of Patient Safety, 15(3), 212–217. https://doi.org/10.1097/PTS.0000000000000218
Rosas Vargas, L. (2017). Factores asociados a la notificación de los eventos adversos por el personal de salud en un hospital de segundo nivel de atención en la Ciudad de México (Tesis de maestría, Universidad Nacional Autónoma de México). Repositorio Institucional de la UNAM.
Santos, M., et al. (2019). Adverse drug event reporting rates after the implementation of an EHR integrated reporting system. Studies in Health Technology and Informatics. https://pubmed.ncbi.nlm.nih.gov/31438276/
Science Museum. (2019, December 11). Thalidomide. https://www.sciencemuseum.org.uk/objects-and-stories/medicine/thalidomide
Sinsky, C., Colligan, L., Li, L., Prgomet, M., Reynolds, S., Goeders, L., Westbrook, J., Tutty, M., y Blike, G. (2016). Allocation of physician time in ambulatory practice: A time and motion study in 4 specialties. Annals of Internal Medicine, 165(11), 753–760. https://doi.org/10.7326/M16-0961
Suárez, J., Varela, J., Fajardo Dolci, G., y Torres, F. (2012). Sistemas de notificación y registro de incidentes en México: Aprendizajes. https://www.researchgate.net/publication/277260270_Sistemas_de_notificacion_y_registro_de_incidentes_en_Mexico_Aprendizajes
Throckmorton, T., y Etchegaray, J. (2007). Factors affecting incident reporting by registered nurses: The relationship of perceptions of the environment for reporting errors, knowledge of the nursing practice act, and demographics on intent to report errors. Journal of PeriAnesthesia Nursing, 22(6), 400–412. https://doi.org/10.1016/j.jopan.2007.09.006
Varallo, F. R., Guimarães, S. de O., Abjaude, S. A., y Mastroianni, P. de C. (2014). Causes for the underreporting of adverse drug events by health professionals: A systematic review. Revista da Escola de Enfermagem da USP, 48(4), 739–747. https://doi.org/10.1590/S0080-623420140000400023

Vincent, C., Stanhope, N., y Crowley-Murphy, M. (1999). Reasons for not reporting adverse incidents: An empirical study. Journal of Evaluation in Clinical Practice, 5(1), 13–21. https://doi.org/10.1046/j.1365-2753.1999.00147.x

Westbrook, J. I., Woods, A., Rob, M. I., Dunsmuir, W. T. M., y Day, R. O. (2010). Association of interruptions with an increased risk and severity of medication administration errors. Archives of Internal Medicine, 170(8), 683–690. https://doi.org/10.1001/archinternmed.2010.65

Wilson, B., Bekker, H. L., y Fylan, F. (2008). Reporting of clinical adverse events scale: A measure of doctor and nurse attitudes to adverse event reporting. Quality and Safety in Health Care, 17(5), 364–367. https://doi.org/10.1136/qshc.2006.021691

Zárate-Grajales, R., Olvera-Arreola, S., Hernández-Cantoral, A., Hernández Corral, S., Sánchez-Ángeles, S., Valdez Labastida, R., Pérez-López, M., y Zapién-Vázquez, M. (2016). Factores relacionados con eventos adversos reportados por enfermería en unidades de cuidados intensivos. Proyecto multicéntrico. Enfermería Universitaria, 13(1), 70. https://revista-enfermeria.unam.mx/ojs/index.php/enfermeriauniversitaria/article/view/110