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REVIEW ARTICLE

Disparities in Patient Safety Voluntary Event Reporting: A Scoping Review

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Voluntary event reporting (VER) systems underestimate the incidence of safety events and often capture only serious events. A limited amount of data is collected through these systems, and they may be inadequate to characterize disparities in reported safety events. We conducted a scoping review of the literature to summarize the state of the evidence as it relates to differences in safety events and safety event reporting by age, gender, and race. Using a broad-based query, a systematic search for published, peer-reviewed literature that discusses patient safety event reporting and differences by age, gender, race, and socioeconomic status was conducted. Based on modified Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, 283 studies underwent title and abstract review, yielding 56 studies for full text review. After full text review, 23 studies were carefully reviewed individually, grouped thematically, and summarized to highlight the most pertinent findings. The studies reviewed yielded important insights, particularly with regard to race, gender, and the ways events are identified. Patients from minoritized groups may be less likely to have events reported and more likely to suffer serious events. Some studies found differences in rates of reporting safety events for female vs. male providers. The rate of VER is consistently lower than the rate of events identified through identified using automated detection. The current literature describing VER data shows disparities by race, language, age, and gender for patients and providers. Further research and systematic change are needed to specifically study these disparities to guide health care institutions on ways to mitigate bias and deliver more equitable care.

In the landmark report *To Err Is Human*, the Institute of Medicine estimated that up to 98,000 patients die each year due to medical errors.[1] This report and the subsequent literature have highlighted particular populations at risk for medical errors: children, older adults, and patients from minority populations, particularly Black patients.[1,2] Despite considerable efforts and rigorous science devoted to understanding and preventing errors, harm as a result of medical care remains common and leads to increased health care costs.[3–5] To promote a culture of safety and create mechanisms for identifying and addressing safety concerns and adverse events (AEs), most major medical centers and federal agencies have created voluntary event reporting (VER) systems.

In the case of institutional VER, reports are typically submitted anonymously and electronically and can help to identify a range of safety events and systems problems, prompting investigation and analysis to prevent future events. These systems empower clinicians to recognize safety events and participate in processes to improve patient safety.[3] However, their voluntary nature underestimates the incidence of safety events, and often only serious events causing patient harm are captured.[3] They also have varying degrees of efficacy. Some studies have shown them to be effective in reducing near misses and AEs, but others have shown no association between reporting rates and mortality.[6,7]

In all types of VER systems, underreporting reduces reliability.[8] Reasons for underreporting are broad. In one study, clinicians cited a lack of clarity on what events required reporting (such as catheter-associated infections or medication effects) and limited perceived benefit of reporting when reviews happen long after the event occurs as barriers.[8] Many US states require that certain conditions are reported, and hospital accreditors are required to include examination of not only whether reporting processes exist, but how those reports are scrutinized, in their accreditation processes.[8] However, the literature fails to address the potential for disparities in safety event reporting.

As part of its six domains of quality health care, the Institute of Medicine (now the National Academy of Medicine) recognizes that health care must not only be safe, but equitable.[9] Although patient safety and health equity are each important areas for which the bodies of research have grown significantly in recent years, their intersection is less well studied. A few studies explore racial and ethnic differences in AEs and the reporting of such events. However, it may be difficult to fully characterize the problem when few VER systems require collection of race or ethnicity information. According to one study collected by a patient safety organization with 400 member hospitals in 10 states, less than

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0.01% of the over one million total reports available included race or ethnicity information.[10]

The objective of this scoping review was to evaluate the current literature on disparities in institutional safety event reporting and summarize the state of the evidence as it relates to differences in safety events and safety event reporting by age, gender, and race. This synthesis of the literature will also shed light on some recommendations for practice and future research.

METHODS

Using a broad-based query, we systematically searched PubMed and Embase for published, peer-reviewed literature that discusses patient safety event reporting and differences by age, gender, race, and socioeconomic status. The queries were designed with the assistance of a medical librarian to use database-specific indexing terms with synonyms, and the database queries were limited to text searches of titles and abstracts. The precise search strategy is included in Appendix 1 (available in online article). The articles generated from the search were then uploaded into Covidence (Veritas Health Innovation, Melbourne, Australia), an online resource for conducting systematic and scoping reviews as well as meta-analyses.[11] The screening approach was based on a modification of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines typically used for health care intervention and effectiveness studies and is shown in Figure 1.

Although the methods are similar for scoping and systematic reviews, they are conducted with different purposes.[12] Systematic reviews with or without meta-analyses are used, for example, to synthesize the results of similarly designed studies to guide policy and decision-making or to identify variations in practice following a structured and predefined process. Scoping reviews, by contrast, are used to identify and map the available evidence, examine how research is conducted in a given field, or identify gaps in knowledge, also using a structured and rigorous approach. A scoping rather than systematic review approach was deemed most appropriate for the purposes of this investigation because the study of disparities in patient safety reporting is an emerging field of study; therefore, a broader search with expansive inclusion criteria would allow a more comprehensive review of the existing data and the gaps in knowledge.

This search yielded 283 articles for review. A wide range of study designs published between January 1, 1990, and November 1, 2022, were included (randomized controlled trials and quasi-experimental, naturalistic, and observational designs). On title and abstract review, 177 of those were excluded based on irrelevance (no mention of AE reporting) and on predefined exclusion criteria: All editorials, review articles, book chapters, and non-US-based studies were excluded. A total of 106 articles underwent full text review. On full text review, 50 additional articles were excluded as having the wrong design or setting (most often, studies were non-US-based; AEs were monitored in the context of mandatory reporting in clinical trials; or there was a lack of age, gender, and/or race data in the analyses). The remaining 56 articles were included and categorized by themes that emerged over the course of the review to allow for thematic analyses and a synthesis of the relevant literature. Among those 56 studies, 33 used data from the US Food and Drug Administration Adverse Event Reporting System (FAERS) or Vaccine Adverse Event Reporting System (VAERS), which were not the reporting systems targeted for this review. The 23 studies on institutional VER were reviewed individually, grouped thematically, and summarized to highlight the most pertinent findings.

RESULTS

An emerging body of literature characterizes the challenges of reliance on institutional VER systems. Reporting and characterizing patient safety events is a cornerstone of promoting patient safety and quality of care, but these mechanisms capture only a small fraction of total events, and the voluntariness of reporting introduces the possibility of bias in reporting—from the types of events reported to the people for whom events are reported. The nature of this scoping review allows for the detection of studies that, although not necessarily designed to answer the questions of disparities among patients for whom events were reported, do yield important insights on types of events and reporters of events. All studies are described in brief in Appendix 2.

Race

Although few studies sought to directly answer questions related to racial disparities in reporting, it is, nonetheless, the best-studied area regarding inequities in VER.

One important study examined near-miss patient safety events reported through a VER system in a large, integrated, nonacademic health care system. In 9 of 10 hospitals studied, significantly fewer near-miss events were reported for Black patients than would have been expected based on the hospital population.[13] There were also differences in the types of events reported by race; notably, Black patients had a higher than expected proportion of safety/security events, as compared to other types of events, such as surgery/procedure, diagnosis/treatment, or medication/fluid events, among others.[13]

A multisite study published in 2009 analyzed 464 events reported by 23 pediatric ICUs (PICUs) over a two-year period. Children for whom events were reported were more likely to be white (73%) and male (55%).[14] However, the study did not include a comparison of these data to the composite demographics of the 23 PICUs. Medication-related events were most common but were less likely to result in harm than other event types, such as those involving lines, tubes, and airways.[14] Multivariate modeling shows that children aged 1 to 9 years and 10 to 19 years were

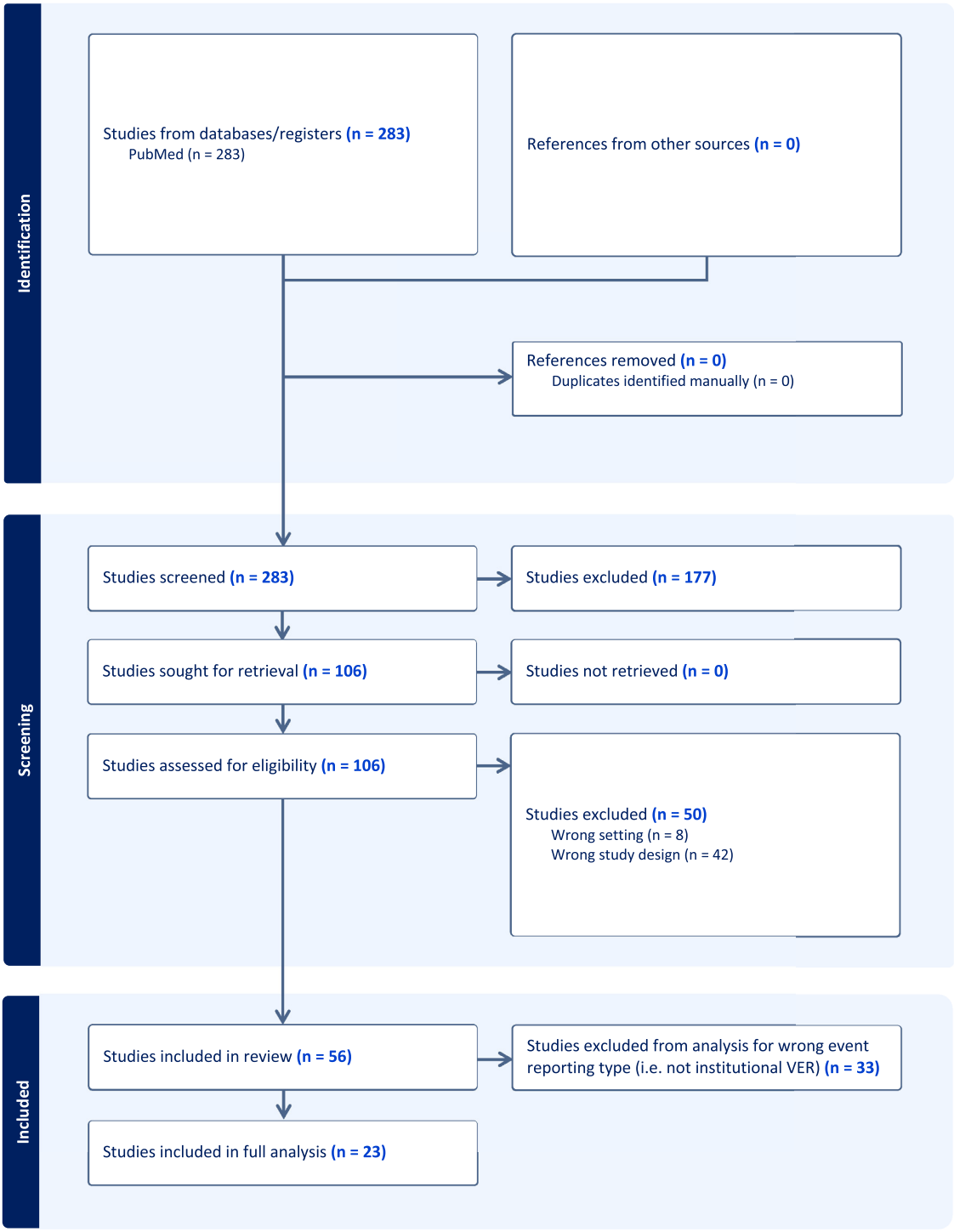

Figure 1: Shown here is the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram for the study selection.

more likely to suffer physical injury than infants, and nonwhite patients and males may have been less likely to suffer any harm than white patients.[14] However, the authors introduce the possibility of reporting bias, even subconscious blaming of patients for events.[14]

In a study conducted through the American Academy of Family Physicians National Research Network, researchers queried VER systems regarding testing process errors in primary care. Errors and events were more commonly reported for white (74.2%) patients than for patients from minoritized communities.[15] However, minoritized patients were more likely to have events with adverse consequences (odds ratio [OR] 2.74, $p = 0.017$) and suffer harm (OR 2.42, $p = 0.016$) than white patients.[15]

Another study tested the hypothesis that patient demographics, including race and obesity, would be associated

with safety event reporting. After examining more than 22,000 patient encounters, 1.5% of which were associated with AE reports, overweight patients (OR 0.69, $p < 0.05$) and Black patients (OR 0.65, $p < 0.05$) were less likely to have a safety event reported.[16] The authors indicate that comparing VER with more objective means such as chart review is a future direction for their research.

Finally, one study illustrated the potential challenge described in the aforementioned work. While using VER to identify cases of childhood antiepileptic hypersensitivity syndrome (AHS), the research team found that females and Black or "biracial" patients were less likely to be reported as having AHS (males to females 8:6, white to Black to biracial 10:3:1).[17] Without information on the prevalence of AHS in various groups, these differences are difficult to interpret; however, they may indicate biases in diagnosing and reporting AHS.[17]

Language

A limited body of work sought to characterize the role of English proficiency in safety events and reporting.

One study examined event reports submitted for patients with a preferred language other than English and then analyzed whether the language barrier was identified as contributing to the event.[18] However, the study team found it difficult to determine the direct role of language barriers on safety events because often the language barrier was not directly addressed in the event report.[18]

Another study examined the use of family-directed event reporting in a children's hospital. Parents reported 8.15 safety events per 100 patient-days (most commonly related to medications and communication), approximately 40% of which met institutional reporting criteria, though only 1.1% of those that met reporting criteria had in fact been reported through the VER system.[19] Notably, Latinx families had significantly lower rates of reporting than their non-Hispanic white counterparts, perhaps reflecting challenges related to language barriers such as access to interpretation services or that this method of reporting was not acceptable to or appropriate for all families.[19]

Age

The studies reviewed demonstrated that there may be increased reporting of safety events for young children and elderly adults, but the literature is very limited and none of the studies reviewed were designed to particularly address this question.

In one study examining safety events reported for pediatric patients undergoing MRI studies, of the nearly 17,000 MRI studies performed, 88 safety events were identified (0.5%).[20] There were a greater number of safety events among patients under 6 years, inpatients, and those undergoing sedation or general anesthesia; there was no difference in events by gender and no analysis on the role of race. The most common events were service coordination issues, but serious safety events were more common in inpatients and those undergoing anesthesia.[20]

Another study compared patients who had experienced falls during their hospitalization to control patients who did not have reported falls; patients were matched based on hospitalization characteristics, including their hospital unit and length of stay at the time of the fall.[21] However, the patients for whom falls were reported were more likely than the controls to have been male (49.4% vs. 40.3%, respectively) and older (63.7 years vs. 61.6 years, respectively).[21]

The findings of these types of studies are heterogenous. A pediatric study examining safety events among patients undergoing radiation therapy compared patient characteristics of those patients for whom a safety event was reported with all treated children.[22] Using a combination of VER review and chart review, 592 safety events were reported for 275 of the 503 patients treated. The analyses showed no differences between the samples of children who had safety events reported and those who did not in terms of age, sex, race, treatment intent, or type of therapy.[22]

Finally, a study that examined major bleeding complications among patients treated with dabigatran and warfarin reported through VER at a single center revealed no differences in age or gender among patients treated with the two medications who suffered reported bleeding events.[23]

Gender

Several of the studies reviewed above have noted differences in reporting based on gender. Another study specifically examined gender differences in reporting of medication errors experienced by older adult patients through a VER system at a single center. In this study, male patients (OR 0.81) and nonwhite patients (OR 0.57) were less likely to have a medication error reported (both $p < 0.05$).[24]

VER systems are designed to capture not only patient safety events occurring at the patient's bedside, but concerns regarding communication or other factors that influence team dynamics and the culture of the health system, which, in turn, can compromise patient safety. Two studies examined provider-oriented reports and differences in gender.

In one study, female and nonwhite physicians were more likely to be reported for low-severity communication issues compared to their male and white counterparts who were more likely to be reported for medication errors.[25] Another study used VER to characterize clinician maltreatment by patients (including physical or verbal threats or sexually harassing comments). After a survey indicating that almost 70% of clinicians experience maltreatment and an institutionwide educational initiative to encourage clinicians to report such maltreatment as a safety event in their VER, clinicians reporting maltreatment were most often female, white, and non-Hispanic, with verbal threats being most common.[26]

Another study examined reports made regarding trainee physicians and found gender differences in both the identification of the trainee physicians and the content of the reports. Women trainees were more likely to be identified by their name only, rather than their professional title, as was seen for male trainees. More men than women trainees were likely to be cited for medical error; more women than men were likely to be cited for lack of communication. On coded review of event descriptions, women trainees were more likely to be described with terms such as "condescending" or "demeaning," which the authors suggest implies a violation of a perceived social hierarchy.[27]

These types of reports in particular might reflect an asymmetry in expectations of male and female trainees based on gender stereotypes.

Studies Comparing Voluntary Reporting to Automated Systems or Manual Review

Several studies highlight the limitations of VER by comparing events identified through VER with those identified using automated detection or trigger tools in combination with manual chart review. Such tools use key lab values, medications, or vital sign abnormalities tailored to different clinical contexts to trigger a more in-depth chart review for the possibility of AEs.[28] This systematic surveillance approach has been shown to increase detection of AEs, and, as records are reviewed randomly for the presence of triggers, they may minimize the contribution of reporters' biases in the reporting process.[29]

One research group identified 134 emergency department visits for procedure-related complaints using an automated system applying predetermined criteria to an electronic health record surveillance system; only 31 such visits were captured by voluntary reporting by the proceduralist.[30]

One study examining the effects of illness severity and comorbidities on AEs found that approximately 4% of hospitalized patients experienced one or more AEs with harm using a trigger tool in combination with retrospective chart review.[31] However, VER captured AE with harm for only 1.5% of patients, indicating that VER failed to capture more than 60% of safety events that reached the patient and caused at least temporary harm.[31]

Another study compared rates of adverse drug events among pediatric patients in a single long-term rehabilitation care facility that were captured using VER to those captured using triggered chart review. Seventeen AEs were detected in the three-year study period, but only 1 had been reported through the facility's VER system.[32]

Another study, although designed to assess the feasibility of a modified global trigger tool with retrospective chart review to detect AEs in an emergency department setting, showed that more AEs were detected than by VER, and demographics of patients for whom AEs were detected by chart review were consistent with those of the patient populations served by the hospitals. This was not the case for demographics of patients for whom AEs were captured by VER alone.[33]

One study was specifically designed to examine differences in inpatient patient safety events for vulnerable populations at one large academic medical center by comparing rates of events detected using triggered chart review and VER.[34] White patients were more likely to have an event reported through VER; Latino and Asian patients were less likely to have an event reported through VER. Black patients were more likely to have an automated event, even in adjusted analyses. Medicaid patients were less likely than other insurance groups to have voluntary or automated events.[34]

Finally, one study compared AE rates detected by the Global Assessment of Pediatric Patient Safety (GAPPS) trigger tool with rates derived from VER for hospitalized children by weight status, race/ethnicity, and English proficiency.[35] Use of VER was associated with systematic underreporting of AE for patients with limited English proficiency, but there were no observed disparities in VER by race or obesity. However, the study revealed dramatic underreporting of AE overall with VER compared to GAPPS.[35]

DISCUSSION

The role of patient safety event reporting in the equitable delivery of safe and high-quality health care requires greater attention. The small body of available research analyzed in this scoping review suggests that there are disparities in patient safety event reporting, particularly pertaining to race and English proficiency.

It is important to acknowledge that the way sex and/or gender data are collected is heterogenous among the studies reviewed, which influences the interpretation of results. In some studies, sex as abstracted from the medical record is used synonymously with gender; others use self-reported gender, but analysis is limited to common subgroups of gender identification. It is important to first recognize the difference between biological sex and gender and to account for how gender is assigned in research. Similar difficulties are present when interpreting results related to race. Standardization of methodology for identification and classification of patient demographics will improve validity of studies investigating the relationship between outcomes with demographics, such as gender and race.

Cumulatively, the data reviewed suggest that reporting biases are present and may be related to clinicians' implicit or explicit biases as well as systemic factors that have been associated with poorer care and poorer health outcomes among minoritized people. Although considerable work has been done to mitigate the effects of bias in the delivery of care, much work remains, from better characterizing the degree and sources of inequity in patient safety to better

understanding mechanisms to improve reporting processes and the environments that contribute to disparities in reporting.[36]

Health systems must apply an equity lens to patient safety. In so doing, harms experienced by patients from vulnerable groups can be better addressed, and measures can be put in place to reduce inequity and improve care. Through a synthesis of the current literature and identification of gaps therein, we offer several recommendations to build on the available data and improve research efforts in this growing and important field.

Health systems should require collection of patient race/ethnicity and gender identity information in institutional safety event reporting and other quality/safety improvement initiatives. Although most facilities collect event reports that include age, binary gender, and details of the event, many do not include information on patient race or ethnicity or diverse gender identity, making differences in reporting more difficult to readily identify. The Joint Commission's Performance Improvement (PI) standards require collection of patient safety information, and the Centers for Medicare & Medicaid Services (CMS) requires reporting of AEs.[37] These requirements could be optimized by mandating collection and reporting of race, ethnicity, and gender identity data with all safety event reports. The collection and reporting of these data would greatly facilitate large-scale research on disparities in safety event reporting and, at the same time, facilitate research aimed at measuring how interventions to reduce disparities in safety are affecting care.[37]

Patient safety organizations should collect and share information on disparities in patient safety. Required reporting of race/ethnicity information and enhanced collection of information on the patient experience must also be accompanied by greater transparency through sharing of these data in the peer-reviewed literature. Patient Safety Organizations are protected organizations that collect and analyze patient safety data as part of the Patient Safety and Quality Improvement Act of 2005 (PSQIA), amending the Public Health Service Act.[38] These groups are well positioned to conduct large-scale studies examining the relationships between age, gender, and race/ethnicity and patient safety events and could be required to perform such analyses through legislation or incentivized to do so by the Agency for Healthcare Research and Quality (AHRQ).

Agencies and policymakers should incentivize adoption of a systematic surveillance approach to safety event identification, similar to triggered chart review monitoring, in addition to VER to capture more events and minimize the contribution of clinicians' biases in reporting. Federal financial incentives and requirements by The Joint Commission for hospital accreditation would promote development, refinement, and widespread adoption of triggered chart review safety event detection protocols. Given that VER is known to underreport and underrecognize safety events, the use of these protocols would help identify more AEs and remove the possibility of bias in reporting, while serving as a complement to institutional VER.

Finally, quality and safety as well as health equity researchers should endeavor to more fully characterize disparities in safety events and safety event reporting based on patients' race, ethnicity, language, gender, and age. More contributions to this body of literature will inform systems-based improvements in reporting systems and data collection, but it will also improve care delivery. For event reporting research, standard reporting on race, ethnicity, language preference, gender, and age should be reported when available. If not available, specific statements noting its absence would be helpful. When safety events are reported, standard reporting on event type and severity of the event is also useful, acknowledging that harm severity scores are not standardized across the United States.

Limitations

We recognize limitations in our scoping review. Most significantly, the existing literature is rarely designed to specifically answer questions about disparities in VER, so the ability of this review to synthesize and comment on such disparities is limited by the literature itself. In addition, the studies included in this review primarily use retrospective observational methodology, which limits the confidence with which we can characterize the association of certain patient characteristics with differences in VER. Furthermore, many studies use different metrics to answer similar questions, ranging from quantity of reports to rates of reporting. This limits the ability to compare the data derived from each study. Finally, we attempted to devise a comprehensive search strategy but may have inadvertently missed relevant studies, which may have contributed to our understanding of this topic.

CONCLUSION

VER is a standard method by which health care institutions identify safety threats and prioritize resources for quality improvement. However, VER is prone to underreporting, and this introduces risk of bias. It is important to understand how different groups of patients may be affected by bias in VER to ensure equitable, high-quality care. This scoping review demonstrates disparities by race, language, age, and gender as described by the current literature. Further research is needed to specifically study these disparities to guide health care institutions on ways to mitigate bias and deliver more equitable care. Finally, improving how patient demographic information is collected as part of safety initiatives and identifying safety threats via methods that are less prone to bias will help health care institutions ensure that safety threats are recognized and addressed for all patients.

Conflicts of Interest. All authors report no conflicts of interest.

SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found, in the online version, at 10.1016/j.jcjq.2023.10.009.

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