Patient Safety Event Reporting in Vermont – 2021

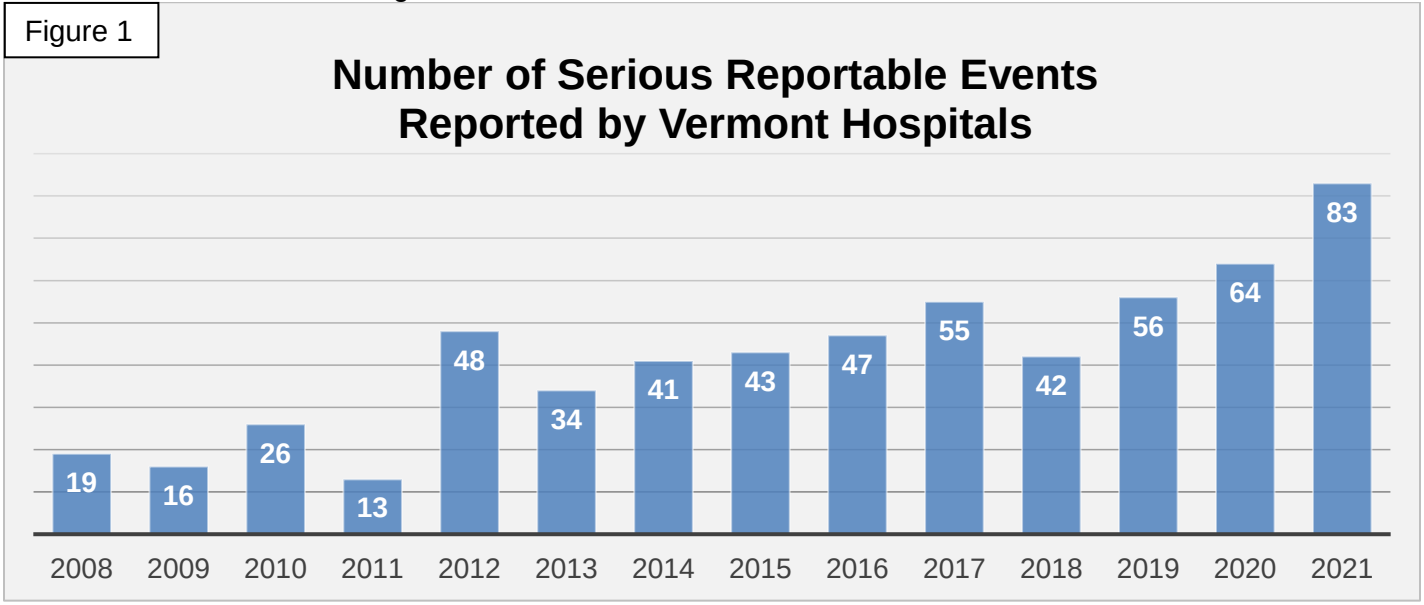
Vermont entered into the second year of the COVID-19 pandemic with many successes, as well as many challenges. COVID-19 vaccines became available at the end of 2020, while at the same time, Vermont hospitals saw record numbers of hospitalizations as a result of COVID-19 variants, as well as individuals with complex chronic conditions who had deferred routine medical care during the initial months of the pandemic. Overall hospital staffing turnover and shortages began to intensify, as hospitals realigned resources and services to meet the demands of the pandemic. The challenges to the healthcare system that had been building for years were exacerbated. Hospitals faced unprecedented shortages of specific supplies, were forced to limit in-person visits, and implement physical distancing measures. The psychological impacts of COVID-19 on the mental health of healthcare staff became evident (Stocking, et al.). During this period of time, "the reorganization of services required to attend to the immediate needs of the PHE pulled resources away from traditional programs for quality improvement and patient safety" (NPSD Data Spotlight).

I. Introduction

Serious Reportable Events, as defined by the National Quality Forum, are largely preventable clinical events that result in serious harm to the patient or even death. While these events are rare, the impact to patients, families, providers, and the community can be devastating. Vermont is one of eight states in which hospitals report on all of the National Quality Forum's Serious Reportable Events (Hanlon et al).

When an adverse event occurs at a Vermont hospital, the event must be reported to the Vermont Patient Safety Surveillance and Improvement System (PSSIS) within seven days. For each event, Vermont hospitals conduct an analysis to get to the root of *why* the event happened, and to create and implement a corrective action plan to prevent the same event from reoccurring in the future. The Vermont Department of Health (VDH) and The Vermont Program for Quality in Health Care (VPQHC) support Vermont hospitals through the PSSIS in their commitment to creating safer care environments.

Figure 1



Serious Reportable Events have been reported in Vermont since PSSIS was implemented in 2008. In order to ensure the confidentiality of patients, VPQHC does not report hospital-specific event information. While small numbers limit our ability to interpret significant changes between years, the increase in cases seen in 2012 is likely due in part to the expansion of the Serious Reportable Event criteria by the National Quality Forum at the end of 2011. The increase in Serious Reportable Events over the past two years will continue to be monitored as the effects of the COVID-19 pandemic on patient safety continue to be studied.

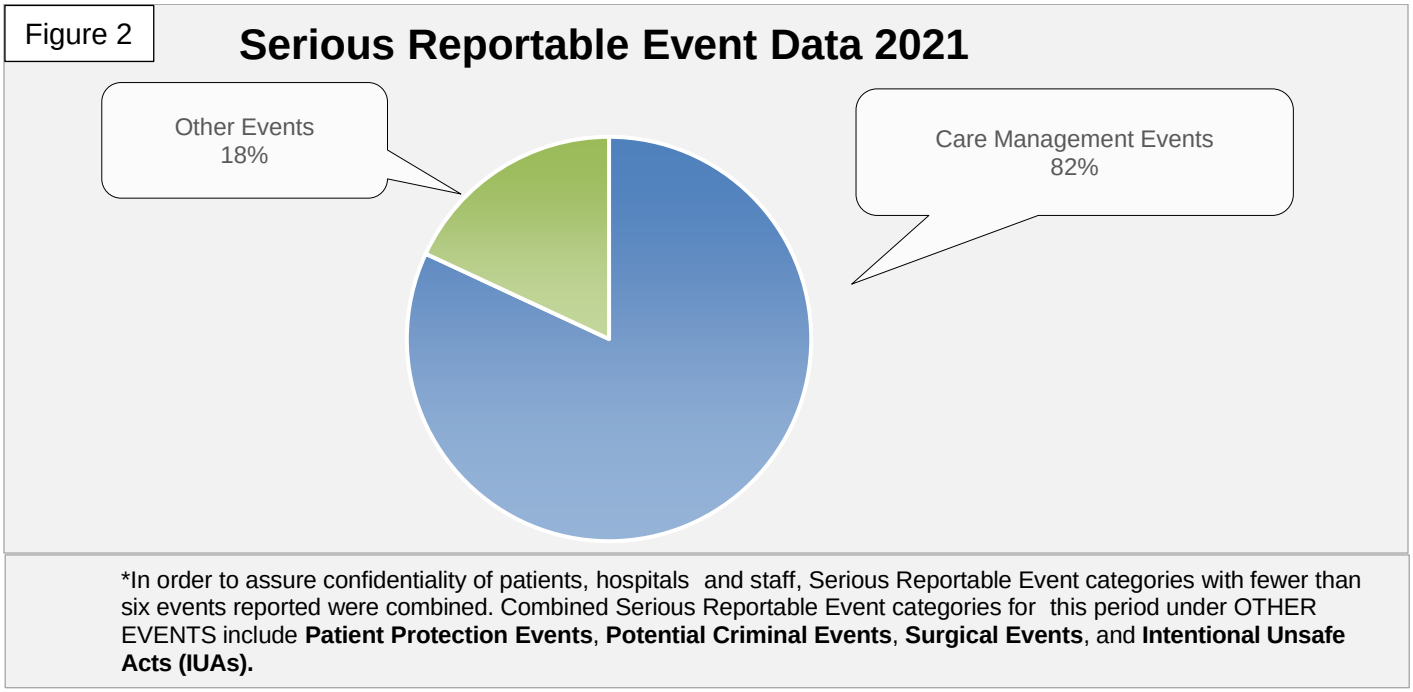
II. Vermont Serious Reportable Events 2021

In 2021, VPQHC reviewed 83 Serious Reportable Events, and Corrective Action Plans were submitted by Vermont hospitals. The majority of Serious Reportable Events (Figure 2) were classified as Care Management Events (82%).

Care Management Events include the following:

- Patient death or serious injury[1] associated with a medication error
- Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
- Patient death or serious injury associated with a fall while being cared for in a health care setting
- Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a health care setting
- Patient death or serious injury resulting from failure to follow-up or communicate laboratory, pathology, or radiology test results

Figure 2



*In order to assure confidentiality of patients, hospitals and staff, Serious Reportable Event categories with fewer than six events reported were combined. Combined Serious Reportable Event categories for this period under OTHER EVENTS include **Patient Protection Events**, **Potential Criminal Events**, **Surgical Events**, and **Intentional Unsafe Acts (IUAs).**

[1] National Quality Forum (NQF) defines serious injury as "a loss of a body part, disability, loss of bodily function, or require major intervention for correction (e.g., higher level of care, surgery)."

Quick Facts – 2021

- **The number of Serious Reportable Events reported increased approximately 14% from 2019 to 2020 and approximately 30% from 2020 to 2021.**
- **Since 2020, Serious Reportable Events classified as "Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission to a healthcare setting" continued to show significant increase. In 2019, this category of Serious Reportable Events comprised approximately 20% of the Care Management Events, 57% of Care Management Events in 2020, and 54% of Care Management Events in 2021.**
- **Serious Reportable Events classified as "Patient death or serious injury associated with a fall while being cared for in a healthcare setting" comprised between 35-40% of the Care Management Events in 2020 and 2021.**

As hospitals across Vermont and the nation face challenges related to pressure injury prevention, in 2020, Black et al. produced a position paper on behalf of The National Pressure Injury Advisory Panel (NPIAP) discussing unavoidable pressure injuries in the context of the COVID-19 pandemic. In this paper, they state that "establishing the criteria applicable in acute care settings for determining whether a pressure injury is avoidable is long overdue and has become a critical priority in the current environment of the COVID-19 pandemic" (Black et. al). Black et al. outline a variety of intrinsic and extrinsic factors under the COVID-19 pandemic that contributed to an increase in pressure injury events and stated, "although the NPIAP does not consider this time the 'new normal,' we need to recognize that the preventative measures possible in pre-COVID-19 times may not have been feasible in the middle of the COVID-19 crisis." (Black et. al) VPQHC, will continue to monitor the Serious Reportable Events associated with pressures injuries in light of the COVID-19 challenges hospitals faced over the last two years. Opportunities for improvement and learnings from the COVID-19 pandemic are disseminated throughout the Vermont hospital network to support and strengthen pressure injury prevention.

III. Vermont Serious Reportable Event Process and Patient Safety Oversight

The Vermont Department of Health (VDH) contracts with the Vermont Program for Quality in Health Care (VPQHC) to administer the Vermont Patient Safety Surveillance and Improvement System (PSSIS). If a Serious Reportable Event occurs at a facility, the hospital must report the event to VPQHC within seven days. For each event, Vermont hospitals conduct a Root Cause Analysis (RCA). An RCA is a structured method used to identify and analyze underlying systemic issues that led to the event, or that could result in a future event if not addressed properly. The most important component of an effective RCA is a focus on the larger systemic issues rather than assigning blame to the individuals or facilities involved. Following the RCA and identification of system or process issues, the hospital must develop a comprehensive Corrective Action Plan (CAP) that addresses the findings identified during the event analysis to prevent a similar event from occurring in the future. The CAP must include:

- the specific action steps needed to correct the identified findings of the event
- a specific person or persons responsible to ensure each action item is completed appropriately
- the anticipated or actual completion date of the action steps
- measurable outcomes to demonstrate compliance and sustainability of the corrective actions

Both the RCA and CAP must be submitted to VPQHC for review within 60 days of the initial event report. Once a comprehensive review is completed to ensure that the root cause or causes that led to the event are appropriately addressed, and that all of the required elements are included, the documents are submitted to the Vermont Department of Health Patient Safety Program for review.

VDH also supports VPQHC with a routine periodic site visit at each hospital at least once every three years. During the site visit, the VPQHC patient safety representative and hospital quality department patient safety staff review the hospital policies, procedures, and education provided for safety event reporting and disclosures. VPQHC staff review the hospital's Serious Reportable Events and the follow through with corrective action plans (CAPs). Hospital staff from multiple departments are interviewed to assess their knowledge of the safety event reporting procedure and the culture of reporting within the hospital.

PSSIS routine site visits were paused in 2020 and for the majority of 2021, due to the COVID-19 pandemic restrictions. VPQHC, at the discretion of VDH, reinstated PSSIS routine periodic site visits at the end of 2021, and VPQHC is scheduling site visits to resume in 2022. VPQHC staff will continue to work closely with hospitals and the VDH to complete timely visits over the next two years.

Beginning in 2020, Ambulatory Surgery Centers (ASCs) became subject to the Vermont Patient Safety statute. VPQHC provided an orientation to the PSSIS program to the ASCs, along with guidance regarding reporting events, analyzing root causes, and developing corrective action plans. In the future, ASCs will also receive periodic patient safety review site visits at least once every three years.

IV. Conclusion

VDH and VPQHC are committed to promoting safe, high quality patient care through our work with the Patient Safety Surveillance and Improvement System. We accomplish this by supporting hospitals and Ambulatory Surgery Centers in Vermont to develop and implement safe systems and processes for their patients and staff. Highlights of the work include:

- VPQHC recruited a hospital's patient safety staff member to present at the September 30th, 2021 Quality Director's Network Meeting regarding steps for performing a credible Root Cause Analysis (RCA) following a patient safety event.

- VPQHC facilitated a case review discussion by a hospital's patient safety staff member at the December 2021 Quality Director's Network Meeting. Relevant guidance and recommendations were provided to Quality Directors by Shireen Hart and Anne Cramer related to the definition and timeframe of "an episode of care."

VPQHC has observed an increase in volume of Serious Reportable Events and complexity of these cases under the COVID-19 Public Health Emergency (PHE). COVID-19 has raised many questions as to how the unique situational factors that have been created by the PHE have, and will continue to, affect patient safety and the healthcare workforce. Psychological safety is defined as a "sense of being able to show and employ oneself without fear of negative consequences to self-image, status or career" (Kingston, Dowell and Mossbury). Organizations that wish to optimize patient safety must support a culture of continuous learning and a high level of psychological safety for the healthcare workforce (Kingston et. al). Moving forward, VPQHC will continue to support hospital leadership commitment to patient safety by reaffirming the importance of a just culture within the hospital and high reliability principles. High reliability learning tools include debriefing, fostering open communication, and staff engagement and involvement in decision making to support psychological safety at the individual, team, and organizational level (Kingston et. al).

Bibliography

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