The surveyor(s) is not authorized to make a determination of whether the event is a sentinel event, or focus on or investigate the event further, nor is the surveyor(s) authorized to review comprehensive systematic analysis documents and determine the credibility, thoroughness, or acceptability of that analysis. Only the Office of Quality and Patient Safety may do this. However, the surveyor(s) is authorized to score a finding of noncompliance if the health care organization has not completed a comprehensive systematic analysis of the event (including a corrective action plan) within 45 days of the event. The surveyor(s) may score only to the time frame for completion of the comprehensive systematic analysis and not to the content of that analysis or the event itself. It is important to note that the hospital must also comply with all applicable laws and regulations regarding these time frames if these differ from the JCI requirements, but this is separate from the JCI process.

In this case, *after* the completion of the current on-site accreditation survey activities, OQPS will contact the health care organization to inquire about the event and determine whether submission of a comprehensive systematic analysis to JCI is required. If so, the health care organization will follow the steps described in the "Required Health Care Organization Response to a Sentinel Event" section of this policy.

# Required Health Care Organization Response to a Sentinel Event

The health care organization must perform a comprehensive systematic analysis for all sentinel events, regardless of whether the events are voluntarily self-reported to JCI (*see* "Conducting a Comprehensive Systematic Analysis" for examples and resources). When a voluntarily self-reported sentinel event is determined to meet the criteria of this policy in a JCI–accredited organization, the health care organization is expected to do the following:

- Prepare a thorough and credible comprehensive systematic analysis and corrective action plan within 30 business days of the event or of becoming aware of the event.
- Submit its comprehensive systematic analysis and corrective action plan to Joint Commission International, or otherwise provide its response to the sentinel event using an approved methodology within 45 business days of the known occurrence of the event for Joint Commission International evaluation.

JCI will conduct a collaborative review with the health care organization's leaders or designee to determine whether the analysis and action plan are acceptable. JCI intends for the process to be collaborative and helpful rather than punitive, and the fact that a health care organization has experienced a sentinel event will not impact its accreditation decision. However, *purposeful* failure to respond appropriately to a sentinel event could have such an impact. In these instances, OQPS would recommend to the executive leaders of JCI and the JCI Accreditation Council to review the health care organization's accreditation status.

## Reporting a Sentinel Event to Joint Commission International

Each health care organization is strongly encouraged, but not required, to voluntarily self-report to JCI any patient safety event that meets the definition of *sentinel event*. In fact, most sentinel events reported to JCI are self-reported by health care organizations. Health care organizations benefit from self-reporting in the following ways:

- Getting support and expertise during the review of a sentinel event
- An opportunity to collaborate directly with JCI
- Raising the level of transparency in the health care organization, which promotes a culture of safety
- Conveying the message to the health care organization's public that it is proactively working to prevent similar patient safety events in the future

A health care organization can report a sentinel event or ask to clarify whether an event meets the sentinel event definition at JCIQuality@jcrinc.com.

When a sentinel event is voluntarily self-reported to Joint Commission International, a clinician is assigned to review it and collaborate with the health care organization. This is the health care organization's main contact if there are questions about completing the process.

## Conducting a Comprehensive Systematic Analysis

The health care organization must complete a comprehensive systematic analysis (*see also* **Standard QPS.03.04**) to identify the root cause(s) and contributory factors to any known sentinel event, regardless of whether the event is voluntarily self-reported to JCI.

A *comprehensive systematic analysis* is defined simply as a process for identifying basic or causal factors underlying variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis (RCA), for example, is one common type of comprehensive systematic analysis. Examples of frameworks for conducting an RCA include the following:

- **The Joint Commission RCA framework:** https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/rca_framework_101017.pdf
- **The Institute for Healthcare Improvement RCA²:** https://www.ihi.org/resources/tools/rca2-improving-root-cause-analyses-and-actions-prevent-harm
- **SWARMing methodology:** https://www.jointcommissionjournal.com/article/S1553-7250(15)41065-7/pdf

The health care organization can determine its internal process, tools, and methodologies to conduct such an analysis. Any comprehensive systematic analysis should include a review of recent evidence-based literature to guide the health care organization in developing a strong corrective action plan (addressed in the next section) with the use of evidence-based practices or tools.

Joint Commission International staff review the analysis, which should focus on systems and processes, to verify that it is thorough and credible (*see* the "Review of Comprehensive Systematic Analyses and Corrective Action Plans" section). The health care organization's selected comprehensive systematic analysis method should address the questions from JCI's Framework for Root Cause Analysis and Corrective Actions. There are a number of mandatory fields within the form which must be completed by the health care organization. If the health care organization chooses to do so, it can upload supporting documents with its submission.

A health care organization's comprehensive systematic analysis should identify system vulnerabilities so that they can be eliminated or mitigated. It should not focus on individual health care worker performance but should seek out underlying systems-level causations that manifested in personnel-related performance issues. To help adhere to these characteristics it is recommended, but not required, that health care organizations consider the following guidelines when developing causative factor statements:

- Use specific and accurate descriptors for what occurred, rather than negative and vague words.
- Clearly show the cause-and-effect relationship.
- Include a preceding cause for any human errors or violations of procedure (that is, do not consider them as root causes or stand-alone causal factors).
- Classify a failure to act as a causal factor only when there is a preexisting duty to act.

*See* the "Review of Comprehensive Systematic Analyses and Corrective Action Plans" section for more detail on what is considered a thorough and credible analysis.

## Developing a Corrective Action Plan

The end-product of the comprehensive systematic analysis is a corrective action plan. The corrective action plan identifies the strategies that the health care organization intends to implement to reduce the risk of similar events occurring in the future. When formulating a corrective action plan, the review team should analyze the strength of its proposed solutions. An evidence-based tool, such as the Action Hierarchy from the US Department of Veterans Affairs (VA) National Center for Patient Safety (https://www.patientsafety.va.gov/professionals/onthejob/rca.asp) or the Action Hierarchy from the Institute for Healthcare Improvement (IHI)

Patient Safety Essentials Toolkit (https://www.ihi.org/resources/tools/patient-safety-essentials-toolkit) can help the team identify strong actions that provide effective and sustained system improvement.

The health care organization should identify at least one intermediate or stronger action (as defined in the action hierarchy) to eliminate or mitigate system hazards or vulnerabilities identified in the comprehensive systematic analysis. The corrective action plan must address the following:

- Identifying corrective actions to eliminate or reduce system hazards or vulnerabilities directly related to causal and contributory factors
- Identifying who is responsible for implementing corrective actions
- Determining timelines to complete corrective actions
- Developing strategies to evaluate the effectiveness of the corrective actions
- Developing strategies to sustain the change

(*See* the "Review of Comprehensive Systematic Analyses and Corrective Action Plans" section for more detail on what is considered an acceptable corrective action plan.)

## Submitting the Comprehensive Systematic Analysis and Corrective Action Plan

A health care organization that voluntarily self-reports a sentinel event must submit a comprehensive systematic analysis, including the resulting corrective action plan that describes the health care organization's risk reduction strategies as well as how the strategies will be evaluated and measured to determine effectiveness. This information is submitted electronically to JCI at JCIQuality@jcrinc.com and will be reviewed in a conference call involving JCI and the health care organization leaders or designee(s). These documents should not include the names of health care organization staff or patients involved in the sentinel event or other protected personal health information (PHI).

## Joint Commission International's Response

JCI assesses the health care organization's response to the sentinel event against three criteria:

1. Thoroughness of the comprehensive systematic analysis
2. Credibility of the comprehensive systematic analysis
3. Acceptability of the health care organization's corrective action plan

JCI will provide collaborative consultation to the health care organization if the response lacks robust key elements and will allow an additional 20 calendar days beyond the original submission period for the health care organization to resubmit its response, including revised corrective actions if necessary.

## Review of Comprehensive Systematic Analyses and Corrective Action Plans

JCI reviews the comprehensive systematic analysis and corrective action plans for thoroughness, credibility, and acceptability.

To be **thorough**, the analysis must do the following:

- Repeatedly ask "Why?" until the analysis identifies the systemic causal factors associated with each step in the sequence that led to the sentinel event.
- Focus on systems and processes, not solely on individual performance.
- Determine the human and other factors most directly associated with the sentinel event and the process(es) and systems related to its occurrence.
- Use the analysis to help determine where redesign might reduce risk.
- Inquire into all areas appropriate to the specific type of event.
- Identify risk points and their potential contributions to this type of event.
- Determine potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future or determine, after analysis, that no such improvement opportunities exist.

To be **credible**, the analysis must do the following:

- Be clear (understandable information).
- Be accurate (validated information and data).
- Be precise (objective information and data without internal inconsistencies).
- Be relevant (focus on issues related or potentially related to the sentinel event).
- Be complete (cover all causes and potential causes).
- Be systematic (methodically conducted).
- Possess depth (ask and answer all the relevant "Why" questions and explain any "not applicable" finding).
- Possess breadth of scope (cover all possible systemic factors wherever they occur).
- Reflect diverse perspectives (include a process owner or designee, a patient or family member when appropriate, and individuals close to the process under review).

Joint Commission International does not require the active involvement of a senior leader in the day-to-day work of the comprehensive systematic analysis team. However, the team should report to the senior leader or designee, and the individual should be involved in deciding or approving the actions the health care organization will take as a result of the comprehensive systematic analysis.

To be considered **acceptable**, the corrective action plan must do the following:

- Identify changes that can be implemented to reduce risk, or formulate a rationale for not undertaking such changes.
- Identify, in situations in which improvement actions are planned, the following:
  - Who (by title) is responsible for implementation
  - When the action will be implemented (including any pilot testing)
  - How the effectiveness of the actions will be evaluated
  - How the actions will be sustained
  - The point at which alternative actions will be considered if improvement targets are not met
  - At least one stronger or intermediate-strength action

All comprehensive systematic analyses and corrective action plans will be considered and treated as confidential by JCI (*see* the "Handling Sentinel Event–Related Documents" section below).

If JCI finds the analysis and action plan thorough, credible, and acceptable, JCI will notify the health care organization and assign one or more follow-up activities.

## Follow-Up Activities

After JCI has determined that a health care organization has conducted a thorough comprehensive systematic analysis (for example, root cause analysis) and developed a comprehensive corrective action plan, JCI will notify the health care organization whether the analysis and action plan have been accepted and will assign an appropriate follow-up activity. This will be a mutually agreed-upon documentation of sustained improvement and reduction of risk, which may include one or more Measures of Success (MOS).

## Sentinel Event Measures of Success

The health care organization's follow-up activity may be conducted through the Sentinel Event Measure of Success (SE MOS) process. The health care organization will identify one or more SE MOS—that is, one or more numerical or quantifiable measures (ideally with a numerator and denominator), usually related to an audit, which determines if the health care organization effectively sustained the planned corrective action(s). The health care organization will track the measure for at least 90 days (or three months) and report its compliance to Joint Commission International. The health care organization's report, due on a mutually agreed-upon date, should demonstrate whether the health care organization reached its identified SE MOS and is sustaining compliance.

The health care organization's accreditation decision may be impacted under the following circumstances:

- An SE MOS submitted on time does not meet preestablished levels of compliance and JCI requests an additional 120 days (or four months) of data that still does not meet preestablished levels of compliance.
- Submission of an SE MOS more than 90 days (or three months) after the mutually agreed-upon date.

# On-Site Review of a Sentinel Event

JCI will generally not conduct an on-site review of a self-reported sentinel event unless it determines that a potential ongoing *Immediate Threat to Health or Safety* exists. An *Immediate Threat to Health or Safety* is a threat that represents immediate risk and may have serious adverse effects on the health or safety of patients and/or others. All potential Immediate Threats to Health or Safety are referred to Joint Commission International's executive leaders for authorization to conduct an unannounced for-cause survey. If an on-site survey is conducted, the health care organization will be billed a sufficient charge, based on an established fee schedule, to cover the costs of conducting such a survey.

## Disclosable Information

If Joint Commission International receives an inquiry about the accreditation decision of a health care organization that has experienced a sentinel event, the health care organization's current accreditation status will be reported in the usual manner without referring to the sentinel event. If the inquirer specifically references the sentinel event, Joint Commission International will acknowledge that it is aware of the event and currently is working or has worked with the health care organization through the sentinel event review process, without disclosing details of the event. All details and materials related to the sentinel event are and will remain confidential.

## Handling Sentinel Event–Related Documents

Joint Commission International restricts access to any submitted comprehensive systematic analysis and corrective action plan to the Office of Quality and Patient Safety in accordance with procedures designed to protect the confidentiality of the documents. Joint Commission International will retain any corrective action plan(s) resulting from the analysis of the sentinel event long enough to serve as the basis for appropriate follow-up activities, such as the SE MOS or other mutually agreed-upon documentation of sustained improvement. After the health care organization implements the corrective action plan and Joint Commission International verifies that it meets the established levels of compliance, the information contained in any electronically submitted analysis will be de-identified after the OQPS completes its review.

## The Sentinel Event Database

Joint Commission International collects and analyzes aggregate data from the comprehensive systematic analyses, corrective action plans, and follow-up activities in its Sentinel Event Database. Joint Commission International develops and maintains the database in a manner that excludes health care organization, caregiver, and patient identifiers.

Aggregate data relating to root causes and risk reduction strategies for sentinel events that occur with significant frequency may form the basis for future error-prevention advice to health care organizations.

## Overseeing the Sentinel Event Policy

The executive leaders of Joint Commission International are responsible for approval of this policy and overseeing its implementation. For more information about Joint Commission International's Sentinel Event Policy, visit Joint Commission International's website (https://www.jointcommissioninternational.org/contact-us/sentinel-event-policy/).