**Serious Adverse Event Investigation: The Better and Improved Version**

By Bonnie Portnoy, Director, Risk Management

Adverse events occur in healthcare every day, causing harm to patients, families, staff and organizations. An adverse event is defined as an event that causes harm to a patient as the result of a medical intervention rather than the underlying condition and is different than a medical error, which is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve the goal. Many adverse events are not caused by error and many errors do not cause harm.

The Joint Commission defines a Serious Adverse Event (SAE) as an unexpected occurrence involving death or serious physical or psychological injury or risk thereof. The phrase “risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. The Center of Medicare and Medicaid Services (CMS) and The New York State Department of Health (NYSDOH) have similar definitions of a Serious Adverse Event. The NYSDOH has mandatory event reporting requirements and requires us to investigate and perform a Root Cause Analysis (RCA) on these events. Investigation of SAEs is also crucial in helping us as an organization identify quality of care concerns and provide us with an opportunity to develop risk mitigating strategies. Another result of these investigations is the identification of potential risk to the providers and organization from a malpractice perspective.

A detailed list of these events can be found on the intranet (RM Policy GPP 402). The Risk Management department investigates these events, and in coordination with the Chief Medical Officer (CMO) and the Quality Improvement Department conducts the RCAs. What has now changed is HOW we are investigating the events and the time frames involved. Notification to Risk Management (via phone, email or MERS) of the following is essential: Never events/sentinel events, Serious Adverse events leading to actual harm, Serious Adverse Events with potential to cause harm or those events meeting NYSDOH criteria. The prompt completion of internal notification triggers the appropriate investigation and assists with external notification within the applicable time requirements.

What is new is the process of *Huddles and Debriefs* after an adverse event. Huddles and Debriefs are tools designed to allow us to rigorously analyze a critical event, to examine what occurred and to facilitate an improved outcome next time (manage events better or avoid event). It is a non-punitive, non-judgmental forum for discussion of individual and team performance, identification of areas requiring improvement and determine reportability to the DOH and/or whether an RCA needs to be conducted.

The Huddle occurs *immediately* after an event occurs, AFTER the patient and/or situation has been stabilized and there is no ongoing harm. The Huddle is led by the most senior local staff member, which can be either a nurse or physician and involves the staff involved in the event. The staff should immediately gather to share their understanding of what factually happened. It is the opportunity to secure suspect equipment, materials, documents, etc. that may have been involved or contributed to the event. It is also the opportunity to alert others to ongoing and/or similar threats and address staff
concerns and safety. Risk Management and Senior Leadership should be notified of the event so that further investigation can begin. As always, objective documentation of the event should be completed in EPIC and a MERS should also be done as well. The staff should not be documenting the details of the Huddle.

Debriefing, especially when it occurs immediately or soon after an event and includes all team members, presents a valuable opportunity to reinforce effective team work and jointly identify needed improvements, both in team communication and systems. The goal is to conduct the debriefing within 24-72 hours after the event has occurred. The debriefing is a meeting of all involved individuals and their leadership, which is led by the CMO and/or the Risk Management staff. The goal is to clarify a detailed chronology of event to develop an accurate timeline. The medical record and other relevant materials will be used and a site visit may occur. It can be conducted via tele- or videoconferencing, if necessary, but it is essential that all involved parties be present for the discussion.

Discussion at the meeting will determine if continued safety risks exist and develop plans to mitigate the immediate risk. It also provides us with the opportunity to discuss disclosure to the patient and family and to identify any areas of potential service recovery. Debriefing is an approach that allows team members to discuss the various decisions that were made, things that could have been done differently, potential need for remediation/training and what was successfully accomplished. The Risk Management team will document a timeline as a result of the debriefing. Huddle and Debrief guidelines are available in Patient Works.

It is at this juncture that we will determine whether there are regulatory reporting obligations that require an RCA, whether an RCA is warranted for any quality of care concerns or whether any additional actions are required. Debriefing allows us the opportunity to provide emotional support to staff involved in the event. If it is determined that an RCA needs to be conducted, it will be scheduled through the CMO office and should occur within 7-14 days after the event.

A Root Cause Analysis is a non-punitive, systems approach to identify the most fundamental specific reason an event has occurred. The RCA is led by the Chief Medical Officer and facilitated by a member of the Risk Management Department. The product of an RCA is an action plan that identifies strategies MSH intends to implement to reduce the risk of similar events from occurring in the future. The results will be reported the Clinical Review Committee and ultimately presented to AEC, where it will be endorsed by Senior Leadership within 30 days of the date of the event. This swift completion of the investigation allows us not only to meet regulatory requirements, but more importantly allows us to put into place corrective action plans that will help mitigate risk and help us provide the safe quality of care to our patients that the know we can deliver and they deserve.