In June 2016, the American Academy of Sleep Medicine (AASM) released revised standards for the accreditation of sleep facilities, which includes new standards focusing on improving the safety of patients undergoing sleep testing. Specifically, standard K-5 requires that facilities define serious adverse events (see table 1) and document their occurrence, while standard K-6 requires that a root cause analysis (RCA) be performed and documented for each serious adverse event which has occurred. Since compliance with the new standards is required by July 2017, staff of accredited facilities should be familiar with the use and limitations of RCA.

RCA is a structured method used to analyze a serious adverse event after it has occurred, and was initially developed to analyze industrial accidents. The central tenet of RCA is that adverse events occur, in part, because of how systems of care are designed, and that by looking at how those systems are set up and functioning (or malfunctioning), we can obtain a better understanding about how to change those systems to make another adverse event less likely. This process involves organizing the team that will perform the analysis of the adverse event, reconstructing the event and identifying the factors that contributed to the occurrence of the event, and then developing an action plan to change those factors.

**STEP 1: ORGANIZE THE RCA TEAM**

Sleep facilities accredited by the AASM vary widely in their organization, from small, independent testing facilities to large academic hospital-based centers that perform studies on specific populations such as children. As such, the human resources available to perform a RCA may vary widely.

The goal of assembling the RCA team is to have representatives from enough disciplines that a variety of perspectives are available, while also balancing the size of the group so as not to become too large and unwieldy to efficiently complete the RCA in a timely manner. Possible RCA team members include the following:

- Facility Director
- Medical Director
- Staff Physician
- Sleep Medicine Fellow
- Patient Safety/Quality Improvement Professional
- Risk Manager/Legal
- Technical Director
- Sleep Technologist
- Nurse
- Office Staff
- Patient Representative

It is recommended that a core RCA team be 4-6 members with additional members added as needed based on the circumstances of the particular adverse event. For example, if the adverse event involves an equipment failure, then a representative from the biomedical department could be invited. If available, a team member with experience with performing RCA should lead the team, and a member should be designated a scribe to document the work of the team and draft the analysis and recommendations.

**STEP 2: RECONSTRUCT THE ADVERSE EVENT AND PERFORM THE RCA**

Once the team is assembled, the goal of the RCA should be made explicit by the team leader — to generate knowledge about the system of care that our patients interact with in anticipation of improving that system and improving patient safety. It is not to assign blame on any individuals.

The first step is to reconstruct the events that preceded the adverse event, taken from the events documented in the medical record, review of polysomnographic data and video recordings if appropriate, and supplemented by interviews with staff that had direct experience with the patient and processes involved in the adverse event. The goal of this reconstruction is to generate a timeline of events that can then be analyzed for factors that contributed to the adverse event.

The second step of the analysis is to review the timeline of events for factors that may have contributed to the adverse event. Table 2 lists types of factors that contribute to adverse events in healthcare settings. As an example, after a patient fall with injury, the analysis may reveal that the involved person has congestive heart failure and chronic obstructive pulmonary disease which limits her ability to ambulate without assistance (patient specific factor). The office staff doesn’t routinely let patients know that technologists are available to assist with a wheelchair (staffing factor), so the patient attempted to walk unassisted and fell while attempting to enter the facility.
STEP 3: DEVELOP AN ACTION PLAN

Once the RCA is completed and a list of factors that contributed to the adverse event is completed, the work of the team has not finished. The final step of the improvement process is to feed the results into the quality improvement processes that the facility should be developing in parallel using a measurable action plan. For example, if the RCA into an adverse event of delayed recognition and appropriate response to a dangerous cardiac arrhythmia identified a factor of poor knowledge of arrhythmias by the technical staff, the team could develop an arrhythmia course and make an arrhythmia the focus of the annual safety drill.

SUMMARY, LIMITATIONS AND RECOMMENDATIONS

RCA is one of the most widely-used tools to improve patient safety; however there is a limited amount of data that supports its effectiveness. Part of this may be due to the considerable heterogeneity of how these methods are performed and how the knowledge developed is utilized in action plans afterward. Despite this, regulatory bodies are requiring the use of RCA after adverse events, and they represent a potentially useful tool in decreasing the frequency of adverse events in our patients. The use of RCA will pose a challenge to facilities that are not familiar with their use.

Finally, there are opportunities to share knowledge generated by RCA and other improvement processes with others in the sleep field, although venues are not readily available currently. Sharing the processes and results of improvement efforts with peers locally, and at state and national meetings, has the potential to increase the quality and safety of sleep medicine for our patients.

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
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</table>
| **K-5: Patient Safety Related Significant Adverse Events** | Within the facility, the facility director must document the occurrence of significant adverse events for its patient population. At a minimum, the following events must be considered significant adverse events:  
• Patient or staff death  
• Permanent loss of function or of a body part by a patient or staff  
• An event that leads to the hospitalization of a patient or staff  
• An event that requires activation of an emergency medical response  
• Sexual or physical assault of a patient or staff or allegations thereof  
• Release of a minor or a patient lacking capacity or competency to an unauthorized individual  
• Elopement of a patient  
• Complications arising from the effects of hypnotics used for the purpose of sleep testing  
• Any event required by the applicable jurisdiction to be reported to a government agency |
| **K-6: Analysis of Significant Adverse Events** | The facility must create a policy and procedure for performing a root cause analysis of any significant adverse events. Consistent with the policy, the facility must conduct an investigation of all significant adverse events that occur. |
TABLE 2: FACTORS CONTRIBUTING TO ADVERSE EVENTS

<table>
<thead>
<tr>
<th>Factor</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Characteristics</td>
<td>medical condition, language/cultural issues, social issues</td>
</tr>
<tr>
<td>Task-related</td>
<td>specific aspects of the procedure that may make harm more likely</td>
</tr>
<tr>
<td>Staffing</td>
<td>knowledge, skills, attitudes and motivation</td>
</tr>
<tr>
<td>Team Environment</td>
<td>communication style, hierarchies, supervisors, and team culture</td>
</tr>
<tr>
<td>Work Environment</td>
<td>staffing levels, workload acuity, nightshift, equipment-specific limitations</td>
</tr>
<tr>
<td>Organizational/Management</td>
<td>culture of safety, patient-centeredness</td>
</tr>
<tr>
<td>Institutional/Regulatory</td>
<td>state &amp; national factors, accreditation</td>
</tr>
</tbody>
</table>

REFERENCES


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