

An Analysis of Adverse Events in the Rehabilitation Department: Using the Veterans Affairs Root Cause Analysis System

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Background. Root cause analyses (RCA) are often completed in health care settings to determine causes of adverse events (AEs). RCAs result in action plans designed to mitigate future patient harm. National reviews of RCA reports have assessed the safety of numerous health care settings and suggested opportunities for improvement. However, few studies have assessed the safety of receiving care from physical therapists, occupational therapists, or speech and language pathology pathologists.

Objective. The objective of this study was to determine the types of AEs, root causes, and action plans for risk mitigation exist within the disciplines of rehabilitation medicine.

Design. This study is a retrospective, cross-sectional review.

Methods. A national search of the Veterans Health Administration RCA database was conducted to identify reports describing adverse events associated with physical therapy, occupational therapy, or speech and language pathology services between 2009 and May 2016. Twenty-five reports met the inclusion requirements. The reports were classified by the event type, root cause, action plans, and strength of action plans.

Results. Delays in care (32.0%) and falls (28.0%) were the most common type of AE. Three AEs resulted in death. RCA teams identified deficits regarding policy and procedures as the most common root cause. Eighty-eight percent of RCA reports included strong or intermediate action plans to mitigate risk. Strong action plans included standardizing emergency terminology and implementing a dedicated line to call for an emergency response.

Limitations. These data are self-reported and only AEs that are scored as a safety assessment code (SAC) 3 in the system receive a full RCA, so there are likely AEs that were not captured in this study. In addition, the RCA reports are deidentified and so do not include all patient characteristics. As the Veterans Health Administration system services mostly men, the data might not generalize to non-VHA systems with a different patient mix.

Conclusions. Care provided by rehabilitation professionals is generally safe, but AEs do occur. Based on this RCA review, the safety of rehabilitation services can be improved by implementing strong practices to mitigate risk to patients. Checklists should be considered to aid timely decision making when initiating an emergency response.

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Health care in the United States is not as safe as it should be—by some estimates, medical errors are the third leading cause of death.¹ The seminal National Academy of Medicine report, *To Err Is Human*,² highlighted this issue, suggesting that 44,000 to 98,000 deaths each year can be related to the wrong medication, surgery, or another medical error within the health care setting.¹ This estimate was later increased to 140,000 preventable iatrogenic deaths.¹ There are multiple effects from medical errors in addition to the tragedy of patient harm. There is a significant financial cost related to poor quality, including direct and indirect costs in legal services, marketing, and operations.³ These costs affect payers, providers, and patients. *To Err Is Human* argued that the frequency of medical errors is not a “bad apple” problem: “more commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them.”²

The rehabilitation department of a medical center provides a variety of core patient care services. In 2015, the Veterans Health Administration (VHA) provided over 2 million patient visits from a combination of physical therapy, occupational therapy, and speech and language pathology (SLP) services.⁴ Patients are most often referred to a specific therapy discipline by other providers in the medical center, though some settings allow patients to self-refer. The combined disciplines treat a large range of acute and chronic conditions. They also treat most of the major body systems, including musculoskeletal, neurological, integumentary, and gastrointestinal systems. This can involve a diverse range of interventions, such as ergonomic changes, physical activity (PA), manual therapy, orthoses, and food consistency.

The services offered by a rehabilitation department are considered conservative. They are rarely invasive and are generally thought to be associated with less risk than other services in modern medicine. However, low risk does not mean *no* risk, and little is known about the level of risk of these services. Sever-

al studies have identified a lack of literature regarding adverse events (AE) in rehabilitation medicine.⁵⁻⁸

Past work on AEs within rehabilitation disciplines focused in 2 domains: PA recommendations and manual therapy. Several studies assessed the safety of PA prescriptions by rehabilitation professionals in vulnerable populations, such as patients with heart failure and patients who are critically ill in the intensive care unit. The majority concluded that PA prescriptions were safe.⁸⁻¹⁵ Two studies disagreed with this conclusion, suggesting some level of risk. The first was a randomized controlled trial of a 12-week, home-based exercise program versus PA counseling in 209 elderly adults who were mobility limited and chronically ill.¹⁶ AEs were reported by 47% (n = 99) of all participants. Six events (n = 4 in the experimental group, n = 2 in the control group) were serious enough that the participants needed to discontinue their participation in the study. The researchers concluded, “Even though the program appears to be safe, high morbidity unrelated to exercise can constitute a critical challenge for sustained exercise participation.” The second study was an isolated case study of a 70-year-old woman who developed rhabdomyolysis after a physical therapy session, resulting in hospitalization.¹⁷

A larger body of work has assessed the safety of spinal manipulations. This treatment is occasionally used by physical therapists and more often used by chiropractors. Potential AEs include stroke (related to cervical vasculature injury) and there is one report of quadriplegia.^{5,18-22} Two studies sought to quantify a level of risk associated with cervical manipulations. The first study was a review of 134 case reports that determined 44.8% of the events could have been prevented if the clinician ruled out all contraindications prior to the intervention.²³ The authors called for improved clinical reasoning and practice. The second study was a systematic review of 5 studies that attempted to assess a risk level to cervical spine manipulation, and the conclusion was that “evidence is lacking for a strong association between neck manipulation

and stroke, but is also absent for no association.”²⁴

Overall, a small body of literature addresses AEs associated with rehabilitation practices. Few studies evaluate AEs resulting from interventions prescribed by rehabilitation professionals. There are no studies on the full spectrum of risks associated with treatment by these disciplines.

One source of untapped information about AEs resulting from activities prescribed by rehabilitation professionals are root cause analysis (RCA) reports. The Veterans Health Administration (VHA) requires each of 152 facilities to complete a minimum of 4 RCAs per year.²⁵ Reports from these RCAs have been archived centrally since 1999.²⁶ To learn more about AEs related to rehabilitation care, we searched the RCA database for AEs involving disciplines in rehabilitation departments. Our objective was to discern patterns from the root causes and recommended actions to mitigate risks. We anticipate that this information will be helpful in further developing a framework for understanding AEs in rehabilitation.

Methods

VA Root Cause Analysis Process

The Department of Veterans Affairs established the National Center for Patient Safety (NCPS) in 1998 to develop a culture of patient safety throughout the VHA.²⁷ NCPS implemented the root cause analysis system, which “shifted analysis of adverse events towards a human factors engineering approach—entailing a search for system vulnerabilities rather than human errors and other less actionable root causes.”²⁸ NCPS defined AEs as “untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical facility, outpatient clinic, or *other VHA facility*.”²⁹ Sample categories of AEs are found in Table 1. NCPS encourages a RCA to take place after both an AE and a near miss or “close call.” Both are considered learning opportunities to prevent future patient harm.³⁰

Table 1.
Different Types of Adverse Events

Adverse Event	Number of Events (Percent of 25 Total Events)
Delay in Care	8 (32.0%)
Fall	7 (28.0%)
Procedure error or inadequate policy	3 (12.0%)
Wrong patient identified for treatment	2 (8.0%)
Medication errors	1 (4.0%)
Airway/Ventilation treatment error	1 (4.0%)
Equipment failure	1 (4.0%)
Weapon on campus	1 (4.0%)
Discharge error	1 (4.0%)

After an event occurs, the local patient safety manager (PSM), who is often a clinician cross-trained in quality methodology, completes several steps to determine if a RCA is warranted. The manager uses the safety assessment code (SAC) tool to determine a score (from 1 to 3) for the incident.³¹ This tool categorizes the event based on severity and probability (high severity and high probability events are assigned a SAC score of 3). A second step for the PSM is to assess whether the event resulted from “a) a criminal act; b) a purposefully unsafe act; c) an act related to alcohol or substance abuse of an impaired provider or staff member; or d) events involving alleged or suspected patient abuse of any kind.”³² If the event fits into one of these categories, it is not appropriate for a RCA.

When a RCA is warranted, the PSM charts a multidisciplinary team of 4 to 10 individuals. Information is collected from the medical record and staff interviews. Interviewed staff members are notified that the RCA is a nonpunitive, safety-based investigation designed for learning rather than for disciplinary purposes. To encourage full disclosure of events within the VA, the RCA process is independent of litigation due to US Code 5705.³³ The final report is stored in a deidentified manner and is not available for legal investigation. Over multiple meetings, the team processes its findings and assigns 1 (or several) root cause contributing factor statements, drafts action plans, and defines outcome measures to gauge the

success of the recommended actions. The RCA report is presented to hospital leadership within 45 days of the initial adverse event. Once approved, the team implements the action plan and evaluates the effectiveness of the action plan using prespecified outcome measures. The report is sent to the NCPS headquarters where it is assigned an identifier and entered into a database.

There are inherent limits of RCAs. First, the reports are deidentified and focus on the systemic vulnerabilities in the facility that may have caused the AE rather than on patient characteristics. Although basic demographics such as sex are included in the report, more detailed characteristics, such as marital status and comorbidities, are absent. Second, because only AEs that are rated SAC 3 are required to receive a RCA, there are many less-severe AEs that are not included in the data set. Therefore, RCA data is an inappropriate source to determine rates of AEs or other epidemiological measures. However, the RCA data do indicate a sample of the nature of adverse events within a nationwide medical system serving more than 7 million veterans. Of this population, there were more than 1.5 million physical therapist, 400,000 occupational therapist, and 140,000 speech and language pathologist encounters in 2015.⁴ There were 1943.0 physical therapy and 1218.4 occupational therapy full-time equivalencies (FTEs) in 2015, and a combination of 1772.6 speech pathology and audiology FTEs.³⁴ These providers practice in a similar scope to

those outside the VHA system, suggesting that RCAs could be generalizable to privatized health care. Therapists in the VHA offer care in inpatient and outpatient services in both the large health centers and the smaller community-based outpatient centers (CBOC). The CBOC rehabilitation setting shares many characteristics with private hospital, offsite clinics.

Identification of Rehabilitation-Related RCA Reports

We conducted a search of reports in the NCPS RCA database for keywords related to physical therapy, occupational therapy, speech and language pathology, physical medicine, and rehabilitation from January 2009 through May 2016. This produced 1218 reports. A report was selected for our study if the AE occurred within the physical setting or location of the rehabilitation department. The event could have occurred immediately before, during, or after treatment. We included events that occurred under the direct care of rehabilitation staff members—whether clinical staff or nonclinical staff—meaning that the AE could occur under the watch of the front office staff of a clinic or under the care of a clinician. Events also were included if they occurred under the direct supervision of rehabilitation clinicians in other areas of the medical center. This narrowed the search to 25 reports. Each of the selected reports were AEs. None was a near miss.

There were several common reasons why reports initially identified in our search did not satisfy our inclusion criteria. One reason is that “PT” was a search term because it is an acronym for “physical therapist.” However, “pt” also is short for “patient” in medical records. Furthermore, “rehab” also was a search term. The search returned reports where patients received other types of rehabilitation, such as treatment for substance abuse. Finally, several selections from the database search indicated that a patient was receiving care from a rehabilitation discipline but was not under the supervision of a rehabilitation professional at the time of the incident. For example, several reports involved a patient who fell in

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Table 2.

Action Plans: Primary Analysis Categorization Glossary

Action Category	Application
Stronger actions	<ul style="list-style-type: none"> Standardize on equipment or process or care maps Architectural/physical plant changes New devices with usability testing before purchasing Engineering control, interlock, forcing functions Simplify the process and remove unnecessary steps Tangible involvement and action by leadership in support of patient safety
Intermediate actions	<ul style="list-style-type: none"> Redundancy/back-up systems Increase in staffing/decrease in workload Software enhancements/modifications Eliminate/reduce distractions Checklist/cognitive aid Eliminate look- and sound-alikes Enhanced documentation/communication
Weaker actions	<ul style="list-style-type: none"> Double checks Warning and labels New procedure/memorandum/policy Training Additional study/analysis

Table 3.

Patient Demographics

Demographic	Patients	Number Identified
Sex	20 men	20/25
	0 women	
Age	54-70 years old	9/25
Location of adverse event	16 outpatient	25/25
	9 inpatient	
Discipline	22 physical therapy ^a	25/25
	5 occupational therapy	
	2 speech and language pathology services	

^aReports involved 2 disciplines.

an inpatient unit. This patient may have received occupational therapy treatment earlier that day, but the AE did not occur under rehabilitation staff's supervision or within the location of the rehabilitation department. Such reports were not selected for further study.

Analysis of Rehabilitation-Related RCA Reports

The 25 reports were analyzed as follows: 1) we collected demographic data if available from the database regarding the patient's age and clinical setting, 2) we reviewed each AE and assigned descriptive codes for the event type, 3) we identified root causes and action plans in each individual RCA report and assigned them to each of these areas, 4)

we ranked the action plans in relation to their relative strength according to the Primary Analysis Categorization (PAC) Glossary,^{5, 35, 36} and 5) in a parallel process, a second author (P.M.) similarly coded the events for their type, root cause, and action plans to determine an interrater Kappa value.

The NCPS created the Primary Analysis Categorization (PAC) Glossary (Tab. 2) as a guide to develop strong action plans after an RCA.^{35,36} This guide shares a human factors engineering approach with the Occupation and Safety Health Administration's Solutions to Control Hazards guideline.³⁷ Stronger actions remove opportunities for human error. They make physical changes

to the environment, install better equipment, standardize work, or remove unnecessary steps to a process. This is in contrast to the weaker actions (eg, education of staff or policy changes), which require decision making by staff in susceptible situations. For example, one remote clinic dialed the wrong number during a medical emergency. A strong action would be a phone or dedicated line at each remote clinic that calls only an ambulance. By contrast, a weak action would be to send out a reminder email with the correct emergency number. Another example of a strong versus weak action plan is centered on a situation where a wrong patient was identified for treatment. The RCA team determined that the complex check-in sequence was a root cause. A strong action would be to centralize and standardize the check-in process for all of the clinical services. A weaker action is to remind check-in staff to pay closer attention.

Results

Reports varied in their description of demographic characteristics. For example, although sex was typically reported, only 9 of the 25 reports indicated the patient's age (Tab. 3). Sixteen of the 25 reports were located in an outpatient setting; 9 were located in an inpatient unit. There were 22 physical therapy, 5 occupational therapy, and 2 SLP related cases (2 cases involved both physical therapy and occupational therapy). The admitting and/or treated diagnosis was related to a variety of musculoskeletal pathologies, with the exception of 2 patients treated for wound care and another treated for neurological disease (Tab. 4). Three AEs resulted in patient death.

We identified 9 categories of AEs (Tab. 1). Delay in care made up the largest type of AE, at 32.0% (8 events) of all reports. Several reports from remote outpatient settings described a slow response to emergency scenarios. The patient's deteriorating medical status was not caused by the rehabilitation intervention. Rather, the proper services were not called or medical equipment could not be located in a reasonable amount of time. Delayed and inade-

Table 4.
Patient Demographics and the Nature of Adverse Events

Admitting Diagnosis (Body Region)	Total Number	Inpatient	Outpatient	Death Result	Discipline	Event Type
Orthopedic pathology (lower extremity)	9	3	6	1	9 physical therapy ^a	Delay in care (2), Equipment failure (1), Fall (5), Procedure (1)
Not identified	8	2	6	1	7 physical therapy, 3 occupational therapy	Medication (1), Delay in care (3), Fall (1), Weapon on campus (1), Wrong patient (2)
Spine pathology	3	1	2	1	3 physical therapy	Delay in care (1), Fall (1), Procedure (1)
Orthopedic pathology (upper extremity)	2	1	1	0	2 physical therapy, 1 occupational therapy	Delay in care (1), Discharge (1)
Wound care	2	1	1	0	1 physical therapy, 1 occupational therapy	Delay in care (1), Procedure (1)
Neurological pathology	1	1	0	0	1 speech and language pathology services	Airway/Ventilation (1)

quate responses to emergency scenarios also occurred within larger medical centers. One RCA narrated a situation where an emergency code was called, but there was not a clear protocol for members of the code team. This too resulted in a delay in care.

Falls was the second most common type of event, 28.0% (7 events). Deficits in procedure was the third largest type (12.0%, 3 events). This was defined as an error occurring during the performance of a defined procedure. There were 2 RCAs (8.0%) related to the wrong patient being identified for care. All other types of AEs occurred only once in our data set.

There were a total of 47 root causes identified by the 25 RCA teams, as several RCA reports had multiple root causes. These causes were categorized into 7 groups (Tab. 5). Overall, errors in procedure/policy (38.3%) and communication (25.5%) were the most common. A root cause related to communication could be due to general communication problems either within a team or between departments. Seventeen percent of the root causes were attributed to patient rather than systematic factors. There were two noticeable differences between outpatient and inpatient root causes. Firstly, 13.8% of outpatient root causes were related to equipment,

while 0.0% of inpatient root causes were related to equipment. Equipment root causes were typically related to improper calibration. Secondly, 38.9% of inpatient root causes were related to communication, while 17.2% of the outpatient causes were related to communication. They were typically related to insufficient verbal or documented communication between staff members.

The RCA reports also generated 80 action plans to address the root causes (Tab. 6). Again, the majority of recommendations involved procedure/policy changes (48.8%). Several of the policy related actions involved developing or refining current processes to address an emergency within the clinic. This could typically relate to addressing a medical emergency during rehabilitation treatment. Deficits in education (21.3%) were the second most common action plan. There were several cases where an employee did not know the standard procedure created by the organization and needed further education. Improved communication (10.0%) and documentation (7.5%) followed. Recommended action plans from outpatient and inpatient settings were generally similar. There were two differences in action plans between outpatient and inpatient RCA teams. Outpatient RCA teams uniquely called for improvements in equipment maintenance

(15.6%), while inpatient RCA teams uniquely called for improvements in documentation (14.3%).

The 80 actions plans were then stratified based on their relative strength using the PAC Glossary. The majority of RCA reports, 56.0% (13 reports) included a strong action plan. Another 32.0% (8 reports) included an action plan with an intermediate strength. This left 12.0% (3 reports) with a weak action plan.

A second author coded the qualitative data for event type, root cause, and action plan. An inter-rater Kappa of 0.9134 was jointly determined for the combination of these 3 categories.³⁸

Discussion

This report summarized AEs related to services within the rehabilitation department in a national RCA database over a 7-year period. While the term AE describes any negative response to treatment, the rehabilitation-related reports in the RCA database focused on situations resulting in significant patient harm. Delay in care was the most common type of event in the database. Falls were a close second. This is consistent with sentinel events data reported to the Joint Commission across medical disciplines.³⁹ The reports with a delay in care often involve an insufficient response to a sudden change in patient

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Table 5.

Root Causes of Adverse Events

Cause	Outpatient	Inpatient	Total
Procedure or policy	12 (41.4%)	6 (33.3%)	18 (38.3%)
Communication	5 (17.2%)	7 (38.9%)	12 (25.5%)
Patient-related characteristic	5 (17.2%)	3 (16.7%)	8 (17.0%)
Equipment	4 (13.8%)	0 (0.0%)	4 (8.5%)
Education or knowledge	2 (6.9%)	2 (11.1%)	4 (8.5%)
Environment	1 (3.4%)	0 (0.0%)	1 (2.1%)
Staffing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Totals	29 (100.0%)	18 (100.0%)	47 (100.0%)

Table 6.

Action Plans

Plan	Outpatient	Inpatient	Total
Procedure or policy	21 (46.7%)	18 (51.4%)	39 (48.8%)
Education or knowledge	9 (20.0%)	8 (22.9%)	17 (21.3%)
Equipment	7 (15.6%)	1 (2.9%)	8 (10.0%)
Documentation	1 (2.2%)	5 (14.3%)	6 (7.5%)
Communication	2 (4.4%)	3 (8.6%)	5 (6.3%)
None	4 (8.9%)	0 (0.0%)	4 (5.0%)
Staffing	1 (2.2%)	0 (0.0%)	1 (1.3%)
Totals	45 (100.0%)	35 (100.0%)	80 (100.0%)

status. In these reports patients suffered from a medical emergency while in the presence of rehabilitation professionals but did not receive the expected level of care. Rehabilitation professionals should have plans in place to respond when patients show signs of deteriorating health during the therapy session with either aberrant vital signs or a cluster of symptoms indicating a medical emergency. When addressing patient falls, there are resource tool kits for hospitals and nursing homes to employ to reduce morbidity associated with falls.⁴⁰

Recommendations

The RCAs suggest that rehabilitation departments need to have clear emergency procedures. However, that alone is not sufficient to improve safety. Several of these anecdotes indicate that policies existed, but were not widely known by staff. Emergency procedures should be practiced at regular intervals with all staff. These events are rare, but important: suggesting that methods such as

simulated procedure rehearsal may be required to familiarize staff with emergency plans.

Secondly, actions to reduce the likelihood of an AE should be strong. Ideally, recommended actions make processes mistake proof or decrease the risk of a future AE. For example, one RCA team placed grip tape on the floor in a locker room used for pool therapy instead of simply posting a sign that reads, “Slippery when wet.” These are considered strong actions because they change the environment in ways that allow the human to function safely without significant effort. Another RCA report that addressed a delay in care revealed that different terms were used for an emergency across the organization. The team standardized the labeling for different emergent scenarios, and the crash carts at all locations. Actions to minimize the risk of an AE should be easy to use for all staff. Ideally, they allow staff to operate in a safe manner and decrease the opportunity for error.

The RCA reports also highlight the importance of rehabilitation staff to recognize “red flag” situations early. This is where a patient’s clinical picture suggests they are experiencing a medical event beyond the scope of rehabilitation practice and would benefit from an outside referral. Some “red flag” situations are emergent and others less time sensitive. The American Physical Therapy Association (APTA) has worked toward improving the skill sets of physical therapists. Its goal is to have most physical therapy care provided by physical therapists with a doctorate by 2020.⁴¹

Other medical specialties have implemented checklists with good effect.⁴²⁻⁴⁵ Many medical centers have instituted pre-operation time-outs where all present confirm the type of surgery and tools present. This reduces the occurrence of wrong site surgery and other associated AEs. It may be beneficial to develop such checklists for rehabilitation professions with two purposes. First, these checklists may clearly identify high risk patients susceptible to deteriorating health. Second, a checklist may assist rehabilitation professionals to quickly identify patients suffering from an acute illness who need a time-sensitive outside referral.

Limitations

There are several limitations in this approach. First, these data are self-reported and only AEs that are scored as a SAC 3 in our system receive a full RCA, so there are likely AEs that were not captured in this study. Second, the RCA reports are de-identified and so do not include patient characteristics. Basic demographic data is collected in most reports such as sex and diagnosis. However, potentially useful information from the patient’s history is excluded to avoid identifying patients. Third, the VHA system services mostly male patients. The data may not generalize to non-VHA systems with a different patient mix.

Conclusion

There is momentum in health care to become a high reliability entity similar to the airline industry which has

reduced its level of accidents in the last several decades. The Joint Commission provides standards and guidelines to achieve this end. Similarly, the Center for Medicare & Medicaid Services (CMS) and the Agency for Healthcare Research and Quality (AHRQ) provide general safety recommendations. However, they do not offer specific, strong actions to keep patients safe in particular locations. Guidelines are beneficial, but unique clinics will need customized strong actions to optimize patient safety.

While care by rehabilitation disciplines is safe, AEs do occur. Rehab departments can strengthen their safety record by developing practices and strong actions to ensure that all staff are prepared for an emergency response. These modifications should minimize unnecessary steps and decision making to mistake proof the response and ensure timely care.

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Ethics Approval

The Research and Development Committee of the White River Junction VA Medical Center approved this project, and the Committee for the Protection of Human Subjects considered this project exempt.

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