Guidance

Restraints

Published 6/6/2017

EXECUTIVE SUMMARY

The use of restraints has the power to humiliate, terrify, injure, or even kill an individual.[1] Deaths caused by the use of restraints may occasionally draw the public's attention, but innumerable sad accounts of individuals being restrained never reach news headlines. In a classic study on the subject of restraints conducted by Strumpf and Evans, one patient said, "I felt like a dog and cried all night. It hurt me to have to be tied up. I felt like I was nobody, like I was dirt. It makes me cry to talk about it." Another patient stated, "I felt like I was nailed to a cross," while another asked, "If there was a fire, how would I get out?"[2]

Restraint and seclusion are among the most common reasons hospitals are cited by the Centers for Medicare and Medicaid Services (CMS).[3] For example, CMS's 2016 fourth-quarter deficiency report revealed nearly 2,000 instances in which hospitals were cited by CMS for violations related to restraint and seclusion.[4] In addition, the improper use of restraints can lead to expensive lawsuits and negative publicity.

To reduce the risk of psychological and physical injury posed by restraints, and to comply with Joint Commission standards and CMS regulations, facilities must ensure that restraints are used only when necessary and in an appropriate and safe manner, that restrained patients are closely monitored, and that restraints are removed as soon as possible.

Action Recommendations

- Develop a restraint policy that clearly defines what is and what is not a restraint and how restraints may be used in the facility.
- Ensure that a restraint policy and any protocols calling for the use of restraints are established and implemented in compliance with accreditation standards, federal regulations, and state laws.
- Assemble a restraint reduction team to oversee restraint reduction efforts and identify barriers to these efforts.
- Measure the use of restraints in the facility and use these data to develop restraint reduction strategies.
- Use a restraint assessment tool to assess an individual's need for restraint.

©2024 ECRI. All rights reserved.

- Monitor and reassess patients who are restrained so that restraints can be discontinued at the earliest possible time.
- Emphasize and provide support for the use of restraint alternatives.
- Ensure that policies regarding use of restraints are effectively communicated to all staff, patients or residents, and family members.
- Provide mandatory and continuing education about restraint risks and less restrictive alternatives as well as information on when it is appropriate to use chemical or physical restraints. This should include monitoring, caring for, and reassessing restrained individuals; documenting restraint use; and educating patients or residents and family members.

WHO SHOULD READ THIS

Administration, Critical care, Diagnostic imaging, Emergency department, Medical staff coordinator, Nursing, Oncology, Patient safety officer, Pediatrics, Quality improvement, Staff education

SHARE WITH LEADERSHIP

Ready, Set, Go: Know Your Risks

TABLE OF CONTENTS

- The Issue in Focus
- Regulations and Standards
- Action Plan
  - Develop a Restraint Policy
  - Assemble a Restraint Reduction Team
  - Conduct Restraint Assessments and Monitor Restrained Patients
  - Use Restraint Alternatives
  - Provide Staff Training and Education

THE ISSUE IN FOCUS

The use of restraints has the power to humiliate, terrify, injure, or even kill an individual.[1] Deaths caused by the use of restraints may occasionally draw the public's attention, but innumerable sad accounts of individuals being restrained never reach news headlines. In a classic study on the subject of restraints conducted by Strumpf and Evans, one patient said, "I felt like a dog and cried all night. It hurt me to have to be tied up. I felt like I was nobody, like I was dirt. It makes me cry to talk about it." Another patient stated, "I felt like I was nailed to a cross," while another asked, "If there was a fire, how

More Help on This Topic

- Falls
- Bed Safety
- Restraint Reduction Training Program

©2024 ECRI. All rights reserved.

would I get out?"[2]

Restraint use has been found to have a number of detrimental psychological and physical effects on patients, including the following[5]:

- Increased risk of falls, contractures, injuries, and death
- Pressure injuries and skin irritation
- Stiffness and muscle atrophy from lack of use
- Psychological and emotional effects such as anger, aggression, depression, trauma, isolation, desolation, feelings of humiliation and loss of dignity, diminished quality of life, and increased confusion and fear
- Increased stress on the heart
- Risk of skin and nerve injuries
- Sleep disturbances
- Decreased appetite

While the restrained individual bears the brunt of risk and pain caused by restraint use, family members and staff are deeply affected as well. Family members who discover their loved one in restraints have reported feelings of hopelessness and anger and distrust of nursing staff.[1] Staff members who must use restraints report feelings of sadness, guilt, and pity for the restrained person.[6]

Restraint and seclusion are among the most common reasons hospitals are cited by CMS.[3] For example, CMS's 2016 fourth-quarter deficiency report revealed nearly 2,000 instances in which hospitals were cited by CMS for violations related to restraint and seclusion.[4] In addition, the improper use of restraints can lead to expensive lawsuits and negative publicity.

National and state efforts to pass restraint reduction legislation and to educate facility administrators on the dangers of restraint use in the 1990s and early 2000s appear to have had an effect on reducing restraint use. For example, between 1993 and 2003, Pennsylvania state hospitals saw the number of hours that mechanical restraints were used on patients drop from 11,000 to just over 90.[7] However, several more recent studies suggest that restraint use is still prevalent in U.S. hospitals, particularly in psychiatric units and intensive care units (ICUs). For example:

- In an observational study of 40 U.S. acute care hospitals published in 2008, researchers conducted rounds on nonpsychiatric units between 5 a.m. and 7 a.m. for physical restraint use and found that, out of 155,412 patient-days, the average hospital had 50 restraint-days per 1,000 patient-days. According to the authors, this means that approximately 27,000 people are physically restrained each day in U.S. hospitals, outside of psychiatric units. In that study, ICUs accounted for 56% of all restraint-days, despite accounting for only 16% of all patient-days.[8]
- Another study examined data for assaults by patients submitted to the National Database of Nursing Quality Indicators during 2007 through the end of 2013 from 438 inpatient units in 317 U.S. hospitals. The author found that, of 8,002 injurious assaults reported over 12.9 million patient-days, restraint was used in response

©2024 ECRI. All rights reserved.

to 2,515 (31.4%). Devices were the most commonly used form of restraint (57.6% of cases), followed by medication (37.0%) and holds (25.9%). Although the author found that the average number of hours patients spent in physical restraints declined consistently across the years of study, there was little evidence suggesting a decline in the incidence of seclusion or restraint during the study period; in fact, restraint was used more frequently in 2013 than in 2007 (34.1% versus 29.8% of assaults, respectively).[9]

To reduce the risk of psychological and physical injury posed by restraints, and to comply with Joint Commission standards and CMS regulations, facilities must ensure that restraints are used only when necessary and in an appropriate and safe manner, that restrained patients are closely monitored, and that restraints are removed as soon as possible.

Defining Restraints

CMS defines a restraint in the following ways[10]:

- Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or
- A drug or medication when it is used as a restriction to manage the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition

In addition, CMS provides the following definition for seclusion[10]:

- The involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

Although this guidance article primarily addresses the issue of restraints, restraint and seclusion are often addressed together in regulatory documentation.

Joint Commission's definition of restraints is in line with CMS's, particularly for hospitals and for rehabilitation and psychiatric units in critical access hospitals that elect the Joint Commission deemed status option. In its glossary, Joint Commission defines a restraint as follows[11]

> Any method (chemical or physical) of restricting an individual's freedom of movement, including seclusion, physical activity, or normal access to his or her body that (1) is not a usual and customary part of a medical diagnostic or treatment procedure to which the individual or his or her legal representative has consented, (2) is not indicated to treat the individual's medical condition or symptoms, or (3) does not promote the individual's independent functioning.

Because both Joint Commission and CMS define restraint by the function of the device and not by the type of device, facilities must educate their staff to identify restraints by their function. If a device not normally considered a restraint restricts a person's normal movement or access

Types of Physical Restraints

Physical restraints are devices or interventions that prevent the patient from moving freely or that restrict normal access to the patient's body. Physical restraints

©2024 ECRI. All rights reserved.

to any part of his or her body—for example, a bed sheet tucked in tightly enough to prohibit a weakened patient from leaving a bed—it is also considered a restraint. For more information, see Types of Physical Restraints.

Facilities must also address—and will be held accountable for—the use of chemical restraints. Depending on why and how they are used, certain medications can be considered restraints.

According to CMS, any medication used solely to manage the patient's behavior or restrict his or her freedom of movement that is not considered a standard treatment or dosage for the patient's condition is considered a form of restraint. This includes medications such as neuroleptics, benzodiazepines, antipsychotics, barbiturates, and opioid analgesics when used, for example, to rapidly control the behavior of a combative patient in the emergency department who is presenting a danger to others.[12,13] CMS provides additional clarification regarding restraints by defining items that are not considered restraints. According to CMS, restraints do not include the following[10]:

> [D]evices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

may include the following:

- Vests, wrist and ankle restraints
- Belt restraints
- Body holders
- Enclosure beds
- Bedrails, in certain cases
- Any intervention that restricts the patient's movement—for example, tucking in bed sheets or other bedding too tightly
- Physical holds for patients behaving violently or self-destructively, or to force medications

Typically, if the patient can easily remove a device, it is not considered a restraint.

The distinction between *falling* out of bed and *getting* out of bed must be noted. CMS will consider any method of keeping a patient in bed against his or her will to be use of restraint.[10] It must also be noted that in long-term care settings, the use of devices to prevent a resident from falling out of bed may still be considered restraint use. For more information, see the guidance articles Falls and Bed Safety.

ECRI RESOURCES

Falls

Bed Safety

In addition, some restraint devices can be used as assistive devices under certain circumstances. For example, CMS states that the use of the bedrail is not to be considered a restraint if any of the following applies[10]:

- Its use is based on the individual's needs.
- The purpose of the bedrail is to prevent the individual from falling out of bed or to aid in positioning while the patient is in the bed or transferring out of the bed.
- The individual demonstrates that the bedrail does not impede his or her ability to leave the bed.

Therefore, if a functionally coherent individual requests that a bedrail be raised to facilitate movement within the bed and if he or she can exit the bed safely while the bedrail is raised, the bedrail is not considered a restraint;

©2024 ECRI. All rights reserved.

however, this does not eliminate the dangers of injury or death inherent in the use of bedrails. The benefits-to-risk ratio of using a potentially restraining device must always be considered, and facilities must educate patients or residents and/or their family members about the risks of the device being considered in a care plan.[14] For more information on bedrails, see the guidance article Bed Safety.

It is also important to note that the patient's physical or mental condition may affect whether a device can be considered a restraint. CMS states that if the patient can easily remove a device, then the device is not considered a restraint.

However, under certain situations, devices such as wheelchair belts—which are generally considered to be removable by patients and therefore not restraints—may be considered restraints if the patient is either mentally incapable of understanding how to operate the release or physically incapable of releasing the device. Restrained individuals should be observed at regular intervals; injury can result if they slide down while the belt is fastened.

Ask *HRC*

An *HRC* member asked us for information regarding safety concerns with use of conducted electrical weapons (Tasers) on patients. See our response.

Forensic restraints—handcuffs, shackles, or other devices applied by law enforcement—are not considered as healthcare restraints and therefore are not governed by CMS's rule. These devices should be handled by the law enforcement entity that applied them. In addition, CMS does not consider the use of weapons—such as conducted electrical weapons (Tasers), pepper spray, or mace—in the application of restraint or seclusion as a safe, appropriate healthcare intervention, and does not support their use by hospital staff as a means of restraining a patient. However, the use of weapons by security staff is considered a law enforcement action, not a healthcare intervention, and should be treated accordingly.[10]

Patient Behavior

In its restraint regulations, CMS states that the patient's current behavior or clinical needs, not history, determine whether a restraint is warranted. Depending on whether the patient is classified as either "violent or self-destructive" or "nonviolent or non-self-destructive," there are different sets of rules to follow.[3,15]

- *Violent or self-destructive patients* may exhibit verbal or nonverbal indications that they will harm themselves and/or others, thereby requiring a restraint. Seclusion may be used only for the management of violent or self-destructive behavior.
- *Nonviolent or non-self-destructive patients* may require restraints for more benign purposes, such as to restrict the patient from removing tubes, dressings, drains, etc., in a way that would compromise the patient's safety, or to prevent patients from ambulating when it is unsafe for them to do so.

If the patient is determined to be "violent and/or self-destructive," the following will apply[10]:

- CMS requires that a physician or other licensed independent practitioner (LIP), registered nurse (RN), or physician assistant (PA) trained under 482.13(f) do a face-to-face evaluation within one hour of the initiation of the intervention (the so-called one-hour evaluation), unless state law is more restrictive. (Note that state law

©2024 ECRI. All rights reserved.

dictates who can be considered an LIP; however, CMS states that medical students are not allowed to write restraint orders.[3]) This evaluation should include all of the following:
    - An evaluation of the patient's immediate situation
    - The patient's reaction to the intervention
    - The patient's medical and behavioral condition
    - The need to continue or terminate the restraint or seclusion
- CMS outlines renewal time limits for orders up to a total of 24 hours:
    - 4 hours for adult patients (18 years or older)
    - 2 hours for children and adolescents age 9 to 17 years
    - 1 hour for children under 9 years

For more information, see One-Hour Face-to-Face Evaluation.

CMS stipulates that, at the end of the 24-hour timeframe for renewal, if the continued use of restraint or seclusion to manage violent or self-destructive behavior is deemed necessary based on an individualized patient assessment, the physician or other LIP must be apprised of the results of the patient's most recent assessment and request that the original order be renewed, if appropriate. It is up to the physician or other LIP, in consultation with the RN who is overseeing the patient's care, to determine whether an on-site assessment is necessary prior to renewing the order. An additional one-hour face-to-face patient evaluation is not required when the original order is renewed.[10]

Joint Commission standards, which previously classified restraint use into two categories (clinical and behavioral management), have been revised to align more closely with CMS's regulations, and now also use the terms "violent and/or self-destructive" and "nonviolent and/or non-self-destructive."

Risk of Litigation or Monetary Penalties

As public awareness has increased regarding the risks of injury and death related to restraints, the number of claims has increased as well. Facilities may be held liable in a variety of ways. These can include the following:

ECRI RESOURCES

An Overview of Nursing Liability

- The inappropriate use of restraints—for example, if a nurse uses restraints inappropriately, the facility that employs the nurse will likely be held responsible for the nurse's errors under the legal doctrine of *respondeat superior*, which holds the employer responsible for the actions of the employee during the employee's normal course of work. For more information on nursing liability issues, see the guidance article An Overview of Nursing Liability.
- The misuse of restraints—for example, if restraints are used in an unsafe or unjustified manner, or if the patient or resident is restrained against his or her will. In such cases, facilities may face charges of battery or false imprisonment.
- Failure to use restraints when justified, if an individual is harmed owing to lack of using a restraint. In such cases, facilities may be sued for failing to keep a patient safe. For example, in a 2002 Alabama case, a rehabilitation facility paid $3.5 million (reduced from a $7 million verdict) to the family of a resident who sustained head injuries after falling out of bed multiple times during her first night at the facility and died shortly

©2024 ECRI. All rights reserved.

thereafter. The plaintiffs alleged that the facility failed to ensure the resident's safety from falling out of bed by not using safety restraints.[16]

- Claims of violation of state regulations and/or federal constitutional rights for restraint-related injuries or deaths. Other violations of federal regulations regarding the proper use of restraints in long-term care facilities have led to civil monetary penalties. In 2006, a nursing facility in New York was denied payment for newly admitted patients who were Medicare recipients. The U.S. Department of Health and Human Services Departmental Appeals Board upheld the decision based on the finding that the facility had used restraints in situations in which alternative methods of keeping the resident safe could have been used.[17] In addition to expending the legal and financial resources needed to defend against restraint-related litigation, the organization may also have to face an onslaught of negative publicity, poor staff morale, and loss of the public's trust. Facility administrators should also be aware that federal prosecutors can use the False Claims Act to investigate facilities that bill CMS but are suspected of not meeting quality-of-care standards, such as using restraints inappropriately. In 2005, an acute care facility in suburban Philadelphia agreed to pay the federal government $200,000 to settle allegations that it had restrained 91 patients improperly over a two-year period. The facility's actions, which allegedly resulted in the death of an elderly patient in 2002, included failing to use the least restrictive methods of restraint, using restraints after the LIP's order for restraint had expired, and failing to educate nurses about its restraint reduction policy. The government brought suit against the facility under the False Claims Act, claiming that the facility knowingly billed the government for treatments provided while improperly physically and chemically restraining patients.[18]

REGULATIONS AND STANDARDS

CMS

Restraint use is addressed at length by CMS. CMS's *State Operations Manual* for hospitals contains over 50 pages addressing restraint and seclusion, comprising tags 154 to 214.

According to CMS:

> All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint and seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.[10]

Broadly, CMS addresses the following issues regarding restraint use:

- The definition of what is and is not considered a physical or chemical restraint.
- Stipulations that restraints may be used only when less restrictive interventions have been deemed ineffective; that staff must employ the least restrictive intervention that will be effective; and that restraint use must be discontinued at the earliest possible time, regardless of the length of time identified in the order.
- Requirements for how restraints can be ordered, who can order them (i.e., a physician or other LIP who is responsible for the patient's care), and whether and how the order can be renewed.

©2024 ECRI. All rights reserved.

- A stipulation that restraints must be used in accordance with a written modification in the patient's plan of care, and implemented in accordance with safe and appropriate restraint techniques as determined by hospital policy in accordance with state law.
- A prohibition on the use of standing or "as needed" (PRN) orders for physical or chemical restraints, with three exceptions (geriatric chair if it is required for the patient to be safely out of bed, raised side rails if a patient's status requires all side rails be raised, and repetitive self-mutilating behavior).
- A requirement that the patient's condition be monitored by a physician, other LIPs, or properly trained staff.
- A stipulation that physician and other LIP training requirements be outlined in the hospital policy.
- A stipulation requiring that patients restrained for violent or self-destructive behavior be assessed face-to-face within one hour after initiation of the intervention by a physician or other LIP, or by an RN or PA who has been properly trained in performing such a task. If the RN or PA conducts the assessment, the attending physician or other LIP must be consulted as soon as possible after the evaluation.
- An acknowledgment that states may have more restrictive statutes or regulations regarding restraint use.
- Requirements for simultaneous restraint and seclusion.
- Requirements for documentation of restraint use.
- Staff training requirements for restraint use, including a stipulation that staff be educated and be able to demonstrate knowledge on restraint use.
- A requirement that deaths associated with restraint use be reported to CMS within certain timeframes.

Many of the above requirements are discussed in further detail in Action Plan.

Joint Commission

Joint Commission addresses the issue of restraints at length in its *Comprehensive Accreditation Manual for Hospitals* (CAMH). In the past, Joint Commission's recommendations for restraint use differed significantly from CMS's; however, in 2016, Joint Commission deleted 90 elements of performance related to restraint use—many of which were covered elsewhere, widely used, or already required by law—and brought their standards into closer compliance with CMS regulations.[19]

The following Joint Commission standards in the "Provision of Care, Treatment, and Services" section apply to restraints[11]:

- PC.03.05.01. The hospital uses restraint or seclusion only when it can be clinically justified or when warranted by patient behavior that threatens the physical safety of the patient, staff, or others.
- PC.03.05.03. The hospital uses restraint or seclusion safely.
- PC.03.05.05. The hospital initiates restraint or seclusion based on an individual order.
- PC.03.05.07. The hospital monitors patients who are restrained or secluded.
- PC.03.05.09. The hospital has written policies and procedures that guide the use of restraint or seclusion.
- PC.03.05.11. The hospital evaluates and reevaluates the patient who is restrained or secluded.
- PC.03.05.13. The hospital continually monitors patients who are simultaneously restrained and secluded.
- PC.03.05.15. The hospital documents the use of restraint or seclusion.
- PC.03.05.17. The hospital trains staff to safely implement the use of restraint or seclusion.

©2024 ECRI. All rights reserved.

Each of these provisions is outlined in more depth in Joint Commission's CAMH; additionally, most of these are further discussed in Action Plan.

Other Accrediting Agencies

Joint Commission, DNV GL, the Healthcare Facilities Accreditation Program (HFAP), and the Center for Improvement in Healthcare Quality (CIHQ) are four healthcare accrediting agencies that have been granted "deeming status" for hospitals by CMS. Because Joint Commission accredits the vast majority of healthcare organizations, including approximately 77% of the nation's hospitals,[20] its standards are used as a reference point in this article. While DNV GL, HFAP, and CIHQ standards are substantially similar (and in some cases identical) to Joint Commission's standards, risk managers should consult their accrediting organization's standards to ensure compliance.

State Laws

Laws regarding restraint use differ from state to state. All hospitals that accept Medicare and Medicaid are required to comply with CMS regulations, except when state laws are stricter; in such cases, the hospital is required to comply with the stricter state law.

State laws regarding restraints often require the following[21]:

- Written authorization by a physician
- A specified period of time during which the restraint can be used
- A stipulation that the restraint be applied only by a physician or other qualified staff member under the supervision of a physician

Risk managers should be well versed in the laws regarding restraint use in their organization's state, and should ensure that staff are trained in those laws and that hospital policy complies with state laws, particularly those that are more stringent than CMS's requirements.

ACTION PLAN

Develop a Restraint Policy

Action Recommendation: Develop a restraint policy that clearly defines what is and what is not a restraint and how restraints may be used in the facility.

Action Recommendation: Ensure that a restraint policy and any protocols calling for the use of restraints are established and implemented in compliance with accreditation standards, federal regulations, and state laws.

Elements of a Restraint Policy

A facility must communicate to staff its commitment to restraint reduction through formal written policies developed with the help of the restraint reduction team. This policy should be communicated to physicians and family members as well as staff—for example, by sending letters regarding the policy to physicians or by including a flyer on the policy in hospital admission packets.

©2024 ECRI. All rights reserved.

In addition, facilities should consult with legal counsel to ensure that their review of restraint policies meets the state's code. For example, in Pennsylvania, each facility is required to review and revise its restraint policy annually.[22]

A formal restraint policy should include the following elements:

Definitions. All restraint policies should include the CMS definitions for physical restraint, chemical restraint, seclusion, nonviolent and/or nondestructive patients, and violent and/or self-destructive patients. The policy should also highlight what *is not* considered a restraint. Organizations may choose to include examples of devices, medications, and interventions that can be considered restraints, as well as some that are not considered restraints. For more information, see the discussion Defining Restraints.

The policy should stipulate that forensic restraints (e.g., handcuffs, shackles, or other devices applied by law enforcement) are not considered restraints and therefore are not governed by CMS's rule.[10]

Additional terms that the facility may want to consider defining in the policy include the following:

- Restraint alternatives (see the discussion Use Restraint Alternatives, including those available at the facility
- Time-out
- Episode
- Therapeutic/physical hold
- Prolonged restraint
- Primary healthcare provider/LIP, including information on who is able to write restraint orders

Restraint purposes. The policy should include information on how to differentiate between restraint use for clinical reasons and for behavioral reasons. CMS, Joint Commission, and other accrediting agencies have different sets of regulations to follow, depending on the intended use of the restraint. The policy should also describe when a restraint can and cannot be used.

Information on protocols. Your policy should include information on how to appropriately use physical or chemical restraints, including protocol for monitoring, caring for, and reassessing restrained individuals. CMS regulations require that certain protocols be followed when restraints must be ordered. These protocols, which should be outlined in your restraint policy, include the following[10]:

- A stipulation that physician orders are required with every restraint use
- A stipulation that the doctor should be notified as soon as possible when restraints are being considered, including a defined timeframe for notifying the attending physician
- Instructions on how to respond in an emergency situation
- A requirement that restraints be used in accordance with written modification to the patient's plan of care
- For patients deemed to be violent or self-destructive, a requirement that an LIP, RN, or PA trained under 482.13(f) do a face-to-face evaluation within one hour of the initiation of intervention, unless state law is more restrictive

©2024 ECRI. All rights reserved.

- For patients who are violent or self-destructive, CMS outlines time limits for order renewals—four hours for adults, two hours for children 9 to 17 years of age, and one hour for children under 9 years
- A stipulation that the original restraint order for violent or self-destructive behavior may be renewed for up to 24 hours; after the 24-hour period has expired, a physician (an MD) or an LIP will need to reevaluate the order
- Information on how to review and determine continuing need for the use of the restraint

Information on fostering open communication. The policy should outline how to involve an interdisciplinary team for a patient, including the patient or resident, family members, and staff in any decisions about restraint use.

Information on conducting assessments. The restraint policy should include information on how to conduct and document a comprehensive restraint assessment, including the type of approved devices considered. For more information, see the discussion Conduct Restraint Assessments and Monitor Restrained Patients.

Documentation requirements. Documentation is a critical aspect of restraint use. The restraint policy should require documentation of all aspects of the process when using restraints. More information on what should be documented can be found in the discussions Conduct Restraint Assessments and Monitor Restrained Patients and Provide Staff Training and Education.

Information on proper restraint use and less restrictive interventions. The policy should include a stipulation that restraints should be used only after less restrictive interventions and other alternatives have been deemed to be ineffective to protect the patient or others from harm. It should also include descriptions of safe, appropriate restraining techniques, in accordance with state law and the manufacturer's instructions for restraint devices, and list restraint alternatives that are available in the facility and how to use them. In addition, organizations may want to include in the policy equipment purchasing strategies that can reduce the use of restraints—for example, purchasing high-low beds or bed alarms to reduce the need to use bedrails. Some of these less restrictive interventions are discussed in Use Restraint Alternatives.

Information on discontinuation. The organization's restraint policy should include stipulations that restraints may be used only for patients' or others' safety, and that they must be discontinued at the earliest possible time. These stipulations should also be included in the patient rights statement. Note that if the restraint is removed earlier than the timeframe stipulated in the restraint order and the patient continues acting in a manner that requires restraint, a new order is required.

Permissions. The restraint policy should stipulate who can write orders for restraints. This will depend on state law, the scope of the licensure of the relevant party, and the granted privileges of the party, and may include LIPs, nurse practitioners, and licensed residents. However, it cannot include medical students.[10]

Prohibition against PRN orders. The policy should include language barring the use of PRN orders for medications used as restraints or for physical restraints. There are three exceptions to this rule[10]:

- When a patient exhibits repetitive self-mutilating behavior
- The use of a Geri-chair
- If a patient's status requires that all bedrails be raised while the patient is in bed, and the patient cannot lower

©2024 ECRI. All rights reserved.

them without assistance

Education requirements. The policy should include information about required ongoing education and training of staff in the proper and safe use of restraints. For more information, see the discussion Provide Staff Training and Education.

Reporting requirements. CMS requires healthcare facilities to report deaths associated with restraint use no later than by the close of business on the day following the death. For more information, see the discussion Reporting Restraint-Related Injuries and Deaths.

Assemble a Restraint Reduction Team

> **Action Recommendation: Assemble a restraint reduction team to oversee restraint reduction efforts and identify barriers to these efforts.**
>
> **Action Recommendation: Measure the use of restraints in the facility and use these data to develop restraint reduction strategies.**

Administrators must make the reduction of restraints and maintenance of a restraint-free environment a top priority. Restraint reduction efforts should be part of the facility's overall patient safety program and must have the full support of the facility's administration. An effective way to implement a restraint reduction program is to establish an interdisciplinary team of caregivers to organize and champion the effort. This team should be responsible for the following[14]:

- Develop a restraint reduction policy, and review all protocols that include the use of restraints.
- Identify and address barriers to reducing the use of restraints.
- Trend and analyze the facility's current restraint assessment process and current restraint use.
- Choose an appropriate restraint assessment tool.
- Implement restraint reduction education for all patients, residents, family members, and staff on the risks of restraint use.
- Educate staff about alternatives to restraints, including the identification and remediation of root causes of at-risk behavior, and provide environmental modifications that may eliminate the need for restraints.
- Provide staff with education on appropriately conducting a restraint assessment and ordering, applying, monitoring, and documenting restraint use.
- Monitor the efficacy of the restraint reduction program, adjusting policies and procedures as needed based on performance improvement data gathered on the use of restraints within the facility.

Examples of those who may be asked to join a restraints reduction team include physicians, nurses, nursing assistants, physical or occupational therapists, administrators, or others with specialized training. Additionally, geriatric nurse or behavioral healthcare specialists may be able to provide support to staff in attempting to reduce restraint use for challenging cases. Risk managers and legal experts may also be consulted for cases in which legality is in question.

©2024 ECRI. All rights reserved.

In addition, facilities should consider appointing a restraint reduction "champion." The restraint reduction champion—typically a member of the nursing, rehabilitation, or quality assurance department—would be responsible for scheduling quarterly or monthly restraint review meetings and promoting the work of the restraint reduction team.[23]

Facilities should allocate time each day specifically for the team's restraint reduction efforts, phasing these efforts into the facility one unit or floor at a time, addressing the easiest cases first. Patients or residents whose needs or behavior present ongoing challenges will require gradual efforts over a longer period, and those individuals whom staff determine to require restraints should be reevaluated for possible interventions on an ongoing basis.[24]

Long-term care facilities should have the restraint reduction team evaluate the appropriateness of each current or new restraint order and approve all new orders for restraints within 24 hours. If the team determines that restraints are not warranted, a plan for implementing and monitoring restraint alternatives should be developed and the ordering LIP should be advised of the plan.

Measure Restraint Usage

Facilities should measure restraint use and use these data to develop restraint reduction strategies. The common formula to determine the overall frequency of restraint use in healthcare facilities is the number of restraint-hours per 1,000 patient-days.[25] Other formulas used include the number of restraint episodes per 1,000 patient-days, the number of restraint-hours per 1,000 patient-hours, and the number of restraint-hours per 1,000 hospital-hours. Because patient and resident populations vary, facilities should trend restraint usage internally, using the facility's past restraint usage as a benchmark.

In addition to measuring the frequency of restraint use, facilities should consider tracking the following:

- Any injuries sustained by the patient or resident while he or she was in restraints
- Any injuries sustained by staff while applying restraints, monitoring and providing ongoing care for a restrained individual, or removing restraints
- The duration of restraint use for each individual
- The reasons cited to justify the need for the restraint
- The staff involved in restraint ordering and usage
- The times and locations restraints are ordered, applied, and discontinued

These data should be reviewed by the restraint reduction team and forwarded to administration and to the nursing and medical staff within its regular performance improvement reporting process.

Conduct Restraint Assessments and Monitor Restrained Patients

Action Recommendation: Use a restraint assessment tool to assess an individual's need for restraint.

Action Recommendation: Monitor and reassess patients who are restrained so that restraints can be discontinued at the earliest possible time.

Assessments are an essential tool to help manage the use of restraints in healthcare facilities. They can be used to

©2024 ECRI. All rights reserved.

determine the root cause of at-risk behavior and can help facilities successfully reduce the use of restraints for clinical and behavioral purposes in acute care settings, including ICUs. Facilities must engage staff and physicians in this process of assessment and encourage them to aggressively assess and treat the root causes of at-risk behavior.[26] This assessment should be conducted at initial intake, and reassessment should occur on a regular schedule or in the event of a change in status.[27] For more on behavioral health issues in non-behavioral-health settings, see ECRI Institute's Top 10 Patient Safety Concerns for 2017 (concern #8).

The Initial Assessment

ECRI RESOURCES

Health Literacy

Setting Realistic Expectations

Direct discussion with the patient or resident and family or caregiver regarding the facility's policy on restraint use, the individual's restraint needs, and the risks of and alternatives to restraints should be included in the initial restraint assessment. Joint Commission recommends that, when conducting the assessment, caregivers explain to the individual and his or her family the facility's philosophy on using restraints or seclusion, establish who in the family will be contacted if restraints or seclusion are required if this is part of the patient's care plan, and determine whether the individual has an advance directive that addresses the use of restraints. If an advance directive is produced, the individual's direct caregivers must be made aware of its existence and intention.[27] The patient or resident's and family's understanding of the risks of and alternatives to restraint use should be confirmed and documented. Failure to educate may be at issue if a patient or resident is harmed as a result of restraint use or lack of use. Such discussions may also help to manage unrealistic expectations, which can be a serious risk factor for negligence claims and lawsuits. For more information, see the guidance articles Health Literacy and Setting Realistic Expectations.

Facilities should use restraint assessment tools that allow caregivers to identify and document the following patient information[27,28]:

- The individual's medical condition, including any current or preexisting conditions listed in the patient's medical record that could cause behavioral changes (e.g., delirium, adverse drug reactions) and any physical disability or limitations that would put him or her at greater physical risk if placed in restraints (e.g., a heart condition)
- The individual's behavioral condition, including the presence of "violent or self-destructive behavior," if any, and the individual's current mental status, mood, and behavioral control

Factors that Increase Restraint Fatality Risk

Certain patient characteristics can increase the risk of fatality during restraint. These include the following[7]:

- Obesity
- Heart disease
- General poor health
- Use of illicit or prescribed medications and/or drug intoxication

In addition, although all restraints may present the risk of injury or death, certain restraint factors increase the risk of fatality during restraint. These factors include the following[7]:

©2024 ECRI. All rights reserved.

- Any psychological risks, including history of mental illness or physical or sexual abuse or trauma
- The individual's risk for falls
- The individual's nutritional status
- The individual's physical strength
- The individual's pain management needs
- The individual's toileting needs
- The individual's medication usage

- Neck holds
- Obstruction of nose, mouth, or chest expansion
- Prone or hobble tying
- Hyperflexion in a seated position
- Exhaustion or prolonged struggling

Certain individuals, such as pediatric patients in acute care settings or inpatient psychiatric patients with a history of aggression, will need more in-depth assessment than individuals who show a high level of communication, comprehension, and willingness to participate in their care. In addition, staff should be aware that certain health conditions and restraint application factors may increase the risk of patient death; for more information, see Factors that Increase Restraint Fatality Risk. Facilities must ensure that the restraint assessment tool they choose is appropriate for their patient population and has the flexibility to provide a more in-depth assessment when necessary.[27]

One-Hour Face-to-Face Evaluation

When restraints are used for patients displaying violent or self-destructive behavior, the priority must be to maintain the patient's safety and dignity. CMS requires that a face-to-face evaluation of the restrained patient be conducted. The evaluation must be performed by an LIP or an appropriately trained RN or PA within one hour of the initial application of restraints. If the face-to-face evaluation is conducted by an RN or PA, CMS requires that the attending physician be contacted as soon as possible.

Information that should be determined and documented during the one-hour face-to-face assessment should include the following[11]:

- An evaluation of the patient's immediate situation
- The patient's reaction to the intervention
- The patient's medical and behavioral condition
- The need to continue or terminate the restraint or seclusion

Patient Monitoring and Reassessment

The requirements for renewing restraint orders vary depending on why the restraint is used and whether a protocol is in place regarding the use of restraint. CMS and Joint Commission both require that patients restrained for violent or self-destructive behavior be monitored at an interval determined by hospital policy, based on the patient's needs, condition, and the type of restraint used.[10,29]

CMS also states that hospital policy should "address the frequency of assessment and the assessment parameters (e.g., vital signs, circulation checks, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity)."[10]

©2024 ECRI. All rights reserved.

A flowsheet can be used to document assessments when monitoring restrained patients. The following information should be included on flowsheets[28,30]:

- Patient clinical needs
- Patient behavior that indicates the continued need for restraints
- Rationale for using the restraint
- Patient's current behavior and mental status, including orientation
- Patient's immediate situation and reaction to the intervention
- The number and type of restraints used and where they are placed, and information on how long they can be used
- A review of whether the restraints are properly applied and if they were repositioned
- A physical health assessment, including:
  - Condition of extremities, including circulation and sensation
  - Extremity range of motion
  - Vital signs
  - Skin condition (e.g., color, intact) and any skin care provided
  - Respiratory condition
  - Food, fluid, and toileting offered
  - Areas of concern or conditions that require further monitoring
- Information that was explained to the patient and/or the patient's family (e.g., reason for intervention, negative effects of restraint, behavioral criteria for release)
- Interventions implemented to assist in meeting release criteria
- Assessment of the stress level of the individual during the restraint period and how he or she is dealing with it
- Plan for continuing care to include continuing or terminating the procedure

Use Restraint Alternatives

> **Action Recommendation: Emphasize and provide support for the use of restraint alternatives.**

Based on the information gathered from a restraint assessment, staff must identify restraint alternatives that can be used to maintain the individual's and/or others' safety. A report of restraint reduction efforts in Texas healthcare facilities indicates that an average of three interventions were used to address root causes and to reduce the need for restraints.[24] Successful restraint alternatives may include falls prevention programs, sitter programs, increased staffing of RNs, and planned diversion or distraction activities. The use of a combination of these tactics, based on the individual's needs, may reduce or eliminate the need for restraints.

Falls Prevention Programs

One of the main reasons caregivers give to justify restraint use is the reduction of falls risk for a patient or resident; however, restraints do not necessarily prevent or reduce the risk of falls—in fact, some studies suggest that they may actually

ECRI RESOURCES

Falls

©2024 ECRI. All rights reserved.

increase the risk of falls.[31] Although CMS states that items used in a hospital setting to prevent a patient from falling out of bed are no longer considered restraints,[10] risk managers should not lose sight of the risks of using items such as bedrails to prevent falls. Facilities must balance the requirement to foster independence and autonomy in their patients against what staff and families might perceive as the need to keep them "safe."

An effective falls reduction program must be a well-coordinated and monitored facility effort and include the following:

- Use of an appropriate falls assessment procedure
- Effective and continuous environmental assessment and modification to reduce extrinsic, or environmental, risk factors
- Use of multiple interventions based on the findings of the falls assessment to address intrinsic, or patient-specific, risk factors or root causes (e.g., incontinence, low blood pressure, gait disorders, lower extremity weakness)
- An appropriate postfall assessment that includes staged evaluations of the patient's or resident's condition, as well as modifications to his or her falls intervention plan, based on the postfall assessment data
- Patient, resident, family, and staff education on falls risk and intervention strategies
- Continuous performance improvement monitoring and adaptations to the falls program based on the facility's falls data gathered from incident reports, postfall assessments, and root-cause analyses, as well as proactive methods such as failure mode and effects analyses

For more information on falls prevention programs, see the guidance article Falls.

Sitter Programs

Some facilities have established one-to-one sitter programs (paid or volunteer) as an extension of their nurse staffing to provide constant supervision as an alternative to restraints. These programs use one-to-one monitoring to ensure that the patient or resident does not engage in at-risk behavior. This restraint alternative requires the establishment of patient or resident eligibility criteria, training and assignment of voluntary or employed sitters, formal distinctions between the role of a sitter and that of licensed or certified care staff, and a means of addressing the program's financial costs.

Ask *HRC*

An *HRC* member asked us for information regarding technology and sitter options for managing falls risks. See our response.

In particular, patients or residents prone to wandering, confusion, or disorientation may benefit from a sitter. Monitoring these individuals' behavior can be difficult, causing many disruptions to the unit's routine and threatening their own as well as others' safety. The use of a sitter, which is generally considered a minimally restrictive alternative to restraints, allows clinical staff to concentrate on patient or resident care.

If a sitter program is used as part of a facility's restraint reduction program, the facility should consider the following suggestions[32]:

©2024 ECRI. All rights reserved.

- Provide clear instructions for sitters (e.g., a brief patient history, specific behaviors or symptoms to watch for, ways to communicate with the patient or resident).
- Develop a sitter program model with policies and procedures that clearly identify the responsibilities of the staff nurses or other frontline staff and the sitters.
- Make clear distinctions between the custodial care provided by a sitter and the professional nursing care a patient or resident using a sitter requires.
- Require mandatory health screenings and inoculations, and instruct sitters on how to protect themselves from violent or abusive patients or residents.
- Educate the nursing staff on diversionary activities that can act as alternatives to sitters.

The Art of Distraction

If a patient or resident is displaying at-risk behavior, planned activities to divert or distract the individual may prove to be successful. For example, in an article for *The Atlantic*, one former medical student describes a scenario in which an ICU patient with acute delirium was trying to leave the floor. Instead of restraining the patient, the medical care team took time to reorient the patient, remind him of his situation, offer him medications to deal with his agitation and anxiety, and call his wife to allow him to hear a familiar voice. Eventually, the patient calmed down, eliminating the need for restraints.[31]

Family can prove to be a calming element to many patients. Before trying to arrange for a sitter, which can be a costly restraint alternative, ask if family can come in on a regular schedule each day to help supervise the patient or resident.

The following are basic principles for refocusing patients and residents who are at risk for restraint use owing to behavior issues[33]:

- Encourage independence, and offer the individual choices. Know what the individual likes to hear, see, smell, taste, and touch, and provide appropriate levels of stimulation based on these preferences.
- Determine what the individual is trying to accomplish with his or her at-risk behavior, and provide distracting activities based on his or her strengths and former work experience.
- Be calm and self-assured, and provide the individual with a sense of security.

Last Resort: Using Restraints Safely

Regardless of a facility's restraint-free goals, the use of restraints will sometimes be warranted to prevent serious injury or death. As previously stated, facilities must ensure that caregivers fully understand how to properly use restraints, including the policies and procedures of the facility; which accreditation standards or federal regulations are applicable based on the reason for use; in which setting the restraint is being used (e.g., acute care or behavioral healthcare settings for Joint Commission, hospitals or long-term care for CMS); and what devices or interventions are considered restraints.

Some interventions may be perceived as alternatives to restraints (e.g., lap belts, lap trays attached to chairs) but both Joint Commission and CMS surveyors will still consider these devices restraints if they are restrictive and the individual cannot easily remove them. Although such a device might be comforting and supportive, if the individual

©2024 ECRI. All rights reserved.

cannot easily remove it, the facility must regard the device as a restraint and comply with regulatory and accreditation standard requirements for restraints, including assessment, observation, reassessment, and documentation. However, the designation of a device as a restraint should not prohibit its use. Unless a more effective and less restrictive device is available, the patient should be given these needed comforts and aids; the goal of achieving a restraint-free unit or facility should never supersede ensuring the well-being of the patient.[34]

Treating the mentally ill. Although restraint use cannot be based solely on the individual's diagnosis or mental health history, restraints may be needed when the patient or resident has a comorbidity of mental illness that prevents him or her from comprehending and adhering to safe behavior. De-escalation techniques may avert the need for restraints in some aggressive or distraught individuals, but the frequency with which caregivers encounter these individuals makes it possible that the need to restrain such individuals may occur. In such cases, caregivers should remain with these individuals continuously to ensure that they do not injure themselves or others.

Individuals who exhibit violent or aggressive behavior place themselves or others in danger and do not have the right to refuse restraints. In these cases, it is recognized that restraints are a measure of last resort but that the use of the restraints must be ended as soon as possible.[14]

Provide Staff Training and Education

Action Recommendation: Ensure that policies regarding use of restraints are effectively communicated to all staff, patients or residents, and family members.

Action Recommendation: Provide mandatory and continuing education about restraint risks and less restrictive alternatives as well as information on when it is appropriate to use chemical or physical restraints. This should include monitoring, caring for, and reassessing restrained individuals; documenting restraint use; and educating patients or residents and family members.

Educate Staff

If restraints must be used, staff must be effectively educated on safely applying restraints; monitoring, caring for, and reassessing restrained individuals; documenting restraint use; and educating patients and family members about restraint risks and alternatives. Anyone who may be involved in tasks related to restraint use, including nurses, physicians, and other clinical staff, should undergo training.

CMS requires that all staff members involved in applying restraints, implementing seclusion, or monitoring or assessing patients in restraints or seclusion attend mandatory in-service training on safe restraint use and on the purpose and goals of the restraint reduction program.[10] Educational programs for staff should include documentation of the staff's understanding of restraint alternatives, the risks of restraint use, and the correct method for applying, documenting, monitoring, and removing restraints.

CMS requires that staff receive training on the proper use of restraints before ever applying restraints. CMS also requires that any RNs or PAs who are allowed, within their scope of practice, to assess restrained patients receive training in evaluating medical and behavioral conditions.[10] This training should be reinforced with ongoing mandatory clinics, and restraint reduction materials should be included in the facility's newsletter. Progress reports

©2024 ECRI. All rights reserved.

are also helpful to maintain staff enthusiasm for a restraint reduction program, and should emphasize use of restraint alternatives.

All staff who might apply restraints or monitor individuals in restraints must be effectively trained to apply the devices properly according to the manufacturer's instructions and to monitor any patient in restraints during the appropriate intervals, based on the type of device and whether it is being used on a patient displaying violent or self-destructive behavior.

Education departments may explore the availability of training videos for staff orientations and in-service training available from manufacturers and distributors. However, these products should be considered a supplement to instruction conducted by staff educators. Risk managers should note that CMS's final rule on patient rights defines the qualifications for staff who will conduct education on restraint use. Risk managers should review these requirements with their facility's education department to ensure compliance.

Educate Patients and Family Members

As previously mentioned, it is important to fully explain the facility's restraint policies to the patient and any family members, and to document that this communication took place. Many times, particularly in aging services organizations, family members insist that healthcare workers employ restraints to keep the patient "safe" without being properly apprised of the issues. To effectively communicate the risks and benefits of restraint use to patients, residents, and family members, facilities must ensure that staff members are effective patient educators.[11] Nurse training and continuing education programs should emphasize skill- or activity-based learning, role-play techniques, and development of cross-cultural communication skills. Nursing supervisors should periodically observe staff nurses while they are teaching patients or residents. Patient or resident satisfaction questionnaires can be used to obtain information about patients', residents', and families' perceptions of nurses' teaching skills.

Proper Documentation

Proper, thorough, and accurate documentation is critical whenever restraints are used. The following information should be documented in the patient's medical record[11]:

- Any in-person medical and behavioral evaluation for restraint or seclusion used to manage violent or self-destructive behavior
- A description of the patient's behavior and the intervention used
- Any alternatives or other less restrictive interventions attempted
- Any education on the facility's restraint policy that was provided to the patient and his/her family members
- The patient's condition or symptom(s) that warranted the use of the restraint or seclusion
- The patient's response to the intervention(s) used, including the rationale for continued use of the intervention
- Individual patient assessments and reassessments
- The intervals for monitoring
- Revisions to the plan of care
- The patient's behavior and staff concerns regarding safety risks to the patient, staff, and others that necessitated the use of restraint or seclusion

©2024 ECRI. All rights reserved.

- Injuries to the patient
- Death associated with the use of restraint or seclusion
- The identity of the physician, clinical psychologist, or other LIP who ordered the restraint or seclusion
- Orders for restraint or seclusion
- Notification of the use of restraint or seclusion to the attending physician
- Any consultations made
- A postrestraint interview with the patient to help prevent the use of restraints going forward

Nurses are responsible for assessing and documenting whether an individual is displaying behavior that requires use of restraint. Because determining and addressing the root cause of the behavior may eliminate the need for restraints, any information the nurse gathers regarding causes of agitation and at-risk behavior should be noted in the individual's chart and flagged for other caregivers.

If restraints are used, documentation of the physician's order, ongoing assessment, and care plans must be included in the individual's medical record.[10,11] CMS's final rule on patients' rights states that the following information must be included in the patient's medical record[10]:

- The one-hour face-to-face medical and behavioral evaluation, if restraint or seclusion is used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others
- A description of the patient's behavior and the intervention used
- Alternatives or other less restrictive interventions attempted (as applicable), and the effect they had on the patient
- The patient's condition or symptoms that warranted the use of restraint or seclusion
- The patient's response to the interventions, including the rationale for continued use of the intervention

In addition, conversations regarding restraint use with patients, residents, and family members should be documented, as well as any attempts that are made to assess and treat or manage the patient's condition underlying the behavior (e.g., delirium).

Reporting Restraint-Related Injuries and Deaths

CMS. Facilities must report to CMS any death that occurs while a patient is restrained or in seclusion or any case in which it is reasonable to assume that a patient's death was a result of restraint or seclusion. CMS requires healthcare facilities to report deaths associated with restraint use no later than by the close of business on the day following the death. The following would be considered reportable under this requirement[10]:

- Any death that occurs while a patient is in restraint or seclusion.
- Any death that occurs within 24 hours after the patient has been removed from restraint or seclusion.
- Any death known to the hospital that occurs within one week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this

©2024 ECRI. All rights reserved.

context includes, but is not limited to, death related to restrictions of movement for prolonged periods, or death related to chest compression, restriction of breathing, or asphyxiation

If no seclusion has been used and the only restraints used on the patient are those composed solely of soft, nonrigid, cloth-like materials and applied exclusively to the patient's wrist(s), the hospital staff must record the following[10]:

- Any death that occurs while a patient is in such restraints
- Any death that occurs within 24 hours after a patient has been removed from such restraints

This information must be recorded in an internal log or other system no later than seven days after the date of death of the patient, and must include the following information[10]:

- Patient name
- Date of birth and date of death
- Name of attending physician/other LIP
- Medical record number
- Primary diagnosis(es)

This information must be made available in either written or electronic form to CMS immediately upon request.[10]

State licensing agencies. In some states, restraint-related deaths or serious injuries may be reportable to state survey agencies. Risk managers should be aware of the facility's state reporting requirements.

Food and Drug Administration (FDA). Physical restraints are designated as medical devices and are subject to medical device reporting regulations.[10] Healthcare facilities, including hospitals, nursing homes, and home health agencies, must report to FDA and/or the manufacturer of a restraint (depending on the circumstances) any event in which the device may have caused or contributed to a patient's death, serious illness, or injury. This report must be filed within 10 working days after the facility becomes aware of the event.

ECRI RESOURCES

Medical Device Reporting

Failure to report in a timely manner may lead to civil or even criminal penalties. See the guidance article Medical Device Reporting for more information.

ECRI Institute. ECRI Institute has maintained a database of medical-device-related problems, hazards, and recalls for nearly 50 years. Restraint-related injuries may be reported to ECRI Institute on a voluntary basis through ECRI Institute's website or by phone, fax, or mail. ECRI Institute provides feedback to reporting institutions about similar problems that may have been reported involving that type of device. ECRI Institute also provides independent accident investigation services for device-related deaths or injuries.

REFERENCES

1. Kielb C, Hurlock-Chorostecki C, Sipprell D. Can minimal patient restraint be safely implemented in the

©2024 ECRI. All rights reserved.

intensive care unit? Dynamics. 2005;16(1):16-9. PMID: 15835454.

2. Strumpf NE, Evans LK. Physical restraint of the hospitalized elderly: perceptions of patients and nurses. Nurs Res. 1988 May-Jun;37(3):132-7. PMID: 3368353.

3. Calloway SD. EPIX Patient Safety Briefs: Restraint and seclusion. Auburn (CA): Emergency Physicians Insurance Exchange RRG; 2016. 8 p. Also available: http://oahq.org/pdf_files/RESTRAINT%20AND%20SECLUSION%20PDF.pdf.

4. Full text statements of deficiencies hospital surveys - 2016Q4. [Microsoft Excel sheet]. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); Available: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Hospitals.html.

5. Providing a quality life while avoiding restraint usage. Milwaukee (WI): Office of Quality Assurance; 1999. Risks of restraint use and benefits of freedom from restraints. Also available: http://www.uwosh.edu/ccdet/caregiver/Documents/Evergreen/Handouts/ednarisksbftsfdm.pdf.

6. Chuang YH, Huang HT. Nurses' feelings and thoughts about using physical restraints on hospitalized older patients. J Clin Nurs. 2007 Mar;16(3):486-94. Also available: http://dx.doi.org/10.1111/j.1365-2702.2006.01563.x. PMID: 17335524.

7. Changing the culture of seclusion and restraint. PA PSRS Patient Saf Advis. 2005 Mar;2(1):22-6. Also available: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2005/Mar2(1)/Pages/22.aspx.

8. Mion LC. Physical restraint in critical care settings: will they go away? Geriatr Nurs. 2008 Nov-Dec;29(6):421-3. Also available: http://dx.doi.org/10.1016/j.gerinurse.2008.09.006. PMID: 19064141.

9. Staggs VS. Trends in use of seclusion and restraint in response to injurious assault in psychiatric units in U.S. Hospitals, 2007-2013. Psychiatr Serv. 2015 Dec 01;66(12):1369-72. Also available: http://dx.doi.org/10.1176/appi.ps.201400490. PMID: 26174946.

10. Centers for Medicare and Medicaid Services (CMS). Revised appendix A, "Interpretive guidelines for hospitals". CMS manual system, Pub 100-07 State Operations Provider Certification transmittal 37. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2008 Oct 17. 370 p. Also available: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R37SOMA.pdf.

11. 2017 Comprehensive Accreditation Manual for Hospitals (CAMH). Oak Brook (IL): The Joint Commission; 2017 Jan.

12. Rose S, Ward K, Giorgi-Guarnieri D. Pharmacotherapeutic options for chemical restraint. J Crit Illn. 2002 Nov;17(11):446-56.

13. Mattingly BB, Schraga ED. Chemical restraint. [internet]. New York (NY): Medscape, LLC; 2016 Nov 21 [accessed 2017 Apr 10]. [6 p]. Available: http://emedicine.medscape.com/article/109717-overview#showall.

14. Hanson L, Murray M, Herman C. Physical restraints: overview. In: Quality Counts: Removing Restraints in Nursing Homes [teleconference]; Carolinas Center for Medical Excellence; 2004 Jan 22.

©2024 ECRI. All rights reserved.

15. Springer G. When and how to use restraints. Am Nurse Today. 2015 Jan;10(1):26-7. Also available: http://www.medscape.com/viewarticle/838521_1.

16. Failure to restrain patient after repeated falls from bed - death - $7 million Alabama verdict. Med Malpract Verdicts Settlements. 2002 Aug;18(8):32.

17. Teresian House Nursing Home Co., Inc. v. CMS, Dec. No. CR1381, (Dep't Health Human Servs. Dep't App. Bd, Civil Remedies Div. Jan. 12, 2006).

18. Tovino SA. Patient restraint allegations and the false claims act. University of Houston Law Center; 2005 Aug 23. 2 p. Also available: https://www.law.uh.edu/healthlaw/perspectives/August2005/(ST)Restraints.pdf.

19. Joint Commission survey standards tighten for 2017. [internet]. OR Manager; 2016 Nov 14 [accessed 2017 Apr 13]. Available: http://www.ormanager.com/joint-commission-survey-standards-tighten-2017/.

20. Facts about hospital accreditation. [internet]. Oakbrook Terrace (IL): The Joint Commission; 2017 Jan 24 [accessed 2017 Apr 13]. [2 p]. Available: https://www.jointcommission.org/facts_about_hospital_accreditation/.

21. Understanding patient restraints: a hospital's decision to use restraints. [internet]. FindLaw; [accessed 2017 Apr 13]. [3 p]. Available: http://corporate.findlaw.com/law-library/understanding-patient-restraints-a-hospital-s-decision-to-use.html.

22. 28 Pa. Code § 155.8 (1998).

23. Gabbidon J. A practical guide to qualitative healthcare. Xlibris; 2015. 224 p.

24. Reducing the use of restraints in Texas nursing homes. Austin (TX): Texas Department of Human Services; 2003 Jan. 10 p. Also available: http://consumerjusticegroup.com/nursinghomeabuse/pdf/restraints_guide.pdf.

25. Evidence-based practice center systematic review protocol: Comparative effectiveness of strategies to de-escalate aggressive behavior in psychiatric patients in acute care settings. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2016 Oct 5. Also available: https://effectivehealthcare.ahrq.gov.

26. Gastmans C, Milisen K. Use of physical restraint in nursing homes: clinical-ethical considerations. J Med Ethics. 2006 Mar;32(3):148-52. PMID: 16507658.

27. Systems analysis: assess early and often to avoid unnecessary use of restraint and seclusion. Jt Comm Perspect Patient Saf. 2004 May;4(5):5-6. Also available: http://www.ingentaconnect.com/contentone/jcaho/jcpps/2004/00000004/00000005/art00003

28. Woodward J. Assessing and documenting patient restraint incidents. Am Nurse Today. 2015 Jan;10(1):32. Also available: https://www.americannursetoday.com/assessment-documentation/.

29. Calloway SG. CMS hospital R&S Conditions of Participation (COPS) 2016: what hospitals need to know about restraint and seclusion. [slide presentation]. 2016 [157 slides].

30. Montana state hospital policy and procedure: use of seclusion and restraint. Policy TX-16. Helena (MT): Montana Department of Public Health and Human Services; 2013 Nov 15. 20 p. Also available: http://dphhs.mt.gov/Portals/85/amdd/documents/msh/volumeii/treatment/useseclusionrestraint.pdf.

©2024 ECRI. All rights reserved.

31. Parikh R. Rethinking hospital restraints. Atlantic. 2014 Aug 18;1-5. Also available: https://www.theatlantic.com/health/archive/2014/08/rethinking-hospital-restraints/375647/.

32. Torkelson DJ, Dobal MT. Constant observation in medical-surgical settings: a multihospital study. Nurs Econ. 1999 May-Jun;17(3):149-55. PMID: 10711154.

33. Restraint alternatives (Prepared by Louisiana Health Care Review, Inc., the Medicare Quality Improvement Organization for Louisiana, under contract 500-99-LA02 with the Centers for Medicare & Medicaid Services (CMS). [internet]. QSource; [accessed 2017 Apr 10]. [1-4]. Available: http://atlanticquality.org/download/508_restraint_altern.pdf.

34. Dimant J. Avoiding physical restraints in long-term care facilities. J Am Med Dir Assoc. 2003 Jul-Aug;4(4):207-15. Also available: http://dx.doi.org/10.1097/01.JAM.0000076989.59710.EC. PMID: 12837143.

RESOURCE LIST

ECRI Resources

- Behavioral Health Issues in Non-Behavioral-Health Settings [ECRI Institute's Top 10 Patient Safety Concerns for 2017, concern #8]
- Education: Restraint Reduction Training Program
- Guidance: An Overview of Nursing Liability
- Guidance: Bed Safety
- Guidance: Falls
- Guidance: Health Literacy
- Guidance: Medical Device Reporting
- Guidance: Setting Realistic Expectations

Additional Resources

Agency for Healthcare Research and Quality

(301) 427-1104
http://www.ahrq.gov

- Physical restraints and side rails in acute and critical care settings [guideline]
- Restraint toolkit
- Roadmap to seclusion and restraint free mental health services

American Nurses Association (ANA)

(800) 274-4262
http://www.nursingworld.org

- Reduction of patient restraint and seclusion in health care settings [position statement]

American Psychiatric Nurses Association

©2024 ECRI. All rights reserved.

(855) 863-APNA
http://www.apna.org

- Position statement on the use of seclusion and restraint

Banner Health
http://www.bannerhealth.com

- Restraint use in non violent situations [policy and procedure]
- Restraint use in violent situations [policy and procedure]

Montana State Hospital
(406) 693-7000
http://dphhs.mt.gov/amdd/MSH.aspx

- Use of restraints for non-violent, non self-destructive behaviors [policy, frequently asked questions, progress note, observation flow sheet]
- Use of seclusion and restraint [policy, assessment forms, information]

North Memorial Health
(763) 520-5200
http://www.northmemorial.com

- Restraint or seclusion [policy and procedure]

Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services
(800) 487-4889
https://www.samhsa.gov
Promoting Alternatives to the Use of Seclusion and Restraint series:

- The business case for preventing and reducing restraint and seclusion use
- Issue brief #1: A national strategy to prevent seclusion and restraint in behavioral health services
- Issue brief #2: Major findings from SAMHSA's alternatives to restraint and seclusion State Incentive Grants (SIG) program
- Issue brief #4: Making the business case

U.S. Department of Education
(800) 872-5327
https://www2.ed.gov

- Restraint and seclusion: resource document

©2024 ECRI. All rights reserved.

TOPICS AND METADATA

Topics

Accidents
Aging Services
Behavioral Health
Ethics
Laws, Regulations, Standards
Long-term Care

Caresetting

Assisted-living Facility
Hospital Inpatient
Emergency Department
Hospital Outpatient
Physician Practice
Rehabilitation Facility
Short-stay Facility
Skilled-nursing Facility
Substance Abuse Treatment Facility

Clinical Specialty

Mental Health and Substance Abuse
Nursing
Pediatrics

Roles

Nurse
Risk Manager

Information Type

PUBLICATION HISTORY

Published June 6, 2017

CITATION

ECRI Institute. Restraints. *Healthcare Risk Control*. 2017 Jun 6.
https://www.ecri.org/components/HRC/Pages/SafSec4.aspx

©2024 ECRI. All rights reserved.