Restrain from Restraints: A Regulatory View
(Hospice Aides and other non-licensed personnel)

- Hospice Aides will receive 1.0 credit of in-service education.
- Licensed professionals will not receive continuing education credit (CEUs, contact hours, etc.) for attending this program.

Highlights

- Discuss how regulations impact care planning when considering restraints.
- Discuss the advantages and disadvantages of using physical restraints.
- Discuss the advantages and disadvantages of using chemical restraints.
- Compare and contrast arguments for and against restraints.
Introduction

In the past, nurses commonly used their clinical judgment when assessing the need to restrain patients. This practice has changed for several reasons. First, reports of strangulation have increased. Second, the standard of care for restrained patients is becoming more restrictive as evidenced in the most recent Medicare Hospice Conditions of Participation (CoP).

The Patient Rights CoP emphasizes a hospice’s responsibility to respect and promote the rights of each hospice patient. The patient has the right to be informed of his or her rights, and the hospice must protect and promote the exercise of these rights.⁶ (Patient’s Rights, Condition of Participation (Proposed § 418.52) Subpart C, Conditions of Participation—Patient Care)

It is important to note that basic human rights are not forfeited upon entry to hospice, regardless of the setting (e.g., home, skilled nursing facility, hospital). The application of restraints can violate a patient’s freedom and right of self-determination. “A competent patient has the right to refuse restraints unless he or she is at risk for harming others. Maintaining medical therapies, while minimizing patient confusion, helps preserve the patient’s dignity and develop the patient’s trust in the care provider. No ethical justification exists for the application of restraints as a punitive measure. Such a practice is abuse. Restraint use should be consistent with the overall goals of therapy. For example, the restraining of a terminally ill patient near the end of life to maintain nutrition and hydration conflicts with the goal of providing pain relief and comfort care. Offering restraints to patients in place of proper medical evaluation, nursing care, and compassion is UNETHICAL.”⁷

This module will look at the current regulatory guidelines and how they impact the use of restraints.

Overview of Restraints

SouthernCare subscribes to the approach that restraints do not routinely belong in the hospice patient’s plan of care, especially in the home environment. However, in the rare event that restraints are indicated, staff must be aware of the most recent regulatory standards. These standards provide very clear guidance about the initiation of restraints, care while restrained and the discontinuation of restraints.

For the record, restraints do not increase patient/resident safety, nor do restraints decrease liability risks. Restraints do not lower care costs, and they do not lower psychoactive drug use. Yet, barriers to decreasing the use of restraints still remain. The barriers lie in staff and family beliefs and knowledge about restraints. By providing proper education to caregivers, we can be assured we are moving toward proper use of restraints.⁴

“Lawsuits are being won for harmful outcomes from using restraints; but fewer and fewer are won for harmful outcomes from non-use of restraints. CMS has stated that the real liability is a lack of care regarding fall risk. Proper care revolves around individualized assessment of fall risk followed by appropriate intervention. Most negative outcomes resulted from substandard monitoring and supervision, lack of documentation to support the care plan, or failure to identify and/or use appropriate alternatives to restraints.” ⁴
A Regulatory Affair: Patient/Resident’s Rights

418.100(a) (CoP Patient Rights) states “….each patient is to be kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.” Additional patient/resident’s rights include:

- Being free from physical or mental abuse, and corporal punishment.
- Being free from restraint or seclusion, of any form, imposed as a means of coercion, discipline convenience, or retaliation by staff. Restraint or 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.
- Having a provider use physical or chemical restraints only if the use is authorized in writing by a physician or the use is necessary in an emergency to protect the patient or others from injury. A physician’s written authorization for the use of restraints must specify the circumstances under which the restraints may be used and the duration for which the restraints may be used.
- Except in an emergency, having restraints administered only by qualified medical personnel.\(^6\)

The Interpretive Guidelines 418.110 (m) emphasizes a hospice’s responsibility to respect and promote the rights of each hospice patient. The patient has the right to be informed of his or her rights and the hospice must protect and promote the exercise of these rights. The guideline states:

*The hospice is responsible for creating a culture that supports a patient’s right to be free from restraint or seclusion. The hospice must also ensure that systems and processes are developed, implemented, and evaluated that support the patients’ rights addressed in this standard, and that eliminate the inappropriate use of restraint or seclusion.*

*The use of restraints for the prevention of falls must not be considered a routine part of a falls prevention program. Although restraints have been traditionally used as a falls prevention approach, they have major, serious drawbacks and can contribute to serious injuries. There is no evidence that the use of physical restraint, (including, but not limited to, raised side rails) will prevent or reduce falls. Additionally, falls that occur while a person is physically restrained often result in more severe injuries and/or death.\(^6\)*

**Working Definitions of Restraints and Seclusion**

- **Restraint** - either a physical restraint or a drug used as a restraint.
- **Seclusion** - the *involuntary* confinement of a person in a room or an area where a person is isolated and physically prevented from leaving.
In 42 CFR Section 483.13 (a) under Interpretive Guidance in the State Operations Manual, the Health Care Financing Administration (HCFA) defines physical restraints as:

“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, not including devices, 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);

or (2) A drug or medication when it is used as a restriction to manage the patient’s behavior or restrict the patient’s freedom of movement and is not a standard treatment or dosage for the patient’s condition.”

Under the HCFA definition, a restraint could include anything from a vest restraint, to a geri-chair or tray table, to a side rail, or even a sheet, if it has the effect of restricting freedom of movement or normal access to one’s body.

**Restraint Use and Negative Outcomes**

**Assessing the Risks**

There are definite risks associated with the use of physical restraints including changes in body systems such as:

- weak muscles, muscle atrophy
- loss of mobility
- poor circulation
- cardiac distress
- incontinence
- chronic constipation
- altered consciousness
- bone demineralization

Restraints can lead to:

- fall-related injuries and increased falls
- pressure ulcers
- dehydration
- orthostatic hypotension
- increased threat of pneumonia
- increased urinary infections
- worsening dementia
- accidental death by strangulation

There are potential changes in **psychosocial/spiritual systems** which may include:

- reduced social/religious contact
- withdrawal from surroundings
- loss of autonomy
- loss of self-determination
- anger, fear, humiliation
Finally, restraints can lead to:

- increased or decreased appetite
- depression
- increased agitation, anxiety
- aggression
- hallucinations, delusions
- altered sleep patterns

Certainly, **improper use of restraints** can lead to some very poor outcomes such as these:

- accidents involving restraints which may cause serious injury
- changes in body systems which may include: poor circulation, chronic constipation,
  incontinence, weak muscles
- weakened bone structure, pressure sores, increased agitation, depressed appetite,
- increased threat of pneumonia
- increased urinary infections, or death
- changes in quality of life which may include: reduced social contact, withdrawal from
  surroundings, loss of autonomy, depression, increased problems with sleep patterns,
  increased agitation, or loss of mobility.

**The Use of Side Rails**

This is a special section dedicated to understanding the use of side-rails while a patient/resident is in bed. Some people do not consider the side-rail a restraint because of the prevalence of its usage. However, we’re about to see how bed rails can cause injury and even death in some cases.

Today there are about 2.5 million hospital and nursing home beds in use in the United States. Between 1985 and January 1, 2009, 803 incidents of patients caught, trapped, entangled, or strangled in beds with rails were reported to the U.S. Food and Drug Administration. Of these reports, 480 people died, 138 had a nonfatal injury, and 185 were not injured because staff intervened. Most patients were frail, elderly and/or confused.¹ (Revised 4/2010)

According to HCFA’s definition, “any time side-rail use (whether partial, full, one or two, or a side rail on one side of the bed with the other side of the bed against the wall) has the effect of preventing an individual from voluntarily getting out of bed, it is a restraint.” ¹
Positive aspects of using bed rails include:

- the use on stretchers or beds while transporting patients following surgery or when relocating a patient to a new room or unit, increases safety
- facilitating turning and repositioning within the bed or transferring in or out of a bed
- providing a feeling of comfort and security, or facilitate access to bed controls
- may be used as a physical barrier to remind the patient of the bed perimeters or to ask for nursing assistance

“When planning patient care, several points should be considered. The potential for serious injury is more likely to be related to a fall from a bed with raised bed rails when the patient attempts to climb over, around, between, or through the rails, or over the foot board, than from a bed without rails in use. Evaluation is needed to assess the relative risk of using the bed rail compared with not using it for an individual patient.”

CMS issued guidance in June 2000 for surveyors to determine hospitals compliance with these regulations. One section of the guidance states, “It is important to note that side rails present an inherent safety risk, particularly when the patient is elderly or disoriented. Even when a side rail is not intentionally used as a restraint, patients may become trapped between the mattress or bed frame and the side rail. Disoriented patients may view a raised side rail as a barrier to climb over, may slide between side rail. When attempting to exit the bed by any of these routes, the patient is at risk for entrapment, entanglement, or falling from a greater height posed by the raised side rail, with a possibility for sustaining greater injury or death than if he/she had fallen from the height of a lowered bed without raised side rails.”

The same device may have the effect of restraining one individual, but not another, depending on the individual patient’s condition and circumstances. For example, partial rails may assist one patient to enter and exit the bed independently while acting as a restraint for another. Bed rails sometimes restrain patients. When used as restraints, bed rails can pose the same risk to patient safety as other types of physical restraints.

“Physical restraints such as vest/chest, waist, or leg/arm restraints used simultaneously with raised bed rails may be medically indicated in certain limited circumstances. Consider that when physical restraints and bed rails are used simultaneously:

- the risk to patient safety, e.g., suffocation or accidental suspension, may increase
- patients should be monitored closely
- appropriate care such as toileting should be provided
- reassessment for medical necessity and removal is needed on a regular basis”

“Patient safety is paramount. In an emergent situation, the caregiver needs to do whatever is necessary in his or her professional judgment to secure the patient’s safety. Consider that using a bed rail or other device to restrain the patient could place the patient’s safety at risk. Strangling, suffocating, bodily injury, or death can occur when patients or parts of their bodies are caught between rails or between the bed rails and mattresses.”
7 Potential Bed Dangers

Zone 1: Entrapment within rail

Zone 2: Entrapment between top of compressed mattress to bottom of rail, between rail and supports.

Zone 3: Between the rail and the mattress. Placing the foot end rail in lowest position or removing foot end bed rails will reduce the risk of entrapment at Zone 3 without placing undue burden on caregivers.

Zone 4: Under the rails, at the end of the rails
Zone 5: Between split bed rails

Zone 6: Between the end of the rail and the side edge of either the head or foot board

Zone 7: Between the head or foot board and the mattress end - Properly fitting mattresses taking into consideration the length, width, depth, compressibility, and characteristics of mattress surfaces will help to reduce openings in entrapment Zones 2, 3, 4, and 7.

Some Additional Points Regarding Bed rails

“The automatic use of bed rails may pose unwarranted hazards to patient safety. The decision to use or to discontinue the use of a bed rail should be made in the context of an individualized patient assessment using an interdisciplinary team with input from the patient and family or the patient's legal guardian.”

The patient's right to participate in care planning and make choices should be balanced with caregivers’ responsibility to provide care according to an individual assessment, professional standards of care, and any applicable state and federal laws and regulations.
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Most patients can be in bed safely without bed rails. Consider the following:

- Use beds that can be raised and lowered close to the floor to accommodate both patient and health care worker needs.
- Keep the bed in the lowest position with wheels locked.
- When the patient is at risk of falling out of bed, place mats next to the bed, as long as this does not create a greater risk of accident.
- Use transfer or mobility aids.
- Monitor patients frequently.
- Anticipate the reasons patients get out of bed such as hunger, thirst, going to the bathroom, restlessness and pain; meet these needs by offering food and fluids, scheduling ample toileting, and providing calming interventions and pain relief.\(^1,2\)

When bed rails are used, perform an on-going assessment of the patient’s physical and mental status; closely monitor high-risk patients. Consider the following:

- Lower one or more sections of the bed rail, such as the foot rail.\(^1\)
- Check for compression of the outside perimeter of the mattress. Easily compressed perimeters can increase the gaps between the mattress and the bed rail.\(^1\)
- Ensure that the mattress is appropriately sized for the selected bed frame, as not all beds and mattresses are interchangeable.\(^3\)
- The space between the bed rails and the mattress and the headboard and the mattress should be filled either by an added firm inlay or a mattress that creates an interface with the bed rail that prevents an individual from falling between the mattress and bed rails.\(^3\)

Physical Restraints: Indication for Use

There are times when restraints might be indicated. They include:

- Central IV or a ventilator used in a resident with high risk for self-disruption of that device
- Repeated, traumatic self-removal of an indwelling bladder catheter
- Acute violent behavior toward self or others (not simply resisting care or ADLs)
- Protection from self-injury after a hip fracture with either no repair or surgical repair (except a total hip replacement)

Guidelines for Restraints in an Emergency Situation

An emergency is defined as an instance in which there is an imminent risk of a patient harming himself/herself or others, including staff; when nonphysical interventions are not viable, safety issues require an immediate physical response, and a physician is not readily available to conduct an assessment and write restraint orders. If the physician is not available to order restraints in an emergency, an RN or other qualified licensed personnel based upon an appropriate assessment of the patient may initiate restraint use.
The Registered Nurse (RN) or licensed staff shall document the assessment findings and justification in the medical record. A verbal physician’s order shall be obtained as soon as possible. If initiation of restraint is based on a significant change in patient condition, the RN shall immediately notify the physician.

Reducing the Need for Restraints

The ultimate goal of care is patient safety and comfort. There may be times when this requires the use of restraints. Restraints should be a measure of last resort, meaning that all other methods of safeguarding the patient have been exhausted. Other measures involve the active participation of the caregivers in the plan of care.

General measures include:

- Keep environment calm, restful
- Eliminate multiple stimuli
- Speak in a calm, gentle manner
- Provide kind, respectful care
- Treat patients/residents as individuals
- Meet patients/residents’ needs, e.g. elimination, positioning, activity

Observation and Problem-solving

The RNCM will make careful observations of the patient to identify what:

- Causes the problem behavior
- Calms or distracts the resident
- Report your objective observations to the nurse to assist the nurse in care-planning.

Provide care (that you are trained to provide) following instructions of nurse and care plan to:

- [x] Eliminate cause of behavior
- [x] Calm or distract resident

Specific measures to reduce the use of physical restraints include:

- Companionship and supervision using staff, family, friends, or volunteers to prevent patients from being alone, especially at night
- Psychosocial interventions such as involving patients in conversations, having distractions such as television, radio, calendar, or clocks, and using therapeutic touch and active listening
- Modification or elimination of treatments such as intravenous lines and nasogastric tubes to prevent the patient from disrupting medical devices
“Other devices that may be used to reduce the perceived need for restraints include playing music tailored specifically to the patient, pressure-sensitive bed alarms, and toileting regimens that meet a resident’s specific needs.”

Modification of the Environment
“Modifications of environmental elements such as better lighting, a bedside commode, placing the patient close to the nursing station, placing a mattress on the floor, leaving bed rails down, making sure that rooms are quiet and that the resident has an accessible call light, responding quickly to call lights, and providing special furniture (e.g., a low bed, modified wheelchair) may all help to prevent falls and improve patient safety.”

Preventing Falls in the Home
First, be sure the home is as safe as possible. Encourage patients and caregivers to:

- Wear shoes with nonskid soles (not house slippers).
- Be sure the home is well lit so that the patient can see things they might trip over. Use night lights in bedrooms, bathrooms, hallways and stairways.
- Remove throw rugs or fasten them to the floor with carpet tape. Tack down carpet edges.
- Don’t put electrical cords across pathways.
- Have grab bars put in bathtubs, showers and toilet areas.
- Have handrails put on both sides of stairways.
- Refrain from climbing on stools and stepladders.
- Don’t wax floors at all, or use a non-skid wax.
- Have sidewalks and walkways repaired so that surfaces are smooth and even.

Alternatives to Restraints
The choice to use alternatives to restraints depends upon patient assessment. The most common successful interventions include ambulation programs, toileting programs, lower extremity strengthening exercises, wheelchair adaptations and wedge cushion seating. Additional restraint alternatives include:

- Voice alarms telling the patient not to get up as a nurse will come by shortly to help
- Freedom splints (sleeves that fit over the forearm and upper arm) to prevent the patient from pulling out tubes
- Torso supports to maintain the patient’s posture and positioning mitts to keep the patient from pulling out IVs and nasogastric tubes
- Anti-skid floor mats that absorb fluids and food
RESTRAIN FROM RESTRAINTS

- Personal strengthening and rehabilitation programs
- Use of "personal assistance" devices such as hearing aids, visual aids and mobility devices
- Use of positioning devices such as body and seat cushions, and padded furniture
- Efforts to design a safer physical environment, including the removal of obstacles that impede movement, placement of objects and furniture in familiar places, lower beds and adequate lighting
- Regular attention to toileting and other physical and personal needs, including thirst, hunger, the need for socialization, and the need for activities adapted to current abilities and past interests
- Design of the physical environment to allow for close observation by staff
- Efforts to increase staff awareness of the patient’s individual needs - possibly including assignment of staff to specific patients in an effort to improve function and decrease difficult behaviors that might otherwise require the use of restraints
- Design of patient’s living environments that are relaxing and comfortable, minimize noise, offer soothing music and appropriate lighting, and include massage, art or movement activities
- Use of bed and chair alarms to alert staff when a patient needs assistance
- Use of door alarms for patients who may wander away

Chemical Restraints
According to the Federal Register/Vol. 70, No. 102/Friday, May 27, 2005/Proposed Rules, a drug restraint means “a medication used to control behavior or to restrict the patient’s freedom of movement which is not a standard treatment for a patient’s medical or psychiatric condition.”

Definition of Unnecessary Drug
An unnecessary drug is any drug when used:
- in excessive dose (including duplicate drug therapy)
- for excessive duration
- without adequate monitoring
- without adequate indications for its use
- in the presence of adverse consequences which indicate the dose should be reduced or discontinued
- any combination of the above reasons
The Risks of Chemical Restraints
Medications used for chemical restraints often harbor significant side effects such as:

- fatal cardiac arrhythmias
- status epilepticus
- orthostatic hypotension
- constipation
- weight gain
- blurred vision
- memory impairment

Discontinuing Restraints
Decisions to use or to discontinue the use of a restraint should be made in the context of an individualized patient assessment using the IDG with input from the patient and family or the patient’s legal guardian. The patient's right to participate in care planning and make choices should be balanced with caregivers’ responsibility to provide care according to an individual assessment, professional standards of care, and any applicable state and federal laws and regulations.²

Performance Improvement Committee
Identifying Opportunities for Restraint Reduction
SouthernCare's Quality Assurance Performance Improvement program (QAPI) consists of measuring high-risk, high-volume, and problem-prone processes. As a part of the local QAPI process, the QAPI committee may:

- monitor frequency of restraint use in their location
- evaluate each case for clinical justifications of restraint use
- identify each care issue that led to restraint use
- implement alternatives to restraints
- review orders, care plans, and (in some cases) actual care to ensure that all parts are congruent

Summary
As hospice professionals, staff must take responsibility for maintaining patient’s comfort and safety while preserving their rights. Remember, basic human rights are not forfeited upon entry to hospice, regardless of the setting. The application of restraints, if used inappropriately, may violate a patient’s freedom and right of self-determination.

A competent patient has the right to refuse restraints unless he or she is at risk for harming others. While it is important to maintain needed medical treatments and therapies, we must always work to preserve the patient’s dignity, as well as their trust in the hospice staff as care providers.
References


