

The Massachusetts Coalition for the Prevention of Medical Errors

Best Practice Recommendations to Improve Patient Safety Related to Restraint & Seclusion Use

Executive Summary

In 1997, the Massachusetts Coalition for the Prevention of Medical Errors launched a statewide initiative to improve patient safety and reduce medical errors. The Coalition's first initiative – the prevention of medication errors – yielded a set of principles, best practice recommendations, and safety alerts now employed by institutions and organizations throughout the Commonwealth.

The Coalition chose as its second initiative – the prevention of restraint- and seclusion-related injuries. This effort resulted in the development of a set of principles and best practice recommendations for use by general hospitals, children's hospitals, psychiatric hospitals/facilities, and long-term care facilities, including rehabilitation and chronic facilities. These best practices are applicable to adults as well as children.¹

The Coalition convened a consensus group that included regulatory agency representatives, physicians, nurses, and administrators. Another level of review and development occurred at "pod" or setting-specific workgroup meetings. The pods included representatives of medical/surgical floors in acute hospitals, emergency departments, children's hospitals, psychiatric facilities, and long-term care facilities. These workgroups and the consensus group represented over 30 hospitals and nursing homes from across the state. **Participants strongly recommend that the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Center for Medicare and Medicaid Services (CMS), previously the Health Care Financing Administration (HCFA) agree on a consistent set of restraint and seclusion guidelines so as to reduce the confusion about the use of such practices.**

To build consensus, the project looked at existing approaches to restraint use, along with available research on the causes and prevention of restraint- and seclusion-related injuries and deaths. This document encompasses physical and chemical restraint use, as well as seclusion. Consistent throughout the literature and in regulation is the importance and protection of individuals' rights, dignity, and well-being during restraint use. Physical restraints are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that is difficult for the individual to remove and restricts freedom of movement or normal access to one's body. Chemical restraint occurs when a patient is given medication involuntarily, controlling behavior or restricting the patient's freedom of movement; it is not a standard treatment for the patient/resident's medical or psychiatric condition. Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving. (See definitions below.)

This effort resulted in the development of a set of [principles and best practice recommendations](#) for use by general hospitals, children's hospitals, psychiatric hospitals/facilities, and long-term care facilities, including rehabilitation and chronic facilities. These best practices are applicable to adults as well as children. The Coalition promoted adoption of these improvements through two successful educational programs, leadership initiatives which highlighted restraint-free organizations, an improvement workbook, and ongoing networking opportunities.

¹ The issue of restraint and seclusion use in residential group homes may be reviewed in another phase of this initiative.

The foundation of the best practice recommendations in this document is made up of two basic principles:

1. the adoption of an approach that minimizes the use of restraints and seclusion; supports use of restraints and seclusion only in emergency situations and after less restrictive interventions have been determined ineffective; ensures patient/resident and staff safety; and
2. the promotion of an approach that values risk assessment, early intervention, and education.

Principles to Improve Patient Safety Related to Restraint & Seclusion Use

Members of the Restraint Consensus Group of the Massachusetts Coalition for the Prevention of Medical Errors developed the following principles and best practice recommendations to promote patient safety by supporting the appropriate use and enhancing the reduction of restraints and seclusion.

Principles to Improve Patient Safety Related to Restraint and Seclusion Use

1. **Adopt an organization-wide approach, reflected by a commitment from senior leadership that optimizes care and treatment while minimizing and supporting the use of restraints or seclusion only in emergency situations (i.e., when there is a greater likelihood of injury to self or others). The organizational approach should include the consideration and feasibility of less restrictive alternative treatment interventions.**
 - **Rationale:** In recent years, there has been an increased focus on restraint - and seclusion-related injuries and death. Since the JCAHO began tracking sentinel events in 1996, it reviewed 20 sentinel event cases related to deaths of patients who were physically restrained. The cause of death was asphyxiation in 40 percent of the cases. The remainder of the cases were caused by strangulation, cardiac arrest, or fire. The severity of injuries associated with the use of restraints highlights the importance of considering restraints only in emergency situations and after early intervention with less restrictive methods have been considered. The leadership standard at the JCAHO for restraint use is based on prevention, preferred interventions, and patient/resident dignity.
 - **Supporting Literature and/or Standards:** JCAHO Performance Improvement Standards, 4/99; American Hospital Association (AHA) and National Association of Psychiatric Health Systems (NAPHS): Guiding Principles on Restraint and Seclusion for Behavioral Health Systems, 2/25/99; Statement of National Alliance for the Mentally Ill (NAMI) before the Labor, Health and Human Services and Education Subcommittee, Senate Committee on Appropriations, 4/13/99; Department of Mental Health (DMH), 104CMR 27.12 and Bill #MA99RSB 569, 12/2/98; JCAHO Sentinel Event Alert, 11/18/98; HCFA 54FR5359, Section 483.13 Resident Behavior and Facility Practice.
2. **When appropriate, promote safe restraint or seclusion use that values and incorporates risk assessment, early intervention, and patient/resident and responsible party input.**
 - **Rationale:** Thoughtful assessment regarding the use of restraints and seclusion requires strong leadership to shape the culture of the organization. Establishing a system for assessing and understanding the needs of patients before they enter treatment is critical to providing the most appropriate and least restrictive care. Using the least restrictive and safest method is determined by the individual's assessed needs and the effective or ineffective methods previously used on the individual (e.g., informational histories).

- **Supporting Literature and/or Standards:** JCAHO Performance Improvement Standards, 4/99; AHA and NAPHS; Guiding Principles on Restraint and Seclusion for Behavioral Health Systems, 2/25/99; Statement of NAMI before the Labor, Health and Human Services and Education Subcommittee, Senate Committee on Appropriations, 4/13/99; DMH, 104CMR 27.12 and Bill #MA99RSB 569, 12/2/98; Executive Office of Health and Human Services (EOHHS) Report of the Work Group on Physical Restraint of Children, 12/22/98 JCAHO Sentinel Event Alert, 11/18/98.

Best Practice Recommendations To Improve Patient Safety Related to Restraint & Seclusion Use

- 1. Promote the appropriate use of restraints and seclusion by ensuring there are well trained and an adequate number of staff to handle the complexities of the population served by the organization. All staff involved with patients or residents (e.g., physicians, nurses, other licensed professionals, all unlicensed staff, and security) should have new staff orientation and annual training related to restraints and seclusion. The training should include appropriate use of restraints and seclusion, crisis prevention techniques, and use of least restrictive treatment alternatives that help to de-escalate a situation and avoid restraint or seclusion use. A component of staff training programs should ensure staff competency in restraint and seclusion use.**

Rationale: There is considerable support for the idea that substantial risk, such as personal injury and physical assault, could be significantly reduced with staff orientation and ongoing education programs. These programs should be aimed at teaching non-restrictive and non-authoritarian ways of interacting with patients, alternatives to unnecessary confrontational approaches and power struggles, effective de-escalation methods, and CPR and first aid in the event of an unexpected injury.

Supporting Literature and/or Standards: JCAHO Performance Improvement Standards, 4/99; AHA and NAPHS; Guiding Principles on Restraint and Seclusion for Behavioral Health Systems, 2/25/99; DMH, 104CMR 27.12 and Bill #MA99RSB 569, 12/2/98; EOHHS Report of the Work Group on Physical Restraint of Children, 12/22/98; HCFA 54FR5359, Section 483.75 Administration.

- 2. Implement a strategy that includes a comprehensive clinical assessment at the initial point of contact, during behavioral changes, before restraint application, and after a restraint is removed or the person is removed from seclusion. Identify a strategy that helps to reduce the patient/resident's health and safety risks, assess their environment, promote the reduction of restraint and seclusion use, and determine their vulnerabilities to restraints or seclusion. The assessment strategy and collected patient/resident information should be part of the treatment plan. The assessment should determine:**
 - a) If the need for a restraint or seclusion is based on behavioral or medical problems. (e.g., check for medication contraindication or side effects, infection, hydration status, and bowel and bladder needs);**
 - b) any special procedures necessary for handling patients at increased risk of injury or death, or who have experienced psychological trauma, (e.g., children, adolescents, elderly, developmentally disabled, patients under the influence of anesthesia, drugs, or alcohol); and**
 - c) Any special procedures necessary for the special handling of restrained patients who smoke, have deformities, or are in the supine or prone positions.**

- **Rationale:** Potential risk factors have been associated with age, gender, medical and psychiatric condition, and history. Concerns about trauma associated with the use of restraints or seclusion highlight the importance of developing special procedures for handling patients at risk of injury or death. Systems should be modified to ensure that informational patient histories are available at intake. The assessment process should include a determination of historical physical, sexual, or substance abuse, aggressive or assaultive behavior, previous restraint experience, history of trauma, particular approaches or strategies that have been most helpful in reducing agitation and distress, as well as input by patients and responsible parties. Additionally, medical conditions such as dementia, head trauma, neurological problems, and substance withdrawal should be clearly noted.
- **Supporting Literature and/or Standards:** JCAHO Performance Improvement Standards, 4/99; AHA and NAPHS; Guiding Principles on Restraint and Seclusion for Behavioral Health Systems, 2/25/99; DMH, 104CMR 27.12 and Bill #MA99RSB 569, 12/2/98; EOHHS Report of the Work Group on Physical Restraint of Children, 12/22/98; JCAHO Sentinel Event Alert, 11/18/98; HCFA 54FR5359, Section 483.20 Comprehensive Assessment.

3. Develop and distribute to all staff involved with patients or residents (e.g., physicians, nurses, other licensed professionals, and unlicensed staff) guidelines that will help determine the need for restraint or seclusion use. While only licensed independent practitioners may order a restraint or seclusion, guidelines should be available to all staff that are in direct contact with patients or residents. Guidelines should emphasize use of the least restrictive method and include:

- 1. Decision points for determining when patients should move from no restraints to restraint or seclusion use;**
- 2. Special procedures for handling patients at increased risk of injury or death, or who have experienced psychological trauma, (e.g., children, adolescents, elderly, developmentally disabled, patients under the influence of anesthesia, drugs, or alcohol);**
- 3. Procedures for the special handling of restrained patients who smoke, have deformities, or are in the supine or prone positions; and**
- 4. Direction and examples of appropriate episode documentation.**

- **Rationale:** Studies on the causes of restraint- and seclusion-related injuries point to a need for guidelines or action steps that staff may follow in the determination to go from no restraint use to the next least restrictive alternative(s) and finally to full restraint use.
- **Supporting Literature and/or Standards:** JCAHO Performance Improvement Standards, 4/99; AHA and NAPHS; Guiding Principles on Restraint and Seclusion for Behavioral Health Systems, 2/25/99; Statement of NAMI before the Labor, Health and Human Services and Education Subcommittee, Senate Committee on Appropriations, 4/13/99; EOHHS Report of the Work Group on Physical Restraint of Children, 12/22/98.

4. Incorporate into quality improvement programs a system for routinely monitoring the safe use of restraints and seclusion and evaluating ways to reduce their use.

- **Rationale:** There is a need for the development of a comprehensive plan for monitoring performance improvement that includes appropriate goals for reducing use of restraints as well as collecting and analyzing aggregate data for trends, efficacy, and appropriateness. The plan should include the management of concerns and complaints from consumers and families regarding their experience with restraints and seclusion. Accountability for monitoring performance improvement

of restraint use and seclusion should be established through an organization’s performance improvement program.

- **Supporting Literature and/or Standards:** AHA and NAPHS; Guiding Principles on Restraint and Seclusion for Behavioral Health Systems, 2/25/99; EOHHS Report of the Work Group on Physical Restraint of Children, 12/22/98.

5. Educate patients/residents and their responsible party, upon admission or as soon as possible, about the organization’s restraint and seclusion reduction efforts and feedback process which include the:

- 1. risks of using restraints and seclusion;**
- 2. encouragement of alternatives to restraint or seclusion use;**
- 3. engagement of the patient and responsible party in the development of the treatment plan; and**
- 4. process for informing the responsible party of a restraint or seclusion episode (when appropriate).**

- **Rationale:** Involvement of patients and their responsible party in discussions about restraint or seclusion use is an important component in the development of a comprehensive treatment plan.
- **Supporting Literature and/or Standards:** JCAHO Performance Improvement Standards, 4/99; AHA and NAPHS, Guiding Principles on Restraint and Seclusion for Behavioral Health Systems, 2/25/99; Statement of NAMI before the Labor, Health and Human Services and Education Subcommittee, Senate Committee on Appropriations, 4/13/99; JCAHO Draft Restraint and Seclusion Standards for Behavioral Health Care, Field Evaluation, 11/99.

DEFINITIONS FOR RESTRAINT & SECLUSION

Presented below are the definitions from HCFA, JCAHO, and DMH.

PHYSICAL and MECHANICAL RESTRAINTS

HCFA	8/13/99	“Any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient’s body that he/she cannot easily remove that restricts freedom from movement or normal access to one’s body.” ¹
JCAHO	1999-2000	“Any method of physically restricting a person’s freedom of movement, physical activity, or normal access to his or her body.” ²
DMH	12/2/98	“Any manual method or physical or mechanical device that restricts freedom of movement or normal access to one’s body, material, or equipment, attached or adjacent to the patient’s or resident’s body that he or she cannot easily remove.” ³
Examples & Clarifications		<ul style="list-style-type: none"> • Examples of physical restraints are trunk restraint (waist or vest), limb restraint (belt, crotch, or wrist restraints), gerichairs, mitts, pelvic rollbars, houdinis, halters, and full bed rails (which are used to restrain rather than enable), other types of bed rails (e.g., one-side half rail, one-side full rail, two-sided half rails). This definition includes locked wheelchairs, recliners, beanbag chairs, comfort cushions, or merry walkers (if the patient or resident cannot get up by himself/herself), and a tab at the front of the resident that prevents rising.

	<ul style="list-style-type: none"> • Devices or equipment used to facilitate mobility is not a restraint. • According to HCFA, “side rails may be appropriate when used to assist the resident maintain or attain or her highest practicable level of physical, mental and psychosocial functioning. The decision regarding whether to raise the side rails need to be made after clinical evaluation at the bedside interdisciplinary care planning. The purpose for that intervention must be determined. That is, if purpose is either to facilitate in-bed mobility and/or transfer, the side rails are not being used for purpose of restraining the resident. If the purpose and effect of the side rail is to prevent a resident from getting out of bed when that resident wants to get out of bed, then side rails are being used as restraints.” • According to HCFA, “when an alert, oriented resident requests side rails, the facility may honor request. This use of side rails is not considered a restraint, but the practice needs to be re-evaluated periodically to ensure that the continued use of the device does not place the resident at increased risk of injury. The resident, who is in a persistent vegetative state, or who is incapable of purposeful movement may have side rails that are not considered restraints because the side rails does not restrict the resident’s movement in some way.”
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CHEMICAL RESTRAINTS

HCFA 8/13/99	“A medication used to control behavior or to restrict the patient’s freedom of movement and is not a standard treatment for patient’s medical or psychological condition.” ¹
JCAHO 1999-2000	“The inappropriate use of a sedating psychotropic drug to manage or control behavior.” ²
DMH 12/2/98	<p>“Occurs whenever a patient is given medication involuntarily for the purpose of restraining the patient. Chemical restraint shall not include:</p> <ul style="list-style-type: none"> a) Involuntary administrations of medication when administered in an emergency to prevent immediate, substantial and irreversible deterioration of serious mental illness, or b) For other treatment purposes when administered pursuant to a court approved substituted judgement treatment plan.³

SECLUSION

HCFA 8/13/99	“Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.” ¹
JCAHO 1999-2000	“Seclusion is the involuntary confinement of a person alone in a room where the person is physically prevented from leaving.” ²
DMH 12/2/98	<p>Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.* Seclusion occurs whenever a patient is both confined and isolated in any one of the three following situations:</p> <ul style="list-style-type: none"> • Closed Door – Physically or Mechanically Maintained • Open Door in Isolated Room – Physically Maintained • Closed Door or Open Door in Isolated Room – Other <p>*For facilities licensed as Class VI or VIII and for units with patients under 19 years of age, open door seclusion does not occur when a patient is placed in his or her room, or in a designated place as part of a “time out” procedure approved in the behavior management plan and the patient’s treatment plan.³</p>

EMERGENCY BASIS for RESTRAINTS and SECLUSION

HCFA 8/13/99	“Seclusion or restraint can only be used in emergency situations if needed to ensure the patient’s physical safety and less restrictive measures have been determined to be ineffective.” ¹
JCAHO 1999-2000	“Restraint or seclusion may be used in response to emergent, dangerous behavior, addictive disorders; as an adjunct to planned care; as a component of an approved protocol; or, in some cases, as part of standard practice.” ²
DMH 12/2/98	“Chemical restraint, mechanical restraint, physical restraint or seclusion may only be used in cases of emergency, such as the occurrence of, or serious threat of, extreme violence, personal injury, or attempted suicide.” ³

¹ “Crosswalk of HCFA Conditions of Participation: Patients’ Rights; Interim Final Rule July 2, 1999 with the 1999 Comprehensive Accreditation Manual for Hospitals”, Revised Draft, 8/13/99.

² “Comprehensive Accreditation Manual for Behavioral Health Care, Standards for Restraint and Seclusion”, 1999-2000.

³ DMH 104CMR 27.12, 12/2/98.

⁴ “Side Rails Interim Policy”, Memorandum dated February 10, 1997, from Robert Streimer, Acting Deputy Bureau Director for Survey and Certification, Health Standards and Quality.