**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0640

**Measure Title**:  Hours of physical restraint use

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: 12/20/2018

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Click here to name what is being measured

Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

The focus of the measure is to evaluate the use of physical restraints for all patients hospitalized in a psychiatric care setting to help health care organizations develop appropriate behavioral interventions to reduce their use. The reduction in the use of physical restraints will lead to a reduction in patient and staff injuries, shorter lengths of stay and decreased costs to the health care industry.

**1a.3** **Value and Meaningfulness:**  **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

Not applicable

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

Not applicable

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

☐ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

Updated literature search did not yield any new guidelines or significant research related to restraint use that would warrant a change in the measure.

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | **Title:** Guiding Principles on Restraint and Seclusion for Behavioral Health Services  **Author: T**he American Hospital Association (AHA) and the National Association of Psychiatric Health Systems (NAPHS)  **Date:** 1999  **Citation, including page number**  American Hospital Association (AHA) & National Association of Psychiatric Health Systems (NAPHS). (1999). Guiding Principles on Restraint and Seclusion for Behavioral Health Services.  **URL:**  https://direitosp.fgv.br/sites/direitosp.fgv.br/files/anexo\_c\_-\_guiding\_principles\_on\_restraint\_and\_seclusion.pdf  **URL:** Retrieved on March 23, 2012 at: https://www.naphs.org/news/guidingprinc?&printview=1  **Rationale for Using this Guideline Over Others:** The NAPHS and AHA are two premier organizations committed to working with consumers, families, regulatory and accrediting agencies, Congress, and others to ensure that the systems designed to protect patients are working, and that clear and appropriate guidelines and standards are in place to protect patients and maintain their dignity related to appropriate restraint and seclusion use. |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | Guiding Principles on Restraint and Seclusion for Behavioral Health Services  Restraint and seclusion, when used properly, can be life-saving and injury-sparing interventions.   * A patient´s overall treatment is based on a comprehensive, individualized treatment plan that includes appropriate patient and family involvement.   • Hospitals and other treatment settings serve individuals with severe mental illnesses and substance abuse problems who are, at times, dangerous to themselves or others.  • Restraint and seclusion should be used as infrequently as possible, and only when less restrictive methods are considered and are not feasible.  • Restraint and seclusion are emergency interventions that aim to protect patients in danger of harming themselves or others and to enable patients to continue treatment successfully and effectively.  Prevention of injury and death is essential.  • Hospitals and other treatment settings must ensure that staff is well-trained and continuously educated regarding the proper use of restraint and seclusion. Detailed policies, procedures, and systems must be developed with input from physicians and other mental health professionals, and they must be understood and followed by all staff. Areas include:  ~ assessment and crisis prevention techniques  ~ use of least restrictive methods  ~ how to employ restraint and seclusion safely (including understanding the risks and benefits of either intervening or not intervening)  ~ a process for continuously reevaluating the need for restraint or seclusion  ~ a process for continuous monitoring to ensure the patient´s safety and other needs are met  • A physician (or other licensed practitioner as permitted by state law) should authorize use of restraint or seclusion in a timely manner. This licensed clinician must be involved in the decision to continue the use of restraint or seclusion.  • Policies and procedures should be reviewed and updated continuously based on clinical outcomes.  • Because these techniques have a potential for causing injury or death, restraint and seclusion policies must be a system-wide resource priority. Adequate allocation of resources and appropriate decision-making guidelines within the institution must be in place.  • Consideration should be given to the safe and appropriate use of medication as an alternative to restraint and seclusion and in reducing the length of any episode.  Appropriate oversight of restraint and seclusion is important.  • Federal protections are in place through accreditation and regulatory bodies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)\* and the Health Care Financing Administration\* and should be supported.  • \*Note: The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is now The Joint Commission. Health Care Financing Administration is now the Centers for Medicare and Medicaid Services (CMS).  • State laws, rules, and regulations enforced through departments of public and mental health and state licensure agencies also protect patients´ rights and should be used to assure appropriate use of restraint and seclusion.  • Overregulation based on narrowly defined problems could divert limited resources to bureaucratic activities. Patients are best served when maximum dollars are devoted to appropriate clinical care. |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | **System Used for Grading the Body of Evidence:** Other  **If other, identify and describe the grading scale with definitions:** Although grading of the evidence was not determined during the systematic review, it was determined that the guideline developers accounted for a balanced representation of information, looked beyond one specialty group or discipline, and provided information that was accessible and met the requirements set out in the NQF criteria. |
| Provide all other grades and definitions from the evidence grading system | **Grade Assigned to the Body of Evidence:** Not Applicable |
| Grade assigned to the **recommendation** with definition of the grade | **Grading of Strength of Guideline Recommendation.** Has the recommendation been graded?No  **System Used for Grading the Strength of Guideline Recommendation:** Other  **If other, identify and describe the grading scale with definitions:** None identified |
| Provide all other grades and definitions from the recommendation grading system | **Grade Assigned to the Recommendation:** Not Applicable |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | **Directness of Evidence to the Specified Measure**  This measure is consistent with the guiding principles on restraint/seclusion recommended by the American Hospital Association (AHA) and the National Association of Psychiatric Health Systems (NAPHS) to develop strategies to reduce the use of restraint and seclusion in behavioral health. Leadership and culture, staff education, assessment and treatment planning, milieu management and early intervention are key aspects of a program addressing restraint use. The focus of the performance measure is to identify the prevalence of physical restraint use, so that a determination can be made if there is an opportunity to reduce use as recommended by the body of evidence.  **Quantity:** In a Cochrane review of containment strategies for patients with serious mental illness (SMI) conducted in 1999, over 2,000 citations for restraint and seclusion were found in the literature.  **Quality:** The quality of evidence supporting a reduction in the use of restraint and seclusion is moderate. It is noteworthy that no randomized control trials have been conducted which support the continued use of restraint and seclusion. There is no way to provide randomized controlled trial data on restraint and seclusion use, as it would be inhumane to do the experiment. The logic and validity of this measure is inherent and the life threatening nature of improper restraint and the traumatic nature of restraint and seclusion are well documented in the Recovery literature. The evidence supports the need for alternative methods of dealing with unwanted or harmful behaviors. As noted above, the AHA and NAPHS have had guidelines in place since 1999 addressing the key aspects of a program addressing restraint and seclusion use. In spite of the fact that all studies reviewed were either observational, case-control or retrospective studies, no study design flaws were noted.  **Summary of Controversy/Contradictory Evidence:** There is no documented evidence regarding controversy related to reducing the use of restraint and seclusion in behavioral health. A review of recent studies also supports the use of behavioral interventions to diffuse aggressive and violent behaviors to reduce restraint and seclusion use. No position advocating increased restraint and seclusion use as a method of controlling unwanted or harmful behavior was identified in the literature.  **Based on the NQF descriptions for rating the evidence, what was the developer’s assessment of the quantity, quality, and consistency of the body of evidence?**  Quantity:High  Quality:Moderate  Consistency**:** High |
| Estimates of benefit and consistency across studies | **Benefit:** A reduction in the use of physical restraint and seclusion will improve patient safety, reduce overall organizational costs, leading to a decrease in staff and patient injuries, staff turnover and increased staff productivity. Focusing on behavioral interventions to defuse aggressive and violent behaviors will result in less retraumatization for patients with trauma histories leading to shortened length of stays and improved recovery. As previously noted, one public psychiatric facility demonstrated a 46% reduction in restraint after implementing the Nonviolent Crisis Intervention® training program. Additionally, another hospital studied the economic benefit of reducing restraint use and noted a 91% reduction in costs.  **Consistency:** The body of evidence consistently supports the benefit of reducing restraint and seclusion use. The studies consistently support the need for health care organizations to develop appropriate behavioral interventions to reduce their use. No position advocating increased restraint and seclusion use as a method of controlling unwanted or harmful behavior was identified in the literature. |
| What harms were identified? | No harms to the patient receiving a behavioral intervention instead of using restraints or seclusion were found during the literature review. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | An updated search conducted in 2006 yielded an additional 2800 citations. All of the studies identified were observational, case-control or retrospective reviews. No randomized control trials (RCTs) were identified. In another Cochrane review of seclusion and restraint for people with SMI conducted in 1999, over 2155 citations were found. Again, no RCTs were identified. |

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**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

Not applicable for this submission

**1a.4.2 What process was used to identify the evidence?**

Not applicable for this submission

**1a.4.3.** **Provide the citation(s) for the evidence.**

Not applicable for this submission

**From previous submission:**  **Citations for Evidence other than Guidelines *(Guidelines addressed below)*:**

• Bergk, J., Einsiedler, B. & Steinert, T. (2008) Feasibility of randomized controlled trials on seclusion and restraint. Clinical Trials. 5: 356-363.

• Besemer, D., Siler, J. and Vargas, LA. (2008). Sanctuary longitudinal study: Innovation, collaboration and frustration. Paper presented at the Alliance for Children and Families National Conference, Baltimore.

• Canadian Institute for Health Information. (2011). Restraint Use and Other Control Interventions for Mental Health Inpatients in Ontario. Retrieved March 23, 2012 at: http://secure.cihi.ca/cihiweb/products/Restraint\_Use\_and\_Other\_Control\_Interventions\_AIB\_EN.pdf

• Cromwell, J., Gage, B., Drozd, E., Maier, J., Osber, D., Evensen, C., et al. (2005). Psychiatric inpatient routine cost analysis. Centers for Medicare and Medicaid Services, Baltimore.

• Curie, CG. (2005). SAMHSA’s commitment to eliminating the use of seclusion and restraint. Psychiatric Services. 56:9, 1139-1140.

• Flood, C., Bowers, L., & Parkin, D. (2008). Estimating the costs of conflict and containment on adult acute inpatient psychiatric wards. Nursing Economic$, 26(5), 325–330.

• Florida TaxWatch. (2008). Florida State Hospital—Chattahoochee wins award for reduced patient seclusion and restraint. Adaptable achievements from the 2007 Prudential Financial Davis Productivity Awards competition. Retrieved March 13, 2012, from http://www.floridataxwatch.org/resources/pdf/TaxWatchDPA2007MGPweb.pdf.

• Friedman, RA. (2006). Violence and mental illness. N Engl J Med. 335, 20. 2064-2066.

• General Accounting Office [GAO]. (1999a). Mental health: Improper restraint or seclusion use places people at risk. (GAO/HES-99-176). Washington, DC: United States

• General Accounting Office. General Accounting Office [GAO]. (1999b). Extent of risk from improper restraint or seclusion is unknown. (GAO/T-HEHS-00-26). Washington, DC: United States General Accounting Office.

• Haimowitz, S., Urff, J., & Huckshorn, K A. (2006). Restraint and seclusion: A risk management guide. Alexandria, VA, National Association of State Mental Health Program Directors.

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• Institute of Psychiatry [IOP]. (2002). The recognition, prevention and therapeutic management of violence in mental healthcare, UKCC, London, UK. Retrieved on March 13, 2012, from http://www.positive-options.com/news/downloads/UKCC\_-Therapeutic\_Management\_of\_Violence\_-\_summary\_-\_2002.pdf.

• Knutzen, M., Mjosund, NH., Eidhammer, G., Lorentzen, S., Opjordsmoen, S, Sandvik, L. & Friis, S. (2011) Characteristics of psychiatric inpatients who experienced restraint and thoses who did not: a case-control study.Psychiatric Services. 62:5, 492-496.

• LeBel, J., & Goldstein, R. (2005). The economic cost of using restraint and the value added by restraint reduction or elimination. Psychiatric Services, 56(9), 1109–14.

• LaFond, R. (September 2007). Reducing seclusion and restraint for improved patient and staff safety. Journal of Safe Management of Disruptive and Assaultive Behavior. 8-12.

• McCue, R., Urcyo, L., Lilu, Y., Tobias, T. & Chambers, M. (2004). Reducing restraint use in a public psychiatric inpatient service. Journal of Behavioral Health Services & Research, 31(2), 217-224.

• Mead, H., Cartwright-Smith, L., Jones, K., Ramos, C., Siegel, B. & Woods, K. (2008) The Commonweath Fund: Racial and ethnic disparities in U.S. health care: a chartbook. Retrieved on March 7, 2012 at: www.commonwealthfund.org

• National Association of State Mental Health Program Directors. (1999) Position Statement on Seclusion and Restraint. Alexandria, VA: NASMHPD.

• Paxton, D. (2009). Creating and supporting coercion-free and violence-free treatment environments: The Village Network and the Knox County Children’s Resource Center restraint reduction effort. Paper presentation. Columbus, OH: Ohio Association of Child Caring Agencies Learning Community conference.

• Richter, D., & Whittington, R. (Eds.). (2006). Violence in mental health settings: Causes, consequences, management. New York: Springer Science+Business Media, LLC.

• Short, R., Sherman, M E., Raia, J., Bumgardner, C., Chambers, A., & Lofton, V. (2008). Safety guidelines for injury-free management of psychiatric inpatients in precrisis and crisis situations, Psychiatric Services 59(12), 1376–1378.

• Smith, GM., Davis, RH., Bixler, EO., Lin, HM., Altenor, RJ., Hardentstine, BD. et al. (2005). Pennsylvania state hospital system’s seclusion and restraint reduction program. Psychiatric Services. 56:9, 1115-1122.

• Stokowski, L. (2007). Alternatives to restraint and seclusion in mental health settings: questions and answers from psychiatric nurse experts. Medscape. Retrieved on March 22, 2012 at: http://www.medscape.com/viewarticle/555686

• Substance Abuse and Mental Health Services Administration. The Business Case for Preventing and Reducing Restraint and Seclusion Use. HHS Publication No. (SMA) 11-4632. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2011.

• Success Stories and Ideas for Reducing Restraint/Seclusion. (2003). A compendium of strategies created by the American Psychiatric Association (APA), the American Psychiatric Nurses Association (APNA), the National Association of Psychiatric Health Systems (NAPHS), and the American Hospital Association Section for Psychiatric and Substance Abuse Services (AHA). Retrieved on March 9, 2012 at http://www.naphs.org

• The Joint Commission. (2011). Sentinel Event Data - Root Causes by Event Type. Retrieved March 20, 2012 at: http://www.jointcommission.org/Sentinel\_Event\_Statistics/

• The Joint Commission, unpublished data, 2012.