Evidence Synthesis Program

Protocols to Reduce Seclusion in Inpatient Mental Health Units

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This report was prepared by the Evidence Synthesis Program Center located at the **VA Providence Health Care System,** directed by Eric Jutkowitz, PhD and James Rudolph, MD and funded by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development.

PREFACE

The VA Evidence Synthesis Program (ESP) was established in 2007 to provide timely and accurate syntheses of targeted health care topics of importance to clinicians, managers, and policymakers as they work to improve the health and health care of Veterans. These reports help:

- Develop clinical policies informed by evidence;
- Implement effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- Set the direction for future research to address gaps in clinical knowledge.

The program comprises 4 ESP Centers across the US and a Coordinating Center located in Portland, Oregon. Center Directors are VA clinicians and recognized leaders in the field of evidence synthesis with close ties to the AHRQ Evidence-based Practice Center Program. The Coordinating Center was created to manage program operations, ensure methodological consistency and quality of products, interface with stakeholders, and address urgent evidence needs. To ensure responsiveness to the needs of decision-makers, the program is governed by a Steering Committee composed of health system leadership and researchers. The program solicits nominations for review topics several times a year via the program website.

The present report was developed in response to a request from the VA Office of Mental Health and Suicide Prevention (OMHSP). The scope was further developed with input from Operational Partners (below), the ESP Coordinating Center, the review team, and the technical expert panel (TEP). The ESP consulted several technical and content experts in designing the research questions and review methodology. In seeking broad expertise and perspectives, divergent and conflicting opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Ultimately, however, research questions, design, methodologic approaches, and/or conclusions of the review may not necessarily represent the views of individual technical and content experts.

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Operational Partners

Operational partners are system-level stakeholders who help ensure relevance of the review topic to the VA, contribute to the development of and approve final project scope and timeframe for completion, provide feedback on the draft report, and provide consultation on strategies for dissemination of the report to the field and relevant groups.

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Technical Expert Panel

To ensure robust, scientifically relevant work, the TEP guides topic refinement; provides input on key questions and eligibility criteria, advising on substantive issues or possibly overlooked areas of research; assures VA relevance; and provides feedback on work in progress. TEP members are listed below:

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The Coordinating Center sought input from external peer reviewers to review the draft report and provide feedback on the objectives, scope, methods used, perception of bias, and omitted evidence (see Appendix K for disposition of comments). Peer reviewers must disclose any relevant financial or non-financial conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The Coordinating Center works to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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ABBREVIATIONS TABLE

aOR	Adjusted odds ratio
BCW	Behavior change wheel
CI	Confidence interval
ESP	Evidence Synthesis Program
EssenCES	Essen Client Evaluation Schema
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HR	Hazard ratio
KQ	Key questions
HBIPS	Hospital-based inpatient psychiatric services
MeSH	Medical subject headings
N	Sample size
NR	Not reported
NS	Not significant
NRCS	Nonrandomized comparative study
OMHSP	Office of Mental Health and Suicide Prevention
PCC	Patient-staff conflict checklist
PCC-SR	Patient-staff conflict checklist shift reports
RCT	Randomized controlled trial
RoB	Risk of bias
RR	Relative risk
SD	Standard deviation
TEP	Technical expert panel
US	United States
VA	Veterans Affairs
VHA	Veterans Health Administration

EVIDENCE REPORT

INTRODUCTION

PURPOSE

The Veterans Affairs (VA) Evidence Synthesis Program (ESP) was asked by the VA Office of Mental Health and Suicide Prevention (OMHSP) for an evidence review on protocols to reduce seclusion practices for adults ≥18 years of age hospitalized in inpatient mental health units. Previous systematic reviews have found limited benefits of seclusion, raising ethical concerns with the continued use of these practices. A 2017 report commissioned by the Joint Commission found that VA hospitals use more seclusion than non-VA hospitals. In response to the Joint Commission report, OMHSP developed a seclusion and restraint reduction toolkit, which was credited with a voluntary reduction in seclusion practices within the VA. OMHSP is in the process of updating the national Inpatient Mental Health Directive. This evidence review will inform the Inpatient Mental Health Directive and determine whether some level of seclusion practices provide benefit or if the harms merit a complete ban, relative to alternative practices.

BACKGROUND

In psychiatric inpatient settings, conflict behaviors such as patient aggression, agitation, self-harm, and other potentially dangerous behaviors require immediate intervention to prevent physical and emotional injury to the patient, other patients, and staff.[1] Conflict behaviors also contribute to staff stress and burnout.[2,3] There are limited data on the incidence of challenging or dangerous behaviors in inpatient settings, with estimates varying from 8% to 76%.[4] The large variation in estimates is, in part, due to ambiguous definitions of these behaviors and lack of processes for standardized reporting.[4,5] Managing aggression, agitation, and other potentially dangerous behaviors is challenging because it requires balancing the autonomy and safety needs of the patient with other individuals who may be impacted by the patient.[6]

Seclusion is 1 type of intervention that is used to manage conflict behaviors that place patients and staff at risk of immediate harm.[7] Although definitions in the literature vary, seclusion generally is recognized as involuntarily confining a patient alone in a locked room or restricted area until the patient's conflict behaviors subside.[8] How seclusion is implemented can vary significantly across settings. For example, the characteristics of the restricted area can vary (*eg,* furnished or unfurnished room), and seclusion may or may not be combined with other involuntary interventions such as physical restraints or pharmacological methods.[9]

There are few randomized controlled trials (RCTs) examining the benefits and harms of seclusion.[10-13] There is widespread ethical concern that seclusion is a coercive[a] practice that violates patients' rights and autonomy and some evidence that patients prefer forced medication over seclusion.[9,14-16] Staff also have negative perceptions of seclusion.[17] In addition,

[a] We use the term "coercion" in this report without judgment or intention of implying clinician stigma. Rather, we use this term to be consistent with our observations of how the literature describes a group of measures that may be applied "against the patient's will or in spite of his or her opposition" (such as seclusion, restraint, and forced medication) to manage patient care (Chieze 2021). If a study reported coercion as a composite outcome in their results (*ie,* a combined outcome of seclusion and other coercive measures), we report the study definition of coercion. If the study did not report the definition of coercion, we indicate it was not reported.

epidemiologic and quasi-experimental studies have found that seclusion may cause harms to patients including exacerbation of post-traumatic stress symptoms, emotional distress, negative attitudes toward psychiatric treatment,[18] and increased length of stay.[11,19-22] Furthermore, the practical act of placing patients in seclusion may expose staff to additional risk of injury and can cause staff to experience emotional distress.[23,24]

In 2008, the Joint Commission established the Hospital-Based Inpatient Psychiatric Services (HBIPS) measure set which includes hours of seclusion per 1,000 patient hours as a quality measure.[25] Data from hospitals reporting HBIPS show large variation in the use of seclusion across the United States (US).[26,27] For example, in 2014, psychiatric facilities in the US reported using seclusion for an average 0.3 (standard deviation [SD] 0.8) per 1,000 patient hours with a wide interquartile range (0.02 to 0.22).[26] When these data were stratified by hospital type, for-profit psychiatric hospitals used seclusion for the least amount of patient hours (mean 0.1 [SD 0.7], interquartile range: 0.002 to 0.1) and VA hospitals used it the most (mean 0.4 [SD 0.8], interquartile range: 0.0 to 0.3). It is important to note that these estimates do not account for patient case-mix, which may vary substantially across settings (leading to more or less aggressive or agitated behaviors potentially requiring seclusion). Less is known about the practical implementation of seclusion practices (*eg,* space and personnel resources associated with its use, or context-specific factors that may lead to greater or lesser use).

Over time, seclusion has increasingly been viewed as an intervention of last resort and there are multiple policy initiatives to reduce seclusion.[27-30] This includes the Veterans Health Administration (VHA) Handbook 1160.06, which states that "seclusion and restraint are interventions of last resort" and directs clinicians in inpatient units to explore ways to prevent, reduce, and eliminate seclusion.[30] However, reducing clinicians' use of seclusion requires safe and effective alternative intervention(s) to replace seclusion. Safewards is an example of a protocol to reduce seclusion and consists of a package of intervention strategies that target conflict-originating factors, flashpoints that indicate imminent conflict behaviors, and the link between flashpoints and conflict behaviors.[31] Examples of Safewards interventions include mutually agreed upon standards of behavior by and for staff, short advisory statements on handling flashpoints, distraction and sensory modulation tools to use with agitated patients, displays of positive messages around the ward for patients, and implementation of de-escalation plans.

Multiple inpatient unit-level policies, which we define in this review as protocols, have been devised to help reduce challenging patient behaviors that precede seclusion in an effort to reduce seclusion itself or help staff manage challenging patient behaviors when they occur; yet the effect of protocols on patient and staff outcomes and the resource needs required to implement these protocols remain unclear.[11-13,32] We therefore conducted a systematic review on protocols to reduce seclusion for adult patients in inpatient mental health units. In this report, we describe protocols and synthesize the evidence of the effects of the protocols in terms of high-priority clinical outcomes, resource utilization, and staff outcomes to help guide decision-making.

METHODS

TOPIC DEVELOPMENT

We worked with representatives from OMHSP and our technical expert panel (TEP), which included individuals from OMHSP, the VA Office of Nursing Services, and VA Inpatient Mental Health Program, to refine the review scope and develop the key questions (KQs). We focus on studies that report protocols to reduce seclusion practices for adult patients in inpatient mental health units. We define protocols as guidance documents or strategies recommended or already employed as alternatives to seclusion. Protocols needed to include multiple components or a general overall policy to reduce seclusion. We define seclusion as the use of involuntary time restricted to a space physically removed from other patients.

KEY QUESTIONS

KQ1: What protocols have been described to reduce seclusion practices for adult patients in inpatient mental health units?

KQ1.1: What are the described resource needs (such as personnel and space needs) of these protocols?

KQ2: What are the comparative effects of protocols to reduce seclusion practices on resource use, staff and unit practices, patient experiences, and staff experiences versus usual protocols?

PROTOCOL

A preregistered protocol for this review can be found on the PROSPERO international prospective register of systematic reviews (www.crd.york.ac.uk/PROSPERO/; registration number CRD42022363787).

DATA SOURCES AND SEARCHES

We conducted a preliminary search in PubMed which was focused on Medical Subject Headings (MeSH) terms for patient isolation and inpatient mental health, together with free text synonyms for both (identified from experts and a list of known relevant publications). Searches were expanded to capture additional terms identified in preliminary screening.

For our final searches, we searched PubMed, Embase, the Cochrane Register of Clinical Trials, PsycINFO, CINAHL, cairn.info, and ClinicalTrials.gov from date of inception to September 6, 2022 (see Appendix A for complete search strategies). Additional citations were identified from hand-searching reference lists of relevant systematic reviews and consultation with content experts. In addition to the above, for KQ1 we contacted VA experts to request relevant protocols (published or grey literature) on strategies to reduce seclusion practices.

STUDY SELECTION

Citations were uploaded into Endnote, where duplicates were removed. Remaining citations were uploaded into Abstrackr, abstract screening software (http://abstrackr.cebm.brown.edu).[33] Title and abstracts were reviewed for eligibility by a team of 8 researchers. To ensure

consistency and clarity of eligibility criteria, we held several pilot rounds of screening in which all team members screened the same set of titles and abstracts and any conflicts were resolved through discussion (Table 1). Subsequently, 2 independent reviewers screened titles and abstracts. Conflicts between screeners were resolved through group discussion or a third senior researcher.

Abstrackr uses machine learning algorithms to predict the likelihood that unscreened abstracts are relevant.[33] Based on empirical evidence, we stopped screening when all remaining unscreened abstracts had a prediction value of <0.40 (on a 0-1 scale), and subsequently 400 abstracts in a row were rejected. Full text of potentially relevant citations were obtained and rescreened for eligibility using an evidence mapping process by 1 researcher with confirmation of excluded articles by a second senior researcher. Although qualitative studies did not meet our eligibility criteria, they were noted of interest to the stakeholders, and thus isolated for bibliographic purposes during full-text review.

For KQ1, our focus was on reporting the characteristics/features of protocols to reduce seclusion in general inpatient psychiatric units for patients ≥18 years of age. Eligible records were either organizational documents of protocols to reduce seclusion or primary studies that described a protocol to reduce seclusion. These records did not have to report outcomes. To ensure relevance to the VA setting, we only included protocols produced by organizations in the US or Canada or protocols intended to be implemented in these countries for KQ1. Records had to describe protocols with a callout of how these may differ from usual seclusion protocols.

For KQ2, eligible populations were patients ≥18 years of age with psychiatric conditions being treated in hospital inpatient units or the frontline staff who worked in these units. Our focus was on the effects (or comparative effects) of protocols to reduce seclusion. To be included, studies had to compare protocols to reduce seclusion to some form of comparison (*eg,* another protocol to reduce seclusion or "usual care"). Recognizing the challenges of conducting RCTs and non-randomized controlled studies (NRCS) with concurrent control groups, we allowed for the inclusion of pre-post studies (*ie,* same unit assessed before and after the implementation of the protocol) to satisfy these criteria. We only included protocols intended to be implemented in the US or other high-income countries.[34]

For both KQ1 and KQ2, studies were excluded if they included incarcerated or institutionalized populations, as these settings and populations were outside the scope of interest to our stakeholders.

Table 1. Inclusion and Exclusion Criteria

	Inclusion Criteria	Exclusion Criteria
Population	• KQs 1 & 2: Adults with psychiatric conditions admitted (voluntary/involuntary) and being treated in hospital inpatient units • KQ2 (additional): Frontline staff and other psychiatric unit and hospital personnel	• Incarcerated • Institutionalized
Intervention	• Psychiatric unit-level protocols to reduce seclusion practices • Protocols to be defined by research study or organization guidance as strategies recommended (or already employed) as an alternative to seclusion. Protocols needed to include multiple components or a general overall policy to reduce seclusion (*ie,* not a single strategy only).	• KQs 1 and 2: Laws or regulations related to use/disuse of seclusion
Comparator	• KQ1: Not required explicitly (as KQ1 did not include an evaluation of protocols) but implicitly the protocols should be in contrast to seclusion practices. • KQ2: Usual seclusion protocols (*ie,* no protocol directly aimed at reducing or minimizing seclusion) ○ Example comparisons include: same unit pre-intervention (*ie,* pre-post protocols to reduce seclusion) or concurrent controls from other units that do not use protocols to reduce seclusion.	.

Outcomes	• KQ1: Descriptions of protocols, with explicit callout of how these may differ from usual seclusion protocols
	• KQ1.1: Center/unit/hospital resource use:
	  ○ Staffing needs and mix
	  ○ Environment (home-like vs clinical)
	  ○ Programming (*eg,* meaningful activities)
	  ○ Security personnel needs
	  ○ Space (*eg,* rooms) requirements
	  ○ Equipment needs
	  ○ Documentation needs (*eg,* patient engaged in treatment planning and update of treatment plan)
	  ○ Staff debriefings
	  ○ Other direct medical use
		• KQs 1.1 and 2: Dollar (or other currency) costs, hospital charges or payer costs, patient costs (direct or indirect), or other indirect costs/resources

Outcomes (continued)	• KQ2: Patient outcomes
	  ○ Injuries
	  ○ Aggressive incidents or behaviors
	  ○ Patient satisfaction with treatment (assessed post-hospitalization)	

	Inclusion Criteria	Exclusion Criteria
	○ Psychiatric medication use, either as needed, urgent/emergency, scheduled, or forced • KQ2: Staff outcomes ○ Staff/personnel injuries (including physical, emotional, or other harms to staff) ○ Staff/personnel satisfaction with policy ○ Debriefings (whether occurred and qualitative description) • KQ2: Process measures ○ Characteristics of seclusion events ▪ Episodes of seclusion ▪ Episodes of restraint ▪ Time in seclusion (per inpatient stay, and per episode) ▪ Time in restraint (per inpatient stay, and per episode) ○ Staffing ▪ Time to perform checks on patient ▪ Time to perform documentation ▪ Changes in other service provisions ○ Center/unit/hospital resource use ▪ Staffing needs and mix ▪ Security personnel needs ▪ Space (*eg,* rooms) requirements ▪ Equipment needs ▪ Documentation needs ▪ Other direct medical costs	
Timing	KQ1: Published since 2012 KQ2: No restrictions	
Setting	• In hospital inpatient units • KQ1: Produced by North American organizations or implemented or intended to be implemented in North America only • KQ2: High-income countries defined by the World Bank	• Emergency department, prisons, and outpatient settings • KQ1: Not produced by organizations in the US or Canada or implemented or not intended to be implemented in US or Canada • KQ2: Not intended to be implemented in US or other high-income countries

	Inclusion Criteria	Exclusion Criteria
Study Design	• KQ1: Organizational documents of protocols to reduce seclusion or intervention and observational studies (only for protocol descriptions) • KQ2: Comparative studies (pre-post same unit or comparison of units), interventional or observational, prospective or retrospective, surveys with explicit comparison of intervention and comparator	• Case studies, opinion pieces, letters, editorials • KQ1: Published before 2012

DATA EXTRACTION AND ASSESSMENT

For both KQs 1 and 2, we extracted details about the organization/research group that produced the protocol (*eg,* country, organization, rationale, process) and specific protocol elements. As protocol elements may have varied depending on the target of the element (staff vs patient), we extracted elements for staff and patients separately. We categorized extracted protocol elements into 1 of 9 Intervention Functions defined by the behavior change wheel (BCW), which characterizes behavior change interventions.[35] The framework is relevant to describing the protocols included in this review, as the protocols often tried to change behavior (staff, patients, or both) to reduce seclusion events. The 9 intervention functions include *education*, *persuasion*, *incentivization*, *coercion*, *training*, *restriction*, *environmental restructuring*, *modelling*, and *enablement* (Appendix B lists the intervention functions and their definitions). We also extracted resource use/needs associated with the protocols.

For KQ2, in addition to protocol characteristics, we extracted details on study design (RCT, concurrent non-randomized comparison, pre-post comparison), the setting and population it was implemented in (*eg,* hospital and patient characteristics), and patient, staff, and process outcomes (including seclusion and restraint events). Data extraction was conducted by 1 reviewer and confirmed by a second reviewer. Disagreements were resolved by consensus or discussion with a third reviewer.

Study risk of bias was independently assessed by 1 senior reviewer using questions derived from the Cochrane Risk of Bias and the ROBINS-I (Risk Of Bias In Non-randomized Studies - of Interventions) tools (Appendix C).[36,37] For all study designs, we additionally evaluated whether the article was free of discrepancies and reporting of patient eligibility criteria, protocols, setting, and outcome assessments were sufficiently clear. For RCTs, we also evaluated methods of randomization, allocation concealment, and whether staff were blinded. For NRCSs (with concurrent or pre-intervention controls), we evaluated selection of patients, characteristics of comparison ward, and strategies to deal with confounders.

SYNTHESIS AND CERTAINTY OF EVIDENCE

Due to extensive variability in settings, interventions, and measured outcomes, we synthesized results qualitatively. For KQ1, we described the characteristics of protocols, as well as factors associated with their design (*eg,* organization, intended setting) and potential implementation (*eg,* resource and staffing needs, where reported).

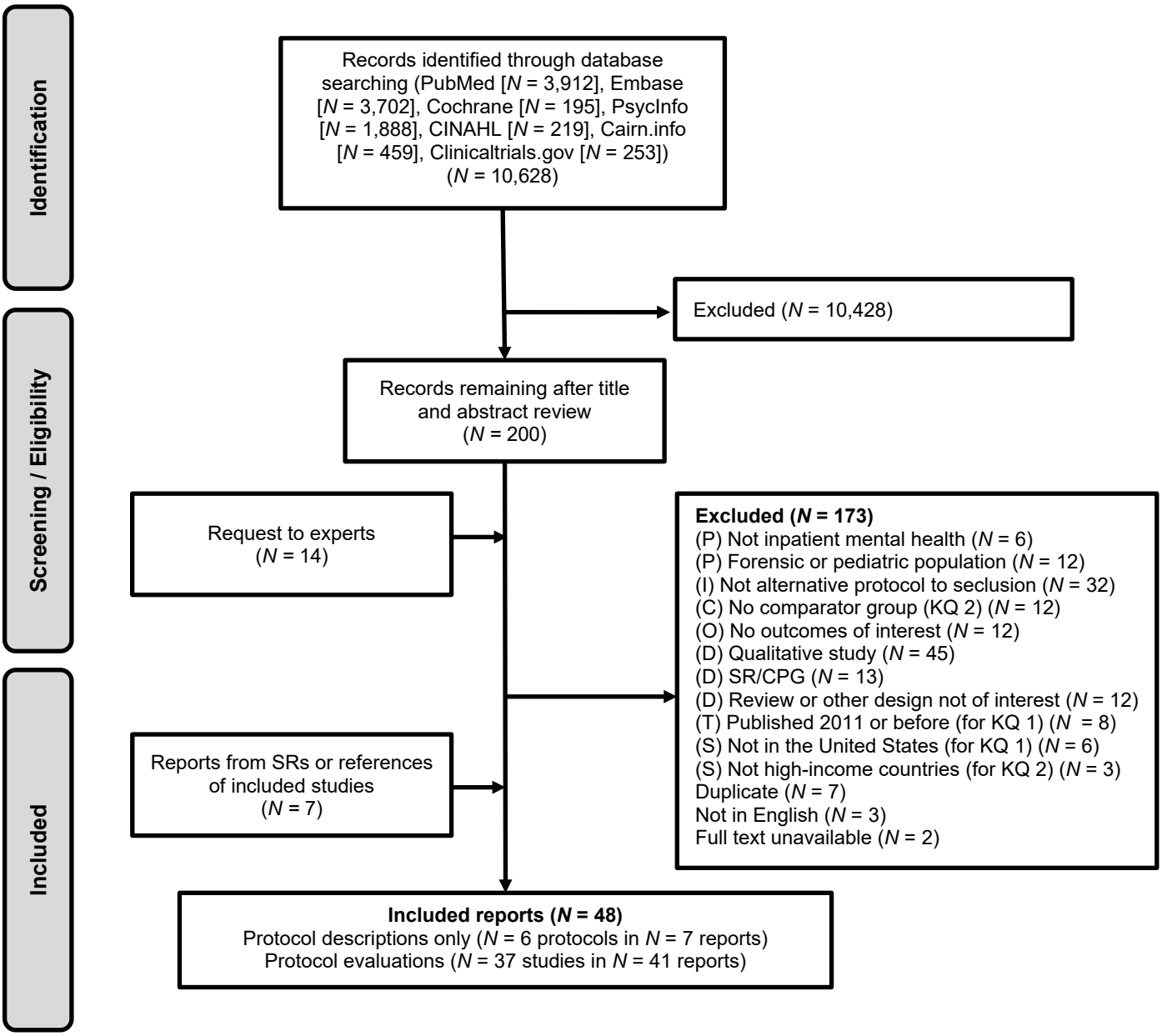
For KQ2, in addition to the information described for KQ1 about the protocols, we describe their design and their implementation. Additionally, we assessed the strength of evidence following the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach

for determining conclusions and certainty of evidence.[38] We compiled key study findings in evidence profiles, which provide the basis for determination of certainty of evidence and summarize conclusions for prioritized outcomes. Within each priority outcome, we considered the study design, the number of studies (and participants), methodological limitations (*ie,* risk of bias), directness of the evidence, precision of the findings, consistency across studies, and other issues. Based on these, we determined certainty of evidence, which could be high, moderate, or low. Where we found extremely limited evidence, we report that there is insufficient evidence to draw conclusions. We report our summary of findings for each outcome, within comparable protocol groups.

RESULTS

LITERATURE FLOW

Figure 1. Literature Flowchart



Abbreviations. C=comparator; CPG=clinical practice guideline; D=design; I=intervention; KQ=key question; O=outcome; P=population; S=setting; SR=systematic review; T=timing.

LITERATURE OVERVIEW

Of 10,628 citations obtained via database searching, 200 were retrieved for full-text review and evidence mapping. An additional 14 records were obtained through expert solicitation, and 7 records were obtained from references of included studies or previous systematic reviews. Upon reviewing the full-text articles, 48 reports were deemed eligible and were included for final review (Figure 1).[31,39-85] We found descriptions of 24 protocols implemented or developed in the US or Canada, of which 6 were described without reporting comparative results of implementing the protocols.[39-45] Overall, 37 studies described an empirical evaluation of protocols to reduce seclusion (in 41 reports), conducted in 9 high-income countries.[31,46-85] A list of studies excluded at full-text review is available in Appendix D. The most common reasons for exclusion included qualitative design (*N* = 45), lack of comparison to alternative protocols to seclusion (*N* = 32), and not being primary studies (13 systematic review for guideline and 12 other non-systematic reviews/editorials).

Table 2 shows the characteristics of the eligible records. Overall, 23 of the 43 protocols were from the US.[39-41,43-45,47,51,52,54,57,59,61,64,67,70,73-75,77,78,80,85] One protocol was from Canada.[62] Seven protocols were from the VA[41,43,44,70,77,78,85] and 4 of these were reported in comparative analyses.[70,77,78,85]

Table 2. Summary Characteristics of Eligible Studies

Characteristics	# Protocols Without Results	# Protocols With Results by Design		
	Protocols (n = 6[a])	RCT (n = 4[b])	NRCS (Concurrent) (n = 5)	NRCS (Pre-post) (n = 28[c])
Countries				
Australia/New Zealand (*N* = 7)	--	--	1	6
Canada (*N* = 1)	--	--	--	1
Finland (*N* = 1)	--	1	--	--
Germany (*N* = 1)	--	--	--	1
Netherlands (*N* = 3)	--	1	2	
Switzerland (*N* = 3)	--	1	--	2
United Kingdom (*N* = 4)	--	1	1	2
United States (*N* = 23)	6	--	1	16
VA Protocol				
Yes (*N* = 7)	3	0	0	4
No (*N* = 36)	3	4	5	24
Protocol Type				
Hospital/unit restructuring (*N* = 4)	--	--	--	4
Staff education/training (*N* = 3)	--	--	1	2
Sensory modulation (*N* = 7)	--	--	2	5
Risk assessment (*N* = 7)	--	2	--	5
Comprehensive/mixed (*N* = 22)	6	2	2	12

Characteristics	# Protocols Without Results	# Protocols With Results by Design		
	Protocols (n = 6[a])	RCT (n = 4[b])	NRCS (Concurrent) (n = 5)	NRCS (Pre-post) (n = 28[c])
Process Outcomes				
Seclusion (*N* = 25)	NA	2	2	21
Restraint (*N* = 15)	NA	1	1	13
Composite (*N* = 14)	NA	2	1	11
Patient Outcomes				
Patient injuries (*N* = 7)	NA	2	--	5
Aggressive incidents/behaviors (*N* = 14)	NA	3	1	10
Patient satisfaction (*N* = 3)	NA	1	--	2
Medication use (*N* = 5)	NA	--	1	4
Staff Outcomes				
Staff injuries (*N* = 5)	NA	--	--	5
Satisfaction with policy (*N* = 8)	NA	2	--	6
Staff debriefing (*N* = 1)	NA	--	--	1

Notes. [a] Reported in 7 reports; [b] Reported in 7 reports; [c] Reported in 25 reports.
Abbreviations. KQ=key questions; NRCS=nonrandomized comparative study; RCT=randomized controlled trial.

Appendix E shows the quality appraisal for all studies in the review, Appendix F shows the study design details (including the setting and study-level eligibility criteria) and Appendix G shows the baseline details for studies. Study eligibility criteria were at the inpatient unit level and consistent across studies, except for 1 study which also reported patient-specific exclusion criteria.[64] All studies included inpatient units with the capacity for seclusion, and units were often described as providing intensive or acute psychiatric care. The 37 studies reporting comparative data included 4 RCTs[31,60,66,69,81-83] and 33 NRCSs.[46-59,61-65,67,68,70-80,84,85] The 4 RCTs included 81 wards ($N > 11{,}341$[b]) and were conducted in Europe; they all relied on record linkage (based on staff self-report) to obtain primary outcome data, resulting in methodological concern. The 33 NRCSs included 99 wards ($N > 36{,}488$[c]) and were mostly conducted in the US ($N = 17$),[47,51,52,54,57,59,61,64,67,70,73-75,77,78,80,85] with the remaining conducted in Europe ($N = 12$),[46,48-50,58,60,66,68,69,76,79,82] Australia/New Zealand ($N = 7$),[53,55,56,63,65,72,84] and Canada ($N = 1$).[62] Most NRCSs were described as quality improvement projects and 4 were conducted in VA settings. Five of the NRCSs were prospective and involved identifying a contemporary comparison ward in the same hospital, health system, or region.[50,54,55,68,76] The remaining 28 NRCSs were pre-post studies evaluating data before and after a hospital/ward/unit change in seclusion protocol. All studies had methodological concerns of bias due to the self-report nature. In addition, most had concerns of bias due to lack of adjustment for confounding as only 5 of these studies analyzed some outcomes using multivariate regression to control for confounders.[46,50,72,76,77]

[b] One study (Bowers 2015) did not report patient sample size.
[c] One study (Blair 2017) did not report ward sample size and 17 studies (Rohe 2017, Bowers 2008, Forster 1999, Lloyd 2013, Azuela 2018, Sivak 2012, Clark 2010, Blair 2015, Dickens 2020, Hellerstein 2007, Khadivi 2004, Lewis 2009, McDonagh 2019, Pollard 2007, Richmond 1996, Stoll 2022 and Taxis 2002) did not report patient sample size.

Outcomes evaluated across studies varied and included episodes or time in seclusion ($N = 25$), episodes or time in restraint ($N = 15$), composite measures of coercion including some combination of seclusion, restraint, or forced medication use ($N = 14$), patient injuries ($N = 7$), aggressive incidences ($N = 14$), patient satisfaction ($N = 3$), medication use ($N = 5$), staff injuries ($N = 5$), staff satisfaction with policy ($N = 8$), and staff debriefing ($N = 1$).

In the following sections, we describe the identified protocols, report results by outcome (*eg,* episodes of seclusion and time in seclusion) for each grouping of protocols (*eg*, staff education), and present overall certainty of evidence for summary findings for each group of protocols regarding these outcomes.

DESCRIPTION OF PROTOCOLS TO REDUCE SECLUSION

Studies described diverse protocols of various elements targeted to staff and patients to reduce seclusion practices. Table 3 shows coded intervention functions of protocols. Protocols often contained elements designed to either reduce patients' aggressive and agitated behavior (*eg,* calming environments, patient-specific strategies to self-soothe) or elements to reduce use of seclusion by staff (*eg,* education on alternative strategies, modeling by peers). The most common elements across interventions included *education*, *persuasion*, *training*, and *environmental restructuring* (including efforts to shift the ward culture). Less common, but still present were elements relating to *incentives*, *restrictions*, *enablement*, or *modelling* (for example, by more experienced peers). Based on our intervention function coding and the stated aims and hypotheses of these protocols (Appendix H), we grouped protocols into 5 categories. From least to most intensive, these included:

1) **Hospital unit/restructuring** ($N = 4$)[46-49]
2) **Staff education/training** ($N = 3$)[50-52]
3) **Sensory modulation** ($N = 7$)[53-57,59]
4) **Risk assessment and management protocols** ($N = 7$)[60-66]
5) **Comprehensive/mixed** ($N = 22$)[31,39-45,67-85]

Below we first describe the features of the protocols within each group, and then we describe the results for comparative studies within each group.

Table 3. Coding of Intervention Functions Across KQ1 and KQ2 Reports

	Staff Behavior Targets										Patient Behavior Targets									
Author, Year	Education	Persuasion	Incentivization	Coercion	Training	Restriction	Environment	Modelling	Enablement	Other	Education	Persuasion	Incentivization	Coercion	Training	Restriction	Environment	Modelling	Enablement	Other
Hospital/Unit Restructuring (N = 4 Studies)																				
Hochstrasser, 2018, pre-post							x										x			
Hunter,1993, pre-post							x				x		x			x	x			
Jenkins, 2014, pre-post							x										x			
Rohe, 2017, pre-post																	x			
Staff Education/Training (N = 3 Studies)																				
Bowers, 2008, concurrent		x						x												
Forster, 1999, pre-post	x	x			x															
Haefner, 2021, pre-post	x	x			x												x			
Sensory Modulation (N = 7 Studies)																				
Lloyd, 2013, concurrent	x	x			x		x		x		x	x					x		x	
Cummings, 2010, concurrent		x					x		x		x	x				x	x			
Azuela, 2018, pre-post		x			x		x										x			
Sivak, 2012, pre-post	x						x				x	x	x			x	x		x	
Novak, 2012, pre-post	x	x					x				x	x					x			
Smith, 2013, pre-post							x										x			
Zimmermann, 2020, pre-post	x						x				x						x			
Risk Assessment (N = 7 Studies)																				
Abderhalden, 2008, RCT	x	x					x													
van de Sande, 2011, RCT					x		x		x											
Blair, 2017, pre-post					x	x	x										x			
Clarke, 2010, pre-post	x						x													
Harrington, 2019, pre-post	x	x			x		x				x	x					x		x	
Manning, 2022, pre-post	x	x			x	x	x					x				x	x		x	
Trauer, 2010, pre-post	x	x			x		x				x	x					x		x	
Comprehensive/Mixed (N = 16 Studies and N = 6 Protocols Without Evaluation Results)																				
Protocols with evaluation results																				

Author, Year	Staff Behavior Targets										Patient Behavior Targets									
	Education	Persuasion	Incentivization	Coercion	Training	Restriction	Environment	Modelling	Enablement	Other	Education	Persuasion	Incentivization	Coercion	Training	Restriction	Environment	Modelling	Enablement	Other
Bowers, 2015, RCT	x	x			x		x	x	x			x					x		x	
Valimaki, 2022, RCT	x	x			x				x											
Boumans, 2014, concurrent	x	x			x		x		x										x	
Noorthoorn, 2014, concurrent					x		x		x						x	x			x	
Blair, 2015, pre-post		x			x		x				x	x					x		x	
Dickens, 2020, pre-post	x				x															
Hellerstein, 2007, pre-post	x	x				x	x					x					x		x	
Khadivi, 2004, pre-post	x				x		x												x	
Lewis, 2009, pre-post		x			x		x		x			x					x		x	
McDonagh, 2019, pre-post	x	x			x		x	x			x				x		x			
Pollard, 2007, pre-post	x	x					x													
Richmond, 1996, pre-post	x	x			x															
Stoll, 2022, pre-post		x																		
Taxis, 2002, pre-post	x	x			x		x				x				x		x		x	
Whitecross, 2020, pre-post	x						x	x												
Zuehlke, 2016, pre-post					x		x		x			x					x		x	
Protocols Without Evaluation Results																				
APNA statement, 2018	x	x			x	x	x										x			
Ashcraft, 2012	x	x			x	x	x				x	x								
Clement, 2021	x	x			x	x	x				x	x					x			
Iwamasa, 2017	x	x			x		x		x	x	x	x					x			
VA Northern California HCS					x	x	x		x			x								
Wale, 2011	x	x	x		x	x				x					x					

Abbreviations. APNA=American Psychiatric Nurses Association; HCS=Health Care System; KQ=key question; RCT=randomized controlled trial.

Hospital/Unit Restructuring

Four pre-post studies (conducted between 1989 and 2015) evaluated physically redesigning an inpatient unit/ward and seclusion outcomes.[46-49] Two studies were conducted in Europe,[46,49] 1 study was conducted in the United Kingdom,[48] and 1 in the US.[47] The studies were conducted in single hospitals with 1,[48] 2,[47] 10,[49] and 15[46] psychiatric units; none of the studies were conducted in a VA setting. The protocols were all locally produced by the hospital in which they were implemented. In 3 cases, restructuring was in response to identified site-specific limitations that were impacting care and possible use of seclusion (*eg,* dated building, staff shortages, change in patient caseload).[47-49] In the fourth study, the authors noted the hospital's motivation to restructure was based on findings reported in the literature.[46] While all implied that the restructuring would lead to reduced use of seclusion, only 1 study stated this hypothesis explicitly.[46] One study hypothesized the new ward environment would be associated with a reduction in arousal and aggression levels.[48] Patient sample size ranged from 18 to 2,924. Patients tended to be in their 40s and often had diagnoses of schizophrenia or mood (affective) disorders.

Environmental restructuring (*ie,* changing the physical or social context) was the common intervention function across the 4 studies. Hochstrasser et al described the implementation of an open-door policy in a Swiss hospital in which 6 previously closed wards were permanently opened in conjunction with a culture shift towards patient-centered and recovery-oriented care.[46] Hunter et al described restructuring an existing locked-door program in the US into 3 complimentary programs that included an intensive care unit, an unlocked day program, and a transitional residential program.[47] Rohe et al described a contemporary building in Germany that replaced the existing 19th century building, outfitting it with open, warm, and bright rooms.[49] Finally, Jenkins described the development of a new ward with better layout, visibility, and therapeutic activity space, in response to an independent assessment that identified environmental difficulties with the old ward.

Hunter et al also included elements of *education* (*ie,* increasingly knowledge or understanding), *incentivization* (*ie,* creating expectation of reward), and *restrictions* (*ie,* using rules to reduce the opportunity to engage in the target behavior or opportunities to engage in the competing behavior), depending on which program patients were triaged.

Only 2 studies reported on the resource needs required for unit restructuring (Appendix I shows intervention resource needs).[47,48] Hunter et al described different *staffing* levels per unit with mental health workers monitoring the residential day program and nurses operating the intensive care unit for high-risk patients. Importantly, when patients were admitted to the hospital, they were assigned a multidisciplinary care team who followed them across units. The study also described changes in *documentation* associated with the restructuring and the introduction of recreation *programming*.[47] Jenkins described *space* requirements needed for the new ward.[48] This included single bedrooms with ensuite facilities to enhance privacy, gender-specific areas, a designated activities room and visiting area, and a seclusion area conforming to the Department of Health guidelines.[48]

All 4 pre-post studies evaluating the impact of hospital/unit restructuring on seclusion practices relied on self-reported outcome data. Three studies conducted only crude analyses and were at

high risk of bias for confounding.[47-49] One study conducted multivariate regression to control for confounders for some key outcomes and had medium risk of bias for confounding.[46]

Staff Education/Training

Two pre-post studies[51,52] and 1 study with a concurrent comparison group[50] (all conducted between 1995 and 2019) evaluated the impact of staff education and/or training on seclusion practices. The concurrent comparison study (which also evaluated outcomes pre-post in the ward implementing the protocol) was conducted in the United Kingdom.[50] The study compared patients in 3 wards where staff received training in conflict and containment strategies (City Nurse intervention; *eg*, positive appreciation of patients and skills to manage response to patient behaviors including low-conflict, low-containment, high-therapy nursing) to 5 wards in the same hospital where staff did not receive the training.[50] The study did not report a sample size, but noted a 58% response rate (N = 5,316) on the patient-staff conflict checklist shift reports (PCC-SR), which was a tool completed by a ward nurse at the end of each shift to document patient behavior and ward containment measures.[50] One pre-post study (N = 5,570) was conducted in an 83-bed acute urban psychiatric hospital in the US and compared the 12 months after the implementation of mandatory staff training on management of behaviors and hospital wide charting to 12 months before the intervention.[51] Another pre-post study (N = 730) was conducted in a 37-bed psychiatric unit located in the US and compared the 2 months after nurses underwent training in verbal de-escalation (TeamSTEPPS intervention) to 2 months before the training.[52] Neither of these studies were conducted in the VA. There was inconsistent reporting of patient sample size and patient characteristics. One study did not report patient sample size[50] and only 1 study reported details about diagnoses of the sampled patient population.[52]

Two studies[50,52] implemented previously tested and named protocols (City Nurse and TeamSTEPPS intervention), while 1 study tested a hospital-specific protocol developed by a multidisciplinary workgroup that sought to support a local policy to reduce seclusion and restraint.[51] The common intervention element across these interventions was *persuasion* (*ie,* using communication to stimulate action), with elements of *education*, *training* (*ie,* imparting skills), or *modelling* (*ie,* providing an example for people to aspire to or imitate) also present. Persuasion related to how the protocol was implemented (whether top-down[51,52] or negotiated with staff[50]) but also to how staff were encouraged to view and respond to patients (*eg,* City Nurses encouraged staff to "appreciate" patients;[50] TeamSTEPPS encouraged staff to have a more "authentic engagement" with patients and to use verbal de-escalation techniques to manage aggressive behavior).[52] Staff training generally consisted of online modules and in-person demonstrations of de-escalation techniques and alternative strategies to seclusion.[51,52] Additionally, the City Nurses intervention used modelling (of 2 nurses recognized as clinical experts in acute inpatient care) to work with ward staff 3 days per week to demonstrate how to reduce conflict and containment and increase positive ward culture.[50]

The primary resource named across the 3 studies was *staffing*. Two interventions[51,52] employed multidisciplinary teams in their design, including the involvement of registered nurses, psychiatric pharmacy technicians, psychiatric nurse practitioners, social workers, occupational therapists, and activity therapists. These interdisciplinary teams met regularly to inform intervention development and implementation. The City Nurses program[50] required the appointment of 2 lead nurses, who were identified as clinical experts in inpatient psychiatric care with experience in practice development.

The concurrent design study did not report the characteristics of patients in the comparison ward and relied on self-reported outcome data, but did conduct multivariate regression to control for confounders for some outcomes.[50] Both pre-post studies relied on self-reported outcome data and used crude (unadjusted) analyses to evaluate all outcomes, and thus were at high risk of bias for confounding.

Sensory Modulation

Seven NRCSs (2 concurrent comparisons[54,55] and 5 pre-post[53,56-59]) conducted between 2011 and 2020 (where reported; Cummings et al did not report date of study conduct[54]) compared units with a sensory modulation room to a comparison unit or a period before the unit installed the sensory modulation room. Three studies were conducted in the US,[54,57,59] 3 were conducted in Australia or New Zealand,[55,53,56] and 1 was conducted in the United Kingdom.[58]

One concurrent comparison study was conducted in a single Australian hospital with 2 20-bed acute inpatient psychiatric units (patients or number of admissions was not reported).[55] Another concurrent comparison study (which also involved a pre-post comparison) was conducted in the US in 2 acute inpatient units in a large psychiatric hospital.[54] One dissertation using a pre-post design was conducted in New Zealand in 2 inpatient units (sample sizes were unclear).[53] Unit A had 29 beds focused on assessment, treatment planning, and group activities, and unit B had 26 beds focused on people with acute episodes of mental illness. Another pre-post study was conducted in Australia in a single hospital 40-bed acute inpatient psychiatric unit.[56] One pre-post study was conducted in the United Kingdom in an inner city male-only 15-bed inpatient psychiatric unit.[58] Two pre-post studies were conducted in the US in rural mental health hospitals.[57,59] None were conducted in a VA setting. Only 2 studies reported sample size data at the patient level ($N = 321$ admissions[59] and $N = 75$ seclusion events [56]).

With the exception of 1 study,[54] all sensory modulation rooms were informed by previous literature,[86-91] although the studies typically described the sensory modulation rooms as being iteratively designed with staff and patient input. Studies hypothesized that sensory modulation rooms would help patients reduce or manage experiences of distress through various sensory stimuli, which would in turn reduce rates of aggression and seclusion on the unit.

Given that the sensory modulation room involved a change of the physical ward space, all studies involved the *environmental restructuring* intervention function. Rooms were designed to meet the multisensory needs of patients, with light colored walls, soothing artwork, or patient-selected murals, and included various features and materials to engage and calm patients such as comfortable seating (*eg*, recliners, rocking or beanbag chairs), TV and videos, CD player and calming music, scented sprays, drawing materials, games and puzzles, and other sensory tools (*eg*, weighted blankets, stress balls, fidget spinners).[53,54,56-59] Five studies provided *education* to staff and/or patients to make them aware of the sensory modulation room and how to use it,[54-57,59] and 1 study provided in-depth staff *training* on competencies and skills for using the sensory modulation therapeutically (*eg*, sensory assessments, selection of sensory modulation therapeutic activities, therapeutic demeanor and attitude while using the sensory modulation room, *etc*).[53] Most studies also included the element of *persuasion,* whereby staff and patients were encouraged to use the rooms for early intervention when patients were feeling distress.[53-57] Some studies encouraged patients to bring their own sensory modulation material, like music,[54] and to keep the room in good condition so others could use it later.[57] Two studies tried to ensure

stakeholder buy-in by involving staff[54] and patients[57] in the planning and implementation of sensory modulation rooms. Two studies implemented *restrictions* associated with the sensory modulation rooms such as continuous video monitoring and staff entry privileges should patient behavior become unsafe[54] or requirement that patients sign an agreement prior to their use of sensory modulation rooms (patients who were unable or unwilling to sign the agreement form were not allowed to use the sensory modulation room).[57] Several studies included elements of *enablement* (*ie,* increase means/decrease barriers to increase capability or opportunity) by tailoring sensory modulation rooms to the specific needs and requests of patients,[55,57] and supporting patients to voluntarily use the sensory modulation room if they find it helpful.[54,55,57]

The most common resource need for sensory modulation interventions was the *space* and *equipment* to facilitate the intervention. Typically, 1 room on each unit was converted into the sensory modulation room, named the "comfort room" or "serenity room,"[54-59] and spatial modifications spanned ambient lighting, paint, wallpaper, and chalkboard walls. *Equipment* needs included musical instruments or CDs, sound machines and other auditory equipment to promote relaxation, comfortable furnishings, and other sensory modulation items.[54-56,58,59]

All 5 studies had high risk of bias for performance bias due to self-reported outcome measures and high risk of bias for confounding due to their NRCS design and lack of adjusted analyses.

Risk Assessment and Management Protocol

Seven studies (2 RCTs[60,66] and 5 pre-post[61-65]) compared interventions that incorporated a structured risk assessment and management protocol to usual care. Three of the studies did not report their dates of study conduct (published 2010-2022); the remaining 4 were conducted between 2002 and 2012. Both RCTs were conducted in Europe,[60,66]; 2 pre-post studies were conducted in the US,[61,64] 2 in Australia,[63,65] and 1 in Canada.[62] No study was conducted in a VA setting.

One cluster RCT was conducted in 14 wards (N = 2,364 total) across multiple hospitals in Switzerland; 4 wards were randomized to the intervention, 5 wards were randomized to wait-list control, and 5 wards were not randomized but preferred to implement the structured risk assessment intervention immediately (concurrent, non-randomized control) – we report results for only the randomized comparison.[60] The other cluster RCT, conducted in a single hospital in the Netherlands, randomized 2 wards (N = 36 beds total) to the intervention and 2 wards to the control group (practice as usual) and included all patients admitted to these units during the study period in the trial (N = 458).[66] The remaining 5 pre-post studies were all conducted in a single-hospital setting and evaluated outcomes before and after the implementation of a structured assessment protocol.[61-65]

Four studies (2 RCTs and 2 pre-post) evaluated wards that implemented the Brøset Violence Checklist, which is a 6-item instrument administered by clinical staff to predict conflict behaviors.[60-62,66] The 2 European RCTs (N = 2,822) compared wards where staff were trained to administer the Brøset Violence Checklist at admission to usual care wards.[60,66] One pre-post study reported outcomes before and after an 11-bed psychiatric intensive care unit started using the Brøset Violence Checklist. The study did not report a sample size.[62] Finally, 1 study compared outcomes before and after a 120-bed psychiatric hospital implemented the Brøset Violence Checklist, which it combined with other evidence-based strategies for reducing violence and aggression on the ward (N = 11,913 admissions).[61]

Three pre-post studies evaluated interventions that included investigator-developed or -modified risk assessment tools.[63-65] One pre-post study evaluated a risk assessment tool and management guideline developed by a hospital using a participatory action framework (N = 2,055).[63] Another pre-post study evaluated a risk assessment protocol that incorporated a modified version of the Agitation Severity Scale (N = 742).[64] Finally, a third pre-post study evaluated the Management of Acute Arousal Program protocol (N = 281).[65]

The central hypothesis of the studies using risk assessment tools was that their implementation would help staff to identify potentially aggressive patients to direct clinical efforts towards (*eg,* de-escalation techniques). All studies involved the intervention function *environmental restructuring,* as the implementation of the risk assessments changed the social context of how patients were managed in the unit. Risk assessments became part of standard care, both on admission and regularly during patients' stay, and were incorporated into clinical decision-making[65,66] and triaging patients to different risk categories to receive behavioral interventions and staff care tailored to their level of risk.[63,64] In addition to the risk assessments, studies made additional environment modifications such as increasing staff presence in the "milieu,"[61] having staff perform ward checks every 2-3 hours,[63] identifying patient-specific coping strategies on admission,[61] and introducing sensory modulation rooms.[61] Two studies also introduced greater clinical and administrative oversight associated with seclusion, restraint, and aggressive events (*eg,* clinical directors examined all seclusion and restraint events to determine if formal administrative review was needed,[61] and nurses involved in aggressive incidents were interviewed to see if they could have been prevented[62]).

All of the studies also involved elements of *education* and *training* to teach staff how to use the assessments[62,63,65,66] and act on their results (*eg,* treatment recommendations).[60,63,64] One study also implemented a 2-day training program based on a trauma-informed model of care to reduce staff behaviors that may worsen trauma-related behaviors in patients.[61] Should a seclusion event occur, 1 study offered patients the opportunity to debrief with a member of staff who had not been involved in the incident.[65] Some studies also included various elements of *persuasion* to encourage staff to use the tools,[63,65] to discuss preventive measures with patients and encourage them to engage with these measures,[60,63] to encourage specific treatments,[64] and to use the tools to problem solve as a clinical team.[60] One study encouraged patients to voluntarily take some time out.[65]

To further reduce the use of seclusion and restraint, 1 study *restricted* the length of time a patient could remain in seclusion without renewal of the order from 4 to 2 hours.[61] Another study only allowed the use of seclusion and restraint as a "last resort" for patients scoring above 9 on the modified Agitation Severity Scale combined with physician notification.[64] Finally, 3 studies used *enablement* to engage and encourage patients to be part of their own self-management in selecting strategies to support them.[63-65]

The central resource requirement for the 6 risk assessment studies was *documentation* needs to collect information on symptom severity and mental status via risk assessment scales,[60-66] and for post-event reviews of seclusion events.[61] *Time to perform documentation* was reported by 6 of the studies[60,62-65] with initial risk assessments occurring shortly after admission (*eg,* within 72 hours) and at regular intervals throughout the patient's hospitalization. *Time to perform checks on patients* was also included in 2 interventions.[61,63]

All 7 studies were high risk of bias for outcome ascertainment due to the self-reported nature of the outcomes. All 5 pre-post studies conducted crude analysis and thus were deemed high risk of bias for confounding bias.[61-64] In addition, in 2 studies it was unclear whether the comparator group was similar, [62,63] and in 2 studies it was unclear whether patients were selected at random.[62,64]

Comprehensive/Mixed (Protocols Without Empirical Data, KQ1)

All 6 intervention protocols captured under KQ1[39-45] were developed in the US, with 3 protocols [41-44] produced by VA hospitals. One protocol was published by the American Psychiatric Nurses Association,[39] 1 by New York City Health and Hospitals Corporation,[45] and 1 by Recovery Innovations Inc.[40] The protocols included comprehensive recommendations for staff education and training, culture change headed by organization leadership, as well as limitations on the use of seclusion and restraint with an emphasis on least-restrictive alternatives.

Most protocols included an element of *education*, with staff provided information on alternatives to seclusion and restraint and the organization's goal to reduce coercive and restrictive practices.[39-43,45] Patient education provided information on behaviors that require the use of seclusion and restraint and the criteria for discontinuation[41] as well as brochures for patients and families, including a voluntary treatment agreement.[42,43]

The use of *persuasion* was common across the protocols, with direct messaging from organization leadership to staff for commitment to recovery-oriented care and practices to reduce seclusion and restraint reported in 3[39,40,42,43] guidance documents. Other forms of persuasion entailed oversight and dissemination of performance improvement efforts to reduce the use of seclusion and restraint.[39, 40,45] The Code Green response protocol[41] emphasized that any employee concerned with a patient's potential for a behavioral emergency should notify the care team to trigger clinical consultation that may avert the need for restrictive practices.[44]

Five[39-41,44,45] protocols explicitly discussed the function of *training,* with all recommending de-escalation practices. Attention was also paid to the identification of patient risk factors[41] and sensory modulation training.[45] One protocol[45] involved a 2-day training program for staff which introduced the 6 core strategies to reduce seclusion and restraint, including primary and secondary prevention, leadership roles and responsibilities, key characteristics of trauma-informed care systems, use of data to inform practice, modifiable environmental factors, rigorous post-event debriefing, and consumer and family roles in the inpatient setting.

Some protocols incorporated *restriction* into their interventions, with the most common requirement being the use of least-restrictive alternatives prior to the initiation of seclusion and restraint.[39,41,44] The No Force First policy[40] included a mandate from the CEO that seclusion and restraint would no longer be permitted at any company facility. Other forms of restriction pertained to the time allowed for seclusion and restraint.[39,45] One protocol[41] also specified that a licensed independent practitioner must be notified within 1 hour of seclusion and restraint initiation if an order had not previously been entered into the electronic health record.

Five[39-44] protocols included *environmental restructuring* to modify the physical and social context of the inpatient unit. Three protocols[39,40,42,43] discussed the need to establish a work culture conducive to a reduction in seclusion/restraint, which included safety and recovery-oriented care. One[42,43] protocol stressed the need to develop "home-like, non-institutional, and

patient centered environments," while another[40] highlighted that the staff-patient relationship should be viewed as a partnership of "risk-sharing" rather than "risk management" control. Facility leadership were identified as responsible for ensuring policy compliance,[41] maintaining structures and resources for program implementation,[39] and promoting a therapeutic relationship between staff and patients.[42,43] Changes to the physical environment spanned the use of "quiet" or "comfort" rooms,[42-44] sensory tools,[41] and evaluations of light and noise levels[42,43] to promote a calming environment. Multiple protocols noted a change in social context via seclusion/restraint data reviews.[41,42,43] The Code Green response[44] protocol involved a stepwise modification to the physical environment including a paging system announcement of the Code Green, the removal of nonessential staff and patients from the area, a response team huddle, and movement of the patient to an enhanced monitoring location.

A consistent resource need across the 6 protocols was *staffing*. One protocol[45] created a new position entitled the Behavioral Health Associate who specialized in crisis prevention and de-escalation to take over some duties of hospital police, while 2 protocols [40,42,43] incorporated peer-support specialists onto the unit. Other staffing requirements included multidisciplinary care coordination[41] and the Code Green response team[44] headed by a response leader with the specification that therapeutic containment required at least 3 team members. *Documentation* needs were prevalent,[41-44] particularly in the electronic health record for seclusion/restraint event details that included record of which alternative interventions were deployed and their outcomes. One protocol[40] created an "electronic recovery record" for patients and staff to create wellness plans and track progress. Four protocols[40-44] maintained *staff debriefing* needs, with 2[42-44] specifically noting that debriefing must occur within 48 hours of a seclusion/restraint event. Three[40-43] protocols also defined *programming* needs such as morning recovery activities to create a sense of community[40] and recreational activities.[41,42,43]

Comprehensive/Mixed (Empirical Evaluations, KQ2)

Sixteen studies (2 RCTs,[31,69,82,83] 2 concurrent comparison,[68,76] and 12 pre-post)[67,70-75,77-80,84,85] conducted from 1992 to 2020 evaluated comprehensive/mixed approach interventions. Nine studies[67,70,73-75,77,78,80,85] were conducted in the US, of which 4 were in a VA Medical Center.[70,77,78,85] One VA study was a poster that presented minimal methodological details.[70] Five studies were conducted in Europe[68,69,76,79,82] and 2 in Australia.[72,84] Sample size varied across studies (range: 352 to 8,349 patients),[68,74,76,79,82,84,85] with several studies not reporting these data.[67,70,73,75,77,78,80] Unit or hospital characteristics were also inconsistently reported across studies (range of 15 to 437 beds).[70,73,74,78,80,84,85]

Comprehensive interventions were described as multicomponent and included a variety of intervention functions aimed at targeting multiple levels (hospital, staff, patients) and determinants (knowledge, capability, motivation, procedures of care [and self-care]) to prevent aggressive behaviors and subsequent use of coercive measures. The most common intervention functions targeted towards staff included *education*, *persuasion*, *training*, and *environmental restructuring*. The most common intervention functions targeted towards patients included *persuasion*, *environmental restructuring*, and *enablement*. Two studies (1 RCT[69] and 1 pre-post[72]) evaluated the Safewards intervention. We describe the intervention details and results for the Safewards protocol first followed by the results from the remaining comprehensive protocols.

Safewards

Two studies (1 RCT[69] and 1 pre-post [72]) evaluated the Safewards intervention, which consists of 10 components to reduce conflict and use of coercive measures on inpatient wards. These include: 1) published standard of behaviors for patients and staff, 2) advisory statements to handle flashpoints, 3) de-escalation training, 4) requirement to compliment patients at nurse shift change, 5) protectively identify and intervene when patients receive bad news from friends/family, 6) shared information between staff and patient (*eg*, favorite sports team), 7) regular group meetings for patients, 8) easily available sensory modulation tools, 9) reassurance following frightening incidence, and 10) display positive messages throughout the ward from discharged patients.[69] These components were coded as having elements of *education*, *persuasion*, *incentivization*, *training*, *environmental restructuring* (including restructuring of the social context), *modelling*, and *enablement*. The Safewards intervention was designed (in collaboration with expert nurses, service users, and carers)[69] to address determinants of conflict and containment identified in the Safewards Model.[31]

In the RCT, 31 wards at 15 hospitals within 100 km of central London were randomized to receive the Safewards intervention or a control condition. Control wards implemented an intervention to improve staff physical health (*eg*, healthy snacks and incentives to do physical activity).[69] Although staff in each group were not blind to the intervention they received, they were blind to the research hypothesis (*ie,* that Safewards would be more effective than the physical activity control). Both arms of the study were led to believe that the intervention they received would lead to lower rates of conflict and coercive measures. Thus, as described by the study authors, the comparator arm "controlled for both researcher attention and participant expectancy."[69] Randomization was at the ward level and the study did not provide data on number of patients in each unit. The pre-post study compared 8 wards in a large health district in Australia that implemented the Safewards intervention to a period before the units used the intervention.[72]

Both Safewards studies reported *equipment* resource needs to carry out the intervention, with sensory "crates" and "boxes" deployed on the units that contained stress toys and mp3 players with calming music.[69,72] An additional resource was related to *staffing,* since the Safewards intervention required nursing staff to actively engage with the care model and implement new activities.[69]

Both studies had high risk of bias; they relied on self-reported outcome data and had a high degree of missing data.

Other Comprehensive Protocols

Fourteen studies evaluated comprehensive/mixed protocols with different components that could include staff training, patient education, efforts to improve communication between staff and patients, interdisciplinary clinical team-based approaches, staff/team meetings to discuss cases and alternatives to restraints or seclusion, and proactively identifying patients at risk for restraint/seclusion, among others.[67,68,70,73-81,84,85] Seven studies[67,68,75,76,79,82,85] evaluated interventions that sought to improve or modify elements of ward culture (including staff attitudes towards patients and use of seclusion as a justified course of action), 2 studies explicitly mentioned evaluating interventions that were compliant with Joint Commission mandates,[74,77] and multiple studies noted Joint Commission mandates as a motivation for the development of an

intervention. Eleven protocols were implemented in a single hospital (with 1 to 5 inpatient units, offering 7 to 88 patient beds, where reported).[67,68,70,73-75,77,78,80,84,85] Two protocols were implemented in 2 hospitals (both in 2 units with bed capacity ranging from 19 to 45 each),[76,79] and 1 protocol (an RCT) was implemented in 15 hospitals with 28 inpatient units.[82] Patient sample sizes and characteristics were rarely reported.

Most interventions included the element of *education*. The content of staff education varied from informing staff on the content of intervention/alternative approaches to care (*eg,* recovery-oriented care),[70,82,84] clarifying appropriate indications for seclusion and alternatives to seclusion,[73,77,78,80] information on what agitates patients in their care and how they would prefer to be treated in moments of agitation,[73] and education on the ethical concerns and negative effects of seclusion.[68,80] Patient education involved content to support patients in their self-monitoring and self-care during periods of agitation[70,80] and to inform patients about the model of care (*eg, trauma informed)*.[67]

Many interventions also included the element of *training* to help patients and staff adopt the intervention and/or change their behavior to reduce aggressive episodes and seclusion events, respectively.[68,70,74-76,78,80,82,85] Staff-directed training could include training on preventing and managing patient aggression,[67,74,76,78,82] improving patient relationships,[75,76] improving ward culture,[67,82,85] and specific alternatives to seclusion.[67,75,78] One study provided staff with feedback on the quality of staff's care plans (designed with the study's new model, the Methodical Work Approach), and trained staff on how to used evidence-based principles of searching and reviewing the evidence to refine their care plans.[68] Patient-directed training was used to help patients develop detailed behavioral goals and support collaborative relationship building between staff and patients.[80] One study in a VA medical center provided patients with recovery and management training and social skills training.[70]

Persuasion was often used to reinforce education and/or training, as staff were encouraged by study leaders, hospital administration, or peer champions to change their behavior to align with the new protocols.[67,70,73,75,77-80,82] Two studies seemed to try to persuade staff to use the new protocol by engaging them in the design and implementation of the new processes.[70,77]

Interventions also implemented various forms of *environmental restructuring* to change physical or social context of the wards. Restructuring included adding new staff[70,73] or reorganizing existing staff to better support patient needs (*eg,* the multidisciplinary on-call Psy-BOC team to respond to escalating behaviors of concern),[67,84] introducing new structures (*ie,* calming room),[67,80] self-management plans,[67] or programming for patients,[67,70,85] and introducing new staff/ward processes such as behavioral risk and response assessments,[67,74-76] community meetings and shared meals with staff and patients,[67] regular staff meetings,[67,75,76,85] and staff performance feedback.[76,80] Should a seclusion event occur, processes of debriefing were put in place (often with senior clinicians or ward leadership) to identify factors contributing to the event, determine if alternatives to seclusion were attempted, and ultimately to determine if seclusion was justified.[67,74,75,77,80]

Some studies used the intervention function *enablement*, most commonly to engage and empower patients (and sometimes their families) to work collaboratively with staff towards their care and treatment goals (*eg,* selecting goals, identifying preferential interventions, opening lines of communication to refine over time, breaking down barriers of control-based care).[67,68,75,80,82,85]

One study adapted policies to allow for off-unit privileges earlier during hospitalization.[73] One study also noted efforts to empower staff in terms of decision-making during acute situations and celebrating staff initiatives for improved patient care.[67]

Finally, a few studies also included elements of *modelling* (*eg*, expert guidance and demonstration of the new behaviors)[70,84] and *restriction* (*eg,* clear boundaries for acceptable/not acceptable patient behavior [76] and procedures for when seclusion was allowed and for how long).[73]

Nine studies identified *staffing* as a resource need[67,68,70,73-75,80,84,85] with the incorporation of multidisciplinary teams reported by 2 studies.[84,85] Other staffing requirements included staff-led training and ongoing coaching,[80] coordination across hospital departments for patient programming,[70] and availability of staff to escort patients off-unit as part of the de-escalation process[73] or remaining with challenging patients as needed.[67] Ten studies cited *documentation* resource needs,[67,68,70,73-76,78,80,85] with 5 studies[70,74,75,78,80] including documentation of seclusion or restraint event details, debriefings, or review processes such as a record of which least restrictive alternative(s) were used and the outcome of these interventions. Six studies[67,73-76,85] introduced documentation to capture history of aggressive behavior and information on effective coping methods. Furthermore, 4 studies[67,70,80,85] reported *programming* needs. Group therapy was implemented by 2 studies,[70,80,85] with a VA study[70] providing 4-6 hours of programming per day which included offerings such as social skills training and occupational/resume building workshops.

Two studies (1 concurrent comparison[76] and 1 pre-post study[77]) conducted multivariate regression to account for confounders; the remaining 12 studies conducted crude analyses and thus were at high risk for cofounding bias. All studies used self-report data for outcomes and thus were at high risk for performance bias.[67,68,70,73-75,78-80,82,84,85]

EFFECT OF HOSPITAL/UNIT RESTRUCTURING

Based on evidence from 4 pre-post studies,[46-49] restructuring units to include architecturally positive attributes and open-door privileges may reduce episodes of seclusion, duration of seclusion, duration of restraint, and forced medication use (Table 4). We have low confidence in these findings because studies had serious methodological limitations (relied on self-reported outcome data and conducted crude analyses) and there was some inconsistency in findings between studies for episodes of seclusion, restraint, and patient outcomes. Studies provide insufficient evidence (no conclusion) regarding episodes of restraint, other patient outcomes, and staff outcomes. The studies did not evaluate a composite measure of coercion.

Seclusion

Three pre-post studies compared a period with hospital redesign (including 2 studies that implemented open wards) to a pre-hospital restructuring period.[46-48] One large study (N = 17,359 admissions) found episodes of seclusion significantly decreased (adjusted odds ratio [aOR] = 0.88, 95% CI [0.83, 0.92]; Appendix J shows detailed outcome data) during a 5-year period when the hospital implemented open wards.[46] The same study conducted a crude analysis and found hours of seclusion decreased after the hospital implemented open wards (mean 27.1 hours at the beginning of the period of study versus 18.2 hours at the end of the study, $p <$ .001).[46] A second small study (N = 144) found no difference in episodes of seclusion between the

10 months before and 10 months after a hospital restructured the wards into 3 different programs (including the introduction of open ward) (31 vs 32 events, p = not significant [NS]).[47] Despite no change in frequency of seclusion events, the same study found a significant reduction in duration of seclusion (unadjusted mean 5 vs 2.3 hours, $p = 0.02$). A third very small study ($N = 18$) found fewer seclusion events 3 to 6 months after the move to a purpose-built psychiatric intensive care unit than 3 to 6 months before the move (3 vs 14, $p = 0.001$)[48]. The same study found a decrease in the total duration of seclusion (531 vs 2,117 minutes, $p = 0.001$) but no difference in mean duration of seclusion (190 vs 153, $p = 0.288$).[48]

Restraint

Two pre-post studies reported episodes and duration of restraint.[47,49] One large study found a significant reduction in episodes (reductions ranged between 48% to 63% based on 3 definitions of restraint (p <0.001 for all) and duration (48% reduction, $p = 0.003$) of restraint after a hospital structurally modernized compared to a period before.[49] A small pre-post study found no difference in episodes or duration of restraint after the hospital restructured to include an unlocked day hospital program, transitional residential program, and intensive care unit (number of events: 114 vs 190, p = not reported [NR], and mean 11.1 vs 9.2 hours, p = NS, respectively).[47]

Composite Measure of Coercion

No study reported data on a composite measure of coercion.

Forced Medication Use

Two pre-post studies found the use of forced medications decreased in the period after the intervention compared to before.[46,49] One large pre-post study found the introduction of an open-door policy was associated with a reduction in administration of forced medication (aOR = 0.90, 95% CI [0.83, 0.98]).[46] The same study reported unadjusted decreases in cases with at least 1 forced medication (2.4% beginning of period vs 1.2% end of period, p <0.001) and mean number of forced medications (mean 2.3 beginning of period vs 1.2 end of period, $p = 0.003$).[46] The other pre-post study found forced medication use decreased 84.4% (p <0.001) after the hospital structurally modernized the inpatient psychiatric units.[49]

Patient Outcomes

One small pre-post study conducted in the US reported the crude number of suicide attempts (1 vs 0 events, p = NR), deaths (1 vs 0 events, p = NR), and patient-to-patient assaults (6 vs 6 events, p = NR) before compared to after hospital restructuring (including the introduction of an open day hospital unit) and found no difference.[47] A second very small study in the United Kingdom ($N = 18$) found less aggressive incidents and aggressive patients 3 to 6 months after the move to a purpose-built psychiatric intensive care unit than 3 to 6 months before the move (16 vs 36, $p = 0.01$ and 12 vs 16, p = NR, respectively).[48]

Staff Outcomes

One small pre-post study reported the crude number of patient-to-staff assaults (1 vs 1 events, p = NR) before compared to after hospital redesign to include an open ward and found no difference.[47]

Table 4. Summary of Findings for Hospital/Unit Restructuring

Outcome	Studies (Patients); Design	Methodological Limitations	Indirectness	Imprecision	Inconsistency	Other Issues	Overall Confidence	Summary of Findings
Seclusion episodes	3 (17,521); Pre-post	Serious limitations[a]	Direct	Precise	Inconsistent[b]	Sparse data	Low	May reduce episodes of seclusion
Seclusion duration	3 (17,521); Pre-post	Serious limitations[c]	Direct	Precise	Consistent	Sparse data	Low	May reduce duration of seclusion
Restraint episodes	2 (>144[d]); Pre-post	Serious limitations[c]	Direct	Precise	Inconsistent[e]	Sparse data	No conclusion	Insufficient evidence
Restraint duration	2 (>144 [d]); Pre-post	Serious limitations[c]	Direct	Precise	Consistent	Sparse data	Low	May reduce duration of restraint
Coercion composite	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Forced medication	2 (>17,359[d]); Pre-post	Serious limitations[a]	Direct	Precise	Consistent	Sparse data	Low	May reduce the use of forced medication
Patient outcomes	2 (162); Pre-post	Serious limitations[c]	Direct	Precise	Inconsistent	Sparse data	No conclusion	Insufficient evidence
Staff outcomes	1 (144); Pre-post	Serious limitations[c]	Direct	Precise	NA	Single Study	No conclusion	Insufficient evidence

Notes. [a] One pre-post study conducted adjusted analyses and 2 conducted crude analyses. All studies relied on self-reported outcome data; [b] One large and 1 very small pre-post study reported a reduction in outcomes, and 1 small pre-post study reported no difference in outcomes; [c] All studies used crude unadjusted analyses to evaluate this outcome; [d] Only 1 study reported sample size; [e] 1 study reported a reduction and another reported an increase.
Abbreviations. NA=not applicable.

EFFECT OF STAFF EDUCATION/TRAINING

Based on evidence from 3 pre-post studies,[50-52] training staff (*eg,* de-escalation, alternative strategies to seclusion and preventing violence) may reduce staff injuries and as-needed medication use (Table 5). We have low confidence in these findings because of methodological limitations (mostly unadjusted analyses) and inconsistent findings within and between studies. Studies provide insufficient evidence (no conclusion) for episodes of seclusion, episodes of restraint, other patient outcomes (*eg*, aggression), and composite measures of coercion. Studies did not report on duration of seclusion or duration of restraint.

Seclusion

Two studies (1 concurrent and 1 pre-post) found no difference in episodes of seclusion between patients in wards where staff received training (TeamsSTEPPS and City Nurses) compared to either a pre-period or concurrent comparison.[50,52] In a pre-post study, the rate of seclusion was similar before and after the TeamsSTEPPS intervention was implemented (5.9% vs 4.4%, $p = 0.349$).[52] However, an unadjusted pre-post analysis of the City Nurses intervention found a reduction in mean seclusion events per shift (mean 0.02 vs 0.01, $p = 0.02$).[50] Neither study reported duration of seclusion.

Restraint

One concurrent comparison study (Bowers et al) conducted a pre-post unadjusted analysis among the 3 intervention wards only and found that the City Nurses intervention reduced episodes of restraint per shift (mean 0.06 vs 0.03, $p = 0.02$).[50] A pre-post study (Forster et al) reported a 13.8% decrease (unadjusted) in episodes of restraint in the 12 months after the introduction of a training intervention (pre period 2,379 episodes per 2,560 admissions vs post period 2,380 episodes per 3,010 admissions, p = NR).[51] Neither study reported duration of restraint.

Composite Measure of Coercion

One study found no difference (City Nurse vs concurrent practice as usual comparison) in a measure of total containment as measured by the PCC-SR; the analyses adjusted for both patient characteristics and cluster effects of the ward. A pre-post unadjusted comparison in the same study (of just the 3 intervention wards) found a reduction in events per shift in the composite endpoint (mean 4.56 vs 3.74, $p < 0.001$).[50]

One pre-post study reported a 54.6% decrease in the duration of seclusion or restraint per episode after the introduction of a staff training intervention (13.9 vs 6.3 hours/episode, p = NR).[51]

Forced Medication Use

Patients in wards with staff trained in the City Nurse intervention received fewer as-needed medications ($p < 0.001$ compared to concurrent comparison and in pre-post analysis).[50] In the same study, an unadjusted pre-post analysis of intervention wards only found a reduction in administration in forced intramuscular medication (mean per shift 0.07 vs 0.04, $p = 0.003$).

Patient Outcomes

One concurrent comparison study (with a pre-post analysis) evaluated the City Nurse intervention and reported patient conflict, verbal aggression, physical aggression against objects, physical aggression against others, and physical aggression against self.[50] In adjusted analyses, there was no significant difference in these outcomes (as individual items or as a composite "total conflict" variable) for patients in wards where staff were trained compared to patients in concurrent control wards. In unadjusted pre-post analyses, there were significant reductions in conflict, verbal aggression, aggression against objects, and aggression against self ($p < 0.05$ for all).

Staff Outcomes

One pre-post study (Forster et al) reported a crude 18.8% decrease in staff injuries after the introduction of a training program compared to the 12 months before the intervention (48 vs 39 incidents, p = NR).[51]

Table 5. Summary of Findings for Staff Education/Training

Outcome	Studies (Patients); Design	Methodological Limitations	Indirectness	Imprecision	Inconsistency	Other Issues	Overall Confidence	Summary of Findings
Seclusion episodes	2 (>730); concurrent and pre-post	Serious limitations[a]	Direct	Precise	Inconsistent[b]	Sparse data	No conclusion	Insufficient evidence
Seclusion duration	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Restraint episodes	2 (>5,570); concurrent and pre-post	Some limitations[c]	Direct	Precise	Inconsistent[d]	Sparse data	No conclusion	Insufficient evidence
Restraint duration	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Coercion composite	2 (>5,570); concurrent and pre-post	Some limitations[c]	Direct	Precise	Inconsistent[d]	Sparse data	No conclusion	Insufficient evidence
Forced medication	1 (NR); concurrent and pre-post	Some limitations[c]	Direct	Precise	NA	Single study	Low	May reduce as-needed medication use and forced intramuscular medication use
Patient outcomes	1 (NR); concurrent and pre-post	Serious limitations[c]	Direct	Precise	NA	Single study	No conclusion	Insufficient evidence
Staff outcomes	1 (4,940); pre-post	Serious limitations[e]	Direct	Precise	NA	Single study	Low	May reduce staff injuries

Notes.[a] One study conducted adjusted analyses and a second conducted crude analyses. Both studies relied on self-reported outcome data; [b] One pre-post study reported no difference and 1 concurrent study with a pre-post analysis reported reduction; [c] Self-reported outcome data and unclear if comparator group is similar; [d] One study reported no difference with a concurrent comparison but a reduction with a pre-post comparison and a second pre-post analysis reported a reduction in the duration of seclusion or restraint. One pre-post study reported a reduction; [e] One pre-post study conducted unadjusted analyses.
Abbreviations. NA=not applicable.

EFFECT OF SENSORY MODULATION

Based on evidence from 2 concurrent comparison and 5 pre-post studies,[53-59] episodes of seclusion, but not duration of seclusion, may be reduced by sensory modulation rooms on inpatient wards (Table 6). Sensory modulation rooms may also reduce use of forced medication. We have low confidence in these findings due to serious methodological limitations, inconsistent findings across studies for some outcomes, and sparse reporting of data. Studies provide insufficient evidence (no conclusion) regarding episodes of restraint, composite measures of coercion, patient outcomes (*eg,* self-injury, patient-to-patient assault), and staff outcomes (patient-to-staff assault). Studies did not report on duration of restraint.

Seclusion

Five studies reported seclusion events with diverse findings. One study with a concurrent control[55] found a sensory modulation room reduced episodes of seclusion (percent change not quantitively reported, $p < 0.001$), and 2 pre-post studies found no difference after a unit implemented the room compared to a period before.[56,58] Azuela et al (a pre-post study) found no difference in seclusion episodes in the 2 years after unit A implemented the comfort room compared to the year before (median number seclusion events 8.5 vs 6.5, $p > 0.05$) but found a significant reduction in seclusion events in unit B after the comfort room was installed (median number seclusion events 14.5 vs 7.5, $p = 0.04$). Another pre-post study reported no seclusion events in the 4 months after the introduction of the sensory modulation room; however, this was no different from the 4 months before that observed 0 seclusion events.[57] The lack of use of seclusion at baseline in this study makes it difficult to assess the impact of the sensory modulation room.

The concurrent comparison study (Lloyd et al) found no difference in duration of seclusion.[55] In a pre-post comparison, Azuela et al found no difference in duration of seclusion for patients in unit A (median 126.8 vs 66.7 hours; $p > 0.05$) and a decrease in duration of seclusion for patients in unit B (360.3 vs 145.3 hours, $p = 0.02$).[53] A third pre-post study also found no differences in seclusion duration after the introduction of a sensory modulation room on the ward and possible increase in mean duration time, once outlier cases were accounted for.[58]

Restraint

One pre-post study reported no difference in the use of restraint in the 4 months before the introduction of a sensory modulation room compared to 4 months after (month 1 of pre period 0.39 events per 1,000 client days, months 2-4 of pre period 0 events, and month 1-4 post period 0 events).[57] The low baseline use of restraint in this study makes it difficult to assess the impact of the sensory modulation room. No other study reported data on episodes of restraint and no study reported data on duration of restraints.

Composite Measure of Coercion

One concurrent comparison study (Cummings et al) found no difference in rates of seclusion and restraint after the introduction of a sensory modulation room.[54] The study only reported a qualitative description of their findings and did not report summary data. A second pre-post study reported a reduction in the percent patient days where sedation, seclusion, or restraints were used (13.3% vs 1.6%, $p = 0.14$).[59]

Forced Medication Use

One study reported reductions in the number of benzodiazepines distributed per day (median 2.5 vs 1, $p < 0.001$), total amount of benzodiazepines distributed per day (median 4 mg vs 1 mg, $p < 0.001$), and number of patients given benzodiazepines per day (median 2 vs 1, $p < 0.001$) after the introduction of a sensory modulation room.[59] The study reported no difference in average benzodiazepine dose per patient day among those who received medication (mean 2 mg vs 2 mg, $p = 0.393$). The study did not report whether benzodiazepines were voluntarily taken by patients or forced. No other study reported forced medication use.

Patient Outcomes

One pre-post study reported a crude 12.1% increase in patient self-injurious behavior (4-month average of 2.32 events per 1,000 client days in pre period) and a 23.4% decrease in client-to-client assaults (4-month average of 3.98 events per 1,000 client days in pre period).[57] Another pre-post study administered the Essen Client Evaluation Schema (EssenCES) survey to residents and staff to understand their perception of ward climate and found no difference in Patient's Cohesion subdomain after the installation of the comfort rooms.[53] A third pre-post study reported a non-significant decrease in aggressive patient episodes 12 months after the implementation of a sensory modulation room compared to 12 months before (13.9 vs 19.6, p = NS).[56]

Staff Outcomes

Two pre-post studies reported on staff outcomes. One found a 48.1% decrease in client-to-staff assaults after implementation of the sensory modulation room (4-month average before intervention 2.32 events vs 1.20 events per 1,000 client days after intervention).[57] The second found no difference in the staff portion of the EssenCES (subdomains for experience of safety, therapeutic hold, and overall climate) or Professional Attitudes Towards Seclusion Questionnaire before compared to after comfort rooms were installed.[53] No other study reported staff outcome data.

Table 6. Summary of Findings for Sensory Modulation

Outcome	Studies (Patients); Design	Methodological Limitations	Indirectness	Imprecision	Inconsistency	Other Issues	Overall Confidence	Summary of Findings
Seclusion episodes	5 (>75[a]); concurrent and pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[c]	Sparse data	Low	May reduce episodes of seclusion
Seclusion duration	3 (>75[a]); concurrent and pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[d]	Sparse data	Low	No difference in duration of seclusion
Restraint episodes	1 (NR); pre-post	Serious limitations[b]	Direct	Precise	NA	Single study	No conclusion	Insufficient evidence
Restraint duration	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Coercion composite	2 (>321[e]); concurrent and pre-post	Serious limitations[b]	Indirect	Precise	Inconsistent[f]	Sparse data	No conclusion	Insufficient evidence
Forced medication	1 (321); pre-post	Serious limitations[b]	Indirect[g]	Precise	NA	Single study	Low	May reduce use of forced medication
Patient outcomes[h]	3 (>75[a]); pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[i]	Sparse data	No conclusion	Insufficient evidence
Staff outcomes[j]	2 (NR); pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[k]	Sparse data	No conclusion	Insufficient evidence

Notes. [a] One study reported sample size of number of patients with seclusion events only; [b] Self-reported outcome data and unadjusted analyses; [c] One study with a concurrent comparison reported a reduction in seclusion, 2 pre-post studies found no difference, 1 pre-post study reported 0 events pre and post, and 1 pre-post study reported inconsistent findings in different units that implemented a comfort room; [d] One concurrent comparison reported no difference in duration of seclusion, 1 pre-post study reported inconsistent findings in different units that implemented a comfort room, and 1 pre-post study reported a possible increase in duration once outlier cases were accounted for; [e] One study reported sample size; [f] One concurrent comparison qualitatively reported no difference in outcome and 1 pre-post study reported a reduction in the outcome; [g] Did not specify if medication was forced or voluntarily taken by patients; [h] Self-injury, aggressive episodes, client-to-client assault, and patient cohesion subdomain on the Essen Climate Evaluation Schema; [i] Three pre-post studies reported an increase, decrease, and no change on diverse patient outcome domains; [j] Client-to-staff assault, staff subdomains on the Essen Climate Evaluation Schema, and Professional Attitudes Towards Seclusion Questionnaire; [k] Two pre-post studies reported a decrease and no-difference on diverse staff outcome domains.
Abbreviations. NA=not applicable; NR=not reported.

EFFECT OF RISK ASSESSMENT WITH MANAGEMENT PROTOCOL

Comparisons of Risk Assessments with the Brøset Violence Checklist

Based on evidence from 2 RCTs and 2 pre-post studies,[60-62,66] episodes of seclusion, a composite measure (psychotropic medication use, seclusion, and restraint), and patient aggressive incidents may be reduced by risk assessment protocols that include the Brøset Violence Checklist (Table 7). We have low confidence in these findings due to serious methodological limitations, inconsistent findings for some outcomes, and sparse reporting of data. There is no evidence of differences in episodes of restraint and some evidence to suggest duration of restraint may increase (low confidence). The studies provide insufficient evidence regarding duration of seclusion (no conclusion). The studies did not evaluate use of forced medication or staff outcomes.

Seclusion

Three studies (1 RCT and 2 pre-post) found reductions in seclusion after wards implemented a risk assessment protocol that included the Brøset Violence Checklist.[61,62,66] A RCT found the number of seclusion incidents decreased 15% (p = NS) from the 10-week baseline period (relative risk [RR] = 1.19, 95% CI [0.76, 1.88]) to 30-week intervention period (RR = 1.01, 95% CI [0.74, 1.88]) for patients randomized to treatment wards compared to control wards. The same study found the number of patients exposed to seclusion increased 8% (p = NS) in the experimental wards compared to the control wards (10-week baseline period RR = 1.42, 95% CI [0.83, 2.48] vs 30-week intervention period RR = 1.71, 95% CI [1.12, 2.67]). A pre-post study found the use of seclusion decreased after the introduction of the Brøset Violence Checklist (30 episodes per month before intervention vs 22 episodes per month after intervention, p = NR).[62] A second pre-post study found a 52% decrease ($p < 0.001$) in seclusion events in the 12 months after the intervention compared to 12 months before (events 9.2/100 vs 4.4/100 admissions).[61]

Two studies (1 RCT and 1 pre-post) reported decreases in duration of seclusion for risk assessment interventions that included the Brøset Violence Checklist.[61,66] The RCT reported a 45% decrease ($p < 0.05$) in hours of seclusion per admission (10-week baseline period RR = 1.12, 95% CI [1.01, 1.19] vs 30-week intervention period (RR = 0.62, 95% CI [0.58, 0.66]). The pre-post study reported a 27% decrease in duration of seclusion per admission (p = NR), but mean duration of seclusion events increased (mean 337.7 vs 516.2 min, $p < 0.01$).[61]

Restraint

One pre-post study found rates of restraint decreased 6% after a Brøset Violence Checklist-based intervention was introduced compared to before (events 5.5/100 vs 5.1/100 per admission), although this finding was not significant ($p = 0.44$).[61] The same study reported a 52% increase in duration of restraints per admission (p = NR) and mean duration of restraint increased (mean 286 vs 445 min, $p < 0.01$).

Composite Measure of Coercion

One RCT reported a decrease in a composite measure of coercion that included use of psychotropic medication, seclusion, and restraint (3-month event rate 10% control vs -27% intervention, $p < 0.001$).[60] The study did not report duration of the composite measure and no other study reported a composite outcome.

Forced Medication Use

No study reported data on use of forced medication.

Patient Outcomes

Two RCTs[60,66] (Abderhalden et al and van de Sande et al) reported aggressive incidents/events and 1 RCT (Abderhalden et al) reported physical attacks.[60] In both RCTs, aggressive incidents significantly decreased for patients randomized to wards with structured risk assessment protocols using the Brøset Violence Checklist compared to control wards. Abderhalden et al reported severe aggressive events, defined as a score ≥9 on the Staff Observation Aggression Scale, declined in both treatment (RR = 0.59, 95% CI [0.41, 0.83]) and control wards (RR = 0.85, 95% CI [0.64, 1.13]), and the reduction was larger in the intervention wards ($p <$ 0.001). The same study reported a reduction in physical attacks for patients in wards randomized to intervention compared to control (-41% vs -7%, $p < 0.001$). Van de Sande et al reported a 68% reduction ($p < 0.05$) in aggressive incidents and a 50% reduction (p = NS) in number of aggressive patients in intervention compared to control wards.[66]

Staff Outcomes

No study reported staff outcomes.

Table 7. Summary of Findings for Risk Assessments with Brøset Violence Checklist

Outcome	Studies (Patients); Design	Methodological Limitations	Indirectness	Imprecision	Inconsistency	Other Issues	Overall Confidence	Summary of Findings
Seclusion episodes	3 (>12,371[a]); 1 RCT and 2 pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[c]	Sparse data	Low	May reduce episodes or incidents of seclusion
Seclusion duration	2 (12,371); 1 RCT and 1 pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[d]	Sparse data	No conclusion	Insufficient
Restraint episodes	1 (11,413); pre-post	Serious limitations[b]	Direct	Precise	NA	Single study	Low	No difference episodes of restraint
Restraint duration	1 (11,413); pre-post	Serious limitations[b]	Direct	Precise	NA	Single study	Low	May increase duration of restraint
Coercion composite	1 (NR); RCT	Serious limitations[b]	Indirect	Precise	NA	Single Study	Low	May reduce a composite measure of psychotropic medication use, seclusion and restraint
Forced medication	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Patient outcomes[e]	2 (>458[f]); 2 RCTs	Serious limitations[b]	Direct	Precise	Consistent	Sparse data	Low	May reduce aggressive incidents
Staff outcomes	0 (0)	NA	NA	NA	NA	NA	NA	No evidence

Notes. [a] One study did not report sample size; [b] All studies used self-reported outcome data. RCTs did not blind staff. Pre-post studies conducted unadjusted analyses; [c] RCT reported non-significant decrease in seclusion incidents and non-significant increase in number of patients exposed to seclusion, 1 pre-post study reported significant decrease in proportion of patients secluded, another pre-post study reported decrease in number of episodes of seclusion (p = NR); [d] RCT reported non-significant decrease. Pre-post study reported increase in mean duration of seclusion; [e] Aggressive incidents and physical attacks. [f] One RCT did not report sample size.
Abbreviations. NA=not applicable; NR=not reported; RCT=randomized controlled trial.

Comparisons of Investigator-developed Risk Assessments

Based on evidence from 3 pre-post studies,[63-65] there is no difference in duration of seclusion and staff satisfaction between interventions that include an investigator-developed risk assessment tool compared to usual care, but episodes and duration of restraint may be reduced by these interventions (Table 8). We have low confidence in these findings due to serious methodological limitations and sparse data. The studies provide insufficient evidence regarding episodes of seclusion and other patient outcomes (no conclusion). The studies did not evaluate a composite measure of coercion or use of forced medication.

Seclusion

One pre-post study found a decrease in seclusion per 1,000 occupied bed days in the 18 months after a hospital-developed risk assessment tool was implemented compared to the 24 months before (RR = 0.71, 95% CI [0.63, 0.80]).[63] A second pre-post analysis of an intervention that included the Modified Agitation Severity Scale found no difference in seclusion incidents in the 18 months before compared to 18 months after the intervention (22 vs 28 incidents, p = NR).[64] The same study found no difference in minutes in seclusion before compared to after the intervention (mean 132 vs 137 minutes). A third pre-post study found no difference in seclusion events or duration 6 months after the implementation of the Management of Acute Arousal Program compared to 6 months before (67 vs 64 incidents, $p = 0.51$; 312 vs 299 minutes, $p = 0.19$).[65]

Restraint

One pre-post study reported a 44.1% decrease in total incidents of restraint (68 vs 38 incidents, p = NS) in the 18 months after the introduction of a risk assessment tool compared to the 18 months before.[64] The same study reported a 44.4% decrease in average restraint minuets per incident (mean 18 vs 10 minutes, $p = 0.047$) The other study did not report restraint data.

Composite Measure of Coercion

No study reported data on composite measure of coercion.

Forced Medication Use

No study reported data on use of forced medication.

Patient Outcomes

A pre-post study reported non-significant decreases in aggressive events per 1,000 occupied bed days (RR = 0.78, 95% CI [0.47, 1.27]) and self-harm/suicide (RR = 0.69, 95% CI [0.26, 1.69]) after the introduction of a hospital-developed risk assessment.[63] A second pre-post study found no difference in an 8-item study developed patient safety survey (higher scores indicate positive responses; mean 12.2 vs 13.25, p = NS).[64]

Staff Outcomes

Two pre-post studies reported survey data on staff satisfaction and safety.[63,64] Harrington et al found significant differences on 2 of 6 items on a staff satisfaction survey conducted before and after implementation of the intervention. Staff were more likely to agree with the statement that

they are "satisfied with the practice of visual observations in the management of patients who have been identified as being "at risk'" and "visual observations provide optimum care for the patients at [this psychiatric unit]" after the intervention. Manning et al found no difference in a 6-item study-developed staff survey or on the Oldensburg Burnout Scale before and after the intervention (mean 36.17 vs 36.11, $p = 0.98$).[64]

Table 8. Summary of Findings for Investigator-developed Risk Assessments

Outcome	Studies (Patients); Design	Methodological Limitations	Indirectness	Imprecision	Inconsistency	Other Issues	Overall Confidence	Summary of Findings
Seclusion episodes	3 (3,149); pre-post	Serious limitations[a]	Direct	Precise	Inconsistent[b]	Sparse data	No conclusion	Insufficient
Seclusion duration	2 (1,094); pre-post	Serious limitations[c]	Direct	Precise	NA	Sparse data	Low	No difference in duration of seclusion
Restraint episodes	1 (742); pre-post	Serious limitations[d]	Direct	Precise	NA	Single study	Low	May reduce episodes of restraint
Restraint duration	1 (742); pre-post	Serious limitations[d]	Direct	Precise	NA	Single study	Low	May reduce duration of restraint
Coercion composite	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Forced medication	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Patient outcomes	2 (2,797); pre-post	Serious limitations[e]	Direct	Precise	Inconsistent[f]	Sparse data	No conclusion	Insufficient
Staff outcomes[g]	2 (2,797); pre-post	Serious limitations[e]	Direct	Precise	Consistent	Sparse data	Low	No difference in staff satisfaction

Notes. [a] All studies used self-reported outcome data; 1 study conducted adjusted analyses and 2 conducted crude analyses; [b] One study reported a decrease in events and 2 studies reported no difference; all studies evaluated different protocols; [c] Both studies used self-reported outcome data; 1 study conducted adjusted and 1 conducted crude analyses; [d] Study used self-reported outcome data and conducted crude analyses; [d] One study reported aggressive events and self-harm/suicide. A second study reported a patient safety survey; [e] Both studies used self-reported outcome data and reported crude analyses; [f] One study reported non-significant decreases in aggressive events and self-harm/suicide. A second study reported no difference in patient safety based on a hospital-developed patient survey; [g] Two studies reported staff satisfaction and 1 study reported a measure of staff burnout.
Abbreviations: NA=not applicable.

EFFECT OF COMPREHENSIVE/MIXED

Comparison of Safewards Intervention

Based on evidence from 1 RCT and 1 pre-post study,[69, 72] the Safewards intervention may reduce a composite measure of coercion (restraint and seclusion and/or forced medication use) and patient conflicts (Table 9). We have low confidence in these findings because studies had serious methodological concerns. The studies provide insufficient evidence (no conclusion) for staff outcomes. Studies did not report on seclusion, restraint (other than as a composite outcome), or use of forced medication.

Seclusion

No study reported data on seclusion, other than as a composite outcome.

Restraint

No study reported data on restraint, other than as a composite outcome.

Composite Measure of Coercion

One RCT[69] and 1 pre-post study[72] reported a reduction in a composite measure of coercion for patients in wards that implemented Safewards. In the RCT, the composite measure of containment (defined as actions taken by staff to manage unsafe patients such as coerced medication, seclusion, restraint, special observation, *etc*) was evaluated using the patient-staff conflict checklist (PCC), which is completed by the unit nurse in charge and measures 8 forms of containment. Among wards that experienced containment events, the rate of containment decreased by 26.4% (95% CI [9.9, 34.3%]) per shift for wards that implemented Safewards. The same study reported no difference in rates of shifts with 0 of containment events (RR = 1.04, 95% CI [0.83, 1.34]). In a primary analysis, the pre-post study used the PCC and defined containment as seclusion and/or restraint.[72] In a secondary analysis, containment was defined as seclusion, restraint, and forced medication. With both definitions there was a significant decrease in use of containment (RR = 0.88, 95% CI [0.82, 0.94] and RR = 0.27, 95% CI [0.14, 0.47], respectively). Neither study reported data on duration of containment.

Forced Medication Use

No study reported data on use of forced medications.

Patient Outcomes

One RCT found no difference in self-harm evaluated with the Self-Harm Antipathy Scale (adjusted mean difference = 0.23, 95% CI [-3.38, 3.83]).[69] The same RCT reported a reduction in conflicts as measured by the PCC, which evaluates 22 events such as verbal aggression (RR = 0.85, 95% CI [0.76, 0.94]). There was no difference in wards reporting shifts with 0 conflict events (RR = 1.14, 95% CI [0.92, 1.42]). In adjusted analyses, the pre-post study reported a decrease in conflicts reported via the PCC and physical aggression (aRR = 0.77, 95% CI [0.66, 0.89] and RR = 0.65, 95% CI [0.59, 0.72], respectively).[72]

Staff Outcomes

One RCT found no difference in the Ward Atmosphere Scale, which measures staff assessment of the ward culture and environment.[69] A pre-post study noted no difference in the Violence Prevention Climate Scale, which measures staff and patient perceptions of violence on the ward.[72]

Table 9. Summary of Findings for Safewards Intervention

Outcome	Studies (Patients); Design	Methodological Limitations	Indirectness	Imprecision	Inconsistency	Other Issues	Overall Confidence	Summary of Findings
Seclusion episodes	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Seclusion duration	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Restraint episodes	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Restraint duration	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Coercion composite	2 (NR[a]); 1 RCT and 1 pre-post	Serious limitations[b]	Indirect[c]	Precise	Consistent	None	Low	May reduce composite measures
Forced medication	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Patient outcomes	2 (NR[a]); 1 RCT and 1 pre-post	Serious limitations[b]	Direct	Precise	Consistent	None	Low	May reduce patient conflicts
Staff outcomes	2 (NR[a]); 1 RCT and 1 pre-post	Serious limitations[b]	Direct	Precise	Consistent	Sparse data[d]	No conclusion	Insufficient

Notes. [a] Studies did not report patient sample size; [b] Both studies had high risk of bias; [c] Both studies reported composite outcome "containment" that was measured by the same tool, the patient-staff conflict checklist shift report. The specific scope of events defined by containment may have varied; the RCT reported containment as "actions taken by staff to manage unsafe patients such as coerced medication use, seclusion, restraint, special observation, *etc*" and the pre-post reported containment as seclusion/restraint for the primary analysis and seclusion/restraint/forced medication use for the secondary analysis; [d] Two studies reported different measures of staff outcomes (ward culture/environment and violence on ward).
Abbreviations: NA=not applicable; NR=not reported; RCT=randomized controlled trial.

Comparison of Comprehensive/Mixed Interventions with Different Components

Based on evidence from 1 RCT, 2 concurrent comparison studies,[68,76] and 11 pre-post studies,[67,70,73-75,77-80,84,85] episodes of seclusion, duration of seclusion, duration of restraint, episodes of composite measures of coercion, and duration of composite measures of coercion may be reduced by comprehensive/mixed interventions (Table 10). There is no evidence of differences for episodes of restraints and use of forced medication. We have low confidence in all these findings due to serious methodological limitations (self-reported outcome data and crude analyses) and sparse data. Studies provide insufficient evidence (no conclusion) for other patient outcomes and staff outcomes.

Seclusion

Nine studies evaluated mixed interventions and reported on the incidence or number of seclusion events.[67,68,70,73,75,76,79,82,84] All 9 studies reported fewer seclusion events for patients in intervention compared to comparison (or pre-implementation) wards. Effect sizes, outcome measures (*eg,* comparisons of counts, RR or hazard ratios [HR]), and statistical testing varied between studies. For example, 1 VA pre-post study (reported in a poster) reported a 56.3% decrease (71 vs 31 events, p = NR) in seclusion in the 3 years before compared to after the intervention.[70] A pre-post study evaluating wards trained in moral case deliberation reported a reduction the proportion of patients secluded (16.7% vs 9.6%, $p = 0.034$) but no difference in frequency of seclusion (mean 2.2 vs 3.4, $p = 0.42$).[79] Whitecross et al found a 65.3% decrease (p = NR) in seclusion episodes per 1,000 bed days and a 55.7% decrease in monthly percent of admitted patients secluded after the introduction of a multidisciplinary team "on call" approach.[84] A crisis prevention management intervention resulted in 30% to 63% reduction (depending on unit) in episodes of seclusion.[75] Hellerstein et al reported a reduction in the average number of patients secluded for those in wards that received a multidisciplinary intervention (mean 3.1 vs 1.1, $p < 0.001$).[73] A concurrent comparison study found a higher chance of being secluded if patients where in a ward that did not receive the culture change intervention (HR Year 1 = 2.8 and HR Year 2 = 5.6, p = NR).[76] A pre-post study reported significant reductions in seclusion events over the course of the 13 years since they first implemented their multicomponent model.[67] Finally, a RCT (Valimaki et al) found fewer seclusion events in wards randomized to the intervention compared to control (RR = 0.72, 95% CI [032, 1.63], p group * year interaction = 0.003), and in a secondary analysis fewer patients who were placed in seclusion (RR = 0.76, 95% CI [0.40, 1.46], p group * year interaction = 0.37).[82]

Eight studies reported on the duration of seclusion[68,70,73,76,78,79,82,84] and reported inconstant findings. One pre-post study reported a 50% increase (p = NR) in seclusion hours in the 12 months after a VA Medical Center implemented a comprehensive training program.[78] A RCT showed no difference in length of seclusion for patients in wards randomized to the intervention (log transformed mean difference 0.16, 95% CI [-0.39, 0.71], p group * year interaction = 0.21). The remaining 6 studies reported reductions in duration of seclusion for patients in experimental compared to comparison wards, though not all were statistically significant. For example, Boumans et al found that patients in wards who received the mixed intervention had fewer hours of seclusion (mean difference -63.46 hours, p <0.01).[68] A pre-post study of a mixed intervention incorporating moral case deliberation reported fewer hours of seclusion, although this finding was non-significant (156.2 vs 39.8 hours, $p = 0.115$), and a significant reduction in the mean duration of seclusion events (73.9 vs 10.0 hours, $p = 0.05$).[79] A pre-post study of a

multicomponent intervention that included staff education, hospital-wide policy changes on the use of seclusion/restraint, and efforts to improve communication between patients and staff reported reductions in the total hours patients were secluded in a month (41.6 vs 2.7, p = 0.003) and the proportion of total patient time in seclusion (0.11 vs 0.007; *p* = 0.03) after the intervention.[73] Whitecross et al reported a 71.9% reduction in hours of seclusion per 1,000 bed days (270.4 vs 76.0 hours).[84] Finally, 1 VA pre-post study (reported in a poster) reported an 88% decrease in total hours of seclusion in the 3 years before compared to after the intervention (1204 vs 142 total hours).[70]

Restraint

Six studies evaluating mixed interventions reported on episodes of restraint and found inconsistent findings.[67,70,73,75,79,82] A RCT found the use of limb restraints increased from baseline to follow-up in usual care wards (5.4% vs 7.3%) and remained stable in intervention wards (8.6% vs 8.6%; *p* value group * year interaction < 0.001). The same study reported no difference in the proportion of limb restraint used, physical restraint events, or patients physically restrained.[82] A pre-post study conducted in 5 units reported a 20% to 97% reduction in restraint use after the units implemented a crisis prevention management intervention.[75] Stoll et al found that use of restraint decreased after 2 wards implemented a mixed intervention that incorporated moral case deliberation, though this finding was non-significant (3.2% vs 1.8%, *p* = NS).[79] The same study reported no difference in the frequency of restraint episodes among those exposed to restraint.[79] One pre-post study reported no difference in the number of patients restrained per month (mean 0.35 vs 0.32, *p* = NS) after the introduction of a multicomponent intervention.[73] A VA study (reported in a poster) reported a 10% increase (10 vs 11 events) in total patients restrained in the 3 years after compared to 3 years before the intervention.[70] Blair reported a decrease in restraint events over the course of 13 years since the implementation of a multicomponent engagement model; however, reporting of methods and outcomes in this study was sparse.[67]

Five studies also evaluated time in restraints.[70,73,78,79,82] A RCT found patients in intervention wards spent less time in limb restraints and physical restraint but these findings were not significant.[82] One pre-post study reported no difference in the total hours patients were in restraint per month (mean 1.7 vs 1 hours, *p* = NS) or the percentage of patient hours in restraints (0.005 vs 0.003; *p* = NS) after the introduction of a multicomponent intervention.[73] A VA study (poster) reported an 8% decrease in total hours in restraint. One pre-post study reported a 47% decrease in the total time patients spent restrained in the 12 months after the introduction of the intervention compared to the 12 months before (3387 vs 1812 hours, *p* = NR).[78] One pre-post study reported significant decreases in the number of hours in restraint overall and per episode (14.5 vs 86.8, *p* = 0.02 and 10.1 vs 55.2, *p* = 0.01, respectively) after the introduction of the moral case deliberation approach.[79]

Composite Measure of Coercion

Five pre-post studies[69,70,74,79,80,85] (including 2 studies conducted in the VA)[70,85] reported reductions in composite measures of coercion. In 4 studies, the composite only included episodes of seclusion and restraint,[70,74,79,80,85] and in 1 study the composite included seclusion, restraint, and forced medication use.[79] In 1 VA study, the incidence of the composite significantly decreased after the introduction of the intervention (mean monthly rate 3.17 vs 1.5, *p* = 0.03),[85] and a second VA study reported a 48% decrease in number of combined events in the 3 years

after the intervention compared to the same period before (81 vs 42 events, p = NR). A pre-post study qualitatively reported a 94% reduction in combined seclusion and restraint events (p = NR).[70,80] Another pre-post study reported a significant decrease in total number of episodes in the 12 months after compared to before the intervention (310 vs 148 episodes, $p < 0.01$).[74] Finally, another pre-post study reported a reduction in proportion of patients subject to seclusion, restraint, and forced medication use after the introduction of a mixed intervention that included moral case deliberation (17.2% vs 9.5%, $p = 0.02$).[79]

Three VA studies[70,77,78] reported reductions in a composite of total hours in seclusion and restraint. One VA pre-post study (McDonagh et al) reported an 86% decrease in total hours in seclusion and restraint during the 3 years post intervention compared to same period before (1,711 vs 245 total hours, p = NR).[70] A second VA pre-post study (Pollard et al) reported fewer monthly hours of seclusion and restraint after the introduction of a comprehensive intervention developed in response to the Joint Commission (182 vs.56 hours, $p < 0.001$).[77] A third VA pre-post study reported a 31% decrease in total hours in seclusion and restraint during the 12 months after the intervention was introduced compared to the 12 months before (3783 vs 2600 total hours, p = NR).[78]

Forced Medication Use

Two studies reported on use of forced medication.[79,82] One RCT found no significant differences in the number of patients who experienced forced medication or the total number of patients injected.[82] A pre-post study also found no difference in forced medication use after a hospital implemented a mixed intervention that included forced medications (4.8% vs 4.1%, $p = 0.93$).[79]

Patient Outcomes

Six studies reported patient outcomes including satisfaction with treatment ($N = 1$),[82] death ($N = 1$),[82] assaults/fights ($N = 5$),[70,73,74,77,84] injuries, and self-harm ($N = 2$).[74,84] Two pre-post studies were conducted in the VA.[70,77] One RCT found no difference in a measure of satisfaction (Client Satisfaction Questionnaire) or deaths between patients in wards randomized to treatment or control.[82] A pre-post study reported no difference in the number of patients involved in fights in the 67 months after compared to 20 months before the intervention (mean 0.5 vs 0.3, p = NS).[73] One pre-post VA study reported 3 patient injuries and 1 patient assault in the 3 year pre period and 0 injuries or assaults cumulative in the 3 year post period.[70] A second pre-post VA study reported a reduction in assaults or self-destructive events after the intervention (mean 1.07 vs 0.72 events per 24-hour period, $p = 0.004$).[77] One study reported a significant increase in assaults on patients in the 12 months after compared to before the intervention (67 vs 85 events, p <0.05) and no difference in self-destructive behavior (27 vs 24 events, $p > 0.05$).[74] Finally, another study reported unadjusted reductions in self-harm (change = -25%), physical aggression (change = -25.2%), and verbal aggression (change = -23.4%) after implementation of a multidisciplinary team approach.[84] No other study reported other patient outcomes.

Staff Outcomes

Six studies (3 VA studies[70,77,85] and 3 non-VA studies)[73,74,82] reported staff outcomes. Two pre-post studies[70,73] reported staff injuries, 1 study reported assaults on staff,[74] 1 reported critical incidents (defined as potential or actual assaultive or self-destructive events),[77] 1 study evaluated staff satisfaction,[85] and 1 reported team climate and nurse turnover rates.[82] In 1 pre-post study,

staff injuries significantly decreased after implementation of the intervention (mean injuries per month 0.7 vs 0.18, $p = 0.03$). [73] One pre-post VA study reported 3 staff injuries in the 3 years before the intervention compared to 0 injuries in the 3 years after the intervention (p = NR).[70] The same study reported 0 patients assaults on staff before the intervention compared to after the intervention.[70] Another pre-post VA study found significant reductions in the number of critical incidents (defined as potential or actual assaultive events occurring on the unit in the past 24 hour period) in the 28 months following the intervention compared to the 18 months before the intervention (mean 0.72 vs 1.07, $p = 0.004$).[77] One pre-post study found the number of assaults on staff significantly increased after compared to before the intervention (31 vs 83 events, $p < 0.01$).[74] A pre-post VA study evaluated a recovery-oriented model of care and found significant increases in overall staff satisfaction and in subdomains related to satisfaction with programming, staff collaboration, ability to handle situations without restraints, ability to provide group programming, and belief that patients should be involved in their care ($p < 0.05$ for all).[85] Finally, a RCT found no difference in nurse turnover or team climate between staff in units randomized to intervention or control wards.[82]

Table 10. Summary of Findings for Comprehensive Interventions

Outcome	Studies (Patients); Design	Methodological Limitations	Indirectness	Imprecision	Inconsistency	Other Issues	Overall Confidence	Summary of Findings
Seclusion episodes	9 (>12,913[a]); 1 RCT, 2 concurrent control; 6 pre-post	Serious limitations[b]	Direct	Precise	Consistent	None	Low	May reduce episodes of seclusion
Seclusion duration	8 (>12,913[a]); 1 RCT, 2 concurrent control; 5 pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[c]	None	Low	My reduce duration of seclusion
Restraint episodes	6 (>8,754 [a]); 1 RCT, 5 pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[d]	None	Low	No difference in restraint events
Restraint duration	5 (>8,754 [a]); 1 RCT, 4 pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[e]	Sparse data	Low	May reduce duration of restraint
Composite coercion episodes	5 (>4,125 [a]); 5 pre-post	Serious limitations[b]	Indirect	Precise	Consistent	None	Low	May reduce composite measures of coercion
Composite coercion duration	3 (NR); 3 pre-post	Serious limitations[b]	Indirect	Precise	Consistent	None	Low	May reduce duration of composite measure of coercion
Forced medication	2 (8,754); 1 RCT, 1 pre-post	Serious limitations[b]	Direct	Precise	Consistent[f]	None	Low	No difference in forced medication use
Patient outcomes	5 (>4,724[a]); 5 pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[g]	Sparse data	No conclusion	Insufficient
Staff outcomes	3 (>3,368 [a]); pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[h]	Sparse data	No conclusion	Insufficient

Notes. [a] Several studies did not report patient level sample size; [b] Self-reported outcome data, unadjusted analyses, lack of blinding (RCT); 6 of 8 studies reported a reduction in duration of seclusion; [c] One RCT reported no difference, 1 pre-post study reported an increase, and 6 pre-post studies reported a decrease in duration of seclusion; [d] One RCT reported an increase in one restraint measure and no difference in 4 restraint measures, 2 pre-post studies reported a decrease in restraint, 2 pre-post study reported no difference in restraint, and 1 pre-post study reported an increase in restraint; [e] One RCT and 1 pre-post study reported no difference, 3 pre-post studies reported a decreased time; [f] One RCT found an increase in forced medication use for treatment compared to control ward patients, and 1 pre-post study found no decrease (p = 0.93); [g] Three pre-post studies reported reduction in assaults, 1 pre-post study reported an increase in assaults, and 1 pre-post study reported a large reduction in assaults; [h] One RCT reported no difference in nurse turnover or team climate, 2 pre-post studies reported decreases in staff injuries/critical incidents, 1 pre-post study reported increases in staff satisfaction, 1 pre-post study reported mixed results on staff assaults and injuries, and 1 pre-post study reported increases in staff assaults.
Abbreviations. NA=not applicable; RCT=randomized controlled trial.

DISCUSSION

We identified 48 reports that described 43 protocols (7 reports described 6 protocols without evaluation and 41 reports described 37 studies that reported comparative data). Interventions were multicomponent and targeted multiple levels, actors, and determinants of both patient and staff behavior. Four comparative studies evaluated hospital/unit restructuring, 3 evaluated staff education/training, 7 evaluated sensory modulation/rooms, 7 evaluated risk assessment interventions, and 16 evaluated comprehensive/mixed interventions. All 6 non-comparative protocols involved comprehensive/mixed interventions. Episodes of seclusion was the most frequently evaluated outcome, followed by episodes of restraint and composite outcomes of seclusion and restraint. Key findings include the following:

Hospital/unit restructuring

- Hospital/unit restructuring protocols involved implementing an open-door policy, outfitting rooms with natural light, and a culture shift towards patient-centered and recovery-oriented care (*ie*, intervention function *environmental restructuring)*.
- Restructuring units to include architecturally positive elements and restructuring services (including, in some cases, implementing an open-door policy) may reduce episodes of seclusion, duration of seclusion, duration of restraint, and use of forced medication (low confidence).
- It is unknown if restructuring units reduces episodes of restraint, other patient outcomes, and staff outcomes (insufficient evidence). The studies did not evaluate a composite measure of coercion.

Staff education/training

- Education/training interventions provided staff with de-escalation techniques and alternative strategies to seclusion and included intervention functions of *persuasion*, *education*, *training*, or *modelling*. *Staffing* was the primary resource associated with the interventions.
- Staff training (*eg,* de-escalation, alternative strategies to seclusion, and preventing violence) may reduce staff injuries and as-needed medication use (low confidence).
- It is unknown if staff training reduces episodes of seclusion, episodes of restraint, composite measures of coercion, and patient outcomes such as aggression (insufficient evidence). The studies did not evaluate duration of seclusion or restraint.

Sensory modulation

- Sensory modulation rooms involved creating a dedicated space to meet the multisensory needs of patients. The common intervention element was *environmental restructuring* followed by *education, persuasion, enablement,* and *restrictions*. *Space* and *equipment* to facilitate the intervention were the primary resources associated with sensory rooms.
- Sensory/comfort rooms may reduce episodes of seclusion and forced medication use but may not affect duration of seclusion (low confidence).

- It is unknown if sensory/comfort rooms reduce episodes of restraint, composite measures of coercion, patient outcomes (such as self-injury, patient-to-patient assault), and staff outcomes (patient-to-staff assault) (insufficient evidence). The studies did not report on duration of restraint.

Risk assessment and management protocols

- Risk assessment and management protocols involved using a structured tool to help staff identify potentially aggressive patients to direct clinical efforts. Risk assessment and management protocols included intervention functions of e*nvironmental restructuring, education,* and *training.* Resource requirements included *documentation* and *time staff spent to perform checks on patients*.
- Structured risk assessments that include the Brøset Violence Checklist may reduce episodes of seclusion, a composite measure of seclusion and, patient aggressive events (low confidence).
- There is no evidence of differences in episodes of restraint, and duration of restraint may increase for interventions that include the Brøset Violence Checklist (low confidence).
- It is unknown if incorporating the Brøset Violence Checklist reduces the duration of seclusion (insufficient evidence). The studies did not evaluate forced medication use or staff outcomes.
- Investigator-developed or -modified risk assessment tools may reduce episodes and duration of restraint but not duration of seclusion (low confidence).
- There is no evidence of differences in duration of seclusion or staff stratification for investigator-developed or -modified risk assessment tools (low confidence).
- It is unknown if investigator-developed risk assessment tools reduce episodes of seclusion or other patient outcomes (insufficient evidence). The studies did not evaluate composite measures of coercion or forced medication use.

Comprehensive/mixed interventions

- Comprehensive/mixed protocols included intervention functions of *education* and *training.* Protocols often included elements of *persuasion* to reinforce staff education and *environmental restructuring* to change physical or social context of the wards. The most common resource needs to implement mixed interventions were *documentation* and *staffing* followed by *programming*.
- The Safewards intervention may reduce a composite measure of coercion (restraint and seclusion and/or forced medication use) and patient conflicts (low confidence).
- It is unknown if the Safewards intervention impacts staff outcomes (insufficient evidence). The studies did not evaluate episodes or duration of seclusion, episodes or duration of restraint, or episodes of forced medication use.
- Other comprehensive interventions may reduce episodes of seclusion, duration of seclusion, duration of restraint, and episodes and duration of composite measures of coercion (low confidence).

- There is no difference in episodes of restraint or forced medication use for other comprehensive interventions (low confidence).
- It is unknown if other comprehensive interventions reduce other patient outcomes or staff outcomes (no conclusion).

STRENGTHS AND LIMITATIONS OF THE EVIDENCE BASE

There is great interest from policymakers, hospital administrators, staff, and patients for effective alternatives to seclusion. One of the most reassuring findings of this review is the number of protocols we found that attempted to address this need, and the diversity of intervention functions identified within protocols, suggesting that intervention designers are building complex solutions to address a complex practice problem. For example, 8 of the 9 intervention functions were identified in efforts to reduce staff's use of seclusion (*education*, *persuasion*, *incentivization, training*, *restriction*, *environmental restructuring*, *modelling*, and *enablement*), and 7 of the 9 intervention functions were identified in efforts to reduce patients' aggressive behavior (*education*, *persuasion*, *incentivization, training*, *restriction*, *environmental restructuring*, and *enablement*). It is reassuring that two-thirds of interventions targeted both patients and staff to reduce the likelihood of precipitating behavior requiring seclusion or any alternatives. In such protocols, patients were provided with education on how to manage distress more effectively and were often enabled to do so through efforts to change or re-shift the patient-staff dynamic from one of control to collaboration. Patient-focused interventions also often included environmental changes to support patients to manage their emotions (*eg,* access to a sensory room) along with social changes to the ward culture. While the evidence supporting the effectiveness of protocols to reduce seclusion (or their component intervention functions) is limited due to the quality of the empirical designs (discussed below), the ethos of the interventions aligns with contemporary perspectives of patient-oriented recovery-focused mental health care.

An important limitation of the evidence base is the sparse reporting of outcomes of interest to stakeholders; namely outcomes of patient aggression, patient and staff injuries, and patient and staff satisfaction. While the content of these interventions suggests face validity that they may be preferred by patients (and possibly staff) compared to seclusion, there is insufficient evidence to justify this claim. Although outcomes of seclusion, restraint, or composite of both combined with or without forced medication use were reported frequently, they were not consistently reported in the same study, which made it challenging to evaluate trade-offs between reducing seclusion and other interventions. For example, we found that protocols with sensory modulation rooms may reduce episodes of seclusion, but their impact on episodes of restraint was unknown due to insufficient evidence. Conversely, some studies only reported seclusion and restraint as a composite outcome, which did not allow for direct comparison with other studies that reported seclusion and restraint distinctly.

Although multiple interventions show promise to reduce seclusion, findings need to be interpreted with caution. Only 4 of 37 comparative studies used a RCT design. Of the remaining 33 studies, 5 used a concurrent comparison design (often with non-comparable units as comparison) and 28 used a pre-post design. Overwhelmingly, many of these pre-post evaluations were characterized as quality improvement projects in which a hospital or unit implemented an intervention to achieve an administrative or policy goal to reduce seclusion. While some studies were very explicit in defining their theoretical or empirical basis for the design of their protocol,

others were not and the rationale for the protocol appeared primarily driven by a hospital or policy recommendation or preference to reduce or eliminate seclusion. It is possible then, especially in the latter studies, that observed reductions in seclusion rates could be due to staff responding to administrative goals (or presumed pressure) rather than a specific mechanism of action being targeted by an intervention.[51,92]

A major limitation of the evidence was that all the studies relied on self-reported outcome data: staff were either the target or implementers of interventions and were also the outcome observers. In protocols with patient-directed interventions, they also implemented the intervention. Given that most interventions and quality improvement initiatives were explicit in their aims to reduce seclusion, it is feasible that staff could have either changed their behavior or measured their behavior differently to meet hospital or researcher expectations (*ie,* performance bias). Although it is difficult to change who observes and records coercion events for future studies, it is possible to modify or downplay intervention expectations to alleviate performance bias. For example, 1 RCT included in the review (of Safewards) randomized control wards to a physical activity program and led staff and patients in the unit to believe they were receiving the intervention condition (that would lead to reduced rates of seclusion), thereby countering potential for performance bias.[69] Another limitation of available evidence is inconsistent outcome reporting: some studies reported rates of seclusion per number of admissions, others reported raw counts of events (with limited data on sample size), and others did not clearly specify units of time for duration-related outcomes. With respect to analysis, most NRCSs conducted crude (unadjusted) analyses and did not adequately account for confounding.

STRENGTHS AND LIMITATIONS OF THE SYSTEMATIC REVIEW PROCESS

We followed contemporary standards for conducting systematic reviews. The systematic review was designed broadly to include all possible protocols to reduce seclusion but restricted to protocols that could be feasibly delivered in US health care settings. A strength of this review was our detailed coding of the intervention functions of the protocols. Coding in this way allowed us to see past intervention labels and key phrases to isolate the core of their hypothesized mechanisms of action (where reported) and who was being targeted. Our codes provided a structure to group the protocols into meaningful categories for subsequent syntheses and identified trends of intervention functions both within and across these categories. This coding can be used to inform future practice for units hoping to implement these interventions (or parts of them) or identify opportunities for future research (*eg,* untested or rarely used intervention functions).

This review has several limitations. We defined protocols as guidance documents or strategies as an alternative to seclusion. The operationalization of our definition of a protocol required the review team to make decisions about whether an intervention met our definition of a protocol; it is possible that we may have missed protocols in our operationalizing of our definition. Although we aimed to extract data on the resources needed to deliver an intervention, most studies did not explicitly document these data (*eg,* equipment or security needs), and we had to infer the resource needs based the description of the interventions. We sought to make minimal inferences and stay true to the data in the report. Finally, while we believe a strength of our review was the coding of interventions and grouping into conceptually similar categories, it is possible that the conclusions could change if groupings of interventions changed.

APPLICABILITY

Although we restricted the review to studies conducted in settings that may be most applicable to inpatient mental health units in the US, it is important to note that unique elements of interventions and contexts in which they were applied may not generalize to all inpatient psychiatric hospitals. A strength of many of the studies was the extent to which the protocols were tailored to the local context, designed with stakeholder engagement to support their implementation (*eg,* staff and/or patients were invited to participate in understanding the problem and building solutions to address the problem).[47,51,54] Safewards may offer the most generalizable intervention, given the comprehensive nature of the intervention and that evidence in support of the intervention comes from a RCT (it is well investigated, but few studies of Safewards met our review eligibility criteria). An important consideration in the applicability of these protocols is their associated resource needs. Although resource needs were less formally evaluated compared with clinical events, there is some evidence to suggest that they can at times be substantial and include increased personnel, equipment, and time for staff to complete training, deliver programming, or do additional documentation. Users of this report may consider implementing elements of the reviewed protocols (described in detail in Appendix H, with resource implications in Appendix I) that either map to shared clinical contexts (*eg,* the VA) or complement existing local protocols to reduce seclusion (*eg,* if staff education and training are already present, are there aspects of this that can be refined or additional elements such as staff modeling by expert peers or enablement of patients that can be added?).

IMPLICATIONS FOR VA POLICY AND PRACTICE

We identified 4 pre-post studies conducted in the VA.[70,77,78,85] All 4 studies evaluated comprehensive interventions that involved, at minimum, staff training and creating a patient-centered ward culture. Two studies specifically described protocols based on a recovery-oriented model of care, which align with the requirements in VHA Handbook 1160.06 ("inpatient mental health units also must provide a healing, recovery-oriented environment").[30,70,85] One of these studies was a conference poster presentation with limited information on methods and results.[70] The 4 studies relied on self-reported outcome data, and only 1 study conducted regression analysis to adjust for confounding.[77] All 4 studies reported large reductions in outcomes related to seclusion.

Consistent with requirements from VHA Handbook 1160.06 and the Design Guide for Inpatient Mental Health & Residential Rehabilitation Treatment Program Facilities,[93] the studies we identified found that modifying the environment (*eg,* sensory rooms) reduced seclusion. However, we note that open-door polices may not be relevant to the VA context. VA inpatient mental health units should continue to view the environment as a component of treatment and make modifications as needed. For units in established facilities, this means ensuring that there are opportunities for patient-patient and patient-staff social interaction, meaningful activities, and private spaces for relaxation. As the VA constructs new facilities, it should consider constructing smaller units (*ie,* number of patients) with well-designed layouts incorporating natural light, effective acoustics management, and green space.[94]

As the VA aims to implement less restrictive interventions to manage conflict behaviors in inpatient units, there are opportunities for system-level approaches to monitor and evaluate efforts. VA-wide improvement efforts have already been implemented towards standardized

documentation in the electronic health record, such as the Violence Risk Assessment; however, further opportunities exist which can include standardizing measures in the electronic medical record to document process (*eg,* use of seclusion) and outcomes (*eg,* aggression). Once data are uniformly reported in the electronic medical record, then it is possible to standardize reporting at system levels (*eg,* Medical Center, VISN, and national program offices) to evaluate trends and identify units with above/below average process and outcome measures. With standardized reporting of process and outcomes, VA could use its robust electronic medical record to conduct secondary database analyses to develop interventions to identify Veterans at high risk of being placed in seclusion or who exhibit conflict behaviors.

Although not covered in our review, several studies noted the importance of follow-up outpatient care as a feature of high quality inpatient mental health care. This is also highlighted in VHA Handbook 1160.08. Patients in inpatient mental health wards often have 1 or more readmissions after discharge. An aspect of care that was not covered by our review, but which could have an important role in reducing the use of seclusion, is to reduce the need for inpatient mental health care. As an integrated health system, the VA is positioned to ensure continuity between inpatient and outpatient mental health care.[95-97] For example, VA programs such as the Mental Health Intensive Case Management focus on patients who frequently use VHA mental health inpatient and emergency services, with the goal of reducing hospital use and improving patient functioning, reducing symptoms, and minimizing substance use.

IMPLICATIONS FOR RESEARCH

Multiple NRCSs and quality improvement studies have evaluated alternatives to seclusion. The literature had major methodological limitations, some of which may be easy to overcome. Most studies relied on data from medical records to conduct analysis and did not account for confounding variables. Future observational studies should account for confounders in their analyses by, at a minimum, conducting regression adjustment that includes patient characteristics that are also routinely captured in the electronic medical record. For hospitals that are part of large systems, there are opportunities to use electronic medical record data and quasi-experimental methods to compare units that do and do not implement interventions. Such larger studies should use more sophisticated methods to account for potential confounders such as propensity score matching or inverse probability weighting. Few studies reported outcomes by subgroups and there is an opportunity to use medical record data to identify effects of interventions for patients with specific diagnoses. There are also opportunities to improve the reporting of outcomes, such as reporting different forms of coercion as separate outcomes to allow practitioners and policy makers to understand the trade-offs (if any) between reducing seclusion and other forms of coercion. There are also opportunities to improve RCTs, such as conducting more RCTs with appropriate cluster randomized methods (design and analysis) and with appropriate attention and performance bias controls.[69] Comparative evaluations could be improved by detailed reporting of the elements of their protocols via the use of standardized reporting guidelines (*eg,* the template for intervention description and replication [TIDieR]).[98]

CONCLUSIONS

Despite numerous comparative studies, there are limited data on the benefits of seclusion and concern that the practice could cause harm. Restructuring units to include open wards or positive features, sensory/comfort rooms, structured risk assessments that include the Brøset Violence

Checklist, and comprehensive/mixed interventions may reduce seclusion. Restructuring units may also reduce the use of restraints and forced medication. There is no difference in episodes of restraint for other comprehensive interventions or structured risk assessments that include the Brøset Violence Checklist. It is unknown if sensory modulation rooms reduce episodes of restraint. It is unknown if staff training alone or investigator-developed risk assessment tools reduce seclusion. These findings may generalize to the VA, which is already implementing several strategies demonstrating reductions in seclusion (*eg,* unit restructuring and comprehensive/mixed interventions). The literature was marked by methodological limitations. Opportunities for future research and practice include standardizing reporting of process and outcome measures in electronic medical records and conducting analyses that account for confounders.

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