Seclusion and Restraint: A Review of Recent Literature

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An October 1998 *Hartford Courant* investigative series highlighted alleged cases of brutality and death suffered by involuntarily secluded, restrained, and/or emergently medicated patients. The resulting public and professional furor prompted a spate of new federal regulations and legislative initiatives setting national standards for reporting and clinical oversight. These events provide stimulus for this literature review.

Rates, duration, and methods of seclusion and restraint still vary widely. Little evidence is available to guide clinical practice regarding relative benefits and risks of various methods to control acute adult patient aggression; even less evidence exists in child and adolescent populations. Further efficacy and effectiveness studies are needed to address this issue. Various programmatic efforts successfully reduce seclusion and restraint—at times dramatically—and can be used as examples of systematic quality improvement so "best practices" may evolve and spread throughout psychiatric inpatient settings. (HARVARD REV PSYCHIATRY 2000;8:261–270.)

From time to time, problems with the administration of seclusion and restraint become public issues. The most recent of these occurred in October 1998, when the *Hartford Courant* published a series of investigative articles highlighting alleged cases of injury and death in patients who were involuntarily secluded, restrained, and/or emergently medicated. The *Courant*'s investigative series reported that between 1988 and 1998, 142 deaths occurred nationwide during seclusion and restraint in psychiatric facilities and group homes. Of these, approximately 30% were due to asphyxiation, 12% resulted from cardiac arrest in persons under age 40 with no documented prior cardiac history, and 5% were the result of faulty technique or poor monitoring. Causes of death in the remaining 53% could not be determined with confidence.[1,2] A disproportionate number of these deaths were in children and adolescents; 15% of the hospitalized and institutionalized population were children, but they accounted for 26% of the deaths.[3] Due to variability in state reporting requirements[1,4–6] the *Courant*'s statistical consultant estimated that the actual rate was likely 50 to150 deaths per year.[1,5]

Based on these data, the *Courant* charged that the American Hospital Association, the Joint Commission on Accreditation of Healthcare Organizations, and state regulators had failed to exert adequate oversight.[7] It also accused the legal system of failing to investigate with sufficient vigor deaths that may result from criminal negligence. This task, the *Courant* asserted, was made more difficult because deaths are not routinely reported, autopsies are not routinely done, and staff are quick to clean up the scene after a death.[8] The *Courant* pointed to several programmatic initiatives that had successfully reduced seclusion and restraint, and called for nationwide government oversight since not all states or programs were similarly progressive.[9]

Public outrage following the newspaper series prompted a flurry of activity by professional and advocacy groups, as well as by state and federal authorities. Advocacy groups argued for stricter federal seclusion and restraint guidelines covering utilization, techniques of administration, and the level of physician supervision.[10] The Health Care Financing Administration (HCFA) developed reporting guidelines for hospitals participating in Medicare and Medicaid.[11] Addi-

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tionally, federal mandates concerning utilization and reporting were proposed for institutions receiving federal funds.[10] Senators and Representatives requested that the United States General Accounting Office (GAO) prepare a report on seclusion and restraint in response to the *Courant*'s allegations and public outrage.

The 1999 GAO report agreed that the fragmentary and incomplete reporting of deaths suggested that many more occurred than were reported.[6] The report also recommended that the new HCFA rules apply to all facilities receiving Medicare and Medicaid funds (not just hospitals); that national, systematic reporting of seclusion/restraint use and deaths be required; that the protection and advocacy agencies in each state be given the resources to carry out their charge of investigating seclusion/restraint deaths; and that staff training in prevention of patient aggression and safer administration of seclusion/restraint be documented.[6] Opponents of mandatory techniques and rules of administration argued that these mandates might limit necessary local flexibility in the appropriate use, training, and reporting requirements for a given population.[10] Opponents of mandatory reporting of injuries and death raised concerns that provider efforts to gather information and analyze adverse outcomes would be hampered due to concern that employees would be more likely to cover up their mistakes for fear of repercussions.[6]

Fisher published the most recent comprehensive review of the literature on seclusion and restraint in 1994.[12] He summarized his findings with the following conclusions:

1. Seclusion and restraint can both prevent injury and reduce agitation.
2. The majority of inpatient programs are unable to operate without some form of seclusion or restraint (physical or mechanical).
3. Seclusion and restraint can have substantial and harmful physical and psychological effects on both patients and staff.
4. While clinical factors influence the use of seclusion and restraint, nonclinical factors do as well. Such factors include cultural biases, staff role perceptions, and the hospital administration's attitude.
5. Staff training in predicting violence, de-escalation, and appropriate restraining techniques can decrease utilization as well as patient and staff injury.[12]

He suggested that these conclusions offered a framework for further study to minimize the use and maximize the safety of these procedures.

The clinical reality is that an acutely assaultive and violent patient risks his or her safety and that of other patients and staff. A clinician then must strike a balance between that patient's right to be free from restraint and the rights of other patients and staff to be free from imminent harm. In such situations, seclusion and restraint are prudent emergency remedies. However, the recent concerns of the public, government, and health professionals make it appropriate to review the literature to see how our understanding of involuntary seclusion and restraint utilization has advanced since Fisher's review. This article will also discuss the use of emergency medications. In addition, we will explore how quality assessment initiatives can be used to address seclusion, restraint, and emergency medication use.

Although some literature prior to 1994 will be included, this review will focus on studies published between 1994 and 1999. Particular emphasis will be placed on articles pertaining to practice variability and possible explanations for it, evidence for which methods are most appropriately used in which circumstances, and methods for reducing seclusion, restraint, and emergency medication use on a programmatic and systems level. These were identified by consulting professional organization and government reports and by a computerized search of *Medline, PsycInfo, HealthStar,* and *Scientific Citation Index* through December 1999 using these search terms: seclusion and restraint, emergency medication, droperidol, lorazepam, haloperidol, agitation, and overt aggression scale.

SECLUSION AND RESTRAINT DEFINED

A variety of measures are implemented when patients are assaultive, threatening, or at risk for harming themselves or others. HCFA defines seclusion as "involuntary confinement of a person in a room or an area where the person is physically prevented from leaving."[11] Patients can voluntarily choose seclusion; however, this article will address involuntary use as defined by HCFA. The HCFA definition includes physical or mechanical interventions that restrict movement or control behavior. It may also be a medication that restricts movement or controls behavior and "is not a standard treatment for the patient's medical or psychiatric condition."[11] Mechanical restraint includes, but is not limited to, poseys, bedrails, 4-point restraints, ambulatory wrist restraints, restraint sheets, and cold wet sheet packs (a method that is largely out of favor at present). "Physical restraint" or "therapeutic holding" refers to the staff's physically holding patients (usually children). The literature often uses the term "physical restraint" to include mechanical restraint as well.

Medications are sometimes used to emergently manage violent and/or assaultive patients, and when used for this purpose, they are considered "chemical restraint" by the above HCFA definition. Examples of emergency medications include typical antipsychotics that have an intramuscular formulation (haloperidol, thioridazine, droperidol), lorazepam, and combinations of these medications. Medications have also been used on a nonemergent basis to decrease pa-

tients' tendencies toward aggression and the subsequent need for seclusion, restraint, and emergency medication. These medications include propranolol, atypical neuroleptics, and valproic acid. However, unlike typical neuroleptics, they are not currently used as an emergent intervention to control aggression. Additionally, if they are considered treatment for the patients' primary psychiatric conditions, then they do not meet HCFA criteria for "chemical restraint."

In this article, unless otherwise specified, "physical restraint" or "restraint" will include mechanical restraint; "therapeutic holding" will refer to the physical holding of children as a means of restraint; and emergency medications used to control patient violence will not be included in the term "restraint" but will be explicitly identified. This article will only consider involuntary seclusion, restraint, and emergency medication use as defined by HCFA and as an emergent intervention for acutely assaultive patients. It will not address the management of geriatric aggression.

THEORETICAL JUSTIFICATIONS FOR SECLUSION AND RESTRAINT

For both adults and children, the psychiatric literature describes two standard indications for seclusion and restraint.

1. As a therapeutic modality providing appropriate limit setting[13–15] or decreased stimulation from sensory overload.[16]
2. As a way of containing a patient's violent behavior to protect that patient, other patients on the ward, and staff.[16]

However, it is also worthwhile to note that in the child and adolescent psychiatry literature, there is little agreement regarding the clinical utility and benefit of seclusion and restraint for children and adolescents.[14,15,17,18] And despite the fact that clinical experience suggests otherwise, there are no data that confirm or refute the validity of either of the indications given above.

Current professional organization guidelines and government regulations only address the second of these indications—they do not consider seclusion and restraint as therapeutic modalities. Thus, they call for seclusion and restraint to be used only as a last resort in emergency situations to contain violent behavior;[11,19–21] this criterion also applies to emergency medication.[11,20]

HOW WIDESPREAD IS THE USE OF SECLUSION, RESTRAINT, AND EMERGENCY MEDICATION?

The vast majority of psychiatric inpatients do not receive seclusion, restraint, or emergency medications. One sample of 5580 adult inpatients found that 5.5% of the patients received emergency medication, 1.9% were placed in seclusion or restraint, and 3.4% received one-to-one supervision.[22] Similarly, Joshi et al. describe a series of 410 children admitted consecutively over 3 years to an inpatient unit. In this study 6.5% received emergency medication (droperidol).[23]

Additionally, most patients who are secluded or restrained have one or few episodes per hospitalization and a small percentage have many. In another sample of 23,000 adult and child patients, 3.5% had an episode of seclusion or restraint. Of those patients, 61% had only one episode in a given hospitalization; 94% had fewer than six episodes, while the remaining 6% accounted for 41% of the seclusion and restraint episodes.[24] In a sample of 257 children, 7% of the children accounted for 50% of the seclusion episodes.[25]

PRACTICE VARIATION IN SECLUSION, RESTRAINT, AND EMERGENCY MEDICATION USE

While the percentage of patients who receive these emergency interventions is small, numerous studies have shown widely disparate rates of seclusion and restraint use in different psychiatric hospitals.[6,12,19,26–28] The studies use different methodologies in defining and tracking restraint and seclusion and in specifying the characteristics of the patient populations served,[12] which makes comparing rates across studies difficult. However, there is evidence of improved consistency in reporting methods across state hospitals, thereby improving the external validity of findings in these settings.[28] Despite the difficulty in comparing across studies, these data indicate that considerable rate variability among hospitals exists.

Even after controlling for patients' sociodemographic and clinical characteristics associated with higher seclusion and restraint rates (such as younger age, male gender, short length of stay, African-American ethnicity, and presence of mental retardation or schizophrenia), an individual hospital's rate has been significantly associated with increasing the risk of a patient being secluded or restrained.[29] This weakens the consideration that rate variation is entirely due to some hospitals having more ill or violent patients than others.

In the adult psychiatric literature, the association of seclusion and restraint rates with overcrowding, patient-to-staff ratios, and time of day have been inconsistent. Overcrowding was associated with increased seclusion and restraint in one study,[30] but there was no adjustment for patient characteristics known to be associated with seclusion and restraint. Morrison studied patient-to-staff ratios and found that lower levels of staffing were significantly associated with higher rates of seclusion.[31] Although several studies have looked into the possible relationship between time of day and seclusion or restraint use, only one controlled for patient-to-staff ratio and found that evening shifts have

higher seclusion and restraint rates independent of patient-to-staff ratio.[32] The remaining studies, which did not control for patient-to-staff ratios, had inconsistent results.[24,33,34] One study found a difference in seclusion rates depending upon whether the patients had single or multiple incidents of seclusion. Seclusion of single-incident patients peaked in the morning, while that of multiple-incident patients peaked at night.[35] Studies that have analyzed by the hour (not controlling for patient-to-staff ratio) found peaks at 9:00 A.M., noon, and 5:00 P.M.,[24] as well as 6:00 P.M. and 10:00 P.M.[34] These times cluster around what are likely transitions in daily ward routine, and are consistent with the observation that fewer staff demands on adult patients (i.e., during nontransition times) lead to diminished patient aggression.[36] These studies indicate that factors such as overcrowding, patient-to-staff ratio, and time of day (possibly due to change in routines and staff demands) can affect seclusion and restraint rates in the adult psychiatric population.

The relationship between seclusion, restraint, and emergency medication and staff shifts and patient-to-staff ratios has also been explored in the child and adolescent literature. In one study, patient-to-staff ratios did not affect the use of seclusion or p.r.n. medication.[37] Like the adult literature, studies of children's units are inconsistent regarding the association between particular staff shifts and seclusion and restraint use, with one reporting the most therapeutic holding on the evening shift,[18] others on the day shifts when there were the greatest demands on children.[38,39] None of these studies controlled for patient-to-staff ratios, making it difficult to interpret their differing results. However, given the agreement among several studies that social milieu and less structured activity/transitional periods are associated with increased seclusion/restraint and aggression in children,[18,25,39] it seems clear that there are programmatic or unit factors that affect the use of these interventions.

The data describing how consistently specific interventions are chosen across hospitals is mixed. Studies that look at possible variation in the use of seclusion and restraint together versus separately have had mixed results.[27,28,40] However, there is evidence in the child and adolescent psychiatry literature that emergency medications are not used consistently across hospitals. Kaplan and Busner conducted chart reviews and found rate variation among hospitals in the use of different medications (antihistamines, minor tranquilizers, antipsychotics, and sedatives) administered stat and/or p.r.n. There were some practice consistencies, however: agitation was the most common indication for stat and p.r.n. medications, all hospitals had similar frequencies of stat antipsychotic use, and no hospital used sedatives p.r.n.[41] No study addressed practice variation in using emergency medications in adults.

In sum, despite the inconsistencies in study methodologies and reporting requirements, the balance of the evidence from observational studies continues to indicate that there is considerable variation in the application of seclusion and restraint. Similarly, there is some evidence of variation in the use of emergency medication. The observed practice variation for these interventions is associated with factors independent of patient characteristics in both the adult and child/adolescent psychiatric populations.

RATE VARIATION IN PHYSICAL INJURY TO PATIENTS AND STAFF

Administering seclusion and restraint can carry risks to patients and staff;[12,42] unfortunately, it is less clear if there is rate variation for injuries to patients and staff due to the administration of seclusion, restraint, and emergency medication. While there is evidence that suggests such variation exists,[27] the rates are difficult to interpret because they were not adjusted for hospital case mix or patient acuity. Also, it is unknown what proportion of injuries occur in connection with the administration of seclusion and restraint.

STAFF DECISION-MAKING IN SECLUSION AND RESTRAINT

Given the practice variation that exists, it is important to understand the role of staff decisions in seclusion, restraint, and emergency medication. Klinge questioned inpatient staff of various disciplines who have participated in seclusion and restraint. She found that staff educational level and gender affect attitudes about the choice of intervention, its frequency, and how often patients should be checked when secluded or restrained.[43] Holzworth and Wills tested the consistency of nine nurses' recommendations when given specific clinical vignettes. They found that the nurses' decisions were based on clinical cues of patient agitation, self-harm, assaultiveness to others, and destruction of property; however, the cues were used inconsistently.[44] This finding is consistent with an earlier study indicating poor correlation between the severity of aggression and p.r.n. medication use.[36] Holzworth and Wills also found that the nurses, although generally conservative, agreed only 22% of the time in their specific recommendations regarding seclusion and restraint (i.e., using seclusion/restraint sparingly). That percentage was further reduced to 8% when the data were analyzed for response agreement due to chance alone. Also, nurses with the least clinical experience (less than 3 years) made the most restrictive recommendations.[44]

WHICH METHODS ARE EFFECTIVE IN WHICH SITUATIONS?

Fisher found no controlled studies comparing the effects of seclusion and/or restraints with alternatives (e.g., emer-

gency medication, behavioral interventions, or physical holding)[12] for the acute management of aggression. This lack of information persists in the adult psychiatric literature today. While several descriptions of specific mechanical restraint methods exist, there are apparently no controlled studies of the comparative physical, psychological, or therapeutic risks of these different methods. However, there are some studies that investigate how programmatic changes can affect seclusion and restraint for child/adolescent and adult psychiatric patients.

Programmatic or System Changes Impacting on Seclusion and Restraint

System-wide policy changes can have significant impact on seclusion and restraint practice. In 1997 the state of Pennsylvania's Office of Mental Health and Substance Abuse Services (OMHSAS) implemented new policies regarding seclusion and restraint in its state psychiatric hospitals. The result was dramatic decreases in both the duration and frequency of seclusion and restraint. Restraint hours dropped 97% (from 60.58 to 2.58 hours per 1000 patient days) and number of restraint incidents dropped 65% (from 3.98 to 1.39 incidents per 1000 patient days); seclusion hours also dropped 96% (from 32.83 to 1.37 hours per 1000 patient days) and seclusion incidents dropped 70% (from 3.02 to 0.90 incidents per 1000 patient days). The 1997 policy restricts seclusion/restraint use to only when patients are at risk of imminent harm to themselves or others and when all other interventions have failed. Additionally, only physicians can order seclusion/restraint; orders or reorders cannot exceed 1 hour; reorders require a physician examination; if verbal orders are given, the physician must physically examine the patient within 30 minutes; and each incident must be followed by a patient debriefing. Significantly, each episode also triggers a clinical, administrative, and quality review, as well as a treatment plan revision. All injuries and deaths are reported to the state police and coroner's office and there is public accountability with open disclosure of data to the public and advocacy organizations. The OMHSAS cites other factors critical to the success of their program, including: adequate patient-to-staff ratios (2:1), staff training in verbal crisis de-escalation techniques and safe physical management, systematically addressing and including precipitants of violence in treatment planning, and a strong commitment of state and local leadership to the program. The dramatic reduction in seclusion and restraint use seen in the Pennsylvania state hospital system prompted the OMHSAS deputy secretary to set as a goal the eventual elimination of these interventions in the state hospital system.[19]

Changes in mandatory state reporting also have led to clarifying which methods of seclusion and restraint are associated with increased patient death and have resulted in subsequent changes in practice to improve patient safety. After New York State mandated comprehensive reporting of injury or death during seclusion and restraint, the resulting data indicated that two previously authorized restraint methods (prone wrap-up and the use of a towel to prevent patients from biting/spitting) were associated with higher injury and death rates. These two types of restraint were subsequently banned in New York.[6]

While there are no systemwide data specific for child and adolescent seclusion/restraint use, as described for Pennsylvania, several studies in the child and adolescent psychiatry literature explore different nonpharmacological methods for controlling patient aggression acutely. Some investigators describe units treating severely disturbed and aggressive children who function well without seclusion and restraint and without resulting increases in patient or staff injury.[17,18] These units primarily rely on other management techniques to control aggression, such as giving patients who kick a door soft slippers rather than shoes, early bedtime for patients who cannot get up on time in the morning, or taking sharp objects away from patients who are self-mutilating.[18] But there are some caveats to the claims that these units do not need seclusion or physical restraint. One unit describes young children who are not physically strong; therefore, their strength and size are not a serious physical hazard. Also, the patient-to-staff ratio was very low (2:1).[17] The other, while not using seclusion and physical restraint as a last resort, does use physical restraint in which the patient's limbs are immobilized by several staff after the patient is "taken down" onto the floor and until the patient calms down.[18] The authors do not address whether this type of physical restraint is better than mechanical restraint in terms of patient/staff safety, episode duration, and/or psychological well-being. Therefore, while there is some evidence that nonpharmacologic efforts can reduce the seclusion and physical restraint of children and adolescents, it is unclear if the alternatives are better or if the results can be generalized to other child/adolescent patient populations.

Despite these caveats, explicit protocols for seclusion and restraint have been demonstrated to significantly reduce their use. Kalogjera et al. investigated the effect of a specific "therapeutic management" protocol for inpatient child/adolescent units.[45] This protocol gave staff guidelines for classifying disruptive behaviors into four stages and provided explicit verbal and behavioral interventions to control the behavior at each stage. Patients who required seclusion and restraint were given explicit instructions on how to determine when the seclusion/restraint would be over (e.g., 15 minutes after the patient was no longer physically threatening and promised not to repeat the behavior). They found the number of seclusion/restraint episodes decreased by 64%; the duration decreased by 59%. Also, the number of patients (both voluntarily and involuntarily) receiving seclusion/

restraint decreased by 39%. These results occurred despite an overall increase in admissions during the intervention period compared to the pre-intervention period.

Studies that have looked at the effect of substituting one type of seclusion or restraint for another in child and adolescent units have had mixed results. Swett, Michaels, and Cole reported the experience of one inpatient child and adolescent unit after a state law prohibited the seclusion of children and adolescents. The unit saw an increase in the number of episodes of mechanical restraint, but total time spent in seclusion or restraint prior to the law compared with the total time in restraint after the law was unchanged, and there was no increase in staff injury.[46] Another study found some changes in the open door seclusion (ODS) rate after a new state law prohibited locked seclusion for children and adolescents. The direction of these changes differed by the type of inpatient unit: ODS use decreased in the admission unit but increased in the units with conduct-disordered and oppositional, impulsive, and hyperactive children.[37] A third study, not prompted by state law changes, found that therapeutic holding (i.e., physical restraint) did not alter the duration or frequency of seclusion or total restraint use (i.e., physical and mechanical).[47] Unfortunately patients' sociodemographic or clinical characteristics or medication use was not controlled for in this study. Combined, these studies indicate that for children and adolescents, nonpharmacologic interventions to reduce seclusion or restraint time have had limited, if any, benefit in the overall frequency and duration of time spent in seclusion or restraint.

Other programmatic changes, such as the reorganization of a service or the introduction of innovative patient programs, can also affect seclusion and restraint use. Hunter et al. found that when an inpatient unit and day hospital with a residential "inn" replaced two inpatient units, changes in seclusion and restraint use occurred. Initially the number of restraints increased and was attributed to an increase in admissions and the inpatient staff's concern that the reorganization would lead to higher acuity on their unit. Toward the end of the study, restraint duration decreased to below reorganizational levels, but not to a significant degree. The number of seclusion episodes did not change, but the duration had dropped dramatically; the number of assaults remained the same.[48]

Two studies have looked at the association among assaultiveness, seclusion and restraint, and reward-based behavior programs (i.e., token economies) in adults. Higher performance (i.e., earning more "points" by which to gain rewards) in a token economy has been negatively correlated with assaultiveness and the need for seclusion and restraint.[49] This may have been due to less impaired patients (who may have had a lower risk of needing seclusion and restraint) being more successful in the program than those who were more impaired, rather than the token economy's having a positive influence on behavior. However, another study demonstrated that a token economy was effective in actually reducing the total number of negative events occurring in adult inpatient settings. Negative events were defined as emergency medication needed to control patient's behavior, elopement from unit, and intentional injuries of patients and/or staff by patients.[50] There is one study in the child/adolescent psychiatry literature that indicates that the impact of a token economy was mixed: p.r.n. medication use increased in all inpatient units, but changes in ODS use were mixed in the different child/adolescent units studied.[37] The token economy studies indicate that such programs can decrease patient aggression in adults and some child/adolescent psychiatric populations.

In sum, these studies indicate that programs or system changes that successfully reduce seclusion and restraint are those that focus on reduction rather than the substitution of one type of intervention for another.

Staff Training to Decrease Seclusion and Restraint Use and Associated Patient and Staff Injury

Unlike the substitution literature, a number of earlier studies suggest that staff training can decrease the use of seclusion and restraint,[6,12,51,52] as well as the rates of injury to patients and staff.[6,12,51–54] These studies relied on quasi-experimental, nonrandomized designs that combine retrospective and prospective data about seclusion and restraint. More recent studies, of similar design, found that staff training also alters the repertoire of interventions used when a patient is aggressive,[33] which in turn can decrease seclusion and restraint[55,56] and staff injuries.[55] One child and adolescent psychiatric hospital found that intensive staff training to support a completely restraint-free environment reduced restraint by 98% and seclusion by 50%.[57] Since Fisher's review, only one study was published about the effect of staff training on patient and staff injury, and it had mixed results. In this study, no significant change in the total number of patient injuries was demonstrated, but there was a decrease in head/face injuries; however, staff injury increased significantly after training.[58] The GAO reports that while training in seclusion and restraint alternatives and maintaining appropriate staff levels are costly, the measures save money by decreasing sick leave and overtime pay attributed to staff injury.[6] Government officials in states that have successfully reduced their seclusion and restraint rate assert that management philosophy, not patient acuity, was the key to successfully reaching their goal.[6,19] Despite the methodologic difficulties in interpreting quasi-experimental studies, the consistent outcome of all but one indicates that staff training does decrease seclusion and restraint use as well as patient and staff injury.

Pharmacologic Interventions to Acutely Manage Aggression

While there are no observational studies in the adult psychiatric literature comparing nonpharmacologic methods to manage acute aggression, there are several controlled, double-blind studies addressing the relative efficacy of several intravenous or intramuscular emergency medications. The literature on haloperidol and lorazepam both in comparison and in combination has mixed results. Haloperidol 5 mg or lorazepam 2 mg appear to have similar overall efficacy in controlling aggression, anxiety, or psychosis[59,60] but haloperidol has been more efficacious than lorazepam in controlling agitation.[60] Combining lorazepam with haloperidol improves anxiety more than either medication alone but is no more efficacious than haloperidol in decreasing agitation.[59] The combination is also better at decreasing aggression than lorazepam alone,[61] has fewer extrapyramidal side effects (EPS) than haloperidol alone, and is also the most sedating of the three options.[59,61] These data are difficult to interpret, given that it is unclear what combination of diminished anxiety, agitation, and/or aggression translates into diminished need for seclusion and/or restraint. Perhaps a clearer indication of efficacy is the number of repeated injections needed for each medication to adequately control aggression; according to this measure, the combination of haloperidol and lorazepam is more efficacious than either medication alone.[59] Similarly, droperidol has demonstrated superior efficacy compared to placebo or haloperidol; patients who receive placebo or haloperidol (5 mg IM) require nearly three times the amount of repeat injections as patients receiving droperidol (either 10 mg IV or 5 mg IM).[62,63] These studies found no evidence of EPS in patients receiving droperidol;[62,63] however, EPS did occur in one patient who received haloperidol.[63] While there are no data directly comparing droperidol to the combination of haloperidol/lorazepam, separate studies have investigated these medications and the number of repeat injections required. They found that 3% of patients who received the combination (halperidol 5 mg/lorazepam 2 mg) needed more than two IM injections,[59] while none who received droperidol (10 mg IV) required more than two.[62] Based on these data, it would appear that in adult psychiatric patients with the medication doses and preparations studied, droperidol is a more efficacious emergency medication than placebo or haloperidol. Given the differences in dosage and their administration, it is less clear whether droperidol or the haloperidol/lorazepam combination is more efficacious.

The child and adolescent psychiatry literature has no controlled studies comparing the effects of different emergency medications for controlling patient aggression. Despite the lack of clinical medication trials for children and adolescents, it is not uncommon for emergency medications to be used during aggressive episodes on child and adolescent inpatient units. One retrospective study described p.r.n. medication use as occurring in nearly one third of the aggressive incidents on a child/adolescent unit. In that study, the most frequently used psychoactive medications were thioridazine (68.1%), lorazepam (10.3%), chlorpromazine (9.6%), and haloperidol, diphenhydramine, and benzotropine (a total of 12%).[39]

PATIENT INPUT REGARDING PREFERENCES AND SUGGESTIONS TO PREVENT AGGRESSION

Patient input has been sought to help understand how to manage aggression and minimize patient trauma in the event that seclusion, restraint, and/or emergency medication use are needed. A task force created by the New York State Office of Mental Health to provide policy recommendations for seclusion and restraint found that including patients in its deliberations added meaningful suggestions to proposed policy changes. However, the article does not clarify if these were current or past inpatients or outpatients. This task force found that clinicians and patients often have very different perspectives regarding these interventions. Of particular note, clinicians focused staff training on the mechanics of seclusion and restraint rather than on how to reduce their frequency by using alternative interventions. Patients stated that seclusion and restraint were sometimes used as therapeutic modalities or to enforce discipline and not as an emergency measure only. They also raised concerns that inpatient settings may foster patient violence by, for example, having patients congregate in a closed space (day area) without an occupying activity or allowing no private, quiet place for reflection. They suggested that staff consider the patient's history in administering these procedures, given that many patients have histories of physical and sexual abuse in childhood. They also recommended that patients be asked ahead of time what calms them during a crisis.[64] Some of these patient statements and concerns must be balanced with the knowledge that patients and staff often disagree about precipitants to seclusion and restraint[65–67] and that patients may have poor recall of staff oversight during seclusion and restraint.[68] However, they still provide useful insights that would otherwise be unknown to clinicians and clinician administrators.

Patient preferences have also been explored in an attempt to diminish psychological trauma should these interventions need to be employed. Sheline and Nelson attempted to ascertain whether patients thought emergency medication or seclusion/mechanical restraint was more restrictive. The impetus for the study was the lack of consensus regarding which method was the least restrictive, a legal requirement in emergency psychiatry treatment. They anony-

mously questioned adult patients in the psychiatric emergency room regarding their preference for physical restraint, mechanical restraint, or medication if they should need an intervention to control violent behavior.

With a 63% response rate, they found that 64% preferred medication and the rank order of treatment preference was (1) benzodiazepines (31%), (2) neuroleptics (26%), (3) seclusion (24%), and (4) restraints (10%). Based on these results the authors recommend patient preferences be ascertained when emergency room evaluation and treatment are being initiated.[69]

SUMMARY OF FINDINGS

Beyond Fisher's summary of his findings, the evidence regarding the use of seclusion, restraint, and emergency medication in adults and children/adolescents can be summarized as follows:

1. Variation in the use of these interventions persists and is independent of patient case mix, acuity, or other patient sociodemographic or clinical characteristics known to be associated with seclusion and restraint.
2. Staff decision making is inconsistent regarding the use of seclusion and restraint. Staff characteristics that affect their decisions are gender, educational level, and clinical experience.
3. Nonpharmacologic, programmatic changes can be implemented that diminish dramatically the use of seclusion and restraint in child/adolescent and adult populations. The data are most consistent for the beneficial effect of staff training and specific implementation protocols in reducing use of seclusion and restraint and patient/staff injury. Evidence exists that program innovations such as service reorganization or token economies can reduce seclusion and restraint use as well. However, interventions that substitute one type of seclusion or restraint for another have not been successful in decreasing overall seclusion or restraint use in children or adolescents. There are no comparable data for adults.
4. Patient insights can be useful when addressing seclusion, restraint, and emergency medication practice.
5. When control of patient aggression is needed acutely, there are no data to guide clinical decisions as to which combination of seclusion, restraint, and/or emergency medication would be better in specific patient populations. And there are few data to guide decisions as to which type of seclusion, restraint, or emergency medication would be better in specific populations.
6. The most methodologically rigorous studies testing the efficacy of emergency medications were done in adults. They indicate that droperidol alone is superior to haloperidol or placebo; and it may also be superior to the combination of haloperidol and lorazepam. There are no controlled, double-blind pharmacotherapy studies in the child/adolescent population for the acute management of aggression, despite the common use of emergency medications in controlling child/adolescent aggression.

POLICY IMPLICATIONS

The documented continued practice variation raises the concern that, at least some of the time, seclusion, restraint, and emergency medications represent rationalizations of decisions that are based more on exigency than evidence-based clinical strategy. In the absence of knowing which intervention(s) are best and when, local custom, not evidence, will influence which intervention is chosen. There are two distinct issues that are the main contributors to this variation. One is the inadequate evidence on which to base clinical decisions when it becomes necessary to seclude, restrain, and/or emergency medicate a patient. This absence of data can guide future efficacy and effectiveness studies. The other issue is attention to quality assessment and improvement by systematically implementing staff training with the aim of decreasing seclusion, restraint, and emergency medication use, averting aggression, and decreasing patient and staff injury.

However, while the literature demonstrates that clinicians and clinician administrators can develop effective programs to diminish seclusion and restraint use and improve patient and staff safety, we do not yet know what should be considered the benchmark or appropriate rate. There is considerable evidence that there are hospitals and programs that are outliers from "average care," and also that even in "average care" the use of these interventions can be reduced. The question is how low that reduction can go and still maintain the safety of patients and staff.

Psychiatry is evolving the expertise to do systematic quality improvement; our data, knowledge, and expertise can be used to address these issues. Like other medical disciplines,[70–72] psychiatric programs and systems of care can and are developing ways to pool data, form quality improvement consortia, address variability, and begin to study collegially why outliers occur when they do.[70,73] Even when the pooling of data is driven more by government mandates than by collegial voluntary reporting, important information can be gained, as evidenced by the New York State mandatory reporting of restraint deaths that led to changed practice as described earlier.[6]

Distinguishing outliers from average programs is an important first step toward quality improvement, but it will not identify what is the lowest rate of seclusion, restraint, and emergency medication use that can safely be achieved. Given that there are state programs that have dramatically decreased the use of seclusion and restraint, psychiatric consortia could be formed that compare the "average" to outliers

and also determine "best practices" to improve both "average" and "outlier" programs. Through this use of consortia, practice variability can be addressed and appropriate benchmarks can be determined.

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