Physical Restraint Use in the Hospital Setting: Unresolved Issues and Directions for Research

LORRAINE C. MION, ANN MINNICK, ROBERT PALMER, et al.*

Cleveland Clinic Foundation; Rush–Presbyterian–St. Luke's Medical Center, Chicago

R EDUCTION IN THE USE OF PHYSICAL RESTRAINTS in long-term-care institutions is perhaps one of the greatest changes in the delivery of nursing care to the elderly during the past few decades. Yet the involuntary immobilization or restriction of patients' movement, either by medications (chemical restraints) or by mechanical means (physical restraints), remains a common but controversial practice in the hospital setting. Clinical, ethical, and legal controversies center on the risk-benefit ratios for patients, clinicians, and administrators. Because the use of chemical restraints, particularly psychoactive medications, to control or manage disruptive behavior in hospitalized patients has been largely unstudied, this review addresses only the use of physical restraint.

The use of physical restraints in the care of hospitalized patients has been examined since the mid-1980s. Most of this research, however, has been descriptive in nature, and there are few clinical trials on this topic. We discuss here the state of current knowledge in the following areas:

*Coauthors are listed at the end of the article.

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238 Main Street, Cambridge, MA 02142, USA, and 108 Cowley Road, Oxford OX4 1JF, UK.

the extent to which physical restraint is used in hospitals; the associated clinical decision-making; the cited benefits and risks; and the legal, ethical, administrative, and clinical concerns. Recognizing the level of uncertainty in many of these areas, we present suggestions for future policy and for clinical investigations.

"Physical restraint [is] any manual method or physical or mechanical device, material, or equipment attached or adjacent to the individual's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body" (Health Care Financing Administration 1992, 76). Studies demonstrate that clinicians physically restrain hospitalized patients to prevent falls, to control agitated behavior, and to stop patients from disrupting needed therapy. However, the effectiveness of physical restraints in meeting these objectives has not been well established, and frequent serious injuries, even death, as a direct result of physical restraints have been reported (Miles 1993; Miles and Irvine 1992).

The Omnibus Budget Reconciliation Act (OBRA) of 1987, which became effective in 1990, has had a great influence on the use of physical restraint in nursing facilities. According to OBRA, the nursing facility resident "has the right to be free from any physical restraints imposed or psychoactive drugs administered for purposes of discipline or convenience, and not required to treat the resident's medical symptoms."¹ The burden lies on the nursing facility staff to justify the use of physical restraints; less restrictive alternatives must be tried first. The prevalence of physical restraint use in U.S. nursing facilities was 41 percent before OBRA's enactment; since then, it has dropped to 25 percent (American Geriatrics Society 1992).

The experience of long-term-care institutions in reducing the use of physical restraints may serve as an exemplar for similar reductions in hospitals. It is unknown, however, to what extent the strategies that successfully reduced the use of physical restraint in long-term-care institutions can be adapted to the acute-care environment. Patients' severity of illness, the intensity and delivery of care, the pace of activity, and even the amount of litigation differ significantly between acuteand long-term-care institutional settings. As in nursing facilities, the widespread use of physical restraints in acute-care settings has been

¹42 CFR §483.13(a).

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criticized (Mion and Strumpf 1994; Strumpf and Evans 1988). In light of the many important differences between long-term- and acute-care institutions, changes in hospital practice in response to this criticism must be based on specific knowledge of the incidence of restraint use in this setting: the reasons for its use; feasible alternatives; which patients might benefit the most from those alternatives; and the managerial and financial changes required to implement them.

The Use of Physical Restraints in Hospitals

The Incidence of Use

The incidence of physical restraint use in general hospitals ranges from 6 percent to 17 percent (Frengley and Mion 1986; Lofgren et al. 1989; Mion, Frengley et al. 1989; Robbins et al. 1987). For patients older than 65 years, the rate increases to 18 to 20 percent (Katz, Weber, and Dodge 1981; Mion, Frengley, and Adams 1986; Frengley and Mion 1986; Mion, Frengley, et al. 1989; Warshaw et al. 1982). In other words, approximately one in ten adults and one in five older adults are restrained at some point during their hospitalization. These estimates are considered to be conservative because the rates of physical restraint use in intensive care units (ICUs) have generally not been examined. Indeed, a paper presented at the 1994 annual American Geriatrics Society Meeting revealed that, although the transition unit between the intensive care unit and the general medical floor at a teaching hospital had incidence rates of 8 percent and 5 percent, respectively, the medical and surgical ICUs had rates of 37 percent and 28 percent (Maddens et al. 1994).

These statistics are startling when the frequency of this practice in the United States is compared with that in other countries. In Great Britain and New Zealand, anecdotal evidence exists that physical restraint is not considered a management option in hospitals. In those countries, strategies like altering staff patterns and manipulating the environment are used to manage patients (Evans and Strumpf 1987a; Frengley and Mion 1989; Williams 1989). To determine the extent of physical restraint use in countries other than the United States and Canada, we conducted a literature search using four computerized databases: MEDLINE, from 1966 to 1995; Nursing and Allied Health (CINAHL), from 1982 to 1995; ClinPsych, from 1980 to 1995; and Health Planning and Administration (HEALTH), from 1975 to 1995. A text word search identified any reference in the title, abstract, or body of the article to the terms "physical restraint" or "mechanical restraint." Twenty-eight articles were found that originated from countries other than the United States or Canada. Almost half (46 percent) were published after 1990. The majority of articles were case reports or reviews, and no studies were found that examined alternative techniques for the use of physical restraint.

The few articles on physical restraints originating from other countries during the last 30 years support anecdotal accounts of this practice as one mainly used in the United States, thus fueling the question of whether physical restraint is the "best" strategy for protecting hospitalized patients. On the other hand, the lack of studies may also indicate that physical restraints are used but are not an issue in these countries. Moreover, the lack of studies on the risk-benefit ratio of alternatives to physical restraints in c ther countries limits the ability to prescribe with certainty alternatives to physical restraints.

The Decision to Use Physical Restraint

Several studies of hospitalized patients have examined the decisions of hospital personnel to apply physical restraints. The studies have revealed these facts:

- 1. Nurses instigate the request for physical restraints.
- 2. Nurses, as well as physicians, vary widely in their reasons for using physical restraint for the same patient.
- 3. Although the two major reasons for using physical restraints are to prevent falls and to stop the patient from disrupting therapy, more than one reason for using physical restraint is frequently given for a single patient.

In one of the first reported studies examining the use of physical restraints in a major teaching hospital, Frengley and Mion (1986) observed that the health care professionals (primarily physicians and nurses) seldom discussed the use of physical restraint. This observation was confirmed with a follow-up study (Mion, Frengley, et al. 1989), which found neither documentation (57 percent) nor a physician order (71

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percent) for physical restraint of the majority of restrained patients. The practice was considered one that nurses, as well as physicians, apparently thought benign and unnecessary to monitor or evaluate. The investigators also discovered that nurses disagreed about the reason, or even the need, for physical restraint of the same patient.

MacPherson and associates (1990), in a study conducted at a Veterans Administration Medical Center, similarly found poor agreement between the primary physician and the primary nurse as to whether and why a physical restraint was used for the same patient: kappa coefficients ranged from .02 to .43 between the two types of clinicians on reasons for use of physical restraints. For 15 percent of the cases, physicians were unaware that the patients were restrained. These studies and others have also documented that nurses typically provide more than one reason to use physical restraint on any particular patient (e.g., to prevent falls and to ensure that therapy is not disrupted) and from 24 percent to 43 percent of the patients had more than one type of restraining device (e.g., wrist restraints with waist restraint) (MacPherson et al. 1990; Mion, Frengley, et al. 1989; Robbins et al. 1987; Strumpf and Evans 1988). In most cases (71 to 85 percent), nurses were the ones who decided whether to use physical restraint (MacPherson et al. 1990; Mion, Frengley, et al. 1989; Strumpf and Evans, 1988). These studies establish that the decision to use physical restraint is based on individual judgment rather than on scientifically validated guidelines or protocols.

Patient Characteristics Associated with the Use of Physical Restraints

Researchers have compared the characteristics of restrained and unrestrained patients in the hospital to identify risk factors for the use of physical restraints. Three patient factors predict the use of physical restraints:

- 1. confusion or presence of cognitive impairment
- 2. physical impairment, as evidenced by difficulty with activities of daily living (ADLs) or mobility
- 3. increased severity of illness

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The presence of one or more of these characteristics increased the risk threefold of a patient being placed in physical restraints (Mion, Frengley, et al. 1989; Robbins et al. 1987).

A number of other factors, namely, older age, the presence of medical devices, and the use of tranquilizers, have been found to be associated with the use of physical restraints (Frengley and Mion 1986; Lofgren et al. 1989; Mion, Frengley, et al. 1989; Robbins et al. 1987). The association of tranquilizer use indicates that sedation often is used with physical restraints, not in lieu of them. Whether the sedation occurred before, during, or after physical restraint is unknown. However, researchers found that nursing facility residents become more agitated after being placed in physical restraints (Werner et al. 1989). Thus, one could postulate that physical restraints may cause or intensify agitation, explaining clinicians' subsequent use of sedation in hospitalized patients. Nevertheless, the relation between sedation and physical restraints in the care of hospitalized patients needs further exploration.

The Benefits of Using Physical Restraints

Hospital staff cite the following major expected benefits of physical restraints:

- 1. fall prevention
- 2. maintenance of therapies in the face of patient agitation
- 3. management of disruptive or dangerous behavior
- 4. relatively low cost (versus supplemental staff) when regular nursing personnel are unavailable for continuous monitoring (MacPherson et al. 1990; Mion, Frengley, et al. 1989; Strumpf and Evans 1988)

There is little objective evidence to support or refute these expectations.

Fall Prevention. Patients fall often in the hospital setting, especially patients who are 65 years of age or older (Morgan et al. 1985; Morse 1993). The subsequent morbidity and mortality in the elderly as a result of falling are well known. Falls are the major source of injury-related deaths in the elderly (Baker and Harvey 1985). Moreover, from 1 percent to 5 percent of falls among hospitalized elderly patients result in hip fracture. Hip fractures in the elderly have serious sequelae; up to

30 percent of elderly individuals sustaining hip fractures in various settings die within six months, and another 20 percent sustain long-term disabilities (Baker and Harvey 1985; Magaziner et al. 1989; Tinetti and Speechley 1989). Thus, preventing falls by the elderly is a major concern of health professionals (Morse 1993).

Hospital nurses used the argument that the use of physical restraints protected the patient from falling in 60 percent to 77 percent of the cases (MacPherson et al. 1990; Mion, Frengley, et al. 1989; Strumpf and Evans, 1988). If physical restraints were truly beneficial and effective, then one would expect no falls to occur when physical restraint was used and, conversely, that falls would increase when it was not. Descriptive studies have shown, however, that from 10 percent to 47 percent of older patients who fall are physically restrained and that serious injuries from falls are greater in the presence of physical restraints (Lund and Sheafor 1985; Mion, Gregor, et al. 1989; Tinetti, Liu, and Ginter 1992; Walshe and Rosen 1979).

No studies have tested the effectiveness of physical restraint as an intervention to prevent falls. Powell and associates (1989) observed no increase in fall-related injuries four years after implementing a restraint reduction program in a hospital setting. Tinetti and colleagues (1992), on the other hand, postulated that the injury rates from falls by restrained and nonrestrained residents of nursing facilities may be similar because staffs have accurately identified and subsequently restrained the high-risk patients.

Physicians and other health care professionals have questioned whether reducing restraints is safe for frail, elderly patients: "The abolition of physical restraints is not possible for all patients, and while perhaps well-intentioned, the effort *entails significant risk*, particularly without provision for additional staff training, improved staffing levels, and modification of physical plant" (Read, Bagheri, and Stricklan 1991, 223, emphasis added). Thus, although the evidence does not establish the effectiveness of physical restraints in preventing falls and, in fact, supports the reduction of the practice, clinicians' concerns and their fear of resultant fall injuries need to be addressed.

Maintain Therapy. Clinicians justify the use of physical restraints to maintain technologically complex therapies, such as endotracheal tubes, central venous lines, and arterial lines, based on either the life-sustaining treatment, the high probability of serious harm if the therapy is abruptly self-terminated, or both. Patient self-termination or disruption of therapy

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in hospital settings has been reported for two types of therapy: ventilators and nasogastric tubes. In these studies, all ventilated patients who self-extubated were physically restrained, sedated, or both (Brandsletter, Khawaja, and Bartky 1991; Coppolo and May 1990; Tindol, DiBenedetto, and Kusciuk 1994; Whelan, Simpson, and Levy 1994). The incidence of ventilator self-extubation ranged from 3 percent to 16 percent. Purposeful self-removal of nasogastric feeding tubes by hospitalized elderly patients has been reported to range from 34 percent to 67 percent (Barclay and Litchford 1991; Ciocon et al. 1988; Meer 1987; Silk et al. 1987). The common characteristic of patients who terminated their therapies was confusion. Little is known of the extent to which self-termination of therapy may reflect patient self-determination, the term applied to the individual's right to forgo therapy even when to do so may mean death (Applebaum and Roth 1984). Given the frequency with which these two types of therapy are disrupted, it is not surprising that the second most common reason cited by nursing and medical staff for using physical restraint was to prevent self-termination of therapy (MacPherson et al. 1990; Mion, Frengley, et al. 1989; Strumpf and Evans 1988).

Although patients are known to stop therapies even while restrained, clinicians are reluctant to end their reliance on physical restraint for critically ill patients. Self-termination of therapy is considered to be more immediately harmful and life-threatening than falls, although the few published studies do not support the clinicians' fear of patient harm caused by abrupt self-termination of therapy (Coppolo and May 1990; Tindol, DiBenedetto, and Kusciuk 1994). However, a recent quality management project at a major tertiary center revealed a higher rate of complications: 26 percent of patients who self-extubated from their ventilators suffered an adverse effect as a direct result of the selfextubation (Mion et al. 1996). Nevertheless, because the majority of patients who self-extubate appear not to suffer harmful effects, the practice of physical restraints for all high-risk patients is not supported. Further, the apparent absence of physical restraints in European hospitals that care for patients receiving the same types of therapy is striking. Clearly, more careful analysis of the risk-benefit ratio for protection against harm from self-termination of various therapies is warranted for both physical restraint and alternative nonrestraint strategies.

Disruptive or Dangerous Behavior. Health care personnel in hospitals, especially those who practice in emergency departments, are faced with



potentially dangerous or disruptive patient behavior. In fact, nurses in the emergency department typically cite dangerous or aggressive behavior of their patients as a main reason for using physical restraints (George and Quattrone 1992, 1993). There are few incidence or prevalence data regarding this phenomenon in emergency departments or general hospital settings (Lavoie et al. 1988).

Foust and Rhee (1993) revealed that battery (unconsented-to touching, often involving the use of force) occurs in the emergency department but is underreported, thus making any estimate of its true incidence difficult. In their report, of the patients who assaulted the staff, most (71 percent) were men between the ages of 15 and 19. All had either a psychiatric diagnosis or evidence of alcohol or drug dependency. As Werner et al. (1989) reported, in the nursing facility setting, use of physical restraints was also associated with increased agitated behavior by these patients in the emergency department (Foust and Rhee 1993).

Beck, White, and Gage (1991) compared the characteristics of violent and potentially violent patients with those of nonviolent patients in the emergency department. They reported that violent patients, compared with nonviolent ones, were more often men, were brought in by police, and were more often put into physical restraints or hospitalized. Although dangerous behavior exists among young to middle-aged adults, especially in emergency departments located in the inner city, the extent of this type of behavior among the elderly is unknown.

Lavoie (1992) reported on the extent of involuntary treatment and use of force by personnel in an urban emergency department. Almost all of the patients who were placed in physical restraints were considered "combative." Forty-three percent of the restrained patients required admission to medical or surgical services; only 3 percent of the seclusion or observation-only patients required hospitalization.

Others have reported that violent or combative behavior in general hospitals and emergency departments can be a presenting symptom of delirium or acute confusion (Brayley et al. 1994). Delirium is a common condition among acutely ill, hospitalized patients and among elderly individuals reporting to the emergency department (Foreman 1989; Francis, Martin, and Kapoor 1990; Gerson et al. 1994; Inouye 1994). In spite of the prevalence of delirium in hospitals and the associated sequelae of prolonged hospital stay, functional decline, and institutionalization, studies in acute care settings show that clinicians frequently respond to delirious patients with use of physical or chemical restraints or both (Brayley et al. 1994; Foreman and Vermeersch 1995; Francis, Martin, and Kapoor 1990; Inouye 1994; Rogers et al. 1989; Strumpf and Evans 1988; Sullivan-Marx 1994). The presence or history of cognitive impairment has been well documented as a risk factor in the development of delirium among elderly patients on general medicalsurgical floors (Foreman 1989; Francis 1992). It stands to reason that the prevalence of cognitive impairment among elderly individuals who enter the emergency department, as well as those who are hospitalized, suggests the potential for the subsequent use of physical restraint in the acute care setting.

In summary, these studies indicate that issues pertinent to the acute care setting must be more closely examined. The type of patient, reasons for restraint, and underlying illnesses differ in the various areas of the acute care setting. Thus, it becomes even more critical to examine the issues of physical restraint *within the context of care*. Alternatives applied successfully in a nursing facility may be unsuccessful in a hospital or for certain subgroups of hospitalized patients.

Physical restraints are considered to be inexpen-Cost Effectiveness. sive alternatives to supplemental staffing. A recent study found, however, that reducing physical restraint in nursing-home facilities did not increase costs (Phillips, Hawes, and Fries 1993). Moreover, the Kendall Corporation reported a cost analysis and concluded that if the OBRA standard of care for restrained patients was maintained (e.g., turning and repositioning a physically restrained patient every two hours), it would be more costly to care for restrained patients than unrestrained patients with comparable levels of illness (Blakeslee 1989). On the other hand, hospital administrators are concerned about the anticipated costs of additional personnel used by nursing staff to monitor delirious or agitated but unrestrained patients. For instance, hiring private-duty nurses' aides to monitor patients' behavior is expensive and nonreimbursable. Clearly, in this time of close scrutiny of costs by hospitals and third-party payors, the actual extra costs of alternative nonrestraint strategies, if any, need to be examined in relation to patient outcomes.

Meeting Ethical Obligations to the Patient. Clinicians typically focus on the ethical principles of beneficence and nonmaleficence when caring for hospitalized patients, which leads to a frequent medical moral dilemma: how to prevent harm to the patient and simultaneously preserve the patient's autonomy (Schafer 1985). Imposing catheters for medication, monitoring, and procedures that are designed to help the protest-



ing patient recover from illness may be at odds with preserving respect for the individuality and dignity of the patient. On the other hand, the disruption of such devices may have potentially grave effects, either from the disruption itself or from the absence of the needed therapy. Clinicians' ability to determine patients' preferences for treatment options is further hampered by the frequent presence of severe cognitive impairment in those observed to receive involuntary treatment and restraint (Applebaum and Roth 1984).

We found no systematic attempt to address the moral basis of physical restraint in hospitals. Despite the volumes written on patients' rights and the value of individual freedom, there have been few attempts to justify ignoring or superseding these rights in acute care medicine because the benefits of physical restraint are thought to outweigh these concerns.

A consensus has not been reached on whether physical restraints are *never* to be used in the acute care setting. An interdisciplinary task force of the Gerontological Society of America has established the goal of restraint-free care in all institutions (Evans et al. 1994). On the other hand, a White Paper from the American Association of Homes for the Aging Commission on Ethics in Long-Term Care states:

In emergency situations or in the face of aggressive and violent behavior, restraints may be the best temporary response. Even in less dramatic instances the use of restraints may be appropriate—on a case-by-case basis, when processes of full communication and consent are in place, and when the autonomy and dignity of residents are carefully protected. (Collopy 1992, 5)

The Risks of Using Physical Restraint

Although there are many questions about the benefits of using physical restraint in hospitals, the physical and psychological risks are well known. Harm from physical restraint may occur as a result of enforced immobility or from the restraint itself.

Prolonged immobility results in loss of muscle strength, leading to weakness and difficulty standing or sitting and an increased risk of falling (Miller 1975). Other consequences of restraint-induced immobility include the development of pressure ulcers, incontinence, and, with prolonged use, joint contractures (Evans and Strumpf 1987b; Lofgren et al. 1989; Miller 1975). The risk of developing immobility-

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related adverse events increases proportionally with the time spent in physical restraints (Lofgren et al. 1989), making the determination of how long hospitalized patients are restrained of singular impact. The duration of physical restraint is especially important for elderly patients, who develop complications from immobility more quickly than younger patients. Functional decline as a result of hospitalization and illness has been well documented in elderly hospitalized patients; the additional enforced immobilization from physical restraints contributes to the risk of further decline and loss of independence in an already vulnerable population (Creditor 1993; Hirsch et al. 1990; Narain et al. 1988; Warshaw et al. 1982).

Although cases of direct physical harm, such as nerve injury (especially from wrist restraints) and strangulation, have been reported (Berrol 1988; Katz, Weber, and Dodge 1981; McLardy-Smith et al. 1986; Scott and Gross 1989), the incidence of physical restraint injuries in hospitals is unknown.

Psychological distress, manifested as anger, agitation, or depression, has been reported in approximately one-third of physically restrained hospitalized patients in the hospital setting (Mion, Frengley, et al. 1989; Strumpf and Evans 1988). Case reports of sudden death have linked severe psychological stress to physical restraint use (Miles 1993; Robinson 1995; Robinson, Sucholeiki, and Schocken 1993). Increasingly, case reports from nursing facilities settings indicate that psychological distress persists even after discharge in patients who were restrained while hospitalized (Miles and Meyers 1994).

In summary, the use of physical restraint in hospitals appears to be based primarily on clinicians' perceptions of the benefits of physical restraint without empirical data to support its effectiveness: on the other hand, there was little objective evidence citing an absence of benefit. Although the potential for harm from physical restraint is well documented, the evidence of how often such harm occurs in U.S. hospitals is scant. This situation has led opponents of physical restraint to argue that the potential benefits of physical restraint do not necessarily outweigh its very real risks. Proponents of physical restraint justify its use in hospitals on the basis of the greater risk ratio found in severely ill patients who require intensive therapies for survival. To resolve these uncertainties, the objective benefits and the extent of actual harm resulting from the use and nonuse of physical restraint in hospitals must be thoroughly explored and identified.

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Legal Issues of Using Physical Restraint

Fear of liability usually is cited as a major reason for using physical restraints in hospitals (Francis 1989). In future studies of physical restraint, the anxiety of health care providers and administrators must be addressed. Fear of legal liability for patient injuries, alleged to result from failure to safeguard the patient through the use of physical restraints, has a direct and indirect impact on clinical practice. Much of the use of physical restraints in hospitals may be an example of "defensive medicine" practiced not primarily to benefit the patient but rather as legal prophylaxis for providers and the institution.

As yet, not much is known about the actual risk of legal liability for the failure to restrain hospitalized patients. A thorough examination of the legal risks associated with nonuse of physical restraints in nursing facilities setting has been conducted (Kapp 1992, 1994b). Identification of the relevant similarities and differences between nursing facilities and hospitals may provide direction for researchers, clinicians, and administrators who are considering participation in a restraint reduction study.

Risks of Liability for Not Using Physical Restraint

Kapp (1992, 1994b) and Johnson (1990) examined the risks of liability for nonuse of physical restraint in nursing facilities. Over a four-year period, 247 nursing facility cases involving civil personal injury claims were uncovered in a database that lists filings in all U.S. District Courts and in trial courts of general jurisdiction in 52 cities. Of the 247 cases, four involved residents who sustained injury from wandering and 60 involved residents who had fallen. Many of the cases resulted in judgments for the nursing facility, absolving its staff of any blame for failure to use physical restraints. The legal reasoning in these cases was twofold: (a) lack of obligation by nursing-home personnel to restrain the resident physically; and (b) compliance of personnel with the legal standard of care, even if harm occurred.

Several cases, however, resulted in nursing facility personnel being held legally responsible for injuries incurred by residents who were not restrained at the time of the injury. In none of these lawsuits, however, was liability of a long-term-care facility based *solely* on the failure to physically restrain the resident. Rather, in these cases, there was a preponderance of evidence establishing some *other* form of deviation from the professionally acceptable standard of care. Interestingly, rather than requiring nursing facility personnel to use physical restraints to protect residents, these judicial opinions expressly encouraged the use of less restrictive, alternative methods of care to fulfill the facilities' monitoring and supervision obligations. Kapp (1992, 1994b) concluded that the apprehensiveness of the professional staff about legal liability for failure to restrain residents was largely the product of skewed perceptions.

These findings in long-term-care institutions may not allay hospital clinicians' and administrators' fears of legal liability. The preponderance of health care malpractice litigation arises out of the hospital setting. From the same four-year database that Kapp and Johnson used to conduct their studies, more than 2,000 malpractice cases were brought against hospitals, almost 10 times as many as were brought against nursing facilities. Too, although courts have sometimes ruled that hospitals were not negligent in failing to use physical restraints in the care of patients who fell, a strong clinical argument has been made for the temporary use of restraints in hospitals (Yob 1988). This argument is especially true for patients who are impaired by sedatives. Indeed, many of the legal justifications for use of physical restraint come out of hospital or psychiatric settings. Risk managers and legal counsel in hospitals base their reluctance to dismiss the risk of legal liability for nonuse of physical restraints on these arguments (Kapp 1994a).

Risks of Liability for Using Physical Restraints

Kapp (1992, 1994b) also noted mounting data on the risk of legal liability for the use of physical restraint in the name of defensive medicine. A poor or adverse clinical outcome, especially when unexpected by the patient resident or family, is the most reliable indicator of eventual lawsuit initiation. The legal review of nursing-home cases revealed that there were far more successful cases in response to claims of inappropriate ordering of restraints, failure to monitor and correct their adverse effects, and errors in their mechanical application than occurred as a result of claims for failure to use physical restraints. Indeed, inapproPhysical Setting

priate use or failure to monitor has led not only to negligence claims but also to claims of battery.

Although less common, criminal charges against nursing-home corporations and specific staff members have been brought for negligent homicide in the deaths of residents by vest strangulation. In some states, such as California, the inappropriate use of physical restraints is classified as a form of criminal elder abuse.

The extent of litigation in hospitals arising from the use of physical restraints is unknown and should be determined. Legal claims have been brought successfully against hospitals and their personnel for inappropriate use of physical restraints and for failure to monitor and correct their adverse effects. Unsuccessful suits have been brought for the use of physical restraint while providing care, especially when treatment was lifesaving.

Current Regulations for the Use of Physical Restraints

Government regulations and statutes regarding the use of physical restraints are important to health care institutions and their staff for several reasons. Courts tend to look at these statutes and regulations as evidence of the appropriate standard of care. Also, the possibility of administrative sanctions for regulatory noncompliance carries a real and ominous threat of decertification from Medicare and Medicaid participation or restriction of Medicare and Medicaid admissions.

Regulations and statutes regarding restraint use are more specific for nursing facilities than for the acute-care setting. As noted earlier, the federal regulations implementing OBRA have affected the use of physical restraints in long-term-care institutions. The states also restrict the use of physical restraint. Virtually every state guarantees nursing facility residents the right to be free from unwanted physical and chemical restraints as part of its State Resident Bill of Rights. The nursing home risks loss of licensure or civil monetary fines when it violates state regulations.

Regulations regarding physical restraint are less definitive for hospitals, with the exception of patients on acute psychiatric units. The Joint Commission of Accreditation of Healthcare Organizations (JCAHO) provides a set of standards that are often allowed into evidence on the issue of the acceptable tort standard of care in a specific case. As part of the 1995 JCAHO shift to include multidisciplinary, patient-focused care, the JCAHO standard regarding use of physical restraint has come closer to the OBRA regulations (JCAHO 1995). Although JCAHO provides some guidelines and incentives to clinicians for avoiding physical restraints, the standards are ambiguous and leave room for varying interpretations and applications.

Four years ago, the U.S. Food and Drug Administration (1992) issued a Medical Alert on potential hazards of restraint devices. The Safe Medical Devices Act² requires hospitals, nursing homes, and clinics to report deaths and injuries related to the use of physical restraints to the FDA, where these reports become a matter of public record. The FDA has provided guidelines, reflecting OBRA and JCAHO standards, that suggest less restrictive methods of care, careful and frequent surveillance of physically restrained patients, and assessment of the underlying conditions that precede the use of physical restraints. The FDA also requires that manufacturers of physical restraints label these devices "by prescription only."

Summary and Recommendations

Our review of the literature suggests that physical restraint is a source of serious problems. The acute-care setting is different enough from the institutional long-term-care environment to warrant a separate examination of this practice. Compared to hospitals, nursing facilities have a resident population with relatively stable, chronic conditions, homogenous care needs, and longer lengths of stay. These conditions allow staff to become familiar with individual residents and to evaluate the effectiveness of various care strategies for a given individual. The acute-care setting, however, has a patient population with acute illnesses, greater heterogeneity of needs and responses to care, and relatively short lengths of stay. These conditions impede the hospital nursing and medical personnel's ability to become familiar with patients and to entertain alternative, nonrestraining strategies of care.

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²P.L. 101-629.

A recent national survey of more than 500 hospital, nursing, and medical administrators revealed that few know the extent of the use of physical restraints in their facilities, but most have serious concerns regarding the ethical, legal, and cost implications of their institutional policies on the use of physical restraints (Minnick et al. n.d.). The lack of knowledge about the extent, circumstances, and consequences of this practice would indicate that research on physical restraint in hospitals should focus on the incidence of physical restraint use in relation to patient characteristics: types of restraints, length of time spent restrained, concomitant uses of psychotropic medications, and the medical and legal consequences.

Data from well-designed investigations would serve to guide and support practice changes. Researchers, in cooperation with hospitals or professional groups, may be able to launch a data-gathering campaign among member hospitals that would benefit the individual institution and provide a reliable national database. A series of large-scale, multisite studies of the results of various protocols might also shorten the search for "best" or "effective" practices in the management of common patient care problems, such as falls and delirium with disruption of therapies. With many institutions launching new protocols to reduce or monitor physical restraint use, lack of sufficient resources to evaluate them rigorously or disseminate their findings makes cooperative efforts imperative.

The benefits and risks of physical restraints in the hospital setting must be verified. Studies are needed to determine if the benefits of involuntary treatment and restraint outweigh the potential risk of harm, especially in specific situations, such as safeguarding patients from removing life-sustaining interventions while confused. The lack of definitive guidelines or standards for clinicians in caring for hospitalized patients at risk for falling, delirium, and disruption of needed therapies, or in dealing with dangerous or potentially violent patients, is evident in the variation of the practices from setting to setting, within a setting, and even on the same unit from nurse to nurse. Thus, studies are also necessary to determine ways to understand and respond effectively to the needs communicated by patient behaviors in order to enhance patient outcomes and to avoid episodes of agitation and dangerous selftermination of treatment. All of these studies must incorporate costs in their design.

Legal and ethical issues will, of necessity, be raised in the design of such studies. For instance, a recent proposal to implement a nonran-

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domized, controlled trial of nonrestraint interventions to reduce falls at the Cleveland Clinic Foundation required not only approval from the Institutional Review Board but also prior approval from legal counsel. Clinicians' and administrators' anxieties about potential legal liability, whether well-founded or imagined, for not using physical restraint must be addressed so that it does not remain a major disincentive for hospital personnel who might otherwise attempt innovations of care that do not involve restraints.

The lack of large-scale studies in any of these areas makes it difficult for policy makers to determine whether it is necessary to address hospital physical restraint practices through additional regulation. The support of foundations, hospitals, and clinician associations for the types of studies outlined above could help prevent counterproductive or burdensome restrictions and foster instead more sensible and targeted policies that benefit hospitalized Americans.

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Coauthors of the article are MARSHALL B. KAPP and KAREN LAMB.

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Address correspondence to: Lorraine C. Mion, PhD, RN, Department of Nursing Education and Research/P-32, Cleveland Clinic Foundation, 9500 Euclid Avenue, Cleveland, OH 44195.