

## HOBBY HORSE

# Bed falls and bedrails—what should we do?

In recent years, I have found myself increasingly occupied by the problem of falls on the ward—in particular those from bed. Complaints, Independent Panel Reviews, Coroner's Inquests and Civil Court cases as an expert witness for other trusts have ensued. There are recurring questions: what constitutes best practice? Are policies in place? Why bedrails were or were not applied? Why beds cannot be lowered or patients nursed on the floor? Whether staffing levels were adequate for supervision and safety? How this can have been 'allowed' to happen in the supposedly 'safe' environment of a hospital? Who is to blame? Such incidents occur weekly throughout the health service and concern all involved in the care of older patients. But the answers to these questions are often unclear.

Falls on the ward [1, 2] are common, often injurious, and result in impaired rehabilitation, anxiety and depression. They are associated with prolonged hospital stay and with discharge to long-term care. They lead to anxiety or guilt among staff and to unhappiness among carers and relatives and in turn to complaint or litigation. Thus such falls pose a risk to individual patients and to organizations. In most hospitals there is a managerial imperative that 'something must be done'—leading to falls prevention policies or to *ad hoc* responses—such as the use of bedrails.

A useful framework for informing good practice in such a minefield is to consider (i) the evidence base, (ii) the ethics, (iii) the law and (iv) training/experience as boundaries within which professional decisions are made—these will be briefly considered in turn.

## Research evidence

The research evidence for the prevention of falls in hospital—whether from bed or otherwise is extensive but inconclusive. A recent systematic review [3] showed no consistent evidence for any intervention in preventing hospital falls. Most studies used multiple interventions, including risk assessment, nursing and medical careplans, investigation of patients who had fallen, staff education, equipment safety checks, bed or patient alarms, bedrails or restraints. No one intervention was proven to be effective, though the medical/diagnostic model was largely ignored. We do know from observational studies [1, 4, 5] that 60–70% of all falls in hospital occur from the bed or bedside chair, that more than

80% of falls are unwitnessed and that about 50% occur in patients who fall repeatedly. Also, that many fallers can be characterized using common risk factors such as cognitive impairment, agitation, gait instability, urinary frequency/incontinence or a previous falls history [6].

Series [7] have shown 50–90% of falls from bed in hospital occur *despite* bedrails being applied. Their use has been shown to cause death [8]—with a series of 179 reported in the US and 15 in the past 5 years in the UK [9] directly attributable. Also injuries, with a series of 224 from entrapment or falls reported [10]. Bedrail use may also be associated with worsening of agitation, fear and delirium [11]. There is little evidence that bedrails or other physical restraint can succeed in preventing falls [12]. A recent prospective study of bedrail use reduction in New Zealand [13] showed that when the mean number of beds with bedrails reduced from 45/135 to 18/135 over 12 months ( $P=0.02$ ), there was no significant change in the falls rate and fewer serious injuries ( $P=0.008$ ). Tinetti [14] showed that when restrained and unrestrained patients were compared in 12 settings over 12 months, 4% of unrestrained *versus* 15% of restrained patients sustained serious injury. A restraint reduction programme in US nursing homes [15] was associated with no increase in the rate of serious fall related injuries. Finally, we know that 'chemical' restraint—in the form of neuroleptic use—despite the misguided intention to prevent falls by its use—is associated with increased fall rates [16, 17]. Moreover, restraint or bed rail use can lead to muscle wasting, infection or pressure sores from immobility, and deconditioning [6].

## Ethics

When we turn from evidence to ethics [18, 19], we must consider that the use of bedrails, or even covert restraint [20] (e.g. positioning of furniture, tucking bedclothes in too tight, chair type) infringes the autonomy and dignity of patients—and is therefore maleficent. Similar considerations apply to the use of the various patient alarm devices [1] which could be construed as a further form of restraint. There being no evidence for effectiveness—the use of bedrails or restraints could not be seen to be beneficent. Whilst paternalism (i.e. acting on a patient's behalf or against their wishes in their

presumed best interest) is an acceptable part of duty of care *when the benefits of intervention are clear*, it is not ethical for patients to be restrained in bed on the say so of a third party (a relative) just for the sake of risk management—or keeping the peace. We should also consider the *dysbenefits* of attempting to prevent falls. Rehabilitation of older persons recovering from acute illness requires that many go through a transient period of risk as they regain mobility. Therefore a certain number of falls may be an inevitable consequence of effective rehabilitation—the corollary being that a zero falls rate means no rehabilitation.

## The law

In the UK [21], to demonstrate medical negligence, there needs to have been a *failure in the duty of care* which was *foreseeable and avoidable* and which has *led to a harm*. Since 1957, the Bolam Test [22] has defined the standard for customary care. This rests on there being a body of expert opinion to support a course of action. This test is *descriptive* (what *is done* in practice) rather than *normative* (what *is best* practice). This may, in time, be superseded by the advent of evidence based guidelines, though this has not yet been fully tested. In court, departure from established guidelines may be hard to justify where the evidence for benefit is clear—which is *not* the case for hospital falls. So the question arises—could a hospital be held liable for failing to do something (i.e. prevent falls) for which there was no evidence of effectiveness? On the other hand, the burden of proof in *civil* actions is on the *balance of probabilities*—rather than the beyond reasonable doubt required in criminal law—partially invalidating the scientific rationalist evidence-based medicine paradigm.

In fact, a number of UK claims have been settled out of court for injuries resulting from falls in hospital with both the plaintiff and the trust often keen to avoid the risk of full legal costs. Initial enquiries with the Department of Health and the Defence organizations have identified none where negligence has been established—though there exist no systematized data on such cases [RA Kenny, personal communication]. The European Human Rights Act 2000 [23] may in time add to the complexity of such cases—as there is a provision that ‘no-one shall be subjected to inhuman or degrading treatment’—which might potentially be interpreted either way in the application or non-application of bedrails. What we can say is that whilst there is a duty of care on the hospital to provide a safe environment, there is not a duty to protect from all conceivable risks and that restraint against the will of a mentally competent patient could constitute an assault or civil wrong.

In the US, the overt use of physical restraints—including patented linen or leather devices, or bedrails—has been far more common [7, 24]. This may be because the framework for practice in the US is more legalistic

than the essentially clinical guidance in the UK or Australasia. This has been re-inforced by the Federal OBRA legislation [25]—although this has in turn forced practitioners to re-consider restraint use as much as to apply restraints. Even in the USA, there have been more successful lawsuits as a result of morbidity caused by bedrails and restraints than from failure to employ them, and there is a movement away from the practice [26].

## Where do we go from here?

We should consider; improving the evidence base for falls prevention; physical alternatives to bedrail use; safer use of bedrails when they *are* applied; better communication with patients’ relatives about risk and evidence; policies based on the best current evidence for management of falls and agitation so that staff on the frontline of organizations are not left legally vulnerable.

The evidence for effective fall prevention in hospital is not compelling, there are limitations to many studies using organizational approaches [3, 4] and the balance of evidence is against the use of bedrails or other physical interventions such as alarms or restraints. Ultimately, large scale randomized controlled trials of hospital falls prevention may help. However, there are many subsidiary questions—such as the prevalence and variability of common reversible risk factors for falls in the hospital population; the limitations of using *recorded* falls as an endpoint; the potential dysbenefits of falls prevention on rehabilitation; the use of validated falls risk assessment scores; the extrapolation of successful community interventions to the hospital population and the value of environment and equipment safety checks.

Alternatives to bedrail use should be employed more widely and some hospitals have effectively banned the use of bedrails unless exceptional circumstances apply. Patients can be nursed on floor mattresses—though this must be carefully ‘sold’ to their families on occasion and has implications for lifting and handling—and also for pressure area care. Mats can be used around the bedside, though in the UK the Health and Safety Executive raised concerns about this as the mats can themselves become a trip hazard. There is some evidence that softer flooring can reduce the rate of resultant injuries from falls [27]. We know that hip protectors can be effective in frail older people, but hospital inpatients are unlikely to comply with their use [28]. Not all bedrails [29, 30] are applied with the intention of preventing falls in agitated individuals repeatedly attempting to get out of bed—some are applied (especially on high airflow mattresses) with patients who tend to roll out—especially those with hemiparesis—and in such cases, the use of bolsters or pillows may prevent the rolling without presenting the same injury hazard.

If bedrails *are* to be applied, a reason for their use should be clearly documented, all reasonable alternatives

should have been explored and their use should be reviewed on a daily basis. Their use is often a surrogate for inadequate levels of staffing to supervise agitated individuals with dementia or delirium—many of whom are in the inappropriate environment of acute hospital wards. They should be inspected regularly, of appropriate design and on no account applied if they are broken or ill-fitting. There are very clear guidelines on the safe design, maintenance and application of bedrails on the Medical Devices Agency and US Food and Drug Administration websites [9, 10].

Nonetheless, practitioners and organizations may be left vulnerable or exposed without good practice policies so that guidelines based on Category C [12] evidence (expert recommendation) might help. These could incorporate the provision of safe equipment, a hazard free environment, the use of validated falls risk assessments, the investigation of patients after their first fall and particular attention to better management of known reversible risk factors such as delirium, gait instability, medication or urinary frequency. There may be a natural reticence for provider organizations to be so prescriptive, lest their demonstrable failure to adhere to such guidelines increases legal liability. For instance, the lack of resource to provide one to one nursing for agitated patients or to ensure a safely designed and equipped environment.

Finally, we need to do much better in public information and personal communications with patients' families; combating ageism and misinformation. It may be intuitive to lay people that older patients should not be allowed to take risk, that they should be infantilized 'for their own good', or that they should never be nursed on the floor. It is certainly counter-intuitive to many to discover that bedrails do not prevent falls or that people fall in hospital precisely because they *are* ill on admission and not because the hospital is to blame. We need to emphasize the message that patients should be encouraged to mobilize—not deterred from doing so—and that accidents *will* happen. It is inherent in being a health professional that unpopular decisions must be made either in patients' interest or in line with their own wishes. It behoves us to act on the evidence and not simply on the unsubstantiated fear of successful litigation. At the same time, when we consider that vigilance and pro-active assistance are likely to prevent falls, we need to consider whether current nursing establishments on wards caring for frail, acutely ill older patients are adequate and whether ward design and equipment are optimal for patient safety.

DAVID OLIVER  
Elderly Medical Unit,  
Queen Mary's Hospital Sidcup,  
Sidcup, Kent DA14 6LT, UK  
Fax: (+44) 208 302 2678  
Email: Davido20@hotmail.com

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