Safety design of side rails for metal medical beds

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Abstract:
Background: Medicals metal side rails of beds are designed for patients who need protection from risk, falls, entrapment, slipping, sliding and injuries. Side rails are use increasingly after World War II, to forbid patients falling particularly in hospital setting or in nursing homes (a small private hospital, often for old people) or houses. [Reagan R. 2014]. When designing a side rail, there should be a documented comprehensive assessment of medical necessity which has been made by a team of health professionals. The resident patient must consent to the use of restraints. In obtaining consent, the nursing home is required to explain the risks and to benefit from the use side rails. Also requires the approval of the resident's attending physician. [Kuipers 2014]. Problem: State various side effects associated with medical metal bed side rails suffered by patients, as seen from the designers and team of health professional’s point of view. Objectives: The study objective has been to investigate the design of safety elements in medical bed side rails and hence set up certain design rules for the assessment and design according to real patient’s needs. It achieves safety of patients both in a hospital, a nursing home and even in their own homes. Research studied some factors as type of bed rails, categories of entrapment and side effects of side rails. And simulating technology was studied. Results and discussion showed that the decision to use medical metal bed side rails should be based on a comprehensive assessment according to identification of the patient’s needs, which include comparing the potential for entrapment or injury associated with use or non-use of them. By determining the design criteria and rules, a patient is offered a safe bed environment. When there is a definite need for using medical bed side rail, bed rails must be of variable heights or be adjustable enough to allow for ease of use. An alarm system should be implemented to alert medical staff that a patient has moved from their normal position and probably want to get out of bed.

1- Introduction
Medical metal side rails referred to as cot sides or bed guards affixed to the sides of a bed. They use to reduce the risk of an individual falling out of medical metal bed. They are also called safety rails. Term medical metal side rails were used here to describe rails on the sides of adult beds. They used in healthcare settings. They are safety way intended. They may also be used as reassurance for patients who are anxious about falling from bed. Some patients may use them to assist themselves in changing their own position. [NPSA, 2007] Using medical metal bed rails had collective benefits and weighed against the risks for elderly. [Hignett, S. 2010]. Using medical metal side rails reduced dramatically from almost patients to around 13%. [David Oliver, 2009]. Design of medical metal side rails is aimed to decrease falls and injuries for patients. [Medicines and Healthcare, 2013] Some studies were being procedure to assess clinical consequences. It was clear that, the percent of falling was high with did not use side rails for elderly. [Tehewy et al. 2014] In the UK, an average of around three deaths a year have occurred through Medical metal side rails entrapment or fall in care homes and patients’ own homes. Medical metal side rails can have very different sizes and designs. In the UK may be different from other used in other countries. For example, a New Zealand study describes full length metal side rails more than double the UK standard height. Prevention programs from falling in the hospital have successful in reducing falls and designed to the wishes and needs of individual patients [David J et al. 2010]. There are organizations concerned with metal side rails as Food and Drug Administration (FDA) and the Consumer Product Safety Commission (CPSC). These are two organizations to deal with the warnings and concerns about injuries and metal side rails. This is already included since the middle of 1990. So far, these warnings were not enough to avoid
more injuries on the health. Side rails can result in serious injuries and even death. From 1985 to 2009, the FDA received approximately 803 entrapment reports – 480 of which resulted in death. Reports have also identified the most vulnerable people to be the elderly, especially those who are frail, confused, and restless. They do not have full control over their body movements. There are risks resulting from its used. [Tsacoumis S. et al. 2014]. In 2011, official bodies provided to seek (FDA) demanded to ban the use of side rails. [Portable side rails Pose Life, 2014].

2. Types of side rails
There are many types of side rails:
- Full Length Rail: One piece rail that extends along the side. It is from head to foot section.
  (Fig 1) shows the Full-Length Rail
- ¾-Length Rail: One piece rail that extends along three-quarters of side. The way down is from the head of bed.
  (Fig 2) shows the ¾-Length Rail
- Half-Length Rail: One piece rail that extends along one-half of side from the head of bed.
  (Fig 3) shows the Half-Length Rail
- Transfer Bar: One piece rail, attached to the bed frame on one or both sides. This is grasped to aid in bed entry and exit.
  (Fig 4) shows the Transfer Bar
- Split Rails: A pair of half rails. A set extends along the side from head to mid-section. There is a space between the two sets of rails.
  (Fig 5) shows the Split Rails
- Quarter-Length Rail: A piece rail that extends along the side approximately ¼. It is from head of the bed.
  (Fig 6) shows the Quarter-Length Rail

3. Reasons of Patients’ injuries
There are three categories listed from the highest frequency entrapment to the lowest. Potential risks of using medical metal side rails are entrapment and falls figure (7). [Clinical Guidance 2003].

(Fig 7) shows the raison Potential risks of using medical metal side rails

3-1 Entrapment:
These categories included frequent injuries to the neck and head strangulation, suffocation, or death. A patient is caught between the side rails and the mattress. [Medical metal bed rails 2013]. There are three parts of the body of the patient always exposed to the risk of entrapment, which threatens their lives, are:
- Head: It should be the maximum breadth of the slots 120 mm, to reduce the risk of entrapment of the head with holes.
- Neck: It must be less than 60 mm, to reduce the risk of entrapment of the neck, gaps.
- Chest: It must be larger gaps after 318 mm to represent the depth of the chest. It is as a basis for the borders dimensions, to reduce entrapment of the chest.

The 7 areas or zones that present a potential for entrapment:
Zone 1: The openings at any space along the perimeter of the rail should be small enough to prevent the head from entering. FDA recommended space: less than 43/4". (fig.8)

(Fig 8) shows the Zone 1

Zone 2: Under the rail, between the rail supports, or next to a single rail support. This space is the gap under the rail between a mattress compressed by the weight of a patient’s head and the bottom edge of the rail at a location between the rail supports or next to a single rail support. The FDA recommends that this space be less than 120 mm (4-3/4 inches) to prevent head entrapment. Patient found with head between two bars of the medical metal bed rails. Patient was highly cyanotic. FDA recommended space: less than 43/4". (fig.9)

(Fig 9) shows the Zone 2

Zone 3: Between the rail and the mattress. The space between the inside surface of the rail and the mattress compressed by the weight of a patient’s head should be small enough to prevent head entrapment when taking into account the mattress compressibility, any lateral shift of the mattress or rail, and the degree of play from loosened rails. Patient found with head trapped between rails and mattress & facial injuries and breathing difficulties. FDA recommended space: less than 43/4". (fig.10)

(Fig 10) shows the Zone 3

Zone 4: Under the side rail, at the ends of the rail. This is the gap that forms between the mattress compressed by the patient and the lowermost portion of the rail at the end of the rail. The potential for entrapment in this zone may still exist when the deck is articulated. The patient swung the top half of his/her body into the space between the rails and the headboard. Patient found with thorax trapped between medical metal side rails and footboard. The patient's head was lower than his/her thorax. All resuscitation attempts failed. FDA recommended space: less than 23/8". (fig.11)

(Fig 11) shows the Zone 4

Zone 5: Between split Medical metal bed rails. Between an accessory (pendant control, perfusion arm, etc.) and rail Patient found in her bed, unconscious, with head between the pendant control and the medical metal bed rails. (fig.12)

(Fig 12) shows the Zone 5

Zone 6: Between the end of the rail and the side edge of the head or foot board. Over the rail, an elderly patient suffering from dementia, while attempting to leave bed, caught his feet in the rail and fell, banging his head against the bedside table. (fig.13)

(Fig 13) shows the Zone 6

Zone 7: Between the head or foot board and the mattress end. When there are too large of space between inside surface of the headboard or footboard and the end of the mattress, the risk of head entrapment increases. (fig.14)
3-2-Falls: incidents related to falls includes incidents in which the patient fell off the bed rail, climbed over the bed rail, fell and hit the bed rail, or fell due to raised bed rail. All incidents resulted in a fatality.

Figure (15) standard dimensions (Fig 15) shows the standard dimensions between side rails and elements of the medical bed. [David J. et al. 2010].

4- Simulation and technology

For evaluate metal medical side rails, the scientists used simulation technology. It allows for the design team to predict accurately behavior of patients. This is helping in decrease statically or dynamically negative impact. Moreover they discover erred design in the process of investigation and evaluation of its functionality to them. By embody the virtual models, allow the possibility to verify the efficiency of performance and reach weaknesses. This is lead to entrapment and given a clear vision about capabilities of patients in the optimal using figure (16). Simulation technology achieves safety by conduct completely simulation of the interaction that occurs between the patient and metal medical side rails. As useful in improving, the perception is solving anthropometric and ergonomic problems for the patient. It evaluates side rails to avoid corners or sharp edges or gaps and holes which lead to entrapment or injuries for patients.

5-Studied & analysed Reasons for Patient’s Injuries

Some studies were been procedure in general hospitals which have the same medical metal side rails. Patients may be at risk of falling from bed for many reasons, including poor motion, delirium, visual impairment and the effects of their treatment or medication. Also there are other reasons as Figure (17) that shows some examples of side rails in Egypt hospitals representing a weak fixation.

Older medical metal side rails designs that have tapered or winged ends are not appropriate for use with residents assessed to be at risk for entrapment. Where some studies for medical metal side rails, is show that no maintenance, bad fixed systems, bad treatment methods….etc. Falls represent a serious problem facing hospital patients, and the severity of fall-related complications rises steadily after the age of 65 years. Some incidents with medical metal side rails have been caused by no maintenance. Medical metal side rails should be included in Planned Preventative Maintenance (PPM) schemes.
From the above analysis in figure (17a, b, c, d), it is found that the aspects which appear during planned maintenance include:

- Presence of rust – this can affect on adjustability of metal tubes.
- Welded joints which not showing signs of cracking or failure.
- Cracking of paint or coating – can point to deeper structural failure.
- Free play in joints – this can point towards loose, worn or incompatible components.
- It is essential that all side rails can be fitted correctly allowing safe use to an appropriate bed base.
- Side rails used to prevent an accidental fall from bed would be unlikely to be considered as restraint using these definitions, while using Medical metal side rails to keep a patient in bed
- The bars within the medical metal side rails should be closely spaced to prevent a resident’s head from passing through the openings and becoming entrapped.
- The mattress for medical bed interface should prevent an individual from falling between the mattress and medical metal side rails and possibly smothering.
- Care should be taken that the mattress does not shrink over time or after cleaning. Such shrinkage increases the potential space between the rails and the mattress.
- Check for compression of the mattress’s outside perimeter. Easily compressed perimeters can increase the gaps between the mattress and the medical metal bed rails.
- Ensure that the mattress is appropriately sized for the selected bed frame, as not all beds and mattresses are interchangeable.
- The space between the medical metal side rails and the mattress and the headboard and the mattress should be filled by either an added firm inlay or a mattress that creates an interface with the medical metal side rails that prevents an individual from falling between the mattress and medical metal bed rails.
- Latches securing medical metal side rails should be stable so that the medical metal side rails will not fall when shaken.
- Maintenance and monitoring of the bed, mattress, and accessories such as resident/caregiver assist items should be on going.

6-Safety design aspects
Increase the gap size is mattress compressibility, lateral shift of the mattress or rail, and degree of play from loosened rails. The space poses a risk for entrapment of a patient’s neck. It may change with different rail height positions and as the head or foot sections of the bed are raised and lowered. The space may increase, decrease, become less accessible, or disappear entirely in some positions as:

- Patients who have problems with memory, sleeping, incontinence, pain, uncontrollable body movement or weakness must be assessed for ways to keep them from harm.
- Historically, medical metal side rails were thought to keep some patient safe while in the hospital. To meet patients’ safety who needs healthcare providers, it should:

Assess patients for the high risk of medical metal side rails injury:
- Patients with high risk for falls (e.g. previous falls, poor muscle control, impaired judgment).
- Patients receiving psychoactive or sedative medications.

Evaluate beds to ensure there is no gap wide enough between mattress, bed frames, and medical metal side rails to allow patient’s head or body to be trapped. Use protective barriers or safety devices to fill gaps.

Observe patients at frequent intervals:
- Monitor and reassess patients at risk for medical metal side rails injury frequently to ensure safety.
- Use devices that alert staff that a patient may be getting out of bed unaccompanied.

Anticipate the reasons patients: get out of bed such as hunger, thirst, going to the bathroom, restlessness and pain.

Educate patients and their families:
The discussion with families how the institution ensures the safety of patients when medical metal side rails is used (e.g. individual assessment; use of protective barriers). Inform the patient and his/her family of the potential benefits/risks of medical metal side rails use. [Reagan R. 2014].

Individual patient assessment considers the following:
Risk of medical metal bed side rails are great serious injuries, including head trauma, lacerations, fractures and dislocations. Raised medical metal side rails may increase patient agitation. They enhance feelings of isolation and restriction, thereby negatively affecting self esteem. Moreover, the confinement of it may prevent patients who are able to get out of bed from conducting routine activities, such as retrieving an object or going to the bathroom. Lastly, medical metal side rails are associated with severe bodily injury, creating noise, causing trauma if the patient’s body strikes or becomes entangled in the side rail and creating a sense of being trapped or jailed. The patient populations who have been identified as being at risk from medical metal side rails are those who are frail, elderly and/or have conditions including agitation, delirium, confusion, pain, uncontrolled body movements, hypoxia and acute urinary retention.

7- Results & Discussions
From the previous studies, it is clear that design of the medical metal bed side rails have an important direct and indirect impact on the health and psychological aspects of the patient by three sides:

A. Design ergonomic side
Therefore researcher put foundation design for medical metal side rails must be taken into account in the design.
- Design of side rails for metal medical bed need extensive support of experience and understanding deep knowledge of human psychology. It helps in identifying the human weaknesses that can be reason of slipping something that may prove disaster.
- Medical metal side rails have very different sizes and designs which causes fall or entrapment patients although they must be designed to safe patients.
- Stripped threads on bed frame clamps – does not allow them to be tightened securely.
- Side rails fall occurs when poorly fitted or poorly maintained rails break or become detached, and patients fall from bed.
- Design need side rails for metal medical bed extensive support of experience and understanding of deep knowledge of human psychology. It helps in identifying the human weaknesses that can be reason of slipping something that may prove disaster.
- Medical metal side rails should never be used routinely or unthinkingly, or as a substitute for adequate.
- The side rail are required and that other environmental or treatment considerations may not meet the individual resident’s assessed needs, or have been tried and were unsuccessful in meeting the resident’s assessed needs.
- When designing metal rails, it must be taken into account the relationship between rails and other parts of bed which may due to entrapment.
- Design need side rails for metal medical bed extensive support of experience and understanding of deep knowledge of human psychology. It helps in identifying the human weaknesses that can be reason of slipping something that may prove disaster.
- Medical metal side rails should never be used routinely or unthinkingly, or as a substitute for adequate.
- The side rail require meeting the resident’s needs as environmental or treatment considerations

B. Psychological side
- Medical metal side rails should never be used routinely or unthinkingly, or as a substitute for adequate.
- The side rail require meeting the resident’s needs as environmental or treatment considerations

C. Healthy side
- Decision to use medical metal side rails should be based on a comprehensive assessment and identification of the patient’s needs. These include comparing the potential for injury or death associated with use or non-use of medical metal side rails. Therefore creating a safe bed environment for patient.
- coating metal surface of side rails with antibacterial colors to avoid infections
- Avoid automatic using of metal side rails with any size or shape.
- Restrict using of physical restraints is including chest, abdominal, wrist, or ankle restraints of any kind on individuals in bed.
- It must be inspect, evaluate, maintain, and upgrade side rails to identify and remove potential fall. Entrapment hazards and appropriately are matching the equipment to resident needs considering all relevant risk factors.

Reasons which due to negative effects from using side rail are shown in figure (18).
Decisions about use or removal of medical metal side rails depend on:
- Their effect.
- Information giving on reasons falls and being developed.
- The reports of entrapment which almost all could have been Concentrated on safe dimensions of bed.
- Medical metal side rails may serve a number of purposes including safety in transit, facilitating turning and repositioning within the bed or transferring in or out of a bed, providing a feeling of comfort, facilitating access to bed controls, and providing a physical barrier to remind the patient of the bed perimeters. However no studies have been located exploring or measuring these benefits.

When design medical metal side rails it must be considered:
- Bed rails with variable height used in the lowest position.
- Specially made low height beds.
- Meshed bed sides.
- Put alarm systems to alert staff/careers that a person moved from their normal position and want to get out of bed.

8. Conclusion
Medical metal side rails are an important subset of all patients, especially the patients who are completely immobile. So, designer must be studied carefully the case of patient which he design for. the environment surrounded this patient, the economic case and social case. Then make a comfort design avoided negative consequences.

9. References
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