Mr David Clark
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(Sent by email to: wa-warwksmceng@hmcts.gsi.gov.uk)

Patient Safety
NHS Improvement
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[redacted]

Friday 1st April 2016

Dear Mr Clark,

Regulation 28 Report to Prevent Future Deaths following the inquest of Eileen Annie Thompson who died on 29 December 2015.

I am writing to you to respond to the concerns raised by your investigation into the circumstances surrounding the tragic death of Eileen Annie Thompson.

NHS England's patient safety team regularly reviews serious incidents reported to the National Reporting and Learning System (NRLS) and other sources of data to learn from errors that have occurred in the NHS. When appropriate, we issue Patient Safety Alerts to warn the healthcare system of new risks and to provide guidance on preventing potential incidents that may lead to patient harm or death. Our different types of Alerts (Warning, Resource and Directive Alerts) are issued via the Central Alerting System (CAS) to NHS Trusts in England and others, who have asked for notification (e.g. independent providers of health and social care). It may be helpful to note that the Patient Safety Team will move from NHS England to NHS Improvement on 1st April 2016.

From your report we understand that the incident, which led to the accidental death of Eileen Annie Thompson, involved a bed, which has been designed for use in

residential settings for people with mobility problems or those who need nursing care. In this case, the locking mechanism for the inner wheels was not easily accessible because the bed was placed against a wall.
The two inner wheels were not locked and as a result, the bed moved from the wall. You raised concerns that there is risk of recurrence in respect of service users who are provided with this type of bed when the bed is placed against a wall and asked us to take action, which should include an explanation of the steps we have taken to raise awareness of the risk and to issue appropriate instructions regarding the locking of wheels.

Following receiving your report we have explored the risk and identified the following issues:
Although some beds for use in residential settings are available, which have a central locking mechanism (e.g. all wheels are locked by locking one of the pedals), it seems that most beds are similar to the Minuet bed, which has four individually lockable wheels. We therefore feel that the risk does not only apply to a particular brand, but will relate to a wide range of beds used in residential settings.

We have reviewed some randomly selected user manuals and found that the level of information provided varies and is often not clear. For example:

- Some instructions for use (IFUs) state that wheels have to be locked in certain situations, e.g. during construction, when nursing or positioning a patient, before the user is moving in or out of bed. We feel that IFUs should include the advice that wheels should always be kept locked and only be released if the bed needs to be moved.

- No specific information about brakes has been found if the bed is positioned against a wall. The only advice found is that the pedal/ handle for operating the bed should be on the accessible side if the bed is positioned against a wall.

- A particular IFU advises that the bed should be positioned at an *appropriate* distance from walls. The reason for this was to *prevent damage or patient injury when operating the bed;* the accessibility of brakes or the risk of the bed moving has not been mentioned.

- Some examples suggest that locking two out of the four wheels is efficient (e.g. at least one castor at the head end and one castor in the foot end must be locked.). We feel that this is helpful and adequate advice because the locking mechanism provides lengthwise and crosswise locking and will therefore hold the bed in position.

Good clear instructions for use have a crucial role in the safe and effective use of device. The manufacturer is responsible for supplying appropriate instructions, taking into account the knowledge and training of the intended user(s). Any shortcomings in the instructions should be reported to the Medicines and Healthcare product Regulatory Agency (MHRA) as an adverse incident. It is within the remit of the MHRA to investigate such reported incidents and to ensure that user instructions are clear.

Our planned action:
We will discuss the risk and our findings with the MHRA as we feel that it is within their remit to improve the advice provided in user instructions. We will highlight the fact that some IFUs do not seem to provide enough guidance for staff and that advice is needed on how to safely use a bed with individual wheels, if it is positioned against a wall. Advice is also required on how many wheels need to be locked to hold the bed in position.

You may consider sending the Regulation 28 Report to the MHRA so they can respond directly about the actions they are planning to take to prevent similar incidents in the future. If the company which supplied the bed is currently investigating the incident, the MHRA will probably be already aware of this case.

Further issues identified:

In domestic situations it is not always possible to apply the same standards as in a clinical environment. Spaces can be small and client/patient preferences are being taken into account. Therefore, it is not unusual for beds in residential homes and private residences to be placed against a wall.

The difficulty of locking wheels is not new to many staff as often the brake at the top end of the bed cannot be locked if the bed is positioned in the corner of a room. We are aware that that the risk of beds moving is covered in some local staff training programmes to raise awareness.

Qualified nurses and occupational therapists are often responsible for assessing and prescription of beds. They usually complete a risk assessment, which includes e.g.

- Patient factors (risk of falling and if any equipment such as bedrails are required to minimise the risk)
- Equipment factors (suitability, benefits and risks of particular equipment)
- Environmental factors (assessing space for the bed/ for safe patient care and transfer).

We understand that practices vary greatly; for example, different local providers undertake risk assessments in different ways, and local equipment suppliers provide different services.

There is currently no nationally agreed standardised home visit framework.

We feel that staff is aware of the problem but that the solution is not always straight forward. We therefore think that new resources are required for staff to assess the risks more carefully and to be able to make adequate decisions with regards to the safe use of beds.

Our proposed action:

We will work with the College of Occupational Therapists and other stakeholders to drive the development of new national resources. Opportunity will be taken to ensure that these incorporate and build upon existent national guidance on falls prevention and the safe use of bedrails. Once new resources have become

available, we will explore the option of issuing a stage 2 alert to signpost to the new resources. We feel that this proposal will be more effective in preventing further incidents than just raising awareness by issuing a warning alert to staff.

We would be happy to keep you informed of our process and we are very grateful to you for bringing your findings from your investigation of Mrs Thomson's death to our attention.

Please accept my best wishes,

[redacted]
NHS National Director of Patient Safety
NHS Improvement

Cc:

[redacted], MHRA Director of medical devices [redacted]

[redacted], Professional Advisor for Older People and Long Term Conditions at the College of Occupational Therapists [redacted]