Medicines and Healthcare Products Regulatory Agency

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Mr Peter J Bedford
Senior Coroner for Berkshire
Yeomanry House
131 Castle Hill
Reading
RG1 7TA

Your ref: [redacted]

My ref:

27/02/2015

Dear Mr Bedford

Regulation 28 Report: JAMES WILSON FYFE decd

Thank you for your Regulation 28 report which we received on 31 December 2014.
Here is my reply to your matters of concern (2):

The Jury were informed that MHRA were aware of the investigation of the incident trolley but that it did not appear that the issue had been escalated and notified to all Hospital Trusts and agencies that used this type of trolley. The MHRA's actions in being informed of this potential hazard remain unclear, with particular reference to passing on the known risk to such trolley users.

Background
This incident was reported to MHRA by the Royal Berkshire Hospital (RBH), part of the Royal Berkshire Foundation Trust, on 29 March 2011, without naming the patient, as is usual for patient confidentiality reasons. The Trust did not inform MHRA of the patient's subsequent death. The incident was again reported to MHRA in August 2011 by the deceased's son, [redacted], Senior Medical Device Specialist, confirmed with RBH that this was the same incident that they had reported in March 2011.

The incident details provided by RBH were that a "Patient was admitted to A&E with pain in his hip after a fall at home. The patient went for an X-ray and whilst the film was being processed, the radiographer heard a noise and found patient on the floor. The patient had a large laceration to forehead and various grazes to right arm and right hand. He was seen by a doctor, examined and dressing applied to his forehead, arms and hands. The trolley was removed from use. Checks by nursing staff found it to be in working order, however it is being sent to the Clinical Engineering department for further testing. Clinical Engineering has contacted Anetic Aid Ltd who are sending a technician to examine the trolley".

MHRA asked Anetic Aid Ltd to investigate under the EU medical device Vigilance arrangements and to inform us of their findings and of any consequent action they proposed to

take, liaising with RBH if they required any further details of the incident. They were informed that MHRA had no objection to RBH releasing the trolley involved in the incident for analysis as part of their investigation.

Summary of Anetic Aid Ltd investigation - 2011.
Anetic Aid Ltd visited RBH on 1 April 2011 to examine the trolley. The serial number of the trolley was 2139 and it was supplied to RBH in March 2002. Anetic Aid Ltd had no record of its maintenance history as at that time there was no service contract between Anetic Aid Ltd and RBH. Both side rails were tested by applying weight to each end of the side rail and forcing them downwards. This procedure was repeated in the centre of the side rail. The side rail remained in their upright, locked positions. At the time of their inspection, both side rails' locking mechanisms were working correctly, although they were worn. The manufacturer concluded the cause of the incident was user error and not equipment failure.

MHRA review of incident - 2011.
Anetic Aid sent MHRA their investigation report on 6 April 2011. [redacted] reviewed their investigation report and based on this report, agreed the cause of the incident appeared to be user error and not equipment failure. The incident was transferred to our surveillance database in September 2011.

MHRA did not publish a Medical Device Alert (MDA) concerning the QA3 Patient Trolley. At the time of the incident 11,090 QA3 trolleys had been produced with the same design of locking mechanism for the side rails. There were no prior related incidents reported to either MHRA or Anetic Aid Ltd for the period the trolley had been placed on the market, 1998 to 2011.
It is important to note that not all incidents result in the issue of a MDA. MHRA received 10,984 incident reports (relating to 21,729 incidents) in 2011 and issued 114 MDAs. There would be a real risk of diluting the impact and importance of alerts if the system were to be used to distribute large numbers of alerts. In addition, Government agencies are trying to reduce the burden on the NHS and are working with fewer resources themselves.

MHRA only publish a MDA when it has been identified through our internal governance systems that additional measures are needed to deliver important device safety messages to healthcare providers and users. The decision to publish a MDA is based on a full consideration of an assessment of the risks associated with the adverse incident involved.

MHRA review of incident - 2015
The current version of the QA3 trolley uses the same type of locking mechanism and it is essentially unchanged, having the same characteristics. Anetic Aid Ltd state that QA3 sales now total 11,680 units. Since the incident in 2011 there have been no further reports to MHRA or to the manufacturer of any users other than RBH experiencing problems with the side rails not locking when they are raised. RBH sent us reports in March 2013 and November 2014 which were added to the surveillance database, each detailing one failure.

MHRA were informed by Anetic Aid Ltd that the QA3 trolleys in use within the RBH were placed under a maintenance agreement with Anetic Aid Ltd. from May 2011 and periodic service visits were carried out, together with user training, as and when identified as being required. RBH and Anetic Aid Ltd appear to have worked together to produce a maintenance checklist for RBH's QA3 trolleys: we are not aware that Anetic Aid Ltd have taken this measure with any other hospital as these problems have not occurred elsewhere.

Mr Marsden visited RBH on 14 January 2015 to examine some examples of their QA3 trolleys that they felt had safety issues with the side rails. Whilst there was evidence of some components being defective, such as damping springs, and a variance in the force needed to raise the side rails was apparent, the locking mechanisms seen on all examples were fully functional and, following the instructions for use, were intuitive to use.

Mr Marsden also visited the manufacturing site of the Anetic Aid Ltd QA3 trolley, Portsmouth Surgical Equipment Ltd, on 2 February 2015. The two companies are related. The purpose of the visit was to discuss the design aspects of the locking mechanism. The design of the QA3

was seen to have changed very little in terms of its mechanisms and functions since its inception. The instructions for use, valid at the time of the incident, were deemed to be sufficient for safe use of the side rails, following provision of user training. This is specified in their Quality System (PROC-160) and includes reference to the latest instructions for use. Training is usually provided by either a Regional Account Manager or a Sales Director and the manufacturer keeps a record of the training certificates they have issued. However, it appears that RBH had not received any training from the manufacturer before the incident occurred.

Anetic Aid Ltd revised the instructions for use for the latest model of QA3 in March 2013. The addendum below was added to the section concerning the operation of the side rails. The manufacturer did not issue a Field Safety Notice, as the revision was considered to be part of the process of continuous product improvement.They did not send the revised instructions for use to existing customers, only to new customers.

WARNING: After raising the side rail, it is important to ensure that it has locked in position by pushing down on the side rail; failure to ensure the side rail is properly locked could result in injury to the patient.

[redacted] discussed the QA3 instructions for use with the manufacturer in consideration of your Regulation 28 report, advising the manufacturer to review them again to ensure that they are still accurate and appropriate.

[redacted] additionally contacted four other Hospital Trusts via our Medical Device Safety Officer (MDSO) network, each of which have over one hundred QA3 trolleys in use, to establish whether they have had this problem but had not reported it to MHRA. The three Trusts that replied indicated that they had not experienced this problem, again suggesting that it is a local issue within RBH.

Summary
MHRA does not normally require manufacturers to modify medical devices or instructions for use on the basis of a single report or a single report source, unless it is clear from the report that the device did not function as intended. Enough evidence needs to be gathered in the form of further reports or other evidence before it can be argued that the device is not functioning as intended. It is important for reporters to continue to report further adverse incidents when they happen, rather than assuming that nothing will come of these reports. When enough evidence is submitted, MHRA will act within the measures of the law. It is through these systems, coupled with joint partnership working with the NHS that MHRA can help to protect the safety of medical devices users.

MHRA believes RBH should continue to work with the manufacturer to address any shortcomings in user training regarding the safe use of the QA3 trolley.

MHRA will remind Anetic Aid Ltd to follow their Quality System and ensure all customers are offered training in the use of these trolleys.

I hope this information gives you the assurance that we have acted both appropriately and within our remit.

Yours sincerely,

[redacted]
Director of Devices
Telephone: [redacted]
E-mail: [redacted]