Patient Safety Alert

Stage Three: Directive

Improving medical device incident reporting and learning

20 March 2014

Alert reference number: NHS/PSA/D/2014/006 Alert stage: Three - Directive

NHS England and the MHRA are working together to simplify and increase reporting, improve data quality, maximise learning and guide practice to minimise harm from medical devices incidents by:

- sharing incident data between the MHRA and NHS England, reducing the need for duplicate data entry by frontline staff by developing a new integrated National Learning and Reporting System (NRLS) which will be tested before becoming operational. Separate reporting to the MHRA will then no longer be necessary;
- giving new types of feedback from the NRLS and the MHRA to improve learning at local level;
- clarifying medical device safety roles and identifying key safety contacts to allow better communication between local and national level; and,
- setting up a National Medical Devices Safety Network as a new forum for discussing potential and recognised safety issues, identifying trends and actions to improve the safe use of medical devices. The network will also work with new Patient Safety Improvement Collaboratives that will be set up during 2014.

Continue to report separately to the MHRA and the NRLS until the integrated reporting system becomes operational. Another patient safety alert will then be issued.

Actions (Target date for completion 19 September 2014)

All *large** healthcare provider organisations including NHS trusts, community pharmacy multiples, home healthcare companies and those in the independent sector should:

1. identify a board level director (medical or nursing supported by a senior healthcare professional) or in community pharmacy, or home health care, a senior manager (for example a Superintendent Pharmacist) to have the responsibility to oversee medical device incident reporting and learning;
2. identify a Medical Devices Safety Officer (MDSO) and email their contact details to the Central Alerting System (CAS) team. This person will support local medical device incident reporting and learning, act as the main contact for NHS England and the MHRA and medical device manufacturers and be a member of the new National Medical Devices Safety Network; and,
3. identify an existing or new multi-professional group to regularly review medical device incident reports, improve reporting and learning and take local action to improve the safety of medical devices.

*Small** healthcare provider organisations including general practices, dental practices, community pharmacies and those in the independent sector should:

4. continue to report incidents involving medical devices to the NRLS using the e-form on the NRLS website, or other methods. Report also to the MHRA's online reporting system. Take action to improve reporting and learning locally, supported by medical device safety champions in local professional committees, networks, multi-professional committees and commissioners.

Healthcare commissioners including Area Teams, and Clinical Commissioning Groups are invited to:

5. identify a Medical Devices Safety Officer (MDSO) and email their contact details to the CAS team. The MDSO will be a member of the National Medical Device Safety Network, support reporting and learning and take local actions to improve medical devices safety. The MDSO can use learning to influence policy, planning and commissioning as part of clinical governance in the commissioning organisation; and,
6. regularly review information from the NRLS and the MHRA to support improvements in reporting and learning and to take local action to improve the safety of medical devices. This should be done by working with medical devices safety champions in local professional committees and networks, and with a new or existing multi-professional group.

*Supporting information: www.england.nhs.uk/patientsafety
Contact NHS England: patientsafety.enquiries@nhs.net
Contact MHRA: aic@mhra.gsi.gov.uk

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