The Medicines and Healthcare products Regulatory Agency adverse incident reports and assistive technology (AT)

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Summary
MHRA is the United Kingdom organisation responsible for ensuring medical devices are acceptably safe. Recently the number of adverse incidents of all types has increased: however it has decreased for AT devices. To support MHRA, any concerns regarding the safety or effective use of devices should be reported.

Aims & Objectives
The aims are to review the trends in medical device adverse incident reports for medical devices as a whole, and contrast this with changes in adverse incident reports concerning devices considered to be assistive technology. The reporting source (manufacturer vs. professional user or member of the public) is also considered. Information on common reportable issues and how to support the work of the agency in supporting safety is presented.

Background
The total number of adverse incident reports received from the MHRA has almost doubled between 2011 and 2018. For assistive technology devices, the number of reports has fallen by 31% in the same time. This is due to a decline in reports from professional users. The number of compulsory vigilance reports has increased substantially for devices overall, and has remained constant for AT devices. The number of professional user AT reports has declined.

Many device issues can be reported: material or mechanical failures, quality of instructions for use, inadequate repair or maintenance, and so on. All reported incidents concerning AT are logged on the MHRA database, and whenever possible referred to the appropriate manufacturer for investigation. The MHRA reviews all manufacturer investigations for AT devices and all field safety corrective actions. The MHRA can issue advice or information to users and, in serious cases, can remove non-compliant devices from the market.

Discussion
To support the MHRA:

- Find out who your organisation's medical device safety officer is and how to contact them
- If you are aware of an adverse event involving a medical device where someone was or could have been injured then report this via the Yellow Card website [1]. This should be done in addition to any local reporting procedure
- If you report a failure, please keep the device, and make it available to the manufacturer for examination
- If you receive a field safety notice (FSN) from a manufacturer, read it and carry out the requested actions
- If you receive a medical device alert (MDA) from MHRA related to a device under your control, please read it and carry out the requested actions. You can sign up for alerts on new FSNs and MDAs on the MHRA website
- Be aware of local procedures regarding medical devices

- Be aware of MHRA advice on managing medical devices [2].

For more information, visit the MHRA assistive technology webpage [3]:
www.gov.uk/government/publications/assistive-technology-definition-and-safe-use

References

[1] yellowcard.mhra.gov.uk

[2] www.gov.uk/government/publications/managing-medical-devices

[3] www.gov.uk/government/publications/assistive-technology-definition-and-safe-use

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