**Adverse Incident Reporting and the MHRA**

Medical devices can form a substantial part of the strategy used by healthcare professionals in the treatment, management and rehabilitation of people with mobility issues (Webster and Murphy, 2019). Devices are used in increasing numbers and have over the years developed in complexity. This comes with a risk that if devices fail, then serious harm may come to users, healthcare professionals or those around them.

The Medicine and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medical devices in the UK by ensuring that they perform as expected and that they are acceptably safe in fulfilling its role as the UK National Competent Authority under the provisions of the Medical Device Directive (European Council, 2007) and the Medical Device Regulations 2017 (European Council, 2017). The MHRA’s work is carried out in several ways. For instance, clinical investigations that are carried out in the UK are regulated by the agency. The MHRA provides oversight and accreditation of UK Notified Bodies (independent third-party organisations responsible for approving CE marking of higher-risk devices). The MHRA also monitors the effectiveness of the adverse incident investigations carried out by manufacturers. The MHRA regulates manufacturers only.

Information on the safety and performance of medical devices from the field helps the MHRA fulfil its remit. Manufacturers are legally required to make the MHRA aware of adverse incidents involving their products which take place in the UK and which did, or could have, resulted in a serious injury to the patient, user or other person.

To aid in this process, the MHRA also collects and assesses information about adverse events from other non-mandatory sources, including reports from healthcare professionals, members of the public and others. The MHRA maintains a database of all incidents that are reported to the agency. This allows for identifications of trends of incidents involving particular types of device, and assessment of emerging patterns of issues. Although not every report will result in direct MHRA action, all reports are logged, all final reports from manufacturers related to assistive technology are scrutinised and the incident database is regularly reviewed to identify any possible trends in reports.

Figure 1 contains some examples of reported assistive technology device problems. In recent years the number of assistive technology adverse events reported to the MHRA by clinicians has fallen (Davenport et al. 2017).

If a manufacturer wishes to perform a corrective action for safety reasons to devices already on the market in the UK, then they must inform the MHRA and issue a Field Safety Notice (FSN) to all affected customers. This should clearly explain the problem, the risk to users and solutions to ensure safety. If you receive an FSN, please let the manufacturer know that you have received it and take the recommended actions. The MHRA uses this information to track the effectiveness of the corrective actions.

The MHRA may also take additional action to safeguard public health, such as get in touch with individual hospitals or users directly, or issue Medical Device Alerts for very widespread or serious issues, or even prohibit devices from the market.

Figure 1 - Commonly reported device problems

Failures in assistive technology can cause serious injuries to users or caregivers. Table 1 includes some examples of reported injuries.

|  |  |  |
| --- | --- | --- |
| Bone fractures from a fall from a hoist | Cuts from an unfinished edge to a device  | Orthoses being unavailable due to mechanical failures |
| Limb crush and other entrapment injuries | Allergic reactions to prosthetic socket liners | Delays to effective treatment being provided |
| Lack of appropriate postural support and pressure injury | Fall after corrosion damage to a prosthetic knee | Psychological effects from lack of access to a device |

Table 1 – Examples of reported injuries from assistive technology adverse incidents

For more information, please visit the MHRA assistive technology webpage: <https://www.gov.uk/government/publications/assistive-technology-definition-and-safe-use/assistive-technology-definition-and-safe-use>.

Every report matters and there are several actions that you can take to help the MHRA safeguard public health:

* If you are aware that an adverse event has taken place involving a medical device, and someone was or could have been injured, please report this to the MHRA using the [Yellow Card](http://www.gov.uk/report-problem-medicine-medical-device) website . This should be done in addition to reporting on local systems (e.g. DATIX) and informing the manufacturer about the problem.
* If you report a failure, please keep the device so that the manufacturer can analyse it.
* Please raise awareness of the importance of reporting issues with medical devices with patients and service users
* If you receive a Field Safety Notice from a manufacturer, please read it and carry out the requested actions.
* If you receive a Medical Device Alert (MDA) from the MHRA related to a device in your possession, please read this and carry out the requested actions. You can sign up for updates on newly issued FSNs and MDAs on the MHRA website.
* Please be aware of MHRA’s guidance on managing medical devices (MHRA, 2015)
* Please be aware of local procedures regarding the use and management of medical devices and find out who your organisation’s Medical Device Safety Officer is.

References:

*Council Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market* [Online]. [Accessed 07 January 2018]. Available from: <http://eur-lex.europa.eu/>

*Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC* [Online]. [Accessed 07 January 2018]. Available from: http://eur-lex.europa.eu/

Davenport, P., Blake, C., Cacou, C., Marsden, A. and Vincent, S. 2018. *Contrasting adverse incident reporting in the UK for prosthetics and orthotics with medical devices overall*. ISPO-UK Annual Scientific Meeting. 12-13 October, Southampton.

*Medicine and Healthcare products Regulatory Agency, 2015. Guidance for healthcare and social services organisations for managing medical devices in practice* [Online]. [Accessed 07 January 2018]. Available from: <https://www.gov.uk/government/publications/managing-medical-devices>

Webster, J. and Murphy, D. eds. 2019. *Atlas of orthoses and assistive devices*. 5th Edition, Philadelphia, PA, USA: Elsevier.