HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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Medical Device Safety Notice eAlert System to be implemented in all HSE Health Facilities

Medical Device Management 'Quality Assessment and Improvement Tool' also published

The launch of a newly developed National Medical Device eAlert System designed to streamline the management of medical device safety notices within the public health system was attended by multidisciplinary healthcare professionals at the Royal College of Physicians in Ireland in Dublin recently.

Developed by the HSE's National Medical Devices Equipment Management Committee, in collaboration with the Quality Improvement Division and with assistance from the Health Products Regulatory Authority (HPRA), the aim of the eAlert system is to provide each HSE or HSE-funded voluntary service location assurance in the management of medical device safety or quality related notices issued by the HPRA. A key component of the medical device vigilance system is the dissemination of information, which may be used to prevent recurrence of an incident or to alleviate the consequences of such incidents.

The occasion also saw the launch of a HSE Medical Device Management 'Quality Assessment and Improvement Tool (QA+I tool)' to facilitate assessment against the HSE Medical Device Equipment Management Policy and Best Practice Guidance. Speakers at the event included Mr Tony O'Brien, Director General of the Health Service, HSE, Ms Marie Kehoe-O'Sullivan, Director, Safety and Quality Improvement HIQA, alongside representative of the Acute Service, National Clinical Head of Medical Devices, Mr Ger Flynn of Corporate Estates, HSE and National Decontamination Quality Lead, Ms Caroline Conneely of Quality Improvement Division, HSE.

Interactive panel discussions were chaired by Dr Philip Crowley, National Director of Quality Improvement, HSE, who also presented on the quality improvement methodologies used by the QID to support the implementation of quality improvements within the HSE with the second session chaired by Dr Joan Gilvarry, Director of Human Products Monitoring, HPRA.

The medical devices eAlert system has been implemented and is available throughout the HSE. The web-enabled system is hosted by the HSE's ICT centre and will facilitate the nomination of a 'designated person' within hospitals, community healthcare organisations and other health facilities to take responsibility for the receipt of the medical device alert notifications. The designated person will ensure the further internal

facility distribution to the relevant personnel for implementation of the recommended actions where applicable.

The national eAlert system receives notification directly from the HPRA of all medical device safety / hazard notifications or any internally generated HSE safety notifications for distribution. A priority level is assigned to each alert in accordance with the HPRA traffic light system of red, amber and green. An associated, automated response timescale is also assigned to each notification within which the relevant action must be reported back by the designated person to the central ICT system as being completed or not applicable or other.

Commenting at the event, Ronnie McDermott, Medical Equipment Management Lead, Cavan Monaghan Hospital, "The Medical Device Equipment QA+I tool supports a culture of improving quality across all services in relation to the management of medical device equipment. It provides opportunities for service areas to gain an informed picture of the quality of services and practices in relation to medical device equipment. The assessment process allows services to identify gaps in current service provision, develop improvement plans to address these gaps and demonstrate accomplishments achieved in the management of medical device equipment.

The QA+I tool will support the collation of information generated from the assessment process whilst enabling the development and monitoring of any associated derived quality improvement plans to progress compliance with the HIQA standards", he concluded.

Joan Gilvarry, Director of Health Products Monitoring at HPRA, stated, "Our medical devices team were very pleased to play a part in this project and welcomed the opportunity to work with the HSE's National Medical Devices Equipment Management Committee and Quality Improvement Division. At the HPRA, we're continuously looking at ways to improve our communications to health care professionals."

"The eAlert system provides for an extremely efficient method of disseminating safety information to key medical device users and will contribute to enhanced patient safety across all the health facilities involved. The HPRA in collaboration with the QID and Medical Device Equipment Management Committee developed a Step-by Step guide to facilitate users in reporting medical device adverse events. This guide will be circulated to all users in the Acute Service and the Community Healthcare Organisation in early 2016."

As the national competent authority for medical devices, the HPRA publishes notices relating to the safety and/or quality of medical devices on its website www.hpra.ie. The majority of these notices are for the attention of health professionals including those working in hospitals, community healthcare organisations and other health facilities.

ENDS

FOR FURTHER INFORMATION

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NOTES TO EDITOR:

The HSE recognised the need to have effective systems in place for the management of Medical Devices developing a "Medical Device Equipment Management Policy and Best Practice Guidance" for implementation across the organisation. Since the implementation of the policy, several initiatives have been progressed to drive and support patient safety in a uniform coordinated approach throughout the HSE.