NHS AI and Digital Regulations Service for health and social care

Adopters guidance

Reporting safety issues about medical devices to the MHRA

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This is best practice guidance

Although not legally required, it's an essential activity.

This Guide covers:

- Great Britain (England, Scotland, Wales)

From:

- Medicines and Healthcare products Regulatory Agency (MHRA)

Last reviewed: 13 January 2023



Adopters should report safety concerns about medical devices to the MHRA via the Yellow Card reporting site.

How adopters report safety issues to the MHRA

You should report a suspected safety issue ('adverse incident') with a medical device to the MHRA as soon as possible. How to report it depends on where you are in Great Britain:

- England and Wales - use the Yellow Card reporting site
- Scotland - report it to Health Facilities Scotland (unless you are a private facility providing care to private clients, in which case report to the Yellow Card reporting site and the Care Inspectorate)

You should also notify the developer of the technology.

Please note that reporting medical device concerns in Northern Ireland currently falls under the EU Medical Device Regulations. For more information please contact the MHRA .

Understanding the criteria for reporting adverse incidents

An adverse incident is an event that caused, or almost caused, an injury to a patient or other person, or a wrong or delayed diagnosis and treatment of a patient.

Developers have a legal requirement to report incidents to the MHRA.

The MHRA encourages adopters to follow the same criteria as developers to determine if something is an adverse incident. An event that meets all 3 criteria below is considered an adverse incident and you should report it to the MHRA:

- an event has occurred. This includes situations where testing performed on the device, examination of the information supplied with the device, or any scientific information indicates some factor that could lead, or has led, to an event
- the device is suspected to be a contributory cause of the incident
- the event resulted, or might have resulted, in death or a serious deterioration in state of health of a patient, user or other person

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Not all adverse incidents result in death or a serious deterioration in health. These may have been prevented because of other circumstances, or because of intervention. An event is still reportable if no injury was sustained but could be upon a repeat event. So, you should still send the MHRA a report if:

- an incident associated with a device happened, and
- if it occurred again, it might lead to death or serious deterioration in health

The MHRA, the developer or a medical specialist may investigate the problem depending on how serious it is. It'll be recorded to help prevent similar incidents in future, even if it's not investigated.

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