MHRA Adverse incident reporting

Reporting adverse incidents involving medical devices

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What is a medical device?

Medical devices and equipment are items used for the diagnosis and/or treatment of disease, for monitoring patients, and as assistive technology. This does **not** include general workshop equipment such as power or machine tools, or general purpose laboratory equipment. See more information on what a medical device is in the UK MDR 2002.

What is an adverse incident?

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons.

For example:

- a patient, user, carer or professional is injured as a result of a medical device failure or its misuse
- a patient's treatment is interrupted or compromised by a medical device failure
- a misdiagnosis due to a medical device failure leads to inappropriate treatment
- a patient's health deteriorates due to medical device failure.

Causes may include: design; poor user instructions or training; inappropriate modifications; inadequate maintenance; and unsuitable storage and use conditions.

Why report?

The information from adverse incident reports can help identify faults with medical devices and may prevent similar incidents happening again.

Who should report?

Anyone may submit an adverse incident report to the MHRA – clinicians, healthcare workers, carers, patients and members of the public.

If you report from an NHS organisation you can copy in your Medical Device Safety Officer and/or patient safety manager to comply with local rules.

What should be reported?

Any adverse incident involving a medical device should be reported to the MHRA. Some apparently minor incidents may have greater significance when aggregated with other similar reports.

When should an incident report be made?

All incidents should be reported to the MHRA as soon as possible. Serious cases should be reported by the fastest means possible. Initial incident reports should contain as much relevant detail as is immediately available but should not be delayed for the sake of gathering additional information.

How do I report an incident?

Preferably by using the Yellow Card reporting website or the Yellow Card app. Please download it from the Apple App Store, or Google Play Store. Guidance on how to report can be found here.

What do I do with devices that have been involved in incidents?

All items should be quarantined if possible. Please do not send your device to the MHRA. Hold onto it once you have reported it to us. You can release the device to the manufacturer, with the device owner's agreement. If this is subject to a coroner or police investigation you must obtain advice from them prior to releasing the device to the manufacturer.

What does the MHRA do when it receives a report?

Once a Yellow Card report is received it is evaluated and viewed in the context of other reports and data sources to determine if there is a potential safety signal for investigation and whether further action is needed. If we need further information about your report, we will contact the reporter.

No product is risk free. Our process for deciding whether a signal requires further action involves a benefit risk judgement.

We send reports to the manufacturer of the device. They may contact the reporter for further information. The manufacturer must investigate and submit a formal response to MHRA for every incident which meets the legal reporting criteria. The manufacturer will share their response with the reporter.

Because of a signal;

The MHRA can:

- publish Device Safety Information
- publish guidance for users and patients
- issue a National Patient Safety Alert (NaPSA) giving safety advice to the healthcare service

- use social media to raise safety issues or issue guidance
- assess all allegations of non-compliance brought to us, using a risk-based system.

The manufacturer can:

- issue a recall notice (called a field safety notice) to remove the devices or a batch of devices from use.
  This can be because the MHRA tells the manufacturer to take action.
- make design changes to fix the problem

These types of actions help to reduce the risk of similar incidents happening again and makes sure patient safety comes first.

The MHRA stopped issuing Medical Device Alerts (MDAs) in September 2020.

Users who wish to receive National Patient Safety Alerts and Device safety information will need to subscribe. Those who were signed up to receive Medical Device Alerts will not receive the new publications and will need to sign up again.

It is important that medical device users continue to read and act on the advice contained in Field Safety Notices, which are issued directly by device manufacturers.

The role of medical device Safety officers (MDSOs)

Over 90% of NHS trusts and social services department have an MDSO. Their key roles are to support local medical device incident reporting and learning, act as the main contact for NHS England and the MHRA and medical device manufacturers and to disseminate safety communications.

For general enquiries about adverse incidents involving medical devices contact our Adverse Incident Centre: aic@mhra.gsi.gov.uk or 020 3080 7080.

Incidents occurring in Scotland, Northern Ireland and Wales
Each devolved administration has its own guidance on reporting adverse incidents, available on the respective websites.

Northern Ireland (external link)

Scotland (external link)

Wales (external link)

BSIR Guidance can be seen here