

Report on Devices Adverse Incidents in 2010

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Contents

1 Introduction	3
1.1 Adverse incident reports 2010.....	3
1.2 Periodic summary reports	4
1.3 Comparison with 2009	5
1.4 Online reporting systems.....	6
1.5 Medical device liaison officers (MDLOs)	6
1.6 Central Alerting System (CAS).....	6
1.7 Field Safety Notices and Field Safety Corrective Actions	7
1.8 Devolved administrations	7
1.9 Haemovigilance.....	8
1.10 New adverse incident handling strategy from 2011	8
1.11 Reporting guidance and annual report – future publication.....	8
2 Reporting and investigation of adverse incidents.....	9
2.1 Reporting procedures.....	9
2.2 Devices retained or submitted for examination	9
2.3 Defining an adverse incident.....	10
2.4 Reasons for reporting adverse incidents.....	11
2.5 Recording incident report details.....	11
2.6 Investigation levels – reports received prior to April 2011	12
2.7 Maintaining contact with the reporter	12
2.8 Investigation teams	13
2.9 Medical Devices Alerts (MDAs).....	13
3 Review of specialist technical unit activity in 2010	14
3.1 Assistive Technology (AT).....	14
3.2 Biosciences and Implants (B&I)	16
3.3 Imaging and Acute Care (I&AC).....	19
4 Statistics	22
4.1 Trends in adverse incident reporting.....	22
4.2 Vigilance cases	23
4.3 Report sources.....	24
4.4 Online reporting.....	26
4.5 Incident reports by device group	27
4.6 Investigation levels.....	28
4.7 Causes of adverse incidents	29
4.8 Investigation outcomes	30
4.9 Investigation durations	31
4.10 Medical Device Alerts and CA notifications issued	32
5 Customer survey.....	33
5.1 Conduct of survey and MHRA action	33
5.2 Response and satisfaction levels.....	33
5.3 Questionnaire.....	36

1 Introduction

This annual report provides our regular overview of medical device related adverse incidents reported to the MHRA during the preceding calendar year. It records recent developments in incident reporting and highlights the more significant actions that we have taken during the year.

The narrative includes background information on adverse incident reporting procedures, a summary of the year's key statistics, and a brief analysis of responses to our routine customer survey activity as well as a summary from our specialist technical units.

The format of this report has remained fairly constant over time. This allows a considerable degree of comparison with data from preceding years. However, as the quality and breadth of data develop, new features may be added and existing features revised. Next year's report will contain a number of significant differences that will reflect the new adverse incident handling strategy (see Section 1.10).

The MHRA strives to ensure the accuracy of data held in its databases and so we regularly review, update and amend our records as new data, errors and omissions are identified. As a consequence, there may, in certain instances, be differences between the historical data in this report and that previously published.

For a full list of other MHRA publications, including monthly lists of Medical Device Alerts, please refer to our website: www.mhra.gov.uk

1.1 Adverse incident reports 2010

In 2010 the MHRA received 10,280 adverse incident reports involving medical devices, 13% more than in the previous year. This total represents an increase of 42% over the 7,249 reports received ten years ago in 2000.

	2008	2009	2010
Incident reports received	8,902	9,099	10,280
% change over previous year	+3.1	+2.2	+13.0

1.2 Periodic summary reports

The regulatory basis for periodic summary reporting is described in the 'MEDDEV' – the EU guidelines for medical device manufacturers on the Medical Devices Vigilance System. The MHRA has additional guidance in Directives Bulletin 3. Both documents may be accessed from the MHRA website.

In recent years the MHRA has agreed with a small number of medical device manufacturers that they can submit periodic summary reports (PSRs). This allows the manufacturer to combine – into a single report – similar incidents with the same device or device type, where the root cause is already known, or a FSCA (Field Safety Corrective Action) has been implemented.

In 2010 there were 752 incidents included in periodic summary reports. When these are taken into account, the full total of incident reports received last year is 11,032. This represents an increase of 66% over the total number of reports submitted ten years ago in 2000.

	2007	2008	2009	2010
Periodic summary reports submitted to the MHRA	18	35	60	39
Incidents reported within periodic summary reports	3,506	1,366	1,680	752
Incident reports received – includes periodic summary reports	12,140	10,268	10,779	11,032

The total number of reports submitted within PSRs may also include reports of adverse incidents occurring in clinical investigations of medical devices. Individual reports of incidents occurring in clinical investigations are routinely included in the annual total for adverse incident reports received by the MHRA.

We expect the use of PSRs to increase steadily, particularly as the option to submit them electronically has been incorporated into the MHRA's manufacturer's online reporting system (MORE) and a PSR report form has been agreed for use across Europe.

1.3 Comparison with 2009

The table below compares figures for 2010 with those from 2009.

Description of reports or action taken	2009		2010	
	Number of reports	%	Number of reports	%
Were reported as involving a fatality	202	2.2	301	2.9%
Were reported as involving a serious injury (including implant or pacemaker revision)	1,885	20.7	2,382	23.2%
Prompted in-depth MHRA investigations	2,222	24.4	2,227	21.7%
Were investigated by manufacturers under MHRA supervision	3,539	38.9	4,256	41.4%
Did not require immediate MHRA action, but were entered onto a database enabling trend monitoring and pattern detection	1,661	18.3	2,064	20.1%
Were reports of incidents similar to those already known to the Agency	829	9.1	796	7.7%
Were from secondary report sources, duplicating existing reports	579	6.4	676	6.6%
Did not relate to medical devices	116	1.3	110	1.1%
Were investigated by other organisations and their conclusion made available to the MHRA	180	2.0	103	1.0%

The 2010 figure for the number of incident reports that included a report of a serious injury or a fatality rose considerably from 2,087 to 2,683.

In 2010 we completed 279 investigations of adverse incidents reported as involving a fatality. In 177 of these we concluded that there was no established link between the fatality and the device(s) involved in the incidents.

For incidents reported as involving a serious injury, 2,022 investigations were completed in 2010. In 1,359 of these we found that there was no established link between the injury and the device(s) involved in the incidents.

The following actions were taken as a result of investigations:

- 100 Medical Device Alerts were issued
- 129 notifications were shared with Competent Authorities in EU member states
- 403 manufacturer's Field Safety Corrective Actions and 293 other manufacturer's field actions were undertaken
- 294 cases requiring the provision of advice on safer device use or improved staff training were identified

- 730 manufacturer undertakings to improve designs, manufacturing processes and quality systems.

1.4 Online reporting systems

The MHRA has online systems for reporting adverse incidents involving medical devices that cater for:

- professional medical device users (i.e. clinicians, healthcare and social care workers)
- patients and other members of the public
- medical device manufacturers (MORE: Manufacturers' Online Reporting Environment).

The MORE and user reporting systems continue to provide considerable benefit both to reporters and to the MHRA. For reporters they are fast, simple to use, and provide an immediate acknowledgement of receipt along with a unique reference number. For the MHRA they save resources by avoiding time-consuming re-keying of data when reports are entered onto the Adverse Incident Tracking System (AITS). Importantly, both systems also avoid transcription errors inherent in a paper-based system.

The percentage of incident reports submitted online by device users has continued to increase. In 2010 there were 3,086 user reports submitted online (86% of all reports in this category). The proportion of manufacturer reports submitted online remains largely unchanged. The introduction of online periodic summary reporting and of the MORE XML Manager are both expected to prompt increased MORE usage.

1.5 Medical device liaison officers (MDLOs)

The MHRA's medical device liaison officers act as the local reporting and communication focal points within the NHS and social care sectors. They are also closely involved with the Central Alerting System (CAS – see below) and have their own pages on the MHRA website.

The liaison officer focus group (LOFG) comprises a cross-section of liaison officers drawn from NHS acute, community, ambulance and mental health trusts, primary care trusts and social services departments. Members of the group have their contact details published on the MHRA website so that other liaison officers in their sector can contact them for advice and mutual support. Details of focus group meetings (which are held annually) can be found on the liaison officer pages on our website.

1.6 Central Alerting System (CAS)

The Central Alerting System (CAS) is a web-based system for distributing alerts and urgent guidance on patient safety on behalf of the MHRA, the Department of Health and the National Patient Safety Agency. The MHRA distributes drug alerts, medicines Dear Doctor letters, and Medical Device Alerts (MDAs) via CAS.

The system disseminates alerts to the network of CAS liaison officers in NHS trusts and primary care trusts. Each alert has deadlines for getting action underway and completed. The CAS liaison officer then distributes the alerts within their organisation, responds to alerts, and can raise queries on specific alerts all via CAS.

There is guidance for CAS liaison officers in the CAS Help section, including guidance for primary care trusts when they split. This is only available only after logging in via the [CAS Homepage](#)

Changes in CAS liaison officer contact details should be notified to the CAS helpdesk by telephone (020 7972 1500) or email (safetyalerts@dh.gsi.gov.uk)

1.7 Field Safety Notices and Field Safety Corrective Actions

The EU Medical Devices Directives require manufacturers to monitor the safety of their products and, where necessary, carry out corrective actions on medical devices that have been distributed to customers (i.e. that are 'in the field'). Field Safety Notices (FSNs) are used by manufacturers to inform medical device users about Field Safety Corrective Actions (FSCAs) taken by them (the manufacturer) to reduce the risk of death or serious deterioration in state of health during the use of the device. FSCAs are usually, but not exclusively, prompted by investigations of adverse incidents reported by medical device users. They relate particularly to investigations made by the MHRA and/or manufacturer that have revealed the need to:

- change the design of the device
- remove or replace devices in the field
- make device modifications in the field or amend instructions for use.

The same Directives oblige manufacturers to alert the MHRA, as the UK Competent Authority, about any corrective actions affecting their products that have been distributed within the UK. The MHRA carries out an assessment of each FSCA to determine whether the manufacturer's proposed action is relevant to the UK and whether it is sufficient to protect public health. On most occasions it is, and the MHRA monitors progress to ensure that the action is completed. This approach helps to minimise the need for the MHRA to issue Medical Device Alerts.

If your organisation receives a FSN from a manufacturer, it is very important that the actions advised in the FSN are taken, and that your organisation acknowledges receipt of the FSN. This receipt provides the manufacturer, and subsequently the MHRA, with the means to monitor the progress of Field Safety Corrective Actions. It also minimises the need for the MHRA to issue Medical Device Alerts, which, because of the broadcast nature of the MDA and the extra administrative work required, place an additional burden on the health service.

1.8 Devolved administrations

The MHRA is the competent authority for the United Kingdom. Ongoing arrangements with Scotland and Northern Ireland have allowed delegation of certain report processing and incident investigation responsibilities.

All hazardous medical device related incidents occurring in [Wales](#) are reported directly to the MHRA, with a copy of the report being sent to the Welsh Surgical Materials Testing Laboratory (SMTL). The MHRA undertakes all necessary incident investigations and advises the Welsh Assembly Executive where appropriate. All non-hazardous reports or defects continue to be reported directly to [SMTL](#).

1.9 Haemovigilance

The MHRA is also the UK Competent Authority for blood safety and quality. The Adverse Incident Centre receives reports made under the EU Blood Safety and Traceability Directives and the UK Blood Safety and Quality Regulations. Reports under these regulations are submitted using the dedicated online reporting system, SABRE (Serious Adverse Blood Reactions & Events). SABRE is accessible via the MHRA website. SABRE also prompts reporting to SHOT (Serious Hazards Of Transfusion).

The reports submitted concern serious adverse reactions and serious adverse events relating to the collection, testing, processing, storage and distribution of blood and blood components for transfusion. Each year the MHRA haemovigilance team complete the annual summary report exercise and collate and submit the associated UK summary report to the EU Commission. The team also continues to liaise closely with MHRA colleagues responsible for blood compliance reporting and for the inspection of blood establishments and blood banks. Information obtained from SABRE reports is routinely shared with these inspectors and informs their inspection planning and decision-making processes.

1.10 New adverse incident handling strategy from 2011

Following a review of our adverse incident report handling strategy in early 2011, all reports are now subject to a new risk assessment and triage system. This is supported by an expanded and developed system for identifying, analysing and acting upon emerging incident patterns and trends.

These changes enable us to focus our specialist resources directly upon those issues which present the greatest risk to patient safety, and where our active intervention will make a positive difference to the resolution of the problem.

A letter providing full details of these changes and the new investigation categories was emailed to MDLOs earlier this year.

1.11 Reporting guidance and annual report – future publication

From 2012, the MHRA's two annual publications, 'Reporting adverse incidents and disseminating medical device alerts' and 'Report on Devices Adverse Incidents', will be published as a single document.

This will remove the current duplication of content between the two existing publications and ensure, for medical device liaison officers in particular, that all key information is located in a single reference document.

2 Reporting and investigation of adverse incidents

2.1 Reporting procedures

Each year the MHRA Adverse Incident Centre produces comprehensive guidance on reporting adverse incidents involving medical devices. The latest guidance – ‘Reporting Adverse Incidents and Disseminating Medical Device Alerts’ DB 2011(01), is available on our website (www.mhra.gov.uk). Additional advice on reporting adverse incidents may be obtained direct from the Adverse Incident Centre, either by email: aic@mhra.gsi.gov.uk or by telephone: 020 3080 7080.

Medical device liaison officers in NHS trusts and social care organisations can offer specific advice on local procedures for adverse incident reporting and on local risk management systems. Local procedures should ensure that all relevant members of staff, including contractors, are kept informed, suitably trained, and regularly reminded of their responsibilities with regard to adverse incident reporting and of any relevant and specific local arrangements.

All medical device related adverse incidents should be reported to the MHRA. The MHRA does not encourage liaison officers to ‘filter’ reports.

The Adverse Incident Centre encourages everyone to report through our **online system** on our website. However, there is still the option to use other versions of our report forms and to send them by email, post or fax.

The online reporting system includes a helpful option allowing reporters to send email copies of their incident report directly to one or more colleagues – in particular to their liaison officer, line manager or patient safety/risk manager.

Depending on the nature and location of the incident, **other organisations** may also need to be involved following an adverse incident. This includes the separate arrangements for reporting medical device related adverse incidents in Scotland and Northern Ireland, as well as the arrangements for reporting non-hazardous incidents in Wales to the Surgical Materials Testing Laboratory.

Other organisations that may need to be contacted include the Health and Safety Executive, DH Estates and Facilities, or the defective medicines, medicines adverse reactions and blood safety sectors of the MHRA.

The MHRA also publishes adverse incident reporting guidance for medical device manufacturers. This too is available on the MHRA website.

2.2 Devices retained or submitted for examination

All items that have been involved in incidents should be quarantined together, where possible, with their packaging. Until the MHRA has been given the opportunity to carry out an investigation, the devices should **not** be discarded, repaired or returned to the manufacturer. More detailed information and advice is given in DB 2011(01).

Medical devices that have been involved in an incident should not be sent to the MHRA or the manufacturer unless we specifically request it.

Our document 'Managing medical devices' (DB 2006(05) available only on the MHRA website) contains advice on procedures to be followed if healthcare equipment is contaminated and constitutes a biohazard.

Devices requiring decontamination by the MHRA: 2006 – 2010

Year	Number of devices received	Number requiring decontamination	% requiring decontamination
2006	136	27	19.9
2007	37	9	24.0
2008	128	8	6.0
2009	119	26	21.8
2010	239	30	12.6

2.3 Defining 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 of incidents involving devices may include:

- design or manufacture problems
- inadequate servicing and maintenance
- unsuitable storage and use conditions
- poor user instructions or training (which may result in incorrect user practice).
- not following the manufacturer's instructions for use
- off label use of a device i.e. using the device for a purpose not intended by the manufacturer
- inappropriate local modifications
- selection of the incorrect device for the purpose
- inappropriate management procedures

Conditions of use may also give rise to adverse incidents:

- environmental conditions (e.g. electromagnetic interference)
- location (e.g. devices designed for hospital use may not be suitable for use in a community or ambulance setting).

The occurrence of an adverse incident may identify the **potential** for harm, even though **actual** harm has been averted by the timely intervention of healthcare providers or by good fortune. The MHRA is concerned that users should **report all incidents**, regardless of whether or not actual harm has been caused.

There is also a distinction between **direct** and **indirect harm**. Indirect harm may be caused by a device which does not normally come into contact with patients. For example, a malfunctioning in vitro diagnostic device such as an automated analyser may lead to delayed or inappropriate treatment of a patient, thus causing indirect harm. **These incidents should also be reported.**

2.4 Reasons for reporting adverse incidents

The MHRA is concerned with preventing the occurrence of adverse incidents, **not with assigning blame or liability**. Our aim is to investigate incidents carefully, objectively and in an open manner and through this to prevent similar incidents occurring elsewhere.

No medical device should ever be considered 100% safe. Constant effort is therefore required to reduce both the rate at which adverse incidents occur and the severity of the outcome. Reporting **all** adverse incidents to the MHRA provides valuable information that may be directly responsible for preventing similar incidents from happening again.

The information provided by device users and manufacturers helps us to build up a picture of what is happening with medical devices across the UK. This is supplemented by reports from overseas. All this information is regularly reviewed to identify trends and, where appropriate, early action is taken on specific problems.

Experience suggests that although user error may sometimes be the cause of an adverse incident, or may *contribute* to the cause, there are often other underlying reasons. These may relate to device management and maintenance, or to the adequacy of training for users.

We therefore welcome receipt of all incident reports, even where user error may already have been identified as the likely cause. A one-off incident in one health care or social care establishment, when combined with information on several others, may identify the need for focussed awareness training or for the amendment of a manufacturer's instructions for use.

The MHRA may choose to act in different ways in order to prevent occurrence or recurrence of incidents. This may be through:

- initiating enforcement measures
- monitoring action taken by manufacturers to make devices safe or to remove them from the market
- issuing national warnings and recommendations for action to health and social care professionals
- informing relevant authorities in other EU member states and, where appropriate, the Global Harmonisation Task Force members, so that they can each consider their own need for action.

2.5 Recording incident report details

The Adverse Incident Centre (AIC) teams include data input staff dedicated to ensuring the complete, accurate and timely transfer of all adverse incident report data onto AITS, our Adverse Incident Tracking System.

Routinely, around 80% of all adverse incidents reported to MHRA are recorded on our database and available for our medical device specialists to review on the same day they are received. Within a further 24 hours that percentage rises to almost 95%.

2.6 Investigation levels – reports received prior to April 2011

For reports received prior to April 2011, **'In depth'** investigations were usually initiated as a result of reports of incidents that have lead to **death or serious injury/deterioration in health (or the potential for such)**.

In depth investigations (2,227 in 2010) may have involved:

- contacting the device user and manufacturer
- visiting the site of the incident
- testing the device involved (either by our own test facilities, by an independent test house or by the manufacturer).

'Standard' investigations were usually initiated as a result of incidents where there is a **minor injury or no injury** (and where there was a low potential for more serious injury).

Generally, these incidents have been investigated most effectively by the manufacturer of the device. An MHRA medical device specialist will monitor progress and critically review the manufacturer's investigation and report. In 2010 our medical device specialists supervised the investigation of 4,256 incidents in this way.

In 2010 there were 2,064 incident reports where no immediate action beyond the creation of the database record, acknowledgement of receipt, and an initial risk assessment were considered necessary. These were cases where the situation had already been resolved, either locally or by the manufacturer. These were categorised as **'information only'** incidents. Other incident reports were recorded as **'knowns'**. These were reports that related to existing investigations of the same problem with a particular type of device. Of the reports received in 2010, there were 796 linked in this way to ongoing investigations.

The category of **'echo'** reports (676 in 2010) includes duplicate reports of a specific incident of which we have already been informed. Echo reports may arise when any combination of the device user, the manufacturer or the patient report the incident independently.

In addition to those listed above, there were 103 other incident records relating to investigations conducted by organisations other than the MHRA e.g. the devolved administrations.

A small number of the total reports received (110 in 2010) did not involve medical devices. These were recorded as 'non-MHRA (Devices)' and were referred to other bodies such as DH Estates & Facilities, Trading Standards, Food Standards Agency or the Health & Safety Executive. This also includes reports referred to our MHRA colleagues handling adverse drug reactions and defective medicines. The incident reporter is always informed of the referral.

Note: as it was possible for an incident to be classified, for example, as both a 'known' and an 'echo', the combined numbers above will be more than the stated total number of incident reports received.

2.7 Maintaining contact with the reporter

All reporters are sent a formal acknowledgement as soon as possible after we receive their report. This includes a unique MHRA incident reference number and a short note

summarising and explaining our adverse incident investigation processes. Where possible, these acknowledgements and all subsequent correspondence are sent to the reporter by email. In addition, every *online* reporter receives an immediate, automatic 'on-screen' acknowledgement that includes the unique MHRA reference number assigned to the report in our AITS database.

After this initial acknowledgement, reporters are advised of the action we propose to take, and are then routinely kept informed of progress throughout the investigation. At the end of an investigation, the reporter is provided with a copy or a summary of the incident investigation conclusions.

Feedback is important. Medical device liaison officers and risk managers who forward to the MHRA reports they have received via local reporting systems, are urged to pass on feedback received from us. This is a vital part of the process for ensuring that originators of adverse incident reports are kept informed of both the progress and the outcome of our investigations.

In addition, after conclusion of an investigation, 20% of reporters are sent a survey form requesting feedback (see Section 5). Wider contact is also welcome – reporters are always free to contact the Adverse Incident Centre with any general or specific enquiries and comments. Feedback on these aspects of our work is always welcome.

2.8 Investigation teams

The Devices Division comprises several teams. The Adverse Incident Centre (AIC) is the MHRA's focal point for the reporting of adverse incidents involving medical devices. We also have specialist technical units (see section 3), as well as a clinical team, which provides specialist expertise to support all our businesses and to increase awareness of our agency's role in the NHS and among professional bodies.

2.9 Medical Devices Alerts (MDAs)

Medical Device Alerts (MDAs) are the MHRA's prime means of communicating safety information to medical device users in health and social care. MDAs may also be used to provide updated information.

On 1 May 2011 we ceased making a distinction between the previously used categories of 'Immediate action' and 'Action' alerts because feedback from recipients suggested that these distinctions were poorly understood and added little to the CAS deadlines, which themselves take into account the urgency of the required actions.

More importantly, at the same time, we implemented a revised and streamlined Medical Device Alert production process and shortened maximum production timescales significantly. This ensures that we get important safety information to healthcare establishments as fast as possible. A key enabler for this was the implementation of our revised adverse incident handling strategy in April 2011 (See Section 1.10).

We now issue Medical Device Alerts against two targets.

- 10 working days: most Medical Device Alerts require consultation with our register of experts and with the manufacturer once the need has been identified.
- 6 working days: some Medical Device Alerts can make use of the manufacturer's own Field Safety Notice information and do not require consultation with the manufacturer. Typically these Medical Device Alerts are

used where acknowledgement or reconciliation records in connection with a particular manufacturer's Field Safety Notice may be inadequate, e.g. for high sales volume consumables with widespread distribution. In these circumstances the broadcast distribution of the Medical Device Alert can be extremely helpful in ensuring effective UK field action.

MDAs are reviewed on a regular basis and updated or deleted. Our website provides lists of MDAs that are still in force. If a notice is not listed, it has been superseded or withdrawn.

3 Review of specialist technical unit activity in 2010

The specialist technical units investigate adverse incidents and also provide: technical assessments of applications to conduct clinical investigations on medical devices; investigation and trending of adverse incidents arising during such clinical investigations; and technical advice to support regulatory colleagues during compliance investigations and notified body assessments.

Until April 2011 there were three units: Assistive Technology; Biosciences and Implants; and Imaging and Acute Care.

3.1 Assistive Technology (AT)

This unit covers the wide range of assistive technology devices used in hospitals and in the community. Users of these devices include a vast spectrum from healthcare professionals in hospitals and community services to individuals with physical or mental impairment either living independently in their own homes or with family or carers. Examples of AT devices include: mobility aids, artificial limbs, orthoses, moving and handling systems, posture supports, pressure management mattresses and cushions, communication and hearing aids, beds, environmental controls, telecare, therapy equipment and other devices intended to alleviate or compensate for a disability or used during rehabilitation.

Staff expertise includes: rehabilitation and mechanical engineering; materials science; bio medical engineering; medical engineering and other areas such as pressure care; posture and mobility; moving and handling; prosthetics and transport for the disabled. In addition, staff have experience of working in health services and in industry and as carers. Staff are also members of various professional bodies and national groups that cover these areas.

We received a total of 1,495 adverse incident reports during 2010. This included reports of 30 fatalities where AT devices were being used. 383 reported incidents were investigated in depth by medical device specialists due to the seriousness of the risks involved. Where appropriate, investigations included the provision of reports to coroners and liaison with our Agency's compliance unit, other Competent Authorities in Europe, the police, HSE, Trading Standards and the Department for Transport. The unit published 19 Medical Device Alerts during the year. Some of the significant safety issues covered during the year are set out below.

Beds and mattresses and bed accessories

Adverse incident reports concerning beds and mattresses increased slightly in 2010 to 182 reports. Investigation of these led to four Medical Device Alerts being issued. MDA/2010/002 stressed the need for frequent inspection of mattress covers and

interiors to ensure that any cover damage or contamination of the mattress interior is found quickly to reduce the potential for cross infection. MDA/2010/045 covered the recall of monkey pole handles. MDA/2010/080 raised the need to obtain and follow revised instructions for use for bedrails and MDA/2010/083 involved the failure of CPR function on some beds.

Wheelchairs and children's buggies

Adverse incident reports concerning all types of powered and non powered wheelchairs used by children and adults remained at the same level this year at 701 reports. Investigations led to many changes in designs and instructions for use and four Medical Device Alerts were issued. MDA/2010/004 and MDA/2010/086 raised the need for users to obtain and follow revised instructions for use. MDA/2010/010 involved the need for anti-entrapment covers to be fitted to a powered stair climber. MD/2010/057 covered the recall and replacement of the frame of a pushchair intended for disabled children.

Hoists and slings

Adverse incident reports involving hoists and slings increased slightly to 136. Investigations led to nine Medical Device Alerts being issued. MDA/2010/013, MDA /2010/018, MDA/2010/019 and MDA/2010/029 covered the need for inspection before use, the need for increased maintenance and to obtain revised instructions for use. MDA/2010/022 involved the recall of inappropriate power cables. MDA/2010/049 involved the replacement of the spreader bar. MDA/2010/051 involved the fitting of a safety belt to stop the occupant falling from a bath hoist. MDA/2010/079 recalled bath hoist chargers fitted with dangerous plugs. MDA/2010/085 recalled a hoist due to main frame joint failure.

Therapy, shower and bath aids

Adverse incidents involving shower aids, commodes, toilet aids, bath aids etc reduced slightly in 2010 at 233 reports. Investigation of these led to two Medical Device Alerts being issued. MDA/2010/042 involved the need to upgrade armrests on a therapy chair. MDA/2010/075 involved the need for improved maintenance and labelling on a shower chair.

Liaison with reporters, users, industry and others

Regular contact has been maintained with all main stakeholders. In particular, interaction has been maintained with NHS groups, professional groups and BHTA as the main trade association for assistive technology. The good relationship with the Health and Safety Executive (HSE) has continued and further improved joint working for the future is being discussed. Staff have regularly attended NHS groups covering rehabilitation engineering services, prosthetics, wheelchairs and seating and equipment stores to discuss safety related issues, give advice and raise the need for members to report adverse incidents to the MHRA. We have provided input to the BHTA accreditation training courses for their member companies and have provided input to other NHS training initiatives where appropriate. Liaison with coroners, police, the HSE, Trading Standards and the Department for Transport has also regularly occurred as a part of individual investigations or during the provision of advice. Shortcomings in the published standards for hoist and riser/recliner chairs have been brought to the attention of BHTA as the main trade association and where appropriate the British Standards Institute.

3.2 Biosciences and Implants (B&I)

This unit covers a wide range of devices including all active and non-active implants, in vitro diagnostic medical devices, wound care, medical textiles, barrier contraceptives, insulin injection devices and equipment used for in vitro fertilisation. We also provide advice on decontamination and sterilization, biological safety and the use of animal tissues in medical devices. The broad spectrum of devices covered by the unit means that our responsibilities extend across the scope of all three medical devices directives ie general, active implantable and in vitro medical devices.

The specialists in the unit have a range of technical expertise encompassing materials and biomaterials science, biomedical and clinical science, microbiology, clinical biochemistry, molecular biology, sterilization, textile technologies, biotechnology, medical physics and mechanical engineering.

Much of B&I's work involves providing authoritative advice to stakeholders – members of the public, frontline healthcare providers, policy makers and the medical device industry. We participate in the work of a number of safety committees and expert advisory groups. The information and lessons that we learn from adverse incident investigations helps us to maintain and increase our specialist knowledge; it also helps to inform our opinions and gives a good indication of the effectiveness and impact of our advice.

In 2010, B&I received 4,361 reports of adverse incidents.

In-vitro diagnostic medical devices (IVDs)

Following changes made by the manufacturer to the read time for a number of pregnancy test kits, a Medical Device Alert (MDA) was issued to the health service to support the manufacturer's Field Safety Notice (FSN) and ensure that all users were aware of the change to the instructions for use.

An update to an MDA was issued in relation to testing neonatal samples using a particular type of strip in a blood glucose meter to support the manufacturer's actions. The manufacturer issued a new FSN, which advised that this device should not be used for testing neonatal samples and updated their instructions for use to reflect this change.

A problem was identified by a manufacturer of an analyser that performs diagnostic testing for hepatitis C in blood donations and patient samples whereby a reduction in assay reactivity could occur when the assay diluent is left on board the machine for longer than 24 hours and less than 25% of the volume remained. This could result in false negative results and a delay in the diagnosis and treatment of hepatitis C as well as the potential for disease transmission to patient contacts. A MDA was issued to warn users about this problem and to inform them of the mechanism for ensuring that results were not affected. The MDA also highlighted that users should operate a testing algorithm that conforms to national guidelines and reinforced the need for a look back study if this is not the case.

The IVD team worked alongside the MHRA Devices Compliance Unit and the Health Protection Agency to issue letters to approximately 700 individuals who had purchased self test kits over the internet. Investigations suggested that these tests were poorly sensitive.

As part of ongoing work in relation to the revision of the IVD Directive we worked with MHRA European Regulatory Affairs group and the UK Steering Group established to look at the proposed changes to the directive to canvass UK opinion and respond to the European Commission.

Non-active cardiovascular implants

We published a MDA on a type of brain stent (intracranial aneurysm artery reconstruction device) highlighting to users that the device should not be used without embolisation coils. The MHRA had been notified of a number of patient deaths around the world (including in the UK) associated with the use of this device in patients with large or giant aneurysms who had been treated without the use of embolisation coils. At the time of publication of this MDA, no clinical data were available to support the use of the stent in patients without using embolisation coils. The stent manufacturer also issued advice and amended their instructions for use (IFU) to reflect this. The MDA also contained specific guidance to clinicians regarding follow-up of those patients implanted with this device without embolisation coils.

To improve patient safety and the clinical use of devices, we were involved in a number of important changes to manufacturer IFUs. In particular, we encouraged one European manufacturer of inferior vena cava filters to amend their IFU to include information on the longer term retrievability of these devices. This information enables implanting clinicians to determine the safest future point at which to explant these devices. In another example, a manufacturer of Transcatheter Heart Valve devices had issued a Field Safety Notice alerting users to an updated instruction on an aspect of device preparation prior to implant. We worked with the manufacturer to ensure the IFU reflected the information provided in their FSN.

Pacemakers, implantable cardioverter defibrillators (ICDs) and neurostimulators

After the introduction of security body scanners into airports across the UK, guidance was placed on the MHRA website for patients implanted with pacemakers, ICDs and neurostimulators who were required to pass through this screening.

Following a manufacturer advisory and a MDA in 2009 concerning two models of pacemakers, the MHRA continued to monitor reports related to the advisory using the periodic summary reporting method to continually review failure rates. Pacemakers of the same model which were not part of the advisory were also closely monitored to ensure that their failure rates remained within acceptable limits.

In October 2010 the number of incidents reported to the MHRA regarding in service insulation damage to a certain ICD lead rose above an acceptable level. Insulation damage can cause lead failure or delivery of inappropriate therapy. After consultation with the MHRA and members of the Heart Rhythm UK rapid response panel, the manufacturer issued a worldwide Field Safety Notice recommending enhanced patient follow-up for all patients implanted with these leads. The MHRA issued a MDA which was circulated simultaneously.

Orthopaedic implants

In 2010 we updated the advice from the MHRA Expert Advisory Group (EAG) on the biological effects of metal wear debris generated from hip implants (genotoxicity).

We issued three MDAs providing advice on the use of orthopaedic devices and/or giving additional guidance on patient follow-up. All three MDAs were related to metal-on-metal hip replacements and were linked to the work of another MHRA EAG, which looked at the occurrence of adverse soft tissue reactions associated with these devices. This group involved representatives from the England and Wales National

Joint Registry (NJR), the British Orthopaedic Association and the British Hip Society. The report noted that problems with metal-on-metal hip replacements are rare and their root cause remains largely unknown. The advice in the alerts and the report recommends that all patients implanted with metal-on-metal hip replacements should be followed up.

We continue to work closely with the NJR steering committee and its implant outlier subcommittee, which continues to refine its systems to identify implant 'outliers' from its database. One of the MDAs mentioned above was issued in the light of outlier information provided to us by the NJR.

We are working with manufacturers to improve reporting and analysis of problems associated with orthopaedic implants. In the last year we have further expanded the use of the periodic summary reporting for specific failures in some types of orthopaedic devices to better manage and carry out trend analysis on identified problems.

Ophthalmics

A manufacturer of contact lenses had made changes to the vial stopper of one of their contact lens packs. In a subsequent product stability study several out of specification observations were made, which included problems with product sterility and high pH of the packaging solution. This could cause eye infections and/or mild irritation when the lens was inserted. We published a MDA to ensure that all users were aware that they should not use this product.

A contact lens solution manufacturer identified that certain lots of solution had leaking bottle caps. The leaks could compromise the sterility of the solution within the bottle and use of the solution may have caused eye infections. We issued a MDA to reinforce the manufacturer's recall and to ensure that retailers were aware of their responsibility in informing their customers of this potential problem.

Another contact lens solution manufacturer had received a number of reports from Japan of patients who had experienced stinging, pain, ocular redness, tearing and blurred vision upon insertion of certain lots of contact lens. The root cause was identified as a failure to meet the required standard in one portion of the rinsing process during the manufacture of these lenses with the potential for the lenses to retain a chemical contaminant from the manufacturing process. We issued a MDA to ensure that all customers were aware of the manufacturer recall and the requirement for them to inform patients of this problem.

Breast implants

In March 2010 the French medical device regulatory authority (AFSSAPS) informed the MHRA that it had suspended the marketing, distribution, export and the use of silicone gel filled breast implants manufactured by Poly Implant Prothese (PIP) and that it had recalled all of these devices in France. An inspection of the manufacturer by AFSSAPS established that most breast implants manufactured by the company since 2001 had been filled with a silicone gel with a composition different from that originally approved. The MHRA immediately advised UK clinicians not to implant these devices via a Medical Device Alert.

AFSSAPS carried out tests on these silicone gel implants that included potential for genotoxicity (potential for cancer) and chemical toxicity of the filler material. The MHRA also carried out independent tests on the implant filler material. The MHRA results did not find evidence of a safety issue associated with the filler material. One of the genotoxicity tests carried out by AFSSAPS was inconclusive and further testing is

currently being conducted. AFSSAPS had also carried out mechanical testing of the implant shell which suggested that there may be an increased rate of rupture.

Following extensive consultation with UK experts the MHRA issued a further MDA informing clinicians of the outcome of the tests and advising them that there was no current evidence of any abnormal health risks associated with the silicone implant filler material in PIP implants and that there was no indication for any routine action, in the form of explantation or ultrasound investigations. This advice was endorsed by the professional clinical bodies BAPRAS (British Association of Plastic, Reconstructive and Aesthetic Surgeons) and ABS (Association of Breast Surgery). A dedicated web page was also set up by the MHRA providing updates on the test results and a question and answer sheet for women who were worried about their implants.

Gastric bands

A manufacturer of gastric band devices wished to convey important product related information to their clinical users and they contacted the MHRA seeking advice on the format and content of a Field Safety Notice. Post implant surveillance had identified a higher than anticipated number of device failures. A problem with the sealed motor mechanism in some units prevented the device responding to commands from the device's control unit, resulting in a possible need to explant the device and to re-implant another gastric band device. The manufacturer's FSN was agreed and a copy was placed on the MHRA website.

3.3 Imaging and Acute Care (I&AC)

The unit covers equipment used primarily in acute care settings. We cover a very diverse range of medical devices including: anaesthetic and breathing systems; infusion pumps; dialysis equipment; diagnostic imaging and radiotherapy units; diathermy equipment; surgical instruments; ambulance trolleys and non-implantable vascular devices, including needles and lancets.

The specialists in the unit have wide expertise in: physical and biological sciences; radiation physics and mechanical and electrical engineering. Some members of staff also have experience of working in the health service sector and medical device industries.

In 2010 I&AC received a total of 4,242 reports of adverse incidents. Again over 1,200 of these were assigned to our highest category ('in depth'). A total of 56 Medical Device Alerts were issued across the full range of I&AC products. Highlights of the work undertaken in some of our product areas are given below.

Anaesthetic and respiratory systems

In 2010 we issued 14 Medical Device Alerts in this category, including: tracheostomy tubes, anaesthetic machines, ventilators, breathing systems and airway management devices. Additionally, several One Liners were published on this category of devices, including Issue 77 (July 2010) concerning user error leading to leaks of heat exchanger units in heart-lung bypass machines and Issue 80 (November 2010) concerning the overheating of laryngoscopes due to incorrectly placed batteries.

We continue to maintain close links with professional bodies such as the Society of Critical Care Technologists and the Royal College of Anaesthetists. Working jointly with the Association of Anaesthetists of Great Britain and Ireland (AAGBI), we produced a 'Top tips for pulse oximetry' leaflet (December 2010).

We also continued to provide technical advice to the Department of Health in the procurement and provision of domiciliary oxygen therapy equipment. We have assisted in both coroner and police investigations in determining the functioning of ventilators and domiciliary oxygen supplies.

Vascular, infusion and transfusion devices

Infusion pumps and their associated equipment continue to be a very busy area with over 700 adverse incidents being received in 2010. Nine Medical Device Alerts were issued in this device area.

In November 2010 we revised and re-issued our guidance document 'Infusion Systems' (DB 2003(02) v2.0). This document is intended to raise awareness of the nature of infusion systems, their advantages and risks, together with information on management and training issues. It is hoped that this document will help reduce the number of adverse incidents that arise from their use. A poster on how and what to report was also published to complement the Device Bulletin.

There has again been input into police and coroner investigations regarding the actual functioning of individual infusion and enteral feeding pumps as well as advice and information to the Criminal Cases Review Board.

Following a number of adverse incidents involving interventional vascular procedures carried out under fluoroscopy control, the MHRA chaired a working party to look at best practice in this area. The following bodies were represented:

- Royal College of Radiologists
- The British Society of interventional Radiology
- Vascular Society of Great Britain and Ireland
- Vascular Anaesthesia Society of Great Britain and Ireland
- MHRA Committee on the Safety of Devices

The output from this group was the publication in December 2010 of a guidance document 'Joint working group to produce guidance on delivering an Endovascular Aneurysm Repair (EVAR) Service'.

We have also maintained links with a number of other professional bodies and expert committees including: support and guidance to the NPSA neuraxial working group

Dialysis devices

During 2010, we received 247 reports of incidents related to dialysis equipment. We have liaised with many external stakeholders across a diverse range of issues in this area which included:

- presentation on the work of the MHRA to renal technologists as part of the Association of Renal Technologists 'renal technology' course held at the University of Bradford
- liaising with coroners following a fatality involving the use of a wrong filter during haemofiltration. As a result the MHRA and the associated manufacturers worked to introduce additional labelling to mitigate further risk of incorrect use.

Six Medical Device Alerts have been published in this area including the following topics:

- The importance of consistency in the adoption of colour coding of dialysis fluid connectors.
- The stability of some haemofiltration machines due to the mechanical failure of the wheels and the need for checks to be included in regular maintenance.

- Changes to the manufacturing materials of some bloodline connectors which led to increased risk of blood loss and haemolysis. Information on safe use and the staged introduction of a modified device were implemented.

Radiology

2010 saw cross working with a number of external stakeholders including other government departments. We worked with the Health Protection Agency on their Dental CBCT Guidance and also with the AAGBI on their updated MRI Safety guidelines.

In June we issued a 'Magnetic resonance safety - top tips poster' to remind healthcare professionals of the safety issues in the MR environment

We continue to work with the HSE on the development of the Physical agents (electromagnetic fields) Directive. The Directive was postponed in 2008 and is now due to be implemented in 2012.

Electrosurgery

During 2010 the MHRA chaired a working party of interested bodies on endometrial ablation. This included a workshop attended by a number of manufacturers and clinical representatives from the Royal College of Obstetricians and Gynaecologist (RCOG) and the British Society for Gynaecological Endoscopy (BSGE). The workshop discussed the types of endometrial ablation devices and processes that can be used in different circumstances and the respective advantages and risks of each technique with an analysis of the adverse events. Initial and follow-up clinical training experiences were also discussed. The MHRA will be working with the manufacturers, the RCOG and BSGE to develop guidelines highlighting the importance of device and procedural safety and adequate training which it hopes to publish in early 2011.

Other stakeholder interaction

Across many devices we have worked closely with coroners and the police in determining how devices have functioned. And have assisted in many clinical investigations

The unit has also been proactive in engaging other Competent Authorities and manufacturers to consider adopting reporting by periodic summary reporting (PSR) for a number of medical devices. This is where, for a defined time period and type of device, a manufacturer submits groups of reports regularly, which enable us to look at trends, liaise with the manufacturer about corrective action and establish if the corrective actions have been effective. The MHRA has developed new internal procedures for this topic and placed a manufacturer's reporting form on the website to facilitate this new way of working. We currently use this form of reporting for devices such as dialysis bloodlines and alarms that interrupt therapy. We are continuing to develop it for other device areas.

We have also contributed to and advised many other stakeholders including:

- the Food Standards Agency – provided advice on the use of Bisphenol A in infant feeding bottles
- the NPSA – input to Rapid Response Reports on infusion pumps, gastrostomy devices and enteral feeding
- the US Food and Drug Administration (FDA) – given advice and information on CT dose issues.
- manufacturers – on post-market surveillance expectations of the MHRA.
Outcomes – change to IFUs, recalls of devices, reclassification of devices.

4 Statistics

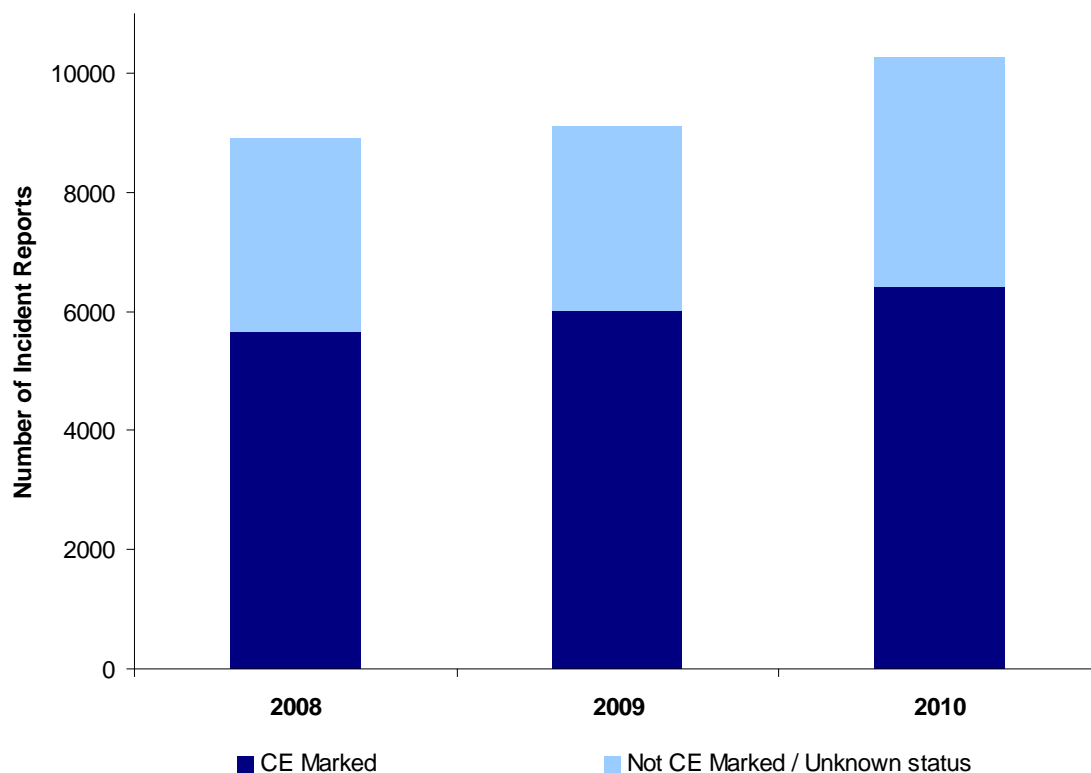
4.1 Trends in adverse incident reporting

We received 10,280 adverse incident reports in 2010. This was an increase of 13 % over the 2009 total. A further 752 reports were submitted as part of periodic summary reports.

The upward trend in reporting by medical device manufacturers has continued, with almost 1,000 more reports received in 2010. This can be attributed both to our ongoing, pro-active contact with manufacturers and to the continuing increase in the range and volume of medical devices available and in use.

Despite the overall upward trend in reporting, we remain concerned at the level of reporting from health and social care staff. The previously reported downward trend may have levelled off, but the number of reports received still remains below the peak reached ten years ago. In our continuing efforts to address this problem we have, once again, used our reporting guidance publication 'Reporting adverse incidents and disseminating medical device alerts' - DB 2011(01) - to emphasise the need for full reporting of medical device adverse incident reports to be an integral part of local systems for the safe management and use of medical devices. This is reinforced by reference to the Care Quality Commission's essential standards for the quality, safety, availability and suitability of medical devices.

Figure 1 Adverse incident reports 2008 – 2010



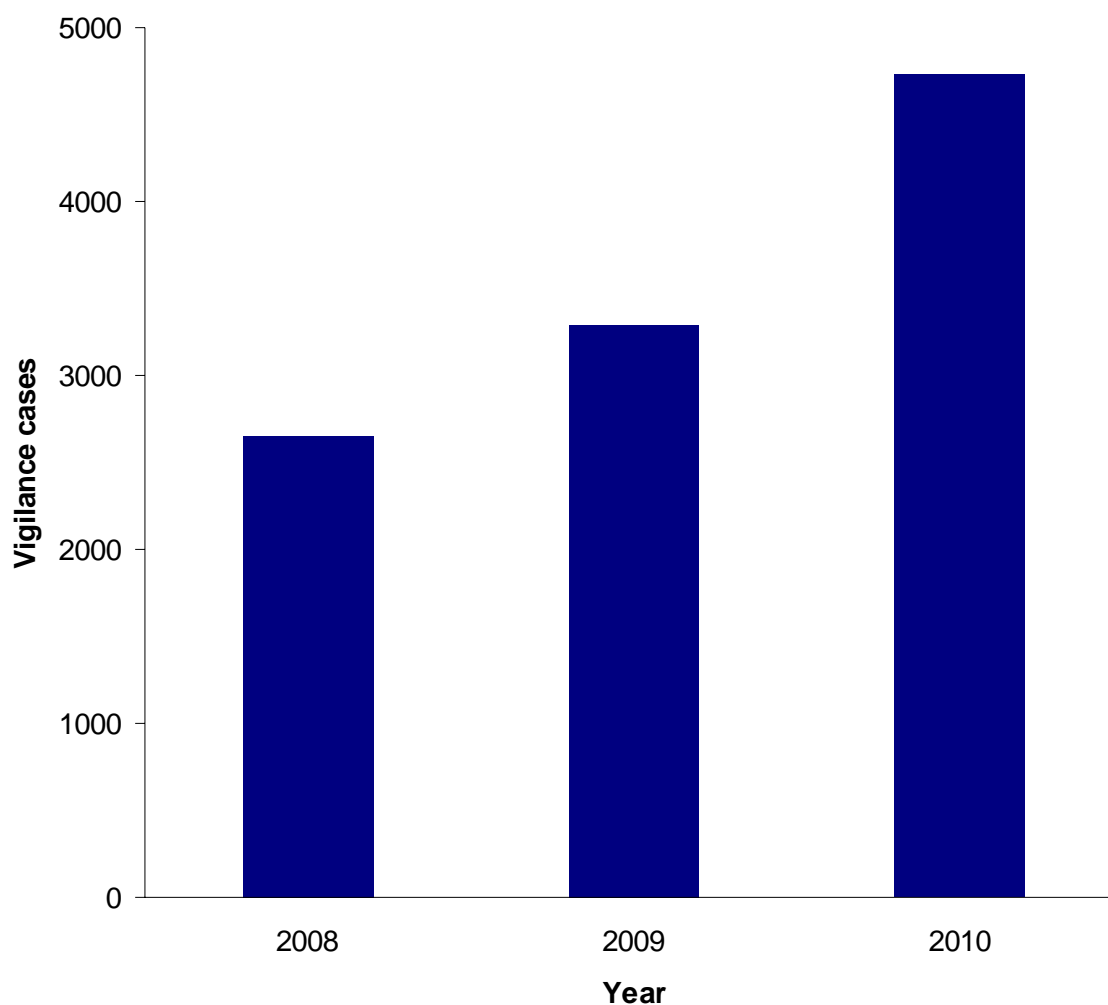
4.2 Vigilance cases

The Medical Devices Directives and UK Regulations place a clear and mandatory reporting requirement on medical device manufacturers. This is known as the 'vigilance system'. Reports submitted to the MHRA by device users may also be classified as vigilance cases if they meet the relevant criteria. These vigilance criteria are described in the MEDDEV – the EU guidance document for medical device manufacturers on the implementation of the vigilance system.

Copies of the MEDDEV and the associated MHRA guidance are available on the website.

In 2010 the number of individual incident reports recorded as 'vigilance' rose to 4,733 (3,293 in 2009). This continues the generally rising trend seen over recent years.

Figure 2 Number of vigilance cases received 2008 - 2010



4.3 Report sources

Report sources, i.e. the origins of the adverse incident reports we receive, are shown in Figure 3a below.

Whilst the *number* of reports received from medical devices users in 2010 barely changed from the previous year, the *percentage* dropped by nearly 5%. This is further highlighted in Figure 3b below. We are continuing to monitor the numbers of user reports closely and will be maintaining our efforts to ensure that all such reports are submitted directly to the MHRA.

Figure 3a Incident report sources 2008 - 2010

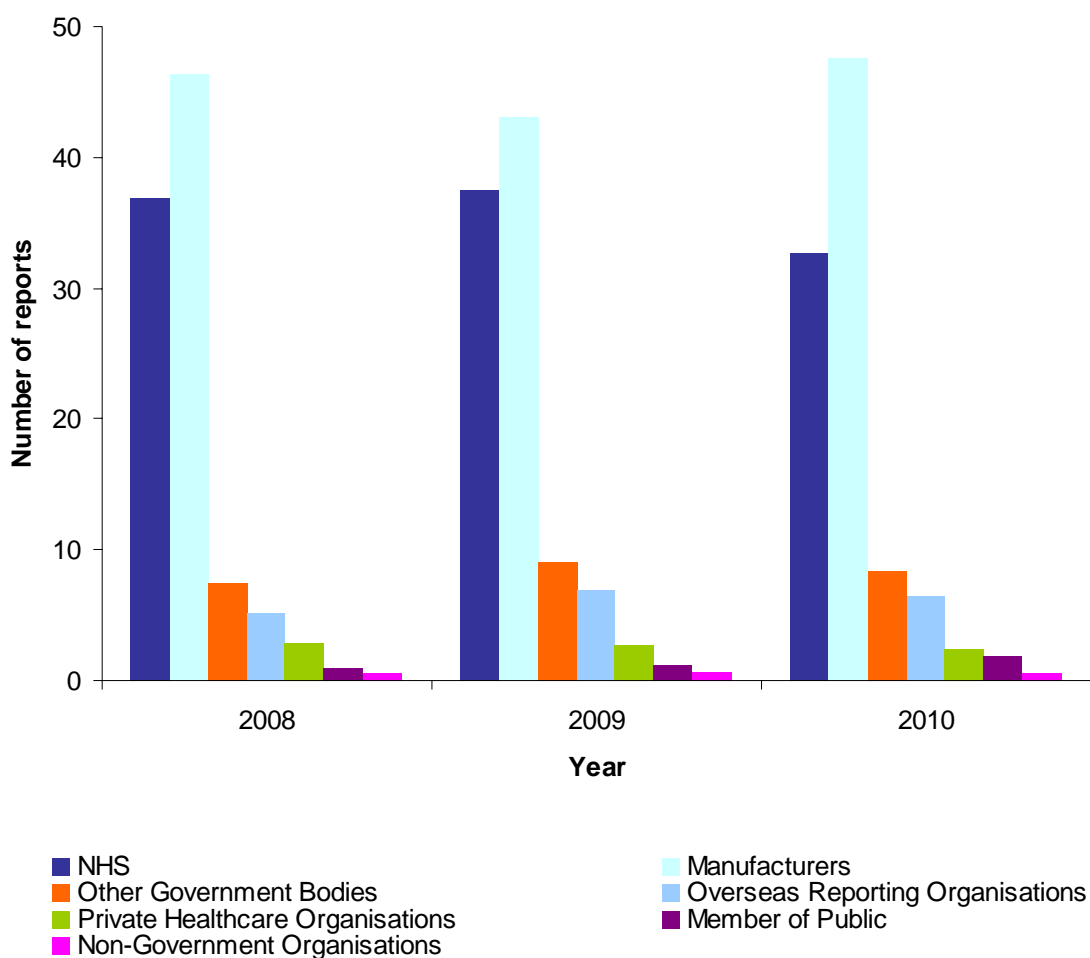
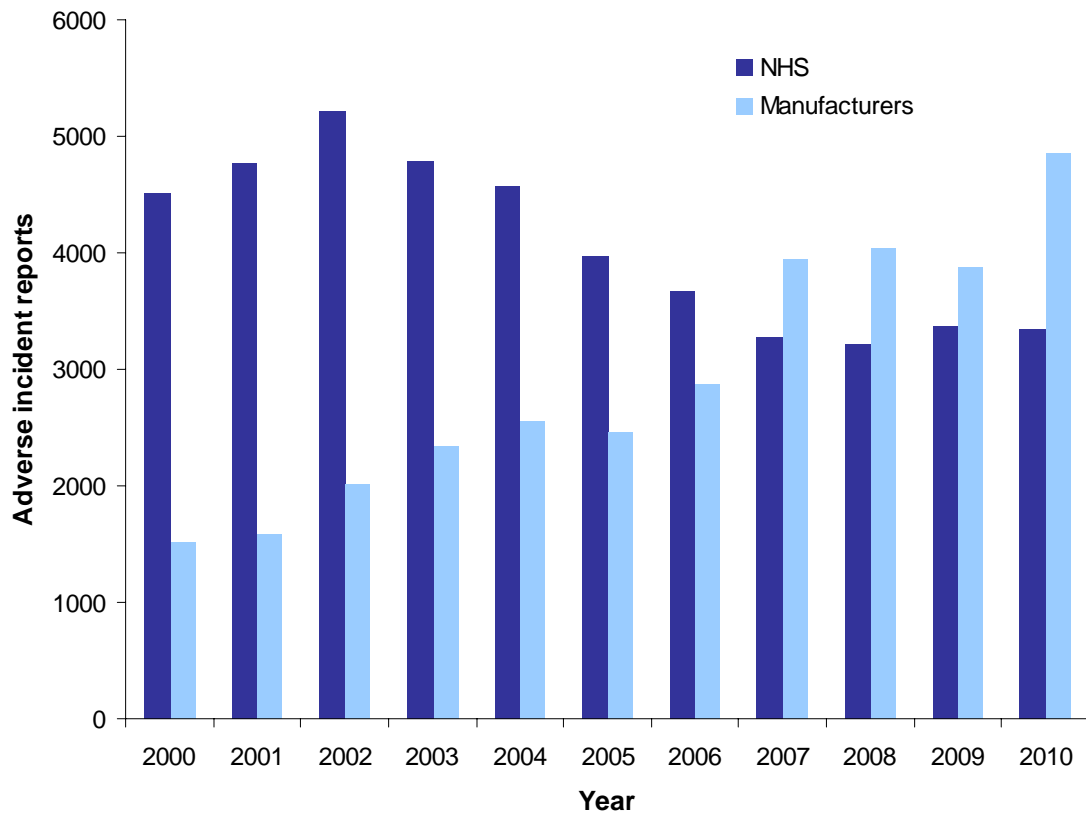


Figure 3b Incident report sources 2000 – 2010: NHS and manufacturers



4.4 Online reporting

Online reporting remains the MHRA's preferred reporting route. Manual data input of incident reports onto our tracking database is both time consuming and inevitably prone to human error, whereas the content of online reports can be transferred into our database quickly, efficiently and accurately.

We now have three separate online systems for reporting medical device adverse incidents. These are for:

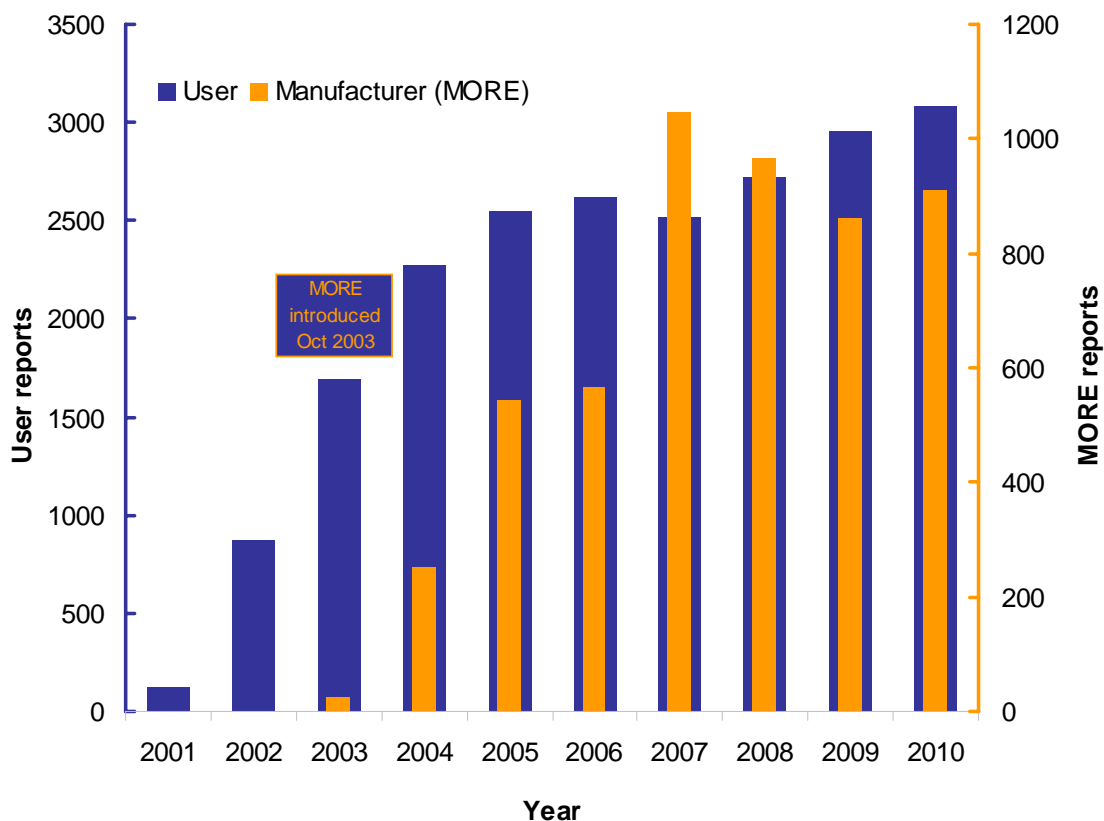
- clinicians, healthcare and social care workers
- patients and other member of the public
- medical device manufacturers.

All of these online reporting systems have now been audited and confirmed as compliant with government standards for website accessibility.

In 2010 over 3,000 user reports were submitted via this route, which is 86% of reports from device users.

MORE (the Manufacturers' Online Reporting Environment) is the system for medical device manufacturers to report online. There are now over 1,000 registered MORE reporters although not all are regular reporters. Nevertheless, 19% of reports from manufacturers now reach us via MORE. The MORE system was further enhanced in 2010 to include an 'XML Manager'. This allows manufacturers to move data directly from their own system into a Vigilance report form that can be submitted electronically to the MHRA.

Figure 4 Online reports received 2001 – 2010

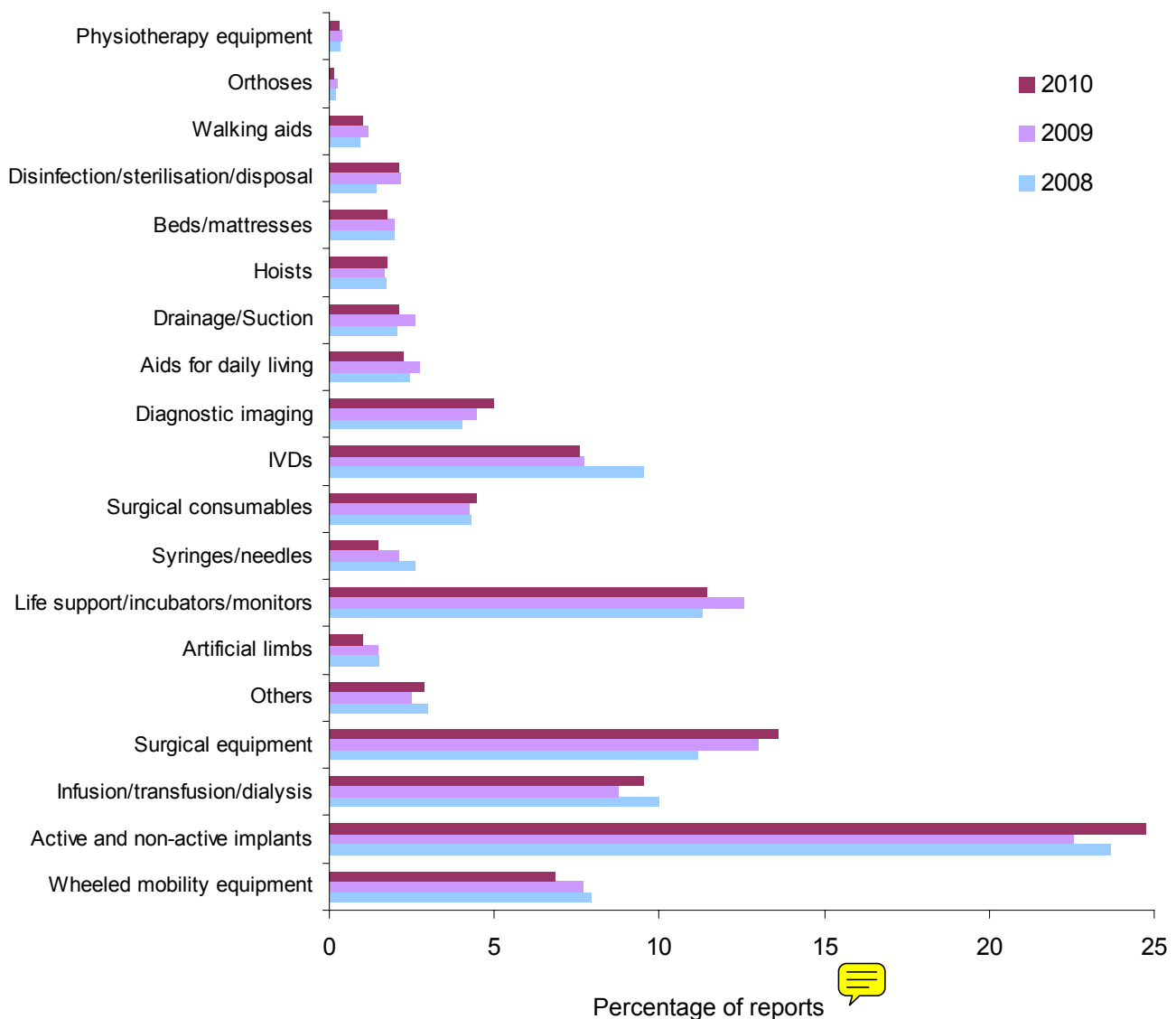


4.5 Incident reports by device group

For the purpose of providing a simple illustration of trends in reporting of incidents relating to specific device types, related devices have been grouped together. This figure illustrates these trends over the last three years.

These figures do not take account of reports submitted within periodic summary reports (PSRs).

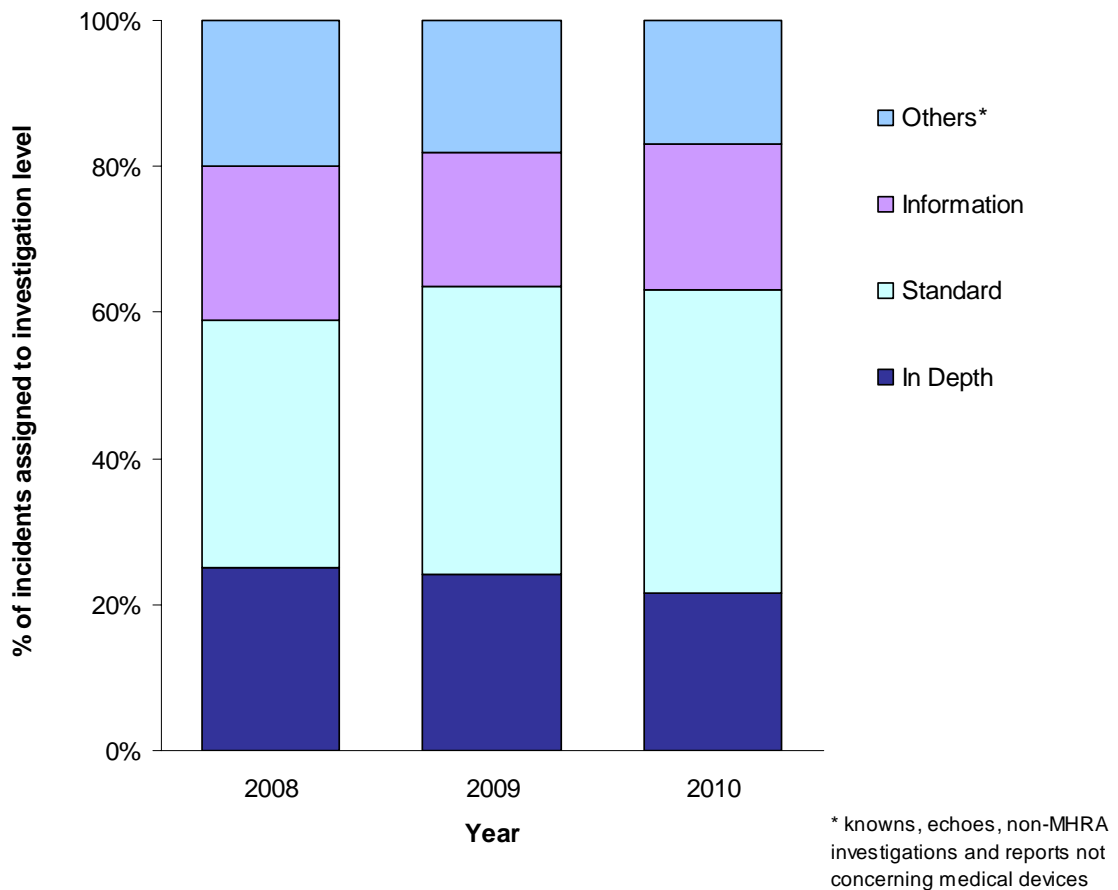
Figure 5 Incident reports by device group 2008 - 2010



4.6 Investigation levels

The pre-April 2011 system for handling adverse incident reports included a structured adverse incident risk assessment process which determined the level of investigation pursued for each adverse incident report received. This system, and the associated investigation types described below, has now been replaced (see Section 1.10).

Figure 6 Investigation level assigned as percentage 2008 - 2010



4.7 Causes of adverse incidents

The data for Figure 7 have been drawn from concluded adverse incident investigations. The chart illustrates the causes of incidents as identified through investigations conducted by device manufacturers and/or MHRA device specialists.

The MHRA's Adverse Incident Tracking System (AITS) incorporates three levels of categorised, contributory causal factors that are used in the record of each incident investigation. The first level provides the three options shown below.

- **Healthcare establishment/user responsibility**

After delivery e.g. performance and/or maintenance failures and degradation.

- **Manufacturer responsibility**

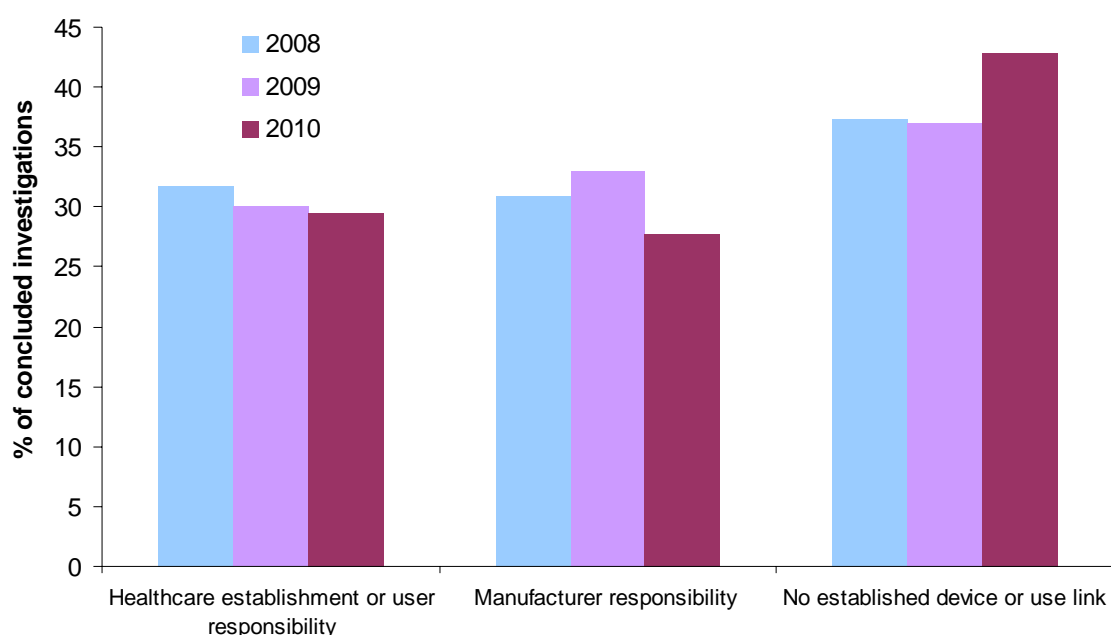
Before delivery e.g. design, manufacture, quality control and packaging.

- **No established device/use link**

Where either the device was subsequently found to work as intended (possibly due to an intermittent fault, tampering or user error, or where the report was made on a precautionary basis) or where the device involved was not available for investigation.

Inferences drawn from the pattern of change seen in Figure 7 can only be tentative. They may simply reflect the continued pattern of change in numbers of reports received from medical device users and from manufacturers. A further influencing factor is the availability of the device for examination and testing as, despite clear MHRA advice to the contrary, the device is often discarded by the user before any investigation can take place.

Figure 7 Causes of adverse incidents 2008 – 2010: percentage of concluded incident investigations

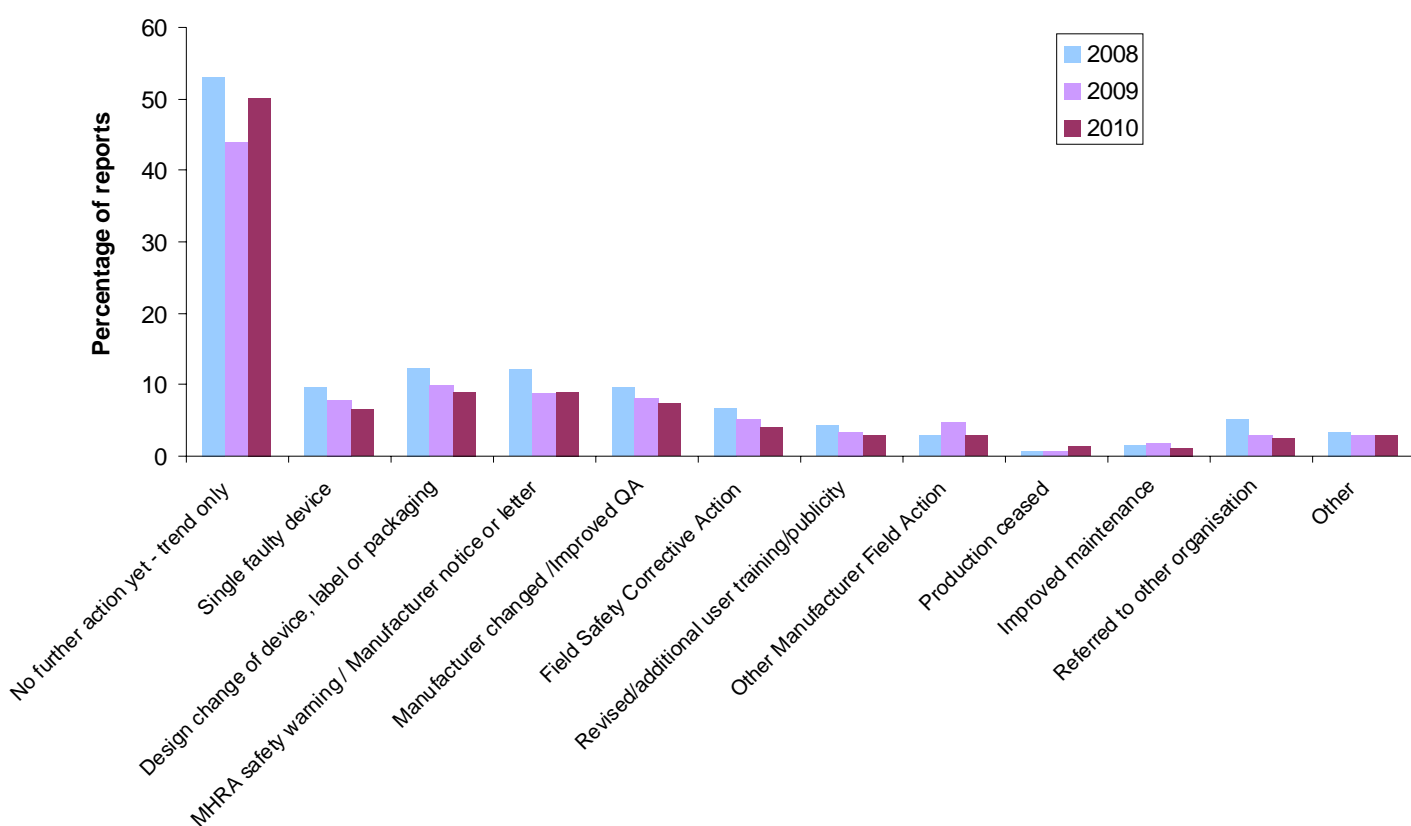


4.8 Investigation outcomes

At the conclusion of an adverse incident investigation, an MHRA device specialist will use our standard category list to record the outcomes of the investigation. This provides a simplified overview of outcomes and helps in spotting emerging trends at an early stage. These categories are not mutually exclusive; more than one may be selected for each concluded investigation. For that reason the annual totals will exceed 100%.

The category 'other' is used to cover a number of low incidence circumstances. This includes, for example, where the device was scrapped or where other regulatory action was taken.

Figure 8 Investigation outcomes 2008 – 2010



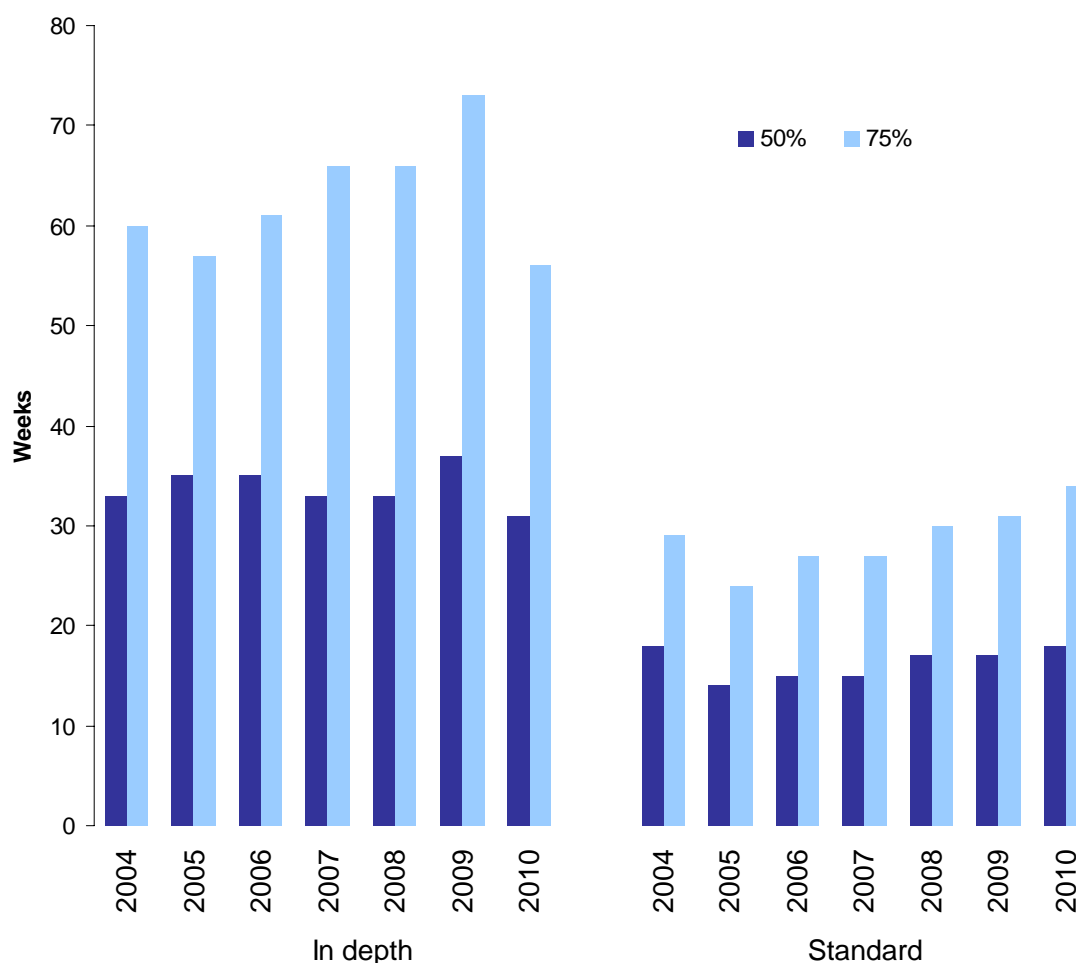
NOTE: Figure 8 includes corrected data for 2009

4.9 Investigation durations

Figure 9 provides an indication of the time taken for the conclusion of both 'in depth' and 'standard' investigations. Whilst for standard investigations the time taken has hardly changed, there is a large rise for in depth investigations.

In 2010 50% of 'standard' and 'in depth' investigations were concluded in 18 weeks and 31 weeks respectively. 75% of 'standard' and 'in depth' investigations were concluded within 34 weeks and 56 weeks respectively.

Figure 9 Time taken for conclusion of incident investigations 2004 – 2010



Note: Some MHRA adverse incident investigations continue for extended periods. This may simply reflect the complex nature of the research and analysis required to fully inform the MHRA investigation, or it may result from difficulty in communicating with the manufacturer and in obtaining substantive responses to our enquiries. Other investigations may remain open for lengthy periods pending the conclusion of legal proceedings.

4.10 Medical Device Alerts and CA notifications issued

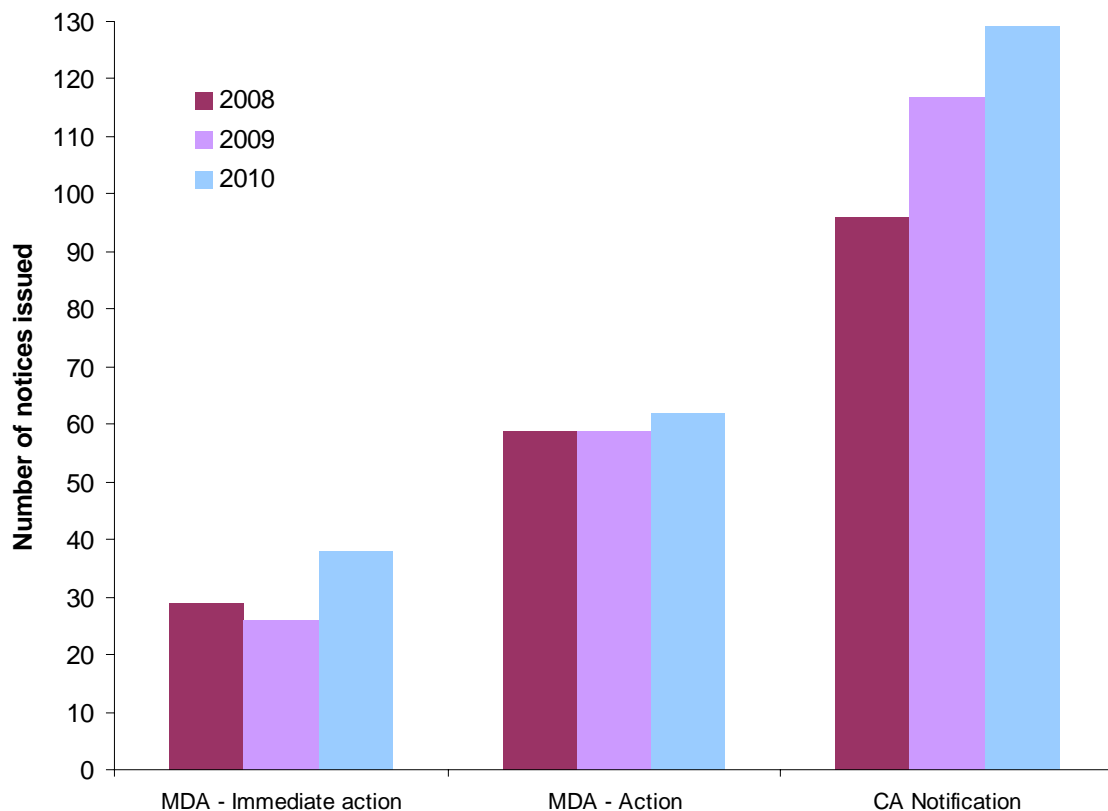
Medical Device Alerts (MDAs) are the MHRA's prime means of communicating safety information to medical device users in health and social care. Until May 2011 an MDA was given one of the following categories:

- Immediate action
- Immediate action update
- Action
- Action update

The number of MDAs issued between 2008 and 2010 is shown below in Figure 10. Of the total 100 MDAs issued in 2010, 32 were designated as 'Immediate action' and 68 as 'Action'. These figures include the update categories.

Competent authority (CA) notifications are issued by the MHRA to other European Union member states under the Medical Devices Regulations. In many cases they are also circulated to member countries of the Global Harmonisation Task Force.

Figure 10 Medical Device Alerts (MDA) and CA notifications issued 2008 – 2010



5 Customer survey

5.1 Conduct of survey and MHRA action

As part of a continuous assessment process the MHRA routinely seeks feedback on our incident reporting and investigation process. This is achieved through customer survey questionnaires that are sent to 20% of reporters (not medical device manufacturers) of 'standard' and 'in depth' investigations that have been concluded during the sample period. Where possible we try to avoid sending multiple surveys to the same reporter – especially if they were all to be sent within a short space of time.

The questionnaire itself does not place any significant time burden on those to whom it is addressed and is now done via email rather than post. A copy of the questionnaire is shown in section 5.3.

After being recorded on our database, all survey responses are reviewed by managers or device specialists within the relevant specialist technical units. Areas of concern are identified and, where appropriate, improvement action is identified and taken.

5.2 Response and satisfaction levels

In 2010 we received 311 completed survey forms. This marked improvement on the 125 received in 2009 is associated with the introduction of the electronic version of the survey form. A further change was seen in the number of responses received relating to 'in depth' investigations: in 2010 this was twice that received for 'standard' investigations. In 2009 the number was one third that for standard investigations.

Analysis of the responses received shows that although satisfaction levels have remained at consistently high levels for many years, 2010 saw reductions in each of the key areas that we routinely highlight. Those three key areas are shown in Figures 11, 12 and 13 below.

Conduct of investigation

The satisfaction level for the conduct of the investigation dropped from 94% to 84% for 'in depth' investigations and from 89% to 82% for 'standard' investigations

Level of communication

The satisfaction level for the level of communication dropped from 94% to 85% for 'in depth' investigations and from 93% to 78% for 'standard' investigations.

Speed of investigation

Surprisingly, the satisfaction level for the speed of investigation dropped from 82% to 80% for 'in depth' investigations and from 85% to 71% for 'standard' investigations. This reduction for In Depth investigations is remarkable as in 2010 the *actual* time taken (see Figure 9 in Section 4.9 above) for the conclusion of In Depth investigations reduced considerably.

Future reporting

Despite the reduced satisfaction levels noted above, 87% of those responding (covering both levels of investigations) still indicated that, as a result of the MHRA investigation, they were **more likely** to report incidents in the future.

Figure 11 Percentage satisfaction with conduct of investigation 2006 – 2010

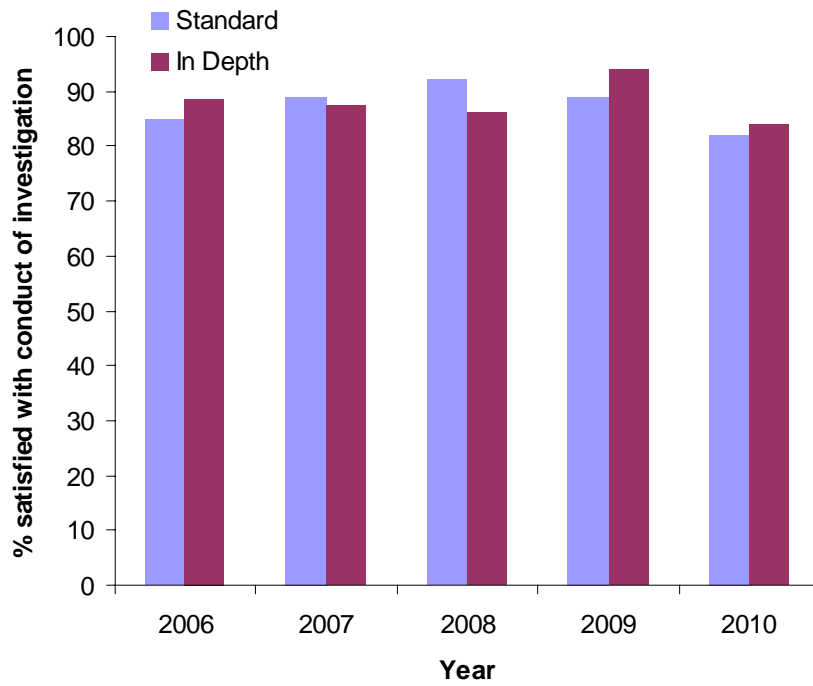


Figure 12 Percentage satisfaction with level of communication 2006 – 2010

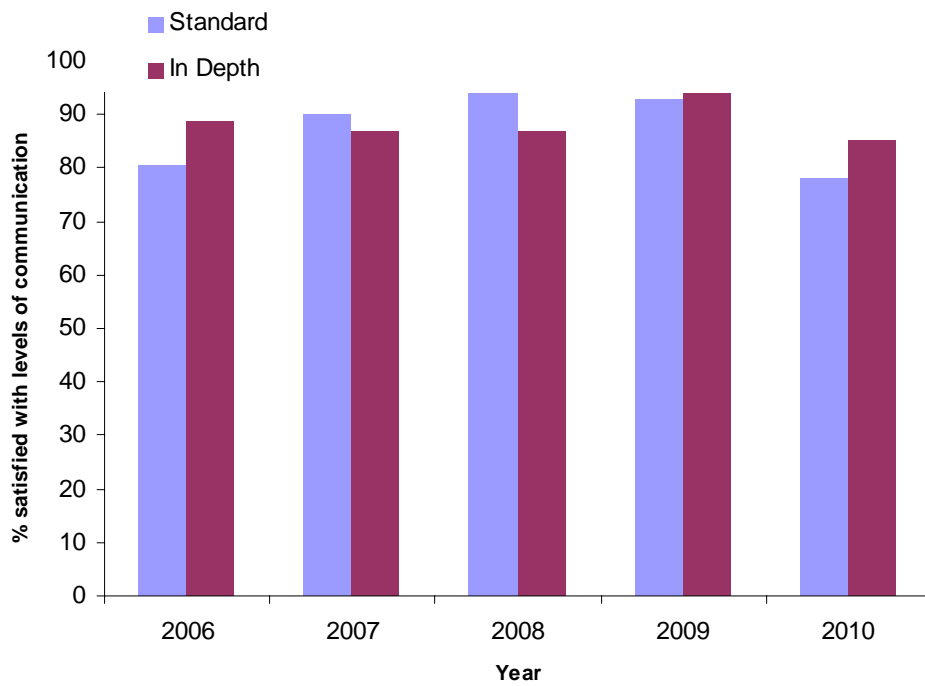
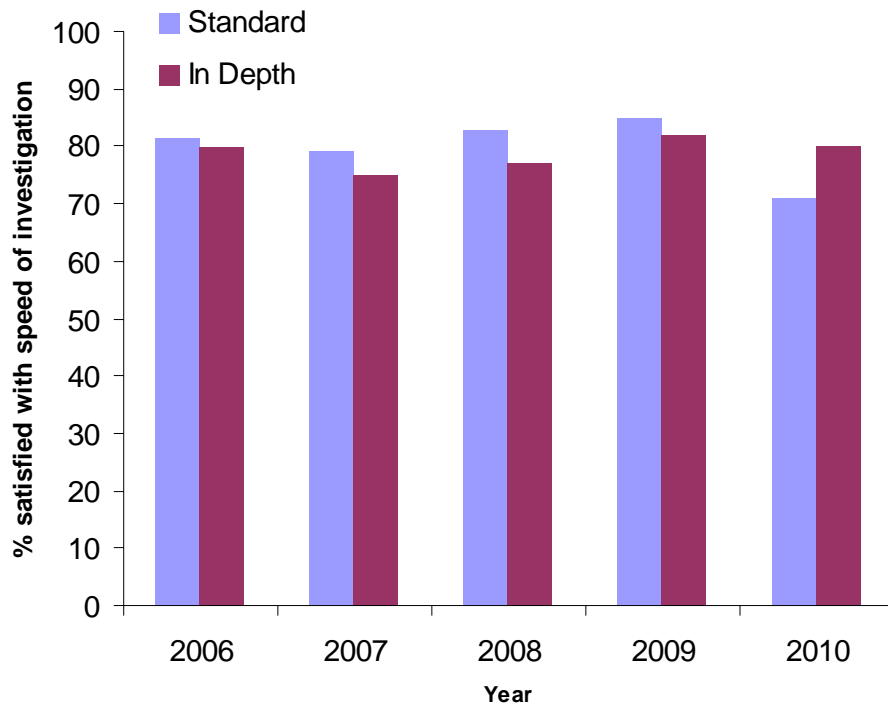


Figure 13 Percentage satisfaction with speed of investigation 2008 – 2010





**Medical device adverse incident investigation
Quality of service survey 2011**

Please help us to improve the quality of the service we provide by giving us your valuable feedback. Your responses will remain confidential.

MHRA adverse incident reference number:

Please answer questions 1–7 about the specific incident (reference number above) and enter any general comments in section 8 at the foot of the page. The grey text boxes will expand as you add your response.

1. What is your role / profession / job title?

Please specify:

- 2. Are you also an MHRA Medical Device Liaison Officer?** Yes No
Are you also a CAS Liaison Officer? Yes No

3. Indicate your level of satisfaction with:

- The way the investigation was conducted
- The speed of the investigation
- The level of communication from MHRA on this investigation
- The outcome of this investigation

- 4. Has this investigation reduced the risk of recurrence?** Yes No

If No, please state why:

- 5. Following completion of this investigation, will you be more likely to report incidents in the future?** Yes No

If No, please state why:

- 6. Have you made any changes to your local procedures as a result of this investigation?**

Yes No

If Yes, please specify:

- 7. What other information, advice or assistance would have been helpful to you?**

8. General comments

**Completed survey forms should be emailed to:
aic@mhra.gsi.gov.uk**

If you have any questions about this survey, please contact the MHRA (Devices) Adverse Incident Centre on:
Tel: 020 3080 7080 Fax: 020 3118 9814 Email: aic@mhra.gsi.gov.uk

Distribution

This Device Bulletin should be brought to the attention of managers and staff in all hospitals and healthcare establishments and others who report adverse incidents.

Enquiries

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This Device Bulletin is available to download from our website: www.mhra.gov.uk

Medicines and Healthcare products Regulatory Agency

An executive agency of the Department of Health

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