Safeguarding public health

MHRA

Device Bulletin

Adverse Incident Reports 2009

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Contents

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 also includes reports from the three specialist technical units that comprise the MHRA's Device Technology and Safety (DTS) division:

- Assistive Technology (AT)
- Biosciences & Implants (B&I)
- Imaging & Acute Care (I&AC)

These units operate alongside the DTS Adverse Incident Centre and work closely with the Devices Clinical team.

As in previous years, the report also 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.

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. For example, Section 1.1 of this year's report provides an expansion of the information provided on periodic summary reporting. In future years we intend to develop this information throughout the data and charts presented.

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 2009

In 2009 the MHRA received 9,099 adverse incident reports involving medical devices, 2.1% more than in the previous year. This total also represents an increase of 37% over the 6,610 reports received ten years ago in 1999.

	2007	2008	2009
Incident reports received	8,634	8,902	9,099
% change over previous year	+8.3	+3.1	+2.2

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 3T. 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 2009 there were 1,680 incidents included in periodic summary reports. When these are taken into account, the full total of incident reports received last year is 10,779. This represents an increase of 63% over the total number of reports submitted ten years ago in 1999.

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

The very high figure for 2007 reflects the fact that the MHRA received a number of very high volume PSRs from one manufacturer. This manufacturer (whilst undertaking a retrospective adverse incident trend analysis in accordance with established EU and UK guidance) identified a significant number of incidents that required reporting to the MHRA. The majority of the reports counted in those PSRs actually referred to incidents occurring over several previous years.

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

We exptect the use of PSRs to increase steadily, particularly as the option to submit PSRs electronically is currently being finalised by the MHRA as part of the enhancement of the manufacturer's online reporting system (MORE). Similar online reporting initiatives are being taken forward in a number of other EU member states. Additional information on these developments is provided in Section 1.3 of this document: Online reporting systems.

1.3 Comparison with 2008

The table below compares figures for 2009 with those from 2008.

	2008		2009	
Description of reports or action taken	**Number of reports**	**%**	**Number of reports**	**%**
Were reported as involving a fatality	212	2.3	202	2.2
Were reported as involving a serious injury (including implant or pacemaker revision)	1,193	13.1	1,885	20.7
Prompted in-depth MHRA investigations	2,242	24.6	2,222	24.4
Were investigated by manufacturers under MHRA supervision	3,003	33.0	3,539	38.9
Did not require immediate MHRA action, but were entered onto a database enabling trend monitoring and pattern detection	1,745	19.2	1,661	18.3
Were reports of incidents similar to those already known to the Agency	960	10.6	829	9.1
Were from secondary report sources, duplicating existing reports	502	5.5	579	6.4
Did not relate to medical devices	103	1.1	116	1.3
Were investigated by other organisations and their conclusion made available to the MHRA	350	3.8	180	2.0

The 2009 figure for the number of incident reports that included a report of a serious injury or a fatality rose considerably from 1,405 to 2,087.

In 2009 MHRA medical device specialists completed 191 investigations of adverse incidents reported as involving a fatality. In 171 of these they were able to conclude 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, 1,828 investigations were completed in 2009. In 1,476 of these we were able to conclude that there was no established link between the injury and the device(s) involved in the incidents.

The following actions were taken by the MHRA as a result of investigations:

- 85 Medical Device Alerts were issued
- 107 notifications were shared with Competent Authorities in EU member states
- 522 manufacturer's Field Safety Corrective Actions and 250 other manufacturer's field actions were undertaken

- 323 cases requiring the provision of advice on safer device use or improved staff training were identified
- 793 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:

- medical device users (i.e. clinicians, healthcare and social care workers)
- patients and other members of the public
- medical device manufacturers.

The percentage of incident reports submitted online by device users has continued to increase. In 2009 there were 2,957 user reports submitted online. This amounts to 88% of all reports from medical device users.

Once again the proportion of individual manufacturer reports submitted online via the MORE system has reduced. It now stands at 22%. However, this is simply a reflection of a move from reporting incidents individually to periodic summary reporting. This pattern is expected to change once the option for online submission of periodic summary reports is introduced.

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 remove the possibility of the transcription errors inherent in a paper-based system.

The ‘accessible’ version of the user online reporting system was successfully launched in November 2009. This was followed in December by the accessible version of the SABRE haemovigilance system. These versions facilitate access for people with disabilities.

Further delays to the completion of the final part of MORE II, the XML Manager, were prompted by the time taken to finalise a common XML standard with other EU member states. The current target is for completion to be achieved in the early part of the 2010/11 financial year.

When MORE II XML Manager is implemented, all medical device related aspects of the MHRA website will be fully accessible in accordance with e-government standards.

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 page on the MHRA website, which provides guidance and information about the MHRA and the liaison officer role.

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 page on our website.

The eighth national Medical Device Liaison Officer Conference 'Partnership Connections' took place on Friday 13 November 2009 in Birmingham. Over 170 delegates, guests and professionals from all areas of the NHS, social care and the private sector attended the conference this year. Speakers included representatives from the MHRA, the University of Birmingham, the Department of Health's Technology Innovation Programme, the Department of Health Patient Safety team and the Freeman Hospital, Newcastle upon Tyne and the Chair of the Committee on the Safety of Devices. The presentations given during the meeting are available from our website.

1.6 Central Alerting System (CAS)

In September 2008 the Department of Health introduced the Central Alerting System (CAS) for distributing safety alerts in England. CAS replaced SABS (Safety Alert Broadcast System) and PHL (Public Health Link) for distributing MHRA safety alerts, emergency alerts, drug alerts, Dear Doctor letters, and Medical Device Alerts (MDAs), which typically account for over 70% of the alerts issued via CAS. CAS also communicates safety alerts originating from the National Patient Safety Agency (NPSA), DH Estates & Facilities and the Department of Health. It incorporates a feedback mechanism to record action taken by trusts following the receipt of alerts.

MDAs are disseminated through CAS to NHS trusts and primary care. The CAS liaison officer ensures onward distribution of the alerts and in this health care sector allows feedback on action taken. Queries on Medical Device Alerts can also be raised for the MHRA via CAS. During 2009 the reporting capabilities of CAS were significantly enhanced for recipients, strategic health authorities and alert originators.

Some MHRA alerts are relevant to care homes and many will be relevant to independent health care providers. Since the establishment of the Care Quality Commission these care providers have had to register directly with CAS in order to receive alerts and all are urged to do so.

Changes or additions in CAS 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 has monitored manufacturer's Field Safety Corrective Actions since the transposition of the European Medical Devices Directives into UK law.

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.

FSNs are frequently accompanied by confirmation receipts to be completed by the medical device user and returned to the manufacturer.

It is important that the actions advised in the FSN are taken, and that receipt of the FSN is acknowledged by your organisation. This acknowledgment of receipt provides the manufacturer, and subsequently the MHRA, with the means to monitor the progress of Field Safety Corrective Actions.

If we are unable to monitor that progress or to obtain assurance of completion of the necessary action, we may have to issue a more widely targeted Medical Device Alert – with the consequent and, perhaps unnecessary, administrative burden that such an Alert would place upon the broader group of recipients.

Manufacturers generally send Field Safety Notices directly to healthcare organisations and these may be addressed to specific individuals or departments. Although the MHRA checks that the manufacturer's distribution lists for FSCAs are credible and likely to achieve a satisfactory result we cannot check for 100% accuracy – this is the manufacturer's responsibility. If a FSN is targeted wrongly (e.g. out-of-date information on staff and equipment locations), crucial information may not be acted upon or documented.

All healthcare staff should be aware that if they receive a manufacturer's FSN they should notify the appropriate member of staff who can arrange for the requested action to be undertaken. This may involve wider distribution and activation of formal risk management procedures within the healthcare organisation.

In response to requests from some medical device liaison officers and CAS liaison officers, and in order to provide transparency concerning Field Safety Corrective Actions in the UK, the MHRA places Field Safety Notices that are relevant to the UK on our website. This is done for information and will not normally require further action unless your organisation has been contacted directly by the manufacturer or if the MHRA has issued supplementary advice.

Medical device liaison officers and CAS liaison officers are not expected to treat FSNs placed on MHRA's website in the same way as Medical Device Alerts. Additional action or direct feedback will usually only be required when a Medical Device Alert has been issued. However, in response to feedback from the liaison officer conference, the MHRA is considering with manufacturer trade associations how the medical device liaison officer network might help further in the distribution, action and receipt of FSNs.

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.

For the last six years all hazardous medical device related incidents occurring in Wales are now reported directly to the MHRA (see Welsh Assembly circular MDA/2004/054), 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 Adverse Incident Centre's haemovigilance team continues to manage SABRE (Serious Adverse Blood Reactions & Events), the haemovigilance online reporting system. During 2009 the team completed the third annual summary report exercise and in June successfully submitted the associated UK summary report to the EU Commission.

The haemovigilance team continues to liaise closely with the MHRA division responsible for blood compliance reporting and for the inspection of blood establishments and blood banks. Information obtained from SABRE reports is routinely shared with inspectors and informs their inspection planning and decision-making processes.

The team also continues to work closely with SHOT (Serious Hazards Of Transfusion) and the MHRA's Blood Consultative Committee.

2 Reporting and investigation of adverse incidents

2.1 Reporting procedures

Each year the MHRA Adverse Incident Centre produces comprehensive procedure guidance on reporting adverse incidents involving medical devices – **'Reporting Adverse Incidents and Disseminating Medical Device Alerts'** DB 2010(01), 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 7084 3080.

Medical device liaison officers appointed locally within NHS trusts and social care organisations will be able to offer specific advice on local procedures for adverse incident reporting and on local risk management systems. These local procedures should ensure that all relevant 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. Contact details for each of the devolved administrations can be found in DB 2010(01).

Other organisations that may need to be contacted include the Health and Safety Executive, DH Estates & Facilities, or the defective medicines and blood safety sectors of the MHRA. Further information and contact details for these bodies are also included in DB 2010(01).

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.

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

More detailed information and advice is given in DB 2010(01). This includes dealing with the manufacturer and, when appropriate, decontamination, returning devices and dealing with devices required for continued use. Despite this clear procedural advice, a small number of devices are still being submitted to the MHRA without having been suitably cleaned prior to decontamination. As a consequence the decontamination process will have been ineffective.

If MHRA staff doubt the decontamination status of a submitted device, arrangements can be made for further decontamination prior to commencement of any investigation. This further processing causes otherwise unnecessary delay in the investigation process. Device Bulletin DB 2006(05) 'Managing medical devices' (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 – 2003-2009

Year	Number of devices received	Number requiring decontamination	% requiring decontamination
2003	827	254	30.7
2004	289	17	5.9
2005	125	27	21.6
2006	136	27	19.9
2007	37	9	24.0
2008	128	8	6.0
2009	119	26	21.8

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
- inappropriate local modifications
- unsuitable storage and use conditions
- selection of the incorrect device for the purpose
- off label use of a device
- inappropriate management procedures

- poor user instructions or training (which may result in incorrect user practice).

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 and investigating incident reports

The Adverse Incident Centre (AIC) employs 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, more than 50% of all adverse incidents reported 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 over 75%. For the remainder, data input is completed within five working days. Priority is always given to reports identified as involving a death or serious injury and to those concerning implant revision, which are completed within three working days.

Once recorded on the AITS database and available to the medical device specialists working within our Device Technology and Safety division, a full **risk assessment** is undertaken. For the most serious incidents (e.g. those involving a death or serious injury), these processes can be completed within hours. Each risk assessment is conducted by a medical device specialist using a tailored risk assessment tool. This helps to weigh up the implications of the incident for the safety of patients, healthcare workers and others. This includes an assessment of the severity of the actual or potential injury caused, and the likelihood of recurrence. It is this assessment that determines the level of incident investigation to be conducted.

2.6 Investigation levels

'In depth' investigations will usually be 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 are led by one of our medical device specialists. Such investigations (2,222 in 2009) may involve:

- 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).

It is these in depth investigations that typically lead to the MHRA issuing a Medical Device Alert.

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

Generally, these incidents are investigated most effectively by the manufacturer of the device. In 2009 MHRA medical device specialists supervised the investigation of 3,539 incidents in this way. The manufacturer is provided with information about the incident, the location and the device involved. Although the manufacturer is asked to undertake these investigations, an MHRA medical device specialist will monitor progress and critically review the manufacturer's investigation and report.

In 2009 there were 1,661 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 are categorised as **'information only'** incidents. Other incident reports may be recorded as '**knowns'**. These are reports that relate to existing investigations of the same problem with a particular type of device. Of the reports received in 2009, there were 829 linked in this way to ongoing investigations.

The category of **'echo'** reports (579 in 2009) 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 180 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 (180 in 2009) did not involve medical devices. These are 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. A further 116 reports were referred to our MHRA colleagues handling adverse drug reactions and defective medicines. The incident reporter is always informed of the referral.

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

The data gleaned from the 'information only' and 'known' categories, coupled with the incident and investigation records retained in the active and surveillance databases that comprise AITS, help us to maintain an up-to-date picture of the various device types and failure modes.

The progress of all adverse incident investigations is subject to regular **review**. The review process enables us to re-assess the assigned level of the investigation and to determine what, if any, additional or changed action is required. These reviews may require the involvement of our Devices Clinical team (on clinical aspects of the incident, including the way the device was used) or members of the Committee on Safety of Devices or experts from our register of experts.

2.7 Maintaining contact with the reporter

As soon as possible after receipt of a report, the Adverse Incident Centre administrative team will ensure that the incident reporter receives a formal acknowledgement including a unique MHRA incident reference number. That acknowledgement is accompanied by a short note that summarises and explains our adverse incident investigation processes.

In normal circumstances, approximately two thirds of report acknowledgements are sent out within a day of the report being received. Almost all are despatched within five days. 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 outcome of the medical device specialist's risk assessment – the investigation level – and are then routinely kept informed of progress throughout the investigation. At the end of the 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 in depth or standard investigation, 20% of reporters will receive a survey form requesting feedback on their perception of the outcome of the investigation, the level of communication throughout, and the overall time taken (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.

Following comments and feedback received from individual reporters and from our medical device liaison officers, we are now considering options for an online system that will allow medical device liaison officers to track the progress of incident reports submitted from their NHS trust or social care establishment. This was discussed at the MDLO conference in November 2009, at the MDLO Focus Group in March 2010, and will be further researched during the coming year.

2.8 Investigation teams

The principal MHRA business areas with an involvement in the investigation of medical device related adverse incidents are **Device Technology & Safety (DTS)** and **Devices Clinical (DC)**.

DTS is responsible for the receipt, recording and investigation of adverse incidents associated with medical devices, for the issue of Device Bulletins and Medical Device Alerts, and for the provision of technical advice on all aspects of medical devices in use in the UK.

As well as investigating adverse incidents, the specialist technical units 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. DC provides specialist expertise to support all our businesses and to increase awareness of our agency's role in the NHS and among professional bodies.

DTS currently comprises the Adverse Incident Centre and three specialist technical units that cover the range of medical device product areas. Cross-directorate support is provided by the DTS Services team. Current responsibilities are set out below.

DTS unit	Activity / Product areas
Adverse Incident Centre (AIC)	Receipt and database recording of medical device related adverse incidents reported by manufacturers or users. Also responsible for the distribution to other European member states of any competent authority notifications resulting from MHRA investigations. Development and maintenance of adverse incident online reporting systems, databases and published reporting guidance.
Assistive Technology (AT)	Mobility aids, moving and handling systems, posture management, pressure management, communication and hearing aids, beds, environmental controls, and aids for daily living. UKAS accredited laboratory for testing wheelchairs and artificial limbs. MHRA's device decontamination laboratory.
Biosciences & Implants (B&I)	In vitro diagnostic medical devices IVDs), active (powered) and non-active implants, materials and microbiology used in medical devices (including animal tissues), and the sterilization and decontamination of medical devices.
DTS Services (DS)	Provide a range of business and administrative support services. They also manage the Medical Device Liaison Officer system (including the MDLO Focus Group) and play a key role in the production of the annual MDLO conference.
Imaging & Acute Care (I&AC)	Diagnostic imaging and measurement, breathing systems and anaesthetic machines, infusion, dialysis, special care baby equipment, therapy and surgical devices.

2.9 Safety warnings and the Central Alerting System (CAS)

The MHRA issues safety warnings on medical devices to health and social care providers and other device users. These Medical Device Alerts (MDAs) warn of particular problems and risks and recommend appropriate action to minimise them. They are the MHRA's prime means of communicating safety information. They may also be used to provide updated information.

Since April 2008 each Medical Device Alerts has been issued on our website as an electronic publication (eMDA) as well as in PDF form. The eMDA allows users to rapidly assimilate the information relevant to them, whether it is the device, the problem, or the intended distribution, by simply choosing the appropriate tab. The

front page of the Alert in PDF form shows clearly: the device involved, the action required, a summary of the problem, who is affected by it, and the level of urgency.

MDAs are distributed to the NHS and social care sectors for direct action and for onward transmission to relevant healthcare professionals. Where the device is used in primary care, this includes general practitioners. Medical Device Alerts are designed to be used throughout the UK and are distributed simultaneously but separately by the devolved administrations in Northern Ireland, Scotland and Wales. A separate section/tab includes any special information relevant to these parts of the UK.

With effect from January 2009 each alert is assigned one of the following revised categories:

• Immediate action
• Immediate action update
• Action
• Action update

Published alerts 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.

The Central Alerting System (CAS), described in Section 1.6 above, is the primary method of distributing MDAs to all NHS trusts (including primary care trusts), care homes and independent health care providers in England.

3 Review of activity in DTS specialist technical units

3.1 Assistive Technology (AT)

This unit covers the wide range of 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 and other aids for daily living.

The majority of staff members in 2009 were based at the MHRA's Centre for Assistive Technology in Blackpool, with some staff based at the MHRA's head office in London. Staff expertise includes: rehabilitation and mechanical engineering; materials science and other areas of assistive technology such as pressure care; posture and mobility; moving and handling; prosthetics and transport for the disabled. In addition, our members of 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 1,529 adverse incident reports during 2009. This is a 3.2% increase over the 2008 figures and to some degree reflects the efforts made by staff to encourage professionals, users and carers to report adverse incidents. We carried

out 411 in depth investigations due to the seriousness of the risks involved. We published 22 Medical Device Alerts during the year. Some of the significant safety issues covered are set out below.

Beds
Adverse incident reports concerning beds and mattresses increased in 2009 by 2% to 177. We issued two Medical Device Alerts – MDA/2009/050 highlighted the poor response to an earlier alert concerning possible delay in CPR due to a faulty emergency release; MDA/2009/051 raised the problem of contamination of mattresses. Further investigation into this subject lead us to issue a further alert in January 2010, stressing 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.

Wheelchairs and children's buggies
Adverse incident reports concerning all types of powered and non-powered wheelchairs used by children and adults decreased slightly in 2009 to 700. Investigations led to many changes in designs and instructions for use and nine Medical Device Alerts were issued. MDAs 2009/61, 79 and 81 involved problems with backrests. MDAs 2009/10, 18, 53 and 5 involved issues concerning the use of the wheelchair as a seat in a motor vehicle. MDA/2009/015 involved problems with castor fixings and MDA 2009/064 involved safety related changes in the instructions for use.

Hoists and slings
Adverse incident reports involving hoists and slings reduced in 2009 by 12% to 129. Investigations led to seven Medical Device Alerts being issued. MDA/2009/41 covered the need for inspection of slings before use. MDAs 2009/57, 59 and 82 raised the potential for hoists to collapse if they are not maintained and assembled correctly. MDA/2009/49 highlighted the need for a safety belt to be fitted. MDA/2009/66 covered the recall of bath lift battery chargers which were overheating. MDA/2009/71 covered problems with weigh scale mountings.

Walking aids
Adverse incident reports concerning walking aids increased by 29% to 109. Investigations led to two Medical Device Alerts being issued. MDA/2009/06 and 67 both covered the need to replace units which could cause the aid to collapse in use.

Paediatric seating
Investigations led to two Medical Device Alerts being issued. MDAs 2009/22 and 33 covered risks to children where the buckles on the posture belts/harnesses could fail in use.

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 the British Healthcare Trades Association (BHTA) as the main trade association for assistive technology. The relationship with the Health and Safety Executive (HSE) has been strengthened, and improved joint working for the future is being discussed. We have regularly attended NHS groups covering rehabilitation engineering services, prosthetics, wheelchairs and seating and electronic assistive technology 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 and have provided seminars for manufacturers to raise awareness of post-market surveillance systems and the need for improved reports to the MHRA. We also had stands at the annual conferences for Moving and Handling, the National Association for Safety and Health in Care Services (NASHiCS) and assisted the Primary Care Live Exhibition, where large numbers of delegates visited the stands to discuss the work of the unit. 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. Meetings were held with the Chief Executive of the College of Occupational Therapists to try to increase the number of adverse incident reports from occupational therapists. Subsequently an article was included in their professional journal to try to raise awareness. The Chartered Society of Physiotherapy has agreed to publish a similar article.

Guidance documents
From investigations and numerous requests for advice it became clear that users and others involved in some major subject areas would benefit from the provision of written guidance. Drafting work is continuing on a guidance document on the safety of hoist and slings. It will highlight the risks and also aim to raise the level of awareness of good practice.

In-house testing
Our laboratory was re-accredited as the only UKAS registered wheelchair test laboratory in the UK following the annual re-assessment in August 2009. The laboratory continues to provide in-house testing to support adverse incident work as well as chargeable testing for industry on a full cost-recovery basis.

3.2 Biosciences and Implants (B&I)

The Biosciences and Implants 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 2009, B&I received 3662 reports of individual adverse incidents. In addition we received 53 summary reports of multiple incidents. 2692 of these reports were

individually investigated; the remainder were investigated using trending techniques and/or surveillance.

In vitro diagnostic medical devices (IVDs)
Following reports of problems with an open system laboratory analyser, we issued a Medical Device Alert to the health service to ensure that all those using the analyser were aware of the need for an important safety retrofit. We continue to work with the analyser manufacturer and a number of their UK distributors to ensure that these important safety messages are distributed to all those who need to know.

A manufacturer of bacteriology culture media issued a Field Safety Notice to all their customers because of raw material contamination. As this problem could have led to incorrect patient results, we followed this up with a Medical Device Alert to remind users to consider a review of previous results.

Non-active cardiovascular implants
We received a number of adverse incident reports concerning the clinical need to explant replacement biological heart valves because of valve leakage. From our investigations we concluded that it may have been possible that the chemical in which the heart valves were stored had not been adequately rinsed off. The preservative chemical has the potential to damage the patient's native heart tissue if it is not completely removed prior to valve implantation. We issued a Medical Device Alert highlighting the importance of using the appropriate rinsing regime during pre-implantation preparation.

We were alerted by users to an issue concerning the deployment of a popular type of abdominal aortic aneurysm stent-graft device. In the majority of cases, the patients receiving the implant did not suffer any adverse consequences. However, there were some associated patient fatalities. Following our investigation, it was apparent that in a small percentage of procedures the clinicians could encounter difficult deployment due to a number of factors relating to the positioning of key components of the device. After discussions with the manufacturer, they issued alternative deployment advice for users encountering this problem. This was reinforced by a MHRA Medical Device Alert. We also raised the possibility of a design change to the deployment mechanism and the manufacturer later tested and released an altered design, which appears to have significantly reduced the numbers of reported deployment complications.

Insulin pen injection devices
The manufacturer of an insulin pen injection device issued an alert to their customers following discovery of a manufacturing defect. Faulty devices may have failed to dispense insulin and users may not have received their full dose. We supported the manufacturer's alert to their customers with a Medical Device Alert to pharmacists and other healthcare professionals.

When we were informed that counterfeit insulin pen needles had been placed on the UK market we issued a Medical Device Alert to the health service. There is no assurance that counterfeit needles have been manufactured to the appropriate standards. Possible consequences of using counterfeit needles could include: adverse reactions to the materials used; pain and discomfort; difficulty in attaching the needle to the pen injection device; and infection.

Neurostimulators
A neurostimulator manufacturer informed us of problems with tubes used during the placement of neurostimulator electrodes coming apart during brain surgery

potentially causing damage to neurological tissue. Investigation demonstrated that this was a manufacturing problem due to inadequate gluing. We asked the manufacturer to retrieve affected batches of devices from the UK market.

In order to encourage greater consistency of reporting amongst manufacturers of neurostimulators we published a vigilance guidance document on manufacturer reporting. The document was developed in consultation with industry.

Pacemakers and implantable cardioverter defibrillators (ICDs)
We issued a Medical Device Alert on some models of two pacemakers that were demonstrating higher than expected rates of failure. The MDA was aimed at healthcare professionals who manage patients fitted with this device. The investigation also led us to issue a report to several other national competent authorities worldwide. Further reports are being reviewed regularly, using the periodic summary reporting method, to monitor the ongoing level of failure rates.

Decontamination, packaging, sterility, associated microbiological issues including TSEs and prions
During 2009 we published two Medical Device Alerts on decontamination and sterilization. The first one was issued as a result of a manufacturer having to recall a batch of their alcohol-free surface disinfection wipes for medical devices. Tests showed an interaction between the active disinfecting solution and the wipe material. This resulted in the wipes having inadequate disinfection properties. The second one was issued due to the potential for onward transmission of abnormal prion protein, the putative infective agent in variant Creutzfeldt Jakob disease (vCJD), when ultrasound transducer probes with an internal lumen are used for taking transrectal prostate biopsies on men at risk of vCJD.

Over the year we have dealt with an increase in reports by hospital device reprocessors reporting non-sterile sets being issued due to failures in their quality control processes. Another has been dirty instruments being found in sets of instruments which have been processed and returned to theatres.

An area which continues to challenge both the reprocessors of medical devices and B&I is that of inadequate or inappropriate decontamination information in the manufacturer's instructions for use. This results in delays in reprocessing or the device being unable to be safely or adequately decontaminated.

We have also dealt with an increase in manufacturers reporting recalls of their sterile devices due to the integrity of the packaging being compromised. The problems relate to: inadequate sealing of packs; transportation damage; devices penetrating the pack or the pack not fulfilling the manufacturer's requirements when being revalidated.

Vascular closure devices
In 2009 we received a steady flow of adverse incident reports relating to the use of all types of vascular closure devices. We issued a poster with safety top tips to highlight the key use-related issues that we had become aware of from these adverse incident reports.

Orthopaedic implants
In 2009 we issued four Medical Device Alerts (MDA) providing advice on the use of orthopaedic devices and/or giving additional guidance on patient follow-up. One MDA, relating to a knee implant with a higher than expected revision rate, was the outcome of an investigation triggered by a report from the England and Wales

National Joint Registry (NJR). We continue to work closely with the NJR steering committee, which is developing systems to identify implant 'outliers' from its database.

We received reports of revisions for a specific hip replacement device and we met with the manufacturer to discuss the issue. Their investigation had identified a training issue for this device and they informed us of their proposed corrective action for re-training users across Europe. The Field Safety Notice issued by the manufacturer was placed on the MHRA website and we sought independent clinical advice on its appropriateness. We continue to monitor the safety of this device via our adverse incident database.

The MHRA is part of a joint working group involving the NJR, British Orthopaedic Association and the British Hip Society looking at the occurrence of adverse soft tissue reactions associated with metal-on-metal hip implants. In the last year, the joint working group has collected information and has been making good progress towards producing a final report, which aims to provide advice to the health service on the use of these devices and on the management of patients already implanted with them.

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

Gastric balloons
We issued a Medical Device Alert on an intragastric balloon (used for weight loss) to address a problem that could have increased the risk of bowel obstruction due to full or partial deflation of the balloon during the intended six-month implantation period. While we worked with the manufacturer to ensure that manufacturing issues were addressed, the Medical Device Alert advised clinicians to schedule elective removal of all implanted affected devices as soon as possible.

Ophthalmics
We issued a Medical Device Alert concerning a staining solution for ophthalmic surgery supplied in a 0.5ml syringe. It was reported that during injection of the solution the plunger may stick within the barrel of the syringe. This had led to the use of excessive force, resulting in a sudden jet of liquid that could cause serious damage to intraocular tissues. Surgeons were advised to ensure that the plunger moves smoothly within the barrel of the syringe by pulling back the plunger prior to priming and injecting the solution.

Another Medical Device Alert addressed damage to tonometer prisms, which are used to determine intraocular pressure. The damage was caused by the use of non-approved disinfectants. Once damaged, the tonometer prism may take up some of the disinfectant solution during the cleaning process. This solution may then come into contact with the patient's eye during the measuring procedure resulting in an increased risk of irritation to, or erosion of, the cornea. The alert advised users of the correct disinfectants to use as recommended by the manufacturer.

We also published guidance on the vigilance system specific to manufacturers of intraocular lenses. The document gives advice on the notification of adverse incidents under the Medical Devices Vigilance System.

Periodic summary reporting
Medical device manufacturers continue to make good use of periodic summary reporting across a range of products including pacemakers, implantable defibrillators, glucose tests and pregnancy tests.

Periodic summary reports help to reduce the number of separate vigilance reports made by a manufacturer and help us to focus on trends in incident reporting.

We continue to encourage periodic summary reporting for all incidents that are common and well documented or that have been described in a Field Safety Notice.

3.3 Imaging and Acute Care (I&AC)

The unit is concerned with 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; non-implantable vascular devices, including needles and lancets. The unit is staffed by medical device specialists with expertise in: physical and biological sciences; radiation physics; mechanical and electrical engineering. Some members of staff also have experience of working in the health service sector and medical device industries.

In 2009 a total of 37 Medical Device Alerts were issued across the full range of I&AC products. Again over 1,200 of the adverse incidents we investigated were assigned to our highest category (‘in depth’).

Highlights of the work undertaken in some of our product areas are given below.

Anaesthetic and respiratory systems
In 2009 we issued ten Medical Device Alerts, covering a wide range of devices including: ventilators, nebulisers, vaporisers and airway management devices. Additionally, in conjunction with our Devices Clinical colleagues and working closely with professional bodies and MHRA medicines colleagues we published 2 dedicated ‘One Liner’ publications (issues 67 and 70) relating to various topics including, concerns about the safe use of anaesthesia machines and the safe use of oxygen cylinders during patient transfer.

We continue to maintain close links with professional bodies such as the Society of Critical Care Technologists and the Royal College of Anaesthetists and have provided expertise to a range of committees for the Association of Anaesthetists of Great Britain and Ireland (AAGBI), including assisting the Safety Committee in their publication ‘Safe Management of Anaesthetic Related Equipment (2009)’.

We also provide technical advice to the Department of Health and are currently assisting in the procurement and provision of domiciliary oxygen therapy equipment. We have advised a number of other NHS organisations including the National Patient Safety Agency (NPSA).

Cardiopulmonary and circulatory assistance devices
In December we published MDA/2009/078 regarding the adequate securing of intra-aortic balloon pumps in use by patients during ambulance transportation.

Infusion and feeding pumps
This continues to be one of our busiest areas with over 375 adverse incident reports investigated during 2009. Five Medical Device Alerts were issued during the year on these devices.

There has been input into police and coroner investigations regarding the actual functioning of individual infusion and enteral feeding pumps.

In September 2009 the MHRA held another infusion pump study day focussing on improving the safe use of these devices. A range of presentations and workshops, with input from external and internal personnel, were attended by over 100 delegates.

We have also maintained links with a number of professional bodies and expert committees including:

- the Society of Critical Care Technicians where we gave a presentation at their annual meeting on the major causes of adverse incidents
- input to NPSA neuraxial working group
- continued membership of the infusion devices e-learning expert reference group which has produced an e-learning module on infusion pumps. The number of people who have undertaken this course now stands at over 4,000.

Dialysis devices
We have continued working with many external stakeholders across a diverse range of issues including assisting investigations in Northern Ireland, close liaison with coroners and the publishing an article in the Association for Renal Technology's publication 'Artery'.

We published three Medical Device Alerts in this area: MDA/2009/012 and MDA/2009/076 were issued to ensure complex safety actions were highlighted and implemented. MDA/2009/060 was issued after the MHRA became aware of a problem with bloodlines which required urgent safety action to be undertaken. In addition, in One Liner issue 71, the importance of correctly inserting bloodlines into machines to prevent internal machine blood contamination was reiterated.

Radiotherapy
Links with the radiotherapy community have continued through a number of channels including the Institute of Physics and Engineering in Medicine (IPEM) and the National Physical Laboratory. We have worked with the IPEM in highlighting a number of issues, including good practice and lessons learned from adverse incident reports and investigations.

Medical lasers and intense pulsed light (IPL) sources
Following on from the 2008 document 'Guidance on the safe use of lasers, IPL systems and LEDs', we published two posters to complement this guidance. One provides general safety tips to follow when using optical radiation equipment and the other poster relates to concerns with the smoke plume that can arise from laser and electro-surgery procedures.

We have attended and presented at laser protection advisor meetings and laser safety courses to inform about the Agency's investigative work.

Other stakeholder interaction
We continue to provide assistance to coroners and the police concerning complex technical issues that have arisen across all critical care devices.

We have provided advice and comments to many government agencies including the Centre for Evidence based Purchasing and the National Patient Safety Agency, on a range of products including 'warm air' blankets and urinary catheters.

Close working also continues with manufacturers on improving post-market surveillance and vigilance reporting. Resulting improvements to safety include changes to the design of products and improvement to the clarity and accuracy of instructions for use.

We produced a poster entitled 'ECG top tips' in which we addressed some of the problems identified through adverse incidents that we received.

The unit has had input to many clinical investigations, thereby supporting innovation and product development relating to devices within our product range.

4 Statistics

4.1 Trends in adverse incident reporting

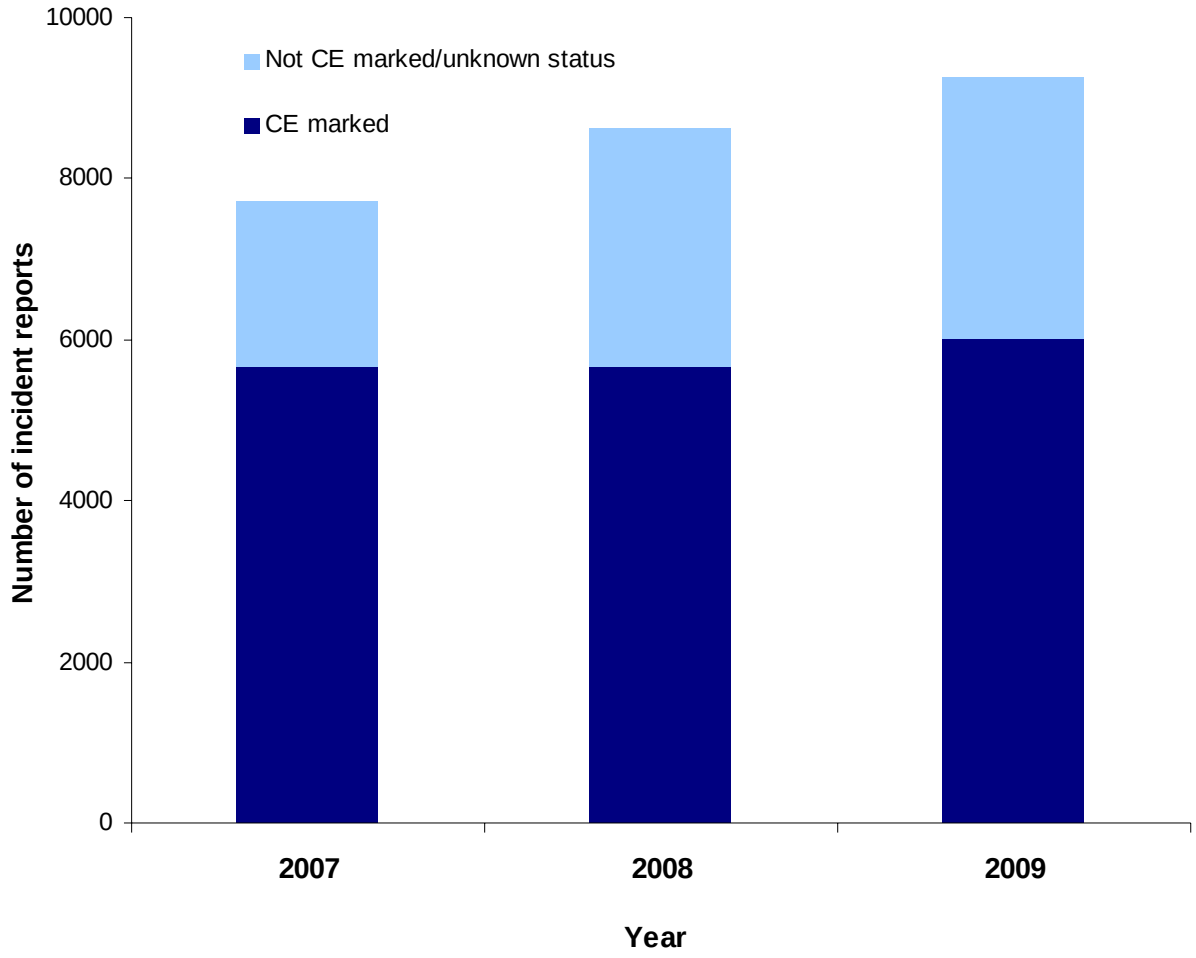
We received 9,099 adverse incident reports in 2009. This was an increase of 2.2 % on the 2008 total. Taking into account the 1,680 further reports submitted as part of periodic summary reports, the increase over the comparable figure for 2008 is almost 5%.

Whilst the overall trend in the number of incidents reported is clearly upward, the MHRA has significant concerns about the number of reports received from healthcare staff. It may be that medical device related adverse incidents are being recorded in local and national patient safety reporting systems, but they are not always being sent directly to the MHRA. We appreciate that entering report data into multiple systems is duplicative and time-consuming but until the more efficient electronic systems currently under development are introduced, it is essential that the MHRA's efforts to safeguard public health in this area are not undermined.

In order to address this problem, the MHRA has issued definitive guidance in 'Reporting adverse incidents and disseminating medical device alerts' – DB 2010(01) – and has made clear reference to the reporting requirements specified in the Care Quality Commission's core standards. We have also reiterated the point that medical device liaison officers and local risk managers should not filter out adverse incident reports that would otherwise have been submitted to the MHRA.

The upward trend in medical device manufacturer reporting has continued. This is largely due to ongoing, pro-active contact with manufacturers in a number of specific device areas where there has previously been apparent under-reporting. The publication of revised guidance on the vigilance system in 2008 and the general growth in the range and volume of medical devices in use are also significant factors.

Figure 1 Adverse incident reports 2007 – 2009



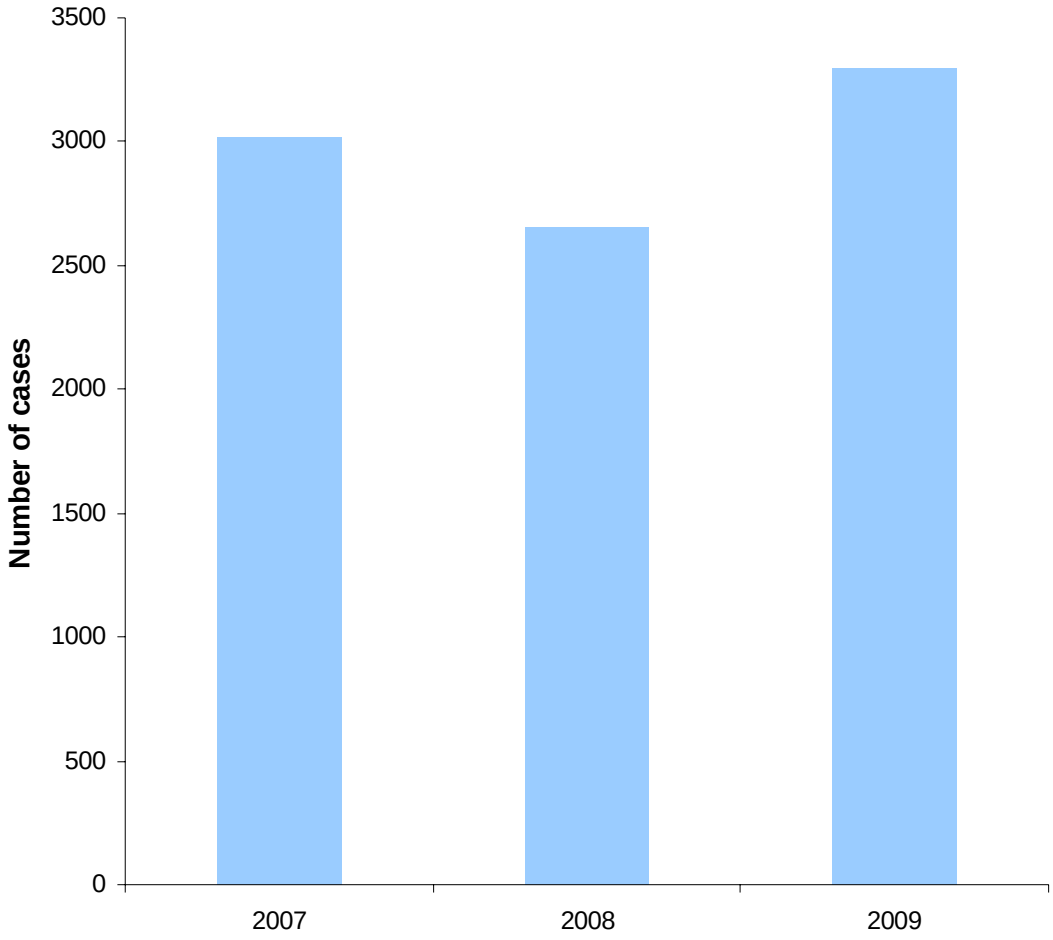
4.2 Vigilance cases

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.

The latest version of the MEDDEV may be found on both the MHRA website (www.mhra.gov.uk) and the European Commission website (http://ec.europa.eu/enterprise/sectors/medical-devices/files/meddev/2_12_1-rev_6-12-2009_en.pdf). The MHRA has its own document providing guidance on this vigilance system – Directives Bulletin 3 (available on our website under Publications > Regulatory guidance > Devices > Directives Bulletins).

In 2009 the number of individual incident reports recorded as 'vigilance' rose to 3,293 (2,653 in 2008). This continues the generally rising trend seen over recent years.

Figure 2 Number of vigilance cases received 2007 – 2009



4.3 Report sources

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

2009 saw a modest rise (0.7%) in the proportion of reports received from NHS medical device users. Although this appears to be a welcome reversal of the recent downward trend, we are continuing to monitor this closely and will be maintaining our efforts to ensure that all medical device related adverse incidents are reported directly to the MHRA.

Figure 3a Incident report sources 2007 – 2009

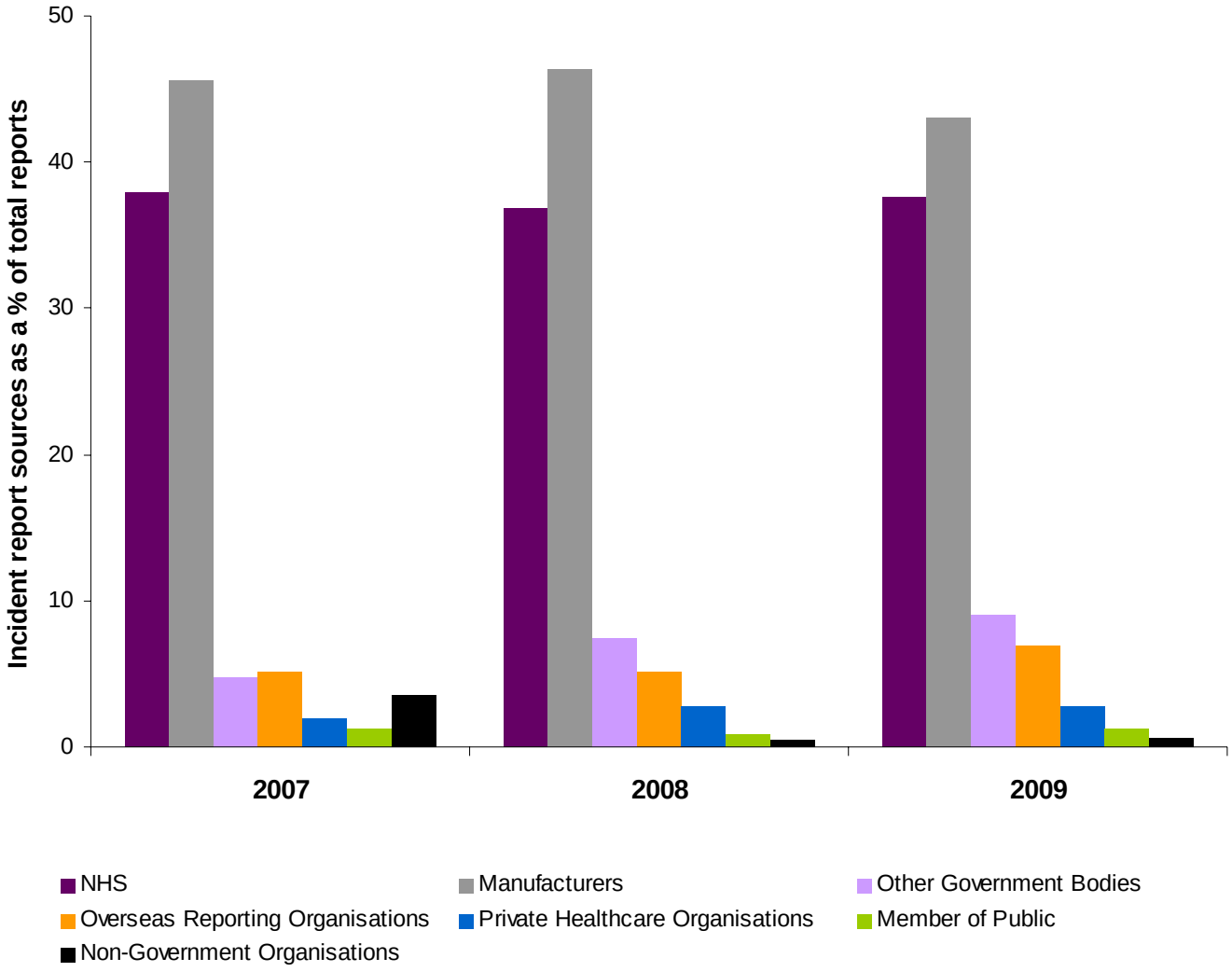
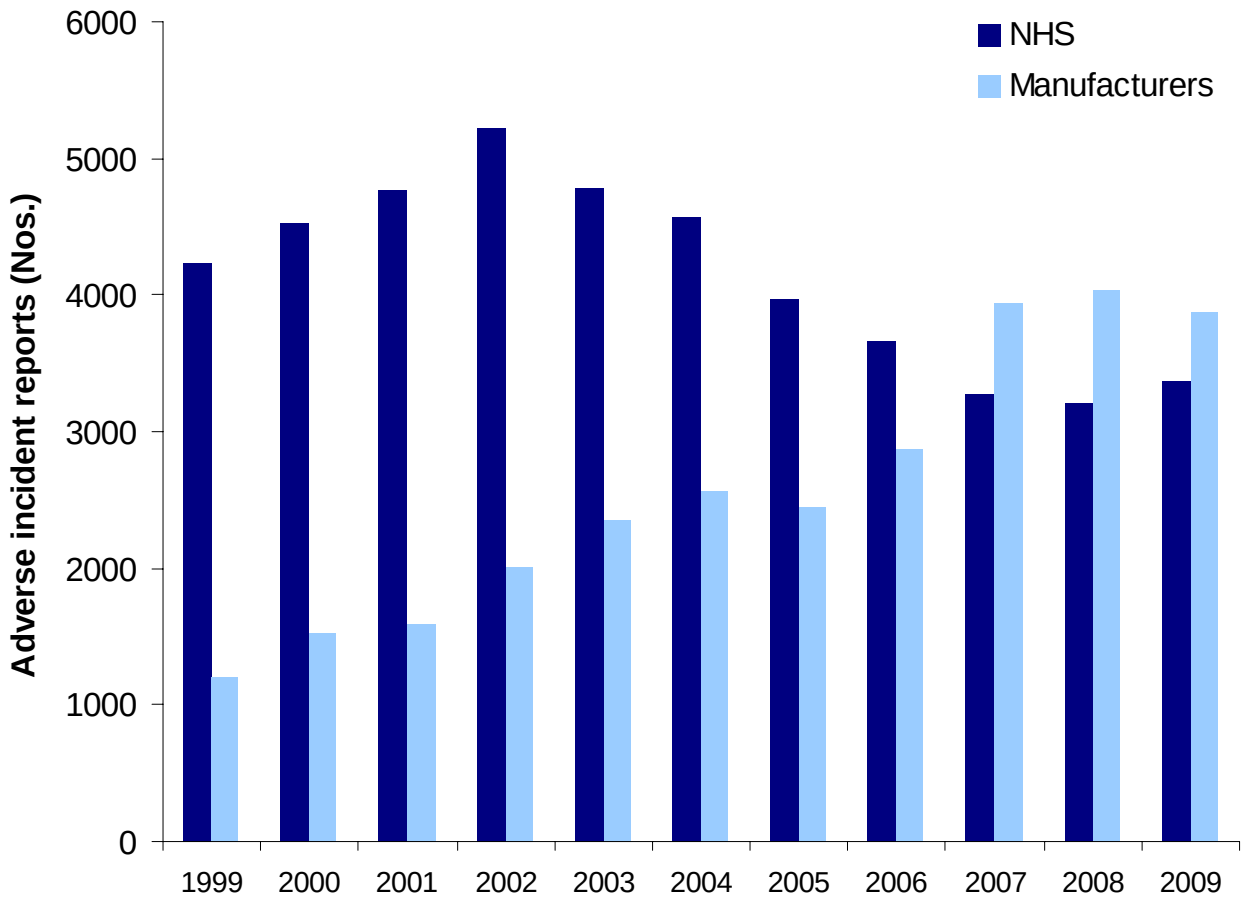


Figure 3b is a new chart, highlighting the different trends in reporting from the NHS and from medical device manufacturers. Whilst the upward trend in manufacturer reporting is welcomed as a reflection of increased medical device usage and improving manufacturer awareness of their post-market surveillance and vigilance responsibilities under the EU Directives, the downward trend in reports from the NHS (as described in 4.1 above) remains a significant concern.

Figure 3b Incident report sources 1999 – 2009: 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.

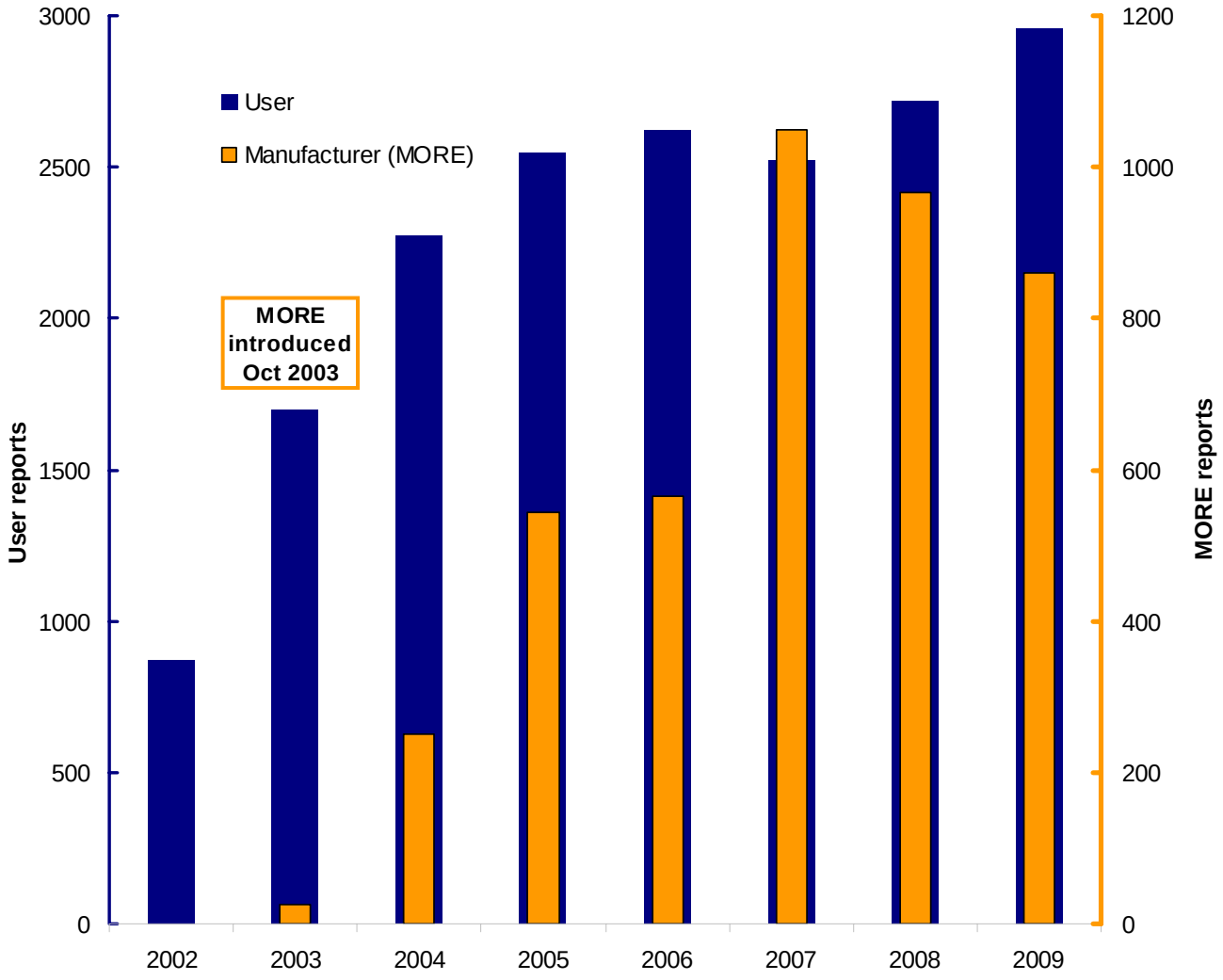
The first two of these systems now meet the new website accessibility standards and have been audited by the RNIB (Royal National Institute for the Blind) to 'See it Right' and 'UseAbility' standards. The update of the third, the manufacturing online reporting system, is due for completion this year.

In the nine years since its launch, the MHRA's first online medical device adverse incident reporting system (for patients, members of the public, clinicians and other health and social care workers) has gone from strength to strength. In 2009 almost 3,000 reports were submitted via this route, which is 88% of reports from device users.

MORE (the Manufacturers' Online Reporting Environment) is the system for medical device manufacturers to report online. There are now around 900 registered MORE reporters although not all are regular reporters. Nevertheless, 22% of reports from manufacturers now reach us via MORE.

The plans to launch the next version of MORE have been much delayed, both by our work on making the system 'accessible' and by continuing discussions with EU counterparts on a common format and structure for electronic exchange of report data. The updated system is now scheduled for launch this year.

Figure 4 Online reports received 2001 – 2009



4.5 Incident reports by device group

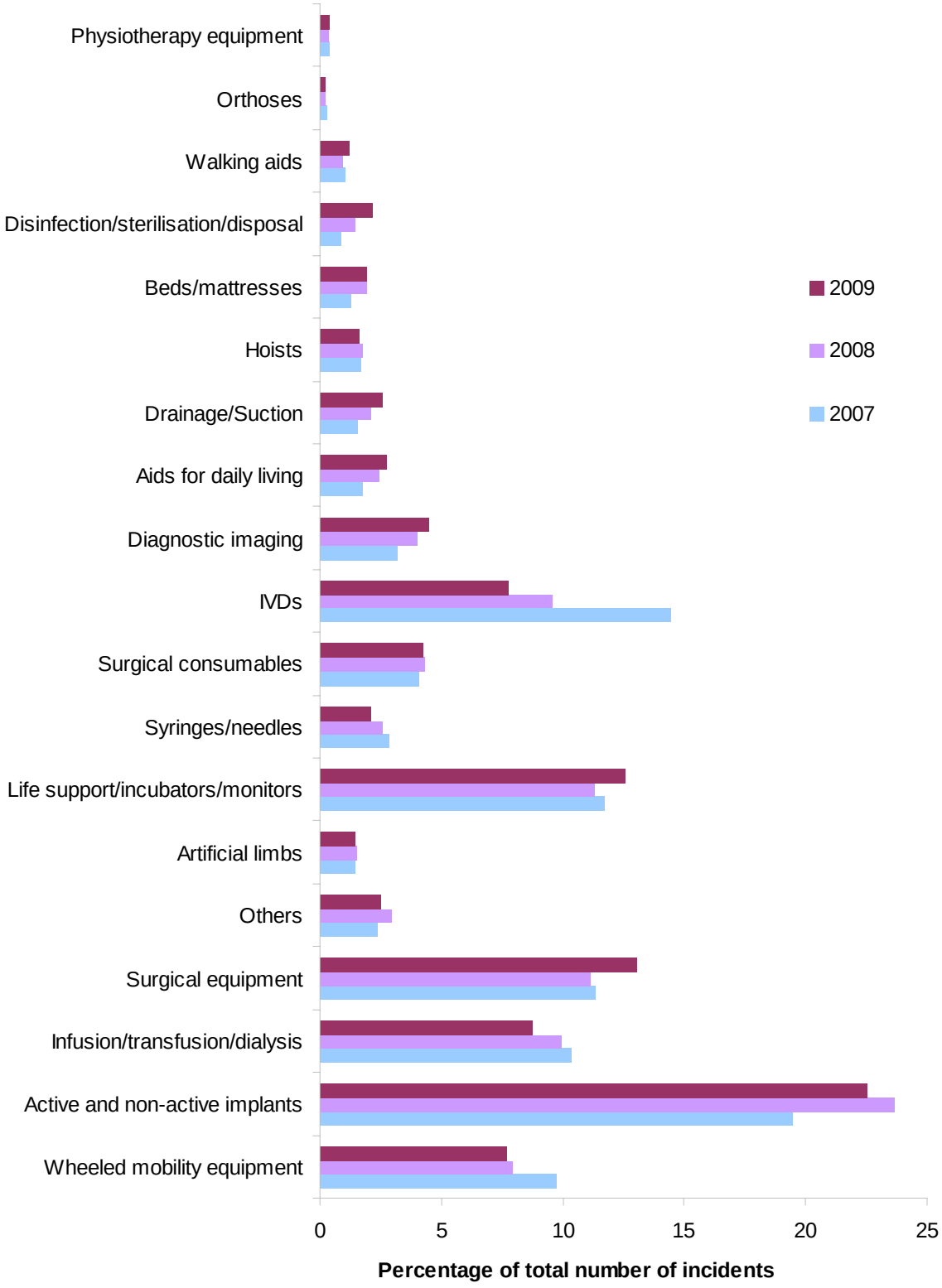
For the purpose of providing a simple illustration of trends in reporting of incidents relating to specific device types, related devices have been grouped together. Figure 5 illustrates these trends over the last three years.

These figures do not take account of reports submitted within periodic summary reports (PSRs). As the use of PSRs is increasing (see Section 1.2 above), this chart will be modified for future reports.

The Assistive Technology Unit saw an increase in reports on walking aids, aids to daily living and mattresses. The number of reports on wheelchairs held steady and for once did not continue the trend of declining numbers seen in recent years. Overall the numbers of reports continues to be low when compared to the increasing elderly population in combination with the move towards the increasing use of assistive technology to help people retain their independence in their own home.

The increase seen in the diagnostic imaging category was primarily due to the number of reports of relatively minor issues submitted to MHRA during the course of a radiotherapy clinical investigation.

Figure 5 Incident reports by device group 2007 – 2009

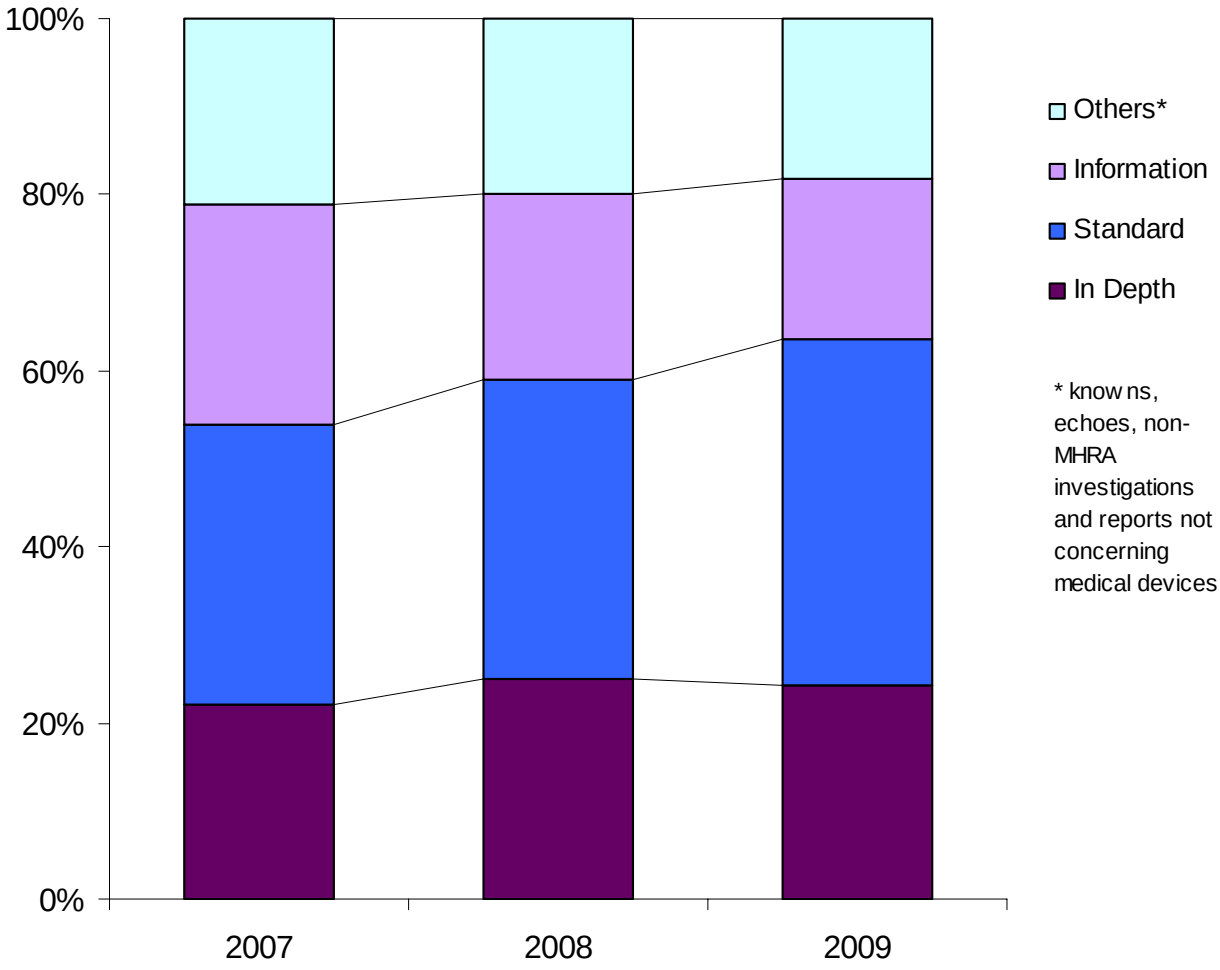


4.6 Investigation levels

Our structured adverse incident risk assessment process determines the level of investigation pursued for each adverse incident report received. As this system has a pivotal role, it is subject to scrutiny by our medical device specialists and the Devices Clinical team, as well as to routine review by our Technical Management Group.

The only significant change in 2009 was in the proportion of reports pursued through standard investigations, which rose to 39%. The consequent falls were to the numbers of incident reports recorded for 'information only' and those that were investigated by other organisations.

Figure 6 Investigation level assigned as percentage 2007 – 2009



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.

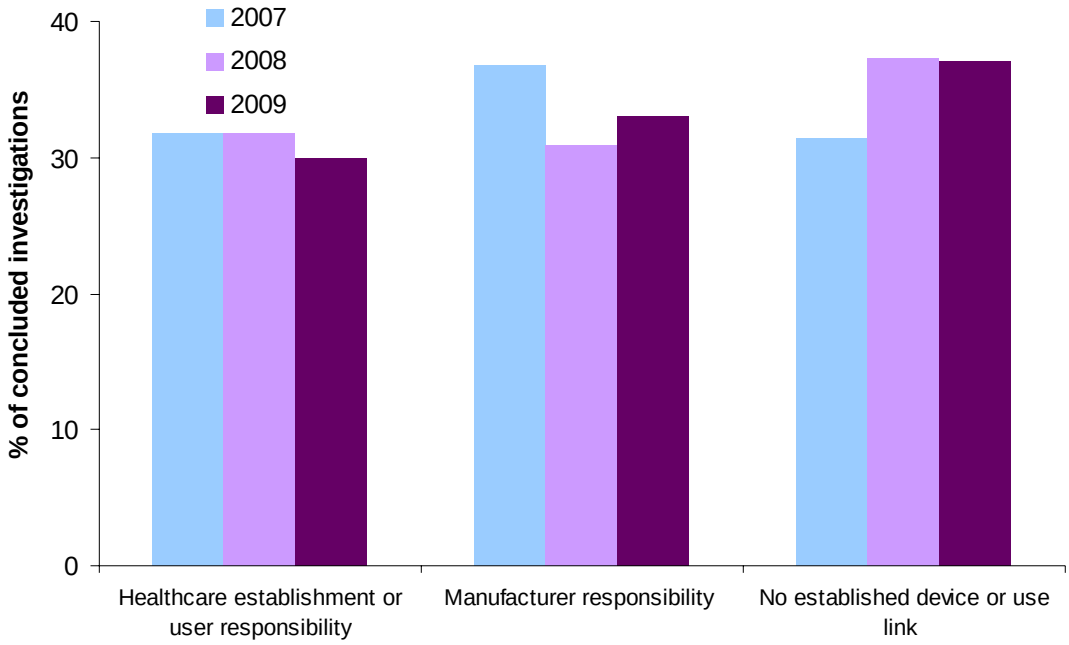
• **Healthcare establishment/user responsibility**
After delivery e.g. performance and/or maintenance failures and degradation.

• **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 frequently discarded by the user before any investigation can take place.

Figure 7 Causes of adverse incidents 2007 – 2009: percentage of concluded incident investigations



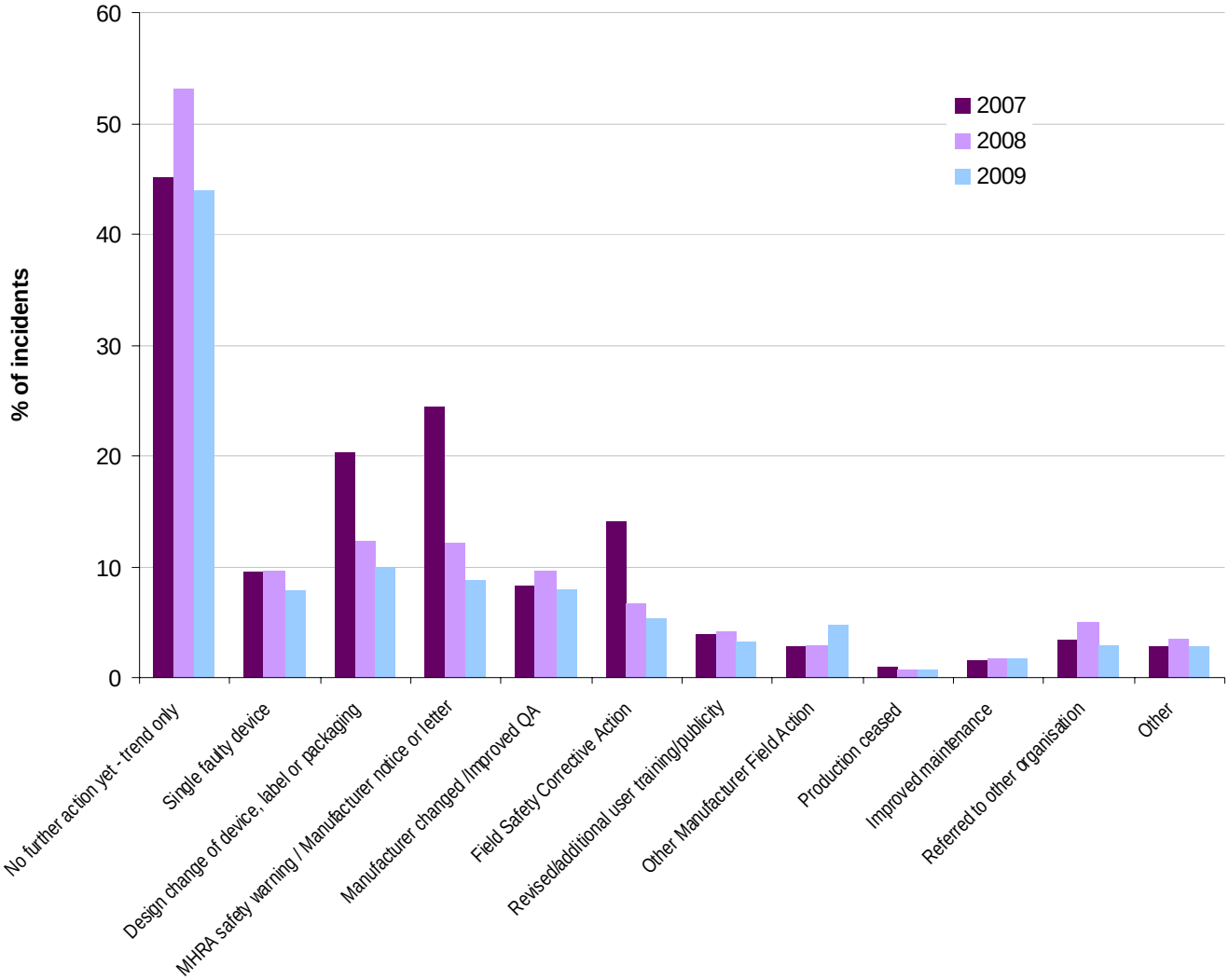
4.8 Investigation outcomes

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.

As noted last year, we have seen regular fluctuation in the percentage of incidents where no further action was taken beyond the initial investigation, and where the details were retained for ongoing trend analysis only. Since 2005 this has varied from 47% in 2005, to 58%, 45% and 53% in subsequent years, before coming back down to 44% last year.

Figure 8 Investigation outcomes 2007 – 2009



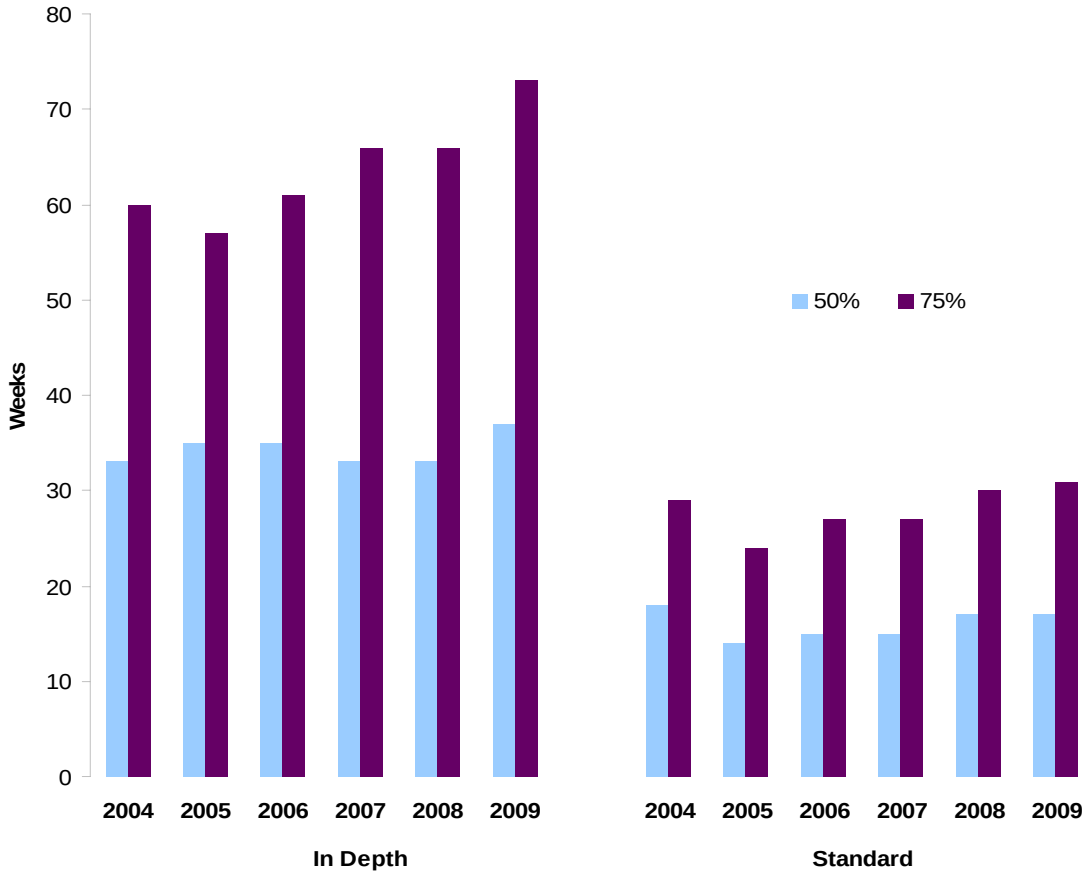
4.9 Investigation durations

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.

Specifically, in 2009 50% of 'standard' and 'in depth' investigations were concluded in 17 weeks (17 in 2008) and 37 weeks (33) respectively. 75% of 'standard' and 'in depth' investigations were concluded within 31 weeks (30) and 73 (66) weeks respectively.

The figures for in depth investigations were largely skewed as a result of a concerted effort by one of the DTS specialist units to bring to a successful conclusion a number of lengthy investigations. The six year time series in Figure 9 illustrates this clearly: for in depth investigations, the 2009 figure is markedly different from previous years.

Figure 9 Time taken for conclusion of incident investigations 2004 – 2009



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. MDAs may also be used to provide updated information. Each Medical Device Alert is given one of the following categories:

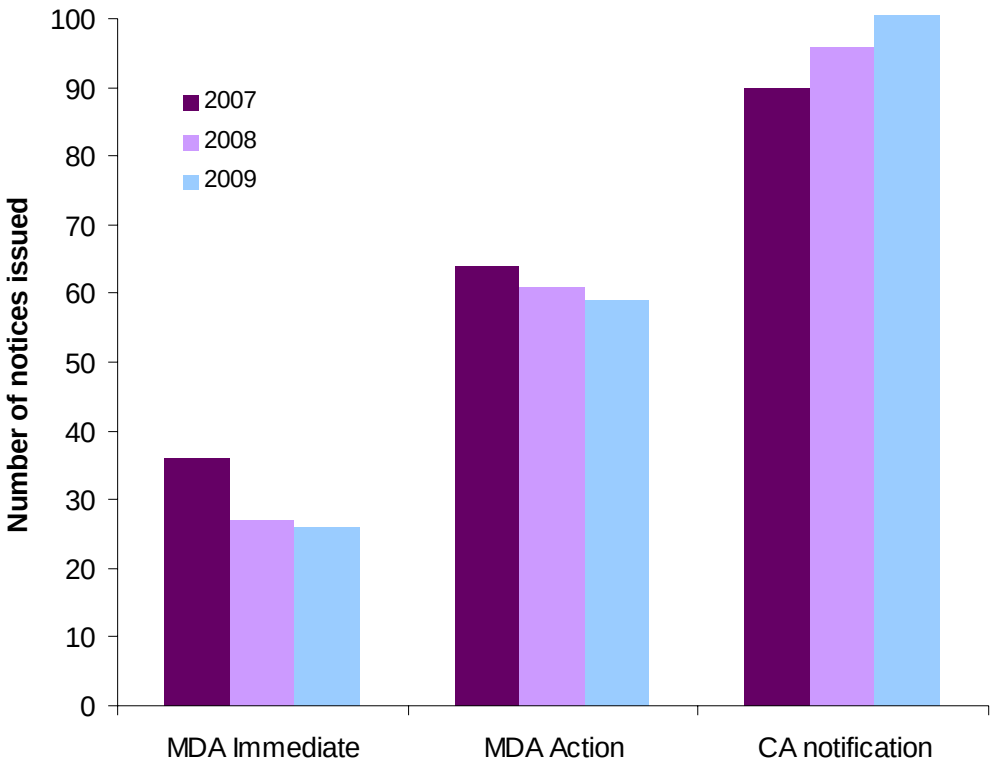
- Immediate action
- Immediate action update
- Action
- Action update

The number of MDAs issued between 2007 and 2009 is shown below in Figure 10. Of the total 85 MDAs issued in 2009, 26 were designated as 'Immediate action' and 59 as 'Action'. These figures include updates and information requests.

Further information on some of these alerts is provided in Section 3. All MDAs are published on the MHRA website.

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 and CA notifications issued 2007 – 2009



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 the 'reply paid' format ensures that there is no cost to the respondent. 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 2009 around 2,500 in depth and standard investigations (excluding 'knowns' and 'echoes') were concluded. Unfortunately, the 20% sample (approximately 500 surveys despatched) elicited just 125 returns – far fewer than in previous years. The number of responses received relating to 'in depth' investigations was approximately one third that received for 'standard' investigations.

We have for some time been considering the introduction of an electronic version of the survey form, to be sent and returned by email. A brief trial of this early in 2010 produced very promising results. Further work on this will be undertaken as and when our resources allow.

Analysis of the responses received shows continued high levels of satisfaction with our performance. There are three key areas that we routinely highlight in Figures 11, 12 and 13 below:

Conduct of investigation
Satisfaction level rose from 86% to 94% for 'in depth' investigations and dropped from 92% to 89% for 'standard' investigations

Level of communication
Satisfaction level rose from 87% to 94% for 'in depth' investigations and dropped slightly to 93% (from 94%) for 'standard' investigations

Speed of investigation
Satisfaction level rose from 77% to 82% for 'in depth' investigations and from 83% to 85% for 'standard' investigations

The proportion of respondents concluding that the MHRA investigation and action had reduced the risk of recurrence of the type of incident reported was 79% – a much higher figure than in recent years.

The percentage indicating that, as a result of the investigation, they were more likely to report incidents in the future was also higher. This figure rose to 89%.

Figure 11 Percentage satisfaction with conduct of investigation 2007 – 2009

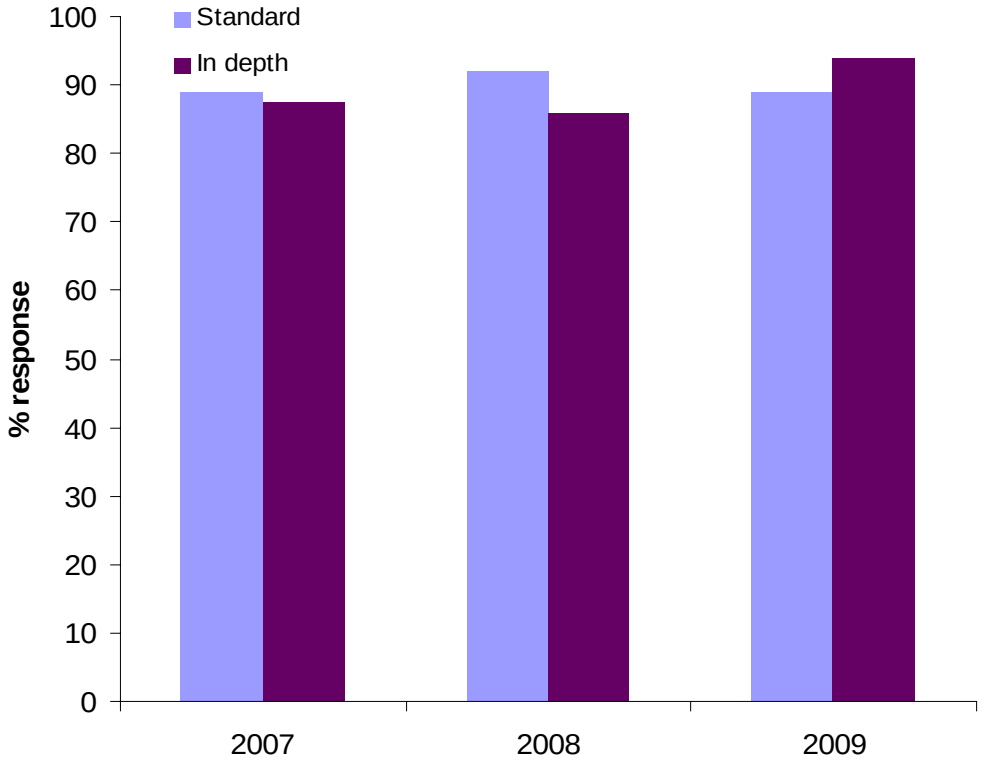


Figure 12 Percentage satisfaction with level of communication 2007 – 2009

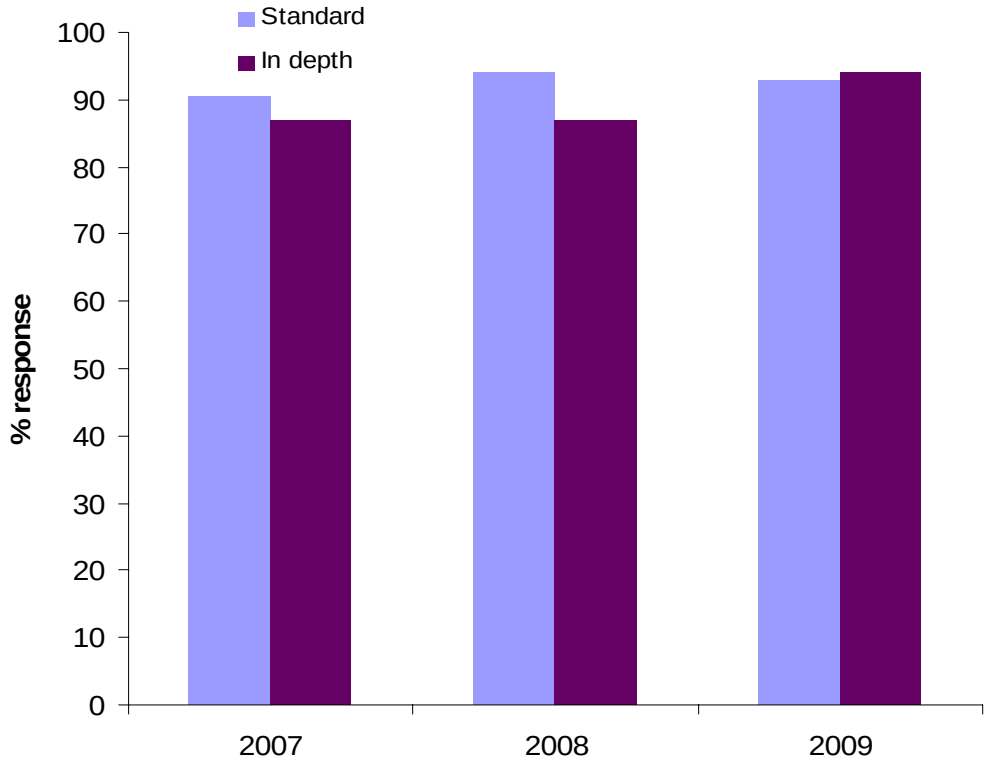
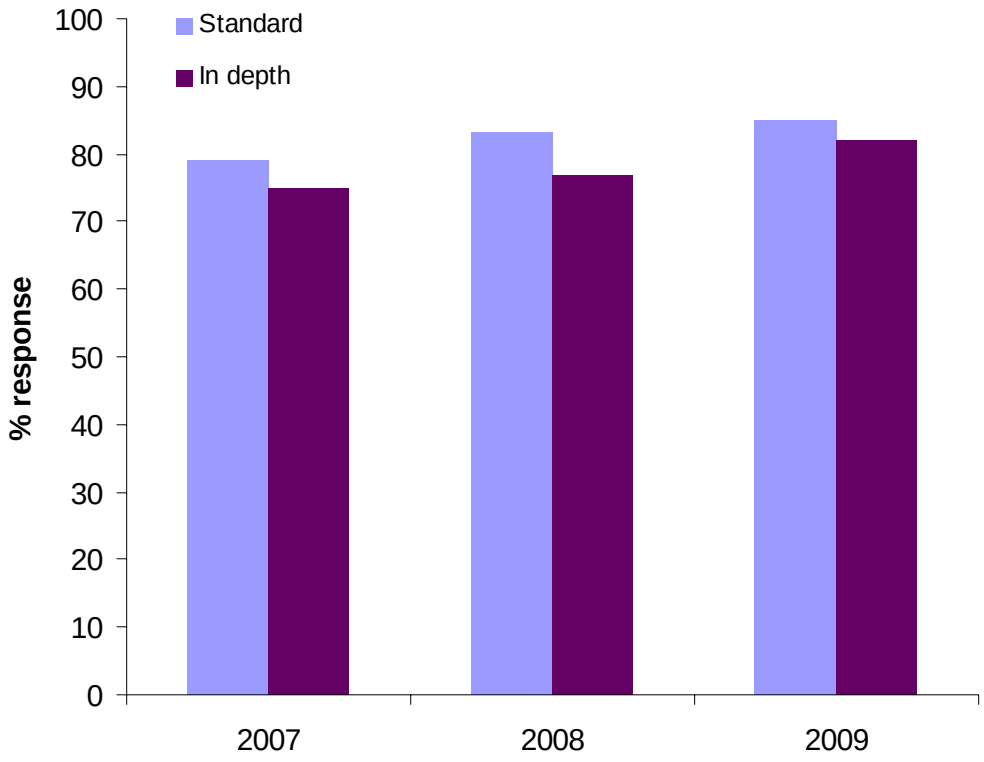


Figure 13 Percentage satisfaction with speed of investigation 2007 – 2009



5.3 Questionnaire

MHRA Device Technology & Safety Adverse Incident Investigation Quality of Service Survey 2009

Please help us to improve the quality of service we provide by giving us your valuable feedback. Individual responses will remain confidential to the MHRA. No stamp is required for your response, just fold the form as indicated and post.

Please answer Questions 1 - 6 about incident reference number / / / /
If you wish to make general comments about our handling of adverse incident reports and investigations, please use the General Comments section (Section 7 at the foot of the page).

1. How is your role best described? (please tick one)

☐ Clinician	☐ Member of public	☐ Rehab engineer
☐ Clinical / biomedical scientist	☐ Nurse	☐ Supplies officer
☐ Dentist	☐ Pharmacist	☐ Surgeon
☐ Engineer	☐ Physicist	☐ Technician
☐ General practitioner	☐ Radiographer	☐ Therapist
☐ Manager / administrator	☐Other – please specify:	

2. Are you also an MHRA Medical Device Liaison Officer? ☐ Yes ☐No

3. Are you satisfied with: (please circle one) 1= totally dissatisfied, 5 = totally satisfied

The way the investigation was conducted?	1	2	3	4	5
The speed of the investigation?	1	2	3	4	5
The level of communication from MHRA on this investigation?	1	2	3	4	5

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. Could MHRA usefully have done more? ☐Yes ☐ No

If Yes, please indicate how:

☐ Giving technical advice?	☐ Ensuring rapid device collection by the manufacturer?
☐ Giving training advice?	☐ Greater thoroughness of investigation?
☐ Assessing the risks involved?	☐ Giving advice on reporting procedures?
☐ Other (please specify)	

7. General comments

If you have any questions about this survey, please contact the MHRA (Devices) Adverse Incident Centre on:
Tel: 020 7084 3080 Fax: 020 7084 3109 E-mail: 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.

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