Device Bulletin

Adverse Incident Reports 2007

DB2008(02)
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Contents

1 Introduction ..........................................................................................................................3
   1.1 Adverse incident reports 2007 .....................................................................................3
   1.2 Online reporting systems .........................................................................................5
   1.3 National Patient Safety Agency (NPSA) ..................................................................6
   1.4 Medical device liaison officers (MDLOs) .................................................................6
   1.5 Safety Alert Broadcast System (SABS) ..................................................................7
   1.6 Field Safety Notices and Field Safety Corrective Actions ........................................8
   1.7 Devolved administrations .........................................................................................9
   1.8 European and global co-operation ..........................................................................9
   1.9 Haemovigilance ......................................................................................................10

2 Reporting and investigation of adverse incidents .........................................................11
   2.1 Reporting procedures ..............................................................................................11
   2.2 Devices retained or submitted for examination .......................................................12
   2.3 Defining an adverse incident ..................................................................................13
   2.4 Reasons for reporting adverse incidents .................................................................13
   2.5 Recording and investigating incident reports .........................................................14
   2.6 Investigation levels ..................................................................................................15
   2.7 Maintaining contact with the reporter .....................................................................17
   2.8 Investigation teams ..................................................................................................17
   2.9 Safety warnings and the Safety Alert Broadcast System .........................................20

3 Review of activity in DTS specialist technical units .....................................................21
   3.1 Biosciences and Implants (B&I) ..............................................................................21
   3.2 Imaging and Acute Care (I&AC) ..............................................................................23
   3.3 Assistive Technology (AT) ......................................................................................26

4 Statistics ..............................................................................................................................29
   4.1 Trends in adverse incident reporting .......................................................................29
   4.2 Vigilance cases .........................................................................................................30
   4.3 Report sources .........................................................................................................31
   4.4 Online reporting ......................................................................................................32
   4.5 Incident reports by device group ............................................................................33
   4.6 Investigation levels ..................................................................................................35
4.7 Causes of adverse incidents ....................................................36
4.8 Investigation outcomes ............................................................37
4.9 Investigation durations .............................................................38
4.10 Safety notices issued .............................................................39

5 Customer survey ..........................................................................40
5.1 Conduct of survey ....................................................................40
5.2 Response and satisfaction levels .............................................40
5.3 Questionnaire...........................................................................44
1 Introduction

This medical device adverse incident annual report, published as Device Bulletin DB2008(02), provides an overview of medical device related adverse incident reports received by the MHRA in 2007, and records recent developments in adverse incident reporting.

There are also reports from the Device Technology and Safety (DTS) division’s three specialist technical units, along with background information on incident reporting procedures, a summary of the year’s key statistics, and a brief analysis of customer survey responses.

The format of this report has remained fairly constant over time. This allows a considerable degree of comparison with earlier years’ data. However, as the quality and breadth of data develops new features may be added and existing features revised.

Revised and updated guidance on reporting adverse incidents and disseminating MHRA safety guidance was published on the MHRA website as Device Bulletin DB2008(01) towards the end of January 2008. The document is available to download and print.

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

1.1 Adverse incident reports 2007

In 2007 the MHRA received 8.26% more adverse incident reports than in the previous year. The 8,634 total for 2007 is almost at the peak levels seen during 2002-2004, and is 19% higher than the total for 2000.

The 2007 total includes 18 Periodic Summary Reports submitted by device manufacturers. Periodic Summary Reporting is an alternative reporting regime that may be agreed between the MHRA (the competent authority) and a device manufacturer. Such an agreement allows consolidation of reporting of similar incidents with the same device or device type where the incident root cause is already known, or a FSCA (Field Safety Corrective Action) has been implemented. In 2007 an additional 3,506 incidents were reported in this way.

<table>
<thead>
<tr>
<th></th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incident reports received</td>
<td>7,896</td>
<td>8,756</td>
<td>8,803</td>
<td>8,840</td>
<td>7,862</td>
<td>7,975</td>
<td>8,634</td>
</tr>
<tr>
<td>% change over previous year</td>
<td>+8.9</td>
<td>+10.9</td>
<td>+0.5</td>
<td>+0.5</td>
<td>-11.0</td>
<td>+1.14</td>
<td>+8.26</td>
</tr>
</tbody>
</table>
The table below compares figures for 2007 with those from 2006.

<table>
<thead>
<tr>
<th>Description of reports or action taken</th>
<th>2006</th>
<th>%</th>
<th>2007</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were reported as involving a fatality</td>
<td>184</td>
<td>2.3</td>
<td>193</td>
<td>2.2</td>
</tr>
<tr>
<td>Were reported as involving a serious injury (including implant or pacemaker revision)</td>
<td>1,197</td>
<td>15.0</td>
<td>1,093</td>
<td>12.7</td>
</tr>
<tr>
<td>Prompted in-depth MHRA investigations</td>
<td>2,127</td>
<td>26.6</td>
<td>1,872</td>
<td>21.7</td>
</tr>
<tr>
<td>Were investigated by manufacturers under MHRA supervision</td>
<td>2,279</td>
<td>28.6</td>
<td>2,754</td>
<td>31.9</td>
</tr>
<tr>
<td>Did not require immediate MHRA action, but were entered onto a database enabling trend monitoring and pattern detection</td>
<td>1,804</td>
<td>22.6</td>
<td>2,031</td>
<td>23.5</td>
</tr>
<tr>
<td>Were reports of incidents similar to those already known to the Agency</td>
<td>1,023</td>
<td>12.8</td>
<td>1,311</td>
<td>15.2</td>
</tr>
<tr>
<td>Were from secondary report sources, duplicating existing reports</td>
<td>415</td>
<td>5.2</td>
<td>370</td>
<td>4.3</td>
</tr>
<tr>
<td>Did not relate to medical devices</td>
<td>106</td>
<td>1.4</td>
<td>76</td>
<td>0.9</td>
</tr>
<tr>
<td>Were investigated by other organisations and their conclusions made available to the MHRA</td>
<td>257</td>
<td>3.2</td>
<td>259</td>
<td>3.0</td>
</tr>
</tbody>
</table>

The table shows that whilst the overall number of incidents reported increased quite significantly, the proportion of those reports that involved a serious injury or a fatality showed a further reduction over last year’s figures.

In 2007, MHRA medical device specialists completed 100 investigations of adverse incidents reported as involving a fatality. In 70 of these they were able to conclude that there was no established link between the fatality and the device(s) involved in the incidents.

The following actions were taken as a result of investigations made:

- 100 Medical Device Alerts (MDAs) were issued
- 86 notifications were shared with Competent Authorities in EU member states
- 674 manufacturer’s field safety corrective actions and 92 other manufacturer’s field actions were undertaken
- 206 cases requiring the provision of advice on safer device use or improved staff training were identified
• 397 manufacturer undertakings to improve designs, manufacturing processes and quality systems.

1.2 Online reporting systems

The MHRA’s two medical device adverse incident online reporting systems continue to play a significant part in reporting activity. In particular there has been a significant growth in the number of reports received online via the MORE (Manufacturers’ Online Reporting Environment) system. Although the number of online reports received from medical device users has shown a small decrease, this mirrors the decrease in the actual number of reports received from device users. The percentage of user reports submitted online has continued to rise - from 68.5% in 2006 to 72% in 2007.

Both 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.

MORE II, an enhanced version of the Manufacturers’ Online Reporting Environment, was launched in February 2008. The new version provides a number of additional facilities for registered MORE reporters:

• **Folder Manager:** by creating and naming folders within the MORE Workspace and by moving reports to and between those folders, MORE reporters can organise and archive their reports

• **Sharer Manager:** ‘sharing’ enables MORE reporters to share the contents of their Workspace report folders with other registered MORE users

• **XML Manager:** from mid-2008, MORE II will include a trial of XML based electronic data exchange between manufacturers and Competent Authorities, using internationally compliant forms for submission of different report types.
1.3 National Patient Safety Agency (NPSA)

The NPSA’s National Reporting and Learning System has now been implemented across the NHS. This system allows reporting of patient safety incidents and near misses, with the aim of ensuring that lessons are both learned and shared throughout the health service.

The MHRA continues to work alongside the NPSA with the aim of mutually beneficial development of our reporting systems, with the common goal of maximising our effectiveness in preventing harm arising from the use of medical devices. Analysis of data from a sample of hospitals has revealed some under-reporting to both organisations and has confirmed the need to work towards a single reporting route.

In October 2007 Lord Darzi, in the interim report of the NHS Next Stage Review, announced the desire to support the NPSA in establishing a 24 hour, single point of access for healthcare workers to report safety incidents: Patient Safety Direct. The MHRA supports this proposal and will be working with NPSA to guide the design of Patient Safety Direct to deliver to all parties all the potential benefits that such a single reporting route can offer.

The MHRA has secured funds from the Department of Health to proceed with a number of improvements to the MHRA’s medical device adverse incident reporting and management system. Proposals, developed following consultations with medical device liaison officers and risk managers, include the creation of links with local risk management systems, in a similar manner to NPSA. However, it is possible that the Patient Safety Direct initiative might provide an alternative means of achieving this.

1.4 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. Their role continues to develop alongside that of the NPSA’s patient risk managers and local risk management systems. They are also closely involved with the Safety Alert Broadcast System (SABS – see below) and have their own homepage on the MHRA website, which provides guidance and information about the MHRA and the liaison officer role.

We have a liaison officer focus group (LOFG) that comprises a cross-section of liaison officers drawn from NHS acute, community 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 (held at least once a year) can be found on the liaison officer homepage on the MHRA website.
The sixth national Medical Device Liaison Officer Conference ‘Reporting Matters’ took place on Friday 2 November 2007 in London. Almost 200 delegates, guests and professionals from all areas of the NHS, social care and the private sector attended the conference. Speakers included representatives from the MHRA, NHS trusts, Cardiff University School of Nursing and Midwifery Studies and the National Wheelchair Managers Forum (NWMF).

For the third time an audience response system was used during conference presentations. As this direct communication between the speakers and the conference attendees was again very positively received, it is likely to be retained for future conferences.

1.5 Safety Alert Broadcast System (SABS)

SABS is an electronic system developed by the Department of Health, which is used to distribute our agency’s Medical Device Alerts (MDAs) to all NHS trusts and primary care trusts in England. SABS 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.

In 2007 we issued 100 MDAs to SABS liaison officers. The SABS liaison officer ensures onward local distribution of the alert and updates feedback on action taken on the SABS website (www.info.doh.gov.uk/sar/cmopatie2.nsf). Strategic health authorities use SABS to monitor receipt and completion of the action required in the MDA.

During 2007 the Department of Health commissioned two studies, to which the MHRA provided input, of relevance to the further development of the SABS system:

- a research study on the implementation of alerts issued via the SABS system, the main findings of this study were presented at our 2007 Medical Device Liaison Officer conference. One strand of feedback to this study was support for pulling together the Public Health Link (this system is currently used by the MHRA to issue Drug Alerts) and SABS systems.
- a major stakeholder requirements exercise to produce a design specification for the development of a Central Alerting System to bring together the Public Health Link and SABS systems. Potentially this would create a single system for alerting healthcare establishments of medical device, medicines, DH, patient safety and estates alerts. Development of the system is expected to continue in 2008.
1.6 Field Safety Notices and Field Safety Corrective Actions

Field Safety Notices (FSNs) are used by manufacturers to inform their customers about Field Safety Corrective Actions (FSCAs) taken by them (the manufacturer) to reduce the risk of death or serious injury from adverse incidents. These are usually, but not exclusively, prompted by investigations of adverse incidents reported by medical device users, and relate particularly to those MHRA and/or manufacturer investigations which 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, etc.

The EU Medical Devices Directives legally oblige manufacturers not only to carry out such corrective actions, but also to alert the National Competent Authority (in the UK this is the MHRA) about any corrective actions affecting their products that have been distributed within the UK.

The MHRA risk assesses and investigates each FSCA and determines whether the manufacturer’s proposed action is both relevant to the UK and sufficient to protect UK public health. On most occasions it is, and the MHRA will then monitor progress to ensure that it is completed. This approach helps to minimise the need to issue Medical Device Alerts.

**FSCAs on the MHRA website** Medical device manufacturers’ FSNs are now routinely placed on the MHRA website for information. MHRA medical device liaison officers are not expected to treat FSNs in the same way as Medical Device Alerts.

Action or direct feedback will only be required when an associated Medical Device Alert has been issued or an FSN has been received directly from the manufacturer or supplier.

We routinely update the status of FSCAs on our website. This provides greater transparency of our ongoing assessment of the FSCA and associated FSNs. The status updates show whether the:

• FSCA is currently being assessed and that further advice may be issued later
• FSCA has been assessed and the MHRA does not intend to issue further advice
• FSCA has been assessed and the MHRA has issued further advice

It is possible to register on the MHRA website to receive e-mailed updates whenever the FSN/FSCA web pages are updated.
The FSN facilities were developed in close collaboration with medical device and SABS liaison officers and also support wider initiatives to improve transparency of the European medical device vigilance system. Similar facilities have been introduced on the websites of several other national Competent Authorities, including those in Germany, France, and Switzerland.

1.7 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.

Since an announcement in 2004 in Welsh Assembly circular MDA/2004/054, all hazardous medical device related incidents occurring in Wales are now reported directly to the MHRA, with a copy of the report being sent to the Surgical Materials Testing Laboratory (SMTL). The MHRA undertakes all necessary incident investigations and advises the Welsh Assembly Executive where appropriate. All non-hazardous reports/defects continue to be reported directly to SMTL and the Welsh Assembly Government continues to issue its own Medical Device Alerts.

1.8 European and global co-operation

This year the European Commission published revised and updated ‘Guidelines on a medical devices vigilance system’ for medical device manufacturers (MEDDEV 2.12-1 rev 5). The MHRA provided significant input to meetings of the European vigilance experts that developed the document.

The guidance now covers:

- Manufacturers’ Field Safety Corrective Actions (recalls)
- the content and structure of manufacturers’ Field Safety Notices
- improved co-ordination and exchange of data by EU competent authorities
- the role of the European Commission and Notified Bodies within the vigilance system
- electronic exchange of vigilance data.

The guidance is also of direct relevance to any healthcare establishments that may be involved in the manufacture of medical devices.

The new document is more comprehensive, clearer and easier to use, and harmonises well with the wider, international Global Harmonisation Task Force vigilance guidance.
Since late 2007 the MHRA has been hosting a number of conferences and workshops to promote this revised guidance to UK based medical device manufacturers.

### 1.9 Haemovigilance

The Adverse Incident Centre’s haemovigilance team continues to manage SABRE, the haemovigilance incident online reporting system. During 2007 the team completed the first annual summary report exercise. In June 2008 this will be taken a stage further with the submission of an overall UK summary report to the EU Commission.

Enhancement of SABRE was concluded in mid-2007 with the implementation of the Workspace Folder Manager and search facilities. Further development of the SHOT interface is still planned. This remains subject to specification and direct contracting by SHOT.

The haemovigilance team continue to work closely with SHOT, NPSA, the MHRA’s own Blood Consultative Committee (BCC), and the BCC’s Adverse Events sub-Committee. Future plans include expansion of the haemovigilance team and the creation of an Expert Group to support the team’s routine review of reported events and reactions.
2 Reporting and investigation of adverse incidents

2.1 Reporting procedures

The MHRA Adverse Incident Centre regularly produces comprehensive background and procedural guidance on reporting medical device related adverse incidents. The most recent guidance document was published as Device Bulletin DB 2008(01) Reporting Adverse Incidents and Disseminating Medical Device Alerts. This includes a helpful, single page ‘quick reference guide’ highlighting key points. This Device Bulletin 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 e-mail: 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 local 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 positively encourages reporters to use our preferred reporting method, the online reporting system available through the MHRA website www.mhra.gov.uk although paper forms are still readily accepted by post or fax.

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

Depending on the nature and location of the incident, other organisations may also need to be involved following an adverse incident. This includes both the separate arrangements for reporting medical device related adverse incidents in Scotland and Northern Ireland, and the arrangements for reporting non-hazardous incidents in Wales to the Surgical Materials Testing Laboratory in Bridgend, Wales. Contact details for each of the devolved administrations can be found in DB 2008(01).

Other organisations that may need to be contacted include the National Patient Safety Agency, the Health and Safety Executive, DH Estates &
Facilities, or the medicines and blood safety sectors of the MHRA. Further information and contact details for these bodies are also included in DB 2008(01).

2.2 Devices retained or submitted for examination

All items that have been involved in incidents should be quarantined. 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 2008(01). This includes dealing with the manufacturer and, when appropriate, decontamination, returning devices and dealing with devices required for continued use.

Devices that have been involved in an incident should not be submitted to the MHRA unless specifically requested.

Despite clear procedural advice being given, some devices are 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 have to be made for further decontamination prior to commencement of any investigation. This causes unnecessary delay in the investigation process.

Device Bulletin DB2003(05) Management of Medical Devices Prior to Repair, Service or Investigation (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

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of devices received</th>
<th>Number requiring decontamination</th>
<th>% requiring decontamination</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>827</td>
<td>254</td>
<td>30.7</td>
</tr>
<tr>
<td>2004</td>
<td>289</td>
<td>17</td>
<td>5.9</td>
</tr>
<tr>
<td>2005</td>
<td>125</td>
<td>27</td>
<td>21.6</td>
</tr>
<tr>
<td>2006</td>
<td>136</td>
<td>27</td>
<td>19.9</td>
</tr>
<tr>
<td>2007</td>
<td>37</td>
<td>9</td>
<td>24.0</td>
</tr>
</tbody>
</table>

Strengthened advice on submitting devices to us and on the need for prior decontamination, has ensured that the fall in the number of devices submitted to MHRA in recent years has continued.
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
- misdiagnosis due to 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
- 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 hospitals may not be suitable for 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. Our Agency is concerned that users should report all incidents, regardless of whether actual harm has or has not 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 around the world. 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 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 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.
In 2007 more than 50% of all adverse incidents reported were recorded on our database and available for our medical device specialists to review on the same day that they were received. Within a further 24 hours that percentage rises to over 75%. For the remainder, data input was completed within five days. Priority is always given to reports involving a death or serious injury and to those concerning implant revision.

Routine internal review continues to show that our high standards of data input speed and accuracy continue to be met.

Once on AITS and available to the medical device specialists working within our Device Technology and Safety directorate, 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 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 follow 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 (1,872 in 2007) may involve:

- contact with the device user and manufacturer
- a visit to the site of the incident
- testing of the device involved (either by our own test facilities, by an independent test house or by the manufacturer).

It is these investigations that typically lead our agency to issue a Medical Device Alert.

‘Standard’ investigations will usually follow incidents where there is a minor injury or no injury (and that had a low potential for more serious injury).

Generally, these incidents are investigated most effectively by the manufacturer of the device. In 2007 we managed the investigation of 2,754 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 2007 there were 2,031 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 particular problem with a particular type of device. Of the reports received in 2007, there were 1,311 linked in this way to ongoing investigations.

From late 2003 a new report category was introduced. This categorised certain reports as ‘echo’ reports (370 in 2007). These are duplicate reports of a specific incident of which the AIC has 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 259 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 (76 in 2007) did not involve medical devices. These are recorded as ‘non-MHRA (Devices)’ and were referred, as appropriate, to other bodies such as DH Estates & Facilities or the Health & Safety Executive. A further 57 reports were referred to our 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. It is here, in this process of routine and ad hoc trend analysis, that the proposed use of new data management and manipulation tools will be of great value.

At all stages of all investigations, the available adverse incident report information is subject to regular review. This process of reviewing all investigations 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 division (on clinical aspects of the
incident, including the way the device was used), and the Committee on Safety of Devices or our register of experts.

### 2.7 Maintaining contact with the reporter

As soon as possible after receipt of a report the AIC ensures that the incident reporter receives a formal acknowledgement including a unique MHRA incident reference number. That acknowledgement is accompanied by a short information note that summarises and explains our adverse incident investigation processes. In 2007, well over half (65%) of report acknowledgements were sent out within a day of the report being received. Overall, 99% were despatched within 5 days. Where possible, these acknowledgements and all subsequent correspondence are sent to the reporter by e-mail.

Every online reporter receives an immediate automatic ‘on-screen’ acknowledgement that includes the incident reference number.

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 who forward to the MHRA reports they have received via local reporting systems, are encouraged 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 the progress and outcome of our investigations.

In addition, after conclusion of an 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.

MHRA is also considering how (subject to resource availability) we might design and develop systems that would allow medical device liaison officers and other reporters to track the progress of incident report investigations online.
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; technical advice to support regulatory colleagues during compliance investigations and notified body assessments; technical advice to the Centre for Evidence-based Purchasing, part of NHS Purchasing and Supply Agency.

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. The DTS Services team provides support across all areas. Current responsibilities are set out below.
<table>
<thead>
<tr>
<th>DTS unit</th>
<th>Product areas</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Biosciences &amp; Implants</strong></td>
<td>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.</td>
</tr>
<tr>
<td><em>(B&amp;I)</em></td>
<td></td>
</tr>
<tr>
<td><strong>Imaging &amp; Acute Care</strong></td>
<td>Diagnostic imaging and measurement, breathing systems and anaesthetic machines, infusion, dialysis, special care baby equipment, therapy and surgical devices.</td>
</tr>
<tr>
<td><em>(I&amp;AC)</em></td>
<td></td>
</tr>
<tr>
<td><strong>Assistive Technology</strong></td>
<td>Mobility aids, moving and handling systems, posture management, pressure management, communication and hearing aids, beds, environmental controls, and aids for daily living.</td>
</tr>
<tr>
<td><em>(AT)</em></td>
<td>UKAS accredited laboratory for testing wheelchairs and artificial limbs.</td>
</tr>
<tr>
<td></td>
<td>MHRA's device decontamination laboratory.</td>
</tr>
<tr>
<td><strong>Adverse Incident Centre</strong></td>
<td>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.</td>
</tr>
<tr>
<td><em>(AIC)</em></td>
<td>Development and maintenance of adverse incident online reporting systems, databases and website content.</td>
</tr>
<tr>
<td><strong>DTS Services</strong></td>
<td>Provide a range of business and administrative support services to all DTS units. They also manage the Medical Device Liaison Officer system and the issue and distribution of Medical Device Alerts.</td>
</tr>
<tr>
<td><em>(DS)</em></td>
<td></td>
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</tbody>
</table>
2.9 Safety warnings and the Safety Alert Broadcast System (SABS)

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

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.

The front page of the Alert shows clearly: the device involved, the action required, a summary of the problem, who is affected by it, and the level of urgency. Each Alert is assigned one or more of the following categories:

- Immediate action
- Action
- Update
- Information request

The Safety Alert Broadcast System (SABS) is the primary method of distributing MDAs to all NHS trusts (including primary care trusts) in England via SABS liaison. The liaison officer then ensures onward distribution of the alert and records the action taken on SABS. All Medical Device Alerts are also placed on the MHRA website. Further information of SABS is provided in section 1.5 above.
3 Review of activity in DTS specialist technical units

3.1 Biosciences and Implants (B&I)

Staff in the unit have a wide range of technical expertise that includes materials and biomaterials science, biomedical and clinical science, microbiology, clinical biochemistry, molecular biology, sterilization and textile technologies, biotechnology, electronic and mechanical engineering and medical physics.

The wide range of devices within our remit extends across the scope of all three of the medical devices directives: active implantable, general and in vitro diagnostic medical devices.

In 2007 the Biosciences and Implants unit received 3,676 reports of individual adverse incidents. A further 3,506 additional events were included in 18 summary reports of multiple incidents. Out of the total of 7,182 incidents, 1,800 were individually investigated: the remainder were investigated in trending and surveillance.

All reports were subject to a range of trending activities to identify any problems that might otherwise be overlooked. The most significant issues identified during our investigations are highlighted below.

**Sterilization and decontamination of medical devices**

Incidents received during 2007 include packaging failures during the manufacturing process which compromise sterility of the device and failure of the sterilization process damaging the device itself. We continue to receive reports from healthcare staff about inappropriate reprocessing instructions and issues with automated washer disinfectors for general instruments and those for endoscopes.

We produced two related Medical Device Alerts concerning the use of ultraviolet light affecting endoscopes during storage in certain drying cabinets. We also issued a targeted letter to some hospitals reminding them of the issues of mutual compatibility between medical devices and the specifically identified sterilization process.

**In vitro diagnostic medical devices (IVDs)**

We published seven MDAs relating to point of care tests and home tests for coagulation and glucose monitoring and pregnancy testing.

We received reports of possible false negative results on pregnancy test strips and issued an MDA to support the manufacturers’ action to recall the affected strips. We continue to monitor for incidents of false results with pregnancy tests. We also issued alerts to support field safety corrective actions for a coagulation D-Dimer assay and urine test strip devices.
Back in 2003 we issued a medical device alert to warn of the potential for falsely elevated results when using particular blood glucose meters on patients receiving treatments that contained, or could be metabolised to, maltose, xylose or galactose. We continued to receive incidents related to this problem and so issued an update MDA to warn users that this problem is still occurring.

We were able to use the information from our surveillance database to identify increasing trends for reports of adverse incidents associated with the use of specific haematology analysers and virology assays. We discussed these issues with the manufacturers of these devices to ensure both the safe design of these devices and that appropriate communication of the issues were sent to users.

**Breast implants**
We ensured that accurate information was readily available for women who are considering breast implants or who are concerned about their breast implants. We updated ‘Current Issues’, which summarises the latest risk assessments for the various types of breast implant and published our current views on the hydrogel breast implant issue in the Journal of Plastic Reconstructive and Aesthetic Surgery.

**Counterfeit condoms**
B&I issued one Medical Device Alert on the presence of counterfeit condoms on the UK market working with the manufacturer and MHRA enforcement officers. Counterfeiting is normally associated with products that are sold directly to the public, so it can be difficult to disseminate safety information to users. We therefore issued a press briefing, which resulted in coverage in newspapers, magazines and professional journals.

**Cardiovascular implants**
We issued a Medical Device Alert regarding a particular type of device to close holes in the heart that, if over-sized, could lead to tissue erosion and haemodynamic compromise.

We also issued a Medical Device Alert regarding the use of permanent inferior vena cava filters which are increasingly being labelled for late retrieval. We reminded users to be mindful when assessing a patient’s filter options, that little clinical evidence existed supporting the safe removal of most of these beyond three months of implant duration.

The worldwide debate continues amongst healthcare providers, regulatory bodies, manufacturers and patients, regarding the relative short-, medium- and long-term safety of drug eluting versus bare metal coronary stents. Focus has now shifted towards interpreting data from clinical trials and real-world usage, to identify the sub-groups of patients who would benefit most from each stent type (or bypass grafting) and the most appropriate antiplatelet and follow-up regimes.
Active implants
Following reports of a study suggesting that personal music players such as iPods can have a temporary effect on the operation of implantable pacemakers, and on the advice of the CSD, we published guidance on our website. Patients with a pacemaker or implantable defibrillator can continue to use personal music players with negligible risk, provided they are not placed directly over the implant. The same advice holds true for other electronic items including mobile phones and pocket PCs.
We issued one Medical Device Alert regarding extended charge times in various implantable defibrillator models. We also issued a Medical Device Alert regarding the in vivo fatigue fracture of certain implantable defibrillator leads, which could cause delivery of inappropriate shocks or loss of therapy.

External/temporary pacemakers
We issued a Medical Device Alert following the discovery that one model of external temporary cardiac pacemaker could deliver inappropriate rapid pacing when it was being switched off. The manufacturer developed a software upgrade to correct this issue, and the MDA also reminded users to check that the rapid pace switch is turned off before shutting down the device.

Cochlear implants
To encourage user reporting we produced a printable poster highlighting the key reportable adverse events with cochlear implants, aimed at cochlear implanting centres. We accompanied this with a new report form specifically for cochlear implants to enable the essential information to be captured consistently at the time of the initial report.

3.2 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; needles and lancets. The unit is staffed by medical device specialists with expertise in: physical and biological sciences; radiation physics; mechanical and electrical engineering. Many members of staff also have experience of working in the health service sector and medical device industries.

In 2007 a total of 56 Medical Device Alerts were issued on I&AC products.

Highlights of the work undertaken in some of our product areas are given below.
Anaesthetic and respiratory systems
We issued fifteen Medical Device Alerts during 2007 covering a wide range of devices including anaesthetic machines, breathing systems, laryngoscopes, medical gas cylinders and airway devices. Much of this work involved paediatric and neonatal devices, including MDA/2007/037, warning of problems with water traps in paediatric circuits, MDA/2007/072 supporting the recall of paediatric endotracheal tubes, and MDA/2007/062 supporting the recall of paediatric laryngoscopes. The safety and effectiveness of these critical paediatric and neonatal devices remains a priority.

Additionally we have published 10 ‘One Liners’ items relating to issues with anaesthetic and respiratory systems. ‘One Liners’ Issue 49 was wholly dedicated to the issues observed with these types of devices.

We continue to provide assistance to the police and coroners concerning complex technical issues that have arisen with these critical care devices. We have maintained close links with professional bodies such as the Society of Critical Care Technologists and have provided expertise to a range of committees for the Association of Anaesthetists of Great Britain and Ireland (AAGBI). We have also provided assistance to the AAGBI and the Royal College of Anaesthetists on new training initiatives.

Infusion and feeding pumps
2007 saw a small decrease in the number of infusion and feeding pump incidents reported to us. Some of the pump problems that led us to issue Medical Device Alerts included:

- the possibility of delivering an unwanted bolus of drug when a pump’s door is closed too quickly. (MDA2007/100)
- misloading of an enteral feeding pump to give free flow of feed resulting in the patient aspirating the feed (MDA 2007/98)
- user confusion over two similar pumps that can be used with target controlled anaesthesia leading to the possibly of obese patients being over or under anaesthetised. (MDA 2007/97)
- under delivery due to the systemic failure of an internal pump component. (MDA 2007/60)
- the possibility of inadequate therapy due to drug and drug cassette interaction. (MDA2007/44)

We also produced a number of Medical Device Alerts on patient monitoring equipment covering the following issues:

- a system failure leading to no alarms at a central monitoring station (MDA2007/025)
- mounting bracket failures leading to the possibility of patient and staff injury (MDA 2007/018)
- a 100% oxygen saturation level being displayed when the transducer became disconnected. (MDA 2007/002)
We continued our commitment to training by hosting another infusion pump study day in London in June, which was attended by over 80 delegates. In addition we continue to contribute to the updating of the NHS Infusion Devices E-Learning Programme as part of its expert reference group.

As in previous years, we once again had a considerable input to police and coroner investigations producing reports for the Lincolnshire, Metropolitan, Nottinghamshire and West Midlands police forces.

**Dialysis devices**
This area has seen a steady increase in incidents during 2007

Two Medical Device Alerts were issued on
- flow rate discrepancies (MDA 2007/012))
- contributory factors causing inadequate fluid removal (MDA/2007/027)

An item in ‘One Liners’ (issue 50) on disconnect alarms on dialysis machines, highlighted the need to set up units correctly.

There has been increased collaboration with manufacturers as part of post market surveillance procedures.

**Vascular devices**
We continue to monitor the introduction of changes to the instructions for use of needle-free intravascular connectors and have advised the NHS to be aware of these changes in MDA/2007/051.
We provided advice during the consultation phase of The 'National Guidance for Preventing Healthcare Associated Infections' (epic2) which recommends monitoring device associated infection rates when new brands of needle-free connectors are introduced and reporting increase in suspected infection rates to MHRA. MHRA raised awareness of this recommendation in the Medical Device alert mentioned above.

**Diagnostic imaging**
The continuing move to a digital imaging has seen a significant rise in the number of software related issues.
We also continue to receive many reports relating to electrical safety. The second edition of our collaborative document on installation guidance for imaging equipment, the Medical Electrical Installation Guidance Notes (MEiGaN), was published on our website during the year to help address some of these problems.

**Magnetic resonance imaging (MRI)**
2007 saw the publication of DB 2007(03), Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use, an update to the 2002 MDA document. We have incorporated updates to standards, guidance and
legislation as well as feedback from users of this document. To make the
document clearer we have also introduced new formatting.

MRI related incidents were slightly down for the year 2007 with the main
problems being related to patient burns and issues concerning quench
venting issues. We continue to contribute to education in this area with
presentations on MR safety at MagNET.

We issued a Medical Device Alert (MDA 2007/007) jointly with our
medicines colleagues regarding the MRI compatibility of certain oxygen
cylinder valve components.

We have worked closely with several major manufacturers during the year
on improving post market surveillance and vigilance reporting especially on
dialysis equipment, infusion pumps and vascular devices.

Publications
The following were issued in 2007:
Transport ventilators-Top Tips leaflet
Intravascular and Epidural Devices- Top Tips leaflet

DB 2007(03) Safety Guidelines for Magnetic Resonance Imaging
Equipment in Clinical Use
MEiGaN - Medical Electrical Installation Guidance Notes 2nd edition.

3.3 Assistive Technology (AT)

The AT unit covers the wide range of assistive technology devices used
within hospitals and in the community. Users of these devices include a
vast spectrum from healthcare professionals to individuals with physical or
mental impairment living independently in their own homes and where
required their carers. Examples of AT devices include; mobility aids
(wheelchairs, walking aids, artificial limbs etc), moving and handling
systems (hoists, bath lifts, transfer devices etc), posture management
(from simple cushions to complex support systems), pressure management
(pressure redistribution/relief cushions and mattresses), communication
and hearing aids, beds (from basic care beds to complex profiling powered
beds), environmental controls (personal alarm/call systems, remote control
of household tasks etc.), and aids for daily living (chairs, commodes, bath
aids etc).

The majority of staff are based at the MHRA Centre for Assistive
Technology in Blackpool, with some members based at the MHRA head
office in London. Staff expertise includes rehabilitation and mechanical
engineering, materials science, pressure care, posture and mobility and
transport for the disabled in addition to experience of working in health
services and in industry. Staff are also members of the professional bodies and national groups that cover these areas.

AT received a total of 1,501 adverse incident reports during 2007 of which 383 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 the police, HSE and trading standards. The unit published 13 Medical Device Alerts during the year. Some of the significant issues covered during the year are set out below.

**Beds**
The unit received 115 adverse incident reports covering a range of safety related issues concerning beds and mattresses; investigation of these lead to five Medical Device Alerts being issued. MDA/2007/009 in February, and MDA/2007/056 in June involved occupant entrapment risks. MDA/2007/038 in May involved risks of fire and explosion due to battery charging problems, MDA/2007/041 in May centred on risks to users or others from cracking welds on the bed frame and MDA/2007/065 in August centred on the potential contamination risks due to inadequate cleaning/decontamination procedures for the mattress.

**Wheelchairs and children's buggies**
The unit received 842 adverse incident reports covering a large range of safety related issues concerning all types of powered and non powered wheelchairs used by children and adults. Investigations lead to many changes in designs and instructions for use and 4 Medical Device Alerts were issued. MDA/2007/074, MDA/2007/075 in September and MDA/2007/096 in December centred on unexpected failures of seating and frame structures and 2007/087 in November centred on the possibility of burns from a charger with a case temperature in excess of 41 degrees.

**Hoists and bath lifts**
The unit received 132 adverse incident reports on safety concerns involving hoists and slings and investigations lead to 4 Medical Device Alerts being issued. MDA/2007/016 in February centred on the potential for an occupant to fall due to drive motor/gearbox failure. MDA/2007/031 in April centred on risks from poor compatibility, poor laundering and maintenance practices. MDA/2007/43 in May centred on the potential for the occupant to fall if the sling attachment device failed in use. MDA/2007/050 in June centred on the potential for the operator to receive burns whilst using an overheating handset.

**Liaison with reporters, users, industry and others**
Regular contact has been maintained with all main stakeholders. In particular, strong relationships have been maintained with NHS groups, professional groups and BHTA as the main trade association for assistive technology. Staff have regularly attended NHS groups covering rehabilitation engineering services, prosthetics, wheelchairs and seating
and electronic assistive technology to discuss safety related issues and raise the need for members to report adverse incidents to the MHRA. Staff have provided input to the new BHTA accreditation training courses for their member companies and have also set up a series of seminars for BHTA members to increase their knowledge, understanding and reporting of incidents under the vigilance system. Staff also had stands at the annual conferences for Moving and Handling and the national Posture and Mobility Group where a large number of delegates visited the stand to discuss the work of the unit. Liaison with coroners, police, the Health and Safety Executive, Trading Standards and the Dept. for Transport has also regularly occurred as a part of individual investigations.

**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. This was to try to highlight the potential risks and also to raise the level of awareness of good practice. In February 2007 a special edition of ‘One Liners’ was issued covering a wide variety of issues concerning AT devices including lifecycles, adjustment of safety belts, compatibility, cleaning and transportation. In October 2007 another edition of ‘One Liners’ was issued specifically aimed at the safe use of hoists and slings.

**In-house testing**

The centre’s laboratory was re-accredited as the only UKAS registered wheelchair test laboratory in the UK following the annual re-assessment in September 2007. 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.
4 Statistics

4.1 Trends in adverse incident reporting

8,634 adverse incident reports were received in 2007. This was an increase of 8.26% over the 2006 total.

It is of some concern that the previously noted reduction in the number of reports being received from the health and social care sectors has continued. The volume of reports submitted by medical device manufacturers has, however, continued to increase. There are many possible reasons for these changes. Healthcare staff may be ‘filtering’ reports through local risk management systems, or may be reporting to other bodies such as the NPSA. MHRA continues to monitor this change closely and is already pursuing this with the Liaison Officer Focus Group.

Device manufacturers’ development of their post-market surveillance systems under the EU ‘vigilance’ system may have been assisted by the MHRA’s pro-active approach in a number of device areas – or more recently by the publication of new EU and UK guidance documents. Last year’s manufacturer report numbers may also have been inflated by high numbers of reports associated with a specific problem with a high volume device. For the part of the year, some of these may have been included in manufacturers’ periodic summary reports.

As always, the total number of incident reports received reflects a balance of rises and falls within different device groups. Some of these are discussed and explained in section 4.5.

Figure 1 Adverse incident reports 2005 - 2007
4.2 Vigilance cases

The Medical Devices Directives and UK Regulations place a clear and mandatory reporting requirement upon medical device manufacturers. This is known as the ‘vigilance system’. Reports submitted to MHRA by device users may also be classified as vigilance cases if they meet the relevant criteria.

At the end of 2007 the EU published the latest revision of the MDDEV – the guidance document for medical device manufacturers on the implementation of the vigilance system. This was followed in February of 2008 by the launch of the draft UK guidance. A final version will be published on the MHRA website following a three month consultation period.

The MEDDEV guidance on the vigilance system may be found on both the MHRA and European Commission websites:
- www.mhra.gov.uk

In 2007 the number of incident reports recorded as ‘vigilance’ rose to 3,022 from 2,992 in 2006. This continued growth reflects not only improvements in manufacturers’ post market surveillance systems, but also the growth in the range of medical devices available and in use by healthcare providers, carers and members of the public.

Figure 2 Number of vigilance cases received 2005 - 2006
4.3 Report sources

Report sources, i.e. the origins of the adverse incident reports received by the MHRA, are shown in the chart below.

The clear trend seen in recent years has continued: the number and proportion of reports originating from medical device manufacturers has risen (by almost 9%) and that from the NHS fallen (by 8.5%). We are actively investigating the reasons for these changes, particularly the downward trend seen in reports from the NHS.

There was also a further small drop (1.2%) in the number of reports received from overseas reporting organisations (predominantly EU competent authorities). However, as the numerical change is relatively small, this change is not considered significant.

Figure 3 Incident report sources 2005 – 2007
4.4 Online reporting

Online reporting is 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 have two separate online systems for reporting medical device adverse incidents. The success of these two systems continues to be seen in the steadily rising proportion of reports submitted that way each year.

The system for medical device users (patients, members of the public and health professionals) has been in service since 2001. Last year over 2,500 reports were submitted via this route. Although the actual number of user online reports decreased in 2007, the proportion of user reports submitted in this way has risen by 3.5% to 72%.

MORE (Manufacturers’ Online Reporting Environment) is the system for medical device manufacturers to report online. Since its launch in October 2003, MORE activity has grown steadily. There are now over 600 registered MORE reporters, submitting around 27% of the total number of reports received from manufacturers.

MORE II, incorporating a number of developments and enhancements, was launched in February 2008.

Figure 4 Online reports received 2001 - 2007
4.5 Incident reports by device group

Figure 5 illustrates trends in adverse incident reporting over the last three years. In order to simplify the illustration, related devices have been grouped together.

The most visible changes seen are for the Biosciences and Implants Unit: an increase for active and non-active implants and a further increase in IVD reports. The latter was primarily due to problems with home use blood glucose meters.

The Assistive Technology Unit saw an increase in reports on hoists, therapy equipment and wheelchairs and a decrease in the numbers of lower risk incidents concerning artificial limbs.

Whilst the groups covered by the Imaging and Acute Care Unit do not highlight any specific major changes, incidents reported still prompted the production of 57 medical device alerts during the course of 2007.

These changes are discussed in Section 3 of this Device Bulletin, the Review of activity in the DTS specialist technical units.
Figure 5 Incident reports by device group 2005 - 2007

Percentage of total number of incidents

- Wheeled mobility equipment
- Active and non-active implants
- Infusion/transfusion/dialysis
- Surgical equipment
- Others
- Physiotherapy equipment
- Orthoses
- Walking aids
- Disinfection/sterilisation/disposal
- Beds/mattresses
- Hoists
- Drainage/Suction
- Aids for daily living
- Diagnostic imaging
- I/DS
- Surgical consumables
- Syringes/needles
- Life support/incubators/monitors
- Artificial limbs
- Others
- Surgical equipment
- Infusion/transfusion/dialysis
- Active and non-active implants
- Wheeled mobility equipment
4.6 Investigation levels

The risk assessment procedures introduced following the MHRA’s 2003 adverse incident strategy review are routinely audited and reappraised by our medical device specialists. In order to maintain both the high level of risk assessment uniformity currently achieved, and the high level of confidence held in our risk decision making process, these procedures are being further developed and a two stage assessment grid system is now widely used. It is this risk assessment process that we use to determine the level of investigation pursued for each adverse incident report received.

In 2007 the proportion of ‘in depth’ investigations opened dropped from 27% to 22%. The proportion of Standard investigations rose from 29% to 32%. There was no change in the numbers record for ‘information only’. The ‘others’ category (comprising ‘known’, ‘echo’, and ‘non-MHRA’ investigations and reports not concerning medical devices) rose by 1%.

Figure 6 Investigation level assigned as percentage 2005 – 2007

* knowns, echoes, non-MHRA investigations and reports not concerning medical devices
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 identified as a result of investigations conducted by device manufacturers and/or MHRA device specialists. Three levels of category listings of contributory causal factors that may be recorded for each incident are used within the MHRA’s Adverse Incident Tracking System (AITS). The first level provides the three options shown in Figure 7.

- **Manufacturer responsibility**
  Before delivery e.g. design, manufacture, quality control and packaging.

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

- **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.

**Figure 7 Causes of adverse incidents 2005 - 2007 – percentage of concluded incident investigations**
4.8 Investigation outcomes

In 2005 MHRA introduced new and revised category listings for recording the outcomes of incident investigations. These changes were made in order to help ensure that the data presented best represent the range of possible investigation outcomes. These categories now include:

- Field safety corrective action
- Other manufacturer action
- Revised/additional user training/publicity
- Referred to other organisation

There is also a new category – ‘other’ - which covers a number of low incidence circumstances, for example where the device was scrapped or where other regulatory action was taken.

The 2007 data show a significant fall in the number of incidents where no further action was taken beyond the initial investigation, and where the details were retained for ongoing trend analysis only.

Note 1: These categories are not mutually exclusive and more than one may be selected. Consequently the annual totals may exceed 100%.

Note 2: Data for 2006 have been amended following correction of an error.

Figure 8 Investigation outcomes 2005 - 2006
4.9 Investigation durations

Of the approximately 8,650 adverse incident reports currently being received by the MHRA each year, 32% are risk assessed as requiring ‘standard’ investigations and 22% as requiring ‘in depth’ investigations. The remainder of the incidents correctly reported to the MHRA are recorded as part of our ongoing trend analyses.

Figure 9 clearly illustrates the decrease in the time taken for in depth investigations when compared with 2006. The time taken for standard investigations remains unchanged.

Specifically, in 2007 50% of ‘standard’ and ‘in depth’ investigations were concluded in 15 weeks (15 in 2006) and 31 weeks (35) respectively. 75% of ‘standard’ and ‘in depth’ investigations were concluded within 27 weeks (27) and 57 (61) weeks respectively.

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 have resulted 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.

**Figure 9 Time taken for conclusion of incident investigations 2005 - 2007**
4.10 Safety notices issued

Following the conclusion of (or sometimes during) an adverse incident investigation, the MHRA may decide that it is necessary to issue safety advice in the form of a Medical Device Alert (MDA). The numbers of MDAs issued between 2005 and 2007 is shown below in Figure 10. Of the total 100 MDAs issued in 2007, 36 were designated as ‘immediate action’ and 64 as ‘action’. The DTS specialist units’ reviews in Section 3 make reference to and provide background on this further increase in the number of Medical Device Alerts issued during 2007.

Competent authority (CA) notifications are issued by the MHRA to other European Union members 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 safety warnings issued 2005 - 2007
5 Customer survey

5.1 Conduct of survey

The MHRA continues actively to seek feedback on the incident reporting and investigation process. To this end customer survey questionnaires are sent to 1 in 5 incident reporters for all ‘standard’ and ‘in depth’ investigations concluded during the sample period. The questionnaire does not place any significant time burden on those to whom it is addressed and the ‘reply paid’ format ensures that there is no direct cost to the respondent. A copy of the questionnaire is shown in section 5.3.

5.2 Response and satisfaction levels

In 2007 over 300 survey forms were completed and returned. A much improved response rate when compared to 2006. Almost twice as many of the responses received related to ‘in depth’ rather than ‘standard’ investigations.

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

Overall, responses in 2007 indicated maintenance of the high levels of satisfaction with our performance. We saw the percentage of respondents expressing satisfaction with our conduct of incident investigations (see Figure 11) remain high: 89% and 87% satisfaction for standard and in depth investigations respectively. The degree of satisfaction with the level of communication from us also remained high. Of particular note was the satisfaction level for standard investigations which rose from 80% to 90% (Figure 12).

Reported satisfaction with the speed of the investigation showed a small drop (Figure 13). For standard investigations this dropped from 82% to 79%, and for in depth investigations from 80% to 75%. This is of particular interest as the actual time taken for in depth investigations (see Figure 9) fell during 2007.

The proportion of respondents concluding that the MHRA investigation and action had reduced the risk of recurrence of the type of incident reported was just under 60% - a very similar figure to recent years.

The percentage indicating that, as a result of the investigation, they were more likely to report incidents in the future rose higher to just over 89% (86% in 2006).
Figure 11  Percentage satisfaction with conduct of investigation
2005 - 2007

% response

Year

2005 2006 2007

Standard  In Depth
Figure 12  Percentage satisfaction with level of communication 2005 - 2007

Year

% response

2005 2006 2007

Standard  In Depth
Figure 13  Percentage satisfaction with speed of investigation
2005 - 2007

% response

Year

Standard  In Depth

2005 2006 2007
MHRA Device Technology & Safety
Adverse Incident Investigation
Quality of Service Survey 2007

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
   - Clinical / biomedical scientist
   - Dentist
   - Engineer
   - General Practitioner
   - Manager / Administrator
   - Member of public
   - Nurse
   - Pharmacist
   - Physicist
   - Radiographer
   - Other - please specify:
   - Rehab Engineer
   - Supplies Officer
   - Surgeon
   - Technician
   - Therapist

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?
   □ Giving training advice?
   □ Assessing the risks involved?
   □ Manager / Administrator
   □ Other (please specify)

   □ Ensuring rapid device collection by the manufacturer?
   □ Greater thoroughness of investigation?
   □ Giving advice on reporting procedures?

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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