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Medical Device recalls in the UK and the device regulation process

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Abstract 383

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Abstract

Background

Medical devices are used widely for virtually every disease or condition. Although devices are subject to regulation, the number of recalls, the clinical data requirements for regulation and the impact on patient safety are poorly understood.

Methods

We defined a device using European directives and used publically available information on the MHRA website to determine the number of devices recalled from Jan 2006 to Dec 2010. Two reviewers independently assessed Field Safety Notices and Medical Device Alerts. We wrote to manufacturers to obtain further information and clinical data. We summarized data by year, CE classification, indication, and FDA recall system of severity.

Results

In total 2,124 Field Safety Notices were issued over the 5-year period, an increase of 1,220% (62 in 2006 to 757 in 2010). 447 Medical Device Alerts were issued in the same period and 44% were assessed as a reasonable probability of causing serious adverse health consequences or death. We wrote to 192 manufacturers of withdrawn devices and received 101 (53%) replies, only four (2.1%) provided the clinical data we requested. Lack of available transparent data prevented full analyses of the safety impact. Of the highest risk recalled devices recalled more than half were related to the cardiovascular system (25%) or musculoskeletal system (33%), and 88% (95% CI, 80% to 97%) were assessed as a reasonable probability of causing serious adverse health consequences or death. For low risk devices the figure was 34% (95%CI, 26% to 42).

Conclusion

The number of medical devices subject to recalls or warnings in the UK has risen dramatically. A substantial number of these devices may have caused serious adverse effects in patients and contributed to health care costs. Significant problems exist in the UK with a lack of access to transparent data and registry of the highest risk devices.

Article focus

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- To describe the number of medical devices recalls in the UK that occurred over a five year period from 2006 to 2010.
- To determine the clinical data required at the time of regulation and the data available at the time of device recall.
- To determine the potential risk to patients associated with recalled medical devices.

Key messages

- There was a substantial increase in Field Safety Notices over the 5 year period
- A substantial number of devices may have caused serious adverse effects in patients and contributed to health care costs over this time. But a lack of available transparent clinical data currently prevents full analyses of the safety impact of recalled devices in the UK.
- Of the highest risk devices recalled more than half were related to the cardiovascular system or the musculoskeletal system.

Strengths and limitations of this study

Strengths

- Quantification of all reported device recalls in the UK over a five year period.
- A breakdown by CE marked classification of device.
- An assessment of the potential harms of device recalls based on freely available published data on the MHRA website.

Limitations of this study

- We were limited by a lack of available clinical data of recalled devices and the absence of a central registry, particularly of the highest risk devices, which limited our ability to fully quantify and assess the implications of recalls on patient safety.
- Our classification of devices and FDA recall status was based predominantly on our clinical experience, requiring assumption which means they may differ from manufacturers' classification and other clinicians.
- Owing to a lack of clinical data made available to us, we were unable to determine the reason for the rise in Field Safety Notices. Also we do not know when the problem first arose, and what kind of pre-market clinical testing had been undertaken for many recalled devices.

Introduction

Medical devices are used for the diagnosis, monitoring and treatment of virtually every disease or condition and include familiar objects such as simple bandages, to high end, MRI scanners. Estimates

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suggest there is a vast array of devices in circulation, with some 500,000 medical devices worldwide available to health care providers and patients. [1]

Because of their vital role in health care, medical devices require regulatory approval. In Europe they are subject to council directives of the European Union (EU) which stipulate, 'devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients'. [2-4] These directives require medical device manufacturers to display CE marking on their products as a way of ensuring/signifying devices are safe and fit for their intended purpose. CE marking is conducted by EU accredited private organisations called Notifying Bodies, rather than by a centralised regulator, [5] who are responsible for the evaluation of the submitted clinical data by manufacturers. [6] Each EU member state is responsible for overseeing this legislation. In the UK, it is the Medicines and Health Regulatory Authority (MHRA) who implement the European medical device directives. However, regulation of medical devices has lagged behind that of pharmaceuticals: formal regulation in Europe only began in the mid 1990s. [7]

Approval of medical devices is co-ordinated by the MHRA, who certify Notified Bodies, which are for-profit organizations authorized to grant a CE mark certification. Currently in the European Union there are 74 separate Notifying Bodies authorized in 25 countries to approve medical devices (six in the UK). Under the current system a manufacturer selects a Notified Body to undertake certification of a new device for CE marking. The Notified Body will request certain materials (e.g., a literature review) depending on the device class and assess the manufacturer's conformity to the essential requirements listed in each directive. A CE mark for a medical device awarded in one country enables access to the entire EU market.

Device regulation in the US is different to the EU. Unlike the EU, all aspects of device regulation fall to a single body - the Food and Drug Administration (FDA). Yet in the US, concerns have been expressed that the current system is sub-optimal and leads to numerous device recalls and serious adverse events. [8-10] Medical devices were responsible for 2,712 deaths in the USA in 2006, double the number in 1997. [11] A recent report of 113 recalled devices which caused serious health problems, highlighted most were approved using less stringent processes or were considered so low risk they had been exempt from regulatory review. [12] Approval of US devices takes more time, requiring more clinical data, and many companies now obtain approval in Europe first, often many years before the device appears on the US market. [13]

These rates of adverse medical device events and differences in regulatory approval suggest they are an important patient safety issue worldwide, but there has been little evidence from the UK. [14] Therefore we aimed to describe the number of medical device recalls in the UK, the clinical data requirements for regulatory approval and determine the subsequent consequences of device recalls for patient safety.

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Methods

For the purposes of this study we defined a medical device using the European medical device directives. These state: a medical device is any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer, to be used *specifically for diagnostic and/or therapeutic purposes* and necessary for its proper application, Additionally, the directives state that a medical device does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but it may be assisted by such means. [2-4]

We used information that is publically available on the MHRA website (www.mhra.gov) to determine the number of devices which had been withdrawn or recalled over the 5 year period Jan 2006 to Dec 2010. Two forms of information were identified: Field Safety Notices and Medical Device Alerts. Since 2006, the MHRA has also published Field Safety Notices which are issued by a manufacturer when a medical device needs to be recalled for technical or clinical reasons. In addition to this, the MHRA issues a Medical Device Alert as a means of communicating safety information to device end-users in health and social care. Each Medical Device Alert is designated either for 'Immediate action' or 'Action', or provides updated information on previous alerts.

Because Field Safety Notices and Medical Device Alerts do not state the CE class of the withdrawn devices, two authors (CH, MT) had to independently classify them into one of three CE marked categories. This was done using the European Union directives for medical device classification. Specifically, these are: Active Implantable Medical Device Directive, AIMDD (90/383/EEC),[2] (General) Medical Device Directive, MDD (93/42/EEC) [3] and the In Vitro Diagnostic Medical Device Directive, IVDMDD (98/79/EC). [4] CE device categories are as follows: Class I (generally regarded as low risk devices); Class 2 (generally regarded as medium risk devices); and Class 3 (generally regarded as high risk devices). Where disagreement occurred in classification between the two authors this was resolved by discussion.

We also categorized the agreed list of Class 3 devices by their main indication for use either by system (i.e. cardiovascular, gastrointestinal, neurological or orthopaedic), or by mode (diagnostic, surgical instrument, in- vitro device, infusion, imaging, radiotherapy, dialysis, sterilization).

We also planned to determine the potential risk to patients associated with each of the withdrawn devices, using the system of classification employed by the Food and Drug Administration (FDA). The FDA system classifies risk of harm from a device using three levels:

- A situation in which there is a **reasonable probability** that the use of, or exposure to, a product will cause serious adverse health consequences or death (FDA Class I).

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- A situation in which use of, or exposure to, a product may cause **temporary or medically reversible** adverse health consequences or where the probability of serious adverse health consequences is remote (FDA Class II).
- A situation in which use of, or exposure to, a product is **not likely** to cause adverse health consequences (FDA Class III).

For Medical Device Alerts we coded whether the device was recalled or withdrawn from the market, and one author (MB) wrote to manufacturers of recalled devices to obtain further information. Specifically we asked for a copy of all field safety notices issued, the country where the CE marking was registered, the name of the Notifying Body, where the device was manufactured, where the device was packaged and details of clinical data that were submitted or in possession as part of the CE marking process or data that has been published since the product was CE marked (the question are in appendix 1). From this exercise we learnt manufacturers' clinical data was proprietary and therefore mainly not available for public scrutiny. Further to this we contacted the MHRA by email to see if they held a central registry and/or clinical data for the CE marked class 3 devices which had been recalled. They responded as follows:

"The Medicines and Healthcare products Regulatory Agency (MHRA) does not have a definitive list of Class 3 medical devices, however, these are usually devices with the highest risk associated with their use, and are invasive, for example, heart valves, ICDs, implants, stents, etc."

Clinical data on these devices would be held by the manufacturer and is reviewed by the notified body before the product can be placed on the market. The MHRA does not routinely request or keep clinical data on medical devices."

We therefore contacted the six Notifying Bodies in the UK by email (appendix 2) for information on Class 3 devices, who clarified:

"that all of the clinical data about medical devices they pass is unavailable to us. The notifying body is a client working on behalf of the manufacturer and sees the clinical data as being commercially sensitive."

Therefore, due to insufficient data, we were unable to apply the FDA system of recalls to Field safety Notices. However, the two authors (CH, MT) were able to independently classify the MHRA Medical Device Alerts. [12] Although the Alerts are not exhaustive, they do contain a summary of the problem, the action to be taken and by whom, as well as the distribution list of the alert. Again, disagreements between the two authors were resolved by discussion.

We summarized data by year, by CE classification, by indication, and Medical Device Alerts by FDA recall system, presenting data as raw counts and proportions. Because the FDA recall system was only undertaken on a subset of the data we calculated proportions and associated 95 % confidence intervals and used Cohen's Kappa c as a measure of inter-rater reliability. We analyzed data using Excel and SPSS version 17.

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Results

In total there were 2,124 Field Safety Notices and 447 Medical Device Alerts issued in the five year period. Whilst the numbers of Medical Device Alerts was consistent over this time period (range 73 to 100), the number of Field Safety Notices increased by 1,220% over the same period, from 62 in 2006 to 757 in 2010 (figure 1).

Of the 2,124 Field Safety Notices, 327 (15.4%) were high risk CE Class 3 devices, and more than half were related to the cardiovascular system (25%) or musculoskeletal system (33%). Table 1 shows there were 1,527 (72%) medium risk devices (CE Class 2) and 270 (12.7%) low risk devices (CE Class 1).

Of the 447 Medical Device Alerts, 147 (33%) devices were marked for immediate action and 197 (44%) were to be withdrawn or recalled (Table 2). We wrote to the manufacturers of 192 withdrawn devices whose contact details were listed on the alerts. We received 101 (53%) replies, of which only four (2.1%) provided the data requested: 21 replies provided partial answers, 11 declined to formally participate, 27 acknowledged the email but provided no response, and 38 emails bounced back due to an incorrect email address or due to an out of office reply.

Table 3 shows that 44% of Medical Device Alerts were assessed as having a reasonable probability of causing serious adverse health consequences or death, 38% caused temporary or medically reversible adverse health consequences, and 12.1% were assessed not likely to cause adverse health consequences. Overall agreement between the two reviewers was moderate (Kohen's Kappa, 0.60);

Of the 447 Medical Device Alerts, 60 (13.4%) were classified as high risk CE Class 3 devices, of which 53 (88%; 95% CI, 80% to 97%) were assessed as having a reasonable probability of causing serious adverse health consequences or death. Of the 53 devices, 16 (30%) alerts were notified as needing immediate action. For medium risk devices, CE class 2b and 2a devices, 54% (44% to 64%) and 31% (23% to 38%) were judged as having a reasonable probability of causing serious adverse health consequences or death respectively. Of the CE Class 1 devices, those which carry the lowest risk, 34% (CI, 26% to 42%) were assessed as a reasonable probability of causing serious adverse health consequences.

Discussion

Main findings

We found a substantial increase in the number of Field Safety Notices issued in the last five years by medical device manufacturers, without concomitant increases in Medical Device Alerts issued by the

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MHRA. The number of Field Safety Notices, which are issued by a manufacturer when a medical device needs to be recalled for technical or clinical reasons, increased by 1,220% over the five year period, which represents a substantial concern for overall safety and impact on health care costs in the UK.

We were unable to access adequate clinical data or pre-market approval data for recalled devices: only 2% of manufacturers were forthcoming in providing data. In the very few cases we did receive data these were mainly literature reviews and were not comparable to systematic reviews.

In addition, we found nearly half of Medical Device Alerts were related to devices that had a reasonable probability of causing serious adverse health consequences or death. Moreover, of the most risky devices (CE Class 3 devices) that were recalled nearly 9 out of every 10 were judged independently by two clinicians to have a reasonable probability of causing serious adverse health consequences or death based on the information contained on the MHRA Medical Device Alerts. However, it was not unusual for us to find low risk devices, CE class I devices, leading to potentially serious adverse events; numerous defective wheelchairs and hoists needed to be recalled which potentially have led to considerable morbidity.

Implications

A substantial number of important issues arise because of our findings. Firstly, why are Field Safety Notices rising dramatically whilst medical device alerts are not? In 1999 the UK Medical Device Agency published only eight Advice Notices, eight device alerts and only 36 safety notices, [7] One reason is medical device numbers have increased substantially over time. One could also argue manufacturers are doing their job, the question then is how many device alerts could or should there be? Collation of medical device alerts associated with a reasonable probability of causing serious health problems or death from US FDA, UK MHRA, Health Canada and manufacturers resulted in a total of 1,588 alerts in 2010 alone. [15]

Secondly, the current system of CE marking is confusing. For instance, whilst contact lens cleaners are CE Class 2b devices, contact lenses could be classified as Class I. Manufacturers ultimately decide on the class of the device and therefore the level of clinical data required. We found the difference between Class 2a and 2b often difficult to determine or justify on clinical grounds alone. A new directive (2007/47/EC) that came into effect in March 2010 highlights this confusion. For instance it states: 'the central circulatory system now includes the vessels aortic arch and descending aorta to the aortic bifurcation,' whereas in the previous directives it did not. Devices in contact with these vessels will now be considered high risk, whereas, one can only surmise, in the past they were deemed at a lower risk and subject to less stringent data requirements at the regulatory stage.

Thirdly, are the requirements for pre-approval clinical data fit for purpose in Europe? Pre-approval data for medical devices in Europe does not require demonstration of efficacy. Clinical data used for

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CE marking may be either a review of the relevant scientific literature, or the results of a clinical study. The first of these is used by the majority of manufacturers of low- to medium-risk devices (Class I, 2a and 2b). Where clinical data is used it may be unpublished, or data generated on an equivalent device. [16] Unlike pharmaceutical regulation, no summaries are publically available for independent assessment.

It is particularly concerning we were unable to review any of the clinical data provided to achieve a CE mark, as the relevant data is held by the company or the notifying bodies and not a public body, such as the MHRA. This means they are not subject to the Freedom of Information Act, a means by which researchers can access information. Again this contrasts markedly with the situation for pharmaceuticals, where this information can be obtained, which are regulated by the European Medicines Agency. Surveillance of devices in practice is therefore lax, [17] and whereas we can access mortality data in adult cardiac surgery for named surgeons [18] we cannot currently do the same for named devices in many different specialities and systems.

Finally, how should the current system of regulation be changed? Since device recalls will continue to occur and seem to be increasing, better communication of the risk of the recall should be considered to help clinicians and patients make decisions that allow appropriate risk assessment. [8] Amongst the new directives (2007/47/EC1) requirements, is the need for more clinical data and more frequent clinical investigations, this data should be made publically available, particularly for the highest risk devices, so that end users have clear evidence on which to base important (and potentially costly) decisions regarding device replacement or recall. In addition, adoption of the US system of recall class, at the time of Device Alert would allow a better understanding of the potential magnitude of the safety problem. Finally because the highest risk devices come from cardiovascular and musculoskeletal systems these areas should be prioritized for independent national registries of implantable devices with publicly accountable data.

Limitations

The main limitation of the study was the lack of available data on details of device withdrawals, or quantification of the number or current use of devices affected. Our CE classification of devices and FDA recall status was therefore based predominantly on our clinical experience based on the information that was publically available, and this judgement may therefore differ from manufacturers' classification and form other clinicians. Owing to a lack of data made available to us, we were also unable to determine the reason for the rise in Field Safety Notices, and therefore cannot speculate on when the problem first arose, and more importantly, what kind of clinical testing had been undertaken prior to the device going on the market. The absence of a central registry containing information on how many devices are currently in use in the UK limited our ability to fully assess the implications of our findings on patient safety. This means we are unable to quantify the true number of patient harms caused by medical device recalls Finally, we are unable to determine which of the safety alerts were

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acted on by the health care and social care community, the proportion of patients (and/or devices) who needed to be traced, and the workload and costs involved in these actions.

Conclusions

The size and scale of the medical device recalls substantially impacts on NHS workload and patient safety and the number of Field Safety Notices continues to grow. Significant problems exist in the UK with a lack of access to transparent data and registry of the highest risk devices, which prevents a full understanding of the size and impact on patient safety.

Contributions

CH and DC devised the study, CH and MT extracted the data for the Field Safety Notices and Medical Device Alerts. MB wrote to manufacturers, Notifying Bodies and the MHRA. CH and MT analysed the data and all authors contributed to the writing of the paper and approved the final draft. CH remains the guarantor of the data. A copy can be obtained on request.

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Conflict of interest

All authors have completed the Unified Competing Interest form at http://www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work [or describe if any]; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

Reference List

(1) Eucomed. What Medical Technology exactly is. Accessed 3rd March [2011 Available from: URL:http://www.eucomed.org/medical-technology

(2) www.ce-marking.com. Active Implantable Medical Device Directive, AIMDD (90/383/EEC). Accessed 3rd March [2011 Available from: URL:http://www.ce-marking.com/medical-devices-active-implantable.html

(3) www.ce-marking.com. (General) Medical Device Directive, MDD (93/42/EEC). Accessed 3rd March [2011 Available from: URL:http://www.ce-marking.com/medical-devices.html

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(4) www.ce-marking.com. In Vitro Diagnostic Medical Device Directive, IVDMDD (98/79/EC). Accessed 3rd March [2011 Available from: URL:http://www.ce-marking.com/medical-devices-in-vitro-diagnostic.html

(5) European Commission. Enterprise and Industry. Accessed 4th March [2011 Available from: URL:http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13&type_dir=NO%20CPD&pro_id=99999&prc_id=99999&ann_id=99999&prc_anx=99999

(6) By Lisa Richwine. Exclusive: "Guinea pig" remark spurs U.S., EU device spat. Reuters [2011 Available from: URL:http://www.reuters.com/article/2011/02/25/us-devices-idUSTRE71O0P020110225

(7) Jefferys DB. The regulation of medical devices and the role of the Medical Devices Agency. *Br J Clin Pharmacol* 2001; 52(3):229-235.

(8) Burkhardt JD, Wilkoff BL. Malfunctions in implantable cardiac devices: putting the risk in perspective. *Cleve Clin J Med* 2005; 72(9):736, 738, 742.

(9) Lenzer J, Brownlee S. Why the FDA can't protect the public. *BMJ* 2010; 341:c4753.

(10) Maisel WH, Sweeney MO, Stevenson WG, Ellison KE, Epstein LM. Recalls and safety alerts involving pacemakers and implantable cardioverter-defibrillator generators. *JAMA* 2001; 286(7):793-799.

(11) health.org. Medical devices: Problems on the rise. ConsumerReportsHealth org [2011 Available from: URL:http://www.consumerreports.org/health/healthy-living/home-medical-supplies/problems-with-medical-devices-12-07/overview/medical-devices-ov.htm

(12) Zuckerman DM, Brown P, Nissen SE. Medical Device Recalls and the FDA Approval Process. *Arch Intern Med* 2011.

(13) Eucomed. **EU Medical Device Approval Safety Assessment** . Accessed 23rd March [2011 Available from: URL:http://www.eucomed.org/uploads/Press%20Releases/BCG%20study%20report.pdf

(14) Samore MH, Evans RS, Lassen A, Gould P, Lloyd J, Gardner RM et al. Surveillance of medical device-related hazards and adverse events in hospitalized patients. *JAMA* 2004; 291(3):325-334.

(15) Medical Device COntrol Office: Dept of Health. Recalls and Alerts. Goverment of the Hong Kong Special Administrative region [2011 Available from: URL:http://www.mdco.gov.hk/eindex.html

(16) Apllied Clinical Trials Online. Medical Device Development: U.S. and EU Differences. Accessed 3rd March [2011 Available from: URL:http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/article/articleDetail.jsp?id=363640

(17) Avorn J. Regulation of devices. *BMJ* 2010; 341:c5730.

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(18) Bridgewater B. Mortality data in adult cardiac surgery for named surgeons: retrospective examination of prospectively collected data on coronary artery surgery and aortic valve replacement. *BMJ* 2005; 330(7490):506-510.

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Figure 1. Total number of Field Safety Notices and Medical Device Alerts per year(2006 to 2010)

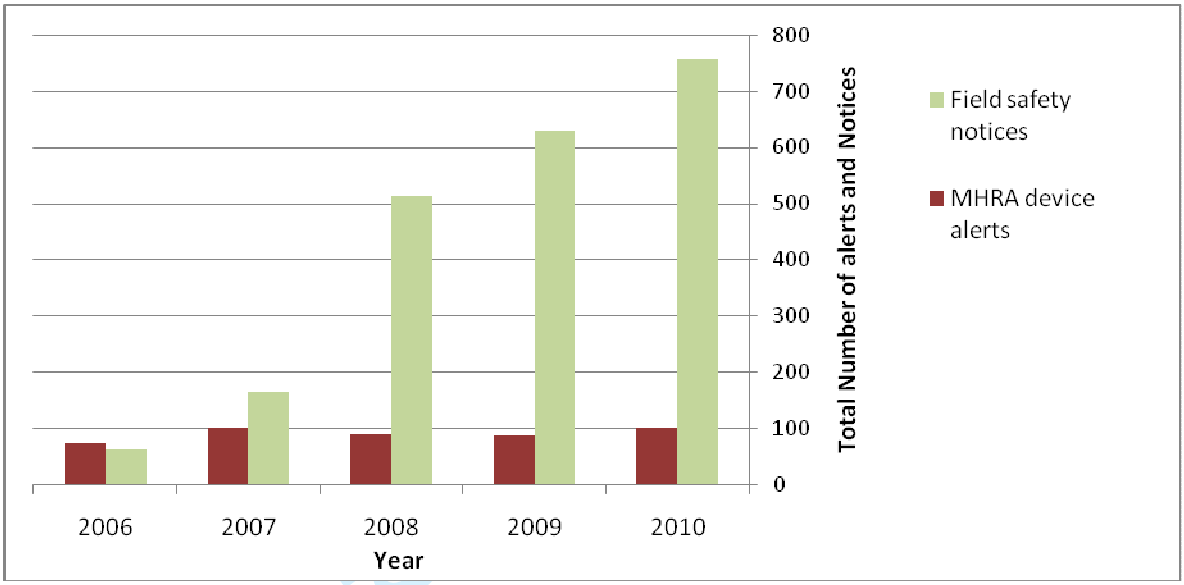

Figure 2. FDA recall status of 447 MHRA Medical Device Alerts by class of device

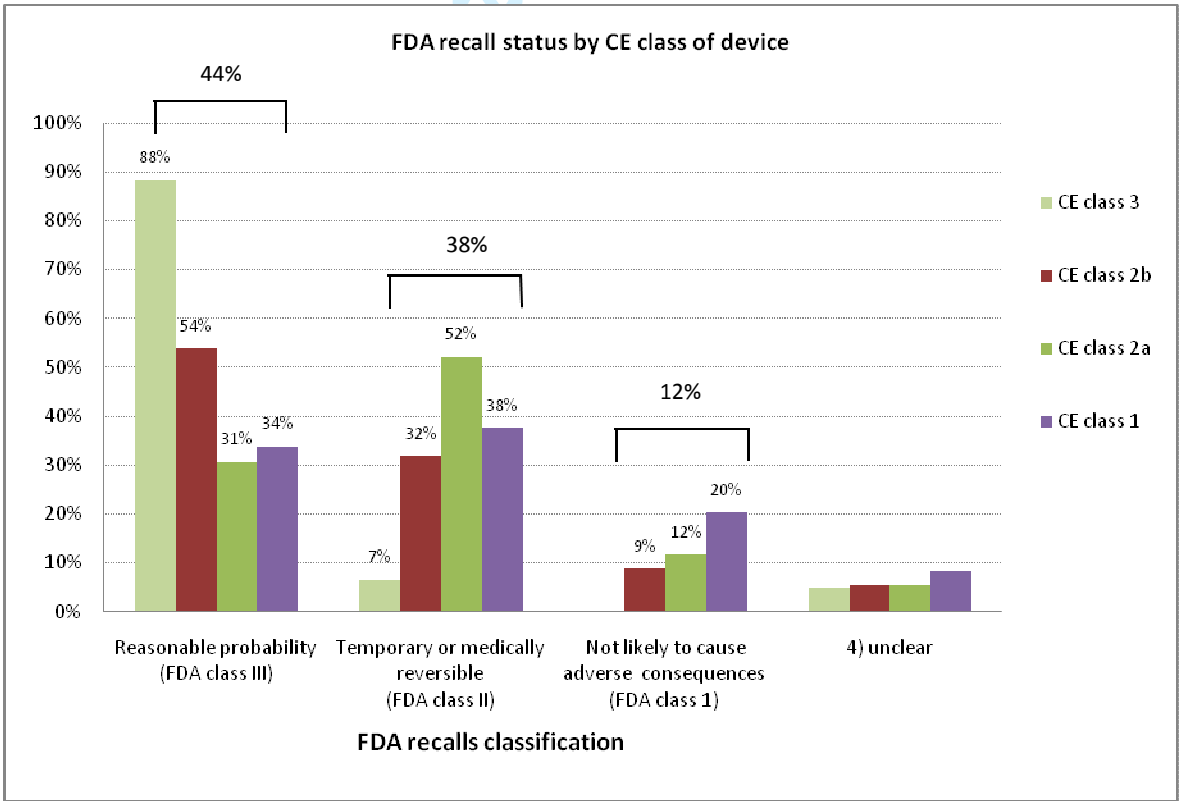

Table 1 Field Safety Notices by year and CE class of device

YEAR	Number of Field Safety Notices	CE Class 3 (%)	CE Class 2 (%)	CE Class 1 (%)
2006	62	6 (9.7)	47 (75.8)	9 (14.5)
2007	164	27 (16.5)	113 (68.9)	24 (14.6)
2008	513	81 (15.8)	362 (70.6)	70 (13.6)
2009	628	92 (14.6)	466 (74.2)	70 (11.1)
2010	757	121 (16.0)	539 (71.2)	97 (12.8)
Total	2,124	327 (15.4)	1527 (71.9)	270 (12.7)

Table 2. Medical Device Alerts by year, and CE class of device

YEAR	Number of Medical Device Alerts	Immediate Action (%)	Number of devices recalled or withdrawn	CE Class 3 devices (%)	CE Class 2b (%)	CE Class 2a (%)	CE Class 1 (%)
2006	73	23 (31.5)	37 (50.7)	9 (12.3)	16 (21.9)	32 (43.8)	16 (21.9)
2007	100	35 (35.0)	45 (45.0)	15 (15.0)	28 (28.0)	39 (39.0)	18 (18.0)
2008	88	28 (31.8)	34 (38.6)	9 (10.2)	15 (17.0)	23 (26.1)	41 (46.6)
2009	86	25 (29.1)	36 (41.9)	12 (14.0)	12 (14.0)	35 (40.7)	27 (31.4)
2010	100	36 (36.0)	45 (45.0)	15 (15.0)	20 (20.0)	34 (34.0)	31 (31.0)
Total	447	147 (32.9)	197 (44.1)	60 (13.4)	91 (20.4)	164 (36.5)	132 (29.8)

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Table 3. Assessment of the relative degree of health hazard by FDA classification of recalls for Medical Device Alerts

Reviewer	FDA recall Class I	FDA recall Class II	FDA recall Class III	Uncertain
Reviewer 1	177 (39.6)	205 (45.9)	32 (7.2)	33 (7.4)
Reviewer 2	189 (42.3)	169 (37.8)	66 (14.8)	23 (5.1)
Agreed total*	197 (44.1)	168 (37.6)	54 (12.1)	28 (6.3)

Kappa for overall agreement 0.6

FDA Classification of recalls: Recalls are classified into a numerical designation (I, II, or III) by the Food and Drug Administration to indicate the relative degree of health hazard presented by the product being recalled.

- Class I - a situation in which there is a reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death.
- Class II - a situation in which use of, or exposure to, a product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III - a situation in which use of, or exposure to, a product is not likely to cause adverse health consequences.

(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/default.htm)

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No checklist available for this study type

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