

**COMMITTEE ON THE SAFETY OF DEVICES**

**THURSDAY 6 MARCH 2008**

**10:30 – 15.00**

**ROOMS CR1/CR2**

**19 FLOOR, MARKET TOWERS, 1 NINE ELMS LANE, LONDON SW8 5NQ**

**Members Attending**

Mr John Williams (Chair)  
Mr Guy Alexander  
Dr Anna-Marie Belli  
Ms Catherine Cairns  
Mr Christopher Earl  
Mr Roger Evans  
Dr Karen Facey  
Mrs Christine Glover  
Professor Ian Kimber  
Mr Peter O'Donovan  
Dr John Perrins  
Dr Sheila Peskett  
Dr Geoffrey Ridgway  
Dr Charles Sears

**MHRA**

Dr Susanne Ludgate (Secretariat)  
Mr Clive Bray  
Dr Christopher Brittain  
Dr Tom Clutton-Brock  
Mr Andrew Crosbie  
Mr Ian Smith  
Mr Stephen Lee  
Mr James Lewis  
Mr Mike Peel  
Dr Khalid Razak  
Ms Swati Singh

**Apologies**

Professor Julie Kent  
Professor David Sharpe  
Mr Arvind Singh  
Dr Carl Waldmann  
Mr Gordon Watkins

**Devolved Administration**

Mr Peter Phillips  
Mrs Elizabeth Qua  
Mrs Silvia Shearer  
Mr Andrew Wong

**Industry**

Mr Mike Kreuzer  
Mr Nigel Bressington

**NPSA**

Ms Emma Boakes

**PASA/CEP**

Mrs Sue Norris

## **1. Welcome**

The Chairman welcomed everyone to the Committee meeting.

## **2. Apologies**

Apologies were received from Professor David Sharpe, Dr Julie Kent and Mr Arvind Singh.

## **3. Minutes of the last meeting (08/001)**

The minutes of the meeting of 23 November 2007 were approved with minor amendments to sections 4.4, 6.1, 6.4 and 6.5.

## **4. Matters arising/Action Points (08/002)**

### **4.1 Metal on metal debris (Andrew Crosbie)**

Three meetings took place on this issue in late 2006/2007. A draft report was presented to the CSD in July 2007. There were no proven health risks associated with metal on metal implants regarding genotoxicity, despite reports of histological changes in regional lymph nodes. Contact has been made with the Department of Health regarding linkage between the National Joint Registry and the Cancer Registry to investigate issues associated with metal on metal replacements and the occurrence of cancers. The report also included research projects and these are to be taken forward.

Mr Crosbie informed the Committee that MHRA representatives had attended the British Hip Society meeting in the previous week. An increasing number of centres are starting to see a phenomenon which was not previously widely reported – adverse effects on the soft tissues associated with hip resurfacing devices and Metal on Metal articulation devices. The MHRA met with the British Orthopaedic Association in January 2008 and representatives from the National Joint Registry were also present at that meeting. It had been agreed that a joint working group would be established between the MHRA and the British Orthopaedic Association to address this issue in more detail and address the advice the MHRA needs to put out regarding these kinds of devices, both in terms of clinical follow-up and their continued usage. The Committee agreed that this issue should be investigated with the help of orthopaedic colleagues.

### **4.2 Electrical safety: Update and Strategy: Production of Poster (Valerie Field)**

Ms Field thanked members for their comments from last time. As a result, the two pictures in the middle of the poster were changed to make them clearer and easier to understand. Large scale distribution of these posters to hospitals and other associations and groups will commence shortly. The Committee agreed that ten copies should go to the liaison officers of every trust in England.

### 4.3 Communication with pharmacists (Christine Glover)

Mrs Glover provided an update on initiatives to improve communications with community pharmacists and their awareness of devices and the role of the MHRA in this. The recommendations are achievable and can be carried out at minimal cost. The aim was to get a line on the yellow card at the back of the BNF regarding reporting devices in order that everyone knows where it is. This is to be done for next September. Most recommendations involve writing to the key players in the pharmacy community. Contact has been made with them and they are all expecting letters from the Agency on this issue. With the correct timing, ensuring everyone receives a letter at same time, the desired effect in education and training is more likely to be achieved.

The Committee found the suggestions of trying to get space on the BPC and targeting five major companies helpful. However, queries were raised, such as the pharmacogenetic side. Committee members were concerned that unless genetic testing was done with a degree of counselling, the moral aspects will have serious consequences. This issue has been raised before with over the counter testing. There are concerns over testing for infections such as Chlamydia without the associated counselling. Mrs Glover said that some pharmacists are trained to test *and* counsel, which is funded by the primary care trust. This is the expected model and is being carried out at certain sites.

On the subject of Chlamydia testing, Dr Ridgway said that originally, home tests were not very effective due to high false positive rates. Results were improved by patients providing a specimen which is then sent to a central laboratory. They then send back to the patient their result and an explanation of the result if positive, along with a list of addresses of local clinics they can attend. This was set up with British Association of Sexual Health and Hygiene. This has now gone a step further as pending with the MHRA is an application for over the counter sale of azithromycin. The package includes a form of counselling and Dr Ridgway emphasised the importance of regulating this type of testing where it is carried out. A member re-emphasised the child protection issue where Chlamydia testing in under 16s is concerned. A member enquired about the implications for contact tracing and Dr Ridgway responded that this is a problem with traditional Chlamydia testing. Current policy dictates that contacts should be treated blind and this has carried over into the over the counter package.

Sheila Fisher suggested that the website may be good place to report problems with devices. On the issue of how to teach students to use items correctly, Dr Ridgway commented that getting samples from manufacturers can sometimes be a problem and suggested that the ABHI could be involved in this.

Dr Ludgate informed the Committee of the feedback from a recent yellow card initiative using Ipsos MORI which discussed with pharmacists what they would like from the drug and device side. Pharmacists reported that they liked receiving device and drug alerts, but did not like requests to report adverse

events. A potential reason for this is that they do not get money for reporting faulty devices and are, therefore, not keen on such initiatives for patients to report them. On some occasions, patients have been told to see their GP.

A member commented that Chlamydia testing is not regulated by MHRA and that the MHRA can only regulate instructions for home use and testing patient leaflets. It has been raised that effective patient leaflets were not provided or that they were not easily understood by the lay public.

#### **4.4 Communication on diabetes**

This issue is to undergo internal consultation.

#### **5. Conflict of Interest: Reminder**

The Chairman informed Members of the need to declare conflicts of interest with any of the day's agenda items. No interests were declared.

#### **6. Centre for evidence based purchasing: What we do to support the Health Service (Sue Norris)**

Mrs Norris gave a short oral presentation on the role of the Centre for Evidence-based Purchasing (CEP) in supporting the Health Service. The four key areas addressed were: strengthening links in the innovation landscape, supporting the Department of Health's priorities, namely value and innovation and new publications. To provide an example of the CEP's work, Mrs Norris informed the Committee that the CEP had produced an insulin pump buyers' guide following NICE Guidance of insulin pumps for Type I diabetics in 2003.

Market research on evidence revealed that information was viewed by 1962 doctors 3202 times, that information was downloaded 225 times, that 55% are more likely to discuss the evidence with their colleagues and that 48% will review their practice in light of the evidence review. The CEP supports the Department of Health through 32 care pathways that have targets to meet the 18 week wait, by providing advanced Horizon Scanning and by embedding information in the pathway to support commissioners and providers. The CEP works in collaboration with CRiSPS and MATCH and considers economic value and cost impact through reports, for example the cost effectiveness of digital radiography.

A member enquired to what extent financial considerations hindered developments in the NHS. Ms Norris replied that financial considerations were of considerable importance therefore clinical engagement in procurement is crucial. She added that evidence would be reviewed as it grew since it is constantly building. The evidence is updated and constantly reviewed; however, there is a need to prioritise, for example, to work on MRSA products at the moment and the usual cancer products. A member asked what authority the recommendations have, for example, if one form of insulin pump is recommended. Mrs Norris replied that these are not recommendations for the best product, merely providing information so that

an informed choice can be made. Only a single product is looked at so products are not ranked. It is providing an information service for procurer and is *not* regulatory in nature.

Mr Smith said that there is not a lot of evidence in Trusts that it ends up benefiting the patients. A Trust is driven more by considerations such as budgets and waiting times and new innovations will require long term investment and thinking. He questioned how this could be reconciled with short term crisis management in NHS. Mrs Norris said that the CEP can only support Trusts and commissioners. Dr Ludgate added that there was also the problem of not being able to generate data. Dr Perrins asked if it is part of the remit to accept NICE guidelines. Mrs Norris said that it will not challenge NICE.

### **7.1 Feedback from the communication Group: Review of the format of Medical Device Alerts (08/003)**

**Clive Bray**

Mr Bray presented feedback from the Communication Group on Medical Device Alerts. The current format has evolved and is a compromise between user requirements and constraints placed by the Department of Health, regulatory considerations and legal advice. A meeting was held on 14<sup>th</sup> January 2008 comprising members of the CSD, Liaison Officers and Devolved Administrations. It was agreed a radical approach should be taken in amending the current MDA format in order to improve presentation, user friendliness and to take advantage of benefits resulting from e-working.

It was agreed that a move to an electronic system would be a positive change as it provides easier access to the information. The group proposed that electronic notices should consist of an email alert with a single A4 e-attachment (which can be printed and distributed within healthcare organisations) containing a link to more detailed information on the MHRA Website. This has certain advantages such as overcoming difficulties with file sizes and would be easier for GPs to access. The group proposed that the e-alert and e-attachment would replace the front page of MDAs by providing key information to allow the reader to identify the product, understand the problem, provide an outline of the action to be taken together with an indication of the urgency of the response. The group proposed that the title of the email should be drafted to identify it as an Alert. The e-attachment should contain a description of the device with a picture where appropriate, an "alert status", action to be taken and by whom and links to the MHRA website, the manufacturer and information on how to report an adverse incident.

It was agreed that the e-MDA would not be published in printed form or distributed by the MHRA but would be available to download from the MHRA website so it could be printed locally if necessary. The group proposed that notices should be sent to the Chief Executive of the organisation as well as having a suggested list of end users. Professional societies were suggested as a way of advertising links to relevant e-MDAs. It was agreed that it would be necessary to identify those who need to take action on the advice given in

the e-MDA and it was recognised that in some cases action could be taken without the involvement of the user. It was agreed that feedback would be provided to the MHRA showing appropriate action had been taken. These proposals are to be discussed at the forthcoming Liaison Officer Focus Group meeting and they are contingent upon further funding being provided by the Department of Health.

A member asked how this system differs from what is said at present. Mr Bray clarified that it is distributed as an email. The user would consequently go to the website to find information. They may search the website and target the information required. Dr Facey asked why it is an e-attachment and not contained within the email itself. She questioned why an attachment is required rather than providing a clickable link within the email. Mr Bray responded that this can be revised. A member queried what advice had been taken from the nursing profession on this issue as there were concerns about clinical staff being busy thus making it unlikely that they would click on these tabs

Mr Bray said that electronic email would be held on the website but that local systems could have their own mechanism. Dr Sears stated that most GPs use the web, as do most community nursing colleagues. He suggested the use of printouts where required. A member suggested that alerts should go through professional societies and Dr Ludgate replied that this is currently done. Sheila Fisher enquired as to how much dialogue there had been with PCTs as IT access is much more difficult at larger teaching hospitals. Mrs Glover suggesting carrying out some testing after it has gone out. Ms Boakes asked how this will be disseminated within an organisation. She pointed out that if people will be printing, the use of pictures and quality of local printing might be an issue. If everyone accesses the MHRA website at once, servers might be affected. Mr Bray said that systems would run in parallel before moving across entirely.

The Committee supported the decision to move towards this system whilst recognising it is a complex change that will require input from the industry and patients.

## **7.2 Feedback from Medical Device Alert review (08/006)**

### **Clive Bray**

Mr Bray presented a paper comparing medical device alerts published in 2005 and 2007. The aim of the report was to assess whether the 'clinical usefulness' of the MDAs sent out to the health service had changed in that two year period. The number of forms returned was disappointing but an analysis of scores was conducted nevertheless. The report covered a spectrum of alerts across the Agency with issues including wheelchairs, blood glucose meters, ICDs and hospital beds. These were rated on a scale of 1 to 4, low to high, on clinical usefulness. The average score was encouraging at 3.5-3.7.

### **7.3 Summary of adverse incidents Clive Bray**

Mr Bray informed the Committee that there has been a decrease in NHS reporting and an increase in reporting from industry – 39% are from users and 46% from manufacturers. For IVDs, 8% of reports are from users and 81% from manufacturers. For wheelchairs, 89% are from users and only 2% are from manufacturers. An investigation of 8634 reports in 2006 resulted in 100 safety warnings published, 86 modifications to authorities in EU member states, 674 product recalls, field corrections involving MHRA supervision or active involvement, 92 other manufacturer's field actions, 206 cases requiring provision of advice on safer device use or improved staff training and 397 manufacturer undertakings to improve designs, manufacturing processes and quality systems.

Dr Facey asked what occurred during extra reports as this only covered a sample. Mr Bray said that very few adverse reports came in from outside the UK despite there being a huge market. Though devices are international, reporting appeared to be one-way. He stated that, in the UK, prior to device regulations, a voluntary reporting system was in place. This has been kept in place and two thirds of reports come in through the voluntary system. Some member states did not have this reporting system. Another factor which may explain the low incidence of reports is categorisation. Product incompatibility, for example, is not reported as vigilance. Mr Bray also clarified that the report was based on Europe only, therefore, did not incorporate the USA or other continents. Mr Crosbie said that reports are being discussed where other European authorities are legally obliged to pass information on to the MHRA, therefore, this report represented only a tiny sample where there is a legal obligation to correspond. Mr Bray added that, at the Liaison Officers' conference, it was deemed difficult due to a heavy reliance on the goodwill of manufacturers to help when there is a shortage. There may be a reluctance to report adverse incidents for a particular manufacturer's product in case they withdraw their support.

### **7.4 How do we promote better reporting from the Health Service (08/004) Susanne Ludgate**

Dr Ludgate updated the Committee on device reports from the Health Service. A recent project with doctors.net showed that 41% had seen device related adverse events, or near misses, within the previous *week*, yet the fact that the MHRA had not been inundated with reports was significant. Dr Ludgate informed the Committee that there had been a recent increase in user reporting. Some of the major events in past five years, some of the most important public health safety issues, have come from clinician reports. This has led to the UK leading in some of these cases. Adverse incident reporting needs to be promoted. Though the project with doctors.net did not prove to be successful, the website was clicked on frequently and numbers have gone up in the past three months. Dr Ludgate concluded that the practice should continue to be promoted at conferences etc.

Dr Sears recommended continuing with one question on this issue in the MRCGP examination in order to keep it on the agenda. Ms Fisher said that the correct people need to be targeted and that, since doctors are so focused on procedures and processes, it may be better to ensure there is a specific person in the team who can be responsible for it. The Chair said that faulty devices are being reported internally but not reported centrally. A member asked where devices are reported and whether it is to multiple agencies, suggesting that a single portal would be more straightforward. The Chair agreed that multiple agencies posed a problem. Mr O'Donovan said that problems arise over the filtering of information that occurs since hospitals call up manufacturers to ask if there is something wrong, leading to problems over who makes the report. Dr Perrins said that if a fault was not picked up by a user as a suspicion, it is not reported, therefore, there is no opportunity to synthesise random reports which may be of significance. Mr Earl said that, in relation to the yellow card, there had been concern about the suggestion of it going through clinical governance as there should not be a restriction on reporting directly.

The Committee agreed that there should be a mechanism where issues not reported by clinicians are picked up.

#### **7.5. Developing a website for individual clinician groups (08/005) Christopher Brittain**

Dr Brittain gave a short presentation on the progress of developing a website for individual clinician groups. The aims of the website were to increase healthcare professional awareness of the MHRA, increase adverse incident reporting, access to publications and drug safety bulletins. Levels of reporting are low and continue to fall. Since the initial development of the website, there had been no specific portal through which healthcare professionals could rapidly access information or publications which are relevant to their specialty. In order to address this problem, the MHRA has commenced production of healthcare professional targeted web pages using ophthalmology as a pilot. This has brought together relevant ophthalmic publications, device alerts and medicines alerts on one easy to access page. The aim is to keep the page simple. Dr Brittain showed the Committee an example of the page layout, with access to ophthalmology publications at the bottom of the page, interactive educational modules, reporting of adverse incidents and a 'Questions and Answers' section.

Dr Ridgway asked if this would include decontamination advice and Dr Brittain replied that it would. Dr Brittain assured the Committee that the MHRA was working on this initiative alongside the Royal College of Ophthalmologists. A member suggested placing the adverse incident report button somewhere more prominent in order to draw more attention to it. Ms Boakes suggested it might be better to be more specific about timeframes. She added that more relevant and recent news should be kept at the top. Ms Fisher suggested adding a counting box where users can see if other reports have been placed

as this might motivate people to report. Dr Sears concurred that this was a positive idea.

## **7.6 National Joint Registry – Functions and Research (08/007)**

### **Andrew Crosbie**

Mr Crosbie gave a presentation informing members of the Committee on the role of the National Joint Registry (NJR) in contributing to patient safety and the challenges it faces. The NJR was set up in October 2002 and began collecting data on hip and knee replacement operations in April 2003. Information is provided to the NJR using online electronic submission by NHS and independent healthcare providers in England and Wales. The work of the NJR is overseen by a Steering Committee (NJRSC) which was set up in October 2002 and which is now an advisory non-departmental public body. NJRSC members consist of surgeons, implant manufacturers, epidemiologists and lay representatives. MHRA and DH officials also attend. The NJR is funded through a levy, which is raised on the sale of hip and knee replacement implants.

The NJR requires a continuous supply of accurate, high quality information about operations carried out in order to achieve its aims. The usefulness of the data depends upon three key factors compliance, consent and linkability. The compliance rate is the percentage of records submitted to the NJR by clinicians compared with the total number of hip and knee replacement operations carried out. The NJR can only achieve its aims if it has high compliance rates so it has had to put a great deal of effort into encouraging hospitals to submit data in order to improve compliance. The target is to achieve 95% compliance by June 2008.

The consent rate is the percentage of records submitted to the NJR with consent given by patients for use of their personal information. The NJR can only achieve its aims if it has high consent rates. The NJR's target is to achieve 90% consent rate by June 2008. Linkability is the percentage of consented records that include patients' NJR number so that all operations performed on the same patient can be linked. The NJR can only achieve its aims if this can be done. The target is to achieve 90% linkability by June 2008. The NJR aims to publicise and promote its work and it has a comprehensive website with sections tailored to the need of clinicians, patients etc. The NJR produces an annual report providing detailed information on the management/development of the registry and in-depth analysis.

A member commented that variables are not being considered as they are being looked at on a generic basis and that the response to problems should take into account the variables, for example, where an implant is not accurately implanted, which could result in wear. Mr Crosbie responded that this seems to be widely related to surgical technique. Devices which are inserted optimally are less likely to have this problem whereas those not inserted optimally are more prone.

## **7.7 Software and Medical Devices: The problems and the User (08/008)**

**Peter Jordan**

Mr Jordan gave a presentation on the risks of software in medical devices. The three main issues were whether software may trigger safety-related functions, whether the software may malfunction in ways that are characteristic of software and whether the use of software may change the nature or use of the device. The main requirements for software were: effectiveness, safety, ease of use, efficiency, cost savings, communication and configurability. However, the user will get unwanted functions, insufficient safety, complex controls, changed practices, de-skilling, network problems and confusion about configuration. On the subject of software malfunctions, the specification, design, implementation all require verification.

Dr Sears asked whether clinical software is classed as a medical device. Mr Jordan replied that it depends on jurisdiction. Dr Ludgate queried whether anything could be done to *ensure* that new software functions provided after an adverse incident were sufficient to address safety. Mr Jordan replied that the MHRA was in a strong position to enforce this.

## **7.8 Adverse Incident Vignettes (Khalid Razak)**

Dr Razak gave a brief oral presentation on adverse incidents in the use of home HIV testing kits purchased via the internet. Two reports were received in the last month, one from a member of the public in January stating they had had a false negative from a home test and the second from a nurse whose patient had received a false positive on a home test but shown to be negative following hospital testing. Dr Razak showed the Committee an example of a home testing kit and its contents. During evaluation of the tests, manufacturers did not demonstrate compliance with the usual diagnostic directive and the essential requirements including those of content specifications. This includes a list of criteria asking that all true positive samples must give a positive result and gives out a minimum number of samples and sample types that a manufacturer must test. Because only one report was received for each faulty device, there is no concrete evidence to suggest that these devices did not meet the manufacturers' claims. Dr Ridgway commented that there are no home testing kits which have a rate of 100% accuracy therefore a positive sample cannot *always* give a positive result.

## **7.9 Gas plasma sterilisation (08/009)**

**Ian Smith**

Mr Smith gave a presentation on gas plasma sterilisation. Gas plasma sterilisation is a low temperature method of sterilising medical devices using hydrogen peroxide vapour and low-temperature gas plasma and is particularly suited to heat sensitive and moisture sensitive instruments. Advanced

Sterilisation Products (ASP), who developed the original technique, announced in November 2007 that they were withdrawing the Compatible Medical Device reference Lists (which provide information on specific brands and models of medical devices that are compatible with the STERRAD Sterilisation System) and associated instrument assessments provided with these systems as they were becoming outdated with the introduction of new technologies and materials. They advised customers to contact device manufacturers directly to determine if specific brands and models of devices would remain functional following sterilisation using this system.

36 hospitals in the UK have a STERRAD system in use or are undergoing validation prior to use. They did not intend at this stage to issue the FSN to hospitals prior to visiting them. However, it was decided that UK customers ought to be made aware of this as soon as possible and, therefore, that a 'targeted letter' should be issued, enclosing a copy of the FSN. This letter advised users to contact ASP to arrange a consultation and reminded them of their responsibility to ensure that any reusable medical devices were compatible with the decontamination process they were using.

**8. Any other business**

None received.

**9. Date and time of next meeting**

The next meeting will be held on **11 July 2008**.

The date of the following meeting has been changed to **28 November 2008**.