

MINUTES OF THE COMMITTEE ON THE SAFETY OF DEVICES MEETING: 5 JULY 2007

Members Attending:

CSD

Mr John Williams (Chair)
Mr Guy Alexander
Dr Anna-Maria Belli
Ms Catherine Cairns
Mr Christopher Earl
Mr Roger Evans
Dr Karen Facey
Dr Sheila Fisher
Mrs Christine Glover
Dr Julie Kent
Professor Ian Kimber
Dr Sheila Peskett
Dr Geoffrey Ridgway
Dr Charles Sears
Professor David Sharpe
Mr Arvind Singh
Professor Irving Taylor
Dr Gary Thorpe
Dr John Turney
Dr Carl Waldmann
Dr Gordon Watkins

MHRA

Dr Susanne Ludgate
Mr Mike Peel
Mr Clive Bray
Mr Alexander McLaren
Mr Philip Grohmann
Mr Andy Crosbie
Dr Tom Clutton-Brock
Mr David Grainger
Mr Tony Sant
Mrs Fran Queen

Devolved Administrations (Observers)

Ms Sylvia Shearer
Mrs E Qua
Mr Andrew Wong

Others

Ms Annette Lankshear
Mr Paul Cryer

Industry (Observers)

Mr Clive Powell, ABHI
Mr Peter Phillips, WAG
Mr Terry Prodger, BDTA

1. WELCOME

1.1 The Chairman welcomed everyone to the Committee meeting.

2. APOLOGIES

2.1 Apologies were received from Dr Steve Bennett Britton, Professor Ian Learmonth, Mr Peter O'Donovan and Dr John Perrins.

3. MINUTES OF LAST MEETING (07/001)

3.1 The minutes of the meeting of 22 March 2007 were agreed. The minutes will be posted on the MHRA website.

4. MATTERS ARISING/ACTION POINTS

4.1 Screws and small implants, letter to Professional bodies: The Chairman stated that a related issue would be discussed later under a main item on vCJD and dental instruments. The Chairman said he had now written to BOA, BAOMS and Spinal Surgery Groups.

4.2 Communication with the Health Service: The Chairman said the MHRA were in the process of setting up a meeting of the Communication Steering Group.

4.3 Over the counter devices: a pamphlet had been produced and a briefing had been held with the press, outlining the problems associated with these devices. This has led to a series of interviews and articles.

4.4 Problems associated with diathermy use: an education module has been prepared for dissemination to relevant Royal Colleges and professional bodies.

4.5 Electrical safety, letter to CMO: a letter from the Chairman to the Chief Medical Officer together with the CMO's response had been tabled at the meeting. The Chairman said he was disappointed that the CMO's response did not address the serious issue of the current lack of standards of electrical safety in hospitals. The Chairman said that this needed to be followed up.

MHRA are trying to publicise this matter and are working with the editor of MEGAN. MHRA are setting up a working group with the aim of circulating information widely to the Health Service to promote awareness, possibly in the form of a poster. This will also involve Estates.

The Chair asked if any Members had a specific interest in this issue, they should correspond with the MHRA electronically. Members agreed that the MHRA should target communications to the Estates Departments. Mr Bray replied that the Estates and Facilities Division is revising its manual on bedhead electronics, so the MHRA may be able to highlight the issue of electrical safety via this route.

4.6 Drug Eluting Stents: Dr Ludgate provided an update on the workshop in Washington between the FDA, European Regulatory Authorities and other interested parties on drug eluting stents. Unfortunately, no real conclusions had been reached at this workshop on a collaborative project but it was agreed that it was important to encourage trials looking at the performance of stents in "off-label" use. so as to provide the evidence necessary for their use under these conditions. The question of optimal anti-platelet therapy should also be addressed.

5. CONFLICT OF INTEREST: REMINDER

- 5.1 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. LOGO FOR COMMITTEE: CSD: 07/16

- 6.1 Mr Peel explained that the Communications Division said that it would cost over £1000 to develop a logo for the CSD, so he had produced an example for the Committee's consideration. He asked if it should be "CSD" and/or "Committee on the Safety of Devices".

Members thought that it should be clear on the paper letterhead, that CSD was part of the MHRA. They preferred Arial font. Members liked the layout of the letterhead with a larger logo, but did not like the stencilled font of the logo itself.

7. MAIN ITEMS

7.1 vCJD and dental instruments: recent advice from DH: CSD: 07/017

Dr Watkins said that the MHRA paper was a good summary of the situation. The Chief Dental Officer had issued a letter to all dentists with guidelines. The British Dental Association thought assumptions had been made with the modelling and the risk assessment needed to be more stringent. They also had concerns about the primate and rodent model, and the lack of clinical input. There was an assumption that dentists were putting instruments into the bone. Overall, the report had reached the right conclusions, but for the wrong reasons. The main reason that single use instruments are used is because they blunt and fracture easily. The British Dental Association will be writing to the Chief Medical Officer requesting that NICE are involved in investigations in decontamination in primary care.

Dr Watkins said that medical devices used in dentistry should comply with the Medical Devices Directive, but in the past products have been lacking in their instructions for use. There is a need for the MHRA to bring this up with manufacturers.

Mr Crosbie said that he concurred with Dr Watkins' comments. Following the letter sent by the Chief Dental Officer to all dentists, Dr A Smith of Glasgow University had written to the MHRA's Chairman, Professor Breckenridge, enclosing a draft paper that will be published in the British Dental Journal. There is a wide range of equipment that has insufficient instructions for use. Focus needs to be on compliance and the MHRA should look into the problem of instructions for use.

Mrs Glover asked if there were any system for inspection of dental practices. Mr Watkins said that there were for NHS practices. It was easy to inspect the equipment, but more difficult to inspect the processes. Members asked what the level of risk was and how many cases of vCJD had there been. Mr Watkins said that there had been 150 cases of vCJD since the problem had been identified and about 6 cases this year. Dr Ridgway explained that there were three forms of susceptibility with vCJD. vCJD can be latent for 40 years. It was noted that hospital memorandum HTMO1 is in the process of being revised.

The ABHI representative explained that they try to ensure that their members are aware of the requirements of the Medical Devices Directive, and that CE

marked Class 2A equipment should have adequate instructions. Mr Crosbie said that much of the equipment in question was Class 1 and so had no Notified Body involvement in its CE marking. Dr Ludgate said that it is the responsibility of the manufacturer of the device and not the autoclave manufacturer for providing instructions for use including sterilisation procedures.

Professor Sharpe said that many items of equipment were single use, because they were either destroyed by the autoclave or could not be completely sterilised. They thought that manufacturers should supply cheap packages of single use instruments such as reamers, or if possible, instruments that can be thoroughly sterilised. The Chair said that he would raise this issue in a forthcoming meeting with ABHI.

7.2 Education programme on Devices: Where we are now and the future: CSD: 07/018

Dr Clutton-Brock gave a presentation updating the Committee on progress of the education programme on devices. He explained that there were four projects - Using Devices Safely, Electrosurgery, Anaesthesia Workstations, and the Operating Table.

The Electrosurgery module had now been completed, and they have developed and tested the website. It is a generic module and no equipment manufacturers could be identified. The module will be up and running this month after secure access has been achieved.

The Anaesthesia Workstations module will also be generic. MHRA will be attending a safety conference in October 2007. MHRA were looking at contributing to the Association of Anaesthetists' (AAGBI) Anaesthetic equipment check. Anaesthetic equipment is becoming more complex and some of the guidance in the Anaesthetic equipment check is inappropriate. MHRA is working with AAGBI to update the training. Training on how to use equipment is given when new equipment is supplied, but because of the turnover of staff during the lifetime of the product, some staff may be faced with equipment that they do not know how to use.

E learning for Health can now be accessed through a common portal. Access is free of charge to registered users. It is web based allowing a variety of text and graphics to be embedded. However, there is no sound, but this could be added.

Members asked if the Anaesthesia Workstation programme would be open to others who were not anaesthetists. Dr Clutton-Brock said that the modules were open to everyone who registers. However, it is meant for healthcare professionals and not the general public.

Members asked if the MHRA could encourage the four anaesthetic equipment manufacturers to produce similar icons and instructions for use. Dr Clutton-Brock replied that as a result of Standards there is already more similarity between these machines than there is between many other devices.

Members thought that there should be written text on the website as well as sound, as it may be accessed by users with impaired hearing. Dr Clutton-Brock replied that the programme has a written transcript of the voice-over.

Members asked why website access was restricted. Dr Clutton-Brock replied that the MHRA had only received consent from patients to use the

material for professional training purposes. To have fully open access would therefore restrict the patient based material.

Health Industries Task Force: Comment

Mr Cryer from the Department of Health gave a presentation on their training and education programme. Their aims were to:

- Establish a focal point including a best practice and information repository around which the medical device community can unite in relation to training and education;
- Devise a national standards framework to underpin competences in relation to medical device training and education;
- Seek to increase targeted investment for medical device training and education through;
 - a better understanding of levels of provision,
 - a more explicit recognition of need by education commissioners and frameworks by which to better articulate value added opportunities and benefits realisation;
- Provide a specific platform for closer and better working relations with the commercial providers of medical devices and associated training and education programmes.

Members asked if the NITF would be working with the National Clinical Library, who had just gone online. Mr Cryer replied that they would, but they had not set a timetable to do so. The Chair said that the NITF must target trainees on instructions for use of equipment, and continue their education throughout their career. The Chair said that the programme must also be open to people outside of the Health Service.

8. UPDATES

8.1 Expert Advisory Group on Metal Wear Debris: CSD: 07/022

Mr Crosbie gave a presentation on the work of the EAG on Metal Wear Debris. The background to the EAG's formation was that in July 2006, Committee on Mutagenicity concluded that there was evidence of genetic damage in patients with certain types of metal implants. Subsequently, the CSD decided to establish an Expert Advisory Group to assess the clinical significance of the COM's findings; to put the findings into a risk-benefit context; and to offer practical advice to clinicians and patients.

Christine Glover is the lay chair of the EAG. Members included experts in orthopaedic surgery, pathology, immunology, toxicology, material science and manufacturing. The EAG had met three times.

The EAG concluded that:

- there is no evidence for any association between hip replacements and an increased incidence of any malignant disease;
- there is no evidence that the genotoxic effects seen in patients with metal-on-metal hip replacements are associated with increased levels of cobalt and chromium ions;

- there is no evidence that increased levels of cobalt and chromium ions are associated with any clinical effects;
- the distribution of cobalt and chromium ions in the body is unclear, particularly the extent to which they can cross the blood-brain barrier or placenta;
- whilst there is evidence for an immunological component in some, rarely seen, responses to wear debris, the precise mechanisms of the effects observed are unknown;
- there is limited evidence to suggest that chromosome abnormalities may also be associated with ceramic-on-ceramic hip replacements. No conclusions can be drawn from this finding at present.

The EAG recommended that:

- all patients should have a full explanation of the choice of hip implants available, the pros and cons of the different implant types, including resurfacing and the reasons for individual recommendation. They should also sign a consent form which sets out the fact that the risks associated with metal wear debris have been discussed, including the genotoxic risk and possible sequelae;
- all hip replacement patients should have careful follow-up at time periods in line with NICE guidance, and should be advised to seek an early appointment if they detect any changes in the implant or their mobility, or if symptoms, including but not limited to pain, develop;
- all hip replacement operations, including hip resurfacing, should be entered on the National Joint Registry (NJR);
- all adverse incidents associated with metal-on-metal hip implants, including early revisions (<10 years) and soft tissue reactions should be reported to the MHRA.

The EAG could not recommend but considered that the following points should be borne in mind:

- metal ions are excreted via the kidneys and, therefore, caution should be exercised in the use of metal-on-metal articulations in hip replacements in people with renal failure, or at risk of renal failure;
- increases in concentrations of cobalt and chromium ions in blood are at their highest during the first few months following metal-on-metal hip replacement. Since these ions have been detected in umbilical cord and placental blood, there is a need to determine whether this represents a health risk during pregnancy.

Members thought that this was a good summary, and that the most important conclusion was that there was no evidence of malignant disease. There was some concern over the immunological change associated with metal wear debris.

Members asked if the question of genotoxicity should be raised when seeking patient consent, and how accessible would the EAG's findings be. They also asked if the EAG had considered systems other than metal on metal. They also had concerns on that lack of evidence.

Mrs Glover said that the EAG process had been thorough and robust and reflected current knowledge. Difficulty had occurred where there was inconsistency in measurements and a lack of comparability. There were no benchmarks on what is acceptable. Evidence may be available in the future, but they wanted to ensure that patients know that there is a risk now, and sign consent if necessary. The EAG's minutes will go on the website.

The Chairman asked if the CSD would endorse the paper as amended in view of comments made. The CSD agreed. The Chairman thanked Mrs Glover for the work she had done chairing the EAG.

Dr Ludgate said that the Agency was in discussion with the part of the Department of Health responsible for the National Joint Registry in an attempt to establish a tie-up between this registry and the Cancer Registry.

9. MAIN ITEMS continued

9.1 Differences of opinion between Regulatory Authorities: actions necessary: CSD: 07/020

Mr McLaren gave a presentation starting with the background to the Shelhigh case. Shelhigh Inc manufacture bio/bio-synthetic devices derived from bovine and porcine tissue.

In April 2007, following an inspection the FDA seized all completed Shelhigh devices and parts. In their public statement, the FDA gave the reasons that "significant deficiencies in the company's manufacturing processes" which may "compromise the safety and effectiveness of the products, particularly their sterility".

In May 2007, the FDA requested that Shelhigh voluntarily recall their products. However, Shelhigh refused to do this.

Within the EU, Shelhigh contracts with a Spanish Notified Body (NB) for auditing against European Medical Devices Directive. Their last audit was in March 2007, where particular attention was given to their sterilization processes. The NB conclusion was that there was nothing of major concern identified.

At the request of the UK and European Commission, a meeting was held at the Spanish Competent Authority's headquarters in June. The objective was to critically evaluate and compare both the FDA and the Notified Body inspection reports. Representatives attended from the Spanish Competent Authority, the European Commission and Technical Specialists from MHRA and the Swedish and French Competent Authorities. They concluded that the NB had fulfilled their inspection requirements and their conclusion to continue certification of the company was justified.

Members asked if the difference between the Spanish and US investigation was that the Spanish was just a paper exercise. Mr Bray said that the Spanish had done a site visit. Members asked how the US and EU results could be so diverse. Dr Ludgate suspected that a lot of work had been done by Shelhigh between the FDA inspection and Spanish NB inspection. The EU and US systems were not too different. Members asked if it was normal practice for Competent Authorities to do overseas inspections. Mr Bray replied that it is the Notified Bodies, not the Competent Authorities that undertake the inspections.

Members asked what is happening with the review of Notified Bodies. Dr Ludgate said that there was no absolute uniformity between the 80 Notified Bodies. However, the Notified Bodies Group had been working to improve systems and to try to create a level playing field.

Members asked how we resolve the EU disparities, let alone the differences between the EU and US systems. The Chairman replied that in the case in question, this was not an issue of EU uniformity, just a difference between the EU and US. The FDA and the EU do meet.

Members said that with respect to dental practices, the US will inspect work in progress and if they had concerns, they could shut the practice down. In the UK and the EU, there is a more collaborative approach where the authorities will encourage or teach best practice.

Members thought that the UK/EU should keep a database of products to prove that we have no problem with them, should questions arise in future.

9.2 Safety Alert Broadcast system: audits and lessons learnt: CSD: 07/019

Annette Lankshear from Cardiff University gave a presentation on the evaluation of the uptake of advice, directives and guidelines to the NHS concerning patient safety by the Safety Alert Broadcast System.

Their methodology was to interview issuing agencies, interview/send questionnaires to SHA and Trust SABS liaison officers, and make site visits to trusts.

The findings on the survey to SABS liaison officers showed that 54% were Medical Device Liaison Officers, with 35% having a clinical background. There were 216 different job titles, with considerably varying seniority, some were secretarial whilst others held senior positions on the risk management board. 61% indicated that they spent between 2-10% of their time on SABS.

With regard to visits to organisations, interviews were held with key managers and front line staff in 10 wards/ 6 clinics. They undertook audits to collect evidence of action.

Their conclusions for SABS distribution itself was that it worked well but there were some glitches in the system. GPs would like the message in the email header, also the timing of issuing the alert was important, in particular that they are not sent out on Friday afternoons.

Their messages for the MHRA were that MHRA Alerts in the main are thought to be clear and easy to implement. However, they should ensure that the action and the risks are clear – not vague warnings. There was also some repetition with manufacturer, MHRA and NPSA notifications. The MHRA should know its audience. Some were badly targeted, especially to Mental Health trusts and PCTs. The circulation lists on Alerts were far too long and largely ignored. SABS liaison officers select for relevance to their Trust and managers then filter out Alerts they deem to be irrelevant. There was concern that the MHRA had not actioned SABS liaison officers concerns.

The conclusions for Trusts were that the workload of SABS liaison officers had increased, yet it is only seen to be a small part of their job (2-10%).

Dissemination systems work well to lower management level. There is overconfidence of senior managers in the system. Some SABS liaison officers have developed sophisticated systems of distribution. There was limited evidence of implementation. Paper copies were still being received at ward/clinic level. Alerts are not self executive. There was little evidence of audit of action. Little evidence of any interest or awareness among doctors, although only medical directors and PCT chairs were interviewed.

Members thought that the MHRA should produce a compendium of advice/alerts issued, so people can refer to which are relevant to their current job.

9.3 IPODS, WiFi and pacemakers: advice to patients: CSD: 07/021

The Chairman announced that Peter Solesbury, who was to present this item, had unexpectedly passed away at the weekend. This was a sad loss.

Mr Crosbie began by stating that an oral presentation about the possible interference between pacemakers and iPods had been presented at the May 2007 Heart Rhythm Society conference in the US. The MHRA had been periodically issuing advice on these devices. A BBC Panorama programme had drawn attention to general health risks and this had subsequently raised interest in Wi-Fi.

Advice had previously been issued to Professionals. However, the MHRA had made the decision that they should put information on the website about such consumer electronic items, so that patients can have direct access to this information.

Members welcomed freer access to this information on the website. However, GPs and a number of patients may go the British Heart Foundation as a first port of call. Mr Crosbie replied that the Agency has a good relationship with the British Heart Foundation and would work with them. Members thought that the MHRA website information would get a lot of hits via search engines. They asked if a hits counter could be put on the webpage. The Chairman replied that the MHRA already has a mechanism for knowing how many hits each webpage gets.

9.4 CSD audit of clinical investigation system 2007

Dr Ludgate said that the last audit for 2007 had been completed this week. The background to these audits is that the UK in the past had been accused of being the most stringent Competent Authority, although it was noted that the UK system is now regarded by Europe as being the "gold standard". The system of independent audit was introduced, however, so as to reassure industry that the correct decisions were being taken and the correct procedures and timescales adhered to.

Three trials chosen this year by the Chairman were the three with which the Competent Authority had experienced the most difficulty in coming to a final decision. This included a difficult trial utilising a bronchial drug eluting stent. The auditors agreed with the decisions taken. There was, however, one extra ground for objection regarding decontamination that should have been raised in one trial; and an additional external assessor was thought would have been of help in one other trial.

Dr Ludgate indicated that the process had once again been helpful to the Competent Authority in ensuring that they were making the correct decisions and adhering to processes; and reassuring to industry.

10. UPDATES continued

10.1 Physical Agents Directive: CSD: 07/023

Mr Grainger said the HSE had funded work in Australia. Imperial College considered that staff will be above the limit of gradient field under the new Physical Agents Directive. There was also Wellcome Trust Research being undertaken.

If the Directive is implemented as it stands, we will need a lot of work in order to comply with its requirements. Information on the problems the Directive raises has been passed to Commissioners. The MHRA hopes the European Commission will postpone implementation or amend the Directive.

10.2 GS1 UK Local Health Care User Group: CSD: 07/024

Mr Grohmann said he had attended the inaugural meeting of the GS1 UK Local Healthcare User group for the use of AutoID in the NHS. DH had produced a new guidance document called "Coding for Success".

9. ANY OTHER BUSINESS

Dr Ludgate thanked Mrs Glover for chairing the EAG on Metal Wear Debris. She also thanked all the Members of the CSD who had provided expert advice at short notice to the MHRA on certain issues.

10. DATE OF NEXT MEETING

23 November 2007.