

**MINUTES OF THE COMMITTEE ON THE SAFETY OF DEVICES MEETING:
23 NOVEMBER 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
Mrs Christine Glover
Professor Ian Kimber
Mr Peter O'Donovan
Dr Sheila Peskett
Dr John Perrins
Dr Geoffrey Ridgway
Dr Charles Sears
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 Philip Grohmann
Mr Tony Sant
Mr Allan Hilderley
Mr Stephen Lee
Ms Valerie Field
Mr Brian Mansfield
Mrs Dianne Leakey
Ms Hazel Randall
Ms Sara Vincent
Ms Louise Mulroy
Mrs Bina Mackenzie
Dr Christopher Brittain
Mrs Fran Queen

Devolved Administrations
(Observers)

Mr A Macleod
Dr G Mock
Mr C Morgan
Mrs E Qua
Dr D Salter
Ms S Davies
Mr Andrew Wong

Others

Mr Brian Winn

Industry (Observers)

Mr Maurice Freeman
Mr M Kreuzer
Mr John Wilkinson
Mr Ray Hodgkinson
Ms Doris-Ann Williams
Mr David Metcalfe
Ms Sue Hill
Ms Beverley Norris
Mrs Sylvia Shearer

1. WELCOME

- 1.1 The Chairman welcomed everyone to the Committee meeting. He also welcomed Christopher Brittain, the Agency's new Senior Medical Officer, to his first meeting.

2. APOLOGIES

- 2.1 Apologies were received from Professor Ian Learmonth, Dr Julie Kent, Dr Sheila Fisher, Dr Steve Bennett Britton and Professor David Sharpe.

3. MINUTES OF LAST MEETING (07/0025)

- 3.1 The minutes of the meeting of 5 July 2007 were agreed subject to minor typographic amendment. The minutes will be posted on the MHRA website.

4. MATTERS ARISING/ACTION POINTS (07/0026, 07/0027)

- 4.1 Metal on Metal Wear Debris: Dr Ludgate explained that the Agency had met with the British Orthopaedic Association following publication of a report containing conclusions and recommendations from the Expert Advisory Group on Metal Wear Debris. Provided the report is endorsed by Council, the minutes of the meeting and the report will be placed on the British Orthopaedic Association and MHRA websites. There are also ongoing discussions with the National Joint Registry and the Cancer Registries in an attempt to form a basis for long-term epidemiological study.

There is an incident of soft tissue necrosis now being reported in association with Metal on Metal Hip Implants which may rise because of hypersensitivity to nickel. Mrs Glover said that the Expert Group had discussed the issue of metal allergies, especially nickel, and whether to test for allergies prior to implant. At the time of the meeting, the group had no evidence to show that this was needed. However, in the light of this new information, this may need to be reviewed.

- 4.2 Auto identification systems and patient safety: Mr Kreuzer said that barriers to trade in the rest of the world, notably Turkey, had arisen. The FDA is proposing a law requiring unique device identification. He was concerned that the European Commission would follow suite with a similar requirement.

- 4.3 Education Module update: The Committee were informed that the Education Module had been successfully launched. Login details were provided in the committee papers.
- 4.4 Update on Scottish Glennie Group: Small Instruments: Mr Hilderley said that although a deadline of December had been given to discuss this issue, neither a meeting date had been arranged nor papers had been circulated.
- 4.3 Update on Physical Agents Directive: Dr Ludgate said that the European Commission have suspended the implementation of the Directive for four years. The MHRA will continue to be involved in the process, to ensure that unreasonable requirements are not placed on the devices sector. The Chair expressed his concern over this issue, and considered that the MHRA should keep the situation under review.

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. MAIN ITEMS

6.1 **Devices and CJD: An update, current MHRA activities: CSD 07/0028**

Mr Hilderley gave a presentation on reusable surgical instrument decontamination and what DH and the MHRA are currently doing. Residual biological material, including protein, can remain adherent to the surface of surgical instruments following current recommended cleaning, disinfection and sterilization practices.

To date, no cases of vCJD disease transmission via surgical instruments have been reported. However, the risks of vCJD transmission via surgical instruments may be significant for "high risk" surgical procedures.

In July 2007, the DH published a vCJD Policy Statement on its website. It states their strategy on vCJD as having five central aims including minimising the risk of secondary transmission via medical interventions including surgery. The DH has therefore convened a number of Advisory Committees to look at the various aspects of vCJD infectivity.

The Advisory Committee on Dangerous Pathogens TSE Working Group's (ACDP TSE WG) remit is to provide practical, scientifically based advice on the management of risks from TSEs in order to limit or reduce the risks of human exposure to or transmission of TSEs in healthcare and other occupational settings.

The Engineering and Science Advisory Committee –Pr (ESAC Pr) and its Working Groups aims to take forward, for potential practical application, the body of maturing research relating to the decontamination of surgical instruments with the emphasis on protein removal and prion deactivation. One of its newly formed subgroups will be looking at the way in which new technologies can be applied in the NHS. This group is called the New Technology SG of ESAC Pr and is chaired by Dr Ridgway, a member of the CSD.

There are recognised problems with removing prions from reusable medical devices. There is uncertainty as to whether trying to destroy prions will only cause them to mutate. It has become clear that an acceptable validation programme for prion removal products has yet to be agreed by the wider scientific community and also the industry itself. Testing of such products outside of the laboratory and research setting and at a practical level within the work environment appears to be limited. Confusion and concern continues to be voiced amongst those wishing to use such products in the NHS.

Mr Hilderley explained that there were currently four products CE marked claiming to remove prions from surgical instruments. However one question that is still being debated is choosing an appropriate animal model that reflects the disease in humans and that can be used to validate such products.

Mr Lee gave a presentation on the MHRA's current activities with regard to regulation of prion assays. At the request of the DH on the basis of the advice from the Advisory Committee on the Microbiological Safety of Blood, Tissues and Organs (MSBTO) and SEAC, MHRA formally approached the European Commission to include prion assays in the highest risk category of annex II list A of the In Vitro Diagnostic Medical Devices Directive.

Following discussion by the Commission's IVD Technical Working Group, a UK delegation headed by the MHRA presented the UK case at a workshop in October 2007 organised by the European Commission in order to examine and explore the substance behind the United Kingdom request to add Variant Creutzfeldt-Jakob disease (vCJD) *in vitro* diagnostic tests to Annex II List A of Directive 98/79/EC. The conclusions

from this workshop were that this issue is an important one and concerns all citizens of the EU; the common opinion of the attendees to the workshop was that this kind of device would appropriately belong in Annex II List A; if added to List A, there would need to be an appropriate CTS drafted, preferably available at the same time that the test is listed; and if the test is not added, it potentially poses a public health issue and could have serious implications for public health authorities.

Dr Ridgway said that they want to prevent a secondary outbreak of vCJD. There were 166 identified cases in the UK, 4 of which were still alive. Tonsillar data will be available at the end of the year. The New Technology Sub group is due to report on its findings in the spring.

Mr Kreuzer said that the Institute of Decontamination Sciences meeting will be held next week. EADMR, the trade association representing companies that reprocess single use devices, will be giving a presentation at the meeting at which Dr Ridgway will be present.

Dr Watkins stated that there had been little protest about certain dental equipment being made as single use, and there had not been a supply problem as previously thought. The General Dental Council now insists that decontamination should be part of the course programme for trainee dentists.

Mr Hilderley said that the Department of Health were rewriting the HTM guidance on decontamination, and will eventually have one all encompassing guidance document. Dr Ridgway said there was already some HTM guidance on the DH website. Dr Watkins was concerned that the dental and primary care guidance would not be available until the end of 2008.

Dr Waldemann thought that there would be difficulty communicating the decontamination issue to primary care. Dr Sears said that PCT inspects for minor operations, but thought that primary care could learn from the dental profession on CPD.

The Chair announced that this was an important issue that the Committee need to be kept up to date with.

6.2 **Electrical Safety: Update and strategy: CSD 07/0029**

Ms Field and Mr Mansfield presented a poster the Agency had been working on to highlight problems of electrical safety. Ms Field said that since March, the Agency had worked closely with the Estates and Facilities division of DH to help produce an alert on electrical safety issues, which was published in June 2007.

She asked for the Committees comments on the poster and to whom they thought it should be sent to. Mr Mansfield explained that it was a non-technical poster aimed at end users. He said that they had the second edition of MEIGaN [Medical Electrical Installation Guidance Notes] were published on the MHRA website in September 2007. Two MEIGaN training courses had already been run, to highlight this new edition, with another scheduled for January. The MEIGaN document is intended as a guide for installation of imaging equipment, but it is being applied to other areas. MHRA would like to consider formally extending the guidance.

The Chair said that although this poster was being aimed at consumers, he thought that the Agency should also focus on theatres. In general dental practice and primary care, the cabinetry is not bespoke, so does not adequately address the electrical standards.

Dr Belli said that modern equipment is directed through Estates. The Agency should contact RCR and the British Institute of Radiology. There was a suggestion that the ODA may also need to be made aware of this issue. Dr Facey said that Local Authorities should be advised of issues relating to Care in the Community installations.

Mr Mansfield said that only Part P trained electrical engineers can perform domestic installation work. Surprisingly however, this does not apply to the installation of medical devices. He also mentioned that the Water Boards are now using plastic piping, so there could be incidences where the electrical systems are not earth bonded if linked to these pipes. Dr Watkins replied that Part P certification is only likely to be enforced if building control regulations are applied. Mr Bray said that health and safety legislation is likely to apply to these installations.

6.3 **Adverse Incident Vignette: CSD 07/0033, 07/0034**

- (i) Ms Randall gave a presentation on super slim ICD leads, the first of three adverse incident vignettes. Ms Randall informed the Committee that Medtronic had introduced Sprint Fidelis leads in September 2004. These leads were thinner and more flexible than before and were better for small/tortuous vascular anatomy. However, extra care was needed for handling and implantation. The Agency had received both manufacturer and user reports of unnecessary shocks due to *suspected* lead fracture.

The Agency met with the manufacturer to raise concerns over the integrity of the leads, if clinician training was adequate, and if an MDA should be issued. A worldwide product recall was effected less than a week after the meeting.

The situation has unearthed some concerning practices with these devices. Different manufacturers' leads and ICDs are being combined and implanted.

(MHRA) There are two reporting systems, manufacturer reporting and voluntary reporting by anyone. Voluntary reporting is decreasing. Therefore, the Agency is trying to highlight this route to reporting.

Dr Facey believed that companies may already have details of suspected cases, but they would not have reported them. It was a concern that this was not covered legally.

John Perrins thought that the manufacturer had acted reasonably in this instance, but this was not the first time this had happened. There needs to be a higher level of proof of efficacy of replacement technology. The process of extracting a pacemaker lead will destroy it, so it would be difficult to examine the lead for problems.

Mr Singh said that in the US, any follow up consultations are paid for. He asked if there was any such funding in the UK. Dr Ludgate replied that this had been discussed recently in the EU. Manufacturers are telling clinicians that it is their responsibility. It is very difficult to work out a uniform compensation scheme.

John Perrins said that device alerts do not contain instructions to advise the patient. Dr Ludgate replied that it would be for the clinician to decide if they need to advise the patient of this alert.

- (ii) Ms Mulroy gave a presentation on a MHRA investigation on cylinders. The MHRA received two reports of dentists receiving burns due to the ignition of the cylinder regulator when opened. The original cylinder manufacturer was no longer in business, so it was difficult to identify where they had come from. The HSE had already been informed on these incidents and were also investigating.

It transpired a company had purchased the assets of the manufacturer from the receivers. Subsequently, a

Medical Device Alert was issued that warned users of this problem and advised them to quarantine affected devices, make arrangements for replacement of the cylinders and contact the British Compressed Gases Association for advice if required. The MDA was issued on the CDO website and an article was published in BDA monthly magazine.

Mrs Glover said that it was unacceptable that equipment should be in use that is unaccountable. Any company that takes over a company's assets should ensure that the equipment is fit for purpose. Mr Singh said that the company should also take over liability. Dr Turney said there is no traceability for a lot of equipment.

- (iii) Ms Vincent gave a presentation on a user reported incident with a skin mesher. The problem had been with how the mesher had been wrongly assembled by the user. The Agency had contacted the US manufacturer about the opportunity for miss-assembly, but the manufacturer thought that there was only one way the device could be assembled. The Trust that had encountered the problem then took photos illustrating how the mesher could be wrongly assembled in three different ways. When this was put to the company, they amended their instructions for use.

Dr Thorpe thought it was good that the instructions had been changed, but considered that the design of the mesher should have also been amended to ensure no possibility of miss-assembly. Mr Bray said that there should be user checks before use. The first principle of the Medical Devices Directive addresses design.

Dr Facey said that the vignettes had been useful, but she would also like to see summary information of adverse incident reporting. Mr Sant replied that the second devices bulletin gives an overview of statistical information.

6.4 **Communication with Pharmacists: CSD 07/0031**

Mrs Glover said that there were 12,500 registered pharmacies in Great Britain. There is a clear impetus from Government for people to be more responsible for their own health and wellbeing. This leads to greater self medication. In Scotland, pharmacies are being paid to take the pressure off GPs by being able to write prescriptions for minor ailments for registered patients.

There has been a huge increase in the use of diagnostic kits, although not all sales go through pharmacies a great many do. She was investigating how the MHRA devices Dept could have better communication with pharmacists. Pharmacists are fully aware of the role of the MHRA with medicines but are much less aware of the MHRA involvement and concern with devices.

Pharmacists are unable to open the device's packaging to read the instructions prior to sale. It would be helpful if pharmacists could have training which includes using and handling the devices. The undergraduate course is very overloaded however including training on devices during the pre-registration year would be ideal. Most of the pre-registration training in community is undertaken by the large groups such as Boots, Lloyds, Coop, etc, and is generally very good. Trainers will need to give guidance on devices. There is potential for a post graduate distance learning package and the DH should be approached for funding.

Mrs Glover thought that devices should be added to the Yellow Card, and said that she would make more positive recommendations at the next meeting.

Dr Turney thought that there should be a database where device instructions could be downloaded (so that pharmacists need not open the device packaging).

Dr Thorpe said a typical example of a device sold in pharmacies in a blood glucose monitor.

Dr Facey said we must ensure we communicate with pharmacists about what they are reporting, for example, the type of suspected incidents.

Mr Sant said the Agency has three focus groups looking at barriers to incident reporting. Their advice will be submitted to CSD in due course.

Dr Ridgway said understanding positive negatives should be included in any paper.

6.5 The problems of EMI: CSD 07/0030

Mr Brian Winn, Head of Technology & Product Introduction at the NHS National Innovation Centre gave a presentation on electro-magnetic interference (EMI). He explained that the problem of EMI affects everything from an alarm system going off to equipment failure resulting in patient deaths. Electro –

magnetic immunity is covered by regulations and by the harmonised standard EN60601-1-2. The problem of EMI is not only caused by mobile phones, but also by walkie-talkies, which are commonly used in hospitals.

The National Innovation Centre commissioned a study on what equipment is currently causing interference and what will cause interference in the future. Existing wireless sources of EMI are from mobile phones, WiFi, pagers, walkie-talkies and outside broadcast equipment. Emerging sources of EMI are from WiMAX and TETRA. Mr Winn said that within the standard, a large section of the radio spectrum was not required to be tested against. WiMAX is an emerging technology that does not require such testing. TETRA handsets will be used in ambulances, and they may disrupt life support systems. Mr Winn thought that micro base stations could be fitted at hospitals, as this would put mobile phones on a low power transmission resulting in reduced emissions.

Mr Winn summed up by stating that leaving NHS Trusts to set 'local policies' runs risks. Equipment is vulnerable to interference mainly from mobile devices in close (<1m generally) proximity to equipment. It is easy to get below 1m without even being in the same room. New portable wireless technologies are emerging that operate at frequencies today's (and tomorrow's) standards do not even require to be tested. Existing equipment vulnerability to these new networks is unknown. He recommended that work was needed through the British Standards Institution to extend the frequency range covered by EN60601 to include (at least) forthcoming WiMax networks. Work was needed through Industry bodies (e.g. ABHI) to encourage equipment manufacturers to design to exceed requirements of EN60601. Consideration of working with PASA or Procurement Hubs to engage Telecom Service Providers and explore techno-economic feasibility for micro-basestations in hospitals. Consideration of installing RF field strength "patches" on critical equipment to alert staff if RF environment exceeds equipment specifications. The NIC are happy to work on a technical solution with MHRA. Consideration as to whether guidance provided to Trusts on mobile phone policy is adequate, e.g. consider asking Trusts to nominate RF Environment guardians.

A Member asked if EMI detectors could be installed. Mr Winn said that that it could, but it would be very difficult as it needed to be put next to the device and would have to be properly maintained and calibrated. Mr Singh said that his hospital had mobile phone detectors which give an audible alert to switch mobile phones off.

6.6 **Communicating safety messages to diabetics: CSD 07/0032**

Mr Lee gave a presentation on communicating safety messages to people with diabetes via GPs and Pharmacists. He explained that where there is a safety problem with a medical device that is used in the home, we rely on healthcare professionals and manufacturers to get the message across to the lay-user. People with diabetes will use medical devices, interact with the health service (GP, Pharmacy, Diabetes Clinic, etc), but will not receive Medical Device Alerts. People with diabetes may register their meter and injection device with the manufacturer or supplier, and/or be members of Diabetes UK.

Mr Lee gave an example of where the Agency had received reports that specific blood glucose meters could change the displayed units of measure. The manufacturer decided to recall the meters, and the MHRA issued guidance to healthcare professionals supplying, managing and using the devices via a Medical Device Alert. A safety information sheet was also attached, for the healthcare professional to distribute to patients as necessary.

Mr Lee informed of a second case study where as a result of increasing numbers of user reports concerning the fracture of a needle-free insulin delivery device, the MHRA published a medical device alert to warn users of the potential failure of the device, under particular circumstances. The alert was sent to a number of healthcare professional groups as they are directly involved in the training of device usage to patients. The manufacturer also agreed to provide a safety message in the device consumables that patients require on a frequent basis.

Mr Lee said that proposed future actions (generic safety warnings) for insulin injection devices included production of a GP poster, and sending messages for diabetes clinics and message to users. A message to users would be sent concerning blood glucose meters. He asked the Committee if given these actions and our proposals for future publications, is MHRA's strategy adequate to target people with diabetes.

Dr Facey asked if the Agency was going to work with pharmacists and Diabetes UK. Mr Lee replied that the Agency was already working with Diabetes UK and wants to send specific messages to pharmacists. Mr Singh asked if the safety warnings to end users were to be targeted UK wide. Mr Lee said they would be sent to England. Mr Wong said that they adhere to the MHRA line in Scotland. Dr Peskett asked if end users could register with the MHRA to receive device alerts. Mr Sant said that anyone could register for medical device alerts,

but they cannot register for specific product alerts. Mrs Glover thought that a registration card should be included in the device packaging, in case a problem arises in the future. Dr Thorpe replied that this may address the problem with the meter, but it would not be feasible for the disposable strips. Dr Sears said that the test strips are a prescription item, so there is traceability to the end user via GPs.

7. REVIEW AND COMPARISON OF MEDICAL DEVICE ALERTS ISSUED IN 2005 AND 2007: CSD 07/0035

Mr Grohmann distributed CDs to the Committee with a Review and comparison of MDAs issued in 2005 and 2007. He said they have chosen 20 paired MDAs from 2005 and 2007. He asked the Committee to look through each of the MDAs and comment on their clinical usefulness. A questionnaire was included in the disc. Members were asked to return their completed questionnaires to Mr Grohmann by 7 January 2008, in order that the data contained could be discussed at a meeting to review MDA format on 14 January.

Mrs Glover commented that the number of Alerts may be rising because the MHRA's communications are improving.

Members asked what was meant by "clinical usefulness". Mr Grohmann replied that he just needed Members' opinions on whether the 2007 MDAs were as specific enough as those issued in 2005.

8. ANY OTHER BUSINESS.

None received.

9. DATE OF NEXT MEETING

The next meeting will be held on 6 March 2008.