

**MINUTES OF THE COMMITTEE ON THE SAFETY OF DEVICES
MEETING: 30 NOVEMBER 2006**

Members Attending:

CSD

Mr John Williams (Chair)
Mr Guy Alexander
Dr Steve Bennett Britton
Mr Christopher Earl
Mr Roger Evans
Prof Karen Facey
Dr Sheila Fisher
Mrs Christine Glover
Dr Julie Kent
Prof Ian Kimber
Prof Ian Learmonth
Mr Peter O'Donovan
Dr John Perrins
Dr Sheila Peskett
Dr Geoffrey Ridgway
Dr Charles Sears
Mr Arvind Singh
Dr Gary Thorpe
Dr John Turney
Dr Carl Waldemann
Dr Gordon Watkins

MHRA

Dr Susanne Ludgate
Mr Mike Peel
Dr Sandra Costigan
Mr Paul Brice
Mr Alan Lynch
Ms Hazel Randall
Mr Jeremy Tinkler
Mr Richard Glover
Dr Elsie Damien
Mrs Catriona Blake
Mr Jonathan Plumb
Mr Andy Marsden
Mr David Grainger
Mr Clive Bray
Dr Nevil Batra
Mr Tony Sant
Mr Philip Grohmann
Mrs Fran Queen

DH

Dr Aniko Zagon, THOTH

Devolved Administrations (Observers)

Mrs S Shearer, SEHD, Scotland
Mrs Elizabeth Qua, DHSS, Northern Ireland
Mr A MacCloud, SEHD, Scotland
Mr Innes Connor, Scottish Healthcare and Supplies

Industry (Observers)

Mr John Wilkinson, ABHI
Mr Mike Kreuzer, ABHI
Ms Samantha Forest, PASA
Ms Beverley Norris, NPSA

1. WELCOME

1.1 The Chairman welcomed everyone to the Committee meeting.

2. APOLOGIES

2.1 Apologies were received from Dr Anna-Maria Belli, Ms Catherine Cairns, Professor David Sharpe and Professor Irving Taylor.

3. MINUTES OF LAST MEETING (06/016)

3.1 The minutes of the meeting of 23 March 2006 were agreed subject to amendment that Dr Sheila Peskett, Mr Roger Evans and Mr Clive Bray who were present were added to the attendance list, and a one word omission in paragraph 10 was corrected. The minutes will be posted on the MHRA website.

4. MATTERS ARISING/ACTION POINTS

4.1 Diathermy: MHRA met with manufacturers to see if they could agree common standardisation. MHRA subsequently decided to produce a CD Rom on diathermy to take this forward. MHRA will update CSD on progress at the next meeting.

4.2 Converging Technologies Unit: Dr Costigan said that the Unit had been set up in July 2005. However, due to budgetary restrictions, the team was made redundant in March 2006. Some of the work that the team was doing is being dealt with elsewhere in the Agency. The Chairman stated that this was an important area of work that should continue. Otherwise, the voice for devices may not necessarily be heard in Europe.

4.3 Royal College of General Practitioners' proposed general practitioner curriculum: The curriculum was still at the drafting stage, but now had bullet points relating to principles.

4.4 Planned changes for Assistive Technology: Mr Lynch updated the CSD on Assistive Technology. The AT Centre was set up on 3 April 2006. The MHRA were raising the awareness of the role of the Agency and the new AT Centre amongst stakeholders by issuing a Press Release, direct contact with stakeholder groups, producing information handouts and giving presentations to a number of bodies. MHRA had received positive feedback to their awareness campaign.

MHRA sought to improve adverse incident reporting by producing some simple handouts following comments made by the CSD at the last meeting. MHRA also wanted to improve training by providing input into training courses. They were working with SEMTA on National Occupational Standards for AT maintenance and repair.

- 4.5 NICE document: The Committee was informed that the NICE document is now available on the NICE website.
- 4.6 Mercury Directive: The Mercury Directive was still under negotiation. It stills restricts the sale of mercury fever thermometers to all and this is unlikely to change. The sale of mercury sphygmomanometers to consumers is also very likely to be restricted. With regard to the sale of mercury sphygmomanometers to health professionals, there is currently a derogation in place for the next two/three years. However, other Member States wanted the derogation removed. The European Council are likely to meet to discuss the Directive in December.
- 4.7 Medical Device Driving Licence: The Committee was informed that this will be the subject of a meeting on 4 December.

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. Professor Karen Facey declared a possible conflict of interest with item 6.1.

6. MAIN ITEMS

6.1 The medical technology industry and the NHS: CSD: 06/017

Mr John Wilkinson, Director General of the Association of British Healthcare Industries, presented a paper on current issues for the UK medical technology industry. He began by informing that the size of the market equates to £6.1 billion sales. The largest single customer in the world was the NHS.

The challenges for the NHS were to provide better patient care, increase productivity, and be more cost effective. Mr Wilkinson said that technology was the enabler to the ten highest impact changes within the NHS. However, there were conflicting messages coming from the NHS. In respect of delivery, there is a policy of devolution and independence, leading to competition for patients (a market force driver for change), which in turn stimulates innovation. However, on the procurement side, the policy is one of centralisation, which restricts and controls the market, thus stifling innovation.

Mr Wilkinson explained that smaller companies do all the high risk research and development, and are then bought up by the larger companies who either market the technology or kill it. However, the NHS procurement system could be putting small innovative companies out of business.

The Committee asked about patent law for devices and were informed that it was the same as for any other products. The Committee remarked that there was no proper planning in the NHS and benefits were not measured. The Healthcare

Industries Task Force was set up to address problems with dealing with the NHS. They thought that the key was how the market is structured and that there is a market structure that may work better than others and go further than just the NHS.

6.2 Implementation of standardised medical device training criteria: CSD: 06/018

Dr Aniko Zagon, managing Director of the NHS's Training Hub for Operative Technologies in Healthcare (THOTH), gave a presentation on medical device training criteria developed by THOTH. She distributed handouts on THOTH to the Committee. THOTH was officially launched in April 2006. Its mission is to identify and develop innovative training tools. The problem in the NHS is that training programmes are developed locally. Therefore, THOTH hopes to import proven training methods into the NHS.

Last year, the NHS paid out over £6 million in negligence claims. Incident reports to the NPSA for 2004/05 show that 68,000 incidents relate to medical devices, but realistically this figure will be much higher. Technology is getting more sophisticated and harder to use, and there is now a wider range and more variable type of medical devices user group.

WHO Guidance on device user training states that education and training of users is as important as the assessment of medical devices in use or product control. Medical device training in the NHS is broad and varied. There are also no clear guidelines with what type of training is required when a medical device is sold.

THOTH's Medical Device Training Criteria establishes a generic standard for medical device user training by listing the core requirements for device user training programmes. It encourages manufacturers to lead on defining user requirements, supports intelligent procurement, and helps NHS Trusts to monitor training need and compliance.

The MHRA said that there is a need to differentiate between high quality training and the means to train people. There needs to be the tools, the time and the people to train the NHS. Some Trusts are working to CB4. What were missing were the competences that people should be trained to.

The Committee thought that there was a need to engage professional bodies, and a need for co-ordination between NHS, MHRA and these professional bodies. The Chairman informed that the MHRA had already written to colleges to try to address this issue. It is a big project and the MHRA were having difficulty finding a budget to pay for it.

The Committee stated that the independent sector should not be forgotten. This sector and Care Homes may still not have adequate device training.

The Committee asked if there was opportunity to label new devices with their training requirements. The Chairman said that modified equipment would have the same problems, but there was no requirement for training under the Medical Devices Directive.

Dr Zagon reiterated that devices are becoming more complicated to use and there was now more of a shift of responsibility to the manufacturer to provide training on their equipment. The Committee asked what the link was between adverse incidents and complexity of devices, as it may not be the high tech devices that are causing most of the problems.

The Committee was informed that there is a new project on injectable medicine and implantable devices looking at strategic purchasing. Pilots will run in 2007 in a number of Trusts, and training will be key. Standard guidelines for training would be a useful aid to this project.

The Committee asked if a code of good practise for purchasing could be produced. They also pointed out that adverse incident reporting was not on THOTH's listed criteria, which they considered an important point.

The Committee also considered the issue of monitoring and thought that to ensure training is done properly, monitoring should be on the agenda of the Trusts' Clinical Governance Committees. They suggested that the MHRA write to Trusts recommending this. Dr Zagon thought that this was a good idea, but said that there was nothing to benchmark training against.

6.3 Auto identification systems and patient safety: CSD: 06/019

Mr Brice gave a presentation on auto identification systems (Auto-ID). The DH had set up a Working Group to consider how patient safety could be improved through standards for uses of machine readable codes in the delivery of healthcare. The Group consisted of DH, PASA, CfH, MHRA and others. The Group aimed to make recommendations to Ministers on options for standardisation of coding on medicines and devices; and to co-ordinate existing and planned activity to implement this technology within the NHS. The Group was keen to hear CSD views.

The benefits of using Auto-ID were primarily in the area of patient safety (for example in reducing error rates in dispensing medication and blood transfusions,) but also had other useful applications such as the and track and trace of devices, informing intelligent purchasing and stock control and helping the fight against counterfeit products. .

A key development within the NHS was that NHS Purchasing and Supplies Agency (PaSA) recommended all suppliers to the English NHS should bar-code their products in EAN.UCC format. Additionally, the NHS Information Standards Board had commissioned work for a fundamental (coding) standard for NHS IT systems, to which all individual projects should relate.

MHRA explained that there were no mandated standards for Auto ID on medical devices in UK or EU legislation. This would have to be negotiated at EU level. However most manufacturers already used auto ID – predominately bar codes – for their own manufacturing, stock control and distribution purposes. There were as yet no common standards in the NHS for the application of the technology to patients and processes. There were however many excellent and successful NHS projects in operation, which were examples of best practice. The NHS Working Group was keen to seek CSD views on how this experience could be promoted and further embedded in the NHS.

ABHI replied that industry was working on a standard for devices, and they had heard from Department of Health that work on the application of standards within NHS systems was underway. GSI – the global body with responsibility for bar-coding standards had established a worldwide Healthcare User Group (HUG). The HUG is looking to amend the GS1 standards to align them more closely with the requirements of the healthcare sector. This programme of work should be complete in 2008 HUG meets three times a year to progress bar-coding and ABHI Auto-ID. There was a need for industry and the NHS to have dialogue to progress this issue.

Patient identification and matching patient to intervention is a much broader issue than Auto ID and is central to patient safety culture within the NHS. It is the subject of a major programme of work by the National Patient Safety Agency (NPSA). This includes work on standards for patient information on wristbands that identify them and match them to their care. The Committee were concerned about patient consent issues, and how patients could access the information held about them on Auto-ID. They also commented on intervention and would like to track things through, with outcomes listed. The Committee stated that some patients do not wear wristbands, for example, in Primary Care, etc.

The Chairman considered that Radio Frequency Identification should not be overlooked. Bar-coding may not be the most appropriate method of Auto-ID. He asked the MHRA to take this further and investigate what would be appropriate for a given Trust. Mr Brice agreed to update the Committee at a future CSD meeting.

6.4 Drug coated coronary stents: the role of MHRA in the light of recent results: CSD: 06/020

Ms Randall gave a presentation on the recent concerns surrounding Drug Eluting Coronary Stents (DES). There appears to be an increased prevalence of late stent thrombosis among DES compared to Bare Metal Stents (BMS). New data also raises the appropriateness of anti-coagulation/anti-platelet regimes for patients with DES. Additionally, there was a concern about the safety of DES in non-standard, non-de-novo lesions.

The MHRA had placed a statement on their website to confirm that they are investigating this issue, but have no firm date to indicate that DES are unsafe or

unfit for use. They are continuing to closely monitor incoming adverse incident reports to see if there are any clear trends both in terms of DESs against BMS or any one BMS against another. MHRA are liaising with FDA, who have taken a clear lead in coordinating clinical and industry experience and opinions and who are due to make further statements early next year. MHRA has met with the two UK market leaders to review their position in defence of the allegations that their DESs cause late stent thrombosis. MHRA is continuing to liaise with BCIS, who have also placed a statement on their website about this issue.

The Committee said that stent use had doubled since the NICE report. The original trials did not address long term use, and had been done only on simple lesions. The problem of very late stent thrombosis was not taken into consideration. In the US, they had looked back at patients' records, but there appeared to be no difference between the number of deaths of patients with DES compared to those with BMS. However, there was a relation to deaths where DES had been used in complex lesions. Those at greatest risk may have aspirin resistance.

The Committee considered that there was a low level risk of late stent thrombosis, but what was an acceptable risk. The risk had been overstated in the media, but it is difficult to explain the risk to patients. There has been complacency, so the MHRA needs to be firm that they accept that there is a very small problem, which they are monitoring. However, it would be inappropriate for MHRA to approach CCAD.

The Chairman thought that there should be guidelines on where and when DES should be used, and the MHRA should approach the relevant bodies to facilitate the drafting of these guidelines. The Committee stated that information needs to be gathered from international sources, and not just nationally.

6.5 Stolen body parts: regulatory, ethical and risk communication issues: CSD: 06/021

Mr Tinkler explained that the Human Tissue Authority (HTA) were responsible for products containing human tissue, which are currently excluded from the Medical Devices Directive. However, when the FDA alerted the MHRA to the illegal procurement of cadaveric tissue and the falsification of donor screening data, the HTA had no staff or procedures in place to deal with this issue. Therefore, the MHRA Devices sector undertook to investigate and take appropriate action in response to any risk to UK patients.

The MHRA's investigation revealed that implicated bone graft material had been received in 22 Trusts in England and Wales. However, the vigorous sterilisation process had resulted in a negligible health risk. Skin products were of greater concern, and one skin product had been implanted in the UK. In this case, MHRA had liaised directly with the implanting surgeon and the patient had been tested for various diseases in line with FDA advice.

MHRA considered that there was negligible risk of infection from bone product sourced from these stolen body parts and had advised implanting surgeons of this. The decision whether to inform patients about this issue was a matter of clinical judgement.

The BBC had contacted the MHRA asking for details of 22 Trusts that had received the implicated bone material, under the Freedom of Information Act. The MHRA initially refused to disclose this information because it was felt that disclosure would be to the detriment both of the individual patient and to public health and therefore not in the public interest. Because there was no infection risk to patients from the products implicated and therefore (contrary to the advice passed on by the supplier) no need to offer patients additional testing, many of the clinicians targeted may have decided, on the basis of their professional judgement, not to inform their patients that they had received the products. Publication of details of the hospitals involved and subsequent identification of individual patients, either by the patients themselves or by third parties, would therefore countermand the professional judgement of the clinician and override MHRA's considered opinion on the most effective risk control measure.

During the time that MHRA was considering the FOI request, the BBC had written under the Freedom of Information Act to all Trusts with similar requests, resulting in the identification of some implicated Trusts. The MHRA therefore wrote to the BBC in September providing details of the 22 Trusts. Some patients who had received the implicated material were subsequently identified by the BBC. Some patients did not realise that they were given human tissue products and were concerned that they had not given their consent for these bone grafts.

The Committee thought that the MHRA had dealt with this matter really well, in spite of all the difficulties they had encountered. They expressed concern that there was a lack of patient information about what products patients were being implanted with. Members questioned whether there was a lack of traceability, as there are supposed to be patient-donor links in case of any problems. However, MHRA assured them that this case had confirmed that traceability requirements were, in fact, operating as intended.

Some members thought that patients should have been told about this issue, and that there should be an obligation on the physician to tell them.

The Committee asked if the HTA had processes in place to deal with future issues. The MHRA informed that HTA now have people in place, are developing processes and would take responsibility for any similar cases in the future.

6.6 DB 98/01: an update and highlights: CSD: 06/022

Mr Glover provided information on the publication “Managing Medical Devices”. The Agency first published guidance on the Management of

Equipment in 1982, which had been updated three times. DB2006(05) had recently been published on the MHRA website, and is the first version to be published as web guidance. The benefits are a reduction in printing costs and a format which is easy to update.

The Medical Devices Directive applies to the EU. This publication informs hospitals of their responsibilities under the Directive if they make and supply their own devices.

The Committee noted the availability of this publication.

6.7 Nanotechnology and medical devices: where are we now? : CSD: 06/023

Dr Costigan introduced a paper on nanotechnology and medical devices. She informed that there is an EU Medical Devices Expert Group looking at whether nanotechnology is adequately covered by the Medical Devices Directive. Initial findings appear that nanotechnology is adequately covered.

A report was submitted to the CSD summarising the publicly available data on the toxicology of nanoparticles for use in healthcare. This same report had recently been discussed by the Committee on Toxicity of Chemical in Food, Consumer Products and the Environment (COT) and the Commission on Human Medicines (CHM). Neither had identified any data or considerations not already discussed in the report.

The Committee said that the report was excellent and COT had endorsed the quality of the paper.

The Committee noted the Forward View in the paper. They understood that there was no MHRA funding for the Horizon Scanning process. However, as this was important issue, suggested the MHRA contact the National Horizon Scanning Centre (NHSC) in Birmingham. The MHRA said they were aware of what the Centre was doing and had already spoken to them. However, the NHSC looks at specific healthcare technologies that are already on the market or close to marketing. They do not distinguish between product upgrades and completely new technologies. MHRA would need to know about technological trends at least five years in advance to allow for potential pro-active regulatory action.

The Chairman referred to the safety of dispersal, which is considered an issue for nanoparticles in general, and that the biodegradable aspect of healthcare nanoparticles makes this less of an issue for healthcare nanoparticles. He considered that the concept of the Converging Technologies Group very important.

7. UPDATES

7.1 Metal wear debris from hip replacements: CSD: 06/024

Dr Damien explained that there was a growing concern over the biological risks of metal wear debris released from metal implants, and that there was evidence that metal hip replacements were associated with increased changes in reticulo-endothelial tissues suggestive of potential genotoxicity in patients.

The MHRA consulted the Committee on Mutagenicity (COM) on their concerns over the biological risks of metal wear debris. The COM prepared a statement in consultation with MHRA, which was published on the website (www.advisorybodies.doh.gov.uk/com/hip.htm). The MHRA also published a statement on 21 July 2006 on their website which summarised the COM findings. This stated that despite the large number of hip replacements performed in the past 30 years, there was no clinical evidence that the genotoxic effects occur after implantation of metal hips and that there was no evidence to suggest that this poses a significant health risk but neither has this possibility been excluded.

The MHRA had set up an Expert Advisory Group to look at this issue, and the EAG will report to the CSD.

The Committee agreed that metallic debris can come from modulation implants. Once hips have been revised, the biological effects are reversed. Nanoparticles generated from metal implants may induce the production of inflammatory cytokines resulting in incidence of implant failure due to aseptic loosening.

In respect of malorientation of implants, the Committee suggested that it should be looked at a latency of 30 – 40 years. They were also keen to look at the influence on the reproductive system, and asked if they crossed the blood barrier.

The Committee said that there were alternatives to metal on metal hip replacements, such as metal on polyethylene and ceramic on ceramic.

The two day meeting in Bristol focussed on this issue was useful.

7.2 Single use medical devices: CSD: 06/025

Mrs Blake said that a new poster on single-use medical devices had been produced incorporating comments made at the last CSD meeting. There was also a web only device bulletin available.

The Committee pointed out that the accepted international spelling of “sterilisation” is “sterilization”. The Chairman asked if there were any specific bodies that the poster should be distributed to. It was suggested that it be sent to the British Dental Association and the Royal College of Ophthalmologists.

7.3 The safe use of bed rails: CSD: 06/026

Mr Plumb and Mr Marsden gave a presentation on the safe use of bedrails. MHRA had revised their advice following comments made at the last CSD meeting. The MHRA's "One Liners" handout had been sent to care homes and had a positive impact.

MHRA had also produced a poster and a Device Bulletin is scheduled to go on the MHRA website next week. A Press Release will publicise their availability.

The MHRA needed to consider how they would effectively distribute this information to 25,000 care homes.

7.4 Defibrillators problems: CSD: 06/027

Mrs Blake informed that the MHRA had produced a top tips leaflet and poster on how to prevent many common incidents in respect of defibrillators. The leaflets and posters had been distributed to hospitals.

The Committee asked what information is made available to airlines, as all planes now carry defibrillators. They were informed that BA has State Registered Nurses on all their long haul flights, who are trained to use defibrillators. In an emergency, ground control will patch a cardiologist through to the plane to further instruct staff.

The Committee considered that hospitals now appear to be training all their staff in defibrillator use. New ALD guidelines state that all Primary Care Trusts require defibrillators. Dental surgeries now have defibrillators as a standard measure.

The Committee expressed concern that on page 3 of the leaflet, under "Indications for Use", it warns that care must be taken not to use on a conscious patient. Since this negative statement appears under a positive heading it was felt that it might easily be mis-read. MHRA replied that this was in the leaflet as there had been reports of defibrillators being used on conscious patients when the algorithm had incorrectly advised a shock.

7.5 MRI/Physical Agents Directive: CSD: 06/028

Mr Grainger provided the Committee with an update on MRI – Physical Agents (EMF) Directive. Since the last CSD meeting, the House of Commons Science and Technology Committee report "Watching the Directive: Scientific Advice on the EU Physical Agents (Electromagnetic Field) Directive" had been published. The report was critical of the response of the HSE and the HPA to concerns raised by the MR community at the consultation stage of the Directive.

The Committee were also informed that the HSE MRI Working Group has met four times since its inception earlier this year and are due to meet next in February 2007. HSE has funded research to look at whether there is actually a problem with occupational exposure to MRI, preliminary results show that exposure to the MRI gradient field and movement near to a scanner will both induce currents above the relevant Exposure Limit Values. Clarification is still required at European level to determine if currents induced by movement in a static field are covered by the Directive.

The Directive must be implemented into UK law by 30 April 2008. The Chairman commented that if the Directive goes ahead unchanged, use of MRIs will be restricted.

7.8 Clinical Investigation Audit: CSD: 06/029

Dr Ludgate explained that, as the UK Competent Authority, the MHRA has the function of authorising clinical trials of non CE marked devices. The audit was started to reassure both industry and investigators because, in the past, MHRA has been accused of being more stringent than other Member States.

Three trials were audited by three separate ad hoc groups, each chaired by Mr Williams, which looked at concordance between the CSD and the Competent Authority in terms of final decision taken, procedures, assessors and timetables. There was complete concordance with suggested comments being incorporated into future procedures.

8. ANY OTHER BUSINESS

None.

9. DATES OF NEXT MEETINGS

22 March 2007, 5 July 2007, and 23 November 2007.