Meeting to discuss Progress on Design Improvement of Surgical Instruments and Way Forward on Thursday 2nd May 2002 at 678D, Skipton House, 80 London Rd, London SE1 6LH

Attendance

Ailsa Wight
Rowena Jecock CJD Policy Team
Mary Holt CJD Policy Team
Valerie Attwood PASA
Beth Loudon PASA
David Jefferys MDA
Terry Donohoe MDA
Allan Hidderley MDA
Julie Pearce
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Apologies Mary O'Mahony

Purpose of meeting
To follow up measures taken and developments with decontamination of surgical instruments. It was agreed that while improvements had been made there were still many areas of uncertainty. It was confirmed that neurosurgery and back of the eye surgery presented the highest areas of risk as far as surgical transmission was concerned. Following Kate Woodhead's work to devise a core pack of neurosurgical instruments it had had to be accepted that after consulting surgeons and eye surgeons it would not be feasible to identify a set of instruments routinely used that could be adapted for single use surgery. SEAC had confirmed that risks associated with re-using surgical instruments had not diminished. This applied equally to general surgery which presented a second tier of risk.

Update on single use and reusable instruments
MDA reported that as many as 25% of single use instruments were being reused in various hospitals and within hospitals in different departments. One common example was with anaesthetic breathing tubes. Usually this was attributed to gaps in the education of staff and misplaced regard to the costs associated with some single use equipment, for instance, cardiac cathetars.
It was agreed that the intended submission to CMO should be widened to highlight these problems, that it would be desirable to consult the surgical instruments industry and that consideration should be given to the measures necessary to police proper instrument use. Greater clarity of instrument labelling could include better information on limited reuse of instruments.
MDA reported that they had had a meeting on 15 March 2002 to try to resolve outstanding issues. MDA considered that their submission to Health ministers would refer to the recent advice issued by the Spanish government which highlighted education of staff in conjunction

with a wider scope to long term instrument design. With the advances in the search for a diagnostic test, including the real prospect that a blood test might be devised within the next 12 months, MDA reported that notwithstanding the good intentions behind the extensive use of bench top sterilisers it complicated the results of the surgical instruments risk assessment.

PASA asked whether there was a requirement for surgery personnel to be told if single use instruments could be reused. It was asked whether the only two options were the redesign of multiple use instruments or single use instruments. In reply MDA stated that cleaning was a key measure as well as controls assurance and CHI. An audit on prevalence conducted by the Patients Association had reported a high level of surgical instruments misuse and reuse. It was agreed that it was imperative that CHI reinforced the message that this was unacceptable. It was agreed that effective cleaning of reusable instruments was important. It was pointed out that in addition to the cost of disposal of single use instruments the expense of the high volume of their disposal had to be taken into account.

The meeting agreed that it would be important to define which instruments could be safely reused eg lumbar puncture, single use instruments should not be reused, move towards the redesign of surgical instruments so that they are more effectively cleanable.

Controls assurance had to take into account the aspect of clinical negligence. It was pointed out that most instruments were manufactured in Pakistan which meant that the UK had limited regulatory influence although purchasers did have a stake in considering the multiple use of surgical instruments and the question of whether they can be reused. The ABHI had considered issues around decontamination as they affected the surgical instruments framework agreement. There were 36 users on the framework agreement and over 80 suppliers which could include single use. Most research supported the message that they could be decontaminated especially as there was sufficient choice in the market. It was explained that PASA could advise but individual Trusts had to decide whether instruments could be sourced for single use. Some suppliers provided the full kit but it would be important to seek advice from CCCDs and Roger Evans. There followed discussion about the method of informing hospitals of the safety of surgical instruments along the lines of PASA's dialogue with neurosurgeons. It was pointed out that it would not necessarily be surgeons who would know about the safety of surgical instruments. It was agreed that it was important to devise such a strategy at today's meeting. The first points were that they were difficult to clean and neuro and eye surgery were the most at risk areas. It would be essential to work with surgeons to identify which surgical instruments were suitable. It was suggested that the question of disposing of just some parts of surgical instruments rather than the whole instrument. The issue was that some parts could be just as expensive to replace as the whole instrument. It was agreed that there could be 3 or 4 options to pursue. It was hoped that one of these options could be introduced within 2 to 3 years although there were questions concerning whether one country on its own could achieve this. It was hoped that with feedback from the NHS the market may be influenced. It was reported that the FDA purchase certain instrument kits and in some cases there is no difficulty with reprocessing them. It was mentioned that the savings on decontamination process could be offset against the cost of single use instruments. It was a matter of concern that since the decision to withdraw single use instruments for tonsil surgery, a lot of these instruments had been manufactured and were now redundant. There was a need to identify which surgical instruments could be decontaminated effectively

especially with the complex instruments used in neurosurgery and consider which of them could feasibly be redesigned to facilitate more effective decontamination. MDA stated that it was the more complex and expensive instruments which tended to be more difficult to clean.

It was agreed that attendees at this meeting would inform PH6.2B of their suggestions of individuals from amongst doctors, neurosurgeons, representatives from PASA including Beth's colleagues and MDA who could best provide advice on which surgical instruments could be decontaminated or would need to be single use. This list should then be checked with Marcia Fry, controls assurance staff, the group of experts who had been consulted during the last review and Sterile Services Control managers. If as a result of this exercise more questions arose then a smaller group might need to be convened to consider those questions. The next step would be to consult Roger Evans about the supply of surgical instruments. It was pointed out that DH already knew details of the network of suppliers. It was agreed that it was difficult for researchers to pool their knowledge and that the issue around instruments was more of an engineering question than a decontamination one. It was reported that there are only 2 or 3 specialist manufacturers of neurosurgical instruments and that there were many more instruments involved in eye surgery than neurosurgery. It is possible to disassemble some surgical instruments but some do not disassemble.

Research has looked at alternative decontamination methods such as gas plasma cleaning but this for instance has resulted in changes to the instrument surface. Systems are already in place for sterilisation as distinct from cleaning but there is still no test to tell how clean a surgical instrument is.

Next steps

It was agreed that the next step would be to consult a group that included the surgeons who had been used in the first review, representatives of CSSM, John Baker, the team of 30 nurses, Henry March, possibly NHS Trust infection control operatives and possibly decontamination experts in each Trust on a series of questions including information on difficult to clean surgical instruments.

It would also be helpful to review Kate Woodhead's work with PASA which would hopefully stimulate dialogue and provide advice on decontamination of surgical instruments. Armed with this knowledge it would then be appropriate to consult with manufacturers and individual suppliers to establish what is feasible bearing in mind that none of the manufacturers are based in the UK and that there might be alternative instruments already available that lent themselves better to decontamination methods.

When conclusions had been drawn from this exercise it would be important to consider how to disseminate any changes recommended to enable best practice in the field.

It would be important to identify the expert group to Beth and her colleagues in conjunction with the controls assurance group. When this group had been identified it would be useful to arrange a meeting with them and the neurosurgeon representatives in about 2 moths time ie mid July followed by a meeting with eye surgeons in the second half of September. Prior to the meetings the surgeons should be given the opportunity to consider and provide answers to the list of

questions compiled. It was agreed that it would not be advisable to invite neuro and eye surgeons to the same meeting because their requirements, perspective and experience were too different.

One question that needed an answer was whether manufacturers involved in the design of instruments consulted with users about designs. It was confirmed that even if one particular surgical instrument kit that can be more effectively decontaminated was identified, it would not be feasible to advertise it to NHS users. Information to the NHS on cleaning instruments was available in HSS 99. The meeting did not know whether specific instruments could be identified although it was suggested that NHS Purchasing might know this. Work was already underway with eye surgeons to identify problems with particular instruments.