SCOTTISH EXECUTIVE

Health Department
Directorate of Finance

29 January 2007

Dear Colleague

DECONTAMINATION – MIGRATION TO SINGLE-USE PRE-STERILISED INDIVIDUALLY WRAPPED SMALL ORTHOPAEDIC IMPLANTS

Purpose

1. A Chief Medical Officer (CMO) letter dated 2nd November 2006 (CMO(2006)13) (a copy of which can be viewed at http://show.scot.nhs.uk/sehd/cmo/CMO(2006)13.pdf) advised Chief Executives of the intention to move to a policy of using pre-packed sterile single-use small bone and other implants across NHSScotland, initially focusing on orthopaedics.

2. This letter now provides an update on:

- The work of the Small Implants Sub-Group
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- Scottish Executive Health Department;
- Deadlines for achieving compliance in Orthopaedic Units;
- Key issues; and
- How to get practical help and advice.

Background

3. Most orthopaedic units in NHSScotland use screws, small plates and other small orthopaedic implants which have been repeatedly reprocessed (cleaned and sterilised) by Central Decontamination Units in racks or trays. Concerns have been raised that these implants cannot be properly cleaned, and we have photomicroscopic evidence that they can retain or acquire organic and/or chemical residues during use and reprocessing.

Addressees

For action
Chief Executives: NHS Boards
Chief Executive, Golden Jubilee National Hospital

For information

NHS Board Directors of Finance

Chief Executive, NHS Quality Improvement Scotland

Chief Executive, NHS Education for Scotland

Medical and Nursing Directors, NHS Boards

Medical Director, HPS

Director, National Procurement

Medical Adviser, National Procurement

General Managers, Independent Hospitals

Enquiries to:

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4. Legally, many of these devices are classified as 'single use', which means they must not be re-processed and/or re-used following contact with a patient, but also that they should only be cleaned and sterilised once, prior to first use. We suspect many of these devices have been recirculating for many years.

5. Besides generic concerns over contamination resulting in transmission of infection or CJD, there is general professional consensus over the importance of using pristine implants as delivered by the manufacturer, and there are also issues of corrosion or surface oxidation caused by repeated processing. This has potential implications for reducing implant failures, and we have no option but to address the legal, regulatory and governance issues this practice raises.

Small Implants Sub-Group

6. Following issues concerning advice on the decontamination and re-use of small implants, it was decided to form a new Glennie Sub-Group to consider the implications for surgical procedures involving re-processed implants, namely orthopaedics, neurosurgery, vascular surgery, plastic surgery and maxillofacial surgery. This multidisciplinary group, which includes a number of front line professionals, has focused towards the use of pre-packed sterile single use implants.

7. In collaboration with the strategic sourcing work on these commodities currently being led by NHS NSS National Procurement, a number of implant suppliers were invited to present on and discuss their products with the sub-group. Those suppliers where asked to focus on the following areas:

- Their respective organisation's plans to introduce implants sterile pre-packed with traceability labelling
- The logistics and storage requirements of pre-packed sterile implants
- Likely cost implications to end users and how this might be managed effectively
- The management of existing inventory and future stock/charging mechanisms

8. Following these presentations, it was clear that the majority of suppliers are moving towards providing pre-packed sterile screws and other implants; it was also indicated that one supplier will discontinue the supply on non-sterile products in the future. The use of pre-packed, sterile and traceable implants will not only address the concerns raised in the CMO letter but also has the added benefits of better stock management, and decreases the amount of unnecessary reprocessing in central decontamination units.

Compliance Deadlines

9. A deadline of **31st December 2007** has been set for all orthopaedic units to have changed over to using pre-packed sterile single-use implants. In addition, all NHS Boards must submit action plans for compliance with this guidance, covering each orthopaedic unit within the Board area. Plans should be submitted to Ross Scott at SEHD (Basement Rear, St Andrew's House or ross.scott@scotland.gsi.gov.uk) for approval **within 3 months from the date of this HDL**.

Key Issues

10. The move towards using pre-packed sterile implants will require new and improved ways of working which will need to be managed in different ways. One example of this might be the

introduction of personnel with dedicated stock management roles. The following key issues need to be considered.

Finance/Stock

11. There is evidence that the prices paid through local arrangements with suppliers vary enormously – up to tenfold. Whilst some suppliers have indicated that there would be a cost differential between pre-packed sterile and non-sterile products, the differential will depend on the amount of business a supplier receives from NHSScotland, therefore, in some cases there may be no additional costs. It is our understanding that most existing stock is likely to have been purchased some time ago (often many years ago) and as such has no impact on current budgets.

12. It may be operationally simpler to implement a stepped programme to move over to individually wrapped sterile small implants, perhaps by procedure or category, than to use up old stock and replace incrementally. Using up old stock would simply prolong what we now recognise as suboptimal clinical practice. Units should seek the help and support from manufacturers to resolve the issue of redundant stock, which in some instances may involve swapping non-sterile products for sterile. We would encourage sites to begin migrating to individually wrapped sterile stock rather than invest heavily in non-sterile items. We will also be investigating consignment arrangements – units only pay for what they use, not for the stock held – and arrangements for the rotation of stock.

Procurement

13. NHS NSS National Procurement is currently working on the new national contract for orthopaedic implants and it is envisaged that the new contract will be in place by November 2007. The national contract for these devices will offer opportunities for significant savings on current prices due to having increased purchasing power with manufacturers. Suitable packaging presentations will be an issue stipulated within the national contract and as stated previously, so will staff training. We are also looking at provision of sterile disposable templates.

14. The contract will allow for a variety of brands and systems to be available. If a particular brand or device is only used very rarely across Scotland or by a very few surgeons for a common procedure, a case would clearly have to be made to explain why other makes are unsuitable.

Storage

15. Manufacturers have indicated that mobile cabinets are available from which single-use packs can be dispensed and used in theatre. The provision of such cabinets will be included in the national contract negotiations. Manufacturers may also be able to help with storage solutions. In units already converting to single-use, many storage problems have been solved by simply installing wall shelves or free-standing shelves in the middle of a storeroom.

Packaging & Traceability

16. Most major manufacturers are currently moving towards providing their trauma implants as sterile pre-packed, with product traceability enclosed. The packaging varies between manufacturers but as a minimum there requires to be 2 sealed layers (either soft plastic or hard plastic with blister packing apparently the most common). External boxes are often used. The key element should be

visualisation of the implant where possible to avoid opening the wrong implant, and where possible, low bulk to aid storage and reduce the volume of waste.

17. All implants come with a minimum of 4 traceability labels, either internal or external to the implant sterile packaging. This allows labels to be attached to the operation note, patient care plan and an implant register plus others for, for example, reordering.

Labelling

18. Often the implant size/type is not immediately obvious leading to potential time consuming delays in selecting and presenting the implant at operation. Discussions have been held with the manufacturers to help improve their implant labelling, making the size/type of product more obvious whilst still maintaining all the other required information on the labels.

Training/Education

19. Experience suggests the training issues for theatre staff around moving to single-wrapped sterile devices are relatively simple and straightforward, and we hope to incorporate this into contracts with manufacturers. Furthermore, the working group aims to run a series of regional workshops and to link directly with professional groups and clinical meetings. We fully appreciate the need to engage with surgeons, theatre managers, theatre nurses, decontamination staff and chief executives.

Practical Help and Advice

20. Two Scottish centres have already moved to pre-packed sterile single use implants for the majority of procedures, those centres being at Aberdeen Royal Infirmary and the Royal Infirmary of Edinburgh. The Theatre Managers for these centres, both of whom are members of the Small Implants Group, have offered to share their experience with others in dealing with the practical issues and new ways of working, and for their respective sites to be used as ‘exemplars’. Contact details for both sites are as follows:-

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or mhiggins@nhs.net

Jim Nelson
Theatre Manager
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21. Both Mark and Jim would welcome enquiries from Theatre Managers and Senior Nurses across the service directly involved in the running of Orthopaedic/Trauma Units.

22. In addition, Kevin Baird, Consultant Orthopaedic Surgeon, NHS Highland and Chairman of the sub-group, would welcome enquiries from surgeons. Charmaine Lomax, Clinical Supplies Liaison Officer, NHS Lothian, Andrew Marsden, Medical Adviser and Scott Pryde, Commodity Manager, both of whom are at National Procurement, would all welcome enquiries on procurement aspects. Contact details are as follows:

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23. All other enquiries should be addressed to the following:

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Action

24. NHS Board Chief Executives must comply with the action plan and compliance dates, and bring the contents of this HDL to the attention of:

- Orthopaedic/Trauma Leads
- Infection Control Managers
- Theatre Managers
- CDU Managers
- Procurement Leads

Yours sincerely

ALEX SMITH
Interim Director of Finance