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SUMMARY

1 Sterile Services is an essential support function which exists in all Health Authorities and accounts for about 1% of Health Authority expenditure. This represents about £200m per year for the NHS in England and Wales - an average of about £1m per Health Authority. Over 60% of the cost is in internally produced products and services (Exhibit 1).

2 There is a lack of information at both local and national level on Sterile Services Departments (SSDs) which are not specifically identified in the Korner returns or NHS Performance Indicators. One valuable result of the audits has been to provide up-to-date performance indicators to put local performance in perspective. There is a wide range of cost but most authorities spend between £2 and £4 per patient day (Exhibit 2 overleaf).

3 Sterile Services is recognised as a distinct function and is represented professionally by the Institute of Sterile Services Management. However, there is no consensus on its place within the hospital management structure. The Commission's view is that SSDs should be contractors to general managers of provider units who will be the clients. The customers of the service will be clinical staff. This structure will promote customer satisfaction and quality of service; it is also consistent with the NHS reforms.

4 Investment will be required to meet...
the new standards of Good Manufacturing Practice (GMP). 

The study has identified savings in operational costs and working capital which will help to make this affordable. The result will be an improved service from fewer, upgraded facilities. A necessary consequence is that, in a decentralised management structure, some units will purchase their sterile services from commercial suppliers and/or other NHS units rather than maintain an in-house department. The resulting flexible structure of contracts will allow the service to develop in a way which reflects clinical customers' needs and allocates the resources devoted to the activity efficiently.

5 The Department of Health's policy of not manufacturing single use packs in-house where a commercial supply is available unless there is a clear financial benefit, has not generally been implemented. Nearly 50% of these packs are still manufactured internally but the audits found unit costs on average 25% higher than commercial packs before accounting for overheads and capital charges.

6 The Commission advocates the following initiatives:-
• development of business plans for sterile services provision to meet GMP quality criteria, identifying the investment required and the options of supplying other users and using other suppliers;

• phasing out in-house single use pack production in favour of a limited range of commercially supplied packs with a potential saving of over £5m a year;

• management of all sterile products for patient use to be the responsibility of the Sterile Services Manager;

• all packs and trays to be priced to make users aware of the full cost;

• major in-house customers to be identified and a budget for sterile products and services to be agreed. Active management and financial control reducing costs by 10%, would save £12m per annum;

• user groups to be established to actively review products against full costs and identify future service requirements;

• stock control to be the responsibility of the Sterile Services Manager with a target to reduce total stock to less than 1 month's supply and free up £10m nationally;

• inventory of theatre trays to be reviewed against current demand. Surplus instruments valued at up to £25m nationally to be re-allocated or disposed of to achieve perhaps £10m in cash flow benefits;

• business, administrative and systems support and training to be provided to the Sterile Services Manager. Computer systems should be modernised and made effective for an investment of about £1m nationally. Training in business and quality management should be introduced at a cost of less than £1m.

7 The identified opportunities amount to £20m as a one-off cash flow benefit with continuing savings of £17m per year. The cost of upgrading facilities to GMP standards is not yet clear. If 250 sites are upgraded at an average cost of £100,000 the £25m investment could be financed by the identified opportunities. The balance of investment requirements and operational opportunities will need to be established in business plans at unit level.
1. INTRODUCTION

From November 1989 to September 1990 Department of Health and Audit Commission staff have carried out Value for Money (VFM) audits on Sterile Services in the NHS. This joint exercise was one of the first to reflect the increased emphasis on VFM with the transfer of NHS external audit to the Audit Commission. Auditors were provided with briefing material and a consistent approach through an Audit Guide to enable them to deal with local issues effectively.

The supply of sterile products and services is an essential support function. Sterile dressings and instruments are required throughout the Health Service for wound treatment and many other procedures. The cleaning and sterilizing of trays of surgical instruments and other equipment is vital to surgical procedures in operating theatres. The risk of cross infection, with its impact on quality of patient care and length of stay, is very real and product liability introduces a financial risk to Health Authorities.

The VFM audit has been carried out in nearly 100 District Health Authorities (DHAs) in England and Wales and overview information has been obtained for many of the remainder. Detailed financial returns were made for 35 early audits to support the analysis in this paper and the results, including Performance Indicators, were fed back to auditors as an input to their local reports. Overview data from over 100 authorities was also available for local and national analysis. In addition, the Audit Guide has been used in Northern Ireland and 6 hospitals in Germany were visited to identify good practice for implementation in the UK. The Audit Guide has been updated and published to make the concepts and methodology available to NHS Management and support implementation of the agreed action items.*

4 The work years carried out under the overall direction of Ken Sneath (formerly of the Department of Health Audit Branch and now an Associate Director of the Commission) working closely with the Commission’s Health Studies Directorate. Day to day project management was carried out by Roy Maxwell from the Department of Health and Ray Beatty for the Commission. Barbara Simmons, an experienced Sterile Services Manager and member of the European standards committee on sterilizers, has acted as technical consultant to the project. The team has been helped by many people in the Department of Health, the Institute of Sterile Services Management, Health Authorities, the German Hospital Federation (DKG) and commercial suppliers. This positive co-operation has been essential to the success of the audit.

5 Section 2 of this paper provides an overview of Sterile Services in the NHS today based on the information collected in the audits and Section 3 discusses the challenges facing sterile services in achieving higher quality standards in the reformed NHS.

6 The audit approach focused on specific issues in the areas of management control, financial control, quality control, logistics and performance monitoring. Section 4 sets out the findings, conclusions and recommendations in each case. Section 5 discusses the way forward for local implementation and the general direction of the service.

2. STERILE SERVICES IN THE NHS TODAY

7 The average cost of sterile products and services to a District Health Authority in 1989/90 is estimated at nearly £1m including unit overheads and capital charges (Table 1)

<table>
<thead>
<tr>
<th>Average Cost</th>
<th>Total Cost</th>
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<tr>
<td>DHA</td>
<td>NHS</td>
</tr>
<tr>
<td>Theatre tray service</td>
<td>£310</td>
</tr>
<tr>
<td>Sterile products bought in</td>
<td>£290</td>
</tr>
<tr>
<td>Sterile packs:</td>
<td></td>
</tr>
<tr>
<td>– single use</td>
<td>£120</td>
</tr>
<tr>
<td>– made</td>
<td>£80</td>
</tr>
<tr>
<td>– with re-usable items</td>
<td>£150</td>
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<tr>
<td>Medical Equipment Disinfection</td>
<td>£10</td>
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These estimates are based on audit returns from 35 DHAs with an average revenue expenditure of £70m in 1989/90 - very close to the national average of £68m. Sterile packs, theatre tray service and sterile products each account for over 30% of the total (Exhibit 3 overleaf).

The costs of both the theatre tray service and sterile products may be understated. Where the work is carried out...

by theatre staff, theatre service costs are not easily identified and many units do not identify the sterile product element within the medical and surgical goods category. Recorded expenditure on the disinfection of medical equipment, identified as a task of the model Hospital Sterilizing and Disinfecting Unit (HSDU), is very low on average and zero in many authorities.

8 The costs shown above also exclude the value of the surgical instruments and linen used in theatres. The total tray/instrument inventory value is of the order of £100m. Depreciation and interest charges on this would add £26m annually to the cost of the theatre tray service. This brings the total annual resource cost of sterile services in England to £200m or £1.1m for an average DHA.

9 Nearly all District Health Authorities have a Sterile Services Department. 40% of DHAs also carry out sterilizing functions at Theatre Sterile Supply Units (TSSUs) using theatre staff (Exhibit 4). The total number of major sterilizing sites in the NHS in England is approximately 400 of which 280 are run by SSDs and 120 by theatre staff. (This excludes small sterilizers for local instrument sterilization and sterilizers used within pathology laboratories which were outside the scope of the study). Only one SSD in five supplies products and services outside its authority - either to other DHAs or to third parties and 40% of DHAs still produce most of their single use packs in-house. In contrast, commercial suppliers generally have a single manufacturing point and distribute nationally. The West Midlands Regional Sterile Supplies Unit operates on a similar scale producing 11 million packs per year.

10 In Sterile Services, labour costs represent only 27% of the total. The average Health Authority SSD has 26 whole time equivalent staff with 80% having between 10 and 30 WTEs. In the NHS as a whole this amounts to about 5,000 staff - approximately 0.6% of total HA staff. 40% of SSDs operate with only one person at manager grade and 40% have less than half a whole time equivalent person for clerical support (Exhibit 5).

11 The key technology for sterilization in the NHS is the high vacuum, high temperature steam, porous load sterilizer. These units cost about £25,000 to buy and install and annual maintenance costs £5-10,000. The average DHA has 5 of these units in operation. Normally at least 3 Sterilizers are installed (Exhibit 6).

12 The average SSD supplies over 60,000 packs a month, made up as follows:

- 42,000 single use packs
- 12,500 packs with re-usable items
- 2,750 theatre instrument trays
- 4,300 theatre linen packs

(Exhibit 7)
Only the single use packs are widely available from commercial suppliers. The reprocessing of instruments and linen 'owned' by the individual units has tended to make this a local, in-house activity. Nearly half the single use packs are still manufactured in-house despite the Department of Health's 1984 policy, set out in HC(84)3, of not manufacturing where a commercial supply is available unless there is a significant, demonstrated, financial benefit. The variety of packs and trays supplied by the average SSD is over 500. (Exhibit 8 overleaf). Commercially sourced packs tend to be high use items (average usage 800 per month as opposed to 300 per month for in-house packs).

3. CHALLENGES FOR THE FUTURE

13 NHS Sterile Services face a number of challenges in the immediate future including, in particular:

- the need to achieve 'Good Manufacturing Practice' standards to demonstrate quality for product liability assurance;
- the need for cost-effective service provision in the decentralised management structure envisaged in the NHS reforms.

GOOD MANUFACTURING PRACTICE (GMP)

14 Accepting product liability means that the NHS will need to demonstrate quality control in sterile services operations. GMP standards have been
applied to commercially sourced products for many years and comparable standards now need to be applied internally. in December 1989 the Institute of Sterile Services Management produced a guide to the appropriate standards* and its implementation is commended to HAs by the Department of Health. The Department expects emerging EEC standards to require even higher levels of quality control after 1992.

15 The audits found that hardly any NHS facilities meet GMP standards. The requirements include environmental control, process control, training and documentation and, often, building improvements. The overall cost of upgrading sterile services facilities to meet GMP standards is not yet established. Some facilities would be too costly to upgrade, relatively new HSDUs should require little work but older units may require alterations costing up to £250,000. Investment will not be justified at all existing facilities and management in all units needs to identify the deficiencies and the options for providing a GMP quality service.

16 GMP, and the need for effective management control, should lead to rationalisation of sterile services operations with users being supplied from a smaller number of upgraded facilities. However, the operational management of the Health Service in the reformed structure is being transferred to unit level. DHA's will move to the role of purchasing health care to meet the needs of their population. In the new structure individual provider units will need to buy sterile services from other units. (The alternative - for each unit to have its own in-house SSD - is neither practical nor affordable). This will require prices and specifications for contracts between units.

17 The audit concentrated on providing the necessary basis for this by focusing on identification of customer requirements and development of full costs for both product pricing and SSD budgeting. It is clear that the necessity of operating in a more competitive environment will make new demands on SSD management. Many Sterile Services Managers are keen to respond to the challenge but Unit General Managers in hospitals with SSDs need to plan for training and financial and commercial support to ensure that business with other units is carried out effectively. Inter-unit sterile services transactions are likely to become the norm rather than the exception as at present.

VALUE FOR MONEY

18 The increased awareness of the cost of sterile services whether supplied internally or externally will lead to more emphasis on cost effective operations and the audits have identified opportunities in the areas of:

-- capital avoidance (facilities and equipment); running cost savings; -- inventory reductions; -- income generation.

4. KEY ISSUES - FINDINGS AND RECOMMENDATIONS

19 To assist SSDs to meet these challenges the study focused attention on specific issues in five areas:

Management Responsibility
Financial Control
Quality and Customer Satisfaction
Logistics
Performance Monitoring

(Exhibit 9)

This description of the problem set was also used in communications meetings which were attended by over 150 Sterile Services Managers and in the Commission's Review paper briefing General Managers on the work. It can be applied to many support functions in
Health and other fields. For each issue the findings of the audits are outlined followed by the Commission's conclusions and recommendations and an indication of the likely benefits.

MANAGEMENT ISSUES

ORGANISATION 20 Sterile Services Departments are currently found in many different places in the Health Service District or Unit management structure. Nursing, Pharmacy, Hotel Services, Support Services, Engineering Services and Supplies organisations can have responsibility for SSD but there is no consensus on the most appropriate management reporting line. In addition, the revised NHS management structure, with operational management devolved to unit level, clearly indicates that Sterile Services cannot be a District management function even though most SSDs will be supplying units throughout the District.

21 The Commission's recommendation is that the SSD should be seen as a CONTRACTOR with general management of provider units as the CLIENT and clinical users as the CUSTOMERS. This concept is consistent with the new organisation and enables the service to be delivered to a number of different units which may not be in the same Health Authority. It requires the SSD Manager as the contractor to negotiate the service deliverables with users and all parties to recognise the full cost of the service. It represents an important step towards enabling competitive tendering for all or part of the service to any unit.

STERILIZATION OUTSIDE THE SSD

22 40% of DHAs have major sterilizing functions which are not managed by the Sterile Services Department. They are usually managed as part of the operating theatre organisation and often the work is carried out by various grades of theatre nursing staff. Auditors found very little financial or volume information and it is unlikely that these sites could demonstrate GMP compliance as they are currently managed. In some cases, instruments are sterilized, unwrapped, in downward displacement sterilizers. In addition, auditors found up to 50 small sterilizers in use around each District for patient treatment items. Laboratory sterilizers for internal use are separately managed and were not within the scope of the audit.

23 The Commission recommends that all sterilization of goods for patient treatment should be reviewed by provider units to ensure that a GMP quality service will be available with the expectation that GMP will become part of the quality specification in contracts with the DHA purchasers. The objective should be to develop a plan for a professionally delivered, quality service where clinical users, in particular nurses, are the customers and not the providers of the service. This may require the extension of sterile pack services to outlying sites, frequently replacing the use of local sterilizers. It should also involve SSDs negotiating to take over the management of nurse operated TSSUs.

24 Customer satisfaction and committed service levels in terms of 'turnround' time will be critical to achieving this. Clinical staff are highly sensitive to the availability of instrument sets and will be reluctant to relinquish control, particularly if the service is to be provided from a remote site. This is a management challenge for SSDs but it could bring two important benefits.

25 First, nursing resources could be released:

there are probably 120 sites in England where nurses are involved in washing, packing and sterilizing theatre instruments;

if SSDs can take on this workload we estimate that up to 500 staff, many of them increasingly scarce, highly skilled and high cost nurses could be deployed more effectively.
Second, facilities could be rationalised:

if theatre trays can be provided another site, valuable space adjacent to theatre suites can be released for clinical use.

MANAGEMENT OF STERILE PRODUCTS

26 The expenditure on single use sterile products supplied, pre-sterile, by industry is high (about £1 per patient day) and not well controlled. The data was not available in 40% of the authorities studied and in others information was incomplete. In the North Western Region, where auditors were able to access and analyse the Regional database, the cost per patient day was 35% lower in an authority where the SSD controlled these items than in other neighbouring authorities. High value prostheses and implants which are sterilised in theatre trays before use are not always well controlled. In some DHAs these items are effectively managed by Sterile Services Managers.

27 The Commission recommends that the role of the SSD Manager should cover the whole range of sterile products which would allow the most appropriate alternatives to be considered by users. SSD involvement should include:

advice to users on cost and quality; control of stock levels;
• input to purchasing decisions;
physical handling and distribution of all sterile packs and products where this is practicable.

28 Active management of these products by knowledgeable staff can significantly reduce wastage.

More rational management of the use of sterile products in conjunction with sterile procedure packs should also improve the service to clinical users and the effective effectiveness to patients.

FINANCIAL ISSUES

BUDGETARY CONTROL

29 The average DHA budget for sterile services is about £1/2m per year - about half the true costs when overheads, capital charges and sterile product costs are included. Financial controls are generally deficient with budgets and expenditure reports:

* not volume based;
not agreed with or available to users; not available to SSD managers; late and not consistent with operational management information.

in most authorities the budgetary control process does not contribute to the effective management of sterile services either by the SSD Manager or the users.

30 In line with the recommendations on organisation the Commission believes that the budget process should be developed into a ‘contract’ between the SSD and the main users to define:

-- key deliverables in terms of volume, quality and service levels;

-- charges based on full costs including overhead and capital recoveries.

The SSD Manager would be responsible for full cost recovery, including a contribution to unit overheads, and the users would be responsible for effective use of the service, minimising waste.

31 To be fully effective this process needs to be combined with delegation of financial control to the SSD manager and delegation of budgets, including the cost of sterile services, to users. There is widespread evidence that when users are given budgets and are allowed to control usage, a significant reduction in wastage is achieved. A 10% reduction in usage of all sterile packs and products would be worth about £12m per year nationally or £65,000 to the average DHA. Longer term, the balance of usage of different products and services is likely to be optimised from a clinical ‘total treatment cost’ perspective.

UNIT COSTS

32 Most NHS users have no information at all on the cost of packs, trays and sterile products supplied to them. However, where SSD Managers have priced individual items or reported monthly costs to users, this has produced a positive reaction and a high level of interest. In every case, users and SSD managers believed the service to be more valued and wastage to be reduced.

33 The audit included a sample costing of packs and trays to arrive at the true cost of internal production on both a full cost and a marginal cost basis. The results showed that, on average, internal costs were 25% above indicative commercial costs (including VAT, delivery and handling charges) on a direct cost basis and 55% higher if overheads and capital charges were included. Results for some of the sample packs are shown in Exhibit 10. Some of the variation will reflect
specification differences but all commercial production meets GMP standards.

In nearly every case where internal costs were below commercial prices the packs were produced in Industrial Therapy Units using patient labour at token cost. If, as recommended by the Department, patients were paid at a rate which reflected their productivity this cost advantage would be eliminated.

34 48% of single use packs are still manufactured in-house despite the 1984 policy direction. Some SSD managers believe that their needs cannot be met from commercial sources but others

Successfully source 100% commercially (Exhibit 11 overleaf).

35 SSD Managers under-estimate the true cost of pack manufacturing.

Standard minute values costed at hourly, rates do not reflect full costs of employment and achieved productivity. The audit methodology (set out in the Audit: Guide) allocates full departmental costs across the output produced and provides a better measure of the real costs of materials and labour as well as full costs, including overheads and capital charges.

36 If is essential to tell users the full unit cost of all the sterile items supplied to them if the products are to be valued and used correctly. This cost should include all labour, materials (allowing for losses and waste), sterilization costs, cover heads and capital charges. It is not necessary or desirable to cost every item explicitly to fractions of a penny. Prices can be set for groups of products of similar size and value with standard mark-ups applied. Most SSDs have the base information available but realistic budgets for full costs and forecast volumes are needed. Prices should be visible at the point of use and also published to users as part of the product catalogue. Commercially sourced items could be priced at list price if the bulk discount achieved covers internal handling and distribution costs.

37 SSD manufacturing of single use packs should be phased-out as soon as possible. There may be a case for producing special packs in limited numbers alongside theatre trays in an HSDU where a more economical commercial product is not available. There is no
case for investing to bring volume pack manufacturing facilities up to GMP standard. SSD managers should look for commercial alternatives and agree the change-over with key users. Even at direct cost level the saving is likely to be worth £5m per year. The management overheads and facilities released can be devoted to higher value added activities - many of which have been identified in the audits.

REVENUE OPPORTUNITIES
38 Only 22% of the SSDs surveyed showed income from any source and half of these showed less than £1,000 per month. Usually the arrangements involved a block charge to other DHAs. Instances of both serious overcharging and undercharging have been found.

39 The requirement for sterile product and services is not confined to hospitals and community units. Obvious potential customers are G.P.s, dentists, vets, nursing homes, private hospitals, industry, public events organisers etc. Even 5% of internal demand represents an average annual revenue potential of £50,000 per DHA. Extensive marketing or advertising is not appropriate. A product specification and price list should be published to potential customers and supply arrangements negotiated. Simple ordering, billing, credit and distribution systems should be used to minimise administrative costs. A first priority would be to capture revenue from informal use of NHS products and assets that may already occur; particularly the use of theatre trays in private sector surgery.

QUALITY ISSUES
GOOD MANUFACTURING PRACTICE
40 As noted in paragraph 14, the December 1989 Guide to Good Manufacturing Practice published by the Institute of Sterile Services Management has been commended to Health Authorities by the Department of Health. While many SSD Managers have ideas on how they would implement GMP in their facilities, specific plans had not been put to management for approval. The expectation is that action will be required to upgrade facilities and/or procedures at all sites where operations are to continue. It will be essential to demonstrate compliance with GMP for external business and transactions with other units.

41 The Commission recommends that all units review their sterilising operations and produce specific plans to meet GMP. These plans could include switching to external sources (commercial single use packs and other NHS units for theatre tray service) as well as upgrading of in-house facilities. Opportunities within SSD operations can yield savings which could be used to fund early implementation and secure a competitive advantage.

CUSTOMER SATISFACTION
42 An important part of the audit consisted of interviews with the main users of sterile services. The questionnaires were designed to promote the users' perception of themselves as customers of the SSD. The results were generally very positive. Users were willing to take more interest in sterile products and services and, even where there were no major problems with the current service, ideas for improvement were often generated.

43 Informal contacts between SSD managers and users, although necessary and valuable, are rarely sufficient to ensure that users' changing needs are identified. The Commission recommends that formal user groups are established for sterile products and services, managed by the SSD Manager, with key users represented and all users informed of meetings, topics for discussion and decisions. In addition, SSD managers should attend relevant opera
A management concern was that user groups might generate expectations which could not be satisfied, leading to a negative reaction among clinical users. To avoid this, it is absolutely essential to provide the cost implications of all options discussed by user groups. A rational trade-off between options is particularly valuable when total expenditure is constrained.

LOGISTICS

STOCK CONTROL

Nearly every audit identified opportunities to reduce stocks, even with existing delivery frequencies and supplier lead times. On average, stocks could be reduced by 40% without affecting service levels; indeed a better allocation of stocks according to demand would in many cases improve service levels as well. The opportunities exist in user stocks, raw material stocks and sterile product stocks. Data on the value of these stocks was rarely available but immediate cash flow opportunities ranging from £10,000 to £65,000 were estimated by the auditors in individual DHAs.

The team's discussions in West Germany showed management and auditors to be very conscious of the need to control stocks. German hospitals and the public sector auditors target their hospitals to a 12 times annual stock turn i.e. 1 month's supply. This is the total stock with no District or Regional store back-up. Tough financial criteria are supported by strict rules on shelf-life for drugs and sterile goods which generally limit user stocks to less than 1 week's usage.

The German experience and improvements in industry generally show that there is a real opportunity to reduce stocks; first by relating stocks to current usage and secondly by negotiating better and more reliable delivery performance from suppliers - including Regional stores where they are part of the logistics chain. The SSD manager should take responsibility for this. If stocks of sterile packs can be reduced from 2 month's supply to 1 month this would free up working capital of £5m nationally - about £30,000 in the average DHA. Information on sterile product stocks is very limited but a similar opportunity could well exist in this area.

INSTRUMENT TRAY INVENTORY

Auditors were asked to test the inventory of a sample of trays against current usage patterns and 'turn around' times. Nearly all reported overall tray inventory to be surplus to current requirements but one DHA suffered a general shortage and many were short of specific sets. Few DHAs knew the total value of the instruments in theatre trays but auditors' estimates showed average values of £501,000 in 614 tray sets of 148 different types. The average estimated surplus was 25% of tray sets - £125,000 worth of inventory in a typical DHA. Given the sensitivity of the availability of surgical instruments to clinicians, SSD Managers will need management support and the confidence of their customers in this task. Review of the variety, as well as the total inventory of trays, should be a continuing activity as clinical procedures and clinicians change. Additional sets of instruments may be required to support remote units or new day surgery theatres but better utilisation of existing inventory will reduce the incremental expenditure required.

PACK RATIONALISATION

There is a wide range in the variety of sterile packs in use (Exhibit 12 overleaf). This is particularly the case for packs containing re-usable items. For single use packs an average of 111 different packs were in use but 25% of DHAs used less than 60 different packs. The average for all packs was 346 but 25% had more than 500 in their catalogue.

German hospitals do not use sterile procedure packs containing a number of different items for particular clinical procedures. None of the hospitals visited had more than 4 'procedure packs'. Sterile items are supplied individually and used in combination as required.
This approach is indicative of a very different aseptic technique and is not necessarily recommended for NHS application. However, Scotland has made major progress in rationalising packs, reducing single use procedure packs to 6 with 60 supplementary; all supplied commercially. Phasing out in-house single use pack production could dramatically reduce the variety of packs while continuing to meet clinical requirements. This will enable much better control of pack usage, stocks and logistics as well as offering opportunities for volume discounts from commercial suppliers.

FACILITIES RATIONALISATION

52 To test the scope for rationalisation of facilities, the utilisation of sterilizers and washing machines was measured against capacity after allowing for downtime, loading and unloading. Some authorities achieved over 100% utilisation of sterilizers on these estimates but 20% had less than 50% utilisation and 40% had less than 70%. Half those reporting were using less than 50% of washer capacity.

53 There should be an opportunity for capital avoidance by limiting replacement of major equipment. This can be done by first ensuring that capacity is properly utilised. Additional capacity will be freed up from phasing out in-house pack manufacturing. Thereafter, GMP investment should be restricted to priority sites. If 100 ageing sterilizers can be taken out of service without replacement, maintenance costs of at least £0.5 m per year can be saved and replacement capital costs of about £2.5 m can be avoided.

INFORMATION SYSTEMS

54 80% of the SSD sites reviewed have computer systems installed and 70% have software with adequate capability. However, 40% have implemented less than half the available features and are not obtaining the full benefit in terms of management information from their systems.

55 All sites that are likely to continue in operation should have computer systems to provide the operational, management and financial information to support service improvements. In addition, Systems and Finance support should be provided to these new systems and the existing systems which are not fully implemented. 50 new systems could probably be installed for £0.5 m and full implementation at 100 sites might cost a further £0.5 m.

MONITORING PERFORMANCE

56 Performance indicators provide a 'top-down' assessment of the service. The results from the initial audits have allowed sterile services performance indicators to be produced for the first time and they have been used in subsequent reporting to local management. The full set is shown in Appendix A. Quartiles have been used to help with interpretation of the results. They ignore extreme cases (which may affect the average) and provide an intuitive assessment of the significance of the result; half the results lie between the quartiles. Cost indicators below the lower quartile may suggest under recording of costs. Where unit costs are high, the volume indicators help to differentiate high usage (for which there may be a clinical rationale) from high costs. The interpretation of some of the individual indicators is discussed below.

57 As expected, the cost of sterile services reflects the size, level of activity and total expenditure of the authority but the share of total expenditure varies more within authorities of similar size and type than between large and small authorities or teaching authorities (Exhibit 13). A low percentage may be indicative of inadequate sterile service provision or an inability to identify the
full cost of sterile products supplied direct to users. The individual cost elements need to be reviewed before judgements of performance can be made.

58 The number of patient days (including day cases but excluding mental health patients) is expected to provide the best single indicator of sterile services demand and is similar to the bed-day parameter used as the key mechanism for funding hospital inpatient costs in West Germany. The initial results are encouraging and the experience in Germany suggests that this is a workable unit cost statistic. Many of the DHAs with the lowest cost per day have no costs recorded for sterile products (Exhibit 14). The performance indicators have been adjusted for this to arrive at an average cost per day of £3.17 with upper and lower quartiles of £3.41 and £2.59.

59 The cost of disinfection services supplied by SSDs was small everywhere and zero in half the Health Authorities studied (Exhibit 15 overleaf). The Department of Health's concept of central disinfection of medical equipment in the HSDU has not been effectively implemented by most SSDs. Three types of medical equipment requiring a disinfection service are identified by the Department of Health:

- re-usable accessories (e.g. for anaesthetic systems),
- large items (e.g. ventilators),
- fast turn-round devices (e.g. flexible endoscopes).

The Department expects demand for decontamination services to increase and has issued several guidance notes to increase awareness of this. It must be questioned whether ad hoc arrangements for disinfection will be satisfactory in the future. In West Germany, disinfection of beds and mattresses is the norm and can cost more than the entire sterilization function. Although the value of bed disinfection is questioned in Germany, it may indicate that disinfection in general is an area for future SSD service development.

60 The major cost element of theatre tray service has been related to the volume data on theatre cases. The average cost is £17 per theatre case, excluding the value of the instruments, but varia-
variation is high (Exhibit 16). Depreciation and interest on instruments would bring the total up to about £25 per case.

Certain surgical specialties (Trauma and Orthopaedic, ENT, Oral, Neurosurgery, Plastic and Cardiothoracic) are particularly heavy users of theatre trays. Nationally, they account for 33% of theatre cases and a very different proportion might explain part of the variation in costs.

61 Based on the audit data a normalised performance indicator ratio for sterile services has been developed which allows comparisons between authorities taking account of activity levels in terms of patient days and theatre cases. The results still show wide variation between authorities (Exhibit 17).

62 Another way of examining costs in a particular authority is to break down the elements of cost in an analysis tree comparing each element with the average. An example is shown in Exhibit 18.

5. THE WAY FORWARD

ACTION PLANS

63 The next step in nearly all units will be to review the options, including site rationalisation, for bringing all sterile service provision up to GMP standards (Exhibit 19). This is likely to have an impact on current capital spending plans if early implementation is to be achieved. The implications should be recognised by Regional Health Authorities.

64 The cost of meeting GMP is not yet clear. Some units cannot be upgraded because of limitations of the site. Pack manufacturing CSSDs and units due to be replaced by new HSDUs will not justify major investments. For the remainder, the costs may range from almost zero to £250,000. If 250 of the estimated 400 sterile services facilities in the NHS are upgraded, at an average cost of £100,000, £25m of capital will be required. The Commission believes that £10m of this could be funded through cash-flow savings from sterile stock control and a further £10m from instrument inventory reductions. The instrument inventory reduction represents 10% of the total and should be achievable through reduced replacement purchases over a two year period. Further savings of £17m per year from phasing out in-house manufacturing and active management - by users and sterile services managers - of the use of sterile products should make the investment affordable. The balance of invest-
ment requirements and operational opportunities will need to be established by each unit.

65 Specific action plans will have been developed from audit recommendations and agreed with General Managers in each authority studied. These plans should identify the responsible manager, provide the necessary resources and define check-points. General management support and review will be needed to achieve the improvements in financial and service performance identified in the audits. The actions agreed will reflect the specific local situation but should include many of the recommendations developed in this paper:

- establishing effective user groups
- phasing out single use pack manufacture
- visible pricing of products
- budgets assigned to major users
- stock reduction targets
- tray inventory review
- control of sterile product usage
- review of disinfection requirements
- support to the SSD Manager.

66 As in Local Government, the Commission will put in place a mechanism for tracking the benefits of audit recommendations over time. Experience shows that major benefits arise in the 2nd and 3rd years after the audit and follow up by auditors will help to secure these improvements.

PERFORMANCE INDICATORS
67 The performance indicators derived from audit results can be applied in Health Authorities not covered by the audit to focus management attention on potential improvements. This paper and the Audit Guide can then be used to identify specific opportunities and elements of good practice for implementation.

SERVICE DIRECTION
68 The cornerstone of the audit recommendations is the identification of the real cost of sterile products and services and communication of this to users. Only when this information is available can sensible judgements be made about the demand for and the supply of these services. Free goods are not usually valued and are liable to be wasted. GMP provides a benchmark for the technical quality requirements but the critical element of "meeting customer requirements" must come from active user groups and 'contracts' for services built into budgeting processes. The direction of sterile services provision in the NHS in the 1990s will come from individual agreements made between suppliers and users at local level rather than from national directives. Independent management of hospital units will result in different patterns of provision being tried - and probably being adjusted over time.
BUSINESS PLANS FOR STERILE SERVICES

69 To justify the investment in GMP standards some units will be looking for increased throughput from their SSD facilities, others will be looking for alternative sources to avoid the investment in upgrading. Business plans for SSDs should help to set out these options for management decision. The benefits of scale and management control from a central SSD serving a number of hospital units should offer unit management an alternative to running their own SSD. The need to provide a service to demanding, independent clients and customers will mean that SSD managers and commercial suppliers will have to constantly focus on the value, the costs and the quality and reliability of the services provided.

70 SSD Managers should aim to move into areas of more value to clients and customers e.g. advice on the use of sterile products and solving new problems in the areas of sterilization and disinfection of high technology equipment. Managers will need training in the areas of planning and control, business development, systems and quality management. The requirements are common to other areas of NHS management and courses should be available to meet the need. A budget of up to £5,000 per DHA should provide the necessary training for less than £1m nationally.

71 Purchasing of sterile packs and products could continue on a shared basis with Regional contracts or with some SSDs specialising in particular areas. Similarly, Regional stores should compete with manufacturers' direct supply by offering superior lead times and delivery service; enabling hospitals to reduce their stock levels and to capture the available cash flow benefits.

72 Local SSD recycling of packs with re-usable instruments could offer a competitive service to manufactured single use products by emphasising quality of the product in use and the handling of the waste disposal problem for the user. This is already a major issue in Germany and could become one in the UK. One of the hospitals studied in Germany was moving back to re-usable items for some procedures.

73 Theatre tray service should be able to benefit from rationalisation in terms of meeting GMP and improving utilisation of sterilizers and surgical instruments. The requirements for increasing day surgery activity and the development of new non-invasive surgical techniques will also affect the demand for traditional tray sets; emphasising the need for control of this inventory.

A COMPETITIVE MARKET IN STERILE SERVICES

74 The essential feature to enable the evolution of these service improvements is the promotion of inter-unit transactions in sterile products and services. In turn, this requires a sound basis for costing and pricing the transactions concerned. This does not have to be highly sophisticated - the costs of most items are generally available and overheads can be allowed for in a general mark up. The penalties of underpricing a product will quickly
become apparent unless comparable cost savings are achieved.

75 Unit Managers should consider whether they have, or could develop, a significant competitive advantage in their in-house SSD. If not, they will probably decide to buy in at least part of the service. Where development of the in-house unit is an attractive option, this could be done within the unit organisation or under a joint venture or facilities management arrangement with a commercial firm. Management buy-out may also be an option. In all cases the unit would expect to benefit from a successful SSD operation and earn a return on resources employed.

76 Competitive tendering will be one mechanism for choosing between these options. Experience of competitive tendering in other areas will be highly relevant but the requirements of the clinical user will need to be fully reflected in the tender specifications for SSD provision.

77 The Commission's studies in the Sterile Services area reinforce experience elsewhere in the public sector that real improvements in value for money are achievable. In many areas, dedicated staff and management are working to provide a critical service without the flexibility and resources to make real improvements. The Commission believes that the opening up of a market in sterile services with independence of operational management can provide significant benefits to the NHS both as a consumer and a provider of the service.
APPENDIX A

PERFORMANCE INDICATORS FOR STERILE SERVICES

COST INDICATORS

<table>
<thead>
<tr>
<th>Cost Description</th>
<th>Average</th>
<th>Quotile Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Sterile Services Cost</td>
<td></td>
<td></td>
</tr>
<tr>
<td>As % HA spend</td>
<td>1.40%</td>
<td>1.06 - 1.73%</td>
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<tr>
<td>Per acute bed per yr</td>
<td>£1377</td>
<td>£1063 - 1614</td>
</tr>
<tr>
<td>Per Patient day*</td>
<td>£3.17</td>
<td>£2.59 - 3.41</td>
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<tr>
<td>Sterile Pack Cost</td>
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<tr>
<td>Per acute bed per yr</td>
<td>£523</td>
<td>370 - 624</td>
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<tr>
<td>Per patient day</td>
<td>£1.22</td>
<td>£0.76 - 1.47</td>
</tr>
<tr>
<td>Theatre Service Cost per Case</td>
<td></td>
<td>£17                  £12 - 21</td>
</tr>
<tr>
<td>Other Sterile Products</td>
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<td></td>
</tr>
<tr>
<td>Cost per patient day</td>
<td>£0.97</td>
<td>£0.62 - 1.15</td>
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<tr>
<td>Equipment Disinfection</td>
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</tr>
<tr>
<td>Per patient day</td>
<td>£0.03</td>
<td>£0.00 - 0.04</td>
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</table>

VOLUME INDICATORS

<table>
<thead>
<tr>
<th>Volume Description</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Sterile Packs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per acute bed per month</td>
<td>71</td>
<td>56 - 74</td>
</tr>
<tr>
<td>Per patient day</td>
<td>2.02</td>
<td>1.46 - 2.34</td>
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<tr>
<td>Theatre Trays</td>
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<td></td>
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<tr>
<td>Per theatre per month</td>
<td>165</td>
<td>129 - 184</td>
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<tr>
<td>Per theatre case</td>
<td>1.45</td>
<td>1.02 - 1.88</td>
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</table>

NORMALISED INDICATOR RATIO

<table>
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<th>Cost Description</th>
<th>Normalised</th>
<th>Quotile Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Sterile Services Cost</td>
<td>1.00</td>
<td>0.90 - 1.15</td>
</tr>
</tbody>
</table>

Normalised P.I. Ratio

= Actual cost./normalised cost estimate

Normalised Cost Estimate

= £2.22 x patient days + £17 x theatre cases

* excluding mental health patient days.
GLOSSARY OF TERMS

CSSD
-- Central Sterile Supply Department - original concept for SSD with focus on sterile pack production.

EQUIPMENT DISINFECTION
-- Disinfection of medical equipment or accessories between patients or prior to repair or servicing.

HSDU
-- Hospital Sterilizing and Disinfecting Unit combining theatre tray service with limited pack production and disinfection - current Department of Health concept for new hospital facilities.

PATIENT DAY
-- All patient days except for mental health/handicap patients - includes all acute, maternity, geriatric in patients and day cases but not out patients.

PROCEDURE PACKS
-- Packs containing all items needed to carry out a particular procedure.

RE-USABLE PACKS
-- Packs containing re-usable items which are returned to SSD for re-processing - may also contain single-use items.

SINGLE USE PACKS
-- Packs containing only single use (disposable) items - sometimes called 'soft' packs but may include single use plastic instruments.

STERILE PRODUCTS
-- Products supplied pre-sterile from industry e.g. dressings, syringes, gloves, catheters.

SUPPLEMENTARY PACKS
-- Packs containing one commodity for use in conjunction with other packs.

THEATRE LINEN
-- Drapes, gowns and linen which may be sterilized as separate linen packs or with instruments in trays.

THEATRE TRAYS
-- Standard UK practice of packing instruments, dressings, swabs, and linen for particular procedures in a tray with paper wrap for use in a porous load sterilizer.

TSSU
-- Theatre Sterile Supply Unit - original concept for theatre sterilization providing service to theatres only and often operated by theatre staff.

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