Reuse of Sterile, Single Use and Disposable Equipment in the NHS

Proceedings of a conference
held on December 2 and 3, 1985 at the
Royal Institute of British Architects,
London

King Edward's Hospital Fund for London

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INTRODUCTION

The reuse of sterile medical devices designated for single use only is a controversial practice. It is nevertheless known to take place not only in the NHS but in other countries with highly developed health care systems, as well as in developing countries. Such reuse raises many issues, including legal and ethical ones. There are even concerns about whether it is, in fact, cost effective when the costs of reprocessing are taken into account. A number of different interest groups have concerns about the practice, including the doctors and nurses using reprocessed devices, central sterile supply managers, other district and regional officers, the industries which produce the devices and central government departments who might be expected to provide guidance on the appropriateness of reuse. At the head of this long list should be the patients, if they knew what was happening.

The King's Fund was approached by the DHSS (Department of Health and Social Security). It was also known that industry was keen to have reuse discussed. Because of the range of issues raised by reuse and the number of different interests involved, the Fund agreed to organise a conference on the reuse of single use, sterile, disposable medical devices. The two day conference attracted a total of 250 people from a broad mix of disciplines and backgrounds. The report of the proceedings which follows includes the papers presented as well as summaries of the discussion sessions.

The report, which follows the outline of the conference covers these topics:-

1 The general perspectives of the various groups involved.

2 Clinical issues.

3 Legal and ethical implications.

4 Technical issues.

5 Economic issues.

6 A paper from the United States describing the conferences and developments taking place there concerning reuse.

The King's Fund was keen that the conference should not merely be a forum for airing the issues associated with reuse but should also indicate what might be done about them. It therefore appointed a four member panel to listen and take part in the proceedings so that they could prepare a series of recommendations for future action. It was not expected

that the members of the panel would give guidance on specific aspects of reuse or on reprocessing, but rather that they should suggest steps which might be taken to help resolve the main underlying issues. The four member panel included the Chairman of the Conference, Dr S Anderman, Reader in Law, University of Warwick, Dr J Hurst, Deputy Chief Economic Adviser, DHSS, Mr G Kennedy, Chairman, BHTIC (British Health Care Trades and Industries Council), Portex Limited, and Professor J Tighe, Pathology Department, St Thomas' Hospital.

Each member of the panel contributed to the summary and recommendations given in the first section of this report. In addition each of them was responsible for summarising the issues raised in one of the main sections of the conference. These summaries are given at the end of the respective sections. The King's Fund is particularly grateful to the members of the panel for all their work.

The panel concluded that it would be desirable to have explicit written policies about reuse of single use equipment, rather than leaving policy decisions to individuals. The prime responsibility for producing such policies should rest with DHAs. However, the DHSS should issue guidelines to health authorities on the drawing up of these policies. It should also commission occasional evaluations of particularly important or vexed examples of reuse and provide a focus for technical contacts with manufacturers.

The panel recommended that DHA policies should cover a number of categories of reuse:-

a) Items reused on the same patient

i) During one procedure such as a surgical operation. Guidance will be required where syringes are reused with different substances, to avoid incompatibility within the syringe.

ii) Repeated reuse, such as with diabetic syringes. Guidance will be required about sterilisation and storage procedures, as well as advice about the number of times the equipment may be reused.

b) Items reused on different patients

i) Items that may be sterilised by CSSDs without difficulty. Forceps and scissors may be included in this category.

ii) Items where the packs have been opened but the items within have not been used. Manufacturers guidance on lubrication/sterilisation will be required for this category. Guidance will be required on the number of occasions the items may be relubricated/resterilised.

iii) Items that have been used. Guidance will be required from the manufacturers concerning the dismantling, cleaning, lubrication, reassembly and sterilisation of the equipment. It is in this category in particular where the "Guide to Good

Manufacturing Practice" will need be followed to ensure the equipment retains the original standard.

iv) Items that have been used and where the original standard of the equipment cannot be achieved. Guidance will be needed on the conditions (if any) under which reuse can be justified.

The panel noted that, where cost is the major reason for reuse, then the full cost of reuse, including treatment of consequentially infected or otherwise harmed patients, should be considered in reaching a policy decision. Where the reused equipment is of a lower standard than the original equipment a policy decision will be required about informing the patient and obtaining consent.

If information is currently not available on technical issues (eg the number of times reprocessing could take place before standards are impaired), on economic aspects (eg the full costs of reprocessing and quality control) or on the legal and ethical implications, the panel recommended that there should be interim policies accompanied by the commissioning of relevant studies.

The King's Fund is grateful to the speakers at the conference and to the audience for their perspectives. Thanks must also be given to officials of the DHSS, the National Association of Theatre Nurses, and Medispa, for their help in planning and organising the conference. Finally thanks must go to a number of staff at the King's Fund, including Nichola Nightingale, who made all the practical arrangements for the conference, and to Jennifer Hunt and Peter Marlow, both on the Faculty of the King's Fund College, who worked with the panel and edited the proceedings, and to the secretarial staff who typed them.

April 1986

Barbara Stocking
Fellow, King's Fund College
and Robert Maxwell, Secretary,
Fund for London

Summary and Panel Recommendations -

Dr S Anderman, Dr J Hurst, Mr G Kennedy, Professor J Tighe

There is a large range of sterile medical items being manufactured for and supplied to the health services which are designed, labelled and identified for single use only. The NHS requires such labelling to reduce the risk of infection and of equipment failure. Recently it has become apparent that numbers of these items have been reprocessed and reused in the NHS. Reprocessing may occur when a pack containing sterile single use items is opened and the contents are not then used but subsequently resterilised; reuse occurs when a sterile single use item which has already been used on one patient is reprocessed and sterilised for reuse on the same or another patient. The items involved range from relatively expensive and invasive equipment such as angioplasty catheters to inexpensive items such as "disposable" syringes. Perceptions concerning the amount and the acceptability of reuse that is occurring may be different leading to some confusion in different parts of the organisation.

Such decisions to reuse are being taken at different levels by different grades of staff. These principally include doctors, nurses and CSSD managers but other staff may be involved. Perceived economy is the main reason cited for reprocessing and reusing single use items, particularly where these are expensive since the possible savings arising from reprocessing equipment rather than buying replacements appear attractive. Some single use items may be reused because they are superior to equipment previously used; for example, "disposable" anaesthetic tubing is both lighter and more robust than some reusable types. A further reason arises from difficulties in maintaining supplies of equipment. In such circumstances, reprocessing and reusing single use items has enabled patient care and treatment to be continued until adequate stocks are again available. However in normal circumstances it should be possible to maintain adequate supplies from the manufacturer. Central bodies concerned with overall budgetary control may concentrate on potential savings arising from reprocessing, whereas, the nearer to the patient the decison is made, the more specific treatment-centred factors such as convenience will influence the extent of use. However, a clinician may also decide to reuse single use items for financial reasons, especially where, due to budget constraints with which to buy new equipment he would otherwise be unable to afford to undertake certain procedures. As clinical budgeting is increasingly considered in the NHS, such pressure on clinicians may increase.

The decision to reuse or reprocess single use medical devices has important legal implications for health authorities and health care professionals which should be taken into account at the time such decisions are taken. Where manufacturers of

single use equipment clearly state that their product is for single use only, the decision to reuse or reprocess such items would make the reuser legally responsible to take reasonable care in resterilisation of the equipment to avoid risks of malfunction. A recent survey undertaken by the National Association of Theatre Nurses has shown that methods of cleaning and reprocessing single use items differ widely. A majority of the work appears to be undertaken in sterile supply departments. Where the equipment is to be used for a different patient the duty to take reasonable care in sterilising and reprocessing may, indeed should, include a standard of testing and inspection which is comparable to that imposed upon the manufacturer. Indeed it has been suggested that if a device has been used, then even more stringent conditions are necessary for re-processing. Whilst it is true that some reuse may be consistent with maintaining safety, it is equally true that the liability for reuse will be affected by the fact that such a decision ignores an instruction from the manufacturer that the medical device is for single use only. Although reuse itself would not automatically amount to negligence, the normal duty on health care professionals, such as physicians, to minimise risks would place a duty upon them to establish that the reuse itself does not add materially to the risks posed to the patient. Finally, decisions to reuse not only make the health care professional personally responsible at law; they also make the health authority vicariously liable for any injuries that may occur from negligent reuse. These potential costs of litigation need to be taken into account in any analysis of benefit to patients.

The decision to reuse single use devices also raises important ethical issues. By reuse it may be that more patients can be treated. However, if the patient is likely to be significantly less benefited or more harmed from the reuse then there is not only an ethical obligation to consult with the patient before taking such a decision but also a question about whether the decision should be taken in the first place. The decision to reuse single use equipment calls for a careful harm-benefit analysis in which a distinction is drawn between the benefits to the patient and the benefits to others. At the same time, the fact that decisions are being taken to allocate limited resources cannot be entirely ignored, and the potential risks associated with infection or device failure considered.

Since the introduction of single use products, items have been made to an increasingly high level of quality and often sophistication. Regulatory affairs within the UK now encompass manufacturers registration schemes and guides to good manufacturing practices. The latter concentrates on the production facilities and the need to monitor the process at every stage. Manufacturers feel that the controls exercised cannot currently be duplicated within the existing resources of the NHS.

During the same period, the pressure to contain costs in order to maintain services has increased. Many users feel that by reprocessing, the cost of buying replacement single use items can be avoided, especially since this type of equipment now takes up a large part of supplies expenditure.

A re-evaluation of product categories may be desirable therefore to determine more accurately which products could be examined to at least allow re-processing of opened but unused devices since it is unclear to many users why some items are now regarded as appropriate for single use only when the same equipment was considered reusable by manufacturers in the past. There is concern that health authorities could be placed in a position by manufacturers of having to dispose of a large amount of equipment after use. For many users, the facilities to reprocess reusable equipment are already available to them and they consider that sterile supply departments and hospital pharmacies have the knowledge and practical experience of sterilisation to reprocess and resterilise single use items. However, it is unclear the extent to which decisions in the past to reuse single use items have been based on a comprehensive and accurate view of the issues involved, especially where financial criteria have been used. We have heard of examples of interruption of supply and in extreme cases reuse may be the only alternative to non-treatment. It would be worth incurring reprocessing costs which exceed the original purchase price of items or worth taking risks with patients safety if these were outweighed by the risks of non-treatment. There are, however, serious problems in equity if some patients are offered treatment with new items and others are offered treatment with less satisfactory, reused items. Patients consent to reuse is surely required. The process of balancing costs and benefits therefore is more complex than may be realised and there is some doubt as to whether perceptions about reuse in the NHS are always accurate.

There seems to be little literature on reuse, particularly on whether or how often particular "single use" items might satisfactorily be reprocessed. Particularly, there seem to have been few, if any, clinical trials on the potential risks of reuse, perhaps because of the difficulties of conducting such trials or the ethical questions they would raise. Although some studies of the cost of reprocessing have been undertaken, it is not clear whether these were always comprehensive or conducted according to an appropriate methodology. As well as the wider question of whether the reprocessed "single use" item is comparable to the original and how often an item may be reprocessed before it become significantly inferior to the original, adequate assessments of the procedures and costs of all activities associated with reprocessing are difficult. Furthermore, for correct financial comparison to be made regarding reuse, the full cost of reprocessing, including overheads, capital costs and quality control and Guide to Good Manufacturing Practice (GMP) requirements needs to be included. The time period over which such comparisons are made can also affect the outcome and need to be specified. While NHS financial accounts can provide evidence on the cost of buying new items they are not designed for cost comparisons where reprocessing is involved. Should a large number of hospitals adopt a policy of reprocessing and reusing "single use" items the consequent drop in sales may cause manufacturers to increase the purchase price. While such an outcome may not be quantifiable beforehand, the relative savings of a policy of reuse may decline and may even disappear.

It would seem that, in the past, the NHS has relied mainly on

local professional judgements about reuse. There are difficulties here. The CSSD manager is not in a position to make broad judgements about reprocessability; nor to study the specific circumstances in which reprocessed equipment was used; nor to monitor the effect on patient outcome. Nurses and doctors are in a good position to balance identifiable risks and benefits but might, for example, find it difficult to identify the source of the occasional infection due to reuse. Also, there is definitive evidence that clinicians tend to underestimate the cost of hospital services, such as reprocessing. Appropriate decisions on reuse require that information and judgement be brought together from several different sources in the hospital and from manufacturers but it is not clear that the mechanisms exist to bring this about.

The Panel's Recommendations

In view of the doubts about the accuracy of judgements regarding the economic, ethical and legal aspects of reuse in the NHS, we feel it desirable that there should be explicit, written policies about reuse of single use equipment and that such policy decisions should not be left to individuals. The DHSS should consider issuing guidelines to health authorities on the drawing up of such policies taking note of the conclusions of the US Institute of Health Policy Conference on Reuse held in Washington 1985, which stated:

"1) Quality of care is paramount, and must be maintained - if there is doubt about the safety of reuse, it should not be practised.

2) There is collective responsibility among all the parties involved - hospitals, physicians, industry - to establish policy and the standards of the practice of reuse.

3) There is an important need for more studies and for more data and on reprocessing and reuse. Reprocessing should be distinguished from reuse.

   * Hospitals should obtain information on outcomes
   * Industry should provide more product information
   * Experience in reuse and reprocessing should be published

4) There should be a repository for information and it is the responsibility for all parties to contribute. Anonymity should be protected.

5) Patients should be informed, at least about critical care items when these are reused.

6) All hospitals should have a written policy on reprocessing and reuse.

7) Hospitals practicing reuse and reprocessing should have written procedures and protocols.

8) There should be guidelines for reusables."

As well as central guidance, the DHSS should also consider

commissioning evaluations of particular important or vexed examples of reuse and provide a focus for technical contacts with manufacturers.

It is considered that the prime responsibility for producing written policies on reuse should rest with DHAs. In drawing up such policies, health authorities should consider the following categories:

a) Items reused on the same patient

i) During one procedure such as a surgical operation. Guidance will be required for example where syringes are reused with different substances to avoid incompatibility within the syringe.

ii) Repeated reuse, such as with diabetic syringes. Guidance will be required about sterilisation and storage procedures as well as advice about the number of times the equipment may be reused.

b) Items reused on different patients

i) Items that may be sterilised by CSSDs without difficulty. Forceps and scissors may be included in this category

ii) Items where the packs have been opened but the items within have not been used. Guidance on such matters as lubrication/sterilisation will be required for this category. Guidance will also be required on the number of occasions the items may be relubricated/resterilised.

iii) Items that have been used. Guidance will be required from appropriate specialists concerning the dismantling, cleaning, lubrication, reassembly and sterilisation of the equipment. The "Guide to Good Manufacturing Practice" should be followed to ensure the equipment retains the original standard.

iv) Items that have been used and where the original standard of the equipment cannot be achieved. Guidance will be needed on the conditions (if any) under which reuse can be justified

Where cost is the major reason for reuse then the full cost of reuse, including treatment of consequently infected or otherwise harm to patients should be considered in reaching a policy decision.

Where the reused equipment is of a lower standard than the original equipment a policy decision will be required about informing the patient and obtaining consent.

Health Authority policies should also take account of the following:

a) **Technical Aspects**

i) The technical possibilities of reprocessing items to given standards of function and sterility;

ii) The number of times, if any, that reprocessing could take place for a given item before standards are impaired;

iii) The risks to patients if substandard, reprocessed items are used.

b) **Economic Aspects**

i) The original purchase price of the item;

ii) The full economic cost of reprocessing and quality control;

iii) The likely effect, if any, on the original purchase price of the item if a major fall in sales occurs.

c) **Legal Aspects**

The legal implications of reuse and liability of the NHS through the Health Authority and its staff

d) **Ethical Aspects**

The ethical argument for seeing the consent for any patients put at risk by a policy of reuse.

When information is lacking on these issues, there should be an interim policy accompanied by the commissioning of relevant studies.

GENERAL PERSPECTIVES

DISPOSABLE OR RE-USABLE - WHO MAKES THE CHOICE? -
Miss J Greaves

The widespread use of medical disposables has raised as many new problems as it has solved old ones. Furthermore, cost implications, the present economic restrictions within the Health Service and the effect the implementation of the Griffiths Report will have on clinical budgeting emphasise the need for a National policy. It was felt that a nececssary first step was to determine the extent to which disposable items are re-used, and a study was therefore undertaken.

It is this study that forms the basis for my paper today. The study was conducted by means of a questionnaire distributed throughout the United Kingdom. It was posted to Divisional Nursing Officers and Unit Hospital Administrators, requesting distribution to those involved in the purchase, distribution and use of disposable items.

500 questionnaires were posted, of which 135 (22%) were returned of which 129 were completed. Of those 129, 75 [58%] reused items, 54 [42%] did not.

The response was disappointing. However, the information obtained provides much "food for thought" and stresses the need for action. Details of this information follow:-

1. Disciplines involved

Tables 1a & b shows that many disciplines are involved according to Nurse Administrative; and Table 2, the disciplines involved according to the Unit Hospital Administrator.

Accident and Emergency	13
Community	3
E.N.T.	1
Intensive Care	3
Medical Unit	1
Maternity Unit	4
Outpatients Department	4
Orthopaedic Unit	2
Surgical Ward	2
Theatre	32
Wards not identified	2

Table 1a

Physiotherapy	5
Radiography	2
Sterile Supply Units, HSSD, TSSU, CSSD	29

Table 1b

Other disciplines from whom information needs to be obtained include:

Supplies Officers
Surgeons
Anaesthetists
Physicians
Microbiologists

Having established the overall response, we will now look in detail at specific questions:

Q. From which category do re-processed disposable items come?

Used	21
Open but unused	13
Both	39
Any other	2
TOTAL	75

Table 2

Just over half the respondents said items came from both used and unused sources, while of the remainder, only 17% reused items which had only been opened but not used.

Q. State items re-processed

Over 120 items were given in the answers to this question, ranging from the simple to the most complex.

Q. How are items which are re-processed cleaned? [Table 3]

The cleaning methods fall into 3 main categories: by hand; by machine; by soaking. The majority [80%] of items are washed by one of the first two methods, the remaining 20% are cleaned by soaking.

Washing	By Hand	8
	Washed with detergent	1
	Soap & Water & Bottle Brush	8
	Washed	7
	TOTAL	24
Soaking	Normal saline	1
	Hydrogen Peroxide	2
	Cidex	2
	Savlon	3
	Hibitane	1
	Antiseptic	2
	TOTAL	11
Machine	Utlrasonic	12
	Helplex	1
	Dawson	2
	Deluge	3
	Tunnel	1
	Denton Helye	1
	TOTAL	20

Table 3

Q. By whom are the items cleaned?

TABLE 4

Nursing staff in wards	2
Recovery	1
District Nurses	2
Maternity Units	1
Theatre Units	10
X Ray Department	1
Physiotherapists	2
C.S.S.D.	22
T.S.S.U.	15
H.S.D.U.	2
Not stated	16
TOTAL	75

Table 4

Half of the respondents stated that items were cleaned by either CSSD or TSSU, with another 13% being cleaned in Theatre Units.

There was still considerable variation in the type of personnel responsible for cleaning, implying varying standards and probably practice.

Q. By whom are the items packed?

C.S.S.D.	37
T.S.S.U.	17
H.S.D.U.	4
Physiotherapy Department	1
Maternity Department	1
Wards	1
Casualty Department	1
Outpatients Department	1
Theatre	7
Not stated	5
TOTAL	75

Table 5

Table 5 shows that the majority are packed in the "correct" place, i.e. Sterile Supply Units and Operating Theatres.

However, it also shows that the packaging of some disposable items for re-processing is undertaken in departments and by staff who probably do not know or observe the requirements of the "Guide to Good Manufacturing Practice".

Similarly the sterilisation of most items takes place within the SS Units and Theatres [Table 6].

C.S.S.D.	33
H.S.S.U.	5
T.S.S.U.	17
Laboratory (Ethylene Oxide)	2
Theatre	7
Not stated	9
TOTAL	75

Table 6

The grades of staff involved in sterilisation were also quite varied.

Items from some units were reported as being resterilised before being sent to CSSD or TSSU. This may have been misinterpretation of the term sterilisation, and the items been disinfected instead.

Q. How are the items sterilised?*

Almost all items were sterilised using autoclaves, with a minority [14%] using Ethylene Oxide 55 o C. However a number of other methods were mentioned, e.g. "Savlon soak then boil", which could indicate appropriate methods are not known.

Low temperature autoclave, formaldehyde	5
Low pressure autoclave	14
Autoclave	48
Ethylene Oxide 55 o C	13
Hot air oven	1
Ethicon Pack Fluid (sutures)	1
TOTAL	82

Table 7

*Some replies stated more than one method.

Questions were also asked about the number of times certain items would be re-processed and how a check was kept on this. There were considerable variations in the respondents' answers. Of particular concern is the vagueness of many of the answers, the number of "don't knows" and the fact that many decisions were unrelated to the item's function. Only 8 respondents for example stated that they had a policy of recording the number of times an item has been re-processed.

Finally, questions were asked about the reasons for re-processing [Table 10] and how that decision was made [Table 11].

Cost - to achieve savings in budget
Cost - savings
Cost - effectiveness
Economy
Expense
Too expensive to throw away
Too good to throw away
It would be a waste to discard
Adequate for purpose
To save waste
Found to be possible
Erratic supply and demand
Awaiting delivery
Short term use
Convenient

Table 8

Scrub Nurse taking case	1
Theatre Nursing Officer	9
Nursing Staff Theatre	8
Nursing Staff General	12
C.S.S.D.	2
Physiotherapy Staff	5
Bacteriology Staff	3
T.S.S.U.	4
Medical Staff	7
Radiography	2
Not stated	12
Midwife	1

Table 9

The replies to the latter question stated to whom rather than how the decision was made. As can be seen, responsibility is widely spread over many disciplines. The question is - have they the authority to make the decision? Do they realise the implication that to take on the role of manufacturer = standards = liability.

Do the medical staff using these products know that a dual standard of product is in use? Will it affect results, patient care, clinical trials?

Ladies and gentleman - A great deal of re-use of disposable products is taking place. A larger investigation is required, preferably in a joint venture with industry. Furthermore, terminology is apparently misleading and new definitions are needed.

The Industrial Perspective -
Dr G Briggs-Phillips

Because in almost all instances the sole reason for remanufacturing and reusing single use medical devices is cost savings, it is appropriate to position the practice of reuse within the context of why we require sterility for so many types of medical devices and the function of sterile devices in preventing patient infections.

There is perhaps no modern country that does not have a concern about the high and rising costs for the delivery of health care.

Indeed many governments, as we know, have instituted programmes to stem these rising costs. In the United States, the total cost of health care approaches 11% of the Gross National Product (GNP), representing a two-fold increase over the past three decades. With the pressures, therefore, that exist to reduce or contain health care costs it is not surprising that consideration in some quarters has been given to reusing single use items.

The state-of-the-art in health care is now such that only a very small proportion of patients who are subjected to exposure to industry sterilised single use medical devices could possibly become infected due to the failure of industry to properly sterilise the devices. But, 4 or 5 decades ago when reusable syringes were used with patient after patient with only a water boiling procedure between users, epidemiology records listed serum hepatitis from inadequately sterilised syringes and needles as a major cause of inadvertent patient infections. Indeed, in the 1950's eminent scientists such as Evans and Spooner (1) and Sir Alexander Fleming (2) discussed the transfer of infection by syringes and needles due to the several ways that mass inoculation techniques were carried out. Today this problem has been essentially eliminated because of the wide use of industry sterilised disposable single use syringes and needles.

To put the issue of properly sterilised medical devices into perspective, it is important to recall the seriousness and extent of hospital acquired nosocomial infections (3). In the United States, for example, 5% to 10% of hospitalised patients acquire nosocomial infections. This equates to some two million infections per year with a fatality rate of about 15% or 300,000 deaths. These infections add about $2 billion, or 15%, to the total hospital charges. Most infections fall into four general categories:

- Urinary Infections - 50% (often due to the use of contaminated catheters)
- Infection of surgical wounds - 25%
- Pneumonia - 10%
- Blood stream infections - 5%

If the US fatality rate for nosocomial infections was considered an average for all countries, then the worldwide toll would be a

the cost point of view, that any country that could eliminate nosocomial infections could potentially reduce its overall health care bill by about 15%. On the other hand eliminating the purchase of ALL sterile single use devices would, in my estimation, reduce the health care bill by no more than 5%.

This introduction is simply trying to make two general points:

1) In trying to reduce health care costs by reusing single use devices, one is dealing with a cost category which to begin with is only a small fraction of the total health care bill.

2) Against the existing staggering cost of nosocomial infections, reuse raises the question of whether this cost would be further exacerbated by infections due to the use of improperly recycled and resterilised devices.

In presenting an overview of the industrial perspective on reuse, I will begin with several statements about reuse, then discuss some evidence of patient harm resulting from reuse and, finally, offer a synopsis of industry's views.

One significant statement is attributed to my fellow countryman, Dr Seymour Perry of the Institute for Health Policy Analysis at Georgetown University Medical Center. Dr Perry stated recently (4) "It often is assumed that the reuse of disposable tubing, syringes, catheters and other medical devices produces savings, although this has not been documented." Since achieving savings is the cardinal motivation for reusing it seems clear that reuse makes no sense if savings cannot be documented.

This leads me to my second statement which is that in the reuse of a sterile single use device there is an implicit approval of a double standard relative to the quality of that device. There can be no doubt that the quality of a device that is used, then cleaned, packaged, and resterilised is not the same as the quality of a new device obtained from the original manufacturer. (5)

A third statement relates to the ethics of reuse. In experimental medicine and surgery dedicated men have always taken risks and explored the unknown in order to advance the cause of patient care. But medical and surgical procedures in the usual setting are marked by rigid adherence to procedural rules, aseptic techniques, standards for nursing care, etc. If it is uncertain that remanufactured, resterilised devices are equally as safe as the original devices and it is not adequately documented that reuse saves money, the question is, "Is reuse in the best interest of our patients, should it have a priority at all, and isn't quality of care the issue with which we must not compromise?"

The following anecdotal examples document the types of mishaps that can occur when devices are reused.

1) The deaths of 16 premature infants in 1982 were linked to rinse water containing benzyl alcohol used to flush central venous catheters in order to reuse them. (6,7)

2) Three patients undergoing cardiac catheterisation showed unexplained endotoxic reactions including fever, chills and

hypertension. Investigation revealed that the procedures used to clean, disinfect, and resterilise the catheters resulted in contamination of the catheter lumens with from 0.3 to 7.4 nanograms of endotoxin as measured by the Limulus Amebocyte Lysate assay. (8)

3) Another series of reactions in a hospital involved the same symptoms in 32 patients undergoing cardiac catheterisation. While resterilisation procedures were apparently adequate, other recycling steps introduced pyrogens that resulted in endotoxic reactions. (9)

4) In still another hospital recycling of both single use and reusable catheters resulted in pyrogenic reactions in 19 patients. When single use catheters were substituted and not recycled, the population of more than 380 catheterisation patients experienced no further pyrogenic reactions. (9)

5) In the 1970's a company sold a 60-inch, sterile, single use catheter used in performing angiograms. Manufacture of the catheter was discontinued in December 1978. In February 1985, 7 years and 2 months later, one of these catheters had been resterilised an unknown number of times with ethylene oxide. During the angiogram the tip of the catheter broke off in the patient and travelled down into the patient's arm. The tip of the catheter then had to be surgically removed at the elbow of the patient.

6) The reuse of flow-directed pulmonary artery catheters resulted in potentially dangerous complications. In two reuse instances thromboses developed within 30 minutes to two hours. (10)

7) During a 4 month interval, 25 hospitalised patients acquired *Serratia marcescens* bacteremias from reused, single use pressure monitoring domes. Four patients died. When the procedures were changed and the domes were not reused, no further infections were detected. (11)

8) A jury, in 1982, ordered a physician and an hospital to pay $970,000 in damages to a patient who was treated with a reprocessed intravenous catheter. The tip of the catheter that had been resterilised 19-27 times broke off and travelled through the patient's circulatory system to lodge in her left thigh. The catheter was labelled by the manufacturer as being reusable for a maximum of three times. However, the manufacturer had recalled that model catheter nine years prior to the incident and, at the time of the recall, the hospital had informed the manufacturer that none of the catheters were in stock. Following the incident, 53 of the catheters that were being reused regularly were found in the hospital. Laboratory tests revealed that 22 of these catheters, resterilised and ready for reuse, contained traces of "body fluids" from previous patients. (12,13,14)

9) Twenty seven bacteremia cases occurred among 140 haemodialysis patients in two centres. Investigations showed that all were being treated with dialysers labelled for single use that were reused following decontamination with 2% formaldehyde solutions. The infecting microorganisms were non-tubercular Mycobacteria to formaldehyde (17,18) and the widespread nature of these bacteria lead to the conclusion that decontamination, as compared to

sterilisation, was not sufficient.

10) Eighteen cases of Hepatitis B infections were traced to a physician's office where a nurse reused single use blood lancets for haemoglobin testing. (19)

11) Finally, reuse of syringes has reportedly resulted in contamination of insulin solutions with silicone lubricant and attendant loss of insulin potency. (20) Syringe reuse in allergy testing also produces obvious problems.

The variety of problems and seriousness of the risks illustrated by these examples are significant. While some risks are inherent in the use of invasive devices, the potential risks associated with reuse are additive to those normally encountered in health care. At present, it is impossible to estimate the full extent of patient harm resulting from reuse of medical devices. It is unlikely, however, that adequate, uniform reuse procedures, adequate quality checks, and record-keeping will be implemented by all health care providers who reuse single use items. Thus, the full extent of the patient harm problem will remain unknown.

I mentioned at the beginning of my talk that in almost all instances the sole incentive to reuse is cost savings. The industrial perspective on reuse originates in the identification of the disincentives for reuse. Many of these will be discussed later by other speakers but the potential disincentives, even if some cost savings could be realised, include technical, legal, medical, ethical and regulatory implications. In addition, work place hazards may be created by reuse procedures by potentially exposing remanufacturing personnel to Hepatitis B, AIDS virus or other infectious agents and to toxic chemicals such as formaldehyde and ethylene oxide.

Manufacturers of sterile single use medical devices do not support the practice of reuse. However, they lack the power to prevent reuse. Continued or increased reuse will lead to a double standard for medical device safety and efficacy that could have far reaching consequences for the health care system. This is because it is unlikely that health care providers can develop and implement the controls needed to remanufacture products to the same standards used when the devices are initially manufactured in accord with regulations. (21)

The device industry is committed to supplying the highest quality medical devices consistent with intended use and cost requirements. By contrast, the practice of reuse may put cost ahead of quality and good patient care. In view of this, any decision to reuse single use items should be made only at the highest authority level and only after resolution of all the issues.

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THE CENTRAL GOVERNMENT PERSPECTIVE -
Mr G.R. HIGSON, DHSS

The Government's concerns are mainly with safety (for staff, but primarily for patients), quality and cost to the taxpayer.

The "single use" items with which we are concerned are those whose function demands that they are sterile when they are put into use. The procedures that are necessary to ensure that products made in very large numbers all arrive at their place of use in a sterile conditon and in conformity with standards have been developed over many years and are now fairly well understood.

My Division in conjunction with Industry has been active in developing these procedures and they are embodied in our publication "Guide to Good Manufacturing Practice for Sterile Medical Devices and Surgical Products". (1) We have a vigorous programme of inspection of manufacturers wishing to sell sterile products to the NHS and satisfactory firms are notified to the NHS via our Manufacturers Register. (2)

The procedures involve control over all parts of the manufacturing process - not just the sterilisation - and make demands on the organisation and the training of the staff involved. Adherence to these procedures gives a high degree of confidence in the quality and sterility of the end products and provides records which permit corrective action to be taken if some breakdown has occurred.

There is an obvious temptation to reuse an item, rather than buy another, and to assume that this saves the cost of the replacement. This superficial view starts to be modified by consideration of the processes that have to be gone through to prepare the item for reuse.

To restore a once-used item to the same conditon as a new one is very difficult - generally appreciably more difficult than starting from scratch. Many items such as catheters have small orifices and cleaning is particularly difficult. A surface finish that is uneven or absorbent also makes cleaning a problem. Labour costs can be very high if the mass production facilities of a factory cannot be applied. Indeed the high labour cost of reprocessing is one of the main reasons why single use was adopted in the first place. This is the case in other industries - such as catering - where throw-away cutlery and crockery have been introduced to save the costs of washing and drying.

Many studies of the cost of reprocessing have been reported. They present a confusing picture - not only are the economics suspect in many of them, but the success of reprocessing has rarely been assessed in any reliable way. Few people involved have taken a wide enough view of "costs", especially the cost of reprocessing to an adequate standard. As far as I know, none of these studies has taken the analysis as far as considering the totality of the economic effects of reprocessing - i.e. the effects on the

manufacturing industry and the possible effect on costs if there were a significantly smaller market.

Another of our concerns is the ability of the materials used to withstand a second cycle (or even more) of cleaning and sterilisation while still maintaining the dimensional tolerances and physical properties required for adequate performance.

Besides a saving in labour costs to hospitals, one of the other main reasons for the introduction of single use items was reduction in cross-infection. It is, of course, often argued that in many cases, particularly that of reuse on the same patient when the risk of cross-infection is not present, it is not necessary to restore the original condition and hence cost can be low. This can be a valid argument, but it then becomes necessary to define some lesser standard of performance (and I don't know that anyone has done this): to define the ways of ensuring that even this lesser standard is consistently met, and then to define the circumstances in which this lesser standard is acceptable. To the best of my knowledge these steps have been attempted only in the case of dialysers.

If reprocessing could be shown to be satisfactory in terms of both performance and cost, we would have to take steps to ensure that reprocessing standards were defined and that necessary information about products - such as material characteristics and appropriate cleaning and sterilising methods - was provided by manufacturers. We would have to make sure that products were not reserved for single use just because a manufacturer identified it as such.

I began by saying that Government's concern is with safety and costs. The most important of these is safety. We have procedures for ensuring that sterile devices are provided for use on patients to consistently high standards of performance and sterility. We are not prepared to jeopardise these standards to save a bit of money - especially if these savings are unreal. If there are real savings to be made without losing what we have gained in terms of patient safety, we should seize them but until it can be reliably demonstrated that this is the case, the Government must remain cautious.

I hope this Conference will do something to settle the issues or at least clarify those areas in which carefully controlled studies may produce useful results. There is a need to determine those manufacturing areas where full sterility must be maintained, and to agree if there are other areas where a lesser standard will do. If some lesser standards are appropriate and subsequent cost studies demonstrate savings, there will be a need to produce a new GMP giving amended instructions to manufacturers and to hospitals.

If there is money to be saved, we must save it, but we must not throw away the standards we have already achieved in the proceess.

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THE NHSS PERSPECTIVE -
Mr P Le Fleming

BACKGROUND

We have heard of the extent of reuse of equipment and devices intended to be used once and then disposed of, but I doubt whether many General Managers know the extent of the practice within their own organisation. It is left to clinicians and SSD Managers to decide. It is very obvious that the prime motivation is financial pressure. I suspect that as the strength and quality of disposables continues to improve and as the financial climate continues to chill, the practice will extend. The raison d'être of disposables is to produce a sterile product fit in every respect for its intended use. But SSD's already have a long history of cleaning and sterilising equipment that is designed to be reused. The days when disposables really were cheap, and when manufacturers were the only ones with ethylene oxide equipment and access to processes using chemicals such as formaldehyde are long since gone, and SSD's now have a capacity for managing sophisticated processes. Besides, who has decided that an item should be disposable after a single use? The manufacturers. We have heard their views on this, but the fundamental question is still whether the end product of reprocessing is fit for the job in terms of sterility and function.

To a General Manager, the whole question of reuse represents the swing of a pendulum. In the 1950s/1960s we began to use disposables because in some areas we persuaded ourselves that they were cheaper than the reprocessed equivalent. They were also far more convenient. The disposables were probably also of a consistently higher level of sterility. Today we are persuading ourselves back into reprocessing some items, because it is said that it is cheaper than using a disposable only once, especially when the product appears to be well constituted. I wonder? It seems to me that there are two important areas where we may be relying more on hunch than by evidence, namely quality assurance and cost. I am ignoring any ethical questions because I assume that in a State funded service, subject to the equipment being fit in all respects for its purpose, the questions that would arise about using second-hand items where the patient is paying directly, do not apply. Nevertheless some of this equipment is put to critical use and quality assurance must be as good in a State service as in a private service.

QUALITY ASSURANCE

We have heard of the procedures and standards required of manufacturers. These quality constraints are not required of the NHS, even if an SSD or other department processing a disposable adopts a locally agreed procedure with its own standards.

For example, an SSD contemplating reprocessing is faced with the problems of cleaning out blood from devices not designed to be cleaned and reprocessed.

Then again what effect does the reprocessing have on the physical properties of the device? The classic example is the 1976 outbreak of bacteraemia in 25 patients in America resulting in 4 deaths. The cause was the reuse of disposable blood transducer domes. It was shown that the repeated sterilisation of the polycarbonate membrane by ethylene oxide caused tiny defects, and leaks. Admittedly this type of serious incident is rare, but the reuse of cardiac catheters affects their structure and decisions on the number of times they can be used regularly comes back to the clinician's judgement. That in itself is not wrong, but in general terms it leaves a big question mark over quality assurance, as the decision is based only on experience. The same type of question about the effect of the sterilising process on the structural quality of the item applies to many other devices put to critical use.

A related question is whether the process leaves behind any toxic material that could affect the patient and processing staff.

We will be told by those in favour of reprocessing that in practice there is a sound body of empirical experience, and that ill effects are few. They may point to the considerable practical experience of reusing dialysis coils and hollow fibre elements for some renal patients, and to the studies into the reuse of disposable syringes and needles by diabetic patients. These of course are special cases of repeated use of equipment by the same patient. That there are few reports of incidents harming patients so far is no basis for extending the practice without adequate nationally agreed processes and standards.

COST

Although I am anxious not to introduce unnecessary regulations into the NHS, it seems to me that the GMP and other standards that manufacturers have to follow must be required of the NHS.

Here we are getting near the 'make or buy' decisions that are very much the immediate concern of General Managers in the NHS. Last year's circular from the DHSS said: "Ministers are anxious that, as a general rule, the NHS should manufacture products only when it is clearly more economical to do so than buying them in, or when no suitable product is otherwise available." Clearly more economical ! What are the facts? Costings in the NHS are notoriously unreliable and not designed for this sort of comparison. We have all had experience of the very detailed ad hoc examinations that are needed to compare real costs for what are ostensibly identical services in identical districts. Similarly, if the NHS is not required to follow the same operating standards required of manufacturers there is another large question mark over the cost comparisons that help us to make decisions. Many of you will have read the Deloitte Haskins proposals in their discussion paper on the costing of sterile devices. Those proposals are still something for the future but they underline my scepticism about our present costings. When it comes to it, it is at least probable that with many devices it really is cheaper just to manufacture and sterilise on a commercial scale, than to collect, clean, reassemble, package, sterilise and store a used item. The NHS does not know because our costing is suspect. I also believe that the people who might insist on suitable costing, if they had to make the decision on whether to buy or process, are not aware of the scale of what is happening.

CONCLUSION

I have tried to keep away from the emotion semantics of words like "second-hand". One may say reused equipment has been "field-tested". I am more concerned with providing clinicians with items in a suitable condition at the lowest cost. It is dificult to see, however, what standards we use in the NHS to be confident that the item will be as suitable after we have reprocessed it, as it was when it left the manufacturer. It is difficult to trust our costs, if we are to compare them fairly with manufacturers' costs. The percentage of disposables that can be reprocessed may be small, but may have a potential for a worthwhile saving. We must clearly examine the real position very closely before coming to any decisions.

1) We need a clearer picture of what items are reprocessed at present, and where.

2) We need controlled trials on the methods used with a view to safety, and to quality in terms of sterility and functional integrity. The standards used in manufacturing may equally be applicable to reprocessing.

3) We need reliable financial information and costings for the reprocessing methods agreed on, including meeting the quality assurance requirements.

4) We need a cautious approach to extending the practice of reprocessing in the absence of agreed standards of quality assurance and a credible costing system for purposes of comparison with manufacturers' costs.

5) General Managers should become more aware of the extent and status of present practice and should then become involved in any decisions to extend it.

6) Ideally a better flow of information between manufacturers and SSD Managers should be developed with a view to openly moving from the manufacture of single use items to the manufacture of items capable of limited reuse.

But who will be responsible for getting this suggested range of activities started? The DHSS seems the obvious catalyst, with the scientific and technical branch, the Microbiological Advisory Committee, and representatives of the Finance, Supplies and SSD functions playing leading parts. Undoubtedly representatives of manufacturers must have a part to play in this. I hope that this conference will open up the whole matter, with a view to introducing better more factual information for making decisions that must have an effect on the wellbeing of patients.

REGULATORY DEVELOPMENTS IN THE REUSE OF SINGLE USE EQUIPMENT - Mr C Grenshaw

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I must apologise in advance for this rather boring and in many respects irrelevant aspect of our debate. Why irrelevant? Simply because the scope and extent of reuse practices bear little apparent relation to the legislation and recommendations issued by regulatory bodies.

Often existing practices are tolerated so long as no-one rocks the boat by asking equestions such as why this and not that? How is it controlled? What criteria are used to decide? Who takes responsibility? When do you report an adverse reaction? To address fully this type of question could lead along paths which no-one wants to go when all the implications are appreciated and the need for conscious and recorded decisions accepted.

When some two years ago we wrote to many of the responsible regulatory bodies identifiable in Europe for their policy on reuse, the response revealed a 'sitting on the fence' approach sometimes combined with a 'head in the sand' attitude which refused to acknowledge reuse practices or, referenced legislation, requirements or guidelines which they had no means, nor perhaps the intention, to enforce. If some of my remarks seem provocative it is in the hope that they may provoke those involved to clarify their position.

Austria - The Federal Ministry of Health and Environmental Protection claim no knowledge of any incidents in relation to the improper reuse of single use devices. The Chamber of Pharmacists claim no knowledge of reuse and proclaim that any profit arising from reuse would be incompatible with the risk.

Australia - In about 1981 officially recognised reuse which excited a violent reaction leading to a total ban. This also caused reaction, leading finally to adoption of the USA FDA position.

Belgium - The Ministry of Health and Family does not recommend reuse but make the physician and pharmacist fully responsible.

Canada - The situation is developing along similar lines to the USA.

Denmark - The 'Health Council' issues no guidance because by definition they should not be reused. If asked, it discourages reuse strongly.

France - The authorities do not seem prepared to commit themselves to any position or even to comment.

West Germany - Authorities approached responded variously that:-

1) reuse is inherently dangerous with consequences that no-one can anticipate;

2) reuse is a non-intended application which violates the ethics of the medical profession;

3) reuse is not justifiable from a medical or hygienic point of view;

4) devices for single use are not allowed to be reused.

Holland - No response obtained.

Ireland - The Department of Health identified the principal factors as the prevention of cross-infection and the circumstances of use which should be appreciated by the professionals involved.

Italy - The Ministry of Health said that reuse is strictly forbidden by the regulations embodied in the Italian Pharmacopoeia.

Japan - Reuse is known to occur although the practice is alleged to be 'illegal', e.g. for dialysers.

Norway - The National Institute of Public Health finds reuse unacceptable in principal but acknowledges the existence of the practice in Norway on the full responsibility of the physician.

Sweden - The National Board of Health and Welfare does not recommend reuse. (In practice, Sweden is probably the country where reuse is least practiced.)

I propose now to devote a little more time to the USA, because that is in the forefront of development, and the UK, because that is our major concern.

UK - The DHSS issues no general guidance. Technical advice on the subject has been obtained but with no decision to make this generally available, with the exception of specific advice relating to cross-infection from reuse of gastric tubes and the reuse of explanted pacemakers if reprocessed by the manufacturer. This could lead to the inference that reuse not specifically condemned is acceptable. It is very doubtful whether the authorities, NHS administrators, or even some manufacturers are aware, or wish to be aware, of the extent of reuse. It appears that there is no Government policy on the subject.

USA - The FDA in its compliance policy guide 7124, requires reusers of single use equipment to demonstrate:-

1) that it can be adequately cleaned and sterilised;

2) that its physical characteristics or quality are not adversely affected;

3) that it remains safe and effective for its intended use.

Consequently the reuser has to address many of the areas covered by GMP during original manufacture including:-

i) that any cleaning materials are removed completely or that residues of such can be demonstrated to be non-hazardous;

ii) that any cleaning process has been adequately validated by challenge with the most stubborn form of contamination in 'worst case' conditions;

iii) that records are kept of adequate processing and inspection;

iv) that, after cleaning, products are adequately protected from recontamination;

v) that all processes and procedures are properly specified in writing and written records are kept of their implementation for each batch processed with adequate means for their retrieval;

vi) that there is proper validation of any sterilisation process;

vii) that packaging and labelling are adequately controlled;

viii) that there is a procedure for independent audit of compliance with these requirements.

Due to the publicity given to the subject recently in the USA it appears that reuse is rapidly diminishing.

In the USA responsibility resides not with the manufacturer but the user who is not encouraged to reuse and is recommeneded to develop substantial evidence to assure that safety and efficacy are not compromised. Failure to comply with these requirements results in violation of certain sections of the prohibited acts and adulteration provisions of the Food, Drug and Cosmetic Act.

The FDA also requires that a manufacturer with knowledge of his device being used for a condition or purpose other than that for which he offers it must provide adequate labelling (instructions) for such an unintended use. This could be construed to require that manufacturers of single use devices provide information or warnings concerning reuse, e.g. where degradation of device properties due to reprocessing could constitute a health risk.

The FDA may also be empowered to regulate reusers if they deviate from (or ignore) instructions issued with a device or if, by reprocessing, they become in effect 'manufacturers'.

It has also been suggested in the USA, and could be considered elsewhere that 'informed consent' is obtained from patients before single use devices are reused in their treatment.

The Joint Commission on the Accreditation of Hospitals (JCAH) sets a standard that 'Disposable items should not be reused'. It does however acknowledge that some reuse occurs.

We have seen that no-one appears to recommend reuse of single use devices on different patients. An American review of reuse identifies seven disincentives for the practice to manufacturers,

thirteen for hospitals, seven for physicians, six for patients but recognises it as a dream for the legal profession. I do not intend to explore the byways of reprocessing of unused devices nor the reuse of a device on the same patient. Such practices have been acknowledged and may in some instances provide incidental benefits, e.g. reduction of dialyser first-use syndrome and the limited provision of sterile single use syringes and needles to diabetics.

The main regulatory concern will continue to be the remanufacture of used single use devices for use on other patients. Whether the device is sold and used as sterile for its first use is almost irrelevant, what is sure is that second time around it almost certainly should be sterile. How this can or should be achieved with the degree of assurance required of industry fails within the realms of GMP of which we shall hear much more later on in Dr Dadd's and Mr Cutler's papers. Adequate autoclaving of contaminated material may be accepted as effective but other methods such as exposure to EO, radiation, LTSF, disinfectants, etc., are recognised as fundamentally inadequate. Few single use devices will survive autoclaving without damage so how are they treated in the NHS? There is a strong suspicion that of the 150 EO and LTSF sterilisers in regular use out of a total of 450 in the NHS many will be used to treat single use devices. This practice is potentially microbiologically and physiologically offensive and without question is aesthetically repugnant.

If I were faced with medical treatment I would prefer that single use devices used on me were taken unsterile straight from the production line of a DHSS registered manufacturer rather than ones which had been salvaged after use, remanufactured and "sterilised".

Finally, let us take a superficial look at the attempts to regulate manufacture and therefore by implication any remanufacture which occurs in the NHS.

DHSS Health Circular HC (84) 3 January 1985 addressed to RHS's, DHS's and other NHS bodies for action concerns Health Services Management and, specifically, manufacture of products in the NHS.

It introduces a policy designed to ensure that NHS manufacture takes account of the cost compared with that of buying from industry. The HSSC strongly commends the guidance given and as a result commissioned a review to be made by Deloitte Haskins & Sells, which proposed bases for NHS costing of Sterile Service Department production and particularly sterile soft packs. Assuming that the NHS wishes to continue manufacture, this policy could act as a direct incentive to manufacture by methods believed to be cheapest, i.e. rightly or wrongly by reusing single use products and by ignoring GMP's essential to ensure safety and quality. The policy requires compliance with relevant GMP's where they exist and specifically includes CSSD activities. This requirement is of dubious legality, probably impossible to interpret in the absence of an identifiable relevant guide and impossible to police in the context of Crown immunity. Furthermore, probably some of the worst offenders against GMP such as rehabilitation workshops, occupational and industrial

therapy, etc., are exempted from the policy.

It has been proposed that a separate GMP be developed for NHS manufacture - this will be a doubly difficult task if it has to address (as it should) the remanufacturing procedures necessary for reuse of single use products. A used product has potentially lost most of the positive attributes which it acquired during original manufacture, namely:-

Cleanliness

Sterility

Manufacturing identity and therefore historical and distribution traceability

Protection (shelf life, etc.)

The assurance of readiness for use and the ability to perform adequately and safely.

These attributes are conferred by the application of good design, management and manufacturing practices commencing with the controlled supply of pure, clean, virgin materials and finishing with a properly validated and appropriate sterilisation process. To have any hope of restoring these essential attributes to a used and contaminated product will require the application of very precise and tight controls to dismantling, cleaning, reassembly, inspection, packaging, labelling and sterilisation. The personnel involved will need appropriate qualifications, training, experience and management. The process involved will require stringent validation, monitoring and control and the whole operation will need appropriate premises and environment - a costly operation little of which they acknowledge features in the costing manual prepared for the NHS by Deloitte Haskins & Sells.

I have deliberately avoided certain legal aspects of reuse as these will be explored later, but I must remind you that the legal view is that the decision to reuse a product clearly labelled 'single use' by the manufacturer transfers all product liability to the decision-maker or worse still the hospital administrator(s) who may be unaware of the practice. I believe that in full awareness of all the implications few will be brave enough to shoulder that responsibility.

Discussion

The questions following this session centred around three main issues

- what did we mean by the terms used
- what did we know about re-use and re-processing within health authorities
- what were the views of industry and the NHS on this issue

The discussion was vigorous. Although agreement was not achieved, the issues were clarified and a basis established for further exploration during the remaining sessions.

CLINICAL ISSUES

A NURSING PERSPECTIVE -
Miss B Baxter

INTRODUCTION

With the advent of the throw-away age, disposables came into the nurses' life. No more washing syringes, cleaning and sharpening needles, making up swabs, patching gloves and cleaning rubber intravenous giving sets. Disposables saved nursing time and since they ended up as rubbish anyway this affected our view of them. That was in the time of plenty.

New materials were developed which made innovative new techniques possible, the disposable changed from the cheap syringe into the expensive cardiac catheter. We also moved from the time of plenty into the time of cost containment and accountability for public spending. There are many different types of disposable items and the situations where their reuse is considered vary, but in all cases there are a number of questions raised. Is the item suitable for resterilisation? What method should be used? Is the product's reuse really more economical? Does it provide safe patient care? Who assumes liability for the reuse of the article? What are the risks and if there are risks, as part of informed consent should the patient be told when a reuse article is used?

Let us now consider a number of specific points.

1 ITEMS OPENED BUT NOT USED

(a) Has the item been handled by staff during the procedure? Although not used has it been contaminated? If so, how is it cleaned?

(b) Are there manufacturers' instructions, in writing, on how the items should be repacked and sterilised?

(c) What effect has resterilisation on the material of the product?

(d) How many times will the product stand up to resterilisation and what marking system is used to denote the number of times this has occurred?

(e) Who is responsible for the quality control in the sterilising process?

It occurs to me that we should institute an immediate programme for all health care staff which instills within them the idea of never opening a sterile pack until it is needed, coupled with training to ensure they can open all packages so that the sterile items within are not contaminated.

2. ITEMS FOR REUSE ON THE SAME PATIENT

(a) Where is the patient? Is he a diabetic patient in the "privacy of his own home" reusing his disposable insulin syringe and needle, or is he in an acute hospital ward where life automatically becomes more hazardous?

(b) Does the item need cleaning and sterilising between use? If so, what method is used to ensure the same patient gets back the same piece of equipment?

(c) Can the item be mechanically washed, or does it need cleaning by hand? If by hand, does this endanger the person involved in the cleaning?

The debate concerning diabetic patients reusing insulin syringes in their own homes appears to be running its own course. In this situation it appears to work, with no harm to the patient, but that cannot be taken as the "green light" for all other single use items.

3. DISPOSABLE ITEMS WHICH ARE USED ON ONE PATIENT, AND ARE THEN TO BE REPROCESSED FOR USE ON ANOTHER

(a) Can the item really be effectively cleaned and freed from all debris?

(b) Who takes the decision that this should happen, and are they fully aware of the implications?

(c) Does the health authority know this is happening and who takes legal responsibility when something goes wrong? What guidance do we have?

When pressured for information the Department of Health advises that single use items are exactly that.

The Joint Committee for Accreditation of Hospitals in the United States notes in its manual:

"There shall be written guidelines for the selection, storage, handling, use and disposition of disposable items. Disposable items should not be reused."

A paper published by the Centre for Disease Control in Atlanta, Georgia, entitled "Guidelines for the Prevention and Control of Nosocomial Infections" states as a Category 1 recommendation: "No disposable object designed for [sterile] single use should be resterilised."

"Practices for Inhospital Sterilization" states "Single use items should be reprocessed."

There is however clear indication that the advice is not being followed therefore a code of practice should be available, to protect the patient.

As you have heard, a survey is at present being undertaken by two members of the National Association of Theatre Nurses, financed and supported by the Association's Education and Research Fund, regarding the reuse of disposable medical and surgical devices. This should provide evidence about the extent of the practice in Operating Theatres but what about other departments?

There is a marked difference in my opinion between a disposable drape which has been opened in error, not contaminated, which can be appropriately packaged and autoclaved, and a single use item which has been used for an invasive procedure on a patient, being considered for reprocessing for use on another. Any code of practice must take account of this difference.

Before a single use item is considered for reuse the procedure must be proved safe for the patient on whom it is to be used and also for the staff involved in the procedure of reprocessing. It must also be cost effective.

The Health Authority should be aware of such practices. In the United States, the Food and Drug Administration have decided that hospitals which reuse disposable products should demonstrate that the item is adequately cleaned and sterilised, that the physical characteristics of the device have not been altered, that the device is safe and effective for its original use, and the hospital maintains full responsibility for the reused products' safety and effectiveness.

Without clear written policies, prepared by the fully informed, on the agreed reprocessing of any such device, such reprocessing should not be happening.

CONCLUSIONS

During my professional life I have lived through the time when theatre sisters lost no time in reminding me that every suture needle, piece of thread, swab, etc., was far more valuable than the time I spent reprocessing them, through the age when the enlightened Theatre Sterile Supply Department Manager was at pains to inform me that to salvage was dangerous and uneconomical, to the present day when the staggering cost of some disposable items has led to nurses being involved in attempts to get as many uses as possible from an article noted by manufacturers as single use. The pendulum has swung from disposables being a load of rubbish to them being, in some instances, elevated to the level of spun gold. Nurses are accountable for providing safe, high quality, cost effective care. They are also taxpayers and concerned that money is spent wisely. To reuse or not to reuse, that is the question.

Without proof that such practices are safe for the patient then the answer has got to be do not reuse until a code of practice exists, supported by evidence that the patient will not be harmed and the reprocessing is cost effective.

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EXAMPLES OF REUSE OF HAEMODIALYSERS -
Dr S Rodger

INTRODUCTION

Haemodialysis is the treatment used for the majority of patients with terminal renal failure, despite the availability of other techniques such as continuous ambulatory peritoneal dialysis (CAPD), haemofiltration and renal transplantation.

During haemodialysis blood is taken from the patient via a access device, passed through a haemodialyser and returned to the patient. The haemodialyser contains a semi-permeable membrane, the outside of which is bathed by a fast flowing salt solution (dialysis fluid), containing physiological concentrations of electrolytes. Metabolic waste products from the blood pass to the dialysis fluid by diffusion and are eliminated. Proteins and formed elements are prevented from passing through the membrane by their molecular size. Excess water accumulated between treatments is removed by convection (ultrafiltration) using either a hydrostatic or osmotic pressure gradient. Treatment by haemodialysis is performed intermittently two or three times per week with each session lasting 3 to 6 hours.

THE EXTENT OF REUSE OF HAEMODIALYSERS

The reuse of haemodialysers has been practised in the United Kingdom since the introduction of maintenance haemodialysis as a mode of treatment in the early 1960's. The dialysers used at that time were principally Kiil rebuildable type or the coil single use type. Both were reused but for different reasons. Kiil dialysers were formerly built on each use and then sterilised; reuse lengthened the interval between rebuilding and was thus time saving. Reuse of the coil dialyser was on economic grounds. In 1976 Gurland reviewed the extent of reuse in the United Kingdom (1). His survey showed that at that time 56% of haemodialysis patients were reusing. In 1981, 63% of the patients treated in the UK reused haemodialysers (2) By this time, however, the number of patients using rebuildable dialysers had fallen significantly, while the use of 'single use' dialysers had increased. In a questionnaire based survey carried out in 1984, only 27% of the patients receiving dialysis treatment in the UK were reusing.

REUSE TECHNIQUE

The technique of reuse may be divided into four distinct stages:

1) **Rinsing:**

At the end of treatment the contents of the extracorporeal circuit are returned to the patient by rinsing of the extracorporeal circuit with saline. The dialyser, having been disconnected from the patient, is further rinsed, usually with

treated tap water, although some centres use untreated tap water.

2) **Cleansing:**

After water rinsing the dialyser may be further rinsed by chemical agents such as sodium hypochlorite or hydrogen peroxide to remove any clotted residue.

3) **Sterilisation:**

The dialyser is then filled with formaldehyde and stored until subsequent use.

4) **Flushing:**

This stage of the procedure is carried out prior to the subsequent use of the dialyser and entails the flushing of the sterilant from the device.

Manual and automated techniques for single or multiple patient use based on these principles have been described in the literature (3,4). The aim of reuse is to increase the number of uses obtained from a single device and most dialysis centres aim for a minimum of six uses.

BENEFITS OF REUSE

Cost

The original justification for reuse was based partly on convenience and cost of the disposable items used. In recent years, however, the cost of disposable dialysers has gradually fallen and rebuildable dialysers are seldom used. Costing of the reuse procedures must take into account the staff, space and equipment expenditure, as well as the materials used. Our own costing based on these factors has indicated that at the current prices being quoted for the bulk purchase of haemodialysers (approximately £6 per unit), it is no longer justifiable since the process is more expensive than the use of a new dialyser.

Morbidity

Pyrogen reactions and infections relating to reuse procedure appear to be infrequent in current clinical practice, while the incidence of Hepatitis is not increased in centres who reuse (5). Despite these hazards, there is evidence in the literature that morbidity is improved in patients who reuse compared with patients who do not (6). The reasons for these differences are unclear and it is uncertain whether they apply to current practice. One explanation is that this is because first use syndrome is avoided, that is the occurrence of allergic symptoms such as dyspnoea, wheezing and fever at the onset of treatment with a new dialyser. The cause of this syndrome may be a result of an allergic reaction to ethylene oxide residues or to the membrane itself (7), however, when reusing dialysers its absence has been demonstrated.

DRAWBACKS OF REUSE

i Occupational exposure to formaldehyde

Exposure to formaldehyde causes respiratory tract and eye irritation when present in the atmosphere at levels greater than 2 parts per million. Repeated handling of formaldehyde may be associated with contact dermatitis and asthma. Animal studies have demonstrated that it may also act as a carcinogen but this has not been substantiated in epidemiological studies based on humans, possibly because of the small number of subjects studied (8).

ii Inadequate removal of formaldehyde from the dialyser

All reuse procedures employ some method of detecting residual formaldehyde in the flushing stage prior to subsequent use. Some of the methods used are unable to detect formaldehyde at concentrations associated with the development of anti-N antibodies (9). These anti-N antibodies have been implicated as being responsible for reduced red cell and renal transplant survival in affected patients (10,11).

iii Haemodialyser performance

The adequate removal of blood products and proteins deposited on the membrane surface is mandatory when reusing in order to maintain an effective surface area. Functional performance of haemodialysers during reuse has shown a slight, but clinically significant, drop in small molecular clearance and ultrafiltration capacity when reusing. In addition, if chemical cleaning agents are used, particularly sodium hypochlorite, the membrane strength may be altered, resulting in an increase of membrane leakage, thereby limiting the number of reuses achieved (9).

iv Reuse achievement

In order that reuse may be cost effective where it is practiced, at least six uses of each dialyser is aimed for. When using a manual technique of reuse our studies have shown there is significantly higher reuse achievement from a single committed operator compared with that obtained when this task is shared by members of the dialysis unit staff. The failure to achieve optimum reuse its attributed to discarding of the dialyser by the operator due to is cosmetic appearance, failure to maintain effective surface area, accidental damage during the reuse procedure or failure to observe the correct protocol.

CONCLUSION

Manufacturers of haemodialysers are subject to rigorous and mandatory control and legislation to ensure that their products achieve satisfactory quality control, are sterile, safe, effective and reliable. Dialysis centres are not subject to any such requirements and in consequence those centres practising reuse of 'single use' haemodialysers should demonstrate that their method of reuse effects adequate cleaning of the device without altering its performance and that the patient will not be

exposed to sterilants or other contaminants introduced by the procedure. Evidence, as outlined in this paper, indicates that current reuse procedures may not satisfy these criteria.

The primary incentive to reuse disposable dialysers has been cost. However, the recent fall in the cost of single use dialysers and rise in reuse expenditure must make the practice questionable at the present time. In the face of an increase in the price of haemodialysers the ability of central government funding to finance this demand will dictate the future practice of reuse in the UK.

ACKNOWLEDGEMENTS

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EXAMPLES OF REUSE : DIABETIC SYRINGES -
Dr A Bloom

Nobody has greater dependence on his equipment than the insulin dependent diabetic. In the course of 30 years, he may have injected himself subcutaneously some 200,000 times. The syringe and needle is of vital importance to him. Early in 1983, the British Diabetic Association initiated a change from the two strengths of insulin previously available (40 units/ml and 80 units/ml) to a single strength insulin (100 units/ml). The changeover resulted in the introduction of new syringes (designated BS 1619/2) specially calibrated for U.100 insulin and this change added impetus to the longstanding debate on which sort of syringe is preferable - glass or plastic. The latter came into common use almost 10 years ago. The controversy is based on at least four levels: cost, sterility, convenience and accuracy.

Cost

Disposable syringe costs 12p each, glass syringes £6.00, each with a life of approximately 6/12. (1,2) Patients usually have a spare glass syringe for emergencies because they are apt to break. The syringe (with needle attached) should be kept in a special case half filled with industrial methylated spirit. The needles are dispensed separately and are either reusable steel needles or single use disposable silicon coated needles. Glass syringes, reusable and disposable needles, industrial methylated spirit, and the syringe carrying case are all available on a National Health Service prescription from the general practitioner. Procedures are not maintained by the patient, but infection at the site of injection is very rare.

Disposable plastic syringes are made of polypropylene (called SAN) with plungers of polystyrene. They are sterilised in their packets, either by y-rays or by ethylene oxide gas, and are supplied with or without an attached needle. They are not available on prescription but may be obtained "where they are considered medically essential for a particular diabetic patient" through the hospital diabetic clinic, when the cost falls on the hospital budget (3).

The Secretary of State for Social Services has estimated that it would cost about £10 million a year to supply these syringes on prescription (3). This is, however, probably an overestimate, for it is based on the assumption that a disposable syringe with needle attached would be used once only, while in practice many diabetics use the same syringe and needle for longer periods, even up to several weeks (1). So is this method of use safe?

In clinical practice the procedures that are recommended to prevent infection at the site of insulin injections - keeping the glass syringe in spirit and boiling it at intervals, washing hands before the injection, and cleaning the top of the insulin

bottle with spirit - are seldom followed (4). Nevertheless, infection at he site of injection is rare, and studies confirm that when the same disposable syringe and needle are reused by the same patient (sometimes for many weeks) there is no appreciable bacterial contamination of syringe or insulin nor evidence of infection at the site of injection (1,2,5,6,7).

Most diabetics find that the needles becomes less sharp after five or six injections and want to use a new needle for that reason. Maintaining sterility does not seem to be a problem, and simply by covering the needle (attached to its syringe) with its cap and then leaving the syringe in the refrigerator, evidence of infection was not detected even when the same syringe was used for up to two months (1). Thus in practice reuse of disposable syringes appears to be safe, and if these syringes are reused they work out cheaper than glass ones. (6). Furthermore, most diabetics prefer disposable syringes because they are lighter than glass and metal syringes, they do not break, they do not need boiling or to be kept in special containers, and they are easier to take on holiday (2). In addition, the disposable syringes with needles attached have fine needles, which cause minimal discomfort. On the debit side the markings, though clear when new, are less durable than those on glass syringes and tend to become faint or blurred with use over a week or so.

Another difference between the two types of syringes is in the size of the dead space. This may be defined as the volume of insulin remaining in the hub and needle when the plunger of the syringe is fully depressed. With the use of the more concentrated U100 insulin this volume assumes greater importance (8). The dead space in the BS 1619/2 glass syringes has been estimated to be equivalent to 5 units of U100 insulin. The dead space in a plastic disposable syringe, with needle attached, is, however, negligible. The dead space in the glass syringes has two disadvantages: firstly it may lead to inaccuracies when a mixture of short and intermediate acting insulins is used; and secondly, when the glass syringe and needle are kept in spirit the fluid in the dead space is likely to be a mixture of insulin and spirit. This has to be ejected by forcible use of the plunger before the next injection and results in a wastage of about 5 units of insulin at each injection. This represents an estimated annual cost to the NHS of £2 million. (9).

These disadvantages must, however, be kept in perspective, and anybody who has seen children drawing up their insulin at diabetic camps can be under no illusion about the accuracy with which prescribed insulin is drawn up - and older patients may be even less accurate (10). Furthermore, the amount of insulin lost in the dead space of a glass syringe is probably negligible compared with the insulin left in discarded insulin bottles. For in the NHS there is no reward for thrift and few penalties for profligacy, and little heed is paid to either the amount of insulin dispensed or the insulin used.

Leaving aside the economics of the situation, disposable syringes and needles are convenient for the patient and in practice safe to reuse. More and more diabetics are using them and would not want to go back to glass syringes.

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EXAMPLES OF REUSE: CARDIAC CATHETERS -
Dr D Scott

My introduction to the reuse of disposable products came at the age of nine when my father, who was a general medical practitioner, started to use plastic disposable syringes. It was not long before I persuaded him to dispose of a syringe in my direction. It was an excellent water pistol, a useful pop-gun, and a valuable status symbol among my school friends. As the years have gone by I have often made use of items being disposed of by the National Health Service.

This type of reuse does not involve patients, but I have also reused a number of sterile, disposable, single use items on patients. Many of them are not very expensive and money will only be saved if each item is used many times over. The first item that I will discuss, a cardiac catheter, is expensive, and it was hoped to save a lot of money by reuse.

In 1970 Professor H J C Swan and Dr W Ganz (1) introduced the concept of catheterising the pulmonary artery using a balloon tipped catheter which was inserted into a large vein and carried along in the blood flow through the right atrium and ventricle and into the pulmonary artery to obtain information about the normally inaccessible left atrium. The great advantage of such catheters is that they can be inserted into the patient at the bedside.

Their cost is a major disadvantage. In 1979 they cost £84 each (VAT extra). The disposable equipment for a standard anaesthetic cost £3 at that time (2) and my plans to increase the cost thirtyfold did not go down well with my senior colleagues. I was instructed to wash, resterilise and reuse the catheters. It did not take long to discover problems with the reused catheters (3). Large blood clots quickly developed around them. One catheter developed problems only half an hour after insertion. Not only did the clots interfere with the function of the catheter, but they were likely to break off and cause pulmonary embolism in the patient and if in an artery the patient could get systemic embolism. The most likely reason for the problem was that plasma proteins became attached to the plastic catheter (4) during their first use and were altered by the sterilisation process to provide a surface that rapidly produced clotting when inserted into the bloodstream.

While not feeling as strongly as George and Banks (5), I most certainly cannot recommend the reuse of plastic products in this fashion, when they are going to be inserted into blood vessels for a prolonged period, i.e. cardiac catheters.

While I no longer reuse plastic products that are going inside patients, I do reuse many other items, in situations which fall into the following categories:

1) Resterilisation of opened but unused products;

2) Reuse without sterilisation on the same or another patient;

3) Reprocessing and returning to stock.

To a Scotsman the first category is normal practice, and many manufacturers give instructions on safe methods of sterilisation (6).

Reuse on the same patient without sterilisation is common in anaesthesia. One syringe may be used to give several different drugs during the course of an anaesthetic, and it is routine practice in Britain to use the same giving set to administer all the intravenous fluids.

On different patients, I do not reuse without sterilisation products which ought to be sterile, but several nondisposable products are not sterilised between patients, and I have no hesitation in reusing their disposable equivalents. This category includes splints, ECG electrodes, space blankets, diathermy plates and anaesthetic breathing circuits.

Reprocessing and returning to stock requires very careful thought before it can be safely adopted. The items must be cleaned, packed, sterilised and stored, yet still perform their intended function, and be microbiologically safe. Plastic items are particularly liable to lose both strength and shape during sterilisation, e.g. anaesthetic airway.

The usual reason given for reuse is cost, but it may well be the convenience or supply problems may in fact be even more important. On occasion, we come across a disposable product which even when reused is far superior to its non-disposable equivalent.

A much more serious problem with disposables is supply and storage. When a unit moves onto the use of disposables it must find space (always at a premium in hospitals) to store a reasonable stock, and have an efficient ordering system to provide a constant supply of the product. It is a disaster when the supply system breaks down.

The humble wooden clothes peg is an excellent example of a supply problem. It has many uses in Intensive Care, and as it only costs 4 pence it is not worth cleaning and sterilising between patients. My hospital stores have great difficulty in obtaining them, however, because they have no hard cash which would let the office boy buy them at the local supermarket, and they cannot find a medical equipment firm who lists clothes pegs in their catalogue. My wife insists that we reprocess the ones that we have rather than take any more of hers.p

Supply difficulties have forced me to reuse several items rather than do without. These are usually rarely used or specialist items which take a long time to reorder but that is not always the case. Items that I have reused because of lack of fresh supplies include guide wires for an intravenous catheter, a special type of wrist split, clothes pegs, a T-piece for a breathing system and "space blankets" which are used to keep patients warm.

Disposable corrugated tubing for anaesthetic breathing circuits

is an example of a disposable product that is far superior to its non-disposable equivalent. The complete circuit weights 200 grams as opposed to almost 1 kilogram and has a radius of torque at the patient of 15mm compared to 100mm. The force required to hold this system onto a patient's face is reduced thirtyfold, an important consideration for both patient and anaesthetist. With our routine methods of disinfection, disposable tubes last longer than traditional rubber tubes, and cost £3 as opposed to almost £30.

CONCLUSION

I do not reuse cardiac catheters and similar plastic disposables which will have prolonged contact with patients' blood, but I can see reasons why other people feel it is in the patient's best interests to do so.

Cost is not the only reason for reuse. Convenience and superiority of disposable products are important considerations, and failure of the supply chain may force clinicians to reuse disposables to maintain the service to their patients.

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AN OVERVIEW OF THE RISKS OF REUSE -
Dr M Cooke

I shall consider the risks of reuse of single use items from the point of view of the experience I have gained in hospital infection control in District General Hospitals and from my experience in the Division of Hospital Infection.

The title of this Conference, 'Reuse of Sterile, Single Use and Disposable Equipment in the NHS', appears at first sight to be rather perverse. Why should we reuse items which are designed for single use? However, when one considers the subject further, the reasons become obvious. The first is that single use items are readily available to us at the present time.

The second is related to the regulatory requirements which industry faces and I would like initially to say something briefly about legal requirements in relation to reuse. The first point to be made is that although litigation is increasing, hospital associated infection still forms a relatively small proportion of the cases which come to trial and, indeed, I know of no case of litigation in this country associated with reuse of single use items. The second point is that before we consider legal requirements we must be able to satisfy ourselves, and other people, that we can reprocess, resterilise and reuse items without any risk of danger to our patients. If reuse is regarded as a second rate service, then it will be difficult to defend its application.

The use of disposables in hospitals is recent and not universal. I well remember that in the late 1950's the main problem in taking blood from patients was finding a syringe in which the plunger moved smoothly within the barrel and to which the needle could be firmly attached. We must not forget the enormous advantages which the use of disposables has conferred. There are also parts of the world in which the use of disposables is extremely limited.

Mr Hoffman in the Division of Hospital Infection has recently been carrying out some work for the World Health Organisation Expanded Programme of Immunisation. In this work he has been looking at small autoclaves used for syringe sterilisation. The syringes provided are labelled that they may be resterilised 200 times.

Not only are there parts of the world in which disposables are not regularly used but there are also many parts of the hospital in which equipment is reused. This equipment is often that in which sterility is not regarded as critical and it may be disinfected or sterilised. We have experience of outbreaks of infection associated with the disinfection of reusable equipment and some of the infections occurring during these outbreaks may be serious. While such outbreaks are themselves worrying one aspect gives rise to considerable concern. On occasion we have noted that the outbreak has come to attention because it has been caused by an organism which is unusual in appearance or characteristics. It may be that if the contaminating and infecting organism had been a common one, the infections would

not have come to light.

I am sure we need information about the extent of reuse in our hospitals. The Central Sterilising Club recently set up a working party to report on sterilisation and disinfection of heat labile equipment. This report will be available next year but I have kindly been given permision to quote from part of it. In the hospitals studied the working party found variable levels of reuse of different types of equipment. 39% of hospitals reused cardiac catheters but 83% reused anaesthetic tubing. The methods of sterilisation and disinfection used also varied from the almost exclusive use of ethylene oxide or low temperature steam and formaldeyde for critical items to hot low temperature steam and disinfectants for such articles as anaesthetic tubing.

The disadvantages of single use items are well known. These are cost, storage problems, problems of disposal and even an excessive use of basic materials. The risks of reuse include damage to the article, dangers to staff health, problems associated with inadequate processing and failure of sterilisation. I am going to consider briefly problems asociated with sterilisation.

Even in hospitals with good infection control arrangements it is possible for there to be a surprising number of areas of the hospital in which sterilisation and disinfection is carried out. This may be done using small autoclaves, the operation of which may not be adequately supervised and in some areas old autoclaves which do not comply with modern requirements may still be in use. This decentralisation of sterilisation arrangements is potentially dangerous. We know that in the past autoclaving arrangements were not satisfactory. There is no doubt that they have improved considerably in recent years but vigilance is required to maintain satisfactory arrangements throughout a Health Authority.

However, for much of the equipment that we are discussing at this conference we must use ethylene oxide or low temperature steam and formaldehyde. Ethylene oxide is toxic, explosive and requires strict control of concentration, time, temperature and humidity. However, deleterious effects on materials are rare and the toxic residues formed can be eliminated by correct handling and storage.

Low temperature steam and formaldehyde sterilisation requires careful control of temperature, pressure, duration of various stages of the cycle and the amount of formalin used. There are complex inter-relationships between all these factors.

For both these methods of sterilisation there are difficulties in process control and biological indicators are necessary. There is also a lower margin of safety than with autoclaving so that the initial cleaning and processing is extremely important in reducing the bacterial load to be eliminated.

Some hospital groups have drawn up very strict protocols for the reuse of articles such as cardiac catheters and one of which I am aware has 17 sections on initial cleaning and processing. These sections do not include the sterilisation arrangements which are dealt with separately. This level of care, control and

attention to detail is what will be required if we are to reprocess critical items of this sort. I have no doubt that reprocessing and resterilisation can be made to work well in our hospitals but the experiences I have gained with autoclaving and the particular sorts of problems I have outlined make me very aware of the problems that we are likely to encounter. There is a need for sterilisation to be highly centralised. Clear lines of management responsibility must be laid down for all sterilisation arrangements and the role of managers, CSSD managers, supplies officers, microbiologists, engineers and other health service workers will need to be clearly defined in each instruction.

This conference is timely. However, as always in complex subjects such as this, more research work is required. The report of the Central Sterilising Club will be very useful and will provide answers to some of the questions we are raising. We need however to consider the experience we have gained not just in individual units but on a broad front so that we may profit by the knowledge gained by many workers in the Health Service. Retrospective surveys may be valuable but prospective studies in which the problems of reuse are looked at carefully are required.

Discussion

It was stressed that the developments in the use of 'disposables' were recent and rapid which meant that problems were bound to occur.

Following on from that, questions were directed to more specific issues, in particular, to types and problems of sterilisation methods and specific instances of reuse. The issue of what standard was possible in less developed countries was also raised.

SUMMARY OF ISSUES -
Professor J Tighe

The reuse of sterile single use equipment in the NHS is already accepted on a wide scale. The basis for this reuse is predominantly cost saving but other factors such as convenience, availability of new items and, in some instances, a better product than the alternative planned reusable equipment contribute to this practice. Pilot studies have demonstrated the scale of this reuse. For example, 83% of anaesthetic equipment and 39% of cardiac catheters planned for single use are reused.

It is not always clear whether reuse of disposable equipment is cost effective. For low cost equipment, the cleaning, repackaging, reprocessing and sterilisation of equipment almost certainly results in an uneconomic product. However, some high cost single use equipment may be economically reused provided that the final product is of value and is safe. It is important to consider the total cost of the equipment, for a large production item may have a low unit cost. Dialysers for renal haemodialysis machines were frequently reused (63% in 1981) but with reduction in unit cost this reuse has fallen (27% in 1984).

Analysis of single use and disposable equipment which is reused shows that it is not a homogenous group. Some is expensive and is used for invasive and potentially life-saving procedures, for example, angioplasty catheters used for relieving coronary artery obstruction. Other equipment is cheap and non-invasive or only very superficially so, such as diabetic syringes. Consideration of a policy for reuse will need to take account of these different costs and of the effectiveness of this reuse.

The introduction of clinical budgeting into medical practice is likely to increase the pressure on medical staff to reuse expensive equipment. Although physicians and surgeons are largely responsible for the expenditure on patient care incurred by a health authority, most of this expenditure is on staff salaries and is not available for the clinician to control his budget. Consumables such as single use equipment are directly controllable and, with a diminished budget, the clinician will be faced with the alternative of reuse of this equipment or inability to investigate and treat patients with life-threatening diseases.

Manufacturers have high standards for the production of equipment which must conform with the DHSS 'Guide to Good Manufacturing Practice for Sterile Medical Devices and Surgical Products'. Where it is impossible to dismantle equipment to clean or sterilise, or where repeated sterilisation may alter the physical properties of the product, it is marked "For Single Use". Yet some of this equipment is knowingly reused on a regular basis, for example, disposable diabetic syringes. It is not always clear why this single use guidance is used.

The practice of sterilisation, reprocessing and control of

reused equipment varies from one health authority to another. This variability is in itself of great concern and is sometimes left to inexperienced and inadequately trained personnel. It is essential that guidelines are given for the centralisation of these processes so that they conform with accepted policy. Dual standards for manufacturers and users of equipment are only acceptable where the reuse of equipment can be shown to be of benefit to the patient without materially increasing risk.

LEGAL AND ETHICAL ISSUES

THE LEGAL IMPLICATIONS -
Mr Dodd-Smith

INTRODUCTION

The advances witnessed in recent years in drug treatment have been mirrored by advances in the design and manufacture of medical devices and in particular sterile medical devices designed for single use. But while the technological revolution has been taking place there has also been a marked change in social attitudes in terms of compensation for those suffering injury or loss through no fault of their own. We have become an increasingly litigious society and, when something goes wrong, we are less likely to shrug our shoulders and put it down to bad luck.

The manufacturer is normally in the firing line because of what Americans call the "deep pocket" approach to litigation, but the professions are not immune from this change in attitude. The public are less in awe of the expert, be he an accountant, lawyer or doctor. The mystique surrounding the professions is evaporating and where personal injury is involved the law already offers the injured person various procedural advantages in pursuing a claim. The law continues to develop in ways that assist would-be claimants. Thus the Court of Appeal has recently suggested that there may be not only a duty to inform a patient of proposed treatment but also, if the treatment results in unexpected injury, the doctor and hospital must make full disclosure of the facts to the patient.

As both medicines and devices are designed for intimate contact with the human body and invariably are intended to have a disruptive effect, their potential for being associated with injury is high. Even if the association turns out not to be causal, it has to be recognised that today all involved in health care are particularly exposed to the risk of litigation where their actions will be analysed and judged often against an increasingly strict standard of care.

If a patient is injured as a result of infection or other adverse event arising out of the reuse of single use medical devices, the patient has to decide who he should proceed against - the manufacturer, the health care professionals directly involved in his treatment, the Health Authority or against some or all of them in a joint action.

The purpose of this paper is to examine the legal implications of the reuse of such devices for each of these parties.

1. POSITION OF THE MANUFACTURER

Product Liability Generally

English law provides several remedies that can lead to

compensation for faulty products. First, if a patient actually buys a product from a manufacturer that causes him injury, then he has a contract with the manufacturer and therefore he has the benefit of certain implied conditions that are incorporated by statute into any contract of sale. In such cases the manufacturer is strictly liable to the *purchasing patient* for product defects.

However, normally the patient will not personally buy the product, but will be treated under the NHS. Therefore rather than having a contractual right against the manufacturer the patient must rely on a claim of negligence.

Liability in Negligence

A person who manufactures or distributes a product may be liable to compensate a patient suffering injury caused by that product notwithstanding the fact that no contractual relationship exists between the manufacturer and that patient.

The law imposes a duty upon the manufacturer to take reasonable care in the design and manufacture of his products and in the formulation of the information he supplies with them, so as to avoid causing injury to those who he can foresee might be injured by his carelessness. The Plaintiff must prove that the duty is owed in the first place, breach of that duty and actual damage flowing from the breach of a type that was foreseeable, i.e. causation. The Plaintiff must prove his case on the balance of probabilities.

The manufacturer of medical devices clearly owes a duty of care to the patient whose treatment will involve the use of the manufacturer's product. However, while the basic concept of a duty to take care is easily understood, it is less clear what is the amount of care that is required to be exercised in any given circumstance.

In English law, the required standard is that of the reasonably careful and knowledgeable manufacturer operating under the conditons of that time. Essentially, in relation to any decision concerning the marketing of a product, the manufacturer will be expected to weigh on the one hand the risk to which he may be exposing the user against the difficulty and expense of taking precautions which have a reasonable chance of averting the danger or the seriousness of it.

Although in the case of medical devices there is no regulatory control of the type applicable to medicinal products, the Department of Health issued all embracing guidelines on Good Manufacturing Practice in 1979 (revised in 1981) which deal with quality, safety and performance of such products and provide the basis for the Government's approval and registration scheme for suppliers to the National Health Service. This is a detailed code of practice covering matters such as suitable premises, equipment, materials, the standard of persons required and the maintenance of appropriate batch and product records. The aim is said to be to produce a finished product which is sterile in its unit container and correctly labelled.

These Guidelines have no statutory force and therefore they are only admissible evidence tending to show what the reasonably prudent manufacturer will do in relation to any given aspect of manufacture. Compliance with the Guidelines, while not decisive, will be strong evidence that reasonable care has been exercised. Equally, while failure to follow the Guidelines will not automatically lead to a finding of negligence, it may well create a presumption of negligence.

Manufacturing defects

Where a device is defective because it is not in conformity with the manufacturer's own specification for the product, either in terms of quality or sterility, and that manufacturing defect causes injury, it will be extremely difficult for the manufacturer to avoid liability. An inference of negligence must arise whenever a defect, which does not ordinarily arise in a finished product, in the absence of negligence, occurs as a result of some failure in the manufacturing or inspection process.

Design defects

Even though it has been manufactured to specification, a device may be viewed as defective on the grounds that it suffers from a design defect. In such cases the question is whether the manufacturer ought to have foreseen, by reference to the prevailing state of technical knowledge, that the nature of the device was such that it would carry an unacceptable risk of causing injury. Sometimes the answer will be that the manufacturer could not reasonably have been expected to discover the facts that rendered the device unsafe and therefore the possibility of injury is treated as a development risk for which the manufacturer will not be liable at common law.

Failure to Warn or Supply Adequate Instructions

Increasingly today product liability actions are based on an allegation of failure to supply adequate instructions for use or failure to warn properly of possible hazards. In this regard, the manufacturer or distributor of a device has a duty to take care to see that the product is properly labelled, for he must foresee that failure to provide adequate information will be likely to expose the patient to the possibility of injury.

Where a product necessarily has to be supplied to a third party before being used in the treatment of a patient, it is generally accepted that the duty of care owed to the patient is discharged by warning "the responsible intermediary" which may be the hospital or the physician or surgeon himself.

Manufacturer's Knowledge of Reuse

It is here that the issue of reuse of devices comes into play because if reuse may be hazardous it may be argued that the manufacturer's duty of care extends not only to warning of that fact in his literature but also to supplying information which has a reasonable prospect of ensuring that if reuse occurs the risk to health is kept to a minimum.

It might be said that the manufacturer's duty of care is not limited to supplying information to see that his product is safe when used for its intended and recommended purpose , if "abnormal" use is foreseeable. Should the manufacturer of disposable medical devices provide detailed information on sterilisation and reprocessing procedures?

Clearly, the manufacturers of certain disposable medical devices do foresee the possibility of abnormal use; indeed they have actual knowledge of it. They also know that their products may be dangerous when reused if the hospital fails to adhere to the stringent sterilisation and other processes required to minimise the risk of problems.

However, if a manufacturer is marketing a device to professional third parties such as doctors or hospitals, it is suggested that the duty of the manufacturer is fully discharged by making the recommendation for single use clear, for it is reasonable for him to assume that either the instruction will be carried out or that any reuse contrary to his instruction will not take place unless and until the product has been subjected to appropriate examination, resterilisation and testing.

In short, the manufacturer of a single use device is almost certainly entitled to rely upon the fact that he is placing the product in the hands of a person who is in a position to avoid injury to others by exercising reasonable care himself, either by following the recommendation or making sure that he can reprocess to the standard required to ensure safety. It follows that it is most unlikely that the Courts would find that the intermediary who ignores such a recommendation can reasonably expect the manufacturer to give him information that may enable him to reduce the risk attaching to the reuse that he proposes.

The practical aspects are also important in considering the adequacy of warnings. Even where a manufacturer foresees the reuse of his device he has no control over that reuse either in terms of the number of times it will be reused or how it will be sterilised and inspected. No amount of information and warnings on the product can instruct the intermediary in all the aspects of how to ensure safe reuse. It is therefore suggested that the Courts would take the view that it is impracticable for the manufacturer to provide sufficient information to remove the risk that attaches to reuse and that fundamentally it is not the manufacturer's duty to provide information that might make it safer to reuse, as he is not selling it for that purpose. There is no English case directly on the point, but several American cases adopt this reasoning when dealing with injury resulting from "abnormal use".

2. THE HOSPITAL

There is no obligation upon the health authorities to provide specific types or quantities of medical devices and, furthermore, the reuse of a medical device does not violate any provision of the Act or any other statute relating to the safe use of products. Indeed the Health Authority might view the reuse of disposables as wholly consistent with the need to take account of finite financial resources. But there is an overriding duty at common law to take such precautions as are necessary and

practicable to protect patients from avoidable harm. In examining this principle, reference will be made to the liability of the hospital, but in practice a Plaintiff must sue the responsible Health Authority.

Contractual Considerations for Hospitals

The generally accepted view is that there is no contract between the Health Authority and a patient treated under the NHS scheme. The Health Authority has a statutory duty to provide treatment. Some treatment in NHS hospitals is done privately and here the hospital has a duty to carry out the service with reasonable care and skill with a view to seeing that the patient is properly treated and not exposed to unnecessary risks to health. This obligation has, since July 1983, had a statutory base through Section 13 of the Supply of Goods and Services Act 1982 .

Liability in Negligence

Even in the absence of a contract, the Health Authority still owes a duty to NHS patients to take reasonable care. In relation to circumstances within the hospital's control it must take care to ensure that patients are properly protected by ensuring that any medical device used in the course of treatment is fit for purpose, sterile and without any risk to health that could reasonably be avoided.

Examination and Testing

Where the hospital receives a device in its original pack and it is not reasonably contemplated that the product will undergo detailed examination or testing prior to use, the hospital will not normally be under any liability to the patient, if the product turns out to be defective.

The position may be different if an inspection by the relevant member of the hospital's staff before use is practicable, and a defect in the product is patent and obvious. If even the most cursory of inspections would have revealed the defect, and it is not in fact detected, the hospital may, through the negligent act of its employee, be jointly liable with the manufacturer for injuries caused by that defect. The manufacturer will probably not escape liability completely unless inspection was recommended before use.

The hospital will also be liable for defects that have developed through poor storage which can result in the package breaking and the product being damaged or contaminated. In summary, the hospital will be liable for the consequences of its own negligence.

It follows that if a hospital decides to ignore an instruction that a medical device is for single use only it bears the responsibility of ensuring that reasonable care is taken in resterilisation so that reuse does not lead to injury. Reuse may be consistent with maintaining safety; all will depend upon the nature of the device, the extent of reuse, and the facilities for reprocessing available to the Health Authority. The Courts expect commercially practicable precautions to be implemented and their view of what is practicable is likely to favour the injured

patient. Shortage of money in the NHS is likely to be treated as a policy matter outside the remit of the Court.

The question therefore arises as to the extent of the duty of the hospital with regard to resterilisation and inspection and testing. Is it reasonable for it to adopt less stringent measures than were adopted by the manufacturer? Given the fact that the hospital is specifically ignoring the manufacturer's recommendations it is thought that the Courts would impose a very strict standard. The Courts would be viewing the hospital's conduct in the context of the general view that the risks of reprocessing disposables in terms of non-sterility and malfunction are likely to outweigh any cost benefits.

The susceptibility of many types of single use device to damage is well known, and the durability of a product is in large measure a function of the intended period of use. The problems of ensuring that the sterilisation and reprocessing procedures take proper account of the material from which the product is made and the microbes to which it has been exposed are extensive. In short, safe reprocessing does not appear to be easy and the FDA and most European health authorities advise against it.

Thus while the hospital is in principle under a duty only to take such care as is reasonable to ensure that a device does not carry a risk to health, reasonable conduct in a case of reuse might involve the imposition of a very onerous standard which addresses testing for sterility, toxicity, pyrogenicity and the physical state of the reprocessed device in terms of dimensional tolerances. It would be difficult for a hospital to argue that a defect was not reasonably discoverable where it had not adhered to the prevailing rules of Good Manufacturing Practice.

If the problem in question has arisen out of a defect that adherence to Good Manufacturing Practice would probably have isolated then the hospital will be vulnerable for another reason. There is a legal maxim which translated means "the facts speak for themselves" and where it aplies the burden of proof is reversed so that instead of the Plaintiff proving negligence, the Defendant has to show that he was not in fact negligent.

Where a disposable medical device being reused has been found to be contaminated, and its sterilisation was under the control of the hospital, the Courts will probably say that because the incident is not one that would ordinarily happen if proper care had been exercised, the fact of the incident is reasonable evidence that the hospital was negligent unless the hospital can provide a proper explanation as to how the device could have become contaminated without negligence. This would be a difficult task.

3. HEALTH CARE PROFESSIONALS

Duty in Contract

Traditionally, the law of contract has been the principal method by which the Courts have monitored the conduct of professional men. If a physician or surgeon contracts to carry out certain treatment privately, regardless of the existence of any express terms in correspondence establishing the contracts, there is an

implied warranty that he has the requisite ability to perform the treatment he has undertaken and that he will exercise reasonable care and skill. But, as has been pointed out, there is no contract as such between the NHS patient and those treating him.

Duty Independent of Contract

As in the case for the manufacturer, there is no doubt that a physician or surgeon owes a duty to his patient regardless of whether a contract exists and that duty is to carry out the treatment discussed with the patient with proper care and skill and to exercise reasonable diligence and caution throughout having due regard to the current state of medical and scientific knowledge. The care and skill he must show is that of the average competent medical man.

Duty in relation to devices

Where a defective medical device has caused injury, the effect of the standard of care imposed is such that only if the physician or surgeon knew, or should reasonably have known, of the defective nature of the device will he be liable to negligence. Usually, this issue is reduced to a question of fact, namely whether the device's defect was patent (obvious) or latent. If normal visual inspection should have revealed the defect then the physician may be vulnerable to a claim in negligence, possibly along with others such as nurses involved in the procedure and the manufacturer, but if the defects are latent only, it is unlikely that the physician or nurse would be found negligent. The law does not expect even the most skilled of health professionals to isolate latent defects because by definition latent defects tend to be ones that cannot be detected by the exercise of reasonable care and skill.

A possible difficulty arises where the physician knows that the device being offered to him is a resterilised device that was indicated for single use by the manufacturer. There are risks inherent in all forms of treatment and the Courts have made it clear that the physician is under a continuing duty "to keep these risks to the minimum to which reasonable skill and reasonable care can reduce them." The fact remains that certain problems associated with reuse are well known in the medical profession.

By way of example, the reuse of flow-directed balloon-tipped catheters received some attention in the medical journals quite recently. The obligation to inspect is certainly greatest where the user has knowledge of a possible defective condition and several American decisions have highlighted this point.

It is thought, therefore, that while use of a resterilised device would certainly not automatically amount to negligence, the physician is put on special inquiry to satisfy himself that reuse in the specific case before him does not pose a material risk to his patient. It could be argued that he must establish how many times the device has been reused and what data there are on the incidence of defects after reprocessing on a given number of occasions. If he does not do this, by condoning a potentially hazardous practice he could be exposing himself to liability jointly with the hospital.

4. NURSES

The physician will not be liable for the negligence of nurses and other auxiliary staff in the hospital unless employed by him but, as with other persons professing some special skill, a nurse owes an independent duty to exercise the proper care and skill of a reasonably competent nurse. Thus failure by a nurse to note a defect in a medical device, where it is her defined responsibility to examine all devices to be used, might give rise to liability if the defect causes injury to the patient and that defect should reasonably have been noted. As with the case of physicians, nurses are unlikely to be fixed with liability for latent defects.

5. VICARIOUS LIABILITY

Finally, it should be noted that a hospital authority is vicariously liable for the negligent acts of its staff, be they physicians, surgeons or nurses, provided the negligent act was committed while discharging a professional function at that hospital. In the case of a hospital under the National Health Service Act the consultants and specialists are employed under the terms of the Act, so that the hospital is liable for their negligence too, even if they are working only part time for the authority.

6. THE FUTURE: THE INTRODUCTION OF STRICT LIABILITY

In July 1985, the EEC Directive on Product Liability was notified to Member States with the result that by July 1988, the United Kingdom must amend its law to ensure that it is consistent with the Directive's provisions. The Directive provides that the 'producer' of a product shall be strictly liable for damage caused by a defect in this product.

A product is deemed defective when it does not provide the safety that a person is entitled to expect taking into account all the circumstances including the presentation of the product (e.g. instructions for use and warnings) and the use to which it could reasonably be expected that the product would be put. The 'producer' will have a defence to any claim by an injured party if "having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him."

It would seem, therefore, that reuse by hospitals of single use medical devices will not expose the manufacturer to more claims under the new law either because the manufacturer will be able to show that the product was not defective when first sold or because the intervening act of the hospital removes the necessary causal link between the sale of the product and the injury ultimately caused to the patient.

As regards the position of the hospital and health care professionals, on the face of it they are unlikely to be treated as 'producers' under the Directive, even if they reprocess single use devices. Their liability to the NHS patient will

remain governed by the law of negligence. There are cases from some jurisdictions in the United States that suggest otherwise, but strict liability principles are not generally applied to hospitals and doctors there either.

It is possible to imagine, however, that on particular facts the Court could take the view that the extent of reprocessing is such that the hospital is in effect holding itself out as having the abilities of the manufacturer and producing a product to be used as if new, and should be treated as a 'producer' and strictly liable if the product causes injury.

7. CONCLUSION

The reuse of single use disposable medical devices is fraught with legal difficulties for all parties in health care but where injury arises relating to such reuse the exposure of the health authorities to claims in negligence is likely to be the greatest. It is not exercising reasonable care under the law to ignore a clear direction that a product is to be used only once unless the reuser is in a position to ensure that any foreseeable hazard arising from reuse is removed. Some reuse may be consistent with exercise of reasonable care but the wide variety of factors that are relevant to maintaining safety with a reused product indicate that the risk that reprocessing will affect the integrity of the product will always remain and with it vulnerability to claims for compensation. Health care professionals may also be exposed to claims if they have knowledge of reuse.

The safest course legally would seem to be strict adherence to any manufacturer's instruction that a device is to be used only once and then disposed of. Manufacturers are unlikely to be judged negligent for failing to provide detailed information on the means by which single use devices might be reprocessed.p

ETHICAL ISSUES -
Mr R Gillon

Before being asked to give this paper, I had never thought critically about the ethical aspects of reusing disposable medical equipment and prostheses. I certainly ought to have done so, for not only do I have a special interest in medical ethics but, as I immediately realised, I had been resterilising disposables for several years, ever since, as a group of general practitioners at Imperial College, we obtained the kind assistance of the directors of one of the college's nuclear reactors to resterilise plastic disposable vaginal specula, proctoscopes, and nursing dressings forceps as well as the non-disposable metal items for minor surgery which we had previously resterilised in an old fashioned boiling water steriliser.

I use a fairly simple structure for examining medico-moral problems - too simple for some philosophers, too complex for some doctors, but perhaps of some use in applied ethics. It is based on the structure of Beauchamp and Childress's excellent textbook, Principles of Biomedical Ethics (1), and requires assessment of the potential relevance of four important ethical principles which most adequate theories of ethics would acknowledge. These are: the principle of respect for autonomy; the principle of beneficience; the principle of non-maleficence; and the principle of justice.

Autonomy

The principle of autonomy requires us to respect other people's right to make their own deliberate decisions and act on them, insofar as to do so is compatible with respect for the autonomy of all concerned. Among the many implications of this principle for medical ethics are that by and large we are not allowed to do things to other people without their consent; we are not allowed to lie to them or otherwise deceive them without their consent - which means among other things that we must not cheat them or break our implied or actual promises to them; and we are not allowed to use them for the benefit of others without their consent.

Do we infringe the principle of respect for autonomy if we reuse disposable medical equipment? So far as consent is concerned I, and I suspect most doctors, certainly do not obtain patients' explicit consent when reusing disposable equipment. But then neither do I usually get patients' explicit consent to reuse non-disposable equipment, nor do I get explicit consent for countless other individual components of my service to my patients.

There is no good reason for the norms for consent in relation to reuse of disposables to differ from those applying to medical

practice generally - and a vast amount of the interaction between patients and doctors is based on a norm of implied consent. Central to this norm - part of the social contract, as it were, between doctors and patients - is that a doctor undertakes to assess the patient's problem, to outline what he believes is the best way to deal with it, and then, unless he anticipates significant - or as the lawyers say, material - risks, to accept the merest indication of the patient's consent as confirmation that he should get on with it.

Of course if there are material risks of harm to the patient then the doctor should - in my opinion - consult the patient, and discuss the available options. Similarly, if the patient wants to know about any particular aspects of the proposed course of action, again the doctor ought to respond to the request truthfully and as reasonably comprehensively as the patient wants (bearing in mind the requirements of other patients). Otherwise the test is for the doctor to ask himself: would this particular patient reasonably be expected to wish to be consulted about this particular decision? Usually the most important ethical reasons (a) for consulting the patient about proposed reuse of disposables, or (b) for deciding against such reuse from the start, are that the patient would be likely to be significantly or materially less benefited or more harmed by such reuse.

Beneficience & non-maleficence

Whatever the general scope of the principle of beneficience - of a requiremnt to benefit others - there is no doubt that doctors take on an obligation to benefit their patients. Because to do so they often have to inflict a certain amount of harm - or at least risk of harm - doctors are under a constant moral obligation to weigh up the harm and benefit of any proposed intervention, and to undertake it only if there is a likely net benefit for the patient.

The universal obligation to avoid harming others (non-maleficence) is particularly important, a counterbalance in medical practice where the possibilities of harming patients and others in the pursuit of benefit are already so extensive and constantly growing. Harm and benefit assessments are of course very complex - much more complex than we as doctors may sometimes remember. Both in terms of benefit and in terms of harm we have to separate out the nature of the harms and benefits anticipated, the probability that they will occur, and the perception of how beneficial or harmful they would be if they did occur.

For examples let us consider the use of the recycled plastic intra-arterial catheters to be used for carotid artery angiograms as well as the use of recycled plastic vaginal specula. Let us further suppose that one of the effects of resterilisation by gamma irradiation is gradually to make the plastic more brittle. Clearly the harm risked if a bit of plastic breaks off in the carotid artery is enormously greater than the harm risked if a bit of plastic breaks off in a woman's vagina. On the other hand the probability may be the same or similar, and very low, in both cases. Moreover the perception of both harms and benefits is a very personal and idiosyncratic matter.

Thus for example some people would find the reuse of cardiac pacemakers quite repellent. Similarly some would find the reuse of vaginal specula and rectal proctoscopes quite repellent. They might be even more repelled if they learned, as I did when I looked into the matter for the purpose of giving this talk, that thoroughly sterilised does not mean 100% elimination of micro-organisms - standards of sterility are based on the exponential reduction of bacterial numbers by increasing doses of radiation (4) .

But here again one needs to recall that there is no particular reason for the reuse of disposables to be treated differently from the reuse of non-disposables. Presumably the gut feelings would be just as powerful in both cases.

There are of course a wide variety of potential benefits and harms of using medical instruments and prostheses which would or should be weighed up before a doctor takes the decision to use one. And of course it is important to differentiate harms and benefits to the patient from harms and benefits to others. Such differentiation applies equally importantly to what might I believe be called the marginal benefits and harms of reusing an instrument or prosthesis as compared with using another new one.

The benefits to the patient thus depend on the circumstances, and these vary enormously. If there are plenty of the new disposable instruments or prostheses available, the only benefit presumably available to the patient is the possible saving of money if he is paying for the item in the first place and if he will pay less for a recycled equivalent. Thus in the NHS there will generally be no increased benefit to the patient. On the other hand, if there are no other new disposable items available, e.g. when expensive items run out, then all the benefits of the item itself accrue to the recycled disposable item - discounted for any impairment of beneficial function that such reuse might be expected to produce.

Disbenefits to the patient will be whatever increased risk there is of the item causing him harm. Thus if the financial incentive is removed, so far as the patient is concerned it is no benefit to him to have a reused disposable where new disposables are available; instead there is a likely disbenefit or risk of disbenefit. That however does not entail that disposables should not be reused if new ones are available. On one hand it is maximal benefit and on the other of maximum disbenefit.

Justice

Finally, the assessment moves to the issue of how much harm and risk of harm is acceptable in order to achieve how much benefit or probability of benefit, i.e. it turns largely on the last of my four ethical principles, that of justice.

Even in the purest of private medicine contexts there is always the potential for considerations of justice, fairness, or equity, to conflict with the doctor's obligations to this individual patient. At the very least, one's obligations as a doctor to others among one's patients may require one to curtail one's ministrations to the particular patient of the moment. In any case we do not function in the purest of private medicine

contexts, we function in the context of a National Health Service funded by a democracy which is obliged to allocate its resources to health care in the context of competition from all sorts of other worthy national enterprises such as education, non-medical social services, and defence. Once allocated to health care the available medical resources then have to be distributed accordingly to some principle of justice.

In trying to achieve fairness and efficiency the normal medico-moral obligation of optimising a particular patient's, or group of patients', care may have to take second place to a greater need to benefit a different patient or group of patients. One person's new rather than reused titanium hip joint may be another person's year on waiting list for hip replacement assuming of course that significant savings can indeed be obtained by reuse of disposables, an assumption that requires rigorous verification, as previous speakers have indicated.

Clearly there are enormous potential costs, especially because of litigation.

In this area of resource allocation, as in so much to do with ethics, there are alas no neat answers. However steps in that direction can be taken by trying to improve the rationality of our decision making processes, by basing them on mutually agreed principles and on methodologies which reflect those principles. In this context wherever the underlying ethical objective is equitable, benefit-maximising harm-minimising, distribution of resources, the analytical techniques of harm and benefit analysis beloved of economists are of central importance.

In this context, I personally was impressed with the potential sensitivity of a technique described at a previous Kings Fund conference by the health economist, Professor Allan Williams, which used QUALYS - quality adjusted life years - in making comparisons between the harms and benefits of different medical techniques (5).

While as I have indicated to start with, the principle of justice is not the only ethical consideration relevant to medical ethics, many medical ethics decisions do, or should incorporate such assessments of overall comparative harms and benefits, with perfection for one patient being sacrificed for benefiting others. Certainly the particular set of ethical problems associated with the reuse of disposable medical equipment and prostheses requires such concern.

Thus the fact that an available option to reuse disposable prostheses or items of medical equipment may involve suboptimal results for the one particular patient does not necessarily mean that it is unacceptable. It depends upon how great a reduction in benefit and increase in risk the patient will suffer in comparison to standards of acceptability which themselves must be established in the context of a just distribution of available resources.

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2. Anonymous. Adequately informed consent (editorial). Journal of medical ethics 1985; 115-116.

3. McCallum DB, Perry S. Reusing disposable medical devices raises ethical, legal and cost questions. Business & Health, January/February 1985; 53-54.

4. Tallentire A. Philosophies underlying sterility assurance of radiation-treated products. Medical device and diagnostic industry 1983; 5(3): 36-42.

5. A brief account of the concept and use of QUALYS is in: Williams A. The economic role of health indicators. In: Teeling Smith G., ed. Measuring the social benefits of medicine. London: Office of Health Economics, 1983.

Discussion

The questions made it obvious that many in the NHS were unaware of the legal and ethical implicatons of reuse.

The need for much more discussion of the issues involved was stressed as was the need for clarification of the responsibility and accountability of both manufacturers and health authoritiees, and individual NHS staff.

SUMMARY OF ISSUES -
Dr Steven Anderman

A. Legal Issues

The reuse of sterile use medical devices is a practice with extensive legal implications for manufacturers, health authorities and health care professionals. The law of negligence and in some cases the law of contact apply to establish liability for compensation in the case of any injury arising out of the reuse of such medical devices. The legal rules should therefore be taken into account in evaluating risks and responsibilities at the time when decisions are taken to reuse.

Broadly, manufacturers are directly liable to patients for their negligence in providing defective products whether owing to faulty design or faulty manufacturing. In exercising due care, manufacturers must follow the DHSS guidelines in Good Manufacturing Practice and the DHSS Guidelines on Sterile Products. These guidelines do not have statutory force but are admissable evidence of the practices a reasonably prudent manufacturer should follow.

Along with these legal responsibilities, manufacturers also have a legal responsibility that it is for single use only: it is not obvious that he must also provide information on resterilisation procedures. Where manufacturers supply equipment to a hospital or doctor with a clear indication that the product is for single use only, with no representations to the contrary, and in all other respects comply with the labelling requirements of the DHSS guide, they may satisfy their legal responsibilities to users and patients. As a consequence, the decision to reuse single use medical equipment would be regarded far more as the responsibilities of the health care professional making the decision to reuse rather than the original manufacturer. This would mean that the health care professional may be personally liable for such a decision. It would also mean that the hospital or health authority could be vicariously liable for the decisions of its employees to reuse single use equipment.

In either case, liability will be heightened by the fact that the hospitals or its employees have decided to ignore an instruction that the medical device is for single use only. It is true that some reuse may be consistent with maintaining safety - but the reuser will have the responsibility to take reasonable and due care in the resterilisation. In many cases, the duty to testing and inspection which is comparable to that imposed on the manufacturer.

In the case of the reuse and reprocessing of single use equipment, the duty of care to patients owed by health care professionals such as physicians is based on what the physician either knew or reasonably should have known. In the case where a physician knows that the device being offered to him is a resterilised device that was indicated to be for single use by the manufactuers, whilst the reuse itself would not automatically amount to negligence, the normal legal obligation of the physician to mininise risks would place a duty upon him to establish that the reuse itself did not add materially to the risk posed to his patient.

B Ethical Issues

The ethical issues arising from the practice of reuse of single use equipment can be approached by reference to the ethical principles of respect for autonomy, beneficence, non-maleficence and justice. The principle of autonomy places upon doctors reusing single use equipment a duty to obtain consent. As with the use of other equipment, however, the consent can be implied. There must be a warning of material risks and reasonably comprehensive response to questions, but the test for the doctor to ask himself is would this particular patient reasonably be expected to wish to be consulted about this particular decision.

If the patient is likely to be significantly less benefited or more harmed by the reuse, then not only is consultation called for by ethical priniciples, but such priniciples raise important questions about the decision itself to reuse. In principle there is no particular reason for the reuse of single use equipment to be treated differently from the reuse of multi-use equipment. The priniciples of beneficence and non-maleficence suggest the need for a harm-benefit analysis, with care being taken to distinguish between the benefits to the patient and the benefits to others. When decisions are made to allocate limited medical resources, consideration of justice and fairness must be modified by those of efficiency. Care for any one patient may have to take second place to a greater need to benefit a different patient or group of patients. In the area of resource allocation, there are no neat answers, but the rationality of the decision making process can be ignored by making use of the analytical techniques of harm benefit analysis.

TECHNICAL ISSUES

PRODUCTION DESIGN/DEVELOPMENT/MANUFACTURE IN RELATION TO REUSE - Mr J Mackey

Yesterday we heard eminent speakers discussing general perspectives on the reuse of sterile, single use and disposable equipment in the NHS. In particular, we heard experts discuss the relative pros and cons in relation to clinical, legal and ethical issues. Today we are going to address the technical isues, and my paper will concentrate primarily on production design/development and manufacture in relation to reuse.

Let me emphasise at the outset that the reuse of sterile, single use medical devices is a complex problem and involves technical, scientific, legal, ethical, regulatory and economic issues. Only when considering a specific product is it possible to analyse all of the relevant factors which relate to patient safety but these include design, construction, materials, packaging, sterilisation, shelf-life and storage conditions, method of use and the significance of medical procedure. In my paper, because of time restraints, only generalised comments are made, but there should be absolutely no difficulty in applying them to any specific product category.

Next, what types of device are we talking about? Some of you may be under the impression that we are only referring to dialysers and insulin syringes and cardiac catheters.

Indeed, the list is expanding rapidly as is evident from the following examples:

Haemodialysers
Cardiac catheters
Angiographic catheters
Blood lancets
Syringes and needles
Pressure monitoring domes
Endotracheal tubes
Intravenous Administration Sets
Wound drainage systems
Anaesthesia breathing circuits and masks
Surgical lap sponges
Suction cannisters
Scalpel blades
Gloves
Oesophageal Thermometers
Orthopaedic appliances
Etc., Etc.

The manufacturers of these items have designed/developed and manufactured their products for single use only. Little, if any, information has been developed concerning the overall effects of reuse.

Before examining in detail the three major aspects of my paper which are Product Design, Development and Manufacture, in relation to reuse, let me remind you of the three categories of reuse that were identified yesterday in health care.

1. REPROCESSING

This can best be described as a single-use sterile medical device that has been removed from its unit pack for a procedure which subsequently did not take place. The device can then be, and is often, subsequently repackaged and resterilised to minimise any contamination risk which may have occurred.

2. RESTERILISATION

This is when a single-use sterile medical device is put into a procedure tray in its protective package along with other items and is subjected to a resterilisation procedure.

3. RE-MANUFACTURING OR CLASSIC RE-USE

This is where a single-use medical device has been used on a patient, is then cleaned or disinfected, repackaged and resterilised for subsequent reuse on another patient.

So let us first look at product design.

PRODUCT DESIGN

Product design and the selection of materials for single use sterile medical devices are the result of detailed studies of factors relevant to patient safety, functional use and economical manufacture. The physical properties of a device, together with its function and effectiveness have been, in most cases, thoroughly researched, developed and tested by the manufacturers. Reprocessing, resterilisation or remanufacture for reuse could seriously affect these characteristics (e.g. material strengths, dimensions, adhesives, lubricants, etc.), as few, if any, single use devices are made of materials or subjected to processes that are desgigned or tested for multiple use. Currently, most sterile single use device manufacturers have very little knowledge and data about the effects of reprocessing on the materials utilised by them. Repeated cleaning with various chemicals and cleaning agents and also repeated resterilisations may potentially alter the physical and chemical characteristics of the intrinsic materials, and compromise the durability of the device, resulting in increased risks to the patient. When one considers the multiplicity of sterile single use devices on the marketplace, together with the numerous cleaning agents and methods of sterilisation and the effect that these processes have on the multitude of materials used in devices, then the task of obtaining data and knowledge is put into perspective. Let me put this product design aspect into context with a few examples.

- Certain grades of polystyrene can successfully undergo Eto or gamma radiation, however when subjected to temperatures usually utilised in autoclaving the material can shrink.

- Steam sterilisation of single use catheters can lower the tensile strength and increase the risk of a catheter breaking.

- If the product was originally irradiated, the packaging materials do not necessarily have to be porous and therefore would be ineffective for a subsequent Ethylene oxide resterilisation.

- Printing inks, adhesives and lubricants are used by manufacturers where they know the compatibility of these materials with their sterilisation processes. Subsequent resterilisation or remanufacture may adversely affect these various materials.

- Irradiation sterilisation can cause a degradation of certain polymeric materials. This can be controlled by the original manufacturer, but, if the device is subsequently reprocessed or resterilised, the increased degradation may have a deleterious effect on the materials.

The sole motivation for reuse of single use devices, with one or two exceptions, appears to be cost containment. However, reuse once all relevant factors are considered, may actually increase costs. The theoretical cost savings through reuse, however, may be significantly affected by the responses to some of the questions I pose in this paper.

Now let us look at product development.

PRODUCT DEVELOPMENT

Manufacturers determine that their products are non-toxic, and regularly test for non-toxicity at all major stages of the manufacturing process. In the case of remanufacture or reuse, toxic residues could remain from the cleaning or washing process, or from the resterilisation process. Will the reprocessing or remanufacturing procedures have the same controls?

A pyrogenic reaction may arise from the reuse of a device, due to the presence of bacterial endotoxins on its surfaces. Such a condition could arise when a contaminated used product is retained in a warm, moist environment and subsequent cleaning would be most difficult. Manufacturers regularly test for pyrogenicity, even though the materials used in most medical single use devices do not contain pyrogenic substances. Again we must ask, will the remanufacturer test for non-pyrogenicity?

Manufacturers have for their products and processes developed sophisticated and extremely costly process control and test systems to ensure quality assurance. For example:

- Spectrophotometric equipment to confirm chemical compositions of materials.

- Gas chromatographic equipment to verify the absence of Eto residues.

- Tensile strength test equipment to assure strengths of materials and other physical properties.

- Package integrity test equipment to determine seal strengths and microbial barrier assurance.

Much of the above mentioned equipment has been deemed to be necessary by manufacturers, regulators and health care professionals, to ensure standards of safety, efficacy and fitness for use for most medical devices. If then we assume that these standards are necessary to ensure the patients' health and welfare, then it follows that they must also be necessary for the remanufacturer or reprocessor.

Finally a brief look at production manufacture.

PRODUCTION MANUFACTURE

The industry has for many years now manufactured devices in accordance with the principles of Good Manufacturing Practice. GMP encompasses, amongst others, the following:

- Written procedures/specifications

- Batch traceability

- Record keeping

- Personnel training

- Labelling control

- Worker protection (e.g. Eto)

- Gauge calibration systems

- Sterility Assurance
  . validation
  . use of biological indicators
  . sterility testing

Subsequent speakers this morning will discuss in more detail major aspects of GMP and sterilisation so I do not intend to dwell on these items any longer. However I must once again remind you of the previous question I posed. In manufacturing, if all of the above are deemed necessary to ensure the manufacture of a device of the necessary quality; then they must also be necessary for the reprocessor or remanufacturer.

SUMMARY

In conclusion, let me say that while industry recognises the practice of reuse of certain sterile single use medical devices is occurring, they cannot support the practice. Numerous literature references to the reuse of dialysters, catheters, syringes and needles, pressure monitoring domes, etc., are undoubtedly well known to this audience. However, whereas those that allege no resulting patient harm from reused devices are widely circulated those that do identify patient harm are not so

readily quoted. It requires only one lawsuit to more than offset any anticipated savings from reuse.

Continued or increased reuse can lead to double standards for medical device safety and efficacy that could have far-reaching consequences for the health care system. This is because it is unlikely that the controls and standards to which industry manufacture can be effectively and efficiently implemented by the remanufacturer or reprocessor to remanufacture products to the same standards that the devices were initially manufactured.

The industry is committed to supplying the highest quality medical devices consistent with the intended use and cost requirements. In contrast, the advocates of reuse may put cost ahead of quality and patient safety, and this is something that no-one can condone.

GOOD MANUFACTURING PRACTICE AND QUALITY ASPECTS RELATING TO REUSE

Mr I.R. Cutler

Governments have a responsibility to their public for the quality and safety of health care which they provide. As we have already heard, a number of leading countries have established medical device legislation based on GMP compliance, with which responsible members of industry comply.

GMP is not a newly invented concept; it is technical common sense for the industry. The objective of every responsible ethical company is to produce only products which are of the appropriate quality and which are safe and effective.

Good Manufacturing Practice represents the sum total of those activities which are necessary to ensure that a medical device meets the patients' and users' requirements for quality, safety and efficacy.

The major basic principles of GMP relate to:

- premises
- manufacturing environment
- equipment
- materials
- personnel
- manufacturing
- microbiology
- sterilisation
- quality assurance
- documented procedures
- traceability records
- packaging
- labelling
- auditing
- defined management responsibilities

The decision to reuse a single use medical device can arise for a number of reasons:

- perceived high unit cost
- perceived longevity
- reuse on the same patient
- convenience and supplies

In all of these instances it is necessary to dismantle, clean, reassemble, inspect, repackage, relabel and resterilise the device.

There are instances where a device is selected for use and the package is opened in preparation but the device is not used.

Even in these instances the sterility, quality and identity of the product is compromised and several of the actions mentioned below are applicable.

Let us examine and compare some of the implications of this "remanufacturing" process against the principles of GMP.

PREMISES

Manufacturers design or modify their premises to the dedicated task of producing sterile devices. Such considerations take into account the nature of the environment which is required to be maintained from a hygienic and microbiological point of view.

Is "remanufacturing" carried out in such designed and dedicated premises?

ENVIRONMENT

A manufacturer controls the environment in which sterile devices are manufactured for temperature, humidity, airborne particles and micro-organisms. Such measures are expensive (£600+ per square metre).

Is "remanufacturing" carried out in a similarly controlled environment?

MATERIALS

The manufacturer carefully selects by design and testing the appropriate raw materials and components which are needed. Some of the criteria used in their selection are physical, chemical, physiological and microbiological.

Routine supplies are then monitored by quality control procedures to ensure that they comply with the required design standard. Consideration has also to be given to the storage and handling of such materials prior to use to ensure that their physical, chemical and microbiological quality is not compromised.

Do such conditions pertain in the "remanufacturing" situation? The method of sterilisation of the device is a significant factor in the selection of such materials. Certain types of plastic are degraded by some methods of sterilisation and most will not withstand the high temperatures of autoclaving. Such treatment would lead to physical and chemical deterioration of the composite plastics used.

Are these factors taken into account in the "remanufacturing" situation?

PERSONNEL

Manufacturers train and control all personnel engaged in

manufacture to ensure that they avoid any action which would compromise the functioning or cleanliness of the product.

MANUFACTURING

In industry, the manufacturing procedures are based upon the concept that with the approved materials and following a validated sequential manufacturing process, there will be a high level of confidence that the specified product will be produced. The quality of the product is designed into the manufacturing process. This ensures a far higher consistent level of quality than can ever be achieved by 100% inspection of reprocessed devices with their varying quality profiles.

MICROBIOLOGY

The manufacturer has the facilities and qualified personnel which are needed to measure and control all aspects of potential microbiological contamination during manufacture. The very concept of sterility assurance is based upon a known and consistent microbiological load on the product, upon which is based a validated sterilisation process.

A reused device presents a gross and unknown microbiological and physiological challenge. Attempts to clean such a device and its subsequent disinfection are variable and suspect. It is likely to adversely affect the physical characteristics of the device, thereby jeopardising its safety and efficacy. Without effective validation and control of the disinfection process, the resultant microbiological challenge on the device has the potential to be high and variable, both in numbers and species.

Residual traces of the disinfectant on the device may also introduce a chemical hazard.

QUALITY ASSURANCE

The required quality of a device is incorporated in the initial design, and following a successful programme of development is expressed in the written and approved specification (an in-house "standard") for the device.

It embraces all the quality related aspects of the device through materials, manufacturing processes, packaging, labelling, sterilisation and storage. It also includes several comprehensive inspection stages where a regime of sampling and testing is carried out, to demonstrate that the manufacturing process is under control from start to finish.

This process also generates test reports and manufacturing records which constitute the history of each batch of devices.

PACKAGING AND LABELLING

The manufacturer selects and controls the type of packaging which is appropriate for each style of device to protect the product, and to preserve sterility during long periods of storage.

The labelling of the package provides the identity and traceability of the device, and is also used to convey instructions for use and appropriate warnings or contra-indications.

DOCUMENTED PROCEDURES

All the comprehensive procedures in the original manufacturing process are in written form and approved, and are constantly maintained.

TRACEABILITY RECORDS

The manufacturer can produce the documented history of a device which will record its material usage, manufacturing and quality assurance records, test records, sterilistation and labelling.

AUDITING

A manufacturer carries out regular and frequent self-auditing of the application of GMP, supplemented by inspection by the regulatory authorities.

MANAGEMENT RESPONSIBILITIES

The management of a company is legally responsible for the quality and safety of any product which it sells. It is responsible under several laws of this country.

SUMMARY

The application of the principles of GMP to the manufacture of a single use medical device is technical common sense, and a well established and recognised principle in ensuring that they are of the required quality, safety and efficacy.

The practice of reprocessing used, single use medical devices for reuse prompts the question as to whether the GMP compliance embodied in the original manufacturing process can be repeated in a multi-event and uncontrolled manner in the reprocessing situation.

If compliance with all the principles of GMP can be demonstrated in such reprocessing, then there may be a case for its consideration.

If compliance with all the principles of GMP cannot be so demonstrated, then at best a double standard is admitted where quality, safety and efficacy cannot be assured, and at worst the health and life of the patient is jeopardised.

CONCLUSION

It is highly unlikely that any "remanufacturing" process can achieve the same standards of GMP and quality assurance as those embodied in the manufacture of the original device, even with the necessary staffing and finance which would be necessary.

The practice of GMP is expensive and any attempt to apply it comprehensively and effectively in a reprocessing situation would increase the unit cost to a level higher than that of a fresh and unused single use device.

Such derogation of a single use device by reprocessing is in my opinion unacceptable on technical, legal, moral and ethical grounds.

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PROBLEMS ASSOCIATED WITH RESTERILISATION -
Dr A.H. Dadd

We have heard many arguments, with facts and opinions, for and against reuse of single use medical devices and equipment. The problems relating to product function, GMP, quality assurance and so on have been discussed from various viewpoints. I would like to integrate much of what has been presented into a consideration of the factors which concern all of us when deciding to resterilise single use devices. I shall present you with facts and accepted interpretation of these facts and leave it to you to draw your own conclusions on the safety of resterilising such devices.

I think we would all agree that any device or piece of equipment used in the treatment of a patient should be safe, or at least, as safe as is humanly possible, at the time it is used. If we analyse this, it is obvious that the device must be in a condition to function in the intended manner and to do this reliably over the time period required.

It should not, through its presence in or on the patient, produce an undesirable reaction in or on the patient through the presence of such materials in or on the device. And finally, it should be sterile, i.e. it should be free from the presence of microorganisms which might infect the patient, assuming that you really need a sterile device.

Problems may arise in one or all of these areas following resterilisation.

Sterile means that the device is free from all living forms or, as far as we usually take it, free from living micro-organisms. In practice, as we all know, it is impossible to prove this and we have to work to a high probability of the absence of living micro-organisms or germs.

All sterilisation processes result in a gradual reduction in the living (viable) microbial population subjected to that process. Expressed graphically, we get the much reproduced survivor curve. [Fig.1]

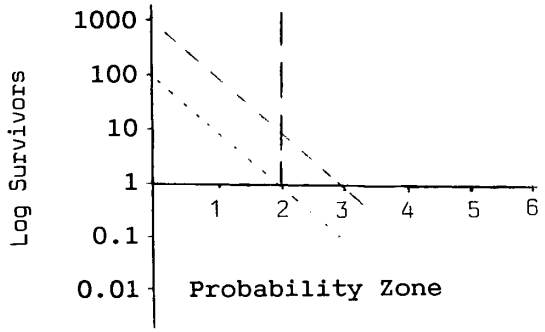
The important points to note are that the number of survivors at any point during inactivation is determined by:

1. the initial number of micro-organisms present on or in the device;

2. the rate at which each type of micro-organism on or in the device is being inactivated or killed.

Fig.1

Survivor Curve



The curve shows the situation for one micro-organism being subjected to one kind of sterilisation treatment. The response here is logarithmic, but this may not always be so. The two lines are parallel with each line representing a different initial microbial population so the rate of killing is the same. However, the number of survivors after any given treatment is different. The higher the initial microbial population or bioburden, the higher the number of survivors there will be after any given treatment.

The second feature to observe is that after we reach a single survivor, we enter the zone of probability of occurrence of a survivor. You will see that when this occurs on the lower curve, the upper curve shows the presence of 10 survivors. As killing goes on, the probability of finding a survivor decreases and this gives us the sterility assurance.

There is no legal requirement for a particular level of sterility assurance but many regulatory bodies do accept a minimum figure of 10 . In industry, the sterility assurance is usually better than this.

With steam under pressure, killing is very rapid but with other methods such as Ethylene oxide and L.T.S.F., both now commonly used in hospitals, it is much less rapid and very dependent on the correct conditions being attained in the steriliser. These conditions must be determined for every type of device and package. A controlled bioburden, a reliable steriliser which is fully maintained and has all its instruments calibrated at regular intervals, physical and biological monitoring of the cycle and a VALIDATED CYCLE are the only ways to achieve a reproducible sterility assurance.

Industry achieves a high sterility assurance with the less effective sterilisation methods through tight control of production, packaging and sterilisation.

Production is, as we have already heard, carried out under GMP conditions. The effect of this is to control the bioburden on the devices within specified limits such that on sterilisation,

a defined and documented sterility assurance level can be consistently achieved.

Packaging too must be carried out under controlled, clean conditions with monitoring of the packing materials and package integrity both before and after sterilisation. The packaging material is chosen to provide suitable conditions for sterilisation by the selected method.

The manufacturer selects the method of sterilisation on the basis of the materials used in the manufacture of the device, its construction and its packaging. He knows or has determined the reaction of the materials to the sterilisation process and ensures that the device will not be harmed by the treatment given, i.e. it is compatible with the product.

Some sterilisation methods present a problem because of absorption of sterilant into the materials making up the device. The rate of uptake and subsequent elution of, for example, Ethylene oxide, varies greatly depending on the nature of the material, temperature, concentration of sterilant and time of contact. A device may be made of several different materials, all known to the manufacturer and he is required to validate and monitor their effective elution before releasing the device for sale.

The purpose of all these controls is to ensure a high level of safety when the device is used on the patient. We can sum it up as controlled, validated and monitored manufacture and sterilisation to produce a device with a KNOWN CONSISTENT STERILITY ASSURANCE.

Now, these devices are manufactured for single use only. Their reuse following resterilisation begs many questions, all of which must be answered by the person attempting reprocessing.

Q.1 Can the device be cleaned to a satisfactory standard both in terms of contaminating materials such as blood, mucus etc. and removal of particles including micro-organisms?

Cleaning involves a dilution of micro-organisms. The process itself must be shown to be effective; it must be controlled and monitored to ensure that a satisfactory level of cleanliness of the device is consistently achieved. Once cleaned, the device must be protected from further contamination before being packed and sterilised. A controlled environment is required for this and strict staff control on those performing the cleaning and repacking. If this is not done the starting point for the sterilisation process will be a device with high microbial count and as we have already seen, this will result in a lower sterility assurance.

We all know how difficult it is to remove dried blood, serum or mucus. Such dried residues may include large microbial populations and may protect them from the action of the sterilisation process. The effectiveness of all sterilisation processes is reduced in the presence of such material but with Ethylene oxide, it may make it very difficult, if not impossible, to kill the micro-organisms trapped in the dried

proteinaceous material. The crust formed protects the micro-organism from access by moisture and Ethylene oxide. This can be easily demonstrated by gently drying micro-organisms in a serum or broth when the resistance immediately increases.

	R-value		
Micro-organism	Undried	Dried from water	Dried from broth
Spores of B. subtilis	100	-	-
Strep. faecium	1	18	311
Staph. epidermidis	1	1	274

Cleaning fluids will become contaminated with micro-organisms and protein during the cleaning process and even growth of micro-organisms may occur in them. These fluids must therefore be monitored. It is very easy to heavily contaminate devices rather than decontaminate them in an uncontrolled or inadequately monitored cleaning process. Additionally, some materials used in devices are damaged by commonly used cleaning processes and their effect on the device must be validated before use. A process that may be satisfactory once or even twice may cause damage to the device with repeated treatment. The same applies to the sterilisation treatment. It is therefore vital to have the necessary equipment and expertise to validate such cleaning cycles. Do you, as a reprocessor, have these essential facilities?

Q.2 How can the number of reuse/sterilisation cycles be controlled and on what basis do you fix the maximum number of cycles to be allowed before the device is discarded?

This will obviously depend on the materials used in the manufacture of the device, the stresses exerted on it, the way it is treated after use and the reaction of the device to the sterilisation process. The reprocessor is required to assess all these although in fact he is likely to have little, if any, data on which to make this assessment. He will probably know little about the characteristics of the materials used in the device, little about its history in the previous use or uses and have no control over the way it has been treated following use.

The sterilisation process itself may affect the reliability and functioning of the device. Repeated sterilisation may change the properties of the materials used in the device. Radiation, through cross linking, may make materials brittle and liable to failure. Even with Ethylene oxide material changes can occur. Crazing is a commonly observed material change resulting from over-exposure to Ethylene oxide. This results in loss of strength, making the device dangerous to use. It has been established that in certain circumstances, sterilisation by a second and different method from the first, may result in

material changes which render the device unsafe to use. Is the reprocessor in a position to assess this? How can he know the right method to use? Where can he be expected to obtain this information?

Q.3 Can the reprocessor control the sterility assurance?

Perhaps if he knows the bioburden on the devices he is sterilising. Of course this implies that he is able to control this bioburden such that effective limits can be set to ensure a consistent sterility assurance.

Q.4 Can the reprocessor provide the conditions necessary for de-gassing in an ethylene oxide process?

Has this been validated to show that it is effective and that the level is safe when the devices are released for reuse? A further problem for the reprocessor is that he is usually involved with small loads made up of a variety of very different devices, packed in different forms. How can such mixed loads be validated? The next load may be totally different [in volume, mass and surface area]. It then needs to be validated again.

What then can the reprocessor do? He quite obviously cannot meet the level of safety of the original device as received from the manufacturer. He can of course, pop them into his little magic box (he calls it a steriliser, although this is an act of faith), give it a whirl (he calls it a sterilisation cycle) and at the end, issue the devices as sterile and safe for use. As a scientist, I am not inclined to accept such faith. It is vital to know what you are achieving; faith does nothing to help you on that.

It is clear that the probability of a device failing for some reason, whether this be non-sterility, mechanical failure, present of toxic residues, or so on, is higher for a resterilised device than for one supplied direct from the manufacturer. Is this important? You must decide this. In any case, there is no justification for operating a dual standard system, one for the manufacturer and another and lower standard for the hospital that insists on resterilising single use devices.

REUSE PRACTICE IN CENTRAL STERILE SUPPLY DEPARTMENTS -
Mr J Hansford

Central Sterile Supply Departments were established in the late 1950's to upgrade the quality of sterilisation practice, and to centralise the provision and processing of sterilised equipment to wards, departments and clinics. Many departments are still involved in the storage and distribution of a wide range of commercially sterilised products intended for single use.

Today hospital based departments should concentrate their productive resources on reprocessing reusable equipment and provide those packs that only 'in-house' facilities can manufacture on a cost effective basis.

The concentrated use of high cost instruments and equipment in operating theatres indicated in the 1960's the economic wisdom of developing processing units in close proximity to the users of the service. Theatre service centres (TSC's) and Theatre Sterile Supply Units (TSSU's) exist today to provide a localised and specialist service to complement that of a nearby or integrated central Sterile Supply Department under the same management structure.

The philosophy of concentrating the reprocessing of specialised and expensive equipment has now extended to a range of items requiring disinfection between patient uses. Much of the skill and machinery required to cleanse, inspect and pack instruments prior to sterilisation is common to the processing of anaesthetic sundries and life support equipment. This added function has given rise to the hospital sterilisation and disinfection unit (HSDU).

A network of departments now provide a service for the vast majority of NHS hospitals and clinics. Each department has its own characteristics and methods of providing that service, but collectively they can be referred to by the generic title of "Sterile Supply Service Departments".

Although there are still differences in the scope and scale of the service offered, there are many similarities. Each Manager is required to safeguard the working environment, establish and monitor production processes and set standards of departmental discipline that together form the basis of a quality assurance standard. Our production facilities should bear comparison with industrial procedures but we are continually reminded that 'in-house' facilities are intended, if not designed, to cope with the wide range of known and unknown pathogens contained in the soils born on used instruments and equipment returned for reprocessing. This major difference sets SSDU's apart from other commercial organisations.

formaldehyde and Ethylene oxide gas continues from the articles processed long after the end of the sterilisation process, and therefore may, if the return of sterilised items to the user is accelerated, pose a hazard to the patient.

There are chemical solutions such as gluteraldehyde for unwrapped items, e.g. endoscopes. This may seem a reasonable option for the resterilisation of items required for more immediate use. To be effective, the actual chemical must reach all parts and contact must be maintained for a minimum of three hours. Rinsing by water is essential but often fails to remove all the residual gluteraldehyde to the detriment of the staff or the efficiency of the item being reprocessed.

In general, and in over simplified terms, the potential for each sterilisation method to overcome the bioburden carried by the items being processed is at maximum in the porous load steam steriliser (hence its preference for stable materials) and decreased for low temperature steam with formaldehyde, Ethylene oxide and is least for gamma irradiation.

Ionising radiation facilities are available to NHS users and it would be prudent to follow the precedent of commercial industry and use only selected virgin materials that are manufactured, assembled and packed in 'clean room' conditions.

Those tempted to resterilise once irradiated products by Ethylene oxide are referred to the work of Boucher in America and Professor Cunliffe here, who indicated that poly vinyl chloride implants may release chlorhydrin compounds into blood circulation and resin bonding agents may soften.

The extent to which Sterile Supply Departments are involved in recycling single use equipment is increasing particularly in hospitals providing specialist services. (Table 1) A commitment to reprocess should not be given without circulating the risks involved and the assurance that all the necessary resources of staff time, machine capacity, production space, storage facilities and revenue consequences are available, and will continue to be available.

The costs involved in reprocessing single use items form a much narrower band than those of new product costs. There is therefore the option to concentrate effort on infrequently used items of high initial cost or those which are commonly used and where the diference between initial cost and reprocessing charge is much less. Much single use equipment originates in the United States whose Food & Drug Administration's Bureau of Medical Devices has clearly stated its view and placed responsibility on the institution or the practitioner for the consequences of reusing single use devices. A more succinct statement was made in 1972 by the Committee of Ministers of the Council of Europe who resolved that "Re-utilisation of disposable materials should be prohibited and their correct use and disposal should be ensured." An unequivocal statement endorsed by many disciplines, as an ideal but far removed from the reality of the present situation.

Reprocessing must err on the side of safety. My recommendation must be that if visible soils cannot be coaxed from an intended single use product, the Manager must discard the item. One problem is that manufacturers give little information to identify the materials of which their products are made or the methods used to unite components. Then too the design of many single use items is such that they are unsuitable for cleaning by mechanical methods. All items for reprocessing must be cleaned. Best results are obtained by correctly presenting goods to a mechanical process with a regulated cycle.

Two methods of mechanical cleansing are commonly used:

1. Traditional hot detergent solution followed by rinsing and drying resulting in a time/temperature exposure such as 80°C for one minute capable of disinfection.

2. Chemical methods using tanks of solvent and flurocarbon drying chemicals to which a lubricant may be added.

Both systems require the loading of baskets or crates by hand and it is at this stage that care and discipline are required, if hazards to staff are to be minimised.

Cleaned and dried items enter a production area where conditions do not normally meet those of a 'controlled area' as defined by the Guide to Good Manufacturing Practice, but every effort is made to maintain a high standard of environmental and personal hygiene.

At this point instruments and equipment are inspected for cleanliness and functional efficiency. If acceptable, a pre-determined mix of instruments and equipment is checked and disposable dressings, paper products, man-made fibre items and reusable linen used to complete a set of equipment for a specified procedure or, alternatively, additional or supplementary items may be packed individually even if they are delivered in multiples to the user. Reprocessed single use items are often in this category.

Prepared packs and trays are sterilised or disinfected according to item and intended use. The method of sterilisation or disinfection will be determined by the individual item with the least tolerance to heat and pressure. The method of choice is the porous load steam steriliser, which is widely used for most instruments, dressings and paper goods. Other methods in common use are low temperature steam at 73°C for disinfection to which formaldehyde may be added. This addition results in a sterilisation process and the lower temperature makes this process suitable for heat labile items.

Ethylene oxide gas sterilisers are available at selected centres where environmental monitoring standards and protocols to safeguard products and staff have been approved. The gas may be used in a low or high pressure system either neat or diluted with carbon dioxide. As a sterilant it is costly but effective for heat labile items. In selecting goods for this process the pressure sensitivity of the weakest component must be known as functional efficiency may otherwise be impaired.

It is important to recognise that the desorption of both

Reuse of single use or disposable items

(Analysis from 39 completed questionnaires)

Item	Total no. of hospitals	No. reporting single use	No. reporting reuse	Method of decontamination (no. of hospitals) EO	LTSF	LTS	D	HW	A	Hospital reuse (%)
Cardiac catheters	23	14	9	7	2	0	0	0	0	39.1
Pacemakers	16	7	9	9	0	0	0	0	0	56.3
Pacemaker electrodes	17	10	7	5	2	0	0	0	0	41.2
Guide wires	19	8	11	7	2	1	0	0	1	57.9
Eye shields	18	11	7	2	2	2	0	0	1	38.9
Oxygen masks	28	17	11	3	1	5	1	1	0	39.3
Suction tubing	23	17	6	1	2	2	0	1	0	26.1
Airways	35	17	18	1	4	9	1	0	3	51.4
Anaesthetic tubing	29	5	24	3	1	8	3	7	2	82.7
Suction catheters	27	24	3	0	1	2	0	0	0	11.1
Tracheostomy tubes	25	16	9	4	1	0	1	0	3	36.0
Endotracheal tubes	26	6	20	4	2	6	2	1	5	76.9
Foetal scalp electrodes	21	12	9	1	3	0	0	1	4	42.8

EO Ethylene oxide
LTSF Low temperature steam and formaldehyde
LTS Low temperature steam
D Disinfectants
HW Hot water
A Autoclave - Porous Load Steam Sterilizer

Central Sterilizing Club Study Group Report 1985.

Every practitioner and manager must be aware that manufacturers of sterile single use equipment choose designs and materials that are adequate within defined safety margins for a single use product. If reprocessing is to be undertaken, the following questions must be asked and answered:

1. Can all parts and component structures be cleansed and dried so that any residual bioburden is within the destructive capability and reach of the terminal process - either sterilisation or disinfection?

2. Are the cleaning and terminal processes available likely to adversely affect the nature of any materials or bonding agents used in the device?

3. Are either of these factors likely to impair the efficient working of the device and can this be tested prior to clinical use?

Local policies must then be agreed and implemented.

In my own experience, the most common reason for reprocessing is that the product is 'out of date'. That is, its stated shelf life has expired.

Some products are made of materials that denature and change their characteristics with age. In these circumstances an expiry date is recommended and supported by the International Standards Organisation.

Suppliers of single use equipment have a responsibility to their customers to ensure that successive deliveries arrive bearing progressive expiry dates and no more than a quarter of the total shelf life should be in the past at the time of delivery. It would be helpful if Trade Associations would write such a clause into their 'Codes of Practice'.

Conferences such as this can provide the incentive to work for a common policy on 'shelf life' and product use and abuse. Beyond the formal agreements and statements, national policies related to the practical considerations and constraints of the day must be developed and implemented.

It would be appreciated if manufacturers would give more details of the products, material specifications, tolerances, etc., and recognise that some items could be classed as consumable, for that is how they are regarded.

It would be helpful if, where appropriate, sterile single use items bore a statement beginning "Do not reprocess because.....". The reason that followed would provide the evidence to support the case of those seeking to establish a practical policy.

In conclusion, risks are more difficult to quantify than costs, and I acknowledge to you that I have reprocessed items without full knowledge of the risks involved because often the information is not available. It may reasonably be argued that this is indefensible as the statement has been made "Re-utilisation of disposable materials should be prohibited and their correct use and disposal should be ensured."

To practise by this ethic is to deny the reality of today. Reprocessing must be selective, very selective with patient safety as the first consideration.

Discussion

The discussion following this session returned to some of the issues raised earlier in more detail, such as industry's and CSSD's control systems, the technical aspects of manufacturing, the effects on re-processing, and the costs involved.

Summary of Issues -
Mr G Kennedy

The papers presented so far show that the adoption of 'single use' products originated in the USA more than 20 years ago where the high cost of reprocessing simple but high volume products (eg syringes) made a single use product attractive in economic terms. Initially there was no suggestion that CSSD's and other in-hospital units were fundamentally incapable of re-processing reuseable products. However the adoption of single use products made from virgin materials processed in factories (without the high background contamination level of hospitals and used products) has reduced risks to patients resulting from re-processing.

In industry, sophisticated processes and equipment are used to measure the particular contamination and 'bio-burden' of products before sterilisation. Although steam sterilising at 136 C for 3 minutes is recognised as an effective method, many single-use products cannot withstand this process and have to be processed by methods which are only effective if the bio-burden is known to be below a specified level.

Apart from the costs of re-processing, many single use products have been designed for low cost-production using complex tooling which makes it impossible to dismantle the product. Also, many products, eg catheters, have narrow passages which cannot be mechanically cleaned. Furthermore the materials used can be low cost types, but if re-processing is to be a constraint high cost materials would have to be used to resist the physical and/or chemical stress involved.

Current shortage of funds in hospitals coupled with increasing demands for expensive hardware is forcing clincians to look for economies. Re-processing of used 'single-use' products is seen by them as a cost effective and adequately safe procedure which will achieve this aim. Such re-processing and re-use are common and largely uncontrolled although individual experts are obviously capable of dealing with their own individual area. Overall, however, from industry's point of view the whole process from cleaning to point-of-use, including controls and documentation, leaves a great deal to be desired.

The view of industry therefore is that key issues need to be addressed, namely,

1. the application of GMP to re-processing units
2. that re-processing should only be carried out in CSSD's or similar specialist units by properly trained staff
3. the need to set up accurate costing systems
4. the need for national and local leadership and policies

ECONOMIC ISSUES

AN OVERVIEW OF FINANCIAL IMPLICATIONS FOR THE NHS - Mr E Welsh

In a session which is intended to give a broad overview it is not possible nor yet desirable to draw firm conclusions or to put forward detailed arguments. Because of the uncertainty concerning the extent to which disposable items are reused - uncertainty which this seminar will go some way to dispel - I feel that the most I can do is to ask a number of questions and perhaps look down one or two avenues not yet fully explored.

Before doing so, I think it will be useful to provide some information drawn from Health Authorities to show the financial scale or background against which I am talking.

We have been dealing with items of medical and surgical application. For accounting purposes, Health Authorities group a wide range of items under this heading of Medical and Surgical.

In a Region with around 27,000 available beds the annual expenditure on such a heading is around £27m. In one typical District with about 3,000 beds, the annual expenditure is £1.5m. Thus sum covers all medical and surgical equipment and purchases but excludes dressings and procedure packs. This District carried in store an average of about £80,000 worth of stock and makes issues of about £60,000 in value per month.

The stocks include re-usable and disposable medical and surgical items. It must be remembered, however, that not all items of medical and surgical equipment or supplies are subject to stores control. In this typical District, only about half of the expenditure goes through stores.

The items held in stores include disposable airways as well as the black rubber reusable airways, with monthly issues of 1,000 and 20 respectively and costs of about 20p each as compared to £2 each.

This District store issues about £3,000 worth of intravenous cannulae a month, about £5,000 worth of surgeons' gloves, £1,500 worth of hypodermic needles, and about £5,000 worth of hypodermic syringes.

At one time all these items were supplied in materials which could be reprocessed.

Two questions that need to be asked are:

1) Is there evidence to show that disposable items are more economic in use than reusable items?

As far as I can tell, disposable items have been introduced continually over the last twenty or thirty years but without the carrying out of any comprehensive studies to demonstrate their cost effectiveness.

To take an illustration from the airways kept in store in my typical District:-

- Can it be demonstrated that the disposable item at 20p is more cost effective than the reusable item at £2? The costs of reprocessing will have a significant bearing on the answer to this question.

A formula I recently came across suggests that to be cost effective, the cost of reprocessing plus the cost of the original article spread over the number of times of reuse has to be lower than the cost of the disposable equivalent.

2) Is it because this cost effectiveness cannot be determined that hard-pressed managers are adopting good housekeeping practices and reusing some of those items which we now regard as disposable?

Note that I am not taking into account the ethical or legal implications, nor am I making a judgement on whether NHS reprocessing methods are comparable in effect to those of the manufacturers.

Is it because the reprocessing costs are incapable of definition that they are possibly overlooked and thus not taken fully into account?

In the District I am using as my illustration, there is evidence:

a) of reuse of single use items;

and

b) of reprocessing of sterile items after opening.

Items in the first category might include some syringes and biopsy needles. Items in the latter might include prostheses and catheters.

The overriding argument used to defend the reprocessing will be that it saves money and avoids waste.

It is not possible with the information systems available to calculate what money is being saved, but with an annual expenditure of £1.5m even a saving of 1% will amount to £15,000. In the Region as a whole, this might be as high as £270,000.

The reasons usually cited for the introduction of disposable items are:-

a) convenience for the user;

b) elimination of cross-infection risks.

It is not clear from the literature on the subject whether the demand for disposable items was created by users, or whether the demand was stimulated by producers and manufacturers. The likelihood is that both users and producers worked together but my natural scepticism leaves me to think that the profit motive tilted the balance.

Further questions arise:

- Could it be that the only reason why some items are regarded as single use or disposable is because manufacturers say they are?

- To what extent are Health Authorities led by manufacturers into positions where disposing of an item after use is the only option available when carrying out certain fuunctions?

- Could it be that we need to re-examine the need for some of the disposable items?

In view of the reprocessing of opened but unused items which takes place, could it be that manufacturers might reprocess the items for us?

In the absence of comprehensive knowledge of the extent of reuse of disposable items, it might be worth speculating on the implications for the NHS of both increasing the practice of reuse and alternatively of ceasing the practice altogether.

If we increased the practice significantly, my stores would look much tidier. Disposable items take up a great deal of space. Space and the handling of goods both cost money. It is almost certain that stock values would be lower.

If we increased the practice of reusing disposable items significantly, we would need to spend money on our sterilising and reprocessing units. All would presumably need to meet GMP standards, and this might need substantial investment in equipment. A further question:

- If a patient suffered harm arising directly from the use of an item reprocessed in a National Health Service unit, could the Health Authority afford the possible bill for legal damages?

If we increased the practice significantly, could we save more than the hypothetical 1% mentioned earlier? The answer purely in money terms appears to be yes.

If we increased the practice significantly, would we stifle development in product design? Would we see a falling-off in manufacturers' interest in this market? Would I have sufficient competitors to enable me to negotiate best prices?

And if we cut out the practice altogether, what would then be the implications? No reprocessing might mean the disposing of CSSD equipment. It might mean an increased demand on storage space. It would seem from the evidence available that it would cost more money, both in expenditure on the actual purchase of the items and - because of working practices in theatres - an increase in waste.

The recent studies on procedure packs have done much to highlight the in-house costs of processing as compared to the buying-in of standard packs.

But as I said earlier, all of these questions need examination in the light of other factors which this seminar is designed to explore.

The argument from finance may not be the decisive one.

AN ACCOUNTANT'S APPROACH TO COSTING -
Mr G Jones

In broad terms, the NHS is concerned to provide the best possible care to patients in hospitals and people in the community at the lowest possible cost. In other words, the NHS has to achieve value for money (VFM) by providing effective prevention, diagnosis and treatment at an efficient and economic cost. One of the ways in which the NHS has sought to make savings and achieve VFM is to reuse sterile, single use and disposable equipment. Yet, despite the extensive reuse taking place, there is little evidence of systematic and rigorous evaluation of the cost savings achieved or achievable.

In this session of the conference, therefore, I want to put forward, firstly, how an accountant would approach the costing of reusable items and, secondly, examine what is the appropriate comparison to make between the cost of NHS reuse and the new prices. At the end of the session, I would like to make one or two suggestions on the way forward.

NATURE OF THE PRODUCT

An accountant is interested to ensure that a comparison is not being made between an apple and a lemon. Does the reused item have the same desired characteristics for patient care as the apparently similar bought-in item? Fitness for use is not an issue on which an accountant can pass judgement, but to ensure fairness, particularly given differences in the application of the Guide to Good Manufacturing Practice (GMP), such a comparison should be made. Product characteristics such as sterility, non-toxicity, pyrogenic reactions, biocompatibility and various physical properties need consideration. For the rest of this session, I am assuming that suitably qualified experts will vouch for the validity of the comparison.

COSTING - BASIC STEPS

Costing information is required for a variety of purposes concerned with planning, decision-making and control. Depending upon the purpose, the relevant cost information may be different. However, irrespective of the purpose, two basic steps are required - product/process specifications and determination of the bill of resources. Together these lead to a total reused product cost which should be analysed by type of cost.

The first basic step, product specification, is to ensure that a precise picture is obtained of all the direct physical resource inputs into reprocessing a product are identified. These will include the following:- - the original product (an estimate is

needed of the life-cycle of the reprocessed item, i.e. how many times can it be reused before being discarded

- the grade of labour and standard minutes per operation (washing, sterilisation, packing etc) required

- the type of equipment and machine times required by operation

- the type and quantity of packing material required.

The second basic step is to establish the bill of resources for the reused product. This involves establishing:

- the financial value of each quantity of physical resource input reprocessing

- financial values, and appropriate methods for their allocation, of overheads associated with the reprocessing of items (these will include such costs as rates, equipment maintenance, depreciation, management salaries, uniforms etc).

The full costs of reusing items, therefore, can be seen to include:-

- a proportion of the original price of the product (the relevant portion is the original price plus VAT divided by the number of uses)

- the reprocessing costs, including overheads.

COST CLASSIFICATION

Once the basic steps are complete, the reused product costs should be classified by type. An appropriate classification is as follows:-

- variable costs: these change directly in proportion to the volume of production and can be divided as follows:-

    - direct material and packaging
    - direct labour
    - variable overheads (e.g. detergents, chemicals, energy)
    - fixed costs - these are unchanged in relation to volume.

The variable or fixed behaviour of costs clearly depends upon the time period being examined. The relevant time period depends upon the purpose for which the cost analysis is required. It is perhaps obvious, but, in the long term, all costs are variable.

USE OF COSTING INFORMATION

The basic steps outlined above are required to develop cost information for most purposes. The total product cost derived as a result is most appropriate, however, for routine purposes such as inventory valuation and for re-charging user departments. To make non-routine decisions such as whether to reprocess items or buy-in requires a selective use of this and other cost information. The comparisons can be complex depending upon

circumstances, particularly if:-

- NHS reprocessing requires imminent capital expenditure
- there is a range of other products produced such as sterile soft packs.

Whatever the particular circumstances, the key comparison is the difference betrween the future costs of alternative arrangements. At one extreme, a simple decision could be required whether or not to increase or decrease marginally NHS reprocessing of reused items short term. The relevant cost comparison in such circumstances would be the total NHS variable costs of the reused item compared to the cost, including VAT, of buying-in. In the short term, the NHS's fixed costs will not change with the volume of production and can be ignored in decision-making on this scenario.

In a more complex example, which is likely to apply to most hospitals at some time, the NHS could be faced with investing capital to provide equipment such as an autoclave to allow reprocessing of items in-house. In these circumstances, the relevant future costs of NHS reprocessing must take account of the cost of the investment and the cost of capital. To reflect the economic impact of the timing of investment cash flows the optimal approach to the make or buy decision should use the discounted cash flow (DCF) method of investment appraisal. The NHS fixed costs which would be relevant to include in an evaluation of alternatives would only be those which can be avoided by not reprocessing in-house.

MANUFACTURERS' PRICES

In making make or buy decisions, one or two observations about manufacturers' prices are relevant:-

- it is wise to obtain competitive quotes, prices do vary in the market place for a variety of reasons
- do not necessarily take manufacturers' list prices, it is not uncommon to find discounting away from list prices particularly for high volume purchases of standardised products made by a number of companies
- apart from price and quality, speed and reliability of delivery are factors to consider which are not easily quantified.

WAY FORWARD

The existing approach to costing in the NHS needs to be developed along the lines put forward to provide relevant information for decision-making. At present it is unclear whether or not cost savings are really being made through reuse. Special studies should also be considered to independently review the position taking account of all the revenue and capital costs involved.

IS REUSE COST EFFECTIVE? -
Ms B Simmons

This question in relation to such broad terms of reference and narrow limits of time deserves an early answer. YES. NO. MAYBE! Having heard confirmation during this Conference of the extent of reuse, it is apparent that indiscriminate practice is occuring. Three examples of indiscriminate practice are:-

1) Urinary drainage bags from catheterised patients being collectively washed before reuse.
(Indiscriminate practice through ignorance)

2) A request from a consultant to reprocess a single use item, as it was the only sample he had.
(Indiscriminate practice for clinical convenience)

3) General reuse because items were out of stock.
(Indiscriminate practice caused by bad management)

Indiscriminate because the reuse is in respect of single use items which have been:

a) opened and used;
b) opened but unused;
c) unopened and unused (out of date, whatever that may mean) and resterilised.

Single use items are designed and manufactured and marked for that purpose under the guarantee of the manufacturer and reuse of them in any way constitutes abuse which cannot be cost effective because the possibility exists of danger to the patient. Perhaps a more appropriate word in this context - client.

One must not condemn out of hand the perpetrators of indiscriminate reuse, everyone reacts to their own particular expediency whether it be political or financial or through ignorance, "Let them eat cake". Rather the question to be asked is: Why is this pattern of reuse occurring?

Three different perspectives have been given in previous papers, those of Central Government, Industy and the National Health Service. I suggest that reuse is occurring because of the independent and seemingly insular development of all three, each reacting to their own form of expediency. This is creating conflict and confusion at grass roots level because of the absence of a cohesive code of practice or nationally agreed discipline.

Cost effectiveness is subjective and demonstrations of it have often lent more to art form than the logic of mathematics, even statistics are surrealistically slanted. Probably every filing cabinet will house glossy and erudite reports - "Single use drapes, can you afford not to use them?", by A Company. "Linen,

an in-depth study of cost effectiveness," by A Laundry Manager.

Currently then the answer to the question is NO. MAYBE reuse can be cost effective, if a system and discipline is implemented. How could this be done? Examination of all items reprocessed in the National Health Service would appear to be a good beginning. Such examination shows the list to be very lengthy. (Table 1)

What are these items? Seemingly, "single use", "reusable" or "disposable". At this point I will reiterate the need for the elimination of the word "disposable" from common use. It has no implicit meaning and causes confusion. "single use" is now accepted terminology so reusable is a suitable and accurate antonym.

With regard to devices: (See Table 2) It appears that material and design could be the criteria for whether an item should be single use or not, as these two dictate an ability to be effectively reprocessed.

It was mentioned earlier that there were no cohesive national guidelines. What about the Guide to Good Manufacturing Practice? Sections of the Guide in relation to "Sterile Single Use Devices", recommend standards of manufacture and packaging and labelling. However, the Guide is not mandatory and there are a few expedient loopholes. Very recently it is common to issue products before certificates are issued. It does not attempt to recommend groups of devices that should or should not be single use and it is in relation to some of these that the Cost Effective Factor is very relevant. (Table 3)

Applying my own cost formula in relation to anaesthetic airways for routine anaesthesia shows clearly that reuse is cost effective. The safety of the practice is now validated by the data of fifteen years of 20,000 procedures per year, with overall savings of some £250,000. The formula may not be perfect but it has yet to be disproved. Single use airways are used throughout the country. What a waste of money!, but cost effective to the manufacturer. An environment of double standards exists at the moment at every level and through every level. Also, some items are sold as reusable but are impossible to sterilise.

The formula can be used to prove the reprocessing of a Reusable item could be cost effective.

Earlier, the word discipline was used. Consideration of this old fashioned word by courtesy of Dr Roget could well provide an answer.

DISCIPLINE
- Regularity , uniformity, SYSTEM, ECONOMY
- Restraint , control, limitation, PROTECTION, monopoly, ECONOMIC PRESSURE .
- Punishment , infliction, trial, judgement, PENALTY.
- Teaching , instruction, education, DIRECTION AND GUIDANCE .

TABLE 1

	RE-USABLE		SINGLE USE	
	ADVANTAGES	DISADVANTAGES	ADVANTAGES	DISADVANTAGES
SOLID SURFACE INSTRUMENTS	Cost Effective	Plant Labour (Skilled)	!	Cost Impractical
HEAT LABILE INSTRUMENTS	Cost Effective	Technical Problems Skilled Labour	!	Cost Impractical
DEVICES	Cost Effective Continous Availability to User	Difficult to Effectively Clean Heat Labile Labour Intensive	Guarantee from Manufacturers No Possibility of Cross Infection	? Cost Availability of Supply Monoooly Supply Base Material Shortage
ANAESTHETIC ITEMS	? Cost Effective Continuous Repetitive Need	Labour Intensive Some Heat Labile Technical Problems (Small in Size: Loss Rate)	Guarantee from Manufacturers No Possibility of Cross Infection	? Cost
GENERAL EQUIPMENT	? Cost Effective	Labour Intensive	No Processing Problems	? Cost
DRESSINGS	Bulk Available ? Cost Effective	Time Consuming Waste	Guarantee from Manufacturers No Cross Infection	? Cost Base Material Shortage
LINEN	? Cost Effective	No Barrier Linting Etc. Laundry Availability Loss Factor	Improved Bacteriological Barrier	? Cost

MATERIAL	DESIGN	DIRECT INVASIVE USE	INDIRECT INVASIVE USE	RE-USABLE	SINGLE-USE	COST BAND
METAL	Simple i.e. tube	✓	✓	✓	✓	£0.19 - £100.00
METAL	Complex with Screws, valve, etc.	✓	✓	✓	✓ X	£6.00 - £50.00
Combination METAL & PLASTIC	Simple	✓	✓	X	✓	£0.02 - £100.00
Combination METAL "PLASTIC"	Complex	✓	✓	X	✓	£2.00 - £500.00
"PLASTIC"	Simple Design	✓	✓	✓	✓	£0.30 - £150.00
"PLASTIC"	Complex Design	✓	✓	✓	✓	£10.00 - £300.00
"RUBBER"		X	✓	✓	✓	£2.00 - £10.00

TABLE 2

TABLE 3

COST FORMULA

RE-USABLE	SINGLE USE
LIST PRICE	LIST PRICE .....
V.A.T.....	V.A.T.....
SUB TOTAL	SUB TOTAL .....
	OVERHEADS 15% .....
REPROCESSING COST (LABOUR RATE AT ANC3)	TOTAL TRUE COST .....
LABOUR WASH .....S.M.V.	COST EFFECTIVE FORMULA
PACK .....S.M.V.	
TOTAL	
W.S ON COSTS 18.5%	GW. FACTOR
.....	
WRAP MATERIAL	
.....	
OVERHEADS 68.85%	CONCLUSION
TOTAL TRUE COST	

The government has recently implemented a rationalisation of drugs, not the most popular of moves, but definitely cost effective. Currently there is no such restraint or control in purchase in the National Health Service. The Supply Council failed miserably, or miserably failed, largely because it was unable to offer a uniform system, or prove economy and did not enjoy executive status. What is needed is the authority to impose a system of uniformity. It is truly believed that this need will not require to be a "Labour of Hercules", in taking years of democratic commodity adviser group discussions and response to individual cries of clinical freedom. Let me say: Why should the DHSS not have mandatory powers? Just because they have not had them, there is no reason why it should not happen.

It is suggested that an executive body be set up to:

1. FORBID REPROCESSING OF ANY KIND OF SINGLE USE ITEMS CURRENTLY AVAILABLE.

2. DRAW UP A LIST OF DEVICES THAT SHOULD BE SINGLE USE OR PUBLISH CRITERIA FOR WHAT SHOULD COMPRISE A SINGLE USE ITEM.

3. ALLOW THE BENEFITS OF THE GUIDE TO GOOD MANUFACTURING PRACTICE TO BE EXTENDED TO THE NATIONAL HEALTH SERVICE PRODUCTION UNITS AND PROVIDE THE MONEY TO DO SO.

4. IMPOSE ON NATIONAL HEALTH SERVICE PRODUCTION UNITS THE NEED TO PROVE:-
   a) ability to clean effectively items;
   b) ability to reprocess and sterilise without impairing the function of an item or damaging the inherent structure of the material;
   c) ability to quantify or qualify that processing permits an acceptable level of safety in the treatment of the patient;
   d) ability to prove cost effectiveness against national guidelines.

5. UP-DATE THE DRUG TARIFF IN LINE WITH MODERN NEED.

6. ENCOURAGE THE PROFESSIONAL BODIES TO EDUCATE THEIR MEMBERS MORE EFFECTIVELY IN ALL ASPECTS OF THE USE OF STERILE EQUIPMENT.

If these relatively simple steps are taken, the abuse will stop because everyone will know where they are:-

Industry will have the profit on registered single use items.

The National Health Service will have the choice of single use or reusable and will be able to justify their choice.

The Government will be seen to have exerted their authority and have been seen to be fair with everyone and can truly say they have improved the service to the patients.

Then and only then I suggest reuse will be cost effective.

The Chancellor of the Exchequer usually has about three hours on his budget speech. I know I have been less costly, I can only hope that I have been as effective.

If nothing is done to alleviate the present confusion, imagine the results when the Channel Tunnel is completed.

Discussion

A lot of questions were directed as to how comparative costs of buying single-use items and re-processing could be accurately established. The lack of the necessary detailed financial data base was also raised. Again the question of comparing like with like that is whether industry and SSD's should, can or do, work to identical conditions and regulations was identified as a critical issue.

SUMMARY OF ISSUES -
Dr J Hurst

It seems clear that reuse of single use equipment is happening frequently in the NHS and that the motives for reuse are often perceived to be economic.

There have been one or two suggestions that if only budget constraints were eased in the NHS the 'problem' of reuse would go away. I doubt it. In the USA health expenditure per capita is two and a half to three times that in the UK, yet reuse is still an issue there.

The main policy question that the conference has posed is: "Should we use single use items once only or should we use them more than once." It is clear that this question has as many answers as there are items of equipment. Moreover, a given item may have different applications, each with different indications for reuse. Nevertheless, it seems from the papers and discussion that the economic issues can be grouped into certain broad categories. These include:-

1) reuse of items on the same patient without reprocessing;

2) reuse of items on different patients, with reprocessing, to a standard not materially different from new (say, to the standard of the Guide to Good Manufacturing Practice;

3) reuse of items on different patients, with reprocessing to a standard materially different from (less satisfactory than) new.

Reuse in the first category is illustrated by the reuse of disposable syringes on the same patient, say, during an operation. It has been suggested that this raises few, if any, problems about infection. The choice is between using a new syringe every time an injection is required, at a cost per injection of, say, 12 pence, and reusing the 'disposable' syringe, say twice, at an average cost per injection of 4 pence. Clearly reuse is cheaper than buying new and it may save further costs by being more convenient.

Reuse in the second category raises more complicated issues. It may be ruled out on technical grounds. If not, then, by definition, the reprocessed item is rendered as good as new but it may require careful monitoring and quality control to ensure that this standard is met, particularly in respect of sterilisation. Provided that the benefits of new and reused items are not materially different, the choice rests on cost alone. Suppose that 1,000 items of a particular piece of equipment are required per year, and that the purchase price of each item new if £5. It will be necessary to buy only 250 new items each year. The cost of a reuse policy will be (250 x £5) + (750 x £3) = £3,500. So long as the reprocessing cost of the item is less than the purchase price it will be worthwhile to reuse and the saving will be greater the more times that the item can be reused.

If one hospital adopts such a policy it is unlikely to affect the purchase price of the item. If all hospitals adopt such a policy, however, the consequent drop in sales may cause the purchase price to rise. If this happens, the relative savings of a policy of reuse will decline and may even disappear. If the purchase price rises by n times the difference between the original purchase price and the reprocessing cost, where n is the number of times the item can be reprocessed, the savings from reuse will be nullified. In the example above, the savings from reuse would disappear if the original purchase price of £5 rose by 3 x £2 = £6, to £11. Other things being equal, savings from a policy of reuse will be higher, the larger the gap between the original purchase price and the reprocessing cost, the more the number of times the item can be satisfactorily reprocessed, and the lesser the purchase price rises with a decline in sales.

Of course, as Mr Jones has indicated, it is necessary for a policy which relates to the long run to be based on the full cost of reprocessing to the NHS, including overheads, capital costs and quality control if correct decisions are to be made. It is not clear that hospitals can compete with industry here. Also, there is evidence that some clinicians over-estimate the cost of materials and under-estimate the cost of services in hospitals (see, D Wynick and JH Jessop, 'A survey of cost awareness among hospital staff' Health Trends , 1985, Volume 17, p.24). If reuse is based solely on clinical hunch about costs it may lead to false economies. Reuse in the third category, that is where reprocessed single use items are of a quality lower than that of new items, raises still further issues. It may simply be ruled out if the risks are unacceptable. If they are acceptable in some circumstances, any savings in equipment costs have to be balanced against lower quality care for, or harm to, some patients. Moreover, it is easy to envisage the existence of false economies where the cost of treating, say, the occasional infection caused by the reuse of single use equipment would more than outweigh any annual savings in the equipment budget. However, we have heard of examples of interruption of supply. We have heard, also, of clinicians being faced both with budget constraints for very expensive single use items and with more patients, with life-threatening conditions, than they can treat with their ration of new devices. In extreme (and unusual?) cases of supply failure reuse will be the only alternative to non treatment. It would be worth incurring reprocessing costs which exceed the original purchase price of items or worth taking risks with patient safety if these were outweighed by the risks of non treatment.

In the case of budgetary restrictions, which cannot be lifted, reuse to a lower standard of performance than single use may be ethically and economically justified if more, needy patients can be treated for a given budget and the total gains in health outcome exceed the total losses. There are, however, serious problems in equity if some patients are offered treatment with new items and others are offered treatment with less satisfactory, reused items. Patients' consent to reuse is surely required, here. As Dr Gillon has indicated, we may envisage handling such questions formally by comparing the quality adjusted life years (QALYs) generated for a given budget by a policy of single use with the QALYs generated by a policy of reuse. However, in practice, such reuse may be a temporary and expedient affair,

not permitting of careful trials to establish objectively benefits and risks to patients. In other words, it may be a matter for clinical and nursing judgement.

This leads on to the question of whether NHS managers, in the broadest sense, have enough information about the costs and benefits of reuse to arrive at soundly based policies on reuse. The answer given by the Conference to this question seems to be 'no', with a few exceptions. There is very little literature on the subject. Routine NHS accounts tell us the purchase price of new items but not their reprocessing cost. There seems to be considerable technical doubt about whether and, if so, how many times most single use items can safely be reprocessed. Clinicians and nurses must find it difficult to identify the full effect of reuse on patient outcomes, especially where infection is concerned. Even if clinicians and nurses are in a position to make observations and judgements about relative benefits and risks and SSD Managers (for example) are in a position to make judgements about the functional state of equipment, sterility and costs, it is not clear that the mechanisms always exist to bring the two sets of judgements together.

Closer attention to the cost effectiveness of reuse seems to be indicated at a local or national level, or both.

REUSE IN THE USA - AN OVERVIEW OF THE CURRENT SITUATION -

Dr S Perry

The reuse of medical devices intended for single use is an interesting story and, in a sense, a sign of the times in health care delivery. Reuse appears to have intensified in recent years in the United States as a consequence of pressures to contain health care expenditures, but it should be remembered that prior to the development of plastics and other synthetic materials, reuse was widespread and hospital personnel were involved in cleaning, sharpening when appropriate, wrapping, and sterilising such items as rubber tubing, rubber gloves, needles and scalpel blades, and syringes.

With the advent of plastics, manufacturers began producing medical devices that were intended to be discarded after single use. Disposables were attractive to hospitals, laboratories, and physicians because they were cheaper, safer, and in some instances superior (e.g. disposable needles) to their durable counterparts. Within a few years, disposables and pre-sterilised packaged devices intended for one-time use became a major item in hospital budgets. The items reused ranged from "non-critical" devices such as water jugs and bedpans to "critical" devices such as cardiac catheters and haemodialysers.

Haemodialysers for end-stage renal disease occupy a unique place in the history of reuse, since, of all the devices known to be reused, there is far more information about haemodialyser reuse than of any of the others. Reuse in haemodialysis has been cyclical. When chronic haemodialysis was first employed in 1979, dialysers were scarce and each dialyser had to be assembled by hand. After use, the dialysers were taken apart, cleaned, reassembled and sterilised before use on either the same or another patient. The tubing was also reused, at least while elasticity was retained. (1)

By the late 1960's, pre-packaged sterile tubing had appeared and was intended to be disposable but was sometimes reused. Dialysers were still largely assembled by hand, although pre-packaged, presterilised dialysers were gradually coming into wide use. Since the new dialysers were considered more expensive than the hand assembled units, they were routinely cleaned and reprocessed in many centres. However, with the passage of legislation in 1972 in the United States providing Federal coverage and reimbursement for patients with end-stage renal disease there was a large increase in the number of patients on dialysis and this expansion in volume led to decreases in the price of dialysers. Thus, there was less incentive to reuse dialysers and within a relatively few years, only a minority of dialysis procedures involved reuse. (1)

However, as health care expenditures began to escalate in the mid 1970's, pressures on health care providers to contain costs intensified, and reuse of haemodialysers again increased. Simultaneously and for the same reason, reuse of other devices, particularly the more expensive devices such as cardiac catheters,

also increased. Recent surveys in the US conducted by the Institute for Health Policy Analysis (IHPA) at Georgetown University indicate that a large variety of items are being reprocessed and reused and that apparently a significant number of hospitals and clinics engage in this practice.

In 1983, a conference on the reuse of disposables was convened by the Association for the Advancement of Medical Instrumentation (AAMI) which, although emphasising reuse of haemodialysers, surfaced some of the issues surrounding the reuse of other disposables. (2).

In March 1984 the IHPA convened a 3-day conference, (The International Conference on the Reuse of Disposable Medical Devices in the 1980's,) which was aimed at identifying and addressing, although not necessarily resolving, the technical, economic, ethical, legal, and public policy issues associated with reuse. (3)

The meeting was designed to enable all the parties at interest (including hospitals, industry, consumers, government, insurers and standard-setting groups) to provide their perspectives on the issues. A series of recommendations was agreed upon by a panel charged with reflecting the deliberations at the conference. The recommendations included, among others, the establishment of a steering committee under the aegis of the IHPA to guide further activities in reuse, including a survey to delineate the extent of reuse and an examination of its medical, technical, legal liability and public policy implications. (4)

Simultaneously, and perhaps stimulated in part by the increasing activities in the United States, the Canadian Government has established a Working Group on the Reuse of Disposables which has conducted a survey of the extent of reuse and has developed guidelines for those engaged in reuse. Additionally, in June 1986, at a major meeting of the World Health Organisation in Washington, there will be a session on reuse, emphasising the perspective and problems of the Third World. A recent article in NATURE (Sept '85) describes the situation in Poland where disposables are in short supply, so reuse is extensive.

EXTENT OF REUSE

In 1976, the Food & Drug Administration (FDA) surveyed a group of 148 representative hospitals to determine their policies and practices concerning resterilisation and reuse of disposable medical devices. (5) Approximately 14% of the hospitals practised resterilisation and reuse, most commonly in non-profit hospitals, but only 3 hospitals provided instructions for reuse. About 9% had a written policy forbidding the practice.

Except for the FDA survey, there has been no attempt to determine the prevalence of reuse and the types of disposable devices being reused. Last year the IHPA conducted four informal surveys beginning with the conference convened under its aegis in 1984 mentioned above. The other surveys were conducted at annual meetings in 1984 of three professional organisations: the American Association of Central Service Personnel; the International

Society of Central Service Personnel and the American Association of Respiratory Therapists. Whereas the participants at the IHPA sponsored conference were a self-selected (obviously interested in reuse) group, the participants in the other three meetings constituted a more random selection of hospital personnel. All types of hospitals were represented, ranging in size from 28 to 1500 beds (average, 367 beds) as well as home health agencies, health maintenance organisations and ambulatory care clinics. At the initial survey, 82% of the respondents (167 of 204) were aware of reuse or reprocessing of single use devices. (3)

At the subsequent surveys, about the same proportion of personnel reported reuse or reprocessing in their respective institutions. (6) A large number of disposable instruments and devices were identified as being reused, ranging from haemodialysers, cardiovascular catheters and guidewires, and respiratory therapy breathing circuits to tracheostomy tubes, surgical gloves, urinary bags, and bedside utensils.

Only a minority of respondents reported that their hospitals had a written policy or protocols for reprocessing or reuse.

Adverse effects reported were as follows:-

Table 1 Informal Surveys 1984

Adverse effects total number	19 (8%)
Nature of Problem	Number of Comments
General Device Malfunction	10
Compromised Functional Integrity	4
Toxic Residue	2
Mis-assembly	2
Infection	1

Table 2

Informal Surveys 1984 Description of Adverse Effects

General Device Malfunctions	-	Balloons on cardiac catheters failing to inflate
	-	Endotracheal tubes failing during surgery
		Decreased output from aerosol nebuliser
	-	Malfunctional or nonfunctional devices
Compromised Functional Integrity	-	Ventilator circuit developing pinholes
	-	Cracking, leaking and clouding of plastics
Toxic Residue	-	Lingering odors on devices
	-	Burning of nose and throat
Mis-assembly	-	Devices reassembled improperly subsequent to reprocessing
Infection	-	Secondary to reuse of "dilateria"

Although these informal surveys do not permit firm conclusions and may not accurately represent the national extent of reuse, the results indicate that reuse and reprocessing are widely recognised and that cost containment is the principal driving force. Furthermore, there appears to be a paucity of information on product durability, function, and safety subsequent to reprocessing. It appears that reports of adverse effects [Tables 1&2] are at the minimum since hospitals in the US purely have quality control and tracking procedures for reprocessing and reuse. In that setting, it would ordinarily be difficult to establish a causal relationship between improper reprocessing and an untoward event.

It is of interest that a recent survey of 1238 Canadian hospitals revealed that 47% engaged in reprocessing and 49% practised reuse. Nebulisers and humidifiers were the items most frequently both reprocessed and reused. (7) A working group commissioned by the Department of National Health and Welfare has developed "guidelines for standards" on the reuse of disposables. (8)

While reprocessing and reuse of disposable medical devices are widely known, it is of interest to note that there are relatively few articles on the subject in the published literature. Not surprisingly, most of the papers deal with haemodialysers, although the reuse of disposable insulin syringes and needles has also received some attention. In addition, there are scattered articles on other devices such as the reuse of mechanical ventilators, cardiac catheters and guidewires, cardiac pacemakers and disposable endotracheal tubes. The panel at the IHPA Conference took special note of the relative paucity of information on reuse, urging that "Research on the reuse of disposable devices should be supported and published in the medical literature." (4)

ISSUES IN REUSE: TECHNICAL AND MEDICAL

Of all the disposables being reused or reprocessed haemodialysers are the only major medical device for which there is significant documentation of the risks and benefits of reuse. While there is a good deal of information concerning the multiple use of haemodialysers, there are relatively few studies concerning the safety, efficacy and performance of other disposable devices which are reprocessed or reused. In addition, in contrast to haemodialyser reuse, there are no data demonstrating that the reuse of other devices bestows any medical benefits on patients.

Cardiac catheters have been reused for a long time, but there is little documentation in the published literature on the procedures used for their cleaning, resterilisation, and for assessing their functional integrity. (9,10) However, the Society for Cardiac Angiography has developed a protocol for the reprocesing and reuse of catheters. (10) A detailed procedure for reprocessing of intracardiac probes has also been published. (11) There is evidence that, if improperly handled, pacing catheters lose their electrical conductivity and develop structural defects. (12) While pyrogenic reactions have been reported in patients undergoing cardiac catheterisation, (13), a recent study in which catheters were reused up to four times showed no statistically significant increase in the incidence of fever, chills or hypotension associated with reuse. (14) There has been one report of a cardiac catheter that broke while being used in a patient thus requiring emergency surgery, (15), and there are anecdotal accounts of balloons on reprocessed catheters failing to inflate (unpublished).

Cardiac pacemakers, while not strictly speaking "disposable", are considered as items for single use only in the US, but there are a number of countries where reuse of pacemakers has been reported.(16) The few published studies thus far suggest that the reprocessed units are reliable and that their reimplantation is not associated with adverse immulogic reactions, hepatitis, or an increased incidence of bacterial or other infections. (16,17) A recent conference sponsored by the North American Society of Pacing and Electrophysiology concluded that reuse of selected cardiac probe generators was safe and effective and urged that appropriate

criteria be established to permit reuse. (18) It was estimated that 20% or more of implanted pacemakers could be reused.

In aneasthesiology, respiratory therapy, intensive care and monitoring, there are few reports in the literature on reuse, although the surveys done by IHPA indicate that the relevant devices are at least being reprocessed and in some instances (e.g. anaesthesia, breathing circuits and face masks) are being reused. There would appear to be no medical benefits but significant potential for adverse effects, particularly infection, in reuse of respiratory assist devices and pressure monitoring domes (14) and for equipment failure during anaesthesia. (19,20)

The reuse of disposable insulin syringes and needles appears to be a common practice, not only in the US but elsewhere. As indicated previously, there have been a number of studies reported in the literature of the reuse of both glass and disposable plastic syringes. While infections have been described, it appears that on the whole, the multiple use of syringes and needles is a reasonably safe procedure, (21). Hepatitis B has been reported with the reuse of single use blood lancets (cited in ref.13).

In summary, while there are many devices designed for single use that are being reused, information about the safety and effectiveness of these practices is almost entirely anecdotal and reports in the published literature are infrequent.

ECONOMIC

The major stimulus to reuse and reprocessing is the potential for cost savings, although evidence for such savings is often lacking and the full economic implications of this practice are not appreciated. The difficulties of arriving at accurate cost savings estimates arise because the medical effects are not known and the complete range of costs associated with reprocessing and reuse are often not considered. (22) Nevertheless, a number of cost studies have been reported, particularly in the multiple use of haemodialysers and disposable insulin syringes. (23-25)

As for the large number of other disposables that are being reused, there are virtually no data in the published literature concerning cost savings to be realised with reuse. It is obvious that such information is of great importance, particularly in the current environment of pressures for the reduction of health care costs.

POLICY AND REGULATION

The Medical Device Amendments of 1976 gave the FDA the authority to regulate the manufacture and marketing of medical devices. The extent to which this authority extends to reuse of disposable devices is uncertain at this time.

In 1975, the FDA issued a guideline prohibiting the reuse of disposable guidewires and catheters. In 1981, in response to enquiries, the FDA reviewed its position and found that there were inadequate data to support the reuse of disposable devices. It concluded that the institution or practitioner must bear the responsibility for the safety and effectiveness of devices reused or reprocessed. However, manufacturers of devices intended for single use who are aware of reuse are obliged to make available to

the provider a warning about the practice or instructions for reprocessing and reuse (26) but in actuality, this does not seem to occur very often.

At the state level, very few states have apparently even considered the issues raised by reuse. The notable exceptions are California and Colorado. In 1981, California adopted legislation mandating the development of a protocol by its Department of Health Services for the reprocessing and reuse of disposable dialysers. The protocol covers quality assurance procedures, informed consent, sensitivity testing for formaldehyde residue, record keeping including the history of each dialyser, training, etc. The regulations embodying this protocol have not yet been adopted.

In 1981, Colorado enacted legislation which prohibits reuse of devices other than haemodialysers, balloon-assist catheters (reprocessing only) and devices not requiring maintenance of sterility (e.g. bedpans). The legislation also includes requirements for approval of written reprocessing procedures, quality assurance, training of personnel for dialyser reprocessing, and standards for dialyser reprocessing facilities.

The Joint Commission on Accreditation of Hospitals (JCAH) does not oppose reprocessing or reuse providing patient health and safety are not adversely affected. (27) It is currently in the process of developing a requirement that hospitals have written policies and procedures for reprocessing and reuse.

LEGAL LIABILITY

Since reuse of disposable medical devices is a practice engaged in primarily because of cost concerns and, generally, in the absence of adequate information about safety, the legal implications appear to be potentially threatening, and as was brought up at the IHPA conference in March 1984, there are several parties at risk when reuse is practised including manufacturers, retailers and providers. (28) In order of priority, the potential for liability rests with (1) hospitals, (2) physicans, (3) manufacturers.

Last month, the Insitute convened a conference in Washington to focus on legal liability and public policy issues in reuse.

There was a consensus that:

1. Quality of care is paramount and must be maintained - if there is doubt about safety of reuse, it should not be practised.

2. There is collective responsibility among all the parties involved - hospitals, physicians, industry - to establish policy and the standards of the practice of reuse.

3. There is an important need for more studies and for more data on reprocessing and reuse. Reprocessing should be distinguished from reuse.

   - Hospitals should obtain information on outcomes.

   - Industry should provide more production information.

- Experience in reuse and reprocessing should be published.

4. There should be a repository for information and it is the responsibility of all parties to contribute. Anonymity should be protected.

5. Patients should be informed, at least about critical care items, when these are reused.

6. All hospitals should have a written policy on reprocessing and reuse.

7. Hospitals practising reuse and reprocessing should have written procedures and protocols.

8. There should be guidelines for reusables.

9. The CDC and the FDA should isue a policy statement implementing the foregoing as appropriate.

IMPACT ON INDUSTRY

The medical device industry opposed the reuse and reprocessing of disposable medical devices on the basis of several concerns. There are currently certain agreed upon standards for the design, manufacture, safety and effectiveness of devices intended for single use only. There are no such guidelines for disposable items now being reused and reprocessed except perhaps for haemodialysers.

Reused items are in effect "remanufactured" and from industry's perspective, the same standards should apply as if they were newly manufactured. It is industry's view that reprocessed devices may "lack assurance of sterility, non-toxicity, non-pyrogenicity, and functionality."(13) Since disposable items are by definition not intended for reuse, manufacturers understandably have not conducted studies to obtain the data necessary for safe and effective reuse analogous to the data now required for newly manufactured devices.

Industry representatives also raise questions of environmental safety when disposable devices are reprocessed by providers who usually do not have the facilities to handle large quantities of materials such as plastics. There is also the potential for harmful exposure of workers to cleaning materials, sterilising compounds, and infectious agents including Hepatitis B. (13)

CONCLUSION

The Institute for Health Policy Analysis has been involved in a series of activities aimed at increasing the awareness of the isues and implications surrounding the reuse and reprocessing of medical devices intended for single use. Reuse is a practice which, at least in the US, appears to have intensified largely because of pressures, particularly on hospitals, to reduce health care

costs. The Institute shares with others the concern that in the efforts to reduce such costs, providers and others engaged in reprocessing or reuse should institute methods to assure that the practice is safe and effective, that it is truly cost effective, and that above all else, patient care is not compromised.

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Mr G Jones	Partner Deloitte, Haskings and Sells, Management Accountancy Division, London
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Panel

A 4 member panel attended the conference, summarised the key issues in each of the main sections and jointly prepared the final summary and recommendations. They were:-

Dr S Anderman (Conference Chairman)	Reader in Law University of Warwick
Dr J Hurst	Deputy Chief Economic Adviser Department of Health & Social Security
Mr G Kennedy	Portex Limited Chairman BHTIC
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KING'S FUND CONFERENCE: REUSE OF STERILE, SINGLE USE AND DISPOSABLE EQUIPMENT IN THE NHS

December 2 and 3, 1985

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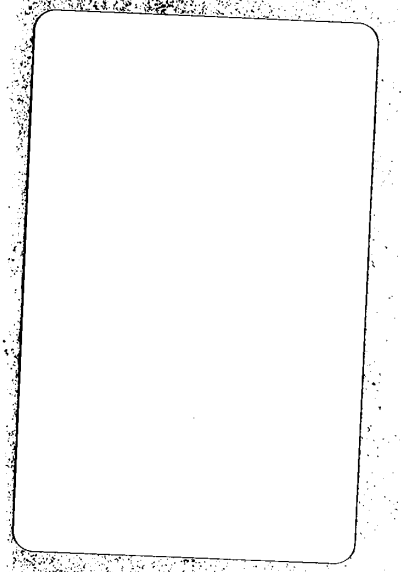

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