STERILISATION BY STEAM UNDER INCREASED PRESSURE

A REPORT TO THE MEDICAL RESEARCH COUNCIL BY THE WORKING PARTY ON PRESSURE-STEAM STERILISERS *

DURING the past few years a number of incidents and reports published in the medical and lay press have suggested that pressure-steam sterilising procedures followed in hospitals have not been achieving a satisfactory standard of efficiency, and that there is a need both to define the performance required of such sterilisers and to consider how it can be attained (Thiel, Burton, and McClemont 1952, Bowie 1955, Howie and Timbury 1956, Howie 1956, Scott 1957, Nuffield Provincial Hospital Trust 1958). In May, 1957, the Medical Research Council set up a working party to examine this question, and this report presents their findings and recommendations.

The report is based on a number of extensive and detailed investigations into existing arrangements for the sterilisation of surgical equipment in hospital wards, surgical units, sterile-supply departments, laboratories, and pharmacies. These have shown that the situation in this country is as unsatisfactory and unsafe as that in United States hospitals, as described by Walter (1948). While it has revealed a number of technical causes contributing to the inefficiency of sterilising processes, it has also shown that the underlying factor responsible for the situation as a whole is a widespread lack of understanding throughout the Health Service of the exact conditions required for efficient sterilisation and for the safety of those who operate sterilisers. It is to this aspect of the situation as much as to any other that the Working Party wish to draw attention.

PRINCIPLES OF STERILISATION BY STEAM UNDER INCREASED PRESSURE

The need for sterilisation by steam under increased pressure arises from the fact that the spores of many common and dangerous bacteria are strongly resistant to dry heat. The most effective way of killing the spores is by means of steam at high temperature and high humidity which will condense into their substance and moisten them thoroughly.

To bring about this effect all parts of the load to be sterilised must be free of air, so that it may be permeated by the steam; and the steam must be not only hot—at 120° or 130°C—but nearly saturated; that is, it must be at a pressure so high that in spite of its high temperature it is close to the point of condensing to liquid water. Steam in this condition is termed " just dry ". Departures from this condition, to be discussed later, result in inefficient sterilising operations.

In medical work steam sterilisers are mainly used for:

(*a*) Surgical dressings and other packaged goods.
(*b*) Unwrapped instruments and bowls.
(*c*) Surgical rubber gloves.
(*d*) Bottled fluids.

For the preparation of sterile water and saline some hospitals use a tank type of steriliser; this is discussed below.

The necessary conditions for steam sterilisation are most difficult to meet in the sterilisation of dressings, since it is not easy to remove air from the pores of close-packed fibrous material. Most of this section is therefore concerned with the problem of sterilising textiles, with particular reference to dressings.

Removal of Air

The removal of air is the first essential in the sterilisation of textiles. There are two methods in general use, the " high-vacuum " method and the " downward-displacement " (or gravity-displacement) method, and two corresponding types of steriliser.

THE HIGH-VACUUM METHOD

From a high-vacuum steriliser air is removed by a powerful pump which reduces the absolute pressure of air in the chamber to a value of a few millimetres of mercury column before steam is admitted. This is often described as drawing an almost perfect vacuum, and it means removing more than 98% of the air initially present.[1]

It must be emphasised that this is the only method of sterilisation that can overcome the effects of bad packing or overloading of the steriliser (Bowie 1958a, Knox and Penikett 1958).

Degree of Vacuum

Cotton or any other hydrophilic material left in a constant atmosphere will take up or lose water until equilibrium is reached—i.e., until the vapour pressure of water over the material equals the actual partial pressure of water in the air. If the material is then placed in a steriliser chamber and the pressure is reduced there will be little loss of water until the point is reached where the absolute pressure in the chamber equals the equilibrium vapour pressure over the material. At this point the water will " boil " out, sweeping the residual air ahead of it. This absolute pressure constitutes a vacuum sufficient to start the process of sterilisation. Evidently pressures need to be lower for cold dry conditions than when they are hot and moist.

The pressure of water vapour in equilibrium at 15°C with cotton containing 4% by weight of water (and substantially lower humidity is unlikely to prevail in normal conditions in this country) is about 5 mm. Hg (communication from British Cotton Industries' Research Association [Shirley Institute]). In theory a pump capable of drawing a vacuum of this high order is necessary. In practice preliminary vacua of a slightly lower order may be acceptable. Knox and Penikett (1958) for example, reported satisfactory results only when their vacuum reached a level of 20 mm. Hg absolute pressure, and some manufacturers and users are content with an " almost

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1. In this country the degree of vacuum is commonly expressed in inches of mercury column. We have retained this usage in parts of our text where those most interested would be more familiar with this form. In other parts of our text, where high-vacuum apparatus is described, measurements are given in terms of absolute pressure in mm. of mercury. For convenience the following table gives approximate equivalents of these two usages in terms of each other.

VACUUM CONVERSION TABLE

Degree of vacuum	Absolute pressure	
(in. Hg)	(in. Hg)	(mm. Hg)
29·5	0·5	12·5
28·0	2·0	50·0
25·0	5·0	125·0
20·0	10·0	250·0
15·0	15·0	380·0

perfect vacuum ", which is in practice a vacuum of the order of 50 mm. Hg absolute pressure (Bowie 1958a and b). More experimental evidence is clearly required.

It appears that the efficiency of this process of air removal increases with the proportion of the chamber volume occupied by the material, since the more material there is, the more water vapour is available to remove less air.

Effect of Oxygen Removal

Since oxidation kills spores it might be assumed that sterilising efficiency is reduced by the complete removal of air. The available evidence (Savage 1944) suggests that the effect of removing air is equivalent to a drop in temperature of less than 1°C.

DOWNWARD-DISPLACEMENT METHOD

In a downward-displacement steriliser the air is removed from the load by gravity—i.e., it is allowed to trickle out under its own weight (Bowie 1955, Perkins 1956). More precisely, the difference in density between cool air and hot steam, of the order of 1 mg. per c.cm., gradually forces the air downwards out of the load.

It must be emphasised that this method will render contaminated material sterile *only* if the steriliser is skilfully operated, carefully packed, and not overloaded.

Use of Vacuum

Many existing downward-displacement sterilisers are fitted with steam ejectors capable of withdrawing 30-50% of the air from the chamber. This so-called vacuum is sometimes drawn two or more times, steam being admitted between each vacuum, before sterilisation is actually begun.

Clearly, if air and steam mix well before the vacuum is again drawn, the air content will drop progressively, in fact by geometrical progression. This condition can usually be met in sterilising gloves, bowls, instruments, and bottled fluids, so that the practice is worthwhile in that application. On the other hand, in the pores of a textile material air and steam mix very slowly, so that successive low-order vacua (15 in. Hg or less) merely produce a " breathing " motion of the same air inside the material. Thus in the sterilisation of dressings one or more pre-vacua of this low order are not worth drawing; indeed it is wasteful of costly steam and less efficient than good downward-displacement. Furthermore no time is saved, and since it is not possible to predict the rate of air removal from the material in the steriliser the temperature in the chamber drain cannot be taken as a reliable indication of the temperature inside the load. Between high-order vacua (greater than $29^1/_2$ in. Hg) of whose value there is no doubt, and these low-order vacua (15 in. Hg or less) which we consider ineffective, the possible applications and usefulness of intermediate-order vacua await definition.

Packing of Material and Penetration by Steam

The pressure difference pushing the residual air out after steam has been admitted is comparable in degree with, though working in the opposite direction to, the draught developed in a short chimney over a feebly burning open fire. Therefore, to appreciate the rate of air removal from, say, a packed drum, it might be compared with the rate at which the gases from such a fire would pass through such a drum if it were jammed upside down in the chimney. Clearly, then, in downward-displacement sterilisers the load must be loosely packed, and arranged so that no pockets of cool air can form within it. Even so it will generally be necessary to allow a penetration time of fifteen minutes or more while the steam is flowing into the chamber and air is escaping from the load in large amounts; so that it is essential to make provision for the continued automatic removal of air and condensate from the chamber, and to ensure that it works; when the penetration time has been completed the sterilising period can be said to begin.

A skilled operator can sterilise perfectly reliably with such apparatus, but the conditions for success must be strictly observed, and the task should never be entrusted to untrained staff.

Quality of Steam

The quality of steam is known to vary with the degree of saturation, the amount of water-fog carried in it, and the amount of air it contains. As has already been mentioned, it is an essential requirement for steam sterilisation that the steam should be " dry ". In practice this is achieved by means of a steam separator in the supply pipe just in front of the entrance to the reducing valve, and is entirely an engineering matter.

The available evidence suggests that steam of a dryness fraction above 90%—i.e., having less than 10% of its weight made up of liquid water—is acceptable for sterilisation. Steam that is wetter than this is likely to result in inefficient sterilisation (see below).

Trouble may also arise through superheating, a condition in which the steam is hotter than saturated steam at the same pressure, as discussed by Walter (1948).

For the purposes of sterilisation the maximum acceptable upward deviation for steam in contact with spores is a temperature of 5°C.[2] Cotton materials that are not sensibly damp at the outset have the characteristic of adsorbing water so strongly that even if the steam entering the steriliser is saturated there will be a superheat of 3°C or more in the interstices of a cotton load. No additional superheat must therefore be allowed, and accordingly the common practice of running the jacket at a temperature up to 10°C hotter than the chamber is strongly deprecated.

The superheat just described exists in pure steam: in a superficially different sense superheat may exist in air-steam mixtures.

Thus a mixture containing 10% by volume of air, at 121°C and 15 lb. per sq. in., contains steam at 121°C and a partial pressure of $13^1/_2$ lb. per sq. in. This pressure in pure dry saturated steam corresponds to a temperature of only 118°C. On cooling at constant pressure this mixture will shed no water and so will yield no latent heat of condensation until it has cooled by the necessary 3°C. Therefore in a steriliser containing such a mixture it is not possible to ensure that the temperature in any part of the load is within 3°C of the external temperature. A temperature drop of 3°C in (now saturated) steam corresponds nearly to a doubling of the sterilising time, which is outside the margin of safety.

The situation described here is not just a theoretical one but it is one which can exist in a steriliser when the removal of air is incomplete and the pressure is maintained by the incoming steam. The air-steam mixture will meet cool parts of the load but will not begin to transfer heat to them until it has lost 3°C. It is therefore wise to ensure that the air content of the steam in any part of the load should not exceed 5% by volume during the sterilising period.

It must be emphasised that this *does not* mean that only 95% of the air need be removed from the steriliser at the outset, for the steam entering a mass of cotton will push the air ahead of it to form a central " bubble " of nearly pure air, which is very slow to diffuse out. Such a bubble will prevent sterilisation of the dressings in contact with it. In practice under correct conditions of packing and loading it will be displaced slowly by gravity.

Timing

When the steam has reached the correct temperature, sufficient time must be allowed for the physical changes that kill the bacteria and their spores to take place through-

2. A wider deviation may be tolerable at the highest temperature (134°C), but experimental evidence on this is still decidedly inadequate.

out the load; it is these changes that constitute the sterilising process.

Times corresponding to different temperatures have been given by Perkins (1956) as follows:

2 min. at 132°C	18 min. at 118°C
8 „ „ 125°C	30 „ „ 116°C
12 „ „ 121°C	

To allow for deviations in steam quality a further (safety) period is added. Adapting Perkins' figures (above) to the pressures most commonly employed, we recommend the following times and temperatures as a minimum:

3 min. at 134°C (30 lb. per sq. in.)
10 „ „ 126°C (20 „ „ „)
15 „ „ 121°C (15 „ „ „)

Damage to Spores and to Materials

The deterioration of cotton and rubber and the inactivation of bacterial protoplasm are not wholly dissimilar processes, and efficient sterilisation depends largely on achieving the latter while keeping the former to a minimum.

As the steam temperature rises, the time required for killing resistant spores falls faster than does the time required for doing a given amount of damage to cotton. Consequently, were the sterilising period the only consideration, sterilisation would be best effected at the highest temperature available. As regards pressure, however, the size and cost of autoclaves make it undesirable to operate at above two atmospheres gauge pressure for general-purpose sterilisers.

It is probably uneconomic to reduce the sterilising period much below the time required for steam to penetrate the load, so there is little point in running a downward-displacement steriliser above 126°C; at the same time there will be little point in spending money on doubling the pump speed of a high-vacuum steriliser in order to improve upon a pumping-down time of about four minutes, when the holding time is itself about four minutes for a sterilising temperature above 130°C.

Because it requires a longer period for steam penetration, retains more oxygen, and has a lower working temperature, a downward-displacement steriliser gives rise to more damage to goods per sterilising cycle than a high-vacuum steriliser, even when it is operated with equal care.

The question of damage is not of great importance if materials are to be used only once and then discarded; and there is much to be said for placing responsibility for the sterilising of such goods on the manufacturer, if subsequent contamination can be avoided.

Drying

At the end of a sterilising run it is necessary to dry the load without recontaminating it.

The state of dryness of the load will be fixed by the equilibrium established between the vapour pressure over the load and the pressure in the chamber—the lower the chamber pressure the more rapid will be the " boiling off " of the water. At this stage practically no air should be present in the chamber, and, since only steam with very little permanent gas needs to be removed, a water jet pump is specially suited to do this effectively and rapidly. Such a pump need be of quite simple design, for small sterilisers at least, and a vacuum of 28 in. Hg can readily be attained. In practice, the vacuum of 20 in. Hg obtainable by an efficient steam ejector will usually give satisfactorily dried dressings from a modern downward displacement steriliser, but only if a dry steam supply can be guaranteed. The usefulness of a water jet pump on such sterilisers seems not to be sufficiently widely known.

If the dressings have not been made grossly wet by inadequately dried steam, the mere attaining of the vacuum should be sufficient to achieve drying without a need to maintain it. Henry (communication from the Shirley Institute), and Penikett, Robson, and Rowe (1958) found that with a high-vacuum steriliser operated with dry steam, the load was back at its starting condition, as regards temperature and humidity, at the end of the sterilising cycle.

Air must be admitted to break the vacuum before the steriliser is opened. This air must be drawn from a clean source through a bacteriological filter (see below).

THE COMMONEST FAULTS AND THEIR TREATMENT

Seven main faults affect the efficiency of sterilisers used for surgical dressings and rubber gloves; these will be discussed in turn. It is emphasised that these faults apply only to the operation of the downward-displacement type of equipment commonly in use, and not to the modern high-vacuum steriliser. Indeed, the installation of a high-vacuum steriliser would provide a satisfactory remedy for most of the defects discussed.

Use of Wet Steam

Wet steam is a frequent cause of incomplete sterilisation. It causes the dressings in the steriliser to become soaked with moisture, usually early on in the sterilising process, so that they become less amenable to steam sterilisation by downward-displacement. Moreover, the subsequent drying of the wet dressings is a lengthy process which is damaging to rubber gloves and some other materials, and when it is accomplished by prolonged airing it carries a serious risk of recontamination by airborne organisms.

Wet steam is usually caused by inadequate lagging, inadequate condensate trapping, and inadequate separation in the steam supply pipe. In some sterilisers this defect may be overcome by the installation of a steam separator in the supply pipe just in front of the entrance to the reducing valve.

Incomplete Penetration of the Load

There are three main causes of inadequate penetration of the load by steam:

Retention of Air and Condensate

In many sterilisers there are no arrangements, or no reliable arrangements, for the automatic removal of air and condensate from the goods during sterilisation. Unless air and condensate are removed, the sterilising process cannot be fully effective in any steriliser, and will be particularly ineffective in all sterilisers which rely upon downward-displacement of air with or without the partial vacua attainable with steam ejector mechanisms—that is to say, in almost all the sterilisers in use in surgical units in Britain today.

The fitting of an efficient automatically operated near-to-steam trap (Northcroft 1956) is not a difficult procedure in sterilisers which have a discharge channel. Sterilisers which have no such channel—and even today these are not rare—cannot safely, and in reasonable time, sterilise packaged goods intended for surgical operations. It is sometimes possible to fit discharge channels to such sterilisers; but, since most of them have other serious faults of design, it is usually advisable to replace them.

Every chamber discharge channel should be of adequate diameter and fitted with a non-return valve and a readily visible sight-glass showing the flow of condensate. A continuous flow of condensate indicates to the operator that the discharge channel is open. The channel should drain into a tun-dish (which should be removed far enough from the steriliser to prevent free steam from being a nuisance); the

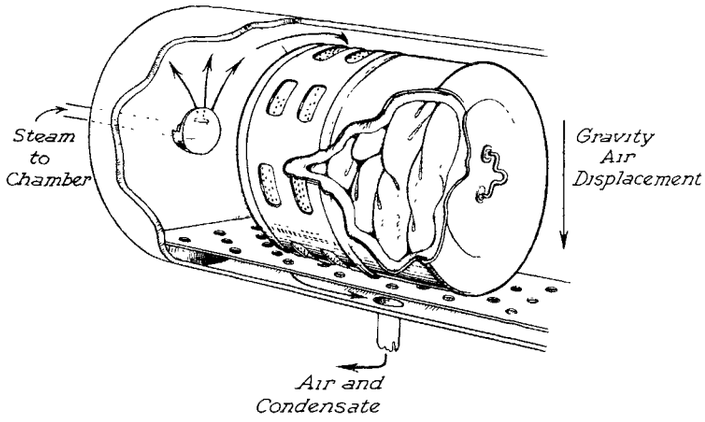

Fig. 1—Correctly packed drum with open ports positioned to allow gravity air displacement. (See section on the Use of Packs instead of Drums.)

air-break provided by the tun-dish will ensure that there will be no reflux contamination from drains—a remarkable but not unknown phenomenon (Bowie 1955).

Overloading of Drums and Caskets

Steam cannot penetrate thoroughly into the contents of drums and caskets that are tightly packed. It is apparently not generally understood that a drum which can only be closed with difficulty is grossly overpacked. The articles in a drum must fit loosely together and be laid flat. To avoid the formation of air pockets, sheets of mackintosh or jaconet should be interleaved and rolled with some permeable fabric, so that no two surfaces of the non-permeable material are in contact. Even with this precaution, mackintoshes may fail to be sterilised.

Incorrect Positioning of Containers in the Sterilising Chamber

Sterilisers are often incorrectly loaded, as many containers as possible being crammed into the chamber irrespective of the position of the ports. In downward-displacement sterilisers this practice renders the sterilising process completely unreliable. The ports or vents of the container must always be fully open during sterilisation, and the container itself should be so positioned in the steriliser that steam can flow through it by way of the open ports from top to bottom without impediment (fig. 1). In addition, the dressings or other material in the container must be so packed that when the container is correctly positioned in the steriliser the folds in the fabric run vertically; there will then be no obstruction to the natural downward displacement of air by steam.

If the steam pathway is correctly directed, the drums loosely packed and correctly positioned, the discharge channels adequate, properly trapped, and fitted with a thermometer, then, and only then, can a simple downward-displacement steriliser be efficiently run.

Incorrect Timing of Sterilising Runs

A common fault is that sterilisers are run for periods of from two to five hours. These long cycles destroy gloves and other heat-sensitive materials and add nothing to the efficiency of the sterilising operation. Furthermore they reduce the sterilising capacity of the unit, which, in turn, leads to over-packing, and sometimes to postponement of sterilising operations until the night staff come on duty. Thus it may happen that junior and inexperienced members of staff may be left in charge of a process which they do not understand.

A correctly timed sterilising run is one that will ensure that all parts of the load are held at a sufficient temperature for a time adequate to kill bacteria and their spores. The exposure time consists of the sum of (1) the penetration time, during which steam permeates the load and raises all parts of it to the required temperature; (2) the holding time, which is the minimum time known to kill spores at this temperature; and (3) the safety period, which in the downward-displacement steriliser is usually about half the holding time. The following recommended minima for combined holding time and safety period have already been mentioned:

3 min. at 134°C
10 „ „ 126°C
15 „ „ 121°C

For operations in which packing and loading are satisfactorily accomplished and a fully efficient steriliser is correctly operated, the following table indicates the exposure times required at 121°C and 126°C using downward displacement for the removal of air:

	121°C (15 lb. per sq. in.)	126°C (20 lb. per sq. in.)
Instruments and utensils ..	15 min.	10 min.
Fabric packs	30 „	20 „
Dressing drums	45 „	30 „

The run should be timed from the moment when a thermometer correctly placed in the discharge line reaches a temperature within 2–3°C of that corresponding to the chamber pressure. A thermometer placed in the centre of a dummy load of standard composition and suitably positioned would probably provide an even truer reading of the temperature in the chamber.

At the end of the timed exposure period, if the steam and dressings were dry at the outset, and the load was correctly packed and positioned, all that is required to dry the dressings is to draw a vacuum of about 20 in. Hg. There is no need to hold this vacuum for five to ten minutes, as is sometimes advised. Should it be found necessary to do so, wet steam or an incorrectly packed load should be suspected. Thus the whole operation will require a total duration of around sixty minutes at the longest, in marked contrast to the overlong runs of two to five hours mentioned above.

With high-vacuum equipment the total sterilisation time can be greatly reduced, a complete cycle taking as little as twenty minutes (Bowie 1958a). The penetration time is greatly reduced, because after an almost perfect vacuum has been drawn, steam permeates the load almost instantaneously. Also, with a minimal penetration time a high sterilisation temperature may usefully be employed, with a consequent reduction in the holding time and safety period. Thus, at 134°C, under ideal conditions, an accurately timed exposure period of three minutes is adequate. These higher temperatures cannot usefully be employed with downward-displacement equipment, since the long penetration time would mean that the outside of the load would be damaged before steam had reached the inside.

Incorrect Treatment of Gloves

The instructions given to staff often stipulate that surgical rubber gloves should be exposed at some 10 or even 5 lb. per sq. in. for periods of fifteen minutes or less. Such exposures cannot guarantee sterility, and their widespread use should cease. In at least one outbreak of postoperative tetanus the gloves were "sterilised" differently from the rest of the packaged goods and were the only articles, among many known to be contaminated with tetanus spores, which were not cleared of these organisms by the procedures intended to produce sterility.

From experiments specially conducted for this investigation we are satisfied that if gloves are properly packed

—that is, on their sides, with slips of gauze inside the wrists to facilitate steam penetration, and in correctly loaded containers (fig. 2)—they may be treated at a pressure of 20 lb. per sq. in. (126°C, 259°F) for an exposure period of fifteen minutes. With an initial period of five minutes for the chamber-drain temperature to reach its required value, and with a drying period also of five minutes, the gloves are safely sterilised during a run of twenty-five minutes.

Under these conditions solution-dipped surgical gloves are still usable after 6 runs, although they are by then showing signs of oxidation. Survival for 6 such sterilisations represents the life specified for such gloves. The hardier latex-dipped gloves show virtually no signs of deterioration after 6 such exposures, but some surgeons dislike latex-dipped gloves because they lack elasticity, do not give so sure a grip, and take up water; if this type of glove could be made acceptable to surgeons, the problem of glove sterilisation would be considerably reduced. Solution-dipped gloves are obviously more delicate, but even they will have an acceptable period of usefulness if properly sterilised.

Our evidence suggests that high-vacuum, high-pressure sterilisers permitting very brief exposures of gloves at 130°C or over probably combine safety with the minimum deterioration (Bowie 1958a and b, Schmidt and Moller 1954).

Recontamination of Sterilised Loads

Recontamination can undo the work of a sterilising operation before or after the load is removed from the steriliser. Before removal, and during the drawing of the drying vacuum, a faulty non-return valve in the chamber drain can lead to the aspiration of dirty air where a tundish airbreak is provided, or of dirty water where it is not.

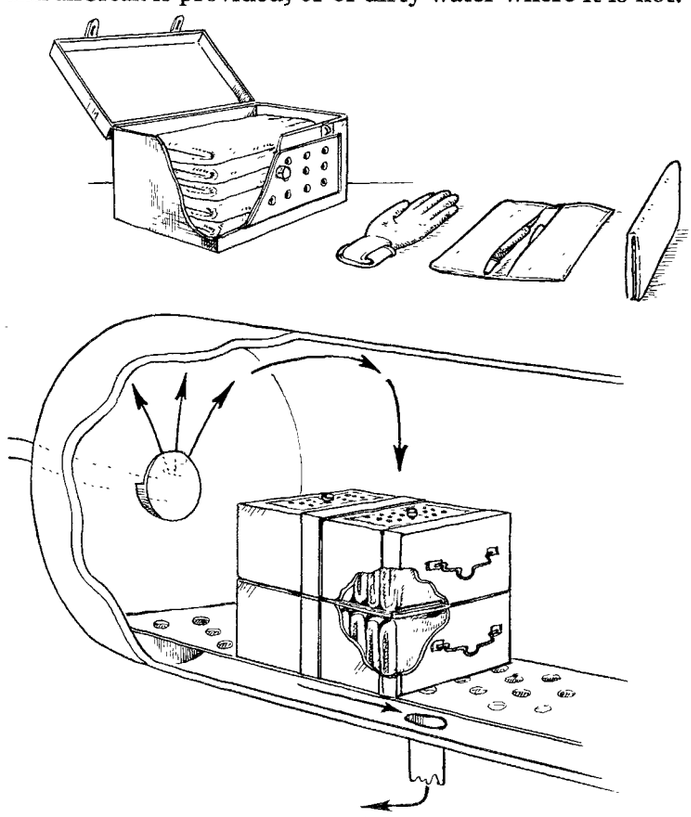

Fig. 2—Top figure shows, from left to right, a container for gloves properly packed ready for insertion into a steriliser; a glove folded and lined with gauze; a pair of gloves packed in fabric envelope; and a fabric envelope on edge to show its correct position during the sterilisation.

Lower figure shows a container as actually loaded in the steriliser. Note that the envelopes are set on edge by turning the container so that the steam passes directly from above downwards through the holes. The air and condensate are discharged below through the vent.

A more common cause of recontamination is an inadequate air filter.

Recontamination During Drying

In many hospitals it is the practice to dry dressings by drawing warm filtered air through them for periods which appear to range from eighteen minutes to several hours. The longer periods are sometimes due to forgetfulness on the part of the operator, but they are sometimes adopted because the dressings have been allowed to become soaked during sterilisation, so that prolonged drying is required to render them acceptable to the surgeon. For this purpose drying periods of one to three hours are common. (We have heard of one hospital where drying was being completed by leaving the drums with their ports open on top of a hot water radiator.)

The outstanding drawback to this practice is that with the filtration methods currently employed it is technically extremely difficult to ensure the sterility of the air drawn into the steriliser. In the first place its temperature is often in the region of 56°C, and since dry air at this temperature has little if any bactericidal power the sterility of the air depends on the efficiency of its filtration. In the second place many sterilisers have no provision for filtration of air: others provide filters which do not merit the name.

In many sterilisers the filters are maintained by the occasional insertion of pieces of cotton wool or other fabrics. Sometimes these are well chosen, adequate in size, and carefully sterilised. Much more often the filter cup contains an ill-fitting plug of dirty cotton wool—or nothing. In such circumstances dressings have been found to be contaminated with a great variety of bacteria, including most often saprophytic staphylococci and diphtheroids, but also, and not infrequently, *Staphylococcus aureus* and *Clostridium welchii* (Howie and Timbury 1956).

At present the best known way of avoiding recontamination during drying is to ensure that the dressings are dry at the outset, to use dry steam, and to draw a vacuum of 20 in. Hg after sterilisation. The vacuum need not be held even for five minutes (see sections, above, on Drying and on Incorrect Timing of Sterilising Runs) as is commonly advised, and should be broken by admitting air from a clean source through an air filter. The filter may be a metal cup which should be filled with a dry sterile plug of slag wool or non-absorbent cotton wool; this should be replaced daily and never allowed to become wet. Specially designed filters with or without a cotton wool plug may prove more satisfactory (Rice 1958).

In addition to the main air inlet many sterilisers have one or more petcocks connecting the chamber with the exterior; obviously these must also be provided with efficient air filters.

Recontamination during Removal, Transport, and Storage

A load may become contaminated during its removal from the steriliser, in transport, and during subsequent storage in wards or theatres. In some wards 23% of the dressings have been found to be contaminated (Darmady et al. 1959).

After sterilisation a typical sequence of events is as follows:

As the drums cool, air from the surroundings is drawn through the ports and through the space between the lid and rim. After a variable interval the vent over the ports is closed. The drums are hot, and a rough pair of gloves or a heavy duster or piece of sacking is commonly used to handle them; the attendant is not dressed in sterile clothing, nor does he wear a cap or mask. Frequently the drums are old and dented, so that the ports can be closed only with difficulty if at all, and the gaps between the ill-fitting lids and the rims afford a permanent

means of entry for the dust of the sterilising room—which is often sited near a source of gross dirt. For these various reasons it is essential that there should be protective material covering the ports inside the drums.

When the drum is opened, in theatre or ward, the protective material is either discarded or folded back. In either case there is a grave risk of further contamination, either immediately or on subsequent reopening. This may take place simply through contact with the surrounding air, by means of the forceps used for the removal of individual articles from the drums, or through the nurse who removes or uses the articles.

The Operation of Sterilisers by Uninstructed Staff

It will have been seen that steam sterilisation is a complicated technical procedure requiring not only that the apparatus should be in good working condition and not of obsolete design, but also that the operator should have a thorough understanding both of the underlying principles and of the practical procedures involved. There is a clear need for these important matters to be made the responsibility of a single member of the medical staff.

In practice, however, most surgeons assume the sterility of all goods treated in pressure-steam sterilisers. In effect they almost always delegate responsibility for the working of the steriliser to the theatre superintendent, and through her to nursing staff or attendants. It is a fault of present-day arrangements that the specialised knowledge of the engineer and of the bacteriologist is not regularly used to support that of the nursing staff in the supervision of sterilising procedures.

More often than not the engineer is only called in when things are visibly wrong, and his main concern is often simply to ensure that the apparatus fulfils safety requirements. Similarly, bacteriologists may not be called in until treated dressings are found to be contaminated. Even then they may mistakenly base their advice on their experience with laboratory or pharmacy autoclaves, which are simple to operate, and so overlook the much greater problems involved in sterilising dressings.

Laboratory autoclaves are mostly used for sterilising media, fluids, and unwrapped instruments and bowls, and they do this with a gratifying efficiency which, moreover, is automatically checked, at least for bacteriological media. A flask of fluid or agar medium in a laboratory autoclave producing steam under pressure of 15–20 lb. per sq. in. will be sterilised in fifteen minutes or less, even if there is no gravity discharge mechanism to get rid of the air. Such a procedure is not comparable with the complex operation involved in effecting the penetration by steam of a load of dry surgical dressings so that all air is displaced and steam of sterilising quality reaches every fibre of every article of the load.

Nursing staff tend to apply in all circumstances the sterilising methods they were taught when first instructed in the use of surgical sterilisers. We know of many instances where potentially efficient sterilisers were being wrongly operated according to a card of instructions clearly modified to fit the ideas of someone who had not realised that sterilisers are not all alike. Reports have also been received of junior nurses suffering or narrowly escaping serious accidents through opening or trying to open the doors of sterilisers containing steam still under pressure. Evidently, then, the tuition of staff needs greater emphasis as regards both the general principles of sterilisation and the detailed operation of different types of sterilisers.

Concerning the latter, an immediate improvement could be effected by the relabelling of all valve-control handles on existing sterilisers with their names (e.g., " steam to chamber "; " air filter "; " vacuum ", and so forth), instead of with letters or numbers. It would then be possible to issue unequivocal and standard instructions at least on the general principles of operating a steriliser of any reasonable pattern with some degree of certainty that the instructions would not be reduced to confusion by the different functions of control handles labelled A, B, C, or 1, 2, 3, on different sterilisers. Indeed, where complicated and dangerous pieces of apparatus are likely to be operated by persons who are not familiar with the procedures involved, a sound precaution is to make their operation as fully automatic as possible, and it is recommended that this should be applied to sterilisers.

Defects of Installation and Maintenance

It is of great importance that sterilisers should be correctly installed and that there should be adequate arrangements for their maintenance. At the present time the development of defects is usually unforeseen and breakdowns are therefore not prevented. This situation would be improved by the provision of more trained maintenance staff.

DEFECTS IN INSTALLATION

Defects observed include:

1. *Incorrect Siting*

Sterilisers should be installed only in places that are clean and free from obvious sources of infection. Theatre suites are not the places for sterilising dressings because these may be contaminated initially with spores and other micro-organisms.

2. *Steam Supply of Poor Quality*

The pressure head of steam is often too low or inconstant, heat insulation may be absent or insufficient, and condensate trapping or separation inadequate. The supply pressure at the site of installation, whether the steam is generated in a boiler-house at some distance from the steriliser or in a high-pressure boiler adjacent to it, should be constant and at least 20 lb. per sq. in. above the pressure used in the steriliser.

3. *Incorrect and Insanitary Connections with Service Pipes*

Air breaks should be provided at the steriliser, so that there is no direct connection between the steam jacket or chamber discharge channels and condensate returns, water mains, and common drain pipes.

4. *Inefficient Steam Venting or Condensing*

In many sterilisation rooms, waste steam from sterilisers, instrument boilers, and similar apparatus is discharged directly into the room. This not only causes much damage to walls and ceilings, but, what is more important, it permits breaks in aseptic technique; with pressure-steam sterilisers the discharge is often noisy and disturbs the surgeon.

5. *Unhygienic Mounting*

Sterilisers should preferably be built into a cabinet or panel, and not mounted in the open as is commonly the case; they should, however, be easily accessible to inspection. When sterilisers are " built in ", the ventilation shafts of the recess or cabinet should be conducted to atmosphere outside that of the theatre suite, and not directed backwards into the sterilisation room.

6. *Insufficient Sterilisation Space*

This is very evident, particularly with regard to packaged equipment such as casketed or wrapped dressings for use in busy surgical units. Since most existing dressing sterilisers are cylindrical and deep, usable space is still further reduced and loading and unloading is awkward.

DEFECTS IN MAINTENANCE

Defects in maintenance include:

1. *Lack of Cleanliness*

Arrangements seldom exist for the regular cleaning of either boilers or sterilisers for instruments and bowls. Steriliser

chambers, discharge channels, chamber walls and fittings, and headring drains all require regular attention; many air-filter cups are never opened.

2. *Instruments Out of Order*

Pressure gauges may not function properly, either because the hollow "Bourdon" tube is punctured, or, more often, because the gearing has been out of adjustment for a long time, so that the indicating pointer never reaches gauge zero and the pressures indicated are always several pounds per square inch too high. Similarly recording thermometers and pressure gauges may often remain out of adjustment for long periods. Records of pressure are sometimes misleadingly translated into temperature by the incorrect use of temperature charts with pressure-sensitive recording apparatus. It appears that indicating thermometers and temperature recorders are seldom checked at regular intervals with a standard thermometer or with the pressure gauges of the steriliser.

3. *Leakages in Gaskets, Stop Valves, and Safety Valves*

Such leakages are often allowed to persist for very long periods before adjustment, repair, or replacement by the engineer.

4. *Blocked Discharge Channels*

These blockages are often due to the accumulation of foreign matter. Sleeves and steam strainers are generally dismantled only after the channel has become choked—in spite of the fact that they are specially designed for easy maintenance. Steam traps are seldom checked for correct functioning, and really efficient "near-to-steam" traps are mistakenly replaced by traps designed for heating apparatus other than autoclaves. At least one outbreak of postoperative tetanus has been proved to be due to a blocked discharge channel (J. W. Howie, personal communication).

5. *Damaged Door Fittings*

Hinges, gears, and other door fittings, including safety mechanisms, are seldom tested for efficiency or maintained in proper functioning order, but are repaired only when they become unworkable. Lack of maintenance work on doors not infrequently leads to such dangerous practices as the use of a lever to secure or open a steriliser. It should perhaps be emphasised that inspectors employed by insurance companies dealing with sterilisers are concerned with the safety of the steriliser—not with the safety of the operator or with steriliser design in relation to sterilising efficiency.

SOME MISCELLANEOUS QUESTIONS

The Sterilisation of Instruments

Small pressure sterilisers that are efficiently designed and operated are wholly preferable to boilers for the sterilisation of clean instruments. For one thing they eliminate all temptation to dip an instrument in water presumed to be boiling and hurry it to a waiting surgeon. The dangers implicit in such a practice are not fully realised. If traditional instructions to boil for twenty minutes were to be faithfully observed, the advantages of sterilising instruments for a few minutes in small pressure-sterilisers would soon be fully recognised.

On grounds of function and economy, pressure-sterilisers to be used only for the sterilisation of unwrapped instruments and bowls need not be of rectangular form. For routine use with a loading carriage inside the chamber a convenient size is approximately 24 inches in diameter and 40 inches in length. If the apparatus is to be used only for the emergency sterilisation of a dropped or forgotten instrument, the size may be limited to approximately 8 inches in diameter and 22 inches in length. A steam jacket is not essential, but its use enables the operator to complete the process of sterilisation more rapidly. Since air in the chamber and between individual articles of the load is easily and rapidly flushed from the chamber by way of a suitable vent and bleeder valve [3] on the discharge channel, and since the load may be flash-dried after sterilisation, a preliminary vacuum for the extraction of air or a vacuum for drying the load after sterilisation is unnecessary, and, in fact, prolongs the process time. In general-purpose, high pre-vacuum pressure sterilisers, however, there is no other objection to the use of these vacua; the use of a 28 in. Hg vacuum for drying results in rapid cooling of the load.

The most suitable design for instrument and utensil pressure-sterilisers is more simple than that of any other form of steam steriliser—other than the cheapest domestic pressure cooker—and many sterilisers in existing theatres may be converted with ease to this specialised use (Bowie 1958 b). Provided instruments and bowls are clean, the appropriate process of sterilisation merely involves the transfer of heat and humidity to the freely exposed solid surface of the load. There is no need to allow time for steam penetration and "heating up"; so the chamber pressure gauge and the discharge-channel thermometer are safe guides to the conditions of exchange at the load surfaces. From the time the chamber thermometer indicates the temperature selected for sterilisation, the total requisite holding period for sterilisation and for a suitable safety margin is confidently recommended as fifteen minutes at 121–123°C or as three minutes at 132–134°C. These are the sterilising temperatures most commonly used; but it must be understood that they represent the two extremes of an acceptable range, limited on the one hand by excessive time and on the other by excessive cost. Within this range any convenient temperature may be used, provided that it is held for an appropriate time.

The process of sterilising unwrapped instruments and bowls is so simple and so rapid (less than five minutes at 132–134°C) that operation by means of manually operated stop valves is justified, although semi-automatic control (camshaft or multiport valve) is safer, and fully automatic control is safer still.

A typical operation of such a steriliser is as follows:

With jacket pressure gauge indicating 32 lb. per sq. in. (or 17 lb.), chamber loaded, door secured, and chamber vent open, steam is admitted to the chamber; air is extruded by way of the vent and the chamber is filled with steam more rapidly than could be effected by means of a preliminary vacuum. When the pointer of the thermometer has passed 100°C the vent is closed. The chamber pressure gauge indicates the rapidly rising pressure, closely followed by the thermometer. Residual air is evacuated through the discharge-channel bleeder. When the thermometer indicates 132°C (or 121°C), timing of the three-minute (or fifteen-minute) period of sterilisation is begun. When this is over the steam-to-chamber valve is closed and the chamber abruptly vented through a wide-bore discharge-channel or vent. When the chamber pressure reaches gauge zero the door may be opened; the unwrapped instruments and bowls dry instantaneously.

The Sterilisation of Bottled Fluids

The process of sterilising hydrated fluids is relatively simple, because any contaminating bacteria will already be moist and their destruction merely necessitates heating the fluid in each container to the appropriate temperature and holding it there for the appropriate time, e.g., 121°C for twelve minutes (Perkins 1956) or 115°C for thirty minutes (*British Pharmacopœia*). The usual procedure is:

1. To admit steam slowly through an inlet near the top of the chamber until the air in the chamber is displaced through the discharge channels in the bottom of the chamber and the temperature of the contents is raised to the required point.
2. To hold the temperature at this point.
3. To exhaust the steam to atmospheric pressure over a period of not less than ten minutes.

For convenience the steriliser should preferably be

3. On this type of steriliser an automatic steam trap, although effective, would be less rapid.

rectangular in shape and fitted with trays or a carriage on which the bottles may be placed. To avoid corrosion due to the spilling of liquids during sterilisation the chamber should be lined with nickel; alternatively it may be washed out thoroughly after each run or sprayed with a corrosion-resistant layer. No vacuum-producing apparatus is necessary, since downward displacement is quite satisfactory for removing the air, and drying is not required. It is not essential for the sterilisers to be jacketed provided they are efficiently lagged, and in this country many of our largest jacketed pressure steam vessels—often at present functioning inadequately as dressing sterilisers, particularly in central sterilisation rooms—could easily be converted for use as sterilisers for bottled aqueous solutions.

Where possible, sterilisers for bottled fluids should have multiple discharge channels, particularly if the chamber is large. These discharge channels may be fitted either with one or more near-to-steam balanced pressure traps (Northcroft 1956) or with a manually operated stop valve with or without a " bleeder " or by-pass. The heating-up time within the containers depends, of course, upon their wall thickness and volume. G. Sykes (personal communication) gives the following times as those required to heat containers of various sizes in flowing steam:

	Room temperature to 100°C	100°C to 115°C
100 ml. bottle	7 min.	3 min.
1 pint bottle	22 „	10 „
5 litre flask	40 „	15 „

In large containers heat " layering " may be present. Sykes found that in an 8-litre flask there was a twenty-five minute difference between the rates of heating in the top and bottom layers of the liquid. For this reason it is an advantage to have a thermometer actually in the fluid to be sterilised (Bowie 1958b); but, if such containers are being used repeatedly for bottled fluids, once an adequate cycle has been determined experimentally it can be controlled subsequently by the thermometer in the chamber drain.

Since bottled fluids may be required for intravenous injection it is essential that they should be pyrogen-free, and it is worth remembering that no amount of sterilisation will remove pyrogens from solutions already contaminated. Adequate steps should therefore be taken in the preparation of such fluids to ensure that they are not contaminated. This will also enable the minimum exposure period to be used; this is an important factor because a sterilisation cycle for bottled fluids takes considerably longer than one for instruments or fabrics. Unduly prolonged exposure periods should be avoided since deterioration of the properties of the solutions may result (Thiel et al. 1952).

In order to avoid excessive breakage due to heating or cooling the bottles too quickly, dialled flow-regulators may with advantage be fitted to the chamber steam inlet and to one of the discharge channels; thus the time taken to raise and lower chamber pressure before and after sterilisation may be controlled automatically (Bowie 1957). The appropriate intervals can again be determined by experiment with standard loads so that the regulators will not need further adjustment. It is, of course, possible, though probably less satisfactory, to control the sterilisation cycle by means of the more ordinary pattern of stop valve. In this case it is highly desirable that the position of the various valves (all of which should be clearly labelled with the function peroformed) should be standardised in relation to each other, and to the gauges and steriliser container.

The Tank Form of Steriliser

This type of steriliser was developed at a time when surgical teams were almost entirely self-supporting as far as the preparation of surgical equipment was concerned. Even the best designs are necessarily most complicated, and theatre staffs find their operation both lengthy and confusing. In any case, the continued sterility of the contents cannot be assured, since stop valves and delivery faucets cannot in practice be made bacteria-proof. In America they have long since been regarded as bacteriologically unsafe, and there they have now become obsolete owing to the supply of sterile fluids in bottles, including wash-basin fluids for the surgical team at the operating table. The bottles are stored within surgical suites in warming cupboards at temperatures suitable for immediate use; each bottle has a special pouring lip the sterility of which is preserved by a hermetically sealed cap (Perkins 1956) suitable for repeated use. On the Continent of Europe there has been a similar development, and we recommend the practice in this country.

The Use of Packs Instead of Drums

Wrapped packages of surgical dressings and other goods for use in the theatre and wards possess many advantages:

1. Two wrappings are used, the outer being handled by the " dirty " nurse, the inner being taken and handled only by the " clean " nurse.
2. There is no risk of aspiration of dust and air on cooling, since there is no rigid container.
3. Dressings or other materials sufficient for only one procedure are put in each pack, so the question of reopening does not arise.

The disadvantages of packs are:

1. More detailed packing is called for.
2. A relatively large number and variety of packs needs to be prepared and kept in hand.
3. Provision must be made for suitable cupboard space for their storage. These storage cupboards should have perforated shelves, close-fitting doors, and dust-proof vents, and they should be slightly warmed to ensure that they are thoroughly dry.
4. Care must be taken to exclude insects and to prevent contamination of the packs by wetting. This risk can be minimised by the use of such plastic wrappings as allow the passage of steam but not of water or bacteria.

It will be seen that the advantages of packs far outweigh the disadvantages, especially where the only dressing sterilisers available are of the downward-displacement type.

THE TESTING OF STERILISERS

From what has been said earlier it will be realised that the chamber-drain temperature record (or the temperature inside a standard dummy load) is the main indicator of whether a steriliser is working correctly and whether the load is receiving an adequate heat treatment. Even with a perfectly designed and completely automatic steriliser, and with correctly packed and positioned loads, there will always be occasions when a test of the overall efficiency of the sterilising process is desirable. There are two methods of testing: one uses bacteriological preparations, and the other uses chemical indicators.

Although in theory spore preparations provide the most realistic test, in practice the results may be dangerously misleading unless such preparations are carefully prepared and tested for heat resistance. The commonly used mesophilic organisms are unlikely to provide an adequate safety margin, and thermophils may be too heat-resistant and lead to needless rejection of a sterilising procedure. Soil samples are very variable and often too resistant. Satisfactory spore-papers can be made from *Bacillus stearothermophilus*, a non-pathogenic thermophilic organism; for spore-papers the minimum heat resistance should be five minutes at 121°C or one minute at 130°C. However, even with a satisfactory spore preparation there must be a delay of several days before the results of the test are known.

Chemical indicators have the advantage of being standard in performance and readable immediately the test is done. While the ideal chemical indicator has yet to be devised, the Browne's tube (type I—dressings) has been found by a number of authors to be satisfactory in the ordinary downward-displacement steriliser (Howie and Timbury 1956, Scott 1957, Alder and Gillespie 1957, Nuffield Provincial Hospitals Trust 1958). If used intelligently and stored correctly it probably provides the best routine test now available for this type of steriliser. There can be no justification for using a less exacting test for gloves (cf. section on Incorrect Treatment of Gloves), and in this respect the type-II Browne's tube is not recommended.

High-vacuum sterilisers are fully instrumented and automatically controlled, and once a sterilisation procedure has been laid down and checked with suitable spore preparations the temperature record should provide an adequate assurance of sterility. An additional safeguard is probably desirable; although at the high temperatures used, Browne's tube type I has too great a safety margin, and even the type II tube may be too insensitive, but it may be taken that if the latter turns green during a high-vacuum sterilising cycle a satisfactory heat treatment has been given.

In general, we suggest that spore preparations should be used only for assessing new techniques or equipment, for research purposes, and for occasions when a rigorous " full-dress " inspection is needed for administrative or forensic reasons. Such preparations must be of known resistance to heat. For routine tests with downward-displacement sterilisers chemical indicators should be used (Kelsey 1958).

In addition to tests for adequate sterilisation, tests for subsequent recontamination should be carried out from time to time (Howie and Timbury 1956), cf. section on Recontamination of Sterilised Loads; such tests can be done by culturing clean swabs placed in the outermost layer of the contents of packs or drums. If satisfactory air filters are provided this need not be a routine test.

It must be emphasised that a daily inspection of the temperature record by a responsible person is of more importance than the most elaborate laboratory tests carried out at long intervals.

REPLACEMENT POLICY

In deciding a policy for the replacement of inadequate equipment it is of course necessary to take account of any existing equipment and the uses to which it may still be put, as well as considering what new equipment is essential. In this section, therefore, the capabilities of the various kinds of sterilisers are summarised and examples are given of the ways in which the old equipment may best be used in conjunction with new.

Existing Equipment

Sterilising equipment currently in use in hospitals may be classified according to functional design:

1. *Boilers* of various kinds, operating at atmospheric pressure and used for instruments and utensils, and for water and saline.

2. *Tank forms of autoclaves* for water and saline.

3. " *Dressing sterilisers* ".—In practice the instruments so designated include sterilisers of all shapes, sizes, age, and design. They are of great importance because they are used for the final preparation of all categories of medical and surgical equipment suitable for sterilisation by steam under pressure. It is a serious matter, therefore, that such sterilisers are often improperly designed, installed, operated, or maintained, and cannot therefore be relied on for the sterilisation of packaged loads.

4. *Modern steam sterilisers.*—These include:

(*a*) *Downward-displacement sterilisers* of specialised design used for:

(i) unwrapped instruments and utensils. These sterilisers are of horizontal cylindrical shape. Some are controlled by hand-operated stop valves, some by a single hand-operated wheel, and a few by automatic devices. Small sizes are suitable for the rapid processing of a single dropped or forgotten instrument, larger ones for routine use;

(ii) bottled fluids. These sterilisers are rectangular and their chamber capacity is generally greater than 25 c. ft.;

(*b*) *High pre-vacuum sterilisers* with automatic control, used according to size, as follows:

(i) small sizes for unwrapped instruments and utensils;

(ii) large sizes for packaged equipment (casketed or wrapped);

(iii) sizes of capacity up to 9 c. ft. are supplied as general-purpose sterilisers for all categories of equipment suitable for sterilisation by steam under pressure.

Procedure Recommended

It is considered advisable that all hospital boilers operating at atmospheric pressure and used for sterilising instruments and utensils should be replaced by pressure-steam sterilisers of type 4 (a) (i) or 4 (b) above; also that boilers and tank forms of autoclaves for water or saline should be replaced by type 4 (a) (ii), and conveniently located to serve the whole hospital. For the storage of sterile water and saline an adequate supply of bottles with special caps that preserve the sterility of the contents and of the pouring lip might be said to be a necessity.

Depending upon their design, size, and shape, existing and serviceable downward-displacement " dressing sterilisers " will be best employed in such places as ward preparation rooms, hospital laboratories, and pharmacies; in minor theatres that are used only once or twice a week; and for the disinfection of mattresses. Alternatively they might be converted, as appropriate, to fill one of the roles outlined in 4 (a) above. In this way, all serviceable sterilisers, many of them at present functioning inadequately as " dressing sterilisers ", could be used to advantage for purposes within their operational capacity.

It is recommended that when new sterilisers are purchased those to be used for the treatment of packaged equipment should always be of the high pre-vacuum type, automatically controlled, and preferably rectangular in shape for more efficient packing. The proposed location will determine the size to be chosen, which, for efficiency, should not exceed approximately 26 c. ft. and probably not exceeding 9 c. ft. where the steriliser will be used for general purposes.

In output of sterile packaged equipment per hour, a well-designed, high pre-vacuum general purpose sterilizer of 9 c. ft. (with essential automatic control) is equivalent to the most efficient downward-displacement steriliser of 40-50 c. ft., with or without automatic control; also, in high-vacuum apparatus, unnecessary damage to heat-sensitive materials is avoided.

Essential Features of the Modern Automatically Controlled High-vacuum Steriliser

General

Since the Working Party are of the opinion that the high-vacuum steriliser should replace many other types, the main requirements for its operation are outlined. It is essential that means should be provided for drawing a high-vacuum before admission of steam, and for maintaining at the same time a steam pressure of up to 34 lb. per sq. in. in the jacket, if one is present, and a vacuum

within a few mm. Hg of absolute pressure in the chamber. But this does not necessarily mean that the operating steam pressure need always be as high as 34 lb. per sq. in. For many purposes a pressure of 15–20 lb. held for slightly longer periods may be equally satisfactory.

The Chamber

There are obvious advantages in having machines of standard size, or of two or three standard sizes at most—the largest being about 25 c. ft. A rectangular chamber is the most convenient, and its dimensions should of course be such that containers of the most common sizes will fit it economically. The doors of the chamber (there may be one only or one at each end) should carry safety devices which make it impossible to open them when the chamber is under pressure, and they should also be insulated in such a way that the heat loss from the closed chamber is approximately the same in all directions. The chamber may be either steam jacketed or insulated.

The Steam

It would greatly facilitate the operation of sterilisers if manufacturers would undertake to state the range of variations in quality of steam within which each machine will operate efficiently. All machines should be fitted with devices to ensure that the steam entering the chamber is not superheated nor has a dryness fraction of less than 0·95, and that the steam entering the chamber is as free of air as possible. It is in any case essential that such devices should be attached permanently to the steriliser, so that its steam connections may be made to mains steam, a boiler, or its own generator. The jacket and the chamber must be supplied through the same reducing valve, or valves, set within the range 35–10 lb. per sq. in. The adjustment of these valves should not be possible by the operator. The condensate discharge pipe should be fitted with satisfactory means for air removal and for preventing reflux aspiration.

Air Removal

A pump should be provided which will reduce the absolute pressure in the chamber before the admission of steam to a very low figure. The figure suggested is 15 mm. Hg or below when the chamber is fully loaded with cotton fabrics containing 4% by dry weight of water, and having a temperature not exceeding 15° C. The pump should preferably be capable of reducing the pressure to this figure within five minutes. Such a pump will not remove all the air; but in practice, on the basis of temperatures actually recorded (Knox and Penikett 1958, J. H. Bowie, personal communication), it is acceptable. The steriliser is designed to ensure the removal of residual air continuously from the moment that steam is admitted to the chamber. In view of the difficulties discussed in the section on Removal of Air it is clear that more experimental evidence is required before standards of performance are rigidly defined.

Steam Removal

At the end of the sterilising operation the pump must be able to reduce the abolute pressure to 50 mm. Hg or less within five minutes. The same standard of performance should be possible after a number of successive runs.

Air Entry

A filter should be provided whereby sterile air can be admitted to the chamber after the removal of the steam. Apart from opening the door there should be no means of letting air into the chamber except through a device which ensures sterility.

Instruments

For the chamber, a large pressure and vacuum gauge and a large dial temperature gauge should be provided in positions convenient for easy reading. If two doors are provided two chamber-pressure gauges are required to prevent attempts from being made to open the door while the pressure within the chamber is still raised. An instrument for accurately reading absolute pressure in mm. Hg is required. The temperature gauge should have its sensitive element so placed that it records the lowest temperature in the chamber or load during sterilisation. A combined temperature, pressure, and vacuum pen-recorder operating from sensitive elements in similar positions to those operating the non-recording instruments should be provided. For the jacket, a pressure gauge is likewise required. Temperature and pressure gauges on the steam supply would be useful additions.

Controls

A simple control such as a wheel is the most suitable, and should be provided for automatic as well as for hand-controlled machines. In automatic machines, which are activated by sensitive elements which measure physical conditions within the chamber, the sterilising period must be controlled by the temperature of the coolest point in the load, and the exposure time must be in accordance with the accepted period for that temperature. Should there be a failure to achieve sterilising conditions, an alarm should sound and the chamber be vented to atmosphere. The pre-set controls should not be accessible to the operator.

Maintenance and Testing

It would be an advantage if manufacturers would provide with their machines a maintenance schedule and instructions for testing steam quality, gauges and the sensitive elements of instruments, and that where necessary—e.g., for testing steam quality—the necessary test valves were fitted to the machine.

Manufacturers might be encouraged to provide a monthly maintenance service, and to issue certificates of operational efficiency.

For a detailed discussion of the modern high vacuum steriliser, see Bowie (1958a).

Modification of Existing Sterilisers

Pending the replacement of downward-displacement sterilisers used for dressings by high-vacuum equipment, it is advised that every effort be made to upgrade them. By undertaking relatively simple modifications some can be made safe and effective. This may be done by carrying out ordinary engineering repairs, by fitting near-to-steam traps,[4] discharge-line thermometers, and air filters (Scott 1957), by running jacket and chamber at the same temperature, by providing a regular supply of dry steam, and by providing for a terminal vacuum adequate to remove steam from the chamber, thus ensuring simpler, quicker, and more thorough drying (Knox and Penikett 1958, Penikett, Robson, and Rowe 1958). Some sterilisers may be raised to high-vacuum status by the fitting of special pumps and automatic controls.

Some of the problems involved are helpfully indicated by Magee and Oakes (1958). These workers fitted a pump to a 120 c. ft. disinfector, with whose previous performance as a steriliser they were dissatisfied. The fitting of the pump produced considerable improvement although, as would be expected with so large a chamber, the results fell short of those

4. Such traps are now made by a number of manufacturers, who will advise on the choice of trap for any particular application. For recent studies on this subject, see Barson et al. 1958.

specified in this report as being attainable in chambers of 25 c. ft. or less.

CONCLUSION

It has been the aim of this inquiry to re-examine the requirements for efficient sterilisation by steam under pressure, and to discover how and why the conditions in many hospitals today apparently fail to meet them. An account is given of the principles and technical procedures of sterilisation by this method, and the more common defects leading to inefficient processing are described. Some immediately applicable remedies are described, and longer-term matters of policy are discussed.

It is the conclusion of the Working Party that while there are a number of causes contributing to inefficient sterilisation the underlying factor responsible for the situation as a whole is a widespread lack of understanding of the technical requirements involved. This in its turn is because no one member of the medical staff is given the final responsibility of ensuring the provision of suitable equipment and its proper use and control by specially trained operators. Until this is done, and until routine supervision of the sterilising apparatus by a member of the engineering staff is insisted upon, patients in many hospitals will continue to be exposed to the unnecessary hazard of infection caused by the use of imperfectly sterilised articles.

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ASPECTS OF PREVENTIVE CARDIOLOGY *

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(*Concluded from p.* 382)

II—THE RISE OF BIOCHEMISTRY

AN outstanding feature of 20th-century medicine is the advance of biochemistry. In that field are proceeding most of the present-day laboratory researches into atherosclerosis, and much may be expected from that biochemical approach.

Statistics on Atherosclerosis

In postmortem examinations of people over 50 years of age some intimal changes are to be seen in the arterial walls, although—even in the very old—the lesions may be slight in extent and degree, interfering little with the blood-flow. In life the condition may be practically symptom-free, recognisable only when obstructive complications come. We know atherosclerosis by its works, disturbing and often disastrous. Mortality figures give some indication, for nearly all cardiovascular-renal (C.V.R.) deaths in people over 50 are certified to be so caused. The fact that it is cessation of the heart-beat that constitutes the principal criterion of death doubtless accounts for some exaggeration of the number allocated to that category; cases of sudden death, for instance, are especially likely nowadays to be attributed to coronary thrombosis.

The need for caution when comparing figures from different countries has already been stressed. The range of crude death-rates (all causes) is from 767·7 (Netherlands) to 1206·0 (Belgium); rates for senility (B45) vary from 6·2 (New Zealand) to 225·9 (France)—for vascular lesions (B22) from 59·6 (Belgium) to 186·6 (Scotland). There are great differences, even in similar and often adjacent countries; but some of these are less significant than at first appears. They often reflect differences in the concept, reporting, and classification of causes of death (Lew 1957). The studies by Yerushalmy and Hilleboe are notable (1957).

The incidence of C.V.R. deaths in Australia for various age-groups is shown in fig. 9; the percentage change in several recent census years, using the year 1911 as the standard, indicates a continuing fall for all ages under 50, but increases for ages above that and for all ages combined. When, as shown in fig. 10, the figures for the senility and ill-defined categories (both small) are added to C.V.R. deaths, a decline in the rates is shown for every ten-year age-group, although the all-ages rate has increased—a curious possibility well known to statisticians.* Fig. 11 shows the rapid increase in Australia in the death-rate from coronary heart-disease since 1930. Fig. 12 shows the steady ratio of 2/1 in male/female death-rates from that cause for each year from 1940 to 1955.

Some investigators claim that the increase recorded in deaths from coronary heart-disease is largely an artefact. Lew (1957), for instance—reviewing a series of death certificates sent to the Metropolitan Life Insurance Company (New York)—finds that about 30% of the increase from 1940 to 1955 in the crude death-rate from coronary disease is accounted for by the greater proportion of old people, another 40% can be ascribed to statistical practices and classification, and most of the remaining 30% represents merely " the acceptance of a broader concept of coronary disease, better diagnoses, and increasing usage of the term coronary artery disease in certifying causes of death ". That is an extreme view. Most physicians think that deaths from coronary heart-disease, especially in middle-aged men, are commoner than they used to be.

* From the Milroy lectures for 1959, delivered before the Royal College of Physicians of London on Feb. 3 and 5.

* Being an amateur in statistics, I did not readily see how it could be possible for an increase in the death-rate for all ages to be compatible with a decrease in *all* of a series of subgroups. Playing with hypothetical sets of figures cleared the difficulty:

—	Ages	Population	Deaths	Death-rate
Year A	0–40	400,000	8	2
	40–	200,000	100	50
	All ages	600,000	108	18
Year B	0–40	200,000	3	1·5
	40–	400,000	160	40
	All ages	600,000	163	27