The development of isolators

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Summary
A series has been developed of closed-system isolators which provide patients with the same effective control of microbial infection as is possible in the laboratory animal. These isolators are used to protect susceptible patients from exogenous infection as well as to prevent the spread of dangerous pathogens from infected patients. The six models of isolators are designed for use in operating theatres, or on the wards and to transport patients.

Established isolation technique, whether used to contain pathogens shed by an infected patient, or to prevent infection in a susceptible patient, forms an open system in so far as the attending personnel work within the isolated space. The design has the advantage of causing minimum interference with the treatment and care of the patient but it has the disadvantage of making it impossible completely to prevent infection. A closed system gives an alternative technique; it utilizes a microbiologically impervious barrier which surrounds a given isolated space and excludes the attending personnel. This system has the advantage of effectively preventing infection but may present some interference with the treatment and care of the patient.

The security of closed-system isolation has been demonstrated by its widespread use in the maintenance of gnotobiotic animals, i.e. animals which are free from all microbes other than those transmitted via the placenta or egg, or deliberately introduced as pure cultures. Reproducing colonies of gnotobiotic rats and mice have been kept continuously in isolators since 1954, all the common domestic and laboratory animals (except the hamster) have been reared under these gnotobiotic conditions. The isolation system used for maintaining gnotobiotic animals is sufficiently versatile to accommodate practically any laboratory procedure (Coates, 1968; Heneghan, 1973). The continuous maintenance of reproducing colonies of animals free of microbial flora is undoubtedly the most rigorous test of the effectiveness of microbial isolation; this is because such animals provide (1) a great variety of culture media; (2) cumulative contamination, since any microbes introduced accidentally remain in the colony until they multiply sufficiently to be detected; (3) widely distributed groups in many laboratories where they are examined extensively for the possible presence of contaminating microbes.

Although several different types of isolator have been developed for use in the hospital none has been widely used. Before the programme reported here, isolators had been developed either for limited research objectives (Levenson et al., 1964; Dietrich and Fliedner, 1973) or to exploit a patented device (Shadomy et al., 1965; Saint Martin, 1973). Over the past 5 years, a series of hospital isolators has been developed at the Royal Veterinary College in collaboration with several medical teams; this programme has been sponsored jointly by the National Research Development Corporation and the Medical Engineering Division of Vickers Ltd. The purpose of the development has been to provide patients with the same efficient control of microbial infection as is possible in the laboratory animal.

Experience with the management of both gnotobiotics and laboratory animals infected with dangerous pathogens has established the following features of closed-system isolation: (1) Effective control of microbial contamination can be achieved; (2) the apparatus can be operated routinely by personnel with no training in microbiology; (3) the apparatus 'automates' contamination control and enables personnel to devote more attention to other aspects of their work; (4) effective apparatus and work routines can be designed for practically any application.

The requirements of our hospital isolation programme include all the above features and the additional need for the apparatus to fit readily into hospital routines; it must also have a positive cost-benefit. Close liaison with hospital staff during the development programme has helped to keep our designs compatible with hospital routines. A clear-cut cost-benefit is more difficult to measure. Microbial contamination affects many aspects of hospital design and management as well as having an immediate impact upon the treatment and care of the patient, all of which makes a cost-benefit analysis
seem futile until firm designs and procedures have been established for an application of obvious merit.

A typical closed-system isolator used for managing gnotobiotes (Fig. 1) consists of the following: (1) A flexible plastic envelope enclosing the isolated space; (2) a means for manipulating within the space, e.g. gloves or half-suits; (3) ventilation, usually through filters attached to the envelope wall; (4) a means for introducing and removing supplies, e.g. a sterile lock or germicidal dunk-bath; (5) cones of flexible film to enable wires and cables to be passed through the envelope wall as needed. To exclude contamination from an enclosed space, the isolator is maintained under positive pressure: to protect the space outside from contamination, the isolator is maintained under negative pressure.

The isolators we have developed for clinical use are based upon the principles used for animal isolators but they differ in at least two respects:

1. Thinner films and gloves are used to ease manipulation. While this does not greatly increase the risk of leakage, it is advisable to operate any isolator as if it leaked rather than to depend upon taking precautions after a leak has been detected. The maintenance of a pressure differential prevents airborne contamination but contact contamination can occur if a glove or other portion of an isolator is punctured. Isolators containing patients with highly dangerous pathogens should be maintained in isolation rooms or wards; the use of an isolator would greatly reduce the risk to attending personnel.

2. The usual method of introducing sterile supplies into isolators in the laboratory is not suitable for routine use in the hospital because of the time it takes and the unpleasant odour of the peracetic acid solutions used. A universal port (Fig. 2) has been developed recently in which (i) wrapped sterile supplies can be introduced against an emerging stream of sterile air, (ii) a sterile drum can be attached to a replaceable plastic cap and the contents introduced by cutting a passageway through the cap and drum closure, (iii) plastic bags containing sterile supplies can be attached for introduction in the same way, (iv) for containment isolation, supplies can be placed in an open bag, attached to the port and introduced through a passageway cut in the port closure; materials can be removed from the isolator in this bag which is then sealed off and cut, leaving the port closed and the materials in a separate sealed bag.

The first production isolator developed was designed for orthopaedic surgery (McLauchlan et al., 1974). It consists of a sterile transparent envelope which encloses the operating field and is attached to the skin of the patient by a standard adhesive surgical drape which forms a portion of the floor of the isolating envelope. The surgical team works through replaceable gloves attached to sleeves continuous with the isolator wall. Instruments and supplies are prepared in the usual way, double-wrapped and introduced against a stream of sterile air emerging from a horizontal entry port. This isolator and its operation will be described by Mr McLauchlan in the following paper.

Several prototype wound isolators have been developed; these are cemented to the site of a wound in the same way as the surgical isolator and the patient managed in the normal way without breaking isolation or examination and treatment without contamination of either wound or environment.

A series of isolators has been developed which, effectively, either protect a susceptible patient or contain dangerous pathogens. The patient enters the isolator through a port closed by a replaceable cap similar to that of the universal port. Once within the isolator a patient can be transferred to other units without breaking isolation and can remain isolated for any length of time during which he can be moved to other areas within a hospital, over to other hospitals, across continents and even returned home! This isolator system (Fig. 3) consists of five variations, namely (1) supply, (2) bed, (3) cot, (4) intensive care unit, (5) transit isolator.

The supply isolator (1) is the central working unit since it has a work space for the preparation of medication and food, provides for the introduction of the majority of supplies and contains storage space. This isolator is connected to the others by means of the large (80 mm x 65 mm) patient entry port and can operate satisfactorily under either positive or negative pressure.

The bed isolator (2) consists of a rectangular envelope of plastic film (approximately 1·9 m long x 1·8 m wide x 2·0 m high) that fits over a bed and is supported by a light metal frame. In order to simplify sterilization or decontamination, the mattress, bed, tables and chair remain outside the isolated space, each encased in a plastic film pocket so that they
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remain as useful as if they were actually within the isolator; the pockets are continuous with the isolator wall. The patient enters the isolator through an entry port at the foot of the bed either lying on a stretcher or by climbing in himself and then remains confined to the bed and its walk-space which lies along one side of the bed and into which a chair or commode may be fitted. The medical and nursing attendants are accommodated in half-suits and gloved sleeves continuous with the envelope wall. All the instruments required for examination and treatment may be used either from within the isolated space or from the pockets or invaginations of the isolating envelope. Ventilating air is passed through attached filters and the pressure can be controlled to maintain either a positive or negative differential across the isolator wall.

The cot isolator (3) is similar to the bed isolator in principle, the small size of its patient enables manipulations to be carried out through gloved sleeves rather than half-suits. To enable the attendants to reach across the cot, no supporting frame is used and for this reason a positive internal pressure is required to maintain inflation. This isolator is always used with a supply isolator and the universal port of the latter conveniently allows the introduction of the small patient.

The intensive care isolator (4) is similar to the bed isolator in construction and operation. It is modified to enable the attendants to reach the patient quickly.

Fig. 2. The Universal Port for passage of materials across the isolator wall. (i) Introduction of sterile supplies against an emerging sterile air-stream; (ii) introduction of the contents of a sterile drum through a replaceable film cap; (iii) introduction of sterile material from a plastic bag; (iv) introduction and removal of materials from a containment isolator using plastic bags.
Because the patient is usually confined to bed, much of the space otherwise used to keep personal articles and to accommodate the activity of the patient can be utilized for the more elaborate instrumentation required for the treatment and care of this type of patient.

There are two types of transit isolator (5); one is designed for positive and the other for negative pressure. The envelope is a plastic film tube with the same circumference as the patient entry port to which it is attached, and with six pairs of gloved sleeves along the sides for handling a patient on a stretcher—(a) the positive pressure model: in this the positive internal pressure used to protect the patient inflates the envelope which sits upon a ward trolley. The two ends of the envelope are closed by dia-}

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**FIG. 3.** The principal types of isolators for use on the ward. Top, supply and bed isolators; centre, supply and cot isolators; bottom, transit and bed isolators.
The closed-isolator systems described here have been developed over the past 5 years as a result of the hospital experience with prototype models based on an extensive background experience in the veterinary field. Only the surgical isolator is produced as an off-the-shelf item and is now on clinical trial: a ‘Mark II’ version of the isolator (Fig. 4) with a modified universal port is now in the prototype stage and, if this version proves successful, all the isolators will have a similar port device, which greatly simplifies personnel training and usage.

The development of all these isolators has reached a stage where they can be used in hospitals provided with adequate microbiological monitoring. For the next year, at least, the results of microbiological monitoring and nursing experience should provide information for further development to derive production designs. Using effective designs, clinical trials can be initiated, where appropriate, as well as cost-benefit studies.

It is felt that the use of adequate closed-isolation systems will have a considerable impact upon the design and operation of hospitals since effective microbiological isolation can be provided wherever it is needed. The automation of sterile and aseptic techniques will reduce the burden now associated with the established methods and any concomitant reduction in infection will be of benefit to all.

Simple but effective methods for maintaining sterility provide a new environment in which intractable diseases can be treated; and the few observations made on laboratory animals support the view that this is worth exploring. While the obvious benefits of infection control justify the use of isolation per se, the additional benefits accruing from a wider clinical use will provide a substantial bonus.

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References