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MICROBIOLOGICAL ASPECTS OF CLEAN ROOM TECHNOLOGY AS APPLIED TO SURGERY

—with special reference to unidirectional airflow systems

Jet Propulsion Laboratory
California Institute of Technology
Pasadena, California 91103

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Michael D. Wardle

Jet Propulsion Laboratory
California Institute of Technology
Pasadena, California 91103

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PREFACE

This work presents the results of one phase of research carried out at the Jet Propulsion Laboratory, California Institute of Technology, under Contract NAS 7-100, sponsored by the National Aeronautics and Space Administration's Applications Technology Office.

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CONTENTS

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CONTENTS (contd)

TABLES

CONTENTS (contd)

FIGURES

ABSTRACT

The microbiological aspects of clean room technology as applied to surgery were reviewed. The following pertinent subject areas were examined: (1) clean room technology per se and its utilization for surgery, (2) microbiological monitoring of the clean room surgical environment, (3) clean rooms and their impact on operating room environmental microbiology, and (4) the effect of the technology on surgical wound infection rates. Conclusions were drawn for each topic investigated.

SUMMARY AND OVERALL CONCLUSIONS

In its formulation and initial applications, clean room technology was aimed at controlling nonbiological environmental parameters. The demonstration of the clean room's value for the control of viable contamination in NASA programs and its merit in the reduction of postoperative wound infection rates as interpreted from European studies provided the basic impetus for the transfer of the technology to the operating room. The transfer has, to date, not seen the development of a standard that is definitive with respect to the microbial control afforded by clean rooms in the surgical context. Therefore, the environmental control provided by surgical clean rooms is often described per existing standards relating to the control of nonviable particulates. However, the surgeon employing this technology is not concerned about nonviable particulates (as were its originators and many of its present day practitioners), but, rather, he is interested in the environmental microbiologic control it affords and the effect of such on wound infection.

In line with the objective of microbiological control, the use of HEPA filtration, efficient at the submicron level, may not be necessary in light of data that indicate the preponderance of airborne surgical wound infection producing particles can probably be removed from incoming operating room air by filters efficient in the retention of larger size particles.

Human beings, rather than the air-handling system, account for the major contribution of microbial contamination in the modern operating room. Recent studies of surgical apparel systems, cited as effective microbial barriers, tend to indicate the feasibility of the rigid control of human source microorganisms in the operating room, as a technique capable of enhancing the clean room technology approach to reducing microbial contamination of the surgical wound.

There exists a great danger in total reliance on clean rooms for environmental microbiologic control; they cannot be depended on to compensate totally for improperly applied or faulty aseptic technique. Clean rooms, be they turbulent or unidirectional flow, are not in themselves the final solution to problems of control of the operating room's microbiological environment. For maximum benefit, technology applied towards this goal must

be tailored to its surgical use. Research in this area is not complete and efforts should be continued to define the most meaningful, effective and economical methods for regulating the microbial environment of the operating room.

It will require a large, controlled study to directly evaluate, in a statistically significant manner, t' e effect of the clean room on the incidence of postoperative surgical wound infection. However, pertinent data do exist that point to the value of a reduced level of operating room airborne microbial contamination in lowering the incidence of wound infection for certain surgical situations.

DEFINITION OF TERMS

The following terms are used throughout this document and therefore require special attention as to definition:

CLEAN ROOM (defined per Federal Standard 209 B (1973))	An enclosed area employing control over the particulate matter in air with temperature, humidity, and pressure control, as required; with a particle count not to exceed a total of 100,000 particles per cubic foot (approximately 3500 per liter) of a size 0.5 μm and larger, or 700 particles per cubic foot (approximately 25 per liter) of a size 5.0 μm and larger.
CLEAN AIR	Air issued directly from a HEPA filter (see page 9).

The clean rooms under discussion employ HEPA filtration, hence the terms clean room and clean air will be used interchangeably. Other terms are defined as they appear in the text.

SECTION I

INTRODUCTION

It has been estimated that one of every 13 surgical patients [illegible] a postoperative wound infection (National Academy of Sciences—National Research Council 1964) and that the cost of these infections runs into the billions of dollars per year (General Accounting Office 1972). In the sixties, unidirectional airflow (UAF—also referred to as "laminar") was introduced into the hospital operating room as a means of reducing the incidence of post-operative wound infection. Since that time, a controversy has been growing over whether clean air (i.e., air supplied via high efficiency particulate air (HEPA) filters) in general, and UAF in particular, is in fact effective in reducing such infections.

Infection control aims at identifying and evaluating factors that give rise to infection. Microbial contamination of the wound during surgery has been proposed as an event that, for certain surgical procedures, can lead to a postoperative wound infection. The following three primary sources of surgical wound microbial contamination can impact the operative stage: (a) contact: Microorganisms are introduced into the wound through direct contact by the physicians, instruments, etc.; (b) endogenous: The patient's own microflora invade the wound; and (c) airborne: Microorganisms are deposited in the wound as a result of an inadequate air-handling system or contaminating events in the operating room. Contact and airborne contamination are generally considered in terms of exogenous microorganisms, i.e., those not native to the patient. Traditional measures have been developed for guarding against all of these modes of wound contamination; however, the recent interest in clean rooms for surgical application has emphasized the need for further evaluation of the role of airborne microorganisms in surgically induced wound infections. The specific purpose of employing clean room technology in surgery is to control airborne contamination.

The move toward clean room surgery in America was, more precisely, a move toward unidirectional flow clean air. The UAF clean room was first described in 1962 (Whitfield 1962). It was initially used for surgery in

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January of 1966 at Bataan Memorial Hospital (NASA 1971). A recent survey of hospitals employing clean room facilities found that the number has grown from 23 in 1970 to well over 300 in 1972 (anonymous 1972). This survey included only surgical, in-hospital, or full-room (portable rooms included) patient care facilities. Portable UAF isolation beds were not enumerated; it was found that a vast majority of the recorded facilities employed UAF.

It will be the aim of this document to carefully review the status of clean room technology in surgery from the basics of the technology to its value in the reduction of postoperative wound infection rates attributable to microbial contamination of the surgical wound during the operation. Owing to the prevailing interest in the UAF method of supplying clean air, emphasis will be placed on this aspect of the technology.

Although it is recognized that clean room technology is employed in the hope of controlling infections other than those surgically induced, e.g., for the treatment of burn patients and immunologically deficient transplant and cancer patients, it is the aim of this document to confine the discussion to its application to surgery.

It is also to be noted that this document has restricted its definition of clean air to that supplied by HEPA filtration. This should not be to imply that similar results in terms of microbial air quality cannot be achieved by alternate means (e.g., other filtration methods, surgical isolators, ultraviolet irradiation, and chemical treatment). The present discussion will be styled to provide meaningful interpretation for other methods capable of reducing microbial contamination in the operating room air to levels comparable to the subject clean rooms.

SECTION II

CLEAN ROOM TECHNOLOGY

A. CLASSES OF CLEAN ROOMS

Several classes of clean rooms are generally recognized, i.e., Classes 100, 10,000, or 100,000 as defined by Federal Standard 209B (1973). (For a discussion of how Federal Standard 209B differs from its predecessor, 209A, see Garst 1973.) Federal Standard 209B makes reference only to the particulate control parameters to be expected and not to desirable microbial control conditions: It recognizes that airborne microorganisms are particulates and as such are reflected in the total particulate count of the different air cleanliness classes. Figure 1 shows the particle size distribution curves (with metric equivalents) as defined by 209B for the three classes of clean rooms. The curves indicate average particle size distributions that exist in the air. A Class 100 environment is one containing a maximum of 100 particles of 0.5-μm diameter and larger per ft^3 (3.5/ℓ). Class 10,000 environments have up to 10,000 particles (350/ℓ) of this size range and similarly for Class 100,000. These curves are plotted semilogarithmically, with the total number of particles per cubic foot (liter) expressed logarithmically. As an example, for the Class 100 curve where the X-intercept is just before the 5-μm size, the particle reading is 1 per cubic foot (0.035/ℓ), not 0. Were the curve to be extrapolated, one would expect there to be a finite, but low, frequency of occurrence of larger particles (e.g., 25, 50, and 100 μm).

Reference to performance of these rooms in terms of microbiologic control can be found in National Aeronautics and Space Administration (NASA) document NHB 5340.2 (NASA 1967). Table 1 shows the standards for microbial cleanliness set by this document (surface contamination levels are for horizontal surfaces). The NASA Standards document was developed as a direct extension of Federal Standard 209, to provide for definitions and degrees of microbiological environmental control in consonance with the United States policy (see Hall and Lyle 1971) for controlling the spread of terrestrial microorganisms to planets of biological interest by unmanned

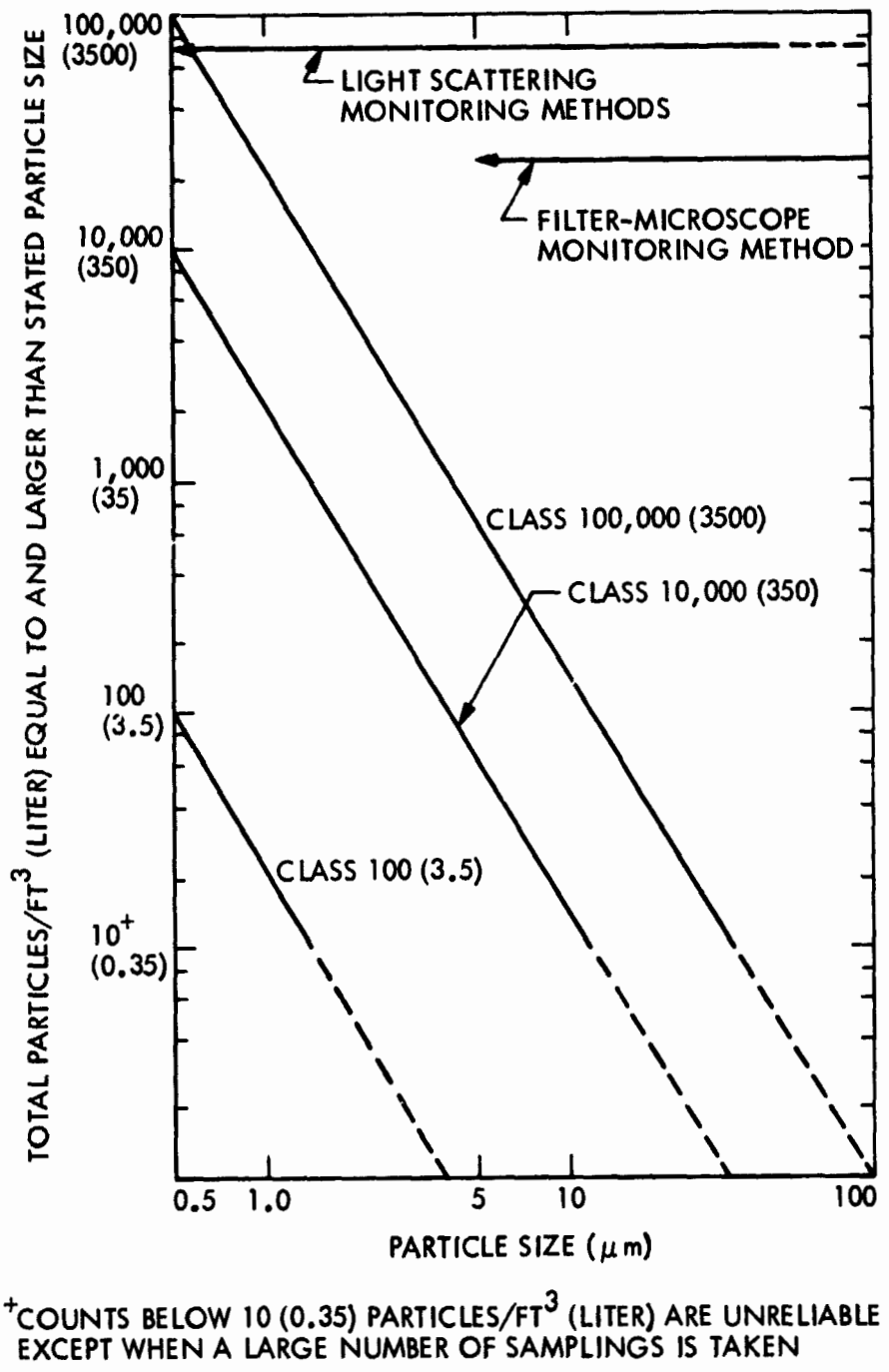

Fig. 1. Particle size distribution curves (Federal Standard 209B 1973)

Table 1. Air cleanliness classes (from NASA 1967)

Class English system (metric system)	Maximum number of particles/ft^3 0.5 μm and larger (per liter)	Maximum number of particles/ft^3 5 μm and larger (per liter)	Maximum number of viable particles/ft^3 (per liter)	Average number of viable particles/ft^2/week (per m^2 per week)
100 (3.5)	100 (3.5)	*	0.1 (0.0035)	1,200 (12,900)
10,000 (350)	10,000 (350)	65 (2.3)	0.5 (0.0176)	6,000 (64,600)
100,000 (3,500)	100,000 (3,500)	700 (25)	2.5 (0.0884)	30,000 (323,000)

*Counts below 10 (0.35) particles/ft^3 (liter) are unreliable except when a large number of samples is taken.

exploratory spacecraft. Recently, the American Society for Testing and Materials (ASTM) has been working to develop procedures for the assessment of microbiological contamination in clean rooms (anonymous 1972).

B. HIGH EFFICIENCY PARTICULATE AIR (HEPA) FILTERS

Many types of clean rooms exist (see below); however, they usually have one feature in common — the use of high efficiency particulate air (HEPA) filters to provide to a work station air that is low in both particulate and microbial content. The HEPA filter is described as follows by NASA document SP-5076 (NASA 1969): "The HEPA filter uses a media of dry ultrafine fibers (usually less than 1 μm in diameter), which may be 100% glass fiber or a combination of glass and asbestos fibers. This media is formed in a thin porous sheet which is pleated or fan-folded to form pockets, with separators interleaved between the folds to prevent its collapse and to render the maximum area for air filtering. ... The media/separator configuration is assembled in a rigid frame. The media surfaces and edges adjacent to the interior sides of the frame are sealed and bonded to the frame with

adhesive. The filter frame may be made from (a) plain resin-glued plywood, (b) fire retardant-type plywood, or (c) metal, either steel or aluminum, with hard nonflaking or nonscaling finish. The depth of the pockets or folds in the media and the size of the frame determine the filter media area and the airflow capacity of the filter assembly. A standard size filter assembly, 24 × 24 × 5-7/8 in. (61 × 61 × 15 cm), will provide a minimum airflow capacity of 500 ft^3 (14, 158 ℓ)/min." The HEPA filter is defined in 209B as: "A filter as specified in Mil-F-51068 with a minimum efficiency of 99.97% as determined by test. The test can be by the homogenous dioctylphthalate (DOP) method or other equally sensitive method at an airflow of 100% of the rated flow capacity for all size filters and at 20% of the rated airflow for sizes 4, 5, and 6." The DOP fog test provides for a minimum efficiency estimate of 99.97% for particles ≥ 0.3 μm. Leaks in HEPA filter banks can occur in the filter medium itself, at the interface of the filter medium with the support frame, the frame itself, and at the interface of the support frame with the clean room wall. Therefore, it is imperative that HEPA filter banks be judiciously monitored for leaks and, for those interested in the microbial control they provide, that microbiological monitoring be conducted in addition to physical testing (Goddard 1963, Irons 1967, Songer 1963). To prolong the life of HEPA filters (nominally 10 to 15 yr), prefilters are used to capture gross particulates. Their efficiency, as determined by the NBS Discoloration (Dust Spot) Test (see Federal Standard 209B 1973), varies from 20-30% for initial prefilters to 80-90% for intermediate prefilters.

C. UNIDIRECTIONAL AIRFLOW (UAF)

Clean (HEPA-filtered) air can be provided to an operating room in a multitude of ways. Unidirectional airflow is one mode, and must be defined at this point in order that it may be distinguished from other clean air systems.

The unidirectional airflow clean room is often referred to as a laminar airflow system. Federal Standard 209B (1973) states that, for purposes of the Standard, laminar airflow shall be defined as: "airflow in which the entire body of air within a confined area essentially moves with uniform

velocity along parallel flow lines." In recent years the term "laminar" has been judged to be somewhat of a misnomer when used with reference to a surgical application. The air does not proceed in a truly laminar configuration, even in the absence of obstructing objects in its path; it moves, in the absence of obstructions, in a minimal-turbulence, unidirectional fashion. Instances of turbulence and reverse flow of air can occur in work areas supplied with this type of airflow; however, for purposes of simplicity and discussion no attempt will be made to develop additional nomenclature to denote these systems and the term unidirectional airflow (UAF) will be used throughout this document.

D. TYPES OF UAF SYSTEMS

1. Vertical UAF Rooms

The vertical UAF room (Fig. 2) employs HEPA-filtered air that flows vertically from a filter bank located in the ceiling, down through the room, and out a grated or perforated floor. Beneath the floor is a set of prefilters through which the air passes into an exhaust plenum and, by means of blowers, is recirculated through the HEPA filters and into the room. These rooms are commonly capable of tight temperature and humidity control. The HEPA filter-supply plenum system may be arranged in another way, with HEPA-filtered air being supplied from a remote site to the ceiling and through a diffuser system into the room. However, such a modified system should be checked out for homogenous airflow of adequate velocity per the recommendation of 209B that an airflow velocity of 90 ± 18 ft/min (27.5 ± 5.5 m/min) be maintained throughout the unoccupied enclosure of a UAF system. The vertical UAF room provides good control over contamination to areas adjacent to a contaminating event because such airborne contamination is rapidly carried down and out of the room with minimum chance of lateral spread. Properly utilized, it easily provides a Class 100 environment.

The 1972 census of ultraclean hospital facilities (anonymous 1972) did not list any full room vertical UAF systems. Probably, the reason they have yet to be employed is that they are expensive and their permanent nature restricts the use of the room in which they are placed.

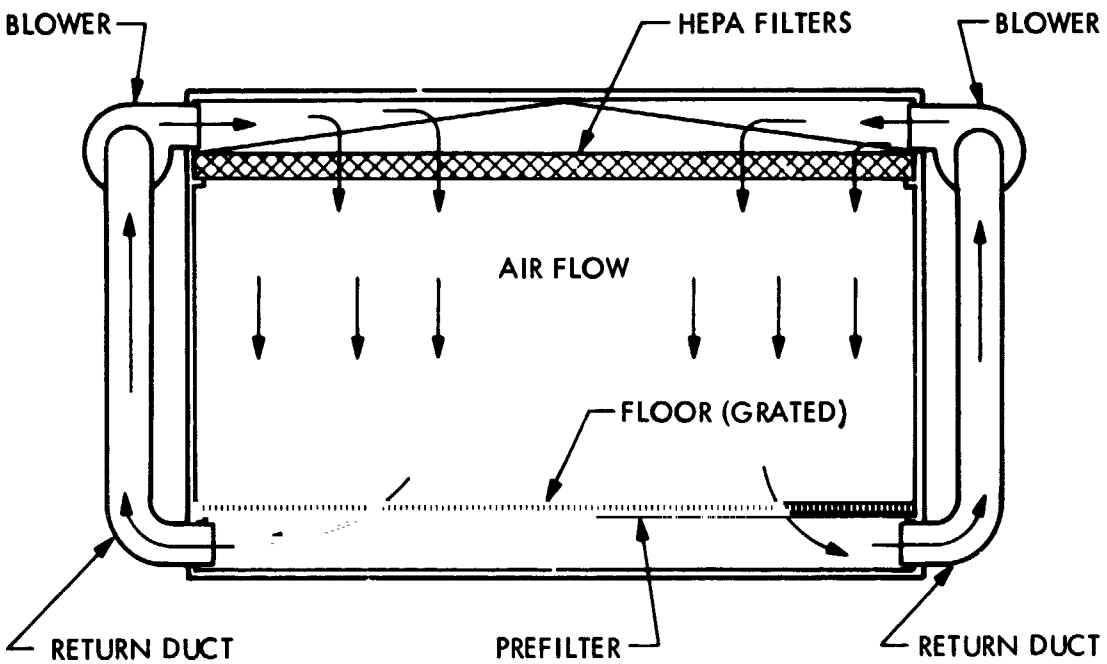

Fig. 2. Vertical unidirectional airflow room (after NASA 1967)

2. Vertical UAF Tunnels

Often eferred to as "greenhouse" units, these systems (Fig. 3) are similar to the ertical UAF rooms. They differ in that they use movable rigid plastic or nonstatic plastic curtain sidewalls, open loop intake and exhaust (100% of intake air is from the ambient surroundings and 100% of exhaust is to ambient), and a solid floor, and are, in some cases, portable. Temperature and humidity of the unit are governed by the surrounding room. These tunnels provide for a clean room within a room. The lack of a grated or perforated floor to provide for a closed loop air recirculation requires that the sidewall edge be held sufficiently high off the floor to allow for adequate airflow out of the enclosure. This in turn requires that any critical work station be high enough above the sidewall edge to be under UAF conditions and at minimum risk of contamination from a possible ambient air migration. As applied to surgery, vertical UAF tunnel systems present a problem in terms of location of surgical lights. It is preferable that lights be situated so as to be nonobstructive to the airflow emanating from the filter bank. These units are increasingly seen in surgical applications and have often been used in the space program to provide Class 100 conditions for spacecraft that would be difficult to manipulate in a stationary, rigid wall vertical flow room.

3. Vertical Wall-Less UAF

A vertical wall-less UAF enclosure (Allander 1968) is shown in Fig. 4. An outer air curtain, formed from a rectangular slotted delivery system in the ceiling, passes HEPA-filtered air downward and outward from the inner working area at a velocity of approximately 10.7 m/min. The inner areas are supplied with HEPA-filtered air that passes through the enclosure at approximately 7.6 m/min. The wall-less systems have seen limited acceptance in surgery.

4. Horizontal UAF Rooms

These rooms (Fig. 5) are essentially identical to the vertical UAF rooms except for the configuration of airflow. The environment at any

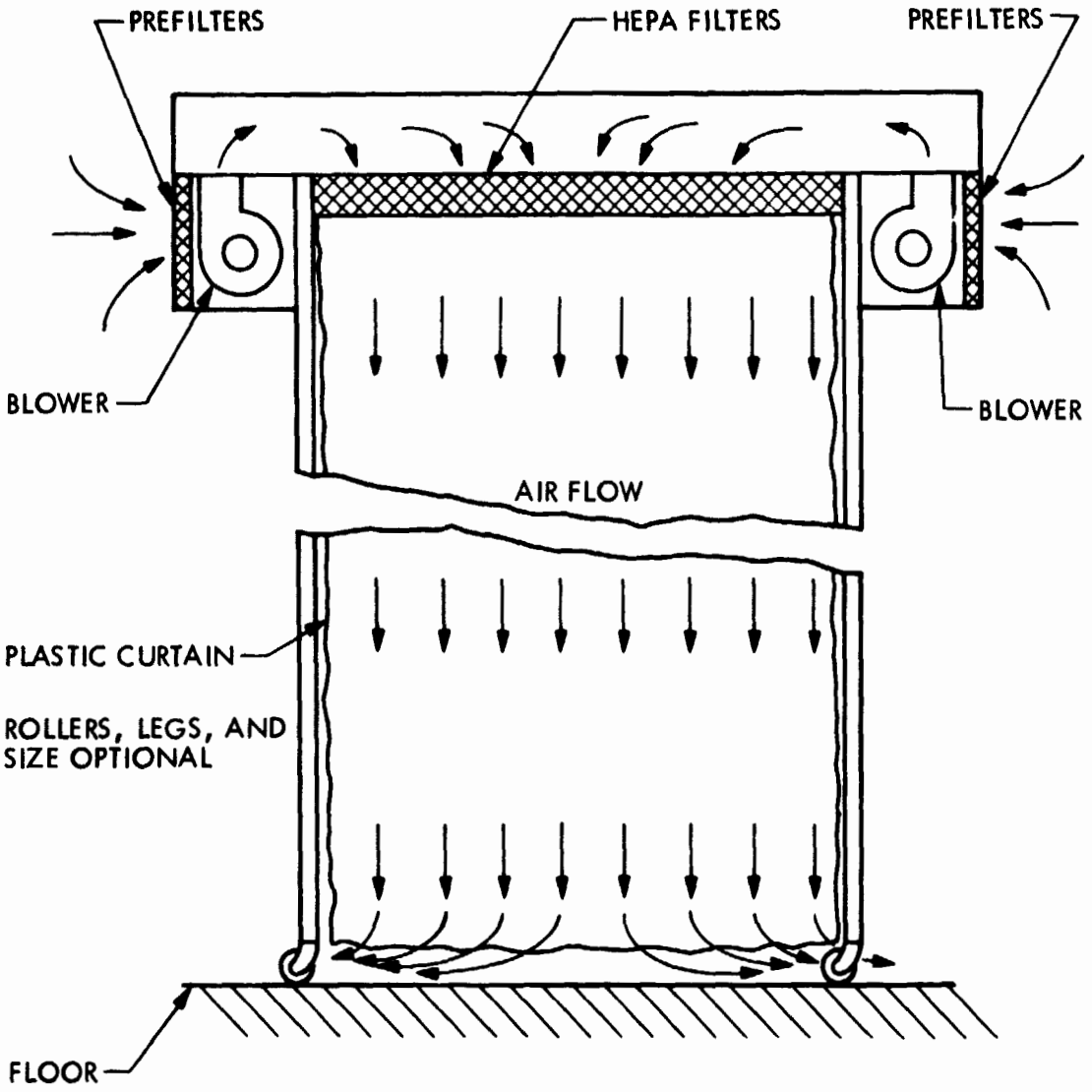

Fig. 3. Vertical unidirectional airflow tunnel (after NASA 1967)

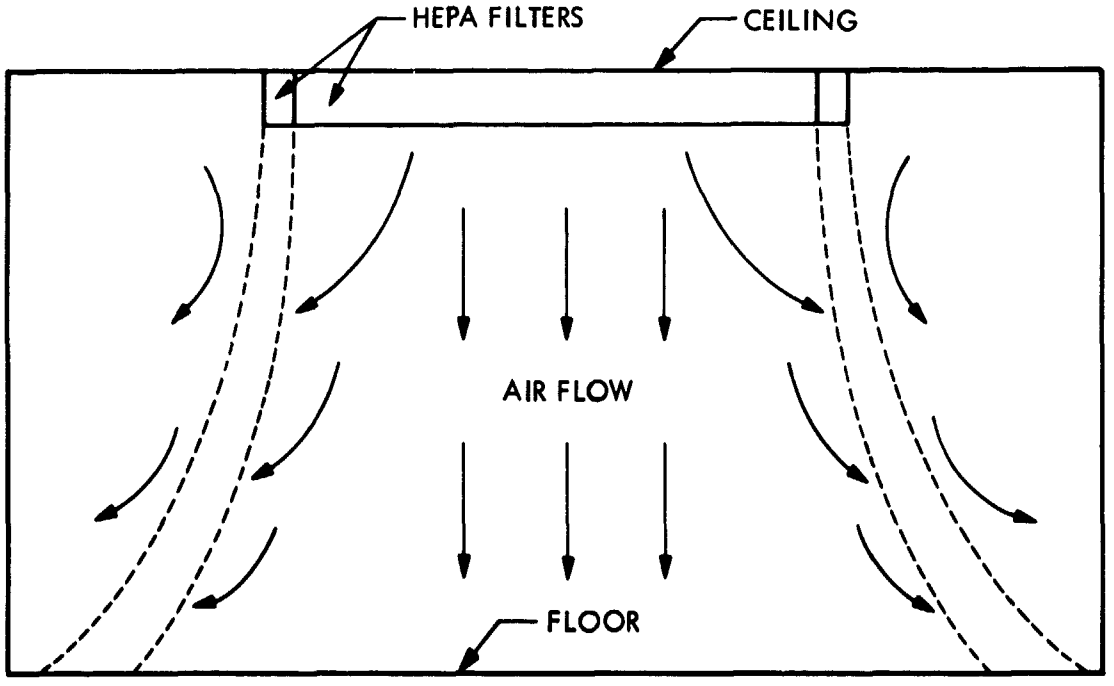

Fig. 4. Vertical wall-less unidirectional airflow unit

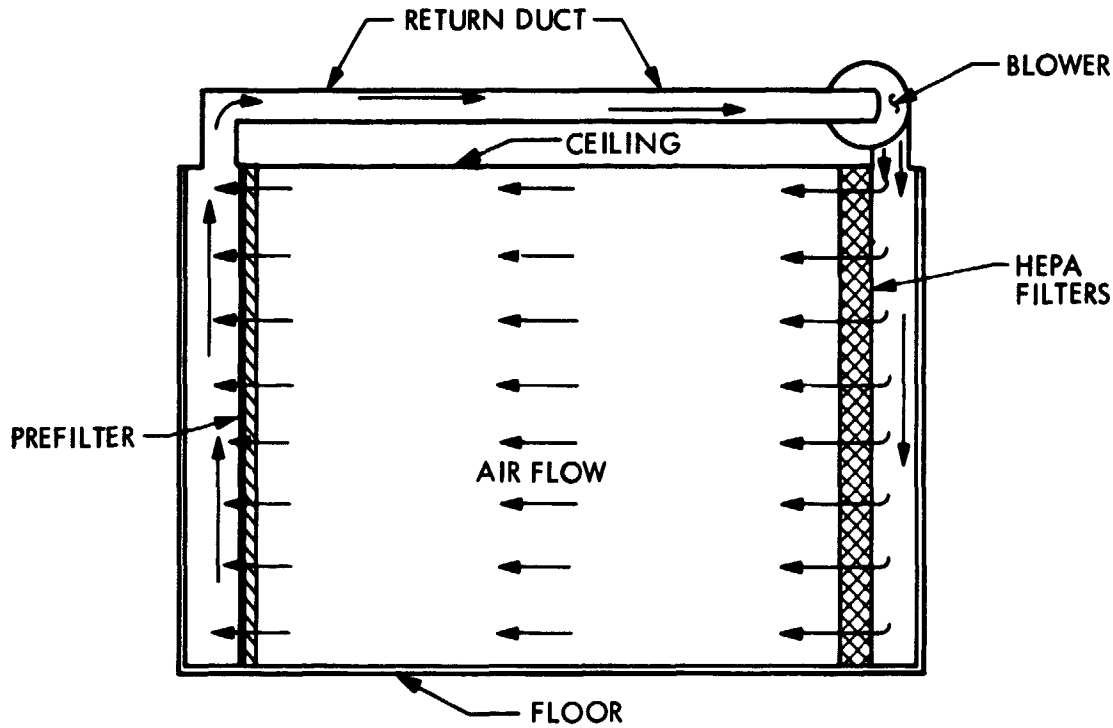

Fig. 5. Horizontal unidirectional airflow room (after NASA 1967)

locale in this room is dependent on activities at work stations between it and the incoming HEPA-filtered air. First work locations (those nearest the HEPA filters) generally meet Class 100 conditions. The air velocity requirements for these rooms, depending on their length, are often greater than the nominal 27.5 ± 5.5 m/min (see NASA [illegible] 9). Obstructions on the ceiling of these units (e.g., surgical lights) can lead to undesirable turbulence and interference with the room's cleandown capability. The design of these rooms (length greater than width) usually calls for fewer HEPA filters, fewer supporting structures, and less equipment than the vertical rooms. A few of these rooms are presently in use; however, many more are planned for new hospitals (Agnew 1972).

5. Horizontal UAF Tunnels

The horizontal UAF tunnel (Fig. 6), except for direction of airflow, is similar to the vertical UAF tunnel unit. Its sidewalls and ceiling are often made of plastic for easy assembly and disassembly. As with the vertical tunnels, the horizontal tunnels can provide Class 100 environments as "rooms within rooms," and are subject to the prevailing temperature and relative humidity of the surrounding room. These tunnels are also subject to the restraints noted for the horizontal UAF rooms and are comparable in effectiveness to them. They are among the most economical of UAF room-size enclosures and are therefore popular for surgical use.

6. Horizontal Wall-Less UAF

Horizontal wall-less UAF units are available in a variety of sizes. The full size units (Fig. 7) typically consist of a 1.8 to 2.4 m HEPA filter bank that supplies air to the surgical wound site. The "first air" of these units can supply Class 100 conditions (Ritter et al. 1973). Airflow velocities (36.6 to 42.7 m/min) are somewhat higher than for other systems. This type of unit represents a large fraction of the UAF operating room systems currently in use (Agnew 1972). A small version horizontal UAF wall-less module is shown in Fig. 8. Such units are employed to provide clean air directly to the wound site.

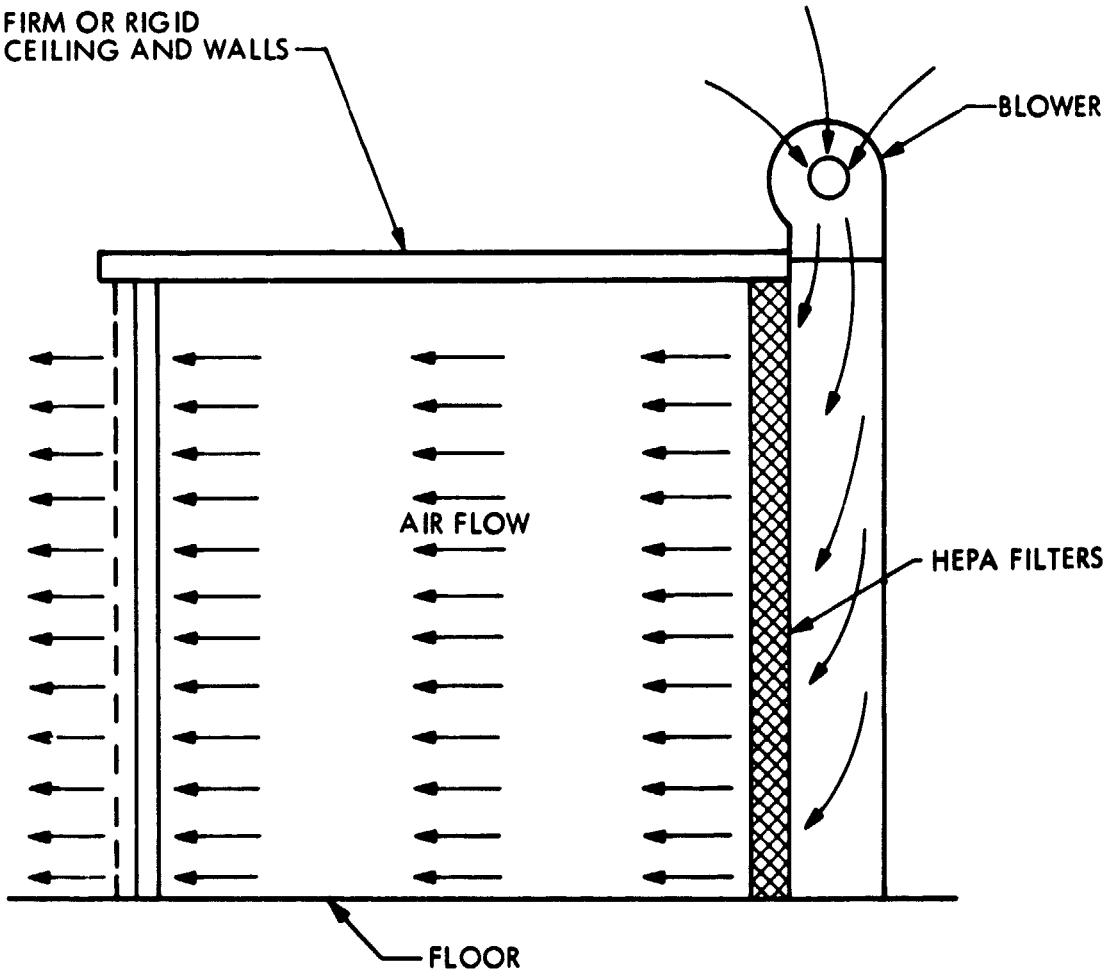

Fig. 6. Horizontal unidirectional airflow tunnel (after NASA 1969)

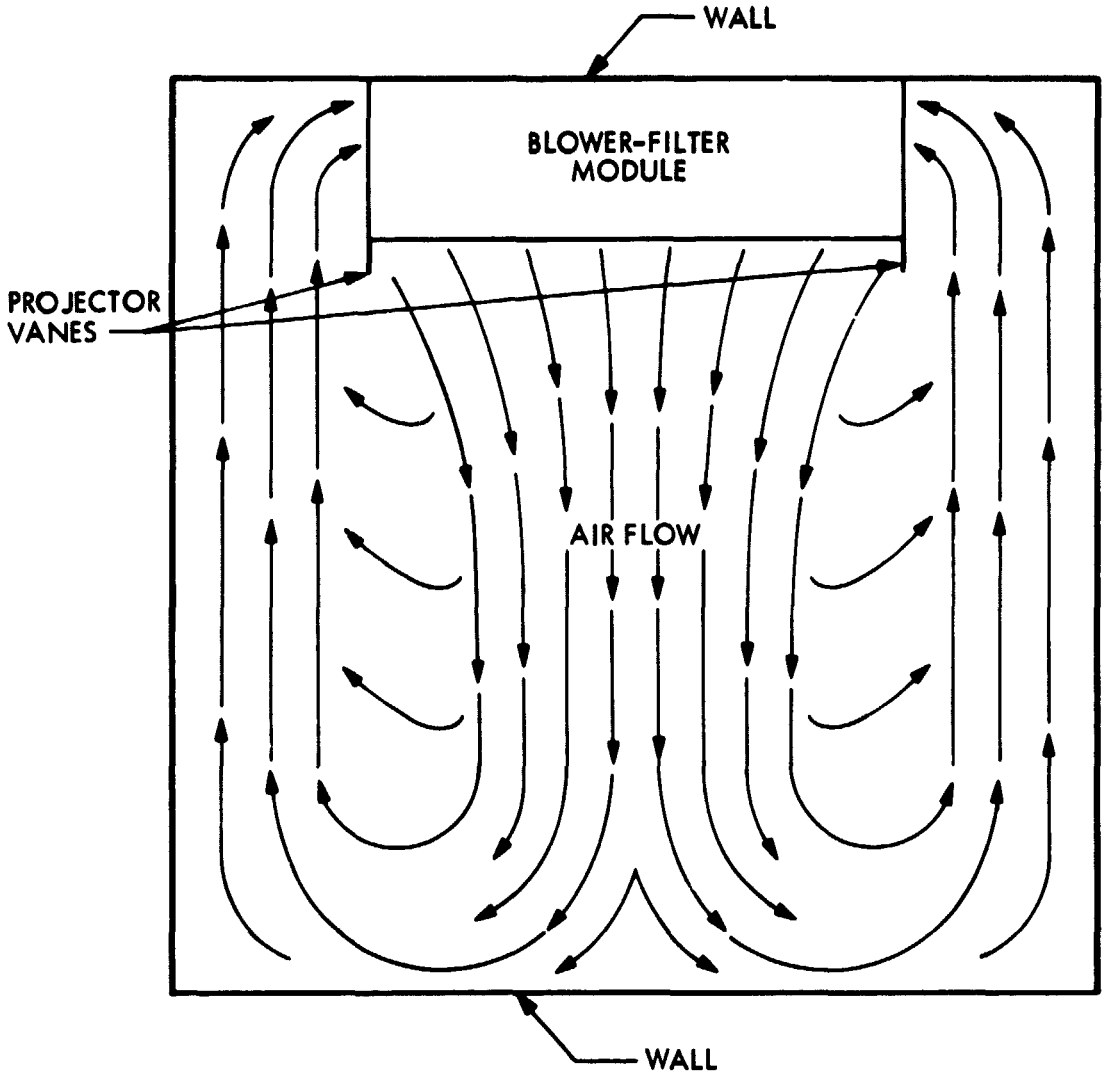

Fig. 7. Horizontal wall-less unidirectional airflow unit (top view)

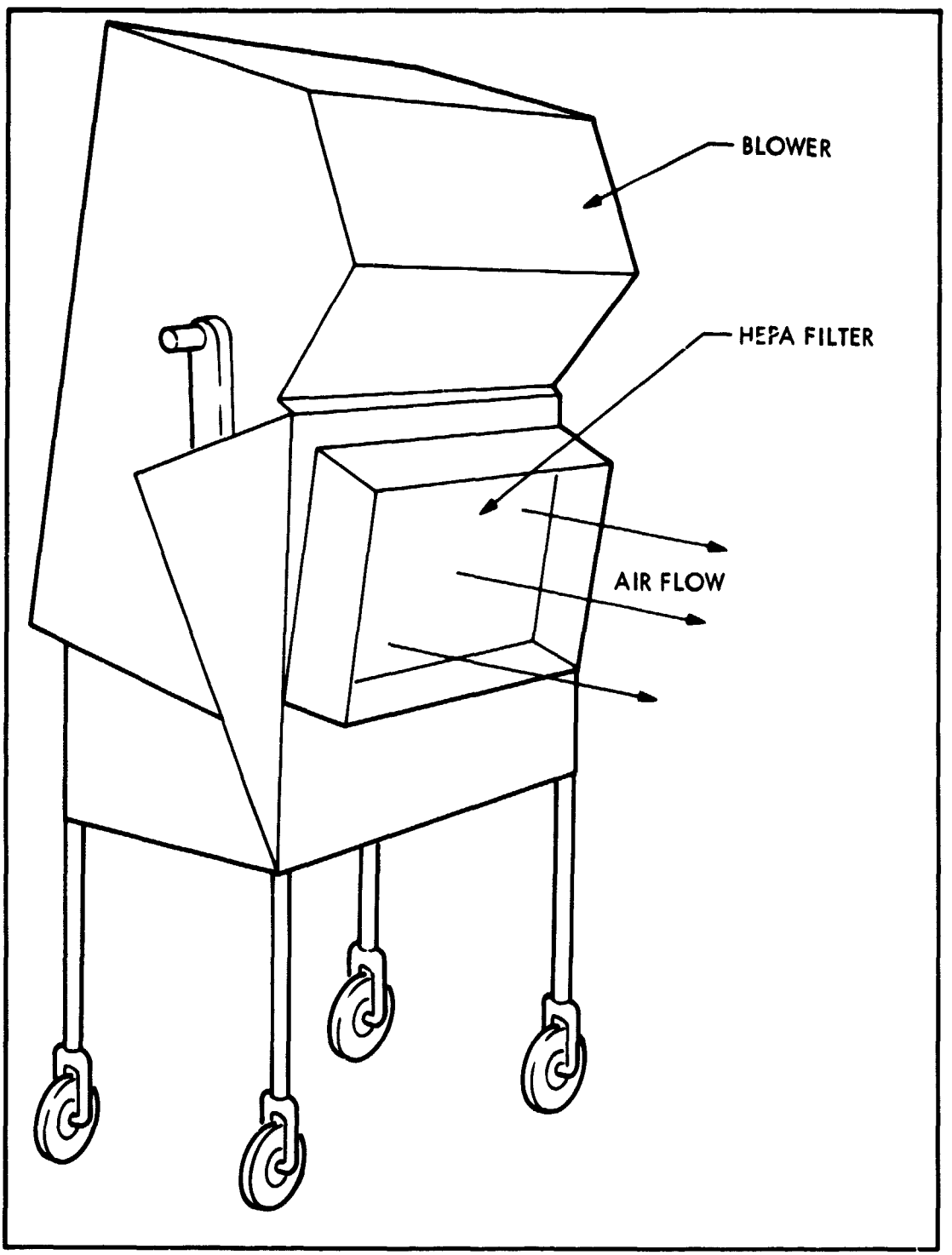

Fig. 8. Horizontal unidirectional airflow wall-less module

E. NONUNIDIRECTIONAL AIRFLOW CLEAN ROOMS

Federal Standard 209B refers to a nonunidirectional (nonlaminar) flow clean room or work station as being "supplied with filtered air with no specified requirement for uniform airflow patterns of uniform air velocity." The non-UAF room, often referred to as the "conventional" clean room, furnishes HEPA-filtered air to a work area but in a turbulent manner (Fig. 9). In addition, the number of air changes per hour (15-20) is much less than for the UAF facilities (200 to 500). Compared to UAF facilities, the time required to remove generated contamination in these rooms is much longer. Filtered and conditioned air is typically supplied to the room through ceiling diffusers and exhausted through return ducts situated near the floor around the room periphery. These rooms are not considered capable of meeting Class 100 requirements under operating conditions, but under restrictive use can achieve Class 100,000 and, in some instances, Class 10,000.

F. CONCLUSIONS

Clean room technology was developed primarily as a means of controlling the concentration of airborne particulates. The particulate nature of airborne microorganisms renders them amenable to regulation by application of this technology; however, existing standards are not definitive with respect to the microbial control afforded by clean rooms in the surgical context.

In terms of nonviable particulates, the nonunidirectional flow clean room cannot achieve the levels of cleanliness achievable by unidirectional flow systems. However, the control of nonviables has little meaning in the application of clean room technology to surgery.

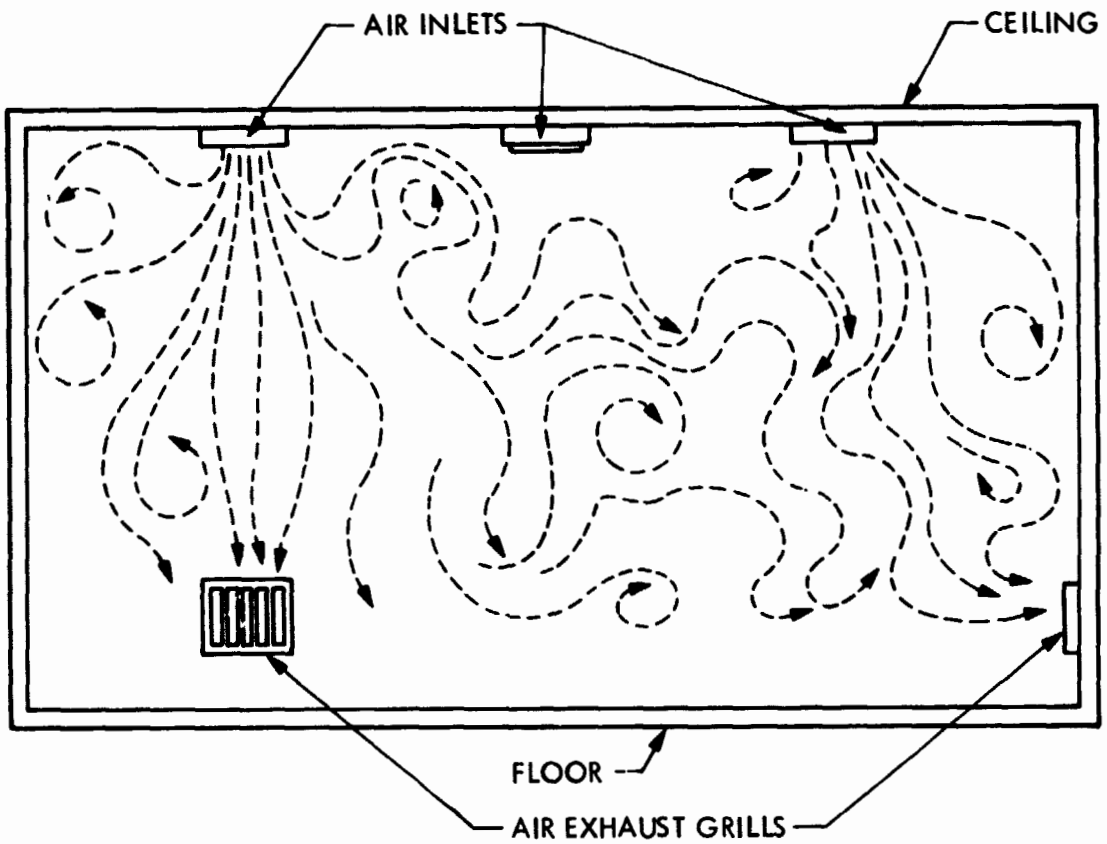

Fig. 9. Nonunidirectional airflow clean room (after NASA 1969)

SECTION III

MICROBIOLOGICAL MONITORING OF THE SURGICAL CLEAN ROOM ENVIRONMENT

The desire to minimize the number of microbes in operating room air has necessitated the development of appropriate microbiological monitoring techniques. The efficiency of clean air operating rooms is primarily measured by their effect on the level of environmental microbes. This section discusses methods of microbiological monitoring in the operating room and how such methods relate to the special case of the clean room environment in surgery.

There is no presently known sampling technique that will yield estimates of the numbers of all viable microbes present in an environment. The detection of viable microbes is dependent on the media, growth temperature, relative humidity, etc., employed in the sampling technique. Therefore, the results of the microbiological monitoring of an environment must be considered relative rather than absolute. The key word in operating room microbial sampling is viable, for the enumeration of microbes by methods that do not distinguish between viable and nonviable cells (e.g., direct microscopic counting, light-scattering methods, and tracer techniques) is of questionable usefulness in monitoring for organisms capable of producing infection.

Modern microbiology encompasses the study of bacteria, fungi, viruses, algae, and protozoa. The term "microbiological," as applied to environmental sampling in the operating room, is usually defined to include only bacteria and fungi.

A. VOLUMETRIC SAMPLING OF AIRBORNE MICROORGANISMS

In the course of evaluating operating room environments, much attention has been directed to determining the number of microorganisms per unit volume of intramural air. An intense interest in the microbiological contamination of operating room air was fostered during the 1950's by a rise in the number of antibiotic-resistant staphylococcal infections and concern over control of their dissemination.

Microbiological aerosols are composed of particulates ranging in size from less than 1 μm to approximately 50 μm (or in some cases larger) (Wolf et al. 1959). The particles may represent single organisms or clumps composed of many cells. Usually, organisms exist in aerosol form attached to larger nonviable particles or as free-floating forms surrounded by dried organic or inorganic matter. Vegetative cells are generally present (in areas of low human activity) in lower concentrations than spores owing to their sensitivity to drying and other deleterious factors inherent in the airborne state. Vegetative cells are more prevalent in wound infection than are spores. Staphylococci, streptococci, and tubercle bacilli are quite resistant to the inimical effects of the airborne state and hence are commonly cited as the prevalent disease-producing organisms disseminated by airborne routes. The sampling of microbiological aerosols can provide a number of different types of information, e.g., the total number of viable organisms, a particular fraction of the total population present (through the use of selective media), and the number and/or the size distribution of particles bearing viable cells. To an investigator seeking a finer resolution in his environmental sampling, it is important to choose a media selective for a particular organism or supplemented with growth factors essential for the proliferation of cells injured in the sampling process (see Kingston 1971 for a review of this subject).

The purpose of this discussion will be to provide insight into some common approaches for microbiological air sampling in the hospital operating room. Air sampling methods and devices will not be comprehensively referenced; for such a treatment, see Wolf et al. 1959 and the American Conference of Governmental Industrial Hygienists 1972 (includes commercial sources).

Volumetric sampling involves collecting a sample of the ambient environment by means of a sampler operating on a vacuum principle. This technique leads to a sampling bias in favor of small particles, which are readily captured by the sampler airstream (Sehmel 1970). In ordinary practice the error introduced by this factor is small; however, for sampling

in unidirectional flow environments, the need to reduce this bias is more critical. The best approach in such environments is to utilize isokinetic sampling, i.e., sampling that adjusts the velocity of the sampler airstream to equal that of the unidirectional flow airstream. Such adjustment is most readily accomplished by modifying the sampler orifice to a size that will permit isokinetic flow and situating it so that it faces head-on into the ambient airstream.

The basic methods for volumetric sampling of airborne microbes include (1) impaction on solid surfaces, (2) filtration, (3) centrifugation, (4) impingement in liquids, and (5) electrostatic precipitation. These same methods are basically those used to sample airborne nonviable particles; the difference is the addition of a growth medium (e.g., the impingement or impaction menstruum), to provide for enumeration of viable microorganisms. The methods most popular for use in the operating room have been impaction on solid surfaces and filtration.

Most impactor samplers are designed to detect the number of viable particles per unit volume of air. This number is to be distinguished from the number of viable organisms; most viable particles are associated with more than one viable cell. The most popular impactor samplers used in sampling operating room environments are the slit (e.g., Reyniers (no longer commercially available)) and sieve (e.g., Andersen) samplers. These samplers require a vacuum source and are normally calibrated and operated to sample at 1 ft^3 (28.3ℓ)/min.

The slit sampler pulls a determined volume of air through a narrow slit placed at a critical standoff distance from the surface of an agar-filled petri dish. The sampler is equipped with a timing mechanism that rotates the agar surface, thereby providing a time correlation with detected contamination. The steady rotation of the plate presents a fresh agar surface in line with the incoming airstream, thus guarding against media desiccation and permitting long sampling intervals before samples are changed (commonly 1 to 2 h). Goldberg and Shechmeister (1951) evaluated factors affecting the recovery of viable particles with a slit sampler (Bourdillon). They found

that slit-to-agar distance, slit width, and air velocity interact in the determination of sampling efficiency. It is commonly stated that the main cause of loss in sampling efficiency of the slit sampler is the harmful effect on cell integrity of the above-mentioned critical sampling parameters.

The Andersen sampler (Andersen 1958) consists of a series of six sieve type samplers which have holes of progressively smaller diameter in each succeeding plate after the initial air inlet. Beneath each plate is a petri dish containing agar. The velocity of the air impacting the agar increases for each succeeding plate (stage) resulting in a separation of viable particles into six size ranges as follows:

Stage	Particle size (μm)
1	8.2 and larger
2	5.0 - 10.4
3	3.0 - 6.0
4	2.0 - 3.5
5	1.0 - 2.0
6	to 1.0

Thus the sampler provides for a correlation of colony count with particle size range.

Filtration sampling in the operating room is most commonly accomplished using membrane filters. The membrane filter sampler is unique among filtration sampling techniques in that organisms collected can be enumerated in situ, i.e., viable particles do not have to be removed from the filter material in the assay procedure. Therefore, the membrane sampler eliminates one step in the assay protocol that could reduce the viable count (Wolochow 1958) or introduce contamination. Owing to the severe desiccating action of the airflow through the filter medium, this is not the best method for recovering vegetative cells. For certain applications gelatin matrix membrane filters may provide an increased recovery of vegetative cells as compared to cellulose membrane filters.

Less commonly used methods of volumetric sampling in the operating room include samplers which employ centrifugal force for propulsion of microbial particles to a collecting surface (usually agar) and liquid impingement samplers. The Wells sampler is an example of a centrifugal type sampler. It collects microbial particles on the walls of a broth- or agar-filled glass cylinder, which is then incubated and counted. The all-glass impinger (AGI) is perhaps the best known of the liquid impingers. Besides its selectivity for particles greater than 15 to 17 μm, the instrument provides optimal results only when short sampling times are used; usually 1 min – at most 10. Therefore, it is a most inconvenient instrument to use in the operating room since it must frequently be replaced with one carrying fresh media. In addition, the sample requires further processing, which entails dilutions and plating. The small sampling volume (usually 12.5 l/min) makes the AGI less appealing for sampling unidirectional flow environments.

Methods of microbial sampling in the operating room that rely on electrostatic precipitation have been avoided because of the safety hazards inherent in the handling of high voltages and the resultant electrically charged surfaces.

B. FALLOUT AND SURFACE MICROBIOLOGICAL SAMPLING

The simplest method of sampling airborne contamination in the operating room is to measure the number of viable particles settling out of the environment onto petri dishes filled with nutrient agar. This technique favors the detection of the larger particles. For example, in still air a 4-μm particle settles at 2.9 cm/min, but a 20-μm particle settles at 73.2 cm/min (Wolf et al. (1959) – includes values for other size particles.) Of course, the air movement in the test environment will have an influence on particle settling. However, the agar fallout technique for assessing the number of viable particles in the operating room environment is stated by many investigators to be representative of wound site contamination. This assumption is not entirely valid since there are some obvious dissimilarities between an agar surface and a surgical wound, e.g., the wound is concave in shape and has a number of surface irregularities, and suction is often applied

to drain the wound. It must be remembered that the fallout method measures only viable particles and, to formulate an estimate of viable organisms, a technique to break up clusters of organisms and dislodge microbes from inert particulate matter must be incorporated.

An alternate and less commonly used method of sedimentation sampling is the fallout strip technique. This technique utilizes small strips (e.g., stainless steel) exposed to the environment for a specified period of time. At the end of the exposure period the strips are assayed for the number of microorganisms accumulated on them. This procedure has been commonly employed by NASA for monitoring the microbiological environment of spacecraft assembly areas and has resulted in its incorporation into a NASA standard (NASA 1968). The NASA version calls for the removal of microbes from strips by sonication; the resultant counts approximate the number of viable organisms. Fallout strips favor the collection of spores as opposed to vegetative forms because of the unfavorable conditions present, such as desiccation and material effects.

The two most commonly used methods for assessing surface microbial contamination in the operating room are by swab and agar contact. The swab-rinse technique involves the movement of a moistened cotton swab over a surface so as to remove microbes from a defined area. The swab head is then broken off, dropped into a tube of diluent, and treated (e.g., by agitation or sonication) to remove microbes entrapped in the cotton. Appropriate serial dilutions are performed and the assay is completed using the pour plate method. The swab-rinse technique has been described as having a poor recovery efficiency (Angelotti et al. 1964), since it is affected by the chemical and physical properties of the sampled surfaces as they relate to the removal of microbial particles; by the actions of the person taking the swab sample (the speed and pressure of swabbing will vary with the same or different individuals); and by the assay procedure, which is usually unable to remove all of the organisms entrapped in the cotton.

The agar contact method is a quick and easy technique for assessing surface microbial contamination in the operating room. The basic technique consists of pressing a nutrient agar surface against the surface for which a

microbial population estimate is desired, incubating the plate at a specified temperature and humidity, and counting the colony-forming units. The most common form of this sampling method is the RODAC plate (Hall and Hartnett 1964). It is most effective for smooth, flat surfaces. Since dilution is not possible, the technique is only applicable to surfaces with relatively low contamination levels. Angelotti et al. (1964) found this method to have low accuracy but high precision in assessing surface contamination. Agar contact plate results represent numbers of viable particles.

Surface contamination can also be determined by immersion methods. Immersion in a diluent followed by shaking or ultrasonic treatment and a pour plate assay is useful in determining total numbers of viable cells. Puleo et al. (1967) have shown ultrasonic energy to be more effective in breaking up bacteria cell aggregates than mechanical agitation. The aforementioned stainless steel fallout strips are assayed by the immersion technique. Another form of immersion is the direct overlay of a surface with nutrient agar followed by incubation and counting. This method is usually restricted by the size compatibility of the test surface and the agar holding vessel and, since dilution cannot be invoked, is unsuitable for highly contaminated surfaces. A technique for an in situ assay of surfaces by agar spraying has been described (Hughes et al. 1968).

A recently developed method of microbiological surface sampling is the vacuum probe. This device was originally developed at Sandia Laboratories (Dugan 1967). A vacuum source is used to pull air into an orifice tip that is placed close to the surface to be sampled. A high air velocity is established at the tip-surface juncture that disrupts the boundary layer of air at the surface and draws microbes present on the surface into the airstream entering the tip. The airstream entering the sampler is directed onto a membrane filter which along with the tip and filter housing is assayed by an immersion-sonication technique. Peterson and Bond (1969) have evaluated an aluminum version of the probe and found it 98% efficient in removal and 88% efficient in recovery of the surface organisms deposited from air. Improved design vacuum probes have been reported by Farmer et al. (1971) and Phillips and Pace (1972).

In the hospital environment perhaps the most critical problem in assessing surface contamination is that of residual germicides. Therefore, techniques aimed at such an assessment should incorporate, if appropriate, agents to neutralize residual germicides. Quite often, negative samples are interpreted as indicating a surface is free of microbial contamination when in actuality such samples originate from the transfer of a germicide from the surface to the growth medium, resulting in a bacteriostatic or bactericidal effect. Favero et al. (1968a) have accumulated a list of neutralizers for common germicides.

C. CONCLUSIONS

Microbiological monitoring of the clean room surgical environment requires unique considerations. These are most apparent in the application of monitoring techniques to unidirectional flow environments, where aerodynamics has a significant effect on the acquisition of a representative sample. Since the function of UAF systems is to prevent random dispersal of microbial contaminants, only locales of interest should be selected as sampling sites. In addition, it should be kept in mind that, for most air sampling techniques, only a small fraction of the large volume of air presented to the sampling site by UAF is actually sampled. Finally, the sensitivity of the sampling technique must be honestly evaluated in the context of its application. A statement on contamination levels in a clean room surgical environment is warranted only in light of results from proper control samples. Depending on the complexity of the technique, a portion of the samples will be contaminated in the assay procedure rather than as a function of environmental exposure.

SECTION IV

EFFECT OF CLEAN AIR SYSTEMS ON THE ENVIRONMENTAL MICROBIOLOGY OF THE OPERATING ROOM

Clean air (HEPA-filtered) has been defined in Section II-B as air filtered to a minimum of a 99.97% efficiency for the removal of particulates 0.3 μm and larger. Such a definition does not, however, distinguish between viable and nonviable particulates. In terms of its application to surgery, the main attribute of clean air is that it contains a low number of viable particles per unit volume. In actual practice, the levels of contamination in a clean room are not absolute but relative, and depend on the interaction of the clean room system *per se* and the particular mode of its utilization.

Statements as to the level of microbial contamination at a site within a clean room are highly dependent on the monitoring techniques employed (see Section III). Federal Standard 209B (1973) and NASA Standards NHB 5340.2 (NASA 1967) and NHB 5340.1A (NASA 1968) have provided aerospace microbiologists with guidelines in the application of clean room technology to the control of spacecraft microbiological contamination. The rote application of these standards to clean room technology as used for surgery is highly questionable. NASA Standard 5340.2 specifies that Class 100 air shall have no more than 0.0035 viable particles/ℓ and Class 10,000, 0.0176/ℓ. What meaning do these figures hold in the operating room? It is impossible to state *a priori* the acceptable level of microbial contamination in an operating room. A large number of studies have been conducted to define such contamination levels. In some instances attempts have been made to correlate them with the incidence of postoperative wound infection — the ultimate factor in establishment of operating room air quality standards. A discussion of the impact of clean room technology on wound infection will be presented in Section V. The present section will set the stage for that discussion by reviewing some of the more pertinent data concerning the effect of clean room technology on the environmental microbiology of the operating room.

Discussion of the microbiology of clean rooms *per se* will not be attempted here. Rather, the emphasis will be on data that provides a direct tie with surgical applications of clean room technology. The following

references provide a good data base on the microbiology of clean rooms: Beakley et al. 1966, Cown and Kethley 1967, Favero et al. 1966, Finkelstein 1965, Gavin et al. 1969, Gehrke-Manning 1969, Goddard 1963, Irons 1967, Kapell et al. 1966, Lindell and Garst 1969, McDade et al. 1965, Paik et al. 1966, Paik and Stern 1968, Portner et al. 1965, Powers 1965.

A. OPERATING ROOM ENVIRONMENTAL MICROBIOLOGY

This section presents some representative studies of the environmental microbiology of non-clean room (conventional) and clean room surgical environments.

1. Non-Clean Room Environments

Much of the surgical community evaluates microbial contamination levels in the operating room in terms of the work of Bourdillon and Colebrook (1946) which has been restated by Girdlestone and Bourdillon (1951) as follows: "For the total number of airborne particles carrying organisms which grow to visible colonies after 24 h on blood agar at 37°C, after sampling during periods of quiet operation, the figures suggested were as follows: (1) for rooms used for dressing small wounds or for minor operations only, 20/ft^3 (0.71/ℓ), (2) for theaters used for ordinary major operations, 10/ft^3 (0.35/ℓ), and (3) for theaters used for long operations on easily infected tissues, 2.0-0.1/ft^3 (0.07-0.004/ℓ). The lower counts can only be maintained by taking pains and spending money on ventilation plants."

Greene et al. (1962) performed an evaluation of the environmental microbiology of hospital air over a 15-mo period and found a mean count of 10.5 colonies/ft^3 (0.37/ℓ) in the operating room, with a representative variation as great as 1 to 24 over a relatively short time span (circa 1 h). Sampling was conducted using Casella and Andersen volumetric samplers to alleviate the bias introduced against small particles when sampling is conducted using sedimentation plates. The following table shows the qualitative results reported by these workers for isolates recovered from operating rooms:

Number of isolates	1887
Gram-positive cocci	
Hemolytic	18.3%
Nonhemolytic	48.4%

Gram-positive rods	14.3%
Gram-negative rods	6.7%
Other bacteria	3.7%
Penicillin-resistant bacteria	20.6%
Molds	6.5%
Yeasts	1.0%
Actinomycetes	1.1%

Ford et al. (1967) observed bacterial counts ranging from 15 to 18.3/ft^3 (0.53 to 0.65/ℓ) during surgical activities and determined that the contamination levels were in direct correlation with the amount of human activity. Identification of the environmental isolates showed the majority to be traditional nonpathogens, with Staphylococcus epidermidis as the predominating organism. Although present in low numbers, S. aureus was found in 84.6% of the samples (3987 clean cases were performed with 71 (2.41%) giving rise to infection; 31 of these infections (43.7%) resulted from S. aureus and 5 (7%) from S. epidermidis).

2. Clean Room Environments

Favero et al. (1968b) performed a study that compared types and levels of microbes in hospital operating rooms with those found in industrial clean rooms. The highest levels of airborne microbial contamination were detected in the hospital operating rooms, and the lowest were observed in a Class 100 horizontal unidirectional flow clean room. Their quantitative results were as follows:

Room	Class of area	Average number of viable particles/ft^3 (per liter)
Operating Room A*	---	10.7 (0.38)
Operating Room B	---	9.8 (0.35)
Clean Room A	100,000**	5.3 - 6.0 (0.19 - 0.21)

*Operating rooms from two different hospitals.
**Per Federal Standard 209.

Room	Class of area	Average number of viable particles/ft^3 (per liter)
Clean Room B	II-III***	1.0 - 1.4 (0.035 - 0.049)
Clean Room C	II-III***	0.2 - 1.1 (0.007 - 0.039)
Clean Room D	100**	0 - 0.8 (0-0.03)

**Per Federal Standard 209
***Per U.S. Air Force Technical Order 00-25-203.

An examination of the types of microorganisms showed the hospital operating rooms to contain a higher percentage of microbes associated with dust and soil (sporeformers, fungi, and actinomycetes) than those commonly of human origin (staphylococci, micrococci, corynebacterium-brevibacterium, and streptococci). The previously cited work of Greene et al. (1962) found the opposite to be true with respect to hospital operating rooms, i.e., that the majority of isolates were of human, rather than dust and soil orgin. The studies of Favero et al. indicated the value of clean room technology in the operating room for reducing airborne contamination. These workers properly pointed out, however, that the control afforded by clean room technology (especially unidirectional flow systems) is most meaningfully measured at the surgical wound site and that the true expression of any improvement in the quality of operating room air must be evidenced in controlled studies of postoperative infection rates.

Michaelsen et al. (1967) found that conventional clean rooms typically yielded contamination levels some one order of magnitude lower than found in hospital operating rooms and that approximately 75% of the contaminants were human-source species. In addition, they noted that the unidirectional downflow room could improve by several orders of magnitude the levels of contamination found in the best conventional clean rooms.

Whitfield (1966) relates early studies of his pioneer vertical unidirectional flow room that showed levels of contamination significantly lower than

in modern surgical facilities. Initial testing of his room to define its capability in reducing airborne contamination showed the following results:

	Ambient air	Unidirectional flow
(1) Average number of colonies/ft^3 (per liter)	12 (0.42)	<0.02 (<0.0007)

	Unidirectional flow	
	Blowers off	Blowers on
(2) Average number of colonies/settling plate	8.8	<0.1
(3) Average number of colonies/ft^2 (per m^2) (impression plate)	610 (6566)	3-15 (32 - 161)

Tests of the vertical unidirectional flow room as used for surgery and compared to a conventional operating room yielded the following results:

	Colonies/ft^3 (per liter)	Colonies/settling plate
Vertical Unidirectional Flow	0.5 (0.018)	0
Conventional Operating Room	14.4 (0.51)	9

A critical factor in the assessment of contamination levels in a unidirectional flow operating room is the site at which samples are taken. Because the airflow in these rooms functions to sequester and remove contamination, thereby preventing its lateral spread, the averaging of contamination at different sites or the discussion of contamination at other than the critical site (i.e., the surgical wound) clouds the interpretation of the degree of contamination control afforded by a unidirectional flow system (Cown and Kethley 1967, Favero et al. 1968b, Fox and Baldwin 1968). Baldwin et al. (1965) in their study of the environmental microbiology of the wound site during neurosurgery in a conventional operating room found an average of 2 organisms/ft^3 (0.07/ℓ) of air. These workers note that, to their knowledge, their monitoring (circa 1964) was the first documented instance wherein

"bacterial air samplers were moved from their traditional location at the periphery of the room to the sterile field over the wound."

Coriell et al. (1968) studied a vertical unidirectional flow room and found that, during general surgery, the use of the clean air system provided for a marked reduction in airborne microbial contamination levels (e.g., from 4.4 to 0.4 colony-forming units/ft^3 (0.16 to 0.014/ℓ) during a bilateral varicose vein ligation) at the wound site. These workers consistently found higher counts in the operative field (wound site) than at other locales in the operating room and determined that the activation of the clean air system could render the air virtually free of microbial contamination within 2 to 3 min.

McDade et al. (1968) reported on the "Whitfield room" as used at Bataan Memorial Hospital in Albuquerque, N.M. during assorted surgeries. Their data on wound site contamination show levels of 0 to 0.2 viable particles/ft^3 (0 to 0.007/ℓ) during aortic bifurcation resection and 0 to<1 (0 to< 0.035/ℓ), for pleural biopsy. Organisms recovered in the unidirectional flow room were primarily those commonly associated with humans and compared qualitatively (but not quantitatively) with those recovered during inguinal herniorrhaphy in a conventional operating room.

Charnley (1972), using vertical unidirectional flow and a filtration system efficient to the 1-2 μm level, achieved wound site contamination levels of 0 to 0.05 colonies/ft^2/min (0 to 0.5/m^2/min) and 0.1 colonies/ft^3 (0.004/ℓ) during total hip replacement surgery.

During mock neurosurgical procedures, Fox (1969), studying the control of microbial contamination afforded by a horizontal unidirectional flow system, found that the levels of wound site contamination varied from 0.02 to 0.05 organisms/ft^3 (0.0007 to 0.002/ℓ) of air sampled as compared with levels of 0.1 to 2 organisms/ft^3 (0.004 to 0.07/ℓ) in a conventional operating room.

Cook and Boyd (1971), using a modified unidirectional airflow module that directed a horizontal flow of air over the wound, achieved significant reductions in the number of bacteria settling at the operating site during a series of miscellaneous operations (11.2 bacteria/ft^2/min (121/m^2/min) without unidirectional flow versus 2 (22/m^2/min), with unidirectional flow).

The predominant organism type recovered from the operating site was coagulase-negative staphylococcus (75% with the airflow unit versus 79% without).

Anspach and Bakels (1973), also using a modular unidirectional flow unit, were able to significantly reduce the level of airborne bacteria at the wound (1.0 to 0.12/ft^3 (0.035 to 0.004/ℓ) as measured by an agar impact sampler; 12.5 to 0.83/ft^3 (0.44 to 0.029/ℓ) using a broth sampler).

The list of citations showing similar effects of clean room systems, especially unidirectional flow, on the environmental microbiology of the operating room, could be expanded (e.g., see Beck 1964, Beck 1966, Clark et al. 1971, French et al. 1973, NASA and Midwest Research Institute 1971, Nelson and Greenwald 1973, Nelson et al. 1973, Scott 1970, Scott 1971, Tevebaugh and Nelson 1972, Wardle 1973, Wardle et al. 1974, Whyte and Shaw 1971, Whyte et al. 1973).

B. SOURCES OF AIRBORNE MICROBIAL CONTAMINATION IN CLEAN ROOM OPERATING ENVIRONMENTS

It is widely agreed that the main source of airborne microbes in the modern operating room is the people within the room and that the level of microorganisms in the room can be correlated with the type and amount of their activity (e.g., Bernard et al. 1967, Cockcroft and Johnstone 1964, Cole et al. 1965, Ford et al. 1967). Riemensnider (1966) has shown that the average individual sheds thousands of viable particles per minute. Smith and Bruch (1969) have shown that this microbial shedding can be effectively controlled in clean rooms by the use of certain types of apparel. Microbes on shed epithelial cells (Bernard et al. 1965, Davies and Noble 1962) and fomites from the respiratory tract (Hart and Schiebel 1939) are prime contributors to viable particle generation by the surgical team. It has been observed that individuals vary greatly in the number of microbes they shed (Riemensnider 1967). The problem of the effectiveness of surgical apparel in controlling such viable particle generation has been well established (Alford 1973, Belkin 1966, Bergman et al. 1970, Bergman et al. 1972, Bernard et al. 1965, Bernard et al. 1967, Charnley and Eftekhar 1969, Cockcroft and Johnstone 1964, Devenish and Miles 1939, Dineen 1969, Ford et al. 1967, Lovell 1945, May 1973).

With the advent of UAF systems in surgery it was thought that the large volumes of air directed over the wound site would effectively and rapidly remove any surgical-personnel-generated contamination. However, recent studies indicate UAF systems that employ a relatively high speed and number of air changes may not be as efficient as originally believed in removing people-generated contamination in the operating room (see IV-C). Gould et al. (1973) have pointed out that people obstructing the airflow between the incoming air and the wound can lead to turbulence and suspension of microbial aerosols, with eventual settling of organisms in the wound. Walter (1970) states that ventilating air contributes to the problem of airborne contamination and that laminar flow concentrates organisms in the surgical wound.

Often it is felt that the clean room will cure all the problems of operating room contamination. Michaelsen et al. (1967) caution as follows: "The room will never be able to compensate for careless techniques by workers involved." This point has also been emphasized by Shooter and Williams (1961), who note that the care with which aseptic techniques are carried out has a tremendous impact on sepsis originating in the operating room.

C. CLEAN ROOMS AND IMPROVED SURGICAL APPAREL

In the initial applications of UAF to surgery little concern was shown over the traditional surgical garb which was transferred to this new surgical arena. However, with impetus from Charnley (Charnley 1964), a number of surgeons began investigating the merit of improved garment systems in UAF. Charnley and Eftekhar (1969) inspected cotton textile gown material and found apertures up to 50 μm in diameter and speculated that organisms could be forced through the fibers of the textile and result in direct contamination of the wound. They also noted that such a route for wound infection from the surgeon's body could escape detection by volumetric air samplers and settling plates. Charnley recommended, from this and his previous work, that a body exhaust suit (composed of a microbe-impermeable material and an aspirator for removal of nasopharyngeal

exhaust and body cooling) be employed in operating rooms that utilize special air-handling devices, i.e., UAF.

The development by NASA of biological isolation garments (Guyton et al. 1967) for the isolation of sterile spacecraft also set the stage for the incorporation of highly efficient microbial barrier systems in UAF surgery in the United States. Jones et al. (1972) have demonstrated the value of face exhaust masks in conjunction with UAF during mock surgeries. Wardle et al. (1974) have shown the merit of body exhaust suits patterned in principle after Charnley's suits (but similar in appearance to the NASA bioisolation suit) in the reduction of wound site contamination during orthopedic procedures performed under UAF conditions. They noted an approximately two-fold reduction in airborne contamination at the wound site, based on a series of 129 orthopedic procedures. Herndon (1973) has found the body exhaust concept to be of value in reducing wound site contamination in an operating room supplied with HEPA-filtered air. Most recently, Poplack et al. (1974) have described a self-contained isolation garment system that, in principle, may have applicability to surgery.

The above work demonstrates the value of improved microbial barriers between the surgical personnel and the operating room environment in terms of reduced microbial levels at the wound site. It does not provide a measure of value in terms of the control of postoperative wound infection. However, if viewed with the philosophy that the incidence of wound infection (especially for clean surgery) can be correlated with the environmental microbiology to which the wound is exposed, it would appear that such techniques would be of value in infection control. To prove this statistically, however, is probably impractical because of the inherent difficulties in such an investigation (see Section V-A-4): the change in infection rates that might be expected with such a relatively small improvement in the environment would appear to be slight.

An encouraging feature of the application of improved apparel systems in surgery is that they have refocused the attention of the surgical community on people as the leading microbial polluters of the operating room environment. This problem was well recognized long before the introduction of clean room surgery. For example, Adams (1957) found that, when there

was no activity in his operating rooms, the number of colonies forming on fallout plates was essentially zero (air sampled from the air-conditioning inlet ducts was essentially sterile); he found appreciable counts when personnel (and patients) were present. Hence, he was convinced that human activity in the operating room is an important source of airborne contamination. His overall conclusion was that more protection is necessary for surgical wounds than just the provision of sterile air and that strict clothing and masking measures must be instituted to control personnel shedding.

It has been shown (e.g., Coriell 1968) that HEPA-filtered air delivered through conventional air conditioning ducting is capable of producing operating room environments that exhibit zero microbial counts when people are not present. Laufman (1973) has cited such rooms as suffering from intramural contamination only as a function of inadequate utilization of the rooms in terms of garments and/or technique. (Laufman (1973) cites his unpublished work as indicating that cultures of air immediately over the open surgical wound were almost universally sterile regardless of the air-handling system and that this is apparently due to the "upward convection currents from the warm wound into the cooler environment.") Recent studies (Herndon 1973, LeDoux and Gustan 1974) indicate the possibility that, with proper attention to aseptic technique and an emphasis on control of personnel and patient (Dineen 1969) generated microbial contamination (along with adequate air filtration), the level of microbes at the wound site can be reduced to a magnitude comparable to that achieved by UAF systems.

D. EFFECT OF CLEAN ROOM AIRFLOW CONFIGURATION ON WOUND SITE CONTAMINATION

In using a clean room for surgery, which type of airflow results in the most effective control of microbial contamination at the wound site — turbulent, horizontal, or vertical? As has already been pointed out, although turbulent-flow clean rooms provide essentially sterile air at the inlet points (as passed through HEPA filters), they are not as efficient as unidirectional flow systems in preventing lateral spread of contamination and in providing for a rapid removal of airborne contamination through a high number of air changes per unit time (although, as pointed out in Sections IV-B and -C, this

aspect of UAF may have shortcomings in the surgical application). Therefore, the question is frequently reduced to which unidirectional airflow configuration, vertical or horizontal, provides for the most effective control of microbial contamination at the wound site?

McDade et al. (1965), in reporting on NASA-sponsored efforts to control microbial contamination of spacecraft surfaces, have indicated that vertical flow systems appear to be superior. NASA microbial contamination control techniques during assembly of flight craft have relied principally on vertical unidirectional flow environments (e.g., Christensen and Ohanesian 1970, Ervin 1968).

The first use of a unidirectional flow unit in the United States occurred at Bataan Memorial Hospital in Albuquerque, N.M.; it provided vertical flow. However, as this technology grew in popularity among surgeons, it was quickly recognized that vertical flow environments were much more expensive to install than were horizontal. Only recently have data appeared that elucidate the effect of unidirectional airflow configuration on the level of microbial contamination at the surgical wound site.

Scott et al. (1971) compared horizontal versus vertical unidirectional flow in industrial clean rooms (studies of turbulent flow conventional operating rooms were also conducted). These workers found that the mean number of bacteria/ft^3(ℓ) at critical work sites was reduced to 0 in the vertical flow industrial clean room, and to 0.2 (0.007/ℓ) in the horizontal flow industrial clean room. Their conclusion (see also Scott 1970) was that the evidence pointed to vertical flow as the optimum airflow configuration for application in the operating room.

Whyte et al. (1973) studied the effect of airflow configuration on wound site contamination during operations on the spine and total prosthetic replacements of the hip and knee. The unidirectional flow unit was constructed so that, through use of a baffle, the airflow could be interchanged between vertical and horizontal. These workers found that, at airflow speeds of 60-80 ft/min (18.3 to 24.4 m/min), the bacterial count would be reduced by approximately 90% with horizontal flow and by 97-99% with

vertical flow. At speeds of 60, 80, and 100 ft/min (18.3, 24.4 and 30.5 m/min), 3.5, 9, and 4.5 times less airborne bacteria were found, respectively, with vertical flow than with horizontal. They note that these differences were seen when conventional operating room attire was worn; and add that, with impervious clothing, the difference might have been nil.

Wardle (1973) in a study of two different unidirectional-flow operating rooms (one vertical, one horizontal), conducted during orthopedic surgery that was designed to segregate airflow configuration as the critical variable, found that vertical flow provided superior control of airborne microbes at the wound site. Although surgeons in both operating rooms wore body-exhaust suits composed of microbe impermeable material, average wound site contamination levels of 0.60 colony-forming units/m^3 (as detected with a slit sampler) and 0.16 (with a membrane sampler) were found in vertical flow, compared to levels of 3.6 and 3.9, respectively, in horizontal flow.

Van Der Waaij and Van Der Wal (1973) performed a study of UAF configuration under nonsurgical conditions. Their conclusion was that crossflow (horizontal flow) is more advantageous as compared to downflow (vertical flow) because contamination upstream from the patient is easier to prevent. They observed that at air velocities of 0.2 m/s the downflow environment provided for a more rapid removal of experimental aerosols (10 s versus 60 s for an aerosol formed from a suspension of 10^5 E. coli/m ℓ), but that the removal was mainly by sedimentation – an undesirable feature for operating conditions. Removal in crossflow appeared to be by the airstream. These workers hypothesized that smaller aerosols, as experienced in real life surgery, would mitigate the differences they found between the two airflow configurations.

E. CONCLUSIONS

Clean room technology cannot be relied upon to compensate totally for inefficient apparel systems or improperly executed aseptic technique.

Human beings are the prime sources of microbiological contamination in the operating room. Given an operating room of proper design and maintenance, HEPA-filtered air introduced into that room will remain essentially

free of the predominant causative agents of wound infection until contaminated by human sources. Although the configuration of clean room airflow may have an effect on wound site contamination, it would appear possible to negate it by use of absolute microbial barrier techniques that separate the surgical team and patient from the operating room environment.

SECTION V

CLEAN ROOMS AND SURGICAL WOUND INFECTION

It has been estimated that 7.5% of surgical wounds become infected (National Academy of Sciences – National Research Council 1964). In most cases, the organisms causing postoperative wound infections are staphylococci; however, infections caused by Escherichia, Proteus, Pseudomonas and other gram-negative genera are becoming increasingly frequent (Feingold 1970, Fekety and Murphy 1972, Johnson 1971).

Surgical clean rooms are used in hopes of reducing the incidence of surgical wound infections – more precisely surgically induced wound infections. Surgically induced wound infections are usually defined as infections that originate in the operating room and are due to contaminating events that deposit exogenous infection producing organisms in the surgical wound. The control of exogenous organisms by sterilization, aseptic technique, and air-handling systems has been traditionally considered in operating room protocol. Endogenous organisms, however, are not generally regarded as being amenable to control by air-handling systems. Inherent in the application of clean room technology to surgery is the rationale that some wound infections are caused by microbes that gain entry to the wound via operating room air and, therefore, a reduction in the level of airborne microbes at the wound site can lower infection rates. The controversy surrounding this view will be discussed.

The concern over the merit of clean room technology for surgical application has of necessity identified a number of related problems regarding operating room air quality, and these will be investigated in this section.

A. SURGICAL WOUND INFECTIONS

1. Definition

The term "surgical infection" can be used in a sense that encompasses more than the surgical wound proper. For example, the insertion

of a catheter into the urinary tract, a common surgery-related procedure, accounts for the most prevalent hospital-related (or nosocomial) infection. Laufman (1973) cites other types of surgery-related infections as follows: respiratory infections, cellulitis, abscesses, infected body cavities (e. g., peritonitis and pleuritis), infected organs remote from the surgical site, septic thrombi, mycotic emboli, toxemias, and septicemias.

The present discussion is directed to one specific type of surgical infection-surgical wound infection. Beck and Carlson (1962) have presented the following parameters as requiring consideration in the formulation of a workable definition of a surgical wound infection: (1) the wound origin (planned vs. traumatic); (2) the class of the surgery (see below); (3) the state of the patient (old, young, debilitated); (4) the type of operation; (5) the critical postoperative period for appearance of an infection; (6) the site of suppuration; (7) the microbiology of the infection; and (8) the degree of infection. They state that only with a precise identification of the criteria employed in the definition of a surgical wound infection can a meaningful statistical statement be made in the comparison of infection data. Considering the above, Beck and Carlson arrived at the following basic definition of a surgical wound infection: "An inflammatory reaction of a wound, beyond the inflammatory reaction of healing, with the accumulation of pus."

An important step toward refining the discussion of surgical wound infections came in 1964 when a nationwide study, coordinated by the National Academy of Sciences (National Academy of Sciences – National Research Council 1964), classified surgical operations as a function of their cleanliness level. Four classes were identified as follows:

1) Clean.

   Gastrointestinal or respiratory tract not entered; entrance of genitourinary or biliary tracts in absence of infected urine or bile; no inflammation; no break in technique.

   Subdivision: Refined-clean (elective, not drained, and primarily closed).

2) Clean-contaminated.

Gastrointestinal or respiratory tracts entered without significant spillage; biliary or genitourinary tracts entered in presence of infected bile or urine; minor break in technique.

3) Contaminated.

Major break in technique; acute bacterial inflammation without pus; gastrointestinal spillage; recent trauma from relatively clean source.

4) Dirty.

Pus encountered, perforated viscus, old traumatic wound or dirty source.

The study found the incidence of surgical wound infection to vary markedly as a function of operation class with Clean procedures yielding 7. 5% infection (Refined-clean, 3. 8%); Clean-contaminated, 10. 5%; Contaminated, 14. 3%; and Dirty, 26. 3%.

The controversy among physicians as to the definition of a surgical wound infection remains when attempts are made to define "surgically induced infections" — those identified as being directly influenced by clean room technology (see Section V-D). Quite often what one surgeon would classify as a surgically induced infection would be cited by another as one with a different etiology, e. g., caused postoperatively in a dirty ward. The predominant thinking among orthopedic surgeons is that only deep infections should be considered as possibly surgically induced (NASA 1971).

A number of wounds — some superficial and some deep — have been found to drain sterile pus. Such conditions raise the question as to the involvement of microbes in these cases. Was the "infection" a result of physical conditions at the surgical locus (e. g., tight stitches or pressure from an ill-fitting prosthetic device), or of microbes that had completed their growth curve, or of microbes that were not detectable by the culture methods employed? Such cases are included in some infection statistics but not in others.

The type of operation should obviously be a part of any definition of surgical wound infection. This is of particular consequence in the discussion of the role clean rooms play in controlling infection rates. While an intestinal operation which focuses on a microbe-laden environment would not appear likely to benefit from clean air, a total hip replacement might. Shaw et al. (1973) have cited data that shows that the rate of wound infection for different types of operations, done in the same operating room, can vary from 0.8 to 50%; hence the need for discussing wound infection in terms of a particular type of surgical procedure.

2. Factors Involved

A number of factors can be cited which have a bearing on the incidence of postoperative wound infection (and possibly the definition of such) (Cohen et al. 1964, Davidson et al. 1971, National Academy of Sciences – National Research Council 1964). The following are most often discussed in this respect: Microbial contamination of the wound during surgery; patient age, sex, race, and condition (e.g., diabetes, steroid therapy, obesity, and malnutrition are considered relevant); presence of a remote infection; type of wound closure; wound drainage; duration of operation; use of prophylactic antibiotics; urgency of operation (e.g., emergency versus elective surgery); and duration of preoperative hospitalization. The interplay of these factors can often confound attempts to trace the origin and compare the frequency of surgical wound infections.

3. Sources

Where do infectious organisms arise in the operating room? Four reservoirs of operating room microbes exist: the surgical personnel, the patient, the surfaces of inanimate objects within the room (the walls, floors, instruments, etc.), and the air entering the room (from an air-handling system per se or from the opening and closing of operating room doors.) From the standpoint of airborne contamination (see Section IV-B), the human sources are very significant and exist primarily on fomites in the form of nasopharyngeal droplets and shed epithelial scales (Bernard et al. 1965, Davies and Noble 1962, Hart and Schiebel 1939). The role of intimate objects in airborne contamination as it affects wound site contamination

appears minimal. In the modern operating room, the incoming air will probably exhibit a minimum of microbial contamination if the filtration system is in good working order (see Section IV-C).

This raises the question: Why employ a clean room if the conventional air conditioning of an operating room can provide air low in microbial content? The answer most commonly given is that the clean room provides air filtered to a higher level of efficiency and discrimination; but more importantly that, in the case of UAF at least, it provides a high volume flow of air over the wound site and adjacent critical locales and therefore flushes away any microbes that might otherwise contaminate the wound (see Sections IV-B and -D).

4. Statistics

It would appear that the ultimate test of the theory of clean room infection control would involve a double-blind study with the only variable being the air-handling system. Unfortunately, such a study has not been done, and possibly never will be. If some medical group(s) were to venture on this experiment, it would require that they control such potential variables as the surgical personnel involved, the surgical technique, and the operating room protocol throughout the study. In addition it would necessitate that a sufficient number of procedures be performed under each experimental condition to demonstrate that any differences in infection rate carry significance at a high level of confidence. This last criterion is perhaps the most difficult to meet and still comply with the other experimental criteria. Lidwell (1973) notes that a 50% reduction in infection rate from 3.0% to 1.5% would require 780 observations in each group to demonstrate a significant difference ($P = 0.05$) due to the treatment imposed (in the present case, a clean room). Charnley (1973) states that to establish a clean room as effective in reducing infection from 1 to 0.5% would require 2600 observations and 2600 controls. Such a controlled study would also have to be responsive to any unique infection considerations of the type(s) of operation under investigation. For example, it has been noted that conclusive statements on postoperative wound infections for total hip replacements require a 2- to 3-yr follow-up after the surgery (Charnley 1972).

Despite the absence of relevant data taken under controlled experimental conditions, there have been a number of attempts to compare infection rates between clean room and conventional operating environments. Kaufman (1973) cites data from four different surgical teams performing total hip replacements in conventional operating rooms that indicates an overall infection rate of 0.45% for 3622 procedures with a 9- to 42-mo patient follow-up and notes its comparability to the best reported by Charnley using his special air-handling system. Such a rate is, according to Charnley, of an order of magnitude expressing the limits of control of exogenously induced infection during surgery (Charnley 1973). (Charnley (1973) believes that the residual 0.5% infection rate he currently experiences with his replacements is due to infections of endogenous origin.) Whitcomb (1971) reports an infection rate of 0.79% for 3408 operations performed in vertical unidirectional flow and contrasts this with rates of 0.93% and 1.14% for 4162 and 4091 operations, respectively, performed in two conventional operating rooms. Whitcomb and Clapper (1966) feel that the already low infection rate experienced lessened the magnitude of infection rate reduction.

How authoritative are such comparisons of infection rates as determinants of the merit of clean rooms? Careful inspection of the groups that are compared often reveals other variables besides air quality that could influence infection rates, e.g., the use of prophylactic antibiotics, the type and technique of surgery, the operating room protocol, and even the patients themselves. Therefore, it is obvious that such comparisons do not scientifically answer the questions of the relative merit of clean rooms in surgery.

B. AIRBORNE INFECTION OF SURGICAL WOUNDS

Chapin (1914), shortly after the turn of the century, cites a changing attitude in the medical community concerning airborne infection in aseptic surgery. He notes that the rationale for the emphasis, in "modern surgery," on airborne infection had its origin in the works of Schwann, Pasteur, Tyndall, and others on spontaneous generation, putrefaction, and fermentation. These works showed that, when microorganisms floating in the air were excluded, these processes did not occur. Hence, the initial assumption in surgery that air was the principal source of infection appears quite natural.

Chapin presents the philosophy that both the number and virulence of microbes must be considered in determining infection and the idea "that a single germ will cause disease is a myth of the early days of bacteriology." It is seen today that some surgeons do not consider the one-microbe theory a myth, and hence are swayed by the microbial control afforded by clean rooms. On the other hand, others have found that, for particular surgical situations, success is independent of the environmental microbiology of the operating room.

It is undoubtedly true that number and virulence of microbes are critical parameters in infection. But how many virulent organisms are necessary to cause an infection and does the presence of microbes mean an inevitable infection? Again the other factors — the patient, the type of surgery, etc. — must have some bearing on the answer. Owing to the complexity of the process involved in answering this question, very few concrete answers are available. Burke (1963) found that 100% of thoracic and abdomen wounds exhibited microbial contamination at the end of surgery. Coagulase-positive staphylococci were present in 92% (average of 14 CFU* per wound); however only 4% of the wounds became infected. Davidson et al. (1971b), in evaluating 1000 surgeries, found that the presence of bacteria in the wound at the end of surgery was three times as significant as any other factor in the incidence of wound infection. Condie and Ferguson (1961) noted that wound closure technique in dogs has a highly significant effect on the development of infection in wounds contaminated with large numbers of virulent staphylococci. Nelson et al. (1973) observed a 22% contamination in wound cultures taken in a conventional operating room as contrasted to 5% or less in a UAF operating room; a corresponding drop in infection rate was evident in comparing the two environments (see Section V-D-1).

The literature on airborne infection commonly makes reference to the following mechanisms of spreading airborne contamination: contact, droplets, droplet nuclei, and dust. Langmuir (1961) offers definitions of these terms; the following describes them in terms of operating room considerations:

1) Contact.

Ordinarily, contact spread refers mainly to contiguous touch-

*CFU = colony-forming units.

ing; however, this mechanism can be classified as a form of airborne spread when the contamination of objects (e.g., surgical instruments) originates primarily from "dirty" operating room air.

2) Droplets.

Microbes expelled from the mouth, and sometimes from the nose, during talking, coughing, and sneezing. Since such droplets settle rapidly, they do not spread beyond the immediate vicinity of the point of origin (usually less than 1 m).

3) Droplet Nuclei.

Residues originating from small dried droplets that remain suspended. These contaminants may be spread throughout the operating room on air currents or passed through ventilating ducts.

4) Dust.

Unusually large particulates that exist on floors, clothing, etc., and may be periodically suspended and resuspended in air by human activity.

Langmuir points out that methods for the control of contact (defined in the strict sense) and droplet mechanisms of spread, unlike droplet nuclei and dust, are not amenable to the engineering approaches of controlled ventilation, ultraviolet irradiation, disinfectant vapors, and dust suppression.

A fifth mechanism of airborne spread in surgery is the shedding of epithelial fomites that carry microorganisms to the wound site. The use of surgical gowns and drapes is directed towards the control of such contamination. The shortcomings of the ordinary approach to such control and the possible benefits of clean rooms are discussed in Section IV-C.

For infection to be spread by the airborne route, the organism involved must be able (in many instances) to survive severe desiccation. Staphylococci, streptococci, tubercle bacilli, some viruses, and bacterial spores are capable of airborne transmission, whereas a number of gram-negative organisms are not (Dimmick and Akers 1969).

Noble et al. (1963) report that airborne organisms associated with human disease or carriage are usually found on particles in the range of 4-20 μm equivalent diameter.* The range of particle size distribution was found to be determined by two opposing factors: gravity, which tends to eliminate the large particles; and the fact that the larger the particle the more likely it is to carry a microorganism. They found that the median equivalent diameters measured for microbe-associated particles were much greater than the dimensions of the microbial cell, thus indicating that airborne organisms are usually disseminated into the air in association with matter derived either from the menstruum with which they were originally associated or from some transient resting place. Greene et al. (1962) studied the relationship between airborne microbial contamination and particle size in the hospital environment and found that, in 75.6% of the samples, the majority of the contaminants were associated with airborne particles >5 μm. May and Pomeroy (1973) in a study of bacterial dispersion from the human body found in excess of 92% of colony-forming particles to be associated with particles ≥5μm.

As has been noted previously (Section IV-A-2), there is ample evidence as to the efficacy of clean rooms in reducing the number of airborne microorganisms in the operating room. It is all well and good if these systems reduce airborne contamination, but such contamination control is of little value if there is not a concomittant reduction in the incidence of postoperative wound infection.

There is much to be found in the literature concerning airborne infection in surgery and a representative fraction of it will be explored here. Before entering into such a discussion, the reader must be cautioned on the complexities inherent in any such discussion. The critical question is "Do clean rooms serve to reduce airborne infection of surgical wounds?" Before that question can be answered, it will be necessary to determine if airborne infection in surgery does in fact occur. The evidence, pro and con, will involve variables which in themselves could be as important as the one under discussion – the level of microbes in operating room air. Such factors aside, an attempt will be made to resolve the crux of the matter, i.e., can

*"The equivalent particle diameter of a sphere of unit density which has a settling rate in air equal to that of the particle in question" (Noble et al. 1963).

the microbial quality of the operating room air be shown to be related to wound infection rates? An affirmative answer to this question would appear to argue in favor of clean rooms; a negative, against. However, it must be remembered that the general case may not always be applicable to the special.

What follows is an attempt to present pertinent data, mostly pro or con, on the value of reduced levels of airborne microbial contamination in lowering surgical wound infection rates. It should be noted that perhaps a bias exists in such a presentation since positive reports on the effect of efforts to lower the microbial content of operating room air may be more likely to be reported than negative.

1. Pro

Blowers et al. (1955), proceeding on the premise that airborne infection is the prime agent in surgical wound infection, directed their attention to reducing the numbers of airborne microbes in the hospital in general and the operating room in particular. Their work dealt with chest surgery and was prompted by the appearance of penicillin-resistant Staphylococcus aureus infections. Circumstances surrounding surgery led them to believe that the principal mode of transmission for these infections was airborne. Correction of faulty operating room protocol and ventilation improved the air quality and was correlated with a reduction in infection rate from 10.9 to 3.9% (Table 2).

Shooter et al. (1956) found that by creating a positive pressure in their operating room relative to the corridor and instituting a powerful stream of filtered air across the wound site they were able to reduce airborne contamination and simultaneously drop the wound infection rate from 9 to 1% (Table 2).

Burke (1963) determined, using a staphylococcal phage typing method, that the air in contact with the surgical wound was responsible for contamination of 68% of the wounds, followed closely by patient-carried strains from the nose, throat, and skin which contaminated 50% of the wounds. This study was aimed only at identifying the sources of coagulase-positive staphylococcal strains found in the wound just before closure, and, because of the problem of strain shift, conclusive statements could not be made as to the sources of the organisms yielding infections. Abdominal and thoracic pro-

Table 2. The effect of reduced airborne microbial levels during surgery on wound infection rate

Method of reduction	Airborne microbial levels: CFU[a]/ft^3 (per liter) Before	After	CFU/ft^2/min (per m^2/min) Before	After	Infection, % Before	After	Reference
Improved ventilation and protocol	~19 (0.67)	2 (0.07)	5.1 (55)	0.66 (7.1)	10.9	3.9	Blowers et al. (1955)
Improved ventilation	~40 (1.4)	~10 (0.35)	---	---	9	1	Shooter et al. (1956)
Ultraviolet	---	---	3.08[b] (33.2)	1.34[b] (14.4)	3.8[c]	2.9[c]	National Academy of Sciences (1964)
Improved protocol	71 (2.5)	20 (0.71)	---	---	56[d]	28[d]	Vesley et al. (1966)
Ultraviolet	---	---	7.98[e] (85.9)	0.078[e] (0.84)	3.2	1.5	Hart et al. (1968)
[f]	---	---	100[g]	21[g]	1.8	3.6	Seropian and Reynolds (1969)
Improved ventilation	18 (0.64)	0.1 (0.004)	18 (194)	0-0.05 (0-0.5)	7	1.5	Charnley (1972)
Improved ventilation	1.4 (0.05)	0.57 (0.02)	---	---	2.8[h] 2.6[i]	0[h] 2.5[i]	Gould et al. (1973)

[a] Colony-forming units.

[b] Petri dish agar surface area of 0.085 ft^2 (0.0079 m^2) assumed.

[c] Rates for refined-clean procedures (see text for discussion of rates for these and other procedures).

[d] Infection deaths of nonhuman subjects.

[e] Cited by Hart et al. (1968) as typical example of UV effect on airborne bacteria in the operating room.

[f] Airborne contamination and infection rates are shown in comparison of operating room environments in two hospitals.

[g] Average sedimentation plate counts – not expressed on a unit area, time basis.

[h] Deep infections in total hip arthoplasties.

[i] Infection rate for all operations before and after introduction of UAF.

cedures were monitored. No wound was found to be sterile upon closure; 92% contained coagulase-positive staphylococci in numbers sufficient to make them easily identifiable (the average number was 14 CFU; total staphylococci were 24.2 CFU).

Cockcroft and Johnstone (1964), in a study of infections following open heart surgery, attributed contamination of the wound site to air currents which disseminated personnel-generated microbes.

Walter et al. (1963) have attributed an airborne origin of wound infection to a disseminating nasopharyngeal staphylococcal carrier present in the

operating room during an elective nephrectomy and cholecystectomy on two healthy patients (ages 24 and 44). Sterile air was introduced into the room at positive pressure with seven changes of air per hour. The exogenous staphylococcal infections occurred despite the tremendous dilution of the contamination from the carrier (who was located in the periphery of the room), which resulted in only 11.2% of the air samples containing the particular strain. The culpable strain was also detected on the instrument table and masks of the surgical team. The mechanism of airborne contamination spread was cited as droplet nuclei.

Payne (1967) also points to the origin of infection-producing organisms shed from a member of the surgical team and diluted in air prior to wound impingement, hence exposing the wound to a relatively low number of challenge organisms.

Vesley et al. (1966) performed an interesting series of experiments to define the effect of environmental microbiologic control on surgical infection rates. The "patients" studied were dogs rather than humans, because of the impossibility of manipulating environmental parameters in the presence of susceptible patients. Laparotomies and thoracotomies were performed. The microbiologically clean test operating room exhibited air contamination over threefold less than the control room. Although the majority of infection deaths appeared to be of endogenous origin (62%), the overall reduction in fatal infection rate was from 56% in the "control" room to 28% in the "sterile" room. Hence, the "control" room, with a three and one-half fold greater air contamination level, had twice the infection death rate (Table 2).

In an effort to reduce the infection rate found with his total hip arthroplasty procedures, Charnley (1964a, 1964b) instituted means to control exogenous contamination of wounds. The results (Charnley 197.., Charnley and Eftekhar 1969) point to a drop in infection rate from 7% to 1.5%, primarily attributed to the installation of an air-handling system that provided essentially sterile air to the operative field (Table 2).

Alpert et al. (1971), using a surgical isolator that provided for isolation of the wound from the ambient operating room environment, found a reduction in wound infection from 7.8% in a conventional operating room to 2.3% with the isolator system in use.

Gould et al. (1973), studying a series of 190 total hip arthroplasties (80 operated in UAF; 110 without), were able to correlate a reduction in deep wound infections attributable to improved air quality (Table 2).

The biocidal action of ultraviolet (UV) radiation is well established (Hollaender 1955) and has been intensively studied as to its ability to reduce microbiologic contamination of operating room air and, as a consequence, postoperative wound infection rates. Hart et al. (1968) in reviewing their 30 years of experience with UV in the operating room cites an unequivocal benefit of UV irradiation in reducing infections of clean, general surgical, cardiac, thoracic, orthopedic, and neurosurgical wounds due to its deleterious effect on airborne microbes (Table 2). From 4293 operations performed without UV irradiation, an infection rate of 3.2% was observed as compared to 11,840 operations with UV irradiation and an infection rate of 1.5%. The following reductions in infection rates were noted for different classes (see V-A-1) of operations performed with UV when compared to the controls:

Class of operation	With UV		Without UV	
	Number of operations	Percent infected	Number of operations	Percent infected
Refined clean	7,046	0.3	2,875	1.5
Other clean	1,881	1.5	357	4.5
Contaminated (included clean contaminated, contaminated, and dirty)	2,913	4.3	1,061	7.4

Overholt and Betts (1940) showed that UV irradiation reduced infection rates in clean thoracoplastic procedures from 13.8% to 2.7%, and Woodhall et al. (1949) reported infections in clean neurosurgical operations were reduced from 1.1% to 0.4% as a result of UV irradiation of the intramural air.

Perhaps the most extensive study of airborne infection in surgery was that coordinated by the National Academy of Sciences – National Research Council (1964) to determine the influence of UV irradiation in the operating room on the incidence of postoperative wound infection. The study

encompassed 5 institutions and 16 operating rooms. UV irradiation provided significant reductions in airborne bacteria in the operating rooms (Table 2), but the overall infection rate in the irradiated rooms (7.4%) was comparable to that found in the control rooms (7.5%). However, when the comparison was confined to refined-clean wounds (see Section V-A-1 for wound classifications), the class least susceptible to contamination from sources other than air (i.e., endogenous), a drop in infection rate from 3.8% for the control wounds to 2.9% for the irradiated was observed (P = 0.05). The study of refined-clean wounds represented a large proportion of the operative wounds observed (6656 out of a total of 15,613). "Other clean" wounds (5034) also had a lower rate of infection when irradiated (7.3 versus 7.5%), but the difference was not statistically significant. When other classes of operation (clean-contaminated, contaminated, and dirty) were compared, no beneficial effect of UV irradiation was noted. In fact, for these classes the rate of infection was consistently higher (but not statistically significant) with UV irradiation than without.

2. Con

Bernard and Cole (1962a) in a study of the relationship between air contamination and surgical wound infection found inguinal herniorrhaphies to exhibit an infection rate of 0.95% (1916 operations) and gastrectomies, 10.2% (825 operations) in similar environments. They concluded that wound infection attributable to air contamination was an unimportant factor in the overall problem of postoperative sepsis. They observed (Bernard and Cole 1962b), however, that the rate of infection of clean wounds (e.g., inguinal herniorrhaphy) should correlate with exogenous sources of contamination (ineffective sterilization techniques, excessive air contamination, and/or a breakdown in aseptic surgical technique resulting in a transfer of microbial contamination from the environment to the patient); it was also noted that potentially contaminated and dirty wounds risk infection from both exogenous and endogenous sources. They found it is unrealistic to expect the improvement in air quality (unless exceedingly dirty conditions are present) to have any significant effect on contaminated operations (e.g., gastrectomies). By attention to housekeeping, traffic control, and isolation techniques, but without using germicidal lights or air-filtering equipment, these workers were

also able to effect a reduction in airborne contamination from 20 colony-forming units/ft^3 (0.71/ℓ) to 5 (0.18/ℓ) or less.

Howe and Marston (1962), in a study of 330 surgical patients, found little evidence of airborne transmission, although they attributed the origin of most of their serious infections to surgical personnel or patient-source wound seeding in the operating room during surgery.

Oldstine (1966) found that airborne transmission of staphylococci per se was of minimal importance in the dissemination of staphylococcal infection of thoracic operations. He states that studies which show a reduction in staphylococcal infections when the airborne staphylococcal count is lowered are biased because the reduction in the airborne count is accompanied by intensified efforts on the part of hospital personnel to improve aseptic technique and cleanliness, matters which are in themselves of tremendous infection-control importance.

Seropian and Reynolds (1969) found, in comparing operating rooms differing up to 8 times in airborne contamination risk, that the lower infection rate (1.8 versus 3.6%) prevailed when surgery was performed in the dirtier environment (Table 2). The study included a variety of surgeries and found that the trend held for clean procedures in particular. Airborne contamination was found not to be a determining factor in the incidence of wound infection.

Davidson et al. (1971a), studying 1000 general surgical procedures, found pathogenic staphylococci to be seldom cultured from a wound at the end of an operation (positive cultures usually were precursors of infection with the same phage type of organism). Those infections observed to result from activities in the operating room were judged as being of an endogenous origin; hands and masks of the surgical team could not be demonstrated as sources of contamination during the operations.

Shaw et al. (1973) surveyed the incidence of wound infection for a variety of general surgical procedures and deduced that operation type was more significant than exogenous factors in the incidence of postoperative infection. Operations were performed in positive-pressure plenum ventilation operating rooms. The air was filtered to a particle size of 5 μm and

underwent 20 changes per hour; the mean bacterial count was 1.7/ft^3 (0.06/ℓ). It was felt that a comparison of operations of similar magnitude and duration should yield similar rates of infection if the sources were primarily exogenous. Lumbar sympathectomy and heart and great vessels procedures yielded 1% infection rates as compared to 16% for stomach and duodenum operations and 26% for vascular surgery of the upper thigh. From these results it was concluded that future infection control efforts by the general surgeon should be directed to the control of endogenous infection and that laminar flow ventilation rooms or operating enclosures with a high rate of air exchange are unlikely to produce a significant reduction in general surgical procedures.

Laufman (1973) states that evidence is accumulating that shows a reduction of the wound-site bacterial count to almost zero has shown no significant effect on an already low infection rate.

Gould et al. (1973) present data that indicate the introduction of UAF into the operating room lowered the microbial contamination level at the wound site, but that for other than total hip arthoplasty deep infections no significant reduction in infection rates occurred (Table 2).

C. ENDOGENOUS INFECTION

There is increasing evidence that endogenous infections are more prevalent than exogenous ones (Altemeier et al. 1968, Fekety and Murphy 1972). Altemeier et al. (1968) list five sources of endogenous infection as follows: skin, respiratory tract, gastrointestinal tract, genitourinary tract, regional lymphatics, and blood stream. Unlike exogenous infections, endogenous infections are not commonly thought to be spread by airborne routes; however, it is conceivable that a patient source of organisms could contaminate the operating room air and reach the wound by a direct airborne transfer (Gould et al. 1973) or an indirect one, for example, via deposition on instruments prior to use. If a clean room were to function in a manner that would allow effective purging of the surgical field and hence a removal of such endogenous source contamination, it could possibly have an impact on endogenous source infections.

D. INFLUENCE OF CLEAN ROOMS ON SURGICALLY INDUCED WOUND INFECTION

Up to this point the parameters necessary to a discussion of surgical wound infection and in particular its relation to airborne contamination in the operating room have been considered. As has been mentioned, the crux of the matter of clean rooms in surgery is the effect of such rooms on surgically induced wound infections, i. e., those seeded during surgery and of an exogenous origin (however, see Section V-C, above).

In the whole controversy over the influence of clean rooms on infection rates, perhaps the most difficult question to answer definitively is whether or not a postoperative infection was induced at the time of surgery. This difficulty arises from an inability to determine accurately the exact point during patient care at which an infection producing organism was introduced into the wound, and its source. Some workers favor the view that surgical infections are introduced primarily in the operating room (Howe and Marston 1962); others favor the wards (Lindbom 1964, O'Riordan et al. 1972); and still others cite both locales as sources of infection-producing organisms (Cohen et al. 1964, Williams et al. 1966). In those instances where workable phage typing techniques are available (e.g., staphylococci), the isolation of an exogenous strain from an infected wound does not prove conclusively that the responsible contaminating event occurred during surgery. For example, contact between surgeon and patient that extends into postoperative recovery could conceivably account for the appearance of infection attributable to a strain of organism indigenous to the surgeon (Mitchell et al. 1959, O'Riordan et al. 1972, Williams et al. 1966). The emergence of nontraditional pathogens as being of clinical significance in wound infections has found the epidemiologist lacking the phage typing tools he had at his disposal for tracing staphylococcal infections. The increasing appearance of a wide variety of organisms in clean wound infections has placed a determination of their origin beyond the technology presently available.

1. Orthopedics and Clean Rooms

The orthopedic surgeon has been the foremost member of the surgical community in the application of clean room technology for the

control of surgically induced infections. In particular, there has been extensive use of clean air (especially unidirectional flow) in total hip surgery. As performed in conventional operating rooms, these surgeries have been reported as having infection rates of from 4 to 12% (Nelson et al. 1973). In contrast, Coventry (personal communication cited in Nelson et al. 1973) observes a 1% rate for total hip replacements in a conventional operating room (see also p. 49). The data accruing from these procedures offers us the clearest assessment of infections deemed to be of a surgically induced nature. Orthopedists are most concerned about deep infections in total hip replacements (those involving the prosthetic implant), and it is often argued that such deep infections are prime candidates for surgical inducement and therefore influenceable by clean room technology.

Charnley (1972), in reporting on 5800 total hip replacements performed over a 10-yr period, cites data to indicate that measures taken to prevent exogenous infection (improved ventilation and the institution of body exhaust apparel) reduced the deep infection rate from 7 to 0.5%. Nelson et al. (1973), in a small series of total hip operations, found a deep infection rate of 5.2% in a conventional room (134 procedures) and 1.1% (270 procedures) in a horizontal unidirectional flow room. He notes, however, that final confirmation of the data will require additional follow-up of the appearance of postoperative infection. A number of other orthopedic surgeons have reported very low infection rates in UAF (Amstutz 1973, Anspach and Bakels 1973, Bechtol, 1971, Crane 1972, Faber 1972, Gould et al. 1973, Nelson and Greenwald 1973, Ritter et al. 1973), but have not performed an adequate number of control operations in conventional rooms; consequently, these surgeons cannot make a definitive statement concerning the efficacy of UAF in reducing infection rates.

2. American College of Surgeons Statement

The place of special air systems in surgery has been voiced in the form of a statement from the Operating Room Environment Committee of the American College of Surgeons (1971). The committee took the stand that "there is no conclusive evidence at this time that laminar (laminar flow in surgical operating rooms is defined as air flow which is predominantly unidirectional when not obstructed), clean (clean air in surgical

operating rooms is defined as first air emitted from the final bacterial filter) airflow, in itself, has a favorable influence on the incidence of surgical wound infections." The committee's statement goes on to say that controlled studies of the effect of clean air factors on wound infection rates are necessary before the proper use of special air-handling systems for operating rooms can be defined. It notes that present standards of aseptic operating protocol must be maintained regardless of the air-handling system employed. However, it does point to the advisability of considering air-handling methods that may reduce airborne infections (e.g., HEPA filtration systems and air profiles and rates of change) for new construction. In conclusion the committee's report emphasizes that alternate (other than new or special air-handling systems) methods should be considered in the improvement, where deemed necessary, of the microbiological environment of the operating room. These statements of caution by the American College of Surgeons reflect quite accurately the present knowledge concerning clean room systems in the operating room.

E. CONCLUSIONS

It will require a large, controlled study to directly evaluate, in a statistically significant manner, the effect of the clean room on the incidence of postoperative surgical wound infection. However, pertinent data do exist that point to the value of a reduced level of operating room airborne microbial contamination in lowering the incidence of wound infection for certain surgical situations.

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NASA — JPL — Coml., L.A., Calif