Clean air symposium—Part II

Confusion in application of clean air systems to operating rooms

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Confusion exists over the need to install air handling devices and systems in the operating rooms to supplement basic air filtering and distributing systems in surgical suites.

Surgeons, architects, and planners are being subjected to heavy pressure by surgical colleagues and by manufacturers to install so-called laminar flow enclosures in both newly planned and existing operating rooms, particularly for hip replacement surgery.

Difficulties in accumulating unbiased evidence on the possible clinical value of such installations are increased by emotional or defensive views, both pro and con. Neither the enthusiastic testimonial statements by some orthopaedic surgeons on the lower incidence of wound infection rates with such enclosures, nor the reaction against their use are the result of completely acceptable evidence at this time. Moreover, there is no known conclusive evidence to support the superiority of vertical over horizontal flow, or vice versa, nor that of unidirectional over turbulent flow, or vice versa, insofar as these parameters affect infection rates.

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One fairly obvious point which seems to have escaped many proponents of special air chambers is the difference between operating rooms containing obviously dirty air and those with good ventilation, insofar as their need for a new system is concerned. Many operating rooms built 20 or more years ago, before current codes of federal agencies guided the mechanical engineering installations, contain fairly dirty air and have poor ventilation. Other more recently built installations are poorly maintained, or function poorly. Visits to several British and European hospitals revealed that operating rooms in old hospitals often contain untreated air, except perhaps for relatively unfiltered air conditioning. In some surgical suites there is virtually unrestricted traffic for people not dressed in operating clothing, and in several the connection to common corridors is direct with no special handling of air whatsoever. Surgery is commonly performed with the door to the corridor open or with people going through the door repeatedly and often unnecessarily.

When bacteriologic testing is done in an operating room which does not have an adequate air handling system, cultures taken by slit sampling or by settling plates reveal high colony counts. It is in this context that the special glass enclosure with unidirectional air flow was developed.

Such a background is rather different from the modern operating room with well-filtered, humidified, temperature-controlled, properly dispersed air, with an air handling plant which is properly designed and maintained and kept in good repair, and in which constant bacteriologic monitoring is carried out. Many of these operating rooms are ventilated by efficient bag-filtered or HEPA-filtered systems. The environment of such operating rooms suffers only by abuse, but otherwise has been shown to be virtually as clean as that produced in special chambers.

If such ventilating systems are in good working order, the bioparticulate matter in the ambience of such rooms is virtually nil until the room is occupied by the surgical team. Shedding of scurf by personnel is the single greatest contributor of bioparticulate matter in these rooms.[1] With air changes of under 30 changes per hour, these particles, which are produced on an average of 1 to 15 per cubic foot, settle to the floor where they remain unless they are reactivated by rapid air motion. With faster air movement, previously settled particles tend to become recirculated. Not all particles carry bacteria, but in general, those shed from human skin are considered bacteria carriers. All people do not shed equally. Those who shed heavily are known as "shedders."

It has been suggested that the introduction into operating rooms of clean air systems with high speed blowers may serve the reverse purpose for which they were originally intended.[2] Particulate matter, instead of settling, remains in circulation, thereby endangering sterile surfaces. Entrainment of particles at the periphery of such air streams may contaminate otherwise sterile surfaces or instruments.

Abuse of otherwise clean operating room environments includes such practices as leaving a door open during operative procedures, permitting unrestricted opening and closing of the door as people come and go, not cov-

ering long hair, sideburns, or beards, and allowing technical and anesthesia personnel to wear short-sleeve shirts in the operating room, thereby enhancing the shedding phenomenon. Other abuses are excessive numbers of improperly gowned visitors, unnecessary activity of people including flapping of drapes, towels and gowns, and any other maneuvers which may unsettle shed particles from the floor.

The quality of the evidence in favor of special enclosures suffers not only from statistical defects, but also from defects in the design of the investigations such as the introduction of many other changes in technique instituted at the time the enclosure or system was put into use.[3] Among such changes: complete covering of the heads of members of the surgical team in place of caps and masks; use of impermeable gowns instead of permeable linen; use of two pairs of surgical gloves; use of an air cooling and exhaust system under the surgeon's gown, mask and hood; especially rigid measures of surgical asepsis in materials handling; prohibition of traffic in and out of the room during the operation; forbiddance of visiting observers; the use of antibiotics, and changes in surgical technique such as closure of subcutaneous fat by sutures and by pressure sponges, using two drains instead of one, and so on. Moreover, there is reason to believe that prevention of infection in patients operated on in special enclosures may be more dependent upon extra attention to all previously known details of aseptic procedure than upon the enclosure per se. If the installation of an enclosure is considered experimental for the purpose of gathering statistics, one must be aware of the well-known effect of experimentation, as such, upon results, over and above the specific effect of one altered parameter.

Laminar flow has been used as a catch-phrase to describe unidirectional flow. In fact, laminar flow cannot really exist in an actively used operating room. To quote an advocate of enclosures:

"... it is clearly of the greatest importance that we should finalise our ideas before hospital architects are irreversibly committed. I believe, from practical experience during the past four years, that laminar flow is already out of date for operating-theatres.

"The fallacies in laminar-flow theory as applied to operating-theatres are as follows:

"An air-speed of 90 feet per minute may sound quite impressive to the uninitiated, but it is a slow rate of air movement and can barely be detected as a draught on the face. Positive displacement of air can only be detected against the face when reaching velocities in the region of 200 feet per minute, so that the flow of air at 90 feet per minute will be violently disturbed in the vicinity of the wound ..."[4]

Mounting clinical evidence is emanating from several quarters in the United States that negligible wound infection rates can be attained in hip replacement surgery without the use of special air handling equipment in the operating room as long as the air is ventilated according to present standards. A number of orthopaedic surgeons in the United States who direct surgical teams known to have performed large series of hip replacements were canvassed. One series of more than 600 cases of hip replacements performed in a conventional operating room without an enclosure

had a zero incidence of wound infection in patients up to 3 years. Another series of 430 cases followed up to 34 months had only one infection. Still another series of over 2,000 cases had less than 1% infections. It is significant that all these series now totalling some 3,000 hip replacement operations performed in operating rooms without special air enclosures or other special air systems report infection rates as low or lower than those of surgeons using special air system enclosures. While this small survey cannot be considered conclusive, it points up the inadequacy of the evidence, either pro or con, with respect to the specific effects of special air enclosures upon infection rates.

Except in rare instances of an obviously faulty or malfunctioning air distribution system, the bacteriology of infected surgical wounds can be linked with that of the patient or the surgical team. For instance, the most common organisms in abdominal wound infections are those of the patient's viscera or skin.[5] Lower abdominal wounds are more frequently infected than upper abdominal wounds. When the source is exogenous, it is traced in most instances to the persons in the room. Contact from exogenous sources may arise from shed skin or hair particles, permeation through surgical apparel, oral or nasal droplets, and technical errors of contact with unsterile objects. Even in the series of orthopaedic surgeons, many of whom are convinced that the airborne route is important, there is poor correlation between the bacteriology of the wound and that of airborne particles.[6]

A faulty or malfunctioning air handling system may bring heavily contaminated air into the operating room. Reports have appeared of open heart surgery in which cases of bacterial or fungal endocarditis were traced to a defective air handling system.[7] Oddly enough, in these same rooms, everyday operations such as cholecystectomy, herniorrhaphy, and so on, were accompanied by acceptably low wound infection rates and no unusual morbidity despite the contaminated air. This information emphasizes the fact that under special circumstances such as strong suction and implantation of a large foreign body, for example, heavy air contamination may contribute to surgical infection more importantly than under other circumstances. However, with a conventional nonfaulty air system, but nonetheless without special air enclosures, open heart surgery as well as hip replacement surgery is being performed with a negligible incidence of infection throughout the United States.

Equipment salesmen and surgeons have been quoted as saying that unless special air handling enclosures are installed, the surgeon and his hospital would be vulnerable to law suits "for not taking all due precautions." There have been reports of an insurance company purportedly not issuing a malpractice policy "unless the surgeon worked in a laminar air enclosure." Such rumors were checked with the insurance committees of the medical societies of all the states to which they could be traced. In every instance, after careful investigation, a denial was issued that there was any such restriction on the part of any insurance company in relating either to hospitals or surgeons. Further, authorities know of no mention made of special

air handling equipment in any malpractice insurance contract or in any lawsuit in the United States. Investigation of a number of other false rumors, most of them spread by surgeons themselves, did not confirm a single case in which a surgeon or a hospital has been sued or is being sued for not using a special air enclosure.[8] The counter-question might well be raised as to what the legal consequences might be in the instance of infection occurring in a patient operated upon in an enclosure.

Formal papers presented at meetings and those published over the past several years have suggested that operating room particle counts might be equated with airborne bacteria and therefore with the potential for wound infection. However, in no case do particle counts appear to correlate with the incidence of wound infection, whereas viable bacterial colony counts appear to have a closer relationship to wound contamination, but not necessarily with actual clinical infection rates.

Efforts to translate NASA clean room data into the operating room specifications have been made. The conclusion that the Class 100 Clean Room (100 particles of 0.5μ or larger per cubic foot) is a good standard for surgical operating rooms may or may not be true. There is no evidence at this time that NASA Clean Room specifications have any relevance to surgical operating rooms.

The use of published studies to collect data is hampered by a number of constraints: data from empty or simulated rooms; differences in methods of data collection; inadvertent distortion of conclusions by bias for, or defense of, either a method or a system; the low incidence of known rates of wound infection; differences in types of source material (kinds of surgery, techniques, dead space, tissue ischemia, constricting sutures, and the condition of the patient). Because of the relatively low contribution of any one factor to the incidence of surgical infection (e.g., air, technique, time of day, length of operation) the effects of the alteration of any one factor on wound infection rates can only be adjudged after an enormous number of cases and an extremely long time in order to have real significance. During such a study, keeping all but one factor constant is almost impossible. For these reasons, conclusions at this time must be arrived at by a combination of available data, experience, logic, and deduction.

Improvement and standardization in methods of keeping surgical infection statistics should be sought. Difficulties in gathering accurate data are exemplified by the questionable accuracy of wound infection statistics within a single hospital. Difficulties in interpretation are exemplified by opposing points of view which use the same data for support, but arrive at opposite conclusions.

Not to be overlooked are cost considerations. The practicability of employing any equipment system must be gauged by applying cost-effectiveness, up to a point. Equipment costs of special room air systems and enclosures before installation are, at this time, between $10,000 and $21,000 per room. Installation costs vary with the type of architectural configuration, geographical location and other factors. Experimental or investigative studies may perhaps be excepted from

cost consideration, but their applicability to practical use eventually requires attention to cost.

In December 1971, certain members of the Committee on Operating Room Environment met to consider the subject of special air handling devices for operating rooms. Various other individuals including industrial representatives participated in a review of opinions and data in the field. Recognizing the changing character of opinion as new data are added, the Committee developed the following statements with respect to special air systems for operating rooms.[9]

"1) There is no conclusive evidence at this time that laminar,* clean† air flow, in itself, has a favorable influence on the incidence of surgical wound infections.

"2) At the present time, systems of air handling exist which, when properly used, may reduce the number of airborne bacteria in critical areas of the operating room.

"3) However, carefully controlled studies are required on the efficacy of clean air factors upon wound infection rates before the proper use of air handling systems for operating rooms can be defined.

"4) Therefore, all presently accepted surgical, technical, and hygienic methods of achieving surgical asepsis must be rigidly maintained regardless of the type of air systems employed.

"5) In new construction, it is advisable to give consideration to methods of air handling which may reduce airborne infection, such as the use of High Efficiency Particle Air (HEPA) filters, air distribution, and changes per hour. This does not necessarily indicate the special equipping of one or more operating rooms for a specific type of surgery, but should be considered as standard for all operating rooms. Existing guidelines are available from a number of hospital planning agencies for this purpose.‡

"6) In existing surgical facilities, consideration should be given to the routine periodic study of the environmental bacteriology. Improvement in the bacteriologic environment does not necessarily mean the purchase of new air handling equipment. If new air handling equipment is deemed necessary, this need not necessarily include special enclosures nor laminar air systems of other types in operating rooms. Appropriate application of fundamental surgical, technical, and hygienic measures of achieving surgical asepsis may be sufficient."

"* *Laminar flow in surgical operating rooms is defined as air flow which is predominantly unidirectional when not obstructed.*

† *Clean air in surgical operating rooms is defined as first air emitted from the final bacterial filter.*"

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