# Clean air symposium—Part II Medical-legal implications of clean air systems

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The question most frequently asked of me these days by orthopaedic surgeons is whether our courts would consider it negligence in a malpractice lawsuit for a surgeon to perform a total hip replacement operation without utilizing laminar flow air conditioning in the operating room. The answer is a complicated one requiring a basic understanding of the present state of the law as well as of medicine.

#### Law

Malpractice is merely negligence on the part of a professional person in the conduct of his profession. Negligence is a breach of a duty owed. The duty owed by a surgeon to his patient is to use ordinary care:

"The duty is always the same—to conform to the legal standard of reasonable conduct in the light of the apparent risk."

Supreme Court of Illinois quoting Dean Prosser on Torts, in the opinion of the Court in Darling v. Charleston Community Hospital (Sup. Ct. Ill. 1965), 33 Ill.2d 316, 211 N.E.2d 253; rehearing denied, cert. denied 383 U.S. 964.

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\* Arter & Hadden, Attorneys at Law, Cleveland, Ohio. How does the law determine what ordinary care requires in a given medical situation.

First, the ultimate answer to this question lies with courts and juries, not with the medical profession, for a whole profession may be negligent and it cannot set standards for itself below the requirements of ordinary care:

"Customary methods or conduct do not furnish a test \* \* \* which is conclusive or controlling on the question of negligence or fix a standard by which negligence is to be gauged \* \* \*

"Methods employed in any trade, business or profession, however long continued, cannot avail to establish as safe in law that which is dangerous in fact."

> Ault v. Hall (Sup. Ct. Ohio 1928), 119 Ohio St. 422, 164 N.E.518 (paras. 4 and 5 of syllabus).

" \* \* \* As Judge Learned Hand said, 'There are no doubt, cases where courts seem to make the general practice of the calling the standard of proper diligence; we have indeed given some currency to the notion ourselves \* \* \* . Indeed in most cases reasonable prudence is in fact common prudence; but strictly it is never its measure; a whole calling may have unduly lagged in the adoption of new and available devices. It never may set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission.""

Illinois Supreme Court in Darling case, supra; 211 N.E.2d 253 at p. 257.

Second, to determine what constitutes ordinary care in a complicated medical situation, about which the judge and jury have no expertise, the law resorts to the opinion of experts, not to set the standard of ordinary care, but to help the courts and juries determine just what ordinary care in a particular situation requires. "Custom is relevant \* \* \* because it illustrates what is feasible, it suggests a body of knowledge of which defendant should be aware, and it warns of the possibility of far-reaching consequences if a higher standard is required."

Illinois Supreme Court in Darling case, supra; 211 N.E.2d 253 at p. 257.

Thus, in seeking the answer to this question of just what it is that ordinary care requires in this situation, our courts are going to have to be guided, in part, by what the experts in the medical profession have to say on the subject. However, our courts are not bound by the opinions of these experts should they find ordinary care requires more or less than such opinions.

**Comment.** Thus for a court to charge a jury that the only duty of the defendant surgeon in a malpractice case is to meet the accepted standards of his profession is reversible error, for the duty of the surgeon to his patient is to use ordinary care in the light of the foreseeable (or apparent) risk, which duty may require more (or less) than that which most doctors are taking to be "accepted practice": *Oberlin v. Friedman* (Ct. App., Lucas County, Ohio 1965), 1 Ohio App.2d 499, 205 N.E.2d 663 (reversed on other grounds in 5 Ohio St.2d 1, 213 N.E.2d 168).

The distinction is subtle, but it nonetheless exists and must be kept in mind. Since the question asked is a complex medical one about which a lay judge or jury can have no independent opinion, resort must be made to the opinion of experts, but only as a guide not as a law: Modrzynski v. Lust (Ct. App., Ohio 1949), 55 Ohio L. Abs. 106, 188 N.E.2d 76; Ault v. Hall (Sup. Ct., Ohio 1928), 119 Ohio St. 422, 164 N.E. 518.

The ultimate answer then becomes,

as stated by our own Supreme Court of Ohio many years ago, that a surgeon's duty is to be measured by the answer to the question:

" \* \* \* (whether the doctor) in the performance of his service did some particular thing or things that physicians and surgeons of ordinary skill, care and diligence would not have done under the same or similar circumstances, or that the defendant failed or omitted to do some particular thing or things which physicians and surgeons of ordinary skill, care and diligence would have done under the same or similar circumstances."

> Ault v. Hall (Sup. Ct. Ohio, 1928), 119 Ohio St. 422, 164 N.E. 518 (para. 7 of syllabus).

What then is an opinion of the experts on this subject?

## Medicine

**Preamble.** Total hip replacement is a new advanced technique just coming into vogue. At this writing, a few pioneers lead the field and have to date performed a sufficient number of said operations to have acquired expertise and even a backlog of cases by which to measure results and formulate, for themselves, their own standards of what they think their duty to their patients requires.

**Caveat.** Their requirements are not necessarily the same things that courts and juries may later say ordinary care required.

These advanced "experts" are now beginning to train others who are anxious to set sail on this, to them, as yet unchartered sea. How then to define, in advance of court decisions, what the legal duty will ultimately be held to be?

The apparent risk. Let us start with the knowns. That is to say, the apparent or the reasonably foreseeable risks.

As I understand the medical problem, it is simply this: When a person walks, his leg articulates at the hip through a ball and socket joint. The "ball" is the head of the femur. The "socket" is the acetabulum which contains it. Until recent years, when a joint "froze" from arthritis or disarticulated due to fracture, dislocation, subluxation, demineralization, osteoarthritis, etc., orthopaedic surgeons treated only the ball parts of the joint by removing it and replacing it with an artificial ball (stainless steel, titanium, plastic, etc.). Except to smooth the surface of the "socket" during open surgery, nothing was done about the other half of the joint, the socket.

Then they began to treat both: first came metal sockets screwed or driven into the acetabulum, articulating metal to metal with the metal ball prosthesis. These proved to loosen up over time causing articular failure.

Then came plastics yielding light, strong, nonirritating surfaces out of which to fashion artificial sockets.

Then came polymers, or acrylics, producing wonderful glues (methyl methacrylate) of enormous strengths permitting a plastic cup or socket to be glued to the properly prepared acetabular surface.

Then came trouble. The acrylic cement is a foreign body (as is the plastic cup) and as such it renders itself an "attraction" site for infection to settle, whether blood stream, airborne, or whatever. In addition, total hip replacement surgery is deep open surgery exposing much to infection.

Hence the apparent risk: Infection! Infection which is always present in some degree in hospitals and which

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will be attracted to this new "attraction" site during or after surgery. Infection which will be deadly in its consequences if not carefully controlled, destroying the hip joint with nothing left to help the patient thereafter.

The Medical Question, then, is: How best to control infection during total hip replacement surgery so as to minimize this hazard of infection.

The Legal Question, then, is: In the light of this apparent and reasonably foreseeable risk, what does the duty of ordinary care require of a surgeon to safeguard his patient against the consequences of such an apparent risk?

## Legal solution

To a trial lawyer, trained in the expertise of the courtroom, the legal answer is readily apparent; i.e., determine what "surgeons of ordinary skill, care and diligence would do or would not do under the same or similar circumstances." (Ault v. Hall, supra.) Unfortunately, since this is a new field, not yet pioneered by the law, no decisions exist on the books to differentiate what courts and/or juries will accept or will not accept as the discharge of such duty of ordinary care in the light of the apparent risk of infection. Accordingly, I went to the experts to obtain their views, bearing in mind that their opinions could not set the standards of ordinary care but would only help the courts and/or juries to formulate what was required by the duty of ordinary care.

**Comment.** Each of these experts may yet be proved wrong—future knowledge may yield a better way. But failure today to employ tomorrow's solution normally is not negligence—it is merely lack of hindsight:

"Negligence is not proved merely because someone later demonstrates that there would have been a better way. Reasonable care does not require prescience nor is it measured with the benefit of hindsight. Tort law does not expect Saturday manufacturers to have the insight available to Monday morning quarterbacks."

> Dean v. GMC (USDC), La., 1969), 301 F. Supp. 187 at p. 192.

—unless today's surgeon either now knows or should know of that better way—in which event his failure to employ it today is negligence—albeit the fact that none of his colleagues are employing it now either:

"' \* \* \* there are precautions so imperative that even their universal disregard will not excuse their omission.""

Darling v. Charleston Community Hospital (Sup. Ct. III., 1965), 211 N.E.2d 253 at p. 257.

What then say the experts?

## The medical expertise

In search of the answer, I discussed this problem with three Board-Certified, very prominent, orthopaedic surgeons in this area already performing this technique. My memoranda concerning their views is set forth herein:

**Caveat.** The following is my version, from my notes, of what they told me. None of these experts was ever given the opportunity of reviewing my comments for error correction. Accordingly, none should be held thereto:

## -Experts A & B

(2/3/72, reaffirmed 9/22/72):

There is no magic to laminar flow. The problem is not that the cement attracts the infection but that if you do get an infection in a patient who is undergoing total hip replacement and it settles in the cement area which as a foreign body attracts it, then you have a failure of the total hip replacement and there is nothing left to do for the patient. Accordingly, every conceivable effort must be made to hold infection to an absolute minimum.

Laminar flow is a help but it is not a necessity. What is a necessity is for the surgeon to discuss it with the engineer of the particular operating room in question, and to test that operating room at the time of surgery, to make sure that the bacterial fallout count is close to zero. One of the things that must be done is to hold the operating time to a minimum, Another is to use all of the antiseptic devices available. Another is to be sure that the doors are locked and sealed so there is no movement of air about in the room. Another is to run the various bacteriological counts to make sure the fallout is close to zero. Another is to use an evacuation system of all exhaled air of all people in the operating room either by hooded helmets or a vacuum exhaust system. Another is to make sure the filters for filtering the air going into and out of the operating room are of excellent quality, etc.

We know of several lawsuits now pending concerning this matter. The makers of the glass cage for laminar flow urge that laminar flow glass cages must be used in all cases, but the manufacturer of the methyl methacrylate cement does not say anything about this.

#### Expert C:

On June 1, 1972, Dr. C stated that Dr. D of University of "Z" Medical School told him that there is no proof that laminar flow air conditioning helps reduce the danger of infection in operations, and that on a recent survey throughout the country he found that laminar flow air conditioning was loosing its popularity among surgeons in this regard.

Medical literature. I also researched the medical literature which revealed:

#### . "Special Air Systems for Operating Rooms

"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 representation 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:

"1) There is no conclusive evidence at this time that laminar,\* clean<sup>†</sup> 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 availa-

<sup>&</sup>quot;\* Laminar flow in surgical operating rooms is defined as air flow which is predominantly unidirectional when not obstructed."

<sup>+</sup> Clean air in surgical operating rooms is defined as first air emitted from the final bacterial filter.

ble 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.

"Another meeting of those Committee members concerned with air handling is tentatively scheduled to examine the state of the art late in 1972. \* \* \*"

> Bulletin: American College of Surgeons, Vol. 57, p. 18, May, 1972.

## Summary re laminar flow air conditioning

Ordinary care towards his patient requires a surgeon undertaking to perform upon such patient total hip replacement to use that degree of care exercised by similar surgeons undertaking this procedure in the light of the foreseeable risk of infection. Clearly, such ordinary care requires careful knowledge and control of the operating room environment to reduce to the minimum acceptable to surgeons employing ordinary care this risk of infection. Reduction of this

"Office of Architecture and Engineering Health Care Facilities Service U.S. Public Health Service 5600 Fishers Lane, Room 9-45 Rockville, Maryland 20852

"National Fire Protection Assn. 60 Batterymarch Street Boston, Massachusetts 02110" risk to zero is not humanly possible. What must be done, however, is to take all reasonable precautions to reduce this risk to an acceptable (to a careful surgeon) level. This means on a "benefit-to-risk ratio," the risk has to be reduced to that level which makes the expected benefits of the procedure worth it to the patient to take the risks left remaining. This, of course, is a matter of professional judgment nonetheless it must meet the standard of the law—ordinary care. Would a careful surgeon judge it so?

**Comment.** What if different careful surgeons judge it differently—why then a court and jury must decide— i.e., just what decision on a "benefit-to-risk ratio" ordinary care would have required.

Laminar flow is an engineering air conditioning device designed to help reduce the risk of infection during operations (and elsewhere). It is but one of many devices available to the surgeon to help him reduce the risk of infection. Like all such devices, it has its "pros and cons," its proponents and its opponents. Whether to use it, instead of or in addition to other such devices, is, as we see it (and believe the law will see it), purely a matter of professional judgment. On the one hand, its use will not guarantee legal absolution; on the other hand, its nonuse or unavailability to the surgeon is not a contraindication to the performance of total hip replacement surgery.

The medical-legal question is not whether or not laminar flow was used, but whether or not the operating surgeon used ordinary care to reduce to an acceptable minimum the known risk of infection. What devices he employed to get that risk so reduced lies within sound professional judgment.

<sup>&</sup>quot; ‡ Center for Disease Control 1600 Clifton Road, N.E. Atlanta, Georgia 30333

The danger to the doctor is that laminar flow air conditioning as a device to reduce the risk of infection during surgery is a known procedure to the state of the art today. If it is available, not to use it is to run the risk of being hindsighted should infection later develop (by a court and/or jury and/or patient's medical-legal expert). This would seem to be a danger not worth running unless valid reasons for its nonuse can be substantiated. If it is as yet unavailable in a hospital, its unavailability, per se, should be no contraindication to total hip replacement surgery providing the surgeon can show he employed ordinary care to reduce the risk of infection to the patient to within acceptable limits by employing other devices just as reliable.

Comment. Because of the factor of hindsight (which is not the law, but unfortunately often the practical reality of life in the courtroom), if I were a surgeon contemplating total hip replacement surgery, I would wish to employ all devices now known to the state of the art, including laminar flow air conditioning if available in my hospital, unless I felt I could completely justify my failure to employ any one of them. But then the lawyer grows overcautious-"burn, bury and cremate" is his motto. If this were to become the surgeon's motto, while it might protect the surgeon in court, alas, it would probably be the patient who would be forced to undergo the motto.

Surgeons should practice good medicine, not cautious law. If the surgeon has satisfied himself that he has done all possible to know, and to reduce to the absolute minimum possible, the bacteriological count in his operating room, and if, in his professional judgment, he has determined that the risk of infection has been reduced to a level acceptable in the light of the benefits hoped for, a level that would be acceptable to him if he were the patient under the same circumstances, then that surgeon is justified in proceeding with total hip replacement surgery-with or without laminar flow air conditioning as the case may befor then the operation with its foreseeable risk of infection is, on a "benefit-to-risk ratio" basis, truly in the best interest of the patient whose only hope of becoming ambulatory ever again lies in total hip replacement surgery even with such attendant risk (as well as other risks, for after all infection is only one of the risks of major surgery, all of which every patient undergoing any major surgery, total hip replacement or otherwise, must assume).

Ultimately, then, the patient's welfare is the test of good medicine. It is also the test of the law.

## Other considerations

Beyond the answer to this specific question of whether or not the absence of a laminar flow air conditioning system is a contraindication to the performance of total hip replacement surgery, the medicolegal problems raised by such systems are basically those raised by nosocomial (hospital iatrogenic) infections generally. Although rumor has it that several lawsuits have been filed involving infections in total hip replacement surgery and in burn cases invoking the problem of clean air systems, these are evidently too recent to have yet been litigated to appellate court review opinions. A careful search of cases in the two periods 1960-1970 and 1970-September 1972 failed to reveal any such yet reported in the law

books. Accordingly, we must extrapolate our medicolegal guide lines from those reported cases of similar nature, i.e., infections following surgery occurring at the site of the surgery itself.

Looking, then, to the reported cases on a broader base, we find that the greatest percentage of lawsuits against hospitals involve the operating room. However, of these, those involving infections rank only sixth in a list of eight (see "Hospital Operating Room and the Law," Bernard J. Ficarra, Medical Trial Technique Quarterly, 1970 Annual, pp. 71-72 at p. 72). In one survey conducted by the writer, in The Citation, which is put out by the American Medical Association and lists almost every medical malpractice suit in this country as it comes out, there were approximately 540 legal cases in the period 1966 through 1970, 12 of which related to nosocomial infection. That is 2.5% of the total cases. Of those 12, only six were deemed important, and that's 1.25%. Thus malpractice suits involving nosocomial infections are not common.

Before examining such cases, perhaps we should first explore just how far the law will go in imposing upon the operating surgeon legal responsibility for the proper operation of the laminar flow air conditioning system or other clean air system utilized in the operating room.

Here we must resort to the analogy of other mechanical devices utilized in the operating room. Thus in May v. Broun (Sup. Ct., Oregon 1972), 492 P.2d 776, the operating surgeon employed an electric cautery machine to cauterize blood vessels during a hemorrhoidectomy. At the conclusion of the operation the patient was found to have sustained burns at the site of the electrode placed against her chest to complete the electrical circuit generated by the machine during cauterization. The patient settled her claim against the hospital and the circulating nurse in charge of assembling and controlling the mechanical unit of the machine. She then brought suit against the surgeon and against her family physician who had selected the surgeon and assisted him during the surgery. At the trial, the trial court refused to apply res ipsa loquitur or respondeat superior to the defendant doctors (which would have made them responsible for the machine's malfunction) and then granted judgment in favor of the doctors on the grounds that the plaintiff had failed to prove negligence on the part of the doctors in their use and/or operation of the machine. In affirming this judgment, the Supreme Court observed (at pp. 777-782):

"Plaintiff's surgery was the fifth operation which defendants had performed that day, and they had used the machine in the prior operations. The first two times the surgeon attempted to use the applicator on plaintiff it did not deliver sufficient heat to cauterize the vessels properly, and both times the surgeon requested the circulating nurse to check the machine. Thereafter, it worked satisfactorily and the operation was completed. After the operation, it was found that plaintiff was burned where she had contact with the electrode. There is no evidence as to the cause of the injury, other than the testimony of the defendants, who were called as witnesses by plaintiff, to the effect that the machine had been hooked up incorrectly. It is apparent that they had no personal knowledge of this fact and were relying upon what they had been told by hospital employees. They testified also that it was possible for such a burn to have been caused by a malfunction of the machine.

"All equipment used in the operating room, including the electrical cauterizer, was owned and cared for by the hospital. All persons in the operating room, with the exception of the anesthetist and the two defendants, were selected and paid by the hospital. Besides the anesthetist and the two defendants, there were present in the operating room a scrub nurse, a circulating nurse, and a nurse's aide. These persons were subject to the supervision of the chief surgeon during the operation.

"After completion of the operation immediately prior to the one under consideration, the defendants retired to doctors' room, or dressing room, to rest and to await preparation of the operating room for the surgery upon plaintiff. Usual procedure is that the operating room is cleaned, all used equipment is removed, and a new sterile pack is brought in and prepared for use. \*\*\* Included in the sterile pack are the cauterizer applicator and the cord to which it is connected.

"The patient, after being brought into the operating room on a wheeled cart, is anesthetized while he is still lying on the cart. Thereafter, the patient is removed from the cart and is placed face down, with his knees doubled up under his abdomen. His chest is placed on the electrode, and the patient is, then, completely draped with sterile cloths except for a small opening at the operative area. The cauterizer applicator is pinned to the outside of the sterile draping, where it can be reached by the surgeon as need dictates. The doctors are notified when these preparations for the operation will be completed in sufficient time for them to commence scrubbing their hands and arms. After scrubbing for ten minutes, they enter the operating room while they hold their hands and arms before them to avoid contamination. There they are met by the scrub nurse, who places sterile gowns and gloves upon them. The operation then commences.

"One of the defendants testified that he knew nothing about the cauterizing machine and had no idea how it functioned. The chief surgeon testified that he had used such a machine for many years, but he had never had any training concerning its mechanical operation. He knew how the machine functioned, but he had never set one up for an operation. He further testified that it was the circulating nurse's duty to set the machine up for the operation.

"Plaintiff relies on the doctrine of res ipsa loquitur \* \* \*. In the instant case, the inference can undoubtedly be drawn that plaintiff was injured as the result of someone's negligence other than her own. The principal question is whether, under the evidence, it can be said that the person or instrumentality which caused the injury was sufficiently within the control of the defendants for the doctrine to apply to them.

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"Before the doctrine of *res ipsa loquitur* would apply to defendants, one of two situations would have to exist. It would have to be shown that it was more probable than not that either the defendants were personally negligent or someone was negligent for whose actions defendants were responsible under the doctrine of *respondeat superior*.

"A fair analysis of the evidence relating to the manner in which plaintiff was injured leads only to the conclusion that her injury was caused by a machine which was defective, or which was incorrectly hooked up in relation to plaintiff, or which was improperly operated.

"It is our conclusion that the evidence is insufficient to establish a jury question concerning defendants' personal negligence. The evidence does not show whether the machine can be tested by a surgeon for defects. It does not show

<sup>&</sup>quot;\*\*\*

whether surgcons, in the exercise of reasonable care, normally check the manner in which a machine is hooked up in its relation to a patient or even if such a check is practical. Neither does it show that it is logical to expect surgeons, while they are cauterizing severed blood vessels, to be several feet away overseeing the operation of a machine.

"Plaintiff contends it was the duty of defendants, at the commencement of the operation when the machine failed to function properly, to suspend the operation and to determine the difficulty before they proceeded further. This argument necessarily presupposes that plaintiff's injury was occasioned by defendants' continuing to operate after the machine was checked by the nurse and functioned properly. It is just as reasonable to assume that plaintiff was burned at the time the machine failed to function upon its initial use as it is to assume that she was burned when it did function.

"The next, and more difficult, step is the determination whether defendants are responsible on a *respondeat superior* basis for the actions of the circulating nurse. The evidence justifies the drawing of an inference that either she hooked up the machine incorrectly in its relation to plaintiff or that she operated it improperly during the surgery.

"We start out with the nurse being an employee of the hospital which selects, trains and pays her. \*\*\* If there were nothing more, we would say that a surgical nurse was the employee and agent of the hospital. However, depending upon the circumstances, the nurse can become a loaned employee in the service of the surgeon. The difficulty is in determining at what point and under what circumstances this metamorphosis takes place.

"\*\*\* There is no doubt that a surgeon has the right to control the employees of the hospital, including the nurse, in the preparation of the hospital room and of the patient for surgery, as well as in the carrying out of their functions during surgery. However, \*\*\* courts do not now usually hold that she changes from a general employee of the hospital to a special employee of the surgeon until she is under the surgeon's direct supervision or control. See cases cited in Annotation entitled, 'Surgeons-Nurse's Negligence,' 12 A.L.R.3d 1017 at 1021-1022. Thus, courts are now usually holding that the surgeon's responsibility for the hospital's employee's negligence is limited to situations in which the negligence occurs during the course of the actual operation when the surgeon is present and that he is not responsible for pre- or post-operative procedures which it is usual for the hospital's employees to perform in the surgeon's absence.

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"Changes have also been occurring in the confines of the operating rooms. Surgeons are operating more and more in a highly mechanized environment wholly created by hospitals. Much highly technical equipment, now considered necessary, is furnished by the hospital and operated by personnel which the hospital hires and trains. As a result, in most instances, a surgeon cannot actually have direct supervision or control over such equipment and the persons who operate it even when he is present, if he is going to give the concentration and attention to the surgery which his patient has the right to expect.

"There are only three cases which we have been able to find where patients were burned by the electrode of a cauterizer. Two resulted in the courts' refusing to hold the doctors liable. \* \* \*

"In Clary v. Christiansen, 54 Ohio Law Abst. 254, 83 N.E.2d 644 (Ohio App. 1948), one cauterizing machine, after having been inspected by the surgeon, was replaced with another by hospital personnel without their informing the surgeon of the change. The plaintiff was burned as a result of the substitution. The court held that the surgeon was not responsible, stating as follows:

'We are of the opinion that the scrub

nurse was not in any sense an employee of the defendant in the task of preparing the room preceding the actual beginning of the operation and that whatever negligence occurred in that connection cannot be attributed to him.' 83 N.E.2d 644 at 645-646.

"In the third case, Monk v. Doctors Hospital, 131 U.S.App.D.C. 174, 403 F.2d 580 (DC Cir 1968), the court held that there was sufficient evidence to go to the jury relative to the liability of both the nurse and the surgeon. There was evidence from which it could be found that the electrode was improperly placed against the body of the patient by the nurse when the doctor was not present. However, there also was evidence that the nurse asked the surgeon to check the propriety of the placement and that he did so. It was evident that the electrode was in such a position that the surgeon necessarily had notice of the manner of its placement. The surgeon also was shown to have had special knowledge of the cauterizing machine and that he had written a treatise on it. The court held that under such circumstances there was sufficient evidence of the surgeon's personal negligence to go to the jury. The court specifically did not pass upon the subject of whether there was sufficient evidence to support a finding that the nurse functioned as the surgeon's agent.

"We hold that when technical equipment and the personnel to operate it are furnished by the hospital to the surgeon and injury is caused by malfunctioning equipment or negligent operators, and it is not shown that the surgeon was personally negligent or that the circumstances were such that it was practical for him to exercise direct supervision or control over the machine or its operation, respondeat superior liability does not attach to the surgeon. There is no evidence in this case that indicates defendants had the ability, consistent with their duty to the patient, to supervise or control directly the machine or its operation."

In Watson υ. Elberton-Elbert County Hospital Authority (Ct. App., Ga., 1971), 186 S.E.2d 459, the patient was severely burned by a flash fire while being treated for a coronary disorder with utilization of an oxygen tent. The patient sued the hospital and at the trial the court submitted to the jury the question of the hospital's negligence in the maintenance and operation of the equipment. However, the jury's verdict was in favor of the hospital. In affirming this on appeal, the court found no error in submission of the case against the hospital to the jury for determination, saying in its opinion (at pp. 462-3):

"Plaintiff's witness, Thomas Maxwell, testified at great length concerning the oxygen equipment. It was brought into the courtroom. He testified that the equipment was used with a tent or canopy and testified how the air circulating and flowing past the canopy over the machine could set up a difference in polarity or create an electrical field with a different potential from that of the patient's body. Defendant's expert witness testified that about six days after the fire he inspected the machine which was smoked up and about 20% of its area melted. \* \* \*

"State Fire Marshal Mauldin testified that during his investigation he found a partially burned pajama top on the floor \* \* \*. The witness responded that there was a Salem cigarette pack lying very near."

By analogy, it would seem to be safe to conclude that the operating surgeon may rely upon the hospital to install, maintain and control in proper operating condition the full clean air system, providing the surgeon neither knows nor should have known from anything occurring either during the particular surgery or prior thereto that would alert him to anything improper

in the functioning of the particular clean air system in that particular operating room. Notwithstanding this, however, the surgeon would seem to retain responsibility towards his patient to inform himself of the bacteria count of the particular operating room in question at the time of the patient's operation and to be able to show that he had discharged the law's duty of ordinary care to ascertain that he had reduced the risk of infection to within acceptable limits on a benefit-to-risk ratio basis by the selection of a properly equipped operating room with acceptable minimal bacterial counts and the utilization of all reasonable devices or systems to insure same. Bevond that, if one of those devices or systems should malfunction unknown to him, the surgeon should not be held liable therefor, although the hospital might be so liable depending upon the circumstances.

Beyond such cases, nosocomial infection cases fall into two main categories. First, homologous blood transfusion cases, mainly with regard to serum hepatitis (not here relevant); second, all other infections, mainly staphylococcal cases. Time does not permit analysis of all of these, but everything said about a staphylococcal case applies to every other infection with any other microbe.

To win a suit involving "staph" or any infection, the plaintiff must prove that he got the infection he claims in the hospital, that the hospital was negligent in allowing the plaintiff to contract any infection, and this negligence directly caused not only the infection but any injury that stems from it. The patient's attorney will claim that the hospital violated its own rules on housekeeping. He will try to show there were cross-infections from other patients, he will try to prove there was an epidemic and the hospital did not isolate the infected patients, he will say some of its personnel were carriers. This is the sort of attack you see in the legal suits, and the defense against such suits is, of course, good housekeeping and good infection control.

Now, let me state a concern of mine. To run a hospital right, we set up rules. We set really high standards. But the patient's lawyer can turn these rules for the benefit of patients against us, and there is nothing more devastating than being caught violating one's own rules. It's *prima facie* negligence. What irony!

I was sent a book on infections control in the hospital published by the American Hospital Association, which I have read. It is a good book from your point of view, but I can just hear some plaintiff's attorney say, "Now let's see. Did you have positive pressure ventilation in this operating room, and did you have negative pressure ventilation in that?" And he will go right down that list and find something you didn't do. You've got another handsome book, Control of Communicable Diseases put out by the American Public Health Association. I saw another one from the U.S. Public Health Service, Isolation Techniques for Use in Hospitals. One thing I have had to fight ever since the Darling decision (Darling v. Charleston Community Memorial Hospital (Sup. Ct. Ill. 1965), 33 Ill.2d 316, 211 N.E.2d 253, cert. denied 383 U.S. 946) is the set of rules of the Joint Commission on Accreditation. All of my client hospitals are accredited, which is just great until I get in court where the first thing the plaintiff's attorney does is produce a copy of the Joint Commission's rules and go down the list to find one we violated, to make the jury think we didn't do something we should have. This is a game of the courtroom. I know you have to have rules, but when you draft them, or redraft them, be practical, not idealistic. Don't set impossible standards. Don't set unreachable goals for personnel.

Let's discuss another case-one that occurred in 1963-Helman v. Sacred Heart Hospital (Sup. Ct. Wash. 1963), 381 P.2d 605. The medical facts are these: Patient A was in an auto accident, had multiple fractures of the left hip and pelvis, was taken to the hospital, admitted, and put in a two-bed room with patient B. Patient B was paralyzed from the waist down. On August 1, extensive surgery was done on A's hip, and he was returned to the room in good condition. On August 9, B complained of a boil under his right arm. Hot compresses were used. On August 10, purulent discharge came from B's boil. On August 13, the discharge was found to contain Staphylococcus aureus coagulase-positive, so B was removed to an isolation ward. That same day, A's surgical wound erupted and discharged pus. A culture was rushed to the laboratory. The laboratory reported the same staph organism. For 12 days the nurses had gone from one patient to the other, ministering to their needs. Patient A sued the hospital.

Testimony at the trial was that the nurses had gone from one to the other. Until they knew that B had a staphylococcal infection, no phage typing was done, only antibiograms. The verdict of the jury was \$69,839.97 for patient A against the hospital. The Supreme Court of the State of Washington affirmed the verdict in these words (at pp. 607-609):

"Crucial \* \* \*question \* \* \*did (patient A) show by substantial believable evidence, that he acquired his infection from his roommate (B)? Essential to this finding is proof that these two patients were infected with the same strain of staphylococcus aureus positive. It is undisputed that cross infection between patients would be a medical impossibility unless it was of the same strain.

**''** \* \* \*

"Two tests identify \* \* \* these bacteria \* \* \*. [One is] the antibiogram sensitivity test \* \* \* [and the other, the really sophisticated test,] the phage [type] test. \* \* \*

"The phage-type type test is not [used in hospitals in this area], but is used principally by governmental and centralized agencies for epidemiological investigation, that is, to locate the sources of staphylococci infections which threaten to reach epidemic proportions. \* \* \*

"\*\*\* (Plaintiff's experts) a bacteriologist from Sacred Heart Hospital, and a professor of microbiology from the University of Washington Medical School attributed definitive qualities to the antibiogram sensitivity test, which [the hospital's expert] witness, head of the bacteriological laboratory for the Idaho State Department of Health, found lacking.

"Experts whose opinions shaded strongly toward the antibiogram test agreed that, although it was employed as a therapeutic tool to aid the physician in deciding which particular antibiotic medicine to prescribe, \* \* \* the test then became a strong one to indicate which strains of staphylococci were present. [The hospital's expert], on rebuttal, testified to the contrary, however; he testified that \* \* \* he did not believe that the sensitivity test gave a reliable basis for determining strains of staphylococcus. [He] held to the opinion that the only purpose of the antibiotic sensitivity test

was to aid the physician in determining the best antibiotic to use on a particular patient. His laboratories never use this test to ascertain a strain of staphylococcus. In his opinion, the sensitivity test is unreliable in determining strains because it is subject to too many variables \* \* \*"

The court held there was no evidence of cross-infection from patient B to patient A. Then the court said (at p. 612):

"\*\*\*We do not have an inference founded upon another inference or conjecture, but rather strong circumstances pointing one way or the other from which the jury could and did find the ultimate facts."

In another case, Kapuschinsky v. United States of America (USDC, D. So. Carolina, Charleston Div. 1966), 248 F.Supp. 732 (see also 259 F. Supp. 1, 9 months later in the same year for opinion on damages), K.G., a sweet young high school graduate, entered the Navy as a Wave and was sent to a Naval hospital corps school for 4 months' nurses training, including service in the pediatric ward handling sick children during her last 2 weeks of training. After graduation, she was given a physical examination that did not include a throat culture and assigned to the defendant VA Hospital. On reporting for duty, she had no physical examination and no throat culture. She was assigned to the nursery for premature babies.

One month later, a staff sergeant's wife gave birth to a premature baby girl, A, who weighed 2 pounds, 15 ounces. She was placed in an isolette in the premature nursery.

Shortly after birth, baby girl A appeared jaundiced. The jaundice was progressive, and the baby was increasingly lethargic. At age 4 days, she went on the critical list. Femoral taps for bilirubin determinations were made, three femoral taps over a 5-day period. These taps were discontinued because the jaundice gradually cleared and the baby appeared to be recovering. When the umbilical cord fell off, there was some redness around the naval. This area contained *Proteus vulgaris*, and an antibiotic, bacitracin ointment, was applied.

The physician in charge of the nursery testified:

"The nurses called my attention to the fact that the child had not been wiggling her legs as much as usual on the 25th (age 11 days) \* \* \*. [On] Sunday morning the 26th \* \* \* there was obvious swelling and warmth in the child's hips. She had fever. She had not had fever before, and it was apparently an infectious process."

The child was transferred on the 26th from the premature nursery to the pediatric department. There both hips were incised, drained, and irrigated with an irrigation drain. The child was started on antibiotics. X-rays confirmed the initial diagnosis of osteomyelitis involving both the right and left femur, the pelvic girdle, and the right humerus.

Culture and sensitivity studies showed the material from the left hip contained *Staphylococcus aureus* coagulase-positive, sensitive to chloramphenicol and Furadantin. The material from the right hip contained pseudomonas. It was suspected that this was an overgrowth and that this material actually also contained *S. aureus* coagulase-positive.

As a result of these laboratory findings, nose and throat cultures were done on all personnel in the nursery, and all were negative except Wave K.G. whose nose culture showed S. aureus coagulase-positive, sensitive to aureomycin, chloramphenicol, Terramycin, tetracycline, and Furadantin.

The disease was finally arrested, but baby girl A was left permanently and severely handicapped.

The U.S. District Court acting as jury held for the plaintiff, stating (at p. 736):

> "'The degree of care exacted of private institutions toward their patients is such reasonable care and attention for their safety as their mental and physical condition, if known, may require, and should be in proportion to the physical and mental ailments of the patient, rendering him unable to look after his own safety.'

"Of course, a higher degree of care is required of a hospital in caring for a child than an adult. \* \* \* a premature infant is entitled to the highest possible degree of care, consistent with good medical practice, because of its precarious toe-hold on life and its helplessness."

The hospital had broken its own rule forbidding Corps Waves to handle or minister to premature infants of the plaintiff's age and development; K.G. was asked to and did pick up the baby, change her diapers, transfer her to the car to take her for feedings, and feed her.

The staphylococci from the child and Wave K.G. were not phage typed because of alleged unavailability of that kind of testing in the area in 1961. Instead, sensitivity tests (antibiograms) were done. They showed that organisms from the baby were sensitive to chloramphenicol and Furadantin, whereas organisms from Wave K.G. were sensitive to these and to aureomycin, Terramycin, and tetracycline.

The court observed from this:

"\*\*\* does this mean that the two strains were different?

"The Court concludes that they were not different \* \* \*. (at p. 739)

"It is clear that there is no direct evidence, as opposed to circumstantial evidence, upon which to make a determination of the identity of the strain, or the method of actual transmittal to the child. Nevertheless, circumstantial evidence is competent to show both. \* \* \* (at p. 742)

" \* \* \* The mere fact of infection is not enough to open the door to the awarding of damages, but when the admitted direct evidence is considered in light of the different means of transmittal about which all the doctors testified, then it can be seen that plaintiff has met the burden of proof." (at p. 743)

Concerning accepted practice of the community not being equal to the proper standard of care, the court observed (at p. 746):

"\*\*\* the testimony of Dr. John R. \* \* \* Chief of the Department of Pediatrics at the Medical College \* \* \* has given the Court great concern.

"'Q Now with regard to the testing at the Medical College Hospital, did I understand that at one time there was testing (culturing), routine testing of the personnel in that nursery?

'A This was put into practice before I took over charge of the service.

\* \* \*

'Q And then, as you said, you forbade this particular practice?

'A Yes.

'Q And you would prefer not to know whether you had such a carrier on the staff in the nursery?

'A Right.

'Q Because if you knew about it, it might upset whether you were able to assign these people or not?

'A It would make it impossible for us to run the nursery.

'Q So you feel that it is better simply

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to be in ignorance as to whether you have carriers working in your nursery? 'A Yes.

<sup>6</sup>Q You don't think it would be better to have this knowledge and then make a determination based upon the other qualifications of the person and whether they had any other signs of disease?

'A We prefer not to know it. That is absolutely correct.' "

The court wouldn't buy this. Quoting from another case, the court said (at p. 747):

"To relieve a member of the medical profession from liability for injury to a patient on the ground that he followed a degree or standard of care practiced by others in the same locality is, in our opinion, unthinkable when the degree or standard of care in question is shown to constitute negligence because it fails to meet the test of reasonable care and diligence required by the medical profession. To hold otherwise is to exempt one from \* \* \* negligence \* \* \* on failure to take a known precaution for the safety and welfare of a patient on the ground that others in the same profession follow a similar course."

But not all courts are unsympathetic to hospitals. In Thompson v. Methodist Hospital (Sup. Ct. Tenn. 1963), 367 S.W.2d 134, a husband and wife and their newborn infant sued for injuries suffered from Staphylococcus aureus infection contracted by the baby at the hospital and transmitted later at home to adult mother and then to adult father. At the trial the verdict of the jury was \$25,000 for the three plaintiffs against the hospital. The Court of Appeals set aside the judgment entered thereon and dismissed each of the cases. The Supreme Court of Washington affirmed the dismissal of the Court of Appeals, holding that the baby got *S. aureus* in the hospital and gave it to the mother who gave it to the father, but there was no proof of negligence or proximate cause.

The medical facts were that the mother entered the hospital on February 28, 1958. The baby was born that day. The mother and baby went home on March 3. When they were taken home, the father noticed some rash and pimples here and there upon the body of the infant. In the course of some days, these became worse. The mother became afflicted, and some days later the father also became afflicted.

In the last six months of 1957, staphylococcus appeared frequently in and out of hospitals in Memphis. As a part of tightening up of aseptic techniques, in the early part of 1958 doctors and hospitals began to take nose and throat cultures from hospital personnel.

After this mother was discharged, some four to eight persons in the hospital were discovered to be carriers of staphylococcus. Among them was an intern, Dr. H. Dr. H examined the mother when she entered the hospital, but there was no evidence that he ever came in contact with the baby.

Mrs. W, a practical nurse, with duties consistent there, appeared from time to time in the hospital with a boil. When that was made known to her superior, she was at once sent home and requested to remain there until her doctor had discharged her as having been "cured." She was in the newborn nursery for only 3 days in more than a year at this hospital. There was no evidence that this baby at any time was exposed to her, or that

<sup>\* \* \*</sup> 

she was in this nursery during the baby's stay there.

A trained nurse, E, testified to certain conduct in the labor section that was not in keeping with aseptic techniques. Mrs. W likewise gave testimony to that effect. All the evidence is that these were infractions of the rules of the hospital. None of the other many employees or doctors observed these violations.

In its opinion, the Supreme Court said (at pp. 135–137):

"The conclusion is inescapable that the acts to which these witnesses testified were occasional violations of the rules rather than the practice in this hospital. It must be recognized that some occasional violations of the rules of a large hospital employing a large number of people will occur without regard to how strict the hospital is in the enforcement of its rules. There is no evidence that any of these violations occurred during the time Mrs. Thompson and her baby were there. \* \* \*

"\*\*\* every doctor testifying in this case, unequivocally stated that the aseptic technique, the care, skill and diligence used by the Methodist Hospital in its newborn nursery and in its entire obstetrical department were up to the standards prevailing in any hospital in Memphis and better than in some of them. \*\*\*

"The original plaintiffs in this case concede that their case is based upon circumstantial evidence. The circumstances hereinbefore stated do not, in the opinion of this Court, furnish any evidence of negligence on the part of the hospital at the time this baby was there \* \* \* .

"The plaintiffs principally rely upon certain rules and regulations designed to lessen, insofar as they could, the obtaining of this infection. \*\*\*These rules are entitled, 'Standard and Recommendations for Hospital Care of New Born Infants, Full Term and Premature.' "\*\*\* these rules and regulations, if they could be absolutely followed, present a hospital Utopia \*\*\* no hospital of the usual endowments, funds and facilities could possibly comply with these rules. Nor is it necessary to do so.

"By way of extreme illustration, it is shown that at the Methodist Hospital porters enter certain portions of the obstetrical department for the purpose of taking out bags of soiled linen. These bags are too heavy for the nurses to handle. One of the personnel of the hospital called as a witness for the plaintiffs was asked by the plaintiffs this:

'Does the porter take a bath before he goes in every time?'

meaning the entering of the delivery area from the labor room to remove the heavy cases of soiled linen. The reply \* \* \* was that such porter:

'is garbed \* \* \* in the proper things; that he puts on a cap, a mask and a gown and washes his hands when he goes in.'

Obviously it would be impossible in the average hospital to make such a requirement of the porter. Many other such recommendations are contained in [the] book of rules.

"\*\*\* some eight to ten babies are born in this hospital each day. \* \* \* babies remain there for some four to five days, it would mean that always there are from thirty-two to forty babies in the new-born nursery at a time. The practice in this hospital was to carry the babies for feeding six times a day in a vehicle known as a carrier. Each baby was separated from the other in this carrier by a partition which is at least several inches above the body of each baby. One of the recommendations of [the] book of regulations is that each baby should be carried separately to its mother by a nurse, who returns and washes her hands, etc. and then carries another baby to its mother, with same procedure followed each time. This would require some 240 to 300 trips the nurses would have to take each day for this one service alone. It is obviously impractical. The proof shows, without dispute, that this hospital does not have the personnel to carry out such procedure and could not obtain that many nurses, considering the shortage which exists, and assuming it could be financially afforded in the average hospital."

Well, this court would agree with the practicalities of hospital life, i.e., What will the personnel tolerate? You reach human limitations. Personnel are unable to follow too many restrictions.

In Smith v. Curran (Colo. Ct. App. 1970), 472 P.2d 769, the patient suffered a fracture of the knee in a traffic accident. He was taken to Denver General Hospital where he received emergency treatment. Later he was taken to a private hospital where dean orthopaedic surgeon, fendant. undertook his care and treatment. Upon examination, the injury was diagnosed as a closed and partially dislocated fracture of the left femur with subluxation and fragmentation. A closed reduction of the fracture was performed and a cast applied. A few days later, X-ray examination revealed that the reduction was lost. The surgeon then performed an open surgical procedure in which the bone fragments were brought together with pins and screws and a cast applied. Antibiotics were administered as a preventative measure for 6 days and then discontinued. Twelve days after the operation, a spot appeared on the cast. The cast was opened and it was observed that the operative area was infected. Cultures were taken and antibiotic therapy was instituted. The following day, upon the basis of the cultures, a diagnosis of staphylococcus

was made. Treatment was administered. About 2 weeks later, X-rays revealed osteomyelitis in the bone joint. The osteomyelitis had severely and permanently damaged plaintiff's leg.

The plaintiff and the defendant were the only witnesses at the trial. The doctor stated that he did not know the source of the staphylococcus infection and the subsequent osteomyelitis. He also stated that such conditions are recognized complications which sometimes follow surgery even though the surgeon has followed accepted surgical practices.

The patient sued his surgeon. At the trial, the patient produced no expert witnesses, relying on the doctrine of *res ipsa loquitur*. The trial court gave judgment in favor of the surgeon which was affirmed on appeal by the Court of Appeals which observed (at p. 771):

"\*\*\* the mere fact that a patient develops an infection in the area under treatment does not raise a presumption or inference of negligence on the part of the attending physician. The mere presence of infection following an operation is not prima facie evidence of negligence."

But in Mershon v. McWhirter and Palomar Hospital (Cal. Super. Ct. 1970), not officially reported—see The Citation (AMA), Vol. 21, No. 12 (10/ 1/70) at p. 182, the patient prevailed against her orthopaedic surgeon but not against the hospital, both of whom she had sued. Here the following medical facts were involved:

"A hip fracture patient who claimed that a physician negligently allowed a Neufeld nail to penetrate the acetabulum won a suit against the physician in a California trial court.

"The patient also alleged that during the postoperative period the physician allowed her to remain in a room with a patient who had contracted a staphylococcus infection. The woman contended that, as a result, she became infected and developed osteomyelitis of the femur. The hospital, which had also been sued, was found not liable.

"The patient had sustained a severely comminuted intertrochanteric hip fracture. Her physician used a Neufeld nail and performed a displacement osteotomy to repair the hip. She alleged that the nail penetrated the acetabulum and that the physician was unable to remove the nail. After breaking two extractors, he elected to leave the nail until restoration processes occurred. The nail was later removed. The physician contended that nail penetration can occur even when due care is used.

"The patient alleged that her roommate in the hospital suffered a staph infection and that she herself became infected 16 days after hip surgery had been performed. The infection allegedly resulted in osteomyelitis of the femur.

"The patient claimed that, as a consequence of the alleged negligent care, she suffered a  $1\frac{1}{2}$  inch shortening of the right leg, severe external rotation, and knee problems.

"The woman said that the physician knew the roommate was infected. She also charged that the hospital's physicians and nurses failed to follow proper sterile techniques.

"Testimony indicated that the hospital was filled to capacity and that neither the patient nor the roommate could be moved. The physician and the hospital contended that when a hospital has no other available space, it is proper to place infection patients in the same room with other patients if correct isolation techniques are followed.

"An orthopedist testified that the shortening of the leg was due to the nature of the fracture, that angulation was not warranted, and that ambulation was possible with a lift. He said that the patient would not need future surgery but might require physical therapy. She might have to use a cane, he commented.

"The patient requested an award consisting of \$8,000 for medical expenses, \$10,000 for future medical expenses, and \$80,000 for loss of future earnings. The jury held the physician liable for \$100,000 but found in favor of the hospital.

> Mershon v. McWhirter and Palomar Hospital, (Cal. Super. Ct., San Diego Co., Docket No. 309260, 1970)"

## Summary of nosocomial infection cases

Let me summarize: Nosocomial infections, like death and taxes, are going to be with us forever. And so long as our present jury system prevails, and I don't know how long it will prevail without some drastic changes, we will have patients bringing lawsuits based upon nosocomial infections. Our best defense will be to prove to the court and jury that the hospital and surgeon were not negligent, that we used "due care," first to minimize the potentially virulent organisms in the hospital environment and, second, to maximize the patient's ability to combat those "bad bugs." Third, we must minimize the chance and the duration of each patient's exposure to these organisms. Fourth, we must maximize the infected patient's chances of recovery. If we show a jury all of these things, I think we will be a long way toward winning.

Unfortunately, the new techniques of diagnosis and treatment of the past 10 years have increased the risk of inducing infection, i.e., iatrogenic induced infections. We have now got to go back and reanalyze what is being done with these new techniques, with the latest respirators, with open heart lung bypass machines, and all the rest. Are these inducing more infection? If so, the duty to exercise "ordinary care" is there, and we will have to meet it.

Also, you face a dilemma with your rules, the two-edged sword. You have to have them to run a tight ship, but they will be used against you, so be realistic about them, don't ask more of personnel than is practical, because we are going to get hurt with these rules in the courtroom.

Concerning proximate cause, the patient must prove that the alleged negligence of the hospital directly led to his infection, that without the negligent act he would not have gotten it. I foresee a more sophisticated "detective hunt" on the part of the plaintiff and the defendant. Which is a "bad bug"? Is it masked by another "bad bug"? Is the real "bad bug" the "bug" underneath? Why does it do harm? Is the harm due to the hospital's negligence, or is it due to a patient's idiosyncrasy, or an unforeseeable intervening event? For example, babies in a premature nursery were infected. It was found that the only ones who got lung abscesses and died were on ACTH therapy. It might not have made the difference there, but we are going to get some really sophisticated "detective hunts" on proximate cause issues. Sometimes they will help us, sometimes not.

The more you learn, the more will be required of you.

## Conclusion

Laminar flow air conditioning as a specific method of producing a clean air system evidently has yet to prove itself. Until it does, its absence should not contraindicate total hip replacement surgery or other patient treatment or care, although if available, not to use it, at least at the time of this writing, would seem to be fraught with the medicolegal peril of being hindsighted for its omission should infection later develop.

Some sort of clean air system, however, as part of overall bacterial control, both in and out of the operating room, would seem to be a necessity. The risk of infection increases with more extensive surgical procedures such as total hip replacement. Just what measures are required to be taken to combat infection in order to meet the law's test of ordinary care also increases.

Such measures would seem to include a course of antibiotic therapy, perhaps both before and after the surgery; as strict control of the operating room environment as possible to hold the bacterial count to the minimum possible by whatever means are available and recognized in the present state of the art; as strict control of the patient's postoperating room (and even preoperating room) environment as is possible, including screening of roommates, clean air systems for the patient's room or living area, etc.

Insofar as the clean air system component of such measures is concerned, initial responsibility for selection would seem to rest partly on the operating room surgeon and/or treating physician submitting his patient to such environment for treatment, and partly on the institution offering such facilities for such treatment. Responsibility for proper maintenance and operation of such system thereafter, however, would seem to rest primarily upon the institution, with the surgeon and/or physician bearing responsibility only for his own negligence in either not making the minimal checks ordinary care would require of such a person to insure adequate functioning of said equipment for the purpose intended and immediately at hand, or in continuing to treat his patient after acquiring knowledge that the system was not then functioning properly. If the surgeon and/or physician neither actually knew, nor, in the exercise of ordinary care, should have known of any malfunction in said system, he should not be held liable therefor.

To recapitulate: The test of good medicine is the patient's welfare. It is also the test of the law.