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Carl E. Wasmuth

John Homi

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MAN'S STRUCTURE AND FUNCTION require him to live in air at atmospheric pressure. However, he can survive exposure to some variation in his usual environment. The atmosphere that we breathe is approximately 80% nitrogen and 20% oxygen; there are only minute amounts of inert gases and carbon dioxide. At atmospheric pressure, the human respiratory system removes the carbon dioxide from the circulating blood and permits the absorption of sufficient oxygen into the blood for it to become "saturated" and thus oxygenated adequately to maintain life.

As one ascends into space, the air becomes thinner or rarified, and while the proportion of oxygen and nitrogen remains constant, the total number of molecules becomes less. Ultimately, a point is reached, where man cannot survive without accessory oxygen or increased ambient pressure. Such is the case of the astronaut who ascends hundreds of miles above the surface of the earth into an extremely rarified gas environment. Though the lack of atmospheric content permits phenomenal speed and accounts for the absence of friction, nonetheless, the one who is in the space vehicle must breathe to survive.

Before man can explore space, science must provide a means to keep the astronaut alive: oxygen at fifteen pounds pressure must be available to him to breathe, and also, in the space capsule, carbon dioxide that is eliminated with each breath must be removed. A decreasing oxygen and increasing carbon dioxide content rapidly becomes incompatible with life. All of the endeavors of the space project are wholly dependent upon the ability to control these variables. As a result, extensive medical research has been carried on in the field of respiratory physiology.

While the space agency has been groping into the unknowns of rarified atmospheres, the United States Navy has been investigating the physiology of life under increased atmospheric pressure. In the past fifty years, the United States Navy has investigated underwater physiology in its efforts to carry on rescue

* M.D., LL.B.; of the Dept. of Anesthesiology of Cleveland Clinic; Assoc. Prof., Cleveland-Marshall Law School of Baldwin-Wallace College.
** M.D.; of the Dept. of Anesthesiology of Cleveland Clinic.

work. One has only to recall the loss of the submarine *Thresher* and the rescue operations undertaken to save the lives of the crew imprisoned in it, to realize the need for such investigations. Oxygen and nitrogen content of gases increase as pressures increase. At a water depth of thirty feet, which is equivalent to one additional atmosphere of pressure, the diver experiences no ill effects when breathing air. However, it was found that air breathed below sixty feet of water could become toxic to the diver. The nitrogen at that level may cause nitrogen narcosis or "rapture of the deep." In addition, when the deep diver surfaced he was most likely to get the "bends" or caisson disease. The nitrogen dissolved in the body formed bubbles in the tissue as pressure decreased. Oxygen at increased pressure may have toxic effects on man, resulting in convulsions.

Medical investigators have learned much from the experience of the caisson workers. For more than one hundred years engineers have been concerned with the increased pressures in caissons. Similarly, high pressure is provided to enable sandhogs to dig into the river bed to construct tunnels. For the most part, these operations are carried out under relatively low levels of increased atmospheric pressures (*i.e.,* fifteen to thirty pounds per square inch above atmospheric pressure). This pressure is equivalent to swimming at from thirty to sixty feet under the surface of the water. At these pressures, the cardiorespiratory physiology of man is not compromised. However, thirty pounds per square inch, or sixty feet of water, is the usual limit. Beyond this depth, complications begin to appear.

Clinical Use of Pressure Changes

Clinical medicine now takes advantage of all the research that has been performed both in the low pressure and in the increased atmospheres. Under basic physical laws, it became obvious that the administration of oxygen under increased pressure may force fantastically large amounts of oxygen into tissues. In order to accomplish this so-called "oxygen drenching," the patient must be placed within a steel tank (hyperbaric chamber) and the pressure raised, while he is breathing an atmosphere of 100% oxygen.

The use of the hyperbaric chamber is not new to medicine. However, the previous excursions into the realms of hyperbaric therapy were not always entirely scienitfic. In centuries past, such facilities were built and the self-styled "physicians" turned to the administration of air under increased pressures as the panacea of all ills. Though they were not able to prove that pressurized air was such a panacea, they did succeed in initiating the study of engineering and theory, which much later led to the application of hyperbaric oxygenation. Such chambers were built in Europe as early as 1662. In this country, in the late '20's, there were instituted a series of financial ventures, some of which were attacked successfully by the American Medical Association. Some Clevelanders may even remember the large spherical hyperbaric chamber that was constructed by Cunningham on a site close to Euclid Beach Park. This chamber, demolished for scrap metal during World War II, was built for the treatment of diabetes and syphilis. These diseases, according to our present-day concepts of hyperbaric oxygenation, unfortunately are not amenable to such therapy.

The clinical use of hyperbaric oxygen is based upon the simple fact that by increasing the pressure of a gas its density is increased. When the pressure is doubled, twice the number of molecules of a gas is available for use. Likewise, the partial pressure of the gas increases proportionately. This means, therefore, that the gas is under a greater force. If an organic cell requires a certain gas, oxygen, and has an insufficient supply of it, but basically has not lost the ability to receive and to utilize the substance, then a quantitative increase of gas tension at the site of activity of that cell must constitute a benefit for the cell. Notwithstanding all that is known about organic need for oxygen, it would be difficult to state in greater detail the mechanisms of cellular respiration, in general, or the respiratory efficacy of hyperbaric oxygen.

Breathing air at atmospheric pressure (one atmosphere absolute or fifteen pounds per square inch), by a human being with normal respiratory capabilities, the alveolar tension of oxygen is approximately 100 mm. Hg. The partial pressure of atmospheric oxygen is approximately 150 mm. Hg (20% of 760 mm. Hg, or, one atmosphere absolute). By the time the air is inhaled and mixed with some of the other elements in the respiratory tree, the partial pressure of oxygen in the alveoli is reduced to approximately 100 mm. Hg. Should the individual breathe 100% oxygen at the atmospheric pressure on the other hand, the partial pressure of oxygen in the alveoli then is increased to approximately 600 mm. Hg.

If the blood circulating in the lungs becomes equilibrated with the alveolar gases, the tension of oxygen in the arterial blood is approximately 100 mm. Hg. if the person is breathing room air. If the person is breathing 100% oxygen, theoretically, the arterial oxygenation should be approximately 600 mm. Hg. However, due to certain pathophysiologic states, equilibration of the arterial blood with alveolar gaseous tensions might not be obtained. The degree of this shunting effect is variable, but under hyperbaric conditions arterial oxygen content is always increased significantly.

It becomes evident that, in certain pathophysiologic states, the administration of 100% oxygen to a person is not sufficient to provide adequate oxygenation at the tissue level. A person who has just suffered an acute and massive coronary occlusion might not survive, because of the lack of oxygen to the heart muscle or myocardium. The administration of 100% oxygen at atmospheric pressure is insufficient to provide adequate oxygenation to the myocardium, and the person dies. However, should the person be placed in a chamber whereby the pressure of the chamber can be elevated to two or three atmospheres absolute, effective arterial oxygenation tension may be increased many times.

The air within the chamber is compressed by means of oil-free compressors to fifteen pounds per square inch gauge (two atmospheres absolute) and in some circumstances to thirty pounds per square inch gauge (three atmospheres absolute) and the patient breathes 100% oxygen by way of face mask or endotracheal tube. The alveolar concentration of oxygen under these circumstances is raised to approximately 1,400 mm. Hg at fifteen pounds per square inch, or approximately 2000 mm. Hg at thirty pounds per square inch pressure. It can be seen that breathing 100% oxygen at three atmospheres absolute (*i.e.*, about 2000 mm. Hg) increases the effective arterial oxygen tension approximately twenty times over the value when breathing air (100 mm. Hg) at normal atmospheric pressure. Under these conditions, it is possible for life to exist without red blood cells being circulated in the circulatory system. If one were to replace all the blood with a suitable substitute, life could be sustained without the red blood cells or hemoglobin being present.

One should avoid the metaphysicians' mistakes—: hyperbaric oxygenation is not a panacea. Nevertheless, experimentation and expectation should not be burdened by rigid skepticism; the rationale of administering oxygen under pressure is firmly based. Much more work needs to be done, and some inquiry into hyperbaric oxygenation seems to be in order, but there is enough evidence to suggest that the technic deserves a respected place in clinical practice. Even in the minds of cautious surgeons, the promise of hyperbaric oxygenation is broad; in fact, a measure of their enthusiasm is the increasing frequency of their warnings against overenthusiasm.

Hyperbaric oxygenation has been shown to have definite therapeutic value in the treatment of caisson disease, carbon monoxide poisoning, gas gangrene, and tetanus. Since a high concentration of oxygen in cells potentiates their susceptibility to radiation, the effect being greater in cancerous than in normal cells, hyperbaric oxygenation has proved useful also as an adjunct in radiotherapy. The value of the technic in carbon monoxide poisoning can be attributed to the ability of oxygen vigorously to facilitate carbon monoxide unbinding from the hemoglobin, allowing its elimination through the lungs. Concomitantly, large quantities of oxygen dissolved in the plasma supplies the peripheral tissues. The carbon monoxide molecule binds itself to the hemoglobin molecule of the red blood cell, thereby denying the oxygen molecule access to this method of distribution to the tissues. Under hyperbaric conditions, sufficient oxygen is present in simple solution in the plasma to help supply the tissue demand.

In gas gangrene, the technic rapidly reestablishes oxygenation of the tissues, and the circulatory competence, thereby inducing a cyclic improvement. It is not clear why hyperbaric oxygenation is useful in tetanus, since the organisms (anaerobic *Clostridia*) are dead by the time the disease is manifest. Concentrated oxygen appears to give general physiologic support in this instance.

In the facilities currently being planned at the Cleveland Clinic, the treatment of several pathophysiologic states is contemplated. Medical science is now entering the era of the *Transplantation of Organs* from one person to another. Much of the original work performed in this area has been in the transplanting of kidneys from donors to patients suffering from destruction of their own kidneys by disease. Currently, at the Cleveland Clinic, a program now exists whereby a patient who is maintained upon the chronic kidney dialysis program is, when the opportunity presents itself, operated upon and has a donor kidney implanted in him. Whether such a kidney is donated by a volunteer or is removed from a patient who has just succumbed from other disease, the time elapsing from the moment of cessation of circulation to the donor kidney is of great importance. From the time of the ligation of the blood supply, the kidney suffers from a lack of oxygen. Therefore, it is imperative that the recipient be ready to receive the kidney immediately after it becomes available. Were the donor as well as the recipient placed in a hyperbaric chamber where 100% oxygen can be administered under increased atmospheric pressures, the abundance of oxygen as well as increased partial pressure of oxygen would provide advantages not otherwise obtainable. Were the kidney to be removed from the donor in this increased atmospheric environment, the quantity of oxygen available to the kidney tissue during the period of transplantation would be increased and less damage from hypoxia would occur. Likewise, the recipient, being under the same hyperbaric conditions would have oxygen-enriched blood circulating at the time of the operative procedure and, consequently, the kidney graft would receive well oxygenated blood immediately upon implantation.

In the very near future, after immunosuppressive technics become perfected, the transplantation of hearts, livers, and lungs in the human will become a clinically available procedure. However, inasmuch as these organs suffer acutely from oxygen lack, it may then become desirable that such operative procedures take place under increased atmospheric conditions to insure more efficient oxygenation of the transplanted organs.

In the patient suffering from vascular disease, the basic problem is decreased arterial blood supply resulting in transportation of too little oxygen to the peripheral tissues. Adequate oxygenation of these tissues conceivably can be accomplished by increasing the oxygen concentration of the blood that circulates through the peripheral tissues. In limbs where the arterial supply is occluded by arteriosclerosis, by atherosclerotic plaques or by other pathologic mechanisms in the arteries, a diseased artery can be removed, if of sufficient size, and a new artery grafted into the area. Unfortunately, in many cases, the operative procedure involves a physiologic trespass not consistent with continued life. The circulation has been so disturbed that in spite of a surgical "cure," the patient succumbs to shock.

It is hoped that the condition known as surgical shock can be treated successfully in the hyperbaric chamber. Ultimately death from the surgical shock is due to the lack of oxygen in the peripheral tissues. While one recognizes that many factors enter into this complex picture of surgical shock, no one will deny that hypoxia plays a most significant role. Unfortunately, all modern surgical operations involving the transplantation of organs, or of the grafting of major arteries, carry with them the hazards of surgical shock. Unless and until this syndrome in the post-operative period can be conquered, the exercise of reasonable surgical medical judgment may deny the patient the possible benefits of such surgical advances.

The basic pathologic lesion in coronary artery disease is atherosclerosis, which leads ultimately to the narrowing or occlusion of the vessel lumen by progressive intimal thickening, intimal ulceration, hemorrhage, or superimposed thrombosis in the coronary arteries. As a result of this occlusive process, there is a decrease in the arterial blood supply to the heart muscle, resulting in a decreased oxygen supply to the muscle. The current treatment of patients with acute myocardial infarction has been almost standardized: bed rest, anticoagulants, and the frequent administration of oxygen. The treatment of patients with severe angina pectoris at rest (angina decubitis) is the same. Various surgical procedures to improve the blood supply to the heart have been proposed whereby other blood supplies are implanted into the heart muscle. None have won wide acceptance, because conclusive evidence of their therapeutic effect has not been shown. A more logical surgical approach would seem to lie in those procedures designed to restore normal blood flow in the obstructive segment of the coronary arterial tree by endarterectomy (i.e., removal of the atheromatous plaque within the lumen of the coronary artery), by bypass graft or patch graft. Such procedures, up to the present time, unfortunately have been associated with a considerable mortality rate. The patients with severe angina pectoris or acute coronary artery occlusion could be treated under hyperbaric conditions to increase the oxygen content of the blood. In addition, patients with serious coronary artery disease undergoing operation for other conditions might be carried through the operative procedures and the postoperative period in a hyperbaric chamber. Surgical procedures to improve the blood supply to the heart, such as coronary endarterectomy, should be carried out under hyperbaric conditions in an attempt to lessen the operative risks. Patients undergoing vascular surgery for occlusive disease of the legs, brain, or for aneurysms, who have associated coronary artery disease, could be operated on under hyperbaric conditions. In addition, these patients, in order to avoid the pathophysiologic effects of such a surgical procedure, could be treated during the immediately postoperative period in the hyperbaric chamber.

Hyperbaric Chamber Construction (Legal Problems)

The installation and utilization of the hyperbaric facility for the administration of oxygen to patients under increased atmospheric pressures presents several legal problems. Before 1905, boiler explosions had been regarded either as an inevitable evil or "an act of God." In 1908, the State of Ohio passed legislation, the Ohio Board of Boiler Rules, which was patterned after the Massachusetts Statutes.[1] Other states began to formulate rules and regulations to control the manufacture as well as the operation of boilers. As regulations differed from state to state and often conflicted with one another, manufacturers began to find it difficult to construct vessels for use in one state that would be accepted in another one. Because of this lack of uniformity, an appeal was made in 1911 by both manufacturers and the users to the Council of the American Society of Mechanical Engineers to correct the situation. After three years of study, the first American Society of Mechanical Engineers "Rules for Construction of Stationary Boilers and for Allowable Working Pressures" was adopted in 1915.[2]

Subsequently, the boiler manufacturers met with the chief inspectors of the states and cities that had adopted the ASME code and formed the National Board of Boiler and Pressure Vessel Inspectors for the purpose of presenting the ASME code to governing bodies of all states and cities.[3] It is now possible for an authorized shop to build a boiler or pressure vessel that will be accepted anywhere in the United States or Canada after it has been inspected by an inspector holding a National Board Commission.[4] It is therefore customary for users of pressure vessels to order ASME code vessels. This insures that such vessels will be designed, fabricated and inspected in compliance

[1] Chuse, Robert, Unfired Pressure Vessels (New York, N. Y., F. W. Dodge Corp., 4th ed.).

[2] Fish, E. R., Objectives of the ASME Boiler Code Committee, National Board Bulletin (Oct. 1944).

[3] Greene, Arthur M., Jr., History of the ASME Boiler Code (Amer. Society of Mechanical Engineers, 1955).

[4] Myers, C. O., The National Board and Its Functions in Jurisdiction and Uniformity, in, Proceedings of Eighteenth General Meeting (National Board of Boiler and Pressure Vessel Inspcetors, May 1948).

with a safe standard as well as an accepted standard.[5] The State of Ohio requires unfired pressure vessels to comply with Section VIII of the ASME code; in addition, however, the shop inspectors must have a commission from the State of Ohio as well as from the National Board.[6]

According to the regulations, repair or alteration of ASME code vessels may be made in any shop that manufactures ASME code vessels, or in the field by any welding contractor qualified to make repairs on such vessels. Recognizing the board application of welding in repair work, the National Board of Boiler and Pressure Vessels Inspectors has approved a set of rules called "The Recommended Rules for Repair of Power Boilers and Unfired Pressure Vessels by Welding."[7] These rules, combined with rules for riveted repairs, are intended to apply only to used vessels and pressure vessels. Many states have adopted these rules as part of their boiler and pressure vessel laws. However, before repairs are made on any ASME code boiler, the method of repair must be approved by an authorized inspector. The inspector will examine the vessel, identify the material to be welded, and compare it with the material to be used in repair. He will then make sure that the welding contractor or shop has a qualified welding procedure for the material being welded, and that the welder who does the job is properly qualified to weld that material.

The operation of a hyperbaric chamber is also subject to the restrictions set down in the city or state regulations relating to the ventilation of operating room facilities. In several jurisdictions, the code demands adequate ventilation of the operating theaters without recirculation. In the State of Ohio[8] the Board of County Commissioners is granted the authority to inspect a public or private hospital within its jurisdiction. Again, under Section 3703.01 of the Ohio Revised Code, the Department of Health is directed to inspect all public or private institutions, sanitariums, hospitals, et cetera, and to condemn all unsanitary or defective plumbing, or order such changes in the method of

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5 Myers, C. O., The National Board Inspection and Stamping, National Board Bulletin (April 1956).

6 The National Board Inspection Code (National Board of Boiler and Pressure Vessel Inspectors, 1954).

7 "The National Board of Boiler and Pressure Vessel Inspectors Organizes," Power (Feb. 15, 1921); see also, National Board Bulletin (April 1953).

8 Ohio Rev. Code, Sec. 2919.18.

construction in drainage and ventilation, as well as in arrangement of the plumbing appliances, as are necessary to insure the safety of the public health. However, the Department, by virtue of the same statute, shall not exercise any authority in municipal corporations or other political subdivisions in which ordinances have been passed or resolutions or regulations have been adopted and are being enforced by the proper authorities regulating plumbing or prescribing the character thereof.

Section 4103.06 of the Ohio Revised Code provides that when a person desires to manufacture a special type of boiler, the design of which is not covered by the rules formulated by the Industrial Commission, he shall submit drawings and specifications of such boiler to the Commission, which may permit the installation of the same.

Hyperbaric Chamber Operation (Legal Problems)

Inasmuch as there are no statutory or code regulations for the operation of a hyperbaric facility within the hospital, one might look to administrative regulations promulgated by the Department of Labor of the State of New York. The Industrial Code, Rule No. 22 entitled "Work in Compressed Air," is set down by the State of New York, Department of Labor. These regulations delineate the responsibilities of the owner, and regulate the general operation of such pressure facilities, including

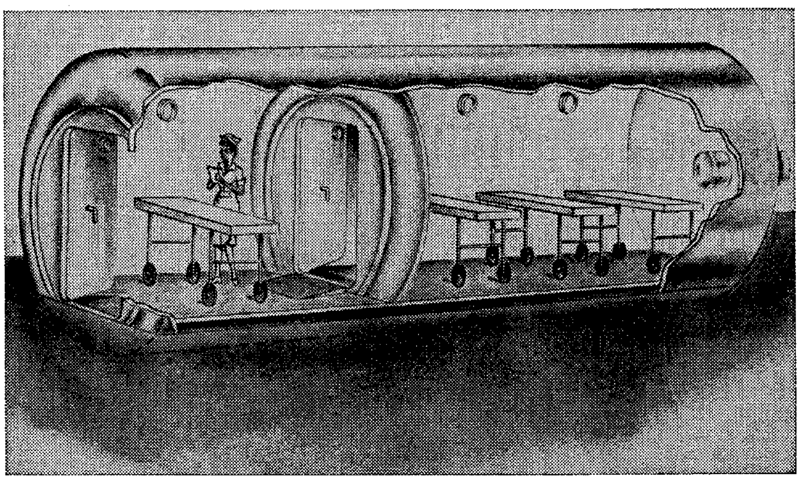

Figure I. The modern design of a clinical hyperbaric chamber, accommodating three patients in the main chamber. One bed can be located in the entrance lock where patients or personnel are compressed or decompressed.

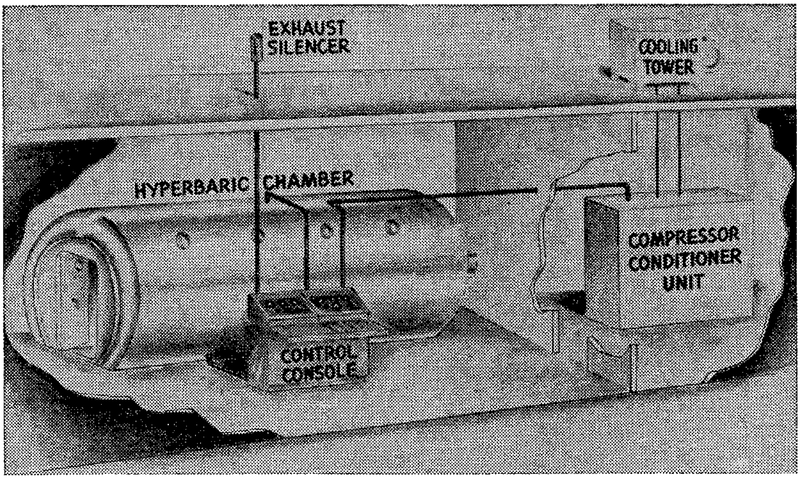

Figure II. A schematic drawing illustrating an entire hyperbaric complex. The compressor-conditioner unit compresses cleaned air. Because compression heats the air, it must be cooled before entering the chamber.

the work periods, rest periods, and decompression time. These rules also contain special provisions in regard to such matters as regulating the compressors, lighting, fire prevention and first-aid.

In addition, the National Fire Protection Association Committee on Hospitals has codified specifications relative to compressed gases as well as ventilation in the operating room. It is readily apparent that the operation of the hyperbaric facility comes within the purview of many statutes, regulations, and administrative rules dealing with varied aspects of the problem. It is suggested that the Committee on Hospitals of the National Fire Protection Association, or the Hyperbaric Committee of the National Academy of Sciences, set down a model code for the operation and maintenance of hyperbaric facilities. Should any legal action be instituted against a physician or hospital, the evidentiary weight and sufficiency of such a code would be most helpful in defense.

Professional Liability

It is axiomatic in the law of negligence in malpractice that the physician shall exercise reasonable degree of skill and care in the treatment of a patient. The physician in the hyperbaric chamber must treat his patient with reasonable care, and he must possess reasonable knowledge of the effects of high ambient pressures upon the physiologic processes of his patient. It is not sufficient that the surgeon possess reasonable skill and exercise reasonable care as compared to another surgeon in the same or similar locality. The surgeon in the hyperbaric chamber must understand the physiology of increased ambient pressures and the concurrent effects upon the surgical procedure of the patient being operated upon.

Recently, in the United States, the legal doctrine of *informed consent* has developed. In the several cases tried thus far, the courts have held uniformly that a physician must explain to the patient the hazards inherent in the proposed treatment. Should the physician fail to explain the dangers of the contemplated therapy, and should the patient suffer injury as a result of such therapy, then this becomes a fact situation submissible to the jury. In effect, the courts have held that the physician is liable in negligence should he not exercise reasonable care in explaining the possible dangers in his suggested method of treatment.[9]

Thus far, the doctrine of informed consent has been applied to new and/or inherently dangerous methods of treatment. The leading case involved the use of a new method of irradiation by the "cobalt-60 bomb." At the time of treatment, few patients had heard of this equipment or method of therapy. The court held that the thoracic wall of the patient was destroyed as a direct result of therapy employed to treat the cancer in the breast. Great emphasis was placed upon the inherent hazards of cobalt-60 irradiation. The court held that the patient should have been given the choice: (1) to gamble that the excised carcinoma had not metastasized, or, (2) to accept the hazards of cobalt-60 irradiation.

The doctrine of informed consent may well be applied to treatment in the hyperbaric facility. This method of therapy is new and possesses many inherent dangers. Few people had heard of hyperbaric administration of oxygen before the birth of Patrick Bouvier Kennedy. In spite of the publicity concerning high pressure oxygen equipment for the purpose of this discussion, and, to prevent subsequent legal complications, proper authorization must be obtained from the patient before submitting such person to hyperbaric therapy.

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[9] Natanson v. Kline, 350 P. 2d 1093 (Kans. 1960).