Communications to the Editor

Communications for this section will be published as space and priorities permit. The comments should not exceed 350 words in length, with a maximum of five references; one figure or table can be included. Exceptions may occur under particular circumstances. Contributions may include comments on articles published in this periodical, or they may be reports of unique educational character. Please include a cover letter with a complete list of authors (including full first and last names and highest degree), corresponding author’s address, phone number, fax number, and email address (if applicable). An electronic version of the communication should be included on a 3.5-inch diskette. Specific permission to publish should be cited in the cover letter or appended as a postscript. CHEST reserves the right to edit letters for length and clarity.

Catamenial Pneumothorax
An Example of Porous Diaphragm Syndromes?

To the Editor:

I recently read the letter of Dr. Kirschner (November 2000), who commented on my letter (December 1999). I would like to address some remarks and questions raised by Dr. Kirschner.

First, is the pathogenesis of catamenial pneumothorax recognized as the transdiaphragmatic passage of gas? If this is the case, then why does this disease occur in connection with menses?

Second, if the pore hypothesis is correct, then catamenial pneumothoraces seem to occur bilaterally due to the negative intrathoracic pressure.

Third, the subdiaphragmatic lymphatics communicate with the diaphragmatic pleura but not with the intrathoracic space. As a result, hydro- or pneumoperitoneum does not seem to develop hydro- or pneumothorax in a normal lymphatic state, even if fluid or gas are absorbed from the stomata. Furthermore, based on the fact that the absorption of intraperitoneal fluid is more extensive in the right hemidiaphragm, I think that the distribution of the peritoneal stomata may have a right-side predominance, and that diseases caused by such a physiologic function appear to have the same tendency.

Fourth, the article by Allen appears to have solved the controversy regarding whether peritoneal stomata represent normal open or acquired holes in the diaphragm. In the left upper quadrant, the solid, more-or-less-fixed liver acts as a piston when the right hemidiaphragm contracts, raising the intraperitoneal pressure locally, trapping the offending substance as a piston when the right hemidiaphragm contracts, raising the intraperitoneal pressure locally, trapping the offending substance (ie, air, fluid etc.), and forcing substances through preexisting or acquired holes in the diaphragm. In the left upper quadrant, the relatively loose stomach, colon, and spleen are not mechanically likely to produce the same pressure changes as on the right side.

I cannot accept a lymphatic mechanism to explain these phenomena, nor can I consider the microscopic stomata to play any role in these porous diaphragm syndromes, as they are too small to permit such massive rapid fluid and/or gaseous shifts into the chest.

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References

To the Editor:

My comments to all of the remarks posed by Dr. Funatsu can be found in my paper entitled “Porous Diaphragm Syndromes.” In that article, I collected and documented the many disparate clinical syndromes, united by a common denominator, namely, gross diaphragmatic defects. This is the “gestalt” of this article.

These defects facilitate the phenomenon of peritoneopleural transphrenic passage of air (catamenial pneumothorax), other gases (CO2) in artificial pneumoperitoneum, and laparoscopy fluids (ascites from liver cirrhosis, and peritoneal dialysis fluid in treatment of renal failure), and possibly Meigs syndrome and tissue (endometriosis), as well as blood, exudate, chyle, bile, and urine.

The right-sided predominance of the thoracic manifestations of this phenomenon is, I believe, the result of the anatomic difference between the two upper quadrants of the abdomen. In the right upper quadrant, the solid, more-or-less-fixed liver acts as a piston when the right hemidiaphragm contracts, raising the intraperitoneal pressure locally, trapping the offending substance (ie, air, fluid etc.), and forcing substances through preexisting or acquired holes in the diaphragm. In the left upper quadrant, the relatively loose stomach, colon, and spleen are not mechanically likely to produce the same pressure changes as on the right side.

I cannot accept a lymphatic mechanism to explain these phenomena, nor can I consider the microscopic stomata to play any role in these porous diaphragm syndromes, as they are too small to permit such massive rapid fluid and/or gaseous shifts into the chest.

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Reference

Work-Related Inhalation Injuries

To the Editor:

I am writing with respect to the article by Valent et al (March 2002). This article is a very useful contribution to the literature.
Injuries, our referenced source of data. As one who has represented these victims for events within a single workday or shift. An injury is defined in this context as the result of acute exposure to energy, such as heat, electricity, or chemicals. It might be useful, however, to report here the definition of an injury as it is used throughout the article, as we clearly state throughout the abstract and the results sections. We do not think that any misunderstanding could arise from the reading of our article.

Mr. Kazan is right when interpreting that our article in the March 2002 issue of CHEST deals only with acute exposures. However, we do not think that any misunderstanding could arise from the reading of the article, as we clearly state throughout the article, as we clearly state throughout the abstract and the results sections. We do not think that any misunderstanding could arise from the reading of our article.

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Intraoperative Photodynamic Therapy After Pleuropneumonectomy for Malignant Pleural Mesothelioma

To the Editor:

We read with great interest the article by Schouwink et al (October 2001) about intraoperative photodynamic therapy after pleuropneumonectomy for the treatment of patients with pleural mesothelioma. In the series by Sugarbaker et al, pleuropneumonectomy has a low postoperative mortality rate (3.8%) and relatively satisfying long-term results. Their technique involves opening the pericardial cavity and resecting the diaphragm while preserving the peritoneum. However, mesothelioma is one of the most rapidly disseminating tumors. As recommended by Schouwink et al., it would seem preferable not to open the pericardium, as we were able to do in the five most recent pleuropneumonectomies that we have performed for the treatment of patients with mesothelioma. Similarly, it is often possible to leave diaphragmatic muscle and fibers in place in order to avoid tearing the peritoneum when retracting it. The high rate of peritoneal recurrences following pleuropneumonectomy reported by Baldini et al (26%) and Rusch et al (31%) may be due to seeding by transdiaphragmatic invasion before surgery or to peroperative tearing of the peritoneum or to secondary peritoneal necrosis.

To be sure, adjunct local treatment is essential to prevent intracavitary recurrence, which is otherwise inescapable. Radiotherapy is effective in treating mesothelioma. However, the local recurrence rate remained high (35%) in a series of 49 patients who underwent surgery in Boston between 1987 and 1993. Radiation therapy, which was performed in only 35 of these patients, consisted of a median dose of 30.6 Gy to the hemithorax and a boost dose of 50 Gy to areas with gross residual disease or localized positive resection margins. Higher radiation doses of up to 54 Gy to the entire hemithorax appear to significantly reduce the local recurrence rate (13%) in the series reported by Rusch et al. Decrease the liver and intestinal toxicity associated with high radiation doses to the diaphragmatic sinus, the abdominal organs may be lowered by reconstructing a taut prostatic prosthetic diaphragms during surgery. However, radiation doses of > 50 Gy to the heart remain potentially toxic, in particular doses delivered to the left side of the heart, and intraoperative photodynamic therapy, as suggested by Schouwink et al, seems to be an interesting alternative.

I was fortunate to be invited to Amsterdam and to obtain light dosimetry equipment there. For large pleural cavities, the potential complications associated with the technique are due to a narrow anatomic zone that includes in particular the esophagus, the bronchial and vascular stumps, and the myocardiun. These anatomic structures are located very close to the light source that illuminates the cavity during intraoperative photodynamic therapy. We have studied the fluence (at the wavelengths that react with the meso-tetra(hydroxyphe)lene) chlorine) emitted by the surgical theater lights during resection. Although our calculations are approximate, fluence may be as high as 5 j/cm². We therefore decided to shield the esophagus, the bronchial and vascular stumps, and the pericardium. Conversely, the most difficult zone to illuminate was the pericardium. The diaphragm is lowered by running taut polylactic acid sutures from one edge to the other, before illumination. Three patients received 0.15 mg/kg meso-tetra(hydroxyphenyl) chlorine and were operated on using these modified techniques.

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REFERENCES


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REFERENCES


while the cavity was illuminated with a 652-nm laser light and a fluence of 10 J/cm², except for the shielded zone. The large quantity of fluid drained postoperatively gave an indication of the effect of phototheraphy on the pleural cavity walls. Slowing of esophageal motor activity was observed in all three cases.

Postoperative electrotherapy was performed in the first two patients on the thoracotomy scar and the pleural cul de sac. No recurrence was observed after 2 1/2 years in one patient (as determined by follow-up CT scan) and after 26 months in the other patient (as determined by follow-up CT scan and negative thoracoscopy findings at 12 months). The third patient developed an infection of the chest wall, which was complicated by an infection of the pneumonectomy cavity. Radiation therapy was impossible to perform. Thoracostomy was performed 9 months later and revealed a late esophageal fistula involving the upper one third of the esophagus (in an unshielded zone). The fistula was closed with a muscle flap. No recurrence was observed in the pleural cavity. Unfortunately, the patient eventually died.

In our limited experience, high-dose preoperative phototherapy therefore appears capable of destroying tumor residues but seems to require major precautions, such as shielding of the incision and the mediastinal organs. Consequently, its place among other techniques seems limited if future series confirm the low local recurrence rate reported by the New York team with the adjunction of high-dose hemithoracic radiation therapy and if the toxicity associated with radiation therapy remains low.

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5 van Veen RLP, Schouwink JH, Star WM, et al. Wedge-shaped applicator for additional light delivery and dosimetry in the diaphragmatic gutter, still seems possible.1,5 These improvements may better determine the exact place and indication of PDT-mediated therapy in malignant pleural mesothelioma.

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REFERENCES

End-of-Life Care: Data Supportive?

To the Editor:

I read with interest the article on ethics in end-of-life care by Kelly et al in CHEST (March 2002). Their objective was to...
determine whether the strength of do-not-resuscitate (DNR) recommendations varies with medical specialty and experience. Their conclusion, that the strength of DNR order recommendations varies with different internal medicine specialties and with different levels of experience, is not supported by their data.

None of the seven groups in the study varied significantly in the number of DNR orders recommended, so that all groups demonstrated a similar approach to this end-of-life issue. Only three findings were statistically significant, each in only one group of physicians, and these involved only strength of opinion, not the number of DNR orders recommended. One of the three significant findings, that the more senior house staff recommended DNR more strongly than did the younger interns and junior residents, may reflect increased confidence with increased length of training.

The authors' use of statistics may have misled them. Statistics, which is concerned with correlations, can be applied to any problem but is not sufficient to show causation, which is the cardinal function of scientific research. The improper use of statistics often results in what has been termed "statistical malpractice." Findings that are not statistically significant should not be reported as a trend.

Cultural influences are important when dealing with end-of-life issues. The new field of bioethics has created an ethic that places the needs of society and third parties above those of the individual patient. Because of this, the attitudes and behaviors of physicians toward the terminally ill that were reported in the 1970s (references 10 and 11 in the article by Arnett et al) may not be comparable to those from recent years.

Finally, how this study will "help to target educational interventions and ... ensure effective collaboration with colleagues and communication with patients," as the authors claim in their conclusions, is not explained.

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REFERENCES


To the Editor:

Dr. Arnett's interest in our publication is appreciated. We again acknowledge that the number of do-not-resuscitate recommendations was not different between subspecialist groups. However, the purpose of the study, as stated in the introduction, was to determine whether the strength of do-not-resuscitate order recommendations, not the absolute number of decisions, varied with medical subspecialty and years of training. Our results did indeed find statistically significant differences in the degree of these convictions. This is important and is of interest to internists in general and chest physicians in particular. We believe that the strength of physicians' convictions affects their guidance to patients who are making end-of-life decisions.

Dr. Arnett charges statistical malpractice by the confusion of correlation with causation. In our study, we never claim to show any causation. We only report observations from our limited database. Our statistical significance does add greater clarity to these findings by suggesting they are not a result of chance. Additional findings that approached but did not meet significance are so disclosed with p values and statistical methods.

The specific differences that we found among medical subspecialties are consistent with the results of other reports in the medical literature. Dr. Arnett suggests that such references may be out of date (ie, references 10 and 11) but fails to note our citation of this same subspecialty bias in physician actions (reference 9) and in end-of-life publications over the subsequent 20 years (reference 18).

We propose that understanding and respecting subspecialty differences in end-of-life opinions may advance us toward more effective collaboration with colleagues and more effective communication with our patients. We hope that we have shed some light on these differences and invite readers to generate their own hypotheses about causation.

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How To Blow Your Defense

To the Editor:

I was recently consulted by a medical malpractice attorney who asked for assistance in the defense of his client, a board-certified pulmonologist who had been managing a patient with very difficult steroid-dependent asthma. The patient also smoked cigarettes. The man, age 41, had acquired aseptic necrosis in both femoral heads requiring total hip replacements.

The patient had suffered from asthma since the age of 6 months. He had had several hospitalizations for asthma and frequent trips to the emergency department for life-threatening attacks. He had been appropriately managed by this pulmonologist, with the use of inhaled short-acting as well as long-acting agonists, inhaled corticosteroids, leukotriene modifiers and, at times, bursts of systemic steroids to deal with exacerbations of asthma and/or associated acute and chronic sinusitis.

The major issue in the plaintiff's strategy was the fact that this pulmonologist had never done spirometry at any time during the management of this patient. Accordingly, the plaintiff argued that the patient never had asthma, which was one of the contentions of the medical expert hired by the plaintiff, also a board-certified pulmonologist. Fortunately, however, numerous measurements of peak flow during exacerbations, which demonstrated increases from low values up to the "personal best" level of approximately 450 to 500 L/min while in remission following corticosteroid treatment had been recorded. But why a simple spirogram was not done by the pulmonologist, as well as other pulmonary function tests, is beyond me. It certainly would have helped in this physician's defense. Later, an allergist did perform spirometry, which showed severe airflow obstruction and air trapping with a normal diffusion test result.

This is the fourth or fifth time I have been asked to defend a
board-certified pulmonologist or internist in a similar malpractice action. The simple use of spirometry would have made the defense much easier.

John Hutchinson introduced spirometry in 1846. Some time ago, noted physiologist Joseph Milic-Emili wrote on 150 years of blowing, citing the work of Hutchinson, who coined the term vital capacity, and Tiffeneau of Paris, who added the timed vital capacity (ie, FEV1) to spirometry.

Today, the National Lung Health Education Program recommends spirometry for all smokers ≥45 years old and anyone with dyspnea on exertion, chronic cough, mucus hypersecretion, or wheeze. Certainly the patient had all of these. The National Asthma Education Program has recommended spirometry in the evaluation of asthmatics for more than a decade. Thus, spirometry has to become the standard of care.

Physicians who treat asthma, COPD, and other pulmonary disorders for which steroids may be required will be well advised to “blow their defense” in the form of doing spirometry in conjunction with the initial patient assessment and for documentation of responses to therapy.

The issue of aseptic necrosis of the femoral head has been commented on for some time. It is not clear, however, if aseptic necrosis in patients treated with corticosteroids represents a drug complication, a complication of the disease process, or both. It is interesting that in 1965, a Massachusetts Supreme Court ruling (Freecourt vs Frederic, 353 Mass 679) held that the risk of acquiring aseptic necrosis from long-term prednisone use was so negligible that the “informed consent” issue should not be used. Simple spirometry is a requirement for the initial evaluation of patients with both obstructive and restrictive ventilatory disorders. It is key to monitoring responses to therapy. The use of spirometry will also help avoid trips to the courthouse. So always remember to blow your defense!

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REFERENCES

1 Hutchinson J. On the capacity of the lungs, and on the respiratory functions, with a view of establishing a precise and easy method of detecting disease by the spirometer. Medico-Chirurgical Transactions (London) 1846; 29:137–161


What About the Role of the US Food and Drug Administration?

To the Editor:

As a professional couple with one half in the world of human subjects’ protection and the other half in the world of academic pulmonary medicine, we read the article by Miller and Shorr1 and the accompanying editorial by Perkins2 with great interest. The article, in the April 2002 issue of CHEST, elucidated the many challenges faced by all of us who conduct research involving human subjects. The authors have brought into focus the ethical challenges presented to the investigator, the institutional review board (IRB), and the sponsor. Although we agree with the authors regarding the problems that they have identified, we suggest that the responsibility for the problems is not limited to the three groups they have identified. We would like to point out some of the inherent and fundamental problems of industry-sponsored randomized clinical trials as they are currently conducted.

The current practice is that industry (with some input from expert consultants) designs clinical trials, the US Food and Drug Administration (FDA) reviews them, and then the sponsor then seeks sites for these trials. As Miller and Shorr3 point out, clinical trials have seen a tremendous change in recent times, moving away from academic medical centers and toward private practice settings. The scrutiny of IRB applications for these trials is different given the context of an independent IRB relative to the academic IRB. There is a potential and very real problem of “IRB shopping” with the obvious benefit that sponsors can have clinical trials conducted, unopposed and without modification. IRBs, both local and independent, are under extreme pressure to review protocols quickly and without requesting modification. By contrast, there is a strong tradition and clear need for local control of IRBs so that their actions reflect the communities that they serve. However, Miller and Shorr1 have pointed out the universal nature of the ethical dilemma confronting the investigators, the IRB, and the sponsor. Obviously, these groups did not meet this ethical challenge in the mometasone trial.

In this context, such review standards and, in fact, this level of review would be more appropriate at the level of the FDA. At the present time, the role that the FDA plays in the risk/benefit analysis for the subject is ambiguous. This realization leads to a variety of troubling questions. What was the role of the FDA in allowing a study such as the mometasone trial to proceed? In general, what kind of review does an investigational new drug application undergo? Is it reviewed by experts in the area of study? Does the FDA consider whether the protocol meets current guidelines for the treatment of the condition under study, or does the FDA see this as the responsibility of the sponsor or the local IRB?

Our local IRB is frequently told by sponsors that we are the only IRB that has issues with a particular protocol. These issues usually relate to our concerns with including a placebo arm, or with withdrawing or withholding proven treatment. Industry-sponsored clinical trials that do not pass ethical muster or put patients at unjustifiable risk should be stopped at the FDA review. They should be rewritten according to currently accepted guidelines for the treatment of the condition under study, and according to regulations meant to protect any vulnerable subjects who might be included.

At national IRB meetings last year (Public Responsibility in Medicine & Research), Robert Temple, MD, of the FDA
suggested that the agency preferred to allow protocols to have broad inclusion and exclusion criteria so as not to limit multicenter trials. He saw narrowing of inclusion and exclusion criteria to make a study safe as the responsibility of the IRB. At the same IRB meeting, a representative of the pharmaceutical industry was quick to point out that academic IRBs were a problem for industry, and they would prefer that independent IRBs review all multicenter trials. The implications of this latter statement are obvious. However, the suggestion of the FDA that narrowing criteria should be done at the local IRB feeds this somewhat dysfunctional relationship. The federal government has now begun to realize that IRB shopping is a real phenomenon. Currently, proposed regulations to prohibit IRB shopping are available for public comment. However, prohibiting IRB shopping alone will not resolve the current problems involving the clinical trials industry that lead to conducting trials such as the one reviewed and analyzed by Miller and Shorr.1

Unquestionably, unethical clinical trials have been funded by sources other than industry, and have been approved by local IRBs, including academic IRBs. National Institutes of Health-funded studies have also failed the risk/benefit analysis. In this time of heightened public awareness of the shortcomings of the human subjects’ protection process, we would argue that rigorous risk/benefit analysis should be applied before protocols reach the local IRBs. In this way, we can help prevent local conflicts of interest and ensure that research is conducted at a standard deserving of the public trust.

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REFERENCES


Errata
In the September 2002 issue, the book review of Cancer of the Lung: From Molecular Biology to Treatment Guidelines (CHEST 2002; 122:1108–1109), by Albert Miller, contained an error. On page 1109, the last sentence of the fourth paragraph should read “This is fortunate, since T3N0M0 is not included in the former, and stage IV is erroneously defined as any T, any N, M0.” Also the “important article by Henschke” is referenced as: Henschke CI, McCauley DI, Yankelovitz DF. Early Lung Cancer Action Projection: overall design and findings from baseline screening. Lancet 1999; 354:99–105.

In the August 2002 issue, the article, “IV Magnesium Sulfate in the Treatment of Acute Severe Asthma: A Multicenter Randomized Controlled Trial” (CHEST 2002; 122:489–497) by Silverman et al, contained editing errors in study site affiliations. The affiliations should read as follows: *From the Department of Emergency Medicine (Drs. Silverman and Mancherje), Long Island Jewish Medical Center, New Hyde Park, NY; Department of Emergency Medicine (Dr. Osborn), Lincoln Hospital Medical Center, Bronx, NY; Department of Emergency Medicine (Dr. Runge), Carolinas Medical Center, Charlotte, NC; Department of Emergency Medicine (Dr. Gallagher), Jacobi Hospital Medical Center, Bronx, NY; Department of Emergency Medicine (Dr. Chiang), Bellevue Hospital Medical Center, New York, NY; Department of Emergency Medicine (Dr. Gallagher), Boston City Medical Center, Boston, MA; Department of Emergency Medicine (Dr. Gaeta), St. Barnabas Medical Center, Bronx, NY; Department of Biostatistics (Dr. Freeman), Montefiore Medical Center, Bronx, NY; Department of Biostatistics and Epidemiology (Dr. Levin), Columbia University School of Public Health, New York, NY; and Division of Pulmonary and Critical Medicine (Dr. Scharf), Department of Medicine, Long Island Jewish Medical Center, New Hyde Park, NY.

The current affiliation information for Drs. Osborn, Runge, Gallagher, and Gaeta is correct.

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