

LETTERS TO THE EDITOR

The Journal welcomes Letters to the Editor. If found suitable, they will be published as space allows. Letters should be typed double-spaced, should not exceed 400 words, and are subject to abridgment and other editorial changes in accordance with Journal style.

ULTRASOUND IN PREGNANCY

To the Editor:

I am sorry to join the battle at such a late date, but the letter from Pacala and Jack (*Ultrasound screening during pregnancy, letter. J Fam Pract 1990; 30:393*) regarding the debate over the routine use of ultrasound in pregnancy (*Should ultrasound be used routinely during pregnancy? Youngblood JP: An affirmative view. Ewigman BG: A negative view. J Fam Pract 1989; 29:657-664*) seems to contain a serious misunderstanding of the position of at least a large number of those of us who are advocates.

After Pacala and Jack's somewhat condescending remarks about Dr Youngblood's position, they seem to be much more positive about Dr Ewigman's. The acceptance by Pacala and Jack of the misconception by Ewigman that routine use of diagnostic ultrasound examinations during pregnancy constitutes a "screening" procedure is unfortunate and is perhaps best described as simplistic. Using the terms *scientific vs empirical* as descriptive of the views of the opposing authors is certainly simplistic.

Diagnostic ultrasound is just that, *diagnostic*, and it is used to diagnose such things as intrauterine growth retardation, placenta previa, abruption placenta, twins, polyhydramnios, and incorrect dating. To suggest this is screening is similar to arguing that a chest x-ray examination on a patient with a fever and cough is screening. Since it does not fit a reasonable definition of screening, then it is begging the question to argue that it cannot be justified as a screening tool.

Pacala and Jack voice concerns over "possible adverse effects of routine ultrasound." Certainly one cannot argue with concerns about safety of anything in medicine. That being said, it is important to also say: "Of the studies of actual infants exposed

to diagnostic ultrasound in utero, no harmful effects have been demonstrated and no case reports have been made of an infant who suffered as a result of exposure to diagnostic ultrasound. Most animal or in vitro studies of the effects of diagnostic ultrasound show no biologic effects. Those studies that seem to show an effect are either irreproducible or suffer from serious flaws in study design, which make their results suspect or inapplicable to the clinical setting."¹ Considering that diagnostic obstetric ultrasound has been in use for a generation, and that the British and some Scandinavian countries use it routinely, if there are any adverse effects, they must indeed be subtle.

On the other hand, there is more information that can be obtained from the obstetric ultrasound examination than from almost anything else we do to the pregnant woman,² and there is at least some evidence that routine obstetric ultrasound might well *save* money when one considers the costs of extra care for the infant in whom intervention was inappropriate because of lack of good dating of the pregnancy, and the costs of maternal lost income and excess hospitalizations or long-term care of the inadvertently damaged infant.

Proving anything safe is virtually impossible. Fortunately, in medicine, even scientifically, we recognize that everything is a trade-off between what one gives for what one gets. Statistically, we can make anything we wish to be true appear so. "Today's science is tomorrow's joke." The double-blind crossover study was not part of the Sermon on the Mount.

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References

1. Hughey MJ: Routine versus indicated scans. In Sabbagha RE (ed): *Diagnostic Ultrasound Applied to Obstetrics and Gynecology*. Philadelphia, JB Lippincott Company 1987, p 51
2. Smith CB: Diagnostic ultrasound, letter. *Am Fam Physician* 1985; 31:22,24,32

The preceding letter was referred to Dr Ewigman, who responds as follows:

Dr Smith and I share respect for the impressive information that obstetric ultrasound provides. He accepts on faith, however, that this rich diagnostic information leads to a benefit in normal healthy pregnancies. This is where we part ways; I expect convincing evidence (clinical trials) of efficacy before advocating its use. Although the virtues of clinical trials were admittedly not part of the Sermon on the Mount, neither were those of routine ultrasound.

There are several other points on which we disagree. First, the difficulty of proving safety does not excuse us from attempting to do so. Nor does it justify ignoring the possibility. In the case of ultrasound the evidence supports a lack of adverse effects. But why take the risk when the evidence on efficacy (which is of better quality than the evidence on safety) suggests that there is no benefit to routine ultrasound?

Second, Dr Smith appears not to understand the difference between a screening test and a diagnostic test. Any test applied to an asymptomatic person for the purpose of detecting unsuspected disease is a screening test. As Dr Smith points out, a chest x-ray examination performed on a patient with fever and cough is a diagnostic test. The patient has symptoms suggestive of a disease. However, a chest x-ray examination performed on a healthy person is a screening test. Routine ultrasound is performed with no suspicion of abnormality. It is therefore a screening test.

I am interested to know where Dr Smith found the "evidence that routine obstetric ultrasound might well save money." He hypothesizes that dating by ultrasound might save considerable costs generated by inappropriate intervention on poorly dated infants. In the six clinical trials I reviewed (10,318 patients studied), there are no reports of such events in the control patients.¹

I agree with Dr Smith that people can and do distort statistics to support their individual beliefs; however, this is not a defect of statistics. Any information is subject to misrepresentation. In fact, one of the reasons clinical trials are preferable to case series is that it is more difficult to misrepresent or misinterpret the findings of a clinical trial. The data supposedly showing benefit quoted by most advocates of routine ultrasound come from case series. Clinical trials have not yet confirmed this benefit.

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Reference

1. Ewigman B: Should ultrasound be used routinely during pregnancy? An opposing view. *J Fam Pract* 1989; 29:660-664

COMPUTERIZED MEDICAL RECORD

To the Editor:

I would like to thank Drs Spann and Rodnick for expressing their views on the topic of computerized medical records in the April issue of your journal (*Should the complete medical record be computerized in family practice?* Spann SJ: An affirmative view. Rodnick JE: An opposing view. *J Fam Pract* 1990; 30:457-464). Improving the accuracy and utility of medical record keeping is a laudable goal for family practice and the medical profession as a whole. Computers, as the premier da-

ta-processing tools of the information age, are becoming central to any effort to improve the quality and availability of information used by physicians. Besides the technical issues of cost, security, and data entry, there are some other fundamental considerations I would like to raise.

Consider first the dilution of the medical record by internal forces, such as group practice, and external forces, such as peer review and third-party payment. What began as a simple repository for clinical observations has ballooned into a complex conglomeration of medical, legal, social, and economic data. In addition, the reliability of the information contained in the medical record is increasingly suspect.¹ In my opinion, computerization only adds to the pressures placed on the already overburdened medical record. Since many of these issues ("defensive medicine," fear of discrimination against HIV-positive individuals, and so on) reflect societal demands, they will be difficult to address from a purely medical record management perspective.

Patients do not exist in isolation; they tend to seek health care services from many sources. The conventional clinic chart will always be incomplete for this reason. The confusion created by multiple prescriptions from multiple physicians is a classic example of the current system's inadequacy. A computer-based medical record that exists in isolation will continue to be of limited value. One could argue that the need for standardized and portable clinical information is more important than computerization as such.² Limitations in this area are organizational, not technological. The means for rapid electronic exchange of patient information have existed for many years, but are only now finding meager use.

Medical record needs in family practice are essentially the same as those of other primary care specialties, eg, general medicine or pediatrics. The question, "Should the complete medical record be computerized in family practice?" needs to be addressed in this broader context. Only

through consultation and cooperation with other specialties will solutions to societal and organizational problems be possible. Just as with ambulatory care and recertification, this area is one in which family physicians have an opportunity to take a leadership role.

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References

1. Burnum JF: The misinformation era: The fall of the medical record. *Ann Intern Med* 1989; 110:482-484
2. McDonald CJ, Hammond WE: Standard formats for electronic transfer of clinical data. *Ann Intern Med* 1989; 110:333-335

INFORMATION RETRIEVAL SYSTEMS

To the Editor:

As librarians providing information services to the membership of the American Academy of Family Physicians, we were very interested in the recent article by Dr Connelly et al concerning the results of their survey, and especially the finding that apparently little use is being made by practicing family physicians of computer-based bibliographic retrieval systems (Connelly DP, Rich EC, Curley SP, Kelly JT: *Knowledge resource preferences of family physicians*. *J Fam Pract* 1990; 30:353-359).

Our experience, including a recently completed survey of 942 family physicians (47% of those polled), suggests a higher level of utilization of such resources than reported by Connelly et al. Our experience, however, has demonstrated a basic finding of his study, namely, the importance of information resources for family physicians being "close to the clinical action." Consistently over the years, Huffington Library staff have asked physicians the purpose for which their request is placed. The stated purpose of patient care (as opposed to teaching, research, adminis-

tration, etc) has predominated (60%+) in the use of our resources whatever the format.

If, indeed, the family physician is "the doctor who specializes in you," then we must always keep in mind the great diversity in the persons, families, and health care needs that must be served. This is one of the greatest strengths and challenges facing family physicians. And those of us concerned about improving access to the information critical to that care must become comfortable with using a variety of constantly changing and improving resources, while never overlooking or diminishing the human resources available. The Huffington Library constantly strives to provide such access and diversity in its information services.

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POWER ANALYSIS AND CLINICAL SIGNIFICANCE

To the Editor:

Simulation techniques are versatile tools and may be used to estimate the power of a study, as noted by Davis and Mengel.¹ Consideration of underlying reasons for estimating power is needed if the result is to convey the desired meaning, however.

It is fundamental to distinguish between the calculation of power used to choose an appropriate sample size before a study is conducted, and a calculation of power used to interpret a completed study with "negative" results.² The former calculation attempts to choose a sample size with an acceptable chance of discerning meaningful differences between groups at an acceptable cost. Pragmatism concerning available resources, as well as the limited true importance of any one study, leads to a customary planned power of .8 in current practice. Only in this sense is the

"nominal standard for power"¹ equal to .8.

Calculation of power after a study is completed is an attempt to explore the certainty of the premise that two treatments will result in equal outcomes. Rather than determining the necessary departmental or grant support for a proposed project, the results of such post hoc power calculation may (correctly or incorrectly) influence clinical practice and policy worldwide for many years. Deeming two treatments as equivalent must be done with great care, realizing that this function of quantitative research methodology is perhaps the weakest. A confidence level that is comparable to the requirements for rejecting the null hypothesis (ie, .05) is in order when power is calculated to estimate equality of treatments in a completed study.

A post hoc calculation of power differs also in that the study itself contains valuable observations that provide an estimate of treatment effect. Although significant difference is not achieved, the ability of the data to approximate the true population mean for treatment effect is not diminished. The value of this approximation is ignored in power calculations that are designed to be used before conducting a study.²

Including these theoretical refinements to the estimation of power, the following changes are suggested to the simulation technique described by Davis and Mengel. First, the simulated study outcomes should be compared with the actual study result, determining what percentage of simulated outcomes are as contrary or more contrary to the hypothetical (ie, 25%) treatment effect. This comparison may be done by comparing each simulated study test statistic against the actual test statistic of the completed study. The result will estimate post hoc power as discussed above. For example, if actual results showed a trend toward treatment effect, but that trend did not reach statistical significance, the power of the study to exclude a treatment effect would be (correctly) diminished. Second, the analysis should be inter-

preted as supporting "no treatment effect" only when power reaches a level acceptable for post hoc analysis. Considering the impact of published studies on standards of care, this level may need to be at or in excess of 95%, much like the usual criteria for studies with "positive" results.

George A. Corey, MD
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References

1. Davis AB, Mengel MB: Estimation of power using simulation techniques. *J Fam Pract* 1990; 30:578-584
2. Detsky AS, Sackett DL: When was a "negative" clinical trial big enough? How many patients you needed depends on what you found. *Arch Intern Med* 1985; 145:709-712

The preceding letter was referred to Drs Davis and Mengel, who respond as follows:

Dr Corey's letter has raised an important issue regarding post hoc power analysis, ie, power analysis of hypothesis tests after the data have been collected. The issue is what level of power is required to rule out the possibility of a clinically significant effect. We would like to submit that other factors, such as the severity of illness and the cost of treatment, may be used to decide that level of power. For example, in comparing inexpensive treatments for a relatively benign infectious disease such as bacterial vaginosis, the example we used in our report, a power level of .80, given the specification of a realistic effect size, may be more than adequate for most clinicians. Before concluding that an inexpensive treatment is equivalent to a more expensive, efficacious treatment for a life-threatening disease, such as cancer, however, most clinicians would probably demand a higher level of statistical power.

As Dr Corey's letter and we ourselves point out in our paper, the statistical power of a study should ideally be specified before the study is conducted. We continue to stand in favor of reporting post hoc power

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BACTROBAN®

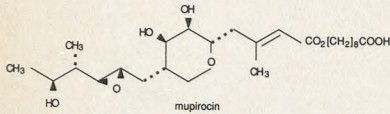
(mupirocin)

Ointment 2%

For Dermatologic Use

DESCRIPTION

Each gram of BACTROBAN® Ointment 2% contains 20 mg mupirocin in a bland water miscible ointment base consisting of polyethylene glycol 400 and polyethylene glycol 3350 (polyethylene glycol ointment, N.F.). Mupirocin is a naturally-occurring antibiotic. The chemical name is 9-4-[5S-(2S,3S-epoxy-5S-hydroxy-4S-methylhexyl)-3R,4R-dihydroxytetrahydropyran-2S-yl]-3-methylbut-2(E)-enoxyloxy-noranoic acid. The chemical structure is:



CLINICAL PHARMACOLOGY

Mupirocin is produced by fermentation of the organism *Pseudomonas fluorescens*. Mupirocin inhibits bacterial protein synthesis by reversibly and specifically binding to bacterial isoleucyl transfer-RNA synthetase. Due to this mode of action, mupirocin shows no cross resistance with chloramphenicol, erythromycin, fusidic acid, gentamicin, lincomycin, methicillin, neomycin, novobiocin, penicillin, streptomycin, and tetracycline.

Application of ¹⁴C-labeled mupirocin ointment to the lower arm of normal male subjects followed by occlusion for 24 hours showed no measurable systemic absorption (<1.1 nanogram mupirocin per milliliter of whole blood). Measurable radioactivity was present in the stratum corneum of these subjects 72 hours after application.

Microbiology: The following bacteria are susceptible to the action of mupirocin *in vitro*: the aerobic isolates of *Staphylococcus aureus* (including methicillin-resistant and β-lactamase producing strains), *Staphylococcus epidermidis*, *Staphylococcus saprophyticus*, and *Streptococcus pyogenes*.

Only the organisms listed in the **INDICATIONS AND USAGE** section have been shown to be clinically susceptible to mupirocin.

INDICATIONS AND USAGE

BACTROBAN® (mupirocin) Ointment is indicated for the topical treatment of impetigo due to: *Staphylococcus aureus*, beta hemolytic *Streptococcus**, and *Streptococcus pyogenes*.

*Efficacy for this organism in this organ system was studied in fewer than ten infections.

CONTRAINDICATIONS

This drug is contraindicated in individuals with a history of sensitivity reactions to any of its components.

WARNINGS

BACTROBAN® Ointment is not for ophthalmic use.

PRECAUTIONS

If a reaction suggesting sensitivity or chemical irritation should occur with the use of BACTROBAN® Ointment, treatment should be discontinued and appropriate alternative therapy for the infection instituted.

As with other antibacterial products prolonged use may result in overgrowth of nonsusceptible organisms, including fungi.

Pregnancy category B: Reproduction studies have been performed in rats and rabbits at systemic doses, i.e., orally, subcutaneously, and intramuscularly, up to 100 times the human topical dose and have revealed no evidence of impaired fertility or harm to the fetus due to mupirocin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing mothers: It is not known whether BACTROBAN® is present in breast milk. Nursing should be temporarily discontinued while using BACTROBAN®.

ADVERSE REACTIONS

The following local adverse reactions have been reported in connection with the use of BACTROBAN® Ointment: burning, stinging, or pain in 1.5% of patients; itching in 1% of patients; rash, nausea, erythema, dry skin, tenderness, swelling, contact dermatitis, and increased exudate in less than 1% of patients.

DOSE AND ADMINISTRATION

A small amount of BACTROBAN® Ointment should be applied to the affected area three times daily. The area treated may be covered with a gauze dressing if desired. Patients not showing a clinical response within 3 to 5 days should be re-evaluated.

HOW SUPPLIED

BACTROBAN® (mupirocin) Ointment 2% is supplied in 15 gram tubes. (NDC #0029-1525-22)

Store between 15° and 30°C (59° and 86°F).

0938020/B88-REV. FEB. 1988

Reference:

1. Data on file, Medical Department, Beecham Laboratories.

Beecham
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analysis, however, to let the readers decide whether the research study was an adequate attempt to find an effect.

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LATERAL CUTANEOUS NERVE ENTRAPMENT

To the Editor:

I was interested to read the Brief Report by Sharf et al (*Sharf M, Schwartzman P, Farkash E, Horvitz J: Thoracic lateral cutaneous nerve entrapment syndrome without previous lower abdominal surgery. J Fam Pract 1990; 30:211-214*) regarding lateral cutaneous nerve entrapment. Apparently the authors feel they have stumbled on to a previously unrecognized condition. Unfortunately, their literature search was incomplete. Had they looked further, they might have found my article published in *Surgery*,¹ on abdominal cutaneous nerve entrapment syndrome in which the syndrome is thoroughly discussed, defined, and anatomically researched.

When I first published my findings, I, too, thought they constituted new information. My search of the literature back to 1930 revealed no such reported syndrome. About 1 year after my research was published, I received a letter from an Australian physician who said that he recalled reading about this in 1927. Sure enough, on looking further, I found John Berton Carnett's article² de-

scribing almost exactly what I thought I had discovered. I subsequently found other references.³⁻⁷ It seems that the medical profession forgets and continues to rediscover. Too bad our system of reference retrieval does not go back to the very beginning. It might save us a lot of time and effort restudying conditions already well defined.

I continue to see patients with abdominal cutaneous nerve entrapment in my own practice and on referral from others inside and outside my own medical group. By the time I see patients on referral, however, they have often gone through extensive workups that might have been avoided had the examining physician paid more attention to the history or more precisely located the site of tenderness.

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References

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2. Carnett JB: Chronic pseudoappendicitis due to intercoital neuralgia. *Am J Med Sci* 1927; 173:579-599
3. Mehta M: Intractable Pain—Major Problems in Anesthesia (vol 2). Philadelphia, WB Saunders, 1973
4. Hembrow CH: Some obscure causes of chronic abdominal pain. *Aust N Z J Surg* 1935; 5:77-82
5. Applegate WV: Trapped nerves (letter). *Br Med J* 1972; 3:351
6. Ranger I, Mehta M, Pennington M: Abdominal wall pain due to nerve entrapment. *Practitioner* 1971; 286:791-792
7. Mehta M, Ranger I: Persistent abdominal pain: Treatment by nerve block. *Anaesthesia* 1971; 26:330-333