

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.

Pediatric Training in Family Practice

To the Editor:

I wish to both commend and criticize the study by Poole (Poole SR: *Pediatric behavioral science in family practice. J Fam Pract* 16:365, 1983) regarding pediatric curriculum development for family practice. His work is an excellent example of the type of curriculum development that must take place for the continuing clinical development of our specialty. He has addressed in a rigorous fashion such issues of curriculum development as teaching formats, instructor roles, and evaluation.

Despite the overall excellence of this work, I wish to note a serious deficiency in the way in which decisions were made regarding the intensity, or level of capability, at which pediatric problems were taught. As is true of nearly all family practice curriculum development to this point, the providers of this care (in this case, practicing family physicians) were the sole source of advice as to how expert a family physician needed to be to manage certain pediatric problems. As we have clearly shown in our recently

published pilot study (Schwenk TL, Clark CH, Jones GR, et al: *Defining a behavioral science curriculum for family physicians: What do patients think? J Fam Pract* 15:339, 1982), many patients have a much different notion of their expectations of our expertise than we have of ourselves. In particular, many pediatric behavioral problems, including discipline problems, school problems, temper tantrums, and toilet training, are felt to be clearly outside the typical role definitions of a family physician, and patients in our study requested referral in a majority of these cases. The curriculum developed by Poole, on the other hand, places a strong emphasis on competency in these problems, and expects that the family practice resident will develop "definitive" capabilities in these areas. Our study, which has recently been expanded and replicated to include a diversity of demographic and socioeconomic populations, would suggest that this is a waste of critical educational time resources.

I would not suggest that we always fill only the most limited role as defined by our patients, but would note that we need to negoti-

ate our roles carefully with that group most responsible for our existence and our continued success—our patients.

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The Biopsychosocial Model in Medical Education

To the Editor:

As a "mutant" in family practice, and an avid reader of Dr. George Engel's writings, I shared Dr. Smilkstein's concerns¹ upon reading Dr. Engel's *New England Journal of Medicine* paper "The Biopsychosocial Model and Medical Education—Who Are to Be the Teachers?"² I agree that he appeared to assign to psychiatrists the responsibility of teaching the biopsychosocial model to the rest of the medical profession.

Dr. Engel's clarification³ is welcome, though sadly he fails to acknowledge a role for family medicine in bringing the biopsychosocial model to medical students and residents. While he appears to recognize that we have embraced the model he has advocated so effectively, he seems not to see that family medicine has become the first "mutant" specialty (derived from general practice), or that it can now demonstrate the model, in teaching and in practice, in most medical schools.

Many medical students are fortunate enough to have role models in several specialties who demonstrate a biopsychosocial approach to their patients. Nevertheless, the Department of Family Practice is where the approach is most fre-

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ACTIFED-C[®] EXPECTORANT C[®]

LETTERS TO THE EDITOR

INDICATIONS: Based on a review of this drug by the National Academy of Sciences — National Research Council and/or other information, FDA has classified the indications as follows: "Lacking substantial evidence of effectiveness as a fixed combination." For the symptomatic relief of cough in conditions such as: the common cold, acute bronchitis, allergic asthma, bronchiolitis, croup, emphysema, tracheobronchitis.
Final classification of the less-than-effective indications requires further investigation.

CONTRAINDICATIONS:
Use in Newborn or Premature Infants: This drug should not be used in newborn or premature infants.

Use in Nursing Mothers: Because of the higher risk of antihistamines, codeine and sympathomimetic amines for infants generally and for newborn and premature in particular, Actifed-C Expectorant therapy is contraindicated in nursing mothers.

Use in Lower Respiratory Disease: Antihistamines should NOT be used to treat lower respiratory tract symptoms including asthma.

Actifed-C Expectorant is also contraindicated in the following conditions:

Hypersensitivity to: 1) triprolidine hydrochloride and other antihistamines of similar chemical structure; 2) sympathomimetic amines including pseudoephedrine; and/or 3) any of the other ingredients.

Monoamine oxidase inhibitor therapy (see Drug Interactions Section).

WARNINGS: Actifed-C Expectorant should be used with considerable caution in patients with:

Increased intraocular pressure (Narrow angle glaucoma)	Hypertension
Stenosing peptic ulcer	Diabetes mellitus
Fluoroduodenal obstruction	Ischemic heart disease
Symptomatic prostatic hypertrophy	Hyperthyroidism
Bladder neck obstruction	

Sympathomimetics may produce central nervous system stimulation with convulsions or cardiovascular collapse with accompanying hypotension.

Codeine can produce drug dependence of the morphine type, and therefore has the potential of being abused.

Use in Children: As in adults, the combination of an antihistamine and sympathomimetic amine can elicit either mild stimulation or mild sedation in children.

While it is difficult to predict the result of an overdose of a combination of triprolidine, pseudoephedrine, and codeine the following is known about the individual components:

In infants and children especially, antihistamine in overdose may cause hallucination, convulsion or death. Large doses of pseudoephedrine are known to cause weakness, lightheadedness, nausea and/or vomiting. An overdose of codeine may cause CNS depression with muscular twitching and convulsion, weakness, disturbed vision, dyspnea, respiratory depression, collapse and coma.

Use in Pregnancy: Experience with this drug in pregnant women is inadequate to determine whether there exists a potential for harm to the developing fetus.

Use with CNS Depressants: Triprolidine and codeine phosphate have additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc.)

Use in Activities Requiring Mental Alertness: Patients should be warned about engaging in activities requiring mental alertness such as driving a car or operating appliances, machinery, etc.

Use in the Elderly (approximately 60 years or older): Antihistamines are more likely to cause dizziness, sedation and hypotension in elderly patients. Overdoses of sympathomimetics in this age group may cause hallucinations, convulsions, CNS depression, and death.

PRECAUTIONS: Actifed-C Expectorant should be used with caution in patients with: history of bronchial asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease, hypertension.

DRUG INTERACTIONS: MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines and overall effects of sympathomimetics. Sympathomimetics may reduce the antihypertensive effects of methyldopa, decamylamine, reserpine, and veratrum alkaloids.

The CNS depressant effect of triprolidine hydrochloride and codeine phosphate may be additive with that of other CNS depressants.

ADVERSE REACTIONS:

- General:** Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose and throat.
- Cardiovascular System:** Hypotension, headache, palpitations, tachycardia, extrasystoles.
- Hematologic System:** Hemolytic anemia, thrombocytopenia, agranulocytosis.
- Nervous System:** Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesias, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, hysteria, neuritis, convulsions, CNS depression, hallucination.
- G.I. System:** Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.
- G.U. System:** Urinary frequency, difficult urination, urinary retention, early menses.
- Respiratory System:** Thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.

NOTE: Guafenesin has been shown to produce a color interference with certain clinical laboratory determinations of 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

HOW SUPPLIED: Bottles of 1 pint, 1 gallon and 4 oz Unit of Use Bottle with Child Resistant Cap.

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quently taught and modeled by all (or most) of the faculty and residents. For this reason, the next generation should see the more common inclusion of family medicine experience as a recommended part of residency training in other medical specialties.

I share Dr. Engel's abhorrence of the politicizing of the biopsychosocial model of medical care. It is too important a concept to be consigned to one faction of the profession for its investigation and development. It would become less political, however, if Dr. Engel and those psychiatrists who will continue his efforts could acknowledge, welcome, and encourage the past, present, and potential contributions of family medicine to the integration of the biopsychosocial model into medical education and care.

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References

- Smilkstein G: The biopsychosocial model: Whose legacy? *J Fam Pract* 15: 811, 1982
- Engel GL: The biopsychosocial model and medical education—Who are to be the teachers? *N Engl J Med* 306:802, 1982
- Engel GL: The biopsychosocial model and family medicine. *J Fam Pract* 16:409, 1983

Systematic Program Evaluation

To the Editor:

Several issues of the *Journal of Family Practice* and other readings have stimulated the following comment: There is a need to understand the position of program evaluation in the broad spectrum of

research skills and philosophies. This letter is an effort to clarify that position. It is useful, when attempting to understand the place of evaluation in the general body of research, to draw some well-defined boundaries. These boundaries overlap and may appear indistinct, but a clear definition of boundaries is an aid toward understanding, not necessarily a complete statement of reality. However, an imprecise model is usually better than no model at all.

Pure research can be viewed as those research activities that (1) lead to the capacity for broad generalization (that is, conclusions apply to all populations across indefinite periods of time), (2) lead toward the development of fundamental physical, biological, social, or educational laws, and (3) lead to conclusions and implications addressed to all humanity. Examples abound in the physical and biological sciences: genetics evolution, relativity, the laws of thermodynamics.

Applied research consists of those activities that (1) lead to findings that can be generalized across time but are not expected to apply to all populations, (2) may lead to fundamental laws but only as a by-product, not as a primary intent, and (3) lead to conclusions and implications addressed to a restricted audience, for example, a specific ethnic group and its teachers, the physically handicapped, or slow learners and their teachers. Examples of applied research abound, some of which have been cited above. Others include research into innovative methods of child care and investigation of new methods of medical treatment.

Program evaluation consists of those activities that (1) lead to re-

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Minipress®

(prazosin HCl) Capsules 1 mg, 2 mg, 5 mg

Brief Summary

MINIPRESS® (prazosin hydrochloride) Capsules For Oral Use
INDICATIONS: MINIPRESS (prazosin hydrochloride) is indicated in the treatment of hypertension. As an antihypertensive drug, it is mild to moderate in activity. It can be used as the initial agent or it may be employed in a general treatment program in conjunction with a diuretic and/or other antihypertensive drugs as needed for proper patient response.

WARNINGS: Minipress may cause syncope with sudden loss of consciousness. In most cases this is believed to be due to an excessive postural hypotensive effect, although occasionally the syncope episode has been preceded by a bout of severe tachycardia with heart rates of 120-160 beats per minute. Syncope episodes have usually occurred within 30 to 90 minutes of the initial dose of the drug; occasionally they have been reported in association with rapid dosage increases or the introduction of another antihypertensive drug into the regimen of a patient taking high doses of MINIPRESS. The incidence of syncope episodes is approximately 1% in patients given an initial dose of 2 mg or greater. Clinical trials conducted during the investigational phase of this drug suggest that syncope episodes can be minimized by limiting the initial dose of the drug to 1 mg, by subsequently increasing the dosage slowly, and by introducing any additional antihypertensive drugs into the patient's regimen with caution. (See DOSAGE AND ADMINISTRATION.) Hypotension may develop in patients given MINIPRESS who are also receiving a beta-blocker such as propranolol.

If syncope occurs, the patient should be placed in the recumbent position and treated supportively as necessary. This adverse effect is self-limiting and in most cases does not recur after the initial period of therapy or during subsequent dose titration.

Patients should always be started on the 1 mg capsule of MINIPRESS. The 2 and 5 mg capsules are not indicated for initial therapy.

More common than loss of consciousness are the symptoms often associated with lowering of the blood pressure, namely, dizziness and lightheadedness. The patient should be cautioned about these possible adverse effects and advised what measures to take should they develop. The patient should also be cautioned to avoid situations where injury could result should syncope occur during the initiation of MINIPRESS therapy.

Usage in Pregnancy: Although no teratogenic effects were seen in animal testing, the safety of MINIPRESS in pregnancy has not been established. MINIPRESS is not recommended in pregnant women unless the potential benefit outweighs potential risk to mother and fetus.

Usage in Children: No clinical experience is available with the use of MINIPRESS in children.

ADVERSE REACTIONS: The most common reactions associated with MINIPRESS therapy are: dizziness 10.3%, headache 7.8%, drowsiness 7.6%, lack of energy 6.9%, weakness 6.5%, palpitations 5.3%, and nausea 4.9%. In most instances side effects have disappeared with continued therapy or have been tolerated with no decrease in dose of drug.

The following reactions have been associated with MINIPRESS some of them rarely. (In some instances exact causal relationships have not been established.)
Gastrointestinal: vomiting, diarrhea, constipation, abdominal discomfort and/or pain.

Cardiovascular: edema, dyspnea, syncope, tachycardia.

Central Nervous System: nervousness, vertigo, depression, paresthesia.

Dermatologic: rash, pruritus, alopecia, lichen planus.

Genitourinary: urinary frequency, incontinence, impotence, priapism.

EENT: blurred vision, reddened sclera, epistaxis, tinnitus, dry mouth, nasal congestion.

Other: diaphoresis.

Single reports of pigmentary mottling and serous retinopathy, and a few reports of cataract development or disappearance have been reported. In these instances the exact causal relationship has not been established because the baseline observations were frequently inadequate.

In more specific slit-lamp and funduscopic studies, which included adequate baseline examinations, no drug-related abnormal ophthalmological findings have been reported.

DOSAGE AND ADMINISTRATION: The dose of MINIPRESS should be adjusted according to the patient's individual blood pressure response. The following is a guide to its administration:

Initial Dose: 1 mg two or three times a day. (See WARNINGS.)

Maintenance Dose: Dosage may be slowly increased to a total daily dose of 20 mg given in divided doses. The therapeutic dosages most commonly employed have ranged from 6 mg to 15 mg daily given in divided doses. Doses higher than 20 mg usually do not increase efficacy; however a few patients may benefit from further increases up to a daily dose of 40 mg given in divided doses. After initial titration some patients can be maintained adequately on a twice daily dosage regimen.

Use With Other Drugs: When adding a diuretic or other antihypertensive agent, the dose of MINIPRESS should be reduced to 1 mg or 2 mg three times a day and retitration then carried out.

OVERDOSAGE: Accidental ingestion of at least 50 mg of MINIPRESS in a two year old child resulted in profound drowsiness and depressed reflexes. No decrease in blood pressure was noted. Recovery was uneventful.

Should overdosage lead to hypotension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished by keeping the patient in the supine position. If this measure is inadequate, shock should first be treated with volume expanders. If necessary, vasopressors should then be used. Renal function should be monitored and supported as needed. Laboratory data indicate MINIPRESS is not dialysable because it is protein bound.

TOXICOLOGY: Testicular changes, necrosis and atrophy have occurred at 25 mg/kg/day (60 times the usual maximum recommended dose of 20 mg per day in humans) in long term (one year or more) studies in rats and dogs. No testicular changes were seen in rats or dogs at the 10 mg/kg/day level (24 times the usual maximum recommended dose of 20 mg per day in humans). In view of the testicular changes observed in animals, 105 patients on long term MINIPRESS (prazosin hydrochloride) therapy were monitored for 17-ketosteroid excretion and no changes indicating a drug effect were observed. In addition, 27 males on MINIPRESS (prazosin hydrochloride) alone for up to 51 months did not demonstrate changes in sperm morphology suggestive of drug effect.

HOW SUPPLIED: MINIPRESS is available in 1 mg (white #431), 2 mg (pink and white #437) capsules in bottles of 250, 1000, and unit dose institutional packages of 100 (10 x 10's); and 5 mg (blue and white #438) capsules in bottles of 250, 500 and unit dose institutional packages of 100 (10 x 10's).

More detailed information available on request.

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2. Adapted from Kaplan NM: Summary. *J Cardiovasc Pharmacol* 4 (suppl 2): S265, 1982. 3. Lund-Johansen P: Hemodynamic changes at rest and during exercise in long-term prazosin therapy for essential hypertension, in Prazosin Clinical Symposium Proceedings. Published as a special report by *Postgraduate Medicine*, New York, McGraw-Hill Book and Education Services Group, 1975, pp 45-52. 4. Pitts NE: The clinical evaluation of prazosin, a new antihypertensive agent, in Prazosin Clinical Symposium Proceedings. Published as a special report by *Postgraduate Medicine*, New York, McGraw-Hill Book and Education Services Group, 1975, pp 117-127.

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sults applicable only to the particular population studied at the particular time it is studied, (2) will not lead to fundamental laws except by an unwarranted extension of inference far beyond the data, and (3) lead to conclusions and implications addressed to a small group (or one person) of decision makers. Their decision is relevant only to the restricted population. Evaluation of clinic efficiency is an appropriate example.

The implications of this conceptual framework are simple and direct: there is nothing wrong with how we have been going about pure and applied research. A great deal more of both needs to be done. The model, however, does lead to the conclusion that program evaluation should be viewed as a system to aid decision making, not as a series of small applied research projects. Evaluations should be viewed as a worthwhile subject matter deserving of our best and most talented—not as second-rate research projects.

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demonstrated that antisperm antibodies form in both men and monkeys after vasectomy,¹ vasectomized monkeys show a greater frequency of atherosclerosis than matched controls,^{2,3} and nonhypertensive vasectomized men under 40 years of age show an increase in retinal arteriolar changes when compared with matched controls.⁴ Although their data were limited, Walker et al⁵ showed that with the passage of time, vasectomized men have higher rates of hospitalization for arthritis and connective tissue disorders than do nonvasectomized men.

At present, the vasectomy-atherosclerosis-autoimmune disease relationship in man remains uncertain. Long-term observational data of vasectomized men have not yet been published. In addition, the relative risk of vasectomy in men who have hypertension or hyperlipidemia, who smoke, are sedentary or overweight, or who are prone to occupational or family stress is unknown. Nevertheless, I recommend that presterilization counseling include a discussion of these possible risks.

Rick Kellerman, MD

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References

1. Alexander NJ, Anderson DJ: Vasectomy: Consequences of autoimmunity to sperm antigens. *Fertil Steril* 32:263, 1979

2. Alexander NJ, Clarkson TB: Vasectomy increases the severity of diet-induced atherosclerosis in *Macaca fascicularis*. *Science* 201:538, 1978

3. Clarkson TB, Alexander NJ: Long term vasectomy: Effects on the occurrence of atherosclerosis in rhesus monkeys. *J Clin Invest* 65:15, 1980

4. Fahrenbach HB, Alexander NJ, Senner JW, et al: Effects of vasectomy on the retinal vasculature of men. *J Androl* 1:299, 1980.

5. Walker AM, Jick H, Hunter JR, et al: Hospitalization rates in vasectomized men. *JAMA* 245:2315, 1981

Vasectomy, Atherosclerosis, and Autoimmune Disease

To the Editor:

"Vasectomy" by Brownlee and Tibbels (*Brownlee JH, Tibbels CK: Vasectomy. J Fam Pract* 16:379, 1983) was a fine review article.

However, mention was not made of the important, though still unproven, theory that vasectomy may induce atherosclerosis and autoimmune disease.

Alexander and colleagues have