ETTERS 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.

SCREENING FOR FAMILY DYSEUNCTION

To the Editor:

The paper of Dr. Mengel¹ concerning the use of the Family APGAR² in screening for family dysfunction in a family practice center provides some very important and useful information concerning this instrument. Dr. Mengel suggested that this instrument should be assessed in the light of his data and the criteria for screening given by Dr. Paul Frame.³ This letter presents an analysis of the applicability of the Family APGAR as a screening tool for family dysfunction according to Dr. Frame's six criteria.

Criterion 1: The condition must have a significant effect on the quality and quantity of life. There is little question that dysfunctional families have a decreased quality of life. The relationship between family dysfunction as measured by Family APGAR and "psychosomatic illness" has been well documented. Thus criterion 1 is met.

Criterion 2: Acceptable methods of treatment must be available. It is apparent from Mengel's paper that the physicians being studied did not believe that acceptable treatment was available to their patients. Since acceptable treatment is a requirement for a valid screening test, the unavailability of treatment invalidates the Family APGAR as a screening tool. The use of this screening tool must be limited to situations where treatment may be offered when indicated. Thus criterion 2 is met in some situations but not in others.

Criterion 3: The condition must have an asymptomatic period during which detection and treatment significantly reduce morbidity or mor-

tality. The concept of asymptomatic family dysfunction was not defined in the paper. Family dysfunction was noted by the physicians in 56 percent of families with APGAR s of less than 6 (Mengel's Figure 3), indicating that family dysfunction is frequently symptomatic when detected. Assuming that asymptomatic family dysfunction exists, no available studies demonstrate that treatment in the asymptomatic phase decreases the morbidity or mortality of either family dysfunction or of psychosomatic complaints. Thus the Family APGAR fails criterion 3.

Criterion 4: Treatment in the asymptomatic phase must vield a therapeutic result superior to that obtained by delaying treatment until symptoms appear. Therapeutic results to treatment in an asymptomatic phase have not been demonstrated; therefore, the Family APGAR fails criterion 4

Criterion 5: Tests that are acceptable to patients must be available at reasonable cost to detect the condition in the asymptomatic period. The test is inexpensive and generally acceptable to patients. Dr. Mengel, however, reports a significant number of false-negative results but did not give the rate. Knowledge of that rate would be very helpful. Assuming a reasonable number of false-negative and false-positive findings, the Family APGAR fulfills criterion 5.

Criterion 6: The incidence of the condition must be sufficient to justify the cost of screening. The cost of screening is minimal. The incidence of family dysfunction is estimated to be 15 to 25 percent.¹ Criterion 6 is easily met.

Screening for family dysfunction fulfills criteria 1 and 6. It fulfills criteria 2 and 5 on a conditional basis, continued on page 556



Each capsule contains 40 mg. caramiphen edisylate and 75 mg. phenylpropanolamine hydrochloride.

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FOR COLDS WITH COUGHS*

Before prescribing, see complete prescribing information in SK&F literature or *PDR*. The following is a brief summary.

Indications

For the symptomatic relief of coughs and nasal congestion associated with common colds.

N.B.: A final determination has not been made on the effectiveness of this drug combination in accordance with efficacy requirements of the 1962 Amendments to the Food, Drug and Cosmetic Act

Contraindications: Hypersensitivity to either component; concurrent MAO inhibitor therapy, severe hypertension; bronchial asthma; coronary artery disease. Do not use 'Tuss-Ornade' Spansule capsules in children under 12 years of age.

Warnings: Warn vehicle or machine operators of possible drowsi-ness, Warn patients of possible additive effects of alcohol and other CNS depressants

Precautions: Use with caution in persons with cardiovascular disease, glaucoma, prostatic hypertrophy, thyroid disease or diabetes and in patients in whom productive cough is desirable to clear excessive secretions from bronchial tree. Patients taking this medication should be cautioned not to take simultaneously other products containing phenylpropanolamine HCI or amphetamines.

Usage in Pregnancy: Do not use in pregnancy, nursing mothers, or women of childbearing potential unless the anticipated benefits outweigh the potential risks.

Adverse Reactions: Drowsiness; nervousness; insomnia; nausea, constipation, diarrhea, dizziness, includances, insumma, inducea, angina pain, irritability, palpitations, headache, incoordination, tremor, difficulty in urination; hypertension, hypotension; anorexia; visual disturbances; dysuria; gastrointestinal upset.

Supplied: 'Tuss-Ornade' Spansule capsules, in bottles of 50 and

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CREME RINSE permethrin

PEDICULICIDAL/OVICIDAL ACTIVITIES: In vitro data indicate that permethrin has pediculicidal and ovicidal activity against *Pedic-ulus humanus* var. *capitis*. The high cure rate (97-99%) of Nix in patients with head lice demonstrated at 14 days following a single application is attributable to a combination of its pediculicidal and ovicidal activities and its residual persistence on the hair which may also prevent reinfestation

INDICATIONS AND USAGE: Nix is indicated for the single-appli-cation treatment of infestation with *Pediculus humanus* var. *capitis* (the head louse) and its nits (eggs). Retreatment for recurrences is required in less than 1% of patients since the ovicidal activity may be supplemented by residual persistence in the hair. If live lice are observed after at least seven days following the initial application, a second application can be given.

CONTRAINDICATIONS: Nix is contraindicated in patients with known hypersensitivity to any of its components, to any synthetic pyrethroid or pyrethrin, or to chrysanthemums.

WARNING: If hypersensitivity to Nix occurs, discontinue use PRECAUTIONS

General: Head lice infestation is often accompanied by pruritus, erythema, and edema. Treatment with Nix may temporarily exace bate these conditions

Information for Patients: Patients with head lice should be advised that itching, redness, or swelling of the scalp may occur after application of Nix. If irritation persists, they should consult their after application of Nix. If irritation persists, they should consult their physician. Nix is not irritating to the eyes; however, patients should be advised to avoid contact with eyes during application and to flush with water immediately if Nix gets in the eyes. In order to prevent accidental ingestion by children, the remaining contents of Nix should be discarded after use.

Combing of nits following treatment with Nix is not necessary for effective treatment. However, patients may do so for cosmetic or other reasons. The nits are easily combed from the hair treated with Nix after drying. Carcinogenesis, Mutagenesis, Impairment of Fertility: Six car-

Carcinogenesis, Mutagenesis, Impairment of Fertility: Six car-cinogenicity bioassays were evaluated with permethrin, three each in rats and mice. No tumorigenicity was seen in the rat studies. However, species-specific increases in pulmonary adenomas, a common benign tumor of mice of high spontaneous background incidence, were seen in the three mouse studies. In one of these studies there was an increased incidence of pulmonary alveolar-cell carcinomas and benign liver adenomas only in female mice when permethrin was given in their food at a concentration of 5000 ppm. Mutagenicity assays, which give useful correlative data for inter-preting results from carcinogenicity bioassays in rodents, were a battery of *in vitro* and *in vivo* genetic toxicity studies.

Permethrin did not have any adverse effect on reproductive func-tion at a dose of 180 mg/kg/day orally in a three-generation rat study

Study. Pregnancy: Teratogenic Effects: Pregnancy Category B: Repro-duction studies have been performed in mice, rats, and rabbits (200-400 mg/kg/day orally) and have revealed no evidence of impaired fertility or harm to the fetus due to permethrin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always pre-dictive of human response, this drug should be used during preg-nancy only if clearly peeded.

Aure of informating sporse, this and should be used during preg-nancy only if clearly needed. Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the evidence for tumorigenic potential of permethrin in animal studies, consideration should be given to discontinuing nurs-ing tomerselive south the studies of the bulk to be the studies.

ing temporarily or withholding the drug while the motinning nursing. Pediatric Use: Nix is safe and effective in children two years of age and older. Safety and effectiveness in children less than two years of age have not been established.

ADVERSE REACTIONS: The most frequent adverse reaction to Nix is pruritus. This is usually a consequence of head lice infestation itself, but may be temporarily aggravated following treatment with Nix. 5.9% of patients in clinical studies experienced mild temporary itching: 3.4% experienced mild transient burning/stinging, tingling, numbness, or scalp discomfort; and 2.1% experienced mild tran-sient erythema, edema, or rash of the scalp.

DOSAGE AND ADMINISTRATION:

Adults and Children: Nix is intended for use after the hair has been washed with shampoo, rinsed with water and towel dried. Apply a sufficient volume of Nix to saturate the hair and scalp. Nix should remain on the hair for 10 minutes before being rinsed off with water. A single treatment is sufficient to eliminate head lice infestation. Combing of nits is not required for therapeutic efficacy, but may be done for cosmetic or other reasons.

SHAKE WELL BEFORE USING.

HOW SUPPLIED: Nix (Permethrin) 1% (wt./wt.) Creme Rinse is supplied in plastic squeeze bottles that contain 2 fl. oz. weighing 56 g. (NDC-0081-0780-81)

Store at 15°-25°C (59°-77°F).

1 DiNapoli J, Austin R, Englender S, et al: Eradication of lice with a single treatment (unpublished data, 1987). 2 Taplin D, Meinking T, Castillero P, et al: Permethrin 1% creme rinse for the treatment of pediculus humanus var capitis infestation. *Pediatr Dermatol* 1986; 3,4:344-348. 3 Davies J, Dedhia H, Morgade C, et al: Lindane poisonings. *Arch Dermatol* 1983; 119:142-144.

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while criteria 3 and 4 are not fulfilled. A valid screening test must fulfill all six criteria, and thus screening for asymptomatic family dysfunction using the Family APGAR or any other screening test is not justified.

According to this analysis, the physicians in Dr. Mengel's study acted appropriately. Eighty-seven percent of patients with psychosomatic symptoms and low Family AP-GAR scores were assessed for family dysfunction (Mengel's Figure 5). The presence of low Family APGAR in the absence of symptoms, however, did not change the physicians' behavior

This is not to say that symptomatic family dysfunction should not be investigated and treated when found. The diagnosis and treatment of symptomatic illness in a patient or a family is not a screening procedure and thus need not meet the criteria for screening. The Family APGAR may be used to assess the severity of family dysfunction in a symptomatic family and to follow the family's response to treatment.

> Martin Urberg, MD, PhD Department of Family Medicine Wayne State University School of Medicine. Detroit, Michigan

References

- 1. Mengel M: The use of the Family APGAR in screening for family dysfunction in a family practice center. J Fam Pract 1987: 24:394-398
- 2. Smilkstein G: The Family APGAR: A proposal for a family function test and its use by physicians. J Fam Pract 1978; 6:1231-1239
- 3. Frame PS: A critical review of adult health maintenance: Part 4: Prevention of metabolic, behavioral, and miscellaneous conditions. J Fam Pract 1986; 23:29-39

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

Dr. Urberg's letter provides an excellent critique of the use of the Family APGAR in screening for family dysfunction using Dr. Paul Frame's screening criteria. I agree with Dr. Urberg's main conclusion that the Family APGAR does not fulfill all six

of Frame's criteria and thus cannot be advocated as a screening tool for family dysfunction. There are several points of disagreement and one point of clarification, however, that I would like to discuss.

First, Dr. Urberg mentioned that it would not be justified to screen for family dysfunction using an instrument other than the Family APGAR. The basis for this statement seems to be Dr. Urberg's belief that no screening instrument will ever meet criteria 3 and 4 because there is not a true asymptomatic period for family dysfunction. I disagree, primarily because criteria 3 and 4 apply to asymptomatic periods of diseases, not behavior or social dysfunctions such as family dysfunction. Just as depression is defined by its symptoms and does not have an asymptomatic phase, so, too, family dysfunction is defined by behaviors within the family that impede the growth of its members. Thus, criteria 3 and 4 need to be modified to speak of early family dysfunction when patterns of behavior have not become rigidified, or family dysfunction in which members have not developed medical symptoms or exacerbations of existing medical conditions. With criteria 3 and 4 so altered, it is conceivable in the future that a screening instrument may detect family dysfunction in its early stages, significantly reduce morbidity and mortality, and yield a therapeutic effect superior to that obtained by delaying treatment until dynamics are more established and resistant to therapy.

Second, I believe that acceptable treatment is available for family dysfunction in more instances than Dr. Urberg's statement, "criteria 2 is met in some situations but not in others," leads readers to believe. Campbell's recent review entitled the "Family's Impact on Health: A Critical Review"¹ supports the belief that treating family dysfunction leads to an improvement in a large number of acute, chronic, and mental illnesses that present commonly in the family practice setting. In addition, treatment of family dysfunction in the absence of an ill member is also supcontinued on page 558



INDICATIONS AND USAGE: Entex is indicated for the symptomatic relief of sinusitis, bronchitis, pharyngitis, and coryza when these conditions are associated with nasal congestion and viscous mucus in the lower respiratory tract.

CONTRAINDICATIONS: Entex is contraindicated in individuals with known hypersensitivity to sympathomimetics, severe hypertension, or in patients receiving monoramine oxidase inhibitors.

WARNINGS: Sympathomicitic amines should be used with caution in patients with hypertension, diabetes mellitus, heart disease, peripheral vascular disease, increased intraocular pressure, hyperthyroidism, or prostatic hypertrophy.

PRECAUTIONS: Information for Patients: Do not crush or chew Entex LA tablets prior to swallowing.

Drug Interactions: Entex should not be used in patients taking monoamine oxidase inhibitors or other sympathomimetics.

Drug/Laboratory Test Interactions: Guaifenesin has been reported to interfere with clinical laboratory determinations of urinary 5-hydroxyindoleacetic acid (5-HIAA) and urinary vanilmandelic acid (VMA).

Pregnancy: Pregnancy Calegory C. Animal reproduction studies have not been conducted with Entex. It is also not known whether Entex can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Entex should be given to a pregnant woman only if clearly needed. Nursing Mothers: It is not known whether the drugs in Entex are excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the modulet. believe

product, taking into account the importance of the drug to the mother. Pediatric Use: Entex LA: Safety and effectiveness of Entex LA tablets in children below the age of 6 have not been established.

Entex Liquid: Safety and effectiveness of Entex Liquid in children below the age of 2 have not been established.

ADVERSE REACTIONS: Possible adverse reactions include nervousness, insomnia, restlessness, headache, nausea, or gastric irritation. These reactions seldom, if ever, require discontinuation of therapy. Urinary retention may occur in patients with prostatic hypertrophy. OVERDOSAGE: The treatment of overdosae should provide symptomatic.

OVERDOSAGE: The treatment of overdosage should provide symptomatic and supportive care. If the amount ingested is considered dangerous or excessive, induce vomiting with lpeace styrup unless the patient is convulsing, comatose, or has lost the gag reflex, in which case perform gastric lavage using a large-bore tube. If indicated, follow with activated charcoal and a saline cathartic. Since the effects of Entex may last up to 12 hours, treatment should be continued for at least that length of time.

DOSAGE AND ADMINISTRATION: Entex LA: Adults and children 12 years of age and older – one tablet wice daily (every 12 hours); children 6 to under 12 years – one-half (1/2) tablet kivice daily (every 14 hours); chieldren 6 to a is not recommended for children under 6 years of age. Tablets may be broken in half for ease of administration without affecting release of medication but should not be curshed or cheved noir to swallowing.

Entex Liquid: All dosage should be administered four times daily (every 6 hours).

Children:			
2 to under 4 years	1/2 teaspoonful (2.5 ml		
4 to under 6 years	1 teaspoonful (5.0 ml		
6 to under 12 years	.11/2 teaspoonfuls (7.5 ml		
Adults and children 12 years of age and older:			

2 teaspoonfuls (10.0 ml)

HOW SUPPLIED: Entex LA is available as a blue, scored lablet imprinted with "ENTEX LA" on the smooth side. Entex Liquid is available as an orange-colored, pleasant-tasting liquid.

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 Entex LA

 NDC 0149-0436-01 bottle of 100

 NDC 0149-0436-05 bottle of 500

 Entex Liquid

 NDC 0149-0436-06 bottle of 500

 COLD 0149-0414-16

 16 FL. 0Z. (1 Pint) bottle

 CAUTION: Federal law prohibits dispensing without prescription

 LQ-BS5/LA-BS8

 REVISED JULY 1985 (Entex LA)

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ported by a large number of outcome studies reviewed in Gurman and Kniskern's *Handbook of Family Therapy*.² Thus, I feel that criteria 2 is met in the great majority of situations and is largely fulfilled.

Third, Dr. Urberg correctly identified that I failed to report a falsenegative rate for Family APGAR screening. The reason is that I did not evaluate all patients with a "gold standard" test for family dysfunction. such as an evaluation by a family therapist. The criteria for estimating the false-negative rate in my study was agreement between nurses and physicians in our clinics that family dysfunction existed in patients even though the APGAR score was above 6. We regard this estimate as low because there were a large number of cases in which either the nurses or the physician felt that family dysfunction was present in a particular patient's family, but both together could not agree. Thus, our estimate of the falsenegative rate is conservative. As reported in our study, there were 44 patient visits in which patients scored above 6 on the Family APGAR, but both nurses and physicians felt family dysfunction was present. There were no instances when both nurses and physicians felt family dysfunction was absent and the APGAR score was 6 or less. Thus, an estimate of the falsenegative rate would be 44 divided by 238(194 + 44) or 18.5 percent. I feel that this rate is unacceptably high, and thus I agree with Dr. Urberg that the Family APGAR does not fulfill criteria 5

Fourth, Dr. Urberg concludes that although we should not screen for asymptomatic family dysfunction, perhaps it would be appropriate to screen patients or their families with symptomatic illness, as that process would not need to meet the stringent screening criteria. Although I definitely feel an adequate evaluation of family function should take place on all patients who have symptoms suggestive of family dysfunction, I do not feel that our lack of criteria for this process justifies the Family AP-GAR's use in this situation. First, criteria similar to screening criteria can be established for this tertiary prevention activity. Second, the Family APGAR should be evaluated for its ability to detect family dysfunction at a reasonable cost, encourage physicians to institute treatment, reduce morbidity and mortality, and improve patient quality of life when screening symptomatic patients or their families. I feel it would be unwise to advocate use of the Family AP-GAR as a screening tool for assessing the presence of family dysfunction in symptomatic patients and their families in the absence of studies that prove it of benefit in this setting.

Finally, it is a gross understatement to say that this area is ripe for research. While no instrument currently meets the criteria established for screening, it is conceivable that such an instrument could be developed and would prove beneficial. Given recent empirical work and theoretical advances in the field of family functioning, it seems an appropriate time to move past the simplicity of the Family APGAR and develop new tools that have a better potential to meet Frame's screening criteria. Development and testing of more theoretically based instruments has the potential of not only moving the field of family systems medicine forward but also the possibility of improving our patients' health.

> Mark B. Mengel, MD, MPH Department of Family Medicine University of Oklahoma Oklahoma City

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- Gurman AS, Kniskern DP: Family Therapy Outcome Research: Knowns and Unknowns. In Gurman AS, Kniskern DP (eds): Handbook in Family Therapy. New York, Brunner/Mazel, 1981, pp 742–775