# The Effect of a Rural Preceptorship During Residency on Practice Site Selection and Interest in Rural Practice

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Rural areas of the United States face serious shortages in health care personnel. This report evaluates the effect of a rural preceptorship during the second or third year of a family practice residency on interest in rural practice and on practice site selection. A majority of participants (n = 123) felt that this experience influenced their choice of a practice site. Furthermore, a large majority felt that it increased their interest in rural practice opportunities. Rural preceptorships during residency are a timely solution to increase the number of family physicians interested in rural practice.

The geographical maldistribution of physicians, especially of family physicians in rural areas, is a major health care problem in the United States in general and in rural states in particular. The American Medical Association's recent multidisciplinary publication *The Health Policy Agenda for the American People*<sup>1</sup> states, ". . . what is needed is a concerted effort to get health professionals into geographic areas and settings where they are needed . . ., special attention should be directed at recruitment and retention of health care professionals practicing in under-served areas."

The number of physicians per 100,000 population in the United States as a whole was 163.3 in 1985. In counties with populations of less than 10,000, however, it was 53. Furthermore, in the ten years from 1975 to 1985, the growth rate in physicians per 100,000 population was 32.5 percent for the entire United States, while it was only 14.2 percent for rural counties of less than 10,000.<sup>2</sup>

One method of increasing the number of family physicians in practice in a rural area is to provide a rural training period during residency. The purpose of this report is to examine the effect of this type of program. The Montana Family Practice Residency Satellite Program has been previously described in the literature.<sup>3</sup> It is a training

program that places second- and third-year family practice residents from various residency programs in educational rotations throughout Montana. The residents work with board-certified family physicians for periods of one to two months. The program began in 1982, and at the time of the most recent resident alumni survey in July 1987, 123 residents had completed an educational rotation.

Rural preceptorship programs have been used in many aspects of medical education. They have been extensively used at the predoctoral level. They have also been used at the residency level in several specialties for various periods of training time. The purposes of the rural rotations have included providing an enhanced clinical experience, exposing physicians in training to clinical medicine in rural settings, and increasing the number of physicians interested in rural practice.

This paper utilizes data gathered from the second- and third-year family practice residents who participated in rotations offered by the Montana Family Practice Residency Satellite Program. Most of Montana is rural in character; it ranks 48th among the states in population density, with only Wyoming and Alaska possessing less dense populations. Montana is one of three states (Alaska and Wyoming are the others) where the entire state is designated "frontier," with a population density of less than six people per square mile (actual 5.6 people per square mile) (F. S. Newman, personal communication, July 3, 1987). Only two of the 30 rotation sites in the Montana program are in metropolitan areas (>25,000 population). Thus, almost all of the rotations are rural in

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TABLE 1. RESULTS OF SURVEY QUESTION ON WHETHER A RURAL ROTATION INFLUENCED CHOICE OF PRACTICE SITE (N = 95\*)

Resident Year	Positive	Negative	Percent Positive
1982-83	4	114 000	80
1983-84	7	4	63
1984-85	20	8	71
1985-86	19	7	70
1986-87	13	10	54
Totals	63	. 30	66

<sup>\*</sup> In some cases not all residents answered a particular question, so the number of answers may not equal the number of surveys returned

character. This report evaluates the effect of these rotations on the participants' choice of a practice site and their interest in rural practice.

# **METHODS**

At the end of each resident training year (July 1 to June 30), all physicians who have done a rotation in the Montana Family Practice Residency Satellite Program are mailed an alumni survey. The survey is designed to elicit basic information concerning when the resident will finish residency, where the resident plans to practice, the population of the practice site, and the type of practice site (ie, nongovernmental vs governmental, such as National Health Service Corps, Indian Health Service, military). Additional information collected determines the resident's perception of the influence of the Montana rotation on the choice of a practice site and the influence on consideration of rural practice opportunities (positively, negatively, or not at all). The returned surveys for the first five resident years of the Montana program have been collected and analyzed. The resultant data are presented here.

# RESULTS

During the first five resident years of the Montana program, 123 residents from over 100 approved family practice residency programs participated in Montana rotations. An alumni survey was mailed to each of these residents following the rotation. Ninety-five residents (77 percent) returned their surveys. The number of residents returning their surveys in each year varied from a low of 60 percent in 1982–83 and 1986–87 to a high of 100 percent in 1983–84.

TABLE 2. EFFECT OF ROTATION ON INTEREST IN RURAL PRACTICE OPPORTUNITIES

Resident Year	Positively	Negatively	Not at All	Percent Positive
1982-83	5	0	1	83
1983-84	10	0	1	91
1984-85	27	0	1	96
1985-86	26	0	0	100
1986-87	22	0	2	92
Totals	90	0	5	95

The residents' responses to the question "Did your rotation in Montana influence your choice of a practice location?" were recorded as those who answered the question positively and those who answered negatively. The percentage of those who answered positively (vs negatively) was then calculated. The percentages are based only on those who returned the survey, not on the entire group. These results are shown in Table 1. In addition to analyzing these data for all residents who responded to the survey, the responses were also analyzed for the subset of residents who did a rotation in a town with a population of fewer than 10,000 people. In both cases 66 percent of the residents felt their Montana rotation influenced their choice of practice site.

Responses to the question "How did this rotation influence your consideration of rural practice opportunities? Positively, Negatively, Not at all," were then tabulated. Once again, the data were evaluated for all residents who returned the survey (and answered this question) as well as analyzed for the subset who were assigned to towns of fewer than 10,000 population. The percentages shown represent the number of those who answered the question positively compared with the total number of surveys returned that year. Ninety-five percent of all residents responding and 96 percent of the residents assigned to smaller towns responded positively. The 95 percent and 96 percent averages, respectively, indicate a significant impact on positive consideration of rural practice. This information is presented in Table 2.

The last comparison from these surveys is a listing of the population sizes of the communities where these residents have entered practice. The information is presented as a general breakdown of how many residents are practicing in metropolitan (>25,000 population) communities and how many are practicing in nonmetropolitan (<25,000) communities (Table 3). Also presented is a listing of residents in practice in very small communities (<10,000). It is notable from the survey that out of 36 residents who entered practice in towns with fewer than 10,000 people, 32 of them (89 percent) did their Montana

		Metropolitan	Nonmetropolitan	Smaller Communities		
Resident Year	사람들은 사람들은 사람들은 사람들은 사람들은 사람들은 사람들은 사람들은	Community < 25,000	0 to 2,500	2,500 to 5,000	5,000 to 10,000	
1982-83	10	5	5	1 100000	2	1
1983-84	11	4	7	2	2	0
1984-85	22	3	19	6	4	1
1985-86	19	8	11	4	3	0
1986-87	19	5	14	3	4	3
Totals	81	25 (31%)	56 (69%)	16	15	5

rotations in towns of less than 10,000 population. The data on practice sites also indicate that 19 of the first 123 residents who participated in this program selected a practice site in Montana, all in nonmetropolitan communities. If all of the survey respondents who are in governmental practices are deleted from the analysis on the basis that they might not have been able to select their practice site, then 71 percent of respondents are practicing in nonmetropolitan communities.

# DISCUSSION

The purpose of this study was to assess the effect of a one-to two-month rural rotation during the second or third year of family practice residency on interest in rural practice and on practice site selection. Previous studies have indicated that 64 to 74 percent of graduates of family practice residencies have chosen to practice in the state where they completed their residency. <sup>14,15</sup> It has also been noted that any previous residential stay in an area predisposes a physician to locate in that area. <sup>16,17</sup>

The physicians who participated in the creation of the Montana Family Practice Residency Satellite Program hypothesized that an exposure to a high-quality rural family practice training site during residency would increase the resident's interest in rural practice, especially if he or she were accompanied by spouse and family. They further hypothesized that such a rotation would influence the choice of a practice site for some of the residents. The data presented here indicate that both of these hypotheses were correct. A large majority of the residents (95 percent) felt that the rotation had a positive effect on their interest in rural practice. In addition, a majority (66 percent) felt that the rotation influenced their choice of a practice site. Perhaps of more significance is the fact that 36 residents from this group of 123 actually entered practice in a community with a population of less than 10,000. Furthermore, 19 residents (15.4 percent) who participated in the program entered practice in Montana. This finding is of special significance, since Montana has no residency programs, and only one year of medical school is available within the state.

Comparison of the data presented here with the national experience regarding distribution of graduating residents by community size reveals some interesting findings. The American Academy of Family Physicians survey of 1987 graduating family practice residents indicated that 46 percent (764 of 1,648) of the 1987 graduating residents chose practices in communities of less than 25,000 population. 18 Among the residents who participated in the Montana program over the last five years, however, 69 percent (56 of 81) of those in practice chose communities in this size range. Since the study group was self-selected (ie, they freely chose a rotation in Montana), it is not possible to generalize these results to all residents. There may have been a preexisting heightened interest in rural practice or Montana that led these residents to participate in this program. It is encouraging, however, that the Montana program seems to positively influence both the residents' perception of rural practice and the likelihood of their selecting a rural practice site.

Access to medical care in rural areas remains a major problem for Montana as well as for other rural states. <sup>19</sup> The data presented here indicate that programs of this type, essentially rural preceptorships during residency, can have a positive impact on the problem.

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Neurology. James L. Bernat, Frederick M. Vincent. Medical Economics Books, Oradell, New Jersey, 1987, 645 pp., \$39.95 (paper). ISBN 0-08749-407-7.

This textbook is the first in a new series entitled Problems in Primary Care. The purpose of *Neurology* is "to provide a terse, practical and ready office and bedside guide to the common complaints and disorders likely to be encountered in primary care practice." The authors are only partially successful in meeting this laudable goal.

Neurology is well organized for use as a quick reference. Its four main sections cover neurologic assessment, common presenting symptoms, specific neurologic diseases, and emergencies. Individual chapters are divided into easily identified sections on signs and symptoms, laboratory tests, and management. Helpful tables abound. The bibliographies are annotated and include 1986 references. An unusual and valuable feature is the appendix of patient resource groups.

Unfortunately, the actual content of the book is of mixed value to this primary care physician. The most helpful chapters outline a diagnostic approach to common problems such as dizziness and syncope. Chapters on other challenging problems such as weakness, aphasia, or the floppy infant are less helpful because they merely list the extensive differential diagnoses.

Similarly, the writing style varies tremendously. Some chapters are quite dry, making extensive use of statistics and anatomy descriptions. Others, such as the demyelinating diseases and movement disorders chapters, were very interesting and readable. This degree of variation is surprising for a text with only two authors.

My major criticism, however, concerns some of the authors' management recommendations, particularly in the sections "When to Consult." Although referral patterns vary throughout the country, I question whether all patients with dementia require consultation with a neurologist, as is stated here. Similarly, do all

patients with suspected meningitis really need the aid of a neurologist and infectious disease specialist? Another alarming statement made in this book is that "a preschool child with minor head trauma should be admitted to the hospital even if the neurologic examination is unremarkable." Although these recommendations are indeed terse and practical, many primary care physicians will disagree with them.

In summary, Neurology is well organized and contains some very valuable chapters. A large portion of the book is not helpful, however, and several of the authors' recommendations are questionable. This book does not seem to be a sufficient improvement over the neurology sections of standard medical textbooks to warrant its purchase by primary care physicians.

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Cutaneous Side Effects of Drugs. Konrad Bork. W. B. Saunders Company, Philadelphia, 1987, 466 pp., \$95. ISBN 0-03-012688-5.

Many patients who present with dermatologic conditions are on medications, and it can be difficult for physicians to determine whether the drugs are the cause of the problem or simply innocent bystanders. This text helps to lessen the difficulty in making the correct diagnosis. The author states that it is not correct that "any drug can cause any type of side effect." Rather, most medications cause specific sequences of drug-induced cutaneous changes, and recognizing these changes takes much of the randomness out of making the diagnosis.

This excellent reference text is intended for family physicians, internists, and pediatricians. It is succinctly written and includes 448 high-quality color illustrations. The beginning chapters, which provide an overview of the basic mechanisms involved in cutaneous drug reactions, make up a section that every physician would benefit from reading. The remainder of the book, more for reference purposes, depicts important

and frequent manifestations. Both a general index and a medication index give easy access to the information one needs at the time of the patient visit. A brief, well-written text supports the photographs.

The cost of the book is reasonable, given the number and quality of the photographs and the comprehensiveness of the material. This reference text is appropriate for small group practices or residency clinics, and it is one that will not be outdated soon.

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Infections of the Hand. Ronald J. Mann. Lea & Febiger, Philadelphia, 1988, 190 pp., \$43.50.

The author of Infections of the Hand has successfully undertaken the task of updating this area of orthopedic surgery. Apparently this text is the first major revision of its type in several decades. Mann's intent is to provide a specific and aggressive approach to the management of hand infections using a team concept, which he believes is critical to a patient's good outcome. The value of the team is reflected in the book's organization in that rehabilitation and nursing care are continuously emphasized when dealing with the major types of hand infections.

The initial chapter presents clearly an in-depth review of hand anatomy. Diagrams add much to its clarity. Subsequent sections build on the topic by sequentially introducing more complex clinical problems, such as paronychia, felons, deep tenosynovitis, deep space infections, and bone infections. Chapters are organized similarly: first they address etiology, then diagnostic considerations, bacteriology, treatment, and, finally, complications. Surgical treatment is presented in depth. Complications are reviewed at each juncture with warnings given to assist the reader in anticipating pitfalls early and avoiding them. Photographs, diagrams, and radiographs are plentiful and effectively illustrate points made by the author.

The most beneficial section from a primary care point of view is the chapter devoted to rehabilitation and splinting. Here the seldom-emphasized yet critical aspects of infection care, including dressing changing, wound cleaning, and occupational and physical therapy, are appropriately highlighted with a special consideration given to patient education.

Taken as a whole this text would be best suited to the physician who actively participates in treating hand infections of more than superficial clinical concern. Its technical level of discussion would in all likelihood not interest the casual reader who elects to refer all but the most trivial infections of this nature. The target audience, however, will find the book easy to read and efficient at yielding useful concepts in diagnosing and treating hand infections.

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Clinical Method: A General Practice Approach. Robin C. Fraseer. Butterworths, Stoneham, Mass, 1987, 87 pp., \$19.95 (paper). ISBN 0-407-00430-0.

This short book has been written by a group of general practitioner academicians from the Department of General Practice at the University of Leicester, England. Its aim is to present clearly to medical students the physician's role in patient management in the ambulatory care setting. The book is organized into seven chapters, which cover epidemiology and illness behavior, problem solving and diagnostic processes, the physician-patient relationship, communication, patient management and counseling, and anticipatory care.

Although there are features that relate specifically to the British health care system, a major part of each chapter deals with material that is generic to the teaching of physicians in any country. Although much of the material has been presented before in other texts or articles, the attraction for the reader in *Clinical Method* is that it has been extremely well dis-

tilled and very clearly written. It is well referenced and includes a number of references from the American literature. There are few illustrations but the authors include a number of useful tables on the epidemiology of symptoms, diagnosis, and health care utilization. This book would be most useful for medical students taking a family medicine clerkship or elective on introduction to medicine course. It would also prove an excellent basis for discussion during orientation for incoming residents in any primary care discipline. The cost is high, however, just under \$20; consequently, it is unlikely that a copy would be purchased for each student or resident. In some ways this slim volume makes an impractical proposition unless provided by a faculty person to share often with certain students or residents

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Handbook for the Academic Physician. William C. McGaghie, John J. Frey (eds). Springer-Verlag, New York, 1986, 398 pp., \$49.50.

With the establishment in 1969 of family practice as the 20th medical specialty, the major focus of the new specialty was the organization of new training programs for residents and medical students. Many of the first generation of family practice faculty members were recruited directly out of clinical practice, without previous academic experience. Their leadership guided family practice throughout what Dr. John P. Geyman has termed "phase one" in the evolution of the specialty. The "second phase" requires the further development of an intellectual method and content not central to any other clinical discipline. Academic viability also depends on addressing the various research questions that flow from the special interests and skills of family practice. Thus, the academic physician must be proficient in caring for patients, teaching, conducting and presenting research, and participating in institutional and community organizational administration.

Fellowship training programs, such as the excellent one at the University of North Carolina, School of Medicine at Chapel Hill, have been organized to prepare family physicians for academic careers. Handbook for the Academic Physician is based on the fellowship curriculum developed at Chapel Hill. The faculty there identified a need for educational materials relevant to their program's goals and trainees. Although a myriad of journal articles, chapters, and handouts were available from numerous sources, there was no single book that could be used as a primary textbook The Handbook fulfills this need. Its five sections reflect the five-part fellowship curriculum: (1) professional development and career management, including how to function successfully in professional organizations and committees; (2) teaching and evaluation: (3) clinical research and data management; (4) written and oral professional communications: and (5) ethics in patient care and medical education.

While the majority of chapters are authored by individuals affiliated with Chapel Hill, their nationally recognized expertise as educators and administrators prevents the book from being parochial in scope. Moreover, although the Handbook was originally written for family physicians, it is a valuable resource for those in other medical specialties pursuing academic careers. Experienced academicians should not overlook this book's usefulness as an excellent review of methods for success in their chosen profession. Such strategies as the formulation of a professional development contract are appropriate for academic physicians in any stage of their careers.

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Community-Oriented Primary Care: From Principle to Practice. Paul A. Nutting (ed). Government Printing Office, Washington, DC, 539 pp., 1987, \$16 (paper).

This book, edited by a prominent American community-oriented primary care (COPC) physician and the recent director of the Office of Primary Care Studies in Washington, has brought together 75 contributing authors covering a wide spectrum of topics relating to COPC. Dr. Nutting and his many contributors have put together a well-organized and thoughtfully planned text that will not only help the reader fully understand COPC, but also will inform the present and future COPC physician how to do it.

The book is divided into nine sections or parts and includes methods utilized to define a community, identify community health problems, develop and monitor "emphasis" programs, and monitor the impact of the emphasis programs. Also covered are patient and community participation. practice management for COPC, data analysis, and resources needed to build and develop COPC. After each one of these parts a special chapter referred to as a coda is written by a well-respected academician from the general field of public health or primary care and community medicine, which gives that author's views on the general subject relating to the section.

The book's many authors are from diverse backgrounds including family practice, public health, academic family medicine (including research), clinical epidemiology, community and preventive medicine, social medicine, internal medicine, and the National Center for Health Services Research. Their contributions vary in scope, quality, and content, as one might expect in a volume with authors of such varied backgrounds in

skills, experience, and perspectives. They provide interested parties with the methods that can be used to implement COPC in a variety of different settings in this country's highly diversified health care delivery system.

COPC, which integrates the principles of epidemiology, community medicine, and comprehensive health care, was originally conceived by Dr. Sidney Kark in South Africa and further developed with Joseph Abramson in Israel. The ideas expressed by these authors are likely to be familiar to many academic and practicing family physicians. The basic model consists of three essential components, including a primary care program or practice, a defined population, and a process by which health problems are identified, monitored, and evaluated.

There are many show-and-tell examples of how to put together a COPC program in part or in whole in various different settings including private practice and public health clinics in both urban and rural communities. The community is looked upon not only as a people to be served but also as a resource and a "partner in coalition" for COPC.

In the concluding chapter, Dr. Nutting offers the reader a set of five questions that will help one determine the ability to establish a COPC program. The most important has to do with commitment.

The difficulties in the implementation of COPC in family practice has more to do with the varied and complex practice settings, financial limi-

tations, support staff to collect and even analyze the data, and just overall cost containment efforts and pressures in the current delivery systems rather than a lack of appreciation of the principles and merits of COPC. The so-called denominator and numerator problem is explored by many of the authors and helps one also better understand the complexities involved in the integration of COPC into practice. Another well-described issue is the need in COPC practice to understand or define the community. To help develop COPC practices, our residency programs will need to incorporate more effectively the disciplines of epidemiology and behavioral sciences into the curriculum. Moreover, COPC requires multiple community resources and a team approach if we expect this approach to primary care to flourish. The book makes this abundantly clear.

In summary, therefore, the book is recommended to any practicing or academic family and primary care physician interested in COPC. It is also recommended to those same people even if the interest is limited just to epidemiologic research and the evaluation of one's practice in a private office, family practice center, or outpatient clinic. Dr. Nutting, now completing a family practice residency program, has moved COPC in this country from rhetoric to practice. This book is also very affordable; \$16 is well worth the price.

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The following is a brief summary only. Before prescribing, see complete prescribing information in CEFTIN® (cefuroxime axetil, Glaxo) Tablets product labeling.

CONTRAINDICATIONS: CEFTIN® is contraindicated in patients with known allergy to the cephalosporin group of antibiotics

WARNINGS: BEFORE THERAPY WITH CEFTIN® IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS, PENICIL-PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPOHINS, PENICIL.

INS, OR OTHER DRUGS. THIS PRODUCT SHOULD BE GIVEN CAUTIOUSLY TO
PENICILLIN-SENSITIVE PATIENTS. ANTIBIOTICS SHOULD BE ADMINISTERED
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Pseudomembranous colitis has been reported with the use of cephalo-sporins (and other broad-spectrum antibiolics); therefore, it is important to consider its diannesis is anti-other than the contract of th spurins (and other broad-spectrum antibiotics); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use.

Treatment with broad-spectrum antibiotics alters normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis. Cholestyramine and colestipol resins have been shown to bind the toxin in

Mild cases of colitis may respond to drug discontinuance alone. Moderate to

Mild cases of colitis may respond to drug discontinuance ations. Moretare to severe cases should be managed with fluid, electrolyte, and protein supple-mentation as indicated. When the colitis is not relieved by drug discontinuance or when it is severe, oral vancomycin is the treatment of choice for antibiotic-associated pseudo-membranous colitis produced by C offficile. Other causes of colitis should also

PRECAUTIONS: General: If an allergic reaction to CEFTIN® occurs, the drug FRECAUTIONS, tenerat: If an alregic reaction to CEFTIN Occurs, its drug should be tiscontinued, and, if necessary, the patient should be treated with appropriate agents, eg. antihistamines, pressor amines, or corticosteroids. As with other antibiotics, prolonged use of CEFTIN may result in overgrowth of nonsusceptible organisms. If superinfection occurs during therapy, appro-

of nonsusceptione organisms. It superimection occurs during therapy, appro-priate measures should be taken.

Broad-spectrum antibiotics should be prescribed with caution for individuals with a history of colitis.

with a history of colitis.

Information for Patients: (Pediatric) CEFTIN is only available in tablet form. 
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swallow the tablet whole. Children who cannot swallow the tablet whole may 
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administering this drug occurred in 13% of children (range, 2% to 28% across 
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Interference with Laboratory Tests: A false-positive reaction for glucose in the urne may occur with copper reduction tests (Benedicts or Fehling's Solida with Climitest' Tablets), but not with enzyme-based tests for glycosuria (eg. Climistix", Tes-Tape\*). As a false-negative result may occur in the ferricyanide test, its "enzymended that either the glucose oxidase or hexokinase method tests, its "enzymended that either the glucose oxidase or hexokinase method." he used to determine blood plasma plucose levels in patients receiving CEFTIN.

Cefuroxime does not interfere with the assay of serum and urine creatinine by the alkaline picrate method. Carcinogenesis, Mulagenesis, Impairment of Fertility: Although no long-term studies in animals have been performed to evaluate carcinogenic potential, no mutagenic potential of cefuroxime was found in standard laboratory tests. Reproductive studies revealed no impairment of fertility in animals.

Pregnancy: Pregnancy Category B: Reproduction studies have been performed in rats and mice at doses up to 50 to 160 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to cefuroxime axetil. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly

Nursing Mothers: Since cefuroxime is excreted in human milk, consideration should be given to discontinuing nursing temporarily during treatment with CEFTIN® (cefuroxime axetil, Glaxo).

ADVERSE REACTIONS: The adverse reactions to CEETIN® are similar to RADVERSE REACTIONS. The adverse reactions to the critical similar to reactions to other orally administered cephalosporns. CEFTIN was usually well tolerated in controlled clinical trials. Pediatric patients taking crushed tablets during clinical trials complained of the bitter taste of CEFTIN Tablets [see ADVERSE REACTIONS: Gastrointestinal and PRECAUTIONS: Information for ADVENCE REACTIONS: Gastrointestinal and PRECAUTIONS. Information for Patients: (Pediatric), The majority of adverse events were mild, reversible in nature, and did not require discontinuance of the drug. The incidence of gastrointestinal adverse events increased with the higher recommended does. Twenty-five (25) patients have received CETIN 500 mg twice a day for one to 25 months with no increase in frequency or severity of adverse events.

one to 2.5 months with no increase in frequency or severity of adverse events. The following adverse reactions have been reported.

Gastrointestinal: Nausea occurred in 2.4% of patients. Vomiting occurred in 2.0% of patients. Disperance occurred in 3.5% of patients. Loose stools occurred in 1.3% of patients. There have been rare reports of pseudomembranous collitis. Crushed tablets have a bitter taste. In pediatric clinical studies conducted with crushed tablets, complaints due to taste ranged from 0/8 (0%) in one center to 47/71 (66%) in another center.

Hypersensitivity: Rash (0.6% of patients), pruritus (0.3% of patients), and nupreasessivity: A patient (OC) or in pacing, jurinous (OC) and ease of severe bronching urbana (OC) and occupant of the occupant of the occupant of the occupant of the occupant occu

Central Nervous System: Headache occurred in less than 0.7% of patients, and dizziness occurred in less than 0.2% of patients.

Other: Vaginitis occurred in 1.9% of female patients

Clinical Laboratory Tests: Transient elevations in AST (SGOT, 2.0% of patients), ALT (SGPT, 1.6% of patients), and LDH (1.0% of patients) have been observed. Eosinophilia (1.1% of patients) and positive Coombs' test (0.4% of patients) have

In addition to the adverse reactions listed above that have been observed in In addition to the adverse fleations listed above an lave been used were in patients treated with CEFTIN, the following adverse reactions and altered laboratory tests have been reported for cephalosporin class antibiotics: Adverse Reactions: Allergic reactions including anaphy-laxis, fever, colitis, renal dysfunction, toxic nephropathy, and

laxis, fever, colitis, renal dysfunction, toxic nephropathy, and hepatic dysfunction including cholestasis. Several cephalospornis have been implicated in triggering sezures, particularly in patients with renal impairment when the dosage was not reduced. If seizures associated with drug therapy should occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated. \*\*Altered Laboratory Fests: Increased prothrombin time, increased BUN, increased creatinine, false-positive test for urinary glucose, increased at lakine phosphatase, neutropenia, thrombocytopenia, and leukopenia.

## I FITTERS TO THE EDITOR

continued from page 469

In reply to Dr. Ganiat's letter, there is an error in Table 1. It should be as shown below.

	Posi- tive	Nega- tive	Total
High prevalence (10%) for 1,000 tests			
Positive	90	360	450
Negative	10	540	550
Total	100	900	1,000

For the example, the incidence (10) percent), the sensitivity (90 percent) and the specificity (60 percent) were set. I apologize, for there was an error. and I did not fix it correctly. The positive predictive value of the low-prevalence case is correctly calculated. For the example percentages were all quoted as full numbers. I did not think it necessary to carry calculations to tenths of a percent.

> Lucy M. Osborn, MD Department of Pediatrics The University of Utah Medical Center Salt Lake City

## LSD INTOXICATION

To the Editor:

Lysergic acid diethylamide (LSD) burst upon the drug scene in the mid to late 1960s and was popularized by reports of its use in the Haight-Ashbury district of San Francisco. We are seeing it with increased frequency today in our county hospital. The purpose of this letter is to alert medical practitioners that the drug is resurfacing and that the majority of toxicology laboratories do not routinely screen for LSD. The test needs to be specifically requested by the suspecting clinician.

The most recent case seen in our hospital involved a 22-month-old toddler. The patient was taken to Medical Center Hospital by his parents. Upon admission to the emergency room, the child was crying loudly, was highly agitated, and complained of seeing rats. The mother initially denied any drug ingestion by the child but then admitted that the child might have gotten into some LSD their friends left in their house The patient vomited twice. Physical examination revealed a blood pressure of 84/62 mmHg, temperature 100.6°F, pulse rate 148 beats per minute, and respirations 32/min. The remainder of the physical examination was normal. The child was given 1 mg of diazepam, spent the night in the hospital for observation, and was released the next day under the care of the Texas Department of Human Services.

LSD is rapidly absorbed from the gastrointestinal and nasal mucosa. Oral forms include tablets, powder, sugar cubes, or postage stamps impregnated with liquid LSD. The duration of symptoms averages about six to eight hours depending on the dose and the personality of the user. The plasma half-life is three hours.<sup>2</sup> Most LSD is excreted within 24 hours through the feces. The lethal dose in humans is not known, and fatalities are usually secondary to trauma, incurred when the user attempts unrealistic feats, such as jumping out of a window to "fly."

Clinically the patient who has ingested LSD may develop drowsiness. paresthesias, diaphoresis, ataxia, and tremors. Pupillary changes are inconsistent. Severe toxicity may result in coma, bleeding, convulsions, and respiratory arrest.3

Most cases of LSD intoxication resolve without incident. Acute panic reactions and gross motor stimulation may require intravenous diazepam, as in our patient's case.

Physicians confronted with patients who are intoxicated and hallucinating should once again consider LSD in their differential diagnosis and specifically request that an assay unique for this drug be performed for verification.

> Joyce G. Schwartz, MD Aviva M. Hopkovitz, MD University of Texas Health Science Center at San Antonio

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# HISPANICS, LOW BIRTHWEIGHT, AND PRENATAL ACCESS

To the Editor:

Readers have contacted us directly concerning an apparent omission in our paper, which compared maternal factors and low birthweight infants of blacks and Mexican-Americans.<sup>1</sup>

Although inadequate prenatal care was considered as a variable—one of six behavioral conditions—in our analysis, as mentioned in the Methods section, the actual data were omitted through an oversight from the characteristics listed in Table 2. The table should have included the following information concerning the timing of the first prenatal visit.

# Blacks (n = 236)

Month of First Visit	No. (%)
1–3	150 (63.4)
4-6	73 (31.1)
7–9 or none	13 (5.5)

# Mexican-Americans (n = 236)

Month of First Visit	No. (%)
1–3	141 (59.8)
4-6	70 (29.8)
7–9 or none	25 (10.4)

When the two groups are compared, a significantly higher proportion of Mexican-Americans than blacks ( $\chi^2 = 4.1212$ , P < .05) in our

study population received either no prenatal care or delayed care until the last trimester.

These figures are consistent with national data which report that both Hispanics and blacks have inadequate access. <sup>2,3</sup> In spite of the low incidence of low birthweight reported in our study, it is incorrect to assume that Mexican-Americans have good access to medical care. For this particular group the incidence of low birthweight does not correlate with health needs or access.

Patrick Dowling, MD, MPH
Department of Family Medicine
Brown University/Memorial
Hospital of Rhode Island
Pawtucket, Rhode Island

Michael Fisher, MD Chicago, Illinois

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   Government Printing Office, 1980, p 39

# PAPANICOLAOU SMEAR AND ENDOCERVICAL CELL YIELD

To the Editor:

I was quite interested to read the recent article "Improved Endocervical Cell Yield with Cytobrush" in *The Journal of Family Practice (Deckert JJ, Staten SF, Palermo V. J Fam Pract 1988; 26:639–641).* This study is yet another that has shown the value of using the Cytobrush to collect endocervical cells on Papanicolaou smears. This study was helpful in that there were large numbers of patients studied. We feel it is indeed important to harvest endocervical cells with our

Papanicolaou smears and feel probably the absence of endocervical cells on Papanicolaou smears constitutes an inadequate sampling in most women.

The results of this study were further cemented by your other recent article "Comparison of Two Papanicolaou Smear Techniques in a Family Practice Setting" (Reissman SE. J Fam Pract 1988; 26:525–529). This study also echoes the previous literature showing that the Cytobrush is indeed helpful in increasing the harvesting of endocervical cells in Papanicolaou smears.

We were particularly interested in these results, since we have just completed a study on the comparison of the cotton swab and the Cytobrush in Papanicolaou smears in our Family Practice Center. We feel that we answered two other questions that have not been previously addressed in doing our study. We conducted a formal and instructional program for the residents and attending physicians in the use of the Cytobrush before the initiation of the study. We then returned to the cotton swab after the use of the Cytobrush for a period of time to determine what the significance of the educational intervention was as opposed to the Cytobrush itself. We again went back to the Cytobrush at a later date both to determine whether the Cytobrush again showed a similar endocervical cell harvesting rate, and to demonstrate the ability of the residents and attending physicians to retain skills that would harvest the same increased percentage of endocervical cells.

This answers the question of how much drop-off will there be in endocervical cell collection rate after time as physicians possibly lose their skills over time.

Again, we applaud the study in this area and the publishing of these results to further underline the need of increased endocervical cell harvesting rates in Papanicolaou smears.

Robert F. Shadel, MD Family Practice Residency Program Lutheran General Hospital Park Ridge, Illinois

# INFORMATION FOR AUTHORS

THE JOURNAL OF FAMILY PRACTICE is a peer-reviewed scientific journal specifically intended to meet the needs of the developing specialty of family practice. Manuscripts are considered in relation to their significance in the advancement and definition of the discipline of family medicine, the extent to which they represent original work, and their interest to the practicing family physician. High priority is given to clinical studies that have practical implications for improved patient care. Some papers that are accepted for publication will be selected for concurrent commentary by other invited authors addressing issues raised by the papers. Manuscripts are considered individually on the basis of content, originality, and relevance to the goal of this journal.

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**References.** References will be critically examined at the time of editorial review. Personal communications should not be included. The journal abbreviation style of *Index Medicus* should be followed in preparing references. References should be numbered consecutively as they appear in the text and arranged in the order of citation, not alphabetically. References to a journal and a book are illustrated.

- Fishbane M, Starfield B: Child health care in the United States: A comparison of pediatricians and general practitioners. N Engl J Med 1981: 305:552-556
- Dubovsky SL, Weissberg MP: Clinical Psychiatry in Primary Care. Baltimore, Williams & Wilkins, 1978, p 46

Tables. Tables should be self-explanatory, clearly organized, and supplemental to the text of the manuscript. Each table should include a title, be typed on a separate sheet, and be numbered in order of its appearance in the text. Tables should be used to compare or classify information for easier understanding and should not duplicate data included in the text or figures.

Figures. Figures should be used only if they clearly increase understanding of the text. Figures include all material that cannot be set in type, such as graphs, charts, line drawings, and tracings. All figures must be professionally prepared (usually  $5\times7$ ) and submitted in duplicate. Only black-on-white glossy prints and black ink drawings will be accepted. Photocopies of original figures will not substitute. All figures should be unmounted. Each should have a gummed label on the back listing the figure number, title of manuscript, and author(s), with an arrow indicating the top. Figures should be numbered and cited in the text, and each should have a legend.

Book Reviews. Each issue will include a section featuring reviews of books of interest. Books for review should be sent to: Claire Griebling, Assistant Editor, *The Journal of Family Practice*, Department of Family Medicine, RF 30, School of Medicine, University of Washington, Seattle, WA 98195.

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25 mg. Hydrochlorothiazide/50 mg. Triamterene/SKF Before prescribing, see complete prescribing information in SK&F CO. literature or PDR. The following is a brief summary.

Indications and Usage: Hypertension or edema in patients who develop hypokalemia on hydrochlorothiazide alone; in patients who require a thiazide diuretic and in whom the development of hypokalemia cannot be risked.

This fixed combination drug is not indicated for the initial therapy of edema or hypertension except in individuals in whom the development of hypokalemia cannot be risked.

'Dyazide' may be used alone or as an adjunct to other antihypertensive drugs; dosage adjustments may be necessary.

Contraindications: Concomitant use with other potassium-sparing agents such as spinoniactione or amilioride, potassium supplements (except in presence of severa hypokalemia), amura, acute and chinonic real insufficiencies or significant renal impairment, hypersensitivity to drug or other sulfonamide-derived drugs; preexisting elevited setum plassium concentration.

Marnings. Ahormal elevation of seum potassium levels (greater than or equal to 5.5 mEgitilet) can occur with all polassium-conserving diureite combinations, including "Dyazide". Hyperkalemia is more likely to occur in patients with renal impairment, dielarle (even without evidence of renal impairment), elderly sevelly ill patients. Since uncorrected hyperkalemia may be fatal, serum potassium levels must be monitored at frequent intervals especially in patients list receiving "Dyazide", when dosages are changed or with any illness that may influence renal function.

arly mines that firsty intidence retail function. If typerkalemia is expected, obtain an ECG and monitor serum potassium. If hyperkalemia develops, disconlinue 'Dyazide' and initiate thiazide therapy if needed. Persistent hyperkalemia may require dialysis. Monitor serum electrolytes frequently in patients with mild enal dystuction and in diabetic patients. In patients who may develop respiratory or metabolic acidosis, monitor serum electrolytes and acidosase balance frequently.

mind read oysluricion and in diaderic patients. In plateits with may develop registratory or metabolic acidosis, monitor serum electrolytes and acidibase balance trequentify.

Precautions: The bioavailability of the hydrochlorothiazide and triamterene components of Dyazde is about 50% of the maximum oblantable with oral therapy. Theoretically, a patient transfered from therapy with hydrochlorothiazide with or without triamterene might show an increase in blood pressure, fluid retention, or change in serum potassium. Extensive cinical experience with "Dyazde", however, suggests that these conditions have not been commonly observed in clinical practice. (See CLINICAL PHARMACOLIGAY) Use this paides caudiously in patients with majent ehapatic function. They can precipitate oral impartant in this connection; administer "Dyazde" calinoslys and the after to such early signs of impending coma as contission, drowsness and tremor; if mental confusion increases, disconditure "Dyazde" in a level days: attention must be given to other factors that may precipitate hepatic coma, such as blood in the gastronitestinal tract or previsiting bestored the patients develop hybokalemia, which is uncommon with "Dyazde", increase polassium minkse (i.e., with supplements or polassium-rich florids.) If repeat determinations show seum polassium concertations the suco or micro, discontinue "Dyazde" increase polassium intake (i.e., with supplements or polassium-rich florids.) If repeat determinations show seum polassium concertations flequently, especially in patients reverting diguilation for these with a history of cardiac arrhythristic orrective measures caudiously and monitor serum polassium concertations frequently, especially in patients reverting diguilation from the electority determinations (garantucinos in patients on sali-restricted determination divertions, to periodic seum electority determinations (garantucinos in patients on sali-restricted determination divertions, in patients the and a short of read of the patient of metabo

Dyadue Cadiousy in Jenaics with a fixey of very continuous. If hyperkalemia develops when heating for hypoxialenia, lake corrective measures, Also discontinue "Dyazide" and, if appropriate, substitute a thiazide duralet until potassum levels return for normal. Do periodic BUM and serum creatinine determinations, especially in the elderly and in patients with suspected or confirmed meal insufficiency. Serum PBI levels may decrease without signs of thyroid disturbance. Discontinue thiazides before conducting paralityroid function tests.

levels may decrease without signs of flymoid disturbance. Discontinue thiazides before conducting parallymid function tests.

Angiolesian converting enzyme (ACE) inhibitors can elevate serum potassium; use with caution with 'Oyazide'. Concurrent use with chiopropamide may increase the risk of severe hyponaterian. A ten occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in patients on 'Dyazide' with related with indomethacin. Therefore, caution is advised in administering nonsebroidal anti-inflammatory agents with 'Dyazide'. Divinest: reduce renal clearance of lithium and increase the risk of lithium toxicit. Clinically insignificant reductions in artical responsiveness to morpinephine here been reported. Thinazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocuranine. Therefore use cautiously in patients undergring suscepts. Montire electrolytes in patients taking amphoterion B, contiossteroids or corticolropia muscle relaxants such as tubocuranine. Therefore use cautiously in patients undergring suscepts whomicin electrolytes in patients taking amphoterion B, corticosteroids or corticolropia concomitantly. This-zides may appear be needed: "Dyazide" may raise the level of blood unit acid, discage adjustments may be electrased when used concurrently with hydrochioribinates do casage adjustments may be needed. "Dyazide" may raise the level of blood unit acid, discage adjustments and panels (were with trainment may promote serum potassium accumulation and possibly result in hypertalemia, especially in patients with meal insufficiency blood from blood bank (may contain up to 160 mtg, of potassium per liter) potassium containing may be decreased when used concurrently with hydrochioribinate decaused with entreased solumin minke. Chronic or overuse of acathers may reduce serum potassium concentralions by promoting excessive potassium has from containing may be decreased

measurement of quinding.

There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. Thisades and triamferene cross the placental barrier and appear in cord blood. The use of thisades in pregnancy requires weighing the anticipated benefit against possible hazards, including fetal or neonatal jaundice, pancreatilis, thrombocyfopenia, and possibly other adverse reactions which have occurred in the adult. Thisades appear, and triamferene may appear in breast milk. If use of the drug is essential, the adent should stop nursing. Safety and effectiveness in children have not been established.

Adverse Reactions: The serious adverse effects associated with "Dyzide" have commonly occurred in less than 0.1% of palients treated with this product. Anaphylaxis, rash, urticaria, photosensitivity, cardiac arthythmias, postural hypotension, diabetis rash, urticaria, photosensitivity, cardiac arthythmias, postural hypotension, diabetis reallus, hyperschennia, hypocomerina, glycosuria, hyperunterenia, hypodelemia, hypotensia, addo six, hypochioremia, jaundice and/or liver enzyme abnormalities, pancrealtis, nausea and vormiting, diarrhea, constipation, abdominal pan, acute renal failure, interstibila nephritis, renal stones composed primarily of tramteene, eterated BUN and serum regaliohiscita emenia, muscle carnos, weakness, falique, dizziness, headache, dry mouth, impotence, siadardinis. Thicardes alone have been shown to cause the following additional adverse reactions; parethesias, verifor, oxanthopsia, transert burred viscon, allergic pneumonitis, pulmonary edema, respiratory distress, neroritizing vasculinis, exacerbation of burs, aplastic areairia, agranulos/osis, hemolytic areain. In neonates and infants: thrombocy/openia and pancrealtis—rarely, in newborns whose mothers have received thiazides during preprancy.

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# LETTERS TO THE EDITOR

# DRUG TREATMENT OF MODERATE HYPERCHOLESTEROLEMIA

To the Editor:

The controversy article on drug treatment of moderate hypercholesterolemia<sup>1,2</sup> presented the evidence supporting the affirmative and opposing views clearly and, for the most part, accurately. Comparing our respective closing statements, however. it appears that Dr. Zweig and I may have attributed different meanings to the word "routinely." Webster's New World Dictionary defines routine as "a regular, unvarying procedure, customary, prescribed, or habitual." This denotation, which Dr. Zweig appears to have had in mind, differs from the connotative meaning that I employed, which was "frequent, as opposed to infrequent" or "more likely than not." If restricted to the literal denotative meaning, I would agree that not all patients with cholesterol values in the range in question should be treated with drugs. Individual decisions about drug treatment are best made by considering the patient's age and sex, the presence or absence of established atherosclerotic disease. and the number and severity of other risk factors for coronary heart disease.

Some recent evidence suggests that many individuals with cholesterol values in the 6.20 to 6.85 mmol/L (240 to 265 mg/dL) range would benefit from treatment. Most of the subjects in the Cholesterol-Lowering Atherosclerosis Study who had had a coronary infarction had total cholesterol values in or below the range in question, and the subjects with the lowest cholesterol values benefited almost as much as those with the highest values.3 Given the incidence of acute myocardial infarction, several hundred thousand Americans each year are prime candidates for postcoronary infarction cholesterol lowering to stabilize or to bring about the regression of obstructive coronary lesions or prevent the occlusion of coronary bypass grafts.

Dr. Zweig's discussion of the unfavorable cost effectiveness of cholesterol-lowering treatment highlights a major obstacle to widespread preventive treatment with medicationsexcessive cost of the medications. The high cost of drug treatment may be better justified in the post-coronary infarction population, where cholesterol control usually is still ignored. The recent emergence of psyllium hydrophilic mucilloid as an inexpensive (\$7 to \$12 a month), safe, effective means for lowering low-density lipoprotein cholesterol4 will, it is hoped, precipitate competitive reductions in the cost of the prescription lipid-lowering medications.

Dr. Zweig's statement that the Helsinki Heart Study<sup>5</sup> does not address the value of drug therapy in men with moderately elevated serum cholesterol is incorrect. The value he cited for the subject's baseline mean serum cholesterol level, 7.50 mmol/L (289 mg/dL), was the nonfasting screening mean value, not the fasting baseline mean for the study, which was 7.00 mmol/L (270 mg/dL). The difference mostly stems from higher very low density lipoprotein cholesterol values for the screening samples that were drawn relatively soon after caloric intake. The Helsinki article does not provide the range and distribution of cholesterol values, but with anything

# **ERRATUM**

In the August 1988 article on sigmoidoscopy by Buckley et al (Buckley RL, Smith MU, Katner HP: Use of rigid and flexible sigmoidoscopy by family physicians in the United States. J Fam Pract 1988;27:197-200), the fourth sentence of the abstract should read, "Nationwide, more of the flexible procedures are performed in private offices than in the hospital. Physicians in communities of less than 500,000, however, are more likely to use the flexible sigmoidoscope in a hospital setting than are physicians in larger urban areas."

close to a normal distribution, almost one half of the subjects' baseline cholesterol values would be in or below the range under discussion.

The evidence is far from conclusive on this matter. Many clinicians may consider the existing evidence to be insufficiently strong to be convincing, but phrases such as "the evidence simply does not exist" and "the lack of evidence from clinical trials regarding this group" are inaccurate overstatements. What Dr. Zweig also describes as "little evidence" is already comparably substantial to the evidence upon which some previous treatments were judged to be justifiable (for example, moderate hypertension). It is puzzling to me that the treatment of hypercholesterolemia continues to be viewed by many with an unusually high degree of intellectual scepticism, approaching therapeutic nihilism, compared with the clinical empiricism with which the evaluation of so many other issues is tempered.

I agree wholeheartedly that it will take a combination of individualized and population-based strategies for reducing the risk of coronary heart disease. I would also support a heavy emphasis on population-based strategies despite (again) a relatively modest amount of evidence supporting the cost effectiveness or efficacy of such approaches. The issues of long-term safety, cost, and cost effectiveness are formidable problems. To clarify and resolve these problems, further research and dramatic reductions in drug costs are needed.

Michael A. Crouch, MD, MSPH Department of Family Medicine and Comprehensive Care Louisiana State University Medical Center at Shreveport

## References

- 1. Crouch MA: Should cholesterol-lowering drugs be used routinely to treat moderate hypercholesterolemia in patients with serum cholesterol levels of 6.20 to 6.85 mmol/L (240 to 265 mg/dL): An affirmative view. J Fam Pract 1988; 26:665-670
- 2. Zweig S: Should cholesterol-lowering drugs be used routinely to treat moderate hypercholesterolemia in patients with

- serum cholesterol levels of 6.20 to 6.85 mmol/L (240 to 265 mg/dL): An opposing view. J Fam Pract 1988; 26:670-675
- 3. Blankenhorn DH, Nessim SA, Johnson RL, et al: Beneficial effects of combined colestipol-niacin therapy on coronary atherosclerosis and coronary venous bypass grafts. JAMA 1987; 257:3233-3240
- 4. Anderson JW, Zettwoch N, Feldman T, et al: Cholesterol-lowering effects of psyllium hydrophilic mucilloid for hypercholesterolemic men. Arch Intern Med 1988; 148: 292-296
- Frick MH, Elo O, Haapa K, et al: Helsinki Heart Study: Primary-prevention trial with gemfibrozil in middle-aged men with dyslipidemia. New Engl J Med 1987; 317: 1237-1245

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

Although each of us had sufficient opportunity to express our views on the drug treatment of moderate hypercholesterolemia, I feel compelled

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# Maximum Strength Compound

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to address some of Dr. Crouch's comments. I suppose he is correct that I defined "routine" as "regular." This interpretation grows out of recommendations to measure total serum cholesterol in all adults 20 years of age and older1 and the implications of such screening. The large body of literature that we both addressed deals particularly with primary prevention of coronary heart disease. This is appropriate because asymptomatic nondiseased individuals make up the vast majority of individuals for whom primary care physicians must make decisions regarding dietary and drug therapy for hypercholesterolemia. I believe that "routine" especially refers to this group of people without coronary heart disease.

Dr. Crouch does refer to the Cholesterol-Lowering Atherosclerosis Study (CLAS) illustrating the benefit of secondary prevention.2 Implications from this study must also be interpreted with care, however, Lesions that progressed and new coronary artery lesions were significantly more common in the placebo group compared with the treatment group (P < .03, one-sided t test) over the 24month period of the study trial; however, the number of cardiac and vascular events was the same for both groups. In addition, in order to have been randomized, subjects must have already been found to be responders to the drug therapy used in the trial (colestipol and niacin), thus excluding noncompliant individuals and nonresponders to drug therapy. This design impairs the generalizability of the findings. The two groups were also consuming different diets; the placebo group diet included more cholesterol and fat.

I too am encouraged by the work of Anderson and co-workers who have demonstrated reductions in low-density lipoprotein cholesterol in men with oat bran and bean diets, as well as more recently with psyllium hydrophilic mucilloid.<sup>3,4</sup> Perhaps in distinction to Dr. Crouch, I believe that intellectual skepticism is appropriate when evaluating any medical intervention, particularly when considering expensive and long-term pharmacotherapy for asymptomatic

healthy individuals such as those most often considered for primary prevention. It is simply not wise medical practice to jump on a drug treatment bandwagon before good evidence is available. That we physicians may have done so before does not make me more willing. I would agree with Dr. Crouch that long-term safety and cost effectiveness are issues that must be resolved.

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# CARDIAC ISCHEMIA DECISION-SUPPORT TOOLS

To the Editor:

Green and Smith<sup>1</sup> are to be congratulated for investigating decisionsupport tools in their setting. Their report, however, follows a pattern of assumption and speculation, common in the decision-support literature, that might have been avoided.

The three dimensions of (1) predictive accuracy, (2) usefulness, and (3) acceptability are described in the literature relating to assessment of predictive instruments.<sup>2</sup> Addressing each of these dimensions allows the researcher to describe more fully the decision-support tool as a part of the environment in which it is intended to be used.

Green and Smith studied only predictive accuracy of the heart disease predictive instrument (HDPI) and the electrocardiographic scoring systems of Brush et al. Unfortunately, insufient numbers of outcome variables (complications) were interpreted as a drawback of the Brush et al protocol rather than (correctly) as a limitation in sample size. The authors' conclusion that the HDPI has several advantages over the Brush et al protocol lacked support in their data.

Usefulness of the HDPI output in helping a physician direct a patient to intermediate care rather than a coronary care unit was assumed by Green and Smith to be calculable by simple substitution of the HDPI output for the physician's decision. Previous studies of the HDPI have acknowledged that such a simple substitution is not an adequate model for decision support, and that usefulness must be empirically determined by prospective randomized controlled study of physician admitting behavior.<sup>2-4</sup>

Acceptability of the HDPI to the physician was correctly assumed to be an important variable. Green and Smith have chosen to speculate on the variables which they called "physician acceptance" and "user friendliness" rather than measure them. Acceptability of the HDPI has been previously found to be poor in a small study.<sup>2</sup> Acceptability may be addressed by both rationalistic and naturalistic methods, contributing essential information to a study without adding significant cost or sample size requirements.

Reports of decision-support tools promising multimillion dollar savings must measure the three essential dimensions or be viewed with skepticism. Investigators should be encouraged to consider predictive accuracy, usefulness, and acceptability in the development, testing, and reporting of decision-support tools.

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#### INDICATIONS AND USAGE

Male pattern baldness (alopecia androgenetica) of the vertex of the scalp. No effect has been seen on frontal baldness. At least four months of treatment are generally required before evidence of hair growth can be expected; further growth continues through one year. The new growth is not permanent; cessation of treatment will lead to its loss in a few months

#### CONTRAINDICATIONS

Hypersensitivity to minoxidil, propylene glycol or ethanol.

#### WARNINGS

1. Need for normal scalp: Before starting treatment, make sure that the patient has a normal, healthy scalp. Local abrasion or dermatitis may increase absorption and hence the risk of side effects. 2. Potential adverse effects: Although extensive use of topical minoxidil has not revealed evidence that enough minoxidil is absorbed to have systemic effects, greater absorption due to misuse, individual variability or unusual sensitivity could, at least theoretically, produce a systemic effect.

Experience with oral minoxidil has shown the following major cardiovascular effects (Review the package insert for LONITEN®

Tablets for details):

- -salt and water retention, generalized and local edema -pericardial effusion, pericarditis, tamponade
- -tachycardia

-increased incidence of angina or new onset of angina

Patients with underlying heart disease, including coronary artery disease and congestive heart failure, would be at particular risk of these potential effects. Additive effects could also emerge in pa-

tients being treated for hypertension.

Potential patients should have a history and physical, should be advised of potential risks and a risk/benefit decision should be made. Heart patients should realize that adverse effects may be especially serious. Alert patients to the possibility of tachycardia and fluid retention, and monitor for increased heart rate, weight gain or other systemic effects.

#### **PRECAUTIONS**

General Precautions: Monitor patients one month after starting ROGAINE and at least every six months afterward. Discontinue ROGAINE if systemic effects occur.

The alcohol base will burn and irritate the eye. If ROGAINE reaches sensitive surfaces (eg, eye, abraded skin and mucous mem branes) bathe with copious cool water.

Avoid inhaling the spray.

Do not use in conjunction with other topical agents such as corticosteroids, retinoids and petrolatum or agents that enhance percutaneous absorption. ROGAINE is for topical use only. Each mL contains 20 mg minoxidil and accidental ingestion could cause adverse systemic effects.

Decreased integrity of the epidermal barrier caused by inflammation or disease of the skin, eg, excoriations, psoriasis or severe sunburn, may increase minoxidil absorption.

Patient Information: A patient information leaflet is included with each package and in the full product information.

Drug Interactions: No drug interactions are known. Theoretically, absorbed minoxidil may potentiate orthostatic hypotension in patients taking guanethidine.

Carcinogenesis, Mulagenesis and Impairment of Fertility: No carcinogenicity was found with topical application. Oral administration may be associated with an increased incidence of malignant lymphomas in female mice and hepatic nodules in male mice. In rats, there was a dose-dependent reduction in conception rate.

Pregnancy Category C: ROGAINE should not be used by pregnant women.

Labor and Delivery: The effects are not known.

Nursing Mothers: ROGAINE should not be administered. Pediatric Use: Safety and effectiveness have not been established

#### under age 18 **ADVERSE REACTIONS**

J-8603

ROGAINE was used by 3510 patients in placebo-controlled trials. Except for dermatologic events, no individual reaction or reactions grouped by body systems appeared to be increased in the minoxidil-

treated patients.

Respiratory (bronchitis, upper respiratory infection, sinusitis)
5,95%; Dermatologie (irritant or allergic contact dermaticis)
6,37%; Dermatologie (irritant or allergic contact dermaticis) 5.27%; Gastrointestinal (diarrhea, nausea, vomiting) 3.42% Neurology (headache, dizziness, faintness, lightheadedness) 2.56%; Musculoskeletal (fractures, back pain, tendinitis) 2.17% 2.56%; Musculoskeletal (fractures, back pain, tendinitis) 2.17%; Cardiovascular (edema, chest pain, blood pressure increases/ decreases, palpitation, pulse rate increases/decreases) 1.28%; Allergy (non-specific allergic reactions, hives, allergic rhinitis, facial swelling and sensitivity) 1.03%; Special Senses (conjunctivitis, ear infections, vertigo) 0.94%; Metabolic-Nutritlonal (edema, weight gain) 0.69%; Urinary Tract (urinary tract infections, renal calculi, urethritis) 0.46%; Genital Tract (prostatitis, but of the control of the con epididymitis) 0.46%, **Psychiatric** (anxiety, depression, fatigue) 0.28%; **Hematology** (lymphadenopathy, thrombocytopenia) 0.23%; **Endocrine** 0.09%.

Patients have been followed for up to 5 years and there has been no change in incidence or severity of reported reactions. Additional events reported since marketing include: eczema, hypertrichosis, local erythema, pruritus, dry skin/scalp flaking, sexual dysfunction visual disturbances including decreased visual acuity, exacerbation of hair loss, alopecia

Caution: Federal law prohibits dispensing without a prescription

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LETTERS TO THE EDITOR

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2. Corey GA, Merenstein JH: Applying the acute ischemic heart disease predictive instrument. J Fam Pract 1987; 25:127-133

3. Pozen MW, D'Augustino RB, Mitchell JB, et al: The usefulness of a predictive instrument to reduce inappropriate admissions to the coronary care unit. Ann Intern Med 1980; 92(part 1):238-242

4. Pozen MW, D'Augustino RB, Selker HP, et al. A predictive instrument to improve coronary-care-unit admission practices in acute ischemic heart disease: A prospective multicenter clinical trial. N Engl J Med 1984; 310:1273-1278

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

Dr. Corey raises a concern about whether the conclusion we reached regarding the Brush et al instrument<sup>1</sup> was simply a reflection of lack of sample size. Recall that their instrument categorized 57 percent of our patients as high risk, while less than 4 percent sustained major complications. A large enough study might indeed demonstrate a statistically significant association between the instrument's classification and patient outcomes. Statistical significance is not clinical significance, however. An instrument that classifies most patients as high risk in a population that clearly has a low risk of complications is simply not useful in that popula-

The usefulness of the HDPI<sup>2</sup> and its acceptability in actual practice certainly cannot be deduced from our study, as Dr. Corey points out. Our retrospective review can only demonstrate that the HDPI would be applicable in this population if physicians actually used it as intended. A prospective study is necessary to determine whether, why (or not), and how physicians actually use the HDPI. Such a prospective study has been underway since July 1, 1988 at our institution. The details of the implementation of the HDPI in the prospective study were designed with Corey and Merenstein's results in mind, and it is our hope that this will shed some light upon ways to improve the acceptability of the HDPI in clinical practice.

> Lee Green, MD Department of Family Practice The University of Michigan Ann Arbor, Michigan

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- 2. Pozen MW, D'Agostino RB, Selker HP, et al: A predictive instrument to improve coronary-care-unit admission practices in acute ischemic heart disease: A prospective multicenter clinical trial. N Engl J Med 1984; 310:1273-1278
- 3. Corey GA, Merenstein JH. Applying the acute ischemic heart disease predictive instrument. J Fam Pract 1987; 25:127-133.

# PAPANICOLAOU SMEAR **TECHNIQUES**

To the Editor:

Two recent research articles by Reissman<sup>1</sup> and Deckert, Staten, and Palermo<sup>2</sup> add to the accumulating data on the increased capture rate of endocervical elements with use of the Zelsmyr Cytobrush cell collector. The outcome of either study, however, may have been a result of the research design or method, not the Papanicolaou smear collection technique. I will address three specific points related to research design and method for Papanicolaou smear studies: (1) populations and controls, (2) protocols, and (3) cytology review.

First, several factors unrelated to choice of instrument used to collect the Papanicolaou smear sample can influence the rate of capture of endocervical cells. The factors that must be controlled among treatment and control populations in studies of cell collection techniques are age,3 pregnancy status, parity, and gravidity status,4 contraceptive method used, day of menstrual cycle,5 and history of cervical destructive surgery. Dr. Reissman did consider pregnancy and age by breaking the populations into age groups and excluding pregnant women. His study did not consider the other factors. The gynecology clinic population in Reissman's study could easily have been of lower parity, higher rates of oral contraceptive use, and higher rates of previous cervical surgery than the family practice clinic population; such differences could account for the lower rate of capture

of endocervical elements. In addition, the population in the family practice clinic may have differed on any of these factors between the phases of the study, thus effecting the outcome unrelated to the intervention. Deckert, Staten, and Palermo excluded pregnant women from the study and demonstrated no difference in mean age of the three study populations Again, the population receiving Papanicolaou smears may have had lower rates of capture of endocervical elements with the extended-tip spatula or cotton swab than with the Cvtobrush cell collector because the groups differed on any one or more of these factors. Thus in either study. the noted increased rate of capture of endocervical elements with the Cytobrush cell collector may have resulted from differing characteristics of women studied and not from the intervention.

Second, the protocol used to collect the Papanicolaou smear can affect the cytologic findings significantly.<sup>6</sup> Studies comparing the effectiveness of tools for collecting endocervical elements must adhere rigidly to an ideal collection protocol. This ideal protocol<sup>7</sup> should include the following:

- 1. All smears collected from nonmenstruating women with no douching or vigorous sexual intercourse 24 hours prior to examination
- 2. No lubrication of the speculum except water or saline
- 3. Visualize the cervix and remove only excessive vaginal discharge. Do not clean the cervix
- 4. No procedures performed on the cervix prior to collecting Papanicolaou smear
- 5. Sample endocervix and fix on slide immediately
- 6. Sample ectocervix and fix on slide immediately

In addition, some method of monitoring adherence to this protocol must be used, such as observation by a trained nurse. The Reissman protocol for the family practice clinic population dealt only with applying the tools to the cervix, transferring the material to the slide, and training of

the physicians. His comparison population received Papanicolaou smears by an unknown protocol, which easily could have resulted in the lower capture rate of endocervical elements regardless of tool used. Deckert, Staten, and Palermo do not indicate whether the Papanicolaou smears were collected using standard protocol or whether physicians received any training. Neither study had a method to monitor adherence to a standard collection protocol.

Third, the persons performing the interpretation of the cytologic findings should be blinded to the presence of a study and the tool used to collect the specimen. Cytologists or cytotechnologists who are aware that the study is in process may change their screening patterns. The change may affect the results in a number of ways as the technicians attempt to be more diligent. The need to blind the cytologists to the tool used for collection is obvious. In addition, one should use a cytology service that has an established practice of reporting the presence or absence of endocervical elements. The study must not require changes from usual methods of reviewing the slides. If the study mandates such changes, then the effect of these changes must be evaluated separately from any intervention on collection techniques. Reissman did not provide information on any of these aspects except that two cytotechnologists performed all of the reviews. Deckert, Staten, and Palermo indicate the cytotechnologists reviewed the slides in the usual manner and were trained to estimate the number of endocervical elements present. Thus, it appears the cytotechnologists were aware of the study and may have changed the routine in reviewing the slides. No information was provided on blinding of the cytotechnologists to tools used. In addition, the amount of endocervical elements present has no clinical significance.

In summary, studies of cervical cell collection methods must adhere to several rigid design requirements. Establishing that the populations studied have essentially the same distribution of factors that can affect the

cytologic findings is of primary importance. Adherence to the ideal protocol for collection of the material is the next requirement, with a method to monitor adherence to the protocol Finally, the slides must be reviewed by cytologists or cytotechnologists blinded to study and tools. The difference in capture of endocervical elements shown in Reissman's study may reflect different population characteristics, different tools, and different protocols used to collect and transfer the cytologic material. Deckert, Staten, and Palermo demonstrated that the difference in capture of endocervical elements may reflect different population characteristics. protocol differences, or changed reviewing procedures of the slides by cytotechnologists.

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