Certification of Added Qualification in Geriatrics: The Academic Perspective

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On April 20, 1988, a new examination was administered to test for competency in geriatrics. Successful examinees will be given a "certificate of added qualifications," a name that specifically implies an added skill rather than a subspecialty status. To be eligible for the examination, candidates must be certified by the American Board of Internal Medicine or the American Board of Family Practice. The examination is the same for both specialties.

This new certification raises certain questions. Is it mainly intended as an academic title, for example, or will it be advantageous for practicing physicians to hold this certification? Will those certified be more employable in some spheres? Will physician selection by patients be influenced? Will certain faculty members be encouraged by their chairman to sit for this examination, and if so, which faculty members?

To obtain the viewpoints of academic leaders about such questions, the opinions of department chairmen of training programs were gathered by questionnaire and are reported here.

METHODS

A questionnaire was developed to obtain information relative to the certification examination in geriatrics. The questionnaire was pre-tested by 20 family medicine and internal medicine faculty at the University of Utah School of Medicine. After using their suggestions, a revised questionnaire was sent to all US family medicine (n = 378) and internal medicine (n = 441) program chairmen in October 1987. The survey was anonymous but coded so that nonrespondents could be sent another survey. A second mailing was conducted in December 1987. The 12 items on the questionnaire were either of the yes–no or Likert scale-type, and comments were encouraged.

RESULTS

Surveys were received from 335 (89 percent) family medicine programs and 296 (67 percent) internal medicine programs. Almost all responding family medicine chairmen reported receiving information about the certificate of added qualifications (94 percent); proportionally fewer internal medicine chairmen reported receiving such information (79 percent). Of those family medicine and internal medicine chairmen who alleged receiving such information, fewer than one half felt it was adequate to help them make plans for their educational programs (family medicine: 31 percent adequate, 10 percent very adequate; internal medicine: 19 percent adequate, 8 percent very adequate).

Based on their present understanding, just over one half of the family medicine chairmen thought that adding this certificate was a positive contribution to medicine (39 percent positive, 15 percent very positive). One fourth thought it was a negative contribution (16 percent negative, 9 percent very negative), and one fifth thought it was neutral (21 percent). About the same proportion of the internal medicine chairmen thought the certificate was a positive contribution (36 percent positive, 12 percent very positive). One fifth thought it was negative (12 percent negative, 7 percent very negative), and one third, neutral (33 percent).

By and large, family medicine and internal medicine chairmen view the credential as much more important to faculty than to private practitioners; however, family medicine chairmen are more likely to encourage their own faculty to take the examination (82 percent) than internal medicine chairmen (55 percent). Of those family medicine chairmen who plan to encourage faculty to take the examination, 32 percent plan to select one faculty member with special interest in geriatrics, and 36 percent plan to select two or more faculty with special interest. Others

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(15 percent) plan to encourage all faculty, and 18 percent plan to take a "wait and see who chooses it" strategy. Of the internal medicine chairmen who plan to encourage faculty, 23 percent plan to select one person, 55 percent two or more, 9 percent everyone, and 13 percent plan to use the "wait and see" strategy.

In general, one half of the chairmen would be inclined to hire someone with the certificate over someone without it, assuming other qualifications are equal (family medicine: 41 percent yes, 9 percent strongly yes; internal medicine: 34 percent yes, 11 percent strongly yes). Neither group, however, thought that generalists would prefer to refer a patient to a holder of the certificate over a subspecialist who deals with the patient's problem (family medicine: 17 percent yes, 2 percent strongly yes; internal medicine: 22 percent yes, 1 percent strongly yes). Moreover, neither group strongly felt that certification would have an impact upon physician selection by patients (family medicine: 17 percent yes, 2 percent strongly yes; internal medicine: 22 percent yes, 2 percent strongly yes). Finally, neither group thought that the certificate of added qualifications would become of equal importance to other subspecialty boards (family medicine: 11 percent yes, 52 percent no, 37 percent don't know; internal medicine: 11 percent yes, 53 percent no, 36 percent don't know).

DISCUSSION

A divergence of opinion about the certification was found. There was even divergence about whether adequate information was received about the examination, with just under one half of respondents feeling the information was adequate.

While the majority of respondents did not feel that the certification is highly important, about one half reported that for a teaching position they would hire a person holding the certificate over a person not holding the certificate if other qualifications were equal.

There is not an overwhelming feeling that this certification is a positive step. It would be interesting (though not possible from this study) to know whether chairmen with strong programs in geriatrics tend to feel that the step is positive. None of the comments on the questionnaire was enlightening about why the respondent did not feel this step to be positive.

Whatever else may be an outcome of this examination, it is fairly certain that the content of geriatrics as an academic discipline will become better defined. The content of the examination, whatever that may be, will be likely to have a strong influence on curriculum planning and content topics, probably bringing greater uniformity among programs in what is felt to be geriatrics. Program planners will have a focus for the teaching of geriatrics—that focus will be to prepare learners for the examination. It is likely that the rate of success of trainees on the examination will implicitly become a measure of the success of any given training program, an outcome that will justify the existence of the certificate.

If greater uniformity among programs and ease of planning a curriculum are outcomes of this certification examination, those benefits probably will justify the effort.

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Family Medicine: The Maturing of a Discipline. *William J. Doherty, Charles E. Christianson, Marvin B. Sussman, (eds.). The Haywood Press, New York, 1987, 236 pp., $34.95.*

The stated purpose of this book is to judge the progress the field of family medicine has made in the past two decades. To accomplish this task the editors have assembled a large group of authors to "assess the major issues in family medicine." Issues addressed include education, research, the consumer's perspective, alternative health care movements, and several chapters evaluating the field of family medicine overall. Unfortunately, important clinical and economic issues receive little attention.

As could be expected, given the long list of authors, chapters in this book vary tremendously in quality. Unfortunately, many of the authors simply state their ideas and desires on how family medicine should develop without the benefit of a thorough analysis of the data that are available. Others base their analysis on superficial genetic or familial analogies that are also not based on a thorough data analysis. Although many of the authors are able to identify the critical tensions within the area they analyzed, there is little coherent synthesis of those tensions into a firm statement on where family medicine is currently and where we ought to be heading in the future. In addition, at the end of the book, after all the various issues have been addressed, no attempt is made to tie together all the various themes into overall conclusions on the development of family medicine. Finally, many portions of the book are redundant, and illustrations are few and of poor quality.

Several chapters deserve special mention. Dougherty, Baird, and Becker's chapter on the biopsychosocial model's integration into the practice of family medicine is a true gem. Culpepper and Becker's analysis of family medicine research is similarly well-grounded in data and offers the reader a meaningful analysis of the status of family medicine research. Lastly, Cogswell, Aluise, Shahady, and Thomas's chapter on family medicine from the consumer's perspective reminds family physicians that they are not so closely in touch with consumer's needs as they might assume, supporting that conclusion with data and a meaningful analysis.

In summary, this book does not subject the field of family medicine to the kind of penetrating analysis that Paul Starr performed on the entire field of medicine in his book entitled *The Social Transformation of American Medicine.* Rather than being a competent reflection upon the field of family medicine based on the data and experience we have accumulated over the past 20 years, this book often only offers the reader a series of truisms and weak analogies. Thus, although this book may prove useful to academic family physicians who may find the chapters on research and education useful, the book will probably not be useful to family physicians in general or members of the public who wish to gain an understanding of family medicine.

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Primary Care of Cancer. *Edward A. Mortimer, Jr. (ed), Joseph Robinson, Stephen H. Smookler (assoc eds). Case Western Reserve University School of Medicine, Cleveland, 1987, 195 pp., $15 (paper).*

This short, very readable text is intended for a wide audience, from the medical student and primary care resident to the practicing primary care health provider. It is divided into 29 chapters, each of which describes a specific type of neoplasm, beginning with the urinary bladder and ending with Wilm's tumor.

Each chapter is subdivided into approximately ten segments, which include a general description, epidemiology and risk factors, etiology, prevention, screening, symptoms and signs, diagnostic tests, treatment, prognosis and post-treatment follow-up. Each chapter describes the appropriate staging nomenclature. The chapters are only a few pages in length and the printing is large. Exceptional effort is made to provide a concise overview of each topic without getting bogged down in specifics. The final chapter covers home care of the terminally ill patient. There are five general references in the appendix.

The book appears to meet the editor's objectives quite adequately, not as an exhaustive text, but as a brief overview of the 30 most commonly reported malignancies, with special emphasis on screening, prevention, diagnosis, and team management. It should prove to be a handy supplement to any medical library.

Robert L. Bass, MD
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Nutritional Influences on Illness: A Sourcebook of Clinical Research. *Melvyn R. Werbach. Third Line Press, Tarzana, California, 1987, 498 pp., $49.95. ISBN 0-9618550-0-2.*

When used as intended by the author, this hardbound reference will be of great value to the family physician who is interested in using appropriate and safe nutritional therapy. Clinicians frequently refrain from prescribing nutritional therapy because of the confusion that results from contradictory studies and philosophical differences among leaders in the field of clinical nutrition. In this volume Dr. Werbach presents a practical, disease-oriented, balanced guide to research on 92 common diseases. Each chapter presents a series of statements concerning a specific disease and nutrients relevant to that disease, with each statement followed by selected abstracts from the literature either substantiating or refuting it. This presentation allows the clinician to make decisions about nutrition therapy based on the strength of the scientific evidence.

The volume also contains fairly good sections in an appendix including "Common Nutritional Deficiencies," "Dangers of Nutritional Supplementation," "Guidelines to Nutritional Supplementation," "Laboratory Methods for Nutritional Evaluation," "Nutrient Bioavailability and Interactions," and "Syn-

dromes due to Abnormal Tissue Nutrient Levels."

What makes this book particularly valuable is its organization by specific disease and its succinct review of the literature. The author makes several suggestions for the appropriate use of this book in deciding the value of nutritional interventions compared with other therapeutic options. Practicing family physicians and family practice residents could use this book in making such therapeutic decisions, while medical students and allied health professionals would find this to be a valuable educational resource. As with most nutrition resources, it will be important for the author to update this sourcebook frequently if it is to remain relevant and useful.

Ronald Arlo Kahn, MD
Little Rock, Arkansas

The Care of Patients: Perspectives and Practices. *Mack Lipkin. Yale University Press, New Haven, 1987, 235 pp., $10.95 (paper). ISBN 0-300-03771-6.*

When the original edition of this book was published in 1974, I would have applauded its stirring and idealistic wisdom about humane and compassionate personal medical care. The medical world was reveling in a biotechnological orgy that discounted the importance of psychosocial forces in the etiology, diagnosis, and treatment of suffering and illness. The development of family practice was in its early stages, its future unclear. This book, with its emphasis on "the importance of humanistic qualities in the relationship between physician and patient," would have served as a guide for medical students and residents pursuing a counterprevailing professional value system.

Now, 15 years later, the book is no less wise, but the environment has changed. Biomedical reductionism continues, but compassionate, personal medical care exists, albeit in less-than-adequate quantities. Family practice is a thriving and established specialty that has as its raison d'etre the practice of comprehensive and compassionate personal medical care. Thousands of family practice residency graduates practice Dr. Lipkin's advice on a daily basis. Compelling importance of caring and compassionate concern has not influenced all of medicine, but strong role models and training programs exemplifying this ideal are readily available to those students and residents who seek it. Dr. Lipkin's message, once unconventional and controversial, is now widely accepted, if not always demonstrated, by mainstream medical practice.

This book can be recommended to medical students as a wise and scholarly discussion of the subtleties, richness, and power of the physician-patient relationship, but a month spent with a wise and scholarly family physician would be a more powerful educational experience.

Thomas Schwenk, MD
University of Michigan Medical School
Ann Arbor

Dear Doctor, A Personal Letter To A Physician. *Charles E. Odegaard, The Henry J. Kaiser Family Foundation, Menlo Park, California, 1986, 172 pp., $3 (paper).*

Dear Dr. Odegaard,

Since your book was written as a personal letter, I would like to respond in the same spirit. My formative years in medicine were spent at your great university. At the time you were president, I was too junior to think of communicating with anyone in authority, let alone the president, on any issue of substance. Now that I have been asked to review your book for the main journal in my discipline, I would like to summon the courage to answer your letter.

I believe that your book (with the exception of Appendix 1) should be read by family practice faculty members and by practicing family physicians. Selected parts of it would be useful for students and residents. Strangely, first-year students appear to be the most open and would be most receptive to your book. Especially recommended are your 1952 address to the American Council of Learned Societies and your chapter entitled "Rise of Heresy." You might be interested to know that for many years at the University of Washington while teaching the Introduction to Clinical Medicine course to freshmen medical students (during your tenure), we had a session given by one of the professors of Comparative Literature. This was always my personal favorite, though the students were generally split (between Flexnerians and post-Flexnerians?).

Of great interest was your critique of the GPEP report. You pointed out it was regrettable that GPEP did not more explicitly and vigorously invite debate on the personal qualities, values, and attitudes appropriate to physicians. This startled me and made me go back and review GPEP. I was also envious of the attention given to the Board of Internal Medicine's *Guide to Awareness and Evaluation of Humanistic Qualities in the Internist.* I particularly enjoyed the recounting of your personal conversations with Flexner.

You called for acceptance by physicians of the need to broaden the base to include at least from the humanities and social sciences knowledge about "(1) man's social and personal life relevant to disease and illness in the presenting patient, (2) an expanded rational analysis of the doctor-patient relationship, and (3) ethical issues in medicine." This speaks very clearly to family medicine and provides one of the best statements of the intellectual underpinning of our discipline that I have seen.

I will admit that the article in the appendix by Schwartz and Wiggins confused me. However, the historical perspective, your explanation of Flexnerian and post-Flexnerian thought, and the philosophy of interweaving the humanities and social sciences with biologic medicine rang true. Our own department is in the process of creating a Division of Humanities and Education.

Thank you for taking the trouble to write this book. I believe members of our discipline will learn from it.

With best regards,

Sincerely,

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Eastern Virginia Medical School
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Lower respiratory tract infections of mild to moderate severity caused by *Streptococcus pyogenes* (group A beta hemolytic streptococci); *Streptococcus pneumoniae (Diplococcus pneumoniae).*

Respiratory tract infections due to *Mycoplasma pneumoniae* (Eaton's agent).

Pertussis (whooping cough) caused by *Bordetella pertussis*. Erythromycin is effective in eliminating the organism from the nasopharynx of infected individuals, rendering them noninfectious. Some clinical studies suggest that erythromycin may be helpful in the prophylaxis of pertussis in exposed susceptible individuals.

Diphtheria—As an adjunct to antitoxin in infections due to *Corynebacterium diphtheriae*, to prevent establishment of carriers and to eradicate the organism in carriers.

Erythrasma—In the treatment of infections due to *Corynebacterium minutissimum*.

Intestinal amebiasis caused by *Entamoeba histolytica* (oral erythromycins only). Extraenteric amebiasis requires treatment with other agents. Infections due to *Listeria monocytogenes*.

Skin and soft tissue infections of mild to moderate severity caused by *Streptococcus pyogenes* and *Staphylococcus aureus* (resistant staphylococci may emerge during treatment).

Primary syphilis caused by *Treponema pallidum*. Erythromycin (oral forms only) is an alternate choice of treatment for primary syphilis in patients allergic to the penicillins. In treatment of primary syphilis, spinal fluid should be examined before treatment and as part of the follow-up after therapy. The use of erythromycin for the treatment of *in utero* syphilis is not recommended. (See CLINICAL PHARMACOLOGY in full prescribing information).

Erythromycins are indicated for treatment of the following infections caused by *Chlamydia trachomatis:* conjunctivitis of the newborn, pneumonia of infancy, urogenital infections during pregnancy. When tetracyclines are contraindicated or not tolerated, erythromycin is indicated for the treatment of uncomplicated urethral, endocervical, or rectal infections in adults due to *Chlamydia trachomatis*.

Legionnaires' disease caused by *Legionella pneumophila*. Although no controlled clinical efficacy studies have been conducted, *in vitro* and limited preliminary clinical data suggest that erythromycin may be effective in treating Legionnaires' disease.

Therapy with erythromycin should be monitored by bacteriological studies and by clinical response (See CLINICAL PHARMACOLOGY—Microbiology, in full prescribing information).

Injectable benzathine penicillin G is considered by the American Heart Association to be the drug of choice in the treatment and prevention of streptococcal pharyngitis and in long-term prophylaxis of rheumatic fever. When oral medication is preferred for treatment of the above conditions, penicillin G, V, or erythromycin are alternate drugs of choice.

Although no controlled clinical efficacy trials have been conducted, erythromycin has been suggested by the American Heart Association and the American Dental Association for use in a regimen for prophylaxis against bacterial endocarditis in patients allergic to penicillin who have congenital and/or rheumatic or other acquired valvular heart disease when they undergo dental procedures and surgical procedures of the upper respiratory tract. (Erythromycin is not suitable prior to genitourinary surgery where the organisms likely to lead to bacteremia are gram-negative bacilli or the enterococcal group of streptococci).

NOTE: When selecting antibiotics for the prevention of bacterial endocarditis the physician or dentist should read the full joint 1984 statement of the American Heart Association and the American Dental Association.

CONTRAINDICATION: ERYC is contraindicated in patients with known hypersensitivity to this antibiotic.

WARNING: There have been a few reports of hepatic dysfunction, with or without jaundice, occurring in patients receiving erythromycin ethylsuccinate, base, and stearate products.

PRECAUTIONS: Caution should be exercised when erythromycin is administered to patients with impaired hepatic function (see CLINICAL PHARMACOLOGY, in full prescribing information, and WARNING).

Erythromycin use in patients who are receiving high doses of theophylline may be associated with an increase in serum theophylline levels and potential theophylline toxicity. In case of theophylline toxicity and/or elevated serum theophylline levels, the dose of theophylline should be reduced while the patient is receiving concomitant erythromycin therapy.

Erythromycin interferes with the fluorometric determination of urinary catecholamines.

Prolonged or repeated use of erythromycin may result in an overgrowth of nonsusceptible bacteria or fungi. If superinfection occurs, erythromycin should be discontinued and appropriate therapy instituted.

When indicated, incision and drainage or other surgical procedures should be performed in conjunction with antibiotic therapy.

Pregnancy Category B—Reproduction studies have been performed in rats, mice and rabbits using erythromycin and its various salts and esters, at doses which were several times multiples of the usual human dose. No evidence of impaired fertility or harm to the fetus that appeared related to erythromycin was reported in these studies. 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 needed.

Labor and Delivery—The effect of ERYC on labor and delivery is unknown.

Nursing Mothers—Erythromycin is excreted in milk (see CLINICAL PHARMACOLOGY, in full prescribing information).

Pediatric Use—See INDICATIONS AND USAGE and DOSAGE AND ADMINISTRATION.

ADVERSE REACTIONS: The most frequent side effects of oral erythromycin preparations are gastrointestinal and are dose-related. They include nausea, vomiting, abdominal pain, diarrhea and anorexia. Symptoms of hepatic dysfunction and/or abnormal liver function test results may occur (see WARNING).

Mild allergic reactions such as rashes with or without pruritus, urticaria, bullous fixed eruptions, and eczema have been reported with erythromycin. Serious allergic reactions, including anaphylaxis have been reported.

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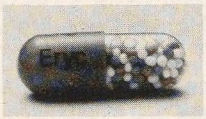

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Pregnancy Category B—Reproduction studies have been performed in rats, mice and rabbits using erythromycin and its various salts and esters, at doses which were several times multiples of the usual human dose. No evidence of impaired fertility or harm to the fetus that appeared related to erythromycin was reported in these studies. 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 needed.

Labor and Delivery—The effect of ERYC on labor and delivery is unknown.

Nursing Mothers—Erythromycin is excreted in milk (see CLINICAL PHARMACOLOGY, in full prescribing information).

Pediatric Use—See INDICATIONS AND USAGE and DOSAGE AND ADMINISTRATION.

ADVERSE REACTIONS: The most frequent side effects of oral erythromycin preparations are gastrointestinal and are dose-related. They include nausea, vomiting, abdominal pain, diarrhea and anorexia. Symptoms of hepatic dysfunction and/or abnormal liver function test results may occur (see WARNING).

Mild allergic reactions such as rashes with or without pruritus, urticaria, bullous fixed eruptions, and eczema have been reported with erythromycin. Serious allergic reactions, including anaphylaxis have been reported.

There have been isolated reports of reversible hearing loss occurring chiefly in patients with renal insufficiency and in patients receiving high doses of erythromycin.

Caution: Federal law prohibits dispensing without prescription.

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What starts off as a small lesion on the mouth of an immunocompromised patient can develop into a serious and even life-threatening herpes simplex virus infection.[1] In the compromised host, oral infection may extend opportunistically to involve the esophagus or lungs or may disseminate to the liver, brain, and other organs.[2] Before a limited nonlife-threatening HSV infection has a chance to spread, prompt recognition and treatment with ZOVIRAX Ointment 5% can stop viral replication, accelerate healing, and reduce the accompanying pain.[3]

References: 1. Whitley R, Barton N, Collins E, et al: Mucocutaneous herpes simplex virus infections in immunocompromised patients: A model for evaluation of topical antiviral agents. Proceedings of a symposium on acyclovir sponsored by Burroughs Wellcome Co. and the National Institute of Allergy and Infectious Diseases. *Am J Med* 1982;73(1A):236-240. **2.** Nahmias AJ, Roizman B: Infection with herpes-simplex viruses 1 and 2 (third of three parts). *N Engl J Med* 1973;289:781-789. **3.** Whitley RJ, Levin M, Barton N, et al: Infections caused by herpes simplex virus in the immunocompromised host: Natural history and topical acyclovir therapy. *J Infect Dis* 1984;150:323-329.

*The sun can bring out cold sores.**

For most, it's an annoying problem.

In the immunocompromised, it can become a deadly serious one.

ZOVIRAX®
(acyclovir)
OINTMENT 5%

Now available in convenient 3-gram size

Stops viral activity, speeds healing

*Due to herpes simplex virus.

INDICATIONS AND USAGE: Zovirax (Acyclovir) Ointment 5% is indicated in the management of initial herpes genitalis and in limited nonlife-threatening cutaneous Herpes simplex virus infections in immunocompromised patients. In clinical trials of initial herpes genitalis, Zovirax Ointment 5% has shown a decrease in healing time and in some cases a decrease in duration of viral shedding and duration of pain. In studies in immunocompromised patients with mainly herpes labialis, there was a decrease in duration of viral shedding and a slight decrease in duration of pain.

By contrast, in studies of recurrent herpes genitalis and of herpes labialis in nonimmunocompromised patients, there was no evidence of clinical benefit; there was some decrease in duration of viral shedding.

Diagnosis: Whereas cutaneous lesions associated with Herpes simplex infections are often characteristic, the finding of multinucleated giant cells in smears prepared from lesions exudate or scrapings may assist in the diagnosis.[1] Positive cultures for Herpes simplex virus offer a reliable means for confirmation of the diagnosis. In genital herpes, appropriate examinations should be performed to rule out other sexually transmitted diseases.

CONTRAINDICATIONS: Zovirax Ointment 5% is contraindicated for patients who develop hypersensitivity or chemical intolerance to the components of the formulation.

WARNINGS: Zovirax Ointment 5% is intended for cutaneous use only and should not be used in the eye.

PRECAUTIONS:

General: The recommended dosage, frequency of applications, and length of treatment should not be exceeded (see DOSAGE AND ADMINISTRATION). There exist no data which demonstrate that the use of Zovirax Ointment 5% will either prevent transmission of infection to other persons or prevent recurrent infections when applied in the absence of signs and symptoms. Zovirax Ointment 5% should not be used for the prevention of recurrent HSV infections. Although clinically significant viral resistance associated with the use of Zovirax Ointment 5% has not been observed, this possibility exists.

Drug Interactions: Clinical experience has identified no interactions resulting from topical or systemic administration of other drugs concomitantly with Zovirax Ointment 5%.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Acyclovir was tested in lifetime bioassays in rats and mice at single daily doses of 50, 150 and 450 mg/kg/day given by gavage. These studies showed no statistically significant difference in the incidence of benign and malignant tumors produced in drug-treated as compared to control animals, nor did acyclovir induce the occurrence of tumors earlier in drug-treated animals as compared to controls. In 2 *in vitro* cell transformation assays, used to provide preliminary assessment of potential oncogenicity in advance of these more definitive lifetime bioassays in rodents, conflicting results were obtained. Acyclovir was positive at the highest dose used in one system and the resulting morphologically transformed cells formed tumors when inoculated into immunosuppressed, syngeneic, weanling mice. Acyclovir was negative in another transformation system.

No chromosome damage was observed at maximum tolerated parenteral doses of 100 mg/kg acyclovir in rats or Chinese hamsters; higher doses of 500 and 1000 mg/kg were clastogenic in Chinese hamsters. In addition, no activity was found in a dominant lethal study in mice. In 9 of 11 microbial and mammalian cell assays, no evidence of mutagenicity was observed. In 2 mammalian cell assays (human lymphocytes and L5178Y mouse lymphoma cells *in vitro*), positive response for mutagenicity and chromosomal damage occurred, but only at concentrations at least 1000 times the plasma levels achieved in man following topical application.

Acyclovir does not impair fertility or reproduction in mice at oral doses up to 450 mg/kg/day or in rats at subcutaneous doses up to 25 mg/kg/day. In rabbits given a high dose of acyclovir (50 mg/kg/day, s.c.), there was a statistically significant decrease in implantation efficiency.

Pregnancy: *Teratogenic Effects. Pregnancy Category C.* Acyclovir has been known to cause a statistically significant decrease in implantation efficiency in rabbits, when given at subcutaneous doses providing mean plasma levels of drug 2.2 times those expected from use in patients with normal renal function.

Reproduction studies were negative for impairment of fertility or harm to the fetus in mice given oral doses, and in rats given subcutaneous doses providing mean plasma levels of drug 84 times and 4 times (respectively) greater than those expected from use in patients with normal renal function.

Acyclovir was not teratogenic after subcutaneous administration of up to 50 mg/kg/day during the period of organogenesis in rats and rabbits; doses up to 450 mg/kg given daily by gavage to mice were not teratogenic. There are, however, no adequate and well-controlled studies in pregnant women. Acyclovir should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Zovirax is administered to a nursing woman.

ADVERSE REACTIONS: Because ulcerated genital lesions are characteristically tender and sensitive to any contact or manipulation, patients may experience discomfort upon application of ointment. In the controlled clinical trials, mild pain (including transient burning and stinging) was reported by 103 (28.3%) of 364 patients treated with acyclovir and by 115 (31.1%) of 370 patients treated with placebo; treatment was discontinued in 2 of these patients. Other local reactions among acyclovir-treated patients included pruritus in 15 (4.1%), rash in 1 (0.3%) and vulvitis in 1 (0.3%). Among the placebo-treated patients, pruritus was reported by 17 (4.6%) and rash by 1 (0.3%).

In all studies, there was no significant difference between the drug and placebo group in the rate or type of reported adverse reactions nor were there any differences in abnormal clinical laboratory findings.

DOSAGE AND ADMINISTRATION: Apply sufficient quantity to adequately cover all lesions every 3 hours 6 times per day for 7 days. The dose size per application will vary depending upon the total lesion area but should approximate a one-half inch ribbon of ointment per 4 square inches of surface area. A finger cot or rubber glove should be used when applying Zovirax to prevent autoinoculation of other body sites and transmission of infection to other persons. **Therapy should be initiated as early as possible following onset of signs and symptoms.**

HOW SUPPLIED: Zovirax Ointment 5% is supplied in 15 g tubes (NDC 0081-0993-94) and 3 g tubes (NDC 0081-0993-41). Each gram contains 50 mg acyclovir in a polyethylene glycol base. Store at 15°-25°C (59°-77°F) in a dry place.

REFERENCE: 1. Naib ZM et al. Cancer Res *33*:1452-1463, 1973.
U.S. Patent No. 4199574

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IMPROVING LIVES THROUGH ANTIVIRAL RESEARCH

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highlight the dilemma faced by family medicine educators. A considerable amount of training occurs, not in the community settings where most practitioners will ultimately practice, but in the rather unique obstetrical units of perinatal referral centers. It is not surprising that residents who emerge from these referral institutions are well steeped in the theory and practice of "maximum" obstetrics[1] but have little confidence in their ability to manage patients in less technologically endowed settings.

Obstetricians confront problems that are qualitatively similar to those faced by family physicians. By spending 50 percent of their time in obstetrics, however, they are able to master and retain a wider spectrum of technical skills than their family physician colleagues and also amortize their malpractice premiums over a much broader base.[2] The development of a rational science of low-risk obstetrics—with attention to the biopsychosocial elements that are probably as important to optimal outcomes as many of the technical interventions that we take for granted—is likely only to flourish in settings where the preponderance of patients have low rates of complications.[3] All obstetrical practitioners—family physicians, obstetricians, and midwives—will benefit from the knowledge generated by research in these real-life laboratories.

The comments of Meenan are echoed by reports from around the world that exemplify the superb results that have been achieved by midwives and general practitioners working in low-intensity settings.[4] The example of Weyrauch and Berman from Group Health of Spokane demonstrates that it is possible to design a system that meshes the particular skills and perspectives of different kinds of obstetric practitioners into a very effective system of care. Models such as these demonstrate the benefits to patients and providers of building collaborative models of obstetrical practice. Such collaborative models acknowledge that each discipline can play a unique and complementary role in assuring that all women have access to the full range of appropriate perinatal care. Our current task is to define that role for family physicians.

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MATERNAL SERUM α-FETOPROTEIN SCREENING

To the Editor:

Dr. Campbell[1] has written a comprehensive review of the current information available regarding serum α-fetoprotein screening for all prenatal patients. We disagree, however, with the conclusions reached.

Frame and Carlson[2] have proposed the following criteria for good screening tests that are now routinely used:

1. The disease must have a significant effect on the quality and quantity of life.
2. Acceptable methods of treatment must be available.
3. The disease must have an asymptomatic period during which detection and treatment can significantly reduce morbidity or mortality.
4. Treatment in the asymptomatic phase must yield a therapeutic result superior to that obtained by delaying treatment until symptoms appear.
5. Tests must be available at a reasonable cost to detect the condition in the asymptomatic period.
6. The cost of screening must be justified by the incidence of the condition.

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LETTERS TO THE EDITOR

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The serum α-fetoprotein screening test falls short on several of these criteria: Only the first is clearly met when screening for neural tube defects with maternal serum α-fetoprotein (MSAFP). Each of the subsequent criteria fail or are controversial. Most notably, the abnormalities detected by the MSAFP screening test are not treatable. The only "treatment" available for anencephaly is abortion, although lack of treatment results in the same final outcome—death—for the fetus. The treatment for spina bifida is surgical and rehabilitative, although here again abortion can be used to avoid the need for such therapies. Patients have a legal option to pursue abortion. To suggest a medical interpretation of abortion as a "treatment" for disorders, as opposed to a service provided for those who would opt not to "treat" the anomaly, however, is taking a stance regarding quality and sanctity of life issues that society and the medical community have not agreed to take.

Analyses of the cost-benefit ratio of prenatal screening for MSAFP assume that a patient whose fetus has spina bifida will choose to abort.[3] Data regarding these children suggest the abnormality, the necessary surgery and rehabilitation, and the resultant disability vary greatly.[4] In contrast to Down's syndrome, mental function of most of the children is unaffected.[4] Primary care physicians with experience counseling women at increased risk for Down's syndrome are well aware that many women are unwilling to consider abortion for their unborn child regardless of the child's "normality." While accurate data are lacking regarding women with known spida bifida fetuses in utero, one would expect a diversity of opinions and desires in these women.

The benefits of screening, as presented in this article and after careful analysis by Dr. Campbell, consisted primarily of detection of three of the four spina bifida cases. Detection of the anencephalic cases, as well as the twins and inaccurate gestational age pregnancies, could occur with routine use of ultrasonography alone. Data are lacking regarding the sensitivity and the benefits of detecting Down's syndrome and high-risk pregnancies by this method. The risks of screening include one miscarriage secondary to amniocentesis, one orthopedic deformity or case of respiratory distress in the fetus secondary to the removal of amniotic fluid, and approximately 500 pairs of prospective parents experiencing moderately severe anxiety during the screening procedures. The author concludes the benefits are relatively small but appear to be significantly greater than the risks. Does the awareness of the three parents that they have a child with spina bifida clearly outweigh the damage to two potentially normal fetuses, as well as the moderately severe anxiety of 500 families, even if abortion is chosen by all three? And if any of the three choose not to abort (irrespective of what they thought they would do at the beginning of the screening), the benefit-risk ratio falls precipitously.

The presence of neural tube defects is only one of many risks the pregnant patient has for an adverse outcome. Other screening tests are available, have had positive cost-benefit analyses, have lower costs per case detected, and lead to treatments that may lower morbidity or mortality for the fetus and for the woman. Examples include screening for gestational diabetes, testing for Chlamydia trachomatis in early pregnancy, the routine use of ultrasound for detection of twins or inappropriate growth, and so on. Funds for health care in general, and prenatal care specifically, are limited. Each time money is spent on one procedure or test, that money becomes unavailable for other methods of assuring that patients obtain the most health or the most favorable outcome for the resources used. Furthermore, each time a physician spends 20 minutes of the patient visit discussing a one in 1000 possibility, then the time that should be spent counseling the patient on topics known to relate to fetal outcome (smoking cessation, nutrition, stress management, signs of premature labor) must be cut.

The recommendation by American College of Obstetricians and Gyne-

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cologists to inform all pregnant patients of maternal MSAFP screening (in communities where well-coordinated programs exist) has been taken as a specialty and legal mandate that the benefits of screening for MSAFP outweigh the potential risks and the costs—both monetary and emotional. The strength of the data at this time does not support this conclusion.

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The preceding letter was referred to Dr. Campbell, who reponds as follows:

Drs. Reed, Ratcliffe, and Sayres raise some important and controversial issues in MSAFP screening. As mentioned in my paper, the ethical issues involved in prenatal screening are complex and beyond the scope of the review. Society and the medical community, however, currently offer abortion as an option or "treatment" for serious fetal anomalies.

There are data regarding the desires of women with known spina bifida in utero. In the three prospective studies of MSAFP screening reviewed in my paper, 50 of the 54 screened women with fetuses affected by neural tube defects chose to abort them. This 8 percent rate of women declining amniocentesis for detected neural tube defects does not substantially affect either the benefit-risk ratio or the cost-effectiveness of screening. Women who oppose abortion on all grounds generally choose not to be screened for fetal anomalies.

The decision whether to undergo MSAFP screening must be made by each pregnant woman and her partner in consultation with her physician. Making the risks and benefits of screening explicit will assist them in this decision. The benefits appear to outweigh the risks, and thus screening should be offered to all women. Each woman must weigh these risks and benefits and make her own decision. For example, many women may take considerable risks (including risks of moderate anxiety and terminating a normal pregnancy) to prevent the delivery of a severely handicapped child. Others will not want to assume these risks.

Analyzing how MSAFP screening will influence the allocation of finite medical resources is more complex than Reed et al suggest. Even when a procedure of treatment is cost effective, the overall impact of its use is difficult to predict. For instance, while the costs of MSAFP screening are mostly medical, one third of the savings are nonmedical (costs of education and residential care of children with spina bifida).[1] This demand may result in fewer dollars for health care and more for social needs (which may affect health). The overall economic benefits of MSAFP screening equal or exceed the cost, but the differential effect on health care dollars vs other monies must be considered by health care planners, public policy makers, and society in general.

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Reference

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