Letters to the Editor

The Journal welcomes letters to the editor. If found suitable, they will be published as space allows. Letters should be typed double-spaced, should not exceed 400 words, and are subject to abridgment and other editorial changes in accordance with Journal style. All letters that reference a recently published Journal article are sent to the original authors for their reply. If no reply is published, the authors have not responded by date of publication. Send letters to Paul M. Fischer, MD, Editor, The Journal of Family Practice, 519 Pleasant Home Rd, Suite A-3, Augusta, GA 30907-3500, or Fax (706) 855-1107. E-mail: jfampract@aol.com

JEWISH HOLIDAY HAZARDS

To the Editor:

I want to report two cases of Jewish holiday hazards. Yom Kippur, the Jewish Day of Atonement, is observed with prayer and a fast from sundown to sundown. It is common to "break" one's fast with relatives and friends by consuming a deli or dairy meal that is often high in fat. Patient M.L. observed the traditional fast and indulged herself at a "break" fast celebration. Two hours following her meal, she experienced increasing epigastric pain radiating to her back, which increased in severity until she contacted me at 2:00 AM. She was evaluated in the emergency room, where she was noted to have elevated amylase and lipase levels. She was put on a clear liquid diet for 24 hours and then advanced to a low-fat diet, which she tolerated with resolution of her pain and elevated amylase value.

The celebration of Chanukah commemorates the recapture of the Temple from the Greeks. Relatives and friends come together during the eight nights of the festival to light candles, exchange gifts, and eat. The traditional foods are potato pancakes (latkes) and jelly doughnuts. Patient F.C., a 43-year-old woman, noted pain on swallowing that increased with each day of the holiday. She consulted an ENT, followed by a gastroenterologist, who treated her with H_2 blockers for reflux esophagitis. The pain progressively worsened until she could barely swallow. A second ENT ordered a radiograph, which demonstrated a radiopaque filling defect in the mid-esophagus. An endoscopy was performed and a piece of Chanukah "gelt" (chocolate wafers encased in foil to resemble coins) was retrieved. When presented with the foreign body, F.C. recalled purchasing a cake decorated with Chanukah gelt for her religious school class. In the press of helping the children with the party, she ate a piece quickly and must have swallowed the gelt. It was after this party that she began experiencing pain with swallowing. At endoscopy, she was noted to have signs of an early perforation. She was treated with 4 days of intravenous antibiotics, and her symptoms resolved.

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DERMATOLOGY SCREENING WITH TELEMEDICINE

To the Editor:

Telemedicine has been used to connect a patient with a physician in a remote location using two-way interactive telecommunication linkages during which clinically relevant exchanges can take place.[1] A high degree of accuracy in a physician-to-physician consultation using telemedicine techniques has been achieved, as demonstrated in a recent letter to the editor.[2] This study attempts to demonstrate that a high degree of accuracy can be obtained in a dermatologic screening event with a population at high risk for skin cancer. Participants who needed further evaluation or referral for treatment or biopsy were identified.

Thirty-four geriatric patients, residents of a retirement community, volunteered to participate in a 1-day "skin screening." Participants were self-selected and self-referred regardless of whether they had known or unknown skin lesions. On the day of the screening, they were taken by bus to the remote telemedicine site, where a primary care physician and support staff were present. From the primary site, Presbyterian Hospital of Dallas, skin lesions were viewed and recorded using a dermoscope connected in-line with the telemedicine equipment and a standard VCR. At the primary telemedicine site, dermatologists and a geriatrician conferred with the primary care physician at the remote site to determine the nature of the lesion, correlate opinions, and recommend referral or treatment.

The two clinical sites were linked with dedicated asynchronous transfer mode (ATM on OC3) technology, which transports high-resolution, interactive broadband signals over a 39MB-per-second video link, 1.7MB-per-second audio link, and a 10MB-capacity ethernet over a 154MB-per-second fiberoptic circuit. The ATM switch is a JPEG CODEC, which is a state-of-the-art digital communication compression device. Equipment was provided by an in-kind grant from Southwestern Bell Telephone.

The thirty-four patients yielded 145 discrete skin lesions or conditions as summarized in the Table. Thirty-eight lesions (26.2%) were considered premalignant or malignant. The two examiners had very good correlation (97.9%) identifying lesions, with agreement on all but two lesions (one was benign nevus vs basal cell carcinoma, and one was seborrheic keratosis vs actinic keratosis). One patient's condition could not be determined by telemedicine examination because the dermatological manifestations of Cezary's syndrome were nondescript.

Telemedicine is an effective way to screen populations at risk for cancerous and precancerous skin lesions that may need referral to specialty dermatologic care. However, personal and diligent follow-up should always be provided once

Table. Dermatologic Lesions Identified During Telemedicine Screening of Geriatric Patients (N = 34)

Skin Lesion Type*	No. of Occurrences	Malignancy Status
Seborrheic keratosis	40	No
Actinic keratosis	21	Premalignant
Angioma	13	No
Lentigo	9	No
Basal cell cancer	7	Yes
Healed lesions or scars	6	No
Dysplastic nevus	5	Premalignant
Squamous cell cancer	3	Yes
Senile purpura	3	No
Eczema	3	No
Solar elastosis	3	No
Sebaceous cyst	3	No

**Other lesions included: 2 each of junctional nevus, keratin plug, onycholysis, atrophic area, insect bite, normal vessel pattern, rosacea, fibroma, and papilloma; and 1 each of lipoma, varicose vein, petechiae, xerosis, tenia pedis, actinic keratosis with horn, melanoma, cheilosis, venous lake, rectal fissure, and Cezary's syndrome.*

problems are detected by means of telemedicine examinations.

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PROTEINURIA AS A MARKER FOR ORGAN DAMAGE

To the Editor:

Proteinuria, especially in diabetes mellitus and hypertension, is recognized as a predictor of renal decline and is a marker for patients with cardiovascular end-organ damage.[1–5] Recent work by Guthrie and Lott[6] detected increased levels of proteinuria in patients being treated for hypertension and diabetes in a primary care practice.

The charts of 152 patients who participated in the urine screening project and in whom hypertension or diabetes mellitus had been previously diagnosed were evaluated further for the diagnosis of cerebrovascular disease (stroke or transient ischemic attack), coronary artery disease (with or without myocardial infarction), and congestive heart failure.

There was a pattern of increased levels of cardiovascular end-organ damage when patients exhibited proteinuria with hypertension alone, or in combination with diabetes. The results are summarized in the Table. Owing to the limited number of patients with proteinuria, the differences showed a trend that did not achieve statistical significance ($P = .15$).

Our data support the Framingham Study's finding that proteinuria is an independent risk factor for increased cardiovascular complications in hypertensive patients.[3] This finding is confirmed in two other longitudinal trials on patients with hypertension,[4,5] in which the presence of proteinuria was a risk factor for cardiovascular morbidity and mortality in hypertensive patients. Proteinuria should be considered to be a *marker for patients at risk for end-organ damage.*

Proteinuria is due to either glomerular leakage, primarily of albumin, or failure of tubular resorption of various proteins from primary renal tubular defects.[7] Proteinuria is poorly studied in hypertension. There are two long-term studies that showed that proteinuria is associated with hypertensive renal diseases[8] and with increased left ventricular hypertrophy and cardiomegaly.[9]

For the primary care physician, our data have significant clinical usefulness. Using a urinary dipstick, proteinuria can be detected rapidly, easily, and inexpensively. Our data emphasize that proteinuria on the convenient dipstick can identify hypertensive patients at increased risk for hypertensive end-organ damage, and its presence can help identify patients whose blood pressure control requires special attention.

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ETHICAL USE OF PLACEBOS IN CLINICAL TRIALS

To the Editor:

Rush and colleagues have confirmed the effectiveness of ranitidine for the treatment of gastroesophageal reflux disease (GERD) and have also shown that it works in a family practice outpatient setting.[1] While their results may be reassuring, their use of placebo controls is troubling.

The question of when it is ethically permissible to use placebo controls in clinical research remains controversial. Critics maintain that it is always unethical to expose some subjects to placebo if there is an effective treatment available, even with valid informed consent.[2] Others argue for the selected use of placebo, eg, in situations in which such use will not expose the control subjects to danger, when there is no known effective treatment, and when it is not known whether the proposed treatment will be effective.

This Clinical Experience Network (CEN) study clearly falls outside the accepted practice for the use of placebo controls because (1) nontreatment of GERD can lead to stricture, ulceration, hemorrhage, or aspiration; (2) effective therapy *is* available to treat the symptoms

Table. Pattern of Increased Levels of Cardiovascular End-Organ Damage Among Patients with Proteinuria with Hypertension Alone or in Combination with Diabetes

Factors	No. of Patients	Cardiovascular Accident, n (%)	Coronary Heart Disease, n (%)	Congestive Heart Failure, n (%)
HBP	84	1 (1.2)	12 (14.3)	6 (7.1)
HBP + Prot	18	2 (11.1)	2 (11.1)	2 (11.1)
HBP + DM	23	1 (4.3)	2 (4.7)	3 (13.0)
HBP + DM + Prot	16	6 (37.5)	5 (31.3)	8 (50.0)

HBP denotes hypertension; Prot, proteinuria; DM, diabetes mellitus.

and prevent the complications of GERD; and (3) ranitidine has already been shown to be effective for GERD.

Several questions for the investigators: What was your reason for using placebo controls? Did the consent process ensure that the subjects understood the burdens and the risks of the research? Were they offered an inducement to enroll? Was the study sponsored by the manufacturer of ranitidine? Were the investigators given an inducement for each subject recruited? Did one or more institutional review boards approve this multicenter study? How were you able to find 812 "patients" who were sufficiently altruistic that they were willing to take a 50–50 chance that they might have to put up with 6 weeks of persistent heartburn for the good of science?

Clinical research in the outpatient family practice setting has long been neglected. Now that it is feasible through such endeavors as the CEN, clinical research needs to be encouraged. It should, however, be conducted by accepted ethical standards as well as good scientific standards.

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2. Rothman KJ, Michels KB. The continuing unethical use of placebo controls. N Engl J Med 1994; 331:394–8.

The preceding letter was referred to Drs Rush and Stelmach, who respond as follows:

We welcome the opportunity to reply to Dr Orr's correspondence regarding our recent publication.[1]

Dr Orr's concerns about the ethical use of placebos are germane to all investigators involved in clinical research. The Rothman and Michels "Sounding Board" article[2] should be required reading for all researchers. We certainly disagree, however, with Dr Orr's conclusion that our study "clearly falls outside the accepted practice for the use of placebo controls." A careful rereading of the article itself should allay his concerns, as he completely missed the point of the structure of our study.

There was no breach of any ethical canon, as we did not leave any study subject without a mode of proven effective treatment. There are many therapies available for the management of GERD that fit normal practice patterns of treatment. These include the H_2-receptor antagonists and antacids. None of the subjects in our study went without treatment for their GERD symptomatic episodes.

Our double-blinded placebo-controlled study design is the optimal design for this type of investigation. While there was an active treatment arm of ranitidine and a comparative arm of ranitidine placebo in the design, there was also an active agent (antacid use) escape treatment for both of these populations. If the ranitidine or the placebo failed, the subject was instructed by the investigators to take antacid doses should their symptoms persist, and to record these instances.

Our study was in compliance with the proper use of controls in clinical trials, ethical considerations, and placebo use as outlined in Dr Bert Spilkers recent landmark book, *Guide to Clinical Trials.*[3] This reference may be helpful to Dr Orr and others involved in investigational study construct.

Our study was approved by a central institutional review board as well as nine other hospital or university-based IRBs. None found problems with the construct of our study, our patient consent forms, or our use of an active escape treatment in conjunction with a placebo control. The consent forms had separate sections on the benefits and risks of the study, alternative therapies, and the subjects' rights to ask questions and/or withdraw from the study.

Study subjects were reimbursed a very minimal $25 to cover their costs for the travel to their extra clinic visit, weeks of diary completion, and their completion of self-assessment forms. Investigators were reimbursed for their physical examinations, office visits, and completion of data collection forms, as is usual for investigational studies.

We clearly stated that this project was funded by a grant to the CEN from Glaxo Inc, the manufacturer of ranitidine. This information appeared as an acknowledgment, which is the format preferred by this journal* for communicating such information.

**The Journal of Family Practice* follows the *American Medical Association Manual of Style, 8th edition*, which clearly states that financial information be stated in the acknowledgment.

In conclusion, our work did not sacrifice any ethical standards for the sake of science. We were able to properly balance both, and hope to continue to pursue office-based clinical research in the real-world office practice of the family physician.

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1. Rush DR, Stelmach WJ, Young TL, et al. Clinical effectiveness and quality of life with ranitidine vs placebo in gastroesophageal reflux disease patients: a Clinical Experience Network (CEN) study. J Fam Pract 1995; 41:126–36.
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Tips from Practice

Repacking Abscesses

Incision and drainage of an abscess is a painful procedure for the patient. It is customary to use lidocaine or other injectable anesthetic to anesthetize the area and minimize discomfort. Depending on the size of the abscess, many physicians use Iodoform gauze as a packing agent. Repacking can be as painful, however, as the initial procedure.

After removing the bandage and packing, I suggest filling the cavity with viscous lidocaine 2%. Remove the excess with swabs. In a minute or less, the tissue will be anesthetized and can then be packed with ease and comfort.

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