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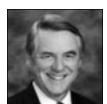
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The Use of Electronic Biofeedback for the Management of Post-Herpetic Neuralgia – A Report of 3 Cases

Malcolm R. Ing MD



Malcolm R. Ing MD

Abstract

The purpose of these case reports is to describe treatment of three consecutive patients with post-herpetic neuralgia using a bioelectronical device (SCENAR). The instrument is approved as a Class II device in the United States. The electrode of the device was stroked gently over the involved skin area for up to 15 minutes per session. No more than 5 sessions over a 3-week period was required. All patients experienced substantial relief of pain from the first treatment. One patient required only 1 treatment lasting 10 minutes. The other 2 patients required 4 to 5 treatments over a 3-week period. One patient required a treatment for skin itch after one year with a follow up period of 6 months to 24 months. An electronic biofeedback device (SCENAR) may be successfully utilized in the management of post-herpetic neuralgia.

Introduction

Herpes zoster is a relatively common disease with an incidence of 1 to 5 per 1000 patients per year. The disease affects the ophthalmic branch of the trigeminal nerve in 20% of cases and is known as herpes zoster ophthalmicus. Typically, the first division of the trigeminal nerve involving sensory innervation of the brow, forehead, and scalp is affected on one side with blister skin lesions extending to the midline. If blisters appear along the nose it is often associated with eye inflammatory involvement. However, after the blisters disappear, the patients may experience persisting neuropathic pain that, if it persists more than 1 month, it is termed chronic post herpetic neuralgia (PHN). The risk of developing PHN is higher with increasing age of the patient and represents a major public health issue. Various types of medicinal treatment plans have been utilized with varying success. 2 These medicines include off-label uses of anti-depressants, opiods, anti-convulsants and topical analgesics. There have been a limited number of randomized trials with mixed results. Additionally, symptoms from medication include anti-cholinergic effects, sedation, postural hypotension from tricyclic anti-depressants and dizziness, and somnolence.³ Constipation and sedation from opiods make these drugs poorly tolerated in the elderly. Topical medication, such as Lidocaine patches (local anesthesia) and capsaicin

extracts have also been utilized to treat PHN with limited success. It is generally acknowledged that post herpetic neuralgia is difficult to treat with usual analgesics.

Biofeedback

Biofeedback as defined by the National Library of Medicine, medline database, is a process that utilizes instrumentation to give a person immediate and continuous signals of change in his/her body.

Biofeedback is a well-accepted therapeutic modality. Electronic devices are often utilized in biofeedback therapy. With the development of computers, instrumentation has improved. As the instruments became more sophisticated, it has become possible to develop a cybernetic loop between the device and the body. The body's electronics can be measured in response to a signal sent from the instrument, and the instrument can then send back a signal designed to modify the body's abnormal signal. The resulting response signal can then be measured and a new modifying signal returned with a continuous dialogue being established. Therefore, with modern biofeedback, the body's abnormal electronics can be modified. A team of physicians and scientists in Russia based at Sochi University and led by Alexander Revenko, MD, a neurologist, and Alexander Karasev, an electronics expert, in the late 1970's developed a computerized method of treatment biofeedback that was compact, efficient, and non-invasive.

Electronic biofeedback (EB)

The establishment of a biofeedback mechanism led to the development of a device in which output was dependent on the electric response of the skin. The term SCENAR, which stands for self-controlled neuro adaptive regulation, was applied to this new technology. It has been said that SCENAR is a brilliant marriage of Western electronic technology and Eastern energetic healing skills. The device is similar to a hand-held massager. A small amount of electrical current is applied at the affected area. During the treatment the patient experiences a mild tingling sensation as a result of the biofeedback process.

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SCENAR Photo.

Federal Regulations regarding EB

The Scenar/EB is currently accepted for FDA as a class 2 biofeedback muscle relaxation and re-education device. Federal law requires EB devices to be distributed by or on the order of a licensed health care practitioner. EB devices are regulated by the United States Food and Drug Administration under the provision of the US Code of Federal Biofeedback Device, Product Cod HCC, Class II. The maximum current is 70MA and the peak voltage is 250 powered by a 9 volt battery. The power output can be set by the operator to be detectable but comfortable to the patients. The random variations of the pulse amplitude from zero to a chosen comfort limit assure that no 2 impulses are the same. This feature discourages adaptation. A feedback mechanism is provided by the constant monitoring of the skin impedance.

The patient feels a gentle tingling, and all sensations are reported to the health practitioner. At no time is the level of electrical energy allowed to cause sustained pain because the health practitioner can instantly reduce the intensity at any report of an adverse sensa-

This report describes the outcome of the use of electronic biofeedback (SCENAR) in the management of post-herpetic neuralgia in 3 consecutive patients.

Case Reports

CASE 1: A 63-year-old Caucasian man had a history of severe left-sided brow and scalp pain following ophthalmic zoster. This patient received anti-viral medication within the first day of the skin lesions, with clearing of the blisters in 10 days. Despite anti viral treatment with acyclovir, the patient was unable to return to work because of the continued skin discomfort, despite use of opiod pain medication. He received electronic biofeedback treatment over the affected area for 10 to 15 minutes on July 9, 2004, 3 weeks after the clearing of the skin blisters. The patient reported a 90% reduction of pain within 12 hours of treatment, and he was able to return to work that next day without needing any oral pain medication. He continues to be pain-free 2 years since his affliction.

CASE 2: An 84-year-old Asian man presented with a history of continued debilitating pain over his right brow and scalp for 2 years following ophthalmic zoster. His management included 300 mg of gabapentin (Neurontin) twice daily, but he reported that he could

not sleep through the night because of recurrent bouts of severe skin pain. He also complained the medication made him drowsy. The first treatment with the bioelectrical device was applied on August 12, 2004. After 12 hours, the patient noted a 50% improvement, and he was treated 3 more times over a 9-day period, during which time, the pain reduced to a level less than 10% of the original pain and he could sleep throughout the night without awakening to any skin pain. He was able to discontinue gabapentin. The patient has not experienced return of pain for 2 years following his treatment.

CASE 3: A 55-year-old Caucasian woman had severe persistent pain over the left brow and scalp for 1 month following a bout of ophthalmic zoster. This patient was treated with an anti-viral as soon as the skin lesions appeared, and the lesions had healed. However, the patient was unable to sleep through the night because of intermittent bouts of burning sensation in the skin. She tried capsaicin topically without relief of her symptoms. She was treated with electronic biofeedback on May 19, 2005. The next day she reported she was able to sleep through the night, and said that there was an 85% decrease in the pain level. She received four additional treatments over a 1-month period for a slight persistence of symptoms. Each treatment was administered for a decreasing intensity of residual symptoms, the last being applied for only a "mild itching." She was 100% pain free for 12 months, but required a single additional treatment for "itchy sensation" over the same area 1 year after the initial treatment. She continues to be symptom free at this time, 15 months after the initial treatment.

Discussion

The pathway for pain relief is said to be the simulation of the C-fiber neural system. According to developers of this mode of electronic biofeedback, the C-fibers, which comprise 85% of all the nerves of the body, react most readily to electronic stimulation.⁵ These fibers are responsible for the production of neuropeptides and other regulating peptides. The body apparently can become accustomed to a stable pathological state, which may be caused by illness or injury. The device is said to catalyze the process to produce regulatory peptides by stimulation of the C-fibers. It is these neuropeptides that, in turn, re-establish the body's natural physiological state and are responsible for the muscle retraining and relaxation. As the device is moved over the skin a tingling prickly sensation is felt. Most patients report a relaxed state of well being after the treatment with subsequent reduction in pain.⁶ All 3 patients in this study had experience with other pain relief modalities such as narcotics, capsaicin skin treatment, and gabapentin without success prior to treatment by electronic biofeedback.

Although the response to EB has been favorable in 3 consecutive cases of PHN, this report is considered preliminary and anecdotal at this time. A standardized pain scale was not utilized in the present study. A controlled study with the instrument and a sham device and a standardized pain scale is required for full evaluation of this treatment modality.

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Risk Factors for Venous Thromboembolism in Japan: A Hospital-Based Case-Control Study

Hwee Yong Lim MB, BCh, BAO, Mitsumasa Kishimoto MD, Hidetaka Kitazono MD, Hiroki Ito MD, Masashi Narita MD, Rebecca P. Gelber MD, MPH, and Yasuharu Tokuda MD, MPH

Abstract

Background: Previous studies suggest that Asians may be less likely to develop venous thromboembolism (VTE) than Caucasians. While inherited thrombophilias occur infrequently among Asians, the distribution of other VTE risk factors in these populations remains unclear.

Objective: To identify VTE risk factors in a Japanese population.

Patients and Methods: We evaluated 131,060 patients admitted to Okinawa Chubu Hospital in Japan (January 1987-December 1999). Patients with VTE were identified through discharge diagnoses using the hospital database. Medical records were reviewed for information on demographics, potential VTE risk factors, and diagnostic modalities. Controls were randomly selected from the same database, matched 1:1 to cases on age, sex, year of hospital admission, and nearest medical record number. We used conditional logistic regression to examine potential VTE risk factors.

Results: We identified 141 cases of newly diagnosed VTE (128 with deep vein thrombosis, 41 with pulmonary embolism). In multivariable analyses adjusting for all measured potential risk factors, statistically significant VTE risk factors included lower extremity paralysis [odds ratio (OR), 3.07; 95% CI, 1.01-9.33], immobilization >7 days (OR, 4.96; 95% CI, 2.26-10.9), diagnosis of an acquired hypercoagulable state (OR, 19.1; 95%CI, 1.75-209.2), body mass index ≥25.0 kg/m² (OR, 2.35; 95% CI, 1.13-4.89), and prior VTE (OR, 22.37; 95% CI, 2.35-213.4).

Conclusion: The VTE risk factors identified in this Japanese population are similar to those previously described among Caucasians. Further study is needed to define how the distribution of VTE risk factors in Asian populations may influence appropriate preventive strategies.

Introduction

Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE), accounts for more than 250,000 hospitalizations annually in the United States, ¹⁻⁴ with an associated 3-month mortality rate for PE as high as 17%. ^{4,5}

The prevalence, incidence, and risk factors for VTE have been described in certain populations. However, US studies of VTE have traditionally included Caucasians and African Americans, with sparse information

concerning other populations. Studies of VTE prevalence from Asia and the United States have suggested that VTE is less common among Asian ethnic groups as compared to Caucasians.⁶⁻¹⁰ However, few studies of Asian ethnicities have addressed risk factors in these populations.

Proposed reasons for a possibly lower prevalence of VTE in Asian populations include differences in genetics (lower prevalence of Factor V Leiden and prothrombin gene G20210A), ^{6,11-15} lifestyle and dietary factors, ^{16,17} lower prevalence of hyperhomocysteinemia, ^{16,17} differences within the coagulation cascades (lower levels of Factor VIIc and Factor VIIIc), ¹⁸ and differences within the fibrinolytic pathway (higher incidence of asymptomatic DVT and higher risk of hemorrhagic strokes). ^{19,20} Such potential biologic differences may suggest that other risk factors for VTE may differ among Japanese as compared to Caucasians.

Venous thromboembolism score systems²¹⁻²⁴ have been developed to risk-stratify patients for DVT and PE. Such scores are affected by the prevalence of VTE in a population, as well as the relative importance of each risk factor. Knowledge of the prevalence and risk factors for VTE among Asians is needed to determine appropriate preventive strategies. We therefore aimed to identify risk factors for VTE among Japanese patients admitted to a teaching hospital in Okinawa, Japan.

Methods

Study Population

We studied all patients admitted from January 1987 through December 1999 to Okinawa Chubu Hospital, a large, university-affiliated medical center in southern Japan. Nearly all patients admitted during the study period were Japanese (~99.5%). Patients of other ethnicities (ie, Taiwanese, Caucasian) accounted for <0.5% of admissions.

We identified patients with VTE based on discharge diagnoses for DVT or PE through computerized medical records. We reviewed the hospital discharge summary electronic database (Filemaker Pro), which is updated and reviewed using ICD-9 (International Classification

Correspondence to: Hwee Yong Lim MD Department of Medicine University of Hawai'i John A. Burns School of Medicine 1356 Lusitana Street, 7th Fl. Honolulu, HI 96813 Ph: (808) 586-2910 Fax: (808) 586-7486 E-mail: hwee@hawaii.edu of Diseases, 9th Revision, Clinical Modification) codes, as well as the radiology department databases. Manual chart reviews were then performed on all patients with a diagnosis of VTE. Only those with radiologically confirmed diagnoses were included in analyses. A diagnosis of DVT was documented by radionuclide venography using technetium-99m-MAA and/or lower extremity ultrasound examination. PE was confirmed by pulmonary perfusion scintigraphy and/or contrast enhanced computed tomography.

Using the computerized medical database, patients with definite diagnoses of VTE were first matched 1:1 to controls by age (±1 year), sex, and year of admission (±1 year). If more than one patient met the above matching criteria, those with the closest medical record number were selected as controls.

Data Collection

We obtained basic demographic data on all selected patients admitted during the study period using the hospital's electronic data registry. We then manually reviewed hospital charts on all patients with a VTE diagnosis as well as the selected control patients. Data extracted included information on VTE risk factors, diagnostic methods, symptoms and signs at presentation (eg, pain, tenderness, edema, warmth, erythema), site of DVT, patient's location prior to hospital admission, comorbidities, and body mass index (BMI, defined as weight in kilograms divided by the height in meters squared).

VTE risk factors were defined as postoperative diagnosis (surgery requiring general anesthesia during the same hospitalization, including general, orthopedic, neurologic, and gynecologic surgery), major surgery within 3 months prior to admission, other institutionalization (psychiatry hospital, rehabilitation hospital, nursing home) within 3 months prior to admission, personal or family history of VTE, active cancer (diagnosed active cancer within 6 months with or without treatment), BMI≥25.0 kg/m², lower extremity paralysis, immobilization for more than 7 days, personal or family history of hypercoagulable states (polycythemia vera, antiphospholipid antibody syndrome, nephrotic syndrome), heart failure, varicose veins, inflammatory bowel disease, pregnancy, and hormonal therapy (oral contraceptive use, hormone replacement therapy, or tamoxifen therapy).

Statistical Analysis

We determined the prevalence of VTE among hospital admissions and calculated 95% confidence intervals (CI) based on the normal approximation to the binomial distribution and estimated the prevalence of risk factors among cases and controls. We used conditional logistic regression to estimate the odds ratios (OR) and 95% confidence interval (CI) for VTE among cases as compared to controls, in both univariate analysis and

after multivariable adjustment for all potential risk factors. We used SAS statistical software for all analyses (version 9.1, Cary, North Carolina, USA). All *P*-values were two tailed.

Results

During the study period, there was no fixed policy for prophylaxis against VTE at Okinawa Chubu Hospital. Compression stockings were rarely used, and other forms of prophylaxis (ie, intermittent pneumatic compression devices, heparin, and warfarin) were never used. All patients with VTE were Japanese, except one Caucasian patient who was excluded from our analyses.

We found a low prevalence of radiologically-confirmed VTE in our population during the 12-year study period (0.11% of 131,060 hospital admissions; 95% CI, 0.09-0.13%). Among all 141 VTE cases, mean age (± SD) was 64±17 years, and 70.2% (n=99) were women. DVT was diagnosed in 91% and PE in 29%. Among men with VTE, 95% had DVT and 36% had PE. Among women, 89% had DVT and 26% had PE. Among individuals 50-69 years of age, VTE was significantly more common among women than men (0.31% vs 0.08%; OR, 3.88; 95% CI, 1.45-6.31).

Among the matched controls (n=141), common admission diagnoses included infectious diseases (26%) and cardiovascular diseases (14%).

We evaluated 13 potential VTE risk factors in univariate comparisons of the 141 VTE cases and 141 matched controls. Only history of an acquired hypercoagulable state, prior VTE, BMI ≥25.0 kg/m², lower extremity paralysis, and immobilization >7 days were significantly associated with a VTE diagnosis (Table 1). Patients with VTE were more likely to have any associated risk factor noted in medical records (OR, 95% CI for at least one risk factor: 3.11, 1.47-6.59).

Table 2 shows results of multivariable analyses adjusting for all other potential risk factors. Statistically significant VTE risk factors included lower extremity paralysis (OR, 3.07; 95% CI, 1.01-9.33), immobilization for more than 7 days (OR, 4.96; 95% CI, 2.26-10.9), diagnosis of an acquired hypercoagulable state (OR, 19.1; 95% CI, 1.75-209), BMI ≥25.0 kg/m² (OR, 2.35; 95% CI, 1.13-4.89), and history of prior VTE (OR, 22.4; 95% CI, 2.35-213). No cases of hereditary thrombophilic states (i.e., protein C deficiency, protein S deficiency, antithrombin III deficiency, prothrombin 20210A mutation, MTHFR gene mutation, Factor V Leiden gene mutation) were noted on chart review.

Among men, immobilization for more than 7 days was the only significant VTE risk factor (OR, 4.11; 95% CI, 1.17-14.4). Among women, independent VTE risk factors included active cancer (OR, 3.35; 95% CI, 1.15-9.75), lower extremity paralysis (OR, 6.47; 95% CI, 1.20-35.0), immobilization for more than 7 days (OR 7.31; 95% CI, 2.47-21.6) and history

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Table 1.— Characteristics (%) of cases (n=141) and controls (n=141) and unadjusted odds ratios (OR) for VTE.

Characteristic	Cases	Controls	OR	95% CI
Admission for surgery	22.0	19.1	1.21	0.66-2.22
Major surgery within 3 months prior to admission	2.1	0.7	3.00	0.31-28.8
Institutionalized within 3 months prior to admission*	17.7	20.6	0.80	0.42-1.54
Prior VTE	8.5	0.7	12.00	1.56-92.3
Active cancer	16.3	14.9	1.12	0.58-2.15
BMI ≥ 25 (kg/m2)	40.4	25.5	2.24	1.26-3.96
Lower extremity paralysis	18.4	6.4	3.43	1.48-7.96
Immobilization > 7 days	52.5	24.1	3.86	2.14-6.94
Hypercoagulable state	8.5	0.7	19.14	1.75-209.2
Heart failure	9.9	12.8	0.77	0.37-1.57
Varicose veins	2.1	0.7	3.00	0.31-28.8
Pregnancy	1.4	2.8	0.33	0.04-3.21
Nephrotic syndrome	2.1	0.7	3.00	0.31-28.8
Any risk factor †	90.1	76.6	3.11	1.47-6.59
Two or more risk factors †	67.4	47.5	2.87	1.59-5.16

^{*} Hospital or non-acute care facility (ie, psychiatry hospital, rehabilitation hospital, nursing home).

CI=confidence interval, VTE=venous thromboembolism, BMI=body mass index

Table 2.— Multivariable-adjusted odds ratios (OR) for VTE $(n = 141 \text{ cases}, n = 141 \text{ controls}).*$						
Characteristic	OR	95% CI				
Admission for surgery	0.66	0.27-1.62				
Major surgery within 3 months prior to admission	12.2	0.87-171.9				
Institutionalized within 3 months prior to admission †	0.58	0.23-1.48				
Prior VTE	22.4	2.35-213.4				
Active cancer	1.61	0.67-3.83				
BMI ≥ 25.0 (kg/m2)	2.35	1.13-4.89				
Lower extremity paralysis	3.07	1.01-9.33				
Immobilization > 7 days	4.96	2.25-10.92				
Hypercoagulable state	19.1	1.75-209.2				
Heart failure	1.87	0.71-4.95				
Varicose veins	1.89	0.14-25.7				
Pregnancy	0.20	0.02-2.60				

^{*} Adjusted for all covariates listed.

of an acquired hypercoagulable state (OR, 17.1; 95% CI, 1.32-223). No female controls had major surgery within 3 months prior to admission or history of prior VTE. Types of active cancer among women with VTE included gastrointestinal cancer (n=6), cervical cancer (n=4), breast cancer (n=2), endometrial cancer (n=1), bladder cancer (n=1), brain astrocytoma (n=1), lung cancer (n=1), meningioma (n=1), and metastatic cancer of unknown origin (n=1).

Discussion

Multiple studies have suggested that Asians may have a lower prevalence of VTE than Caucasians. Such differences in observed VTE prevalence may be due to differences in the prevalence of risk factors, a lower clinical suspicion for diagnosing VTE, or both. Defining risk factors in Asian populations will be important for developing appropriate preventive strategies for VTE.

This study is the first to identify potential risk factors for VTE among Japanese patients. In our population, immobilization, lower extremity paralysis, acquired hypercoagulable states, body mass index ≥25.0 kg/m², and prior VTE were independent risk factors in multivariable-adjusted analyses, with immobilization for more than 7 days associated with a 4-fold increased risk for VTE. Immobilization or lower extremity paralysis were identified in 54% of our study population.

In contrast to studies of other ethnic populations,²⁵ recent institutionalization prior to admission was not a statistically significant VTE risk factor in our population. This may be related in part to insufficient study power or differences in risk factor definitions, as we included in this category nursing home residents as well as psychiatric and rehabilitation hospital residents who subsequently required an acute admission.

As expected, patients with a history or new diagnosis of an acquired hypercoagulable state or a history of prior VTE had an increased risk of VTE. Previous studies of primarily Caucasian populations have similarly reported increased VTE risk among these patients. ^{25,26} The acquired hypercoagulable states diagnosed in our study were polycythemia vera, antiphospholipid antibody syndrome, and nephrotic syndrome. In contrast to Caucasian populations, inherited thrombophilic states are rare among Asians, and none were noted in our population. Prior studies have described a carrier frequency of factor V Leiden among Caucasians of 5 –8%, ^{11,12} in contrast to 0.45% among Asian Americans. ¹³ Factor V Leiden and prothombin gene mutations have not been reported in Japanese. ¹¹⁻¹⁵

Overweight and obesity (BMI ≥25.0 kg/ m²) were associated with a 2-fold increased risk of VTE. Previous studies among Caucasians have produced conflicting results with some reports^{27,28} suggesting increased risk associated with obesity and one study²⁵ failing to identify BMI as a significant risk factor for VTE.

[†] Includes risk factors above and postoperative diagnosis or current hospitalization, family history of hypercoagulable state, inflammatory bowel disease, pregnancy, nephrotic syndrome, and hormonal therapy in women (not including age).

[†] Hospital or non-acute care facility (ie, psychiatry hospital, rehabilitation hospital, nursing home). CI=confidence interval, VTE=venous thromboembolism, BMI=body mass index

Previous World Health Organization Expert Consultation analyses of data from 10 Asian countries found that Asians generally had a higher body fat percentage at a given BMI, as compared to Western populations.²⁹ This may suggest that the association of BMI with VTE may differ by ethnicity. Our study is the first to report BMI as a likely independent risk factor for VTE in a Japanese cohort.

Among men, immobilization was the only statistically significant VTE risk factor, with a 4-fold increase in risk. However, our study only included 43 men and may lack sufficient power to detect other statistically significant risk factors among men. Among women, active cancer, immobilization for more than 7 days, lower extremity paralysis, and diagnosis of an acquired hypercoagulable state were significantly associated with VTE. The 3-fold increased risk of VTE associated with cancer is consistent with previous reports. ^{30,31} Previous studies ³²⁻³⁶ have identified hormonal treatment as a risk factor for VTE among women. Due to the lack of hormonal treatment among women in our study, we cannot determine its association with the risk of VTE in our population. However, separate analyses for men and women in our study may lack adequate statistical power due to the low prevalence of VTE in our patient population.

Several limitations to this study should be considered. The study evaluated patients at a single institution in Okinawa, so the results may not generalize to other populations in Japan. Second, assessment of VTE prevalence and risk factors is limited by the existing level of clinical suspicion for VTE and willingness to test for it, which have traditionally been low in Asia.⁶ Third, the study's matching strategy precludes the researchers from evaluating age or sex as VTE risk factors in this study. However, the authors previously found that the prevalence of VTE increase with age,⁶ as in prior studies.^{3,37} Also previously described is a higher prevalence of VTE among women in the Japanese population.⁶ Finally, interpretation of the study results is limited by the small sample size, particularly in analyses of less prevalent risk factors.

Despite these limitations, this is among the largest studies to define potential risk factors for radiologically confirmed VTE in an Asian population. Furthermore, data from electronic records was supplemented with medical chart review to ensure the completeness of data collection and a large number of potential risk factors were evaluated.

In summary, the study identified risk factors for VTE in a Japanese inpatient population in Okinawa, Japan. While the inherited thrombophilias are rare among Asians, and none were noted in this population, other VTE risk factors similar to those previously described for Caucasians were found. Additional studies are needed to define further the risk factors for VTE among Asian populations and to determine how the distribution of these risk factors may shape appropriate preventive strategies.

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Structural Birth Defects Associated with Neural Tube Defects in Hawai'i from 1986 until 2001

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Abstract

Using birth defects registry data, this study identified birth defects associated with anencephaly, spina bifida, and encephalocele. Musculoskeletal defects were associated with anencephaly; central nervous system defects, gastrointestinal atresia/stenosis, genitourinary system defects, and musculoskeletal system defects with spina bifida; and central nervous system defects, respiratory defects, oral clefts, genitourinary system defects, and musculoskeletal system defects with encephalocele.

Introduction

Identification of birth defects that occur in association with one another is important. It assists in the understanding of the embryology, etiology, risk factors, and recurrence risk of the defects¹ as well as the identification of potential malformation syndromes.

Neural tube defects (NTDs) are known to frequently occur with other structural birth defects.²⁻⁹ The overall rate of occurrence of associated structural birth defects has been reported to be 9-50% for anencephaly, 12-53% for spina bifida, and 23-60% for encephalocele. However, there is less information on the specific structural birth defects associated with NTDs.^{2,3,5,7}The association of specific birth defects varies by the type of NTD.^{2,3,5} This might be expected, considering that the epidemiology of NTDs has been reported to depend on type of defect and its location.^{4,10}

Only one of the studies appeared to determine whether the number of associated defects was greater than expected. This study observed higher than expected rates among NTDs for oral clefts, omphalocele, tracheoesophageal fistula, imperforate anus, and diaphragmatic hernia. However, the study examined all NTDs as a single group.

The purpose of this investigation was to describe the association of various structural birth defects with different types of NTDs using data from a populationbased birth defects registry in Hawai'i. In particular, effort was made to determine which associations were other than might be expected.

Methods

The data source for this investigation was the Hawai'i

Birth Defects Program (HBDP), a population-based birth defects registry for the entire state.¹¹ Inclusion criteria for the HBDP consists of any infants and fetuses of any pregnancy outcome (live birth, fetal death, elective termination) at any gestational age that were delivered in Hawai'i and where a reportable birth defect was diagnosed between conception and one year after delivery. HBDP staff identify eligible infants and fetuses and collect data through review of logs and medical records at all delivery and tertiary care pediatric hospitals, facilities that perform elective terminations secondary to birth defects, cytogenetic laboratories, genetic counseling offices, and all but one of the major prenatal ultrasound centers in Hawai'i. Through these 34¹¹ multiple ascertainment sources, identification of eligible infants and fetuses with diagnosed reportable birth defects is considered to be as complete as possible.

Multiple different procedures and/or tests may provide diagnostic information for a given infant or fetus. HBDP staff review all available reports of such procedures and tests in the available medical records. In order to ascertain the most complete and accurate diagnosis for an infant or fetus, the HBDP ranks the procedures and tests as follows in descending order of likelihood of providing complete and/or accurate information: (1) autopsy, pathology, biopsy; (2) chromosome analysis, toxicity screen; (3) surgery; (4) X-ray, Cat-Scan, MRI, postnatal ultrasound, EKG, echocardiogram; (5) prenatal ultrasound; (6) specialist consultation; (7) medical record. If conflicting information is provided by different procedures or tests, the information provided by the "more accurate" procedure or test is given precedence. For example, if an ultrasound reported a diagnosis of holoprosencephaly but the surgery reported hydranencephaly, the HBDP would list the diagnosis as hydranencephaly. Moreover, all of the procedures or tests that might be most useful in diagnosing an infant or fetus may not be performed. In particular, although an autopsy or pathology report might be considered the "most accurate" diagnostic tool for structural birth defects, all infants and fetuses do not undergo such procedures. Thus, the birth defect was based on the best available information. The same situation is likely to apply to other birth defects registries.

Cases were all infants and fetuses of any pregnancy outcome and any gestational age with a confirmed diagnosis of anencephaly, spina bifida, or encephalocele that were delivered during 1986-2001. Cases with confirmed cytogenetic abnormalities were excluded from the analysis. However, cases with non-chromosomal syndromes were included because it was not always clear whether the NTD was part of the syndrome or had coincidentally occurred with the syndrome. Moreover, a portion of cases with other birth defects also may have malformation syndromes that were not diagnosed.

The rates of defects of 8 organ system categories and 47 specific structural birth defects were calculated for each type of NTD. The specific defects were chosen because they were relatively common, easily diagnosed, or impacted morbidity and mortality.

These rates were then compared to the rates among all other infants and fetuses with all structural birth defects, excluding those that also had confirmed chromosomal abnormalities or NTDs. This comparison was made rather than comparing the NTD cases to the general population because a genetic or environmental factor that causes birth defects would probably influence the developmental processes of more than one organ system and thus might result in multiple birth defects. A large percentage of birth defects do not occur in isolation.¹² This comparison is similar to that performed in another study of oral clefts.¹³

The comparisons were made by calculating the ratio of the rates among NTD cases to the rates among live births and fetuses with all structural birth defects excluding NTDs. Confidence intervals (CIs) of 95% were determined by Poisson probability. The final manuscript was reviewed by the Hawai'i Department of Health (DOH) institutional review board.

Results

Among 1986-2001 deliveries, there were 111 cases of anencephaly, 130 cases of spina bifida, 48 cases of encephalocele, and 12,028 infants and fetuses with structural birth defects excluding NTDs. There were a total of 298,994 live births delivered in Hawai'i during the same 16-year period. Other structural birth defects were identified in 30 (27.0%) (95% CI, 19.0-36.3) of the anencephaly cases, 111 (85.4%) (95% CI 78.1-91.0) of the spina bifida cases, and 30 (62.5%) (95% CI 47.4-76.1) of the encephalocele cases.

Table 1 shows the distribution of structural birth defects among the cases. The most commonly reported defects in association with anencephaly were defects of the limb and musculoskeletal system. However, all of the organ system categories demonstrated lower than expected rates in association with anencephaly when compared to infants and fetuses with birth defects excluding NTDs. Of the 47 specific birth defects, the rates of 10 (21.3%) were higher than expected (anophthalmia/microphthalmia, transposition of great arteries, hypoplastic left heart syndrome, cleft palate, cystic kidney, syndactyly, reduction deformity of upper limbs, reduction deformity of lower limbs, omphalocele, gastroschisis). However none of these elevated rates were statistically significant. Rates that were substantially lower than expected were noted for ventricular septal defect, atrial septal defect, hypospadias and epispadias, and polydactyly.

When the association of structural birth defects among spina bifida cases was examined, the most frequently reported associated defects involved the brain and nervous system, followed by the limb and musculoskeletal system. The rates for defects of these 2 organs systems were higher than expected while the rates for the other organ systems were lower than expected when compared to rates among live births and fetal deaths with structural birth defects excluding NTDs. Sixteen (34.0%) of the specific birth defects had higher than expected rates among spina bifida cases (holoprosencephaly; hydrocephaly; microcephaly; anophthalmia/microphthalmia; single ventricle; tricuspid valve atresia/stenosis; esophageal atresia/tracheoesophageal fistula; small intestinal atresia/stenosis; anal, rectal, or large intestinal atresia/stenosis; renal agenesis/hypoplasia; obstructive genitourinary defect; bladder exstrophy; persistent cloaca; congenital hip dislocation; diaphragmatic hernia; omphalocele). These elevated rates were statistically significant for hydrocephaly; anal, rectal, and large intestinal atresia/stenosis; obstructive genitourinary defect; bladder exstrophy; persistent cloaca; and omphalocele. Substantially lower than expected rates were found for ventricular septal defect, atrial septal defect, and cleft lip with/without cleft palate.

The defects most commonly found in association with encephalocele were brain and nervous system defects, followed by limb and musculoskeletal system defects. The rates were higher than expected when compared to infants and fetuses with structural birth defects excluding NTDs for defects of the brain and nervous system; eye, ear, face, and neck; respiratory system; and orofacial and gastrointestinal system. Fourteen (29.8%) of the specific birth defects were more common in association with encephalocele (holoprosencephaly, hydrocephaly, microcephaly, anophthalmia/microphthalmia, choanal atresia/stenosis, cleft palate, cleft lip with/without cleft palate, cystic kidney, obstructive genitourinary defect, syndactyly, reduction deformity of upper limbs, reduction deformity of lower limbs, diaphragmatic hernia, gastroschisis); however; the elevated risk was only statistically significant for hydrocephaly, microcephaly, cleft palate, cystic kidney, syndactyly, reduction deformity of upper limbs, and reduction deformity of lower limbs. The rate for ventricular septal defect was significantly lower than expected in association with encephalocele.

Discussion

Using data from a population including almost 300,000 live births, this investigation described the association of a variety of specific structural birth defects with different types of NTDs. In particular, this investigation examined whether any of the associations were higher or lower than expected. As a result, this investigation contributes to the limited literature on specific structural birth defects associated with NTDs. Health care providers may use the results of this study to inform parents with an infant or fetus with a NTD what other structural birth defects might be expected in order to assist the parents in making decisions regarding the outcome and management of their infant or fetus. Health care providers may also use the results to decide what diagnostic procedures and/or tests to perform and what types of structural birth defects to look for in order to form as complete an understanding of the condition of the infant or fetus as possible.

Other structural birth defects were present in 27% of the anencephaly cases, 85% of the spina bifida cases, and 63% of the encephalocele cases. Although the rate for anencephaly was within the range reported in the literature, the rate for spina bifida was much higher than the other reported rates and the rate for encephalocele was slightly higher than the highest previously reported rate.²⁻⁹

Table 1.— Distribution of selected structural birth defects among deliveries with neural tube defects (NTDs) compared to deliveries with birth defects excluding NTDs, Hawai'i, 1986-2001.

Diagnosis	Non-NTDs (n = 12,028)		cephaly Spina bifida -111) (n = 130)			Encephalocele (n = 48)	
	Rate	Rate	Ratio ¹	Rate	Ratio ¹	Rate	Ratio ¹
Brain and nervous system defects	6.73	2.70	0.40	69.23	10.28²	39.58	5.88 ²
Holoprosencephaly	0.17	0.00	0.00	0.77	4.41	2.08	11.93
Hydrocephaly	2.32	1.80	0.78	56.92	24.54 ²	14.58	6.29 ²
Microcephaly	2.08	0.90	0.43	3.08	1.48	20.83	10.02 ²
Eye, ear, face, and neck defects	5.97	4.50	0.75	2.31	0.39	12.50	2.09
Anophthalmia/Microphthalmia	0.57	1.80	3.19	0.77	1.36	2.08	3.69
Cataract	0.27	0.00	0.00	0.00	0.00	0.00	0.00
Glaucoma	0.06	0.00	0.00	0.00	0.00	0.00	0.00
Anotia/microtia	0.49	0.00	0.00	0.00	0.00	0.00	0.00
Cardiac/circulatory system defects	40.65	1.80	0.042	11.54	0.28 ²	14.58	0.36 ²
Truncus arteriosus	0.16	0.00	0.00	0.00	0.00	0.00	0.00
Transposition of great arteries	0.89	0.90	1.01	0.77	0.86	0.00	0.00
Tetralogy of Fallot	0.81	0.00	0.00	0.77	0.95	0.00	0.00
Single ventricle	0.17	0.00	0.00	0.77	4.41	0.00	0.00
Ventricular septal defect	9.33	0.00	0.002	1.54	0.16 ²	0.00	0.002
Atrial septal defect	4.36	0.00	0.002	0.77	0.18 ²	4.17	0.96
Endocardial cushion defect	0.28	0.00	0.00	0.00	0.00	0.00	0.00
Pulmonary valve atr/sten	2.00	0.00	0.00	1.54	0.77	0.00	0.00
Tricuspid valve atr/sten	0.36	0.00	0.00	0.77	2.15	0.00	0.00
Ebstein's anomaly	0.09	0.00	0.00	0.00	0.00	0.00	0.00
Aortic valve sten	0.27	0.00	0.00	0.00	0.00	0.00	0.00
Hypoplastic left heart syndrome	0.35	0.90	2.58	0.00	0.00	0.00	0.00
Coarctation of aorta	0.52	0.00	0.00	0.00	0.00	0.00	0.00
Interrupted aortic arch	0.07	0.00	0.00	0.00	0.00	0.00	0.00
Anomalous pulmonary venous	0.31	0.00	0.00	0.00	0.00	0.00	0.00
Respiratory system defects	3.87	0.00	0.00 ²	0.77	0.20	6.25	1.62
Choanal atr/sten	0.28	0.00	0.00	0.00	0.00	2.08	7.37
Orofacial and gastrointestinal system defects	11.87	4.50	0.38 ²	8.46	0.71	16.67	1.40
Cleft palate	1.53	1.80	1.18	0.77	0.50	8.33	5.45 ²
Cleft lip -/+ cleft palate	2.93	2.70	0.92	0.00	0.002	6.25	2.13
Esophageal atr	0.47	0.00	0.00	0.77	1.62	0.00	0.00
Pyloric sten	2.00	0.00	0.00	0.00	0.00	0.00	0.00
Small intestinal atr/sten	0.59	0.00	0.00	1.54	2.61	0.00	0.00
Anal/large intestinal atr/sten	1.11	0.00	0.00	6.15	5.52 ²	0.00	0.00
Hirschsprung's disease	0.54	0.00	0.00	0.00	0.00	0.00	0.00
Biliary atr	0.27	0.00	0.00	0.00	0.00	0.00	0.00
Malrotation of intestines	0.67	0.00	0.00	0.00	0.00	0.00	0.00
Genital and urinary system defects	25.46	1.80	0.072	18.46	0.73	14.58	0.57
Hypospadias and epispadias	6.42	0.00	0.00 ²	2.31	0.36	0.00	0.00
Renal agenesis or hypoplasia	1.01	0.00	0.00	3.08	3.06	0.00	0.00
Cystic kidney	0.96	1.80	1.87	0.77	0.80	6.25	6.48 ²
Obstructive genitourinary def	3.09	0.00	0.00	7.69	2.49 ²	4.17	1.35
Bladder exstrophy	0.05	0.00	0.00	1.54	30.84 ²	0.00	0.00
Persistent cloaca	0.02	0.00	0.00	2.31	138.78 ²	0.00	0.00

Diagnosis	Non-NTDs (n = 12,028)		nencephaly Spina bifida (n = 111) (n = 130)		Encephalocele (n = 48)		
	Rate	Rate	Ratio ¹	Rate	Ratio ¹	Rate	Ratio ¹
Limb and musculoskeletal system defects	27.86	12.61	0.452	40.00	1.44 ²	22.92	0.82
Congenital hip dislocation	2.40	0.00	0.00	3.08	1.28	2.08	0.87
Polydactyly	4.13	0.00	0.00^{2}	0.77	0.19	0.00	0.00
Syndactyly	1.95	3.60	1.85	0.00	0.00	8.33	4.28 ²
Reduction deform upper limbs	0.76	2.70	3.57	0.00	0.00	6.25	8.26 ²
Reduction deform lower limbs	0.32	0.90	2.85	0.00	0.00	6.25	19.78²
Craniosynostosis	1.25	0.00	0.00	0.77	0.62	0.00	0.00
Diaphragmatic hernia	0.53	0.00	0.00	0.77	1.45	2.08	3.92
Omphalocele	0.44	1.80	4.09	3.85	8.73 ²	0.00	0.00
Gastroschisis	0.76	2.70	3.53	0.00	0.00	2.08	2.72
Skin and integument defects	1.41	0.00	0.00	0.00	0.00	0.00	0.00

Ratio of the rate of the defect among deliveries with the NTD to the rate of the defect among deliveries with any major defect excluding NTDs.

Comparisons between the various studies should be made with caution due to differences in inclusion criteria, with some studies including or excluding as cases NTDs associated with chromosomal abnormalities, and completeness of ascertainment of additional birth defects. In addition, the studies may have differed in their definition of associated birth defects. For example, one study excluded lower limb deformities, spinal curvature, vertebral anomalies, Arnold-Chiari malformation, and hydrocephaly, considering these defects to be secondary to the NTD.² If hydrocephaly is excluded from the analysis of spina bifida in the current investigation, then the rate of associated structural birth defects falls to 82/130 or 63%, still higher than the literature. Too much emphasis should not be made on the overall rate of associated structural birth defects because the rates varied widely in the literature.

Of the 47 specific structural birth defects that were examined, 21% occurred more frequently than expected with an encephaly, 34% with spina bifida, and 30% with encephalocele. For anencephaly, those specific defects that had higher than expected rates were mostly limb and musculoskeletal defects. For spina bifida, elevated rates were more likely to occur with specific brain and nervous system defects, gastrointestinal atresia/stenosis, genital and urinary system defects, and limb and musculoskeletal system defects. Most of the elevated rates in association to encephalocele involved specific defects of the brain and nervous system, respiratory system, oral clefts, genital and urinary system, and limb and musculoskeletal system. The only defect that occurred more frequently than expected in all 3 types of NTD was anophthalmia/microphthalmia. Only a few of the specific cardiac and circulatory defects had elevated rates among any of the types of NTD. None of the NTDs were associated with skin and integument defects.

The associations of the specific structural birth defects varied by type of NTD. This observation is consistent with previous studies. ^{2,3,5} Such a finding is not unexpected, considering that the epidemiology of NTDs have been found to depend on the type and location of the NTD. ^{4,10}

The rates of associated birth defects or their patterns between the types of NTDs in the present study were generally similar to those reported in other studies.^{2,3,7,14} However, one study observed anotia/

microtia among 2% of NTD cases;³ in the present study there were no diagnoses of anotia/microtia occurring with NTDs. The same study also found much lower rates of cardiac defects in association with spina bifida and encephalocele. Another investigation reported that 23% of spina bifida cases had congenital hip dislocation,¹⁴ a proportion much higher than the 3% noted in the present study.

One possible explanation for the association of specific structural birth defects with NTDs is differential ascertainment of the defects. Birth defects in general often do not occur in isolation, ¹² and NTDs frequently occur with other defects. ²⁻⁹ So health care providers might be more inclined to check for birth defects in infants and fetuses that have already been diagnosed with one than in those with no known birth defect. However, a number of the specific birth defects included in this investigation are easily identified on even a cursory examination. In addition, for the majority of specific birth defects, their rates were lower than expected among NTDs.

Some of the birth defects may be considered to have occurred as a consequence of the NTD. A number of defects such lower limb deformities, spinal curvature, vertebral anomalies, Arnold-Chiari malformation, and hydrocephaly, are considered to be secondary to the NTD.² However, this explanation is not likely to apply to all of the birth defects with elevated rates among NTDs.

The observed associations between the NTDs and other birth defects could also be a consequence of a common etiology. In a proposed "schisis association" hypothesis, closure defects may be expected to occur together. Some defects such as such as NTDs, oral clefts, diaphragmatic hernia, and omphalocele may be considered to be defects of closure. In the midline developmental field concept, if the formation of the midline field is disrupted, the midline structure might not develop properly. NTDs, oral clefts, cardiac defects, diaphragmatic hernia, abdominal wall defects, and genitourinary defects are defects affecting midline structures. This investigation does suggest that some closure or midline defects such as oral clefts, diaphragmatic hernia, abdominal wall defects, and genital and urinary defects occurred more frequently with NTDs. However, cardiac and circulatory defects were found at lower than expected rates among NTDs.

²Rate ratio is statistically significant, i.e., 95% confidence interval does not include 1.00.

A delivery with more than one structural birth defect will be included in all relevant categories.

Several factors should be taken into account when evaluating the results of this study. The number of cases was somewhat small, and many of the elevated rates for specific birth defects were based on one or a few cases. This limited the statistical significance of the findings and often resulted in wide 95% CIs. However, a number of statistically significant differences were observed. Some results of statistical significance are expected to occur by chance. When calculating 95% CIs, 5% might be expected to be statistically significant by chance. Of the 165 analyses for statistically significance performed in this investigation, 8 would be expected to be statistically significant by chance. However, 31 (19%) of the analyses were statistically significant. Thus a portion of these are not expected to be due to chance. Further investigations using large numbers of cases would be useful to verify the results of this study.

Additionally, a portion of NTD cases are electively terminated.¹⁷ It might be expected that the evaluation of birth defects among fetuses that are electively terminated might be less thorough than for fetuses that are live born. As a result some birth defects among electively terminated cases might be missed. In fact, in a previous investigation, the authors found that the rate of additional birth defects was lower among NTDs in fetal deaths and elective terminations than in live births.¹⁸ Thus the rates for associated birth defects found in this study should be lower limits.

In summary, this study observed that some structural birth defects occurred more frequently in association with NTDs than might be expected. The birth defects associated with NTDs varied with the type of NTD.

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Teaching Medical Professionalism: A Pilot Curriculum for Imi Hoʻola Post-Baccalaureate Students at the University of Hawaiʻi John A. Burns School of Medicine

Winona Mesiona Lee MD, Assistant Professor, and Nanette Judd MPH, PhD, Director Imi Hoʻola Post-Baccalaureate Program, Dept of Native Hawaiian Health, John A. Burns School of Medicine, University of Hawaii

Scope of the Problem

Professionalism is a priority for medical educators who strive to produce competent and caring physicians. Research suggests that professional deficiencies noted in medical school are associated with subsequent disciplinary action by state medical boards. Predictive medical student traits for future unprofessional behavior include low academic achievement, severe irresponsibility, and diminished capacity for self-improvement. Early detection and intervention of these problematic behaviors may lead to effective methods to properly address unprofessional behavior in these prospective physicians.

The Hippocratic Oath speaks of the importance of professional standards—scholarship, altruism, and confidentiality. Physicians take this oath and make a binding commitment to use their knowledge and skills to respond to and improve the welfare of patients.³ Currently, the Association of American Medical Colleges (AAMC), the Accreditation Council for Graduate Medical Education (ACGME), the American Board of Internal Medicine (ABIM), and the American College of Physicians (ACP) are leading initiatives to uphold professionalism as a core competency in medicine.⁴ A report of the joint conference of the AAMC and NBME (National Board of Medical Examiners) identified altruism, accountability, excellence, duty, honor and integrity, and respect as desirable professional behaviors in medicine.⁵

Professionalism Prioritized in the Student Development Plan

Anecdotal evidence regarding the professional behavior of Imi Ho'ola Post-Baccalaureate JABSOM students prompted the development of a curriculum to imbue students with the saliency of medical professionalism. The Imi Ho'ola Post-Baccalaureate Program provides educational opportunities to students from socially, educationally, and/or financially disadvantaged backgrounds who display potential in their ability to become physicians. These students also express a commitment to serve in areas of need in Hawai'i and the Pacific. The one-year curriculum emphasizes the importance of developing students' communication and learning skills while improving their knowledge base in the areas of basic science and humanities. To maximize students' success, the program provides support in seven areas: 1) Academics, 2) Advising, 3) Research, 4) Counseling, 5) Financial Advising, 6) Mentoring and, 7) Professionalism. Faculty members serve as consultants in each area to develop curricula and training initiatives. In addition, a committee consisting of faculty members offers guidance and direction on policies and procedures related to professionalism.

Needs Assessment

A formal needs assessment of Imi Ho'ola faculty members reveals that prominent and common concerns regarding Imi Ho'ola students are issues of accountability and responsibility, honor and integrity, and leadership. Faculty believe that potential methods that would be helpful in both monitoring and improving students' professional behaviors include timely verbal feedback to the student, faculty mid-semester and end-semester written evaluations, and the use of Praise/Early Concern cards. These cards were developed by the American Board of Internal Medicine's Project Professionalism and serve two purposes: to facilitate discussion between student and faculty member regarding observed behaviors; and to provide written documentation that can be used to track a student's progress.⁶ The Imi Ho'ola faculty members felt comfortable in their knowledge of professionalism and assessment of professional behaviors in the students. They agreed that Imi Ho'ola's current policies and procedures allow faculty members to formally address students' deficiencies related to professionalism.

Curriculum

The goals for Imi Hoʻola students involved in the curriculum related to professionalism are: 1) To learn the importance of professionalism in medicine, 2) To learn the elements of professionalism according to the AAMC, 3) To recognize existing challenges to professionalism, 4) To apply the elements of professionalism to potential medical/ethical scenarios and, 5) To recognize and reflect on the elements of professionalism as students and as future physicians.

Seminars are conducted throughout the year during all phases of the program. The seminar series begins with an introduction to the elements of professionalism. It is led by faculty members who provide personal perspectives as well as facilitate student discussion based on hypothetical scenarios. Scenario-based discussions and the use of student role-play are utilized. Issues in professionalism are integrated within the health care problems used in the problem-based learning tutorials. Student discussion is encouraged. Self-reflection is introduced as a powerful learning tool and is used by the students throughout the year to assist them to identify the impact of professionalism on a personal level. The students end the year by completing a written statement on professionalism based on their observations during a community shadowing experience with physicians who serve rural areas in Hawai'i. This statement is then reviewed with a faculty member to promote further reflection.

Evaluation Methods

Written feedback from students for each seminar as well as a survey of student knowledge, attitudes, and beliefs are conducted. Preliminary feedback has been positive. Students have commented that the use of scenarios and role-playing helped to facilitate the sharing of ideas and highlighted the importance of professionalism in medicine.

The professionalism committee's future goals are to 1) Examine the effectiveness of various student evaluation methods, 2) Develop a remediation protocol to provide feedback and monitor students with deficiencies related to professionalism and, 3) Promote faculty development related to professionalism.

Conclusion

It is anticipated that the Imi Hoʻola professionalism pilot curriculum will be a model for other Post-Baccalaureate programs and can serve as a foundation for students to learn about professionalism as they transition through their four years of medical school.

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Involving Hawai'i's Youth as Partners in Global Health Initiatives to Impact Change at the Local Level

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Introduction

Tobacco-related diseases including lung cancer and heart disease continue to be the most preventable causes of death in the United States.¹ Involving young people in tobacco control through leadership development and advocacy is proven to be an effective strategy in reducing tobacco rates at local and national levels.²-8 Given that close to 50% of the world's population is under 30 years old,9 it is logical to include young people in tobacco control and prevention initiatives that impact their generation. Involving youth to actively engage as key stakeholders and decision makers is now being recommended at the global level as a successful strategy to address many different health and social issues that affect this generation.¹0 Also, participation in larger national and global health initiatives can impact state and local health and social issues (Figure 1) because it provides the opportunity to adopt new and innovative strategies from the experience of other states and countries.

REAL: Hawai'i Youth Movement Exposing the Tobacco Industry is a statewide youth-led anti-tobacco campaign for youth ages 13-20 years old. REAL focuses on empowering this generation of young people to stand up to tobacco industry marketing through environmental prevention initiatives and policy change. This article describes the experience of Hawai'i youth who participated in two significant global events that allowed them to develop more advocacy skills, broaden their perspective on health issues, and further youth empowerment and advocacy in Hawai'i.

Global Youth Advocacy Training

In July 2006, two young people from REAL were accepted to participate in the Global Youth Advocacy Training (GYAT) and World Conference on Tobacco Control (WCTC) in Washington, D.C. (Table 1). GYAT was the first international conference designed to train young people who are involved in tobacco control in their home countries. A total of 100 young people between the ages of 13-30 from 35 countries participated. The purpose was to teach participants about international tobacco issues and how to engage in advocacy that was specifically targeted to increase the restrictions on tobacco industry sales and marketing. During the three-day GYAT, young people received intensive training in tobacco industry marketing practices, global measures for tobacco control, youth advocacy, media advocacy and outreach, and mobilization techniques. These activities resulted in the development of a series of activism events including a march through Washington, D.C., to protest the Motion Picture Association's portrayal of smoking in Hollywood movies, to enforce stronger tobacco trade policies by the United States Trade Commission, and to ask for the US ratification of the Framework Convention on Tobacco Control (FCTC) at the White House. Youth also organized a street rally outside of a nightclub where a tobacco

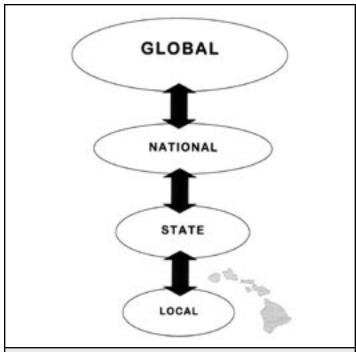


Figure 1.— Involving Youth in Multi-Level Social Norms Change

Table 1.— Summary of Global Health Advocacy Events							
EVENT	Global Youth Advocay Training (GYAT)	Global Youth Meet on Health (GYM)					
PARTICIPANTS	100 (ages 13 - 30)	200 (ages 13 -24)					
COUNTRIES REPRESENTED	35	33					
LOCATION	Washington, DC	Agra, India					
TOPICS COVERED	Tobacco Industry Marketing Practices Global Measures of Tobacco Control Youth Advocacy and Mobilization Media Advocacy	Tobacco, Drug, and Alcohol Addiction Reproductive Health and HIV Prevention Nutrition and Physical Activity Road Safety Conflict Resolution					
ACTIVITIES	3 Day Interactive Advocacy Training Organize Tobacco Control March to: U.S. White House, U.S. Trade Commision, and Motion Picture Association Media Outreach and Interviews Networking Speak in sessions at the World Conference on Tobacco Control.	5 Day Intensive Training Informational Presentations and Forums Meeting with Key Decision Makers: World Health Organization (WHO), Prime Minister of India Drafted a Global Health Charter Media Interviews Networking					

industry-sponsored hip hop concert was taking place during the WCTC. GYAT Youth Participants' contributions to the WCTC included presentation on youth advocacy and counter-marketing initiatives as well as leading the conference's closing ceremony and call to action. For more information on GYAT, please visit the Website at: http://www.gyatnetwork.org/.

Global Youth Meet on Health

Based on the contributions of Hawai'i's two youth participants at the above event, both were recruited for participation in the Global Youth Health Meeting in New Delhi, India. In November 2006 the same two young people from REAL were part of a team of five US youth representatives for the first Global Youth Meet on Health (GYM) event in New Delhi, India. More than 200 young people between the ages of 13-24 from around the world participated representing 33 countries (Table 1). Many youth participants were actively engaged in health promotion in their home countries. During the five-day training youth discussed a broad range of global health issues that affect their generation, including: tobacco, alcohol and drug addiction, reproductive health and HIV prevention, nutrition and physical activity, road safety, and conflict resolution. Youth were then asked to identify potential public health strategies and draft a global health charter that all participants agreed to work toward in their home countries. They also had opportunities to meet with key decision makers including the Prime Minister of India and World Health Organization representatives. Additionally, youth gave media interviews about youth involvement in health promotion. Hawai'i's two representatives played a crucial role during the tobacco prevention portion of the training and in drafting the tobacco control section of the health charter because of their expertise in tobacco control. For more information on GYM, please see the website at http://www.hriday shan.org/hriday/gym.html.

Impact of Participation

As a result of participation in GYAT and GYM, Hawai'i's young people gained an understanding of the national and global efforts currently underway to address specific health issues. They also returned to Hawaii with a better understanding of the importance and impact of their involvement in addressing health and social issues that affect their peers, particularly in the development of strategies that will resonate with their generation. Youth also came back with increased enthusiasm, motivation, and skills to mobilize their peers to successfully defend Hawaii's statewide smoke free workplaces law. They helped to implement new local prevention efforts including counter-marketing and environmental prevention projects and served as peer trainers at advocacy events and youth trainings where they disseminated newly acquired information about youth advocacy and global health issues to other REAL members statewide. They also became active members in the GYAT and GYM Advocacy Networks to share their experiences from local advocacy work.

Recommendations

Young people continue to be one of the strongest resources that public health professionals have in order to identify and understand effective strategies and messages that will reach their generation. It is critical that young people are involved as partners with key stakeholders, community representatives, and government agencies

to represent the views of peers and affect social norms change. In order to address health and social issues that affect young people, communities must continue to engage them as partners and leaders for social norms change at the local, state, national, and global levels. This includes providing ongoing opportunities for training and acquisition of new skills in order for them to become stronger advocates for health promotion. Participation in national and global training and initiatives must be followed up with local opportunities such as programs, youth advocacy networks, and community organizations where youth can utilize their skills and implement their vision. Young people will bring to these endeavors a greater understanding of the big picture and, importantly, an energy and optimism of how they can create change in their communities.

Acknowledgement

Support for youth participation in GYAT and GYM was provided by the Cancer Research Center of Hawai'i at the University of Hawai'i and The Master Tobacco Settlement Trust Fund through Hawai'i Community Foundation. We would like to offer special acknowledgement of REAL's Statewide Youth Leaders, Denise Della and Tyson Suzuki, who served as youth participants at the GYAT and GYM. For further information about REAL: Hawaii Youth Movement Exposing the Tobacco Industry, please see the Website: www.therealmessage.net.

For more information about the Cancer Research Center of Hawaii, please visit the Website at www.crch.org.

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Youth Delegates Tyson Suzuki (left) and Denise Della (middle) with REAL Project Director Nicole Sutton (right) at the Global Youth Meet on Health in India.

Issues in Medical Malpractice XV

S.Y. Tan MD, JD, Professor of Medicine, John A. Burns School of Medicine, University of Hawai'i

Question: As an internist with a large practice, you own your own X-ray machine, and regularly obtain and interpret your patients' X-rays instead of having a radiologist read them. Assume that the community standard is for radiologists rather than internists to read X-rays. What level of accuracy or standard of care will you be held to?

- A. Other general internists.
- B. Board-certified radiologist.
- C. Non board-certified radiologist.
- D. A standard between a radiologist and a general internist.
- E. An X-ray technician whose expertise in the field of radiology is similar to yours.

Answer: B and C are correct

Every doctor is held to the standard of his/her specialty. However, if one assumes the duties of another specialty, the law will consider you as holding yourself out as one who is capable of functioning at that level. In the above case, if internists do not regularly read their own X-rays and you, an internist, choose to do so, you will be held to the standard of a radiologist. The standard expected of a radiologist, however, is not dependent on board-certification.

Standard of Care

The legal duty owed by doctors to their patients is that of reasonable care. What is this standard? It is similar in both American¹ and English² law. The American standard is best taken from Prosser's Textbook on Torts:

"The formula under which this usually is put to the jury is that the doctor must have and use the knowledge, skill and care ordinarily possessed and employed by members of the profession in good standing . . ."

The British standard was articulated in 1957 in the **Bolam** case:

"...the question to be asked when determining medical negligence is whether a doctor, in acting in the way he did, was acting in accordance with the practice of a competent, respected professional." 3

It has long been recognized that the average layperson was incapable of judging what the acceptable level of medical care ought to be. The law therefore, has taken the position that the standard is that level of care expected of the reasonably competent doctor, rather than the reasonably prudent person. Alabama, for example, has held that physicians must "exercise such reasonable care, diligence, and skill as reasonably competent physicians" would exercise in the same or similar circumstances.⁴

An Illinois court used similar words:

"[a] physician must possess and apply the knowledge, skill, and care of a reasonably well-qualified physician in the relevant medical community."⁵

In legal proceedings addressing the standard of care, the doctor is judged according to his or her specialty. A general practitioner (GP) will not be held to the same standard of care as a specialist. The surgeon will be judged according to the community standard of the ordinarily skilled surgeon, and the GP to that of his fellow GPs. But there is a separate duty to refer to a specialist if the case is outside the doctor's field of expertise. If the standard of care is to refer to a specialist, the GP who undertakes to treat the patient within that specialty will be held to that higher standard. In <u>Simpson v. Davis</u>, ⁶ a general dentist performed root canal work and was therefore held to the standard of an endodontist.

Inexperience is not a defense. This seems particularly harsh to the trainee who cannot be expected to perform at the level of a fully trained or experienced practitioner. Yet, the trend is to hold medical trainees to the same standard as a qualified doctor in that specialty.

Finally, terms such as "error in judgment" and "best judgment" tend to confuse the jury, and courts including the Hawai'i Supreme Court have re-emphasized the objective reasonableness standard against which medical negligence is to be measured. In Hawai'i,

"...the question of negligence must be decided by reference to relevant medical standards of care for which the plaintiff carries the burden of proving through expert medical testimony."8

This article is meant to be educational and does not constitute medical, ethical, or legal advice. It is excerpted from the author's book, "Medical Malpractice: Understanding the Law, Managing the Risk" published in 2006 by World Scientific Publishing Co., and available at Amazon.com. You may contact the author, S.Y. Tan MD, JD, at email: siang@hawaii.edu or call (808) 728-9784 for more information.

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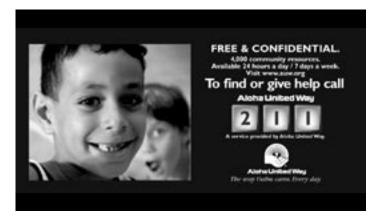
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Date	Specialty	Sponsor	Location	Meeting Topic	Contact
October 2007					
10/6-10/12	PD	University Children's Medical	Hyatt Regency Maui Resort,	"Aloha Update" Pediatrics 2007	Tel: (800) 354-3263
		Group	Maui		Web: www.ucmg.org/cme.html
10/7-10/11	Multi	Ironman Triathlon World Championship	Royal Kona Resort, Kailua-Kona, Big Island, Hawai'i	18th Annual Official Ironman Sports Medicine Conference	Tel: (877) 843-8500
10/10-10/13	OMF	American Association of Oral and Maxillofacial Surgeons (AAOMS)	Hawai'i Convention Center, Honolulu	89th Annual Meeting & Scientific Sessions	Tel: (847) 678-6200 Web: www.aaoms.org
10/16-10/20	Multi	American Society for Bone and Mineral Research	Hawai'i Convention Center, Honolulu	29th Annual Meeting	Tel: (202) 367-1161 Web: www.asbmr.org
10/17-10/19	Multi	University of California - Davis	Waikoloa Beach Resort & Spa, Hawai'i	27th Annual Current Concepts in Primary Care Cardiology	Tel: (916) 734-5390
			riawari	Timary care cardiology	Web: cme.ucdavis.edu
10/18-10/20	GE	Stanford Hospital & Clinics	Mauna Lani Bay Resort, Kohala Coast	GI Cancers	Tel: (650) 724-7166
			Noticial Godst		Web: www.cme.stanfordhospital.
10/19-10/21	Multi	Guam Memorial Hospital	Hyatt Regency, Guam	3rd Micronesian Medical Symposium	Tel: (671) 647-2349
				Symposium	Web: www.micronesianmedical- symposium.org
10/20-10/24	ORS	Orthopaedic Research Society	Hawai'i Convention Center, Honolulu	6th Combined Meeting of the Orthopaedic Research Societies	Tel: (847) 698-1625
10/00 10/07	CVAL	Maria Olinia Callana af	Lhiett Dananai, Mari	Ooth Annual Techniques in	Web: www.ors.org
10/22-10/27	GYN	Mayo Clinic College of Continuing Medical Education	Hyatt Regency, Maui	20th Annual Techniques in Advanced Gynecologic, Endoscopic & Laparoscopic Surgery	Tel: (480) 301-4580 Web: www.mayo.edu/cme/
10/28-11/2	R	University of California, San Francisco	Hyatt Regency Resort & Spa, Maui	Diagnostic Radiology Seminar	Tel: (415) 476-5808
10/29-10/31	Multi	AIDS Education Project John	Palace Hotel, Guam	Pacific HIV/AIDS Training	Web: www.cme.ucsf.edu
10/29-10/31	Multi	AIDS Education Project, John A. Burns School of Medicine, University of Hawai'i	Falace notel, dualii	Conference	Tel: (808) 441-1586 Web: www.hawaii.edu/ hivandaids/index.htm
10/29-11/2	AN	California Society of Anesthesiologists	Grand Hyatt Kaua'i Resort and Spa, Poipu Beach, Kaua'i	CSA Hawaiian Seminar	mvandads/mdex.mm
					Web: www.csahq.org
November 200)7			,	,
11/8-11/10	Multi	Mayo Clinic College of Continuing Medical Education	Grand Hyatt Kauai Resort & Spa, Koloa, Hawai'i	Parkinson's Disease and Other Movement Disorders for the Practitioner, 2007	Tel: (480) 301-4580 Web: www.mayo.edu/cme/
11/9	Multi	Hawai'i Society of Addiction Medicine	ТВА	Addiction Medicine: Perspectives and Practicalities	Tel: (808) 327-4848
11/9	Multi	Pu'ulu Lapa'au	Kapiolani Medical Center for Women and Children	The Disruptive Physician	Tel: (808) 678-1581
11/9	Multi	Telehealth Research Institute, John A. Burns School of Medicine, University of Hawai'i	JABSOM Telehealth Research Institute	Crisis Team Training	Tel: (808) 692-1093
11/10-11/13	Multi	American Medical Association	Hawai'i Convention Center, Honolulu	AMA Interim Meeting	Web: http://www.ama-assn.org/
January 2008					
1/13-1/18	R	University of California, San Francisco	The Fairmont Orchid, Kona	Breast Imaging in Paradise	Tel: (415) 476-5808
		Sall Flaticisco			Web: www.cme.ucsf.edu

1/19-1/21	Multi	Pan-Pacific Surgical Association	Sheraton Waikiki, Honolulu	28th Annual Congress:	Tel: (808) 941-1010
				Connecting Surgeons Throughout the Pacific	Web: www.panpacificsurgical.
1/20-1/25	R	University of California, San Francisco	The Fairmont Orchid, Kona	Body Imaging in Paradise	Tel: (415) 476-5808
					Web: www.cme.ucsf.edu
1/21-1/25	AN	California Society of Anesthesiologists	Hyatt Regency Maui Resort & Spa, Ka'anapali Beach, Maui	CSA Hawaiian Seminar	Web: www.csahq.org
February 2008	3				
2/6-2/9	Multi	Society of Laparoendoscopic Surgeons	Hilton Hawaiian Village, Honolulu	Asian-American MultiSpecialty Summit III: Laparoscopy and Minimally Invasive Surgery	Tel: (800) 872-1119
2/9-2/15	OBG	Keck School of Medicine of USC	West Maui, Maui	Perinatal Medicine 2008	Tel: (800) 872-1119
2/16-2/19	OTO, HNS	Tripler Army Medical Center and the University of California,	Hilton Hawaiian Village, Honolulu	Pacific Rim Otolaryngology - Head and Neck Surgery Update	Tel: (415) 476-5808
2/17-2/22	R	San Francisco University of California,	The Fairmont Orchid, Kona	Neuro and Musculoskeletal	Web: www.cme.ucsf.edu Tel: (415) 476-5808
2/17-2/22	n	San Francisco	The Fairmont Orchid, Rona	Imaging	Web: www.cme.ucsf.edu
2/17-2/22	IM	University of California,	Grand Hyatt, Kaua'i	Infectious Diseases in Clinical	Tel: (415) 476-5808
		San Francisco		Practice	Web: www.cme.ucsf.edu
2/21-2/26	GE	Keck School of Medicine of USC	Kaua'i Marriottt Resort, Kaua'i	Medical and Surgical Aspects of Esophageal and Foregut Disorders: Pathiophysiology and Treatment	Tel: (800) 872-1119
March 2008		•		,	
3/30-4/4	IM	University of California, San Francisco	Wailea Beach Mariott Resort & Spa, Wailea, Maui	Primary Care Medicine: Update 2008	Tel: (415) 476-5808
					Web: www.cme.ucsf.edu
May 2008	T	T	T	T	T T
5/2-5/6	PD	Pediatric Academic Societies	TBA	Annual Meeting 2008	Tel: (281) 419-0052
					Web: www.pas-meeting.org
June 2008					
6/22-6/26	Multi	University of California - Davis	Hapuna Beach Prince Hotel, Kohala Coast	Update on the Management of Thromboembolic Disorders	Tel: (916) 734-5390
					Web: cme.ucdavis.edu
August 2008					
8/4-8/7	R	Stanford University School of Medicine	Grand Hyatt, Kauaʻi	LAVA: Latest Advances in Interventional Techniques	Tel: (888) 556-2230
				<u> </u>	Web: med.stanford.edu
October 2008					
10/27-10/31	AN	California Society of Anesthesiologists	The Mauna Lani Bay Hotel, Kohala Coast, Hawai'i	CSA Hawaiian Seminar	
		, allocationologists			Web: www.csahq.org



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Russell T. Stodd MD

♦ PATCHES? WE DON'T NEED NO STINKING PATCHES!

At Nottingham University in the United Kingdom, scientists are researching the problem of amblyopia. Typically, therapy involves patching the better eye to stimulate the neural connections in the amblyopic eye, and to encourage the eyes to work together. At Nottingham, experimental treatment revolves around using virtual reality (VR) computer games to create a three dimensional environment. In a VR driving experiment the computer sends images of one's own car to the bad eye, and images of other cars to the fellow eye. Obstacles on the track are sent alternately to both eyes so that the viewer

must combine the images to get through the game. According to the research team the game produced in one hour the same visual level obtained with 400 hours of patching. The technique has not been proven with rigorous peer-reviewed trials, but initial results show remarkable progress.

❖ AT B&L THE LIGHT AT THE END OF THE TUNNEL IS A BOTTLE OF CHAMPAGNE.

Who would have thought just a few months ago when Bausch and Lomb Inc.(B&L) was mired in the frightening findings of contaminated eye solutions that the company would be the sweetheart in a competitive auction? Just a month ago B&L had settled on a deal to sell out to Warburg Pincus, a private investment firm, for \$3.67 billion. The deal included a 50-day option period and before the door closed, Advanced Medical Optics Inc. (AMO) jumped in with a considerably better number of \$4.23 billion. This is a weird picture for two reasons. First, both B&L and AMO have had some serious contamination and infection problems with significant legal vulnerability. And second, in the world of big-time private equity, gentlemen simply do not jump on one another's signed deals. So, at this time B&L stock which had dropped to \$41/share has moved back up, and the Warburg Pincus offer is at \$65/share and the AMO ticket is \$75/share. For B&L shareholders some contaminated eye drops aren't really such a bad thing.

\diamondsuit to see a man at his worst, watch what he does in the name of God.

In Bakersfield, Calif., a woman brought her little girl with an ear infection to a pediatrician. The doctor, Gary Merrill, M.D., refused to care for the child because the mother has tattoos. He based his behavior on the teachings of Christ (?) and has a sign on the office wall, "This a private office. Appearance and behavior standards apply." That means no tattoos, body piercings, and a host of other requirements, all standards according to Merrill, based upon his Christian faith. The child had to wait until the following day before another physician was found. The American Medical Association backed up the doctor (sort of) stating that the doctor has a private office and has the right to refuse any patient. It doesn't take an authority on Christianity to know that this doctor has his head up you-know-where. If a doctor chooses to be a bigot, don't blame Jesus.

TECHNOLOGY IS MAKING OUR CARS SMARTER THAN WE ARE.

Mobileye Advanced Warning System - 4000 is a windshield mounted camera using cutting edge automotive safety technology. It can give the driver night vision, provide alerts when drifting out of the proper lane and/or when moving too close to other objects. It can even make the steering wheel vibrate if it senses a dangerous situation. Moreover, it will nag the driver for failing to use turn indicators. The downside is it cannot function in dense fog or snow (it will notify and deactivate), and with all the bells, beeps and chirps the motorist may become so annoyed, he/she might turn it off. BMW, Cadillac, Infiniti, and Buick offer the options at somewhere between \$1100 and \$2000, depending on variables. Technocrats have still not solved the difficulty with the loose nut at the end of the steering column.

❖ IF SOMETIMES YOU FEEL LIKE A NUT, HEY, GO FOR IT!

Typically, dieticians and some gastro-enterologists have advised patients with diverticular disease to avoid seeds, nuts, popcorn, and other indigestible fiber. It was suspected that these elements would lodge in diverticula and set up inflammation and infection. A study done at the University of Washington in Seattle combined with data from a number of Boston hospitals found the exact opposite to be true. Researchers studied a cohort of 47,228 men ranging in age from 40 and 75 years who participated in the study, and were free of disease in 1986. With follow up every two years for 18 years, the occurrence of inflammatory bowel disease was not increased, but actually decreased by 28% in those men who ate popcorn at least twice a week, and 20% in men who regularly consumed nuts.

❖ STATISTICS THAT MAKE SENSE - EVEN TO THE DOCTOR.

In the world of medical therapy there is a new number called the NNT which translates to *number needed to treat* to prevent one adverse outcome. Many people derive little or no benefit from their medication, but they are never told that. For example, if 67 men take cholesterol-lowering statins for 5 years, one will benefit and the other 66 will not. The NNT is 67, and will have cost about \$5,000, so if patients understood that risk, they might decide to refuse to take the drug. For patients with a bladder infection where three days of antibiotics will cure one out of two the NNT is 2. No question, take the medication. And on the opposite side of the therapy issue is the NNH, which is the *number needed to harm*, which should be introduced in various surgical or other interventions. With the NNH a small number is frightening, a large one reassuring. The point of the NNT and the NNH is to help patients (and the doctor) recognize what is the possible benefit, what is the ball-park cost figure, and what are the risks or side effects.

AGAINST STUPIDITY THE GODS THEMSELVES FIGHT IN VAIN.

In Palm Springs, Calif., a 65-year-old-man was angry because the *Desert Sun* newspaper did not have the coupons he wanted. He phoned the paper to complain, and was told that the coupons would be sent the next day. The coupons were delivered, but he was still not satisfied and phoned the paper again and said "What do I have to do? Come down there and blow up the building?" The newspaper management phoned the police. A search was conducted at the newspaper with dogs sniffing for explosives (negative), and the man was jailed for issuing a terrorist threat. Bail was set at \$25,000. Only idiots joke about bombs these days.

❖ A NEW DIRECTION FOR MAKE LOVE, NOT WAR!

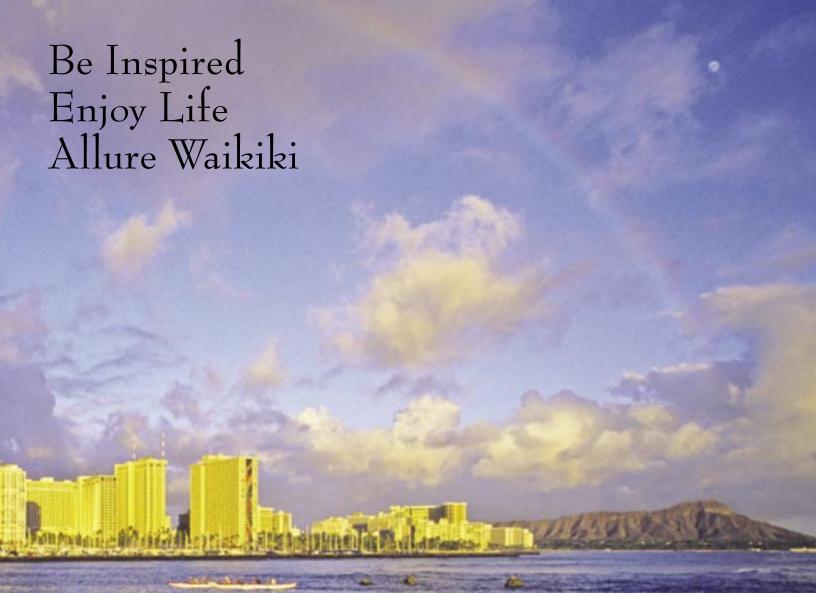
Study done under the sunshine project in the *Freedom of Information Act*, revealed that in 1994 the US Air Force was considering a plan to develop a "gay bomb." The proposal would include a powerful aphrodisiac hormone that would make enemy troops irresistible to one another. The "love bomb" would cause widespread "disgusting but non-lethal" homosexual activity disrupting morale and discipline. This \$7.5 million absurdity was not pursued. I couldn't make this up!

ADDENDA

- The world's oldest intact condom, made from pig intestine, was found in Lund, Sweden. Dating from 1640, the condom came with an instruction manual written in Latin, and is presently on exhibit in an Austrian museum.
- ❖ If pro is the opposite of con, is progress the opposite of Congress?
- ❖ Why doesn't Michael Moore do a documentary on obesity?
- Volkswagen and Energizer have merged to make a battery-operated car, the Bugs Bunny.

ALOHA AND KEEP THE FAITH — rts■

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