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"Poliahu"

Depicting the Hawaiian snow goddess of myth and legend.

HE MANA'O: THOUGHTS FROM THE EDITOR OUR CALLING AND ORGANIZED MEDICINE

know that while the

reward is great, so is

Kalaupapa. I have

a home here (yes,

truly a home), and

stay overnight at least

once almost every week. My trips here

involve a plane ride

of only 50 miles, and

yet it seems I travel

back 50 years, to a

time more simple,

I write this from

the cost.

For the past two years, I have been one of many interviewers for applicants to our University of Hawai'i John A. Burns School of Medicine. Based on the majority of interviews I conduct, I am pleased that our calling will be in good hands in the future. The applicants are generally exceptionally bright. However, as you may remember from your own calling, they also possess the commitment to enter a highly demanding life of serving, intimately tied with the patients they treat, willing to become mentors in maximizing quality of life for our fellow humans. They



S. Kalani Brady MD, MPH, FACP Editor, Hawaiʻi Medical Journal

more peaceful, than that which confronts most of us in the twenty-first century (as some of you may reminisce about your own past, when the hospital here needs me, a messenger is sent to my cottage: pagers and cell phones don't work here). By Hawai'i Revised Statutes and (more importantly) the edict of the patients, I am considered a resident of Kalawao County, and am provided a house (nay, a home) here in the community. I am honored that the patients consider me one of their own. A film crew from Australia recently returned to Kalaupapa to record footage of the Hansen's Disease patients, and many told them that they should interview the resident doctor. The production assistant came to my cottage several times a day for a couple of days before I returned to the settlement, and assumed that, like some of the patients, I was simply avoiding being filmed. Because many of the patients lead dual lives in Kalaupapa and Honolulu, it never occurred to the patients to mention to the film crew that although I was a resident, I spend most of my time in Honolulu. I cannot imagine a life more fulfilling in trust, respect, and intimacy than the one I have with the community here. These are the rewards I sought when I strove for a life as a physician.

And yet, I would not be able to care for these precious souls alone without my two colleagues, Drs. Martina Kamaka and Peter Donnelly (whose brother was my high school classmate at St. Louis). The demands of medicine in our day require more than ever the reliance on a team to optimize the health of the patients we serve. And yet the benefit is not only to our patients, but to ourselves.

As I mentioned at the first, the demands of our calling are great: at times, even overwhelming! Though I may be "preaching to the choir", I implore you to take advantage of your colleagues. In this era of exceptional stress upon physicians, it is appropriate now more than ever to rely on the collegiality of organized medicine, and join in membership. It provides a forum for maximizing the benefits to our patients in the legislature and other governing bodies when we are too busy seeing individuals one after the other to address the greater impact. It provides the opportunity to continue our own medical education so that we may offer our patients the best advances in medical care. It gives us the camaraderie of like-minded healers trying to make an impact on the health of those we serve. And for a few of us, there is a committee which seeks to rescue us from the burn-out of the excessive demands of our work which has placed our own health in jeopardy, and offer us a path back to our own health.

Organized medicine brings me back to the beginning of my column. In addition to being involved in the Hawai'i Medical Association and the Honolulu County Medical Society for twenty years, I am a member of the Council of the Hawai'i Chapter of the American College of Physicians, my specialty society. Last year, the Hawai'i Medical Association honored Edwin C. Cadman, former Dean of the John A. Burns School of Medicine, as Physician of the Year. This year, his specialty society names him Laureate of the American College of Physicians on Saturday, March 4th at the Hawai'i Prince Hotel. Dean Cadman, a unique visionary, has set the course for Hawai'i's School of Medicine for the next decade. He has transformed a school with a mandate to create the next generation of Hawai'i's doctors into a strong research institution with a mandate to improve the health of Hawai'i and the Pacific through solid research. The students drawn to medicine and our school in particular will carry the burden and privilege of caring for our next generation. They will create their medical foundation at an institution much more robust than a decade ago. Let us laud Ed Cadman for the gift he has given us in shaping our future!

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🐨 COMMENTARY

"SEARCH for Diabetes in Youth" By Sharla Montvel-Cohen

he Honolulu-based Pacific Health Research Institute (PHRI) has been awarded \$3 million to complete Phase II of the Hawai'i component of a nationwide study on diabetes in children.

The study, "SEARCH for Diabetes in Youth," started in 2000 and is the first population-based study in the United States that is assessing the burden of diabetes in youth of all major race/ethnicities. SEARCH is funded by the Centers for Disease Control with support from the National Institutes of Health and the National Institute of Diabetes & Digestive & Kidney Diseases. PHRI is leading the SEARCH study to understand diabetes in Hawai'i's youth through collaboration with HMSA, Kaiser and Med-Quest.

"With diabetes increasing at unprecedented rates among adults both in the United States and throughout the world, initial reports suggest a rise globally in Type 2 diabetes among children and adolescents," said Beatriz L. Rodriguez, MD, PhD, who is the principal investigator of the PHRI and a professor at the University of Hawai'i John A. Burns School of Medicine.

"An increase in Type 2 diabetes in young people means that we are going to have more people – children and adults – with diabetes and they will have it for a longer time, which increases the rate of severe complications like blindness, renal failure and amputations," she explain. "The SEARCH study is helping us to increase our understanding of this disease, and may help us find ways to increase prevention and provide better treatment."

Dr. Rodriquez said that almost 16 million people in America are now estimated to have diabetes. It is the third most common severe chronic disease of childhood and, based on SEARCH findings, she said researchers estimate there are about 154,000 children with diabetes in the United States.

"In the State of Hawai'i, there are approximately 50 new cases of diabetes each year."

During Phase I of the SEARCH study in Hawai'i, the most common form of diabetes in youth was found to be Type 1A autoimmune diabetes, in which the immune system attacks cells in the pancreas that produce insulin and destroys them. This finding was consistent with national results. In addition, SEARCH found that Type 2 diabetes—in which the body cannot use insulin well (a condition called insulin resistance)—occurs very rarely under the age of 10. Type 2 diabetes was found in youth of all race/ethnicities, but was more common in ethnic minorities including Asian/Pacific Islanders. Ninety percent of the children with Type 2 diabetes were overweight.

In children and youth (10-19 years) about 1 in 750 Asian/Pacific Islanders has diabetes. Among Asian/Pacific Islanders, the prevalence of Type 2 diabetes is about 3 times higher than non-Hispanic whites.

More youth with diabetes are overweight or at risk of being overweight compared to non-diabetic youth, and minority youth have a higher prevalence of overweight than non-Hispanic white youth. Nutritional intake in adolescents with diabetes was found to be very poor and did not follow current recommendations for a healthy diet. Since there is no uniform standard to differentiate the Types of childhood diabetes, Dr. Rodriguez said this study offers unique opportunities to identify and test methods to correctly classify Types of childhood diabetes. In addition, the collection of many childhood diabetes cases will allow further clinical, epidemiologic, health care, and therapeutic research into what CDC scientists see as a major emerging public health problem. Researchers expect the SEARCH study will help them:

- Learn how many children and youth under the age of 20 have diabetes
- Identify significant changes in the incidence of diabetes over time
- Study how Type 1 diabetes (Juvenile-onset diabetes or insulin dependant diabetes) is different from Type 2 diabetes (Adult onset or non-insulin dependent diabetes)
- Learn more about the complications of diabetes in children and youth
- Investigate the types of care and medical treatment that these children receive, and
- Learn more about how diabetes affects the lives of young people

PHRI is conducting the SEARCH study in collaboration with five other clinical centers in California, Colorado, Ohio, South Carolina, and Washington. Together, they have identified more than 10,000 children and youth diagnosed with diabetes, and have invited them to participate in this study. About 7,600 cases have provided information, and about 4,600 have been seen.

The SEARCH study examination includes an interview, physical examination, blood draw, and questionnaire. The interview collects information on medical history, use of medications, processes of care, socioeconomic status, determinants of health, family history of diabetes, and quality of life. In youth aged 10 years and older, standardized questionnaires are used to assess physical activity, smoking habits, diabetes-related counseling, diet and eating disorders and depression. The physical examination includes blood pressure, height, weight, body measurement and examination for disease associated with insulin resistance as well as a variety of other health factors.

Located in Honolulu, the PHRI is the largest independent life sciences research institute in Hawai'i. Research includes epidemiological studies, clinical trials, and health services research, with a focus on diabetes, cancer, Parkinson's disease, cardiovascular disease, dementia, aging genetics, and primary care. The PHRI was founded in 1960 and has an annual operating budget of about \$11 million. Most of the funding comes from the federal government, with additional support from foundations and private industry. Most of PHRI's research is conducted through collaborations with research centers through Hawai'i, the Pacific, Asia and the mainland United States.

For more information contact: Melissa Matsuura at the Pacific Health Research Institute, (808) 524-4411





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Demographics and Characteristics of Wheezing/Asthmatic Children with Repeat Emergency Department Visits in O'ahu, Hawai'i

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Abstract

A profile of Hawai'i's pediatric asthmatic patients who repeatedly visit the ED is lacking. This multi-centered prospective study found that repeat ED utilization occurs more frequently in a particular subset of patients. Characteristics of the asthmatic cohort can help health care providers, caregivers, children, and their families understand and better manage asthma as a chronic condition and improve quality of life.

Introduction

Uncontrolled asthma exacerbations send one out of every three children with asthma to the emergency department (ED) each year.¹Asthma-related ED visits in children under 18 years of age account for nearly 50 percent of all asthma ED expenditures.² In 1994 alone the total asthma-related ED expenditures approached nearly \$500 million.³ Although more recent studies of ED-specific asthma expenditures have not been published, it has been reported that the annual direct and indirect cost for asthma in Hawai'i was estimated at \$127 million to \$296 million in 2002.^{4.5}

In Hawai'i, approximately 38,600 (9.7 percent) of 17 and under have asthma.⁶ A subset of these asthmatic children return to the ED multiple times for wheezing-related visits. This may result from one or more of the following: (1) a lack of recognition, diagnosis, understanding and management of the child's signs and symptoms, (2) a lack of understanding of the chronic nature of the disease, (3) inappropriate or deficient preventive treatment, or (4) poor continuity of care.

Although studies^{7,8,9,10} have profiled children with recurrent asthma-related ED visits in other communities, no recent attempt has been made to characterize such children on the island of O'ahu, Hawai'i. The purpose of this study is to report the demographics and characteristics of asthmatic children who visit and who return to the ED for wheezing in participating O'ahu EDs. The information is essential for designing tailored interventions that could be used to:

- prevent continuous, uncontrolled, asthma exacerbations;
- (2) improve continuity of care;
- (3) reduce the number of unscheduled ED return visits, hospitalizations, and
- (4) improve quality of life.

Patients presenting to the ED represent a unique group for investigation. Although they account for a small portion of the asthmatic population, they are associated with the largest percentage of asthma costs and are at high risk for uncontrolled morbidity from the disease.

Methods

This was a multi-centered prospective cohort study that included four O'ahu emergency departments: (1) Kapio'lani Medical Center For Women and Children (KMCWC)-a tertiary care children's and women's medical center in urban Honolulu, (2) Kaiser Permanente Medical Center (KPMC)-a general hospital in a residential community of Honolulu serving Kaiser plan patients, (3) Castle Medical Center (CMC)- a general hospital in a rural/residential community of north eastern O'ahu, and (4) Waianae Coast Comprehensive Health Center (WCCHC)-an emergency care center in a rural community of west O'ahu.

Patients ages 1 to 17 that presented to the EDs from 10/1/2002 to 8/1/2003 with wheezing or bronchospasm were eligible to participate. Phase I collected data on 646 patient encounters, 45.8 percent of 1,410 total patient encounters across all four EDs. The 646 encounters included 536 unique patients. Informed consent for participation was obtained. The following assessment data were collected: patient age, gender, ethnicity, medical insurance, the number of emergency department visits in the past 12 months not including the current visit, the number of doctor office visits for asthma in the past four months and past 12 months, asthma medication use (beta agonist, oral steroids, and controller medications: inhaled steroids, fluticasone/ salmeterol in combination, leukotriene modifiers, or cromolyn), hospitalization for asthma within the past 12 months, and asthma chronic severity classification (ACSC). ACSC was based on the National Institute of Health asthma guidelines which categorize asthma severity based on daytime and nighttime frequency of symptoms including coughing, wheezing and trouble breathing.11 Project and ED staff collected prospective data during the ED visit through interview using standardized pen and paper forms. The staff included research assistants, project coordinators, respiratory therapists, nurses and physicians. The data was entered into a database for subsequent analysis.

Ethnicity

Ethnicity was categorized into Native and Part Hawaiian, Filipino, Mixed Ancestry, Samoan, Micronesian, Caucasian and Other Ancestries. The Other Ancestries category included African American, Asian/Pacific Islanders not otherwise specified, Chinese, Hispanic, Japanese, Korean, Laotian, Malaysian, Portuguese, Tongan and Vietnamese since these groups were too small in number to be categorized individually.

Analysis

Patients were categorized into one of three groups depending on their response to the assessment question "How many times did you visit the emergency room for asthma during the past 12 months?" Study staff explained that their answer should not include the current ED visit. This assessment question was asked at the time of the ED encounter. If the patient responded to the study staff by answering "zero" or "none" then the patient was defined as a non-repeater. If the patient reported between one and three visits, the patient was classified as an intermediate repeater. If the patient responded that they had visited the ED 4 or more times, then the patient was considered a frequent repeater. Chi-square analysis was used to examine the relationship between demographic and other variables among the three groups.

Results

Table 1 cross-tabulates the repeater groups by demographic variables. Younger children aged 1-5 were more likely to be frequent repeaters (p<0.01). Patients aged 1-5 composed 71 percent of the intermediate repeater group and 85 percent of the frequent repeater group. Medicaid patients had a significantly higher frequency of repeat visits than those covered by private or no insurance (p<0.01). Medicaid patients composed 57 percent of the intermediate repeater group and 68 percent of the frequent repeater group.

Significant differences were found in the repeater groups when stratified by ethnicity. Ethnic groups that included Native and Part Hawaiians, Filipinos, and Samoans had a higher total number of intermediate and frequent return visits than other ethnic classifications (p<0.025). Native and Part Hawaiian, Samoan and Micronesian ethnicities had a higher proportion of frequent return visits (four or more visits) than other ethnic classifications (p<0.025).

Significant and non-significant differences were found in asthma medication use (Table 2). Frequent repeaters were more likely to use beta agonists than other groups. This finding was statistically significant (p<0.025). Non-repeaters, intermediate repeaters, and frequent repeaters used beta agonists 59.5 percent, 69.4 percent, and 75.4 percent of the time, respectively. On the contrary, use of controller medications did not significantly differ among the groups. Non-repeaters, intermediate repeaters, and frequent repeaters used controller medications only 18.1 percent, 18.1 percent, and 26.2 percent of the time, respectively. Similarly, non-repeaters, intermediate repeaters, and frequent repeaters used oral steroids 7.0 percent, 7.7 percent, and 11.5 percent of the time, respectively (NS).

Frequent repeaters reported a significantly higher rate of past asthma hospitalizations compared to other groups (p<0.001) (Table 3). The mean ± standard deviation (SD) of asthma-related doctor office visits in the previous four months for non-repeaters, intermediate repeaters, and frequent repeaters increased in a graded fashion: 1.0 ± 1.4 , 1.6 ± 2.2 , 3.5 ± 3.1 , respectively. A similar trend occurred in the mean \pm SD of asthmarelated doctor office visits in the past 12 months: 2.1+ $3.2, 3.8 \pm 5.0, 7.6 \pm 7.5$, respectively.

Frequent repeaters had a significantly higher proportion of severe persistent asthma compared to the other groups (p<0.001) (Table 4). The NIH asthma guidelines define severe persistent asthma as continual day symptoms (every day, all day long) and frequent night symptoms (3 or more nights per week). The frequent repeater group was comprised of 33percent severe persistent asthmatics.

Discussion

Study Limitations

The main limitation of this study was the reliance on parental-reported number of ED visits, which were used to designate the patients as either a non-intermediate, or frequent repeater. Study staff were unable to validate the number of ED visits by examining each patient's medical records. The prospective nature of the study permitted analysis of actual ED visits made by 1,002 patients in a prospective 22-month period. However, an ED-based educational intervention was applied during a second phase of this study, which affected control-



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Table 1.— Characteristics of Emergency Department Repeat Visitors						
	Non-repeaters	Intermediate repeaters (1-3 visits)	Frequent repeaters (4 or more visits)	Total		
Number of Patients	227	248	61	536		
Age Group (p<0.01)						
1 to 5 years	142	177	52	371		
6 to 10 years	51	49	8	108		
11 to 17 years	34	22	1	57		
Gender (NS)						
Male	143	156	30	329		
Female	84	92	31	207		
Medical Insurance (p<0.01)						
Medicaid	99	141	42	282		
Private	123	98	17	238		
No Insurance	5	9	2	16		
Ethnicity (p<0.025)						
Native and Part Hawaiian	61	66	19	146		
Filipino	51	40	7	98		
Mixed Ancestry	30	23	4	57		
Samoan	13	28	12	53		
Micronesian	14	22	4	40		
Caucasian	13	24	2	39		
Other	45	45	13	103		

Table 2.— Medications in use prior to ED visit						
	Non-repeater	Intermediate repeater	Frequent repeater	Total		
Beta ₂ agonist (p<0.025)	135	172	46	353		
No	92	76	15	183		
Oral Steroids (NS)	16	19	7	42		
No	211	229	54	494		
Controller Medication (NS)	41	45	16	102		
No	186	203	45	434		

ler medication use and asthma severity classification because patients were discharged with appropriate controller medications, and educated. The intervention impacted the number of return visits. The results of the educational intervention component are to be published elsewhere as part of a requirement of this grant-funded, national research program.¹² Therefore, this paper attempts to depict the usual observed demographics and characteristics of asthmatic children who visit and who return to the ED for wheezing without the confounding application of any intervention. For this reason, only the patients enrolled prior to intervention are considered in this report. This paper does not provide any causal relationships between demographic and characteristics of asthmatic children and repeat visits to the ED. It only reports descriptive findings and demonstrates associative relationships.

Multi-center findings

Demographics for pediatric asthmatic patients with repeat visits to the ED are lacking. This study demonstrates that 74.1 percent of those who returned to the ED for wheezing or asthma were between 1 and 5 years of age. This is an important finding that was consistent with other current studies in the United States. There seems to be a lack of published data regarding ED visits by age group, but data regarding Hawai'i pediatric hospitalization rates exist. Studies indicate that

Table 3.— A. Asthma Hospitalization in past 12 monthsB. Mean number of asthma-related doctor office visits within the past year						
	A. Asthma Hospital	ization in past 12 months				
(p<0.001)	Non-repeater	Intermediate repeater	Frequent repeater			
Yes	9 (4.0percent)	57 (23.0percent)	28 (45.9percent)			
No	218 (96.0percent) 191 (77.0percent) 33 (54.1percent)					
B. Mean ± Standard Deviation Asthma-related doctor office visits within the past year						
Non-repeater Intermediate repeater Frequent repeater						
Past 4 months	1.0 ± 1.4	1.6 ± 2.2	3.5 ± 3.1			
Past 12 months	2.1 ± 3.2	3.8 ± 5.0	7.6 ± 7.5			

Table 4.— Asthma Chronic Severity Classification						
(p<0.001)	Mild Intermittent	Mild Persistent	Moderate Persistent	Severe Persistent		
Non-repeater	129	25	33	40		
Intermediate repeater	123	31	43	51		
Frequent repeater	12	12	17	20		

asthma hospitalization rates are decreasing, except in the under-5 age group.⁶ Within the under-5 age group, hospitalization rates are higher than the Healthy People Hawai'i 2010 goal, which aims to reduce hospitalizations for asthma in children under age 5 from 1999 baseline rate of 45.6/10,000 to 25/10,000 by 2010.¹³

Traditionally, child asthma education and associated resource materials have been targeted to appeal to children aged 7-12 in the form of coloring books, stickers, newsletters, and games. However, by this time, children have already experienced a substantial amount of asthma morbidity. It is well documented that a high proportion of asthma occurs in children under age 5. For this reason, improvements in education may be better directed toward caregivers of these children since they are too young to manage their own symptoms. Education should target both parents and extended family because many children in Hawai'i have multiple caregivers. Interventions prioritized for such caregivers have a greater likelihood of opportunity and potential benefit for improving asthma morbidity from a public health standpoint. This may help reduce asthma severity and prevent inefficient healthcare utilization.

Past studies have examined the frequent use of the ED by asthmatic children in relation to their health insurance status.^{14,15} These studies have confirmed that asthmatic children receiving Medicaid use the ED more frequently than otherwise-insured child asthmatics. Since insurance status is typically used as a marker for socioeconomic status, it provides insight in determining potential disparities that may exist among children burdened by this disease. This study confirmed that children with Medicaid insurance had a significantly higher incidence of frequent repeaters than those covered by private or no insurance. Children with Medicaid comprised the largest proportion of ED visitors in total

(52 percent) and across each visit category (Table 1). It must be noted that although the distribution of insurance status in Hawai'i's general population is 71.7 percent private insurance, 22.3 percent Medicaid (Quest) and 7.4 percent no insurance,¹⁶ this ED cohort revealed 44.4 percent private, 52.6 percent Medicaid, and 3.0 percent no insurance. The ED cohort is skewed with a higher proportion of patients having Medicaid insurance. A focus on asthma management and control efforts on such patients may reduce acute asthma ED utilization and hospitalizations.

Braun et al¹⁷ noted the importance of stratifying ethnicities because it shows that specific groups may be at risk that may otherwise go undetected if grouped. Our findings indicated that repeat visitors were more likely to be Native and Part Hawaiian, Filipino, and Samoan based on the total number of intermediate (1-3) and frequent (4 or more) return visits. Furthermore, Native and Part Hawaiian, Samoan and Micronesian ethnic groups had a higher proportion of frequent return visitors compared with other ethnic groups. Comparing these ED findings with statewide, age-adjusted asthma prevalence data and age, ethnicity-adjusted general population data would provide insight into the nature and extent of disproportionate rates in child asthma prevalence and severity among ethnic groups. Unfortunately, at this time, limited Statewide data are available for such specific comparison. Nevertheless existing, unadjusted data on asthma prevalence by ethnicity will be discussed for informational purposes.

In 1988 the Hawai'i Health Surveillance Program indicated that Hawaiians and Filipinos experienced the highest asthma prevalence rates.¹⁸ Additionally, data provided by the 2001 Hawai'i Health Survey indicated that Native Hawaiians had a lifetime asthma prevalence rate of 143.2 per 1,000, which was twice

that of Caucasians or any other group living in Hawai'i.^{19,20} A more recent 2003 Hawai'i Health Survey indicated the percentage of self-reported asthma among children and adolescents under age 18 when stratified by ethnicity were: 44.1 percent Hawaiian, 19.1 percent Filipino, 9.4 percent Japanese, 7.2 percent Caucasian and 14.4 percent other unknown ethnicities²¹. Data on the Chinese ethnic group were too small for reliability and therefore not presented while data specific to the Samoan ethnic group were not available. Surveys of statewide ethnic distribution of the population are conflicting because of different coding methods and further complicated by Hawai'i's ethnically diverse population. The 2003 Hawai'i Health Survey indicated a Statewide ethnic distribution of the population as 23.7 percent Caucasian, 21.1 percent Hawaiian, 5.8 percent Chinese, 16.8 percent Filipino, 20.3 percent Japanese and 12.4 percent other/unknown.²¹ Whereas the US 2000 Census indicated 24.3 percent Caucasian, 6.6 percent Hawaiian, 4.7 percent Chinese, 14.1 percent Filipino, 16.7 percent Japanese, 1.3 percent Samoan and 1.3 percent other Pacific Islander.²² In both cases, the survey data were not age-adjusted thereby limiting their use for current comparative purposes. What is evident is that these Survey data suggest that an ethnic disparity exists with an unequal burden of asthma affecting Native Hawaiians in particular and, to a lesser extent, Filipinos. Our ED findings are consistent with such prevalence data in this regard. Moreover, our ED data provides information specific to child asthmatics with repeated ED visits and identifies additional ethnic subgroups of Samoan and Micronesian ancestry, which are also disproportionately affected with this disease. Research to determine/confirm any ethnic disparities as well as the role of socioeconomic factors in relation to the childhood asthma burden is needed to identify additional prevention opportunities. In the meantime, culturally sensitive educational programs should be tailored to accommodate the needs of the multi-ethnic families in the ED setting to effectively communicate health information in their respective dialects.

A nationally recognized resource developed to assist health care providers with respect to the treatment and management of asthma is the National Institutes of Health (NIH) Guidelines for the Diagnosis and Management of Asthma guidelines (including the 2002 updates).¹¹ In terms of medication use, these guidelines recommend that asthmatics use beta agonist medications for quick relief of their asthma symptoms. Beta agonist use implies an acute asthma exacerbation, which may result in an ED visit. In our cohort, no beta agonists were used in 41 percent of wheezing/asthmatic patients presenting to the ED for the first time (non-repeaters). These patients may have been experiencing a bronchospastic episode for the first time. These patients may not have been diagnosed with wheezing or asthma and therefore do not own asthma medications or delivery devices. Because these treatments were not available, they were prompted to visit the ED. On the other hand, return visitors, if diagnosed with wheezing or asthma, are likely to already have beta agonist medication and delivery devices at home. Therefore, it is expected that beta agonist use would be higher in those patients with repeat visits (69.4 percent--intermediate, 75.4 percent-frequent) compared with non-repeaters (59.5 percent). Although the majority of repeaters used beta agonists before coming to the ED, if NIH guidelines were followed, 100 percent of both these groups should have taken beta

agonists. Repeat patients who did not use beta agonists prior to visiting the ED may have (1) failed to recognize the warning signs and symptoms indicating the need for quick-relief medication use, and/or (2) run out of medications and/or (3) experienced delivery device failures, in which case it may have taken too long to acquire these items through non-emergent means or services. This is especially problematic at night when other services are unavailable (physician offices and clinics) or not rapid enough (physician exchange, pharmacy) to address the patient's immediate needs. For such patients, education should be focused on prevention. Patients need to know what causes or triggers the asthma, so they can be avoided. Detecting early warning signs of asthma is also important and this may include education on the appropriate use and frequency of beta agonist medication for symptoms like the first sign of a cold, waking up at night with coughing or wheezing and fast breathing. Patients should have and utilize a written asthma action plan. Appropriate delivery technique and emphasis on maintaining a steady supply of asthma medications at home are also important. Parents and caregivers should be encouraged to call for refill prescriptions by using the refill phone number on the prescription labels. Contacting the PCP for additional refills or an office visit is also recommended.

Beta agonist use provides only quick relief and does not treat the inflammatory component of the disease. The NIH guidelines recommend the daily use of at least one form of controller medication, such as an inhaled corticosteroid, for persistent asthmatics, which, if utilized appropriately, would prevent or decrease asthma exacerbations by reducing inflammation of the airways and improving control of asthma symptoms. Data demonstrate that there is no significant difference among the repeater groups with respect to controller medication use, signifying the lack of adherence to the NIH guidelines by the repeater groups. Of the 125 persistent asthmatics in the intermediate repeater group, only 45 (36.0 percent) patients reported the use of any controller medication. Of the 49 persistent asthmatics in the frequent repeater group, only 16 (32.7 percent) patients reported the use of any controller medication. An increase in the use of inhaled corticosteroids and/or other appropriate controller medications has been shown to be effective in reducing asthma symptoms, preventing acute exacerbations, and decreasing ED visits and hospitalizations.^{23,24,25,26,27,28,29}

Patients who utilize both beta agonist and controller medications appropriately, yet revisit the ED, may require step-up therapy, which may include different controller medications, like an inhaled steroid in combination with a long-acting beta agonist, a leukotriene modifier, or oral steroids. A team approach for asthma management is needed.³⁰ PCPs, allied health professionals, parents, extended families, and asthmatic children need to work together to control triggers, manage asthma with medicine, monitor the disease, and educate asthma patients to self-manage. Individuals who understand and utilize asthma action plans would be aware of early warning signs, self-manage their step-up treatment, and contact their PCPs or asthma specialists appropriately. The importance of a written asthma action plan cannot be underemphasized because they provide caregivers with detailed instructions to help them care for their asthmatic child and help improve the child's symptoms, potentially avoiding an ED visit or hospitalization.

As anticipated, past hospitalizations correlated with an increasing

number of repeat visits: 4.0 percent of non-repeaters, 23.0 percent of intermediate repeaters, and 45.9 percent of frequent repeaters were admitted in the past year. Patients requiring hospitalization should be evaluated further to determine what intervention could prevent future hospitalizations. One possible intervention may take place during hospitalization. Allied health professionals (doctors, nurses, respiratory therapists) may utilize the hospitalization time as an opportunity to efficiently educate caregivers about early warning signs of asthma; the differences between lung constriction and inflammation, and quick relief and controller medication; optimal medication delivery technique; and use of a written asthma action plan. This has been shown to be effective in the ED setting.³¹ Reinforcement of consistent asthma education in all healthcare settings at each visit is recommended.

Increasing number of return visits correlated with increasing frequency and severity of persistent asthma (p<0.001). Although the NIH guidelines classify asthma severity based on day- and night-time symptoms alone, chronic severity classification was also associated with past healthcare utilization in a graded fashion. The mean number of asthma-related doctor visits in the past four months and in the past 12 months increased with the non-intermediate, and frequent repeaters. This may suggest either that the asthma in repeaters was severe warranting more frequent PCP visits, that patients were non-adherent or non-responsive to prescribed treatments, that the asthma severity was underestimated with resultant under-treatment, or that referral to an asthma specialist was needed. Research into the role of the PCP/patient encounter and referral practices are needed to identify additional prevention opportunities.

In the frequent repeater group, 11 of 61 patients (18.0 percent) did not visit their PCP in the past four months, while six patients (9.8 percent) did not visit their PCP in the past year. This group utilized the ED as their source of primary care because the ED offers continuous availability (24 hours a day), minimal or no immediate cost to the patient, and easier and faster services. Some parents bring their children to the ED irrespective of severity because they do not know what else to do. This may signal limited knowledge and a lack of understanding of asthma, which are essential aspects of managing this chronic illness.

Traditionally, the role of the ED is to treat the acute exacerbation and discharge asthmatic patients to their PCPs for follow-up. It is not customary for EDs to educate patients with chronic conditions in detail because of the perception that the ED is too busy. However, the role of the ED could change. Recent studies have shown that an educational program implemented in the ED is possible and effective in improving outcomes.^{12,31} Other barriers to the adherence of pediatric asthma management and practice may include non-adherence to appropriate controller medication use, absence of a written asthma action plan, and reliance on the ED for comprehensive asthma care. Distractions due to competing priorities for parents of asthmatic children such as employment, social engagements, marital stress/divorce/hostility, psychopathology, and substance abuse are also barriers to appropriate management. In order to improve asthma management, these barriers must be further investigated and considered in applying any intervention.

This study identifies some of the characteristics of repeaters. These characteristics could aid in tailoring interventions that encourage proper resource utilization and that address the needs of patients at risk for severe asthma. Patients at risk include those aged 5 years or younger, insured by Medicaid, classified persistent asthmatics, treated with beta agonists more frequently, hospitalized for asthma in the past 12 months, and of the following ethnicities: Native and Part Hawaiians, Filipinos, Samoans and Micronesians. There are a number of socioeconomic reasons why patients repeatedly visit the ED for wheezing or asthma that require further investigation.

Repeated ED visits and hospitalizations are costly. This study profiles patients that return to the ED on a frequent basis with a chronic condition (wheeze/asthma). This may assist healthcare providers and planners in developing preventive educational programs and interventions, facilitate communication between the provider and the asthmatic child's caregiver, and better coordinate plans for follow-up to such unique patients. An increase in knowledge and improved asthma management may result in reduced asthma symptoms, decreased ED visits and hospitalizations, and improve quality of life.

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Conclusion

Community Outreach, Training, and Research: The Hawai'i/Pacific Basin Area Health Education Center of the University of Hawai'i, John A. Burns School of Medicine

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Abstract

The Hawai'i/Pacific Basin AHEC is a federal grant program that utilizes academic/community partnerships to recruit students to health careers, train students in rural and underserved areas, and assist with workforce development across the region. Ongoing activities and programs include 1) Outreach for recruitment to health careers for students from kindergarten through adulthood; 2) Individual and interdisciplinary health professions student training in rural and underserved areas; 3) Community health education using distance learning; 4) Assessment of and efforts to improve recruitment and retention of providers in rural areas including continuing education; and 5) Health disparities research. The AHEC programs reach more than 4,000 individuals annually, helps to train more than 1,000 individuals a year and assist with placement of up to 20 providers a year in rural and underserved healthcare practices. This article describes the existing AHEC programs that are community based, community driven and inclusive of all who choose to participate. Collaboration is invited and necessary for success and future program development. Future areas for collaboration activities include increased statewide community health worker training, an expanded health careers pipeline, ongoing rural and underserved health needs assessments and an expanded training network for students in healthcare. Additional information is available at www.ahec.hawaii.edu.

Background

Shortly after joining the University of Hawai'i in 1999, Dean Edwin Cadman made an important decision regarding community outreach, training and research in the region. As part of the mission to make the UH John A. Burns School of Medicine "the best medical school in the world with an Asia-Pacific focus," he relocated the statewide office of the Hawai'i Area Health Education Center to within the medical school under the leadership of Dr. Kelley Withy of the Department of Family Medicine and Community Health. Through the efforts of Dr. Cadman, Dr. T. Samuel Shomaker (then Vice Dean), Dr. Withy and many collaborators, this program has expanded its reach across the Pacific to improve health and education for thousands.

The Area Health Education Center (AHEC) Program is supported through federal funding from the Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professions and local health professions schools, government agencies and community health centers. The program was legislatively mandated under Title VII of the Public Health Service Act in 1965 as part of the health safety net, together with Community Health Centers and the National Health Service Corps. The federal mission of this grant is to improve the diversity, distribution and quality of the health professions workforce. The intent is to educate, train, and support providers to work in underserved and rural communities. Forty-six states have AHEC programs, and there are more than 120 centers nationwide.¹

While AHEC programs are based in academic institutions, more than three-quarters of the activities are carried out by community-based centers. The AHEC program in Hawai'i started in 1995, with a center in Hilo, Ke 'Ānuenue AHEC – followed two years later by a center in Līhu'e, Na Lei Wili AHEC. In 2001, the Hawai'i AHEC Program expanded to the U.S.-Associated Pacific Islands, thereby becoming the Hawai'i/Pacific Basin AHEC. Palau AHEC, the first AHEC center outside of the United States, opened in Koror, Republic of Palau in October of 2001. In 2004, the Yap AHEC opened in Yap State of the Federated States of Micronesia, CNMI AHEC opened in Saipan, Commonwealth of the Northern Mariana Islands, and Huli Au Ola AHEC opened in Kaunakakai representing Maui County. The local AHEC mission is to improve the health of the underserved through education.

Methods

Each AHEC program works with local communities to establish centers that offer culturally appropriate activities for recruitment and training of health professionals and students. These centers link the resources of regionwide programs and academic institutions with local educational and clinical resources in order to develop multidisciplinary training and improve health care delivery in medically underserved areas. Activities at each site are determined by the needs, desires and ideas of the community. Local ongoing activities and programs in the following areas are described briefly below (more information available at www.ahec.hawaii. edu): Outreach for recruitment to health careers; Health professions student training; Healthcare provider recruitment, retention and training; Community health education: and Research.

Outreach for recruitment to health careers:

Each AHEC center has introduced local recruitment programs, some incorporating traditional Hawaiian practices such as lā'au lapa'au, into orientations to health careers. In addition, AHEC employs two recruiters to visit 50 schools across the region every year and contact about 2,500 students a year with the assistance of a National Institutes of Health Science Education Partnership Award grant. The school visits to rural areas are often coordinated together with Bishop Museum Family Science Nights, where families have the opportunity to participate in solving medical mysteries. School visits are then followed up by campus visitations for up to 400 interested students a year to obtain first-hand experience with health professions training programs and research centers.^{2,3} Collaboration with the Hawai'i Department of Education, many health professions training programs, UH Manoa and the community colleges across the region have expanded the reach of AHEC recruitment programs, and any school in Hawai'i that requests involvement is visited. AHEC adds its support to important residential summer programs such as the Health Careers Opportunity Program and the Summer Institute. AHEC also provides teacher training in health education, how to make anatomy and microbiology fun for 200 teachers a year and provides a science tool kit for teachers to use with their students. For the first time this year, students and teachers from the Commonwealth of the Northern Mariana Islands participated in recruitment programs in Hawai'i and will be included increasingly in the future. Contact Marilyn Link at mlink@hawaii.edu or 808-692-1060, for more information.

Health professional student training:

Health professions students from nursing, advanced practice nursing, medicine, social work, public health, dental hygiene, kinesiology and nutrition are encouraged to participate in rural training experiences either individually or as part of an interdisciplinary team. AHEC supports a year long interdisciplinary training program for up to 80 students a year at four healthcare sites on O'ahu: Kalihi-Pālama Health Center; Kokua Kalihi Valley Comprehensive Family Services, Queen Emma Clinics and the Wai'anae Coast Comprehensive Health Center.^{4,5} AHEC also provides travel and lodging assistance for up to 100 students a year from medical, nursing and physician assistant schools in Hawai'i and elsewhere who perform rural/underserved training experiences in Hawai'i.

In addition, Palau AHEC is providing primary care and public health residency training to 10 medical officers (via the University of Auckland and the Fiji School of Medicine) and undergraduate and postgraduate training in public health (via the Fiji School of Medicine) for 150 nurses, environmental health workers, health administrators, and nutrition workers from the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands.^{6,7} Yap AHEC is providing health assistant certificate training to 16 health aides on distant atolls only connected to Yap proper by two way band radio. CNMI AHEC is expanding the health careers pipeline and preparing 15 nurses to pass the NCLEX, the nursing licensure examination. Maui County AHEC is partnering with Maui Community College and Aloha House to expand nursing training opportunities, substance abuse counselor training and home care certification.

Bioterrorism curriculum development

The University of Hawai'i Pacific Basin Bioterrorism Curriculum Development Project has developed a problem-based learning (PBL) curriculum for teaching health professionals and health professional students about bioterrorism and other public health emergencies. These PBL cases have been incorporated into interdisciplinary training settings in communitybased settings such as in the small island districts of the U.S.-Associated Pacific Islands (USAPI) and in Community Health Centers in Hawai'i. Quantitative and qualitative methods have been utilized in the evaluation of the PBL cases, PBL tutorials, and the accomplishment of learning objectives and demonstrate that PBL is a useful modality for settings such as small islands and community settings where the health care staffing and available resources are limited. Evaluation found that PBL encourages learners to identify their knowledge deficits and correct them via active, self-directed learning. Conducting PBL tutorials with interdisciplinary groups encourages understanding of the interdisciplinary nature of the response necessary for bioterrorism and other public health emergencies. The cases are also being implemented in disciplinespecific settings such as public health, medicine, nursing, medical technology, and emergency medical services. The PBL cases will also become the core of

The research and programs described have been supported by Health Resources and Services Bureau of Health Professions grant 2 U76HP00578-105, National Institutes of Health National Center for Research Resources grant R25 RR017312 and Hawai'i Department of Health grant 03-146. an interdisciplinary continuing education curriculum to develop a surge capacity Medical Reserve Corps workforce for Hawai'i and the U.S.-Associated Pacific Islands.

Distance learning

Much of the education performed or supported by AHEC must be administered utilizing distance learning technologies. For this reason, the AHEC centers in Hawai'i have partnered to develop a statewide network of video teleconferencing (VTC) sites that include bridging for hospital, academic and community sites. This system of new and existing VTC sites has been utilized for student education, provider training and local community education.^{8,9} AHEC is working with Hawai'i Primary Care Association to increase capability for and use of telemedicine consultations. In the Pacific, other distance learning modalities have been utilized, including teleconferences with emailed PowerPoint slides, and classes over two way band radio. AHEC is always looking for new effective methods for distance learning, and looks forward to web-based classes and expanded telehealth opportunities.

Healthcare provider recruitment, retention and training

In order to meet healthcare provider needs in rural and underserved areas, AHEC is working to accurately assess healthcare vacancies across the state through participation in the Hawai'i Health Workforce Collaborative. Partners in this endeavor include: the Hawai'i State Department of Health's Office of Rural Health, Papa Ola Lokahi Native Hawai'ian Scholarship Program, the State Health Planning and Development Agency, the Hawai'i Primary Care Association, the Hawai'i Medical Education Council, the Hawai'i Health Systems Corporation, the Hawai'i Health Information Corporation, the Hawai'i State Center for Nursing and the JABSOM Department of Family Medicine and Community Health. Together these groups are analyzing the existing health workforce data,¹⁰ administering a survey of positions under recruitment and developing plans for meeting the health workforce needs in Hawai'i. The goal of this group is to improve access to and quality of healthcare in Hawai'i by identifying unmet health workforce needs and developing solutions. In order to accomplish this, the group is compiling and analyzing existing data, surveying appropriate agencies and researching placement and pipeline activities that may improve workforce inequities.

The Hawai'i/Pacific Basin Area Health Education Center supports provider continuing education through information dissemination regarding available continuing education on our webpage, and provides connectivity and necessary travel for up to 1,000 healthcare providers a year from Hawai'i and the Pacific to attend educational sessions both via distance learning (in collaboration with the Hawai'i Primary Care Association, State Telehealth Access Network of Hawai'i, and the University of Hawai'i System) and in person to meetings such as the Pacific Global Health Conference. In addition, AHEC partnered with the Hawai'i State Department of Health, academia, health care institutions, and private industry to develop and deliver an educational campaign known as Provider Training for Changing Habits (PiTCH). The mission of the PiTCH program was to encourage and empower providers to easily send a consistent message about health to all citizens of Hawai'i by collaborating with schools and communities to promote the State of Hawai'i's social marketing campaign "Start Living Healthy." The Healthy Hawai'i Initiative, funded by part of Hawai'i's tobacco master settlement, encourages (1) Eating Better, (2) Getting Active, and (3) Living Tobacco Free in an effort to improve health by communicating simple and consistent lifestyle modification messages¹¹ to all of Hawai'i's people.

Between 2003 and 2005, the PiTCH curriculum has been delivered to more than 2,000 providers – including physicians, nurses, social service providers, pharmacists, office staff, and health professional students statewide. In addition, the PiTCH presentation was modified for delivery to lay community groups such as the Boys and Girls Club of Hawai'i and groups of retirees. The PiTCH presentation has been delivered to promote workplace wellness with employers such as the Department of Public Safety. Students in high school equivalency classes and health occupations classes also heard the PiTCH message. As part of the presentation pedometers were given to PiTCH participants, and their walking and fruit and vegetable consumption were logged. Evaluation of the presentation via pretest and posttest has demonstrated a significant increase in knowledge. Providers indicated that the PiTCH presentation has encouraged them to address preventive topics with their patients.

Community Health Education

AHEC helps coordinate and support continuing education for 2,000 community members annually. Much of this is done using distance learning modalities and conducted by Ke 'Ānuenue AHEC in partnership with rural community centers. Ke 'Ānuenue provides weekly health education sessions on Thursday nights using video teleconferencing to eight sites a week. These sessions are called E Nīnau Aku I Ke Kauka and utilize local experts to discuss topics of interest to rural community members. Initial results indicate significant behavior change reported after sessions. More information can be found at <u>www.keanuenue.org</u>.

Research

In addition to research described above, AHEC conducts research on the health problems of the underserved.^{12,13,14} AHEC is collaborating with the Hawai'i State Rural Health Association, Papa Ola Lokahi and the Hawai'i Primary Care Association to assist with identifying healthcare needs of rural communities statewide. Through the work of the Comprehensive Rural Health Plan, needs assessment and focus group data is being utilized to assist communities in developing the necessary resources to improve health. Local information sources and database information is being accessed in an effort to determine the most significant healthcare needs in rural areas. AHEC is also researching the barriers to pursuit of health careers training in Micronesians, and assessing the effectiveness of local programs for recruitment using logic models to uncover root cause analysis. Finally, AHEC is working with local churches and coalitions to assess healthcare needs of the homeless in Hawai'i by administering a survey to homeless individuals.

Results

Hawai'i/Pacific Basin AHEC has provided community-based and community-driven education for underserved groups in Hawai'i and the U.S. Associated Pacific Islands. Important areas of concentration have been improving video teleconferencing capabilities, telemedicine and telehealth utilization, performing health and health workforce needs assessments, provider training for encouraging healthy lifestyles, and response for bioterrorism and other public health emergencies.

Every year, Hawai'i/Pacific Basin AHEC performs recruitment visits to 50 schools, 2,500 students, 150 teachers and parents. Two hundred students take part in programs of 20 hours or more. Of the students contacted, only 50 percent know of health professions other than physician and nurse, but when they learned about the other health professions, 83 percent wanted additional information. AHEC also facilitates more than 1,000 hours of continuing education for health professionals and community members, including a weekly rural health education session that has demonstrated self report of health behavior change in participants. Furthermore, more than 600 health professions students are trained in rural and underserved areas annually. These efforts, as well as many other local, communitybased and academic efforts, have helped to encourage students to pursue health careers, and have assisted with the recruitment of as many as 20 providers a year to practice in rural and underserved areas.

Hawai'i/Pacific Basin AHEC has been able to leverage federal funds to obtain local grant funding for research into provider needs for educating patients, as well as other federal funds for distance learning (Department of Commerce Telecommunications Opportunity Program and National Library of Medicine grant) and health careers recruitment (NIH Science Education Partnership Award grant and Idea Networks Biomedical Research Excellence). professions students in rural and underserved areas. Finally, AHEC will continue and support efforts that increase health resources for rural and underserved populations in Hawai'i and the Pacific Basin.

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Discussion

AHEC depends on the partnership of communities, organizations and other local programs to succeed. Since local centers identify the activities to be undertaken, the success of AHEC starts and ends in communities across Hawai'i and the Pacific. The results of such community efforts are blossoming and will exponentially multiply the reach of AHEC programs. Activities are designed to empower communities to take the initiative in healthcare intervention and are designed to develop and appropriately distribute a well-trained health workforce that will meet the needs of all of the areas served.

Future plans for AHEC activities include expanded partnership with Hawai'i Primary Care Association to increase training for community health workers and healthcare executives on all islands of Hawai'i. In addition, ongoing research findings will be utilized to create a multi-tiered region-wide health careers pipeline coordinating with community, healthcare and academic programs throughout the Pacific region. An accurate assessment of and plan to meet the health workforce needs of the region is expected within the year. AHEC hopes to expand the reach of the rural health education sessions to locations across the Pacific. AHEC continues to expand the number of educational experiences for health

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The Research Subject Advocate at The University of Hawai'i Clinical **Research Center: An Added Resource** for Protection of Human Subjects

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Abstract

In early 2001 the National Institutes of Health (NIH) created the Research Subject Advocate (RSA) position as an additional resource for human subjects protection at NIH-funded Clinical Research Centers (CRCs) to enhance the protection of human subjects participating in clinical research studies. The purpose of this article is to describe the RSA position in the context of clinical research, with a particular emphasis upon the role of the RSA in one of the five CRCs funded by the NIH Research Centers in Minority Institutions (RCMI) program. Through participation in protocol development, informed consent procedures, study implementation and follow-up with adverse events. the RSA works closely with research investigators and their staff to protect study participants. The RSA also conducts workshops, training and education sessions, and consultation with investigators to foster enhanced communication and adherence to ethical standards and safety regulations. Although it is too early to provide substantive evidence of positive outcomes, this article seeks to illuminate the value of the RSA position in ensuring that safety of research participants is accorded the highest priority at CRCs. Based upon initial results, we conclude that the RSA is an effective mechanism for achieving the NIH's goal of maintaining the utmost scrutiny of protocols involving human subjects.

Introduction

In September 1999, 18-year-old Jesse Gelsinger died while participating in a clinical trial at the University of Pennsylvania's Institute for Human Gene Therapy. His highly publicized death led to intense government scrutiny and heightened public suspicion of medical research in the United States. After Jesse's death, the National Institutes of Health (NIH) received delayed reports of more than 650 dangerous adverse reactions, including several deaths, that had occurred in other studies around the country.^{1,2} Upon investigation, the NIH learned of widespread noncompliance with federal requirements for clinical research studies. Most disturbing was that several NIH-supported investigators had violated federal mandates by deviating from approved study design, taking risks involving human subjects, and not reporting adverse events to the appropriate authorities. Clearly, the NIH's system of review, oversight and reporting, including involvement of Institutional Review Boards (IRBs) and Scientific Advisory Committees, while comprehensive and extensive, was failing to protect all research participants.^{2,3} In response, the Food and Drug Administration (FDA) and the Office of Human Research Protection (OHRP) shut down human research at several major medical centers and issued sanctions for noncompliance with human subject regulations, dealing a significant blow to the medical research enterprise.4,5

Establishment of the Research Subject Advocate Position

In an attempt to restore public confidence by alleviating safety concerns in the clinical research setting, various federal agencies enacted programs designed to protect human research participants. For example, in 2000, the Department of Health and Human Services empowered OHRP with the authority to regulate research through written assurances from institutions and to investigate complaints and take corrective action. To complement the role of the OHRP, the FDA set up the Office for Good Clinical Practice to monitor individual investigators, industry sponsors and IRBs. One of the most important federal measures was the creation of the Research Subject Advocate (RSA) position by the NIH's National Center for Research Resources (NCRR). The RSA, with training in human subject protection and other appropriate clinical fields, would ensure that all research conducted in NCRRsupported General Clinical Research Centers (GCRCs) comply with federal regulations and prevent harm to research participants.

In early 2001, the NCRR funded the RSA position through the 80 GCRCs across the country, and soon

required that all five Research Centers in Minority Institutions (RCMI) Clinical Research Centers (CRCs) also hire an RSA.⁶ More than 10,500 NIH-supported investigators conduct nearly 8,000 research projects each year at the GCRCs. In addition, more than one 100 projects are conducted at the RCMI CRCs each year.⁷ Thus, the RSAs are instrumental in protecting thousands of individuals participating in research studies in the United States As of 2005, nearly 150 RSAs are working in research centers throughout the nation.⁸

Role of the RSA

RSAs report directly to the Principal Investigator of each GCRC (the medical school dean) or RCMI CRC (the medical school dean or university president), thereby eliminating any potential conflict of interest that might arise by reporting to the GCRC or CRC's program director. The primary responsibility of the RSA is to educate investigators and research staff on human subject protection, ensure compliance with regulatory obligations, and establish data and safety monitoring plans for all CRC clinical studies. But most importantly, the RSA assures the clinical studies are conducted in a safe and ethical manner. The RSA is considered an added resource to the program, and not a hindrance to research. The RSA does not replace the investigator, operational manager or program administrator's oversight of the research, but works in harmony with them throughout the study.

The RSA periodically serves as an unbiased observer during the recruitment and or enrollment process. The RSA may also communicate directly with research participants to help them understand study risks and "ensure that their safety receives the highest priority."⁸

Some RSAs are available on a 24-hour basis to assist with resolution of adverse events if they occur during a study. An important aspect of the RSA's role is to oversee reporting of adverse events and conflicts of interest to the IRBs. If an adverse event arises during a study, the RSA can be involved in the decision-making process related to restoring the patient's well-being, by communicating with the participant, emergency medical staff, or others as necessary to resolve the situation. The RSA also works with the investigator and their staff in reporting serious adverse events to the appropriate agencies. Moreover, in order to preserve participant safety, the RSA has the authority to temporarily halt or permanently close down any study if the risk to research participants is deemed to be too high.

In sum, RSAs monitor research activity through involvement in all stages of the clinical study process, from protocol design and recruitment to implementation and eventually data analysis. The goal of the RSA is not simply to ensure that investigators adhere to regulatory requirements, but ultimately to prevent harm or injury to individuals participating in research.

Importance of the RSA at Minority Clinical Research Centers

Accomplishment of this goal is particularly important in institutions that support research involving minority populations. The Clinical Research Center at the University of Hawai'i's John A. Burns School of Medicine in Honolulu (University of Hawai'i) is among the five RCMI-funded centers that provide infrastructure for clinical research with a particular focus on minority health. These CRCs support studies involving racial and ethnic minority populations. The Institute of Medicine (IOM) report released in March 2002 reports that racial and ethnic minorities tend to suffer from higher rates of cardiovascular disease, cancer, diabetes, infant mortality, and other serious diseases.



The presence of an RSA at minority-serving institutions appears to help reduce such suspicion and provides additional assurances that may contribute to more successful recruitment and retention of participants in research studies designed to benefit minority populations. At the University of Hawai'i CRC, in cases where language or cultural barriers impede proper communication regarding a study, the RSA may determine the need for translators or translated consent forms as part of the process of obtaining valid informed consent. In addition, issues regarding gender, generation, literacy, culture and language are periodically assessed by the RSA to ensure that consent to participate in studies is truly informed. With increased public awareness of the RSA's ability to advocate on behalf of participants, community members may be more willing to consider taking part in research activities.

In sum, the RSA provides an additional protective resource for those participating in the clinical research process. This protection has important implications for any research involving human subjects, but is



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perhaps even more vital to reassuring members of minority communities that it is safe to volunteer for research studies. Clinical investigators must provide assurances to community members in order to establish a trusting relationship and encourage participation in research studies. As the RCMI CRCs embark upon more community-based participatory research projects, the presence of the RSA will hopefully strengthen this element of trust. In turn, minority-based research programs can more effectively achieve results that will lead to improved prevention, treatment, and health outcomes for this target population.

Accomplishments over the Past Two Years

Over the past two years, the University of Hawai'i CRC RSAs achieved the following goals:

- Created a Data Safety Monitoring Plan (DSMP) template and then introduced this concept and requirement to CRC study personnel and investigators.
- Revised the CRC protocol application to include the DSMP template and revised the human subject section requirement to include more detail.
- Assisted key investigators with the development of the human subjects sections of their National Institute of Health applications.
- Established the CRC Data Safety Monitoring Board (DSMB). As of December 2004, the DSMB had seven meetings and reviewed 30 research studies for human subject compliance, and identified 19 studies as requiring a DSMP. A DSMP was subsequently developed for each of the 19 studies.
- Provided written review to the CRC's Scientific Advisory Committee (SAC) on the human subjects section and DSMP of all protocols.
- Became an ex-officio member of the SAC and attended all SAC meetings to participate in human subject discussions of individual research studies.
- Presented an educational overview of DSMP requirements to the SAC.
- Provided several presentations and training in basic human subject protection, data safety and monitoring plan development, and understanding the IRB regulations to various groups of investigators and CRC staff.
- Developed an emergency procedure and contact list for all CRC protocols.
- Recruited three volunteer consultants to the DSMB in different specialty areas.
- Contributed to the development of a proposal to engage health care institutional officials and community leaders to streamline

the IRB process in Hawai'i. The proposal was recently funded by the Hawai'i Community Foundation.

- Offered orientation of new study personnel in human subject protection issues and awareness.
- Assisted CRC staff and study Principal Investigators in the reporting and resolution of adverse events, serious adverse events, and protocol deviations to the appropriate IRBs.

Conclusion

Due to the novelty and innovation of the RSA position in the research setting, it may be too early to offer a valid assessment of its success. It is clear, though, that the number of data and safety monitoring plans and boards at GCRCs and RCMI CRCs has increased since 2001, and a recent survey conducted by the President of the Society of Research Subject Advocates (SRSA) demonstrated that RSAs are accomplishing their goal of helping clinical investigators comply with data and safety monitoring requirements.¹² The SRSA has established several working groups, including a Quality Assurance Committee, and offers mentoring, educational tools, and other resources to assist RSAs in their evolving role.¹³ The NCRR has also noted a positive institutional response to RSAs and plans to continue RSA support for all NIH-funded patient-oriented research at GCRCs and CRCs.¹⁴

Unfortunately, risk to participants is often inherent to the conduct of clinical research. Regardless of improvements in federal oversight, institutional support, IRBs, and investigator-initiated safety measures, adverse events will inevitably occur within the context of research. Nevertheless, RSAs around the country are demonstrating positive results as they strive to reduce risks to human participants. The RSA is one of the key components of a broad strategy to regain public trust by creating a safe environment that is conducive to medical research designed to benefit all human subjects. At the University of Hawai'i CRC, the RSAs have become an integral part of the clinical research process, hopefully contributing to a greater sense of community-wide confidence in safe study design and implementation. With the knowledge that an individual is wholly dedicated to protection of research participants' interests, it is likely that we will begin to see an increased willingness of individuals representing diverse ethnic communities to volunteer for and participate in clinical studies. This will no doubt enhance the efforts of minority CRCs to reduce and ultimately eliminate the disproportionate burden of health disparities upon minority populations.

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See Research Subject Advocate p.54



The Hyperbaric Treatment Center

Richard W. Smerz DO, MTMH, and Frank Farm Jr., Director, The Hyperbaric Treatment Center John A. Burns School of Medicine

Hawai'i is surrounded by the Pacific Ocean, and many who live here and many who come to visit have and will continue to dive and are subject to a diving injury. Due to the popularity of diving in Hawai'i, the Hyperbaric Treatment Center (HTC) is not simply an asset, but a necessity to the Islands and beyond. The HTC meets the specific needs of Hawai'i by providing appropriate and wellsupervised care to those potential victims as well as those who may benefit from hyperbaric oxygen therapy.

During the early 1980s the U.S. Navy (USN) advised then governor of Hawai'i, George Ariyoshi, that they could no longer provide humanitarian treatment to civilian divers. The Navy had provided this care for divers in Hawai'i since the introduction of self-contained underwater breathing apparatus (SCUBA) gear in the early 1950s. The governor identified the John A. Burns School of Medicine as a source of expert medical advisors and requested the school to provide him with a course of action to provide for the care of injured divers.

The Dean of the School of Medicine established a group of interested faculty and appointed the Chair and Professor of Pathology, Dr. John Hardman, to lead the group. The committee produced a well researched report informally known as the "Hardman Report." It recommended the establishment of the HTC by the John A. Burns School of Medicine.

The HTC was established in 1983 at Kewalo Basin, funded by an act of the state legislature. Dr. Edward L. Beckman served as the first medical director and Frank Farm Jr. as its director. In 1994, HTC was relocated to the campus of the Kuakini Medical Center into a modern facility with a state of the art chamber complex, rivaled by few other institutions.

The vision of the HTC is to be the premier U.S. Center for Undersea and Hyperbaric Medicine in Hawai'i and the Pacific region. The mission is to provide treatment to those who suffer a diving accident 24/7/365, to provide hyperbaric oxygen therapy to those who may benefit from such therapy, to conduct relevant clinical research, and to provide teaching to residents and JABSOM students.

In the formative years of the center, the primary focus was the treatment of diving injuries. Over the years, a significant amount of scientific and clinical research has been conducted on the causes and treatment of dysbarism, with special emphasis on the development of treatment tables designed to treat the native Hawaiian fishermen, whose dive profiles were often well *in extremis*, as compared with the average recreational diver. Dr. Beckman conducted animal research related to dysbarism, which culminated in the development of the "Hawaiian Deep Treatment Tables" that continue to be employed

at the HTC in the treatment of more than 1300 divers to date. In a published scientific paper¹ in the *Undersea and Hyperbaric Medicine Journal*, these tables were demonstrated to result in 93 percent complete resolution of disease, nearly 20 percent better than that reported by those employing other treatment tables nationwide.

In addition to diving related disorders, the HTC treats patients who have medical conditions that are amenable to hyperbaric oxygen administration and are approved by the Undersea and Hyperbaric Medical Society (UHMS) based upon substantiated scientific evidence. These conditions are: carbon monoxide intoxication, clostridial myonecrosis, necrotizing soft tissue injury, delayed radionecrosis, acute blood loss anemia, enhancement of healing of problem wounds, preservation of compromised skin grafts and flaps, acute traumatic ischemias, refractory osteomyelitis, intracranial abscess, and thermal burns. More than 600 patients have been treated for conditions other than diving-related injury. Of this number, 62 percent were treated for radionecrosis, 22.5 percent for non-healing problem wounds, 5.5 percent for carbon monoxide intoxication, 3.5 percent for necrotizing soft tissue injury, 2.5 percent each for preservation of compromised skin grafts and flaps as well as for refractory osteomyelitis, and 1.5 percent for clostridial myonecrosis. To date, more than 13,000 chamber treatments have been administered.

The John A. Burns School of Medicine has provided both the vital connection to talented, academic leaders and an avenue for an organizational structure to develop a robust clinical research program for HTC. Since 2001, emphasis has been placed on clinical research. These efforts have resulted in publication in peer reviewed journals, eight papers and twelve abstracts, as well as 15 formal presentations at scientific meetings and symposia. Four of the published papers were "firsts" in the reported literature.²⁻⁵ The HTC has also collaborated in diving research efforts related to women and diving, enhanced diving injury data collection and analysis, and flying after diving, with other research institutions in the United States and Europe. Finally, the HTC has the inherent mission of conducting clinical research to answer questions as to the appropriate use of hyperbaric oxygen, to discover new applications for it, and to refine existing knowledge.

Teaching continues to be a mainstay in the mission of the HTC. Three physicians are board certified in the sub-specialty of Undersea and Hyperbaric Medicine. They are among only 200 in the country who have such credentials. Each holds a clinical faculty appointment in JABSOM. As a component of JABSOM, the HTC is uniquely suited to provide education and experience in the field of Undersea and Hyperbaric Medicine. The center evaluates and treats an average of 50-60 diving accident cases per year, and is the second most-active recreational diving accident treatment facility in the country. Monthly, the HTC staff provides a one-day course to visiting ER residents of Kaiser Hospital as well as fourth-year JABSOM students on ER rotation. Additionally, the HTC offers an elective one month rotation to the JABSOM transitional residency program as well as to anesthesia, emergency medicine, and family practice residents from within and outside Hawai'i. Since 2000, more than 300 residents and medical students have received training and/or education at the HTC. Teaching and education have not been limited solely to medical professionals. Indeed, HTC staff has been very active teaching community via television and radio broadcasts, and through presentations in civic groups and organizations, as well as diving clubs and societies.

In January the HTC started a facility accreditation survey by the Undersea and Hyperbaric Medical Society (UHMS), a JACHO-level inspection for hyperbaric facilities, to ensure that it is meeting the established standards for quality care, maintenance of equipment, professionalism, administration, operations, safety, clinical research, teaching and publishing. This is a significant milestone that will place the HTC among some of the finest institutions in the country engaged in Undersea and Hyperbaric Medicine. Fellowship in Undersea and Hyperbaric Medicine for eligible candidates is being planned. In research, the HTC staff will establish several protocols to conduct randomized, controlled trials to study gender disparity in the incidence of oxygen toxicity while diving, and the efficacy of hyperbaric oxygen therapy in the treatment of global cerebral ischemia within the first six months of injury. The HTC will seek to be a national leader in the field of Undersea and Hyperbaric Medicine.

Since its inception, the HTC has striven to play its small and unique but vital role in the life of JABSOM, the state of Hawai'i, its people, and those who visit here and may have need of our services. For 22 years, the HTC has provided "specialized" care and adhered to the highest standards as promulgated by the University of Hawai'i, JABSOM, and the UHMS. The HTC will continue to build on the legacy of Dr. Beckman in its pursuit of excellence in clinical care, service, research, scholarly activity, and education.

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HAWAIʻI MEDICAL JOURNAL

A Cancer Profile for Hawai'i

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Several years ago, we wrote about strategies and objectives for Statewide Comprehensive Cancer Control in Hawai'i.¹ Since that time, cancer control planning efforts have been proceeding rapidly. Recently, the National Cancer Institute provided cancer registry staff nationwide with a tour through a new website "State Cancer Profiles" (http://statecancerprofiles.cancer.gov/) that promises and delivers dynamic views of cancer statistics for prioritizing cancer control in the nation, states and counties. The website creators have tapped a rich set of data resources, including cancer incidence from the National Cancer Institute and the Centers for Disease Control, mortality statistics and population counts from the National Center for Health Statistics, and support data from the Behavioral Risk Factors Screening Survey (BRFSS). Links to other sources of cancer-related data are readily available. The home page allows users to generate quick statistical profiles for assessing the burden and risk for major cancer sites by site, sex, race/ethnicity, and age for their state. More comprehensive tables and figures are also available including rate (incidence, mortality) and trend comparisons, interactive graphs and maps, and support data on cancer screening and risk factors.

Although there is insufficient space in the Cancer Research Center Hotline to detail all of the available research tools, we highlight each of the general areas, providing examples of what is possible. One of the most useful planning tools is the Rate/Trend Comparison Table. We compared Hawai'i versus United States trends in death rates from 1978 through 2002 for illustration (Table 1). The table suggests that deaths from liver and bile duct cancer among males are rising in Hawai'i and are significantly higher than the rate in the United States overall; whereas, cancers of the breast, colon and rectum, and lung and bronchus among women, and prostate among men are falling and are significantly lower than the rates in the United States. Local efforts to vaccinate a large segment of Hawai'i's population against hepatitis B appear well-founded. Regarding incidence, cancer rates in Hawai'i are generally lower than that in the rest of the United States (Table 2), but there are exceptions to this observation. Breast cancer among white women in Hawai'i is among the highest in the nation (157.4 per 100,000 women per year in Hawai'i compared with an average 129.9 per 100,000 in the United States), although rates among non-whites are substantially lower.

A comparison of incidence of female breast cancer across states is illustrated in Figure 1. This graph, created under Interactive Graphs and Maps, can be generated for most of the more common cancer sites and allows comparisons of cancer incidence and mortality rates to be made in parallel. These graphs and maps provide a powerful tool for cancer planning efforts, allowing comparison of five-year rate changes, historical trends, geographic differences in rates by site and demographic variables, and interactive cancer maps. Figure 1 shows that white women in Hawai'i have the highest incidence of breast cancer in the nation, but their death rate from this malignancy is lower than in any other state, with the exception of Wyoming. Although these rates are subject to error, the comparisons suggest that Hawai'i is doing a good job at identifying breast cancer in its early stages when it can be treated successfully. However, when we generated a Screening and Risk Factors Report by State on the percentage of women ages 50+ years who had a mammogram in the past two years, Hawai'i ranked toward the bottom (6 out of 51, including the District of Columbia). It is not clear how well this overall mammography information represents white women in the state. Alternative explanations for the survival benefits among Hawai'i residents might involve treatment differences in breast cancer outcomes.²

Turning to the Interactive Maps, we examined death rates in 2002 for liver and bile duct cancers by state (Figure 2). The maps are color-coded so that states with the lowest to the highest rates are displayed by color-groupings. The map's interactive features enable the user to highlight each state with their mouse to obtain the precise rates. On our map, Hawai'i's rate of liver and bile duct cancers was the highest in the nation at 10.7 per 100,000 per year.

An extremely useful feature of the website for cancer planners is the ability to show annual percentage change in cancer incidence and mortality by age, sex, and race for their state. Figure 3 shows a significant decline in bladder cancer rates among women during the past five years, along with non-significant declines in other malignancies. A non-significant 8 percent per year increase in thyroid cancer might signal the need for regular palpation of this gland by physicians, especially among Filipino women who are at particularly high risk.³

Additional annual data regarding screening and risk factors associated with cancer are available at the state level from the BRFSS (http://www.cdc.gov/brfss). The data from these tables may be compared to the Healthy People 2010 target values (<u>http://www. healthypeople.gov</u>) to assist with planning cancer control activities at a local level.

In the future, the State Cancer Profiles website promises to be enhanced with more interactive maps, additional variables (smoking behavior, mammography use, and pap smear use), as well as model-based estimates based on the BRFSS and National Health Interview Survey data. We encourage those involved with our Statewide Comprehensive Cancer Control efforts in Hawai'i to make good use of this evolving planning tool.

For more information on the Cancer Research Center of Hawai'i, please visit our website at www.crch.org.

Continues on next page

CANCER RESEARCH CENTER HOTLINE

References

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- Issell BF, Maskarinec G, Pagano I, Gotay CC. Breast cancer treatment among women of different ethnicity in Hawai'. Cancer Invest 2005;23:497-504.
 Goodman MT, Yoshizawa CN, Kolonel LN. Descriptive epidemiology of thyroid cancer in Hawai'i. Cancer 1988;61:1272-81.

	1	All Races, Both Sexes		
	Above US Rate	Similar to US Rate	Below US Rate	
Rising Trend	Priority 1: rising [†] and above [†] Liver & Bile Duct (Males)	Priority 2: rising [†] and similar = Liver & Bile Duct (Females)	Priority 3: rising and below	
Stable Trend	Priority 4: stable — and above 1	Priority 6: stable — and similar = Brain & ONS (Males) Esophagus (Males) Leukemia (Females) Leukemia (Males) Pancreas (Females) Pancreas (Males) Uterus (Females)	Priority 7: stable -> and below + Kidney & Renal Pelvis (Males) Lung & Bronchus (Males) Non-Hodgkin Lymphoma (Females) Non-Hodgkin Lymphoma (Males) Ovary (Females)	
Falling Trend	Priority 5: falling stomach (Females)	Priority 8: falling # and similar = Colon & Rectum (Males) Oral Cavity & Pharynx (Females) Oral Cavity & Pharynx (Males) Stomach (Males)	Priority 9: falling Breast (Females) Colon & Rectum (Females) Lung & Bronchus (Females) Prostate (Males)	
	Trend Rising ↑ when 95% confide Stable → when 95% confide Falling ↓ when 95% confide Rate Comparison Above ↑ when 95% confide Similar = when unable to co Below ↓ when 95% confide	ence interval of annual percent chang dence interval of annual percent chan ence interval of annual percent chan ent the rate is above and Rate Ratio ³ onclude above or below with confide ent the rate is below and Rate Ratio ³	ge is above 0. nge includes 0. ge is below 0. ¹ > 1.10 nce. < 0.90	

Table 2.					
Inc	idence Rate Re	port for Hawaii, All F	Races, All Ca	ncer Sites, All Ages	
		Male		Femal	e
Location	Year(s)	Average annual incidence rate per 100,000	95% Confidence interval	Average annual incidence rate per 100,000	95% Confidence interval
US	2001	544.8	543.5-546.2	404.9	403.9-406.0
Hawaii	1998-2002	479.9	471.9-487.9	381.3	374.3-388.0
Hawaii	2002	458.2	441.3-475.6	374.7	360.5-389.4

HAWAI'I MEDICAL JOURNAL, VOL 65, FEBRUARY 2006

CANCER RESEARCH CENTER HOTLINE



CANCER RESEARCH CENTER HOTLINE





HAWAI'I MEDICAL JOURNAL, VOL 65, FEBRUARY 2006



UPCOMING CME EVENTS						
Date	Specialty	Sponsor	Location	Meeting Topic	Contact	
March 2006						
3/4	IM	Hawai'i Chapter, American College of Physicians: ABrave New World	Hawai'i Prince Hotel, Honolulu	Internal Medicine: A Brave New World	Tel: (808) 586-7478	
April 2006	n			Ĭ		
4/26	ADM, ADP, P	Department of Psychiatry, John A Burns School of Medi- cine, University of Hawai'i	Queen's Conference Center, Queen's Medical Center	Alcohol and Other Addictions: A Cross-Cultural Perspective	Tel: (808) 586-2900	
May 2006	1	Ĭ		Ĭ		
5/4-5/6	Multi	Department of Native Hawai- ian Health, John A Burns School of Medicine, University of Hawai'i	JW Marriot Ihilani Resort & Spam Ko Olina, Oʻahu	He Huliau - A Turning Point: Eliminating Health Disparities in Native Hawaiians & Pacific Peoples Cardiovascular Dis- ease 2006	Tel: (808) 587-8563 Web: http://www.hawaiiexport- center.hawaii.edu/	
June 2006	1		r		l	
6/22-6/24	OBG	American College of Obstetri- cians and Gynecologists	Fairmont Orchid, Kohala Coast	The Art of Clinical Obstetrics	Tel: (800) 638-8444 x2540 Web: www.acog.org	
	l					
6/25-6/27	Multi	John A Burns School of Medi- cine, University of Hawai'i	Hawai'i Convention Center, Honolulu	2nd Annual Hawai'i BioSci- ence Conference: The Mo- lecular Basis of Disease	Web: www.hibiosci.org	
July 2006					-	
7/23-7/27	ORS	North American Spine Society	Ritz-Carlton, Kapalua, Maui	Spine Across the Sea	Tel: (877) 774-6337	
					web: www.spine.org	
10/20-10-22	Multi	Hawai'i Medical Association	Hawai'i Convention Center	150th Annual Meeting	Tel: (808) 536-7702	
10/20-10-22	Wall		Honolulu	1991 A minuter Meeting	Web: www.hmaonline.net	
November 2006						
11/8-11/11	OBG	American College of Obstetri- cians and Gynecologists	Hapuna Beach Prince Hotel, Kohala Coast	Obstetrical and Gynecological Pearls	Tel: (800) 638-8444 x2540	
		, , , , , , , , , , , , , , , , , , ,			Web: www.acog.org	
Interested in having	Interested in having your upcoming CME Conference listed? Please contact Nathalie George at (808) 536-7702 x103 for information.					

Correction to: Hawaii Medical Journal, Vol. 64, No. 12. Medical School Hotline, December 2005. pp. 312-313. Title: *"The Office of Medical Education"* **The listing of authors should have read:**

Richard T. Kasuya MD, MEd, Director, Office of Medical Education; Gordon M. Greene PhD, Assistant Professor, Office of Medical Education; T. Samuel Shomaker MD, JD, Interim Dean; John A. Burns School of Medicine, University of Hawaii



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Diabetes



THE WEATHERVANE RUSSELL T. STODD MD, CONTRIBUTING EDITOR

♦ WOMEN SHOULD WEAR COFFEE AS A PERFUME.

Having failed repeatedly to incriminate coffee in everything except insomnia, researchers have finally come up with an obscure reason to avoid caffeine. In the Blue Mountains Eye Study out of Sydney, Australia, researchers claim they found a relationship of coffee and caffeine intake to intra-ocular pressure (IOP). 3,654 participants completed a detailed questionnaire including average daily intake of coffee and tea, and were followed with Goldmann tonometry and automated perimetry. With the usual adjustments for age, sex and systolic blood pressure, it was found that those patients with open-angle glaucoma who consume more than 200 mg. of caffeine per day (one 8 oz. cup) had a higher mean IOP (19.47) than those with less than 200 mg. daily (17.11). But on the plus side, caffeine will reduce your chances of getting Parkinson's Disease, colon cancer, and type 2 diabetes, and will elevate your mood and often clear up your headache. Pour me a cup, please.

♦ HEY WAL-MART! COME OUT FROM UNDER THAT ROCK SO WE CAN TALK.

Five years ago, Debbie Shank was a shelf stocker at Wal-Mart. She was involved in a terrible vehicle crash with a tractor-trailer and was left seriously brain damaged. She is confined to a wheelchair in a nursing home with severe memory loss and brain stem damage. The trucking company settled a lawsuit for \$900,000, but after the attorney's bill and other charges, the remaining share was \$417, 477, which the court placed in a trust to pay for her long-term care. Her husband received \$119,000 for loss of consortium. This would all be ugly enough, but there is more. Because she was awarded damages in a settlement, Wal-Mart is suing her to recover their insurance claim costs of \$469,216. If Wal-Mart prevails, the Shanks will not just lose all the trust money, they will owe Wal-Mart \$52,000 plus court costs. A spokesman for Wal-Mart stated the suit was a way to preserve options (Like what, taking their house and car?), and that the health plan may decide not to pursue the lawsuit. Experts say this is not an uncommon case, and insurers often have policy clauses requiring that they be reimbursed from lawsuit proceeds. So remember, the large print giveth, the small print taketh away!

♦ BUMMER, DUDE! SURFERS RUN OVER BY THE GREEN MACHINE.

In a brief letter, and without warning, Gordon "Grubby" Clark, said it's all over. With an action that is certain to have major repercussions in Hawai'i, Clark Foam of Laguna Niguel, Calif., suddenly shut down operations. For more than 40 years, Clark has supplied foam blocks for designing and shaping surfboards. With a virtual monopoly, Clark provides blocks for about 90 percent of all custom-made surfboards world-wide, so the surfboard market is in a panic mode. What happened? Clark said his company has been repeatedly hit with local and state regulations about use of non-standard production equipment, most of which he designed himself, and the use of aromatic hydrocarbons such as toluene diisocyanate. He stated he paid \$500,000 in fire code fixes and \$400,000 in defending a lawsuit. Moreover, he was faced with buying a multimillion dollar "scrubber" to comply with EPA pollution issues. "They simply grind away until you either quit or they find methods of bringing serious charges or fines that force you to close.' So, if you are in the market for a new board, shop now while supplies last. Prices are already on a major upswing.

♦ AND RALPH NADER ASKS WHY DOCTORS DON'T SELF-POLICE MORE VIGOROUSLY.

In Minnesota, a creative attorney is trying to rewrite the rules in malpractice cases. The complaint centers on a patient who had gastric bypass surgery, and suffered post-operative complications. The plaintiff's attorney discovered that the surgeon was not board certified and had previous malpractice actions brought against him. The lawsuit was then modified to include the hospital and medical staff for alleged negligent credentialing, and that the doctor should not have been granted privileges. The issue was altered from meeting the standard of care, as is the rule in malpractice cases, and instead involves the peer review process. However, the Minnesota peer review statute "absolutely prohibits the hospital from disclosing the deliberative processes by which the credentialing decision was made ..." rendering the hospital unable to defend itself. The District Court judge ruled that the state did not grant immunity to hospitals or other review organizations in negligent credentialing claims, and he pushed the issue to the Minnesota Court of Appeals. For certain, if peer review deliberations become discoverable, no doctor will agree to serve in that capacity.



A report in the *American Journal of Ophthalmology* from the Casey Eye Institute at the Oregon Health Sciences Center presented data on 892 cases of reported side effects from the use of erectile dysfunction drugs. Ocular side effects were found to be transitory and fully reversible. According to World Health Organization classification, ischemic optic neuropathy is "possible" due to ED drugs, but no conclusive evidence exists to establish a link. As all older eye surgeons know, anterior ischemic optic neuropathy was around long before the arrival of ED medication.

♦ LIFE IS NOT A SPECTACLE OR A FEAST. IT IS A PREDICAMENT.

The majority of malpractice insurance policies offered by physician-owned carriers contains a clause allowing the policy holder to accept or reject a settlement offer. The primary purpose is to discourage nuisance suits, which is good, but the choice has a double edge. In Baton Rouge, La., an obstetrician was sued by the parents of a child who suffered brain damage during delivery. The family claimed that the doctor was negligent, and they offered to settle for \$100,000 in damages. The insurer recommended that the offer be accepted, fearing that the child's condition could cause a sympathetic jury to award a much greater amount. The doctor refused to settle, thejury found him negligent, and awarded \$1.5 million to the plaintiff. Moreover, because the award was far beyond the settlement offer, the defendant was held personally responsible for the plaintiff's legal expenses which the judge reduced to \$10,000. The moral is that insurers and their legal staffs often recognize which cases can and should be defended and which should not. Listen to them.

SCOPES TRIAL - TAKE 2

In what should have come as no surprise, Judge John Jones III struck down the Pennsylvania school board plan to introduce "intelligent design" to high school biology students. He agreed with scientists who testified that intelligent design is little more than biblical creationism in a new suit. "The breathtaking inanity of the board's decision is evident when considered against the factual backdrop which has now been fully revealed through this trial." Interesting to note that Judge Jones is a Dubya appointee with a strong conservative background, who obviously feels that Constitutional amendment article one regarding prohibition of state sponsored religion must be protected. The President thinks intelligent design should be taught in public schools and appears to disagree with the first amendment, but then he apparently disagrees with the fourth also (illegal search and seizure).

◆ TALK IS NOT SO CHEAP WHEN YOU SAY IT WITH THESE FLOWERS.

Why send a predictable dozen roses when you can give a bouquet of "glow in the dark" chrysanthemums or roses? "The market needs new ideas and innovation," said the spokesman for a Dutch company, FloraHolland BV, which is offering flowers that glow in the dark. The costs are about 50 percent more than regular prices. Rumors that their potting soil came from Chernobyl and Three Mile Island have not been verified.

✤ ILLINOIS - LAND OF THE VOTING DEAD.

In Joliet, Ill., Harrahs Hotel and Casino sent out 11,000 coupons to favorite customers. Some of them were for \$525, but the printer made an error and all of the coupons were for \$525. The manager refused to honor the coupons, referring to a disclaimer on the back that stated that Harrahs had the option to change the rules at will. The Illinois gaming commission disagreed and ordered Harrahs to recognize the stated value. Harrahs immediately changed their tune and said they were always glad to provide tops in customer service. Right! What nice guys those casino operators are (when whipped).

ADDENDA

- 42,636 people were killed in traffic accidents in 2004, a decrease of 0.6 percent. Bicycle deaths increased 15 percent, and motorcycle deaths jumped 7.9 percent. Wear a helmet!
- A mere 13 percent of Americans know what a molecule is.
- ✤ The average mall Santa weighs 218 lbs.
- Television is a medium so called because it is neither rare nor well done.
- Learn from your parents' mistakes. Use birth control.

ALOHA AND KEEP THE FAITH - rts

Contents of this Tohome do not hecessarily reflect the Tophe on OP position of the Hawai'i Ophthalmological Society and the Hawai'i Medical Association. Editorial comment is strictly that of the writer.

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