



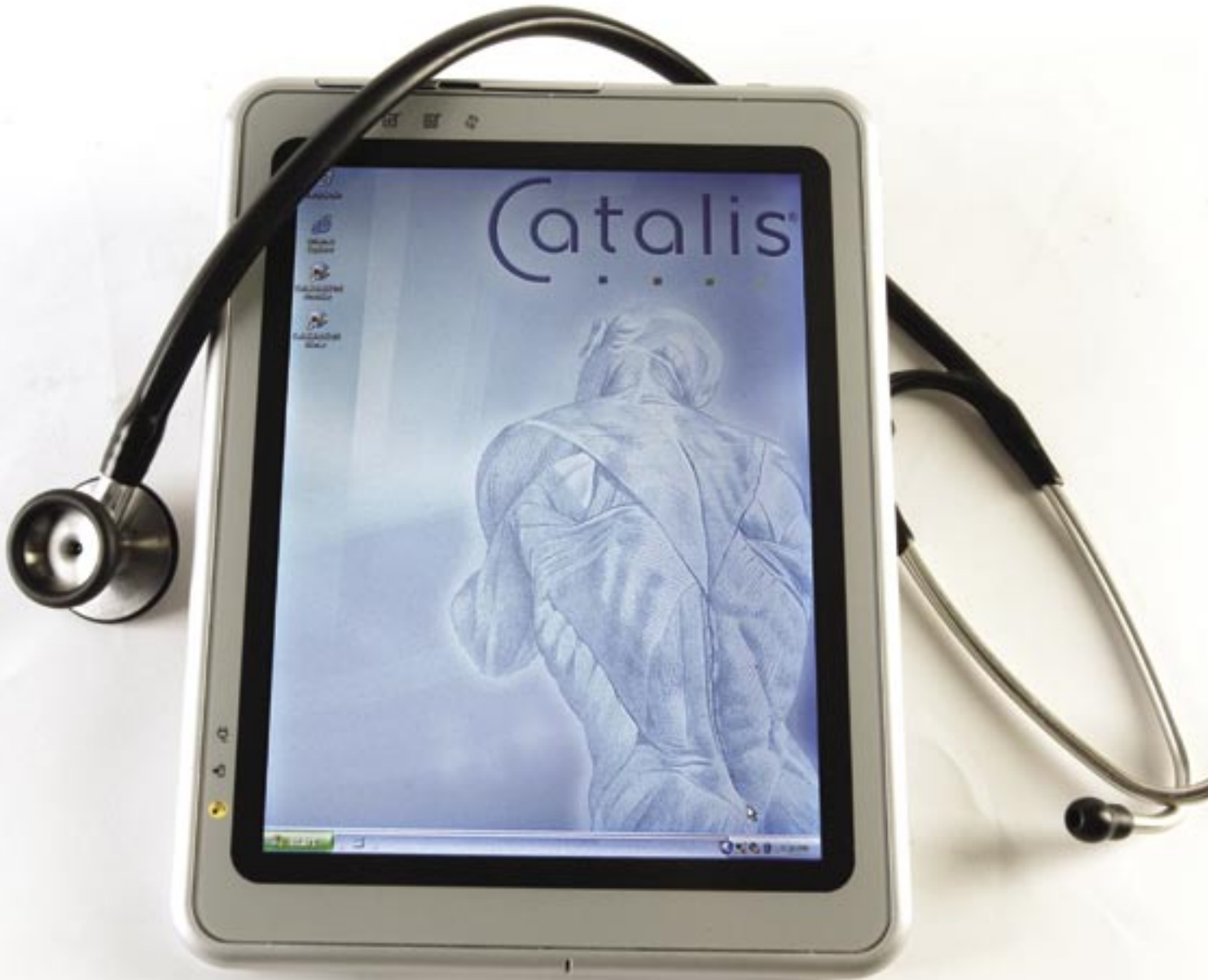
# HAWAI'I MEDICAL JOURNAL

February 2007, Volume 66, No. 2, ISSN: 0017-8594

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(USPS 237-640)

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Honolulu, Hawai'i 96814-1520  
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Postmaster: Send address changes to the *Hawai'i Medical Journal*, 1360 South Beretania Street, Suite 200, Honolulu, Hawai'i 96814. Periodical postage paid at Honolulu, Hawai'i.

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# Potential Impact of Pregnancy Outcome on the Completeness of Diagnosis of Birth Defects, Hawai'i, 1986-2001

Mathias B. Forrester BS and Ruth D. Merz MS



Mathias B. Forrester BS



Ruth D. Merz MS

## Abstract

Using data from a birth defects registry, this study investigated whether pregnancy outcome influences completeness of diagnosis ascertainment for cases with seven selected birth defects. For anencephaly, spina bifida, encephalocele, trisomy 21, trisomy 13, and trisomy 18, the proportion of isolated cases was higher among elective terminations than among live births. This was not the situation for omphalocele.

## Introduction

Investigations of the descriptive epidemiology of specific birth defects frequently separate cases by whether the defect is isolated or occurs with other structural birth defects, a chromosomal abnormality, or is part of a syndrome.<sup>1-8</sup> The assumption is made that the influence of risk factors may vary by the presence of other birth defects or syndromes, and many studies have presented results that appear to support this assumption.

However, one problem with dividing cases into these diagnostic subgroups is that cases may differ in the completeness of diagnosis. All cases may not undergo the same diagnostic procedures. For example, studies of specific structural birth defects have reported that the karyotype was known for only a portion of the cases.<sup>4,8,9</sup> Other studies that have performed systematic diagnostic evaluations of populations have found, for selected birth defects that may be less obvious at birth, rates higher than that reported by other population-based investigations.<sup>10,11</sup>

One factor that may affect whether diagnostic procedures are performed, and thus the completeness of diagnosis, is pregnancy outcome. Due to the nature of elective terminations and fetal deaths, the diagnosis of fetuses that result from such pregnancy outcomes may be limited to prenatal diagnostic procedures and what examinations may be performed on the products of conception, whereas additional procedures may be performed on live births. As a result, it might be expected that specific birth defects might be less likely to have additional diagnoses reported when they are found among elective terminations and fetal deaths than among live births. The objective of this investigation was to test this hypothesis for selected birth defects identified by a birth defects registry that includes all pregnancy outcomes.

## Methods

The source of the cases was the Hawai'i Birth Defects Program (HBDP), a population-based birth defects registry for the state.<sup>12</sup> The HBDP eligibility criteria consists of all pregnancy outcomes (live birth, fetal death, or elective termination) of any gestational age where the pregnancy ended in Hawai'i and one or more reportable birth defect was diagnosed between conception and one year after the end of the pregnancy. Trained HBDP staff identify eligible infants and fetuses and collect demographic and clinical data through review of logs and medical records at all delivery and tertiary care pediatric hospitals, facilities that perform elective terminations secondary to prenatal diagnosis of birth defects, genetic counseling centers, cytogenetic laboratories, and all except one of the major prenatal ultrasound facilities in Hawai'i.

This investigation did not include all infants and fetuses in the HBDP database because selected birth defects differed by pregnancy outcome.<sup>13</sup> If the majority of HBDP records with a selected birth defect consisted of live births, then pregnancy outcome would not be expected to have a major impact on completeness of diagnosis. Thus, for this investigation cases consisted of all infants and fetuses delivered during 1986-2001 that had at least one of the following diagnoses: anencephaly, spina bifida, encephalocele, omphalocele, trisomy 21, trisomy 13, and trisomy 18. These birth defects were selected because a large proportion of the cases were known to consist of elective terminations and fetal deaths. Infants and fetuses where the diagnosis was listed as "possible" or "probable" were excluded from the investigation.

For each case, the pregnancy outcome and the presence or absence of other coded major diagnoses were identified. Pregnancy outcome was defined as live birth, elective termination, and fetal death. No gestational age limits were placed on any of these pregnancy outcomes. The HBDP uses the six-digit birth defects coding system developed by the Centers for Disease Control and Prevention from the British Paediatric Association modification of the International Classification of Diseases, 9th revision. In this system, codes are assigned to structural defects, chromosomal abnormalities, and syndromes. A portion of the defects

This research was supported by a contract with the Hawai'i State Department of Health Children With Special Health Needs Branch, and grants from the Centers for Disease Control and Prevention, Ronald McDonald's Children's Charities, March of Dimes Birth Defects Foundation, George F. Straub Trust, Queen Emma Foundation, Pacific Southwest Regional Genetics Network, and Kamehameha Schools/Bishop Estate.

Authors' Affiliation:  
Hawai'i Birth Defects Program,  
Honolulu, HI 96817

Correspondence to:  
Ruth D. Merz, Administrator  
Hawai'i Birth Defects Program  
76 North King Street, #208  
Honolulu, HI 96817-5157  
Ph: (808) 587-4120  
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Table 1.— Proportion of selected birth defects represented by isolated cases by pregnancy outcome, Hawai'i, 1986-2001

	Total cases	Isolated cases <sup>a</sup>		Rate ratio	95% CI <sup>b</sup>
	No.	No.	% of total		
<b>Anencephaly</b>					
Live births	17	9	52.9	reference	
Elective terminations	79	57	72.2	1.36	0.67-3.13
Fetal deaths	18	12	66.7	1.26	0.49-3.38
<b>Spina bifida</b>					
Live births	98	13	13.3	reference	
Elective terminations	35	6	17.1	1.29	0.40-3.64
Fetal deaths	2	0	0.0	0.00	0.00-16.08
<b>Encephalocele</b>					
Live births	25	7	28.0	reference	
Elective terminations	24	10	41.7	1.49	0.51-4.61
Fetal deaths	4	1	25.0	0.89	0.02-6.95
<b>Omphalocele</b>					
Live births	51	7	13.7	reference	
Elective terminations	26	2	7.7	0.56	0.06-2.94
Fetal deaths	8	3	37.5	2.73	0.46-11.97
<b>Trisomy 21</b>					
Live births	254	61	24.0	reference	
Elective terminations	165	138	83.6	3.48	2.56-4.79
Fetal deaths	36	32	88.9	3.70	2.33-5.77
<b>Trisomy 13</b>					
Live births	23	0	0.0	reference	
Elective terminations	24	9	37.5	infinity	3.24-infinity
Fetal deaths	14	9	64.3	infinity	2.66-infinity
<b>Trisomy 18</b>					
Live births	43	1	2.3	reference	
Elective terminations	72	36	50.0	21.50	3.62-872.50
Fetal deaths	29	15	51.7	22.24	3.42-936.31

<sup>a</sup>No other structural defects, chromosomal abnormalities, or syndromes were coded.

<sup>b</sup>CI, confidence interval.

included in the coding system are considered “minor”, i.e., the defects are only listed and coded if they occur in the presence of other defects that are always listed and coded. These “minor” defects were excluded from the analysis.

For each of the seven specific birth defects, the distribution of cases by pregnancy outcome was determined for all cases and for “isolated” cases (those cases where no other diagnoses such as structural birth defects, chromosomal abnormalities, or syndromes were listed). No attempt was made to examine the distribution of “non-isolated” subgroups such as those with chromosomal abnormalities, other

syndromes, and other structural birth defects because of a lack of consensus as to which cases would fit into these subgroups and because the subgroups would not be applicable to the three chromosomal abnormalities studied. The proportion of all cases represented by isolated cases among elective terminations and fetal deaths then was compared to the proportion among live births by calculating the rate ratio and 95% confidence interval.

## Results

Table 1 shows the proportion of cases that were isolated by pregnancy outcome for the seven birth defects. For six of the birth defects, the proportion of isolated cases was higher among elective terminations than among live births, the exception being omphalocele. For five of the birth defects, the proportion of isolated cases was higher among fetal deaths than among live births, the exceptions being spina bifida and encephalocele. The differences in the proportion of isolated cases between pregnancy outcomes only were statistically significant for the chromosomal abnormalities.

## Discussion

This investigation found that, for selected birth defects where a portion of cases were elective terminations and fetal deaths, a higher proportion of the birth defects were likely to be isolated if the pregnancy outcome were an elective termination or fetal death than if the pregnancy outcome was live birth.

One possible explanation for this observation is that fetuses with isolated birth defects are more likely to result in elective termination or fetal death and fetuses with additional birth defects are more likely to be born alive. However, it might be expected that with the presence of additional birth defects morbidity and mortality would increase. Studies have shown that infant mortality increases for specific birth defects if other birth defects also are present.<sup>14,15</sup> Moreover, research in Europe has reported that cases with multiple defects are more likely to be prenatally diagnosed and electively terminated.<sup>1,2,6</sup>

Thus, a more likely explanation may be that additional birth defects are less likely to be diagnosed among elective terminations and fetal deaths than among live births. This might be expected, considering that for elective terminations and fetal deaths diagnostic procedures are usually limited to prenatal diagnostic procedures such as ultrasound and those examinations that may be performed on the products of conception. In contrast, additional procedures may be performed on live births. Although autopsy is useful for the identification of structural birth defects, autopsy may not be performed in a portion of elective terminations or fetal deaths because either the products of conception are macerated or the health care provider or family did not desire an autopsy. Of the 1,218 elective terminations

and fetal deaths occurring during 1986-2001 that were included in the HBDP, only 260 (21.3%) had diagnoses identified through autopsy.

The results of this investigation are important because descriptive epidemiologic studies of specific birth defects frequently divide cases into isolated and non-isolated subgroups. If studies include as cases elective terminations or fetal deaths, there is a possibility that the proportion of isolated cases would be over reported, thus biasing comparisons between isolated cases and non-isolated cases. This would be less of a problem for those specific birth defects where few cases are comprised of elective terminations or fetal deaths. Moreover, the impact of pregnancy outcome may differ between populations. Elective termination rates have been reported to vary between states and countries.<sup>16,17</sup> Additionally, more diagnostic procedures such as autopsies may be performed on the products of conception in some populations than in others.

It would be useful for analyses similar to the present one to be performed by other birth defects registries in order to provide more information on the topic. This is particularly important because of the variability between populations mentioned above and because of the relatively small number of cases included in this analysis, which limited its evaluation of statistical significance.

#### Acknowledgments

We wish to thank Dr. Laurence N. Kolonel for serving as the program principal investigator, Edward R. Diaz for computer assistance, A. Michelle Weaver and Amy M. Yamamoto for data collection activities, the staff of the Office of Health Status Monitoring at the Hawai'i Department of Health for providing data for determining denominators, and the 33 participating Hawai'i health facilities who allowed us access to their patient data.

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# Community Recommendations on Outreach Activities for QUEST-Expanded: Medicaid Managed Care for the Aged, Blind, and Disabled Population

Kirsty M. McWalter MS, CGC, Christine M. Hughes MA, Nicole K. Masukawa MA, Kelli R. Minatoya CMA, Sarah Miyake MSW, Taryn A. Oyadomari MSW, Joy H. Shimamoto PsyD, and Leolinda Parlin BA



Kirsty M. McWalter MS, CGC



Christine M. Hughes MA

## Abstract

*The Hawai'i Medicaid Program intends to transition its Aged, Blind, and Disabled population from a fee-for-service to a managed care model. To determine the best outreach strategies for this transition, focus groups of beneficiaries were held throughout Hawai'i. Beneficiaries want information in simple language, to be told about the change by someone knowledgeable whom they trust, and to have services that address their individual needs. A model for the transition, including these strategies, is described.*

## Introduction

The Hawai'i Medicaid Program includes QUEST, a managed care (MC) model,<sup>1</sup> and Medicaid for the Aged, Blind, and Disabled Population, a fee-for-service model.<sup>2</sup> Under the fee-for-service model, beneficiaries may choose any willing doctor. Following the lead of other states,<sup>3-6</sup> the Hawai'i Medicaid Program plans a transition to MC in 2008, called QUEST-Expanded.<sup>6</sup>

To facilitate the transition, QUEST-Expanded will launch a "Choice Counseling Program" for outreach and enrollment, including identifying beneficiaries, providing education and choice counseling, and enrollment. Effective outreach to special populations will be essential. Many MC enrollment programs on the mainland are too new to have been tailored to the special needs of population subsets.<sup>8</sup> Thus, there is no current model for Hawai'i.

In addition, little is known about the best types of outreach and communication strategies for health plans, particularly with ethnically diverse populations.<sup>8-9</sup> Enrollment strategies include a range of activities: community-wide orientation to MC, individual communication and outreach, plan/provider choice counseling, auto-assignment of beneficiaries not choosing a plan or provider, facilitating the transition, and collaboration with beneficiary, advocacy, provider, and community groups representing the interests of enrollees with special needs.<sup>10</sup>

The communication needs and desires of beneficiaries within Hawai'i's special populations will be identified and influence the outreach process.

## Purpose

This project set out to determine how Hawai'i Medicaid beneficiaries want to be informed of the change to MC. Beneficiaries shared their understanding of MC, detailed the information wanted from the State and health plans, and described how they would like this information communicated. Findings were presented to Medicaid representatives, consumers, the QUEST-Expanded Advisory Council and legislators at the Hawai'i State Capitol building in December 2005.

## Methods

Six focus groups were conducted by the University of Hawai'i-Manoa Leadership Education in Neurodevelopmental and related Disabilities (LEND) trainees on Moloka'i, Hawai'i, and O'ahu. Each focus group had four to ten participants and included self-advocates and/or family caregivers of Medicaid beneficiaries. Standard scripts and questions were utilized. Cassette tape recordings were transcribed and common themes identified. Results from qualitative data analysis were reported as total counts, by group type, and by island. 495 total responses were coded for six questions.

## Research Questions

Participants were asked ten questions. Questions 1-3 were icebreakers:

1. *What are the kinds of things you look for in selecting a health care provider? A health care provider can be a doctor, pharmacist, therapist, etc.*

2. *In the past, how have you selected your health care providers?*

3. *If you needed to find a certain kind of provider (a specialist, surgeon, hospital, or laboratory) how would you do it?*

This work has been produced as part of the Leadership Education in Neurodevelopmental and related Disabilities (LEND) Program, funded through a Maternal and Child Health Bureau, U.S. Department of Health and Human Services, Health Resources and Services Administration grant through the University of Hawai'i Center for Disabilities Studies.

Correspondence to:  
Kirsty M. McWalter MS, CGC  
Hawai'i Department of Health  
Genetics Program  
741 Sunset Avenue, Honolulu,  
HI, 96816  
Ph: (808) 733-8387  
Fax: (808) 733-9068  
Email: kirsty@hawaiigenetics.  
org



Question 4 introduced the change in Medicaid provision, gathered immediate responses, and allowed participants to share their experiences:

4. *The state is in the process of changing the way it provides your health care coverage. The services you receive right now through Medicaid will be provided to you through a health care plan, starting sometime in 2008. What words or thoughts immediately come to your mind when you hear the words "health care plan"?*

Questions 5-7 identified desirable outreach strategies and communication:

5. *How would you like to be informed about this change in Medicaid, where you now have to select a health care plan?*

6. *From who would you like to hear or get this information?*

7. *What kinds of information would you like from the state to assist you in understanding this upcoming change?*

Questions 8-10 revealed those items important to participants:

8. *How much time would you like to have to make the decision about selecting a health care plan?*

9. *What kinds of information would you like from the health care plans to assist you in selecting a plan?*

10. *What is the one piece of advice that you would like to give the state?*

## Limitations

Assumptions of a study's methodological approach may pose limitations.<sup>11</sup> The assumptions of the interpretivist approach are:

1. reality is multiple and socially constructed,
2. outcome depends upon the researcher's skills,
3. study quality depends upon sufficient immersion,
4. the researcher's presentation can determine participants' depth of shared data,
5. participants' worldviews influence emerging information,
6. there is differential familiarity with the phenomenon,
7. participants may have difficulty articulating experiences, and
8. constant comparative method is used to test hypotheses.<sup>11-13</sup>

"Aged" Medicaid beneficiaries were specifically excluded due to the recent implementation of Medicare Part D; including them may have created confusion and undue harm. Also, no participants were hearing impaired; their unique perspective was not accessed.

The data may be a biased representation of participants able to articulate their experiences and choosing to provide responses.

Member checking, participants examining transcript accuracy, coding strategies, and final portrayal, was not performed. It may therefore be difficult to check the emic accuracy of the portrayal and trustworthiness of study findings.

## Results

### Perceptions of Managed Care (Question 4)

Responses clustered into seven themes, listed in order of frequency. There was a high degree of variability in perceptions and levels of understanding.

**Theme 1: "Personalized Care."** Participants thought MC provides increased continuity of care, follows one through their care, and is akin to Community Care Services (help prevent institutionalization of individuals through home- and community-based services and waiver programs).

**Theme 2: "Hassle."** Participants said it would mean more paperwork, more headaches, and was another change to which they would be subjected.

**Theme 3: "Cost."** Participants thought MC would cost them money. They questioned who would fund the cost of the change.

**Theme 4: "Restrictive."** Participants said there may be less choice and more rules in the MC model. They expressed concern over the quality of care due to restrictions.

**Theme 5: "Government Control."** Some participants felt the government would control provider access and types of conditions approved for access. One participant said that they saw MC as similar to socialized medicine.

**Theme 6: "Accountability."** Participants said that MC would have defined benefits so beneficiaries would know their entitlements. Further, there would be a contact person for any problems.

**Theme 7: "Confusion."** Confusion over the meaning of MC was especially evident in adults with mental health needs.

### How Participants would like to be Informed of the Change (Question 5)

Responses fell into five categories: written materials, personal contact, groups, style, and format.

Most participants wanted written information. In one group, responses reflected the island's unique style; participants stated that Moloka'i residents would only relate to flyers with pictures.

Personal, face-to-face, or telephone contact with a case manager, physician, or someone trustworthy to relay the information in a clear, simple, concise, and objective manner is important.

Participants indicated a desire for group information and question sessions, such as town meetings. Moloka'i participants wanted to share their *mana'o*, or opinions about the change; an example of how they rely on each other for help when making decisions.



Nicole K. Masukawa MA



Kelli R. Minatoya CMA



Sarah Miyake MSW



Taryn A. Oyamomari MSW



Joy H. Shimamoto PsyD



Leolinda Parlin BA

Participants also requested information in alternative formats such as Braille, audiotapes, and an Internet website. They stressed the importance of having information relayed to them in simple language.

#### *From Whom Participants Would Like to Hear the Information (Question 6)*

Three main themes emerged: one identified ideal qualities of the information-giver, and two identified specific people.

**Theme 1:** “*Somebody*.” Participants want somebody trustworthy who is able to relay information in an understandable way. Most often, this was someone they already knew. However, some participants wanted to hear the information from our facilitators. This suggests that minimal contact may be enough to establish trust and become “somebody” from whom participants want to receive information.

**Theme 2:** “*Representative of the Program*.” This response, most frequent among participants with mental health needs, indicated the importance of accountability. They felt a program representative would be knowledgeable.

**Theme 3:** “*Healthcare Providers*.” This response was most prominent among caregivers of children with special health care needs; they want information from people with whom they interact frequently.

#### *Information People Want from the State (Question 7)*

Four main themes emerged.

**Theme 1:** “*How the system works*.” Participants want general system information, plus information relevant to their particular situations. One participant wanted different scenario examples. Participants want to be informed throughout the change process.

**Theme 2:** “*Benefits*.” Participants want plan information and a variety of plans from which to choose. Neighbor Island (NI) participants expressed frustration over limited provider options and concern of being limited to a single choice

**Theme 3:** “*Procedures*.” Participants want to learn about eligibility, application steps, necessary paperwork, the problem-solving process, people to contact with questions or complaints, changing plans if unsatisfied with the original choice, and providers who no longer accept Medicaid beneficiaries. They want information about the State’s roles and responsibilities and about their own responsibilities.

**Theme 4:** “*Cost*.” Participants want to know how the change would affect their costs for services. They want to know how much the State will pay to implement the change.

#### *Time Needed to Choose a Health Care Plan (Question 8)*

Researchers categorized the time needed to choose a plan: 0–3 months, 4–6 months, 7–9 months, and 10–12 months. Most participants indicated that they would need 0–3 months. However, caveats included documentation complexity, volume of information, and extra research required of beneficiaries. The language used and details provided were determinants of time required; the more complex the information, the more time needed.

#### *Information People want to Know from Health Plans (Question 9)*

Four main themes emerged.

**Theme 1:** “*Provider Listings*.” Participants want information about the participating providers. They strongly expressed that the availability of providers, hospitals, and pharmacists *in their area* was important, e.g., NI participants do not want lists of O’ahu doctors.

**Theme 2:** “*Benefits*.” Participants want information about covered services and other related needs: specialty care, vision, dental, and medication, formulary medications, and how to obtain supplies.

**Theme 3:** “*Cost*.” Participants want information about the cost of services, the cost of the plans themselves, and cost of other services such as companion transportation.

**Theme 4:** “*Plan Management*.” Participants want information about plan threshold issues and enrollment caps. They want to know how the plan will address provider availability issues, the process by which doctor recommendations are approved or denied, and who has the authority to determine medical necessity. Parents of children with special health care needs expressed these points most strongly.

#### *Other Concerns*

Other concerns included range of services offered, dental coverage, drug coverage, availability of providers, and access to specialty care on NIs. Participants want routine dental care and assurance that their current drug regimen will be covered by their new plan.

Participants were concerned that enough providers will be contracted. For example, at the time of this study, only one pediatric geneticist served the State of Hawai’i. There was concern, should this specialist leave Hawai’i, about what would happen to her patients. There was also concern that providers will not be able to service all the NIs.

In summary, there was marked anxiety related to the change, confusion about why it is occurring, some distrust/frustration, but also appreciation for being included in the process. Anxiety was particularly evident in parents of adult children with disabilities.

## **Discussion**

### *Recommendations*

A model for the potential outreach process (Figure 1) lays a foundation for the transition to MC. Integral components are community involvement, engagement of partners to assist the state, and honesty and respect for beneficiaries.

This model should be expanded into specific outcome-based actions. Indicators should ensure that the process is client-centered, proactive, coordinated, and consistent. Equity of outreach should be monitored; NI beneficiaries would like equal access to information and opportunity to comment. Finally, perceived outreach quality should be evaluated.

### *Choice Counseling*

The initial step in the outreach process is contracting with an agency to coordinate and implement choice counseling. Focus group comments indicate necessary process characteristics: (a) assisting beneficiaries throughout the transition, (b) several modalities should be designed to effectively reach beneficiaries, particularly special populations, and (c) it is crucial that the contracted agency and the state partner with existing community organizations working with the targeted

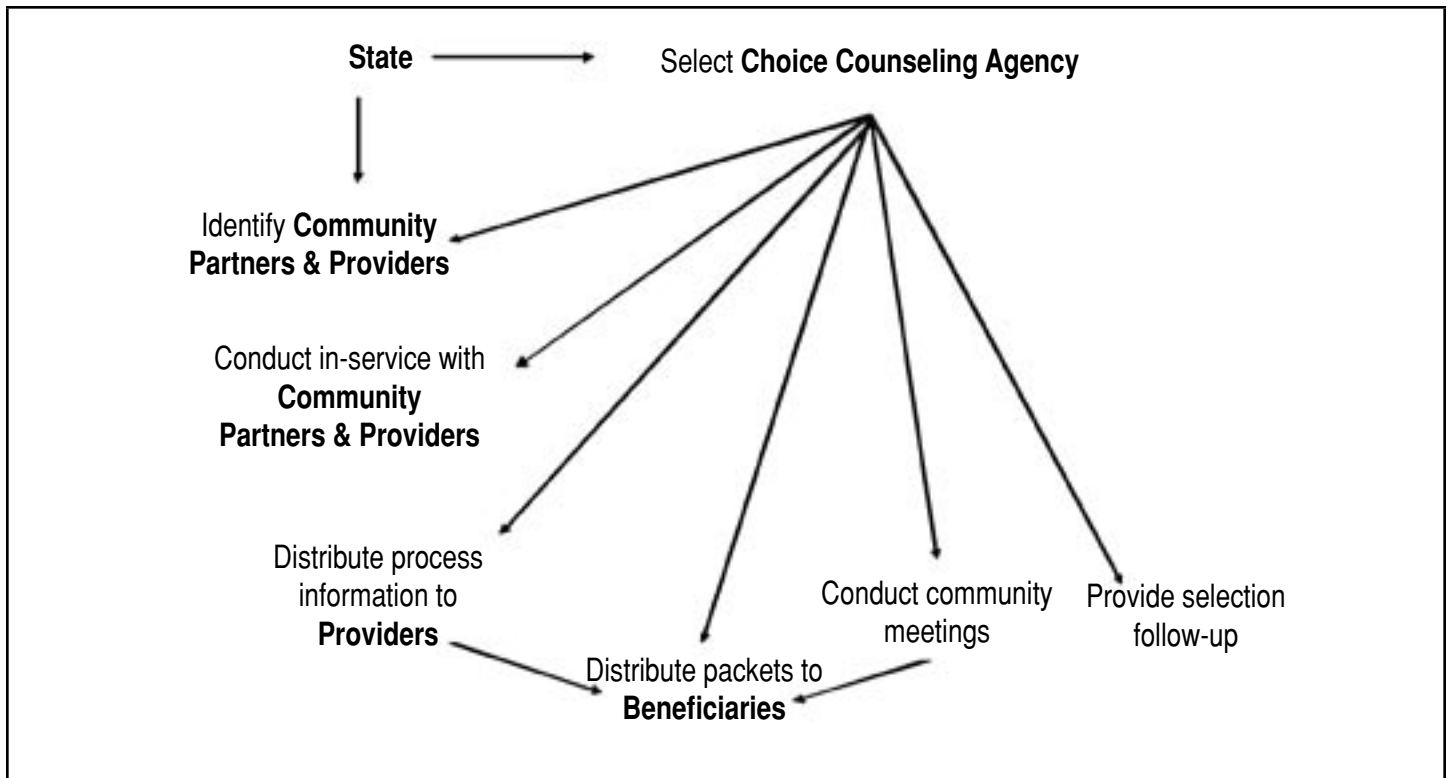


Figure 1.— Diagram of the outreach process

population. The contracted agency must identify community partners and foster collaborative relationships.

#### *Identification of Outreach Partners*

Community and state partnerships are vital components of the process. Often, these partners already have existing relationships with the beneficiaries and are the first point of contact. Participants repeatedly expressed a preference to learn about changes from somebody they know and trust.

The state agencies that should be involved include those within the Department of Health (DOH): the Developmental Disabilities Division (DDD), Early Intervention Section (EIS), Adult Mental Health Division (AMHD), Child and Adolescent Mental Health Division (CAMHD), and the Children with Special Health Needs Branch (CSHNB). Within the Department of Human Services (DHS), the Social Services Division (SSD) should also be a partner.

Community-based programs work with beneficiaries potentially affected by the change. Community partnerships will help reach populations that may not be directly linked with state agencies: community health centers, the Native Hawaiian health care system, and other social service agencies.

#### *Provision of In-Service Trainings*

After identifying collaborating partners, the contracted agency should provide in-service training to explain the transition and the MC model. This is important so that partners can understand how the transition will take place, the timeline, and how the change will affect providers and beneficiaries. Partners will need this information to answer beneficiaries' questions, make appropriate referrals, invite beneficiaries to community meetings, and help them make informed decisions.

The state should consider the partnership structure in order to maximize the benefits of collaboration. How much responsibility should be placed on the partnering agencies? One option is to offer comprehensive trainings to the partners and offer funds/grants to help defray costs of the partnership.

#### *Distribute Process Information to Providers*

Simultaneous with partner training, the state should contact health care providers to assist with disseminating information. Providers are important in the outreach campaign because of their regular contact and recognized health expertise. Resources such as posters, brochures, fact sheets, and listings of community meetings or a referral person to contact should be provided.

#### *Distribute Information Packets to Beneficiaries*

After partner training and information distribution to providers, beneficiaries should receive information packets. A thorough explanation of QUEST-Expanded could include answers to questions: "How is it better?" "How is it going to affect us?" and "What is it going to cost?" Cost should be addressed, as some participants perceived MC as similar to private insurance, including co-payments.

A timeline highlighting counseling dates and plan-selection deadlines would help beneficiaries.

A comprehensive provider list should be included, along with locations, phone numbers, and times available. Additionally, an abbreviated drug coverage formulary is important.

A side-by-side comparison of plan benefits and processes could be included in the information packet. Case scenarios could assist beneficiaries.

A "Frequently Asked Questions" section could include "How is this change going to affect me?" "What happens if everyone chooses

plan A instead of plan B?” “Will I automatically be assigned to one plan if another reaches its maximum threshold?” Should beneficiaries have further questions, a telephone hotline would be helpful.

A Website of information would be a valuable resource.

Following the initial packet, beneficiaries may receive a second notice. This could be a postcard with reminders about meeting dates, locations, and times. Flyers could also be posted to announce community meetings.

### *Conduct Community Meetings*

When scheduling community meetings, a familiar, central location, accessible by public transportation is crucial. Accommodations should be made for those with jobs or child-care needs. Multiple meetings on varied days and times may be necessary. It is a good idea to provide food at meetings; this creates a welcoming atmosphere.

Meeting preparations should be coordinated through a community partner who assists in inviting beneficiaries. The appointed “host” should be someone the beneficiaries have a previous relationship with and trust.

### *Selection Follow-Up*

Subsequent to community meetings, beneficiaries should have opportunities to speak with choice counselors, such as one-to-one office or home visits, telephone consultations, or “break-out” sessions.

## **Conclusion**

Beneficiaries’ perceptions of MC encompassed a wide range of responses, both positive and negative. From the State, individuals want to know how the system works, benefits, procedures, and cost. Participants requested information about plans: provider listings, benefits, cost, and plan management. They wanted to hear about the change from program representatives, providers, and “somebody” they can trust. Participants want materials written in simple language, personal contact, Websites, and group meetings. Most participants felt that three months was an appropriate amount of time to select a plan.

A model for the outreach campaign was formulated based on responses. Honesty, trust, consistency, and client-centeredness are key elements. The first step is contracting an agency to facilitate and implement the process. Subsequently, community partners and providers will be informed about the MC model and will help disseminate information. Choice counselors will respond to referrals from partners and providers. A mailed packet will provide plan information and an invitation to community meetings. The next step is holding community meetings for beneficiaries. Finally, choice

counselors will follow up with beneficiaries.

Beneficiaries, providers, and policymakers share an interest in making informed decisions about transitioning from Medicaid fee-for-service to MC. One of the greatest challenges is translating reliable data into recommendations to inform the decision making process. The findings from this project guide recommendations and strategies for organization, management, and delivery.

In conclusion, it is important that the opinions of beneficiaries are taken into consideration. Participants asked that they be valued and treated with a humanistic approach that allows them the dignity and respect afforded to others. One participant stated:

*“I would just say that these clients deserve the same equal treatment as... a normal person regardless of their position, their status, their mental status; that every individual would be given the same care and consideration... to provide for them as you would for yourself.”*

It is for such families that this project was conducted. It is essential to elicit the input of those affected by the change. The recommendations outline an effective outreach model and will contribute to a smooth transition from Medicaid fee-for-service to the MC model, QUEST-Expanded.

### Authors’ Affiliations:

- Hawai’i Department of Health Genetics Program (K.M.M.)
- American School of Professional Psychology at Argosy Hawai’i (C.M.H., N.K.M, J.H.S.)
- University of Hawai’i at Manoa (K.R.M., S.M., T.A.O.)
- Hawai’i Leadership Education in Neurodevelopmental and related Disabilities (LEND) Program Faculty (L.P.)

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# Failure of Juice or Juice Extract from the Noni Plant (*Morinda citrifolia*) to Protect Rats Against Oxygen Toxicity

John T. Berg PhD and Eiichi Furusawa MD, PhD



John T. Berg PhD



Eiichi Furusawa MD, PhD

Morinda Inc. provided Noni-ppt and Tahitian Noni juice. This study was supported by Hawai'i Community Foundation (Geist Award # 20020619, JTB) and Morinda Inc. (EF).

## Abstract

*Noni juice possesses antioxidant activity and prevents superoxide-mediated tissue injury in laboratory animals. A polysaccharide-rich precipitate of noni juice (noni-ppt) also stimulates tumor necrosis factor (TNF) and interleukin 1 (IL-1) in mice. Endotoxin (lipopolysaccharide) stimulates TNF and IL-1 in rats and protects against superoxide-mediated oxygen toxicity. Accordingly, we hypothesized that noni juice, or noni-ppt, would protect rats against pulmonary oxygen toxicity. Rats were divided into four groups; one received noni-ppt to test for cytokine-induced protection; another received noni juice to test for antioxidant activity; a third received saline as hyperoxia control; a fourth received no treatment in air. Rats were then exposed to either hyperoxia (>97% oxygen at sea level for 52 or 60 hours) or air and lung injury assessed. Rats receiving saline, noni-ppt or noni juice exhibited typical signs of oxygen toxicity with hemorrhagic lungs, large pleural effusions and increases in protein concentration in bronchoalveolar lavage fluid. They also developed heavy lungs with increases in wet/dry weight ratios, hematocrit values and ratios of effusion protein to plasma protein concentration. These results show that Noni juice and Noni-ppt do not prevent oxygen toxicity in rats when administered according to the protocols used in this study.*

## Introduction

Experimental studies have shown that juice from the noni plant (*Morinda citrifolia*) exerts a range of biological responses in laboratory animals and humans.<sup>1</sup> In particular, noni juice exhibits antioxidant activity to reduce superoxide production and lipid peroxidation in both a rat model of carbon tetrachloride (CCL<sub>4</sub>)-induced liver injury<sup>2</sup> and in a mouse model of DNBA-induced DNA adduct formation in heart, lung, liver, and kidney.<sup>3</sup> In addition, a polysaccharide-rich extract of noni juice (noni-ppt) possesses antitumor activity and stimulates release of tumor necrosis factor (TNF) and interleukin 1 (IL-1) to extend survival in mice following tumor transplantation.<sup>4</sup>

Similar to CCL<sub>4</sub>-induced liver injury and DNBA-induced DNA adduct formation, oxygen free radicals (superoxide, in particular) cause pulmonary oxygen toxicity.<sup>5</sup> Also, similar to the above-mentioned examples of protection by noni juice and noni-ppt, endotoxin stimulates TNF and IL-1 to induce antioxidant enzymes

and protect rats against pulmonary oxygen toxicity.<sup>6-8</sup> Because of these similarities, we hypothesized that noni juice or noni-ppt may protect rats against pulmonary oxygen toxicity.

## Methods

### Animals

Specific pathogen free male Sprague-Dawley rats were purchased from Harlan Sprague-Dawley (Indianapolis, IN). Animals were acclimatized to the animal care facility for at least two weeks before use to allow recovery from jet lag and ensure immune responsiveness.<sup>9</sup> Rats were provided standard laboratory chow and water ad libitum during experiments with a total of 25 rats (320 to 550 g) used in the study (ages, 3-7 months old). All procedures were approved by The Animal Care Committee of the University of Hawai'i and conformed to National Institutes of Health guidelines for animal research.

### Study 1 (Noni-ppt)

The noni precipitate (noni-ppt) used in this study was provided by Morinda Inc. (Provo, UT) and is an experimental preparation not intended for commercial use. It was extracted using the procedure of Hirazumi and Furusawa.<sup>4</sup> Briefly, one volume of noni fruit juice was fractionated in four volumes of 95% ethanol. The mixture was then centrifuged and the precipitate rinsed three times in ethanol. Flash evaporation was used to remove the ethanol from the noni-ppt before use in experiments. The yield of the final precipitate (noni-ppt) was 8 mg of polysaccharide-rich substance (over 98% polysaccharide composed of at least four monosugars including glucuronic acid, galactose, arabinose, and rhamnose) isolated from 1 ml of the fruit juice. To maximize solubility for injection into rats, noni-ppt was first dissolved in the required amount of distilled water and sodium chloride was then added to bring the solution up to 0.9 % concentration.

### Treatment protocols for noni-ppt administration

A total of seven pairs of rats were used in Study 1 with 7 different treatment protocols. The goal was to maximize the possibility that one of the treatment regimens would provide protection against oxygen

Authors' Affiliation:  
Department of Tropical  
Medicine,  
Medical Microbiology, and  
Pharmacology  
University of Hawai'i at Manoa,  
Honolulu, HI 96816

Correspondence to:  
J.T. Berg PhD  
Lung Injury Research Institute,  
012 Mamarlao, San Carlos City,  
Philippines 2420  
Ph: 011 6375 531-2086.  
Email: johnberg@hawaii.edu

toxicity and serve as a guide for further studies. The first pair of rats was exposed to hyperoxia for 60 hours and subsequent animals were exposed to hyperoxia for 52 hours. This change in exposure time was required by the Laboratory Animal Committee to reduce lung injury and lessen possible suffering by the animals. Most rats received noni-ppt according to the procedure of Hirazumi and Furusawa<sup>4</sup> where one rat received noni-ppt dissolved in 0.9 % NaCl (saline) by intraperitoneal (i.p.) injection and the other rat received equal volume saline i.p. Pair 6 was the exception where one rat received a split dose of noni-ppt with half of the volume given i.p. and the remainder given intravenous (i.v.). The rationale for administering a split dose was the report by White et al.<sup>10</sup> where split doses of tumor necrosis factor and interleukin 1 were used to protect rats against pulmonary oxygen toxicity. Treatment protocols were: Pair 1 (60 h exposure); noni rat received a total of seven injections (50 mg noni-ppt in 1 ml saline, total dose 350 mg) with five injections given daily prior to hyperoxia and two injections during hyperoxia (one at 20 h and the second at 40 hour exposure). Pairs 2 to 4; noni rats received single injections of 50, 150 or 250 mg noni-ppt in 3 ml saline immediately before hyperoxia (total dose, 50, 150, or 250 mg respectively for Pairs 2, 3 and 4). Pair 5, noni rat received daily treatments with 300 mg noni-ppt in 5 ml saline for 2 days before hyperoxia (total dose, 600 mg). Pair 6, noni rat received 300 mg noni-ppt with half the dose administered i.p. and the rest by i.v. injection before hyperoxia (total dose, 300 mg). Pair 7, noni-ppt rat received a total of three injections with 150 mg noni-ppt, two daily injections before hyperoxia and a third injection at 24 h into exposure (total dose, 450 mg).

### **Study 2 (noni juice in drinking water)**

Tahitian noni juice was provided by Morinda, Inc., (Provo, UT) for investigational use in this study. In Study 2, six rats were given 20% noni juice in water for nine days and exposed to hyperoxia for 52 hours. This concentration of noni juice was recommended by Dr. M-Y Wang (personal communication) based on her observations that a 20% solution provided greater protection against oxidant injury than the more commonly used 10% solution. Fresh solutions of noni juice were provided daily before exposure to hyperoxia and also during exposure and animals had access to rodent chow at all times. As in Study 1 (above) lung injury and pleural effusions were analyzed in all rats following exposure to hyperoxia or air (Air Group, 5 rats).

### **Exposure to hyperoxia**

The exposure chamber was made of clear plexiglass (15 inches x 20 inches with 8 inch high walls). The floor was lined with wood chips and color indicator CO<sub>2</sub> absorbant (Sodasorb, WR Grace and Company, Atlanta, GA) and was separated from rats by a 1-inch high wire mesh floor. Food and water (or noni juice) were provided ad libitum during hyperoxia. Immediately before exposure body weight was determined for each rat and colonic temperature recorded using a rapidly responding thermometer (Model T-6000, Miller and Weber, Inc., Queens, NY). To initiate an experiment, the chamber was flushed with medical grade oxygen (100% O<sub>2</sub>) at 15 L/min until chamber O<sub>2</sub> concentration was >97% (6-7 min) using a MiniOx1 oxygen analyzer (MSA Medical Products, Pittsburgh, PA). Flow was then decreased to maintain O<sub>2</sub> concentration at >97% (typically 3-4

L/min) throughout exposure. CO<sub>2</sub> levels were also measured during hyperoxia using a Beckman Medical Gas Analyzer (Model LB-2) and maintained at levels below 0.15%.

### **Post exposure measurements and assessment of pleural effusions and lung injury**

At completion of hyperoxia one rat was removed from the chamber for data collection while the other rat remained in the chamber to wait his turn. The procedure for data collection was as follows: The rat was weighed and colonic body temperature recorded. The rat was then anesthetized with sodium pentobarbital (50 mg/kg body weight, i.p.) and heparanized blood was collected from the abdominal aorta for hematocrit determination. The rat was then exsanguinated. Next, the trachea was cannulated and the chest opened by midline incision with care taken to avoid blood vessels. Lung appearance was then recorded by assigning values within a range of 1 to 9 to describe hemorrhage on the lung surface (1 indicated normal appearance with an absence of hemorrhage and 9 indicated hemorrhage on the entire visible lung surface) [9]. The pleural effusion volume was measured using a graduated cylinder (or by weight for small volumes) and effusion protein concentration was determined using a hand-held refractometer (Atago, Tokyo, Japan) standardized with albumin. The middle left lung lobe (LL) was then ligated for later determination of lung weight and the remaining lung was lavaged using 5 ml 0.9% NaCl (saline). Hematocrit values were determined on duplicate capillary tube samples (centrifuged at 11,000 rpm/5 min) and plasma protein values were obtained from the plasma portion of the hematocrit sample using the hand-held refractometer. Finally, the bronchoalveolar lavage fluid (BALF) was centrifuged (4,000 rpm/10 min) and protein determinations made on the supernatant using the total microprotein-PR kit (Sigma Chemical Company, St. Louis, MO). This assay is based on the absorbance change (600 nm) that occurs when basic amino acid groups in proteins react with the pyrogallol red-molybdate complex.

### **Statistical analysis**

All hyperoxia-exposed animals (with the exception of Pair 1 in Study 1) received the same period of exposure to hyperoxia. In addition, all animals failed to exhibit protection against hyperoxia with any of the dosage treatment protocols tested. Because of these similarities, data from hyperoxia-exposed animals in each Study were pooled for statistical comparisons. A one-way analysis of variance with Student-Newman-Keuls test (Primer of Biostatistics: The Program, Stanton A. Glantz, Version 3.0, McGraw-Hill, 1992) was used to determine significance at a value of  $p < 0.05$  between groups. All data are expressed as mean  $\pm$  SEM with  $n$  equal to the number of animals per sample group.

## **Results**

### **Similarity of responses within treatment groups**

When the results from all rats were examined, it was found that none of the data points in the Saline, Noni-ppt or Noni juice groups overlapped with comparable values from the Air group. In addition, there were no statistical differences between comparable sets of data points in the Saline, Noni-ppt, or Noni juice groups. Because of these similarities in response, the individual values for each measured variable within groups were pooled for statistical analysis.



### Response of rats to hyperoxia

All rats exhibited labored breathing in hyperoxia and lost body weight. Saline-treated rats lost an average of  $5.6 \pm 0.5$  % in body weight (mean  $\pm$  SEM) following 52-h exposure while noni-ppt rats lost  $7.3 \pm 0.6$  %. In comparison, rats receiving noni juice in the drinking water lost  $3.1 \pm 0.4$  % of their body weight during hyperoxia which was significantly less ( $n=6$  for each of these three groups) than the weight loss exhibited by saline or noni-ppt rats receiving 52-h hyperoxia ( $p < 0.05$ ). The saline-treated rat exposed to hyperoxia for 60 hours (Pair 1) lost 5 % of initial body weight and the noni-ppt rat lost 8.9 %.

All rats lost body temperature following hyperoxia: Saline-treated rats lost  $3.5 \pm 0.4$  °C ( $n=5$ ); Noni-ppt rats lost  $3.7 \pm 0.7$  °C ( $n=5$ ) and rats drinking noni juice lost  $2.9 \pm 0.2$  °C ( $n=6$ ). The two rats exposed to hyperoxia for 60 hours (Pair 1) exhibited a greater decrease in body temperature (-9.0 and -6.8 °C: saline-treated and noni-ppt rats respectively) than the rats exposed to 52-hour hyperoxia, suggesting that morbidity was increased in those rats receiving longer exposure to hyperoxia.

### Lung injury in hyperoxic rats

The lungs of all hyperoxic rats were hemorrhagic with visible signs of lung injury on autopsy (Table 1, LA values). Gravimetric lung weights were also used to assess lung injury because the weights of wet lung tissue increase as fluid accumulates in the vascular interstitium and alveoli. Accordingly, the increased wet weights, increased wet lung weights adjusted for initial body weight (LL/BW<sub>i</sub>) and increased wet/dry (W/D) weight ratios in the lungs of rats receiving saline, noni-ppt and noni juice all show the presence of permeability edema with an accumulation of lung water following hyperoxia (Table 1). Levels of protein in BALF were also elevated in these rats indicating a leakage of protein from the pulmonary vasculature into the alveolar space (Table 2). Clearly, noni-ppt or noni juice did not prevent pulmonary edema in the rats following exposure to hyperoxia.

Lung injury was also apparent in the two rats exposed to hyperoxia for 60 h. Respective values for the 60-h saline-treated and noni-ppt rats were (lung appearance 9.0, 5.0; LL/BW<sub>i</sub> 2.11, 1.53 g/kg; W/D 5.70, 5.18). These data suggest that lung injury in the two rats receiving 60-h hyperoxia was comparable to lung injury in the rats receiving 52-h exposure.

### Pleural effusions in hyperoxic rats

The development of proteinaceous pleural effusions is the hallmark of pulmonary oxygen toxicity in the rat. In this study, rats receiving saline, noni-ppt, or noni juice developed large, proteinaceous pleural effusions with increases in hematocrit (Hct) and ratio of effusion protein/plasma protein concentration (EP/PP) (Table

Table 1.— Gravimetric determinations and lung appearance of the left middle lung lobe in rats receiving saline, noni precipitate (noni-ppt) or noni juice before exposure to normobaric hyperoxia (> 97% O<sub>2</sub>) for 52 h. Air rats received no treatment.

Group	Wet*	Dry*	W/D	LL/BW <sub>i</sub> *	LA*
Saline ± SEM (n)	0.81 0.05 (6)	0.13 0.01 (6)	6.04 0.11 (6)	1.81 0.10 (6)	4.25 0.83 (4)
Noni-ppt <sup>1</sup> ± SEM (n)	0.81 0.04 (6)	0.14 0.01 (6)	5.80 0.15 (6)	1.86 0.09 (6)	3.50 1.24 (4)
Noni juice <sup>2</sup> ± SEM (n)	0.78 0.03 (6)	0.13 0.01 (6)	6.07 0.14 (6)	1.79 0.06 (6)	4.33 0.61 (6)
Air ± SEM (n)	0.44 <sup>a</sup> 0.02 (5)	0.09 <sup>a</sup> 0.001 (5)	4.64 <sup>a</sup> 0.02 (5)	1.12 <sup>a</sup> 0.04 (5)	1.30 <sup>a</sup> 0.12 (5)

Values are mean  $\pm$  SEM ( $n$  = number of animals).

\*Wet [post-exposure wet weight of the middle left lung lobe (LL), g]; Dry (post-exposure dry weight of the LL, g); LL/BW<sub>i</sub> (post-exposure wet weight of the LL divided by initial body weight, g/kg). LA (lung appearance where a value of 1 denotes absence of hemorrhage and 9 denotes total hemorrhage on the lung surface).

<sup>1</sup>Noni-ppt: Rats received total dosages of 50 to 600 mg noni-ppt with treatments varying from 2 days before, to 20 hours after initiation of hyperoxia.

<sup>2</sup>Noni juice: Rats received 20% noni juice in drinking water for 9 days before hyperoxia and during exposure to hyperoxia.

<sup>a</sup> $p < 0.05$  vs. values for other groups by analysis of variance.

Table 2.— Analysis of pleural effusion fluid, plasma and bronchoalveolar lavage fluid in rats receiving saline, noni precipitate (noni-ppt) or noni juice before exposure to normobaric hyperoxia (> 97% O<sub>2</sub>) for 52 h. Air rats received no treatment.

Group	PEV*	EP*	PP*	EP/PP	Hct*	BALF*
Saline ± SEM (n)	4.07 0.74 (6)	5.98 0.19 (5)	7.28 0.15 (5)	0.830 0.04 (5)	56.4 1.7 (6)	246.7 35.0 (6)
Noni-ppt <sup>1</sup> ± SEM (n)	4.67 0.66 (6)	6.18 0.14 (5)	7.22 0.27 (5)	0.850 0.03 (5)	57.8 1.5 (6)	256.7 14.4 (6)
Noni juice <sup>2</sup> ± SEM (n)	4.27 0.90 (6)	6.07 0.12 (6)	6.90 0.16 (6)	0.880 0.02 (6)	56.7 0.9 (6)	264.2 61.0 (6)
Air ± SEM (n)	0.03 <sup>a</sup> 0.01 (5)	3.48 <sup>a</sup> 0.12 (5)	7.56 0.11 (5)	0.460 <sup>a</sup> 0.02 (5)	46.0 <sup>a</sup> 0.8 (5)	14.0 <sup>a</sup> 1.0 (5)

Values are mean  $\pm$  SEM ( $n$  = number of animals).

\*PEV (pleural effusion volume, ml); EP (effusion protein, g/dL); PP (plasma protein, g/dL); Hct (post-exposure blood hematocrit, %); BALF (bronchoalveolar lavage fluid, mg/dL).

<sup>1</sup>Noni-ppt: Rats received total dosages of 50 to 600 mg noni-ppt with treatments varying from 2 days before, to 20 hours after initiation of hyperoxia.

<sup>2</sup>Noni juice: Rats received 20% noni juice in drinking water for 9 days before hyperoxia and during exposure to hyperoxia.

<sup>a</sup> $p < 0.05$  vs. values for other groups by analysis of variance.

2). These observations provide additional evidence of failure by noni-ppt or noni juice to provide protection against oxygen toxicity.

Proteinaceous pleural effusions also developed in the two rats exposed to hyperoxia for 60 hours. Respective values for the saline-treated and noni-ppt rats were (pleural effusion volume 11.0, 12.2 ml; pleural effusion protein concentration 5.3, 6.6 g/dL; BALF 661, 315 mg/dL; EP/PP 0.639, 0.936; Hct 68, 63%; plasma protein concentration 7.7, 7.1 g/dL). These values indicate that rats develop larger pleural effusions and a higher hematocrit (increased hemoconcentration) at 60 hours hyperoxia compared to 52-hour exposure and suggest that these parameters are especially sensitive indicators of hyperoxic lung injury. Again, noni-ppt failed to protect rats against oxygen toxicity.

## Discussion

### *Failure of noni juice or noni-ppt to protect rats against oxygen toxicity*

Noni juice precipitate (noni-ppt) exhibits biologic activity in several experimental models.<sup>1-4</sup> Perhaps most pertinent to the present study is the work of Hirazumi and Furusawa.<sup>4</sup> They used methods identical to those in this study to prepare noni-ppt and found that noni-ppt activated macrophages to enhance cytokine release, specifically, TNF- $\alpha$  and IL-1 $\beta$ , IL-10 and IL-12. In addition, noni-ppt stimulated thymocytes to release interferon- $\gamma$ . Importantly, immunosuppressive agents [Cl-Ade (macrophage inhibitor) and cys-A (T cell inhibitor)] attenuated noni-ppt-induced cytokine production suggesting that noni-ppt may exert immunomodulatory effects involving macrophage and T cell activation.

Also pertinent to the present study are investigations by others demonstrating that noni juice possesses antioxidant activity in both rats and mice. For example, treatment of rats with CCL<sub>4</sub> causes liver injury that is associated with increases in the formation of superoxide radicals and lipid hydroperoxides. Pretreatment of rats with noni juice (10% solution added to drinking water for seven days) lessened CCL<sub>4</sub>-induced liver injury and reduced formation of liver superoxide radicals and lipid hydroperoxides by 50% and 80% respectively.<sup>2</sup> A related study found that addition of noni juice to the drinking water of male mice reduced formation of DMBA-DNA adduct formation by 60% in heart, 50% in lung, 70% in liver and 90% in kidney.<sup>3</sup> In that study the tetrazolium nitroblue assay was used to assess antioxidant (superoxide) activity in noni compared to known antioxidants [vitamin C, grape seed powder (GSP) and pycnogenol (PYC)] using daily dose recommendations by the U.S. RDAs or manufacturers RDAs. Noni was found to possess 2.8 times the superoxide scavenging activity of vitamin C, 1.4 times that of PYC and 1.1 times that of GSP. Similar results were obtained using a lipid hydroperoxide (LPO) assay to quantitate noni LPO quenching activity.<sup>3</sup>

Endotoxin also stimulates release of TNF and IL-1 to induce manganese superoxide dismutase and prevent hyperoxic lung injury.<sup>6,8</sup> Because of the apparent similarities in biologic response we hypothesized that noni, like endotoxin, may protect rats against pulmonary oxygen toxicity. Noni-ppt was administered (Study 1) before and/or during exposure to hyperoxia to hypothetically induce TNF and IL-1 and protect rats against oxygen toxicity. In Study 2 noni juice was added to the drinking water for 9 days before hyperoxia and also during exposure. The expectation of the second study was that noni juice would exert antioxidant activity and protect rats against hyperoxic lung injury.

Examination of rat lungs following exposure to hyperoxia revealed that all lungs were hemorrhagic and injury was similar in all rats regardless of treatment. Wet lung weights were also similarly increased

in all rats (compared to air controls), as were wet/dry lung weight ratios and protein concentrations in BALF. These results (Tables 1 and 2) show that both noni-ppt or noni juice failed to protect rats against oxygen toxicity.

All rats also developed massive, proteinaceous bilateral pleural effusions, which are the hallmark of oxygen toxicity in the rat. The loss of fluid into the pleural space was confirmed by the observed increase in hematocrit and hemoconcentration of the blood. Finally, the extent of breakdown in the vascular barrier to protein leak is seen in the fact that the concentration of protein in effusion fluid approached that in plasma (EP/PP ratio values close to 1).

The results of this study demonstrate that both noni juice and noni-ppt failed to protect rats against pulmonary oxygen toxicity within the limits of the treatment protocols applied. One possible explanation, in the case of noni-ppt, is that treatments did not increase cytokines to levels that were sufficient to protect rats against hyperoxia. In line with this possibility, Hirazumi and Furusawa<sup>4</sup> observed significant increases in both TNF and IL-1 in peritoneal exudate cells following incubation with noni-ppt but, interestingly, the levels attained were less than half of those produced by endotoxin (LPS) which is known to protect against hyperoxia. Other possibilities, among many, are that differences may exist in the responses of tissues or species to these agents. For example, Wang et al.<sup>2</sup> observed antioxidant enzyme induction in rat liver following treatment of rats with noni juice but antioxidant enzyme levels were not measured in lung tissue in that study. Also, the study by Hirazumi and Furusawa<sup>4</sup> was conducted on mice and the response of mice to noni-ppt may differ from the response of rats. Additional studies are needed to test these possibilities and confirm that these agents stimulate cytokines and induce antioxidant enzymes in the rat.

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## Formulating Hawai'i's Public Health Education Needs: Input from the Health Community

**Sharon F. Dellinger BSN, Nandar Aung MBA, Jaime A. Campos BA, Lehua Choy MPH, Jane Chung BA, Lauren Gentry BA, Jinlan Li MPH, Jana Lindsey BSN, Sara Mayet MB, BS, Kristen Mitchell MSPH, REHS, Joan Pan BA, Claudio R. Nigg PhD, Kathryn Braun DrPH., Faculty Advisor**

**John A. Burns School of Medicine, Department of Public Health Sciences, University of Hawai'i at Manoa**

New as well as previously known diseases have re-emerged such as Severe Acute Respiratory Syndrome (SARS), West Nile virus, tuberculosis, malaria, and diabetes. These are a fraction of today's public health challenges. Chronic and vaccine-preventable diseases as well as health, safety, and environmental issues are re-emerging as public health threats and concerns. The ease of travel and a highly mobile society make disease containment anywhere in the world difficult. Places such as Hawai'i, by virtue of its geographic location, are in an unenviable and tenuous public health situation.

Tuberculosis (TB) is an example of a major public health concern that still exists. Its history and course are reflective of other global, national, and local public health challenges. In 1985, TB re-emerged in the United States as a public health concern after almost 30 years of a steady decline in tuberculosis disease rates.<sup>1</sup> Annually, there are more than 2 million TB-related deaths, the second leading cause of death worldwide.<sup>2</sup> Hawai'i's TB rates ranked first and second in the United States for 2004 and 2005, respectively. This rate is in large part due to population mobility from Asia and other Pacific Islands with multi-drug-resistant TB.<sup>3,4</sup>

Today's public health challenges are complex and multi-faceted, and require a well-trained, adequately prepared, and larger public health workforce. Public health encompasses emergency preparedness, creation and implementation of the state pandemic influenza plan, and must pay attention to a myriad of issues that are included in the U.S. Department of Health and Human Services' Healthy People 2010 national initiative, which covers 28 goals pertaining to health, safety, and lifestyle issues, from obesity and immunizations to injury prevention.<sup>5</sup>

To address the management of health issues of this magnitude, coupled with Hawai'i's unique ethnic and cultural diversity issues,<sup>6</sup> a well-trained workforce in sufficient numbers is required. What kind of public health education and training should Hawai'i have that will result in a workforce that is effective in dealing with today's ever-evolving health complexities? Issues that affect or have the potential to impact vast segments of communities and populations. The situation begs the question, "What kind of training is most applicable and effective?"

### Current Public Health Education and Training in Hawai'i

The University of Hawai'i (UH) is the only university in the state and the Pacific Basin with a graduate public health education program. For over 30 years, the UH had an accredited School of Public Health which was comprised of five core graduate programs--epidemiology,

biostatistics, environmental health sciences, health services administration, and social and behavioral health sciences-- and a number of certificate programs. When the School lost its accreditation in 1999 in part due to funding issues, graduate public health education at the UH was re-organized under the John A. Burns School of Medicine as the Department of Public Health Sciences and Epidemiology. Two of the five previous core programs are currently being offered; epidemiology and social and behavioral health sciences. There was also faculty attrition and a decrease in students in the graduate public health programs, from as many as 200 students in the past to 50 in 2006. This translates to a reduction in the public health workforce, and a lost potential for the strengthening of Hawai'i's and the Pacific Basin's workforce.

### Perceptions of Hawai'i's Health Community

The current students in public health course PH649--Needs Assessment and Program Planning (Fall 2006) undertook a project to identify the perceptions of individuals with public health experience as to the training needs required to achieve a competent workforce able to manage health issues that affect Hawai'i's communities.

### Methods

The students developed and conducted a needs assessment to survey the health community's perceptions of Hawai'i's public health education needs. Literature on public health and the public health workforce by the Institute of Medicine, the Department of Health and Human Services, and the Council for Education in Public Health (CEPH, a public health education accreditation entity) were reviewed. Thirty-four interviews were conducted with UH public health students, faculty, and administrative staff, workers in public health, employers, and UH public health alumni. In addition, current students, UH public health faculty and the Hawai'i Department of Health leadership met separately. The purpose of the interviews and focus group meetings was to gather qualitative data (i.e., opinions and perceptions) from target populations.<sup>7</sup>

Questions were tailored for different respondent categories. For example, an employer interview question was, "According to your experience, what kind of additional courses, training, and continuing education would help advance your public health professional skills and knowledge?" Themes or main ideas from the focus groups and interviews were used to develop questions and response categories.

A survey was created and implemented using an online survey service, "Survey Monkey." The final survey included 21 questions,

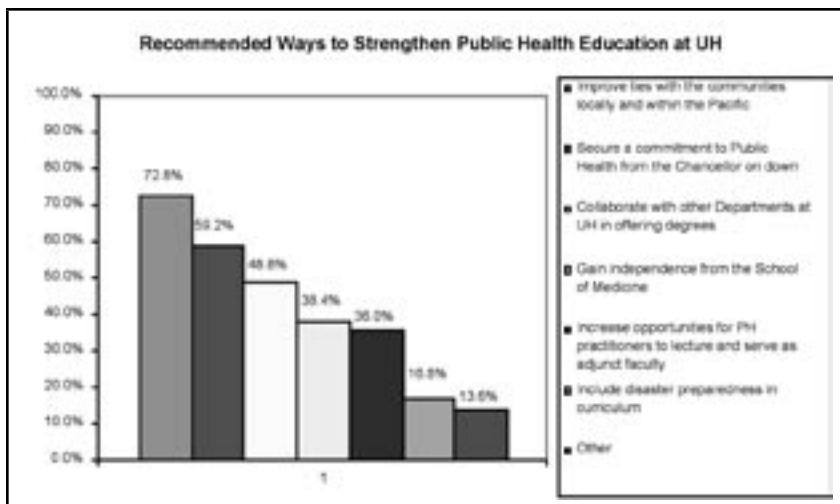


Figure 1

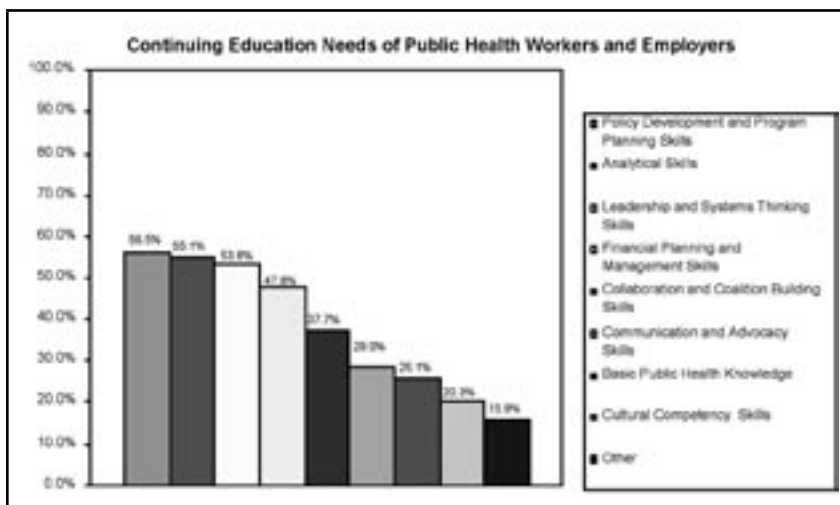


Figure 2

3 of which were open-ended and all respondents were asked to complete. There were 5 sets of additional questions for specific respondent groups: faculty (2 questions); employers (2 questions); students (13 questions); alumni (6 questions); and workers in public health (5 questions) (subgroup analysis not presented, for more information and for the survey questions please contact the corresponding author). The survey was piloted with 8 individuals for readability and understandability prior to implementation. This project was approved by the UH Committee of Human Subjects.

Individuals (n=200) approached to participate included current UH Public Health students and faculty, attendees of the April 26, 2006 Revitalization of Public Health meeting, individuals on a Hawai'i Public Health Association list, and individuals known to the students and the PH 649 instructor. The survey was sent out via e-mail in November 2006. Two subsequent reminder e-mail communications were sent to individuals who did not initially respond. There were 128 (64%) respondents during the two-week data collection window (78% female; 46% were 50+ years old; 63% held a degree in public health; 84% worked in public health for 4+ years).

## Results

Survey results indicated that the top three recommended ways to strengthen UH public health education were to: 1) improve ties with the communities, locally and within the Pacific (73%); 2) secure a commitment to public health from the chancellor on down (59%); and 3) collaborate with other departments at UH in offering degrees (49%; Figure 1).

Survey respondents who were employees and employers in public health (n=69) indicated that the top 3 continuing education needs were: 1) policy development and program planning skills (57%); 2) analytical skills (55%); and 3) leadership and systems thinking skills (54%; Figure 2).

Respondents were also asked to consider the advantages of developing public health education, either by remaining in a Department in the School of Medicine, or by becoming a school once again. The latter would require the re-establishment of the five core graduate programs. The top three responses (n=118) outlining the advantages of staying a Department were: 1) there were *no* advantages to staying a Public Health Department (vs. becoming a School) (37%); 2) as a Department, the quality of the programs could be focused on (37%); and 3) as a Department there would be less financial pressure (36%). The top three responses (n=124) outlining the advantages of re-establishing a School were: 1) there would be greater diversity in classes, more professors, more choices (80%); 2) there would be more visibility (55%); and 3) there would be increased funding (48%).

## Conclusions

The University of Hawai'i is the only university that provides graduate public health education in Hawai'i and the Pacific Basin. Eventually, global public health issues will become this nation's and this state's concerns with a potential to impact large segments of Hawai'i's population. It is hoped that this assessment generates: a) some productive discussion as to what public health education in Hawai'i should look like; and b) action towards preparing the public health workforce to manage today's evolving health challenges. The interest in public health education and the need to further strengthen public health education are obvious, as evidenced by the response rate.

Limitations to be considered are the sample and methodology. The sample was a select population, versus a random sample, and the respondents in each survey category may not be representative of the community at large. Organizations, such as Kaiser Permanente and Hawai'i Medical Service Association (HMSA) that employ a number of individuals affiliated with public health were not enlisted to participate in the survey. The obvious purpose of the needs assessment for the selected population may have resulted in a social desirability bias; however, given the variety of

responses, this factor is not considered a serious limitation. Finally, the question as to whether the UH School of Public Health should be re-established was not explicitly asked in this needs assessment. This project focused on the more general issue of Hawai'i's perception of its public health education needs.

### Recommendations

A general recommendation, based on the survey results, is that public health education in Hawai'i be strengthened. Specifically, there is a call for more collaboration, increases in public health educational options and opportunities, and a commitment to public health from all levels of the UH administration. The needs assessment indicates that further public health education should focus on public health competencies to develop a competent workforce.

It is strongly recommended that the UH Department of Public Health Sciences enhance its marketing efforts to potential public health students on campus and in the community, UH administration and advisors, the public health community, and the community-at-large. This recommendation should be taken seriously when only 50% of the survey respondents were aware that the two current programs, epidemiology and social and behavioral health sciences, are accredited by CEPH (the national accrediting Committee on Education in Public Health). To date, there has been no real, concerted effort to attract prospective students to the public health programs (for information of our programs see: [www.hawaii.edu/publichealth](http://www.hawaii.edu/publichealth)).

### Acknowledgements

The PH 649 students would like to acknowledge the Hawai'i Department of Health, the UH Department of Public Health Sciences faculty and administration, students, and alumni, other respondents affiliated with the Hawai'i Public Health Association and those employed in public health for their participation in this needs assessment project.

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## Mesothelioma

**Michele Carbone MD, PhD, Oriana Strianese MS, Kimberly Theos BA, and Haining Yang PhD**  
Thoracic Oncology Program, Cancer Research Center of Hawai'i

### Abstract

*Mesothelioma is one of the most aggressive human malignancies. In this article the research team of Dr. Michele Carbone reviewed the most significant scientific and medical advances in understanding the pathogenesis of mesothelioma and some novel preventive and therapeutic approaches that are being developed. The public health and litigation issues, together with the economics surrounding mesothelioma research and therapy are also discussed.*

### Mesothelioma: the disease

Malignant mesothelioma is a tumor that is often associated with asbestos exposure. There are other tumors, mostly benign that unfortunately are also called mesothelioma: well-differentiated peritoneal papillary mesothelioma, mesothelioma of the atrioventricular node, multicystic mesothelioma, etc. These rare benign lesions originate from mesothelial cells and are unrelated to asbestos exposure. The term mesothelioma in this article is used to indicate the much more common malignant mesothelioma.

The exact number of mesotheliomas in the US is unknown, however, based on the SEER data it is estimated that approximately 2000-3000 people develop and die of mesothelioma each year. Approximately 80% of mesotheliomas develop in men, 90% develop in the pleura, and 10% in the peritoneum. Mesothelioma limited to the pericardial cavity are extremely rare: this research team seen only one case in a 19-year-old boy.<sup>1</sup> Development at this young age is extremely unusual; in the US most mesotheliomas occur in individuals older than 70, and mesotheliomas are extremely rare in those younger than 40. If left untreated, median survival from diagnosis is about 9 months. Pathologically mesotheliomas are distinguished in epithelial type (about 50-60% of them), fibrous type (10-20%), and biphasic (which means that the tumor has both a spindle and an epithelioid morphology). The distinction is important because the fibrous (also called sarcomatoid) mesotheliomas appear completely resistant to therapy and have shorter median survivals (six months) compared to epithelial type mesotheliomas. Alimta, a drug that is considered by some as the most effective in treating this cancer may prolong median survival of about two and a half months, but only in epithelial type mesotheliomas. Clearly more effective therapies are needed. The benefit of surgery has been debated extensively: surgery appears most useful in patients with Stage 1A disease that can have survivals of 5 or more years. Unfortunately less than 5% of mesotheliomas are diagnosed at this early stage.<sup>2</sup>

### Mesothelioma: the diagnosis

The diagnosis of mesothelioma is challenging because most pathologists see only a few cases in their careers. Therefore, it is prudent to have the diagnosis confirmed by a pathologist who sees many mesotheliomas as part of his/her practice. With the recent develop-

ment of specific antibodies for mesothelioma cells and in the hands of experts, the diagnosis of epithelial mesothelioma and its distinction from the more common carcinomas has become relatively easy. Moreover, in difficult cases, electron microscopy (EM) can definitively confirm or rule out the diagnosis. The diagnosis of fibrous mesothelioma, instead, remains challenging.<sup>1,3</sup> Calretinin and WT-1, two antibodies that react with mesothelial cells (and also with some other cell types) can produce negative reactions against the cells of fibrous mesotheliomas. In these cases the pathologist is left with a possible reactivity of the tumor cells for pankeratin (for example AE1/AE3 or Cam 5.2): when this reactivity is strong and diffuse, most sarcomas can be ruled out and the differential diagnosis would only include mesothelioma versus carcinosarcoma. But when the reactivity is low, and/or only few tumor cells are positive it is very difficult to make a definitive diagnosis. In addition to mesothelioma, other types of sarcomas can have similar positivity for keratins. In these cases, EM may be of help, but more often than not it is of no help at all because no distinctive features can be identified in the tumor cells. The diagnosis at this point often becomes subjective: some pathologists will call the tumor a poorly differentiated spindle cell malignancy of the pleura; others may try to guess the cell type of origin. A more modern approach that is used in the Carbone laboratory requires the use of molecular techniques that allow the identification of genetic rearrangements that characterize different types of sarcomas, for example pleural synovial sarcomas. When such rearrangements are identified, the precise diagnosis can be rendered.<sup>4</sup>

### Not all malignant mesotheliomas are malignant

There are occasional indolent cases of epithelial type mesotheliomas that are associated with survivals of 10 or more years. The Carbone team proposed<sup>5</sup> that these are not mesotheliomas: biologically these are different diseases that pathologists cannot distinguish from the most common aggressive mesotheliomas. Pathologically, the distinction between a benign mesothelial cell proliferation, including the so called well-differentiated papillary peritoneal mesotheliomas, and a malignant mesothelioma, is invasion. If a few mesothelial cells are seen invading the muscle or the fat, the diagnosis of mesothelioma is made. Obviously such unsophisticated methodology is not sensitive enough to identify among the mesotheliomas those rare tumors that have a benign biological behavior in spite of minimal invasion. Over a dozen such cases have been seen by Dr. Carbone, and although most were in women and were in the peritoneum, at least one was in the pleura of a male patient who had lived for over 17 years with this diagnosis (independently confirmed by Dr. Carbone's research team). The reason for focusing on this rare aspect of the disease is to call attention to the fact that even a correct diagnosis of mesothelioma does not necessarily equate to a death sentence: there are



occasional mesothelioma cases that pathologists cannot tell apart that have a benign course or at least that do not appear to influence the life span of the patient.

### **Mesothelioma: Early detection and novel therapeutic options**

Because medical treatment appears effective only when mesotheliomas are detected in the early stages, a considerable effort has been put in early detection of the disease. When the disease causes clinical symptoms, usually pain, cough and dyspnea, the tumor is already well-advanced. The identification of two serum markers that become elevated early in the course of the disease, mesothelin<sup>6</sup> and osteopontin<sup>7</sup> has raised hopes that early diagnosis of mesothelioma may be possible. The Carbone team is currently testing this hypothesis among members of certain families in Cappadocia, Turkey that experience an extremely high rate of malignant mesothelioma.<sup>8</sup> Early detection using these serological markers raises the important issue of how to best treat these patients, especially if the tumor is not detectable radiologically. In Turkey, they will test the possible chemo-preventive effects of Onconase, an RNase inhibitor that has improved survival in a subset of patients with mesothelioma.<sup>9</sup> This drug has the tremendous advantage of having limited occasional (flu-like) side effects; therefore, Onconase can be used as a chemopreventive agent. A subcutaneous dermal preparation of this drug is now being prepared and the Turkish health authorities have approved its use as a chemopreventive agent. This will be the first chemopreventive clinical trial for mesothelioma and will target mesothelioma-family members with high levels of serum osteopontin and mesothelin.<sup>8</sup>

### **Mesothelioma: Public Health, medical legal and economic issues**

Mesothelioma and the asbestos litigation associated with this disease have caused a major transfer of wealth in the US economy<sup>10</sup> that have resulted in the creation and destruction of entire industries: the impact of litigation has been felt throughout various sectors of society. The average plaintiff in a mesothelioma case receives a verdict in excess of six million dollars: when this is multiplied by the number of pending cases, the amount is in the billions. Up to 2001, in the US, companies had paid about 54 billion dollars in claims related to asbestos litigation and future liability estimates have ranged from 145 to 210 billion dollars. Insurance companies had paid 21.6 billion dollars on asbestos claims through 2000.<sup>10</sup> It is estimated that over 50% of this money is spent in transactional costs, mostly attorney fees. An entire industry with lawyers at the apex of it, but that includes medical experts, industrial hygienists, mineralogists, economists, historians, epidemiologists, administrators of insurance companies and of claims-paying trusts, members of the judicial system and other governmental agencies, etc., has flourished, and it is mostly dependent on this litigation. The impact of this litigation on the economics of the US is such, that the current President had made asbestos litigation reform one of the main goals of his re-election campaign. The fact that in spite of having the majority in Congress and in the Senate, the President was unable to convince his own party to pass this legislation, underscores the power of this industry. Please note that the Carbone research team is taking no part on the issue on whether it was or was not a sensible thing to reform asbestos litigation, but is simply stating a fact.

Inevitably, the economics of mesothelioma, have caused significant conflict of interests and the medical literature is riddled by manuscripts that are biased either because they were commissioned by either side of the litigation, or because the results are based on casistics that contain mostly or exclusively medical-legal cases. It is very difficult, and at times impossible, to identify papers that may be biased from papers that are not. As a general rule, papers that have been sponsored by grants from the National Cancer Institute, National Institutes of Health, American Cancer Society or other reputable agencies are the most reliable. When the source of funding is not stated or is unknown, the possibility that either side of the litigation sponsored the manuscript should be considered. This is particularly important in articles that deal with pathogenesis.

### **Pathogenesis**

A critical issue of asbestos and mesothelioma litigation is what caused the disease and why among exposed individuals, for example asbestos miners, less than 5% develop mesothelioma.<sup>5</sup> Clearly some people are more susceptible or resistant to asbestos exposure. Until recently asbestos has been considered the only possible cause of mesothelioma, and the approximately 20% of mesotheliomas that develop in individuals in which no asbestos exposure can be documented were considered idiopathic. The mechanisms of asbestos carcinogenesis were also unknown. Moreover, the argument on whether all types of asbestos cause mesothelioma (i.e., both amphibole asbestos and chrysotile asbestos) or whether mesothelioma is caused only by amphiboles, remains unsettled: billions of dollars revolve around this issue.

Recent progress in mesothelioma pathogenesis comes from research performed in the Carbone laboratory, together with their collaborators in various Institutions in the US and abroad (see reference list). Because our research is entirely funded through grants from the National Cancer Institute, the American Cancer Society, and other reputable non-profit organization, these scientists were able to "survive" the inevitable controversy that follows any finding related to mesothelioma and asbestos pathogenesis. Briefly, they found that crocidolite asbestos (a type of amphibole asbestos considered most oncogenic) causes the secretion of tumor necrosis alpha that in turns activates the NF-kB pathway. This activation promotes cell survival and allows mesothelial cells to grow as tumors rather than die as result of exposure to asbestos.<sup>11</sup> They also found that SV40, a DNA tumor virus that contaminated polio vaccines<sup>12</sup> is present in human mesotheliomas<sup>13,14</sup> and that SV40 is a co-carcinogen with crocidolite asbestos in causing mesothelioma.<sup>15</sup> So far they have not studied chrysotile asbestos. Moreover, they discovered that genetic predisposition to mineral fiber carcinogenesis plays a key role in determining who among exposed individuals develop mesothelioma.<sup>8,16</sup> Their findings, which have been independently confirmed by others,<sup>17,18,19</sup> elucidated how asbestos causes malignant transformation of mesothelial cells, and revealed co-factors that make certain individuals more susceptible to asbestos carcinogenesis or that may cause mesothelioma in individuals not exposed to asbestos. Mesothelioma represents a unique model to study human carcinogenesis, because human cancer is almost always the outcome of interactions among different carcinogens and genetics.<sup>20</sup> To study these interactions Carbone's research team has been awarded a 10 million dollar PO-1 grant from the NCI to study how environmental carcinogens (mineral fibers), infectious agents (viruses) and genetic

predisposition interact to cause mesothelioma, and to isolate the gene/s that predispose to mineral fiber carcinogenesis (M. Carbone PI; B. Mossman at U. Vermont, HI Pass at New York University, and JR Testa, at the Fox Chase Cancer Center, co-PI, N. Cox and I. Steele at U. Chicago, I.Y Baris, S. Emri and M. Tuncer at U. Hacettepe-Ankara, and U.A. Dogan at U. Ankara, co-investigators). This Program Project together with their additional NCI RO-1 grants and ACS National funding makes our research team by far the best peer-reviewed, funded mesothelioma team in the US and worldwide.

For more information about the Cancer Research Center of Hawai'i, please visit its web site at [www.crch.org](http://www.crch.org).

### Acknowledgments

The work of Dr. Carbone is supported by the following grants: National Cancer Institute R01 CA092657, R01 CA106567, PO1 CA114047, the American Cancer Society RSGCCE-106924, The Riviera Country Club of Illinois, and the Mark Butitta Mesothelioma Foundation.

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# HMA ANNUAL MEETING & OLA PONO IKE 2007

*New Dates & Locations:*

## September 14-16, 2007

Ola Pono Ike: Saturday, September 15 at Sheraton Waikiki

House of Delegates & General Membership Meetings:

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*HMA's 2007 meeting features a new format: CME sessions and vendor exhibits will no longer be part of the annual meetings. They will be replaced with the new series of HMA forums held throughout the year.*

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## Issues in Medical Malpractice VIII

**S.Y. Tan MD, JD, Professor of Medicine and Adjunct Professor of Law, University of Hawai'i**

**QUESTION:** Pathologist came to the aid of teenage girl who collapsed in shopping mall after eating a fruit-and-nut chocolate bar. The girl wore a Medic-Alert bracelet with the words: "Anaphylaxis. Has adrenaline in purse." Pathologist performed CPR but did not administer adrenaline because he had not given an injection in over 30 years. Teenager died, and expert testimony indicated that had adrenaline been given, she would have survived.

- A. By coming to the aid of a stranger, a doctor-patient relationship was formed.
- B. Doctors are ethically bound to treat those in need of urgent care.
- C. Doctors are legally bound to treat those in need of urgent care.
- D. Pathologist is obviously liable as it's a simple injection that any doctor should be capable of administering.
- E. The 'Good Samaritan Doctrine' covers aid to strangers and generally provides immunity unless gross rather than ordinary negligence is proven.

**ANSWER: B and E correct.** This case scenario involves a doctor treating a stranger, so there is no formation of the traditional doctor-patient relationship. The law does not require anyone to come to the aid of strangers, even in a life-and-death situation. Medical practitioners, however, have an ethical, but not a legal, duty to help out in an emergency. Thus, choices A and C are incorrect. To encourage aid to strangers, many jurisdictions have enacted statutes to immunize aid-givers against being sued if their negligence results in harm. However, such immunity is withheld if there is a finding of gross negligence, which usually means reckless disregard of risks and consequences.

D is also incorrect. Whether a pathologist should be capable of administering an injection will be judged by what is ordinarily expected of fellow pathologists. Besides, the pathologist in this case will likely escape liability as his failure to administer adrenaline probably does not amount to gross negligence.

### **Negligence, Gross Negligence and Medical Errors**

**Negligence:** Black's Law Dictionary (5th Edition) defines negligence as "the failure to use such care as a reasonably prudent and careful person would use under similar circumstances..." In the medical context, the operational definition of negligence is best referenced in Prosser's Textbook on Torts: "The formula under which this usually is put to the jury is that the doctor must have and use the knowledge, skill and care ordinarily possessed and employed by members of the profession in good standing..." The doctor's standard does not have to reach a high or outstanding level, just the ordinary standard of the practitioner of that specialty, sometimes referred to as the 'minimum common skill.'

**Gross Negligence:** Actions or omissions deemed to constitute 'gross negligence' are usually associated with failure to use the slightest amount of care, some degree of recklessness, or willful and wanton misconduct. The grossly negligent tortfeasor (wrongdoer) is said to have acted in reckless disregard for the safety of others. Thus, gross negligence denotes a higher degree of culpability than ordinary negligence (also termed simple negligence).

Court opinions can be surprising in this regard. In *Jackson v. Taylor*, Dr. James Taylor prescribed birth control pills for plaintiff Lois Jackson, who subsequently developed bleeding liver tumors, allegedly caused by the birth control pills. Plaintiff's expert testified that Dr. Taylor's acts and omissions (which were not spelled out in the appellate opinion) demonstrated his 'conscious indifference' to the welfare of his patient. The Texas Court found that there was sufficient evidence to allow the jury to decide on gross negligence and awarding of exemplary (punitive) damages.<sup>1</sup> Texas law defines gross negligence as "that entire want of care which would raise the belief that the act or omission complained of was the result of a conscious indifference to the right or welfare of the person or persons affected by it."

In another case, *Fox v. Oklahoma Memorial Hospital*, the Supreme Court of Oklahoma ruled the leaving of a six and one-half inch clamp in a surgical incision "might be construed to support a willful, wanton, conduct amounting to gross negligence"<sup>2</sup>

**Medical Error:** The term medical error is used to describe an act or omission that results in a preventable adverse event, which in turn is defined as an injury caused by medical management rather than the underlying condition of the patient. A medical error, mistake or misjudgment is not synonymous with medical negligence. It depends on the nature of the error or misjudgment. If it is one that a reasonably competent professional would not commit, then the standard of care is breached, giving rise to medical negligence. On the other hand, if reasonably skilled practitioners could commit such a mistake, then it would not amount to negligence. As one Court put it: "An honest error of judgment in making a diagnosis is insufficient to support liability unless that mistake constitutes negligence."<sup>3</sup> Nor are all adverse outcomes necessarily the result of negligence. Another Court put it this way: "The mere fact that the physician has failed to effect a cure or that the diagnosis and treatment have been detrimental to the patient's health does not raise a presumption of negligence."<sup>4</sup> Some medical conditions end up with bad results that are wholly independent of the doctor's actions, and the doctor is neither an insurer nor a guarantor of the patient's health. The Hawai'i Supreme Court has ruled that use of the terms 'error in judgment' and 'best judgment' would confuse the jury, and re-emphasized the objective community standard against which medical negligence is to be measured.<sup>5</sup>

*Continues on p. 53*

# UPCOMING CME EVENTS

Interested in having your upcoming CME Conference listed? Please contact Nathalie George at (808) 536-7702 x103 for information.

Date	Specialty	Sponsor	Location	Meeting Topic	Contact
<b>February 2007</b>					
2/14-2/16	OBG	University of Hawai'i Department of OB/GYN and Women's Health	Hyatt Regency Waikiki Resort & Spa, Honolulu	Evidence-based OB/GYN: Practical Application of New Advances	Tel: (808) 203-6528 Email: ckawahar@hawaii.edu
2/16-2/18	OBG	University of Hawai'i Department of OB/GYN and Women's Health	Hyatt Regency Waikiki Resort & Spa, Honolulu	Contemporary OB/GYN Ultrasound: Recent Advances and Clinical Practice	Tel: (808) 203-6528 Email: ckawahar@hawaii.edu
2/16-2/18	Multi	Hawai'i Academy of Family Physicians	Sheraton Waikiki, Honolulu	Hawai'i Update 2007: Planning for the Future	Tel: (808) 864-9812 Web: www.hafp.com
2/24	Multi	The Queen's Medical Center	Koolau Golf Club	Connecting the Dots: The Queen's Medical Center Conference on Quality and Patient Safety	Tel: (808) 537-7009 Email: cme@queens.org
<b>March 2007</b>					
3/3	Multi	Hawai'i Chapter of the American College of Physicians	Hawai'i Prince Hotel	Annual Scientific Meeting	Tel: (808) 586-7478 Email: sharonch@hawaii.edu
3/3-3/10	IM, FM	Keck School of Medicine of USC	Mauna Kea Beach Resort, Hawai'i	Diagnostic Skills in Internal Medicine	Tel: (800) 872-1119
3/5-3/9	Multi	St. Francis International Center for Healthcare Ethics	Hawai'i Medical Center -- East	Becoming an Ethics Consultant	Tel: (808) 547-6050 Web: www.bioethicshawaii.org
3/12-3/16	HEM, OMM	Kirkville College of Osteopathic Medicine	Hilton Hawaiian Village, Honolulu	Primary Care Update	Tel: (660) 626-2232 Web: www.kcom.edu/
3/19-3/23	END	Mayo Clinic College of Continuing Medical Education	Hapuna Beach Prince Hotel, Kohala Coast	An Intensive Review of Endocrinology for the Clinician	Tel: (480) 301-4580 Web: www.mayo.edu/cme/
3/26-3/27	R	Stanford University School of Medicine	Hyatt Regency, Kaua'i	12th Annual Diagnostic Imaging Update in Hawai'i	Tel: (888) 556-2230 Web: http://med.stanford.edu
3/29	NEP	Kaiser Permanente	Hawai'i Prince Hotel	Nephrology for the Non-Nephrologist	Tel: (808) 432-7931
<b>April 2007</b>					
4/3-4/5	P	State of Hawai'i Adult Mental Health Division	Hawai'i Convention Center, Honolulu	Work Works! Supported Employment: The 4th Annual Best Practices Conference	Tel: (808) 586-4686
4/08-4/13	PCP	University of California, San Francisco	Wailea Beach Marriott Resort & Spa, Wailea, Maui	Primary Care Medicine: Update 2007	Tel: (415) 476-5808 Web: www.cme.ucsf.edu
4/10-4/12	Multi	Department of Orthopaedic Surgery, Kaiser Permanente	Grand Wailea Resort & Spa, Maui	15th Annual Update in Orthopaedic Surgery, Hawai'i 2007	Tel: (808) 432-2243
4/12-4/13	Multi	Kaiser Permanente	Hilton Waikiki Prince Kuhio Hotel, Honolulu	Palliative Care Conference	Tel: (808) 432-7931
4/15-4/20	DR	University of California, San Francisco	The Fairmont Orchid, Kamuela, Hawai'i	Diagnostic Imaging on Kona	Tel: (415) 476-5808 Web: www.cme.ucsf.edu

May 2007					
5/18-5/19	Multi	Department of Native Hawaiian Health, University of Hawai'i	Hawai'i Prince Hotel	He Huliiau – A Turning Point, Eliminating Health Disparities in Native Hawaiians & Pacific Peoples	Tel: (808) 587-8570
5/21-5/23	CD	Stanford Hospital & Clinics	Maui, HI	2nd Annual Complex Cardiovascular Patient Management	Tel: (650) 724-7166 Web: www.cme.stanfordhospital.com
June 2007					
6/11-6/15	ON, HO	University of Nebraska Medical Center	Grand Wailea Resort & Spa	2007 Pan Pacific Lymphoma Conference	Tel: (877) 832-6924 Email: conted@unmc.edu
6/16-6/21	OBG	University of California - Davis	Hapuna Beach Prince Hotel, Kohala Coast	UC Davis Women's Health Conference	Tel: (916) 734-5390
6/23-6/29	PD	University Children's Medical Group	Hyatt Regency Maui Resort, Maui	Pediatrics in the Islands... Clinical Pearls 2007	Tel: (800) 354-3263 Web: www.ucmg.org/cme.html
July 2007					
7/28-8/04	ORS	Kaiser Permanente	Grand Wailea Resort & Spa, Maui	Kaiser Orthopaedic Surgery Conference 2007	Tel: (877) 843-8500
7/29-8/03	R	University of California, San Francisco	Fairmont Orchid Hawai'i, Kamuela	Breast Imaging	Tel: (415) 476-5808 Web: www.cme.ucsf.edu
August 2007					
8/5-8/11	IM, FM	Keck School of Medicine of USC	Ritz-Carlton Kapalua, Maui	50th Annual Refresher Course in Medicine	Tel: (800) 872-1119
8/9-8/10	Multi	Kaiser Permanente	Ihilani Resort & Spa, Honolulu	6th Annual Pai Symposium	Tel: (808) 432-7931
September 2007					
9/24-9/29	END	Mayo Clinic College of Continuing Medical Education	Hyatt Regency, Maui	20th Annual Techniques in Advanced Gynecologic, Endoscopic & Laparoscopic Surgery	Tel: (480) 301-4580 Web: www.mayo.edu/cme/
October 2007					
10/16-10/20		American Society for Bone and Mineral Research	Hawai'i Convention Center, Honolulu	29th Annual Meeting	Tel: (202) 367-1161 Web: www.asbmr.org
10/20-10/24	ORS	Orthopaedic Research Society	Hawai'i Convention Center, Honolulu	6th Combined Meeting of the Orthopaedic Research Societies	Tel: (847) 698-1625 Web: www.ors.org

### "Issues in Medical Malpractice VIII," from p. 51

This article is meant to be educational and does not constitute medical, ethical, or legal advice. It is excerpted from the author's book, "Medical Malpractice: Understanding the Law, Managing the Risk" published in 2006 by World Scientific Publishing Co., and available at Amazon.com. You may contact the author, S.Y. Tan MD, JD, at email: [siang@hawaii.edu](mailto:siang@hawaii.edu) or call (808) 526-9784 for more information.

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2. *Fox v. Oklahoma Memorial Hospital*, 774 P.2d 459 (Okla. 1989).
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4. *Bryan v. Burt*, 486 S.E.2d 536 (Va. 1997).
5. *Hirahara v. Tanaka*, 959 P.2d 830 (Haw. 1998).

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To place a classified notice call (808) 536-7702, Ext. 101.

### LOCUM TENUMS

**BOARD CERTIFIED PEDIATRICIAN:** with Hawai'i license, available for locum tenums anytime between April 2007 and October 2007. Contact: **Al Hardness, MD: (910) 988-9186; cookiem4@aol.com.**

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**PART-TIME/FULL-TIME:** MANAKAI O MALAMA Integrative Healthcare Group and Rehabilitation Center continues to expand into its fifth year and welcomes one more physician with an existing practice in primary care or neuromusculoskeletal medicine. Enjoy the practice of medicine in a stimulating atmosphere of collaboration. All of your practice management needs are taken care of, including expert billing. Excellent location in the Honolulu Club Building. Now available. Contact **Vangie 535-5555 (See [www.manakaomalama.com](http://www.manakaomalama.com)).**



Russell T. Stodd MD

❖ AS WITH EXPLOSIVES, AVOID THE FUSARIA, AND NEVER TAKE A LICHEN TO A FUNGUS.

Alcon, Inc. voluntarily recalled its ocular moistening agent, *Systane Free Liquid Gel*, a compound that was touted as non-preservative. The explanation was that 11 consumer complaints had been received of mold present in the gel. Since some ugly fungus corneal infections have been reported, Alcon is recalling this product. Alcon claims that after opening the vial, contamination can occur in the absence of a preservative. The alert recommends that doctors who receive calls from patients, advise them to discontinue its use and in its place use regular Systane drops for moistening dry eyes. Further information can be obtained at the Systane website.

❖ WHO SNUCK DECAF INTO THE COFFEE POT?

According to a study published in *Quality and Safety in Health Care*, patients whose surgeries began after 4 p.m. were four times as likely to experience post-op nausea and vomiting and/or request pain medication than those whose surgeries started around 9 a.m. In comparing the risk of complications in more than 90,000 operations performed at Duke University Medical Center between 2000 and 2004, the results showed that surgeries started in the morning had the lowest rate of surgery related problems and the highest rate among procedures beginning in late afternoon. The types of problems were divided into three categories: errors such as wrong medication or wrong doses; harm including post-op wound infection, prolonged anesthesia, nausea and vomiting; and other adverse events like pain, delays, transportation, rooms not ready, etc. In the words of Vince Lombardi, "Fatigue makes cowards of us all."

❖ ALL ONE CAN SAY IS HALLELUJAH!!

After almost 40 years of being banned, DDT has been promoted by the World Health Organization (WHO) for use to combat malaria in developing nations. It has always been known that DDT is the cheapest and most effective way to contain the disease, but for decades health agencies have resisted using it under pressure from misguided, anti-pesticide greenies. Numerous studies have shown that DDT used in amounts necessary to control malaria mosquitos produces zero harm to humans, wildlife or the environment, yet well-heeled environmentalists have succeeded in banning its use for the world's poorest population. It is a perversion of justice that stuffy Sierra Club officials can sit in sterile offices and claim DDT might cause cancer or soft shells in pelican or eagle eggs, neither of which has ever been demonstrated. Meantime in Africa, malaria is the No. 1 killer of pregnant women and children, and is also a leading cause of death in South America and Asia. No one claims that DDT will eliminate malaria, but it can greatly reduce the horrible toll it is taking on the poorest and the most vulnerable, and WHO has at last shown the guts to confront this cruel and stupid taboo.

❖ EVERYONE LIES, CHEATS OR PRETENDS, BUT THE DRUG MAKERS WIN THE REALITY AWARD.

The Institute of Medicine (IOM), the medical advisory arm of the National Academy of Sciences, at last has recognized that direct to consumer advertising (DTC) has a downside. The IOM recently recommended that the FDA impose a two year moratorium on DTC advertising of new drugs. "FDA lacks the clear, unambiguous authority to enforce sponsor compliance with regulatory requirements and instead relies on the prospect of productive negotiations with industry." Amazing! The IOM is actually suggesting that the pharmaceutical industry cannot be trusted. Like used car lures, the DTC ads are frequently misleading, incomplete, and followed by a rapid disclaimer that a listener can hardly follow. The final statement is "Ask your doctor." Get out of here! When 1360 physicians were polled, 80% agreed with the two year delay because the ads interfere with the physician/patient relationship.

❖ YOU CAN'T MATE A PIG WITH A JUDGE; THERE ARE SOME THINGS A PIG WON'T DO.

Thirty-one years ago Louisiana enacted a cap of \$500,000 on damages in medical malpractice cases. Recently, the Louisiana appellate court concluded that the current cap is unconstitutional and fails to recognize that the cap value has dwindled to around \$160,000 in 2006 dollars. The jurists sent the case back to the trial court for consideration of what constitutes adequate damages. The alarming part of this judgement is that Louisiana has joined at least ten other states, Alabama, Florida, Illinois, New Hampshire, North Dakota, Ohio, Texas, Utah, Washington, and Wisconsin that have invalidated limits on damages. Legislatures can listen to testimony, discuss the issues, parley with colleagues, and finally arrive at a defining statute, but a few judges, often politically appointed lawyers, can trash it all. Additionally, the Oklahoma supreme court has ruled that a medical lawsuit does not even require a statement from an expert in the same field saying that the complaint has merit. Any wonder that tort reform is a constant uphill battle?

❖ AND NOW, IF YOU TRUST THE EPA AND THE DEPARTMENT OF ENERGY HERE ARE THE DATA —

If you are in the market for a 2007 auto and checking on gasoline economy, following are the lowest for city/highway mileage: mini-compact, VW beetle convertible 22/30; compact, Honda Civic hybrid automatic 49/51; midsize, Toyota Prius hybrid 60/51; large car Hyundai Sonata 24/34; SUV Ford Escape hybrid FWD automatic 36/51; minivan, Dodge Caravan 2WD automatic 20/26; pick up, Ford Ranger 2WD, manual 24/29. Of course, like the ad says, "mileage may vary."

❖ THE GREATEST OF FAULTS IS TO BE CONSCIOUS OF NONE.

*Medical Economics* magazine conducted a non-scientific poll of their readers to determine if physicians apologize to their patients for a treatment error. Results showed that 80% said yes, with remarks such as "I always own up to my mistakes," or "Yes, after I first consult with my attorney." Interestingly, 12% said no, and that they feared that an apology would put them at greater risk for a malpractice complaint, and 8% said no, because "When I'm accused of a mistake, it's usually for something outside my control." So, it would seem that 8% of those who responded are incapable of making a medical error, which is precisely the kind of hubris that precipitates lawsuits.

❖ NOTHING THAT WELL-MEANING PEOPLE WOULD DO SHOULD SURPRISE US.

In Pagosa Springs, Colo., a couple hung a 4-foot wreath peace sign on their outside wall for the holiday season. The three-member ruling board of the home owners association told them to take the sign down as such "signs, billboards or advertising structures of any kind" are banned and subject to a daily fine of \$25. Moreover, the sign was called anti-Christian, satanic, and divisive. The result was a public outcry, both local and national, so the board relented and said the sign could remain. Two of the board members had to disconnect their phones and resigned. Satan wins again!

ADDENDA

- ❖ 11,556 deaths have occurred from denture-obstruction since 1965.
- ❖ Number of checkpoints Mary and Joseph would have to cross on their journey from Nazareth to Bethlehem today: ten (10).
- ❖ Now lovemybubbles.com is offering a "push em up" bra for your sagging cheeks called butt boosters. Jeez, you couldn't make this up.
- ❖ Hillary Clinton spent \$1500 of campaign contributions for one hair styling session with hairdresser Isabelle Goetz.
- ❖ I never eat snails. I like fast food.

ALOHA AND KEEP THE FAITH — rts■

*Contents of this column do not necessarily reflect the opinion or position of the Hawai'i Ophthalmological Society and the Hawai'i Medical Association. Editorial comment is strictly that of the writer.*



# HMA Forum: Medical Tort Reform

## Please join us

Hawaii Medical Association invites you to the second installment in a new series of forums featuring a variety of social, economic, and legislative topics in medicine. The March forum focuses on medical tort reform for Hawaii.

**Free Admission** *Light meal included*

**Tuesday, March 6, 2007**

5:30 pm - 7:30 pm

The Queen's Conference Center  
Maybel Smythe Auditorium

**Please RSVP by March 2<sup>nd</sup>:**

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- Fax (808) 528-2376 / toll-free (866) 528-2376
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Next Forum: April 2007, Kailua-Kona *Exact date and location to be announced*



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