# Hawaiʻi Journal of Medicine & Public Health

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## Atypical Presentation of Perforated Sigmoid Diverticulitis in a Kidney Transplant Recipient with Autosomal Dominant Polycystic Kidney Disease

Ekamol Tantisattamo MD and Antonio Guasch MD

## Abstract

Perforated sigmoid diverticulitis, a complication of colonic diverticulosis commonly associated with autosomal dominant polycystic kidney disease (ADPKD), can be life-threatening in allogeneic kidney transplant recipients in the postoperative period. Immunosuppressive medications not only place the patient at risk for intestinal perforation, but also mask classic clinical symptoms and signs of acute abdomen, and subsequently lead to delayed diagnosis and treatment. We report a case of an ADPKD patient post kidney transplantation presenting with nausea, vomiting, and abdominal pain without signs of peritonitis. Chest x-ray revealed free air under the diaphragm consistent with intestinal perforation. Post kidney transplant recipients with ADPKD presenting with abdominal pain should prompt a search for possible perforated colonic diverticulitis in order to diagnose and treat this life-threatening condition early.

## **Keywords**

autosomal dominant polycystic kidney disease (ADPKD), diverticulitis, diverticulosis, kidney transplant

## Introduction

Autosomal dominant polycystic kidney disease (ADPKD) is the most common inherited kidney disease, and is a systemic disease presenting with extrarenal manifestations.<sup>1</sup> Diverticulosis is one of the extrarenal manifestations of ADPKD. It can lead to perforated diverticulitis, a life-threatening complication especially in post-kidney transplant recipients under immunosuppression. Generally, classic clinical symptoms and signs of peritonitis can lead to diagnosis; however, post renal transplant recipients with ADPKD may not have these classic clinical manifestations of diverticulosis and perforated diverticulitis. A high index of suspicion for early diagnosis and timely surgical treatment are warranted to decrease morbidity and mortality of this life-threatening condition.

## **Case Report**

The patient is a 46-year-old Caucasian man with a history of ADPKD, hypertension, and gout. He underwent deceased donor kidney transplantation 1 month prior to admission. Operation was uneventful, and he continued immunosuppressive medications including tacrolimus 3 mg twice a day, mycophenolate mofetil 1,000 mg twice a day, and prednisone 5 mg daily. He had several episodes of acute polyarticular gouty attacks which were treated with oral prednisone 30 mg per day tapered off in 1 week. The last attack was 3 weeks prior to admission. Three days prior to admission, he presented with sudden onset of sharp lower abdominal pain, nausea, vomiting, and one loose stool. He also had a low-grade fever, decreased appetite, and constant abdominal pain. His wife also had similar symptoms. He went to see his doctor as a regular appointment. He was afebrile and vital signs were normal. Abdomen was soft with

no tenderness, guarding, or rigidity. Because he felt unwell, he was admitted on that day. CBC showed leukocytosis with a white blood cell count of 14,800 /mm<sup>3</sup>. Serum creatinine was 1.3 mg/dl (his baseline serum creatinine after kidney transplantation ranged 1.2 to 1.4 mg/dl), and serum electrolytes were normal. Tacrolimus level was 29.9 ng/ml (desired target level range of 8-12 ng/ml). Chest x-ray showed free air under the diaphragm and no pulmonary infiltration (Figure 1). As a result, he underwent emergent exploratory laparotomy. Operative finding showed diverticulitis with small perforation in the sigmoid colon. Partial sigmoidectomy and end colostomy were performed. Tacrolimus was held and it was resumed after the level went down to 5.7 ng/ml (below the target level). Prednisone was also held. Postoperatively, he developed intestinal ileus which was resolved by nasogastric tube suction. He also had acute polyarticular gouty arthritis which responded well to a short course of intravenous methylprednisolone and oral colchicine. He was doing well and was discharged home on postoperative day 11. His renal graft function improved with serum creatinine before discharged of 0.9 mg/dl.

## Discussion

Mortality rate of perforated colon in adults treated with staged operations of primary resection is high, occurring in up to 45% of patients.<sup>2</sup> In post kidney transplant recipients receiving immunosuppressive therapy, colonic perforation causes higher mortality when compared to patients with normal immunity. One study reported the mortality rate of perforated diverticulitis in post renal transplant recipients with ADPKD was 100%.<sup>3</sup>

The incidence of diverticulosis in non-ADPKD with chronic renal failure is similar to that in the general population (32% and 38% respectively).<sup>4</sup> However, ADPKD is commonly associated with colonic diverticulosis<sup>3</sup> which is the leading cause of perforated colon in this population.<sup>5</sup> The prevalence of ADPKD had been reported from 2.8% to 4.1%,<sup>3.6</sup> and prevalence of colonic diverticulosis in ADPKD patients varies from 53.5% to 83%<sup>3,4.6</sup> The onset of intestinal perforation likely occurs in the first 3 weeks post kidney transplantation.<sup>7</sup>

The most common site of diverticulosis in ADPKD is the sigmoid colon.<sup>3</sup> It does not correlate with the location of transplanted kidney.<sup>5</sup> It is thought that a congenital colonic defect in ADPKD contributes to colonic diverticulosis or perforation.<sup>4</sup> Even though, colonic diverticulosis is commonly found in ADPKD patients, perforation is uncommon.<sup>5</sup> Perforated colon in ADPKD patients had been reported from 2% to 4%.<sup>5.8</sup> In one study, colonic diverticulities was the cause of colonic perforation in 6 out of 13 post kidney transplant recipients (46%);<sup>5</sup> how-



ever, a more recent study reported only one case of perforated colonic diverticulitis out of 46 post kidney transplant patients with ADPKD (2.2%).<sup>6</sup> The decreased incidence of perforated colonic diverticulitis from 46% to 2.2% could be due to changes in immunosuppressive regimens especially reduction in corticosteroid doses.6 Being a well-known cause of gastroduodenal ulcers, corticosteroid use is also associated with colonic ulceration.9-12 Its inhibitory effect on collagen synthesis facilitates colonic perforation. In addition, it inhibits inflammatory cells, some pyrogenic interleukins and pain-inducing prostaglandins, masking the normal inflammatory response.<sup>13,14</sup> As a result, symptoms and classic signs of acute abdomen may not occur in intra-abdominal visceral perforations under immunosuppression, and this leads to a diagnostic challenge. Apart from extrarenal manifestation such diverticulitis, abdominal pain in ADPKD patients may result from polycystic kidneys. Enlarged kidneys in ADPKD patients can cause chronic abdominal pain and their complications such as ruptured cysts may present with acute abdominal pain which should be one of the differential diagnoses of acute abdomen in ADPKD patients.

The most common cause of death in perforated colonic diverticulitis in post kidney transplant recipients is sepsis, and one of the most important factors determining the survival outcome after perforation is the duration from the onset of symptoms until surgical treatment. Higher survival rate occurs in the patients undergoing surgery within 24 hours after the onset of symptoms. In addition, renal graft function during the first week after perforation predicts the survival. Patients whose postoperative serum creatinine is less than 2.5 mg/dl have a higher survival rate than those with a serum creatinine more than 2.5 mg/dl.<sup>5</sup> Many studies have reported a high mortality

rate of colonic perforation in post kidney transplant recipients receiving corticosteroids;<sup>10,11</sup> however, the dose of prednisone the patients received before perforation was not different between surviving and non-surviving groups.<sup>5</sup>

There is association between ADPKD and colonic diverticulosis, but complications of diverticulosis including diverticulitis and perforation are not common. However, these fatal complications in post kidney transplant recipients have raised the need to consider aggressive prevention including workup for colonic diverticulosis and further elective colectomy in ADPKD patients who will undergo kidney transplantation. Thus far there is still no conclusion in this matter.<sup>3</sup> It is reasonable to have this workup for patients who have previous history of symptomatic diverticulosis.<sup>5</sup> However, it is crucial to recognize and diagnose early for possible perforated colonic diverticulitis in post kidney transplant recipients with ADPKD presenting with abdominal pain as well as to initiate appropriate antibiotics, decrease immunosuppressive medication, and promptly initiate surgical treatment, as all of these lead to improved survival.<sup>15</sup>

This patient presented with vague, non-specific abdominal pain, and benign abdominal signs which were out of proportion to the underlying perforated sigmoid diverticulitis. Immunosuppressive medications, especially glucocorticoids, play an important role in not only causing perforated sigmoid diverticulitis, but also masking classic symptoms and signs of acute abdomen. As a result, perforated diverticulitis should be one of the differential diagnoses of abdominal pain in post renal transplant recipients;<sup>4</sup> even though signs of peritonitis may be absent. Early recognition and prompt treatment are crucial and decrease morbidity and mortality.

## Conclusion

ADPKD is associated with colonic diverticulosis. Post allogeneic kidney transplant recipients with ADPKD may develop perforated diverticulitis which is a life-threatening condition. A high index of suspicion is needed to recognize and promptly treat this complication early, as typical presentations may not occur in the patients who are immunosuppressed.

This case report was presented as a poster presentation at Biomedical Sciences Symposium, University of Hawai'i, John A. Burns School of Medicine on April 18th, 2012.

## **Conflict of interest**

The authors report no conflict of interest.

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## **Pegloticase for Treatment of Tophaceous Polyarticular Gout**

Rebecca M. Seifried DO and Jefferson Roberts MD

## Abstract

This is a case report of a patient with treatment resistant gout who was prescribed pegloticase and developed a severe reaction. A 30-year-old Hawaiian-Filipino man presented with a nine-year history of gout that progressed from episodic monoarticular arthritis, treated with aspiration and corticosteroid injections, to more aggressive disease with more frequent attacks requiring escalation of therapy. He was treated with systemic corticosteroids, colchicine and nonsteroidal anti-inflammatory drugs, but then required allopurinol. Despite aggressive therapy, the patient continued to have hyperuricemia and tophi developed even after treatment with febuxostat and probenicid. The patient became wheel chair bound due to his pain and, at that point, the decision was made to initiate treatment with treatment; however, he soon began to have elevation in his serum uric acid levels and developed a severe reaction during treatment.

## **Keywords**

pegloticase, tophi, treatment resistant gout, infusion reaction

## Introduction

The prevalence of gout in the United States is rising<sup>1-3</sup> and will continue to challenge treating physicians in the state of Hawai'i. Gout, which is so old that it has been mentioned in many ancient texts including the Bible, can be a finicky disease. As old as this disease is, until recently treatment options have been limited. In general, gout patients have only been offered treatments such as non-steroidal anti-inflammatory drugs, colchicine, allopurinol and even probenicid but there are still those patients who require escalation in therapy.<sup>4</sup> A newer xanthine oxidase inhibitor, febuxostat, is now available. However in some patients this is still not enough. Physicians are often unsure how to guide treatment when patients develop tophi and the current medicines are ineffective. Now, there is a much newer option, pegloticase. An experience in using pegloticase in a Pacific Islander who endured crippling tophaceous gout despite conventional therapy and some interesting surprises is presented.

## **Case Presentation**

The patient is a 30-year-old man, of Hawaiian and Filipino ancestry, who presented to Tripler Army Medical Center with a nine-year history of gout after receiving treatment at multiple medical centers throughout the continental United States. He initially presented with episodic monoarticular arthritis that required needle aspiration and corticosteroid injections. His disease progressed with more frequent attacks. Other medications prescribed included systemic corticosteroids, colchicine and various nonsteroidal anti-inflammatory drugs. Over time his attacks became more frequent requiring initiation of allopurinol for maintenance therapy. Despite aggressive therapy, uric acid levels could not be controlled. Eventually febuxostat was tried but tophi developed and grew quite large, causing contractures and deformity of several joints. He also developed tophi in subcutaneous tissues. He became wheelchair bound at 29 years of age due to severe pain and difficulty with ambulation. Combination uricosuric and xanthine oxidase inhibitors were tried with little success. Upon presentation to Tripler Army Medical Center, the patient's serum uric acid levels rose as high as 13.9mg/dL (reference range 2.5-7.5mg/dL). It was decided to try pegloticase.

After two doses of pegloticase over the course of four weeks the patient reported dramatic improvement in his pain level with resolution of many of his tophi and shrinking of others. He was no longer wheelchair bound and was able to ambulate with the assistance of a cane. His serum uric acid level also fell to 4.5mg/ dL. Before initiation of his third dose, his serum uric acid level was 8.6mg/dL. He was counseled on risk of infusion-related reaction, yet he still wanted to proceed despite the risk. Upon initiation of the third dose he developed tachycardia, hypertension, flushing and complained of shortness of breath. His symptoms improved with two doses of intramuscular epinephrine, and high dose corticosteroids. He was admitted to the hospital overnight for observation with resolution of symptoms and no further complications. He was discharged the next morning.

His treatment was changed to include febuxostat, his steroids were tapered down, and he was started on anakinra as a steroid sparing agent. The patient's pain remained better controlled and he did not develop any new tophi, but his serum uric acid levels have remain elevated at 11mg/dL.

## Discussion

Gout is increasing in prevalence in the United States.<sup>1-3</sup> In many of these cases patients can be well-controlled on conventional therapy. However, in as many as 50,000 patients (1% of the Gout population),<sup>5</sup> gout is refractory to conventional treatment; the serum uric acid levels cannot be controlled below 6mg/dL, patients continue to have frequent attacks, and develop tophi. Pegloticase was approved for treatment of resistant gout, and it may be a good treatment option in those who have persistent hyperuricemia and/or development of tophi.<sup>4,5</sup>

Before the 1960s, treatment focused on controlling inflammation. Allopurinol was approved in 1966 but it has its limitations,<sup>6</sup> including worsening gout flares in the acute setting if not taken with colchicine. It also has multiple drug interactions. Probenecid was originally used in WWII to extend the supplies of penicillin, however, it was not approved for treatment of Gout until 1976.<sup>6</sup> Probenecid requires near normal renal function and does not work when the glomerular filtration rate is less than 50 mL/min. In 2009 febuxostat was approved<sup>6</sup> for the treatment of gout and it can be used in patients with mild to moderate renal impairment, but its use is not defined in end stage renal





Figure 2. Large tophi overlying the right elecranon



Figure 3. Significant destruction of the left second proximal interphalangeal joint with overhanging cortex and sclerotic margins

failure or in patients on hemodialysis.<sup>7-10</sup> Lastly, pegloticase was approved in 2010. However this also has limitations in treatment.<sup>4,5</sup>

Pegloticase cannot be given to patients with Glucose-6-Phosphate dehydrogenase (G6PD) deficiency, therefore G6PD status needs to be determined before initiation of treatment. It also can be associated with severe reactions within 2 hours of infusion and patients need to be monitored carefully.5 Patients with serum uric acid levels greater than 6mg/dL after the treatment is started are more likely to have an infusion reaction. Ninety percent of patients who take pegloticase develop antibodies,5 so it is important to pretreat patients with diphenhydramine and high dose corticosteroids before each dose. When pegloticase antibody titer levels reach 1:2430, patients tend to be unresponsive to pegloticase.<sup>5</sup> A rise in serum uric acid levels tends to precede this level of antibody titer. In multiple studies, it was determined that dosing every two weeks with pegloticase was effective compared to every 4 weeks.<sup>5</sup> Adverse treatment reactions occurred in about 26% of patients on the 2 week dosing schedule, 40% of those on the 4 week dosing schedule, and 5%on placebo.<sup>5</sup> Serious infusion reactions occurred in about 4.7% of patients with twice monthly dosing and 8.3% of patients with monthly dosing.5 There were no reported incidences of anaphylaxis.5

Patients need to stop serum uric acid lowering medications before starting pegloticase because this may falsely reassure the treating physician that the serum uric acid level is less than 6mg/dL. If a patient starts treatment with pegloticase and their serum uric acid level is greater than 6mg/dL on two separate measurements, treatment needs to be discontinued, as risk of infusion reaction is increased.

## Conclusions

Pegloticase can be an effective alternative therapy in patients with tophaceous gouty arthritis that is resistant to conventional treatments. Before starting pegloticase physicians should stop other medications that lower serum uric acid, assess for G6PD deficiency, and pretreat with diphenhydramine and high dose steroids before each dose. Serum uric acid levels also should be checked before each infusion and pegloticase should be discontinued if the serum uric acid level is greater than 6mg/ dL on two separate measurements due to increased risk of infusion reaction. Pegloticase certainly has a place in patients who have failed treatment either because of progression of tophi or intolerance to medication or allergic drug reaction.

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## **Conflict of Interest**

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## Overweight and Obesity Among Hawai'i Children Aged 4 to 5 Years Enrolled in Public Schools in 2007-2008 and Comparison with a Similar 2002-2003 Cohort

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## Abstract

This assessment provides the most recent estimates of overweight and obesity among children 4 to 5 years old who were enrolled in public schools in the 2007-2008 school year, using data obtained from Student Health Records for 12,823 children, which represents 91% of the 14,070 children who were enrolled in kindergarten in 2007-2008. This assessment is a census of 4 to 5 year olds that entered public schools in Hawai'i in 2007-2008 and represents approximately 38% of the total Hawai'i population for those aged 4 to 5 years, since kindergarten is not a requirement. A limited data set with data on age, sex, height, and weight was used to calculate BMI (body mass index) percentiles. We compare this data with age and sex-specific BMI obtained from Student Health Records from 10, 199 children aged 4 to 5 years entering public schools during 2002-2003. The results illustrate that like the 2002-2003 data (28.5%), over one in four (28.6%) of the children aged 4 to 5 years entering Hawai'i public schools in 2007-2008 were either overweight or obese. Total proportions overweight and obese were persistently higher (32.5% or more in both 2002-2003 and 2007-2008) in some specific school complexes on O'ahu as well as in some rural and Neighbor Island school complexes. Physicians, public health and school health professionals, advocates, schools, and communities should be vigilant about this persistent problem and seek to implement practices to combat overweight and obesity. In addition, the use of Student Health Records for on-going pediatric obesity surveillance should be explored more fully.

## Introduction

The number of overweight children in the United States has more than doubled for those aged 2-5 years and tripled among those aged 6-11 years and 12-19 years in the past 40 years, with similar patterns occurring throughout the world.<sup>1</sup> Data from the 2007-2008 National Health and Nutrition Examination Survey (NHANES),<sup>2</sup> which used actual height and weight measurements and does not include Hawai'i, indicated that an estimated 17% of children and adolescents ages 2-19 years were obese. Studies have also shown that children in certain minority ethnic groups (American Indians, Hispanics, and African-Americans) in the United States are particularly at risk for overweight and obesity.3 The Centers for Disease Control and Prevention's (CDC) 2011 Youth Risk Behavior Survey (YRBS) estimates that 28.2% of adolescents in the United States and 26.6% in Hawai'i are overweight or obese,<sup>4</sup> illustrating that Hawai'i is clearly following a nationwide pattern for youth overweight and obesity. However, self-reported height and weight data in the YRBS is likely to contain reporting bias, and large population based, measured anthropometric data for Hawai'i have not been done since 1984.5

The health problems that overweight or obese children and youth develop are similar to problems of overweight or obese adults. Overweight children are at increased risk for numerous health conditions, including type-2 diabetes, hypertension, cardiovascular disease, dyslipidemia (high triglyceride levels), some specific cancers, gallstones, osteoarthritis, rheumatoid arthritis, premature death, sleep apnea, and respiratory problems, as well as poorer physical functioning status and lower life expectancy. <sup>6-11</sup>

Numerous studies of Pacific populations have illustrated that the problems of dietary-related chronic diseases, especially diabetes and obesity, are pervasive for Pacific Islanders<sup>12-14</sup>(eg, Native Hawaiians, Samoans, and Micronesians).

Recent research studies suggest that Hawai'i has a significant problem with childhood overweight and obesity.<sup>15</sup> Most estimates are for infants and very young children and youths or adolescents; only a few studies include elementary school students.<sup>16</sup>These studies have also found significant ethnic differences in the proportions of overweight or at risk.<sup>17</sup> While the studies mentioned above demonstrate a significant problem of overweight among young children and youths and adolescents in Hawai'i, the lack of sufficient and current data on elementary school-age children was the impetus for this study. Another objective was to assess the utility of the Student Health Records as a source of surveillance data for childhood weight measurement, by examining how extensive the data coverage is over the population being assessed, and the utility of the data.

The specific purpose of this project was to re-assess BMI among children aged 4 to 5 years old entering public schools in 2007-2008 and compare them with a previous cohort in 2002-2003.<sup>18</sup> All children entering schools in Hawai'i are required to submit a Form 14-Student Health Record for proof of immunization, that also includes documentation of date of birth, sex, height, weight, date of measurement, and any existing medical conditions. During the 2002-2003 assessment, student health record data from 10,199 complete records were used by the Hawai'i State Department of Health to retrospectively assess children's immunization status and BMI. Baseline estimates of overweight/at-risk for overweight in children aged 4 to 5 years entering public schools in 2002-2003 found that 14.1% of children were at risk for overweight and 14.5% were overweight, with a combined estimate of 28.5% for those with a BMI ≥85th percentile.<sup>18</sup>

It is important to note that in 2005 the previous childhood obesity recommendations were revised by an Expert Committee convened by the American Medical Association, the Health Resources and Services Administration (HRSA), and the CDC and the results were released in 2007.<sup>19</sup> The previous BMI weight categories were changed from "at-risk for overweight" to "overweight" [ $\leq$ 85 to <95th percentile] and "overweight" to "obesity" [ $\geq$ 95 percentile]. The Expert Committee recommended that the standards for BMI classification be changed, whereby children ages 2-18 years (1) with a BMI  $\geq$ 95th percentile for age and sex or BMI exceeding 30 (whichever is smaller), should be considered obese (previously termed "overweight"); and (2) those with a BMI  $\geq$ 85th percentile, but <95th percentile for age and sex, should be considered overweight (and this term replaces "at risk for overweight"). For clarity, this article will use the latest nomenclature for both time periods. The combined estimate for those with a BMI  $\geq$  85th percentile will be referred to as overweight and obese.

The purpose for this study was to provide updated BMI data on children entering public schools, and another objective was to assess the utility of the Student Health Records as a source of surveillance data for childhood weight measurement.

## Methods

Student Health Records are required for students entering public schools, according to Hawai'i Administrative Rules.<sup>20</sup> Under an agreement between the Superintendent's Office of the Department of Education (DOE) and the Department of Health (DOH), an initial assessment was conducted in 2002-2003 to examine childhood overweight among public school students, and to assess the feasibility of using the Student Health Records as a means of surveillance of childhood overweight status.<sup>18</sup> The current study is a reassessment of childhood overweight and obesity status after a five-year interval. For both assessments, the protocol was reviewed and approved by the DOH's Institutional Review Board and the Superintendent's Office of the DOE.

The Student Health Record document contains the student's required immunization history and must be stamped or signed by a medical practitioner, medical personnel, or a clinic. It also contains information on the age and sex of the child along with information regarding existing chronic conditions, such as asthma. Height and weight were measured and recorded by the medical personnel completing the form and it is not known how many different medical personnel completed these forms, and this could have introduced errors. Measurements were recorded in both metric and non-metric measurements, and all records and forms were verified for accuracy and all converted into non-metric measurements for analysis in CDC EpiInfo 2000 NutStat program.<sup>21</sup>

All public schools statewide, including charter schools, were invited by the DOE to participate, but schools were not required to participate. Of the 14,070 children who entered the Hawai'i public school system in 2007-2008,<sup>22</sup> there were 15,536 forms submitted by schools, including Student Health Records and additional forms and papers (physician office records). All key identifying information was removed by the DOE Student Support Services Office (ie, names and other identifying information, including parent's names or home addresses were removed). Of these forms and records, 2,797 (18%) were excluded from the study, including: records that were not complete for age, sex,

weight and height or had implausible anthropometric values (defined by extreme z scores and corresponding percentiles in the CDC EpiInfo 2000 NutStat program), duplicate forms and forms from physician offices with duplicative information, and children who did not meet the age criteria of the study (eg, older students transferring into a school). The study population was limited to those students aged 4 to 5 years (48 to 71 months), resulting in a total of 12,823 students; the mean age was 56 months. The CDC's EpiInfo 2000 NutStat program was used to calculate percentiles for BMI, height for age and weight for height based on the 2000 CDC reference population. The CDC reference population is based on national health surveys from 1963 to 1994 along with supplemental sources, including NHES II &II, NHANES I, II & III and others.<sup>23</sup> CDC growth charts are normalized to the US population, and are different from WHO growth charts. Since BMI is not perfectly or normally distributed, statistical techniques are applied to the data to create a normal distribution and adjust for natural skewing that occurs in BMI. In the reference population, 10% of children would be overweight and 5% would be obese, with a total of 15% combined as overweight and obese. This study follows the CDC protocol and obesity is defined as BMI  $\geq$  95th percentile and overweight was defined as being between  $\geq$  85th and <95th percentiles.

To compare whether there were statistically significant differences within school complexes in the two time periods a statistical test (t-test) was conducted. Confidence intervals were not calculated since this was a census. There were 14,070 students who entered kindergarten in public schools in 2007-2008,<sup>24</sup> and this study captures 12,823 (91%) usable health records among those who were the correct age for entering kindergarten in 2007-2008. The student's ethnicity, household income or other household characteristics were not included on the Student Health Record, therefore, these variables were not available to be included in this analysis.

Although information on individual schools was available for the study, and was provided to the DOE, to ensure privacy, results of individual schools were suppressed under an agreement between the DOH and the DOE. For this analysis, if there were fewer than 30 students in a school complex, the data were suppressed to ensure confidentiality and were listed as "not reported" in the Tables and Figures.

## Results

Tables 1 provides the percentages of children overweight and obese for the State, for each County and for the school complexes within each County for 2002-2003. Tables 2 lists these percentages for 2007-2008. School complexes in Hawai'i are grouped geographically and comprised of those elementary and middle schools that feed into a particular high school.

Overall, the State totals in 2007-2008 (Tables 2) reveal high proportions of 4 to 5 year olds entering Hawai'i public schools overweight (14.4%) or obese (14.2%) for a total of 28.6\%. This is similar to the findings from 2002-2003 where 14.1% were overweight and 14.4% were obese (28.5% total) (Tables 1).

Table 1. Percentage Overweight, Obese, and Total Among Children Aged 4-5 Years Entering Public Schools In 2002-2003	18
HONOLULU COUNTY	

	% Overweight* (BMI >= 85 and < 95)	% Obese** (BMI >=95)	Total
State total (N=10,199)	14.1	14.4	28.5
Oʻahu County Total (N=7,197)	13.8	13.9	27.7
Aiea (n=247)	17.8	8.1	25.9
Campbell (n=440)	13.0	16.4	29.4
Castle (n =370)	13.5	15.4	28.9
Farrington (n =483)	17.2	15.5	32.7
Kahuku (n=188)	16.0	19.7	35.7
Kailua (n=204)	13.7	15.2	28.9
Kaimuki (n=343)	13.7	15.5	29.2
Kaiser (n=119)	10.1	7.6	17.6
Kalaheo (n=305)	12.8	9.5	22.3
Kalani (n=249)	12.9	7.6	20.5
Kapolei (n=334)	10.5	13.2	23.7
Leilehua (n=553)	15.9	13.4	29.3
McKinley (n=373)	13.4	14.5	27.9
Mililani (n=315)	13.7	10.8	24.5
Moanalua (n=241)	12.0	12.5	24.5
Nanakuli (n=148)	10.8	17.6	28.4
Pearl City (n=446)	12.8	13.2	26.0
Radford (n=588)	15.1	12.2	27.3
Roosevelt (n=407)	11.8	11.1	22.9
Waialua (n=59)	17.0	22.0	39.0
Waianae (n=302)	14.2	15.9	30.1
Waipahu (n=483)	12.6	19.9	32.5

Table 1. Percentage Overweight, Obese, and Total Among Children Aged 4-5 Years Entering Public Schools In 2002-2003<sup>18</sup> HAWAI'I COUNTY

	% Overweight* (BMI >= 85 and < 95)	% Obese** (BMI >=95)	Total				
Hawaiʻi County Total (N=1,310)	15.2	15.1	30.3				
Central Hilo (n=215)	14.0	16.3	30.3				
Hilo (n=241)	14.5	17.0	31.5				
Honokaa (n=200)	18.0	16.5	34.5				
Kau (n=41)	17.1	14.6	31.7				
Keeau (n=152)	17.1	15.1	32.2				
Kohala (n=34)	20.6	11.8	32.4				
Laupahoehoe (Not Reported)							
North Kona (n=221)	13.1	15.4	28.5				
Pahoa (n=86)	14.0	14.0	28.0				
South Kona (n=120)	14.2	8.3	22.5				

Table 1. Percentage Overweight, Obese, and Total Among Children Aged 4-5 Years Entering Public Schools In 2002-2003<sup>18</sup> KALIA'L COLINTY

	% Overweight* (BMI >= 85 and < 95)	% Obese** (BMI >=95)	Total			
Kaua'i County Total (N=524)	16.4	12.5	28.9			
Central Kaua'i (n=233)	14.2	9.0	23.2			
East Kauaʻi (n=150)	14.7	16.0	30.7			
West Kauaʻi (n=141)	22.0	14.9	36.9			
Ni'ihau (Not Reported)						

Table 1. Percentage Overweight, Obese, and Total Among Children Aged 4-5 Years Entering Public Schools In 2002-2003<sup>18</sup> MAUI COUNTY

	% Overweight* (BMI >= 85 and < 95)	% Obese** (BMI >=95)	Total
Maui County Total (N=1,168)	13.8	17.9	31.7
Baldwin (n=203)	17.7	17.2	34.9
Hana (Not Reported)			
Kekaulike (n=275)	12.7	15.6	28.3
Lahainaluna (n=124)	17.7	27.4	45.1
Lana'i (n=30)	26.7	20.0	46.7
Maui (n=452)	11.1	15.9	27.0
Moloka'i (n=67)	13.4	17.9	31.3

BMI CALCULATED BY: Hawai'i Dept. of Health, Chronic Disease Management & Control Branch and Maternal & Child Health Branch, 2012. Data Source: Height, Weight, Age, Sex Data were obtained from DOE School Health Record Form 14. \*formerly called at risk for overweight. \*\*formerly called overweight.

In 2007-2008, total overweight and obese among complexes ranges from a low of 14.7% at the Kaiser complex to a high of 39.0% for Lana'i and 39.1% for Moloka'i. Rates are persistently higher (32.5% or more in both 2002-2003 and 2007-2008) in some specific school complexes on O'ahu (Farrington, Kahuku, Waialua and Waipahu) as well as in some rural and Neighbor Island school complexes (Lana'i and Lahainaluna). Other areas also have 32.5% or more of the children overweight and obese in 2007-2008, including: Kau, Keeau, Pahoa, Waianae, Nanakuli and Moloka'i. (Refer to Figures 1-8 which depict the school complexes graphically from 2002-2003 to 2007-2008).

Comparing the proportions of overweight, obese and total from 2002-2003 to 2007-2008, there were some statistically significant differences in six school complexes in these two different 5-year intervals, using the t-test for statistical significance (Table 3). In the Aiea complex on O'ahu, there were significantly lower proportions of overweight combined with significantly more obese (P < .05) from 2002-2003 to 2007-2008, resulting in no difference in overweight and obese combined. In the Kalaheo and Mililani complexes on O'ahu, there was a significant increase in the proportions of obese children from 2002-2003 to 2007-2008, and this is also reflected with an increase in the combined overweight and obese. In the Kapolei (O'ahu) complex there was a statistically significant increase in the total proportions overweight and obese from 2002-2003 to 2007-2008, while in the Lahainaluna (Maui) complex there was a statistically significant decrease. In the Nanakuli complex on O'ahu, there was a statistically significant increase in the

proportions overweight and the total proportions overweight and obese from 2002-2003 to 2007-2008.

## Discussion

With essentially no change in the State total compared to 2002-2003, childhood overweight and obesity status continues to be a problem for many children entering public schools. These data suggest that overweight and obesity among 4 and 5 year olds clearly remain a problem that exists before children start public school in many communities throughout Hawai'i. The communities with the highest proportions of children overweight and obese include those communities with higher proportions of families with lower educational levels, lower per capita income, higher poverty, higher proportions needing government assistance, higher unemployment, and include higher proportions of ethnic groups at risk for overweight and obesity, namely Native Hawaiians, other Pacific Islanders, and Filipinos.<sup>25</sup> However, it is important to reiterate that in the absence of individual level ethnicity and household characteristics of the students (because such information is not included on the Student Health Record), we can only show that these geographic disparities exist, but we cannot make specific inferences about the students or schools based on aggregated data for a group, community or neighborhood. There has been increased interest in the role of neighborhood and community environments and overall health, and recent studies highlight the importance of neighborhood structural factors (high poverty, lower education) and childhood obesity,26-28 suggesting that individual

Table 2. Percentage Overweight,	Obese and To	tal Among	Children aged 4-	5 Years Entering	Public Schools in	2007-2008
HONOLULU COUNTY						

	% Overweight (BMI >= 85 and < 95)	% Obese (BMI >=95)	Total
State total (N=12,823)	14.4	14.2	28.6
Oahu County Total (N=8,918)	14.4	14.8	29.2
Aiea (n=289)	11.8	13.8	25.6
Campbell (n=602)	14.9	12.2	27.1
Castle (n=487)	12.0	13.0	25.0
Farrington (n=547)	15.5	18.6	34.1
Kahuku (n=258)	18.3	17.9	36.1
Kailua (n=380)	14.8	16.1	30.9
Kaimuki (n=379)	12.5	13.3	25.7
Kaiser (n=151)	8.0	6.7	14.7
Kalaheo (n=309)	14.6	15.6	30.2
Kalani (n=451)	9.8	8.0	17.9
Kapolei (n=323)	15.8	15.2	31.1
Leilehua (n=652)	15.9	14.0	29.9
McKinley (n=333)	14.5	11.2	25.8
Mililani (n=616)	14.6	10.4	25.0
Moanalua (n=278)	17.3	13.7	31.0
Nanakuli (n=263)	18.7	16.0	34.7
Pearl City (n=508)	12.2	14.6	26.8
Radford (n=502)	12.6	14.4	27.0
Roosevelt (n=439)	11.0	9.6	20.6
Waialua (n=96)	14.6	19.8	34.4
Waianae (n=466)	20.0	12.5	32.5
Waipahu (n=589)	15.4	18.9	34.3

Table 2. Percentage Overweight, Obese and Total Among Children aged 4-5 Years Entering Public Schools in 2007-2008 HAWAI'I COUNTY

	% Overweight (BMI >= 85 and < 95)	% Obese (BMI >=95)	Total
Hawaiʻi County Total (N=1,694)	14.8	14.7	29.4
Central Hilo (n=287)	13.9	13.2	27.2
Hilo (n=327)	13.4	16.2	29.6
Honokaa (n=238)	14.8	12.7	27.5
Kau (n=78)	18.2	14.3	32.5
Keeau (n=178)	18.0	19.1	37.1
Kohala (n=64)	15.6	15.6	31.3
Laupahoehoe (Not Reported)			
North Kona (n=219)	13.8	10.6	24.4
Pahoa (n=125)	16.3	21.1	37.4
South Kona (n=167)	14.0	11.6	25.6

Table 2. Percentage Overweight, Obese and Total Among Children aged 4-5 Years Entering Public Schools in 2007-2008 KAUA'I COUNTY

	% Overweight (BMI >= 85 and < 95)	% Obese (BMI >=95)	Total			
Kaua'i County Total (N=635)	14.4	13.8	28.2			
Central Kauaʻi (n=255)	13.0	13.8	26.8			
East Kauaʻi (n=185)	16.4	15.3	31.7			
West Kauaʻi (n=195)	14.9	15.4	30.3			
Ni'ihau (Not Reported)						

Table 2. Percentage Overweight, Obese and Total Among Children aged 4-5 Years Entering Public Schools in 2007-2008 MAUI COUNTY

	% Overweight (BMI >= 85 and < 95)	% Obese (BMI >=95)	Total
Maui County Total (N=1,576)	13.0	15.5	28.6
Baldwin (n=274)	13.0	16.3	29.3
Hana (Not Reported)			
Kekaulike (n=321)	12.3	12.0	24.4
Lahainaluna (n=224)	13.1	20.3	33.3
Lana'i (n=41)	19.5	19.5	39.0
Maui (n=579)	12.5	16.6	29.1
Molokaʻi (n=115)	11.3	27.8	39.1

Table 3. School Complex Areas With Statistically Significant Differences in the Percentage Overweight, and/or Obese and/or Total in 2002-2003 and 2007-2008

	Overweight* 2002-2003	Overweight 2007-2008	T-test	Obese** 2002-2003	Obese 2007-2008	T-test	Total Over-Weight and Obese 2002-2003	Total Over-Weight and Obese 2007-2008	T-test
Aiea (Oʻahu)	17.8	11.8	P<.05	8.1	13.8	P<.05	25.9	25.2	
Kalaheo (Oʻahu)	12.8	14.6		9.5	15.5	P<.05	22.3	30.1	P<.05
Kapolei (Oʻahu)	10.5	15.5		13.2	15.2		23.7	30.7	P<.05
Mililani (Oʻahu)	13.7	14.4		10.8	24.8	P<.05	24.5	39.2	P<.05
Nanakuli (Oʻahu)	10.8	18.6	P<.05	17.6	19.8		28.4	38.4	P<.05
Lahainaluna (Maui)	17.7	13.4		27.4	20.1		45.1	33.5	P<.05

\*formerly called at risk for overweight. \*\*formerly called overweight.

level behavioral interventions will not be enough to contain the obesity epidemic.

This study supports the findings of other recent studies, illustrating that childhood obesity is a serious problem in Hawai'i, for both the individuals involved and communities that will experience an increased burden of providing care for individuals with chronic diseases. The problem is more severe in certain communities (school complex areas) even though state averages are not higher than national averages.

Physicians, public health and school health practitioners, community planners, and advocates for healthy community spaces need to be aware of this growing problem, and should seek to implement strategies within their practices to combat overweight among their pediatric patients and families. Guidance on the role of physicians in the prevention of pediatric overweight and obesity is available through the American Academy of Pediatrics.<sup>29</sup> There is recent evidence that awareness of the issue and public health interventions can reduce the prevalence of obesity among public school children.<sup>30</sup>

The main limitation of this study is that kindergarten is not required in Hawai'i, and children are not required to attend school until they are six years old, so this study population was not representative of all children aged 4 to 5 years throughout the State of Hawai'i in 2007-2008. We do not know the exact number of children aged 4 to 5 years who could have entered all schools during this time, although we do know that there were 14,070 students who entered kindergarten in public schools in 2007-2008;<sup>25</sup> therefore, this census (N=12,823) includes 91%



Hawai'i County, 2002-2003



Figure 2. Percent Overweight and Obese (BMI >=85), Public School Students Aged 4 to 5 Enrolled in Public School by School Comple Hawai'i County, 2007-2008



Honolulu County, 2002-2003



Honolulu County, 2007-2008



Kaua'i County, 2002-2003







of those who were the correct age for entering kindergarten in 2007-2008. Since US Census data indicates there were approximately 33,100 children aged 4 to 5 years in the State of Hawai'i in 2007-2008, the 12,823 children in this study account for 38% of the total population of children aged 4 to 5 years in the State of Hawai'i. Furthermore, this group of children was only comprised of public school students and does not provide any estimates of the proportions of children aged 4 to 5 years entering schools who are overweight or obese in private schools. The DOE enrollment figures show that about 16.8% of Hawai'i students were enrolled in private schools during the 2007-2008 school year with 80.4% enrolled in public schools and 2.8% in Charter schools.<sup>31</sup> Another limitation of this assessment is that many of the Student Health Records had information missing, including date of measurement, date of birth, sex, and weight or height. Further, there was no standardization of equipment or staff in measurement protocols, which could have introduced errors. On the other hand, the strength of this assessment is that the BMI-specific data were completed by medical personnel, and based on actual clinical measurements rather than self-report. Since the results show a persistent problem of overweight and obesity among children 4 to 5 years entering public schools in Hawai'i, it is important that (1) physicians, parents, families, and communities be vigilant about this persistent problem and seek to implement practices to combat overweight and obesity among their pediatric patients and families; and (2) public health and school health professionals work on policy and environmental changes to facilitate healthy choices and activities, especially among families whose choices may be constrained by socioeconomic circumstances.

Finally, the idea of converting the Student Health Record into an electronic data system has been suggested for many years in the public health community in Hawai'i and such obesity surveillance would be another reason to develop an electronic system. This could improve the accuracy of data and limit missing information. It is evident from both the 2002-2003 and 2007-2008 assessment that it is feasible to use Student Health Records (Form 14) data on a continual basis for developing a system of on-going childhood obesity surveillance. Such a surveillance system needs to include Student Health Records from private schools as well in order to be representative. Private schools also require students to have completed Student Health Records for immunizations, and therefore, the potential for a state-wide surveillance system for children entering school is feasible. The Department of Health (DOH) and the Department of Education (DOE) have been collaborating on use of Student Health Records to assess childhood overweight and obesity since 2003. Since these Student Health Record data have now become an integral part of childhood obesity surveillance, such surveillance should ideally be conducted at five-year intervals.

## **Conflict of Interest**

The authors report no conflict of interest.

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## Randomized Controlled Trial: Targeted Neck Cooling in the Treatment of the Migraine Patient

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## Abstract

Cold therapy has long been the number one self-care treatment employed for migraine without aura and the second most common for migraine with aura, yet its mechanism remains elusive. In this study, a mechanism by which this time-tested therapy works is proposed (by cooling the blood passing through intracranial vessels) in an attempt to further elucidate its beneficial effects. The study is designed as a randomized, controlled, crossover clinical trial utilizing an adjustable wrap containing two freezable ice packs targeting the carotid arteries at the neck, where they come close to the skin surface. Fifty-five participants successfully completed the study. Pain at onset, as recorded on a visual analog scale, was similar between the two treatment arms. Maximum pain reduction was observed at the 30 minute time point with a 31.8% ± 15.2% decrease in pain in the treatment arm compared to a 31.5% ± 20.0% increase in pain at the same time interval in the control arm. These findings confirm the application of a frozen neck wrap at onset of migraine headache targeting the carotid arteries at the neck significantly reduced recorded pain in participants with migraine headaches (P<.001).

## Introduction

The treatment of migraine with cold therapy has been used for over 150 years. James Arnott was the first to document his application of salt and ice mixtures in the treatment of headache in 1849.1 Since then, many studies have re-examined this technique utilizing various methods of cold application. Ucler utilized a frozen gel cap that covered the entire head and included a chin strap,<sup>2</sup> Robbins utilized an elastic head band with reusable gel packs centered over the forehead,<sup>3</sup> and Diamond utilized simple gel packs held by hand to the area of pain.<sup>4</sup> Lance utilized a complicated helmet system combining cold with variable heat and pressure.5 In an interesting study by Friedman,6 hollow metal tubes chilled by circulating cold water were applied to the periapical area of the maxillary molars. All of the aforementioned studies reported symptomatic relief with their respective cold therapies. Today, many patients utilize cold therapy as part of their treatment regime and Zanchin reports that,<sup>4,7</sup> of all self administered pain-relieving maneuvers, cold therapy is the most common maneuver applied in migraine without aura and the second most common maneuver applied in migraine with aura second only to compression.8

The physiologic effects of cryotherapy are well studied on many systems. Those systems most intimately involved with the application of cryotherapy to migraine are the vascular, neurologic and endocrine. With respect to the vascular system, cold induces vasoconstriction with subsequent decreased downstream blood flow.<sup>9-16</sup> A secondary reactive vasodilation, referred to as the "Hunting response,"<sup>16-19</sup> is thought to occur in less than 20 to 30 minutes of persistent cold application.<sup>20,18</sup> However, the practical effects of this phenomenon have been drawn into question.<sup>21</sup> In addition to vasoconstriction, cryotherapy also decreases local edema.<sup>10,14</sup> This decrease in edema is thought

to result from decreased vascular permeability which in turn is thought to be due to decreased release of inflammatory mediators.<sup>22, 23</sup> In regards to the neurologic system, cryotherapy induces analgesia by slowing nerve conduction velocity with sensory fibers being affected before motor fibers.<sup>24-29</sup> More specifically, small myelinated fibers are affected first followed by large myelinated fibers with unmyelinated fibers being affected last.<sup>29</sup> In following with the gate control mechanism of pain,<sup>30</sup> cryotherapy induces analgesia by affecting the small myelinated nociceptive pain afferents. As for the endocrine system, cryotherapy decreases metabolic and enzymatic activity.<sup>26,31,32</sup> Under such conditions, there is a decreased tissue demand for ATP with a subsequent decrease in local oxygen demand.<sup>31, 33</sup> Finally, a discussion of the physiologic effects of cryotherapy as they apply to the migraine patient would not be complete without acknowledging the important contribution of the placebo effect on patient's subjective assessment of their pain.34,35

In this pilot study, a wrap containing frozen ice packs targeting the carotid arteries at the front of the neck is used to attempt to evaluate the benefits of targeted carotid cooling in the migraine patient. The study stems from a hypothesis that the mechanism through which cold therapy is effective in treating migraine is by cooling the blood passing through intracranial vessels. As such, cold applied to the head would have to penetrate the skull to reach the target vessels. Marathon runners apply ice packs to the armpits and groin after a race because this is where large blood vessels come close to the skin surface. This study uses a similar concept to address the carotid arteries where they come close to the skin surface at the neck to further elucidate the benefits of this time proven therapy.

## Methods

This study is designed as a randomized, controlled, crossover clinical trial utilizing an adjustable neoprene neck wrap that holds two freezable ice packs targeting the carotid arteries in the treatment of migraine headaches. The study was approved by the institutional review boards of the three affiliated institutions. Participants were recruited from the general public through posters, local media, and physician referral from March through June of 2012 and followed through September, 2012. All participants were screened by the same investigator by means of a pre-research questionnaire to ensure they met the following inclusion criteria: male or female, 18-65 years old and met current International Headache Society (IHS) International Classification of Headache Disorders (ICHD-2) criteria for migraine (with or without aura) at time of entry into the study.<sup>36</sup> Participants who were taking more than three medications (including over-the-counter) specifically for migraine at the time of interview, or had failed triptan therapy in the past, were excluded from the study. Participants were not monetarily compensated for their participation; however, they were allowed to keep the investigational neck wrap at the conclusion of the study. Eligible participants were randomized into one of two arms: frozen (treatment) or non-frozen/room temperature (control) according to when they entered the study (odd numbered participants started in the treatment arm and even numbered participants started in the control arm). Participants were educated that cold therapy is the most common self-care treatment employed in migraine, and that this study evaluates this method of treatment in a novel location, at the neck. A concerted effort was made not to lead participants as to what to expect from either arm. All participants were educated how to appropriately apply the neck wrap (Figure 1) with an emphasis on ensuring good skin contact at the anterior most portion of the neck...where the carotid arteries lie. The wrap itself was utilized in exactly the same manner regardless of which arm the participant was in. Specifically, the ice packs were maintained in the wrap during both phases of the study; in the treatment arm, participants were instructed to place the entire wrap (including ice packs) in the freezer. Participants were given freedom to store the wrap in whatever location they felt was most practical with emphasis given to being able to access the wrap at migraine onset. Of note, during the frozen (treatment) phase of the study, storage locations were somewhat limited due to the fact the wrap had to be kept in a freezer. Participants already utilizing pharmacologic migraine prophylaxis at study entry were allowed to continue taking these medications during the course of the study. However, they were instructed to utilize the wrap prior to taking all acute migraine medication(s). Data was recorded on a one page migraine pain diary using the visual analog scale (VAS) shown in Figure 2, at the following time intervals: onset, 15 minutes, 30 minutes, and one hour. The wrap was worn for the first 30 minutes of each episode, at which point the participant removed the wrap and waited another 30 minutes (with the wrap off) to record their final (one hour) pain score. Furthermore, participants were given the option to utilize their acute/rescue migraine medication(s) at any time after they recorded their 15 minute pain score. However, if they elected to do so, they were instructed to cease taking data from that point forward. In all trials, participants answered the following four YES/NO questions: "Do you feel the wrap helped you?" "If it DID work, did your headache come back?" "Did you experience any side-effects from neck wrap use? If YES, please list:" and "Did you have to take any medications to treat your headache?" At one month, participants were asked to cross over from one arm to the other (frozen went to non-frozen and vice-versa) for the second month. If a participant did not experience a migraine (and take data) during the first month, they were asked to wait until they recorded data from at least one episode before switching arms. A minimum of one migraine episode in each arm (frozen and non-frozen) was required to complete the study. All participants received monthly followup reminders by email and/or phone. Data was returned in a



Figure 1. Correct application of neck wrap.

self-addressed envelope.

Mean pain scores were calculated across all participants at each time interval and compared to pain at onset to determine percent change from baseline. Subset analyses were used to further characterize percent change in those without and with aura. Fisher's exact test with mid-p, two-sided values of P<0.05 was used to evaluate for statistical significance.

## Results

## Demographics

One hundred one participants met IHS ICHD-2 criteria for migraine and were enrolled in the study and 64 submitted data. Of these, 9 had incomplete or incorrectly filled out data forms. As such, 55 participants were included in the data analysis. Of these, 25.5% (n=14) met IHS criteria for migraine with aura, the rest (74.5%) met criteria for migraine without aura. 85.5% of participants (n=47) were female. Participant ages varied from 19 to 64 with a mean age of  $43.1 \pm 11.4$  years. Reported frequency of migraine attacks varied from less than one per month to daily with a median frequency of 5.5 attacks per month and an interquartile range of 4.63 (25th percentile) and 28.75 (75th percentile). Of note, reported median frequency and interquartile range are approximations due to the fact that individual averages were used when participants reported a range in monthly migraine frequency.

## Pain Score (using 0-5 visual analog scale shown in Figure 2)

Table 1 shows the mean pain scores at each time interval for both treatment and control arms. Mean pain score at migraine onset was similar in both arms (2.83  $\pm$  0.26 frozen, compared to 2.61  $\pm$  0.25 non-frozen). Participants in the treatment arm



Table 1. Mean pain score at each time interval for both treatment and control arm.

Mean Pain Score (0-5 scale)				
	Onset	15 min	30 min	60 min
Frozen	2.83 ± 0.26	2.24 ± 0.26	1.84 ± 0.27	1.83 ± 0.33
(treatment)	(n=55)	(n=55)	(n=53)	(n=53)
Non-frozen	2.61 ± 0.25	2.94 ± 0.27	3.10 ± 0.32	3.27 ± 0.36
(control)	(n=55)	(n=51)	(n=45)	(n=46)



reported a maximum decrease in pain at 30 minutes, recording a  $31.8\% \pm 15.2\%$  decrease in pain over onset. Those without aura reported a decrease at 30 minutes of  $39.3\% \pm 13.4\%$  and those with aura a decrease of  $11.2\% \pm 43.8\%$ . Once the frozen neck wrap was removed, pain improvement fell to  $27.3\% \pm 17.5\%$  at one hour. In comparison, those in the control arm reported a  $31.5\% \pm 20.0\%$  increase in pain at 30 minutes, further increasing in severity to  $35.4\% \pm 24.1\%$  at one hour. The information presented in Table 1 is represented graphically in Figure 3.

## **Clinical Response**

In response to the question: "Do you feel the wrap helped you?" 77.0% (n=55) of participants in the treatment arm responded "Yes" compared to 6.4% (n=55) in the control arm. In response to the question "If it DID work, did your headache come back?" 52.0% (n=50) responded "Yes" in the treatment arm compared to 20.0% (n=5) in the control arm. In response to the question "Did you experience any side-effects from neck wrap use?" 3 participants responded "Yes" in the treatment arm with 2 participants experiencing neck and/or shoulder tightness and 1 experiencing nausea with rapid heartbeat compared to 1 participant in the control arm who experienced mild dizziness. None of the aforementioned side-effects led to discontinuation of treatment. In response to the question "Did you have to take any medications to treat your headache?" 57.6% (n=55) responded "Yes" in the treatment arm compared to 83.6% (n=55) in the control arm. Response to this question was not limited to the 1 hour trial period only. That is, it included both participants who abandoned the experiment during the trial period, opting to utilize a rescue medication, and those who successfully completed the 1 hour trial but subsequently took medication due to incomplete relief or return of headache.

## Discussion

In hypothesizing how the frozen neck wrap was significantly more effective at decreasing participant recorded pain score over control, effects on the following three systems are proposed: (1) vascular, (2) neurologic and (3) endocrine with its effects on the vascular system being most important. With respect to the vascular system, it is possible that the blood passing through the carotid arteries was cooled sufficiently to induce a physiologic decrease in release of local inflammatory mediators from the walls of the intracranial vessels with an associated decrease in vascular permeability and a decrease in local nociceptive stimulation (including that due to plasma extravasation). Also, there may have been a contribution of cold induced local physiologic vasoconstriction similar to that observed with triptan type medications, albeit through a different mechanism. Of note, the role of vasoconstriction in the treatment of migraine remains unclear. In regards to the neurologic system, a minimal contribution of analgesia associated with the small diameter myelinated fibers located around the cranial vessels is proposed. And as for the endocrine system, there may be a minimal contribution of decreased metabolic activity in locally cooled areas.

An interesting finding in this study is participants without aura recorded a greater mean decrease in pain score compared to participants with aura  $(39.3 \pm 13.4\%)$  compared to  $11.2 \pm 43.8\%$ at 30 minutes). While this association did not achieve statistical significance, it is in line with Zanchin's observation that cold is the most commonly applied maneuver in migraine without aura and the second most common in migraine with aura. Its underpinnings may lie in the pathophysiologic consequences of cortical spreading, more closely associated with migraine with aura. More specifically, since the intervention is primarily targeting a vascular contribution of migraine, those who progressed to cortical spreading may have had a diminished response. For this reason, participants were instructed to apply the wrap at onset of migraine symptoms. However, some participants reported they were unable to do so because they woke up with migraine or did not have access to the intervention until after migraine onset.

Another interesting finding is the subjective return of migraine pain once the ice packs melted as reflected by the 52.0% of participants who answered "Yes" to the question: "If it DID work, did your headache come back?" in the treatment arm. Objectively, this association was not observed at the one hour time point with essentially stable mean pain scores at 30 minutes and one hour  $(1.84 \pm 0.27 \text{ and } 1.83 \pm 0.33, \text{respectively})$ . However, participants responding to this question were not instructed to limit their response to the one hour study period. Rather, it was left to the participant's discretion to evaluate whether they experienced return of migraine pain. While it would have been ideal to have a 2 or 4 hour pain score time point, this was not done in an attempt to keep the study design simple and as manageable as possible for participants. Future studies should include at least a 2 hour follow up to better evaluate for return of migraine pain once treatment is ceased.

The limitations of this study are numerous. However, significant attempts were made to mitigate as many of them as reasonable to create as clear a picture as possible. With respect to selection bias, participants were recruited from the general public through posters, local media, and physician referral. As such, it is possible that participants who elected to be in the study were more motivated than the average migraineur to actively treat their migraines, or suffered more frequent or severe attacks. Along these lines, participants were not monetarily compensated with the exception of allowing them to keep the investigational neck wrap at study conclusion, and the inclusion and exclusion criteria were tailored to attempt to accurately reflect the majority of migraineurs in the general population. Another source for selection bias suffered was a high attrition rate (46.5%). The majority of the observed attrition was due to loss of university students to summer break and graduation, incomplete or incorrectly filled out data, duration of study, and lack of migraine frequency. To minimize these losses, all participants received monthly follow-up by email and/or phone calls. Of note, participants who returned their completed data did not vary widely with those who did not, with the exception of a moderately better return rate in those with more frequent attacks, as expected. The small size of the study is an obvious limitation. Fortunately, statistical significance was achieved. Neck size and carotid anatomy is variable between participants. However, a velcro attachment system that allowed the wrap to be adjustable across a wide range of neck circumferences was utilized, and each participant was shown how to appropriately apply the wrap by the same investigator. Nevertheless, there is inherent variability in wrap application based on personal preference for tightness. A few participants found the wrap uncomfortable. The wrap was constructed of neoprene material and gave a scent that was bothersome to some participants. As such, participants were encouraged to remove the ice packs and wash the wrap prior to use. The silica based blue gel packs utilized in the study were relatively small and only remained frozen for approximately 15-20 minutes (multiple participants complained they wished the packs were larger and stayed colder longer). This relatively short duration was taken advantage of when designing the study to allow for the evaluation of return of migraine pain once the gel packs melted. Another important study limitation is that targeted neck cooling is intended for

headaches with a vascular component (of which migraines were assumed to be included). Current IHS ICHD-2 criteria were used to screen participants prior to study enrollment. However, as with all diagnostic criteria, some participants who were false positive were included in the study and some false negatives were missed. While obvious, this is particularly true in a condition as diverse and poorly understood as migraine. As with all pain studies, one must consider the contribution of placebo effect on the outcomes. This study was designed as a cross-over study such that each participant served as her or his own control to help deal with the contribution of placebo to perceived efficacy. This is not a perfect design, however. Although emphasis was placed on not leading the patient as to what to expect from either condition, it was likely obvious to many, which was the treatment arm. Hróbjartsson identified non-blinded assessments as a major limitation in randomized clinical trial that involve subjective measurement scales.<sup>37</sup> That being said, even with the best designed studies, participants commonly suspect whether they are in the treatment group and only rarely can true blinding exist. Given this caveat, we hope our data is found statistically relevant to the point of intriguing the research and clinical communities to challenge our results and to further elucidate the benefits of targeted neck cooling in the treatment of the migraine patient.

## Conclusion

The application of a frozen neck wrap at onset of migraine targeting the carotid arteries at the neck significantly reduced recorded pain in participants with migraine headaches. Future studies to further elucidate the mechanism by which targeted carotid cooling alleviates migraine include utilizing a cold water circulator connected to a neck garment such that temperature and duration of treatment can be accurately controlled. This would allow investigators to identify whether a dose-dependent relationship exists. Alternatively, a variety of imaging modalities could be used to identify downstream neurologic and/or vascular changes resulting from applied cooling.

## **Disclosure**

None of the authors identify any conflict of interest.

## **Conflict of Interest**

Adam Sprouse-Blum MD, designed the investigational neck wrap and was the lead investigator. The other authors have no conflict(s) to disclose.

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## MEDICAL SCHOOL HOTLINE

## Liaison Committee on Medical Education (LCME) Accreditation and the John A. Burns School of Medicine: What Medical Student Teachers Should Know

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## Background

The Liaison Committee on Medical Education (LCME) certifies whether schools in the United States and Canada meet established criteria on the structure and function of programs leading to the M.D. degree.<sup>1</sup> Accreditation is a quality assurance process that is also meant to encourage institutional and educational program improvement. All medical schools aspire to full LCME accreditation status of eight years.

John A. Burns School of Medicine (JABSOM) received full accreditation in 2008. While the next accreditation visit is scheduled for the 2016-2017 academic year, preparation is constant and ongoing.

Five areas reviewed for accreditation are:

- Institutional Setting (IS)
- Medical Students (MS)
- Faculty (FA)
- Educational Resources (ER)
- Educational Program for the M.D. Degree (ED)

The Institutional Setting (IS) section focuses on administration, school governance, and the academic environment. The Medical Student (MS) section covers issues such as admissions, health services, and academic counseling. The Faculty (FA) section focuses on the faculty number, qualifications, and roles. The Educational Resources (ER) section covers issues such as school finances along with educational, clinical, and library facilities.

The Educational Program for the M.D. Degree (ED) section is the largest section and covers the educational objectives, teaching methods, curriculum management, and evaluation of program effectiveness. This article will focus primarily on this section, as this is the section that is most relevant to those who serve as teachers of medical students.

### The Importance of LCME Accreditation

While accreditation is considered a voluntary process, in reality, it is essential for all US medical schools for the following reasons. Within the United States and Canada, only medical students or graduates from LCME-accredited programs may sit for the United States Medical Licensing Examination (USMLE). Most state licensing boards require graduation from an LCMEaccredited medical school as a condition of licensure. Graduates of LCME-accredited schools are eligible for residency programs accredited by the Accreditation Council for Graduate Medical Education (ACGME). Finally, accreditation by the LCME establishes eligibility for select federal grants and programs.

## **The Accreditation Process**

Schools are notified of the date of their accreditation site visit eighteen months in advance. Each medical school then prepares the Educational Database and the Institutional Self-Study, which serve as the basis of the written information sent to the LCME Secretariat and the LCME Site Survey Team. These two documents consist of written responses by the school on how it meets or exceeds standards for accreditation and often includes supporting tables, charts, and graphs. It is submitted 8-9 months prior to the site visit. The visit by the survey team lasts four days and is done to verify and update the information provided by the school and to clarify issues that were unclear after a review of the Educational Database and Institutional Self-Study. They also examine the facilities and meet with administrators, faculty, and students. At the end of the visit, the survey team meets with the dean and the campus chief executive to summarize its findings about the program's strengths and areas of noncompliance. The team submits a report to LCME on their assessment of the school's compliance with the standards for accreditation. Final determination of accreditation status is made by the LCME based on the Site Survey Team Report, supplemented as necessary by information contained in the Educational Database and Institutional Self-Study.

Medical students in a school preparing for an accreditation survey play a key role. They are expected to organize their own self-study of the educational program, courses and curriculum, student support services, and the environment for learning. Their independent report is shared with the LCME and groups of students are scheduled to meet with surveyors during the school's site visit.

## Standards That Medical Student Teachers May Not be Aware of

There are over one hundred LCME standards that each school must meet to achieve and maintain accreditation. While medical student teachers are familiar with many of these, a selection of standards that teachers and the larger JABSOM community may be less familiar with, include the following:

## ED-5-A. A medical education program must include instructional opportunities for active learning and independent study to foster the skills necessary for lifelong learning.

JABSOM's educational philosophy, value of active learning methods, and its use of problem-based learning (PBL) to foster life-long learning skills, including the search for, appraisal of, and synthesis of biological and clinical information applicable to patient care, have been important ways to meet this standard.

## ED-33. There must be integrated institutional responsibility in a medical education program for the overall design, management, and evaluation of a coherent and coordinated curriculum.

The phrase, "integrated institutional responsibility", means that an institutional body (in JABSOM's case, the Curriculum Committee) composed of faculty with expertise in curricular design, pedagogy, and evaluation methods, as well as students and administration, oversees the educational program and has the authority to make decisions in the best interest of medical education without regard for political influences or departmental pressures. Content should be integrated and coordinated across academic units. There should be logical sequencing of information. The methods of instruction and evaluation should be appropriate for the learning objectives.

# ED-46. A medical education program must collect and use a variety of outcome data, including national norms of accomplishment, to demonstrate the extent to which its educational objectives are being met.

The JABSOM Curriculum Committee examines regularly student performance or feedback on national measures of educational quality such as the United States Medical Licensing Examinations, the National Residency Match Program, and the Association of American Medical Colleges Graduation Questionnaire. In addition, JABSOM surveys the Program Directors supervising the residency programs that our graduates attend to get their feedback on the readiness of JABSOM graduates in comparison to students from other medical schools.

ED-47. In evaluating program quality, a medical education program must consider medical student evaluations of their courses and clerkships, teachers, as well as a variety of other measures. The JABSOM Curriculum Committee administers program evaluation surveys to medical students for all required courses at JABSOM. When weaknesses are noted, the committee asks course directors to address them. At a later date, course directors report to the Curriculum Committee on how they responded to the concern and the effectiveness of that response.

## MS-18. A medical education program must have an effective system of academic advising for medical students that integrates the efforts of faculty members, course directors, and student affairs officers with its counseling and tutorial services.

Over the past several years, JABSOM has been transitioning its academic advising system from a one-on-one assignment of student to advisor, to a model that integrates the efforts of the Office of Student Affairs, faculty members, PBL tutors, course directors, and student peers. The goals are to provide advising and mentoring to medical students across all four years on academic progress, career choice, professional development, and personal well-being. Building upon the Peer Student Mentoring Program established at JABSOM in 2009, this new program, implemented in the 2012-2013 Academic Year and supervised by the Office of Student Affairs, draws upon the knowledge of faculty advisors from both pre-clerkship as well as clinical sources, and takes advantage of the insights and experiences of students across the entire four-year curriculum.

## MS-32.A medical education program must define and publicize the standards of conduct for the faculty-student relationship and develop written policies for addressing violations of those standards.

The policies regarding appropriate conduct are outlined in the University of Hawai'i at Manoa's *Code of Conduct and Harassment Policy*, and JABSOM's *Academic Appeals Policy*, and *Standards for the Assessment of Student Performance*. These policies also prescribe the appropriate procedures to be followed for assessing and managing allegations of student mistreatment. JABSOM takes allegations of student mistreatment very seriously. Students who feel that they have been mistreated are asked to report the event. This is seen as a professional responsibility to his or her peers and to the profession. When students have concerns about mistreatment, they may consult with course directors, faculty members, department chairs, and/ or the Director of the Office of Student Affairs to discuss those concerns.

## FA-4.A member of the faculty in a medical education program must have the capability and continued commitment to be an effective teacher.

Effective teaching requires knowledge of the discipline and an understanding of curriculum design, development, evaluation, and methods of instruction. Faculty members involved in teaching, course planning, and curricular evaluation should possess or have ready access to expertise in teaching methods, curricular development, program evaluation, and medical student assessment. Among the types of evidence the LCME believes demonstrates compliance with this standard are participation in faculty development activities related specifically to teaching and assessment, and attendance at regional or national meetings on educational affairs.

Worthy of note is that JABSOM will host the Association of American Medical Colleges Western Group on Educational Affairs conference in March 2014. This prestigious medical education conference will provide an opportunity for faculty development and for sharing scholarly work in education as required in the following standard.

## FA-5.A faculty member in a medical education program should have a commitment to continuing scholarly productivity that is characteristic of an institution of higher learning.

All faculty, including those whose primary role is student education are required to demonstrate scholarly work such as peer-reviewed publications and presentations. For medical educators this may include educational research and descriptions of the development, implementation, and evaluation of new curricula.

## **New Accreditation Standards**

At its February 2013 meeting, the LCME approved the addition of the following accreditation standard that will become effective on July 1, 2013:

ED-19-A: The core curriculum of a medical education program must prepare medical students to function collaboratively on health care teams that include health professionals from other disciplines as they provide coordinated services to patients. These curricular experiences include practitioners and/or students from the other health professions.

Since 2011, JABSOM has hosted interprofessional educational activities on topics such as Interprofessional Communication, Patient Safety, and Medical Ethics.<sup>3</sup>These sessions bring together the entire first-year student classes from JABSOM and the University of Hawai'i School of Nursing and Dental Hygiene for plenaries and active small group sessions that set the stage for their work together in the clinical setting. In Spring 2013, students from the Daniel K. Inouye College of Pharmacy at the University of Hawai'i at Hilo joined these sessions.

## JABSOM's Ongoing Preparation for LCME Accreditation

The educational and student services leadership at JABSOM continually strive to meet and exceed accreditation standards. This is accomplished through the ongoing efforts of many dedicated faculty, administrative staff and committees. Discussion about accreditation standards is a regular part of the agenda for many committees, subcommittees, and working groups. Many

of the procedures and policies that guide education and student services are based on the latest LCME accreditation standards.

While not a national requirement, JABSOM decided to schedule a limited, internal, mock accreditation site visit for Spring 2013. This visit was coordinated by the Office of Medical Education (OME) and Office of Student Affairs (OSA), and thus limited to the categories and items most specific to the Educational Program and Medical Student services (ED and MS sections). An experienced LCME site visitor, who is also a faculty member from a school that utilizes problem-based learning on the US mainland, was invited to review the JABSOM program.

The planning and preparation for the visit were extensive. Over thirty participants, including course directors, educational committee members, and individuals involved in student services, were present. The JABSOM Curriculum Committee determined that this type of visit would best help prepare the medical school for the actual site visit through a thoughtful reflection on the school's current status in meeting accreditation standards. This activity also provided practice for faculty in responding to site visitor questions.

In preparation, the JABSOM Curriculum Committee convened a one-day retreat to review select educational standards, and outline the preparation required for the limited mock site visit.

Over the course of the week-long mock visit, there were rich discussions and opportunities for reflection on courses, committees and meeting accreditation standards. At the end of the week, both OME and OSA generated a list of issues that constituted their short- and long-term priorities. These included issues related to reviewing, revising, and/or developing policies; greater institutional adherence to selected administrative procedures; and strengthening the fiscal and administrative infrastructure of the curriculum and student services. OME, OSA and the appropriate educational committees have begun work on these items.

## How Medical Student Teachers can Support JABSOM's Accreditation Efforts

JABSOM faculty members and others in the community who teach our medical students can support the school's accreditation efforts in the following ways:

- Continuing to provide meaningful, innovative, and engaging instruction to JABSOM students.
- Mentoring and advising students to support their personal and professional growth as physicians.
- Modeling professionalism in patient care and interprofessional communication.
- Completing student evaluations promptly and providing feedback on a regular basis to help them learn.
- Supporting educational committees, student counseling programs, and departmental educational efforts.
- Providing or attending faculty development activities.
- Contributing to the scholarly work from JABSOM, especially in the area of education.

## Conclusion

Based on its 2008 LCME accreditation survey and the Internal LCME accreditation survey in 2013, the administration, faculty, staff, and students of JABSOM along with community partners should be proud of JABSOM, Hawai'i's only medical school and the only medical school accredited by LCME in the Pacific.

Medical student teachers play a central and critical role in the successful achievement and maintenance of national accreditation. Providing high quality teaching, supervision, and evaluation of medical students, as well as the development of new curricula and participation in educational committees, are a few of the many valuable ways in which teachers help the medical school meet LCME accreditation standards and contribute to the ongoing success of the John A. Burns School of Medicine.

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## INSIGHTS IN PUBLIC HEALTH

## Saving Babies: Reducing Infant Mortality in Hawai'i

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## **Overview**

The death of an infant in the first year of life is a major indicator of the health of a population. The infant mortality rate (IMR) is defined as the number of deaths of children in the first year of life per 1,000 live births. On average, two infants die every week in Hawai'i. Preterm birth is the leading risk factor for infant death, and is also associated with other important negative outcomes, including longer hospital stays, more outpatient visits and parental work absenteeism, increased incidence of feeding problems, and respiratory complications, and other developmental concerns.<sup>1</sup> The annual cost of preterm birth for the nation was estimated to be in excess of \$26.2 billion dollars in 2005 or about \$51,600 per preterm infant.<sup>1</sup> Extrapolating this estimate to the 2,000 preterm births in the State each year would result in costs of almost \$102 million dollars (based on 2005 dollars) in Hawai'i every year. Thus, reducing risk factors such as prematurity has the potential not only to reduce infant deaths, but also to reduce some of the substantial morbidity and costs due to prematurity and other associated risk factors. Selected data on infant mortality nationally and in Hawai'i are presented, as well as a discussion of some programs within the Hawai'i Department of Health and some collaborative efforts working to address this complex issue to decrease this burden on society.

## **Data Summary**

Nationally and in Hawai'i, there have been substantial reductions in infant mortality over the past century. Estimates of infant mortality in Hawai'i prior to 1920 were in excess of 100 deaths per 1,000 live births compared to 5.9 in 2009.<sup>2</sup> Much of this improvement has been related to medical advances and improved management of pregnancy and childbirth. However, there was little improvement from 1990-2010 with the IMR in Hawai'i ranging from 5.3 to 7.6 deaths per 1,000 live births (Figure 1). Data from 2011 is encouraging with the State IMR at an all-time low of 4.9 deaths per 1,000 live births. Nationally in 2010, the leading causes of death among infants were congenital malformations (127.7 per 100,000 live births), preterm-related (105.3), sudden unexpected infant death (91.5, SUID), and maternal complications of pregnancy (39.5) (Table 1).<sup>3</sup> In Hawai'i (data from 2009-2011 is aggregated due to small number of events), the leading cause of infant death was somewhat different with preterm-related (107.7) and congenital malformations (86.5) reversing ranking compared to the national ranking; meanwhile SUID (58.2) was lower, but maternal complications (58.2) higher than found nationally.

According to Hawai'i data (2009-2011), sixty-eight percent of infant deaths occurred among babies delivered prior to 37 weeks, with the highest rates among those born at 32 weeks or shorter gestation (154.8 per 1,000 live births), followed by those born at 33-36 weeks (5.6), with similar rates between those born at 37-38 and 39 weeks or greater (Table 2). There is some uncertainty with measurements of gestational age and two methods are reported in vital statistics: a date based on last menstrual period; and a clinical or obstetrical estimate of gestational age. In obstetric practice, the clinical estimate is used to inform timing of the delivery and generally gives lower estimates of preterm birth than that used on dates based on last menstrual period.<sup>4</sup> In this report the clinical estimate of gestational age was used to calculate the rates shown in the table, as that is the standard method reported by the Hawai'i Department of Health (DOH) since it more closely impacts clinical decision making. The almost identical infant mortality rates shown in the table between term births at 37-38 weeks and 39 weeks or longer is expected, since there was no determination in this analysis of medical necessity for these deliveries such as those shown in a study from 19 sites across the United States that revealed a two-fold risk for infant death among those born at 37-38 weeks from an elective cesarean delivery compared to infants born by elective cesarean at 39 weeks or later.<sup>5</sup> The total number of infant deaths and births with these gestations are small and the information on the birth certificate is limited to assess any increased risk related to American College of Obstetrics and Gynecologists (ACOG) guidelines due to non-medically indicated inductions or cesarean deliveries prior to 39 weeks.6 It is also instructive to note that another measure of fetal maturity, birth weight, shows similar patterns with just over half of infant deaths occurring among very low birth weight (<1500 grams)

Table 1. Leading Causes of Infant Death, United States (2010) and Hawai'i (2009-2011)		
Leading Causes of Death	United States (per 100,000)	Hawaiʻi (per 100,000)
Congenital Malformations <sup>a</sup>	127.7	86.5
Preterm-related <sup>b</sup>	105.3	107.7
SUID°	91.5	58.2
Maternal Complications <sup>d</sup>	39.5	58.2

<sup>a</sup>Congenital malformations based on ICD 10 underlying cause of death codes: Q00-Q99

<sup>b</sup>Preterm-related based on ICD 10 underlying cause of death code: P07

<sup>c</sup>Sudden Unexpected Infant Death (SUID) based on ICD 10 underlying cause of death code: R95, R99, and W75. Revised cause of death following guidance of Centers for Disease Control and Prevention SUID Initiative.

<sup>d</sup>Maternal complications of pregnancy based on ICD 10 underlying cause of death code: P01



births and about two-thirds of infant deaths occurring among low birth weight (<2500 grams) births.

In addition to the overall State estimates, it is informative to examine risk differences across population subgroups. For example, nationally the IMR among non-Hispanic Black mothers in 2011 was 11.4, more than twice as high as that found for non-Hispanic White mothers (5.1).7 These differences have been consistent over time and don't appear to be narrowing, with almost the same gap seen in 1960 when the IMR estimates were nearly 45 in non-Hispanic Blacks and 22 in non-Hispanic Whites.7 The IMR among Hawai'i residents from 2009-2011 also demonstrates significant disparities from the overall State rate of 5.5 deaths per 1,000 live births.8 Mothers of Black (13.4) and Native Hawaiian (7.4) race have the highest rates, while Japanese (3.1) and White (3.0) mothers have the lowest rates (Figure 2, Table 1). The race groups reported for the State of Hawai'i are those reported by the Office of Health Status and Monitoring in the DOH which categorizes those who report more than one race group into a single race.9

In addition to race, there are IMR differences for other characteristics (Table 1). Mothers less than 20 years of age (8.7) and 20-24 years of age (6.3) have higher rates compared to those 25-34 years of age (4.8) and 35 years of age and older (4.9). Higher rates were also seen among mothers whose education level was unstated/unknown (19.6) and those with less than a high school education (8.1), compared to those with a high school or graduate equivalent degree (6.4), with some college (4.3) or college graduates (3.5).

Infant mortality rates also vary by as much as three-fold across communities in the State with lows of 3.9 (Makawao), 4.2 (Wailuku), and 4.2 (Koloa) to highs of 10.1 (Waianae) and 12.4 (North Kohala), with an overall state rate of 6.0 based on data from 2001-2010 (aggregated due to small numbers, Figure 3).<sup>10</sup> Identification of associated factors and sharing this information with community stakeholders and policy leaders could help in engaging the community to develop infant mortality reduction efforts.

The data highlighted in this article show significant differences in rates of infant death across several population groups. To better understand these differences across subpopulations, a more comprehensive assessment will be needed using multiple approaches including collaborative work with governmental and community partners.

Table 2. State of Hawai'i, Infant Mortality Rate by Selected Characteristics: 2009-2011			
	Deaths (n)	Births (N)	IMR (per 1,000)
Age Group			
<20	36	4,116	8.7
20-24	84	13,288	6.3
25-34	142	29,467	4.8
35+	48	9,783	4.9
Maternal Race			
White	38	12,680	3.0
Black	20	1,488	13.4
Native Hawaiian	115	15,595	7.4
Samoan	8	1,453	5.5
Filipino	51	9,866	5.2
Japanese	17	5,436	3.1
All Others	51	9,381	5.4
Unknown/Unstated	10	766	13.1
Maternal Education			
<hs< td=""><td>36</td><td>4,427</td><td>8.1</td></hs<>	36	4,427	8.1
HS/GED	135	21,149	6.4
Some College	61	14,249	4.3
College Grad	55	15,707	3.5
Unknown/Unstated	22	1,121	19.6
County of Residence			
Hawaiʻi	45	7,325	6.1
Honolulu	230	40,543	5.7
Kaua'i	8	2,619	3.1
Maui	27	6,178	4.4
Gestational Age			
20-32 weeks	170	1,098	154.8
33-36 weeks	27	4,824	5.6
37-38 weeks	29	15,486	1.9
39+ weeks	63	35,172	1.8
Birthweight			
<1500 grams	158	722	218.8
1500-2499 grams	36	3,995	9.0
2500+ grams	93	51,921	1.8
State of Hawai'i, Total	310	56,665	5.5

Source: Family Health Services Division, Hawai'i Department of Health. Calculations from birth and linked infant death files provided by Office of Health Status Monitoring, Hawai'i Department of Health.

## **Some Department of Health Activities**

The Hawai'i Department of Health has many programs specifically aimed at reducing risk of adverse health outcomes. Programs working to address maternal and child health outcomes such as infant mortality are primarily located in the Family Health Services Division (FHSD) and its branches. These programs ensure that women at higher risk for adverse maternal and child health outcomes receive adequate early prenatal care, appropriate education, and support as the child grows, and support to promote healthy future birth outcomes. For at least the past 12 years, FHSD programs have monitored performance measures relating to some of the preventable causes of infant death and prematurity such as safe sleep and smoking before, during, and after pregnancy, as part of Title V reporting and through its various service contracts. Since 1999, the Maternal and Child Health Branch (MCHB) within FHSD has administered the Hawai'i Pregnancy Risk Assessment Monitoring System (PRAMS) and utilized the data to inform



program and policy development to address perinatal risk factors that increase the likelihood of infant deaths. MCHB also oversees the statewide Child Death Review (CDR) to address system issues to reduce preventable infant and child deaths. The CDR and PRAMS findings have helped inform strategies to decrease infant mortality, such as working with the State Safe Sleep Committee on ongoing public awareness and prevention activities. The MCHB home visiting programs for at-risk families with children 0-3 years aims to reduce infant mortality through various evidenced-based strategies, including promoting early access to prenatal care, access to health insurance, appropriate interconception care, tobacco cessation, safe sleep behaviors, screening for child abuse, and home and family safety.

In 2009, FHSD worked with partners to pass a resolution by the Hawai'i State Legislature on elective induction of labor and cesarean sections. As a result, birthing hospitals and providers were surveyed on policies and practices related to early induction of labor, elective cesarean deliveries, and prematurity. Hawai'i also supports the March of Dimes (MOD) campaign, "Healthy Babies are Worth the Wait," to educate women with healthy pregnancies about the importance of waiting at least 39 weeks to give birth.<sup>11</sup> An example of health education related to this campaign was placing cobranded placards on city buses and showing public service TV spots during November 2012 that were viewed an estimated 7 million times.

The Special Supplemental Nutrition Program for Women, Infants & Children (WIC) Services Branch in FHSD provides supportive services to about half of all women who give birth in Hawai'i and their children every year.<sup>12</sup> Many of these efforts support infant mortality reduction. For example, ensuring that women receive prenatal care as soon as possible helps promote access to prenatal care. WIC provides nutrition education and support for food with nutrients necessary for a healthy pregnancy. WIC also collects information on anthropometry, hemoglobin levels, medical history and dietary intake, in order to address health risks and provide appropriate counseling and referrals. WIC initiatives also include promoting nutrition for both mothers and their children, including promoting breastfeeding, which decreases health risks in children. In addition, WIC conducts education and counseling activities during regular visits, including promoting safe sleep environment, medical/dental home, and limiting exposure to tobacco smoke.

The Children with Special Health Care Needs Branch also has several programs to reduce infant mortality. For example, the Newborn Metabolic Screening Program has statewide responsibility to ensure that all infants born in Hawai'i are screened and receive timely follow up related to metabolic conditions that can cause intellectual disability, severe health problems and even death if not detected and treated early. The DOH's Genetics program activities include providing information and



education about topics in genetics, administering grants related to genetics, coordinating genetics activities, supporting clinical services, developing public policy surrounding genetics, and providing technical assistance.<sup>13</sup>

Other statewide partnerships supported include: a Prenatal Smoking Workgroup that includes tobacco prevention advocates, and a Perinatal Advocacy Network that addresses preconception and interconception needs of women, including promoting healthy births and outcomes. FHSD has partnered with the Executive Office on Early Learning that was created in 2012 to guide the development of a comprehensive and integrated statewide early childhood development and learning system. The goal is to ensure that all of Hawai'i's children, prenatal to age five, are healthy, safe and ready for school.<sup>14</sup> Reducing infant mortality and improving birth outcomes were some of the key strategies identified in the healthy and welcomed starts goal contained in their action strategy project. These efforts highlight the importance of partnerships and recognize that healthy childhood development depends on a life course approach.

Other partnerships need to account the complex nature of infant mortality and include efforts to promote healthy lifestyle choices in families across the life course. For example, the DOH's Healthy Hawai'i Initiative (HHI) was created in 2000 to support healthy lifestyles by implementing policies and programs to create sustainable changes in Hawai'i's communities, schools and workplaces.<sup>15</sup> A collaborative initiative of HHI was to promote "Baby Friendly" hospitals by highlighting the importance of breastfeeding as an evidenced-based way to decrease child obesity and improve early childhood outcomes. Working with children and families to adopt healthy lifestyle choices can extend well beyond reductions in childhood obesity and lead to improvements in both general health and reproductive outcomes by increasing the likelihood that women begin pregnancy at a healthy weight.

Efforts to expand partnerships around the complex issue of infant mortality will include improved collaboration with partners in the clinical setting. For example, the Medicaid program in Hawai'i, known as QUEST should be a key partner as it pays for nearly one third of all births in the State and serves a generally higher risk population with data showing significantly higher rates of infant death compared to those births covered by private or military coverage.<sup>16</sup> Another evolving partnership for FHSD includes the Hawai'i Collaborative Health Initiative (HI-CHI), a Perinatal Quality Collaborative whose mission is to improve the accessibility and quality of health services for mothers and infants in rural areas of Hawai'i through education and facilitating collaboration between health facilities, healthcare providers, and the community.<sup>17</sup> Additionally, it will be helpful to work with the John A Burns School of Medicine,

its associated residency programs, and with other health care affiliated institutions and organizations to ensure optimal birth outcomes and healthy child development. Partnering with groups such as these has the potential to improve the health of mothers and their children in the State.

Despite recent improvement, Hawai'i and the United States have the opportunity to further decrease rates of infant death particularly among those populations at increased risk. This will require systemic changes that include the development of a comprehensive effort with multiple state, public-private, and community-based level partnerships. This will need coordination between all partners towards a common agenda based on a shared understanding of the problem and identification of joint approaches and actions to achieve statewide goals. Such a comprehensive approach will be needed to meet the 2012 Association of State and Territorial Health Officers (ASTHO). President's Challenge Healthy Babies Initiative pledge to improve birth outcomes by reducing one of the leading risk factors for infant death, prematurity, by 8% over the next 2 years (http://www.astho.org/healthybabies). Hawai'i was recently selected as one of four states to participate in the second round of a learning network to improve birth outcomes from the National Governors Association (http://www.nga.org/cms/ center/health). This learning collaborative will help the State in the development, alignment, and implementation of some of the key polices and initiatives to reduce preterm birth and infant mortality. Continued surveillance of causes of IMR and its risk factors, particularly in subpopulations at greater risk, use of multiple data sources, impact of program effectiveness, and sharing and collaborating with community and organizational efforts can ensure improvement in health of infants and families in Hawai'i.

## Disclaimer

The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention or the Hawai'i Department of Health.

## **Conflict of Interest**

None of the authors identify a conflict of interest.

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## THE WEATHERVANE RUSSELL T. STODD MD; CONTRIBUTING EDITOR

## OOOH, HOW BROWN YOU ARE!

In Chicago a woman went to the Executive Sun Spa seeking to develop a healthy-appearing skin tone. She expressed to one of the tanning salon staff that she was afraid of getting burned. She claims that she emerged from the tanning bed with burns of both her legs and now has permanent scarring. The salon management claims that she had no burns when she left the premises and will fight the suit. Federal health regulators moved to tighten oversight of tanning beds and said people younger than age 18 shouldn't use beds at all. This all comes with growing evidence that indoor tanning is linked to melanoma. The Food and Drug Administration has proposed that manufacturers place warnings on tanning beds and promotional material. Tanning beds continue to be used by millions of teenagers. Hey pale ones, come to Hawaii and get melanoma the old-fashioned way.

## CHICKEN POX: ALMOST GONE, TOO OFTEN FORGOTTEN.

A previously healthy 15-year-old Ohio girl developed shortness of breath, rash and a fever of 101 F. She was admitted to the hospital with a diagnosis of septic shock and treated with intravenous acyclovir, antibiotics, antifungals and given assisted ventilation. She had received DPT, MMR, and flu shots, but no varicella immunization. Over three weeks her condition deteriorated with pneumonia, acute respiratory distress syndrome, pancytopenia, multiple organ system failure, sepsis and death. How she acquired chicken pox infection is not known. Usually mild in younger children, Varicalla infection in older children and adults can be a very serious disease. Centers for Disease Control and Infection (CDC) reports that varicella vaccine is more than 95% effective in preventing severe complications from the virus.

### JUST STOPPING BY TO STAY HIGH.

The enthusiasm for recreational marijuana by the voters of Colorado and Washington states might be lessened by a study from University of New South Wales. Among people diagnosed with mental illness, those who smoked marijuana when they were younger developed symptoms of mental illness three years earlier than patients who had never used marijuana. Another New Zealand study included 1037 subjects followed for 38 years. Those who used cannabis regularly, especially in adolescent years, experienced declines in everyday cognitive function that were noticeable to close contacts. Persistent users also lost several IQ points on average between age 13 years and age 38 years.

### IT'S NOT PAYOLA, IT IS PRODUCT PROMOTION. OR IS IT?

Federal prosecutors filed a civil-fraud lawsuit against Novartis USA, alleging the company provided inducements for doctors to prescribe certain drugs to treat hypertension and other maladies. Prosecutors claim the company's US unit was paying kickbacks. Inducements included invitations for fishing trips off the Florida coast, outings to restaurants like Nobu in Manhattan and meals at Hooters. Another event was held at a salmon fishing lodge in Alaska where speakers received \$750. A Bronx doctor was paid \$500 to speak at Nobu, attended by the doctor, two friends with girl friends and a Novartis rep. The lawsuit described one dinner for three people, including the speaker at a Smith and Wollensky steakhouse in Washington, D.C. where the bill came to \$2,016. Another dinner in Des Moines, Iowa, for three people at a steakhouse and wine bar came to \$3,127. Novartis disputes the claims and "will defend itself in this litigation."

#### LIP COLOR CAN PUT THE STYLE IN THE SMILE.

Consumers often have difficulty discerning the exact shade of lipstick, but it has been even harder for scientists. Now with use of laser light and Raman spectroscopy forensic experts can distinguish closely related cosmetics. A smear of lipstick on glass, paper or clothing can be defined quickly to 95% accuracy, according to Paige Gardner of Virginia Commonwealth University in Richmond. She zapped 80 lipstick samples with laser light, making some of the molecules vibrate. These tickled molecules emit light of a different frequency from what came in. Researchers can read that shift in frequency like a chemical bar code. It's one more valuable scientific tool for criminologists.

#### DON'T LIGHT UP OVER THE GAS TANK.

Domestic consumption of tobacco cigarettes has declined by about 25% in the last dozen years. While most of the drop is recognition of health issues and increasing federal taxes, recent changes relate to the invasion of electronic cigarettes. Marlboro maker, Altria Group Inc., announced it would roll out its own version of e-cigarettes under the Marlboro name. P. Lorillard Inc. paid \$135 million to acquire Blu E-cigs, a leading e-cigarette company. Reynolds American Inc. said it plans to expand distribution of its Vuse e-cigarettes after testing markets in recent months. These battery powered devices convert heated, nicotine-laced liquid into vapor. Users say they like the product because it closely mimics regular cigarettes. Many scientists say e-cigarettes are less harmful than regular cigarettes because most toxins are released through combustion in a lighted tobacco stick. Along with whatever other benefits accrue, e-cigarettes so far have escaped taxes and regulations, including bans in public areas.

#### WHEN NO, IS REALLY NO !!

To protect women from the now widely known culture of rape in India, three engineers in Chennai are about to market women's anti-rape underwear. The lined panties will hit an aggressor with a stun-gun shock and send a GPS location message to police and family members. After the intended victim engages a switch anyone touching the garment will get "the shock of his life."

## HERE, YOU TAKE THE WHEEL. I HAVE TO CONTACT MY HAIR-DRESSER.

Danielle Parker was hospitalized and awaiting DUI charges following a highway crash near Gaston, North Caroline. Ms. Parker was a passenger in the front seat when the driver, Brittany Reinhardt, age 19, wanted to text a message. Parker handled the wheel temporarily as her friend was occupied and a crash occurred. Parker was charged with "aiding and abetting" a DUI. Yea, but did the text get thru?

#### ADDENDA

- The FAA Reauthorization Act orders the Federal Aviation Administration to develop regulations for the testing and licensing of commercial drones by 2015. The FAA projects that 30,000 drones could be in the nation's skies by year 2020.

- When a waitress draws a happy face on a check her tip goes up 18%; when a waiter draws a happy face, his tip goes up 3%.

- A student at the University of Washington sold his soul on e-bay for \$400. He's a law student so he probably won't need it.

- Life is a sexually transmitted disease.

## ALOHA AND KEEP THE FAITH rts

(Editorial comment is strictly that of the writer.)



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