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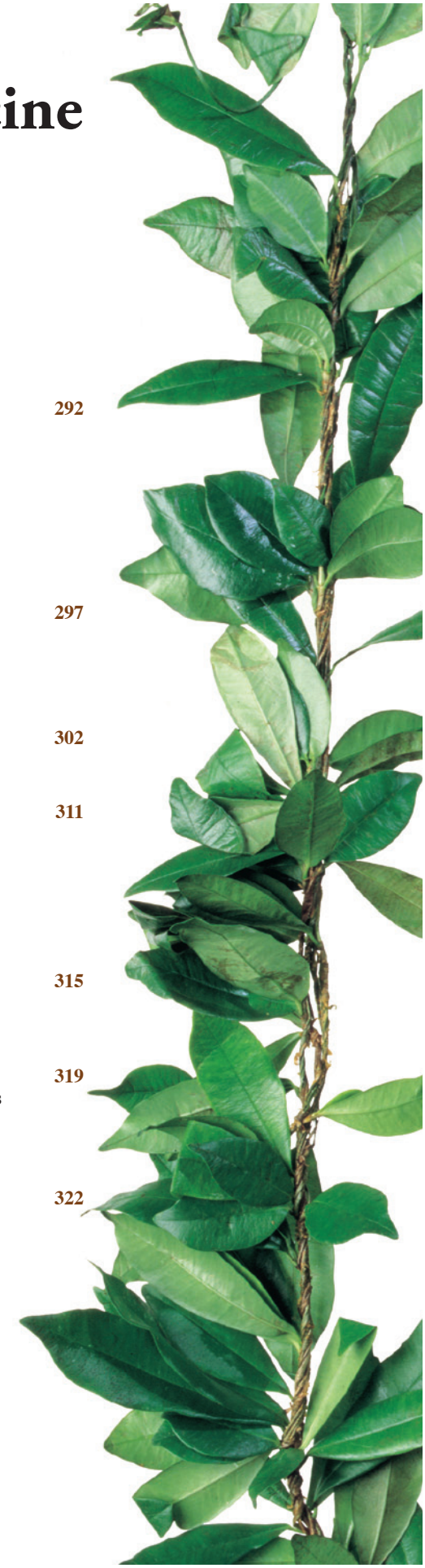

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Early Childhood Vision Screening in Hawai'i Utilizing a Hand-Held Screener

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Abstract

The goal of early childhood vision screening is to detect subnormal vision and amblyopic risk factors that threaten visual development so that treatment can be initiated early to yield the highest benefit. Hand-held, portable, instrument-based vision screening devices can be used in children as young as 6 months of age. We assessed the feasibility of hand-held photoscreeners to screen for vision disorders in pre-school children in Hawai'i. A total of 137 preschool children on O'ahu in the "Tutu and Me"/Partners in Development program were screened at 6 different locations using the Plusoptix S12 hand-held photoscreener. Once technical issues were resolved, screening was fast and well tolerated. Possible vision abnormalities were found in 11 of the 137 children (8%). Poor compliance for follow-up with formal vision examination limited our ability to confirm these abnormalities. We conclude that photoscreening has the potential to facilitate early childhood vision screening in Hawai'i. The optimal referral criteria for use in Hawai'i will need to be determined after considering the age of the screening population and the available medical resources in Hawai'i. Early detection of treatable eye disorders has far-reaching benefits for the visual development and long term health and well-being of children. A comprehensive early childhood vision screening program in Hawai'i utilizing automated hand-held photoscreeners may have public health value. Such a program should integrate referral to an eye care professional for confirmation and management of vision disorders of at-risk children found on screening.

Keywords

amblyopia, vision screening, photoscreening

Introduction

Early childhood vision screening is widely recommended for the detection of preventable and treatable vision disorders.[1,2] Undiagnosed and untreated vision impairments in childhood are known to cause learning difficulties with long term consequences for academic success.[3] Vision screening during pre-school ages also allows the early detection of children at-risk for amblyopia, commonly referred to as "lazy eye," an ophthalmologic condition caused by poor or regressed development of neural pathways from the eye to the brain. While there is some controversy as to the age when amblyopia becomes irreversible, there is consensus that the effectiveness of amblyopic treatment is greatest when initiated before the age of five.[4]

Recent advancements in automated vision screening technology now allow for instrument-based vision screening which is hand-held and portable and screens both eyes simultaneously in less than one second. The screening is fully automated with an immediate simple "pass" or "refer" screening result for various visual abnormalities. Instrument-based photoscreeners are ideal for vision screening in children as young as 6 months as it does not require the full cooperation of the child being screened. In 2012, a joint policy statement by the American Academy of Pediatrics (AAP), the American Academy of Ophthalmology (AAO), the American Association for Pediatric Ophthalmology and Strabismus (AAPOS), and the American Association of Certified Orthoptists (AACO) endorsed instrument-based vision screening for routine use in childhood.[5] We undertook the first, to our knowledge, pilot study of hand-held instrument-based vision screening in preschool children in Hawai'i. Our objectives were to obtain Hawai'i-specific data on the technical difficulties and acceptability of hand-held photoscreening performed in a preschool setting; to obtain an estimate of the rates of vision disorders among preschool children who were largely from local under-served Native Hawaiian communities in Hawai'i; and to assess the false positive rate of the Plusoptix S12 photoscreener through follow-up referral for formal vision testing by an eye care professional.

Methods

This was a cross-sectional study of vision screening in pre-school age children using the Plusoptix S12 hand-held portable vision screener (Plusoptix Inc, Atlanta, GA) (Figure 1). The study was conducted in children attending the Tutu and Me Traveling Preschool program which is a project of the Partners in Development Foundation and is run in collaboration with churches and community organizations serving the Hawaiian and part-Hawaiian community. The Tutu and Me preschool provides a culturally sensitive pre-school educational program designed to meet the developmental needs of educational at-risk Native Hawaiian and Pacific Islander children and the support needs of grandparents, parents and other primary caregivers who are raising them.

Figure 1. Plusoptix S12 Mobile Screener

The study was approved by the University of Hawai'i (UH) Committee for Human Subjects and implemented by the University of Hawai'i John A. Burns School of Medicine's RMATRIX (RCMI Multidisciplinary and Translational Research Infrastructure Expansion) program. All preschool children currently enrolled in the Tutu and Me Program at its six O'ahu locations were eligible. Staff at each of the locations distributed informational sheets about the study and informed consent documents to parents or legal guardians. In a brief written questionnaire, the parents/guardians were asked to provide information about their child's age; ethnic background self-identified as White/Caucasian, African-American, Native American, Native Alaskan, Asian, Native Hawaiian/part-Hawaiian, other Pacific Islander, and mixed race other than part-Hawaiian; the O'ahu district in which they lived (by zip code); and their health insurance plan (left blank for parent/guardian to fill out). Brief questions were also asked about their child's medical history, targeting factors that could influence the child's vision. Questions asked were: "Was your child born at full term/9 months?," "Did your child have normal birth weight?," "Does your child have any known eye disease?," "Has your child been diagnosed with any other disease/illness?," and "Does your child have any history of previous head surgery?" In cases where a visual abnormality was found on screening, it was recommended that the child undergo formal vision testing, and the informed consent requested access to this information. The parent/guardian was informed by the teacher at each site that the Lions Club of Hawai'i would pay for a formal vision examination if this represented an economic hardship for the family.

One-day training in Plusoptix S12 photoscreening was provided by the manufacturer and the photoscreening methodology utilized followed the recommendation of the manufacturer. The photoscanner was operated exclusively by one of the authors (N.H.) who had no prior experience with the scanner. Per the manufacturer's recommendation, we utilized the AAPOS approved Alaska Blind Child Discovery (ABCD) program criteria for the "pass" or "refer" set-points: anisometropia (spherical equivalent $\geq$1.00 diopter [dpt]), astigmatism (cylinder $\geq$2.25 dpt), hyperopia (spherical equivalent $\geq$2.50 dpt), myopia (spherical equivalent $\geq$2.25 dpt), gaze asymmetry (asymmetry $\geq$10.0 degrees), anisocoria (pupil size $\geq$1.5 mm).

The study was performed in a darkened room or area and the patient sat in a chair or on a parent/guardian's lap at a screening distance of approximately 3.3 feet (one meter). The screening process was started by pressing a button which generated a warble sound and blinking lights, calling the child's attention to the photoscreener's smiley face as can be seen on the Plusoptix S12 machine shown in Figure 1. The technician captured both eyes in a white rectangle on the screen and a "pass" or "refer" determination was obtained automatically after a click of a button. The first reading giving a "pass" or "refer" was used as the diagnosis of record. At least 3 attempts were made to obtain a "pass" or "refer" before the child's evaluation was labeled as inconclusive.

The Plusoptix S12 machine generated a form that provided a pass or refer determination for each of 5 visual abnormalities (anisometropia, astigmatism, hyperopia, myopia, gaze asymmetry, and anisocoria), with an overall "refer" determination if one or more abnormalities were detected. This form detailing each child's results was enclosed in individual envelopes, given in batch to the supervising teacher at each site, and distributed to the parent/guardian together with an informational sheet requesting that the child be taken for a formal eye examination if the child had a refer determination. For children with a refer recommendation, up to 2 further attempts by phone or email were made to contact the parent/guardian to encourage formal vision testing for their child.

Results

A total of 137 preschool children were screened between December 2013 and April 2014. Complete data was obtained for all study participants for all variables. Demographic data on the children screened are shown in Table 1. Thirty-five percent of the children were full or part Hawaiian or of other Pacific Islander descent and 55% were male. The ages ranged from 8 months to 5 years 2 months with the majority (88 children, 65%) between the ages of 2 to 4 years. There was no medical history of prematurity or low birth weight reported. In terms of medical history, there was one report each of neutropenia, neurofibromatosis, history of tuberculosis, and concussion at 6 months. Twenty-six guardian/parents (19%) gave no response as to the child's medical insurance with the rest indicating coverage by various medical insurance plans.

Of the 137 children screened, 108 (79%) passed, 11 (8%) were evaluated as refer, and 18 (13%) were inconclusive (Table 2). The inconclusive result varied widely by site from 3% to a high of 25%. The testing conditions at each site were different requiring site specific solutions prior to testing. A particular challenge was obtaining optimal lighting for screening (dark-

Table 1. Demographic Information on the Children Screened

Demographic Parameter	# of Children (%)
Age range (months) of children	
0-12	9 (7%)
12-24	25 (18%)
24-36	46 (34%)
36-48	38 (28%)
> 48	19 (14%)
Mean Age in months (SD)	32 (13)
Male	75 (55%)
Race	
Full/Part Hawaiian or Pacific Islander (HPI)	48 (35%)
Mixed Race other than part-HPI	56 (41%)
Asian	21 (15%)
Caucasian	12 (9%)

Table 2. Results of Plusoptix Screening by Site				
Site	**Total tested (# children)**	**Pass (# children)**	**Refer (# children)**	**Inconclusive (# children, % of children at site)**
Makakilo	23	16 (70%)	3 (13%)	4 (17%)
Papakolea	18	14 (78%)	1 (6%)	3 (17%)
Waianae	18	14 (78%)	3 (17%)	1 (6%)
Waialua	28	20 (71%)	1 (4%)	7 (25%)
Kahaluu	28	25 (89%)	2 (7%)	1 (4%)
Pauoa	22	19 (86%)	1 (5%)	2 (9%)
Total (% of total)	137	108 (79%)	11 (8%)	18 (13%)

Table 3. Information on the 11 Screened Children with "Refer" Diagnosis						
Patient	**Gender**	**Testing Site**	**Participant's District**	**Ethnicity**	**Age (months)**	**Diagnosis**
1	M	Waialua	Mililani	HPI*	27	Astigmatism
2	M	Waianae	Waianae	Asian	35	Astigmatism
3	F	Makakilo	Kapolei	HPI	15	Astigmatism
4	F	Makakilo	Mililani	Asian	11	Astigmatism
5	M	Waianae	Ewa Beach	Mixed Race**	51	Hyperopia
6	F	Waianae	Waianae	HPI	16	Hyperopia
7	F	Makakilo	Ewa Beach	Asian	35	Hyperopia
8	F	Kahaluu	Kailua	Asian	25	Hyperopia
9	M	Pauoa	Honolulu	Asian	24	Gaze Asymmetry
10	F	Papakolea	Honolulu	Asian	47	Anisometropia
11	M	Kahaluu	Kaneohe	Mixed Race	39	Anisometropia

*Full/Part Hawaiian or Pacific Islander; **Race other than part-HPI

ened but with sufficient light to read a newspaper). Increased familiarity and experience with screening ultimately resulted in an ability to test 20 to 30 children over approximately 2 hours with actual time of a screening attempt per child ranging from 30 seconds to 2 minutes.

More details on the 11 refer children are provided in Table 3. Eight of the children with a refer recommendation had bilateral ametropic risk factors. The results for each child was sent home with an informational sheet reiterating the recommendation as initially presented in the informed consent document that a refer diagnosis should be followed by a formal vision examination. Three of the 11 children with a refer diagnosis were subsequently evaluated by an eye specialist. A formal report was obtained on one child with a refer for astigmatism who was subsequently diagnosed with bilateral hyperopia and left astigmatism. The 2 other children, one with hyperopia and one with astigmatism, were found to have no visual problems per their parents' report. Of the remaining 8 children, there were no responses from the parents/guardians despite two subsequent phone attempts to request referral of their child for formal vision examination.

Discussion

This small uncontrolled study is the first Hawai'i-specific experience with early childhood vision screening using a portable hand-held photoscreener. Our screening found 11 children with visual abnormalities, representing 8% of all children seen. Eight of the children with a "refer" recommendation had bilateral ametropic risk factors. There were no excessively high degrees of astigmatism or hyperopia recorded by the Plusoptix S12 photoscreener. Since the prevalence of refractive amblyopia correlates well with the severity of the vision abnormality,[6] the risk for bilateral ametropic amblyopia in these eight children could be considered low. However, the true amount of refractive error and diagnosis of amblyopia can only be determined after a cycloplegic eye examination and evaluation by an eye care professional. At risk for unilateral amblyopia were the two children with the 'refer' recommendation for anisometropia. There was only one child at risk for strabismic amblyopia with an abnormal reading for gaze asymmetry.

There is now substantial experience with vision screening utilizing a photoscreener nationally and internationally includ-

ing large screening programs of preschool children numbering in the hundreds of thousands.[7-11] Experiences specifically with Plusoptix have also been published.[12-16] A recent study comparing three photoscreening devices showed Plusoptix to have good sensitivity and specificity compared to other devices. Sensitivity overall for detection of visual abnormalities associated with risk factors for amblyopia ranged from 72% (iScreen) to 84% (Plusoptix), and specificity ranged from 68% (SPOT) to 94% (Plusoptix).[17]

The effort needed to learn how to operate the Plusoptix photoscreener was moderate and the photoscreener was highly portable. This study required screening at 6 different sites and challenges were encountered in adapting conditions at each site to one conducive for screening. Our inconclusive rate was high overall at 13.1% but differed by screening location from as low as 3.6% to as high as 25%, possibly reflecting both a technical learning curve as well as site specific difficulties in creating an acceptable screening environment. This compared to rates in the literature obtained in 31,000 children of 12.1% for children aged 6 to 11 months and 1.1% for children aged 4 years.[18] Our referral rate was also somewhat high at 8% compared to values of 4%[8] and 5.2%[18] in other community based screening programs. We were unable to establish the positive predictive value of our screening efforts because of non-compliant follow-through for a professional evaluation among those identified for referral and the design of the study was not intended to provide formal ophthalmologic examination to all participants. Poor follow-up has been cited as a major problem in many community screening projects.[7,8]

It is estimated that approximately one in 5 American children have some form of vision problem.[19] Multiple studies found a relationship between vision problems and lower academic performance suggesting that detection of visual difficulties during childhood is of critical importance in maximizing each child's educational potential.[20-23] There is evidence to also suggest that childhood visual problems are a health disparity issue. Higher rates of visual impairment have been reported among persons aged 12 and above among Hispanics and Blacks compared to Caucasians.[24] This association may be due, at least in part, to increased risk of premature birth and low birth weight, both of which adversely affect eye health and processes associated with the normal development of vision.[25] However there is also evidence that low income and minority youth are at greater risk of under-diagnosis and under-treatment of vision problems.[26,27] To our knowledge there are no data on rates of visual problems by ethnic populations among pre-school children in Hawai'i. However, as poverty and health disparity in perinatal determinants of health are both recognized problems facing the Native Hawaiian community,[28,29] it would not be surprising to find that Native Hawaiian children may also be at risk for under-diagnosis and under-treatment of vision disorders.

The need for early detection and prevention of amblyopia is a major focus of early childhood vision testing. There is remarkable consensus by all national pediatric and vision related national organizations that early childhood screening to detect children at risk for amblyopia is important.[1,2] However, there is some controversy in the field. The US Preventive Services Task Force (USPSTF) in 2011, while agreeing with the importance of vision screening in children ages 3 to 5 years of age, concluded that the current evidence was insufficient to assess the benefits and harms of vision screening in children < 3 years of age, citing costs of false-positive rates, and concluded that screening and treatment of amblyopia later in the preschool years may be as effective as screening and treatment done earlier in life.[2] The AAP, AACO, AAPOS, and AAO disagree, citing studies showing increased benefit from detection and treatment of amblyopia earlier than age 3.[30] These organizations have jointly issued a position paper advocating instrument-based vision screening for children between the ages of 6 months and 3 years.[5]

Future efforts should take into account newer guidelines, the cost-benefit aspects, and the Hawai'i-specific resources. While amblyopia has a prevalence during childhood of approximately 2%,[31-33] the prevalence of risk factors for amblyopia are much higher at 15 to 20%,[34-37] leading to the likelihood of over-referral. The positive predictive value of a positive screen also varies widely by age. The positive predictive value has been reported to range from 30% in children in the 6- to 11-month age group to 76% in children 4 to 5 years of age.[18] However, while mild amblyopia may be correctable with spectacle treatment alone, refractive adaptation is less likely to occur in children with deeper amblyopia and thus, must be identified at a younger age.[38] In contrast, older children have less time available for effective treatment and screening should be more sensitive in this age group. Thus, in an effort to update guidelines for screening to reflect cut-offs best able to separate children who are most at risk for developing amblyopia from those who are not, and to minimize the risk of over-referrals, the AAOP Vision Screening Committee has recently recommended an age-based algorithm intended in the youngest children to detect only the greatest magnitude of refractive risk factors before a refer is triggered while increasing efforts to detect lower magnitude amblyopia risk factors in older children.[34]

Per the State-by-State Vision Screening Requirements posted on the website by the AAPOS (updated in 2011),[39] Hawai'i has no state policy on early childhood vision screening despite the report to the 24th legislature, State of Hawai'i, 2008 prepared by the Department of Health which mentions improving vision screening for preschool and school-aged children as an area for further action.[40] Up until 1995, school age children in Hawai'i's public school system were annually screened for vision problems by the Hawai'i State Department of Health. However this practice is no longer in place due to funding issues. More recently, volunteer organizations, in particular the Lions Club and Rotary Club, have attempted to fill the void. From July 2010 to December 2012, the Lions of District 50 completed vision screenings using traditional visual screening methods in 16,901 pre-school, elementary and intermediate school children.[41]

Our study was limited by the small number of children screened, and by the initial need to train personnel and to es-

tablish the optimal environment/setting for such screening at different locations. Sensitivity and specificity data could not be obtained due to the lack of follow-up with formal vision examination in the at-risk children. Nevertheless several conclusions are possible. The photoscreener was quick, reasonably easy to operate, and fully portable. Training time needed for personnel to use the instrument was reasonable and the screening was well tolerated by pre-school children. More work is needed to establish the optimal "pass" and "refer" criteria ideal for use in Hawai'i's pre-school children. As early detection of treatable eye disorders has far-reaching benefits for vision and long term health and well-being of the children involved, a comprehensive early childhood vision screening program should be considered in Hawai'i. Such plans should include an approach to confirmation and management of visual abnormalities of at-risk children found on screening.[19]

Conflict of Interest

None of the authors identify any conflict of interest.

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Privilege as a Social Determinant of Health in Medical Education: A Single Class Session Can Change Privilege Perspective

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Abstract

Accredited medical schools are required to prepare students to recognize the social determinants of health, such as privilege, yet privilege education has been overlooked in medical school curricula. The purpose of this study is to determine whether a single class session on privilege, within a social justice elective offered to first and second year medical students, is sufficient to change the perspective of medical students concerning their own personal privilege. A pre-class survey, followed by a class session on privilege, and post-class survey were conducted. Thirteen of the 18 students enrolled in the elective completed the pre-class survey. Ten students completed the post-class survey, although only 9 completed both the pre- and post-class surveys. The demographic profile of the participants was 93% Asian and 7% White ethnicity, with 57% identifying as being culturally American. There was no significant difference between average male and female or between age groups' self-assessed privilege amounts. For all characteristics tested, except hair color, participants had an increased self-assessed privilege perspective following the class. Three participants had an overall positive difference in privilege perspective, three participants had an overall negative difference in privilege perspective, and three participants had only a minimal change in privilege perspective. The absolute total difference in privilege perspective was 25 units of change. The single class session on privilege was sufficient to change significantly the perspective of medical students on their own personal privilege; however, future studies with larger groups of medical students are needed to elucidate other findings suggested by this study.

Introduction

Within the realm of social determinants of health in medical education, such as education, culture, socioeconomic status, housing and employment, the topic of privilege is often overlooked. Privilege, as defined in this paper, is "when one group has something of value that is denied to others simply because of the groups they belong to, rather than because of anything they've done or failed to do. Access to privilege doesn't determine one's outcomes, but it is definitely an asset that makes it more likely that whatever talent, ability, and aspirations a person with privilege has will result in something positive for them."[1]

Accredited United States medical schools are required to prepare students to "recognize [. . .] determinants of health, [. . .] and to recognize the potential health-related impact on patients of behavioral and socioeconomic factors."[2] However, there is a current lack of research regarding medical school curricula including the topic of privilege, despite it being considered a social determinant of health. The importance of understanding one's own privilege as a future healthcare professional is critical to the delivery of equitable health care to all patients, as demonstrated by the World Health Organization's (WHO) 1996 report entitled *Equity in Health and Health Care*. Equity in health and health care, as explained in this report, "means that people's needs, rather than their social privileges, guide the distribution of opportunities for well-being [. . .] (and) pursuing equity in health and health care means trying to reduce avoidable gaps in health status and health services between groups with different levels of social privilege."[3] Since current data from the Association of American Medical Colleges (AAMC) shows that "for the past two decades, over 60 percent of medical students are from families with incomes in the top quintile of all American families,"[4] there is serious need for medical schools to educate future physicians about their own privilege within the larger social determinants of health to provide better care for future patients. Based on the Liaison Committee on Medical Education's requirements, medical schools should already be teaching medical students about such topics as privilege; however, a search of the PubMed database for the terms "medical student privilege" results in 43 related articles, none of which pertain to medical student education.

The purpose of this study is to determine whether a single class session on privilege within an elective on social justice in medicine offered to first and second year medical students is sufficient to change the perspective of medical students on their own personal privileges; it is hoped that better understanding of personal privilege will enable these future physicians to deliver equitable health care to their future patients.

Methods

The Elective

The University of Hawai'i at Manoa (UHM) John A. Burns School of Medicine (JABSOM) offers an elective in "Social Justice in Health" to first year (MS1) and second year (MS2) medical students. The elective is offered through the JABSOM Department of Native Hawaiian Health. Students receive one credit hour for the class, which meets for one and a half hours weekly for nine weeks. The elective was first offered to the class of 2015, when a four year elective program leading to the "Dean's Certificate of Distinction in Social Justice" was established.[5] The elective is now taught by medical students who took the course the prior year, under the mentorship of two faculty advisors. Due to the student-run nature of the elective, topics covered vary year by year. Topics of the 2015 elective included physician advocacy, gender roles and stereotypes, privilege, sexual orientation and identification, Hansen's disease in Hawai'i, and international medical aid. The 2015 elective was taught by three MS2s, with each class session led by a single teacher or two co-teachers. Eighteen medical students enrolled in the 2015 elective, of whom five were MS2s.

The Class

A class session in January 2015 focused on privilege, defined as "when one group has something of value that is denied to others simply because of the groups they belong to, rather than because of anything they've done or failed to do."[1] One week prior to the class, an online survey (approved by the University of Hawai'i's Institutional Review Board, CHS #22769, which declared this study "exempt") was made available to the 18 students enrolled in the elective. The survey reproduces Paul Kivel's popular walk exercise.[6] A UHM system email was required to access the survey, however, all survey results were submitted anonymously via the Google poll. Prior to the class session, students were also asked to write their definition of privilege and three of their own personal privileges on a note card before class and to read Dowsett's article "What My Bike has Taught Me about White Privilege."[7] The class session on privilege included the following activities: (1) establishment of ground rules; (2) collection of the pre-class notecard assignment; (3) redistribution (to ensure anonymity) and discussion of the notecard definitions of privilege and listed privileges; (4) reading of Allan Johnson's definition of privilege;[1] (5) watching Tiffany Jana's TED^{X}RVA Women talk on "The Power of Privilege;[8] (6) a think-pair-share exercise on race, gender, sexual orientation, and disability status; and (7) Paul Kivel's walk exercise.[6] Following the class session, another survey (also IRB approved), with both identical and new questions as compared to the pre-class survey, was made available to the students. A UHM system email was once again required to access the survey and the survey results were submitted anonymously via the Google poll. Only the identical questions used on both the pre- and post-class surveys were analyzed in this paper, as new post-class survey questions providing feedback on the various educational materials used during the course itself were not relevant to our study. The resulting pre- and post-class survey data was linked to those who participated by matching age, gender, ethnicity, and cultural identity. The resulting data was then analyzed using Microsoft Excel, including the use of a two-sample t-test and analysis of variance.

Paul Kivel's Revised Walk Exercise[6]

To assess the self-privilege of the medical students, the lead author adapted Paul Kivel's original walk exercise questions. The survey consists of 41 questions. The first four questions of the survey instrument, as seen in Appendix 1, were included in order to allow pre- and post-class survey results for participants to be linked for analysis. Question 5 was added to assess a change in personal privilege perspective and is addressed in the following paragraph. Individual responses to Questions 6-41 remained unchanged between the pre- and post-class surveys, and thus, were not analyzed in this study; one question was excluded due to a lack of white participants. To facilitate analysis, the walk exercise questions were reworded to require a yes or no response. To compare results, questions where an answer favored more privilege were given a "Unit of Change" (UC) value of plus 1 (+1), while those that favored less privilege were given a UC value of minus 1 (-1). An example of one of the questions from the survey is "Are any members of your immediate family doctors, lawyers, or other professionals?" where a yes response would receive a +1 UC and a no response would receive a -1 UC. (See Appendix 1 for the survey instrument.) The resulting scores were added for all questions with the total for each participant, termed "Privilege Amount," seen in Table 1.

Pre- and Post-Class Privilege Perspective

Responses to Question 5 in the pre- and post-class survey were used to assess a change in personal privilege perspective due to the class session. Question 5 asked students to rate on a scale of 1 to 10 how certain personal characteristics have given them a privilege over others, as seen in Appendix 1. This resulting data was analyzed separately from the walk exercise questions. The difference between pre- and post-class surveys was found by subtracting the pre-class survey rating from the post-class survey rating for each characteristic listed. A resulting positive value corresponds to an increase in privilege perspective on the post-class survey while a resulting negative value corresponds to a decrease in privilege perspective on the post-class survey. The mean difference between pre- and post-class surveys for each characteristic was then calculated to determine whether the change was significant.

Results

Class Demographics

A total of 13 students completed the pre-class survey (72% response rate), with a participant age range from 21 to 30 years. Participants self-identified their gender, ethnicity, and cultural identity on both the pre- and post-class surveys, as seen in Table 2. No data was collected regarding student socioeconomic background. Roughly two thirds of the participants were female (64%), with most participants being of Asian ethnicity (36% Chinese, 36% Japanese, and 14% Korean) and of an American cultural identity (57%). Ten students completed the post-class survey (56% response rate), with one new participant and 9 participants who completed both the pre- and post-class surveys (50% response rate). There was no significant difference between the Privilege Amount average between female and male participants (two-sample t-test, t= 1.00, 11 d.f., $P < .05$) or between the various age groups at the $P < .05$ level (analysis of variance, ($F(6,6) = 1.02$, $P = .489$), as seen in Table 1.

Pre- and Post-Class Privilege Perspective

The difference between pre- and post-class surveys on how various characteristics give individual privilege were averaged, with each characteristic, except hair color, having a positive change in perspective, as seen in Table 3. The largest changes in privilege perspective were observed for home location, 1.9, disability status, 1.8, and high school attended, 1.1. The smallest changes in privilege perspective were observed for college attended 0.2 and cultural identity, 0.4. The sum of differences between pre- and post-class surveys for the various character-

Table 1. Pre-Class Assessment of Self-Privilege	
Participants	Privilege Amount[a]
Average Female	13.7
Average Male	18.5

[a]The "Privilege Amount" was determined by adding the resulting scores for all analyzed survey questions, as detailed in Appendix 1, where a response to a question in favor of privilege resulted in a 1, and a response to a question in favor of less privilege was given a -1.

1. Difference between the privilege amount average between the female and male participants using a two-sample t-test, t= 1.00, 11 d.f., $P < .05$.
2. Comparison between the various age groups using analysis of variance at the $P < .05$ level ($F(6,6) = 1.02$, $P = .489$).
3. Mean Privilege Amount is 16.

Table 2. Self-Reported Demographic Information from Pre- and Post-Class Surveys		
Gender	**Number of Participants**	**% of Participants (N=14)**
Male	5	36%
Female	9	64%
Ethnicity		
Caucasian	1	7%
Chinese	5	36%
Filipino	1	7%
Japanese	5	36%
Korean	2	14%
Cultural Identity		
American	8	57%
Other	6	43%

Note - Students self-identified their gender, ethnicity, and cultural identity with which they predominantly identify on both pre- and post-class surveys in order for their responses on both surveys to be linked and analyzed. The option of "Other" was given for both the ethnicity and cultural identity questions on both surveys. No definition of what constituted American cultural identity was given to participants.

Table 3. Mean Difference Between Pre- and Post-Class Surveys on How Various Characteristics Give Individual Privilege	
Characteristic	**Mean Difference (N=9)**
Skin Color	0.6
Hair Color	0
Cultural Identity	0.4
Sexual Orientation	0.9
Gender	0.6
Disability Status	1.8
Mother's Profession	0.7
Father's Profession	0.9
Home Location	1.9
High School Attended	1.1
College Attended	0.2

Table 4. Sum of the Differences between Pre- and Post-Class Surveys for Survey Instrument Question 7	
Participants (Gender, Ethnicity, Culture)	**Summative Difference for All Characteristics (N=9)**
F, Korean, American	21
F, Japanese, Japanese	6
F, Chinese, American	4
F, Japanese, American	-19
F, Korean, American	56
F, Chinese, Chinese	-8
F, Chinese, American	10
M, Caucasian, American	58
M, Japanese, American	-47
Absolute Total Difference of all Characteristics	25

istics for each study participant resulted in a positive change in perspective in six participants (66% of participants) and a negative change in perspective in the remaining three participants, as seen in Table 4. There was an absolute total difference in privilege perspective for all of the participants of 25 UC.

Discussion

This study on privilege serves to demonstrate that having a single class session on privilege can change significantly the perspective of medical students on their own personal privileges. Of course, the demographic makeup of the sample, which reflects the student population of JABSOM, differs from other medical school settings in that participants were primarily of Asian ethnicity (93%). Despite the ethnic skewing toward Asian ethnicity, the self-identified cultural identity of the sample was still 57% American, indicating that more than half of the participants identify culturally as American despite having Asian ancestry. Of note, a definition of American culture was not given to participants and thus it was left up to individual participants to define this term prior to making their selection. These demographic findings may be unique to Hawai'i, where the general population census data for one race identifiers is 25% White and 38.3% Asian, and certain findings discussed later may be due to this increased diversity.[9]

Pre-Class Assessment of Self-Privilege

Non-medical literature abounds with references to white male privilege,[10–13] which is consistent with our observation that male medical students have an increased self-assessed privilege compared to their female peers, although not statistically significant in this study. Of note, due to the lack of white participants in our study, no conclusion can be drawn regarding white male medical student privilege compared to others at this time. A power calculation suggests that approximately one half of a JABSOM class, 33 students, would be suitable for results that would potentially be statistically significant for this exercise. If the finding is that both male and female medical students

are really not significantly different in regard to privilege, this would go against the non-medical student literature regarding gender privilege and could open up an entirely new area of study.

Pre- and Post-Class Privilege Perspective

We assessed whether the class was successful in changing the perspective of medical students on their own personal privileges. The anticipated learning point was that medical students would begin the class with a lower self-assessed privilege and after attending the class, would leave the class with a higher self-assessed privilege. There was an increase in privilege perspective on the post-class survey for all of the characteristics listed except for hair color. A possible explanation for this particular lack of change in privilege perspective is that since the majority of the participants are of Asian ancestry, having brown or black natural hair color, there was no change in perspective due to an already low assessed privilege due to their hair color. The purpose of this particular question was to ascertain whether light haired people felt that they had a privilege over others, as seems to be the case in non-medical literature that details white privilege. The lack of change may be the result of the diverse demographics of Hawai'i and the medical school community, or because this particular trait was not covered in sufficient detail during the class session.[12] To determine whether this lack of privilege perspective change is due to the curriculum used or to the demographics of the participants a larger class and survey size would need to be used.

We ascertained the overall change in privilege for each participant. Only three of the participants showed a greater than 15UC positive difference in privilege perspective due to the class, the single Caucasian participant and the only two Korean participants. Due to the lack of educational material regarding non-white privilege, such as Japanese, Korean, and Chinese privilege, a novel culturally validated privilege curriculum needs to be established to make the material more relevant to students from various ethnic and cultural backgrounds. Once established, this curriculum would ideally result in a greater change in privilege perspective between the pre- and post-class surveys, as the material would more broadly relate to students from various backgrounds.

Three of the medical students had a negative difference in privilege perspective following the class, with two of these participants having a greater than -15UC difference. A possible explanation for this finding is that these three participants came into the class with a higher self-assessed privilege value than those of the other participants. The class session, rather than making the participants more aware of their self-privileges, seems to have made them aware that those characteristics they had thought gave them more privilege than others, in fact, do not. This may be due to students who enrolled in the Social Justice in Health elective having prior knowledge of their own self-privileges. To determine whether this is a finding unique to the elective students the surveys and a class on privilege need to be offered to all medical students as part of the normal curriculum.

In order to determine whether the single class session results in a long-term change in privilege perspective for the medical students a future survey of the participants in this initial study will need to be conducted. The goal of the authors is to create a survey instrument that can assess whether the current participants retain their changed perspective at the time of graduation. Since the current participants were either MS1s or MS2s, the future study would take place two years later for the current MS2s and three years later for the current MS1s. It is the hope of the authors that the future study will find that the single class session on privilege does result in long-term changes in privilege perspective; however, this result will not be known for quite a number of years.

Limitations

The small sample size and the imbalance of male and female participants are the primary limitations of this study. The survey instrument was not specific to the population served, as JABSOM has a more multi-cultural student population than do schools elsewhere in the United States. Paul Kivel's walk exercise was developed to examine class and race in the context of a more homogenous Caucasian population, thus the use of this instrument to determine individual participant's privilege amount is not ideal in this diverse population. To the authors' knowledge no culturally and ethnically diverse and validated survey instrument exists at this time and such an instrument is needed to assess more accurately privilege amount in future studies. As noted, the limited research conducted so far focuses on white male privilege, with no studies to date of privilege in multi-ethnic settings such as Hawai'i. Likewise, available educational material focuses on white male privilege, and so is less relevant to students in Hawai'i. Due to the small size of the class, we could match pre- and post-survey results with the same participant; however, in a larger setting, a new means of linking survey results would be needed.

Conclusion

Although it was expected that the class session would improve medical students' perspective on their own privileges, it was found that in certain cases the class session may have decreased their self-assessed privilege. This single class session on privilege was sufficient to change medical students' perspectives on their own personal privilege, in ways that can only be further elucidated through the establishment of a more culturally validated privilege curriculum, surveying a greater number of medical students, and in conducting follow-up surveys later in the students' medical school careers to see if the class affected their perspective in the long term. Future research to correlate medical students' degree of privilege and rates of graduation and practice choices would also complement this study well. By incorporating a single class session on privilege into the general medical school curriculum, medical schools could change the perspective of medical students on their own personal privilege and provide a more thorough understanding of privilege as a social determinant of health. Therefore,

the authors recommend that medical schools supplement their required educational curriculum on the social determinants of health with a session on privilege so that their students can develop a better understanding of their own privilege and the privilege of their patients, which may enable them to pursue equitable health care to their future patients.

Conflict of Interest Statement

We certify that we have no financial affiliation/interest (eg, employment, stock holdings, consultantships, honoraria) in the subject matter, materials, or products mentioned in this manuscript. Neither of the authors of this article have any conflict of interest to report, nor any interests represented with any products discussed or implied.

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Appendix I Survey Instrument

Pre- and post-surveys are the same, except for removal of Paul Kivel's walk exercise questions (6-41) and inclusion of course evaluation questions in the post-class survey (not shown).

1. Age
2. Gender
3. The ethnicity you most identify with?
4. The culture you most identify with?
5. For each of the following characteristics, please rate on a scale of 1 to 10 how they have given you privilege over others:
   a. Skin Color
   b. Hair Color
   c. Cultural Identity
   d. Sexual Orientation
   e. Gender
   f. Disability Status
   g. Mother's Profession
   h. Father's Profession
   i. Home Location
   j. High School Attended
   k. College Attended
6. Were your ancestors forced to come to this country or forced to relocate from where they were living permanently?
7. Were your ancestors restricted from living in certain areas?
8. Would you identify your primary ethnicity to be "American?"
9. Were you ever called names or ridiculed because of your:
   a. Race
   b. Ethnicity
   c. Class Background
   d. Cultural Identity
10. Did you grow up with people of color or working class people who were servants, maids, gardeners, or babysitters in your house?
11. Were you ever embarrassed or ashamed of your clothes, your house, or your family when growing up?
12. Are any members of your immediate family doctors, lawyers, or other professionals?
13. Are pimping and prostitution, drugs, or other illegal activities major occupational alternatives in the community where you were raised?
14. Have you ever tried to change your physical appearance, mannerisms, language, or behavior to avoid being judged or ridiculed?
15. Did you study the history and culture of your ethnic ancestors in elementary and/or secondary school?
16. Did you start school speaking a language other than English?
17. Did your family have more than 50 books in the house when you were growing up?
18. Did you ever skip a meal or go away hungry from a meal because there wasn't enough money to buy food in your family?
19. Were one of your parents ever laid off, unemployed, or underemployed not by choice?
20. Have you ever attended a private school or summer camp?
21. Have you ever received less encouragement in academics or sports from your family or from teachers because of your gender?
22. Did you or your family ever have to move because there wasn't enough money to pay rent?
23. Were you told by your parents that you were beautiful, smart, and capable of achieving your dreams?
24. Were you ever discouraged or prevented from pursuing academic or work goals, or tracked into a lower level because of your race, class, or ethnicity?
25. Did your parents encourage you to go to college?
26. Did you grow up in a single parent household?
27. Did you take a vacation outside of your home state prior to your 18th birthday?
28. Did both of your parents complete high school?
29. Do your parents own their house?
30. Do you commonly see people of your race or ethnicity on television or in the movies in roles that you consider to be degrading?
31. Have you ever got a good paying job or a promotion because of a friend or family member?
32. Have you ever been denied a job/position because of your race or ethnicity?
33. Have you ever been mistrusted or accused of stealing, cheating, or lying because of your race, ethnicity, or class?
34. Have you ever inherited, or are going to inherit, money or property?
35. Do you primarily use public transportation to get where you need to go?
36. Do you generally think of the police as people that you can call for help in times of emergencies?
37. Have you ever felt afraid of violence directed toward you because of your race?
38. In general, are you able to avoid communities or places that you consider dangerous?
39. Have you ever felt uncomfortable or angry about a remark or joke made about your race or ethnicity but didn't feel it was safe to confront it?
40. Have you or close friends or family ever been a victim of violence because of your race or ethnicity?
41. Were your parents raised outside of the United States?

Racial/Ethnic-Specific Reference Intervals for Common Laboratory Tests: A Comparison among Asians, Blacks, Hispanics, and White

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Abstract

Reference intervals (RIs) for common clinical laboratory tests are usually not developed separately for different subpopulations. The aim of this study was to investigate racial/ethnic differences in RIs of common biochemical and hematological laboratory tests using the National Health and Nutrition Examination Survey (NHANES) 2011-2012 data. This current study included 3,077 participants aged 18-65 years who reported their health status as "Excellent," "Very good," or "Good," with known race/ethnicity as white, black, Hispanic, or Asian. Quantile regression analyses adjusted for sex were conducted to evaluate racial/ethnic differences in the normal ranges of 38 laboratory tests. Significant racial/ethnic differences were found in almost all laboratory tests. Compared to whites, the normal range for Asians significantly shifted to higher values in globulin and total protein and to lower values in creatinine, hematocrit, hemoglobin, mean cell hemoglobin, mean cell hemoglobin concentration, and mean platelet volume. These results indicate that racial/ethnic subpopulations have unique distributions in the labortoary tests and race/ethnicity may need to be incorporated in the development of their RIs. Establishment of racial/ethnic-specific RIs may have significant clinical and public health implication for more accurate disease diagnosis and appropriate treatment to improve quality of patient care, especially for a state with diverse racial/ethnic subpopuations such as Hawai'i.

Keywords

Race/ethnicity, reference interval, laboratory test, sex, NHANES

Introduction

Reference intervals (RIs) of clinical laboratory tests are frequently established using distribution-based (eg, normal or log normal) 95% confidence intervals or nonparametric 2.5th and 97.5th percentiles of healthy subjects' laboratory test results. The RIs have an important role in clinical practice in screening for diseases, assessing disease progression and treatment response. The use of accurate RIs can reduce disease misdiagnosis and improve patient care.

The guidelines by International Federation of Clinical Chemistry (IFCC) recommend that every country must establish RIs for health.[1] For example, there were movements to develop locally relevant RIs in Ghana and India.[1,2] In most other non-industrialized nations, however, RIs have not been adequately addressed. Instead, clinicians in those countries adopt the textbook RIs that were mainly developed in Western countries predominantly with Caucasian populations, without consideration of potential racial/ethnic differences.

Several studies have recognized racial/ethnic differences in RIs of various laboratory tests, mainly between blacks and whites.[3-15] Compared with whites, blacks show significantly lower thyrotropin,[12] total white blood cell (WBC), neutrophil counts,[13] platelet counts,[5] hematocrit, mean cell hemoglobin centration (MCHC), mean cell hemoglobin,[13] and hemoglobin[13,14] and significantly higher mononuclear and lymphocyte percent.[13] For example, the hematological (hemoglobin, mean cell volume, platelets, WBC) reference values for the Gambian population encompasses lower limits compared with Western standards and shifted to the lower values.[16]

A few studies have evaluated other racial/ethnic differences in RIs for some laboratory tests. Hispanics were found to have similar RIs as whites in WBC, absolute neutrophil counts[17] and albumin.[18] Similarly, Cheng, et al, (2004) concluded no significant trend differences between whites and Mexican Americans for blood chemistries such as hemoglobin.[13] In a multicenter study from four regions (Milan Italy, Bursa Turkey, Beijing China and Nordic Countries), Ceriotti, et al, (2010) concluded that common RIs for aminotransferase (ALT) and aspartate aminotransferase (AST) are reasonable but that for gamma-glutamyl transferase (GGT) may not be applicable due to differences among regions.[15] Such findings have led many researchers to advocate for usage of racial/ethnic-specific RIs for laboratory tests. This has direct and significant clinical and public health implications, especially for a state like Hawai'i with its diverse racial/ethnic population (Hawai'i, white 24.7%, Asian 38.6%, and Native Hawaiian and other Pacific Islander 10.0% versus the United States, 72.4%, 4.8%, and 0.2%, respectively).[19]

To our knowledge, there are no studies comparing RIs of Asians to other racial/ethnic groups across common laboratory tests in the United States. In studies comparing different racial/ethnic groups, Asians are often ignored due to small sample size. For example, the National Health and Nutrition Examination Survey (NHANES), one of the largest nationwide surveys, combined Asians (until recently) into the "other race" category. Given this important and fast growing racial/ethnic subpopulation, the NHANES 2011-2012, for the first time, included Asians as a separate racial/ethnic group. This study aimed to address the question on whether the RIs of common laboratory tests are different between major racial/ethnic groups including Asians from a representative sample of US healthy adults using NHANES 2011-2012 data.

Methods

Data Source and Study Population

The latest NHANES 2011-2012 data were utilized for this study. NHANES uses a multistage, stratified, cluster sampling design to generate a representative sample of the civilian US popula-

tion. The data were collected from surveys, examinations, and laboratory tests. The detailed description of survey methods and laboratory and examination data collection procedures is available at the NHANES website (www.cdc.gov/nchs/nhanes.htm). Unlike the previous years in which Asians were combined into the "other" racial/ethnic group, the 2011-2012 data oversampled Asians and categorized them as a separate racial/ethnic group. As a result, race/ethnicity was categorized as non-Hispanic white, non-Hispanic black, Mexican American, other Hispanic, non-Hispanic Asian and other race/ethnicity categories.

To compare RIs of laboratory tests in healthy adults by race/ethnicity, only adults aged between 18 and 65 years (inclusive) who rated their overall health status as either "Excellent," "Very Good," or "Good" were included. Mexican American and other Hispanic groups were combined into one group for our analysis. Participants who did not specify their race/ethnicity or identified themselves as other mixed race were not included because their sample sizes were too small to produce reliable estimates.

Laboratory Tests

The following 38 biochemical and hematological laboratory tests were examined: albumin, ALT, ALP, basophils percent, bicarbonate, blood urea nitrogen (BUN), calcium, chloride, creatine phosphokinase (CPK), creatinine, eosinophils percent, GGT, globulin, glucose, hematocrit, hemoglobin, iron, lactate dehydrogenase (LDH), lymphocytes percent, mean cell hemoglobin, MCHC, mean cell volume, mean platelet volume, monocytes percent, osmolality, phosphorus, platelet count, potassium, red blood cell count (RBC), red blood cell distribution width (RCDW), segmented neutrophils percent (SNP), sodium, total bilirubin, total cholesterol, total protein, triglycerides, uric acid, and white blood cell count (WBC). Missing laboratory test rates were relatively small, ranging from 3.44% to 6.11%.

Statistical Methods

Descriptive statsitics were reported on subject charcteristics for the healthy adult population sampled, both unweighted and weighted for complex sampling design. Unadjusted/unweighted upper and lower limits of normal ranges were calculated for the laboratory tests stratified by sex and race/ethnicity. Lower and upper limits of normal range were defined as 2.5^{th} and 97.5^{th} values in percent, respectively. Adjusting for sex, quantile regression models were conducted for the lower and upper limit of normal range for each laboratory test comparing across racial/ethnic groups. Quantile regression is a robust statistical method that models the shape and location of a distribution since it avoids parametric assumptions about the error distribution. Standard error for each parameter was estimated based on a bootstrapping method with 1,000 bootstrap samples and was reported at one more decimal point than its parameter estimate. Sensitivity analyses were performed using the participants who reported "Excellent" or "Very Good" health status to investigate whether different health status provided similar patterns. Finally, weighted quantile regressions were also implemented with consideration of the NHANES complex sampling design. *P*-value < .05 was considered statistically significant. All analyses were conducted in SAS 9.4 (SAS Institute Inc., Cary, NC).

Results

Sample Characteristics

Among the 4,711 participants in NHANES 2011-2012 data, 3,077 subjects met the inclusion criteria. The average age was 39.9 years (standard error=0.3), with about half being male (52.1%) (Table 1). Of the participants, 37.7% were white, 27.4% black, 19.2% Hispanic (about half were Mexican Americans), and 15.6% Asian. About forty-five percent were married, 19.3% had annual household income less than $20,000, and 13.2% self-reported "Excellent" health status.

Normal Ranges of Laboratory Tests by Sex and Race/Ethnicity

Table 2 summarizes unweighted lower and upper limits of normal ranges for the 38 laboratory tests stratified by sex and race/ethnicity (Asian, black, Hispanic, and white). For comparison, the RIs from the NHANES laboratory manual are also included. Although most normal ranges appeared to be close to the relevant RIs, some normal ranges deviated significantly from the corresponding RIs. For example, the NHANES RIs for ALT are 11-47 U/L for male and 7-30 U/L for female but the normal ranges are 12-80 U/L for male and 10-56 U/L for female. The RIs of GGT are 10-65 IU/L for male and 8-36 IU/L for female but the normal ranges are 9-103 IU/L for male and 6-76 IU/L for female. More importantly, shifts in normal ranges among different races/ethnicities were observed in multiple laboratory tests. For example, the normal range of ALP for white males was 35-107 IU/L but for Hispanic males was 43-126 IU/L. The normal range of creatinine for white females was 0.50-1.10 mg/dL but for Asian females was 0.43-0.88 mg/dL.

To address whether these shifts in normal range were statistically significant, quantile regressions were conducted using race/ethnicity and sex as independent variables (Table 3). The parameter estimate of each race/ethnicity allowed us to assess whether its normal range is different from whites after adjusting for sex. All except for five laboratory tests (ie, glucose, phosphorus, potassium, total bilirubin, and uric acid) showed significant racial/ethnic difference in either lower or upper percentile. Racial/ethnic differences varied across laboratory tests. Compared to whites, Asians are more likely to have higher lower limits for bicarbonate, globulin, and total protein and reduced lower limits for most hematological laboratory tests (ie, hematocrit, hemoglobin, mean cell hemoglobin, mean cell volume, MCHC, and mean platelet volume) and creatinine. Asians also had lower upper limit estimates for calcium, creatinine, hematocrit, hemoglobin, mean cell hemoglobin, MCHC, mean platelet volume, and monocyte percent. Asians were also more likely to have higher estimates for albumin, eosinophils percent, globulin, lymphocyte percent, RCDW, and total protein. Blacks had significantly higher normal ranges in CPK, globulin, and total protein and lower normal ranges in

Table 1. Subject Characteristics			
Variable	**n**	**Unweighted %**	**Weighted %**
Sex			
Male	1,603	52.1	51.1
Female	1,474	47.9	48.9
Race/Ethnicity			
White	1,160	37.7	70.8
Black	844	27.4	11.0
Hispanic	592	19.2	13.1
Asian	481	15.6	5.1
Education			
Less than High School	432	14.0	10.4
High School Gradaute/GED or Equivalent	643	20.9	19.7
Some College	939	30.5	32.0
College Graduate or Above	895	29.1	34.8
Refused/Don't Know/Missing	168	5.5	3.1
Marital Status			
Married	1,389	45.1	51.2
Widowed/Divorced/Separated	428	13.9	13.5
Never Married	769	25.0	22.5
Living with Partner	253	8.2	8.3
Refused/Missing	238	7.7	4.5
Annual Household Income*			
<$20,000	595	19.3	13.5
$20,000-$55,000*	1,103	35.9	32.4
$55,000-$100,000	622	20.2	24.1
≥$100,000	628	20.4	27.5
Refused/Don't Know/Missing	129	4.2	2.5
Self-Reported Health Status			
Excellent	407	13.2	14.8
Very Good	1,113	36.2	40.4
Good	1,557	50.6	44.8
Age, mean ± SE	3,077	39.9 ± 0.3	41.1 ± 0.4
BMI, mean ± SE	3,056	28.1 ± 0.1	28.2 ± 0.2

N=3,077. SE = Standard error. BMI = Body mass index.
*'$20,000 and Over' (n=115, unweighted percent=3.8%, weighted percent=2.7%) in income variable of NHANES data was combined to the category of $20,000-$55,000.

hematocrit, hemoglobin, mean cell hemoglobin, MCHC, total cholesterol, triglycerides, and WBC than the referent whites. Hispanics had higher normal ranges in total protein and lower normal ranges in mean cell hemoglobin and MCHC. Figure 1 depicts the variation in the estimated normal ranges by sex and race/ethnicity for the eight laboratory tests that showed significant difference bewteen Asians and whites in both percentiles.

Significant sex differences were also found in both percentiles in the following laboratory tests: albumin, ALT, bicarbonate, calcium, CPK, creatinine, GGT, hematocrit, hemoglobin, iron, mean cell volume, monocyte percent, platelet count, RBC, total bilirubin, total cholesterol, total protein, triglycerides, and uric acid (Table 3). Overall, males had higher estimates except for platelet count and total cholesterol whose direction was opposite.

As a sensitivity analysis, the same models were applied to the participants who reported "Excellent" or "Very Good" health status. The results were very similar in direction and magnitude in parameter estimates for most of all laboratory tests. Weighted quantile regression using the NHANES complex sampling weight also showed comparable patterns (results not shown).

Table 2. Unweighted Normal Ranges of Clinical Laboratory Tests by Sex and Race/Ethnicity

Laboratory Test	% Missing	Male						Female					
		NHANES Reference	All (n=1,603)	White (n=608)	Black (n =425)	Hispanic (n=316)	Asian (n=254)	NHANES Reference	All (n=1,474)	White (n=552)	Black (n=419)	Hispanic (n=276)	Asian (n=227)
Albumin, g/dL	5.98	3.7-4.7	3.6-5.0	3.9-5.1	3.8-4.9	3.9-5.1	4.0-5.1	3.7-4.7	3.6-5.0	3.5-4.8	3.5-4.7	3.5-4.8	3.7-4.9
ALT*, U/L	6.01	11-47	12-80	12-87	11-64	12-102	12-76	7-30	10-56	11-58	9-41	10-62	10-47
ALP, IU/L	6.01	36-113	34-115	35-107	38-114	43-126	38-105	36-113	34-115	31-115	33-121	40-123	29-94
Basophils Percent*, %	3.61	0.1-1.6	0.0-2.7	0.0-2.7	0.0-3.2	0.1-2.2	0.0-2.0	0.1-1.7	0.0-2.5	0.0-1.9	0.0-3.0	0.0-1.7	0.1-1.8
Bicarbonate, mmol/L	6.01	22-29	21-29	21-29	22-30	22-29	22-29	22-29	21-29	21-28	20-29	20-28	21-28
BUN, mg/dL	5.98	6-23	6-21	6-21	6-20	7-22	6-21	6-23	6-21	5-22	4-20	6-22	6-18
Calcium, mg/dL	6.01	8.5-10.5	8.8-10.1	8.8-10.2	8.8-10.1	8.8-10.1	8.8-10.1	8.5-10.5	8.8-10.1	8.7-10.1	8.7-10.2	8.7-10.0	8.6-10.0
Chloride, mEq/L	6.01	102-110	99-109	98-109	99-109	99-108	98-108	102-110	99-109	98-109	99-110	100-110	98-108
CPK*, IU/L	6.14	22-334	56-805	50-534	82-997	62-805	56-1008	22-100	35-372	31-247	45-487	38-317	31-227
Creatinine*, mg/dL	5.98	0.7-1.3	0.69-1.37	0.70-1.27	0.73-1.45	0.65-1.34	0.68-1.24	0.6-1.1	0.47-1.10	0.50-1.10	0.52-1.15	0.46-0.99	0.43-0.88
Eosinophils Percent*, %	3.61	0.7-8.5	0.6-8.4	0.6-7.6	0.6-9.6	0.7-7.7	0.7-8.9	0.6-7.3	0.6-7.6	0.6-7.4	0.6-6.9	0.5-7.4	0.6-8.3
GGT*, IU/L	6.01	10-65	9-103	9-93	10-119	9-96	10-96	8-36	6-76	6-86	7-78	6-64	6-49
Globulin, g/dLa	6.11	2.3-3.5	2.1-3.8	1.9-3.5	2.3-4.4	2.1-3.8	2.1-3.8	2.3-3.5	2.1-3.8	2.0-3.6	2.5-4.1	2.3-3.8	2.4-3.8
Glucose, mg/dL	5.98	60-110	69-178	66-161	69-220	72-211	67-193	60-110	69-178	70-155	70-178	69-140	66-142
Hematocrit*, %	3.44	38.7-51.4	37.0-49.6	38.7-50.0	36.1-49.6	38.8-49.5	36.7-49.4	32.0-45.9	31.3-44.3	33.6-44.9	29.5-43.6	31.0-44.1	32.2-43.8
Hemoglobin, g/dL*	3.44	13.1-17.5	12.5-17.1	13.4-17.3	12.0-16.4	13.5-17.0	12.2-16.9	10.6-15.6	10.4-15.1	11.4-15.6	9.6-14.6	10.2-14.8	10.5-14.9
Iron*, µg/dL	6.08	50--160	41-177	46-177	34-175	40-192	43-173	40-150	20-156	28-159	17-141	17-144	31-167
LDH, U/L	6.08	93-198	86-182	87-178	87-206	83-170	87-183	93-198	86-182	86-172	89-188	85-174	83-171
Lymphocyte Percent*, %	3.61	16.1-47.9	16.0-51.3	16.0-43.5	16.8-54.2	15.6-47.8	16.5-48.8	14.1-47.6	16.3-48.5	16.2-45.3	17.1-51.3	15.2-46.1	16.7-49.6
Mean Cell Hemoglobin*, pg	3.44	26.3-34.0	25.6-34.3	28.5-34.8	24.2-34.2	27.3-34.2	22.3-34.0	24.3-33.8	23.2-34.2	26.3-34.6	21.0-33.7	23.2-33.7	22.1-33.8
MCHC*, g/dL	3.44	32.3-35.3	31.7-36.2	32.7-36.3	31.4-35.8	32.4-35.8	31.8-36.0	32.1-35.3	31.8-36.0	32.6-36.3	31.1-35.6	32.3-35.7	32.3-35.8
Mean Cell Volume*, fL	3.44	79.8-99.1	77.6-98.9	82.6-99.1	74.1-99.1	82.3-98.4	69.9-99.8	74.6-98.2	72.0-98.6	78.7-99.4	66.8-97.8	72.1-96.4	67.8-97.8
Mean Platelet Volume*, fL	3.48	6.8-10.1	6.8-10.5	6.8-10.4	6.9-10.8	6.9-10.5	6.6-10.0	6.8-10.2	6.9-10.4	6.9-10.4	7.1-10.6	7.0-10.4	6.8-10.0
Monocyte Percent*, %	3.61	4.4-13.5	3.8-12.9	3.8-12.6	3.4-12.0	4.4-12.6	3.8-11.1	3.8-11.6	3.3-11.9	3.5-12.0	3.3-12.5	3.3-11.0	3.3-10.6
Osmolality, mOsm/kga	6.01	275-295	268-286	269-285	271-286	271-286	269-285	275-295	268-286	266-285	268-287	268-286	267-286
Phosphorus, mg/dL	5.98	2.6-4.4	2.7-4.9	2.6-4.8	2.6-4.9	2.7-4.9	2.8-4.8	2.6-4.4	2.7-4.9	2.7-4.8	2.7-4.9	2.6-4.9	2.7-5.0
Platelet Count*, %	3.48	152-386	139-339	136-336	134-349	138-343	152-325	168-441	148-385	132-337	153-402	160-386	139-370
Potassium, mEq/L	6.01	3.5-5.0	3.3-4.5	3.4-4.6	3.3-4.6	3.4-4.6	3.4-4.7	3.5-5.0	3.3-4.5	3.2-4.4	3.2-4.5	3.4-4.4	3.3-4.6
RBC*, SI	3.44	4.18-5.86	4.07-5.70	4.18-5.62	3.99-5.79	4.14-5.68	4.06-5.97	3.64-5.2	3.66-5.13	3.70-5.14	3.55-5.16	3.71-5.06	3.66-5.05
RCDW*, %	3.44	11.4-14.5	11.5-14.7	11.5-14.1	11.4-15.5	11.6-14.3	11.4-14.6	11.4-16.3	11.4-17.5	11.4-16.2	11.6-18.8	11.6-18.8	11.3-15.7
SNP*, %	3.61	37.8-74.6	36.2-75.3	43.2-75.3	32.3-75.3	37.5-75.0	40.2-75.4	39.8-78.1	40.3-75.4	42.3-75.4	36.1-74.3	42.4-76.5	39.8-75.0
Sodium, mEq/L	6.01	136-144	135-143	134-142	135-143	135-143	135-143	136-144	135-143	134-143	135-143	135-142	134-143
Total Bilirubin, mg/dL	6.08	0.2-1.3	0.3-1.4	0.4-1.7	0.4-1.7	0.4-1.5	0.4-1.6	0.2-1.3	0.3-1.4	0.3-1.3	0.3-1.2	0.3-1.2	0.3-1.2
Total Cholesterol, mg/dL	6.01	<200	121-276	124-270	111-247	115-278	118-259	<200	121-276	130-297	114-286	127-274	127-278
Total Protein, g/dL	6.11	6.4-7.7	6.3-8.2	6.2-8.1	6.5-8.6	6.5-8.3	6.5-8.2	6.4-7.7	6.3-8.2	6.1-7.9	6.4-8.2	6.3-8.0	6.4-8.2
Triglycerides, mg/dL	6.04	0-1000	37-455	40-512	37-370	46-586	40-520	0-1000	37-455	42-448	30-257	32-349	35-466
Uric Acid*, mg/dL	6.01	3.6-8.4	3.8-8.8	3.9-8.7	3.7-9.0	3.7-8.4	3.9-9.1	2.9-7.5	2.7-7.1	3.0-7.2	2.8-7.5	2.7-6.7	2.7-6.8
WBC*, SI	3.44	3.9-11.8	3.7-11.7	4.0-12.2	3.4-10.6	3.8-12.3	3.8-11.7	4.1-12.9	3.7-11.9	4.1-11.9	3.4-11.4	3.9-12.0	3.9-10.8

N = 3,077. % Missing = percent of missing data. Hispanic = Mexican American or Other Hispanic. ALT = Alanine aminotransferase. ALP = Alkaline phosphotase. BUN = Blood urea nitrogen. CPK = Creatine phosphokinase. GGT = Gamma-glutamyl transferase. LDH = lactate dehydrogenase. MCHC = Mean cell hemoglobin concentration. RBC = Red blood cell count. RCDW = Red cell distribution width. WBC = White blood cell count. SNP = Segmented neutrophils percent.

All the laboratory tests in "Standard Biochemistry Profile" and "Complete Blood Count with 5-Part Differential in Whole Blood" data were utilized from the NHANES 2011-2012 Laboratory Data. Lower and upper limits of normal range were defined as 2.5th and 97.5th values in percent, respectively.

*Different reference interval by sex by the NHANES manual. If there is no distinction between sex, same reference intervals are given for male and female.

[a]Reference interval is not availabe in the NHANES manual. The common reference interval is given, exerpt from the following website, http://musom.marshall.edu/usmle/usmlelabvalues.htm. Note. According to the NHANES manual, reference intervals for most biochemistry laboratory tests were established from Tietz' textbook and reference intervals for blood chemistry laboratory tests were calculated from the NHANES data set (1999-2004) using 95% reference interval(s) determined non-parametrically, through ranking the observations and determining the lower (2.5th percentile) and the upper (97.5th percentile) reference limits. Reference intervals for blood chemistry laboratory tests are those corresponding to the age group of 19-65.

Table 3. Summary of Parameter Estimates Based on Quantile Regression Analysis										
Laboratory Test	**Parameter Estimate (Standard Error) for Lower Limit**					**Parameter Estimate (Standard Error) for Upper Limit**				
	Reference	Male	Black	Hispanic	Asian	Reference	Male	Black	Hispanic	Asian
Albumin, g/dL	3.6*** (0.05)	**0.3*** (0.05)**	-0.1+ (0.06)	-0.1 (0.07)	0.1 (0.06)	4.8*** (0.04)	**0.3*** (0.04)**	-0.2 (0.03)	0.0 (0.04)	**0.1* (0.05)**
ALT, U/L	10*** (0.4)	**2** (0.4)**	**-1* (0.5)**	0 (0.6)	0 (0.5)	58*** (7.0)	**29*** (6.7)**	-18+ (9.3)	5 (16.0)	-11 (7.8)
ALP, IU/L	31*** (1.0)	**5*** (1.2)**	2 (1.7)	**9*** (1.2)**	-1 (1.6)	112*** (4.9)	-3 (4.6)	9 (5.7)	12+ (6.7)	-11+ (6.5)
Basophils Percent, %	0.0 (0.01)	0.0 (0.00)	0.0 (0.01)	0.1 (0.04)	0.0 (0.03)	2.1*** (0.22)	0.3 (0.21)	**0.8* (0.32)**	-0.4 (0.40)	-0.4+ (0.24)
Bicarbonate, mmol/L	20*** (0.2)	**1*** (0.2)**	0 (0.5)	0 (0.4)	**1*** (0.4)**	28*** (0.0)	**1*** (0.0)**	**1*** (0.1)**	0 (0.0)	0 (0.0)
BUN, mg/dL	5*** (0.2)	**1*** (0.2)**	0 (0.5)	**1* (0.4)**	1+ (0.5)	22*** (0.8)	0 (0.8)	-2+ (1.1)	0 (1.0)	-2.0 (1.4)
Calcium, mg/dL	8.7*** (0.04)	**0.1** (0.04)**	0.0 (0.04)	0.0 (0.04)	0.0 (0.06)	10.1*** (0.04)	**0.1* (0.04)**	0.0 (0.07)	**-0.1* (0.05)**	**-0.1* (0.05)**
Chloride, mEq/L	98*** (0.5)	0 (0.4)	1+ (0.6)	**1** (0.4)**	0 (0.6)	109*** (0.2)	**-1** (0.3)**	**1* (0.5)**	0 (0.5)	0 (0.4)
CPK, IU/L	28*** (2.4)	**24*** (2.7)**	**20*** (4.6)**	**10** (3.6)**	4 (3.2)	211*** (30.9)	**408*** (52.9)**	**293*** (60.6)**	106 (91.2)	25 (103.0)
Creatinine, mg/dL	0.5*** (0.01)	**0.2*** (0.01)**	0.0+ (0.02)	**-0.0** (0.01)**	**-0.0* (0.02)**	1.1*** (0.03)	**0.3*** (0.03)**	**0.1* (0.04)**	-0.1 (0.07)	**-0.1*** (0.04)**
Eosinophils Percent, %	0.6*** (0.03)	0.0 (0.04)	0.0 (0.04)	0.0 (0.04)	0.0 (0.04)	6.8*** (0.44)	0.9+ (0.47)	0.8 (0.70)	0.0 (0.81)	**1.4* (0.58)**
GGT, IU/L	6*** (0.2)	**3*** (0.2)**	**1** (0.3)**	0 (0.5)	0 (0.4)	75*** (9.4)	**30** (10.7)**	10 (15.0)	-10 (13.7)	-13 (16.8)
Globulin, g/dL	2.1*** (0.04)	**-0.2*** (0.04)**	**0.4*** (0.05)**	**0.2** (0.07)**	**0.3*** (0.06)**	3.6*** (0.07)	-0.1 (0.09)	**0.6*** (0.16)**	0.2+ (0.11)	**0.2* (0.10)**
Glucose, mg/dL	69*** (1.5)	-1 (1.5)	1 (2.3)	1 (1.6)	-3 (3.0)	142*** (13.1)	33 (16.9)	40 (21.2)	21 (25.8)	10 (25.6)
Hematocrit, %	33.1*** (0.46)	**5.7*** (0.44)**	**-3.2*** (0.60)**	-0.8 (0.81)	**-1.8* (0.80)**	44.7** *(0.25)	**5.6*** (0.34)**	**-0.9* (0.42)**	-0.8+ (0.47)	**-0.9** (0.43)**
Hemoglobin, g/dL	11.3*** (0.19)	**2.2*** (0.18)**	**-1.5*** (0.22)**	-0.4 (0.28)	**-1.2** (0.37)**	15.5*** (0.09)	**1.8*** (0.13)**	**-0.9***(0.16)**	**-0.5***(0.15)**	**-0.5** (0.17)**
Iron, µg/dL	28*** (1.9)	**18*** (2.0)**	**-11*** (2.5)**	**-10*** (2.2)**	1 (3.7)	157*** (5.0)	**23*** (5.7)**	-13+ (6.8)	0 (9.3)	-1 (13.5)
LDH, U/L	86*** (1.5)	1 (1.7)	2 (2.1)	-1 (2.4)	-1 (2.3)	172*** (4.2)	**7*** (4.3)**	**23*** (5.5)**	0 (5.9)	-1 (8.8)
Lymphocyte Percent, %	16.2*** (0.58)	-0.1 (0.69)	0.7 (1.06)	-0.7 (0.78)	0.4 (1.11)	43.6*** (0.86)	0.5 (0.86)	**8.8*** (1.10)**	**3.5* (1.38)**	**5.6*** (1.08)**
Mean Cell Hemoglobin, pg	26.1*** (0.46)	**2.5*** (0.41)**	**-4.7*** (0.52)**	**-1.9** (0.59)**	**-5.8*** (0.89)**	34.5***(0.24)	0.4+ (0.23)	**-0.7* (0.32)**	**-0.8* (0.34)**	**-0.7* (0.32)**
MCHC, g/dL	32.6** *(0.12)	0.1 (0.11)	**-1.4*** (0.13)**	**-0.3* (0.15)**	**-0.7** (0.25)**	36.2***(0.08)	0.1 (0.10)	**-0.5*** (0.14)**	**-0.5***(0.15)**	**-0.4** (0.13)**
Mean Cell Volume, fL	77.8*** (1.26)	**5.1*** (1.17)**	**-9.0*** (1.68)**	-2.5 (1.56)	**-12.6*** (2.09)**	99.2***(0.56)	**1.4* (0.65)**	-1.4 (0.92)	**-2.5*** (0.72)**	-0.8 (1.20)
Mean Platelet Volume, fL	6.9*** (0.06)	-0.1+ (0.06)	0.1 (0.07)	0.1 (0.13)	**-0.2* (0.08)**	10.4*** (0.12)	0.0 (0.14)	0.4+ (0.21)	0.0 (0.19)	**-0.4* (0.16)**
Monocyte Percent, %	3.4*** (0.18)	**0.5** (0.18)**	-0.3 (0.21)	0.2 (0.25)	-0.1 (0.24)	11.8*** (0.29)	**1.1*** (0.30)**	1.0+ (0.56)	-0.6 (0.43)	**-1.4***(0.38)**
Osmolality, mOsm/kg	266*** (0.6)	**3*** (0.6)**	**2** (0.7)**	**2** (0.8)**	0 (0.9)	286*** (0.7)	-1 (0.6)	1 (0.7)	0 (1.9)	0 (1.4)
Phosphorus, mg/dL	2.7*** (0.06)	-0.1 (0.06)	0.0 (0.09)	0.0 (0.10)	0.1 (0.10)	4.5*** (0.05)	0.1+ (0.05)	0.0 (0.06)	-0.1 (0.07)	0.1 (0.07)
Platelet Count, %	142*** (5.6)	**-11* (4.8)**	6 (6.2)	**16* (7.6)**	15 (9.5)	378*** (8.5)	**-44*** (7.8)**	18 (14.8)	8 (9.1)	-8 (10.5)
Potassium, mEq/L	3.2*** (0.04)	**0.1** (0.04)**	0.0 (0.06)	0.1 (0.08)	0.1+ (0.10)	4.8*** (0.07)	0 (0.07)	0.1 (0.09)	0.1 (0.12)	0.1 (0.10)
RBC, SI	3.7*** (0.03)	**0.4*** (0.04)**	**-0.2** (0.06)**	0.0 (0.05)	-0.1 (0.06)	5.1*** (0.05)	**0.6*** (0.05)**	0.1 (0.07)	-0.0 (0.06)	0.4 (0.12)
RCDW, %	11.4*** (0.05)	0.0 (0.05)	0.1 (0.09)	**0.2*** (0.06)**	0.0 (0.06)	16.8*** (0.27)	**-2.8*** (0.24)**	**1.9*** (0.36)**	0.4 (0.27)	**0.6* (0.30)**
SNP, %	42.9*** (0.78)	-1.9+ (1.00)	**-8.2***(1.16)**	-2.7+ (1.59)	-2.3+ (1.31)	75.4*** (0.72)	-0.1 (0.86)	-0.7 (1.24)	0.0 (0.95)	0.1 (1.36)
Sodium, mEq/L	134*** (0.3)	0 (0.4)	**1** (0.4)**	1+ (0.6)	1 (0.7)	143*** (0.3)	0 (0.2)	0 (0.4)	0 (0.6)	0 (0.4)
Total Bilirubin, mg/dL	0.3*** (0.00)	**0.1*** (0.00)**	0.0 (0.00)	0.0 (0.01)	0.0 (0.04)	1.3*** (0.07)	**0.4*** (0.08)**	-0.1 (0.10)	-0.2 (0.11)	-0.1 (0.10)
Total Cholesterol, mg/dL	130*** (2.4)	**-6* (2.8)**	**-13*** (3.7)**	-8+ (4.1)	-4 (5.0)	293*** (7.0)	**-23*** (6.0)**	**-18*** (8.8)**	-6 (8.3)	-14+ (7.4)
Total Protein, g/dL	6.1*** (0.06)	**0.1* (0.05)**	**0.3*** (0.06)**	**0.2* (0.08)**	**0.3*** (0.06)**	7.9*** (0.05)	**0.2*** (0.06)**	**0.3** (0.12)**	**0.2** (0.07)**	**0.2** (0.07)**
Triglycerides, g/dL	38*** (1.8)	**6** (2.0)**	**-7** (2.3)**	-2 (2.9)	-2 (2.8)	423*** (32.8)	**94** (29.2)**	**-165*** (31.4)**	-7 (55.1)	20 (62.1)
Uric Acid, mg/dL	2.9*** (0.11)	**1.0*** (0.12)**	-0.1 (0.15)	-0.2 (0.23)	-0.1 (0.16)	7.2*** (0.15)	**1.6*** (0.16)**	0.2 (0.30)	-0.4 (0.26)	-0.3 (0.23)
WBC, SI	4.1*** (0.11)	-0.1 (0.10)	**-0.7*** (0.11)**	-0.2 (0.21)	-0.2 (0.13)	12.1*** (0.42)	-0.0 (0.45)	**-1.0* (0.51)**	-0.1 (0.61)	-0.9 (0.69)

Hispanic = Mexican American or Other Hispanic. Reference = White female. Lower and upper limits of normal range were defined as 2.5th and 97.5th values in percent, respectively.
ALT = Alanine aminotransferase. ALP = Alkaline phosphotase. BUN = Blood urea nitrogen. CPK = Creatine phosphokinase. GGT = Gamma-glutamyl transferase. MCHC = Mean cell hemoglobin concentration. RBC = Red blood cell count. RCDW = Red cell distribution width. WBC = White blood cell count. SNP = Segmented neutrophils percent.
+$P < .10$. *$P < .05$. **$P < .01$. ***$P < .001$.
Note. Unweighted quantile regression was fitted for each analyte adjusting for sex and race/ethnicity. A bootstrap resampling method with 1,000 bootstrap samples was applied to compute the standard errors of parameter estimates. Female white was the reference group. Weighted quantile regressions accounting for the NHANES complex sampling design provided similar results (not shown).

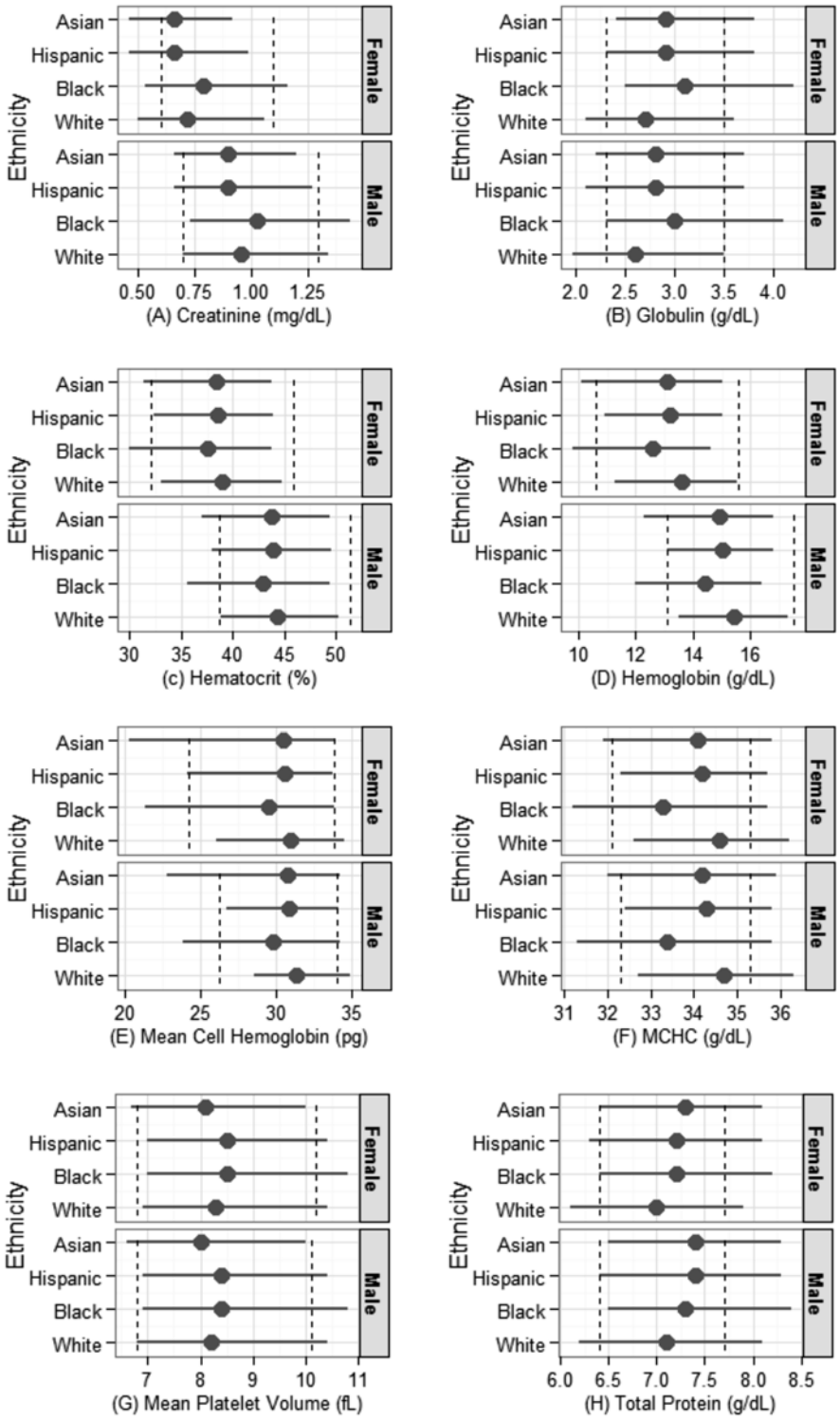

Figure 1. Normal Ranges of Selected Laboratory Tests Adjusted for Sex and Race/Ethnicity.
Dashed lines are the reference intervals for each laboratory test based on the NHANES laboratory manual. The horizontal line represents the lower and upper limits of normal range for the subpopulation and the dot on each line represents the estimated median value based on a median analysis. Lower and upper limits of each normal range are the estimated 2.5th and 97.5th values in percent by sex and race/ethnicity, respectively.

Discussion

Comparing major racial/ethnic subpopulations in the United States, our study aimed to explore whether the use of racial/ethnic-specific RIs is reasonable for common laboratory tests. For this purpose, we used the NHANES 2011-2012 data, a representative nationwide sample, which includes Non-Hispanic Asian as a separate racial/ethnic category. According to the 2010 US Census. Asians alone grew by 43.3 percent from 2000 to 2010.[20] As a result, the NHANES oversampled Asians in its 2011-2012 data in order to compare Asians with other racial/ethnic groups.

Even though researchers have acknowledged racial/ethnic differences in RIs for some laboratory tests since the early 1970's,[6,8] no racial/ethnic-specific RIs have been developed for clinical settings in the United States. Hence, it is important to evaluate whether a single RI for everyone is appropriate, especially in a multiethnic country like the United States. Laboratory tests play a critical role in physicians' clinical decision-making. According to one study, about 60-70% of all clinical decisions regarding a patient's diagnosis and treatment, hospital admission and discharge are made based on laboratory test results.[21] Ignoring the natural variations in the distributions of laboratory test results among racial/ethnic groups could contribute to, among other things, disease misdiagnosis. For example, our study indicated that Asians had lower normal ranges for creatinine than the textbook RI. If our estimated normal ranges are close to true RI for this racial/ethnic group, many healthy Asians with lower creatinine would be considered as having muscle or nerve problems (eg, myasthenia gravis, muscular dystrophy)[22] and clinicians may order unnecessary MRI or biopsy to make a clinical diagnosis. Similarly, our study found that blacks have significantly lower values than whites in hematocrit, hemoglobin, mean cell hemoglobin, and MCHC.[17] According to the study on Tanzanian children by Buchanan, et al, (2010), about 20% of healthy Tanzanian children would be misclassified as having an adverse event related to hemoglobin if the US National Institute of Health Division of AIDS adverse event grading criteria were applied.[23] The development of racial/ethnic-specific RIs for common laboratory tests, therefore, may be important for reducing inaccuracies and misdiagnosis so that treatment can be conducted in a timely manner and patients' health status can be better monitored.

The significant difference between American Asians and whites warrants further discussion. Compared to whites, Asians have lower RIs in creatinine, hematocrit, hemoglobin, mean cell hemoglobin, MCHC, and mean platelet volume and higher normal ranges in globulin and total protein. Asians are the fastest growing population in America, hence, the development of Asian-specific RIs for these laboratory tests may be valuable. This finding is also important to a state like Hawai'i where a significant Asian population exists. Hawai'i's Asian population is unique and diverse, with 57.4% of the state population self-identifying as Asian alone or in combination.[20] More specified diverse Asian groups may need to be considered when developing RIs. According to the 2009 Asian multicenter study for derivation of reference intervals, Ichihara, et al, found significant regional differences in Asian countries among 11 of 40 laboratory tests.[24,25] To our knowledge, there are no published studies comparing the RIs between Asian subpopulations in Hawai'i or on the mainland. Studies showed that RIs of common laboratory tests tend to vary among people who are usually assigned into the same ethnic or racial group.[2,25,26] Therefore, it is anticipated that different Asian populations in Hawai'i may have different distributions of laboratory tests. Our future work is to develop racial/ethnic-specific RIs for Hawai'i residents and compare those with the RIs reported in the literature.

Our study revealed some findings that are inconsistent with previous studies. For example, a shift in platelet count among US blacks was not detected, as observed in a study among blacks in Gambia.[16] This inconsistent result may be attributed to dissimilarities in nutritional status (eg, Western diet style) or regional factors (eg, no malaria infection that may increase platelet count), among other things. Also, utilizing 33 laboratory tests in the NHANES III, Horn and Pesce (2002) suggested combining Hispanics and whites.[27] Our current study, however, showed significant differences in some laboratory tests (ie, mean cell hemoglobin, MCHC, total protein) between Hispanics and whites.

Interestingly, for some laboratory tests (eg, albumin, bicarbonate, calcium, total bilirubin, total cholesterol, and total protein), our analysis results indicate that sex-specific RIs may be more appropriate even though the NHANES provides a single RI for both male and female. Recent studies also reported significant sex differences in albumin,[28] total bilirubin,[28,29] and cholesterol[28,30] among healthy adults in Africa and East Asia. Further study may need to be conducted to address whether sex-specific RIs are relevant for these laboratory tests.

This study has several limitations. First, self-reported health status was used to define healthy adults instead of using other more objective criteria (eg, medical history, medication). Based on the evaluation of laboratory tests, a simple exclusion criterion that could be used to define healthy adults for all 38 laboratory tests was not found. Thus, for simplicity, we selected participants who reported they were healthy. According to Cheng, et al, (2004), however, derivation of RIs in clinical chemistry can be straightforward.[13] A simple set of interview questions (eg, body mass index, smoking, drinking, etc) complemented with glucose and creatinine testing can usually exclude most patients with chronic or acute disease. In addition, one well-known problem of self-reporting is response bias which can impact the validity of our results.[31] We found that more whites and Asians reported their health status as "Excellent" or "Very Good" than blacks or Hispanics did. Although self-reported current health status was shown to have good reliability[32] and predictive validity,[33-36] future investigations will be needed to evaluate the validity of NHANES self-reporting health status to ensure the generalizability of our study results. Second, there are missing values in the laboratory tests. For instance, we found blacks and Asians have more missing laboratory tests ($P < .001$). Although the missing rates were relatively small (< 7%), these

unbalanced missing rates could affect our findings. Along with the response bias due to self-reporting, this can also impact the generalizability of our results.

Our findings highlight the complexity of developing RIs. Potentially, racial/ethnic-specific RIs will reduce misdiagnosis, over- and under-estimation of disease prevalence rates, the failure or delay in the required reporting of critical laboratory values;[12] however, further work is needed to validate these benefits. Physicians and other healthcare providers use the laboratory test results to track clinical outcomes and make clinical decisions,[37,38] to screen asymptomatic people and to identify those at risk and for early detection of diseases.[39,40] Therefore, accurate RIs for for laboratory tests are important for patients and their caregivers to monitor their health and disease progress. Further work will be necessary to evaluate the impact of using racial/ethnic-specific RIs to improve health outcomes.

Conclusion

Inter-racial/ethnic differences are usually not reflected in the widely adopted RIs, which would potentially result in lower quality healthcare and unnecessary high healthcare costs. Racial/ethnic-specific RIs for clinical laboratory tests may help improve disease diagnosis, allow for better tracking and monitoring of one's health status, facilitate clinical decision making and improve healthcare in general.

Conflict of Interest

None of the authors identify any conflict of interest.

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Liaison Committee on Medical Education Accreditation: Part I: The Accreditation Process

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The John A. Burns School of Medicine at the University of Hawai'i at Manoa is scheduled to undergo its Liaison Committee on Medical Education (LCME) accreditation visit in early 2017. This article is the first in a series that will address various aspects of the LCME accreditation process. In this initial installment, we will provide an overview of the LCME accreditation process—from preparation and organization through the actual site visit and notification of the LCME accreditation decision. The goal is provide a preview of the important work that will need to be done in preparation of the upcoming accreditation site visit.

Future articles in this series will take a more detailed look at a number of related accreditation issues. These will include descriptions of the JABSOM Graduation Objectives, Educational Philosophy, Program Evaluation process, Student Wellness programs, Pipeline programs, Faculty Development, Curriculum Management, and Clinical Supervision. We anticipate that these will be published here in the *Hawai'i Journal of Medicine and Public Health* on alternate months moving forward.

"Imagine you are sitting in your office reading e-mail. A message appears in your in-tray with the subject "LCME Site Visit." The message says that JABSOM's accreditation visit will take place from January 29th – February 1st in the year 2017. You reflect on the importance of LCME accreditation and the completion of some important tasks such as the Data Collection Instrument (DCI), the Independent Student Analysis (ISA), and the Self-Study Summary. You recall there are 12 LCME accreditation standards."

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, medical students or graduates from LCME-accredited programs are allowed to sit for the United States Medical Licensing Examination (USMLE). Graduation from an LCME-accredited medical school and passing the USMLE exam are accepted as prerequisites for licensing in most states. 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 such as Title VII student loan programs.[1,2]

The LCME Accreditation Standards

There are twelve LCME standards, each encompassing numerous sub-standards that schools must meet.[3]

Standard 1: Mission, Planning, Organization, and Integrity
Standard 2: Leadership and Administration
Standard 3: Academic and Learning Environments
Standard 4: Faculty Preparation, Productivity, Participation, and Policies
Standard 5: Educational Resources and Infrastructure
Standard 6: Competencies, Curricular Objectives, and Curricular Design
Standard 7: Curricular Content
Standard 8: Curricular Management, Evaluation, and Enhancement
Standard 9: Teaching, Supervision, Assessment, and Student and Patient Safety
Standard 10: Medical Student Selection, Assignment, and Progress
Standard 11: Medical Student Academic Support, Career Advising, and Records
Standard 12: Medical Student Health Services, Personal Counseling, and Financial Aid Services

The Data Collection Instrument

The Data Collection Instrument (DCI), previously called the educational database, consists of an extensive list of questions that require narrative responses and tables requiring completion. The questions are related to each of the standards. The DCI report must be completed by an agreed upon date and forwarded to the LCME accreditation team which reviews it prior to arriving at the host school. To illustrate the depth and breadth of DCI questions, some examples are shown below.[4]

Standard 1.1: Strategic Planning and Continuous Quality Improvement

A medical school engages in ongoing planning and continuous quality improvement processes that establish short and long-term

programmatic goals, result in the achievement of measurable outcomes that are used to improve programmatic quality, and ensure effective monitoring of the medical education program's compliance with accreditation standards.

- Provide the mission and vision statements of the medical school.

- Describe the process used by the medical school to establish its most recent strategic plan, including the school's mission, vision, goals, and associated outcomes. How often is the strategic plan reviewed and/or revised?

- Describe how and by whom the outcomes of the school's strategic plan are monitored.

- Describe how the medical school monitors ongoing compliance with LCME accreditation standards. The response should state which standards are monitored, how often compliance is reviewed, what data sources are used to monitor compliance, and which individual or groups receive the results.

Standard 6.3: Self-Directed and Life-Long Learning
The faculty of a medical school ensures that the medical curriculum includes self-directed learning experiences and time for independent study to allow medical students to develop the skills of lifelong learning. Self-directed learning involves medical students' self-assessment of learning needs; independent identification, analysis, and synthesis of relevant information; and appraisal of the credibility of information sources.

- Describe the learning activities, and the courses in which these learning activities occur during the first two years of the curriculum, where students engage in all of the following components of self-directed learning as a unified sequence (use the names of relevant courses and clerkships from the Overview tables when answering):
  - Identify, analyze, and synthesize information relevant to their learning needs
  - Assess the credibility of information sources
  - Share the information with their peers and supervisors
  - Receive feedback on their information-seeking skills

- Describe the amount of unscheduled time in an average week available for medical students to engage in self-directed learning and independent study in the first two years of the curriculum.

- Describe the content of any policy covering the amount of time per week that students spend in required activities during the preclerkship phase of the curriculum. Note whether the policy addresses only in-class activities or also includes required activities assigned to be completed outside of scheduled class time. How is the effectiveness of the policy or policies evaluated?

The Independent Student Analysis

The Independent Student Analysis (ISA) is a self-study process led by medical students.[5] They create a survey to be completed by all medical students that addresses various aspects of the medical education program, student services, learning environment, and the adequacy of educational resources. The results are analyzed and synthesized by the students into a report that is shared with the medical school administration and the LCME site visit team. Although medical school officials can provide logistical support and technical advice to students to help them conduct their survey and analyses, they must not participate in the development of the student survey, in the analysis of survey data, or in the preparation of the independent student analysis report. The overall survey and analysis should address the following areas:

- Accessibility of dean(s) and faculty members
- Participation of students in medical school committees
- Curriculum, including workload, organization, instructional formats and adequacy of content, balance between scheduled class time and time for independent learning
- Student assessment, including quality and timeliness of feedback
- Opportunity for the evaluation of courses or clerkships and teachers, and whether identified problems are corrected
- Student support services and counseling systems (personal, academic, career, financial aid), including their accessibility and adequacy
- Student counseling and health services, including their adequacy, availability, cost, and confidentiality
- Availability and cost of health and disability insurance
- The learning environment, including policies and procedures to prevent or respond to mistreatment or abuse
- Facilities, including quality of educational space, availability of study and relaxation space, security on campus and at affiliated clinical sites
- Library facilities and IT resources, including access to and quality of holdings and information technology resources.

The Institutional Self-Study

The Institutional Self-Study (ISS) is a process that brings representatives from the school's administration, faculty, student body, and other constituencies together to review the data gathered in the Data Collection Instrument and Independent Student Analysis.[6] This information is used to generate a summary report guided by a list of questions that evaluates the quality of the medical education program and the adequacy of the resources to support it. Institutional strengths and weaknesses are also identified at this time. Self-study reports are mandated by the US Department of Education in all accreditation processes.[7] Examples of self-study questions are provided below.

Standard 7: Curricular Content
Evaluate whether the curriculum includes sufficient experiences to ensure that students develop skills in medical problem-solving and evidence-based clinical judgment.

Standard 8: Curriculum Management, Evaluation, and Enhancement
Does the central committee responsible for the curriculum have appropriate responsibility and authority for overseeing and approving the design, management, and evaluation of the curriculum to ensure that it is coherent, coordinated and integrated horizontally and vertically? Is this authority codified in institutional bylaws and/or policy? Is there evidence that this authority is being appropriately exercised?

Standard 10: Medical Student Selection, Assignment and Progress
Critically review the medical school's criteria for admission and the process for the recruitment and screening of applicants and the selection of students. How are the medical school's selection criteria reviewed and validated in the context of its mission and other mandates? Are the criteria for admission, including technical standards, available to potential applicants and their advisors?

Standard 12: Medical Student Academic Support, Career Guidance, and Educational Records
Evaluate the effectiveness of the medical school's system for early and ongoing identification of students in academic difficulty and of the counseling and remediation processes in place for all students. Comment on the level of academic difficulty and student attrition in relation to the school's academic advising and support programs.

Timeline for the LCME Accreditation Preparation Process

"As you consider how to galvanize the faculty and staff of JABSOM to meet this challenge, you reflect on the LCME accreditation timeline established by the LCME Planning Committee."

April 2015 — Students prepped on the Independent Student Survey

May 2015 — JABSOM team begins work on the DCI

July 2015 — Students begin creation of the Survey

September 2015 — Students distribute the survey to their colleagues

December 2015 — Students present the results and analysis of their survey to the school DCI completed

January 2016 — DCI and ISA are distributed to the Self-Study Task Force

September 2016 — DCI, ISA, and Self-Study Summary Report submitted to the LCME

January 2017 — LCME accreditation site visit at JABSOM

June 2017 — JABSOM receives the accreditation decision by the LCME

Preparing for the LCME Site Visit: Tips for Success

"You sit down with other members of the planning team and review a list of key principles and practices that will help you prepare for the site visit…"

- In the period leading to the site visit and during the visit, the JABSOM team will need to be prepared to promptly respond to requests and questions from the LCME site visit team.
- The team should be careful to follow the LCME guidelines for the submission of any updates to the DCI and self-study.
- All groups should be prepped for their sessions prior to the visit and should be provided with reminders in gatherings before their session.
- Students should be prepared for their role in meeting with site visitors. While students must answer questions honestly, it is appropriate for them to be reminded of how the school has attempted to address student concerns and address related LCME standards. They are often asked if they are aware of key policies and procedures set by the school and whether their educational experience matches that described in the DCI and self-study.
- Similarly, participating faculty should also be prepared for their roles in meeting with the site visit team. The faculty should be able to conceptualize the means by which students are taught, supervised, and evaluated. They should also be able to articulate the responsibilities they have in developing the curriculum and advising students.
- Approximately two weeks before the visit, the school should hold practice sessions with the participating faculty and students. These sessions might include a "mock session" and reminders about how the medical school has addressed the various LCME standards.

What to Expect During the Actual Site Visit

"The formal site visit has begun. You are asked to be one of the individuals at a meeting with the LCME site visit team related to the section on Curriculum Management…"

The LCME accreditation site visit will be organized around a series of meetings between JABSOM faculty, administration and students and a small team of LCME site visitors. Samples of possible questions that might be asked at a session regarding Curriculum Management:

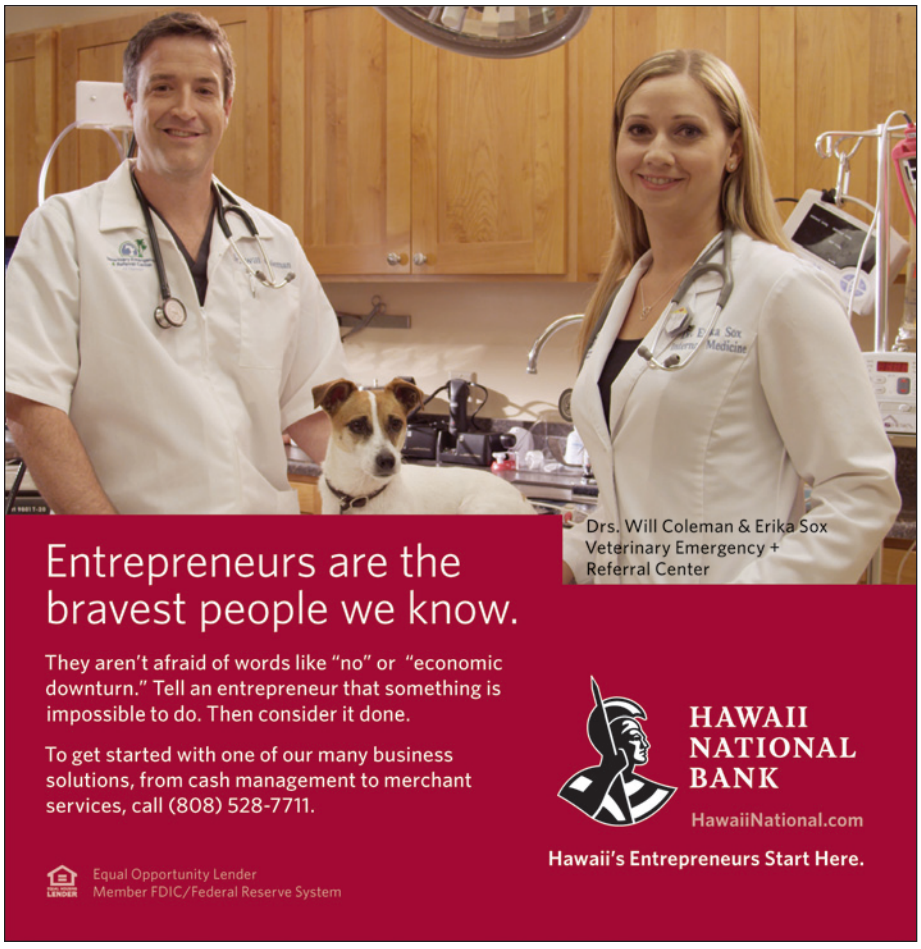
- How are the educational objectives of the curriculum determined and how they are integrated throughout the four-year medical student curriculum? What are the related desired outcome measures, and how are they monitored?
- How are the required disciplines and subject areas covered in the curriculum?
- What instructional methods and student assessment strategies are used to ensure the achievement of the school's objectives?
- How are resident physicians prepared for teaching and assessing students?
- Describe the system for implementation and management of the curriculum. Are there adequate resources to support the educational program and its management?
- What methods are used for evaluating the effectiveness of the educational program?
- Is there evidence that demonstrates the comparability of educational experiences at all clinical training sites?

After the Site Visit

At the end of the final day of the site visit, the LCME site visit team will meet with Dean and campus leadership (usually the UH Manoa Chancellor) to provide their initial feedback.[8] A draft document will be shared subsequent to the site visit to allow the medical school to address potential errors of fact. The site visitors will then complete a formal report that will be submitted to the LCME for their discussion and formal determination of accreditation status. The medical school will receive a letter of notification from the LCME roughly six months after the site visit has been completed.

Final Thoughts

The LCME accreditation process is a critically important endeavor for any medical school. It requires the concerted efforts and meaningful contributions of the entire medical school community, including faculty, administrators, students and community partners. The ultimate goal of the process is not only accreditation itself, but rather to ensure that the medical school is providing the best possible educational experience for its current and future students. In doing so, the medical school will continue to contribute to the betterment of the health of the people of Hawai'i, and fulfill its mission of achieving excellence and leadership in educating current and future healthcare professionals and leaders.



"As you read through the accreditation letter from the LCME, you can't help but feel proud to have been an active participant in the accreditation preparation and site visit. You realize that the collective efforts of the JABSOM team will benefit current and future medical students, and the patients and communities they will go on to serve as graduates of the John A. Burns School of Medicine…"

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Food Waste in Hawai‘i: A Global Problem Manifested Locally

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Insights in Public Health is a monthly solicited column from the public health community and is coordinated by HJMPH Contributing Editors Tetine L. Sentell PhD from the Office of Public Health Studies at John A. Burns School of Medicine and Donald Hayes MD, MPH from the Hawai‘i Department of Health in collaboration with HJMPH Associate Editors Tonya Lowery St. John MPH and Lance K. Ching PhD, MPH from the Hawai‘i Department of Health.

The State of Hawai‘i imports more than 92% of its food[1] including 90% of our beef, 67% of our vegetables, 65% of our fruit and a staggering 80% of our milk.[2] Despite having an agricultural industry that is capable of supplying the local need for produce, 40% of produce in the state is left in fields un-harvested or sent to the landfill as unsellable waste.[3] Hawai‘i generates more than 164,000 tons of food waste a year.[4] This is not a local phenomenon; food waste on a global scale is astronomical. According to the US Environmental Protection Agency, food waste is second only to paper in terms of volume wasted.[5] Yet, while over 60% of paper is recycled, only 3% of food waste is efficiently reused.[5] This level of waste has economic, social and environmental impacts that are increasingly difficult to ignore. Global concerns like hunger, obesity, food scarcity, and climate change have brought the issue of food waste to the forefront of international discussions.

In 2012 alone, more than 36 million tons of food waste was generated globally, with only five percent diverted from landfills and incinerators for composting.[5] This level of waste is occurring in a world where almost 1 billion people go hungry every day.[6] In Hawai‘i, a state in which 19.2% of households are food insecure on a daily basis, the last comprehensive report by the City and County of Honolulu noted that 25,000+ tons of food waste are disposed of at the Waimanalo Gulch each year.[7-8]

Hawai‘i is unique given its geographic isolation, the high shipping costs, dependence on imported food, and large visitor industry and military presence. How do we creatively decrease our reliance on imported food, encourage the consumption of locally grown produce, support the local agricultural industry, transform cosmetically imperfect produce into value-added products, and use modern food rendering techniques to make the most value from what is produced in our state? In order to curb food waste, Hawai‘i must develop more efficient practices and policies including new methods of food distribution, waste recycling and rendering, embracing off-grade produce and make them marketable and attractive to the food industry and consumers. Creatively curbing food waste can potentially inspire new opportunities for economic development through the promotion of value-added products.

Sources of Food Waste

Identifying sources of food waste is critical. Crop shrink is a metric that evaluates the difference between the volume of edible crops available to be harvested and the actual volume that is sold for human consumption.[9] The shrinkage can happen at a variety of stages along the production line. A crop can be eliminated prior to harvest (pre-harvest shrink), can remain in the field/orchard post harvest due to cosmetic grading (in-situ culls), and lastly, once it leaves the field/orchard it can be eliminated at the packing facility and therefore never makes it to the store.[9]

One contributing element to crop shrink is the developed world's obsession with cosmetically perfect looking fruit and vegetables. Consumer demand for perfect looking produce has resulted in a system from farm to store that eliminates 40% of all food produced and upwards of 60% of common crops.[9] This amounts to $165 billion in wasted produce annually.[9] It is important to note that consumers are not solely responsible for this waste due to their discerning eye. The concept of "ideal" food has been slowly formed over time through government policy (USDA regulations require produce to be 90% blemish-free) and marketing.[10] We have been programmed to believe that perfect fruit not only tastes better but is better for us. Both of these assumptions are entirely wrong. Decades of preferential breeding for uniformity and resiliency has basically resulted in mainstream produce that is nutritionally deficient and lacks flavor. Organic farming that produces heartier varieties of produce that are not necessarily aesthetically perfect and need not travel so far to the consumer is one way that farmers are avoiding dreaded losses and returning flavor and nutrients to the consumer.

Reducing Food Waste

Reducing food waste in Hawai‘i is not a new concept. In January of 1997, the Honolulu City Council passed Ordinance 96-20 that requires large hotels, restaurants, grocery stores, hospitals and food manufacturers/processors to recycle food waste.[11] While there are costs incurred to separately collect the food waste, waste disposal costs are lowered by weight

thus allowing businesses to actually reap economic rewards from being food waste conscious. While it is "law," ensuring compliance is impossible since participation is voluntary not mandatory. The Department of Environmental Services admits that the amount "of food waste to recycle may depend on upon your company's commitment to community service, economic benefit, and availability of recycling service."[11] Given the scale of Hawai'i's food waste problem, the soft approach is too permissive. The beginnings of addressing the issue have been present on Hawai'i's law books for almost 20 years however enforcement has not.

Locally-Grown Initiatives

To meet the challenges presented by food waste, multi-faceted, public-private, creative schemes must be developed. In Hawai'i there are a number of local initiatives that are finding ways to tackle the complicated issues regarding food waste. They range from food re-distribution warehouses and airfreight discounts, to waste-to-soil amendment products.

The Hawai'i Food Basket is a local example of an organization that is seeking to reduce food waste by channeling off-grade/surplus produce into the hands of those who need it most. This Hawai'i Island initiative serves as a clearinghouse for all kinds of foods so that local farmers and retailers can "discard" their surplus through the Food Basket to needy individuals and families and those who are disabled or ill.[12] Another local example of a food aggregator is the KTA Superstores on Hawai'i Island. Begun over 20 years ago when the Hawai'i sugar industry was in decline, KTA committed to saving local farms. They now support 80 farms that produce 285 different products from local milk, eggs, and beef to produce and value added products like bread and cakes.[1] These food hubs and retailers also serve as distribution centers for smaller-scale farmers by aggregating and delivering the produce to larger retailers and restaurants. They give smaller farms access to large retailers that they would not otherwise have access to and thus reduce crop waste. In addition, these wholesalers allow farmers and retailers to have fewer buyers to negotiate with, reduce their transportation costs, offer reliable cold storage, and provide marketing expertise.

Another example of a local initiative that is offering creative ways to encourage the use of off-grade produce is the No Waste Project (aka Chefs *Huli Hui*). This innovative project seeks to connect local farmers and manufacturers who have surplus/off-grade produce with restaurants, schools, and other food service providers who can quickly take the produce off their hands.[3] The aim is to encourage local farmers to continue producing healthy locally grown products and reduce food waste at the same time.

The Farm-to-School concept is also an important way to reduce food waste. This concept is not a new one, but has met a number of barriers in Hawai'i ranging from insufficient produce to supply all of Hawai'i's public schools equally and the budget prohibitions that disallow schools to make any budgetary sacrifices in order to buy locally. Most importantly however is the difficulty that many local farms have meeting food-safety guidelines. This also applies to school gardens whose produce cannot be eaten on campus. One exception are charter schools that are exempt from some of these rules and could be the ideal place to pilot successful farm-to-school programs. State support should continue and schools can work towards establishing food safety guidelines so they can actually eat the food they grow. A study conducted by the University of California at Berkley found that children who engaged in school gardening programs were not only more versed in the importance of food and nutrition and the environment but they also consumed between 1-2 servings more of fruits and vegetables daily.[13-14] The long-term impact of school gardening and cooking programs is measurable. In July 2015, Governor Ige signed SB 376 (Act 213) – Relating to Farm to School Program, into law.[14] The bill creates a Farm to School program along with a coordinator position within the Department of Agriculture to oversee the process of procuring local agriculture for Hawai'i's schools.[14] The impetus behind the bill was not to address food waste but rather to encourage children to understand their food sources and eat more fruit and vegetables. Nevertheless, it is a step towards addressing one of the underlying causes of food waste in the state.

Farmers' Markets

Public-private partnerships are key to the success of any program that seeks to encourage the growth and viable use of all locally grown produce. Land is a valuable commodity in Hawai'i and is an issue that constantly puts agricultural interests at odds with developers responding to calls for more housing. However, one successful partnership was established with Aloha Air Cargo and the Hawai'i Farm Bureau Federation. Neighbor island farmers can receive a 35% discount on airfreight services, making it more affordable to bring their produce to market both here in Hawai'i and off-island.[15] The recent growth in farmers' markets in Hawai'i has been impressive. The USDA cites that Hawai'i is one of the top ten states for growth of farmers' markets in the last 10 years, with over 25 farmer's markets currently on Oahu alone serving over a million consumers annually.[16] In addition to the obvious health benefits of eating fresh produce that is locally grown, farmers' markets are the ideal venue for farmers to sell their surplus as well as off-grade and value-added produce at a lower cost to buyers. First established in Kalihi in 1973, the People's Open Market Program was specifically designed to "*support the economic viability of diversified agriculture and aquaculture in Hawai'i by providing market sites for local farmers, fishermen…to sell their surplus and off-grade produce…at low cost…and provide a focal point for residents to socialize*."[17]

Value-added products using off-grade produce can range from fruit butters, leathers and jams to soups and juices to instant *kulolo* from dried unsold poi, to baked goods and frozen foods. Given Hawai'i's growing popularity of farmer's markets and the Made in Hawai'i show, there is most certainly an outlet for off-grade produce that can be sold below market cost or even given gratis to the manufacturer that still allows some profit to the farmer, reduces the amount of food deposited in landfills,

and fills a niche economic market. Additionally, because the produce used is cheaper to acquire, the cost of end products can be priced for the local market, making them more affordable than the imported alternative. The aforementioned KTA Superstores has adopted this model and has created its own brand (Mountain Apple Brand) that has multiple value-added products that use off-grade ingredients.[1]

Food Waste into Energy

Along with the economic and social benefits of reducing food waste there are the environmental benefits of preventing millions of tons of human-related, methane producing food waste from reaching our landfills. According to the EPA, 20% of all methane produced in American landfills is from food waste.[18] This is in addition to the considerable energy (water, pesticides, fertilizers and energy) expended to produce food that is unsold. Using food waste by recycling it into compost that improves soil health, also known as "soil amendment," is one efficient remedy for food waste. Another is to turn it into renewable energy. Hawai'i, being very dependent on imported oil for our energy needs, should be at the forefront of these kinds of initiatives. Two such initiatives exist on Oahu. The Sand Island Waste Water Treatment Plant processes food waste into fertilizer pellets. Begun in 2009, the plant can now divert 25% of landfill waste into pellets.[7] The Kailua, Wahiawa, and Honolulu Waste Water Treatment Plants has contracted with Hawaiian Earth Products to turn 100,000 tons a year of green, food, and sewage waste into a marketable soil amendment product.[7]

Future Possibilities

The environmental, economic, and social consequences of unrestrained food waste are difficult to ignore and any Hawai'i effort to curb waste must be approached from all three angles. Local and government level initiatives that feed the food insecure, curb crop waste, find value in off-grade produce and turn waste into energy are making a slow but important start towards reducing food waste on a global scale. The geographic isolation and relatively small population that makes Hawai'i unique also creates an opportunity for making inroads into increasing self-sufficiency and reducing food waste that can be modeled elsewhere. A number of Hawai'i-grown organizations are attempting to address food waste on their own (eg, *Ulupono*, *Huli Huli*, KTA). However there are few state-wide, government led policy-level initiatives that seek to address the larger environment, social, and economic aspects of the issue in order to give it the attention it needs. If approached from the economic enhancement perspective, it is easier to get government and industry to buy into policies and programs that enhance the production of local food and fund local and larger food distribution hubs; however it is often not enough. An increase of local production of food of only 10% could employ thousands and keep valuable resources in-state.[2] Valuing off-grade produce by channeling it into schools, the hospitality industry, and the military is another way that food waste can be reduced. Offering tax incentives for food donations from farms, distribution hubs, retailers, hotels, restaurants, the military, is another. Supporting farmers with tax incentives for harvesting their entire crop and then donating the surplus and off-grade product to food banks or other food distribution hubs can also curb waste.

Losses in production, distribution, retailing, and at the household level can be minimized by setting targets and making people/retailers/restaurants/hotels/farmers accountable to them. A state-wide goal, a food waste reduction of 15% for example, can then be used as an impetus for all sectors of society to evaluate how they contribute to food waste and what they can do to address it. An effort of this kind takes coordination between multiple government agencies (Health, City and County, Education, Finance, Military) and private sector agencies like the Hawai'i Farm Bureau, Tourism Authority, and the Hawai'i Restaurant Association. If the European Union can be united enough to agree to tackle food waste,[19] then surely the State of Hawai'i can do the same. A joint effort that focuses on increasing food donations to food banks/needy populations and decreasing landfill-bound food waste is a promising place to start addressing the larger issues. Government-led initiatives, like those established by the European Union, to reduce food waste by 50% by 2020 can be looked at as models that states like Hawai'i can follow.[19] If Hawai'i accepts that the reduction of food waste is a "*pono*" thing to do because of its social (ethical), economic, and severe environmental impacts then it is in a better position than the national government that does not have any stance on food waste at all. For example, if the Hawai'i Restaurant Association sets guidelines to encourage proprietors to purchase off-grade produce this could have a major impact on the 40% of crops that go unsold each year. Growing the distribution channels for cosmetically imperfect produce is significant. Public waste management companies are often at the forefront of recycling programs. Hawai'i is no exception. With the City and County of Honolulu already pursuing innovative soil amendment and energy-transforming efforts, they are an excellent choice to lead the environmental charge against food waste.

Lastly, public education is key to any initiative. Children in local schools should be required to have gardens to emphasize the value of fresh foods. Campaigns to inform consumers about the value of eating cosmetically imperfect produce, similar to the *Ugly Fruits and Vegetables* and *Feed the 5000* campaigns in Europe, would be useful, particularly if combined with an effort by locally owned and operated supermarkets (Foodland, KTA, etc) to sell off-grade produce at a discount. Once Hawai'i consumers learn to value their food, they are more likely to buy local, in smaller quantities, and embrace "off-grade" produce as equal in taste and nutrition. In Hawai'i's burgeoning foodie scene, restaurants and higher-end retailers can go a long way to promote the value of local and off-grade produce by proving that they can be equally delicious and nutritious as their imported counterparts.

Conclusion

Food waste is a global problem that can be solved at the local level. Hawai'i is in an exceptional position to make inroads into its own food waste problem. Given our geographic isolation, reliance on imported food, environmental vulnerability, high percentage of population being food insecure, and the luxury of rich soil and a longer growing season, we have no excuse not to make swift changes that can have real impact. Coordinated efforts between government and industry can go a long way to set the example needed to educate the public about food waste so that the issue is addressed from the individual onwards. It is possible to reduce food waste, protect the environment and feed the hungry without sacrificing the economic viability of the consumer, the producer or the retailer. This should be a social policy priority.

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Provider Status for Pharmacists: Why it Matters for Other Healthcare Providers

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Background

Pharmacists are authorized to enter into collaborative practice agreements with physician providers in 47 states and the District of Columbia.[1] Such agreements expand conventional pharmacy services to provide pharmacists with the ability to initiate, monitor, and modify patients' chronic drug therapies. Of these, 31 states allow pharmacists to order and interpret lab tests. Models of care include pharmacists' involvement within a team care approach with patient care rounds prior to and during a patient's visit, with follow up directed to each discipline's area for separate patient follow up if needed.

Hawai'i is one state that authorizes collaborative practice agreements between pharmacists and physician providers. The current collaborative practice agreement between the Daniel K. Inouye College of Pharmacy (DKICP) University of Hawai'i at Hilo and several ambulatory clinics such as Hawai'i Island Family Health Clinic (HIFHC), Bay Clinic (Keeau, Hawai'i), Lau Ola Clinic (John A. Burns School of Medicine [JABSOM], Dept. of Native Hawaiian Health, Honolulu, HI), and Mililani Physicians Clinic, (JABSOM, Dept. of Family Medicine, Mililani, Hawai'i) allows clinical pharmacy faculty to work in tandem with other providers, including physicians, medical residents, psychologists, and nurse practitioners. This team approach provides health care education to each discipline's learners as well as direct patient care. Under this agreement, the clinical pharmacist manages a patient panel and is able to manage ongoing medication management associated with chronic conditions, in particular, diabetes, hypertension, hyperlipidemia, heart failure, depression, and anticoagulation. Common pharmacotherapeutic interventions would include initiating, titrating or discontinuing medications, ordering monitoring labs, suggesting appropriate referrals, and conducting physical assessment as necessary.[2-4]

All parties involved in the collaborative practice agreement benefit. Patients continue to be cared for, often allowing for greater time spent on medication issues; the students are educated; and the team works in unison allowing physicians more time to focus on important acute patient concerns and ailments. Dr. Kristine McCoy, Program Director for the Hawai'i Island Family Medicine Residency at HIFHC states, "I've had the benefit of practicing alongside pharmacist clinicians for the past eight years. Through this collaboration, my patients have received expert and detailed care in the areas of anticoagulation and management of their chronic metabolic conditions. As a result, my patients have better understood not just their medications, but their underlying conditions and how medicines, diet, and lifestyle interventions can improve and lengthen their lives. The other benefit to my patients is the opening up of my clinical schedule to address other medical problems. Without the partnership, my schedule would be bogged down with chronic disease management and my patients would likely have to go to Urgent Care for acute issues. In my previous practice in New Mexico, this collaboration was sustainable."

Although this appears to be a strong model for optimizing patient care, there remains the issue of reimbursement for the pharmacists' services. Pharmacy appointments are usually 40 minutes with significant time devoted to patient education and medication reconciliation, services that are reimbursed, on average, $21/visit from Medicare by billing under the procedural terminology code (CPT) 99211; a level-I established patient encounter.[5] When assessing national estimates by occupation, the usual hourly rate of pharmacists averages $57/hour; regardless of time spent with the patient or level of skill or knowledge required during the encounter.[6] As a result of these reimbursement rates by insurance companies in this setting, it is difficult for many physician practices to budget a pharmacy position despite the positive patient-related outcomes and cost-savings demonstrated. According to Dr. McCoy, "As billable providers, my pharmacist colleagues earn their keep financially and not just in terms of patient outcomes. In Hawai'i, we have been subsidizing our partnership as an academic enterprise, but unfortunately the model is not available to those in commercial practice. Provider status with concurrent reimbursement for ambulatory care pharmacists will change this, opening up the benefits to patients across the state, and helping to make primary care a more attractive career option for physicians and other health professionals who value an interdisciplinary approach."

Why Pharmacists have not been Recognized as Providers

The problem lies within the Social Security Act (SSA) wherein all healthcare providers including physicians, physician assistants, nurse practitioners, psychologists, clinical social workers, nurse midwives, nurse anesthetists, and dieticians are considered "providers" of medical care, with the exception of pharmacists. Due to this omission from the SSA, Medicare does not pay for services rendered by clinical pharmacists. The exception to this is when pharmacists conduct specific services such as medication therapy management as part of Part D benefits to patients or provide services as a certified diabetes educator within accredited diabetes education programs. However, this service is not relegated by third party payers as pharmacist-specific; technically any qualified health care provider may fulfill these services. Concurrently, private and state insurers including those in Hawai'i, like the Hawai'i Medical Service Association (HMSA), University Health Alliance (UHA), and Hawai'i Medical Assurance Association (HMAA), have followed suit, citing omission of Medicare Part B as a reason of lack of compensation for those pharmacists providing patient-centered care.[7]

Changes on the Way: Leading the Way in Other States and a National Bill

Pharmacist provider status is currently maintained at the state level within the scope of pharmacy practice law. In 2013, California passed SB 493, declaring pharmacists health care providers who have authority to provide health care services.[8] This law authorizes all licensed pharmacists in California to administer medications when ordered by a prescriber, provide consultation, training, and education on drug therapy, disease state management, and disease prevention, participate in multidisciplinary review of patient progress with appropriate access to medical records, provide self-administered hormonal contraceptives, travel medications not requiring a diagnosis, and prescription nicotine replacement products for smoking cessation. Pharmacists in California may also independently initiate and administer immunizations to patients three years of age and older and interpret tests to monitor and manage efficacy and toxicity of drug therapies in conjunction with the patient's prescriber.

In addition, SB 493 also established a new "Advanced Practice Pharmacist" (APP) recognition. Those pharmacists meeting the APP designation may perform patient assessments, order and interpret drug-therapy related tests in conjunction with the patient's prescriber, refer to other healthcare providers, and initiate, adjust, and discontinue drug therapy in accordance to established protocols and pursuant to a prescriber's orders in collaboration with other health care providers. Attaining APP recognition is contingent upon earning certification in a relevant area of practice (ambulatory care, critical care, oncology pharmacy, or general pharmacotherapy), completion of a postgraduate residency program, and having provided clinical services to patients for one year under a collaborative practice agreement or protocol with a physician.

There is major movement at the federal level to secure provider status for pharmacists. The Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592/S. 314) is one such piece of legislation that has recently been introduced to increase accessibility and quality of care by enabling pharmacists to provide care consistent with their education, training, and license as governed by the state pharmacy board. If passed, this bill will amend the SSA, thus allowing pharmacist-provided services to be reimbursable under Medicare Part B in medically underserved communities.[9] These communities meet the criteria set by the Health Resources and Services Administration (HRSA) and include regions where residents have a shortage of personal health services (medically underserved areas), groups of persons who face economic, cultural, or linguistic barriers to health care (medically underserved populations), and health professional shortage areas where there is a lack of primary care, dental, or mental health providers.[10]

Healthcare Benefits

The benefits of pharmacists being recognized as providers can be seen nationally as well as locally here in Hawai'i. With the implementation of the Patient Protection and Affordable Care Act, it is projected that an extra 25 million people will enter the healthcare system annually from the years 2016 through 2024.[11] By 2025, it is estimated the United States will have a shortage of between 46,000-90,0000 physicians in both primary and specialty care.[12] As the shortage widens, the need for medical care in underserved communities will also rise. H.R. 592/S. 314 addresses the provider shortages and increases accessibility to care from other types of health care professionals, namely pharmacists in these underserved areas.

All five Hawai'i counties are considered medically underserved with a shortage of 600 physicians statewide and 174 physicians in Hawai'i county itself.[13] There are more than 1200 licensed pharmacists in Hawai'i at present.[14] These pharmacists could help to fill a niche to decrease the shortage of health care providers and to widen the bridge of opportunities for further reimbursement for National Committee for Quality Assurance (NCQA)-driven payments and Accountable Care Organization (ACO) changes.

Pharmacists can contribute to meeting the NCQA Patient-Centered Medical Home (PCMH) standards within this changing healthcare landscape. Involvement can be met particularly with the Healthcare Effectiveness Data and Information Set (HEDIS); these measures are used to ensure performance of quality healthcare.[15] For example, ambulatory-based pharmacists may be tasked with ensuring pharmacotherapy management of chronic obstructive pulmonary disease exacerbation, use of appropriate medications and medication management for people with asthma, initiation of beta-blocker therapy after a heart attack, chronic diabetes, hypertension and cholesterol management. As members of the healthcare team, pharmacists can meet the access-to-care measure for preventative and ambulatory care services.

Financial Benefits

By increasing access to care, the bill promotes healthcare that is cost-effective by increasing the likelihood of early interventions, preventing medication-related morbidity and mortality, improving medication adherence, and improving patient satisfaction. Pharmacists have had provider status within the federal system since 1995 under the VHA 10-95-019 directive. Since then, there have been multiple studies documenting the cost-effectiveness of the services provided by clinical pharmacists. One such study looking at the first 600 recommendations made by clinical pharmacists over one year estimated a mean total cost avoidance of $420,155.[16] Furthermore, in 90% of the cases, patient harm was avoided due to pharmacist intervention. The Asheville Project, conducted over a period of six years, demonstrated both the clinical and economical benefits of pharmacists conducting medication therapy management and providing education for patients with diabetes, hypertension, dyslipidemia, and asthma by improving disease outcomes and decreasing medical costs and hospital/emergency department visits.[17-19]

Under national bill H.R. 592/S. 314 pharmacist services would be reimbursed at 85% of the physician fee schedule as consistent with the precedent that is currently maintained by the SSA for nurse practitioners and physician assistants. If the pharmacist provides clinical duties under the direct supervision of a physician, the pharmacist will be reimbursed at 100% of the physician fee schedule.

Skeptics may wonder why pharmacists are concerned with provider status when fee-for-service payment models are fading away. As pharmacists, we firmly believe we are members of the multidisciplinary health care team working collaboratively for improved patient outcomes. As mentioned above, pharmacists can contribute to achieving ACO accreditation and PCMH recognition as required by NCQA, thus increasing physician pay-for-performance as aligned with quality measures. However, even as these new health care models emerge, the SSA still remains the reference point for which practitioners are eligible for compensation.

Conclusion

Although pharmacists have not been formally recognized as medical providers on the health care team, there is current legislation at the national level moving towards achieving this designation. Pharmacist's provider status will provide: (1) physicians more time to focus on patients' complex medical issues; (2) increase patients' access to care, improve quality of care, and decrease costs; and (3) decrease health care systems' long-term expenditure, while recognizing and reimbursing pharmacists working at the top of their degree.

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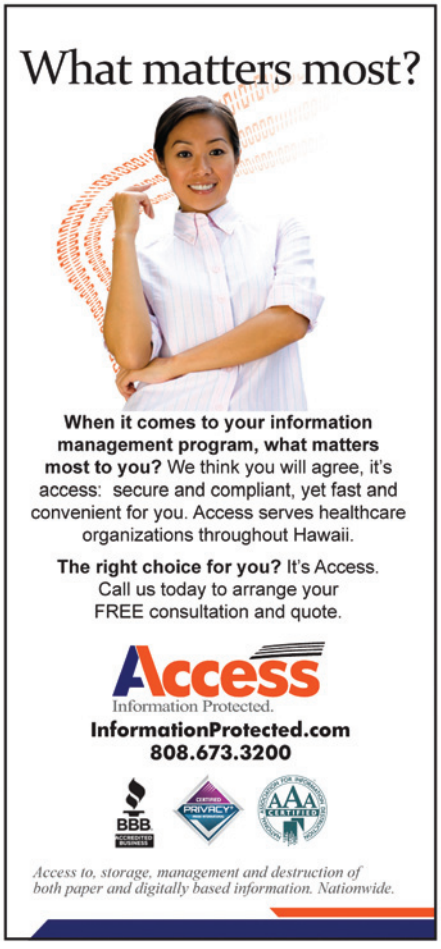

THE WEATHERVANE

RUSSELL T. STODD MD; CONTRIBUTING EDITOR

HOW MUCH SHOULD A MIRACLE COST?

More than 3 million Americans and about 150 million people worldwide are living with potentially fatal hepatitis C. The virus is usually acquired through sharing needles, or poorly sterilized medical instruments, or even transfusions before current screening standards. Sufferers may go for years without symptoms, but during that time the liver can scar, leading to cirrhosis, cancer, and organ failure. Treatment had only limited success and drugs that doctors had in their arsenal often caused unpleasant side effects. Wonder of wonders, now a therapeutic miracle GMO drug has been synthesized that will cure an overwhelming number of cases. Gilead Sciences of Foster City, California introduced Harvoni, the antiviral that will cure the patient in just 12 weeks. Patients need to take just one pill a day with only mild side effects and no injections. The truly painful side effect is Gilead Sciences. Knowing they have a gold mine, Gilead markets the drug for $1,125 per pill, or $94,500 for a 12 week course. This is outrageous greed, without a doubt. Third parties, including Medicare/Mdicaid, Kaiser and other insurers are forced to triage patients and provide drugs only for those with the worst liver disease.

JOAN RIVERS GOT NO RESPECT.

Entertainer Joan Rivers was admitted to Yorkville Endoscopy Clinic for evaluation of "voice changes" and gastric reflux. She signed a consent form for upper endoscopy (EGD) with possible biopsy and possible esophageal dilation by surgeons Cohen and Bankulla. She did not authorize laryngoscopy. With the initial endoscopy, the surgeon noted her oxygen saturation (O_2 sat) dropped due to her compromised airway, and the tube was removed. When the O_2 sat stabilized, the scope was re-inserted and the EGD was accomplished, but the doctors failed to note the drop in vital signs. They may have been distracted as one of the surgeons even took a selfie without the patient's authorization. A third surgeon, Dr. Gwen Korovin, noted for caring for famous performers, wanted to have another look and re-inserted the scope. Ms. River's blood pressure, pulse and O_2 sat had fallen out of sight and an Ambu bag was used in an attempt at resuscitation. When this failed, a tracheotomy tray was called and Dr. Korovin was expected to perform a trach, however she had departed the scene, remarking as she left that she didn't have privileges at the Clinic. No further attempt was made to establish an airway and Joan Rivers expired. A malpractice lawsuit is pending.

THERE ARE LICENSED MEDICAL THUGS.

Dr. Farid Fata received millions of dollars from Medicare ranking him as the highest paid oncologist and seventh highest paid overall among individual health providers in 2012. There is a reason for that. He pleaded guilty to Medicare fraud after being accused of giving hundreds of patients unnecessary or inappropriate treatments, including chemotherapy. Harvard Professor Dan L. Longo testified for the government that many of the 25 files he reviewed showed medically unnecessary treatment that likely could have led to a series of life-threatening complications and painful side effects. Dr. Fata not only wreaked havoc on his victims' bank accounts, but also on their bodies. He individually designed the fraud that necessitated fooling his own employees and professional staff. Federal prosecutors called him the "most egregious fraudster" worse even than Bernie Madoff. Multiple victims will be allowed to testify in the sentencing of the Michigan oncologist. Donald Crabtree's wife will speak on his behalf, because he died following chemotherapy for lung cancer he did not have. Dr. Fata faces a maximum sentence of 175 years.

SORRY. I THOUGHT IT WAS ON SILENT.

Everyone agrees that cell phones are a distraction for vehicle operators, but what about the operating room? In Texas an anesthesiologist was in a text conversation and failed to note his patient's deteriorating oxygen level. After 20 minutes when enough alarms went off, the doctor tried to bring his patient back. Too late. The woman died and the family filed a malpractice complaint. The case never got to trial and was closed in a confidential settlement. This should not be an issue. A hard rule should apply that no distractions, especially cell phones, should be permitted anywhere in the operating suite.

WHAT EVER HAPPENED TO FOOD FOR THOUGHT?

According to the New York Times, Silicon Valley tech workers work long hours with little time for food as we know it. According to celebrity inventor Elon Musk, eating is time wasted, and sit-down meals are a marketing façade. Engineers and code writers are scarfing down Schmilk or People Chow, liquids heavily laden with nutrients, to save time and get back to work. The Times food editor described one drink as oat flour, washed down with the worst glass of milk ever. Another Times reporter called it "pancake batter." Come on people, life is too short. Kick back and have a beer.

WAS IT AS GOOD FOR YOU AS IT WAS FOR ME? DOES THIS DRUG CARRY A FOUR HOUR WARNING?

Regulators for the Food and Drug Administration (FDA) are evaluating a drug called "Viagra for women." Various women's groups have argued that while drugs such as Viagra, Cialis and Levitra exist to help men, there is little available to help women with sexual dysfunction. In reviewing the application from Sprout Pharmaceuticals for its drug flibanserin the FDA data showed an increase of "sexually satisfying events" of 2.5 per month for women who complain of hypoactive sexual desire disorder (HSDD). In the study of 1,543 pre-menopausal women, 12.5% dropped out after experiencing side effects of fainting and low blood pressure. Agency reviewers asked whether these observed effects outweigh positive aspects? Perhaps they should ask the husband.

THE SWEET SMELL OF SUCCESS.

At a charity event in Philadelphia in July, Jack Sexty, age 25, set a Guinness world record for pogo stick jumping. He bounced 88,047 consecutive times over a 10 hour 20 minute period. Sexty admitted that he had some uncomfortable times, but was able to continue. He likely inadvertently set another Guinness record by being the only pogo stick jumper to answer nature's call for "number two" while pogoing. A bystander offered to hold a pot for him, but Sexty said he couldn't control his aim. Ah, the price of fame.

ADDENDA

- Despite the "stampede" to join big groups or seek hospital employment, according to a recent study reported in the JAMA, 60% of practicing physicians are in groups of 10 or less members. This number has not changed since 2012.
- Moles are able to tunnel through 300 feet of earth in a single day.
- Henry Wadsworth Longfellow was the first American to have indoor plumbing.
- Law school is the opposite of sex. Even when it's good it's lousy.
- One for the road: 11% of people admit to having had sex while driving.
- My grandmother's brain was dead, but her heart was still beating. It was the first time we ever had a Democrat in the family.

ALOHA AND KEEP THE FAITH rts

(Editorial comment is strictly that of the writer.)

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