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THE COST-BENEFIT BALANCE OF STATINS IN HAWAI'I: A MOVING TARGET

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The Cost-Benefit Balance of Statins in Hawai'i: A Moving Target

Corey J. Lum DO; Kazuma Nakagawa MD; Ralph V. Shohet MD; Todd B. Seto MD, MPH; and Deborah A. Taira ScD

Abstract

Statins are lipid-lowering medications used for primary and secondary prevention of atherosclerotic disease and represent a substantial portion of drug costs in the United States. A better understanding of prescribing patterns and drug costs should lead to more rational utilization and help constrain health care expenditures in the United States.

The 2013 Medicare Provider Utilization and Payment Data: Part D Prescriber Public Use File for the State of Hawai'i was analyzed. The number of prescriptions for statins, total annual cost, and daily cost were calculated by prescriber specialty and drug. Potential savings from substituting the highestcost statin with lower-cost statins were calculated. Over 421,000 prescriptions for statins were provided to Medicare Part D beneficiaries in Hawai'i in 2013, which cost \$17.6M. The three most commonly prescribed statins were simvastatin (33.4%), atorvastatin (33.4%), and Iovastatin (13.9%). Although rosuvastatin comprised 5.4% of the total statin prescriptions, it represented 30.1% of the total cost of statins due to a higher daily cost (\$5.53/day) compared to simvastatin (\$0.25/day) and atorvastatin (\$1.10/day). Cardiologists and general practitioners prescribed the highest percentage of rosuvastatin (8% each). Hypothetical substitution of rosuvastatin would have resulted in substantial annual cost savings (Simvastatin would have saved \$1.3M for 25% substitution and \$5.1M for 100% substitution, while atorvastatin would have saved \$1.1M for 25% substitution and \$4.3M for 100% substitution). Among Medicare Part D beneficiaries in Hawai'i, prescribing variation for statins between specialties were observed. Substitution of higher-cost with lower-cost statins may lead to substantial cost savings.

Keywords

Statins, Cost-Benefit, Cost-Effective, Rosuvastatin, Healthcare Expenditure, Medicare

Introduction

In 2012, 2.8% of adults in Hawai'i had been told they have some form of coronary heart disease (CHD).¹ Statins are the most commonly prescribed lipid-lowering medications used for primary and secondary prevention of CHD.^{2,3} From 2003 to 2012, the use of statins among all adults aged 40 years and older increased from 18% to 26% in the United States.⁴ Also, in 2013, the American College of Cardiology (ACC) and the American Heart Association (AHA) released updated cholesterol guidelines that presented a landmark change in the recommended evaluation and medical management of patients with hyperlipidemia, greatly expanding the indications for statin therapy.⁵⁻⁷ Rather than low-density lipoprotein cholesterol (LDL-C) targeted therapy, the 2013 ACC/AHA guidelines suggested moderate- or high-intensity statin therapy based on coronary artery disease risk, a change estimated to increase the statin-eligible population by 12.8 million.8

Statin medications generated over \$16 billion in sales in the United States in 2012.⁹ Although statins comprise a substantial portion of drug costs in the United States, they are judged to be cost-effective, as they have been shown to reduce the risk

of acute coronary syndrome and stroke, which in turn reduce the costs of hospitalizations and the requirements for more expensive interventions, including coronary angiography and percutaneous coronary intervention.¹⁰ Over the past 2 years, as spending on prescription drugs has risen sharply in the United States, legislators are evaluating policies to reduce prescription drug spending.¹¹ A better understanding of prescribing patterns may produce strategies for reducing such costs, while maintaining adherence to evidence-based care. The goal of our study was to assess the prescribing patterns of statins among Medicare patients in the State of Hawai'i, with a specific focus on the use of generic and non-generic statins.

Methods

This was a retrospective, cross-sectional analysis of the 2013 Medicare Provider Utilization and Payment Data: Part D Prescriber Public Use File (PUF) for the State of Hawai'i. We analyzed the prescribing patterns by provider specialty, total costs of different statin medications, and the potential effect of substitution with lower cost statin medications. The structure and contents of the database are described in "A Methodological Overview"¹² from the Centers for Medicare and Medicaid Services. The PUF contains prescription drug event information for each prescriber by National Provider Identifier (NPI). The file does not contain beneficiary-level information or indication(s) for the drug prescribed. Only drugs covered under the outpatient Part D benefit are included in the database.

For each drug prescribed by a provider, payment (medication cost), claim count (if >10), day's supply, drug name, generic name, and provider specialty were available for analysis. Providers were characterized as cardiologists, family practitioners, general practitioners, internists, mid-level practitioners (nurse practitioners and physician assistants), and other specialists. The number of prescriptions, total annual cost, and daily costs were calculated according to provider specialty and for the most common prescribed statin medications. Daily costs were calculated using the total cost of a medication divided by the days supplied.

Hypothetical annual savings from substituting the highest-cost statin (rosuvastatin) with lower-cost, commonlyprescribed statins (simvastatin and atorvastatin) were estimated without correction for potential differences in efficacy. Atorvastatin is considered a "high-intensity" statin with anti-hypercholesterolemic efficacy similar to rosuvastatin,¹³ while simvastatin is considered a moderate-intensity drug. In sensitivity analyses, we varied the proportion of rosuvastatin that were substituted from 25% through 100%.

Results

The 2013 Medicare Part D PUF for Hawai'i had records from a total of 1075 providers (44% internists, 26% family practitioners, 12% other specialists, 9% mid-level providers, 5% cardiologists, and 4% general practitioners), and contained a total of 421,000 statin prescriptions, which generated a total of \$17.6M in drug costs. Figure 1 shows the distribution of statin drug prescriptions in Hawai'i in 2013. The three most commonly prescribed statins were simvastatin (33.4% of total statins), atorvastatin (33.4%) and lovastatin (13.9%). The three statin medications that comprised the greatest costs included atorvastatin (\$7.9M, 44.8% of total cost), rosuvastatin (\$5.3M, 30.1% of total cost) and simvastatin (\$1.9M, 10.9% of total cost) [Figure 2]. Although rosuvastatin comprised only 5.4% of the total statin prescriptions, it represented 30.1% of the total cost for statins. Rosuvastatin had the highest daily cost (\$5.53/day) and simvastatin had the lowest daily cost (\$0.25/day) [Figure 3].

The analyses of prescriptions by specialty showed that internists wrote 265,763 prescriptions for statins (63% of the total), family practitioners 85,850 prescriptions (20%), cardiologists 21,631 prescriptions (5%), general practitioners 17,833 prescriptions (4%), mid-level practitioners 11,292 prescriptions (3%), and other specialists were responsible for 18.631 prescriptions for statins (4% of the total). The proportion of each statin that was prescribed for each specialty is shown in Figure 4. Cardiologists prescribed much more atorvastatin than simvastatin (atorvastatin 52% vs simvastatin 22%) compared to all other practitioners (atorvastatin 28% to 33% vs. simvastatin 30% to 39%). Cardiologists and general practitioners prescribed a higher percentage of rosuvastatin (8% each) compared to internists (6%), family practitioners (4%), mid-level practitioners (3%), and other specialists (5%) [Figure 5].

Hypothetical substitution of rosuvastatin resulted in substantial annual cost savings using either simvastatin (\$1.3M for 25% substitution to \$5.1M for 100% substitution) or atorvastatin (\$1.1M for 25% substitution to \$4.3M for 100% substitution) [Figure 6].



Figure 1. Distribution of statin prescriptions among Medicare part D recipients in Hawai'i in 2013 obtained from the Medicare Fee-For Service Provider Utilization & Payment Data Part D Prescriber Public Use File.



\$6.00 \$5.53 \$4.63 \$5.00 \$3.83 \$4.00 \$3.00 \$2.00 \$1.10 \$1.00 \$0.53 \$0.31 \$0.25 \$0.00 Pitavastatin Fluvastatin Rosuvastatin Morvastatin Sinvastatin Pravastatin Figure 3. Cost per day of statin medications, calculated by the total cost of the drug divided by the days supply.







Discussion

Our study observed variation in the prescribing of statins between different provider specialties among Medicare Part D beneficiaries in Hawai'i in 2013. Cardiologists prescribed more atorvastatin compared to other specialties. Atorvastatin and simvastatin were the most commonly prescribed statins. Rosuvastatin made up a small portion of statin prescriptions but produced the second highest cost due to having the highest cost per day. Simvastatin, on the other hand, was the most prescribed statin but had the lowest cost per day.

One likely explanation for the variation in prescribing patterns is that cardiologists see a greater proportion of patients with established CHD so their prescription for a high-intensity statin, which is indicated for this diagnosis, may be greater than other specialty groups. Yet, General Practice physicians, who would be expected to care for a lower percentage of patients requiring intensive therapy, were found to be prescribing rosuvastatin as much as cardiologists (8%). One possible explanation could be differences in the effectiveness of pharmaceutical marketing to different specialties, another might be practice patterns that are formed early and could be "stickier" for general practitioners, who need to master a much broader palette of drugs.

The popularity of rosuvastatin among providers may be explained by previous studies suggesting it to be more cost-effective compared to other statins.14-17 However, when these papers were written, most statins were not yet generic. Since these analyses, most statins, including those comparable to rosuvastatin, have become generic. Another possible reason rosuvastatin is popular among providers may be the perception that it has superior clinical efficacy compared to other statins. However, this was disproven in the 2011 SATURN trial, where high dose atorvastatin and rosuvastatin resulted in a similar degree of regression of coronary atherosclerosis as measured via intravascular ultrasonography.13 In addition, the 2013 ACC/AHA guidelines have changed the approach to prescribing statin therapy for providers. Previous to the release of the 2013 ACC/AHA guidelines, providers prescribed statins based on guidelines released in 2001, when pharmacologic therapy was directed to reach specific LDL-C goals.7 If the goal LDL-C was not reached with the first therapy, then the patient was placed on additional agents until the goal LDL-C was achieved. This occasionally led to multiple lipid-lowering medications, including combinations of statins, fenofibrates, and bile acid sequestrants. With the 2013 ACC/AHA guidelines, although more patients have indications for statin therapy, fewer patients are likely to be on multi-drug lipid-lowering therapy for either primary or secondary prevention of cardiovascular disease, resulting in a marked shift in the cost-benefit balance such that rosuvastatin now has the least economic efficiency for primary or secondary prevention of cardiovascular events.

However, as of April 2016, the United States Food and Drug Administration approved the first generic version of rosuvastatin, previously sold as "Crestor". Currently, AstraZeneca is petitioning to overturn that decision, but if approved, the release of generic rosuvastatin may help alleviate some of the substantial costs of statin medications. However, repeat cost analyses will be needed to determine the effects this will have on medication costs.

The findings of this retrospective analysis could have considerable financial consequences. Among Medicare Part D beneficiaries in Hawai'i, substitution of higher-cost statins with lower-cost statins could lead to substantial cost-savings. The release of generic medications, new clinical studies and new guidelines may alter the cost-effectiveness of statin therapy so that repeat cost-effective analyses of statin therapy are recommended. Our data could translate into public policy changes that could help produce a less expensive outcome including a statin-prescribing algorithm where less expensive statins are preferred over more expensive ones of equivalent efficacy. For example, a provider would prescribe atorvastatin over rosuvastatin if a high-intensity statin is required or simvastatin over rosuvastatin if a moderate-intensity statin is required. In addition, there should be more focused education for the parties responsible for inappropriately prescribing more expensive medications, not only statins. Our study includes statewide data on Medicare Part D recipients so our data can be generalized to this specific population in Hawai'i. If applied on a national level, the potential cost-savings could help ameliorate a substantial amount of health care costs in the United States.

Limitations of this analysis include that our data reflect statin prescriptions prior to the broad dissemination of the 2013 ACC/AHA guidelines. Furthermore, the data does not include patient-level information or clinical characteristics including any adverse effects to previous medications, to evaluate the appropriateness of statin selection, nor does it contain cholesterol data to demonstrate any objective measure of drug efficacy. Another limitation of our study includes the assumption that different doses of the same medication were the same price due to the lack of drug dose data.

Conclusion

Despite the availability of generic statins that are less costly compared to brand name statins, there are a considerable number of prescriptions for expensive, brand name statins in our community. Prescribing providers often get into prescribing habits or patterns without a consideration for cost. Providers should be evaluating and evolving their clinical practice and prescribing patterns based on updated guidelines, recent studies, and availability of generic medications.

Furthermore, the cost-benefit balance of a particular drug class is a dynamic process based on the approval or disapproval of new medications or generic versions of medications. As our understanding of medicine progresses, therapies and guidelines for the treatment of diseases change. For these reasons, repeat cost-benefit analyses following drug cost and therapy-recommendation changes are recommended to provide a more thoughtful approach to the expense of prescription medications.

Conflict of Interest

None of the authors identify any conflicts of interest.

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The Long Term Outcome of the Management of the Posterior Capsule in Pseudophakic Children

Malcolm R. Ing MD

Abstract

This is a long term study of the treatment of the posterior lens capsule in the management of bilateral cataract extraction and insertion of 42 intraocular lenses in 21 children. The purpose of the current study was to compare the long-term outcome of eyes treated by the two different methods of surgery of the posterior lens capsule in bilateral cataract and intraocular lens implantation in children.

The author performed an independent ocular exam on the children selected from a consecutive series at 4 different institutions, followed for a minimum of 5 years. The eyes of children in Subgroup A (n=24), had surgery in which an intact capsule was left at the time of initial surgery. The eyes of patients in Subgroup B (n=18) received a primary central lens capsulectomy and limited anterior vitrectomy at the time of the initial surgery. The eyes of Subgroup A (mean age 7.7 years) were found to be in children older than those eyes in Subgroup B (mean age 3.9 years) (P=.001). The eyes in the two subgroups also differed in the necessity of a secondary YAG laser capsulectomy. Twenty one of the 24 eyes in Subgroup A had received a secondary YAG laser capsulectomy and no eyes of the patients in Subgroup B had required a secondary YAG laser capsulectomy at the time of the author's examination (P=.001). A central capsulectomy during the initial surgery was more likely to be chosen for surgery on eyes of younger children (P=.001).

Keywords

posterior lens capsule, intraocular lens, capsulectomy

Introduction

The incidence of visually significant cataracts among children in the United States is 3-4 per 10,000 persons. The use of intraocular lenses following cataract extraction in children was pioneered in the United States by Hiles despite reservations concerning the use of this modality of treatment for bilateral cases.¹ With the development of safer techniques and lenses, however, there has been an increasing acceptance of the use of intraocular lenses after bilateral cataract extraction in childhood.² Gimbel, et al,³ and Peterseim, et al,⁴ reported excellent results with the use of posterior chamber lenses following bilateral cataract in children. Never the less, there have been few long term studies of this treatment modality among children, and the Food and Drug Administration has officially only approved lens implantation for adult patients.

Management of the posterior capsule has been controversial.⁵ Some surgeons recommend leaving the posterior capsule intact after the lens implantation in children because they believe that eyes with an intact capsule are more stable. These surgeons choose to treat any significant subsequent opacification of the posterior capsule with a secondary YAG laser capsulectomy whenever it is necessary to clear the visual axis. The laser treatment can be performed with topical anesthesia on cooperative patients while they sit in a chair in front of the laser. Other surgeons, recommend performing a posterior capsulectomy with a limited anterior vitrectomy following the insertion of the intraocular lens at the time of the initial cataract surgery. This latter surgical technique of management is known to be more invasive and may dislodge the lens during the initial procedure. Jensen, et al, reported that 64% of 14 eyes of patients aged 1-6 and 19% of patients aged 6-13 with a mean follow up of 2 years required a YAG laser capsulectomy.⁶

The purpose of this report is to present the results of an independent long term study of 24 eyes of 12 patients in which the posterior capsule was left intact compared to 18 eyes of 9 patients in whom the central posterior lens capsule was partially excised combined with an anterior vitrectomy at the time of the initial cataract surgery. The author's hypotheses were that the main outcome measures of visual acuity and incidence of complications would be similar, and that surgeons would choose to include a central capsulectomy during the initial surgery on eyes of younger patients.

Methods and Patients

The author communicated with four different ophthalmic surgeons to request permission to perform an independent examination of the eyes of children upon whom the surgeon had performed bilateral cataract surgery with primary insertion of an intraocular lens by the age of 15 years. To minimize bias in the selection of the patients by the surgeons, each surgeon was instructed to select patients from a consecutive series. To insure adequate length of follow up, the surgeons were also instructed to select only patients for examination with a minimum follow up of 5 years from the date of the surgery on the first eye. All patients received an examination that included outcome measures of: visual acuity, refraction, binocularity tests, slit lamp examination, tonometry (when possible), and a retinal exam. There were no incentives offered to the patients. To minimize any bias of the examiner toward either technique, the author performed the examination prior to examination of the clinical record.

The eyes of patients were divided into two subgroups, according to the management of the posterior capsule. Subgroup A (n=24) was composed of eyes in which the posterior capsule was left intact at the time of initial surgery, and were treated by a subsequent YAG capsulectomy to clear the visual axis subsequently when necessary. Subgroup B (n=18) consisted of eyes that received a primary capsulectomy and anterior vitrectomy at the time of cataract extraction and insertion of the intraocular lens. The eyes of the patients were examined in compliance with institutional review board (IRB) regulations, and an informed consent was acquired when necessary. IRB regulations were developed and were put into effect in 2003; therefore, all patients who were examined after that year received IRB approval for the examination. Patients in both subgroups were compared on the following outcome measures: visual acuity, refraction, binocularity tests, slit lamp examination, tonometry (when possible), and a retinal exam.

Statistical Analyses

Subgroup comparisons were conducted utilizing the Fisher Exact test and analyzed with statistical package R.

Results

The final study sample included 21 patients, for a total of 42 eyes and the complete results are reported in Table 1.

There were differences in the demographics of the two subgroups (Table 1). The two subgroups differed in the mean age of initial surgery Subgroup A(range: 3.3-10.5, mean = 7.7 years, Subgroup B (range 0.04-9.3, mean 3.6 years (P=.001). In addition, the mean age at study examination differed significantly. Subgroup A patients (range 11.2-25.7, mean 18.5 years) were older compared to the patients in Subgroup B range:8.5-23.6, mean 12.8 years (P=.008). Length of follow-up did not differ significantly between subgroups (P=.62). Four patients in Subgroup B were found to have a neurological handicap; zero patients in Subgroup A had a mental handicap (data not shown). It is likely that these patients with a mental handicap were selected for primary capsulectomy/vitrectomy because the ophthalmologist anticipated opacification of the posterior capsule, which would be hard to detect in patients who were not able to respond subjectively for vision testing.

Twenty-one of twenty-four capsules in Subgroup A had been treated by the YAG laser by the time of the exam (Table 1). No eyes in Subgroup B required secondary YAG laser treatment. This result was significantly different (P=.001). Overall, there were no significant differences between the two subgroups in terms of visual acuity (P>.5), refraction (P=.79), ocular motility (P=.62), or incidence of glaucoma (P>.50).

Discussion

Management of the posterior capsule, with the prospect of almost universal opacification and secondary cataract following cataract extraction in children, has been a crucial challenge in this type of surgery. Many investigators have reported a high incidence of this complication in cataract surgery with implantation of intra ocular lenses in children.⁶⁻⁸ Several methods to prevent secondary cataract formation have been utilized. Some surgeons have utilized opening the posterior capsule with a bent needle or a central posterior capsulectomy after the insertion of the intraocular lens.⁷⁻⁹ Other surgeons have combined a limited vitrectomy with an automated device following a capsulectomy.5, 10-15 All 18 eyes of the patients in Subgroup B were treated with this latter technique, and no secondary YAG procedures were necessary. In contrast, as has been found by other investigators, almost all posterior capsules that were left intact in Subgroup A had to be opened with a YAG laser by the time of the examination for this study.

The present study demonstrated that excellent visual acuity could be obtained in the majority of patients after bilateral primary lens implantation following cataract extraction in children. This goal was achieved with a low incidence of major complications. In general, it was found that ophthalmic surgeons chose the technique of leaving the posterior capsule intact (with subsequent capsulectomy if necessary) for the older children treated for cataracts. Surgeons more often chose to treat the posterior capsule with a primary capsulectomy and limited vitrectomy at the time of the initial surgery in younger children. Presumably, these surgeons chose to do an initial capsulectomy with the initial surgery in the younger children and for those with a mental handicap, anticipating that these patients would have an opacification of the posterior capsule and they would be more difficult to have a with a YAG laser capsulectomy at a young age. Almost all eyes treated without a primary capsulectomy at initial surgery required a YAG laser capsulectomy at a later date (P = .001). The high incidence of secondary opacification of the posterior capsule has led some investigators to recommend that a primary capsulectomy be utilized in every case to prevent a decline in vision and possible amblyopia in the eyes of younger children who have cataract extraction.5

Table 1. Comparison of Data for Subgroups						
Characteristic	Subgroup A (n=24 eyes of 12 patients)	Subgroup B (n=18 eyes of 9 patients)	<i>P</i> -Value			
Age at surgery (year)	Range 3.3-10.5, Mean 7.7	Range 0.04-9.3, Mean 3.6	.001			
Age at study examination Range 11.2-25.7, Mean 18		Range 8.5-23.6, Mean 12.8	.008			
Follow up (year)	10.8	10.8 9.3				
Use of Yag laser	21 eyes	0 eyes	.001			
Visual Acuity	Range 20/15-20/50, Mean 20/25	20/20 – 20/70, Mean 20/25	>.5			
Refraction	Range +0.75 to -7.00, Mean -1.25	Range +3.00 to -4.00, Mean -1.29	.79			
Ocular motility (manifest strabismus) 2 patients		3 patients	.62			
Glaucoma	1 eye	1 eye	>.5			

Only one patient (number 21, Subgroup B) had surgery before the age of 1 year. Despite the excellent result in this single patient, due to the paucity of patients in the infantile age group in the present report, this study does not provide sufficient data to answer the question of whether or not intraocular lenses can provide a safe alternative to the use of contact lenses after cataract extraction in infants. Indeed, a recent study by the Infant Aphakia Treatment Study Group has reported that there were no statistically significant differences in visual acuity results between the intraocular lens and contact lens groups, but additional intraocular operations were performed more frequently in the intraocular lens group.⁷

An obvious limitation of the present study is the relatively small number of patients. It would be ideal to collect data on a greater number of patients to see if these findings persist. The present study is retrospective. Perhaps a randomized, prospective study could be performed. However, the possibility of such a study is diminished by the strong belief held by some surgeons that a central capsulectomy during the initial surgery is required for all eyes of the younger children during the initial surgery. These surgeons believe that there is an ever present threat of opacification of the posterior capsule and induction of amblyopia for the younger patients and they would favor a single procedure to accomplish clearing of the visual axis. Nevertheless, to the author's knowledge, the present report of the outcome in 42 eyes of the 21 patients is the first independent study, with the longest follow up, demonstrating excellent results, despite the difference in the management of the posterior capsule, in bilateral cataract extraction utilizing intraocular lenses in children. The study showed that a secondary YAG laser capsulectomy was almost universally used to clear the posterior capsule if a primary capsulectomy was not utilized at the initial surgery.

Conflict of Interest

The author reports no conflict of interest.

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A Case Report of Salmonella muenchen Enteritis Causing Rhabdomyolysis and Myocarditis in a Previously Healthy 26-Year-Old Man

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Abstract

This case report examines an unusual presentation of a non-typhoidal Salmonella serovar with limited prevalence in the literature. This is the first case report to associate specifically the Salmonella muenchen serovar with rhabdomyolysis and myocarditis. This case report reviews the diagnostic criteria for myocarditis and explores the diagnostic dilemma of troponin elevation in the setting of rhabdomyolysis. It demonstrates that Salmonella muenchen has the ability to present in a broad range of individuals with complications extending beyond classical gastrointestinal symptoms. This report also concludes that diagnosis of the many possible complications from non-typhoidal Salmonella infections can be difficult due to patient comorbidities, variability in the severity of the illnesses, laboratory test limitations, and imaging limitations. When a patient presents with elevated troponins in the setting of rhabdomyolysis a careful workup should be done to evaluate for ischemic causes, myocarditis, or false elevation secondary to rhabdomyolysis.

Keywords

Salmonella muenchen, Non-typhoidal salmonella, rhabdomyolysis, myocarditis, troponin

Introduction

Salmonella is a genus of gram negative bacteria with 2,449 known serotypes.¹ It is an important cause of diarrheal illness in humans and its presenting symptoms and potential complications are noted below. Infections are caused by ingestion of contaminated food products including both animal and plant based foods. Contact with reptiles and persons infected with *Salmonella* can also spread disease.¹ Thus, safe practices in food production and handling have been instrumental in combating these types of infection.

Salmonella muenchen accounted for 6,055 of 441,863 (1.3%) cases of documented Salmonella infection in the United States between 1987-1997.¹ Human cases of this Salmonella serotype in Hawai'i County in 2011 was 0.64 cases per 100,000 population.² A 1999 outbreak of Salmonella muenchen affecting 157 people in seven states was related to contaminated alfalfa sprouts from Wisconsin.³ In the Wisconsin outbreak the prevalence of symptoms were as follows: diarrhea (97%), abdominal cramps (84%), fatigue (81%), chills (68%), headache (68%), fever (66%), nausea (65%), body aches (61%), and vomiting (37%).³ There was a 10% hospitalization rate but no report of complication rates. No deaths were reported. Two recent outbreaks of Salmonella muenchen occurred in June 2015 and November of 2015. The first outbreak tracked 22 cases over 17 states. This outbreak was due to contact with crested geckos kept as pets.⁴ The second outbreak infected 26 individuals in 12 states and was presumptively traced to contaminated alfalfa sprouts.5 The symptoms, physical exams, and biochemical findings in

victims of these recent outbreaks are not specifically described. *Salmonella muenchen* infections usually present with fever, diarrhea and abdominal cramping. Victims are usually young children, the elderly, or the immunocompromised. We report a case of *Salmonella muenchen* in an immunocompetent adult with myocarditis and rhabdomyolysis. This case demonstrates that *Salmonella muenchen* has the ability to present in a broad range of individuals with complications extending beyond classical gastrointestinal symptoms.

Case Description

A 26-year-old man with a history of migraine headaches presented to the emergency department in Hilo, Hawai'i with a four day history of progressive symptoms including fever, chills, total body myalgia with chest pain, one episode of un-witnessed hemoptysis (pink frothy sputum), non-bloody emesis, abdominal pain, and non-bloody diarrhea. His maximum temperature on the first day of admission was 101.7 F without other vital sign abnormalities. The white blood cell count was elevated to 18.4 x $10^{3}\mu$ L (normal range 3.8-11.2) with 15% bands. The patient met Systemic Inflammatory Response Syndrome (SIRS) criteria with fever and leukocytosis. He was admitted to the hospital with the diagnosis of probable sepsis.

He was given intravenous (IV) fluids and treated empirically for sepsis with IV ceftriaxone and IV metronidazole. Chest X-ray, complete abdominal ultrasound, and initial electrocardiograms (ECG's) were unremarkable. Computerized tomography (CT) scan of the abdomen and pelvis showed mild colitis. Stool cultures were eventually positive for *Salmonella muenchen*.

Abbreviations ANA: Antinuclear antibodies AST: Aspartate aminotransferase BLIN: Blood urea nitrogen
CCP: Cyclic citrullinated peptide antibody
CHF: Congestive heart failure
CK: Creatine kinase
CT: Computed tomography
cTnI: Cardiac troponin-I
CMV: Cytomegalovirus
EBV: Epstein-Barr virus
ECG: Electrocardiogram
IV: Intravenous
HIV: Human immunodeficiency virus
MRI: Magnetic resonance imaging
SIRS: Systemic inflammatory response syndrome

The remainder of the infectious workup was negative including evaluation for stool ova and parasites, *C. difficile* toxin, two consecutive days of blood cultures, group A *streptococcus* cultures, and serological testing for the following: *leptospirosis*, influenza, parvovirus B19, human immunodeficiency virus (HIV), epstein-barr virus (EBV), hepatitis A, B, and C, and cytomegalovirus (CMV). Rheumatological workup was negative including rheumatoid factor, antinuclear antibodies (ANA), cyclic citrullinated peptide antibody (CCP) and double stranded DNA antibodies. Urinalysis and urine toxicology was non-contributory. The patient denied tobacco, alcohol, and drug use. He states that one of his children had a flu-like illness for 2 weeks prior to hospital admission. He is a welder by trade. He has chickens in his yard which he feeds but states he does not have frequent close contact with the chickens.

On day six from the reported onset of symptoms the creatine kinase (CK) peaked at 9,836 U/L (normal range 58-220). Aspartate aminotransferase (AST) peaked at 207 U/L (normal range less than 31) on day seven of illness. Renal function [blood urea nitrogen (BUN) and creatinine] remained normal throughout the hospitalization. On day seven of illness, cardiac troponin-I (cTnI) levels were found to be elevated and peaked eight hours later at 13.12 ng/mL (normal range < 0.04). At this point a cardiology consultation was obtained. No ECG abnormalities were noted at the time but the patient still complained of intermittent "chest tightness." Transthoracic echocardiography on that day was negative for systolic or diastolic heart failure, hypokinesis or wall motion abnormalities. Serial ECG's showed the development of asymptomatic inferolateral T-wave inversion on day eight and nine with resolution on day ten of illness. CT cardiac angiography showed no abnormalities. Cardiac magnetic resonance imaging (MRI) was not available on island.

The patient was discharged on day 8 of hospitalization after resolution of his presenting symptoms. He was given a 14-day course of ciprofloxacin for the *Salmonella* infection. He was given aspirin and metoprolol due to the complication of myocarditis. At a five-month cardiology follow-up visit the patient had made a full recovery and was without residual symptoms. His ECG on follow up was normal. His treadmill stress test on that date was also normal.

Discussion

The purpose of this case report is to discuss the potential complications of *Salmonella* diarrheal infections and to examine the diagnostic difficulty of troponin elevation in the setting of rhabdomyolysis. There have been case reports of other nontyphoidal *Salmonella* infections causing rhabdomyolysis⁶⁻⁸ but no reports associated specifically with *Salmonella muenchen*. This is likely because of the low incidence of human infections related to this specific serotype. One study noted the non-typhoidal *Salmonella serotype* prevalence in a case series ending in 1984. *Salmonella muenchen* was found to be the causative organism for 2 of 137 cases of *Salmonella* associated meningitis and 2 of 150 cases of *Salmonella* associated osteomyelitis. Neither rhabdomyolysis nor myocarditis were included as a complication in this case series⁹ and the exact risk of these complications remains unknown with *Salmonella* enteritis.

Etiology and Diagnosis of Myocarditis

Myocarditis was suspected in this patient based on symptoms, laboratory studies and ECG findings. The etiology of myocarditis can be divided into infectious, immune-mediated, and toxic myocarditis. Some bacterial infectious causes include Staphylococcus, Streptococcus, Pneumococcus, Meningococcus, Lyme disease, Rickettsial diseases, and Leptospirosis. Fungal causes can include Aspergillus, Actinomyces, Blastomyces, and Histoplasma. Parasitic infectious causes include Toxoplasma, Leishmania, Trichinella spiralis, and Echinococcus granulosus.10 Viral infections have also been implicated and include coxsackie viruses, polio viruses, influenza, dengue virus, cytomegalovirus (CMV), epstein-barr virus (EBV), and parvovirus. Immune mediated causes include infection-negative lymphocytosis, systemic lupus erythematosus, rheumatoid arthritis, Kawasaki's disease, inflammatory bowel disease, thyrotoxicosis, sarcoidosis, and allergic drug reactions. Toxic myocarditis can be caused by amphetamine or cocaine abuse, lithium, clozapine, heavy metal poisoning, envenomation, radiation, beri-beri, or pheochromocytoma.¹⁰

Endomyocardial biopsy is the gold-standard for diagnosis of myocarditis regardless of etiology. However, most patients are not candidates for this procedure because of its high risks. ECG changes can also occur during the initial weeks of illness. Less than 50% of patients with myocarditis present with ST segment elevation or T-wave inversion (the most sensitive ECG criteria for myocarditis). Echocardiograms are used in suspected cases of myocarditis but miss many mild cases.¹¹ Certain nuclear medicine tracers can also be used for a non-specific diagnosis of myocarditis but are rarely used in clinical practice due to tracer availability. Due to its safety profile and consistent accuracy in diagnosis, the cardiac MRI has become the standard tool to confirm the diagnosis of myocarditis.11 However, cardiac MRI is not always available in rural settings and clinical diagnostic criteria for myocarditis includes multiple factors which are discussed below.

Differential Diagnosis of Cardiac Troponin Elevation

Cardiac troponin-I (cTnI) is a very common and useful laboratory indicator of cardiac myocyte injury. Caution must be used in interpreting this test in situations of concurrent rhabdomyolysis. cTnI can be falsely elevated in cases of rhabdomyolysis and it is very difficult to determine if there is both cardiac injury and rhabdomyolysis. A study including 109 emergency room patients with rhabdomyolysis and elevated cTnI determined the presence of true cardiac injury by having either ECG or echocardiographic evidence of myocyte injury regardless of chronicity in the hospitalization.¹² This study found a 55% prevalence of elevated cTnI and a 17% false positive elevation of cTnI in patients with rhabdomyolysis. There was poor correlation between peak cTnI and total creatine kinase (CK) and no correlation between magnitude of peak cTnI between true and false positive cases. Of note, the mean for peak cTnI was 2.2 ± 4.2 ng/mL vs 1.9 ± 3.4 ng/mL for true positive and false positive cases respectively; meaning this test is not helpful to differentiate true from false cTnI elevation. Another study examining the cause of elevated cTnI in rhabdomyolysis patients concluded that the cTnI elevation is not related to the degree of muscle injury but rather to the cause of rhabdomyolysis. The authors noted illicit substance use, hypotension, and sepsis to be the leading causes of cTnI elevation.¹³ In this case the diagnosis of myocarditis is based on the presence of chest pain, the asynchronous rise in cTnI after the peak of the CK levels and the presence of ECG changes during the peak of symptoms which subsequently resolved.

Source of Infection

It is unclear how this patient contracted this enteric infection. Chickens and turkeys account for the highest isolates of Salmonella muenchen in animals² and this patient did keep chickens at home. It is possible, therefore, that this case could be due to food contamination, contact with a previously infected family member, or other unknown causes. It is interesting that pet geckos have been implicated in recent outbreaks of Salmonella muenchen, as the prevalence of wild geckos in Hawaiian households is very high. In Hawai'i, the prevalence of Salmonella in the wild gecko populations can vary. In 1982, researchers found 10 of 13 sites on the island of Hawai'i with geckos positive for Salmonella. The highest incidence of Salmonella-infected geckos was 22.2% with the overall average being 11.9%. The authors postulate that one likely mode of transmission to humans could be through gecko feces. The prevalence of shedding in feces varies as well. Their study found 1.8% of gecko feces positive for Salmonella¹⁴ and another study on the island of Oahu showed 30.4% of gecko feces testing positive.¹⁵ The incidence of gecko to human transmission of non-typhoidal Salmonella infections remains unknown and could be a subject of future research.

Diagnosis

In a healthy young man in excellent physical condition the presence of cardiac complications went unrecognized. The patient was in the hospital for two days before a troponin level was obtained. His chest pain was masked by full body aches and normal initial ECG's. When a troponin was obtained, the presence and magnitude of the findings were completely unexpected. A more careful history was negative for other risk factors such as drug abuse, family history of early cardiac disease or congenital metabolic disease. Although his stool culture was positive for Salmonella muenchen, blood cultures obtained on the fourth and fifth days of illness remained negative. His clinical picture, vital signs and laboratory data did not offer other reasons for rhabdomyolysis such as hypotension, dehydration, or marked electrolyte abnormalities. It is possible that the complications are from bacteremia that had cleared by the time the patient presented to a health care setting or secondary to systemic release of bacterial toxin.16

In this case the question eventually emerged as to whether the patient's troponins were elevated due to rhabdomyolysis or to true myocarditis. The magnitude of troponin elevation was itself very impressive. This patient's troponin peak was greater than 6 times higher than the average false-positive and true-positive troponin peak in patients with rhabdomyolysis in the study mentioned above.¹²A normal CT cardiac angiography ruled out ischemic cause for the troponin elevation. In regards to diagnosis of the myocarditis, there are criteria proposed by the European Society of Cardiology Working Group on Myocardial and Pericardial disease from 2013.10 These criteria proposed clinical diagnosis of myocarditis with acute (less than three months) or subacute (three months or greater) cardiac symptoms and at least one positive study on ECG, holter monitor, stress test, cardiac markers, cardiac imaging, or tissue characterization by cardiac MRI. Asymptomatic patients must meet two of the above criteria. Echocardiography had been normal but this does not rule out milder cases of myocarditis.¹¹ The diagnosis of myocarditis was confirmed by the patient's symptoms, inferolateral T-wave inversion on ECG, and elevated troponins.

Treatment

The question arises as to whether the early diagnosis of rhabdomyolysis and myocarditis would have changed management and outcomes for this patient. His rhabdomyolysis was treated with aggressive I.V. fluids as well as antibiotic therapy to treat the underlying cause. The primary reason to give IV fluids for rhabdomyolysis is to prevent kidney injury.17 The incidence of rhabdomyolysis induced acute kidney injury (AKI) was found to be 58% in patients with a CK greater than 5,000 U/L.18 Aggressive intravenous fluid administration for rhabdomyolysis in a patient with concurrent myocarditis has risks. Most concerning is flash pulmonary edema in the setting of myocarditis related acute congestive heart failure (CHF), which has been noted in a severe case of non-typhoidal Salmonella induced myocarditis.8 In a patient with multiple comorbidities and possibly poor baseline cardiac function this would have to be carefully addressed; however, in a young healthy patient as described above with no echocardiographic evidence of global myocardial hypokinesia and a preserved ejection fraction, this was not a great concern..

Conclusion

This is the first case report of *Salmonella muenchen* serotype causing either rhabdomyolysis or myocarditis. Complications from non-typhoidal *Salmonella* infections are rare but can include rhabdomyolysis, myocarditis, meningitis, endocarditis, pericarditis, mycotic aneurysms, pneumonia, empyema, urinary tract infections, genital infections, both septic and reactive arthritis, osteomyelitis, and soft tissue infections.⁶⁹ Diagnosis of complications from non-typhoidal *Salmonella* infections can be difficult due to patient comorbidities, variability in the severity of the illnesses, laboratory test limitations, and imaging limitations. A careful assessment and high index of suspicion can help aid diagnostic and treatment approaches. In addition, when a patient presents with elevated troponins in the setting

of rhabdomyolysis a careful workup should be done to evaluate for ischemic causes, myocarditis, or false elevation secondary to rhabdomyolysis.

Conflict of Interest

None of the authors identify any conflicts of interest.

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MEDICAL SCHOOL HOTLINE

Hawai'i Medical Education Program: An Innovative Method to Incorporate American Education Methodologies into the Traditional Japanese System

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Background

The current medical educational system in Japan was established more than 60 years ago.¹ Reforms introduced by the Japanese were influenced by the Allied Forces and the US educational system in the 50s and 60s. Currently, Japanese medical education is a six-year program that starts immediately after high school. The curriculum consists of general education for first two years; pre-clinical studies which include basic science during the third and fourth years; clinical clerkships during the fifth year; and exams and preparation for the national licensure examination during the sixth year.² Throughout the six years, the majority of time is spent in lectures, with little or no hands-on clinical experience. Medical education focuses mainly in acquiring didactic medical knowledge necessary to pass the national licensure examination.

In comparison, US clinical experiences in medical education are standardized and strictly regulated by accrediting organizations, the Liaison Committee on Medical Education (LCME) during medical school and the Accreditation Council for Graduate Medical Education (ACGME) during residency training after medical school. In 2004, to address the limited clinical experience in Japanese medical education, the Ministry of Health (Ministry of Health, Labor and Welfare) ordered a two-year mandatory postgraduate training program following graduation and acquisition of medical license. Currently, this is required before physicians can practice independently.²

The Japanese mandatory postgraduate training is similar in its content to that of the clinical clerkship experiences conducted in the third and fourth years of study at US medical schools. Following the two-year postgraduate training, physicians usually continue in residency programs in specific specialty areas. Table 1 is a summary comparison of medical education systems between Japan and the United States.

Medical schools in the United States and Canada are accredited by the LCME with strict educational and administrative standards. Accreditation oversight is conducted by the LCME. Accreditation is granted if all the standards are met by the medical school. Students that have graduated from LCME accredited medical schools take the United States Medical License Examination (USMLE) and apply for the National Residency Matching Program (NRMP) for US residency positions. In US residency programs, trainees are assigned greater patient care responsibility under supervision with focused experiences in the specialty areas.

For foreign medical school graduates to apply for the NRMP, they must obtain certification from the Educational Commission for Foreign Medical Graduates (ECFMG). In July 2010, the ECFMG announced that, effective in 2023, foreign physicians applying for ECFMG certification will be required to graduate from medical schools that have been appropriately accredited.^{3,4} To satisfy this requirement, foreign medical schools must be accredited through a formal process that uses criteria comparable to those established for US medical schools (LCME), or other globally accepted criteria such as those put forth by the World Federation for Medical Education (WFME).

Currently (as of March 2017), most Japanese medical schools do not meet the criteria set by either LCME or WFME. In particular, clinical medical education, such as bedside teaching and patient care responsibility are less extensive in Japanese medical schools than the world standard. The Ministry of Educa-

Table 1. Comparison of Medical Education Systems between Japan and the United States					
Japan	United States				
High School	High School				
Medical School (6 Years) ¹	College (4 Years), Medical School (4 Years) ³				
#Medical Licensure Examination	#USMLE				
Mandatory Post Graduate Training (2 Years) ²	<clinical (2="" clerkship="" years)="">3</clinical>				
Specialty Residency (3 – ? Years)	Residency/Fellowship (3 – ~8 Years)				
Ministry of Education ¹	LCME ³				
Ministry of Health ²					

tion and all Japanese medical schools are aware of this critical issue and are revising their medical school curricula to meet global standards. The majority of Japanese medical schools are planning to launch new curricula for freshmen beginning in April 2017.

To adapt their own curricula to meet the ECFMG requirement by 2023, Japanese medical schools have demonstrated a strong interest in learning about curricula and teaching methodologies used by US LCME accredited medical schools. The University of Hawai'i (UH), John A. Burns School of Medicine (JABSOM), with its long history of collaboration with Japanese medical schools, is offering an innovative method to incorporate a US medical education curriculum and methodologies into the traditional Japanese system as one approach to address the existing challenges.

Hawai'i Medical Education Program

To comply with the regulations, foreign medical school graduates applying for NRMP must obtain certification from the ECFMG. The Hawai'i Medical Education Program (HMEP) was created by the Office of Global Health and Medicine, with the endorsement of the Dean of JABSOM, to help facilitate students in obtaining ECFMG certification. This HMEP fulfills the Japanese medical education requirements by the Ministry of Education simultaneously.

The following are key points of HMEP (see Table 2):

1. During Japanese medical school (JMS) years 1-4, (every Saturday) classes are offered in Tokyo to Japanese medical students as extracurricular educational activities. In these classes, liberal arts, critical thinking skills, basic science, and clinical science are taught (some in English). Faculty members are familiar with the UH JABSOM style of medical education. This is supplemental to the students' regular weekday classes. Also these special classes for Japanese students provide an understanding of UH education, particularly interactive discussion essential in problem-based learning (PBL) and clinical clerkship. Learning English communication, including, interpersonal skills are also emphasized in these classes.

2. The majority of the educational activity of HMEP is conducted in medical schools and affiliated teaching hospitals in Japan, except for the Hawai'i Clinical Clerkship Preparation Program (HCCPP). Before students enter the UH style clinical clerkship in Japan at JMS year 4, they will visit and spend one month at JABSOM in Hawai'i. They will experience the UH style of clinical clerkships by observing bedside teaching teams, by interacting with UH medical students, by experiencing the UH PBL exercises and by clinical simulation education, under the aegis of JABSOM's Office of Global Health. HCCPP is conducted to motivate students to better understanding US style clerkship methods.

3. During JMS years 4-6, Japanese students will undergo newly designed clinical clerkships in major medical specialties, similar to JABSOM clerkships: internal medicine, general surgery, pediatrics, obstetrics-gynecology, family medicine, psychiatry, emergency medicine and geriatrics. These clerkships are conducted at Japanese teaching hospitals, and the majority of the faculty physicians are Japanese clinical educators who have been trained in the United States, with sufficient understanding of the US style clinical clerkships.

4. During JMS years 1-4 (class room years), and also during JMS years 4-6 (clinical clerkship years), HMEP students are encouraged to prepare for the USMLE through self-study, interactive learning with faculty, as well as mock examinations provided by HMEP educators. HMEP faculty will offer additional help and support for students who are interested in joining the NRMP to enter US residencies.

5. JABSOM and HMEP faculty in Japan will offer continued mentoring and support to graduates of the HMEP, even after graduation from Japanese medical schools.

In April 2016, the HMEP was launched in Japan in partnership with Tokai University School of Medicine. This HMEP curriculum meets the ECFMG requirements and global standards. The Japanese academic year is from April to March of the following year. During the 2016 academic year, a total of 30 special classes were completed from April 2016 to February 2017. The current JMS year-1 students participated in these classes.

Many teaching faculty members are dual licensed in Japan and the United States (with US board certification). The faculty members also include non-medical professionals such as PhD faculty members from various fields, politicians, communication specialists, and so forth. The extended faculty members of course also include practicing and teaching American physicians in Japan.

Education System						
Medical School Year	1/2 Year	Japanese System	HMEP	USMLE Prep		
1	1st	Liberal Arts	Weekend Class			
1	2nd	Basic Science	Weekend Class			
2	1st	Basic Science	Weekend Class			
2	2nd	Basic Science	Weekend Class			
3	1st	Clinical Science	Weekend Class			
3	2nd	Clinical Science	Weekend Class	Step 1		
4	1st	Clinical Science	HCCPP at UH, JABSOM*			
		Exam (CBT, OSCE)				
4	2nd	Bedside Learning	Clinical Clerkship in Japan	Step 2 CK		
5	1st	Bedside Learning	Clinical Clerkship in Japan			
5	2nd	Bedside Learning	Clinical Clerkship in Japan			
6	1st	Bedside Learning	Clinical Clerkship in Japan	Step 2 CS		
6	2nd	Graduation Exam				
		Medical Licensure Exam				

*Office of Global Health/Medicine

In the 2017 academic year (from April 2017), basic science will be taught to JMS year-2 students. In 2018, clinical science will be taught to JMS year-3 students, once the current 2016 JMS year-1 students become JMS year-2 and -3. For 2019 and beyond, HMEP is preparing the US style clinical clerkships for JMS year-4 students to be conducted at a new US style international teaching hospital, affiliated with Tokai University. This clerkship will be conducted in both Japanese and in English. Direct patient care will be performed in Japanese since the patients are predominantly Japanese, while teaching rounds and conferences will be conducted in English. Unlike observerships, the students will gain hands-on clinical experience as "student-doctor" team members. Prior to graduation in 2022, these students (current 2016 JMS year-1 students) will prepare for USMLE step 1 and step 2CK/2CS, in addition to preparing for the Japanese medical licensure examination.

A number of other Japanese medical schools have been showing interest in participating in the HMEP. It is expected that 5 or 6 schools will join the HMEP beginning in 2017.

Conclusion

Because of the ECFMG requirement of 2023, Japanese medical schools need to revise their curriculum beginning in 2017 so that these graduates from medical schools in 2023 will be educated under criteria expected by the LCME or WFME. Consequently, Japanese medical schools are reaching out to US medical schools for assistance, particularly in regards to the application of hands-on clinical clerkships.

There have been certain reforms in Japanese medical education and postgraduate residency training in the last 25 years. This

includes implementing the two year mandatory postgraduate medical training, initiating PBL learning curriculum and the achievement test in preclinical core curriculum and medical simulation education.5 Nonetheless, Japan continues to remain a conservative nation in terms of medical education compared to other Asian countries that have enthusiastically imported modern US or European medical educational systems. Moving forward, Japan will benefit by extending further into the international world of medical education. Collaborations with United States and other foreign schools will support the future globalization of medical education in Japan. The new innovative HMEP approach summarized in this article has the strong potential to serve as a role model for Japanese medical schools and can help global standardization of Japanese medical education and help ensure that Japanese medical students are able to obtain ECFMG certification and apply for residency positions in the United States.

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THE WEATHERVANE RUSSELL T. STODD MD; CONTRIBUTING EDITOR

WHEN THE PROMISE OF TECHNOLOGY SEEMS ALMOST MIRACULOUS.

Nothing gives a cancer surgeon more pleasure than to feel confident that he/she removed all the malignancy with the initial operation. But many tumors have multiple portions that extend into surrounding tissue with obscure margins that require a return to the OR. A new device appears to hold the promise of defining lingering cancer cells, so the surgeon can remove them immediately. A hand-held tool the size of a thick pen called MarginProbe allows the doctor to explore the edges of tissue removed. When it spots a cancerous area, the device emits a loud beep and flashes a red light so the surgeon can remove the remaining ugly tissue. When the edge is clear the probe sends out a soft sound with a blue light. The defining points are the margins of a breast lumpectomy or similar tumor that can be readily defined making repeat operations much less common. Reporting in the Annals of Surgical Oncology in 2014, Dr. Freya Schnabel, director of breast surgery at NYU Langone's Perlmutter Cancer Center, stated that reexcision rates dropped from 24% to 11% when the MarginProbe was used. Recently, reporting in the December 2016 American Journal of Surgery, Vincent Reid, the lead author and medical director at the Cancer Center at Mercy Medical Center in Cedar Rapids, Iowa, was skeptical at first. He found that the more he used the probe the more he trusted the technology. It is so sensitive it gives many false positives prompting surgeons to remove extra tissue, but the reverse would be far more consequential. The down side (again) is the cost. Each probe costs \$1,000, not covered by insurance, and it can be used only once. The up side is avoiding the stress of a repeat operation that can run \$9,000 to \$16,000 and up. MarginProbe, was developed by an Israeli physicist and is manufactured by Dune Medical Devices in Pennsylvania and Israel.

...AND THE DOWNSIDE: WHEN DREAMS AND REALITY (AND \$700 MILLION) COLLIDE.

Elizabeth Holmes is the founder of the blood-testing company Theranos. Her promise was that her labs could analyze a drop of blood and determine any number of diagnostic tests in a very short time and at minimal expense. Hi-tech Labs were established in Arizona as well as Silicon Valley. Theranos had 40 attachments to Walgreen Wellness Centers and overall obtained \$700 million in investment capital. She was described by her company as a feminine Steve Jobs, and the media were enamored. Problems came about when her labs failed to produce. When sources found that data could not be substantiated, they pulled the carpet out and Theranos collapsed. Centers for Medicare and Medicaid (CMS) leveled severe penalties on the Arizona lab and revoked the lab's US testing license, barred it from billing Medicare and ordered it to alert customers. In November, Ms. Holmes told regulators the company decided to close its lab before the inspection began "after reexamining its core values and making the business determination to focus its resources on its miniature automated laboratory products." A number of investors are bringing lawsuits, including Walgreen Co. In addition Theranos faces federal civil and criminal probes. Like pie in the sky, it sounded so promising when introduced.

SURELY WE CAN DO BETTER THAN JUST ASKING "HOW MANY FINGERS DO YOU SEE?"

The visual system involves about half of the brain's circuits, and many are vulnerable to head injury. Despite its importance, vision has long been sidelined in evaluating concussion diagnosis and treatment. Most sideline doctors and trainers have not received much training on the visual system and aren't comfortable assessing vision. Evaluation is often brief with limited time to make decisions. Released in March 2013, the Sports Concussion Assessment Tool (SCAT 3) is the most common check used on the sidelines for concussion. It includes a symptom check-list, and also checks for memory, balance and cogni-

tive changes. The examiner does what he knows best, which is to ask questions about how the player is thinking and feeling and he observes how the player is walking. Visual testing is not used at all. Laura Balcer, MD, MSCE at the NYU School of Medicine in New York City found that vision is an intricate piece of neurological disorders. Mild traumatic brain injury (mTBI) can impact several visual tasks, ie, convergence, accommodation, saccadic mechanisms, vestibular-ocular function and pursuit. This can involve cranial nerves III, IV and VI. Neuroophthalmologist David Kaufman, DO at Michigan State University who travels with the team is often called on to assess concussions. He has numerous tests he adds to SCAT 3 for mTBI. When he hears the student athlete use the word "dizzy" that's a signal to look at the ocular motor system quite carefully. It's about time.

ELBOW ROOM? KNEE ROOM? HEAD ROOM? YOU MUST BE KIDDING.

They are at it again, reducing already compromised space. Airlines are shrinking cabins even further, as one passenger's nose may be 3 inches closer to the back of the head in front of him even before the seat in front reclines. The average flight now has 142 seats compared with 137 two years ago. Installing skinny bathrooms and minimizing galleys have let airlines pack in more rows. Stella Lourenco, Emory University psychology professor says, "Everyone has to have some minimal space." Reduced head-room can impact people with claustrophobic fears. Martin Self, New York clinical psychologist and associate director of the Anxiety and Phobia Treatment Center for White Plains Hospital Center says, "The head is probably the most important part. Higher density leads to a greater chance of losing your temper and even air rage." Do the airlines care? Given the increasing incidents of errant passenger behavior causing flight diversions or disturbances in the cabin, obviously not.

HOW FAR OUT MUST WE CARRY THIS THING?

Legislators in Florida and Iowa recently advanced bills giving women who have had legal abortions up to 10 years (or longer in Iowa) to sue the doctor if the abortion winds up causing "emotional distress." A signed consent form may serve to minimize settlement damages, but would not provide immunity. Politics do indeed make strange bedfellows. No doubt any number of these legislators have decried emotional distress as a measure of damages and used it as a reason for tort reform. Maybe they should give voters the right to sue their legislators for the same amount of time for the emotional distress they cause by passing these sorts of laws.

CHRISTMAS IN BARCELONA MUST BE SPECTACULAR.

One of the planet's most bizarre traditions comes from Spain's Catalonia region. Picture passing any number of local nativity scenes where, in addition to the usual suspects, you can find figurines of both local and international citizens (this past Christmas they included Hillary Clinton, President-elect Donald Trump, Pope Francis, Queen Elizabeth, and the all-time best seller, President Barack Obama. All are posed squatting to perform what in Spain must be called numero dos. The explanation (locals claim) lies in the tradition that if the manger is fertilized, 2017 crops can be expected to flourish...eeew.

ADDENDA

- The single most common object involved in choking is the toothpick.
- -British anatomist Richard Owen invented the word "dinosaur" in 1841.
- The shortest film role to win an Oscar was Sylvia Miles, onscreen for 6 minutes in "Midnight Cowboy."

- Children today are tyrants. They contradict their parents, gobble their food and tyrannize their teachers. (Socrates)

- Fuchsia is the most carefully spelled flower in the English language.

ALOHA AND KEEP THE FAITH rts (Editorial comment is strictly that of the writer.)

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