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ON THE COVER: Reed Flute Cave photograph By David D Clarke, MD

The elaborate natural limestone formations in Reed Flute Cave, in Guillin, Guangxi, China, attract many visitors to the area with their diversity and beauty.

The cover of the first issue of *The Permanente Journal*, Summer 1997, featured Dr Clarke's photograph of body pigments for sale in a Kathmandu, Nepal market. Twenty years later, we are proud to be publishing high-quality articles graced by high-quality art.

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ORIGINAL RESEARCH & CONTRIBUTIONS

Body Mass Index and Mortality in a Very Large Cohort: Is It Really Healthier to Be Overweight? Arthur L Klatsky, MD; Jasmine Zhang; Natalia Udaltsova, PhD; Yan Li, MD, PhD; H Nicole Tran, MD, PhD

This retrospective cohort study in a multiracial population of 273,843 persons used logistic regression with 7 covariates (sex, age, race-ethnicity, education, marital status, smoking, alcohol intake). With average follow-up exceeding 30 years, there were 103,218 deaths: 41,215 attributed to cardiovascular causes and 62,003 to noncardiovascular causes. Compared with persons with body mass index defined as normal, persons who were underweight, overweight, and obese were at increased risk of death during a 30-year period.

12 Effect of Age on Outcomes of Shoulder Arthroplasty. Oke A Anakwenze, MD; Tameem Yehyawi, MD; Mark T Dillon, MD; Elizabeth Paxton, MA; Ronald Navarro, MD; Anshuman Singh, MD

In a retrospective cohort study of prospectively collected data, using an integrated health care system's shoulder arthroplasty (SA) registry (1/2007-6/2012), patients were grouped into older (> 75 years) and younger groups (< 75 years). The total SA cohort had 2007 patients, 538 (27% > age 75 years), and the reverse total SA cohort had 568 patients, 295 (52%) age > 75 years. In the total SA cohort, older patients had higher risk of readmission and mortality. In the reverse total SA cohort, older patients had lower risk of revision.

17 Nasopharyngeal Carcinoma Diagnostic
Challenge in a Nonendemic Setting:
Our Experience with 101 Patients.
Kevin H Wang, MD; Stephanie A Austin,
MD; Sonia H Chen, MD; David C Sonne,
MD; Deepak Gurushanthaiah, MD

A retrospective chart review (2007-2010) included 101 patients; 70 were of Chinese or Southeast Asian descent. Median time from symptom onset to treatment was 6 months. One-third of cancers were missed with nasal endoscopy and imaging. An understanding of the risk factors, presenting symptoms, and limitations associated with these diagnostic tests is necessary to support earlier detection of this insidious cancer.

22 Incidence of Pulmonary Arterial Hypertension in Patients with Psoriasis: A Retrospective Cohort Study. Young M Choi, MD; Shannon Famenini, MD; Jashin J Wu, MD

In a retrospective cohort study (1/2004-11/2012), there were 10,115 patients with mild psoriasis, 3821 with severe psoriasis, and 69,360 matched controls. On multivariable analysis, there was a significantly increased risk of pulmonary arterial hypertension (PAH) developing in the severe psoriasis cohort vs their controls. The systemic inflammatory process underlying psoriasis may be a cause for an increased risk of PAH, but there are numerous secondary causes of PAH.

28 Complementary and Alternative
Medicine in an Integrated Health Care
Delivery System: Users of Chiropractic,
Acupuncture, and Massage Services.
Tracy McCubbin, MD; Karin L Kempe, MD,
MPH; Arne Beck, PhD

From 2007-2014, 27,225 patients sought Center for Complementary Medicine (CCM) services (62% female, 73% white). Modalities included chiropractic (67%), acupuncture (18%), and massage (15%). Spine/truncal pain was most commonly reported (71%). Of patients, 59% saw their physician for their condition; 59% had not used CCM services previously; and 60% received medications for their condition. Mean ratings included pain relief with prior treatment (30%), current pain (4.33), and functional impairment ranging from 3.03 for relationships to 5.42 for enjoyment of life.

34 Impact of Longitudinal Electronic Health Record Training for Residents Preparing for Practice in Patient-Centered Medical Homes. Jung G Kim, MPH, CPH; Hector P Rodriguez, PhD, MPH; Katherine AT Estlin, MD; Carl G Morris, MD, MPH

The patient-centered medical home (PCMH) electronic health record (EHR) training consisted of case-based routine clinic visits delivered to 3 resident cohorts (N = 18). Participants (127) completed an EHR competency self-assessment (2011-2016). Comprehensive training designed to improve EHR competencies for practicing in a PCMH resulted in improved assessment scores. Findings indicate EHR training as part of resident exposure to the PCMH measurably improves self-assessed competencies, even among residents less engaged in EHR training.

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40 Mortality After Total Knee and Total Hip Arthroplasty in a Large Integrated Health Care System. Maria C S Inacio, PhD; Mark T Dillon, MD; Alex Miric, MD; Ronald A Navarro, MD; Elizabeth W Paxton, MA

In a retrospective analysis of an integrated health care system population in 2010, 10,163 primary total knee arthroplasties (TKAs), 4963 primary total hip arthroplasties (THAs), 606 revision TKAs, and 496 revision THAs were evaluated. Patients undergoing primary THA and TKA had lower odds of mortality than expected. Patients with revision TKA had higher-than-expected mortality odds, whereas patients with revision THA did not have higher-than-expected odds of mortality.

Special Report

46 Physician Guide to Appropriate Opioid Prescribing for Noncancer Pain. Timothy Munzing, MD, FAAFP

The author highlights key topics in the management of patients using opioids (or potentially needing opioids) in outpatient clinical practice; federal and state law enforcement actions regarding physicians' illegal prescribing of opioids; multimodal approaches to pain control; nonmedication management of pain; response strategies when suspecting a patient of diverting or misusing opioids; and warning signs for abuse or diversion. In addition to individual action, the initiation of systemwide and clinicwide safe prescribing practices supports the physician and patient such that the patient's well-being is at the heart of all pain management decisions.

Special Report

53 The Kaiser Permanente Northern California Enhanced Recovery After Surgery Program: Design, Development, and Implementation. Vincent X Liu. MD. MS: Efren Rosas. MD: Judith C Hwang, MD, MBA; Eric Cain, MD, MBA; Anne Foss-Durant, RN. MSN. FNP. MBA: Molly Clopp. RN, MS, MBA, Mengfei Huang, MSc; Alexander Mustille: Vivian M Reves. MD: Shirley S Paulson DNP(c), MPA, RN, NEA-BC; Michelle Caughey, MD; Stephen Parodi, MD

In this report, the authors describe the design, development, and implementation of an Enhanced Recovery After Surgery program in the Kaiser Permanente Northern California integrated health care delivery system (2014), targeting patients with elective colorectal resection and those with emergent hip fracture repair across 20 Medical Centers. The program leveraged multidisciplinary and broad-based leadership, high-quality data and analytic infrastructure, patient-centered education, and regional-local mentorship alignment. This program has already had an impact on more than 17,000 patients.

REVIEW ARTICLES

S

62 Supporting Muslim Patients During Advanced Illness. Nathan A Boucher, DrPH, PA-C, MS, MPA, CPHQ; Ejaz A Siddiqui, MIS; Harold G Koenig, MD, MHS

Worldwide violence perpetrated by people identifying as Muslim has been a growing fear for people living in the US and elsewhere. This article explores conditions needed for prayer, roles of medical treatment and religious authority, modesty, and the role of family in making medical decisions. Initial recommendations are provided to optimize care for Muslim patients and their families, informed by the described tenets of Muslim faith.

CLINICAL MEDICINE

67 Use of a Technetium99m-Sestamibi Scan to Detect Ipsilateral Double Adenoma in a Patient with Primary Hyperparathyroidism: A Case Report. Joseph Gabriel Gabriel, MD; Alejandro Contreras, MD; Andrew Rosenthal, MD

Patients with primary hyperparathyroidism generally have a single parathyroid adenoma that causes excessive excretion of parathyroid hormone. About 2% to 15% of these patients have a double adenoma. Presurgical imaging and nuclear scans can help to localize multiple lesions, and intraoperative parathyroid hormone assays can confirm the diagnosis and cure.

70 A Clinical Approach to Animal Bites with an Avulsion Flap: A Case Report. Andrew Williamson, MD; Cyril Thomas, MS, PA-C

A 90-year-old white woman sustained a large dog bite to her hand, over the dorsal aspect of the first metacarpal, which was repaired with the avulsion flap as a biologic dressing that employed a perforating technique to successfully treat the wound and allow for optimal wound healing. Photographs at several stages are included.

72 Splenic Abscess in Immunocompetent Patients Managed Primarily without Splenectomy: A Series of 7 Cases. S Divyashree, MBBS, MD; Nikhil Gupta, MBBS, MD

A microbiological diagnosis of splenic abscess is of utmost importance. In this case series, all patients underwent percutaneous aspiration. This was performed under radiologic guidance (either ultrasonography or computed tomography). Only one patient required diagnostic splenectomy. Appropriate antibiotic therapy is the cornerstone of management.

78 Flood Syndrome: Spontaneous Umbilical Hernia Rupture Leaking Ascitic Fluid-A Case Report. Emilie T Nguyen, MD; Leah A Tudtud-Hans. MD

The spontaneous rupture of an umbilical hernia in a 42-year-old man with hepatitis C and alcoholic cirrhosis was complicated by ascites and esophageal varices. This is a

rare complication with high mortality rates and stresses the challenge of treatment that falls in the area between medical and surgical management.

80 Image Diagnosis: Multivessel Percutaneous Coronary Intervention in Dextrocardia: Success with Usual Techniques in a Case of Mirror-Image Heart.

Mohamed Morsy, MD; Pranab Das, MD; Inyong Hwang, MD; Rami N Khouzam, MD, FACC, FACP, FASNC, FASE, FSCAI

Although dextrocardia is very rare, it could be clinically noted in a variety of cardiovascular and noncardiovascular conditions. Patients with dextrocardia can have various clinical presentations, including acute coronary syndrome and congestive heart failure. Successful diagnostic catheterization and multivessel intervention can be achieved through conventional catheters with appropriate reversed rotation and without need for right/left reversal of radiologic views.

82 Image Diagnosis: A Gastric Signet-Ring Adenocarcinoma of Type Linitis Plastica Mimicking Splenomegaly in a Patient with Chronic Lymphocytic Leukemia. Leonid L Yavorkovsky, MD, PhD; Shazia Ali, MD

Typically, adenocarcinoma of type linitis plastica, known as Brinton disease or leather bottle stomach, is characterized by diffuse infiltration of neoplastic signet-ring cells. This imparts a rigid consistency to the stomach wall, with a thickened, fibrotic appearance. These symptoms in this patient mimicked the appearance of an enlarged spleen

84 Image Diagnosis: Rapidly Enlarging Scrotal Hematoma: A Complication of Femoral Access? Raza Askari, MD; Rami N Khouzam, MD, FACC, FACP, FASNC, FASE, FSCAI; Dwight A Dishmon, MD, FACC

Diagnosis of retroperitoneal bleeding is made with abdominopelvic computed tomography. Ultrasound or computed tomography can provide the diagnosis for scrotal hematoma. Treatment of scrotal hematoma has ranged from conservative measures. including scrotal elevation and resuscitation with IV crystalloids or blood products, to open surgical options.

86 Image Diagnosis: Iliopsoas Abscess from Crohn Disease. Ashlev S Abraham: Michelle Y Liu: David R Vinson. MD

Crohn disease is a common cause of secondary iliopsoas abscesses, occurring in an estimated 0.4% to 4.3% of patients. Although long-term corticosteroid use with its attendant immunosuppression could increase the risk for abscess formation, a short course is unlikely to have the same effect.

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COMMENTARY

88 Considerations in the Neuropsychological Evaluation and Treatment of Children with Limited English Proficiency. Alonso Cardenas, MD; Laura Villavicencio, MD, MS; Mani Pavuluri, MD, PhD

Given the large number of Spanish speakers in the US, the authors illustrate, with a case example, the need to test students in their native language especially when the second language has not yet been mastered. Accurate assessment of the brain's potential may yield enhanced opportunities and optimize expectations, rather than undervaluing a developing child's elastic brain maturation.

90 To Err is Human: Can American Medicine Learn from Past Mistakes? Jeffrey B Ritterman, MD

The history of medicine includes many errors. Some persisted for decades and caused great harm. Several are highlighted in this article, including the mythical thymic diseases: thymic asthma and status thymicolymphaticus. Some medical mistakes, such as the diet-heart hypothesis of Ancel Keys, continue to cause harm. To avoid future errors and their associated harm, the author suggests a cultural shift encouraging professional humility and greater questioning of medical dogma. Medical education focused on teaching students this history may help with this cultural shift.

95 The Patient-Centered Medical Home as a Community-based Strategy.

Berkeley A Franz, PhD; John W Murphy, PhD

Although patient perspectives are critical to the patient-centered medical home (PCMH), this article questions whether the PCMH in practice is truly community-based. That is, do physicians, planners, and other

health care professionals take seriously the value of integrating local knowledge into medical care? The argument presented is that community-based philosophy contains a foundational principle that the perspectives of health care practitioners and community members must be integrated.

EDITORIAL

100 Philanthropy and Beyond: Creating Shared Value to Promote Well-Being for Individuals in Their Communities. Thomas E Kottke, MD, MSPH; Nico Pronk, PhD, MA; Andrew R Zinkel, MD, MBA; George J Isham, MD, MS

Health care organizations can magnify the impact of their community service and other philanthropic activities by implementing programs that create shared value. The author uses three initiatives in sectors other than health care to illustrate the concept of shared value, and also presents examples of shared value programs sponsored by health care organizations: telehealth, worksite health promotion, school-based health centers, green and healthy housing, and clean and green health services.

NARRATIVE MEDICINE

105 Lessons Learned in War. Alberto Hayek, MD

In civilian life one does not encounter these kinds of experiences, but the pain of a family with an ill child confronting a fatal prognosis is akin to a missile sent from an unknown source. As a physician, these painful experiences haunt me when all I can do is to be a silent participant while sharing the pain of unavoidable death.

107 Deer in the Headlights.

Tom Paluch, MD

"I just don't know," I respond flatly. The profundity of those four words is not lost on her. Her eyes widen like those of a deer in the headlights on a lonely country road late at night, frozen by the oncoming, unknown terror, unable to run, waiting to see if this thing, this rushing menace will stop, or sweep it away.

109 Abdominal Distension—An Unexpected Gift. Ching Soong Khoo, MD, MRCP (UK)

"That is a baby!" I swiftly showed her the fetal heartbeats on the scan. Her eyes immediately welled up with tears of joy—relieved that the swelling in her tummy wasn't something more sinister. Being underprivileged with limited access to health care services, she had felt helpless and frightened by her abdominal distension.

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Image Diagnosis: Bronchial Anthracofibrosis— A Bronchoscopic Diagnosis.

Ashok Shah, MD; Shekhar Kunal, MBBS

Image Diagnosis: Carcinoid Tumorlets and Pulmonary Sequestration in a Patient With Chronic Cough Without a History of Malignancy. Zhou Zhang, MD; Harleen Hayreh, MD

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Dinesh Atwal, MD; Krishna P Joshi, MD; Rahul Ravilla, MD; Fade Mahmoud, MD Well-Differentiated Neuroendocrine Tumor— A Low b-Grade Tumor's Aggressive Course and Dismal Outcome: A Case Report. Dinesh Atwal, MD; Krishna Prasad Joshi, MD; Susanne Jeffus, MD; James Ntambi, MD; Fade

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■ ORIGINAL RESEARCH & CONTRIBUTIONS

Body Mass Index and Mortality in a Very Large Cohort: Is It Really Healthier to Be Overweight?

Arthur L Klatsky, MD; Jasmine Zhang; Natalia Udaltsova, PhD; Yan Li, MD, PhD; H Nicole Tran, MD, PhD

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ABSTRACT

Context: Controversy persists about optimal body weight. Many experts define "normal" (healthy) body mass index (BMI) as 18.5 to 24.9 kg/m², 25 to 29.9 kg/m² as overweight, and 30 kg/m² or greater as obese. Obesity is subdivided into 30 to 34.9 kg/m² (Grade 1), 35 to 39.9 kg/m² (Grade 2), and 40 kg/m² and above (Grade 3). Studies consistently show higher mortality for underweight and Grade 2 or 3 obesity, but results conflict for the overweight category and Grade 1 obesity.

Objective: To study 30-year risk of death related to baseline BMI.

Design: Retrospective cohort study in a multiracial population of 273,843 persons using logistic regression with 7 covariates (sex, age, race-ethnicity, education, marital status, smoking, alcohol intake).

Main Outcome Measures: Mortality risk by baseline BMI.

Results: With average follow-up exceeding 30 years, there were 103,218 deaths: 41,215 attributed to cardiovascular causes and 62,003 to noncardiovascular causes. Odds ratios (and 95% confidence intervals) for all deaths in BMI categories, with a BMI of 18.5 to 24.9 kg/m² as the referent, were BMI below 18.5 kg/m² = 1.1 (1.0-2.0), BMI 25 to 29 kg/m² = 1.1 (1.1-1.2), BMI 30 to 34 kg/m² = 1.5 (1.4-1.5), BMI 35 to 39 kg/m² = 2.1 (1.9-2.3), and BMI 40 kg/m² or higher = 2.7 (2.4-3.0). Disparities existed regarding age, race/ethnicity, cause of death, and interval to death.

Conclusion: Compared with persons with BMI defined as normal, persons who were underweight, overweight, and obese were at increased risk of death over 30 years.

INTRODUCTION

Despite substantial published literature, there is controversy about the optimal level of body weight and how to best study this important subject. 1-5 A relation of weight to health was first noted more than a century ago.6 Interest was stimulated in the 1940s by life insurance company data⁷ showing increased mortality among persons with body weight 20% or more above "desirable" weights, adjusted for height and body frame. Such persons were charged increased premiums. Desirable weights were defined as the then-current means for each sex at 25 years of age; 20% above these corresponded to a body mass index (BMI) of 27.8 kg/m² in men and 27.3 kg/m² in women. These values became the definition of obesity offered by a 1987 National Institutes of Health (NIH) consensus panel. In the late 1990s the World Health Organization (WHO)⁸ and an NIH panel⁹ recommended categorization of BMI as follows: 25 to 29.9 kg/m² as preobesity or overweight, and 30 kg/m² or greater as obese, with the latter subdivided into 30 to 34.9 kg/m² (Grade 1 obesity), 35 to 39.9 kg/m² (Grade 2 obesity) and 40 kg/m² or greater (Grade 3 obesity). Pleas for standardization of definitions arose.¹⁰

The WHO and NIH categories of BMI remain in widespread use and are familiar to clinicians and the public. Early cohort studies of risks associated with higher BMI often used below 25.0 kg/m² as the referent in categorical models. However, it became clear that overall BMI-related mortality risk is J-shaped, with very lean (underweight) persons also at increased risk. 4,5,11,12 The increased risk at low BMIs

has been thought possibly related to reverse causality, that is, early illness in some of these persons, 13 but this is unproved. An early Kaiser Permanente analysis 11 suggested that increased risk of underweight persons might be concentrated in smokers. The J-shaped relationship has led some experts to feel that "normal" (healthy) BMI should be defined as 18.5 to 24.9 kg/m² and that this should be the standard referent in analytic models.

Studies have consistently shown higher mortality for obese persons, but data are conflicting regarding the overweight category.¹⁻⁵ A 2013 report⁴ showed lower mortality for overweight and Grade 1 obese persons, which received widespread attention in the lay press. Some press reports offered a sarcastic view of medical admonitions about the dangers of being overweight or obese.^{14,15} Some of the disparity between reports may be due to study population differences in age, race, fitness, and sex as well as disparities caused by differences in BMI categorization groups.⁴

Although BMI clearly is not an ideal measure of actual adiposity,^{4,5} it has been a widely available and much-used marker. Results with its use correlate well with other markers of obesity, such as waist circumference and waist-to-hip ratio.² The increased risk for obese persons has been clearest for cardiovascular (CV) diseases,^{1,4,16-18} but increased risks for other conditions have been reported, including liver disease,¹⁹ kidney disease,²⁰ diabetes mellitus,²¹ and some types of cancer.²²⁻²⁴

Arguably, the obesity epidemic may be leveling off,²⁵ but it remains a major public and individual health concern. Weight control is one of the most frequent issues that health practitioners need to consider

Arthur L Klatsky, MD, is a Senior Consultant in Cardiology and an Adjunct Investigator in the Division of Research, Kaiser Permanente Medical Care Program in Oakland, CA. E-mail: hartmavn@pacbell.net. Jasmine Zhang is a High School Student in Orinda, CA. E-mail: jazzy.zhang@gmail.com. Natalia Udaltsova, PhD, is a Data Consultant at the Division of Research in Oakland, CA. E-mail: natalia.udaltsova@kp.org. Yan Li, MD, PhD, is a Hematologist and Oncologist at the Oakland Medical Center in CA. E-mail: yan.li@kp.org. H Nicole Tran, MD, PhD, is an Internist at the Oakland Medical Center in CA. E-mail: nicole.h.tran@kp.org.

when giving medical counsel to patients. Recently reported disparities plus the natural skepticism of many have created confusion among health care practitioners and patients about the optimal level of BMI. Several of our previous studies showed increased risk of mortality from various causes among overweight persons. Therefore, we hypothesized that more detailed study of BMI and total mortality would show this. We believe that the data presented here about mortality risk in a large comprehensive health plan, including stratification by sex and race/ethnicity, will be very helpful to both the public and practitioners.

METHODS Subjects

The institutional review board of the Northern California Kaiser Permanente Medical Care Program approved the study protocols. We performed a retrospective cohort study of 273,843 free-living persons who provided detailed racial classification and underwent health examinations offered by the Kaiser Foundation Heath Plan of Northern California. Voluntarily taken as a health appraisal, the examination included health measurements, such as height and weight, and questionnaire queries about sociodemographic status, habits, and medical history.26 Except for extremes of income, the examinees are thought to represent a cross-section of the population in the area. Detailed racial classification was available for 2 time intervals: 1964 to 1973 and 1978 to 1985. For persons with multiple examinations, baseline data from the first examination in either 1964 to 1973 or 1978 to 1985 were used for all subjects. Mean age at baseline examination was 37.3 years for women and 39.2 years for men.

Mortality Ascertainment

We followed subjects through December 2012 using an automated matching system²⁷ to ascertain death in California that did not require continued Health Plan membership. We accepted primary International Classification of Diseases, Ninth Revision (ICD-9) death certificate codes, converting from International Classification of Diseases, Eighth Revision codes when necessary. Presumption of complete follow-up yielded a calculated 8.21 million person-years of follow-up,

but estimates²⁷ suggest a sensitivity of 89% for the method used. We studied total mortality (n = 103,218) in all persons and models stratified by sex, race/ethnicity, age, and smoking. We also studied 3

interval-to-death end points: deaths within 10 years (n = 12,750), deaths at 10 to 19 years (n = 23,873), and deaths after 20 years (n = 66,595). Finally, we studied deaths due to CV causes (ICD-9 codes

Table 1. Body mass index (BMI) category distributions of subjects by race/ethnicity					
BMI category,	Both sexes, no.	Men, no.	Women, no.		
kg/m²	(column %) [row %]	(column %) [row %]	(column %) [row %]		
All persons	273,843 (100.0) [100.0]	123,361 (100.0) [45.1]	150,482 (100.0) [55.0]		
< 18.5	8463 (3.1) [100.0]	1460 (1.2) [17.3]	7003 (4.7) [82.7]		
18.5-24.9	148,624 (54.3) [100.0]	57,515 (46.6) [38.7]	91,109 (60.5) [61.3]		
25-29.9	74,633 (27.3) [100.0]	45,980 (37.3) [61.6]	28,653 (19.0) [38.4]		
30-34.9	17,323 (6.3) [100.0]	8445 (6.8) [48.8]	8878 (5.9) [51.2]		
35-39.9	4,388 (1.6) [100.0]	1319 (1.1) [30.1]	3069 (2.0) [69.9]		
≥ 40	1919 (0.7) [100.0]	372 (0.3) [19.4]	1547 (1.0) [80.6]		
< 25	157,087 (57.4) [100.0]	58,975 (47.8) [37.5]	98,112 (65.2) [62.5]		
≥ 30	23,630 (8.6) [100.0]	10,136 (8.2) [42.9]	13,494 (9.0) [57.1]		
Whites	188,929 (100.0) [100.0]	87,378 (100.0) [46.2]	101,551 (100.0) [53.8]		
< 18.5	5142 (2.7) [100.0]	849 (0.1) [16.5]	4293 (4.2) [83.5]		
18.5-24.9	104,750 (55.4) [100.0]	40,224 (46.0) [38.4]	64,526 (63.5) [61.6]		
25-29.9	51,729 (27.4) [100.0]	33,566 (38.4) [64.9]	18,163 (17.9) [35.1]		
30-34.9	10,402 (5.5) [100.0]	5479 (6.3) [52.7]	4923 (4.8) [47.3]		
35-39.9	2343 (1.2) [100.0]	812 (0.9) [34.7]	1531 (1.5) [65.3]		
≥ 40	910 (0.5) [100.0]	223 (0.3) [24.5]	687 (0.7) [75.5]		
< 25	109,892 (58.2) [100.0]	41,073 (47.0) [37.4]	68,819 (67.8) [62.6]		
≥ 30	13,655 (7.2) [100.0]	6514 (7.5) [47.7]	7141 (7.0) [52.3]		
Blacks	50,573 (100.0) [100.0]	20,462 (100.0) [40.5]	30,111 (100.0) [59.5]		
< 18.5	1521 (3.0) [100.0]	248 (1.2) [16.3]	1273 (4.2) [83.7]		
18.5-24.9	23,496 (46.5) [100.0]	8836 (43.2) [37.6]	14,660 (48.7) [62.4]		
25-29.9	15,273 (30.2) [100.0]	7741 (37.8) [50.7]	7532 (25.0) [49.3]		
30-34.9	5421 (10.7) [100.0]	2197 (10.7) [40.5]			
35-39.9	` /	` /	3224 (10.7) [59.5]		
33-39.9 ≥ 40	1678 (3.3) [100.0]	388 (1.9) [23.1]	1290 (4.3) [76.9]		
< 25	883 (1.8) [100.0]	121 (0.6) [13.7]	762 (2.5) [86.3]		
	25,017 (49.5) [100.0]	9084 (44.4) [36.3]	15,933 (52.9) [63.7]		
≥ 30	7982 (15.8) [100.0]	2706 (13.2) [33.9]	5276 (17.5) [66.1]		
Asians	20,685 (100.0) [100.0]	9462 (100.0) [45.7]	11,223 (100.0) [54.3]		
< 18.5	1435 (6.9) [100.0]	310 (3.3) [21.6]	1125 (10.0) [78.4]		
18.5-24.9	13,472 (65.1) [100.0]	5878 (62.1) [43.6]	7594 (67.7) [56.4]		
25-29.9	3544 (17.1) [100.0]	2265 (23.9) [63.9]	1279 (11.4) [36.1]		
30-34.9	395 (1.9) [100.0]	201 (2.1) [50.9]	194 (1.7) [49.1]		
35-39.9	54 (0.3) [100.0]	22 (0.2) [40.7]	32 (0.3) [59.3]		
≥ 40	16 (0.1) [100.0]	6 (0.1) [37.5]	10 (0.1) [62.5]		
< 25	14,907 (72.1) [100.0]	6188 (65.4) [41.5]	8719 (77.7) [58.5]		
≥ 30	465 (2.3) [100.0]	229 (2.4) [49.2]	236 (2.1) [50.8]		
Others	13,656 (100.0) [100.0]	6059 (100.0) [44.4]	7597 (100.0) [55.6]		
< 18.5	365 (2.7) [100.0]	53 (0.9) [14.5]	312 (4.1) [85.5]		
18.5-24.9	6906 (50.6) [100.0]	2577 (42.5) [37.3]	4329 (57.0) [62.7]		
25-29.9	4087 (29.9) [100.0]	2408 (39.7) [58.9]	1679 (22.1) [41.1]		
30-34.9	1105 (8.1) [100.0]	568 (9.4) [51.4]	537 (7.1) [48.6]		
35-39.9	313 (2.3) [100.0]	97 (1.6) [31.0]	216 (2.8) [69.0]		
≥ 40	110 (0.8) [100.0]	22 (0.4) [20.0]	88 (1.2) [80.0]		
< 25	7271 (53.2) [100.0]	2630 (43.4) [36.2]	4641 (61.1) [63.8]		
≥ 30	1528 (11.2) [100.0]	687 (11.3) [45.0]	841 (11.1) [55.0]		

390-459, n = 41,215), non-CV causes (all codes except 390-453, n = 62,003), and the largest specific CV and non-CV diagnoses: coronary disease (codes 410-414, n = 20,094), and cancer (codes 140-209, n = 28,013), respectively.

Analytic Methods

We used age-adjusted logistic regression with 7 covariates. They were as follows:

- 1. sex
- 2. race/ethnicity: a model comparing blacks, Asians (to indicate Asian Americans), and other races/ethnicities ("others") with whites as the referent, and another model comparing blacks, Chinese, Japanese, Filipinos, South Asians, other Asians, and other races/ethnicities with whites as the referent
- 3. education: no college (referent), some college, college graduate
- 4. marital status: now married (referent), never married, formerly married
- cigarette smoking: never (referent), exsmoker, less than 1 pack per day, 1 or more packs per day
- 6. alcohol drinking: none (referent), fewer than 3 drinks per day, 3 or more drinks per day
- 7. BMI: for all outcomes, 2 models of BMI categories
 - a. BMI below 25 kg/m² was the referent, 25 to 29.9 kg/m² was overweight, and 30 kg/m² or higher was obese
 - b. BMI 18.5 to 24.9 kg/m² was the referent, BMI below 18.5 kg/m² was underweight, 30 to 34.9 kg/m² was Grade 1 obesity, 35 to 39.9 kg/m² was Grade 2 obesity, and 40 kg/m² or greater was Grade 3 obesity.

All covariate data were obtained from computer-stored information collected at the baseline examination. Analyses were performed using SAS statistical software Version 9.3 (SAS Institute, Cary, NC).

In this article, we present results as odds ratios (ORs), 95% confidence intervals (CIs), and associated p values. The term *significant* is used to refer to estimates with a p value < 0.05. We realize that, with multiple comparisons, many would require a stricter definition. Thus, consistency in multiple strata will also be used as an indicator of validity of associations.

RESULTS

Demographics

We studied 273,843 subjects, of which 45.1% (rounded) were men and 55.0% were women. The racial composition was 69.0% white, 18.5% black, and 7.6% Asian. The remaining 4.9% were mixed race or other. The largest Asian group was Chinese (3.5% of the total); others were Japanese (1.1%), Filipino, (2.1%), South Asian (0.4%), and other Asian (0.5%).

Distributions of Body Mass Index Categories by Sex and Race

Mean BMI was higher in men (25.2 kg/m^2) than in women (23.9 kg/m^2) , but women were about 10% more likely than men to be obese (BMI \geq 30 kg/m²), almost entirely because of an excess of obesity in black women (Table 1). Obesity was

BMI ranged from 18.5 to 24.9 kg/m², underweight men were 32% more likely to die and underweight women were 9% more likely to die. Overweight men were 10% more likely to die and men with Grade 1 obesity were 45% more likely to die. Overweight women were 22% more likely to die, and women with Grade 1 obesity were 56% more likely to die. The footnote data in Table 3 show that the increased risk estimates for the overweight and Grade 1 obese groups were virtually identical in models with referents of less than 25 kg/m^2 and $18.5 \text{ to } 24.9 \text{ kg/m}^2$. In both sexes there were progressively larger increases in mortality risk for persons with Grades 2 and 3 obesity. The associations were slightly stronger for men than for women at the extremes of underweight and marked obesity.

The increased risk of death was similar for overweight and obese whites and blacks ... However, overweight and obese Asians were at substantially higher risk ...

substantially less prevalent in Asians of both sexes. Among whites and Asians, men were twice as likely as women to be overweight (BMI = 25-29 kg/m²), whereas black men were 50% more likely than black women to be overweight. Women were almost 4 times more likely than men to be underweight (BMI < 18.5 kg/m²). The proportion of underweight persons was greatest in Asians, the only racial group with more underweight than obese persons.

The BMI category distributions for the specific Asian ethnic groups varied slightly (Table 2). Proportions of obese persons ranged from 1.5% of Chinese to 3.2% of Filipinos, and proportions of underweight persons ranged from 5.0% of Filipinos to 8.1% of Chinese. The mean BMIs were also lower among Asians (whites = 24.5 kg/m², blacks = 25.6 kg/m², and Asians = 22.6 kg/m²). All Asian ethnic groups had lower mean BMIs than whites or blacks did, ranging from 22.3 kg/m² in Chinese to 23.3 kg/m² in Filipinos.

Mortality in All Persons

The J-curve association of BMI to total mortality is evident in Table 3 and Figure 1A. Compared with persons whose

Racial-Ethnic Differences in Body Mass Index Mortality Risks

The increased risk of death was similar for overweight and obese whites and blacks (Figure 1B). For example, the ORs (95% CIs) for overweight and Grade 1 obese whites were 1.13 (1.09-1.16) and 1.47 (1.40-1.56), respectively. The corresponding ORs for blacks were 1.14 (1.08-1.21) and 1.46 (1.35-1.58), all with p < 0.001. However, overweight and obese Asians were at substantially higher risk (Figure 1B), with ORs of 1.43 (1.29-1.59) for overweight Asians and 2.51 (1.93-2.56) for Grade 1 obese Asians (both p < 0.001). Underweight Asians had no increased risk (OR = 0.95 [0.78-1.16]); underweight whites had an OR of 1.16 (1.06-1.27, p < 0.01), and underweight blacks had an OR of 1.09 (0.92-1.29).

There was no increased mortality risk among underweight persons in any Asian sex-ethnicity group (Chinese, Japanese, Filipino, South Asian), with nonsignificant ORs slightly below 1.0 for most groups (data not shown). Overweight persons in the specific Asian ethnic groups had the following ORs for total mortality: Chinese = 1.41 (1.21-1.65, p < 0.001), Japanese = 1.37 (1.05-1.80, p = 0.02), Filipinos =

 $1.71 \ (1.43-2.05, p < 0.001)$, South Asian = $1.19 \ (0.73-1.94, p = 0.5)$. Obese Asians of each ethnic group had substantially increased mortality risk, but with wide CIs in several subgroups because of small numbers.

Age Differences in Body Mass Index Mortality Risks

The increased mortality risk of overweight and obese persons lessened substantially with increasing baseline age (Figure 1C). For baseline age categories of younger than 40, 40 to 49, 50 to 59, and 60 or more years, the ORs for overweight persons were, respectively, 1.34 (1.29-1.38), 1.22 (1.10-1.28), 1.07 (1.01-1.14), and 1.06 (0.96-1.15). The ORs for Grade 1 obese persons for the 4 age categories were 1.98 (1.86-2.11), 1.54 (1.43-1.67), 1.22 (1.11-1.35), and 1.17 (1.01-1.35).

Body Mass Index Mortality Risk
in Smoking Strata

The increased mortality risk of overweight and obese persons was strongest in never smokers (Figure 1D). Increased risk in underweight persons was strongest in ex-smokers (Figure 1D), with OR = 1.31 (1.06-1.67, p = 0.02); this was present in both men (OR 1.66, p = 0.05) and women (OR 1.27, p = 0.07). For overweight persons the increased OR of death was significant in all smoking categories (data not shown).

Interval to Death Models

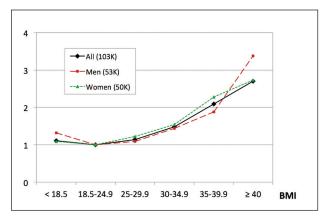
Data from separate models for 3 followup time intervals are presented in Figure 1E. Overweight persons had a slightly decreased risk of dying within 10 years of baseline (OR = 0.95 [0.91-0.99]; p = 0.01), but at 10 to 19 years their risk was slightly increased (OR = 1.05 [1.01-1.08], p = 0.009) and at 20 years or longer their increased risk was more substantial: OR = 1.18 (1.15-1.22, p < 0.001). The Grade 1 obese group had no reduced risk in any timeframe (Figure 1F). Underweight persons had substantially increased risk within 10 years (OR = 1.69 [1.48-1.93], p < 0.001) with some modulation at 10 to 19 years (OR = 1.29 [1.22-1.36], p < 0.001), and no increased risk at more than 20 years (OR = 1.00).

Deaths by Cardiovascular and Noncardiovascular Causes

As shown in Figure 1F for non-CV deaths, the OR for overweight persons was 1.03 (1.01-1.06, p = 0.02) and for CV deaths it was 1.37 (1.33-1.42, p < 0.001). For Grade 1 obese persons, these ORs were 1.23 and 1.99, respectively (both p < 0.0001). The CV/non-CV disparity increased progressively with increasing obesity. For underweight persons, risk

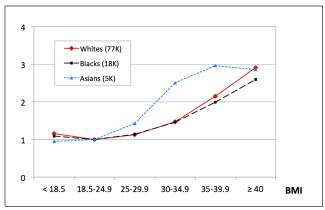
BMI category,	Both sexes, no.	Men, no.	Women, no.
kg/m²	(column %) [row %]	(column %) [row %]	(column %) [row %]
Chinese	9519 (100.0) [100.0]	4553 (100.0) [47.8]	4966 (100.0) [52.2]
< 18.5	768 (8.1) [100.0]	191 (4.2) [24.9]	577 (11.6) [75.1]
18.5-24.9	6433 (67.6) [100.0]	3011 (66.1) [46.8]	3422 (68.9) [53.2]
25-29.9	1299 (13.7) [100.0]	893 (19.6) [68.7]	406 (8.2) [31.3]
30-34.9	128 (1.3) [100.0]	72 (1.6) [56.3]	56 (1.1) [43.8]
35-39.9	11 (0.1) [100.0]	4 (0.1) [36.4]	7 (0.1) [63.6]
≥ 40	4 (0.0) [100.0]	3 (0.1) [75.0]	1 (0.0) [25.0]
< 25	7201 (75.7) [100.0]	3202 (70.3) [44.5]	3999 (80.5) [55.5]
≥ 30	143 (1.5) [100.0]	79 (1.7) [55.2]	64 (1.3) [44.8]
Japanese	2999 (100.0) [100.0]	1214 (100.0) [40.5]	1785 (100.0) [59.5]
< 18.5	197 (6.6) [100.0]	21 (1.7) [10.7]	176 (9.9) [89.3]
18.5-24.9	2029 (67.7) [100.0]	745 (61.4) [36.7]	1284 (71.9) [63.3]
25-29.9	501 (16.7) [100.0]	332 (27.4) [66.3]	169 (9.5) [33.7]
30-34.9	57 (1.9) [100.0]	32 (2.6) [56.1]	25 (1.4) [43.9]
35-39.9	11 (0.4) [100.0]	6 (0.5) [54.5]	5 (0.3) [45.5]
≥ 40	2 (0.1) [100.0]	_	2 (0.1) [100.0]
< 25	2226 (74.2) [100.0]	766 (63.1) [34.4]	1460 (81.8) [65.6]
≥ 30	70 (2.3) [100.0]	38 (3.1) [54.3]	32 (1.8) [45.7]
Filipinos	5808 (100.0) [100.0]	2469 (100.0) [42.5]	3339 (100.0) [57.5]
< 18.5	291 (5.0) [100.0]	48 (1.9) [16.5]	243 (7.3) [83.5]
18.5-24.9	3542 (61.0) [100.0]	1381 (55.9) [39.0]	2161 (64.7) [61.0]
25-29.9	1279 (22.0) [100.0]	735 (29.8) [57.5]	544 (16.3) [42.5]
30-34.9	153 (2.6) [100.0]	71 (2.9) [46.4]	82 (2.5) [53.6]
35-39.9	26 (0.5) [100.0]	9 (0.4) [34.6]	17 (0.5) [65.4]
≥ 40	5 (0.1) [100.0]	2 (0.1) [40.0]	3 (0.1) [60.0]
< 25	3833 (66.0) [100.0]	1429 (57.9) [37.3]	2404 (72.0) [62.7]
≥ 30	184 (3.2) [100.0]	82 (3.3) [44.6]	102 (3.1) [55.4]
South Asians	1117 (100.0) [100.0]	668 (100.0) [59.8]	449 (100.0) [40.2]
< 18.5	, , , -	1	, , ,
	80 (7.2) [100.0] 685 (61.3) [100.0]	32 (4.8) [40.0]	48 (10.7) [60.0]
18.5-24.9 25-29.9	. ,,,	401 (60.0) [58.5] 169 (25.3) [70.1]	284 (63.3) [41.5]
30-34.9	241 (21.6) [100.0] 26 (2.3) [100.0]	10 (1.5) [38.5]	72 (16.0) [29.9] 16 (3.6) [61.5]
35-39.9	20 (2.3) [100.0]	10 (1.3) [30.3]	10 (3.0) [01.3]
<u>>>>>9.9</u> ≥40	_	-	_
< 25	765 (68 5) (100 0)	/33 (6/ 8) [56 6]	332 (73 0) [43 4]
	765 (68.5) [100.0]	433 (64.8) [56.6]	332 (73.9) [43.4]
≥ 30 Other Asiens	26 (2.3) [100.0]	10 (1.5) [38.5]	16 (3.6) [61.5]
Other Asians	1242 (100.0) [100.0]	558 (100.0) [44.9]	684 (100.0) [55.1]
< 18.5	99 (8.0) [100.0]	18 (3.2) [18.2]	81 (11.8) [81.8]
18.5-24.9	783 (63.0) [100.0]	340 (60.9) [43.4]	443 (64.8) [56.6]
25-29.9	224 (18.0) [100.0]	136 (24.4) [60.7]	88 (12.8) [39.3]
30-34.9	31 (2.5) [100.0]	16 (2.9) [51.6]	15 (2.2) [48.4]
35-39.9	6 (0.5) [100.0]	3 (0.5) [50.0]	3 (0.4) [50.0]
≥ 40	5 (0.4) [100.0]	1 (0.2) [20.0]	4 (0.6) [80.0]
< 25 ≥ 30	882 (71.0) [100.0] 42 (3.4) [100.0]	358 (64.2) [40.6] 20 (3.6) [47.6]	524 (76.6) [59.4] 22 (3.2) [52.4]

--- = no cases



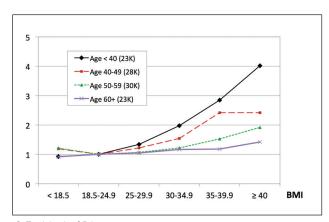
A. Total deaths OR for all persons, men, and women.

ORs for women (49,693 deaths) are on broken green line, for men (53,525 deaths) on broken red line, and for all persons (103,218 deaths) on solid black line.



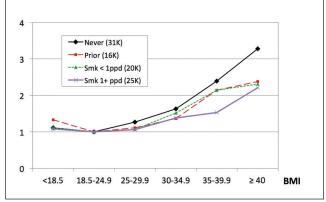
B. Total deaths OR by race/ethnicity.

ORs for whites (76,805 deaths) are on solid red line, for blacks (17,898 deaths) on broken black line, and for Asians (4995 deaths) on broken blue line.



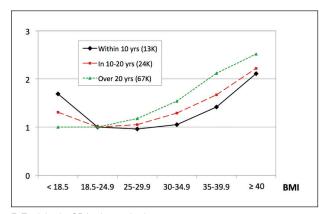
C. Total deaths OR by age groups.

ORs for persons aged below 40 years at baseline (22,530 deaths) are on solid black line, 40 to 49 years at baseline (27,902 deaths) on broken red line, 50 to 59 years at baseline (30,096 deaths) on broken green line, and 60 years or older at baseline (22,690 deaths) on solid lavender line.



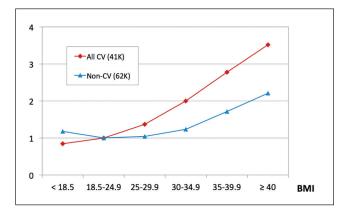
D. Total deaths OR by smoking status.

ORs for never smokers (31,325 deaths) are on solid black line, for ex-smokers (16,037 deaths) on broken red line, for under 1 pack per day smokers (19,793 deaths) on broken green line, and for 1 or more packs per day smokers (24,888) on solid lavender line.



E. Total deaths OR by time to death groups.

ORs for 12,750 persons who died within 10 years are on solid black line, for 23,873 persons who died in 10 to 20 years on broken red line, and for 66,595 persons who died after 20 years on broken green line.



F. All CV and non-CV deaths by BMI.

ORs for persons who died of noncardiovascular (non-CV; 62,003) causes on solid blue line and for persons who died of CV (41,215) causes on solid red line.

Figure 1. Adjusted odds ratios (ORs) for deaths through 2012 according to body mass index (BMI, kg/m²) ascertained from 1964 to 1985 (BMI referent = 18.5-24.9 kg/m²). Number of deaths in rounded thousands (K) are in parentheses. Analysis was by logistic regression models with age, sex, race, education, smoking (Smk), and alcohol. CV = cardiovascular

was increased for non-CV death (OR 1.18 [1.09-1.27], p < 0.001) but decreased for CV death (OR = 0.84 ([0.74-0.95], p = 0.01). Cancer deaths made up 45.2% of non-CV deaths, and coronary disease comprised 48.8% of CV deaths. For cancer deaths, the ORs for overweight and Grade 1 obese persons were 1.09 (1.05-1.13) and 1.15 (1.08-1.25), respectively (both p < 0.001). For coronary disease deaths, these ORs were 1.43 (1.37-1.50) and 2.16 (1.98-2.28), both with p < 0.001. For underweight persons, the risks for cancer and coronary deaths were 1.12 (1.01-1.23, p = 0.03) and 0.62 (0.51-0.76,p < 0.001), respectively.

DISCUSSIONTotal Mortality in Overweight and Obese Persons

Increased 30-year mortality was shown in overweight or Grade 1 obese persons across multiple strata in our study population; this consistency supports the validity of our findings. Although stratified analyses show disparities in the magnitude of increased risk, none show reduction of total 30-year mortality risk among overweight or Grade 1 obese persons. Only for deaths within 10 years was there a slightly reduced mortality for overweight persons. The greatest increase in risk in overweight and Grade 1 obese subjects was at 20 years or more, but our use of baseline BMI only does not allow us to assess the role of BMI changes in this outcome.

Estimates of increased death risk for overweight or slightly obese persons were quite similar in models that used as the referent less than 25 kg/m² or 18.5 to 24 kg/m². Thus, differences in risk estimates related to use of these referents is, in our opinion, an unlikely explanation for disparate findings in published studies. The magnitude of the increased risk among Grade 1 obese persons is substantial

(approximately 50%), with even larger increased risk in Grades 2 and 3 obesity (approximately doubled and tripled).

As previously reported,28 increased risk of overweight and obese persons diminished in our data with increasing age. Although probably mostly an artifact of the increasing dominance of age itself and age-related factors, it has been suggested13 that this might be related to selection of healthy, relatively low-risk persons in population study cohorts. This is a possible factor in our study because the subjects voluntarily took the health examination and persons with known chronic illnesses were presumably underrepresented. Another factor could be selective survival of persons resistant to the metabolic consequences of obesity. This touches on the interesting phenomenon known as the "obesity paradox." This phenomenon refers to data indicating that obese persons with certain medical problems or procedures,

Table 3. Ad	Table 3. Adjusted ^a odds ratios of total mortality according to body mass index (BMI) among 273,843 subjects								
	Number	Odd ratios (95% confidence intervals) of BMI vs < 25 kg/m² as referent		Odds ratios (95% confidence intervals) of BMI vs 18.5-24.9 kg/m² as referent ^b					
Group	deaths	25-29.9 kg/m ²	≥ 30 kg/m²	< 18.5 kg/m ²	25-29.9 kg/m ²	30-34.9 kg/m ²	35-39.9 kg/m ²	≥ 40 kg/m²	
All persons	103,218	1.14 (1.11-1.16)°	1.66 (1.60-1.73)°	1.11 (1.03-1.19) ^d	1.14 (1.11-1.17)°	1.49 (1.43-1.55)°	2.09 (1.93-2.26)°	2.70 (2.40-3.03)°	
All men	53,525	1.09 (1.06-1.13)°	1.55 (1.46-1.64)°	1.32 (1.14-1.55) ^d	1.10 (1.06-1.13)°	1.45 (1.36-1.54)°	1.89 (1.64-2.18)°	3.34 (2.58-4.34)°	
All women	49,693	1.22 (1.17-1.26)°	1.80 (1.71-1.90)°	1.09 (1.00-1.18) ^e	1.22 (1.18-1.27)°	1.56 (1.46-1.65)°	2.27 (2.06-2.50)°	2.73 (2.39-3.12)°	

^a Logistic regressions with age, sex, race-ethnicity, BMI, education, marital status, smoking, and alcohol intake.

[°]p < 0.05.

Table 4. Adjusted ^a odds ratios (95% confidence intervals) to risk of death for selected covariates					
Factor (referent)	All	Men	Women		
Age (per 10 years)	3.40 (3.36-3.43), p < 0.001	3.28 (3.23-3.33), p < 0.001	3.50 (3.45-3.55), p < 0.001		
Male sex (female)	1.57 (1.54-1.61), p < 0.001	_	_		
Black (white)	1.48 (1.43-1.52), p < 0.001	1.50 (1.44-1.56), p < 0.001	1.46 (1.40-1.51), p < 0.001		
All Asians (white)	0.88 (0.84-0.92), p < 0.001	0.84 (0.79-0.89), p < 0.001	0.93 (0.87-0.99), p = 0.02		
Chinese (white)	0.91 (0.86-0.97), p = 0.006	0.88 (0.81-0.96), p = 0.006	0.96 (0.88-1.05), p = 0.40		
Japanese (white)	0.86 (0.78-0.95), p = 0.003	0.87 (0.75-1.00), p = 0.06	0.87 (0.76-1.00), p = 0.06		
Filipino (white)	0.85 (0.78-0.92), p < 0.001	0.76 (0.67-0.85), p < 0.001	0.95 (0.85-1.07), p = 0.39		
South Asian (white)	0.59 (0.48-0.72), p < 0.001	0.55 (0.43-0.70), p < 0.001	0.69 (0.47-1.01), p = 0.05		
Alcohol ≤ 2 drinks per day (none)	0.97 (0.94-1.00), p = 0.03	0.98 (0.94-1.03), p = 0.49	0.96 (0.93-1.00), p = 0.08		
Alcohol ≥ 3 drinks per day (none)	1.27 (1.22-1.33), p < 0.001	1.27 (1.19-1.35), p < 0.001	1.32 (1.23-1.42), p < 0.001		
Ex-smoker (never)	1.08 (1.04-1.11), p < 0.001	1.09 (1.04-1.14), p < 0.001	1.08 (1.03-1.13), p = 0.002		
Smoking < 1 pack per day (never)	1.38 (1.34-1.42), p < 0.001	1.39 (1.33-1.46), p < 0.001	1.38 (1.33-1.44), p < 0.001		
Smoking ≥ 1 pack per day (never)	2.06 (2.00-2.13), p < 0.001	1.98 (1.90-2.07), p < 0.001	2.21 (2.11-2.31), p < 0.001		
College graduate (no college)	0.65 (0.63-0.67), p < 0.001)	0.61 (0.58-0.63), p < 0.001)	0.72 (0.70-0.75), p < 0.001		

^a Logistic models with age, sex, smoking, alcohol, body mass index, and education.

b In another model, odds ratios (95% confidence intervals) for BMI 30-34 kg/m² vs < 25 kg/m² were as follows: all = 1.48 (1.42-1.55); men = 1.44 (1.36-1.53); and women = 1.55 (1.46-1.64). c p < 0.001.

^d p < 0.01.

including chronic renal failure, myocardial infarction, coronary artery bypass grafting, angioplasty, and heart failure, have a better prognosis than those of normal BMI. ²⁹⁻³² Obesity carries increased risk of certain medical conditions, but in persons with these conditions obesity carries lower risk. Attempts to explain the paradox as a statistical artifact have so far not been conclusive. Unfortunately, our data do not cast light on this matter.

Sex and Race Differences

It is noteworthy that the different distributions of BMI categories between men and women and between blacks and whites did not translate into disparate risks for overweight and Grade 1 obese persons. This contrasts with Asian/white comparisons. Our data also concur with reports33-35 showing that, by the usual categorizations, Asians have lower proportions of overweight and obese persons and that these persons have greater increased death risk than do whites or blacks. Our data also agree with reports^{33,34} that Asians have a greater proportion of underweight individuals and that underweight Asians have no increased mortality risk. These relationships were generally similar for the various Asian ethnicities. It has been suggested^{34,36-38} that obesity in Asians be defined as BMI of 25 kg/m² or greater and overweight as BMI 23 to 24.9 kg/m². Our data support this concept and the conclusion in a recent review³⁴ that more data are needed in this area. We plan to pursue this area further.

Risk of Underweight Persons

The increased risk of underweight persons was concentrated in men, non-Asian race groups, the first 10 years of follow-up, ex-smokers, and persons dying of non-CV causes. Presumably, the concentration in early years represents to some extent early manifestations of ultimately lethal conditions and supports this previous suggestion.³⁹ These data show the importance of a long follow-up period in the study of BMI and mortality. The greater risk of underweight men compared with underweight women is likely to be an artifact of the smaller proportion of men with BMI under 18.5 kg/m.² The absence of increased risk among underweight Asians suggests the possible need for revision of both low and high BMI cut-points for this racial group. The high risk of underweight ex-smokers suggests that some ex-smokers are likely to have quit because of symptoms or other evidence of ill health.

Cardiovascular versus Noncardiovascular Causes of Death

As expected, 1,4,13,16 the increased risk of death among overweight and obese persons was more substantial among those dying of CV causes. Risk of death for CV causes was actually reduced among underweight persons. Deaths attributed to coronary disease and cancer comprised almost half of the CV and non-CV composites and made proportionate contributions to these associations. Prior reports²²⁻²⁴ indicate substantial variability of obesity-associated risk among cancer types. We plan to pursue further investigation of BMI associations to specific death causes. For now, we point out that demographic disparities in causes of death could help explain disparate findings in various studies.

Covariate Relationships

There was increased death risk associated with increasing age, male sex, black race, smoking, and heavy drinking (Table 4). Higher educational attainment and Asian race were associated with lower risk (Table 4). These expected relationships help to confirm the validity of our analyses.

Limitations and Strengths

Our study had some limitations, including use of only a single baseline BMI measure, which precludes study of effect of both prior and subsequent weight changes, as well as a similar limitation to baseline measurement of covariates. Additionally, the study was limited to deaths in California, and it lacked controls for diet, exercise, and several other relevant traits. These confounder traits, rather than BMI, could be the operative factors responsible for increased mortality. Furthermore, there was a lack of study of intermediary factors between higher BMI and mortality, such as hypertension, blood lipid abnormalities, and, of special importance, diabetes. The absence of more specific data indicative of adiposity (eg, waist-hip ratio, body fat composition) limited our ability to explain sex and race disparities. Finally, it is possible that a health-conscious cohort was selected, which could bias the results.

Strengths include 1) the large size of a free-living and relatively stable study population, 2) exceptionally long follow-up, 3) excellent ascertainment of race/ethnicity, 4) presentation of data about specific Asian ethnic groups, and 5) availability of data enabling control for several important potential confounders, especially smoking.

Public Health Considerations

Because we present no data about changes in BMI, our findings do not directly support recommendations about weight loss to reduce mortality risk in overweight and obese persons. In this regard, the literature is conflicting. Much evidence suggests that weight reduction has a favorable effect on CV risk factors; yet several reports suggest no mortality benefit or even increased mortality in persons who lose weight, even deliberately. 40-42 A meta-analysis of randomized controlled trials showed that intentional weight loss in obese adults was associated with a 15% reduction in all-cause mortality. 43 These aggregate data do not apply to all persons. As in almost all health issues, advice about losing weight should be individualized.

CONCLUSION

We conclude that it is not healthier to be overweight. In this analysis in a large multiethnic population, persons with "normal" BMI had the lowest 30-year mortality. These data also support the proposition that there should be lower cutpoints for the definition of overweight and obese in Asians than in whites or blacks. •

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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ORIGINAL RESEARCH & CONTRIBUTIONS

Effect of Age on Outcomes of Shoulder Arthroplasty

Oke A Anakwenze, MD; Tameem Yehyawi, MD; Mark T Dillon, MD; Elizabeth Paxton, MA; Ronald Navarro, MD; Anshuman Singh, MD

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ABSTRACT

Context: Outcomes of total shoulder arthroplasty (TSA) and reverse total shoulder arthroplasty (RTSA) as a function of age are not well known.

Objective: To understand the effects of age on revision rate, mortality, and hospital readmissions.

Design: A retrospective cohort study of prospectively collected data. Using an integrated health care system's shoulder arthroplasty registry, we identified patients who underwent TSA and RTSA between January 2007 and June 2012. Patients were grouped into older (> 75 years) and younger groups (≤ 75 years).

Main Outcome Measures: Differences in outcomes between both age groups.

Results: The TSA cohort had 2007 patients, and 538 (26.8%) were older than age 75 years. Older patients who underwent TSA had higher risks of 1-year mortality (2.0% vs 0.6%; odds ratio = 3.34, 95% confidence interval [CI] = 1.00-11.11, p = 0.049) and readmission within 90 days (7.6% vs 4.4%; odds ratio = 1.75, 95% CI = 1.17-2.63, p = 0.007). The RTSA cohort had 568 patients, and 295 (51.9%) of them were older than age 75 years. Older RTSA patients had a lower risk of revision (3.7% vs 8.1%; hazard ratio = 0.45, 95% CI = 0.24-0.89, p = 0.020).

Conclusion: Patient age is one of many important variables that surgeons should consider when performing shoulder arthroplasty. However, the impact of age in the TSA and RTSA populations is different. In the TSA cohort, older patients have higher risk of readmission and mortality. In the RTSA cohort, older patients have lower risk of revision.

INTRODUCTION

Indications for shoulder arthroplasty are expanding, especially for reverse total shoulder arthroplasty (RTSA) which is now being used to treat conditions beyond rotator cuff arthropathy such as acute fractures, posttraumatic conditions,1 and irreparable rotator cuff tears.2 Longer follow-up demonstrates satisfactory midterm outcomes3 for RTSA and durable long-term results for total shoulder arthroplasty (TSA) recipients.4 As a result, there has been a rapid increase in the number of shoulder arthroplasty procedures in the US.5 This increase may be attributable to many factors, including an expanding elderly population. Although a recent study of 26,320 patients who underwent total knee and hip arthroplasty found that patients who were age 80 years and older had a mortality rate that was 3.4

times higher than that observed in patients between age 65 years and age 79 years,⁶ the effect of age on shoulder arthroplasty outcomes has yet to be fully elucidated. As such, we sought to determine whether elderly patients may also be at risk of more complications from shoulder arthroplasty than younger patients.

The purpose of this study was to compare the outcomes of TSA and RTSA in a large series of patients on the basis of age. Specifically, we sought to compare the rate of revisions, 1-year mortality, and readmission within 90 days in younger patients (≤75 years) vs older patients (>75 years). An age cutoff of 75 years was chosen a priori to maintain statistical power yet analyze an age group that represents the older arthroplasty group more suitably than previous studies have done. We hypothesized that outcomes would be similar between both groups.

METHODS

A retrospective cohort study of prospectively collected data from a shoulder arthroplasty registry was conducted. The registry was established in 2005 at Kaiser Permanente, a large health care system that has more than 9 million members throughout the US. The data collection procedures, quality control, and participation of the registry have been described.7 In brief, the shoulder arthroplasty registry collects data (patient, surgical, implant, surgeon, and hospital) for all patients undergoing shoulder arthroplasty using operative forms filled by the treating surgeon, administrative databases, and electronic medical records. The registry monitors postoperative complications such as infections, mortality, revisions, readmissions, and reoperations of the patients. In 2010, the registry captured 100% of procedures performed at our institutions. All elective TSA and RTSA procedures performed between January 2007 and June 2012 in the 2 largest geographic Regions (Southern California and Northern California) that participate in the registry were included in the study.

The outcomes evaluated in this study were revision, 1-year mortality, and readmission within 90 days. Revisions were determined using a comprehensive electronic screening algorithm of electronic medical records. Mortality was obtained from the electronic medical records and membership files in the institution, which tracks member mortality with Social Security Administration files. Readmissions were identified using the inpatient hospitalization encounters also documented by the organization.

Patients were divided into 2 cohorts: TSA and RTSA, then analyzed separately.

Oke A Anakwenze, MD, is an Orthopedist at Olympus Orthopedics Medical Group in San Diego, CA. E-mail: oaa@olympusortho.com. Tameem Yehyawi, MD, is an Orthopedic Surgeon at the San Diego Medical Center in CA. E-mail: tameen.yehyawi@kp.org. Mark T Dillon, MD, is an Orthopedic Surgeon at the Sacramento Medical Center in CA. E-mail: mark.t.dillon@kp.org. Elizabeth Paxton, MA, is the Director of the Surgical Outcomes and Analysis Department at the Sacramento Medical Center in CA. E-mail: liz.w.paxton@kp.org. Ronald Navarro, MD, is an Orthopedic Surgeon at the Harbor City Medical Center in CA. E-mail: nonald.navarro@kp.org. Anshuman Singh, MD, is an Orthopedic Surgeon at the San Diego Medical Center in CA. E-mail: anshu_singh@hotmail.com.

The main exposure of interest was age, which was grouped into those who were age 75 years or younger (younger patients) and those who were older than age 75 years (older patients). Additionally, the patient characteristics, including sex, body mass index (BMI), American Society of Anesthesiologists (ASA) score, and diabetes status, were evaluated as potential risk factors for the studied outcomes. These comorbidity indexes help adjust for confounders other than age, and we included those captured in the shoulder arthroplasty registry as part of the prospective data collection. Randomization would eliminate unmeasured biases in this study, but is simply not feasible retrospectively and with certain metrics, such as age.

The study sample characteristics and the postoperative outcomes were described using frequencies, proportions, median, interquartile range, mean, and standard deviation (SD). Survival analysis was performed on revision using Cox proportional hazard models (Wald test). Cox proportional hazard models assessed the hazard ratio (HR) and 95% confidence interval (CI) for revision while adjusting for other studied risk factors. Follow-up time was defined as the difference between the original operation date and the date of revision, the date of membership termination from the integrated health care system, the date of death, or the end date of the study period, whichever occurred first. Survival analyses censored patients who terminated their membership or died before the end of the study period. A logistic regression model assessed the odds ratio (OR) and 95% CI for mortality and readmission while adjusting for other studied risk factors. All risk estimates are adjusted for surgeon clustering. Analyses were performed using SAS 9.4 software (SAS Institute, Cary, NC), with $\alpha = 0.05$ used as the statistical threshold for significance.

RESULTSTotal Shoulder Arthroplasty

There were 2007 cases included in the TSA cohort, and the patient characteristics are shown in Table 1. The mean follow-up time was 3.1 years (SD = 1.6 years) overall. Of 115 patients (5.7%) who did not complete follow-up, the mean follow-up was 1.8 years (SD = 1.2 years).

Table 2 shows the crude incidence of revision, readmissions, and mortality after elective TSA procedures by patient age group. Overall in the TSA cohort, there were 48 revisions (2.4%), and the cumulative revision rate at 4 years was 3.2% (95% CI = 2.3%-4.3%). Compared with the younger patients, older patients had a higher crude proportion of revision (2.6% vs 2.3%), 1-year mortality (2.0% vs 0.6%), and readmission within 90 days (7.6% vs 4.4%) than did younger patients.

In a model adjusted for age, BMI, ASA score, sex, and diabetes, the risk of TSA revision did not differ between the older and younger patients (HR = 1.24; 95%)

CI = 0.55-2.79; Table 3). In a similarly adjusted model, older patients were found to have a higher likelihood of 1-year mortality (OR = 3.34; 95% CI = 1.00-11.11, p = 0.049) and readmission within 90 days (OR = 1.75; 95% CI = 1.17-2.63, p = 0.007) compared with patients age 75 years or older.

Reverse Total Shoulder Arthroplasty

There were 568 cases included in the RTSA cohort, and the patient characteristics are shown in Table 1. The mean follow-up time was 2.8 years (SD = 1.5 years). Of 31 patients (5.5%) who did not complete follow-up, the mean follow-up was 1.9 years (SD = 1.2 years).

Table 1. Study sample patient cha (January 2007-June 2012) ^a	racteristics after e	lective shoulder arth	roplasty
Patient characteristic	Older cohort (over 75 years)	Younger cohort (75 years or less)	Total
Total shoulder arthroplasty	538 (26.8)	1469 (73.2)	2007 (100)
Age			
Median (IQR)	79 (77-82)	66 (61-71)	69 (63-76)
Sex			
Women	332 (61.7)	666 (45.3)	998 (49.7)
Men	206 (38.3)	803 (54.7)	1009 (50.3)
BMI (kg/m²)			
Lower than 30	353 (65.6)	707 (48.1)	1060 (52.8)
30 or higher	185 (34.4)	762 (51.9)	947 (47.2)
ASA score			
1 or 2	212 (39.4)	819 (55.8)	1031(51.4)
3 or higher	278 (51.7)	509 (34.7)	787 (39.2)
Unknown	48 (8.9)	14 (9.6)	189 (9.4)
Diabetes			
Present	130 (24.2)	351 (23.9)	48 (24.0)
Reverse total shoulder arthroplasty	295 (51.9)	273 (48.1)	568 (100)
Age			
Median (IQR)	80 (78-83)	70 (65-73)	76 (70-80)
Sex			
Women	205 (69.5)	170 (62.3)	375 (66.0)
Men	89 (30.2)	103 (37.7)	192 (33.8)
BMI (kg/m²)			
Lower than 30	223 (75.6)	154 (56.4)	377 (66.4)
30 or higher	72 (24.4)	119 (43.6)	191 (33.6)
ASA score			
1 or 2	118 (40.0)	114 (41.8)	232 (40.9)
3 or higher	150 (50.9)	120 (44.0)	270 (47.5)
Unknown	27 (9.2)	39 (14.2)	66 (11.6)
Diabetes			
Present	82 (27.8)	82 (30.0)	164 (28.9)
^a All values are no. (%) unless otherwise speci	find. Come totals do not o	gual 100% bacause of round	lina

^aAll values are no. (%) unless otherwise specified. Some totals do not equal 100% because of rounding. ASA = American Society of Anesthesiologists; BMI = body mass index; IQR = interquartile range.

Table 2 reveals the crude incidence of revision, readmissions, and mortality after elective RTSA procedures by patient age group. Overall there were 33 revisions (5.8%), and the cumulative revision rate at 4 years was 8.4% (95% CI = 5.8%-12.1%). Compared with the younger patients, older patients had a lower crude revision rate (3.7% vs 8.1%) and higher crude proportion of 1-year mortality (2.4% vs 1.8%). Both groups had the same rate of readmission within 90 days (9.2%).

In a model adjusted for age, BMI, ASA score, sex, and diabetes, the risk of RTSA revision was significantly lower in older patients compared with younger patients (HR = 0.45; 95% CI = 0.23-0.89, p = 0.020; Table 3). After similar adjustment, there was not enough evidence to show differences in the odds of 1-year mortality or 90-day readmission between the different age groups.

DISCUSSION

In this study, we demonstrated that patients undergoing TSA had higher 1-year mortality and readmission rates when they were older than age 75 years, but with no significant differences in the rate of surgical revision. Conversely, older patients who underwent RTSA had lower rates of revision surgery. To our knowledge, no studies have focused on TSA and RTSA in a specific patient population older than age 75 years. ^{3,8} Consequently, our data can provide a more focused insight into the risks present for patients in this specific age group who are considering TSA or RTSA.

In a 2014 study, Griffin et al9 looked specifically at mortality rates and complications during the postoperative hospital stay for patients undergoing hemiarthroplasty or total shoulder arthroplasty and found poorer outcomes in patients older than age 80 years. The mortality rate during inhospital stay was 0.5% for patients older than 80 years vs 0.1% for patients aged 59 to 79 years. The authors also saw longer hospital stays and more frequent complications in this older patient cohort. Our results showed a higher TSA mortality rate looking further out to 1 year of 2.04% in the older cohort vs 0.61% for the younger cohort. Conversely, the mortality rate was similar between older and younger patients in the RTSA population. This difference

may reflect the relative health of younger and more active patients who undergo TSA in contrast to patients younger than age 75 years who undergo RTSA. In our study, 55.8% of the younger TSA cohort had ASA scores that were either 1 or 2 compared with 41.8% of the younger RTSA cohort.

Mahoney et al¹⁰ looked at readmission rates after shoulder arthroplasty and noted a 4.5% and 6.6% readmission rate within 90 days after TSA and RTSA, respectively. Schairer et al,11 using a state inpatient database, looked only at readmission rates after primary shoulder arthroplasty and noted a 90-day readmission rate of 11.2% in the RTSA group and 6% rate in those undergoing TSA. In comparison, our study had a 90-day readmission rate of 5.2% for all patients who underwent shoulder arthroplasty. Schairer et al¹¹ also found a stepwise increase in readmission with increasing age, which is consistent with our significant finding of a higher 90-day readmission rate for our older patients who underwent TSA. We noted a readmission rate of 4.4% in our younger TSA cohort and 7.6% for our patients over age 75. Our RTSA group was noted to have an overall readmission rate of 9.2%, higher than in the TSA population. This finding is likely caused by higher patient morbidity in our study, compromised local shoulder tissue such as bone quality and quantity that does not get captured in overall health scores, and a higher rate of procedure-specific complications in RTSA vs anatomic TSA. In the RTSA group, we did not note a difference in 90-day readmission rate whether patients were in the older or younger cohort.

Our patients who underwent TSA had a lower overall rate of revision compared with the RTSA group (2.4% vs 5.8%) but did not demonstrate a difference in rates of revision between the older and younger patient cohorts. In their series of patients younger than age 65 years undergoing RTSA, Ek et al² reported a complication rate of 37.5% and 25% incidence of prosthesis component exchange, conversion to hemiarthroplasty, or resection. Ricchetti et al¹² studied the differences in complication and mortality rates in patients older than age

5 (1.8)

25 (9.2)

shoulder arthroplasty by patient age group						
Patient characteristic	Older cohort (over 75 years), no. (%)	Younger cohort (75 years or less), no. (%)	Total, no. (%)			
Total shoulder arthroplasty	538 (26.8)	1469 (73.2)	2007 (100.0)			
Revision	14 (2.6)	34 (2.3)	48 (2.4)			
One-year mortality	11 (2.0)	9 (0.6)	20 (1.0)			
Readmission within 90 days	41 (7.6)	64 (4.4)	105 (5.2)			
Reverse total shoulder arthroplasty	295 (51.9)	273 (48.1)	568 (100.0)			
Revision	11 (3.7)	22 (8.1)	33 (5.8)			

7 (2.4)

27 (9.2)

Table 2. Revision, 1-year mortality, and readmission within 90 days after elective

Table 3. Hazard ratios for risk of revision, and odds ratios for 1-year mortality and readmission within 90 days after elective shoulder arthroplasty							
Older than age 75 years vs age 75 years or younger	Ratio	95% confidence interval	p value				
Total shoulder arthroplasty							
Revision	HR = 1.24	0.55-2.79	0.607				
One-year mortality	OR = 3.34	1.00-11.11	0.049				
Readmission within 90 days	OR = 1.75	1.17-2.63	0.007				
Reverse total shoulder arthroplasty							
Revision	HR = 0.45	0.23-0.89	0.020				
One-year mortality	OR = 0.92	0.32-2.47	0.879				
Readmission within 90 days	OR = 0.68	0.41-1.13	0.135				

HR = hazard ratio; OR = odds ratio.

One-year mortality

Readmission within 90 days

12 (2.1)

52 (9.2)

80 years who underwent TSA compared with younger patients. They reported no difference in complications between the 2 groups. Conversely, Dillon et al,⁸ in a study of 2981 patients who underwent shoulder arthroplasty, found that patients who were younger than age 59 years had a significantly higher rate of revision compared with older patients.

... younger patients who underwent RTSA (designed for low-demand patients) had an increased rate of revision and failure.

In our study, we found that younger patients who underwent RTSA had an increased rate of revision and failure. The lower revision rate in elderly individuals is likely multifactorial. First, RTSA is designed for low-demand patients. Elderly patients may be more likely to adapt to chronic pain or modest impairment in function. In addition, surgeons may be selecting for a cohort more likely to need revision by performing RTSA in younger patients with very advanced disease states. Surgeons may simply be more hesitant to revise RTSA failures in older patients with increased morbidity. Finally, the higher BMI in the younger cohort may confound this finding, although the impact of BMI on complications after shoulder arthroplasty is still to be determined. 13-17

In terms of the implications of our findings on health care delivery, a couple of points merit consideration. First is the finding of a greater than 9% readmission rate for patients who underwent RTSA regardless of comorbidities and a readmission rate above 7% in elderly patients who underwent TSA. This likely translates to high utilization of health care resources given the increasing numbers of these procedures. We recommend an analysis of readmission rates, careful patient selection and optimization, and directed support protocols in the perioperative period to decrease the rate of hospital readmission.

Second, our study is not without weaknesses. It is retrospective and subject to the weaknesses and biases of such. However, our registry data are prospectively updated with minimal patient loss, which strengthens our accuracy. This large database study does not have preoperative and postoperative patient outcome scores. However, the clinical improvement after RTSA and TSA has been widely documented^{3,18-20} and was not the aim of this study.

CONCLUSION

To our knowledge, this is the first study comparing patient outcomes in patients older than age 75 years undergoing RTSA and TSA. Age is an important factor and appears to affect both groups differently. In the TSA cohort, older patients had a higher mortality and readmission rate; age did not appear to affect the rate of revision surgery. Conversely, older patients in the RTSA cohort had a lower rate of revision compared with the younger patients. Age did not affect mortality or readmission rates in the patients who underwent RTSA. ❖

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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Lisbon photograph

Samuel H Glassner, MD

This photograph was taken on the streets of Lisbon, Portugal.

Dr Glassner is a retired Emergency Physician from the Walnut Creek Medical Center in CA.

■ ORIGINAL RESEARCH & CONTRIBUTIONS

Nasopharyngeal Carcinoma Diagnostic Challenge in a Nonendemic Setting: Our Experience with 101 Patients

Kevin H Wang, MD; Stephanie A Austin, MD; Sonia H Chen, MD; David C Sonne, MD; Deepak Gurushanthaiah, MD

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https://doi.org/10.7812/TPP/16-180

E-pub: 06/05/2017 ABSTRACT

Introduction: We studied the presenting symptoms, time intervals, and workup involved in the diagnosis of nasopharyngeal carcinoma in an integrated health care system.

Methods: A retrospective chart review of all patients with a nasopharyngeal carcinoma diagnosis between 2007 and 2010 at Kaiser Permanente Northern California. Main outcome measures included diagnostic time intervals, presenting symptoms, diagnostic accuracy of nasal endoscopy, imaging, and diagnosis at first otolaryngologist (Oto-HNS) visit.

Results: This study included 101 patients: 70 (70%) were of Chinese or of Southeast Asian descent. The median time intervals along the diagnostic pathway were symptom onset to primary care physician visit, 6.0 weeks; primary care physician to Oto-HNS, 2.4 weeks; Oto-HNS to pathologic diagnosis, 1.1 weeks; and diagnosis to treatment onset, 5.5 weeks. The most common presenting symptoms were otologic issues (41, 41%), neck mass (39, 39%), nasal issues (32, 32%), and headache/cranial neuropathy (16, 16%). A nasopharyngeal lesion was detected in 54 (53%) patients after the first Oto-HNS visit. Among the initial nasal endoscopy reports, 32 (32%) did not reveal a nasopharyngeal lesion; 32 (32%) initial imaging studies also did not reveal a nasopharyngeal lesion. There was no correlation between diagnostic delay and disease stage.

Conclusion: Nasopharyngeal carcinoma presenting symptoms are extremely variable, and initial misdiagnosis is common. Median time from symptom onset to treatment was almost six months among patients studied. Nearly one-third of nasopharyngeal cancers were missed with nasal endoscopy and imaging. An understanding of the risk factors, presenting symptoms, and limitations associated with these diagnostic tests is necessary to support earlier detection of this insidious cancer.

INTRODUCTION

Nasopharyngeal carcinoma (NPC) is rarely diagnosed outside of the endemic areas of Southern China and Southeast Asia. In the US, NPC incidence is 0.7/100,000 per year.1 As with other cancers, disease stage heavily influences prognosis, and efforts directed toward earlier diagnosis may improve survival. The largest study conducted to date in Hong Kong revealed that the mean symptom-to-diagnosis duration was 8 months and that earlier presentation correlated with improved 10-year survival.² To our knowledge, only a single study from 2001 described NPC in an American health care setting.³ August et al reported a similar average symptom period of 7 months before diagnosis.³ Considering the importance of early diagnosis, the frequency of delayed diagnoses, and the relative lack of literature on this topic, we sought to examine the pathway to NPC diagnosis in our health care system.

METHODS

The tumor registry at Kaiser Permanente Northern California was queried for all patients who received an NPC diagnosis between January 1, 2007, and December 31, 2010. Charts were reviewed for diagnostic time intervals, symptoms, nasopharyngoscopy findings, initial radiographic imaging reports, and initial diagnosis by an otolaryngologist (Oto-HNS). Images were reviewed with an experienced neuroradiologist in a nonblinded fashion.

RESULTS

During the study period, 101 patients met inclusion criteria (demographics are described in Table 1). Most patients (70, 70%) were of Chinese or Southeast Asian descent, and 70 (70%) were men. The mean age (± standard deviation) was age 52 (±13) years. Among patients, 64% had late-stage disease (stages III/IV) at the time of diagnosis.

Table 1. Patient demographics				
Characteristic	Number (N = 101)			
Mean age, years (SD)	52 (13)			
Sex				
Men	70			
Women	31			
Race/ethnicity				
Chinese/Southeast Asiana	70			
Caucasian	22			
Hispanic	6			
African American	3			
Histology				
WHO I	10			
WHO II/III	85			
Unknown	6			
AJCC stage, 7th edition				
Stage I	6			
Stage II	31			
Stage III	33			
Stage IVa	15			
Stage IVb	7			
Stage IVc	9			
T stage	•			
T1	31			
T2	32			
T3	13			
T4	25			

^a Southeast Asian includes Filipino, Hmong, Laotian, Pacific Islander, and Vietnamese.

AJCC = American Joint Committee on Cancer; SD = standard deviation; WHO = World Health Organization.

Kevin H Wang, MD, is a Head and Neck Surgeon at the Oakland Medical Center in CA. E-mail: kevin.h.wang@kp.org. Stephanie A Austin, MD, is a Head and Neck Surgeon at the Oakland Medical Center in CA. E-mail: stephaustin@gmail.com. Sonia H Chen, MD, is a Head and Neck Surgeon at the Oakland Medical Center in CA. E-mail: shchen34@gmail.com. David C Sonne, MD, is a Radiologist at the Oakland Medical Center in CA. E-mail: chris.d.sonne@kp.org. Deepak Gurushanthaiah, MD, is a Head and Neck Surgeon at the Oakland Medical Center in CA. E-mail: d.gurushanthaiah@kp.org.

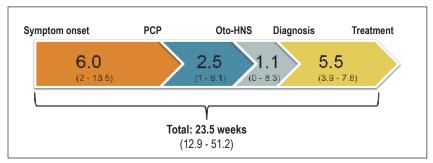


Figure 1. Median time intervals in weeks (interquartile ranges). Oto-HNS = otolaryngologist; PCP = primary care physician.

The median diagnostic pathway time intervals are summarized in Figure 1. The longest interval was from symptom onset to initial visit with a primary care physician. The total median interval from symptom onset to treatment initiation was 23.5 weeks (interquartile range 12.9-51.2).

Presenting symptoms, which were extremely variable, were categorized into 4 groups (Figure 2). The most common symptoms were ear-related; neck masses were second most common. Among patients, 33 (33%) experienced symptoms from multiple categories.

At the first Oto-HNS visit, 54 (53%) patients had a nasopharyngeal lesion diagnosed (Figure 3). For the remaining patients, other diagnoses were made, most commonly middle ear effusion and neck masses. Nasopharyngoscopy was

performed at the first Oto-HNS visit for 84 (83%) patients. Among initial endoscopies, 69 (68%) detected a nasopharyngeal lesion; the remaining results were documented as normal.

The first radiographic study was variable; magnetic resonance imaging (MRI) was most common (Table 2). Radiologists detected nasopharyngeal lesions in 68 of 101 (67%) patients. When the referring clinician indicated a nasopharyngeal lesion (42, 42% of the time), 39 (93%) imaging studies confirmed the abnormality. Among 59 (58%) imaging studies with other indications such as sinusitis or neck mass, only 28 (48%) imaging reports described a nasopharyngeal lesion. All the studies were reviewed again by a neuroradiologist in a nonblinded fashion, and NPC was identified for 30 (91%) of

33 patients who had false-negative imaging study results.

Of the negative imaging studies, 13 (39%) were identified as suboptimal for evaluating the nasopharynx for these reasons: 1) fewer than two slices of the nasopharynx were captured, 2) lack of contrast, 3) lack of axial-oriented slices, and/or 4) dental artifact. Among the positive scans, only 1 (1.5%) was suboptimal.

Upon review of radiographic images, the tumor growth pattern in the nasopharynx was exophytic in 53 (52%) patients, endophytic in 29 (29%), both exophytic and endophytic in 15 (15%), normal in 1 (1%), and not included in the scan in 3 (3%). Mastoid opacification was found in 53 (52%) images. Sphenoid opacification was identified in 32 (32%) patients, and bony skull base erosion in 30 (30%).

Ultimately, a nasopharyngeal lesion was first detected with nasal endoscopy in 64 (63%) patients, with imaging in 33 (33%), and intraoperatively for 4 (4%).

DISCUSSION

In this study, a nasopharyngeal lesion was diagnosed after the first Oto-HNS visit for 54 (53%) patients. No nasopharyngeal abnormality was documented for the remaining patients. Most of these cases were initially misdiagnosed and patients were treated for other conditions such as eustachian tube dysfunction, sinusitis, or epistaxis without undergoing a cancer workup. However, the primary diagnosis was a neck mass for 10 (9%) patients, and neck imaging was obtained for 7 patients within 1 month of the initial visit. Because appropriate workups were initiated, we did not consider misdiagnosis as an issue for these patients. Although clinicians other than Oto-HNS are not expected to diagnose NPC, the high rate of misdiagnosis by Oto-HNS has not been well described. In part, this is attributable to the rarity of NPCs. In our health care system, which includes more than 3 million patient members (15% Asian), approximately 130 full-time Oto-HNS each averaged one NPC diagnosis every 4 years.

NPC is also challenging to diagnose because of its anatomic isolation. Most of these cancers remain clinically silent for a long period of time. Although one-third of patients presented with nasal symptoms

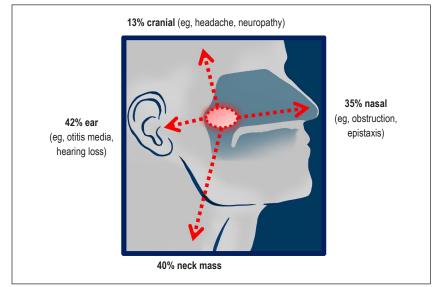


Figure 2. Nasopharyngeal carcinoma presenting symptoms.

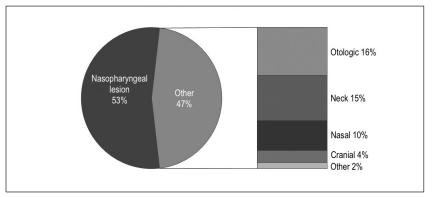


Figure 3. Initial diagnosis by otolaryngologist.

such as epistaxis and nasal obstruction, most presented only when the cancer began to affect the surrounding organs, causing ear symptoms or a neck mass.

Basic demographic data can be used to assess NPC risk in the context of clinical symptoms. Among our patients with NPC, 71 (70%) were men, and 83 (82%) were older than age 40 years. Although other head and neck cancers are rare in people younger than age 40 years, NPC does occur in young adults (18 [18%] of our patients were between ages 21 and 39; 71 [70%] were of Chinese or Southeast Asian ethnicity). This ethnic distinction is important: In our population, there were no patients with NPC of Indian, Korean, or Japanese descent. Other epidemiology studies confirm this ethnic predilection.4 In parts of southern China, NPC is the second-most-common cancer among men, with an incidence 10 to 20 times that of nonendemic populations.5 NPC etiology is thought to involve a combination of Epstein-Barr virus exposure and genetic susceptibility. Those who immigrate to the US from endemic areas are at higher risk for NPC than the general US population, but their risk is decreased when compared with risk for people living in China.5

Table 2. Initial radiographic scan type (N = 101)		
MRI	34	
CT neck	33	
CT sinus	19	
CT head	7	
Positron emission tomography-CT	8	

CT = computed tomography; MRI = magnetic resonance imaging.

Time Intervals

The median diagnostic pathway time intervals in Figure 1 appear to indicate an efficient pathway to diagnosis and treatment. However, the mean time intervals were much longer: Total time from symptom onset to treatment initiation was ten months. The much longer mean time intervals reflect the minority of patients whose care was substantially delayed by themselves or by their physicians. Onethird of patients waited longer than three months before seeking medical attention. Considering that all of our patients had health insurance, this delay probably reflects the fact that they were not alarmed by symptoms such as hearing loss, neck masses, and nasal obstruction. Additionally, for one-third of patients, the Oto-HNS needed longer than one month to establish the correct diagnosis after the initial visit. Even when specialists are equipped with the proper technology with which to examine the nasopharynx, an NPC diagnosis can remain elusive.

Presenting Symptoms

NPC's presenting symptoms are, in descending order, ear-related issues, a neck mass, and nasal and cranial symptoms. This is in contrast to classic teaching, however, which states that a neck mass is the most common NPC presenting symptom. ^{6,7} Ear symptoms occur because the nasopharyngeal tumor compresses or obstructs the torus tubarius and leads to eustachian tube dysfunction, which can manifest as a middle ear effusion, acute otitis media, and conductive hearing loss. In Chinese or Southeast Asian men, new onset of these ear symptoms should

trigger an examination of the nasopharynx. In our study, neck masses were usually referred appropriately by primary care physicians and worked-up efficiently by an Oto-HNS. However, several patients received misdiagnoses of lipoma, reactive lymphadenopathy, and neck abscess. Nasal symptoms such as obstruction, epistaxis, or sinusitislike symptoms were third most common upon presentation. These conditions often were initially treated with nasal steroids, antihistamines, or antibiotics by a primary care physician before referral to an Oto-HNS. Symptoms such as cranial neuropathy and headache occurred in 13 (13%) patients. Cranial neuropathies manifested most commonly as diplopia, followed by facial numbness, facial droop, and tongue numbness. One-third of patients had symptoms from multiple categories, and 42 different symptom combinations were seen. Such variation in symptomatology likely contributes to the challenge in diagnosis.

Nasal Endoscopy

Nasal endoscopy plays a crucial role in NPC diagnosis. It is performed in the Oto-HNS office with topical anesthetic in just a few minutes. For 84 (83%) patients, endoscopy was performed at the first Oto-HNS visit. Findings of the first nasopharyngoscopy were reported as normal for 32 (32%) patients. Of these patients with an initial negative nasal endoscopy result, 21 (66%) had T1/2 tumors, and 11 (34%) had T3/4 tumors. This false-negative rate is surprisingly high (especially for T3 and T4 tumors). These examination records were not available for our review, but we postulate several explanations. Among tumors, 29 (29%) were mostly endophytic on radiographic imaging; therefore, they were likely to be submucosal on endoscopic exam. Most tumors are thought to originate from the fossa of Rosenmüller, which is the posterolateral nasopharyngeal recess. This space is longer than 1 cm in depth and less than 5 mm wide in about 50% of people.8 It is not always possible to visualize the entire fossa, so turning the endoscope 90° or approaching the fossa from the contralateral side may be necessary. We hypothesized that many Oto-HNS do not routinely visualize the fossa's entirety, thereby missing smaller NPCs.

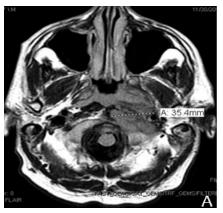




Figure 4. (A) Example of a T4b nasopharyngeal carcinoma (NPC) with an endoscopic examination that was initially normal. (B) Example of an endophytic NPC initially interpreted as normal on this computed tomography sinus scan without contrast. The arrow points to a tumor in the right parapharyngeal space.

The challenge associated with nasopharyngeal assessment was well described by Vlantis et al⁹ in which a 44-point scoring system was used. This exceptionally thorough evaluation system probably would be more accurate than other evaluations, but the time required would pose a challenge in daily practice.

The nasopharyngoscopes used during this study were standard fiber optic scopes. Video nasopharyngoscopes have improved resolution and offer a larger field of view and recording/playback capabilities. These newer scopes have recently been adopted widely in our system; with improved visualization, the incidence of missed NPCs on nasal endoscopy should decrease.

The fact that most (64, 63%) NPCs in our study were first detected by nasal endoscopy underscores the importance of performing nasal endoscopy for highrisk patients at the initial Oto-HNS visit. High-risk patients include any patient from China or Southeast Asia who present with an ear complaint, neck mass, nasal obstruction or cranial symptoms. Considering that nasal endoscopy is relatively quick to perform and virtually risk free, the threshold for its use should be very low for high-risk patients. Additionally, an understanding of the high false-negative rate associated with this examination is important when interpreting the findings. When a high-risk and symptomatic patient has negative nasal endoscopic exam findings, MRI should be considered for further evaluation for NPC. Figure 4A provides

an example of an NPC that went undetected on endoscopic exam; a large tumor is visualized on MRI.

Imaging

A nasopharyngeal lesion was not reported by the radiologist after viewing 33% of initial scans. During our rereview with our neuroradiologist, 91% of these scans revealed a nasopharyngeal lesion. Some lesions were subtle and probably detected on the basis of a priori knowledge of the presence of NPC; however, some lesions were obvious. The first imaging study technique was highly variable (Table 2), which reflects the assorted symptom indications and diversity among ordering physicians. One-quarter of first scans were ordered by a non-Oto-HNS.

Although some scans were suboptimal for examination of the nasopharynx (eg, CT sinus and CT head), we contend that some of the false-negative scans can probably be explained by inattentional blindness. 12 For example, when the indication was sinusitis, the radiologist likely focused on the sinuses and missed NPC (Figure 4B provides an example of a false-negative imaging study). The high false-negative rate underscores the importance of clinicians communicating clinical context to radiologists when ordering scans. The challenge remains, however, that clinicians themselves often do not suspect NPC and do not communicate this need to the interpreting radiologist. Mastoid opacification was found in 53 (52%) patients and sphenoid opacification in 32 (32%) patients. To our knowledge, these radiographic findings were not previously reported as warning signs for NPC. Although the specificity of these signs is unknown, considering that our cohort was entirely patients with NPC, we feel these signs should prompt astute clinicians to closely scrutinize the nasopharynx in high-risk patients.

We did not find a correlation between prolonged diagnostic time intervals and disease stage. This may be explained mainly by the clinically silent nature of NPC. Even with prompt action by both patients and the health care system, many patients with NPC probably do not develop clinical symptoms until advanced T-stage disease or nodal positivity is

Although some scans were suboptimal for examination of the nasopharynx ... we contend that some of the false-negative scans can probably be explained by inattentional blindness.

Other studies that have examined the diagnostic accuracy of MRI for NPC found sensitivity to be higher than 90%. ^{10,11} However, these studies were performed in an endemic area on patients "suspected" to have NPC. In our study, the first imaging study was a computed tomography (CT) scan (neck, sinus, or head), MRI, or a positron emission tomography/CT scan in a nonendemic population for which a nasopharyngeal pathology was not suspected 58% of the time.

present. Nevertheless, once these symptoms appear, patients must receive an efficient diagnosis.

The limitations of this study include its small size, its retrospective nature, and the availability of documentation and examination data. Patient-reported history is prone to recall bias, and documentation by physicians in the medical record was sometimes vague. Although we could review each radiographic study, review was not performed in a blinded fashion. Additionally, endoscopic examinations

were unavailable for review. Finally, the study was conducted at a single institution in a limited geographic area (Northern California).

The Institute of Medicine's recent landmark report, *Improving Diagnosis in Health Care*, ¹³ highlighted the fact that scant data exist on diagnostic error. We hope that our study will provide necessary baseline data regarding NPC.

CONCLUSION

NPC is rarely encountered in our health care system and frequently is misdiagnosed. Thirty-two percent of nasopharyngeal cancers are difficult to visualize upon nasal endoscopy, and 33% are missed upon an initial imaging study. This descriptive study of misdiagnosis incidence and patterns is a first step toward understanding the challenges associated with NPC diagnosis. Further work is required to implement changes that can reduce diagnostic error. ❖

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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Diagnosis

The diagnosis of disease is often easy, often difficult, and often impossible.

— Peter Mere Latham, MD, 1789-1875, British physician and medical educator, physician extraordinary to Queen Victoria

ORIGINAL RESEARCH & CONTRIBUTIONS

Incidence of Pulmonary Arterial Hypertension in Patients with Psoriasis: A Retrospective Cohort Study

Young M Choi, MD; Shannon Famenini, MD; Jashin J Wu, MD

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ABSTRACT

E-pub: 06/22/2017

Context: Inflammatory signaling may play an important role in the pathogenesis of pulmonary arterial hypertension (PAH).

Objective: To assess the incidence of PAH in patients with mild and severe psoriasis compared with their respective controls.

Design: From January 2004 to November 2012, we performed a retrospective cohort study of patients with psoriasis in the Kaiser Permanente Southern California Health Plan. Patients with an International Classification of Diseases, Ninth Revision Clinical Modification diagnostic code for psoriasis (696.1) or psoriatic arthritis (696.0) without a prior diagnosis of primary PAH (416.0) or secondary PAH (416.8) were eligible for inclusion. Patients who had never received a diagnosis of psoriasis were frequency-matched by age, sex, and race to form the control cohorts.

Main Outcome Measures: Incidence of PAH in patients with psoriasis compared with matched controls.

Results: There were 10,115 patients with mild psoriasis, 3821 with severe psoriasis, and 69,360 matched controls. On multivariable analysis, there was a significantly increased risk of PAH developing in the severe psoriasis cohort vs their controls (hazard ratio = 1.46, 95% confidence interval = 1.09-1.94).

Conclusion: The systemic inflammatory process underlying psoriasis may be a cause for an increased risk of PAH, but there are numerous secondary causes of PAH, some of which were not accounted for in our study. Further prospective, randomized controlled trials are necessary to establish psoriasis as a risk factor for PAH.

INTRODUCTION

Psoriasis is a chronic, immune-mediated, inflammatory skin disorder affecting 1% to 3% of the population.¹ As a multisystem disease, psoriasis is also known to cause an inflammatory arthritis in 6% to 42% of patients.² Other comorbidities known to be associated with psoriasis include obesity, metabolic syndrome, Type 2 diabetes mellitus, and coronary artery disease.¹ In fact, an elevated risk of myocardial infarction in patients with psoriasis has been repeatedly documented.³-5

Elucidating cardiovascular disease in psoriasis patients has therefore been an area of active research. Gunes et al⁶ performed transthoracic echocardiography (TTE) in 47 patients with psoriasis and

20 healthy controls to evaluate heart disease in psoriasis. They found that mild pulmonary hypertension was significantly higher among patients with psoriasis (31.9% vs 0%, p = 0.003). Causes of primary pulmonary arterial hypertension (PAH) include idiopathic, familial, associated with other disorders, associated with substantial venous or capillary involvement, and persistent pulmonary hypertension of the newborn. Secondary causes of PAH include left-sided heart disease, lung respiratory disease, and chronic thrombotic or embolic disease.7 We performed a retrospective cohort study of Kaiser Permanente (KP) Southern California (KPSC) members to assess the incidence of PAH in patients with psoriasis.

METHODS Study Design

From January 2004 to November 2012, a retrospective cohort study was performed from members of the KPSC Health Plan. Four cohorts were evaluated, including mild psoriasis (no phototherapy, oral therapy, or biologic therapy), control for mild psoriasis, severe psoriasis (any use of phototherapy, oral therapy, or biologic therapy), and control for severe psoriasis. The diagnosis of PAH by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnostic code during the study period was the primary outcome under consideration. The institutional review board of KPSC approved the study protocol.

Study Population and Data Source

Patients were recruited from KPSC, a large integrated health maintenance organization with approximately 3.6 million members as of November 2012. The demographics of KPSC members are representative of the Southern California population. The data source used was KP HealthConnect, the electronic medical record database of KPSC hospitals, clinics, and pharmacies. Members of KPSC receive nearly all their covered health care at KPSC facilities except for emergency medical care at non-Health Plan facilities. More than 92% of members have prescription drug benefits and use KPSC pharmacies for medications.

Inclusion/Exclusion Criteria

Inclusion criteria for patients were an ICD-9-CM diagnostic code for psoriasis (696.1) or psoriatic arthritis (696.0),

Young M Choi, MD, is a Resident Physician in Dermatology at the Los Angeles Medical Center in CA. E-mail: youngmikechoi@gmail.com. Shannon Famenini, MD, is a Physician at the University of California, Irvine. E-mail: sfamenini@mednet.ucla.edu. Jashin J Wu, MD, is the Director of Dermatology Research for the Department of Dermatology at the Los Angeles Medical Center in CA. E-mail: jashinwu@gmail.com.

received on 3 different dates from January 2004 to June 2012. The third psoriasis diagnosis date was considered the index date. Patients must have been enrolled in the KPSC Health Plan for at least 1 year before the index date and must have had at least 1 medical encounter per year. The severe psoriasis cohort included patients who had received the following therapies during the study period: methotrexate, cyclosporine, acitretin, etanercept, adalimumab, infliximab, ustekinumab, efalizumab, alefacept,

	Mild			Severe			
Characteristic	Controls (N = 50,309)	Psoriasis (N = 10,115)	Mild psoriasis vs control, p value	Controls (N = 19,051)	Psoriasis (N = 3821)	Severe psoriasis vs control, p value	
Age at diagnosis, years							
Mean (SD)	57.6 (14.84)	57.1 (14.86)	0.011	52.9 (13.67)	52.4 (13.68)	0.058	
Median (IQR)	58 (48-68)	58 (47-68)		54 (44-62)	53 (44-62)	1	
Age category, years		, ,	•		, ,	•	
< 45	9552 (19.0)	1987 (19.6)	0.17	4905 (25.7)	1023 (26.8)	0.462	
45-54	10,378 (20.6)	2133 (21.1)		5186 (27.2)	1048 (27.4)	1	
55-64	13,527 (26.9)	2700 (26.7)		5150 (27)	1016 (26.6)	1	
≥ 65	16,852 (33.5)	3295 (32.6)	-	3810 (20)	734 (19.2)	1	
Sex ^b	11,552 (5515)	525 (52.5)		2010 (20)	()		
Women	26,559 (52.8)	5343 (52.8)		9441 (49.6)	1894 (49.6)		
Men	23,750 (47.2)	4772 (47.2)		9610 (50.4)	1927 (50.4)		
Ethnicity	20,100 (41.2)	11.2 (11.2)		1 0010 (00.4)	1021 (00.4)		
Missing	1912 (3.8)	362 (3.6)	< 0.001	763 (4.0)	129 (3.4)	< 0.001	
White	23,369 (46.5)	5829 (57.6)	- 0.001	8568 (45.0)	2025 (54.8)	- 0.001	
Black	5606 (11.6)	467 (4.6)	_	2196 (12)	206 (5.6)	+	
Hispanic	13,516 (27.9)	2348 (23.2)	-	5326 (29.1)	906 (24.5)	-	
Asian/Pacific Islander	4858 (10)	911 (9.0)	-	1783 (9.7)	489 (13.2)	-	
Other			-			-	
Hypertension	1048 (2.2)	198 (2.0)		415 (2.3)	66 (1.8)		
· · · · · · · · · · · · · · · · · · ·	05 405 (50 7)	4700 (40.0)	± 0.004	44.407.(00.0)	4070 (54.7)	4.0.004	
No	25,495 (50.7)	4729 (46.8)	< 0.001	11,467 (60.2)	1976 (51.7)	< 0.001	
Yes	24,814 (49.3)	5386 (53.2)		7584 (39.8)	1845 (48.3)		
Dyslipidemia	05.050.(54.4)	4000 (47.0)	.0004	44.075 (00.0)	0000 (00 0)	0.000	
No	25,858 (51.4)	4833 (47.8)	< 0.001	11,875 (62.3)	2322 (60.8)	0.069	
Yes	24,451 (48.6)	5282 (52.2)		7176 (37.7)	1499 (39.2)		
Diabetes	44 405 (00 4)	0040 (=0 =)		10.00= (0==)	0.400 (0.4.0)		
No	41,465 (82.4)	8043 (79.5)	< 0.001	16,335 (85.7)	3129 (81.9)	< 0.001	
Yes	8844 (17.6)	2072 (20.5)		2716 (14.3)	692 (18.1)		
Lipid medication							
No	31,015 (61.6)	5945 (58.8)	< 0.001	13,550 (71.1)	2612 (68.4)	< 0.001	
Yes	19,294 (38.4)	4170 (41.2)		5501 (28.9)	1209 (31.6)		
Hypertension medication			1				
No	22,889 (45.5)	4228 (41.8)	< 0.001	10,402 (54.6)	1809 (47.3)	< 0.001	
Yes	27,420 (54.5)	5887 (58.2)		8649 (45.4)	2012 (52.7)		
Statin medication							
No	31,059 (61.7)	5951 (58.8)	< 0.001	13,557 (71.2)	2618 (68.5)	< 0.001	
Yes	19,250 (38.3)	4164 (41.2)		5494 (28.8)	1203 (31.5)		
Beta-blocker medication							
No	35,669 (70.9)	6836 (67.6)	< 0.001	14,769 (76.9)	2755 (71.7)	< 0.001	
Yes	14,640 (29.1)	3279 (32.4)		4436 (23.1)	1086 (28.3)	1	
Diabetes medication		, <i>,</i>	•	. , , ,		•	
No	42,759 (85)	8315 (82.2)	< 0.001	16,682 (87.6)	3184 (83.3)	0.0001	
Yes	7550 (15)	1800 (17.8)	1	2369 (12.4)	637 (16.7)	1	

^a Data are number (percentage) unless otherwise indicated.
^b Study groups were matched by sex, so it is not appropriate to calculate a p value for the comparison.

IQR = interquartile range; SD = standard deviation.

psoralen and ultraviolet A phototherapy, or ultraviolet B phototherapy. The mild psoriasis cohort was composed of patients who had not received any of these therapies.

Any patient with a prior diagnosis of primary PAH (ICD-9 CM Code 416.0) or secondary PAH (ICD-9-CM Code 416.8) was excluded from the study. For the control cohorts, patients who had never received a diagnosis of psoriasis were frequency-matched by age, sex, and race to each patient in the mild and severe psoriasis cohorts, thus creating 2 control groups.

Outcomes and Follow-up

The study outcome was the new-onset diagnosis of primary or secondary PAH (416.0 or 416.8). An independent chart review was performed for all 221 patients with psoriasis who had a diagnosis of PAH to verify the presence of pulmonary hypertension on TTE. Follow-up continued until the last visit before the end of the study in November 2012 unless any of the following prior events occurred: 1) diagnosis of PAH, 2) death during the study period, or 3) disenrollment from KPSC.

Confounding Variables

Within 12 months before the index date, we collected information on patient age, sex, obesity, smoking history, and comorbidities that may be potential risk factors for PAH, including hypertension (401.9), Type 2 diabetes mellitus (250.x1, 250.x3), and dyslipidemia (272.4). We also analyzed the use of antihypertensive medications, lipid-lowering drugs, statins, β-blockers, and diabetic medications as potential confounders in our study.

Statistical Analysis

All statistical analyses were performed using SAS Enterprise Guide Version 4.3 (SAS Institute Inc, Cary, NC); all p values are 2-sided, and p < 0.05 was considered statistically significant. Percentages and continuous variables were summarized as mean and standard deviation, and categorical variables were summarized as counts. Associations between psoriasis and various covariates were tested using the χ^2 test for categorical variables and the *t*-test for continuous variables. All statistical tests were 2-tailed.

	M	Mild		/ere
Characteristic	Controls (N = 50,309)	Psoriasis (N = 10,115)	Controls (N = 19,051)	Psoriasis (N = 3821)
No. of person years	179,355	36,005	96,386	19,369
New PAH cases, no. (%)	626 (1.2)	159 (1.6)	191 (1.0)	61 (1.6)
Incidence per 1000 person-years	3.5	4.4	2.0	3.1
Follow-up time, years				
Mean (SD)	3.6 (2.00)	3.6 (2.00)	5.0 (2.2)	5.1 (2.21)
Median	3.5	3.5	5.3	5.3
Q1-Q3 ^a	2.0-4.9	2.0-4.9	3.4-6.9	3.5-7.0

^a Q2 = median.

The incidence of PAH in the mild and severe psoriasis cohorts was compared with the incidence of PAH in the respective control group using an unadjusted Cox proportional hazards model. The incidence rates were then adjusted for age, sex, diabetes, dyslipidemia, hypertension, diabetes therapy, statin therapy, hypertension therapy, and β-blocker therapy. Obesity and smoking were not included in the model because they were insufficiently recorded. Each dichotomous variable in the model was checked for proportionality while adjusting for the other covariates in the model by examining diagnostic log-log survival plots.

RESULTS

Baseline Characteristics

There were 10,115 patients in the mild psoriasis cohort and 50,309 patients in the matched control group. The average age of the mild psoriasis cohort was 57.1 years compared with the average age of 57.6 years in the control cohort. The men-to-women proportion (47.2:52.8) was also equivalently matched. Ethnicity was comparable, except for a notably higher proportion of black patients in the control group (11.6% vs 4.8%). Compared with controls, the mild psoriasis cohort had a higher prevalence of hypertension (53.2% vs 49.3%), dyslipidemia (52.2% vs 48.6%), and diabetes (20.5% vs 17.6%), as well as use of the medications used to manage these comorbidities (Table 1).

In the severe psoriasis cohort, 3821 patients were matched to 19,051 control patients. The average age of the severe

psoriasis cohort was 52.4 years compared with an average age of 52.9 among controls. Sex was matched appropriately as well (men:women, 50.4:49.6). There was a higher proportion of black (12% vs 5.6%) and Hispanic (29.1% vs 24.5%) patients in the control group. Similar to the mild psoriasis cohort, the severe psoriasis cohort had a higher prevalence of hypertension (48.3% vs 39.8%), dyslipidemia (39.2% vs 37.7%), diabetes (18.1% vs 14.3%), and concomitant medication use compared with controls (see Table 1).

Incidence and Risk of Pulmonary Arterial Hypertension

There were 221 patients with mild and severe psoriasis with a new-onset diagnosis of primary or secondary PAH. All these patients demonstrated elevated pulmonary arterial pressures on TTE; 31 patients also received right-sided heart catheterization. Only 6 of the 221 patients with psoriasis received a diagnosis of primary PAH (416.0), now known as idiopathic PAH. The incidence per 1000 person-years of PAH in the mild psoriasis cohort vs control was 4.4 and 3.5; the incidence in the severe psoriasis cohort vs control was 3.1 and 2.0 (Table 2). Kaplan-Meier cumulative incidence plots demonstrated an increased probability of PAH in the mild psoriasis cohort vs control as well as the severe psoriasis cohort vs control (Figure 1). On multivariable analysis, patients with severe psoriasis were at increased risk of PAH compared with their respective controls (hazard ratio [HR] = 1.46, 95% confidence interval [CI] = 1.09-1.94). Patients with

PAH = pulmonary arterial hypertension; Q = quartile points; SD = standard deviation.

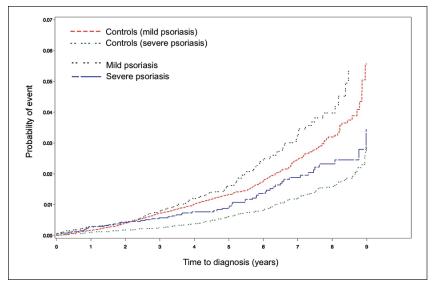


Figure 1. Kaplan-Meier curve for cumulative incidence of pulmonary arterial hypertension (PAH).

Cumulative incidence of PAH developing is greater in patients with mild psoriasis vs their controls as well as patients with severe psoriasis vs their controls.

mild psoriasis were not at significantly increased risk of PAH (p = 0.058).

In our analysis of hypertension, dyslipidemia, and Type 2 diabetes mellitus, hypertension was the only comorbidity associated with a significantly increased risk of PAH (HR 1.32, 95% CI = 1.06-1.64). Other factors associated with an increased risk included older age (≥ 65 years vs < 45 years: HR = 8.27, 95% CI = 5.48-12.47), hypertension medication (yes vs no: HR = 1.39, 95% CI = 1.07-1.81), β-blocker medication (yes vs no: HR = 1.99, 95% CI = 1.72-2.31), and diabetes medication (yes vs no: HR = 1.81, 95% CI = 1.43-2.29; Table 3). Obesity and smoking were not included in our multivariable analysis because they were insufficiently recorded.

DISCUSSION

Through this retrospective cohort study, we found that patients with severe psoriasis are at increased risk of development of PAH. This elevated risk was not seen in patients with mild psoriasis. Of the comorbidities we analyzed, we found that hypertension was independently associated with a higher risk of PAH as well. Our results substantiate the findings by Gunes et al⁶ of a higher prevalence of PAH in patients with psoriasis,

and to our knowledge provide the first study to demonstrate an elevated risk of PAH in patients with psoriasis.

The pathogenesis of PAH has been shown to involve endothelial damage and remodeling of the pulmonary arterial vasculature. Dysfunction of voltage-gated potassium (K+) channels in pulmonary arterial smooth-muscle cells (PASMCs) triggers vasoconstriction and PASMC proliferation, causing vascular medial hypertrophy. Endothelial damage is also present in PAH, which reduces the production of vasodilator substances and predisposes to in situ thrombosis.8 Additionally, recent studies are discovering a nuclear factor-κB (NF-κB) inflammatory signaling pathway in PAH.9 All of these elements combine to cause increased pulmonary vascular resistance, pulmonary hypertension, and ultimately, progressive right heart failure.8

Broadly related to the pathogenesis of PAH, the systemic inflammatory process underlying psoriasis has been known to cause endothelial dysfunction, ^{6,10} and platelet activation in psoriasis has been show to promote a prothrombotic state. ^{6,11} Likewise, NF-κB has also been shown to be an important inflammatory

Table 3. Univariate and multivariable Cox proportional hazard regression models of risk of pulmonary arterial hypertension in patients with mild and severe psoriasis compared with controls

Characteristic	Hazard ratio (95% confidence interval)	p value			
Psoriasis (unadjusted)					
Severe psoriasis vs control	1.55 (1.16-2.06)	0.0031			
Mild psoriasis vs control	1.25 (1.05-1.49)	0.0109			
Severe psoriasis vs mild psoriasis	0.59 (0.43-0.79)	0.0004			
Psoriasis (adjusted)					
Severe psoriasis vs control	1.46 (1.09-1.94)	0.0106			
Mild psoriasis vs control	1.18 (0.99-1.41)	0.0580			
Severe psoriasis vs mild psoriasis	0.83 (0.62-1.12)	0.2280			
Age category, years					
45-54 vs < 45	1.68 (1.07-2.66)	0.0251			
55-64 vs < 45	3.49 (2.30-5.31)	< 0.001			
≥ 65 vs < 45	8.27 (5.48-12.47)	< 0.001			
Other					
Men vs Women	0.88 (0.78-1.00) 0.0				
Hypertension (yes vs no)	1.32 (1.06-1.64)	0.0142			
Dyslipidemia (yes vs no)	1.02 (0.86-1.21)	0.8473			
Diabetes (yes vs no)	1.08 (0.85-1.36)	0.5270			
Lipid medication (yes vs no)	2.25 (0.56-9.11)	0.2540			
Hypertension medication (yes vs no)	1.39 (1.07-1.81)	0.0127			
Statin (yes vs no)	0.47 (0.12-1.89)	0.2874			
Beta-blocker (yes vs no)	1.99 (1.72-2.31) < .0001				
Diabetes medication (yes vs no)	1.81 (1.43-2.29)	< .0001			

mediator in the pathogenesis of psoriasis. ^{12,13} However, as NF-κB is important in numerous chronic inflammatory diseases such as rheumatoid arthritis, asthma, and inflammatory bowel disease, it is not specific to psoriasis. ¹⁴

... the inflammatorymediated pathway underlying psoriasis and PAH may explain the association between these 2 diseases.

Another link between psoriasis and PAH is the tumor necrosis factor-related apoptosis-inducing ligand (TRAIL). Inflammatory dendritic cells in psoriasis have been shown to express TRAIL, which activates keratinocytes to express CCL20, an important chemokine in the pathogenesis of psoriasis.¹⁵ Serum levels of TRAIL are also significantly higher in patients with psoriatic arthritis.16 In PAH, a recent study demonstrated that TRAIL is highly expressed in the PASMCs of patients with PAH, and blockade or genetic deletion of TRAIL in rodent models prevented the development of PAH.17

We acknowledge limitations to our study. The grouping of psoriasis severity based on treatment may have misclassified some patients. However, dermatologists in community practice do not commonly use standardized measurements such as body surface area or the Psoriasis Area and Severity Index. Furthermore, a difference between psoriasis with and without psoriatic arthritis could not be reliably made using ICD-9-CM coding. Although the gold standard for diagnosing PAH is through right-sided cardiac catheterization, most PAH cases were diagnosed with TTE alone. Yet, it is recognized that TTE is the most useful initial screening modality for PAH.18

Also, we did not include all possible confounders in our multivariable analysis, including obesity and smoking (both known to be associated with psoriasis), as well as other diseases associated with PAH, such as chronic obstructive

pulmonary disease, connective tissue diseases, human immunodeficiency virus infection, portal hypertension, congenital heart diseases, schistosomiasis, and chronic hemolytic anemia.¹⁹ Furthermore, our analysis did not account for the potential difference in the number of medical encounters per year between patients with psoriasis and their controls. It is possible that increased number of medical visits in patients with psoriasis increased their likelihood of undergoing studies such as TTE, which would not have been used in a comparable control patient with fewer medical encounters. Given the limitations of a retrospective analysis and the absence of controlled variables, it is possible that our results could be attributed to one or more of these other factors.

Another important consideration is the cardiovascular association with psoriasis. A greater proportion of cardiology patients undergoing TTE for various indications may have psoriasis as well. This raises the possibility that an increased number of patients with psoriasis with asymptomatic PAH received a diagnosis, increasing the incidence of PAH despite a lack of clinical significance. Moreover, the control groups in our study had a higher prevalence of black and Hispanic patients, who at the population level are known to have decreased access to health care.20 This may have further biased our study toward finding an elevated incidence of PAH in the study groups.

CONCLUSION

We performed a retrospective cohort study from the KPSC Health Plan, which possesses a large and stable membership, accurate diagnosis and documentation, substantial longitudinal follow-up, and comprehensive health care coverage. We believe that the inflammatory-mediated pathway underlying psoriasis and PAH may explain the association between these 2 diseases. In a similar study in the KP Northern California Health Plan,²¹ 99 patients with a confirmed diagnosis of psoriatic arthritis were compared with matched control subjects and were found not to have a significant increased risk of atherothrombotic disease but did

have an increased prevalence of systemic hypertension and heart failure. It is important to note that these retrospective studies establish possible associations, but further studies, including long-term prospective trials and/or registries, are necessary to establish psoriasis as a risk factor for PAH. ❖

Disclosure Statement

Dr Wu is an Investigator for AbbVie, North Chicago, IL; Amgen, Thousand Oaks, CA; Eli Lilly and Co, Indianapolis, IN; Janssen Pharmaceuticals, Titusville, NJ; Novartis Corp, Basel, Switzerland; and Regeneron, Tarrytown, NY. The author(s) have no other conflicts of interest to disclose.

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The Prince in a Kingdom

The heart, like the prince in a kingdom, in whose hands lie the chief and highest authority, rules over all, it is the ... foundation from which all power is derived, on which all power depends in the animal body.

 William Harvey, 1578-1657, English physician, first known physician to describe the systemic circulation and properties of blood being pumped to the brain and body by the heart

ORIGINAL RESEARCH & CONTRIBUTIONS

Complementary and Alternative Medicine in an Integrated Health Care Delivery System: Users of Chiropractic, Acupuncture, and Massage Services

Tracy McCubbin, MD; Karin L Kempe, MD, MPH; Arne Beck, PhD

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ABSTRACT

Introduction: Complementary and alternative medicine research has relied primarily on survey data from community populations rather than from patient populations receiving these services in integrated health care delivery systems (IHDS).

Objectives: To describe patients seeking chiropractic, acupuncture, or massage therapy in a dedicated Center for Complementary Medicine (CCM) within an IHDS.

Methods: Patient surveys at the initial CCM visit included chief complaint, prior treatments, and relief with treatment (0% to 100% relief). A modified Brief Pain Inventory assessed average and current pain (0 = no pain; 10 = unbearable pain) and interference with life domains (1 = does not interfere; 10 = completely interferes). Demographics and CCM provider type were obtained from medical records. Analysis included patients who completed the survey.

Results: Between 2007 and 2014, a total of 27,225 patients sought CCM services (median age = 50 years). Most (62%) were female, and 73% were white. Modalities included chiropractic (66.9%), acupuncture (18.1%), and massage (15.0%). Spine/truncal pain was most commonly reported (70.5%). A majority of patients (59%) saw their physician for their condition, 59% had not used CCM services previously, and 60% received medications for their condition. Mean ratings included pain relief with prior treatment (30.07%, standard deviation [SD] = 27.01%), current pain (4.33, SD = 2.4), and functional impairment ranging from 3.03 (SD = 3.09) for relationships to 5.42 (SD = 3.22) for enjoyment of life.

Conclusion: Spine/truncal pain was the most common complaint and chiropractic the most common modality among patients receiving CCM services in an IHDS. More than one-third of patients self-referred to the CCM.

INTRODUCTION

The use of complementary and alternative medicine (CAM), including chiropractic, acupuncture, and massage, has become widespread in the US. A 2007 National Health Interview Survey showed 40% of adults (N = 23,393) reporting use of these services in the previous 12 months, expenditures of \$33.9 billion, and an estimated 354.2 million visits to CAM practitioners.

This report was based on completed interviews with a response rate of 68%.

A national telephone survey of 1539 adults, published in the *New England Journal of Medicine* in 1993, showed that 83% of those using unconventional therapies (now called CAM) for serious conditions also sought care from a medical doctor, but only 28% informed their physician of CAM use.³ Therefore, bringing CAM services into an integrated health care delivery system (IHDS) such as Kaiser Permanente (KP) could be of great value in meeting members' care needs in a manner that ensures coordination with conventional medical care through the use of a joint electronic medical record (EMR). Moreover, given that lawmakers in states such as Oregon and Washington are recognize acupuncture, chiropractic, naturopathy, and massage as covered services, understanding the demand for such benefits is important to both clinicians and insurers.

Much previous research has focused on utilization of CAM services across a broad spectrum of the population through telephone surveys.³⁻⁵ It is unknown if the characteristics of patients seeking CAM therapies in an IHDS would mirror that of the general population. This article describes a large population of insured adults seeking three types of CAM care within a prepaid IHDS during a seven-year period. Unlike the previous surveys about CAM use, we report actual CAM use among a population of patients in an integrated delivery system.

METHODS

Setting

The Centers for Complementary Medicine (CCM) at KP Colorado (KPCO) is a group of CAM clinics in an IHDS that currently serves more than 650,000 members in Colorado. The program was started in 2003 and currently has 5 separate clinics. Four clinics are located in a KPCO medical office building. The fifth clinic is located inside a medical office building adjacent to and owned by KPCO's main contract hospital. All locations offer acupuncture, chiropractic, and massage therapy. Depending on their benefits, KPCO members have a copay for CCM services (eg, Medicare members with chiropractic benefits comprise approximately 30% of our CCM population) or pay a discounted fee for service.

Tracy McCubbin, MD, is the Founder and former Medical Director for the Centers for Complementary Medicine at Kaiser Permanente in Denver, CO. E-mail: tracy.mccubbin@kp.org. **Karin L Kempe, MD, MPH,** is the former Medical Director of Clinical Prevention Services in the Department of Population Care and Prevention Services at Kaiser Permanente in Denver, CO. E-mail: karinkempe@comcast.net. **Arne Beck, PhD,** is the Director for Quality Improvement and Strategic Research at the Institute for Health Research in Denver, CO. E-mail: arne.beck@kp.org.

Center for Complementary Medicine Survey

In 2007, a CCM patient survey was developed and implemented in CCM clinics. Surveys were administered to patients at the first visit to the CCM as part of routine clinical assessment and entered by CCM staff into the EMR. Electronic medical record notes from the first and fifth visits to CCM were routed electronically to the in-basket of the primary care physician (PCP) to facilitate communication with the PCP and coordination with conventional medical care. These notes provided information that the patient was evaluated in CCM for a specified condition, a summary of the CCM survey, and the treatment course for that condition. If no PCP was assigned, the notes were copied to the CCM Medical Director for review. This study focused on the initial CCM visit for patients requesting a single modality—chiropractic, acupuncture, or massage—between May 8, 2007, and December 31, 2014. All patients completed the CCM survey at their first visit during this time period.

Table 1. Demographics of patients receiving complementary and alternative medicine services				
Characteristic	Number (%) ^a			
Age (years)				
Median (25th and 75th percentiles)	50 (36, 64)			
Mean (standard deviation)	50 (17.6)			
Sex				
Female	16,990 (62.4)			
Male	10,235 (37.6)			
Race/ethnicity				
White	19,881 (73.0)			
Hispanic	3290 (12.1)			
African American	855 (3.1)			
Asian American	573 (2.1)			
Native American	72 (0.3)			
Native Hawaiian or Pacific Islander	75 (0.3)			
Other, multiracial, or unknown	2,479 (9.1)			

^a Data presented as number (%) unless otherwise indicated.

The survey included the following information: 1) primary reason for the visit; 2) whether the individual had seen or planned to see his or her PCP for his or her condition; 3) current treatments and medications received for this condition (before receiving CCM services), and degree of relief with current treatment (0% relief to 100% relief). In addition, questions adapted from the Brief Pain Inventory (BPI) were used to assess both the sensory dimension of pain and its interference in various dimensions of the patient's life. These questions include ratings for average pain and current pain (pain ratings ranging from 0 = no pain to 10 = unbearable pain), and the degree to which the condition interfered with general activity, mood, walking ability, normal work, relations with other people, sleep, and enjoyment of life.⁶ Ratings for these measures of interference in life domains ranged from 0 (does not interfere) to 10 (completely interferes). The BPI was originally introduced in 1982. The Pain Research Group at the University of Wisconsin Medical School in Madison, WI, under the direction of Charles Cleeland, PhD, tested and developed the self-report BPI for measuring cancer pain; they subsequently applied the BPI more broadly to studies of other types of pain (eg, chronic pain, musculoskeletal pain, fibromyalgia) and pain treatment in the US and internationally.6

A copy of the modified CCM survey is provided in the Appendix (available online at: www.thepermanentejournal.org/files/2017/16-172-Appendix.pdf). Additional demographic data on age, sex, self-reported race/ethnicity, and type of CCM clinician (massage therapist, acupuncturist, chiropractor) were obtained from a virtual data warehouse populated by EMR data from the IHDS.

The KPCO institutional review board reviewed and approved this study.

Analysis

The CCM survey data as well as CCM clinician specialty and patient age, sex, and race/ethnicity were extracted from KPCO's EMR and entered into a database (SAS 9.4, SAS Institute, Cary,

	Total, No. (%)	Chiropractor, No. (%)	Licensed acupuncturist, No. (%)	Massage therapist, No. (%)
Primary reason for visit	(N = 27,049)	(n = 18,097)	(n = 4897)	(n = 4055)
Spine/truncal pain	19,080 (70.5)	14,813 (81.9)	1899 (38.8)	2368 (58.4)
Extremity pain	2367 (8.8)	1011 (5.6)	792 (16.2)	564 (13.9)
Neurologic	1841 (6.8)	1087 (6.0)	482 (9.8)	272 (6.7)
Other (pain)	1448 (5.4)	387 (2.1)	899 (18.4)	162 (4.0)
Generalized and muscle pain	1088 (4.0)	461 (2.5)	243 (5.0)	384 (9.5)
Stress/anxiety	402 (1.5)	42 (0.2)	186 (3.8)	174 (4.3)
Leg pain	279 (1.0)	177 (1.0)	90 (1.8)	12 (0.3)
Abdominal pain	145 (0.5)	23 (0.1)	112 (2.3)	10 (0.2)
Sinusitis/allergies	123 (0.5)	15 (0.1)	105 (2.1)	3 (0.1)
Insomnia	59 (0.2)	7 (0)	45 (0.9)	7 (0.2)
None reported	115 (0.4)	41 (0.2)	4 (0.1)	70 (1.7)
Missing	102 (0.4)	33 (0.2)	40 (0.8)	29 (0.7)

^a Excludes 2 patients with multiple primary reasons for first visit and another 174 patients because of missing clinician titles (which were used to determine treatment modality).

NC). The primary analyses were descriptive (frequencies, percentages, means, medians), including patient demographics, reason for visit, past treatments, treatment modality, pain intensity, and physical and social/emotional functional impairment.

RESULTS

There were 27,225 unique, initial CCM visits with an associated CCM questionnaire between May 8, 2007, and December 31, 2014. Demographic data for this patient cohort are shown in Table 1. Most patients seeking CCM services were female (62%) and white (73%), with a median age of 50 years. This population was somewhat older and contained a higher proportion of females than the overall KPCO member population, which has an average age of 45 years and is 53% female. The racial/ethnic distribution of patients seeking CCM services was comparable to the larger KPCO adult membership.

Table 2 shows the primary reason patients sought CCM services by treatment modality. Most patients sought chiropractic services (66.9%), followed by acupuncture (18.1%) and massage therapy (15.0%). Spine/truncal pain was reported most often as the primary reason for the visit, regardless of treatment modality (70.5%).

Fifty-nine percent of patients surveyed reported having seen their PCP for their condition before the initial CCM visit, and 59% of patients indicated that they had not used other CAM services before their CCM visit. In addition, 60% reported receiving over-the-counter and/or prescription medications for their condition.

Patients at their initial CCM visit were asked the following question about prior non-CAM treatment: "What percentage describes the relief of your condition with your current treatment?" Using a response scale ranging from 0% for no relief and 100% for complete relief, patients provided an average rating of 30.07% (standard deviation [SD] = 27.01%). Patients were also asked about current pain and functional impairment at their initial CCM visit. On a scale ranging from no pain (0) to unbearable pain (10), the mean rating of current pain was 4.33 (SD = 2.40). Table 3 shows that patients' ratings of the degree to which their condition interfered with various life domains ranged from a mean of 3.03 (SD = 3.09) for relationships to 5.42 (SD = 3.22) for enjoyment of life.

DISCUSSION

In this study, we describe the use of massage, acupuncture, and chiropractic services as they became available within KPCO in the form of a fee-for-service clinic in an IHDS. Unlike many previous studies based on community surveys, our large dataset was obtained from actual patient visits to the CCM clinic during a seven-year period.

Most of this large population of adult CAM users were older white women, the most frequently used modality was chiropractic, and most patients sought treatment of spine/truncal pain. Most patients (59%) had previously seen their PCP for their condition, and most had not previously used CAM services, but they did report using prescription and/or over-the-counter pain medications.

Table 3. Functional impairment rating because of condition at initial visit ^a					
Functional status rating	Mean ^b	Standard deviation			
Enjoyment of life	5.42	3.22			
General activity	5.21	3.02			
Mood	4.77	3.02			
Normal work	4.47	3.33			
Relationships	3.03	3.09			
Sleep	4.82	3.25			
Walking ability	3.67	3.38			

^a0 = does not interfere; 10 = completely interferes.

The KPCO CCM visit volume grew over the study period as additional clinics were added and patient awareness of the program grew, with a substantial minority of patients (41%) self-referring to the CCM. Although most patients indicated that they had not used other CAM services before their CCM visit, we found through an annual postvisit satisfaction survey that patients expressed their willingness to try chiropractic, massage therapy, and/or acupuncture because they were offered within KPCO. In addition, although not tracked formally throughout the study period, we know that physician referrals to the CCM increased during the study period. In the first year of our program, there were no physician referrals, but by 2015, there were approximately 3200 physician referrals. The Mayo Clinic compared physician surveys from 2004 and 2012 and found their physicians developed a more positive attitude toward CAM therapies in that period.⁷ Our informal discussions with KPCO physicians also suggest a more positive attitude toward CAM therapies over time as the volume of CCM visits increased.

The largest volume of visits to the CCM was for chiropractic care. According to a National Center for Health Statistics report, use of practitioner-based chiropractic manipulation is higher in the Mountain Region of the US at 11.4% compared with the national average of 8.5%.

In our dataset, 31% of the patients were older than age 65 years, similar to findings from other surveys.^{3,9-11} In the future, CAM services may play a key role in meeting the needs of our aging population, estimated to reach 20% older than age 65 years by 2030.¹²

Although most (59%) of the patients had already seen their PCP for their condition, they reported pain and functional impairment in the midrange of these rating scales at the start of CAM therapy. This finding suggests that the CAM modalities that patients chose may address an unmet need for adjunctive care for which patients were willing to pay a copay or out-of-pocket fees. Although we do not know the reasons why the other 41% self-referred without first contacting the primary care office, we believe that understanding why so many patients made this choice may help us improve the care provided for these conditions by the conventional medical system or suggest opportunities to better manage them. Furthermore, our findings indicate that most of the patients did not plan to see their PCP in the future for the same

b Means are based on varying response rates across questions, from 25,788 for normal work to 26,303 for general activity.

condition or were undecided after their treatment in the CCM. Shifting of services from primary care settings to CAM clinics for patients with musculoskeletal pain may also have cost-savings potential. ¹³ Davis et al ¹⁴ showed an inverse relation between supply of chiropractors and visits to PCPs because of back and neck

pain among 17.7 million Medicare enrollees. They estimated that chiropractic care is associated with 0.37 million fewer visits to PCPs annually at a cost savings of \$83.5 million.¹⁴

Numerous studies have assessed pain and functional impairment with the BPI across diverse populations (urban vs rural; different nationalities), and medical conditions (cancer, musculoskeletal pain), ^{6,14-16} although fewer studies have focused on the use of the BPI among those seeking or referred for CAM services. ¹⁷⁻²⁰ Comparing results from these studies with those from the present study requires caution about the generalizability to subsets of the population of members with different types of pain

seeking CAM services in an IHDS. In addition, because we used a modified version of the BPI, caution is further warranted in comparing ratings from this study with others using the BPI. Nevertheless, some of the findings from these studies show comparable pain and functional impairment ratings as well as areas where the findings diverge. The cross-sectional study by Peleg et al²⁰ of 163 Israeli patients visiting a complementary medicine clinic because of pain showed similar ratings of current pain and interference with life domains compared with those of KPCO patients. Vallerand et al²¹ surveyed 595 residents from urban, suburban, and rural communities and showed pain ratings generally comparable to those reported by KPCO patients. Average pain relief from conventional treatment was rated lower for KPCO patients compared with Israeli patients and compared with patients surveyed by Vallerand et al. However, these patients used a CAM self-treatment regimen that included a wide variety of herbal products and supplements and/or CAM modalities, including but not limited to chiropractic, massage, and acupuncture.²¹

The primary contribution of this study is that our large dataset was obtained from actual patient visits to dedicated CAM clinics within an IHDS, rather than from population-based estimates of CAM use derived from community surveys, as has been the case with many previous descriptive studies of CAM services. As such, our results are informative regarding the types of pain for which actual patients seek CAM services, and their self-reported degree of pain and functional impairment.

Our study also had limitations. We used descriptive, cross-sectional data to describe the population of patients seeking CAM services during a seven-year period. Although prior research suggests that CAM treatments may be particularly effective in improving clinical outcomes and reducing costs for patients with chronic pain, stress, and/or depressive symptoms who have higher utilization of services, we were unable to evaluate clinical outcomes and track possible cost reductions associated with CCM care. We also did not evaluate the impact of multiple other factors that may influence CAM use within an IHDS, including differential copays, geographic distribution, attitudes of

referring physicians, or the reasons that patients at the CCM did not seek conventional medical care at their PCP's office. Although we studied a large cohort of patients seeking CAM services, our results reflect an insured, care-seeking population and may not be applicable to the general population. In addition, because we

used a modified version of the BPI, we cannot assume that it had the same validity and reliability as the original form of the instrument. Future research may involve linking our CAM questionnaire data to claims and encounter data on diagnoses, medications, health services utilization, and health care costs for patients at the CCM, and examining the relationship between receipt of CAM services and subsequent changes in pain and functional impairment. Additional analyses could also include case-control studies comparing outcomes for CAM recipients with those of matched controls who do not receive such services (eg, acupuncture or massage therapy for low back pain vs physical therapy,

changes in use of narcotics after CAM treatment, impact of CAM on health care utilization and costs for patients with chronic pain).

suggest a more
positive attitude
toward CAM
therapies over
time as the
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Our informal

discussions with

KPCO physicians

CONCLUSION

This large study describes 7 years of data from insured adults receiving chiropractic, acupuncture, and massage therapy in a fee-for-service CAM center within an IHDS. The addition of the CCM clinic to the overall health care delivery model ensured that such complementary care was delivered with quality oversight and using a common EMR which provided communication to primary and specialty care clinicians. This study also provides insight into the demographic and clinical characteristics of this population of CAM users; spine/truncal pain was the most common complaint, and chiropractic services the most common complaint, and chiropractic services the most commonly sought modality. Fully 41% of patients did not see a PCP first for their condition. Those patients who did have initial traditional medical treatment even with clinically significant pain relief (30%) still sought additional CCM services, demonstrating the value of such care to patients with common musculoskeletal complaints. •

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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People

Take care of people, not illnesses.

— Eugene A Stead, Jr, 1908-2005, physician and founder of the physician assistant profession



The Mercantile Truck photograph

April M Day, MD

Always parked next to the Arroyo Seco Mercantile, this old, rusted truck speaks to the heart of artists who find beauty in the mundane. This photograph was taken during the Taos Writing Retreat for Health Professionals in Taos, NM.

Dr Day is a Physician at the Baylor Scott & White Medical Center in Garland, TX.

ORIGINAL RESEARCH & CONTRIBUTIONS

Impact of Longitudinal Electronic Health Record Training for Residents Preparing for Practice in Patient-Centered Medical Homes

Jung G Kim, MPH, CPH; Hector P Rodriguez, PhD, MPH; Katherine AT Estlin, MD; Carl G Morris, MD, MPH

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ABSTRACT

Introduction: Competence in using an electronic health record (EHR) is considered a critical skill for physicians practicing in patient-centered medical homes (PCMHs), but few studies have examined the impact of EHR training for residents preparing to practice in PCMHs. This study explored the educational outcomes associated with comprehensive EHR training for family medicine residents.

Methods: The PCMH EHR training consisted of case-based routine clinic visits delivered to 3 resident cohorts (N = 18). Participants completed an EHR competency self-assessment between 2011 and 2016 (N = 127), examining 6 EHR/PCMH core skills. We compared baseline characteristics for residents by low vs high exposure to EHR training. Multivariate regression estimated whether self-reported competencies improved over time and whether high PCMH EHR training exposure was associated with incremental improvement in self-reported competencies over time.

Results: Residents completed an average of 8.2 sessions: low-exposure residents averaged 5.3 sessions (standard deviation = 1.5), and high-exposure residents averaged 9.0 sessions (standard deviation = 0.9). High-exposed residents had higher posttest scores at training completion (84.4 vs 70.7). Over time, adjusted mean scores (confidence interval) for both groups improved (p < 0.001) from 12.2 (9.6-14.8), with low-exposed residents having greater score improvement (p < 0.001) because of their much lower baseline scores.

Conclusion: Comprehensive training designed to improve EHR competencies among residents practicing in a PCMH resulted in improved assessment scores. Our findings indicate EHR training as part of resident exposure to the PCMH measurably improves self-assessed competencies, even among residents less engaged in EHR training.

INTRODUCTION

When introduced, electronic health records (EHRs) were regarded as key tools to improve the quality of health care delivery. However, the potential for EHRs to improve quality has been clouded because of growing frustration with unintended consequences, including decreased patient encounter duration, limited capacity to support care management, and technology implementation glitches. 1-5 Nevertheless, the functionality and use of EHRs are increasingly important for health care practice and policy. Use of

EHRs supports practice transformation efforts such as the patient-centered medical home (PCMH) model for chronic disease management and point-of-care decision making, aids in achieving financial incentives from the Centers for Medicare and Medicaid Services through Meaningful Use, and moves practices closer toward the Institute of Medicine's vision of building learning health systems that adapt to our nation's evolving health care needs.⁶⁻⁸

However, the content of existing EHR training curricula focuses predominantly

on mastering software functionalities alone rather than applying the EHR to optimize the quality of patient care. 9,10 Because EHR training content is generally not embedded in medical education curricula, training has primarily been delivered in limited, discreet sessions, and often taught as a standard Human Resources onboarding component rather than a professional competency.11 Moreover, assessing the impact of EHR training for future physicians is still in its infancy. Reports on EHR learners in both undergraduate medical education (UME) and graduate medical education (GME) state the tremendous value of being a competent EHR user, not only for measuring performance for the Accreditation Council for Graduate Medical Education competencies such as systems-based practice and practice-based learning but also to promote lifelong learning as future physicians enter practice. 12-14 In recent years, studies on EHR curriculum in core skills for effective patient care and communication, clinical efficiency, and EHR functionality have been reported to be a useful foundation for teaching residents. 12-15

Moreover, longitudinal and continuous training programs have been recently popularized in medical education. The cumulative exposure of learning has been shown to improve both learner outcomes and performance in health systems. ¹⁵⁻¹⁷ Coupled with simulation training that provides immersive training that "replace and amplify real experiences with guided ones," EHR training using clinical cases that simulate practice transformation,

Jung G Kim, MPH, CPH, is a Clinical Teaching Associate in the Department of Family Medicine at the University of Washington School of Medicine in Seattle. E-mail: jung.g.kim@kp.org. Hector P Rodriguez, PhD, MPH, is the Co-Director for the Center of Healthcare Organizational Innovation Research and a Professor of Health Policy and Management at the University of California School of Public Health in Berkeley. E-mail: hrod@berkeley.edu. Katherine AT Estlin, MD, is a Physician at Open Door Community Health Centers in Arcata, CA. E-mail: kestlin@gmail.com. Carl G Morris, MD, MPH, is the Program Director at Group Health Family Medicine Residency and a Clinical Associate Professor in the Department of Family Medicine at the University of Washington School of Medicine in Seattle. E-mail: morris.cg@ghc.org.

such as the PCMH, provides a platform to develop a resident's knowledge and skills, with a potential added benefit to improve health systems. 18,19

The purpose for this study is to describe the Group Health Family Medicine Residency (GHFMR) longitudinal PCMH case-based EHR curriculum and to assess the outcomes of the training on residents' EHR self-assessment scores over time. The EHR training was grounded in clinical cases, taught through an accredited Accreditation Council for Graduate Medical Education program, delivered longitudinally during the three years of the family medicine residency program, and included EHR self-assessments delivered every trimester, totaling nine possible assessments per resident. We hypothesized that residents' EHR training scores would improve in the context of longitudinal EHR training. We also hypothesized that residents with more exposure to EHR training sessions would achieve greater improvements over time compared with residents with less exposure to training.

METHODS

Setting and Participants

The GHFMR is an 18-resident (6 per year of residency), community-based, urban GME program affiliated with the University of Washington School of Medicine. The GHFMR outpatient practice mirrors attending physicians in the sponsoring institution, Group Health Cooperative (Group Health), an integrated health care delivery system throughout Washington state. Residents are assigned a panel of patients through their training period of 3 years and use EpicCare (Epic Systems Corp, Verona, WI) for their EHR.

The GHFMR's EHR is the foundational tool for Group Health's PCMH, a nationally recognized practice transformation designed to achieve the Triple Aim. 20-23 The PCMH optimizes health information technology to improve physician point-of-care decision making in the patient encounter, facilitates better chronic care management, enhances visit preparation, delivers expanded clinician access (secure messaging and telephone encounters), and increases capacity for patient outreach. 21,24

From 2003 to 2009, GHFMR's physician EHR training program was taught by an information technology professional without the knowledge or authority to provide trainees with clinical information on how to use the EHR to improve patient care. The focus of the training was on software navigation. In response to persistent negative program feedback from residents and faculty about EHR training insufficiencies coupled with the lack of a documented GME EHR curriculum in the literature, the GHFMR designed a

				Categories		
ltem	In-Basket α = 0.95	Encounters α = 0.97	Chart Review α = 0.93	Other Activities α = 0.93	Tools α = 0.93	Clinical Efficiency and Quality α = 0.91
1	Attach an inbox	Enter LOS	Use filters	Review and update allergies	Use SmartPhrases ^a	Greet and prepare for documentation
2	Send staff message	Use progress notes	Save filters	Review and update history	Create, edit, and share SmartPhrases ^a	Turn the screen to the patient
3	Respond to patient call message	Complete meds and orders	Review encounters	Review and update problem list	Embed SmartLinks ^a	Agenda setting and roadmap
4	Send patient call back	Enter diagnosis	Review labs	Review and update health maintenance	Use and embed SmartLists ^a	Subjective typed in the room
5	Respond to Rx authorization	Complete patient instructions	Create flowsheet	Review and update immunizations	Use SmartTexts ^a	Order and associate as you go
6	Review cc'd chart	Create a follow-up	Review imaging	Review and update FYIs	Use references	Follow-up is clear (or scheduled)
7	Review and release results	Cc the chart	Review procedures	Review and update patient lists	Use SmartSets ^a	Motivational interviewing using the computer screen
8	Result note and routing	Print the after-visit summary	Review ECG	Use growth chart	Set up preference lists "on-the-fly"	Communicate effectively (say it, type it, read it, share it)
9	Cosign orders	_	Review other orders	Review snapshot and add reports	Set up preference lists in the workbench	Create after-visit summary with the patient
10	Cosign meds	_	Review episodes	Review demographics	Edit preference list entries	After-visit summary using SmartPhrase.a PATIENTINSTRUCTIONS / .DIAG
11	Patient secure message	_	Review meds	_	Create letters	Touch typing skills
12	Create out of office	_	Review letters	_	Review flow sheets	Close as you go
13	_	_	Review admin scans	_	_	In-basket clean
14	_	_	Review media	_	_	Huddle efficiency
15	_	_	Use misc reports	_	_	Dyad efficiency

^a SmartPhrases, SmartLinks, SmartTexts, and SmartSets = predefined automated choices to generate automated text.

α = internal consistency reliability statistics; admin = administrative; cc = carbon copy; ECG = electrocardiogram; FYIs = for your information notes; labs = laboratory study results; LOS = level of service; meds = medications; misc = miscellaneous; Rx = prescription.

longitudinal EHR training curriculum in conjunction with implementing the Group Health PCMH care model.²⁵

The GHFMR EHR curriculum was implemented in 2010. All residents were scheduled to a three-hour training provided every trimester each year. The goals were derived from patient-centered care attributes to improve the core skills of EHR use with chronic disease management and team-based care, patient communication, software navigation, and clinical efficiency and quality. Appendix 1 (available online at: www.thepermanentejournal. org/files/2017/16-122-Appendix-1.pdf) describes the curriculum in detail.

Data Sources

All residents (N = 18) from 3 entering family medicine resident cohorts (2011, 2012, and 2013) each completed 3 years of longitudinal EHR training, for a total of 127 self-assessments. We anticipated heterogeneity in our incoming trainees' EHR knowledge, which may include characteristic differences incorporated during UME; thus, we examined resident demographic differences at baseline.

We developed an EHR self-assessment instrument to measure EHR core clinical skills of central focus to PCMH. The online assessment is a 20-minute self-administered, 73-item form completed after each training session.

Measures

Electronic Health Record Competencies

Cronbach α tests were performed for our EHR skill categories. We assessed an overall score (α = 0.99) and 6 separate skill categories: In-Basket Management $(\alpha = 0.95)$, Encounters $(\alpha = 0.97)$, Chart Review ($\alpha = 0.93$), Other Activities ($\alpha =$ 0.93), Tools (α = 0.93), and Clinical Efficiency and Quality (α = 0.91). Resident core skills under these categories were assessed using a 4-item ordinal scale: 1) not proficient, 2) needs review, 3) proficient, and 4) mastery. We then converted the assessment scale (1-4) for each of the 6 core skill categories and overall EHR score to a standardized scale from 0 to 100. Table 1 summarizes the core skills categories.

Training Exposure

All residents received training but differed in the number of sessions they

attended. We compared residents by the number of EHR training sessions attended, a continuous measure, to clarify the extent to which intensity of exposure had an effect. For regression analyses, we used a dichotomous variable that categorized residents on the basis of median exposure level of eight sessions of a total of nine possible sessions. Residents who attended fewer than eight training sessions were categorized as "low exposed." Residents attending eight or more sessions were categorized as "high exposed."

Medical School Electronic Health Record Exposure

Residents were categorized as having prior exposure to the EHR in UME vs no exposure. Residents who attended the University of Washington School of Medicine had prior exposure to the Group Health EHR while on their clinical rotations at our residency program. Residents not attending medical school at University of Washington were classified as not exposed to EHR training in UME, because these students did not rotate at GHFMR for their clinical rotations.

Statistical Analyses

We compared age, sex, UME training location (locally trained vs not), and number of EHR training sessions attended. We performed \emph{t} -tests for age and number of training sessions, and χ^2 tests for sex and UME. Results for which p was less than 0.05 were considered statistically significant.

We conducted paired *t*-tests comparing low vs high exposure resident to EHR training sessions to analyze pretest and

posttest mean scores from the baseline assessment to final EHR training assessment. Then, we estimated multivariate linear regression models to examine whether overall EHR scores improved over time, as well as for the six core skill categories. These regression models controlled for EHR exposure in UME, but age and sex were not included as control variables because of collinearity concerns with the modest sample size of residents.²⁶ An interaction examining term EHR training exposure and time was also included in the regression models to examine whether residents with high exposure to EHR sessions improved scores more over time relative to low-exposure residents.

Data were analyzed using Stata/IC software, Version 14 (StataCorp LLC, College Station, TX) and Tableau 10.0 (Tableau Software, Seattle, WA). The curriculum, self-assessment tool, and analysis were approved by the Group Health Human Subjects Division.

RESULTS

Group Health Residents and Electronic Health Record Training Characteristics

Table 2 summarizes resident characteristics from the 3 cohorts of the GHFMR. Most residents were women (13/18; 72.2%), with a mean age of 28.4 (standard deviation [SD] = 0.50) years. Five (33.3%) of 18 residents had previous EHR exposure through local UME training. No significant differences in residents' characteristics by EHR training exposure were found. Residents completed an average of 8.2 sessions: low-exposure residents averaged

Table 2. Comparison of family medicine resident demographics with low and high exposure to electronic health record training (2011-2016)											
Characteristic	Low exposure (n = 6, 33.3%)	High exposure (n = 12, 66.7%)	Total (N = 18, 100%)	p value							
Age											
Mean, SD	27.7 (0.95)	28.7 (0.59)	28.4 (0.50)	0.31							
Sex, no. (%)											
Women	6 (41.7)	7 (58.3)	13 (72.2)	0.06							
Men	0 (0)	5 (100)	5 (41.7)								
Undergraduate medical ed	ducation-trained, no.	. (%)									
Local	1 (16.7)	5 (83.4)	6 (33.3)	0.29							
Out of state	5 (41.8)	7 (58.4)	12 (66.7)								
Average no. of sessions completed	5.3 (1.5)	9.0 (0.9)	8.2 (1.8)	< 0.001							

SD = standard deviation.

5.3 sessions (SD = 1.5) and high-exposure residents averaged 9.0 sessions (SD = 0.9).

Pre- and Posttest Scores by Level of EHR Training Exposure

Table 3 summarizes residents' pre- and posttest EHR competency scores at baseline and training completion, by high vs low exposure. For each EHR core skill category, low-exposed residents reported baseline scores ranging from 5.9 to 38.5 and completion scores ranging from 55.6 to 89.3, with improvement for all categories demonstrating statistically significant improvement. The mean overall EHR score improvement for low-exposed residents was 56.0 points (p < 0.001). Highexposed residents reported higher baseline scores from 35.9 to 48.5 and completion scores ranging from 73.9 to 97.7, with all categories statistically significant. The mean overall EHR score improvement for high-exposed residents was 40.9 points (p < 0.001). Although low-exposed residents reported lower baseline scores and greater improvement in scores than the high-exposed subgroup, high-exposed residents reported overall higher posttest scores at training completion.

Figure 1 compares the pre- and posttest mean scores for each category by low- and high-exposed resident at baseline and completion.

Multivariate Analyses

Our multivariate regression analysis estimated the effect of EHR training over time, controlling for UME exposure to EHR training. Table 4 reports the over-time effect, high- vs low-exposure effect, and the incremental effect of high exposure. For every session a resident attended, improvements ranged from 6.7 to 14.4 points across the 6 skill categories. For the overall EHR score, an improvement score of 12.2 for each session was estimated (p < 0.001). High-exposed residents were more likely to achieve greater improvement for each of the core skill categories (12.9 to 39.8) and more likely to have overall EHR score improvement of 28.3 (p < 0.001). The interaction results examining differential improvement over time for residents with high vs low EHR training exposure confirm the pattern observed in unadjusted analyses; residents with reported low exposure had more improvement in competencies over time, but this was largely driven by low baseline scores.

DISCUSSION

We described a longitudinal EHR training using PCMH case-based content, analyzed self-assessed EHR scores, and found that training improved self-reported EHR competencies over time. We designed a case-based EHR longitudinal training curriculum that includes a stepby-step breakdown of the PCMH clinic visit through outpatient teaching cases. We also developed a self-assessed EHR training instrument with a convenient standardized scale (0-100) that measures both core skill categories and an overall EHR training score. This could provide utility in developing faculty/trainer-based assessments for EHR training programs

Table 3. Pre- and posttest una	djusted mean scores by	low and high exposur	e to electronic health record	I training (EHR) training
(2011-2016)				

		Low exposure (n = 6)		Hi	igh exposure (n = 1	2)
Category	Baseline, mean (SD)	Completion, mean (SD)	p value	Baseline, mean (SD)	Completion, mean (SD)	p value
In-basket management	5.9 (2.8)	75.4 (8.2)	< 0.001	44.7 (8.7)	93.1 (1.5)	< 0.001
Encounters	16.7 (6.0)	89.3 (4.4)	< 0.001	48.5 (7.8)	97.7 (1.5)	< 0.001
Chart review	17.3 (7.4)	76.5 (7.9)	< 0.001	45.5 (6.8)	91.5 (2.3)	< 0.001
Other activities	14.3 (7.2)	62.7 (10.8)	0.002	42.7 (6.7)	81.2 (4.1)	0.002
Tools	7.1 (4.5)	55.6 (8.8)	< 0.001	35.9 (6.9)	73.9 (4.9)	< 0.001
Clinical efficiency and quality	38.5 (9.9)	68.2 (4.6)	0.01	45.8 (7.9)	73.7 (2.2)	0.01
Total EHR score	14.7 (4.3)	70.7 (6.4)	< 0.001	43.5 (7.1)	84.4 (2.1)	< 0.001

SD = standard deviation.

Table 4. Multivariate regression analyses^a for score improvements with individual electronic health record training (EHR) assessment categories and total EHR score (N = 127 exposures)

	, ,	,				
	Change over time, average score		Session dose (high vs low exposure),		Change over time vs session	
Category score	(range)	p value	average score (range)	p value	dose, average score (range)	p value
In-basket management	14.6 (10.9-18.2)	< 0.001	39.8 (20.5-59.1)	< 0.001	-10.2 (-14.2 to -6.2)	< 0.001
Encounters	12.7 (8.2-17.2)	< 0.001	30.1 (10.8-49.4)	0.004	-8.0 (-12.8 to -3.2)	0.003
Chart review	13.3 (9.4-17.2)	< 0.001	29.9 (6.8-52.9)	0.02	-8.7 (12.9 to -4.5)	< 0.001
Other activities	12.6 (9.8-15.4)	< 0.001	27.3 (4.1-50.5)	0.024	-8.5 (-11.7 to -5.2)	< 0.001
Tools	12.7 (10.4-15.1)	< 0.001	28.9 (13.5-44.3)	0.001	-9.3 (-12.0 to -6.5)	< 0.001
Clinical efficiency and quality	6.7 (4.5-9.0)	< 0.001	12.9 (0.06-26.4)	0.06	-3.5 (-6.2 to -0.9)	0.012
Total EHR score	12.2 (9.6-14.8)	< 0.001	28.3 (12.2-44.4)	0.002	-8.2 (-11.1 to -5.2)	< 0.001

^a Results were adjusted for undergraduate medical education training location.

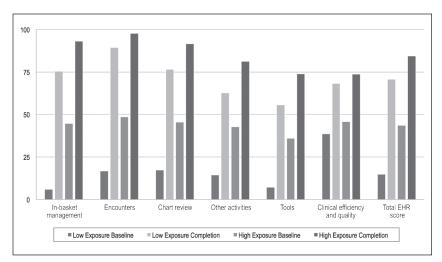


Figure 1. Pretest and posttest unadjusted mean scores for low and high exposure to electronic health record (EHR) training (2011-2016).^a

that wish to assess over-time EHR skills in a PCMH.

The Group Health PCMH practice transformation aims to facilitate various types of physician access to patients, including both face-to-face and electronic visits.25 Given a recent study that reported residents spent a 1:5 ratio with patient time vs computer time, training residents to master technologies in the clinical setting has key implications for physiciansin-training and for lifelong learning as they continue to use the EHR in practice.27 Our results argue that EHR training that simulates the PCMH through a case-based curriculum should be incorporated into physician EHR training. The lack of clinically relevant training content in EHR training from our earlier experiences speaks to this experience, and relates to policy efforts to facilitate EHR meaningful use in practice. 28-30

Our findings also support the growing medical education literature that longitudinal or cumulative exposure to learning experiences influences rates of learning. 15-17,31 Our analysis for differing learning rates based on high vs low exposure to EHR training helps estimate the value of longitudinal training for residents, even when residents are unable to fully engage in all sessions. Low-exposed residents who reported the lowest scores at baseline may be less engaged at the start of training or uncertain about their EHR

core skills but subsequently found EHR training more helpful as they attended more sessions.³² Our results indicate that our residents report improvements with their EHR skills, thus speaking to the potential value of EHR training in the core skills related to a PCMH.

This study has important limitations. First, generalizability to other training settings may be limited because of our small sample size in a single GME program, our training program designed around the PCMH model, and self-assessed competencies that are subject to reporting or social desirability bias. Second, we had no control group because the EHR curriculum was a foundational aspect of orientation to the PCMH and it would be impractical to randomize trainees in experimental groups. Despite the limitations of not having a control group, our analyses highlight that residents report improved competencies from EHR training and that improvement is possible for residents with less-than-optimal exposure to the sessions. Our next steps are to explore these differences influenced by EHR training exposure and to study the link between self-assessed resident competencies to faculty-assigned competency achievements and clinical outcome measures related to the PCMH.

Importantly, we found evidence that early physician engagement in longitudinal EHR training can substantially improve EHR self-reported competency scores among family medicine residents. The results highlight the need to incorporate medical education when implementing new technologies and for health systems undergoing practice changes such as the PCMH. �

Disclosure Statement

The author(s) have no conflicts of interest to disclose

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Kathleen Louden, ELS, of Louden Health Communications provided editorial assistance.

Ethical Approval

The Group Health Human Subjects Division granted an exemption for the use of human subjects for this study on September 3, 2013.

How to Cite This Article

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Practice and Exercise

The art of medicine was to be properly earned from its practice and its exercise.

— Thomas Sydenham, 1624-1689, English physician, known as "The English Hippocrates"

ORIGINAL RESEARCH & CONTRIBUTIONS

Mortality After Total Knee and Total Hip Arthroplasty in a Large Integrated Health Care System

Maria C S Inacio, PhD; Mark T Dillon, MD; Alex Miric, MD; Ronald A Navarro, MD; Elizabeth W Paxton, MA

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ABSTRACT

Context: The number of excess deaths associated with elective total joint arthroplasty in the US is not well understood.

Objective: To evaluate one-year postoperative mortality among patients with elective primary and revision arthroplasty procedures of the hip and knee.

Design: A retrospective analysis was conducted of hip and knee arthroplasties performed in 2010. Procedure type, procedure volume, patient age and sex, and mortality were obtained from an institutional total joint replacement registry. An integrated health care system population was the sampling frame for the study subjects and was the reference group for the study.

Main Outcome Measures: Standardized 1-year mortality ratios (SMRs) and 95% confidence intervals (CIs) were calculated.

Results: A total of 10,163 primary total knee arthroplasties (TKAs), 4963 primary total hip arthroplasties (THAs), 606 revision TKAs, and 496 revision THAs were evaluated. Patients undergoing primary THA (SMR = 0.6, 95% CI = 0.4-0.7) and TKA (SMR = 0.4, 95% CI = 0.3-0.5) had lower odds of mortality than expected. Patients with revision TKA had higher-than-expected mortality odds (SMR = 1.8, 95% CI = 1.1-2.5), whereas patients with revision THA (SMR = 0.9, 95% CI = 0.4-1.5) did not have higher-than-expected odds of mortality.

Conclusion: Understanding excess mortality after joint surgery allows clinicians to evaluate current practices and to determine whether certain groups are at higher-than-expected mortality risk after surgery.

INTRODUCTION

The number of excess deaths associated with elective total joint arthroplasty surgeries in the US is not well understood. Studies estimating risk of death after total knee arthroplasty (TKA) and total hip arthroplasty (THA) in the US use Medicare data, which are limited to patients aged 65 years and older. The ability to evaluate large representative cohorts of patients with arthroplasty procedures for hip and knee joints (either elective or revision) that are not of Medicare age has been limited, and estimates of the excess deaths associated with these procedures remain either unclarified or unstudied.

Conflicting information exists regarding excess mortality in primary hip and knee arthroplasty. Although several

studies have estimated a lower-than-expected mortality rate in elective primary THA and TKA because of the selection of patients for surgery,1-7 other investigators⁸⁻¹⁰ report an increased mortality rate for this subgroup of patients. A reported association between excess mortality and the indications for arthroplasty has been suggested as a possible explanation for some of the excess deaths in subgroups of patients.¹¹ In addition, excess mortality of patients after primary THA and TKA procedures can vary by age, sex, and time since the procedure. 2,5,8,12 Regarding excess mortality after revision THA and TKA, even less is known, but in studies using Medicare data, an increased risk of death after revision THA,4 but not afterrevision TKA,1 has been reported.

We sought to investigate the one-year postoperative mortality of patients who underwent elective joint arthroplasty in a large integrated health care system. Specifically, we evaluated the postoperative excess mortality among patients who underwent primary and revision elective arthroplasty of the hip and knee.

METHODS

Study Design, Sample, Data Collection

A retrospective analysis was conducted of all procedures performed in 2010, and registered by the Kaiser Permanente (KP) Total Joint Replacement Registry from the Southern and Northern California Regions. 13,14 An integrated health care system, KP covers more than 8.2 million people in the Regions included in the study and is mostly sociodemographically representative of the areas it covers. 15-17 The registry identified the elective primary and revision TKA and THA cases in the year studied. Detailed information on the data collection procedures, coverage, and participation of the registries has been previously published.¹³

Whether the procedure was primary or revision, the number of procedures, age, sex, and one-year mortality of patients were obtained from the registry. One-year postoperative mortality was the end point of the study and is prospectively monitored by the registry.

Reference Group

The reference population used for the study was the membership population of the KP integrated health care system for 2010 (Table 1). Data on the membership and mortality for the entire cohort were obtained from an administrative database

Maria C S Inacio, PhD, is an Epidemiologist in the Surgical Outcomes and Analysis Department at Kaiser Permanente in San Diego, CA. Email: maria.cs.inacio@kp.org. Mark T Dillon, MD, is an Orthopedic Surgeon at the Sacramento Medical Center in CA. E-mail: mark.t.dillon@kp.org. Alex Miric, MD, is an Orthopedic Surgeon at the Sunset Medical Center in Los Angeles, CA. E-mail: alex.x.miric@kp.org. Ronald A Navarro, MD, is an Orthopedic Surgeon at the Harbor City Medical Center in CA. E-mail: ronald.a.navarro@kp.org. Elizabeth W Paxton, MA, is the Director of the Surgical Outcomes and Analysis Department at Kaiser Permanente in San Diego, CA. E-mail: liz.w.paxton@kp.org.

within the organization, which monitors the institution's membership and service utilization.

Statistical Analysis

Sex- and age-specific volumes as well as one-year mortality rates for each of the procedure groups (ie, primary THA, revision THA, primary TKA, revision TKA) were summarized. For the reference population, the end-of-year membership was used as the denominator, and mortality rate was calculated from the number of deaths in 2010 divided by the number of members in the end-of-year membership estimates. Expected deaths were calculated by multiplying the reference population death rate of each category by the number of cases for a specific procedure group. Standardized mortality ratios (SMRs, observed deaths/ expected deaths) and 95% confidence intervals (CIs) were calculated. Excess deaths were calculated from the difference of observed and expected deaths. All results are presented for the overall group by procedure type, by age groups, and by sex. Analyses were performed using SAS software (Version 9.2, SAS Institute, Cary, NC).

RESULTS

There were 10,163 primary TKAs, 4963 primary THAs, 606 revision TKAs, and 496 revision THAs performed in 2010. Table 2 reports the overall, sexspecific, and age-specific number of procedures; mortality rate; and number of excess deaths among primary and revision groups. Elective primary TKA (0.9%)

and THA (1.1%) had the lowest 1-year mortality rates.

For elective primary THA (SMR = 0.6, 95% CI = 0.4-0.7) and TKA (SMR = 0.4, 95% CI = 0.3-0.5), patients had significantly lower odds of 1-year mortality than expected. Patients who underwent revision TKA procedures had age-adjusted mortality odds that were higher than expected (SMR = 1.8, 95% CI = 1.1-2.5). Patients undergoing revision THA (SMR = 0.9, 95% CI = 0.4-1.5) did not have significantly higher odds of mortality within 1 year compared with the expected (Table 3).

Differences in sex and age group SMRs were observed in some of the studied groups (see Table 3; Figures 1 and 2). In elective THAs, mortality was lower than expected for both men and women in patients who were aged 75 years and older. In elective TKAs, patients older than age 65 years had lower-than-expected mortality for both sexes. In revision TKA, a higher-than-expected mortality rate was observed in men aged 65 to 74 years (SMR = 5.0, 95% CI = 1.0-9.0) and aged 75 to 84 years (SMR = 3.8, 95% CI = 1.3-6.2), whereas no differences were observed in women.

DISCUSSION

In this study, we found that patients undergoing revision TKA had a higher-than-expected mortality within one year of their surgery. Conversely, patients undergoing elective primary arthroplasty had a lower-than-expected mortality at one year postoperatively, whereas those undergoing revision THA did not have a significantly

different mortality risk than the reference population of this study. This lower-thanexpected mortality in these groups could be explained by patient selection for surgery, or increased medical contact during the perioperative period that resulted in identification of acute medical issues or better management of chronic conditions.

Lower-than-expected 1-year mortality was observed in patients undergoing elective primary THA compared with the reference population. The SMR of 0.6 (40% lowerthan-expected risk of mortality) is consistent with several studies on large cohorts of patients.^{2-4,6,7} To our knowledge, only one single-center study from the United Kingdom reported a higher-than-expected mortality rate in patients undergoing primary THA, and the authors suggest the higher proportion of patients undergoing procedures for reasons other than osteoarthritis as the likely reason for these findings.8 In our cohort, the lower-than-expected mortality rate is probably caused by patient selection (a type of "healthy patient" effect, in which those not healthy have a lower chance of having the procedure) but could also be partially attributed to better management of comorbidities before the surgery, or to the benefits of having the procedure. Because some studies have reported a continuous lower risk of mortality for years after hip arthroplasty procedures, 2,3,5,7 compared with the general population, it is possible having the procedure also affects the life expectancy of these patients.

Conversely, the observed 1-year mortality rate for revision THA procedures was not

		Total			Females		Males			
Age, y	Number	Deaths	Death rate	Number	Deaths	Death rate	Number	Deaths	Death rate	
0-1	136,103	325	238.8	66,350	54	81.4	69,734	64	91.8	
1-4	244,764	43	17.6	119,048	13	10.9	125,697	24	19.1	
5-14	905,751	103	11.4	443,286	39	8.8	462,402	52	11.2	
15-24	878,984	541	61.5	442,627	121	27.3	436,239	247	56.6	
25-34	804,613	584	72.6	431,928	143	33.1	372,624	276	74.1	
35-44	901,831	1141	126.5	468,888	359	76.6	432,880	502	116.0	
45-54	1,005,457	2965	294.9	522,320	964	184.6	483,036	1349	279.3	
55-64	881,361	5840	662.6	466,609	2043	437.8	414,476	2938	708.8	
65-74	487,842	7738	1586.2	260,782	3154	1209.4	226,932	3865	1703.2	
75-84	263,765	11,483	4353.5	146,608	5217	3558.5	117,077	5549	4739.6	
≥ 85	94,796	12,485	13,170.4	60,159	6701	11,138.8	34,595	4880	14,106.1	
All ages	660,5271	43,250	654.8	3,428,605	18,808	548.6	3,175,692	19,746	621.8	

different from expected. The nonsignificant SMR is consistent with the mortality rate reported by a large Norwegian cohort of patients⁵ and by a smaller US series of patients. However, our nonsignificant mortality ratio is different from other large US cohorts, in which one study found a lower-than-expected mortality rate and one found a higher rate. Gur estimates could be different from these studies for several reasons. First, there were different periods

evaluated; both other studies evaluated 90 days, and this study evaluates 1 year. Second, the sampling frames of the studies differed, in that one was a nationally representative sample, the other was a high-volume single center, and the current study was a large multicenter sample from one US geographic region. Finally, the sample sizes evaluated varied; one study evaluated more than 13,000 patents, the other evaluated a little over 1200, and ours had 496 cases. ^{4,6}

The lower-than-expected mortality rate in patients undergoing elective primary TKA reported in the current study is similar to that of other large studies. 1,19-21 In 4 studies of Scandinavian and American samples, the reported lower-than-expected rate of deaths of patients undergoing primary TKA ranged from 3% to 51%, depending on the time parameter and subgroup of patients. Another smaller study in England and Wales reported

		Total case	s	F	emales		Males
Procedure type by age, y	No.	Deaths, no. (%)	Excess deaths, no.	Deaths, no. (%)	Excess deaths, no.	Deaths, no. (%)	Excess deaths, no.
Total hip arthroplasty, primary,	elective		'				<u>'</u>
15-24	14	0 (0.0)	0.0	0 (0.0) 0.0		0 (0.0)	0.0
25-34	49	0 (0.0)	0.0	0 (0.0) 0.0		0 (0.0)	0.0
35-44	125	0 (0.0)	-0.2	0 (0.0)	0.0	0 (0.0)	-0.1
45-54	601	3 (0.5)	1.2	0 (0.0)	-0.5	3 (1.0)	2.1
55-64	1477	11 (0.7)	1.2	2 (0.3)	-1.5	9 (1.3)	4.2
65-74	1497	13 (0.9)	-10.7	7 (0.8)	-4.1	6 (1.0)	-3.8
75-84	1044	23 (2.2)	-22.5	14 (2.1)	-10.1	9 (2.5)	-8.3
≥ 85	156	7 (4.5)	-13.5	6 (5.6)	-5.9	1 (2.0)	-5.9
Total	4963	57 (1.1)	-44.5	29 (1.0)	-22.1	28 (1.3)	-11.8
Total hip arthroplasty, revision							- L
25-34	4	0 (0.0)	0.0	0 (0.0)	0.0	0 (0.0)	0.0
35-44	14	0 (0.0)	0.0	0 (0.0)	0.0	0 (0.0)	0.0
45-54	66	0 (0.0)	-0.2	0 (0.0)	-0.1	0 (0.0)	-0.1
55-64	139	2 (1.4)	1.1	0 (0.0)	-0.4	2 (3.5)	1.6
65-74	128	3 (2.3)	1.0	3 (3.8)	2.0	0 (0.0)	-0.8
75-84	120	3 (2.3)	-2.2	1 (1.5)	-1.4	2 (3.8)	-0.5
≥ 85 years	25	3 (2.5)	-0.3	2 (11.8)	0.1	1 (12.5)	-0.1
Total	496	11 (2.2)	-0.6	6 (2.0)	0.2	5 (2.5)	0.1
Total knee arthroplasty, primar	y, elective	, ,					· ·
25-34	7	0 (0.0)	0.0	0 (0.0)	0.0	0 (0.0)	0.0
35-44	62	0 (0.0)	-0.1	0 (0.0)	0.0	0 (0.0)	0.0
45-54	765	1 (0.1)	-1.3	0 (0.0)	-0.9	1 (0.3)	0.2
55-64	3145	11 (0.3)	-9.8	6 (0.3)	-2.4	5 (0.4)	-3.7
65-74	3706	24 (0.6)	-34.8	11 (0.5)	-16.6	13 (0.9)	-11.2
75-84	2189	46 (2.1)	-49.3	17 (1.2)	-31.8	29 (3.5)	-9.8
≥ 85	289	11 (3.8)	-27.1	3 (1.6)	-17.7	8 (7.8)	-6.5
Total	10,163	93 (0.9)	-122.4	37 (0.6)	-69.4	56 (1.4)	-31.0
Total knee arthroplasty, revision	on		,				·
35-44	4	0 (0.0)	0.0	0 (0.0)	0.0	0 (0.0)	0.0
45-54	62	1 (1.6)	0.8	1 (3.2)	0.9	0 (0.0)	-0.1
55-64	200	3 (1.5)	1.7	0 (0.0)	-0.5	3 (3.3)	2.3
65-74	182	8 (4.4)	5.1	2 (1.8)	0.7	6 (8.2)	4.8
75-84	120	12 (10.0)	6.8	3 (4.3)	0.5	9 (17.6)	6.6
≥ 85	38	2 (5.3)	-3.0	1 (6.7)	-0.7	1 (4.3)	-2.2
Total	606	26 (4.3)	11.4	7 (2.1)	0.9	19 (7.0)	11.4

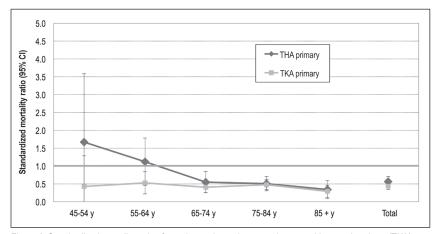


Figure 1. Standardized mortality ratios for patients who underwent primary total knee arthroplasty (TKA) and total hip arthroplasty (THA), by age group.

CI = confidence interval.

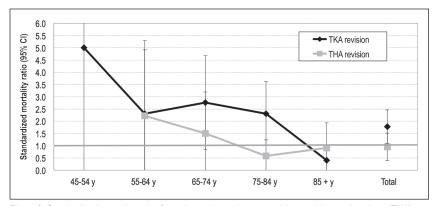


Figure 2. Standardized mortality ratios for patients who underwent revision total knee arthroplasty (TKA) and total hip arthroplasty (THA), by age group.

CI = confidence interval.

lower-than-expected mortality as well for primary TKA, but probably because of the smaller sample sizes these numbers were not significantly different from the overall population mortality used as the reference.¹² In our study, we not only found that patients had a death rate 60% (SMR = 0.4) lower than expected, but we also found an even stronger effect for women compared with men and for older patients compared with younger patients, which again is comparable to what other studies have reported. 12,19,20 Two studies have reported patients who underwent TKA to be at a higher risk of mortality than expected when the comparison group used was different from the general population9 and when only long-term survival of the cohort was evaluated.10

In the patients who had revision TKA, a higher-than-expected mortality risk compared with the general population (SMR = 1.8) was observed. This is different from Medicare cohort data (SMR = 0.9)1 and findings of a Danish (SMR = 0.9) study,²⁰ which reported on revision TKA cohorts. It is possible that the younger age of the patients in our study cohort, and consistently higher-than-expected mortality rates in younger patients with arthroplasty, could explain this difference between our study findings and the ones reported by the other studies. Although our study did not evaluate patient comorbidities, it is likely that these younger patients have more comorbidities. It

Table 3. Sex-specific star	ndardized mortali	ty ratio (SMR) and	95% confidence in	tervals (CI) by proc	edure type and age	group, 2010	
	Elec	tive, primary, SMR (9	95% CI)	R	evision, SMR (95% C	1)	
Procedure type by age, y	Overall	Females	Males	Overall	Females	Males	
Total hip arthroplasty							
45-54	1.7 (0.0-3.6)	NA	3.3 (0.0-7.1)	NA	NA	NA	
55-64	1.1 (0.5-1.8)	0.6 (0.0-1.4)	1.9 (0.7-3.1)	2.2 (0.0-5.3)	NA	5.0 (0.0-11.9)	
65-74	0.6 (0.3-0.8)	0.6 (0.2-1.1)	0.6 (0.1-1.1)	1.5 (0.0-3.2)	3.0 (0.0-6.4)	NA	
75-84	0.5 (0.3-0.7)	0.6 (0.3-0.9)	0.5 (0.2-0.9)	0.6 (0.0-1.2)	0.4 (0.0-1.2)	0.8 (0.0-1.9)	
≥ 85	0.3 (0.1-0.6)	0.5 (0.1-0.9)	0.1 (0.0-0.4)	0.9 (0.0-1.9)	1.1 (0.0-2.5)	0.9 (0.0-2.7)	
Total	0.6 (0.4-0.7)	0.6 (0.4-0.8)	0.7 (0.4-1.0)	0.9 (0.4-1.5)	1.0 (0.2-1.9)	1.0 (0.1-1.9)	
Total knee arthroplasty							
45-54	0.4 (0.0-1.3)	NA	0.7 (0.0-2.0)	5.0 (0.0-14.8)	10.0 (0.0-29.6)	NA	
55-64	0.5 (0.2-0.8)	0.7 (0.1-1.3)	0.6 (0.1-1.1)	2.3 (0.0-4.9)	NA	4.3 (0.0-9.1)	
65-74	0.4 (0.2-0.6)	0.4 (0.2-0.6)	0.5 (0.2-0.8)	2.8 (0.8-4.7)	1.5 (0.0-3.7)	5.0 (1.0-9.0)	
75-84	0.5 (0.3-0.6)	0.3 (0.2-0.5)	0.7 (0.5-1.0)	2.3 (1.0-3.6)	1.2 (0.0-2.6)	3.8 (1.3-6.2)	
≥ 85	0.3 (0.1-0.5)	0.1 (0.0-0.3)	0.6 (0.2-0.9)	0.4 (0.0-1.0)	0.6 (0.0-1.7)	0.3 (0.0-0.9)	
Total	0.4 (0.3-0.5)	0.3 (0.2-0.5)	0.6 (0.5-0.8)	1.8 (1.1-2.5)	1.0 (0.3-2.0)	(1.4-3.6)	

NA = not available because no events occurred in these strata.

is also possible that because revision arthroplasties are not always elective, such as revisions for infection, fractures, or severe loss of function, these patients were not selected for surgery as the elective primary cohorts were.

A general trend toward lower SMR in older patient groups was also observed in all groups. This supports the hypothesis that patient selection is associated with this observed difference in mortality in patients who are undergoing joint arthroplasty and the general population. Younger patients are known to have poorer surgical outcomes than older patients, 22,23 but the reasons for these poorer outcomes can be many. It is possible that their greater activity puts more strain on their joints and therefore leads to poorer outcomes, but it is also very likely that these are the heavier patients with greater comorbidities that put them at a higher risk of complications and therefore mortality after surgery.

The limitations of this study include our inability to evaluate cause-specific mortality and therefore to investigate the reasons for death in the procedures we found to have a higher-than-expected mortality. This study also only evaluated a short-term postarthroplasty period (1 year), limiting its ability to comment on the long-term impact of the procedures and mortality. Because of the limited samples available for the revision arthroplasty groups, the estimates of SMR provided have significant uncertainty (ie, wide CIs) and therefore should be interpreted with care. Furthermore, we did not evaluate how the indication for surgery and comorbidity profiles of our patients could affect excess mortality after surgery.

The strengths of this study include the large sample size of patients undergoing primary arthroplasty, the generalizability of the sample to the larger California population, and the captive comparable group used as the reference group.

CONCLUSION

This study confirms that patients undergoing primary elective lower limb arthroplasty have lower-than-expected mortality within one year of their procedure, whereas those undergoing revision TKA have a higher-than-expected mortality. Understanding how joint arthroplasty and their indications affect a patient's life expectancy is important when considering

this procedure, counseling patients, and preparing for both the preoperative and postoperative care of these patients. �

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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Sherbrooke Cemetery, North Dakota photograph

Stephen C Henry, MD

Not only is the landscape of the northern plains dotted with abandoned farmsteads, but also small and often well-tended cemeteries. This one bordered the now ghost town of Sherbrooke, ND, about an hour's drive from Fargo, ND.

After retiring from The Permanente Medical Group as Chief of Urology at the San Jose Medical Center, Dr Henry worked part-time for several years as a Urologist at the Veterans Affairs Medical Center in Fargo. More of his work can be seen at www.henryimages.net and in an irregularly periodic blog appearing at www.facebook.com/henryimages.

ORIGINAL RESEARCH & CONTRIBUTIONS

Special Report

Physician Guide to Appropriate Opioid Prescribing for Noncancer Pain

Timothy Munzing, MD, FAAFP

Perm J 2017;21:16-169

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ABSTRACT

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Prescription opioid use for relief of noncancer pain has risen dramatically in the last 15 years, contributing to a quadrupling of opioid overdoses and prescription opioid-related deaths. This crisis is resulting in heightened attention by health care professionals and organizations, law enforcement, and the government. In this article, I highlight key topics in the management of patients using opioids (or potentially needing opioids) in outpatient clinical practice; federal and state law enforcement actions regarding physicians' illegal prescribing of opioids; multimodal approaches to pain control; nonmedication management of pain; response strategies when suspecting a patient of diverting or misusing opioids; and warning signs for abuse or diversion. For those patients for whom opioids are appropriate, I describe key elements for prescribing, including documentation of a detailed history and examination, appropriate evaluation to arrive at a specific diagnosis, individualizing management, and ongoing monitoring (including the use of urine drug screening and a prescription drug monitoring program). In addition to individual action, when possible, the initiation of systemwide and clinicwide safe prescribing practices supports the physician and patient such that the patient's well-being is at the heart of all pain management decisions. Physicians are encouraged to further educate themselves to treat pain safely and effectively; to screen patients for opioid use disorder and, when diagnosed, to connect them with evidence-based treatment; and to follow Centers for Disease Control and Prevention guidelines whenever possible.

INTRODUCTION

Opioids are just one of a large armament of tools to treat acute (days to weeks) and chronic (months to years) pain, to relieve the physical distress of patients, and to maximize their quality of life. Physicians wield the power to heal and relieve pain. However, the same power has the potential to contribute to harm, especially in the case of prescribed opioids.

Current prescribing patterns by many have contributed to large increases in abuse, drug overdoses, and deaths. More than 50 people die of opioid overdoses each day in the US,¹ surpassing overdose deaths owing to all illicit drugs and motor vehicle crashes. Careless or criminal physicians are being investigated and prosecuted in increasing numbers by local, state, and federal law enforcement.

To accentuate the severity of the crisis, new action is occurring at the state and

federal levels. Last year, the Centers for Disease Control and Prevention (CDC) released new opioid prescribing guidelines²; the Food and Drug Administration (FDA) added a black box warning for prescribing opioids and benzodiazepines³; US Surgeon General Vivek Murthy sent a letter to all US physicians asking them for commitment to "Turn the Tide" on the opioid crisis⁴; and the White House convened a summit of national leaders on this subject.

Causes of the Crisis

Efforts to increase prescribing for pain were intense in the 1990s and early 2000s. Regulatory bodies, including The Joint Commission, called on pain to be "made visible," resulting in many calls to implement pain as the fifth vital sign. National groups unrealistically recommended "getting pain to zero." In

addition, pharmaceutical companies developed stronger and long-acting opioids, with aggressive marketing to physicians, while minimizing potential risks.⁶ Nonlegitimate users found that short-acting opioids (hydromorphone, oxycodone) and long-acting opioids (when "broken" of their time-release coatings) may result in enhanced euphoria and potentiation of their addictive nature.7 "Pill mill" practices sprang up across the US.^{6,8} Many wellmeaning physicians prescribed high-dose opioids because of a lack of, or erroneous, education and experience, being naïve or exceedingly busy, or not recognizing the dangers that existed. Sadly, some patients who were started on opioid therapy for pain ultimately abused these medications. Tragic for far too many, this resulted in drug overdoses and death. A very small proportion of patients began selling their prescribed opioid medications for profit ("diversion" of medications).6,8

From 2000 to 2014 the rates of opioid sales greatly increased, resulting in a quadrupling of opioid overdoses⁸ and a similar rise in opioid prescription-related deaths.¹ The Sidebar: Potential Side Effects of Opioid Medications lists serious and common potential side effects of opioid use.

Data from the CDC document that more than 47,000 people in the US died of drug overdose in 2014, of which 60.9% involved an opioid. According to the CDC, approximately 44 people per day die in the US of opioid prescription overdoses, resulting in more than 16,000 deaths annually, with benzodiazepine overdoses contributing another 8000 deaths. In addition, drug use and misuse annually result in more than 2.5 million Emergency Department visits, of which 56% are for prescription

Timothy Munzing, MD, FAAFP, is the Family Medicine Residency Program Director for the Kaiser Permanente Orange County Area in Santa Ana, CA. Dr Munzing has more than ten years of experience as a Medical Expert Consultant for the Drug Enforcement Administration, the Medical Board of California, and other law enforcement agencies. E-mail: tim.a.munzing@kp.org.

medications, with 37% accounted for by opioids or benzodiazepines.¹¹

Physicians prescribing opioids and other controlled substances are being scrutinized with greater intensity and numbers. The Medical Board of California reported a 195% increase in disciplinary action outcomes related to controlled substance prescribing between the reporting years 2009 to 2010 and 2014 to 2015. ^{12,13}

Responses by Government and Health Systems

Government agencies and individual health care organizations are attempting to intervene in the opioid overuse crisis. The CDC, FDA, and US Surgeon General have

Potential Side Effects of Opioid Medications¹⁻³

To the user

- Misuse
- Substance use disorder (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition)
- Overdose death
- Respiratory depression
- Somnolence and sedation
- · Withdrawal if abruptly stopped
- Constipation
- Androgen deficiency
- · Depression and anxiety
- Opioid-induced hyperalgesia
- Urinary retention
- Nausea and vomiting
- Hypotension
- Liver toxicity
- Pruritus

To the pregnant user's fetus or newborn

- · Preterm delivery
- Congenital defects: heart, neural tube, etc
- Neonatal abstinence syndrome
- Multiple other possible effects
- Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain—United States, 2016. MMWR Recomm Rep 2016 Mar 1;65(1):1-49.
 DOI: https://doi.org/10.15585/mmwr.rr6501e1. Erratum in: MMWR Recomm Rep 2016 Mar 25;65(11):295.
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become active participants in responding to this problem.²⁻⁴

Local health care organizations are attempting to provide an infrastructure to promote safe prescribing and monitoring of opioid pain medications. For instance, in 2010, Kaiser Permanente Southern California (KPSC) took carisoprodol (Soma) and oxycodone (OxyContin) off the formulary because of the highly addictive and dangerous nature of the medications. Recently KPSC adopted the following opioid prescribing goals:

- Protect our community and schools by decreasing the supply of opioid prescriptions to patients at high risk of diversion
- Help avoid new patients becoming addicted to or dependent long term on opioids
- Help reduce risk of overdose and death in our current patients who are receiving higher-dose opioids
- 4. Treat patients' pain in a safe and effective manner, using medications (including opioids and pain-modulating drugs) and other treatments as applicable.

Thus far, these actions have resulted in a reduction in OxyContin prescribing by more than 85%; reduction of all brand-name opioid prescribing (these have a higher street value when diverted) by more than 95%; and a decrease in the number of patients receiving more than 120 mg/d morphine equivalent dosing (MED) by 31%. ¹⁴

In late 2016, California passed legislation¹⁵ that, once enacted, will require physicians to check the state's prescription drug monitoring program, called Controlled Substance Utilization Review and Evaluation System (CURES 2.0), before prescribing opioids. Similar requirements are being considered in other states.

Legal Implications

The Drug Enforcement Administration (DEA) and local law enforcement have begun to conduct sting operations in which undercover agents present to physicians in the office requesting opioid prescriptions without medically legitimate reasons. Through these and additional efforts, a small number of physicians have been found to have engaged in criminal activity, with other careless physicians noted to have departed from the standard

of care. This has subsequently resulted in incarceration, loss of license, or other practice restrictions.

Physicians and health systems may reduce their exposure to investigation and prosecution by adhering to best practices and standards of care in pain control and opioid prescribing within their specialty. When prescribing opioids, physicians are bound by medical and legal regulations. Federal law16 states that a controlled substance prescription must be issued for a "legitimate medical purpose by an individual practitioner acting in the usual course of his [or her] professional practice" [emphasis the author's].16 To comply, one must follow the standard of care based on one's general specialty (eg, primary care, emergency medicine). For opioid prescribing specifically, substantial compliance with opioid prescribing guidelines is the accepted standard of care and satisfies adherence to the many state and federal laws governing this. Failure to follow the standard of care and guidelines puts both patients and physicians at risk.

General Management of Pain

The approach to a patient's pain must be individualized and multimodal. A thorough history, physical examination, and evaluation is needed to reach as specific a diagnosis as possible. One must weigh the potential benefit of a treatment with the potential risk. A physician's efforts to relieve pain must not violate the mandate to "do no harm." Depending on the pain severity, treatment must be tailored using multiple tools. Such tools include 1) nonpharmacologic (eg, physical therapy, heat, ice, massage, rest, exercise, meditation, cognitive-behavioral therapy, treating comorbid conditions); 2) pharmacologic, including topical medications, nonopioid medications (eg, acetaminophen, nonsteroidal anti-inflammatory drugs, tricyclic antidepressants); 3) opioids; 4) procedures (eg, joint and trigger point injections, nerve blocks, epidural injections); and 5) devices (eg, transcutaneous electrical nerve stimulation, implanted neurostimulators).

Acute and chronic pain are not identical in etiology, evaluation, and management, although overlap exists.¹⁷ The management of chronic pain is complex and at times

controversial.¹⁸ A 2014 Cochrane Review found opioids unproven for the management of chronic low back pain.¹⁹

Safe Prescribing Policies

Initiation of systemwide, clinicwide safe-prescribing practices support the physician and patient such that the patient's well-being is at the heart of all pain management decisions. Policies should emphasize the partnership and commitment of the physician and patient in working for the patient's overall well-being; using and following pain agreements; initial prescribing and refill details; appropriate monitoring; subspecialist referrals for those not improving or deteriorating; and tapering strategies when possible.

OPIOID-PRESCRIBING GUIDELINES

The Medical Board of California²⁰ has published detailed but nondirective guidelines. Other guidelines containing similar key elements include those from the American Academy of Pain Management,²¹ the American Pain Society,²² and the Washington State Agency Medical Directors' Group.²³

Key Elements of Opioid Prescribing Guidelines

The Sidebar: Checklist for Prescribing Opioids provides a detailed checklist of key elements critical in the evaluation and management of a patient when the prescribing of opioids is believed to be indicated. More specifics are expanded on in this section.

History

This must be *detailed* and include current and past information. Physicians ought to "trust but verify" which should be done by reviewing old records, urine drug screening, and checking information from a prescription drug monitoring program. These will confirm or refute the story given by the patient. In light of the large amount of abuse and diversion, physicians must be on the alert for "red flags" (see Sidebar: Red Flags for Drug Abuse, Addiction, or Diversion).

Addiction risk screening is vital and should include personal and family history of alcohol, illegal and/or prescription drug substance abuse (including tobacco, age, history of sexual abuse), and a personal mental health history. Tools include the

Checklist for Prescribing Opioids 1-6

History

- Current specific pain symptoms
- Past pain, imaging, treatment, consultations, procedures, etc (get old records)
- Chronic medical problems

Medications: All including over-the-counter; verify via a prescription drug monitoring program (PDMP)—eg, the California Controlled Substance Utilization Review and Evaluation System (CURES)—or via urine drug screening

- · Alcohol and drugs: Current and past
- · Mental health
- Opioid Risk Tool (ORT), Screener and Opioid Assessment for Patients with Pain (SOAPP), or similar

Physical examination

- Vital signs
- General examination
- Specific detailed examination: Area of symptoms

Additional diagnostic evaluation as indicated

- Imaging: Consider on the basis of pain level, injury, chronicity
- Laboratory tests (including urine drug testing, renal and liver function)
- · Additional testing as needed

Assessment: As specific as possible

Treatment plan with goals (must be medically justified): Individualized Informed consent about risks and benefits

Controlled substance agreement (optional but a good idea)

Medical records documentation: Be thorough

Consultation: When there is failure to improve or deterioration

Periodic review (follow-up visits)

- Analgesia: Pain controlActivities of daily living
- Adverse effects
- Affect
- Aberrant behaviors

Monitoring

- CURES or other PDMP
- Urine drug screening
- · Laboratory testing: As indicated; patient specific
- · Updated brief history, examination, assessment
- Morphine equivalent dosing (MED) calculation and monitoring

Prescribing to addicts

- Specific state and federal laws and statutes
- "Trust but verify": Be on the lookout for red flags of abuse, misuse, or diversion; addicts will say anything to get the drugs desired
- Drug combinations: Common among those abusing or diverting: Opioids plus benzodiazepines with or without carisoprodol

Excessive or high-dose opioids: 100 mg/d MED, also referred to as morphine milliequivalents

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Opioid Risk Tool,²⁴ Screener and Opioid Assessment for Patients with Pain (SOAPP),²⁵ and others.

Analysis, Assessment, and Goals of Treatment

The physician should document an assessment as specific as possible (eg, lumbar radiculopathy rather than back pain) and goal setting (eg, maximizing function while minimizing risk, increasing the ability of the patient to work or perform specific activities, or tapering the medication dosages as tolerated).

Informed Consent

Risks reviewed should include dependence, addiction, overdose, and death. Driving risk while under the influence of opioids must be addressed.

Management Plan

The management plan must be individualized, multimodal, thorough, and consistent with the patient's diagnosis, the current pain severity, and the functional ability or limitations. For new patients with chronic pain, obtaining prior records, testing, and consultations may be warranted. Until trust is built and additional

information is obtained, a small prescription quantity may be justified.

Use the least risky medication or medications and treatments believed indicated on the basis of the evaluation. When the clinician determines that opioids are indicated, new short-acting, immediate-release opioid regimens should be started with as low a dose as possible, generally with a short treatment timeframe, and a plan for discontinuation. Written directions for the prescription should be specific, including how often to use the medication and the maximum number per 24-hour period. Low-quantity prescriptions reduce the risk of unintended diversion of leftover medications.

Patients using opioid medications long term should strongly be considered for dosage reduction if possible, especially for patients taking an MED of 50 mg/d or higher. This requires a therapeutic alliance between the physician and patient that supports the patient's long-term well-being.

Documentation and Record Keeping

Thorough documentation is necessary for patient safety, legal requirement, and billing purposes.

Red Flags for Drug Abuse, Addiction, or Diversion¹

- Early refills/claims that the medications were lost or stolen—even with a police report
- Age 35 years or younger, especially combined with other red flags
- Concurrent use of multiple pharmacies
- Obtaining controlled substances from multiple physicians or "doctor shopping"
- Excessive amounts or drug combinations
- Obtaining or buying controlled substances from family, friends, or others
- Giving or selling controlled substances to family, friends, or others
- Use/abuse of alcohol or drugs—current or past
- Use of tetrahydrocannabinol/marijuana, even with a medical marijuana card
- Use of drug culture street lingo for the names of the medications or other drugs
- Inconsistent results from urine drug screens or the prescription drug monitoring program report
- Patients driving long distances to see the physician for controlled substances
- Multiple family members or those residing in the same household receiving identical or similar controlled substances
- Similar or identical prescribing (eg, medication selection, strengths) regardless of specifics of symptoms such as pain severity, examination findings, diagnosis, etc (lack of individual management plans)
- Failure to improve without adjustment of management plan
- Drug overdoses

Note: Presence of any red flag necessitates additional information to confirm.

 American Academy of Family Physicians; American College of Emergency Physicians; American Medical Association; et al. Stakeholders' challenges and red flag warning signs related to prescribing and dispensing controlled substances [Internet]. Mount Prospect, IL: National Association of Boards of Pharmacy; 2015 Mar [cited 2017 Mar 31]. Available from: https://nabp.pharmacy/wp-content/uploads/2016/07/Red-Flags-Controlled-Substances-03-2015.pdf.

Controlled Substance Agreement

Sample controlled substance agreements are readily available, including from the American Academy of Family Physicians/Family Practice Management²⁶ and Kaiser Permanente.²⁷

Periodic Review and Follow-up Visits

Follow-up visits may be much shorter than the initial evaluation, assuming there are no suspicions of aberrant behavior and the patient is stable or improving. An adaptation of the "4 As" of periodic review²⁸ is analgesia, activity, adverse effects, affect, and aberrant behaviors. Always think about tapering opioid dosages if possible.

Monitoring

Urine drug screening initially and at least every six months; appointment visits every three months; and additional patient-specific laboratory testing may be indicated on the basis of the patient's overall health (eg, kidney and liver testing). If problems or suspicions occur, the timeframes may be shortened. Pay special attention to red flags for abuse and diversion (see Sidebar: Red Flags for Drug Abuse, Addiction, or Diversion). Documented compliant patients with stable controlled pain may on occasion have timeframes briefly extended.

A review of the prescription drug monitoring program initially and at least every four to six months allows the prescribing physician to monitor the patient's controlled substance profile. Physicians may use this information to identify likely adherence to the controlled substance agreement, as well as aberrant (ie, departure from the prescribed therapeutic plan) patient behavior, including "doctor shopping," pharmacy shopping, and early refills.

Consultation

Patients not improving as expected, or deteriorating, or those requiring escalating dosages require consultation by an appropriate subspecialist. Physicians should consider having patients who are receiving long-term opioid treatment see an appropriate subspecialist at least every one to two years to explore additional or new management strategies. Consultant availability (geographic, insurance, etc) may affect this decision and requires specific documentation if indicated but not obtained.

Table 1. Morphine equivalent dosing (MED) summary calculator ^a										
Drug	Brand	Relative strength	100 mg/d MED							
Morphine	MS Contin, etc	1	100							
Hydrocodone	Norco, Vicodin	1	100							
Oxycodone	OxyCodone, Roxycodone	1.5	66							
Hydromorphone	Dilaudid	4	25							
Oxymorphone	Opana	5	20							
Methadone	Methadose	8-12	10							
Fentanyl transdermal patch	Duragesic	100	42							

^a Sometimes referred to as morphine milliequivalents (MME). Oral administration unless otherwise specified. Calculations were made using the Washington State Agency Medical Directors' Group's Opioid Dose Calculator (available from www.agencymeddirectors.wa.gov/Calculator/DoseCalculator.htm).²⁹

Morphine Equivalent Dosing

Patients receiving opioids should have their MED calculated (mg/d) using an opioid calculator²⁹ and documented (Table 1). Overdose risk increases by 3.7% in patients taking an MED of 50 to 99 mg/d. This risk increases to 8.9%, with an annual overdose death rate of 1.8%, when the MED is 100 mg/d or greater.³⁰ When higher dosages are necessary, documentation of specific informed consent by the patient, closer monitoring, and periodic comanagement by an appropriate subspecialist is required. Home naloxone rescue preparations may be warranted if the patient is at higher risk of overdose and death. Patients build tolerance to opioids over time and are at higher risk of overdose and death when there is a gap in opioid medication use (eg, incarceration, rehabilitation), especially if placed back on previous opioid dosages.

Case Example: Appropriate Care of an Acute Injury

A 50-year-old athletic woman sustained an injury while snow skiing, resulting in pain at the distal lateral aspect of the left knee that she described as 10 on a 10-point pain scale. Within 2 hours of the injury, the patient was evaluated, which included a thorough history, examination, and radiographs that confirmed a small proximal fibular fracture. The patient had no history of substance abuse. She was prescribed hydrocodoneacetaminophen, 10/325 mg tablets, to be used up to every 6 hours (4 maximum in 24 hours) for severe pain, ice off and on for 48 hours, knee brace, and crutches or cane as tolerated, with phone advice from orthopedics. Within 48 hours, and after taking a total of 5 opioid tablets, the patient limped with a cane, and the pain level ranged from 5 to 7. As advised, the patient changed her medication to overthe-counter nonsteroidal anti-inflammatory drugs. Physical therapy was started to assist further rehabilitation after 2 weeks. The remaining 5 hydrocodone tablets were appropriately destroyed.

This case exemplifies appropriate evaluation and management, including low-dose, short-course opioids, alternative pharmacologic and nonpharmacologic management, and destruction of leftover opioids.

SPECIAL PRESCRIBING CIRCUMSTANCES

Prescribing to Patients with Substance Use Disorder

Patients with substance use disorder with medically legitimate pain sufficient to justify opioids must be closely monitored, including through random urine drug screening, reviews using a prescription drug monitoring program, appointment visits, and consultation with a subspecialist. Addiction medicine comanagement may be necessary. Detailed documentation is vital.

Response to Potentially Aberrant Behavior

Patient treatment must be individualized, including responses to potential aberrant behavior, on the basis of the entirety of the information. Prescription forgery or theft would generally require involvement of law enforcement. Overdose would require treatment modification and at times medication discontinuation. At the other end of the spectrum, rare diversion of a few tablets to a family member for emergent, acute

pain or a one-time aberrant finding on a urine drug screen may warrant a documented discussion with the patient and closer monitoring.

If it becomes apparent that the patient is not using these medications for medically legitimate purposes, the opioid dosage must be rapidly tapered. ³¹ Abusive or violent behavior by the patient also requires immediate intervention. Options include addiction medicine specialists and buprenorphine treatment. Tapering of opioid dosages and the management of substance use disorder are difficult issues and beyond the scope of this article.

Kidney, Liver, Heart, and Lung Disease

Diseases of each of these organ systems may affect or be affected by treatment with opioids and other controlled substances. Liver disease makes using acetaminophen difficult, and renal disease often prevents the use of nonsteroidal anti-inflammatory medications. When possible, use noncontrolled substance medications, and when opioids are necessary, use lower dosage strengths and quantities with very close monitoring. Additional treatments to consider may include heat or ice, exercise, physical therapy, topical analgesic creams, and alternative medicine approaches.

Dangerous Drug Combinations

Physicians must beware of dangerous drug combinations. Sometimes dangerous combination are prescribed for medically legitimate reasons, without recognition of the dangers. However, other times they are requested by the patient because they are popular in the recreational drug community and commonly diverted. These combinations place the patient at additional risk of overdose and death, as does concurrent use of alcohol and other sedating medications (both prescriptions and over-the-counter). The use of fentanyl transdermal patches and long-acting opioids in opioid-naïve patients also places the patient at a higher risk of oversedation and overdose. Dangerous drug combinations also include the following:

- "Trinity" or "Holy Trinity": Opioid plus benzodiazepine plus carisoprodol
- "Sizzurp": Promethazine with codeine cough syrup plus Jolly Rancher fruitflavored hard candy (The Hershey

Company, Hershey, PA) plus fruitflavored soda (eg, Sprite [The Coca Cola Company, Atlanta, GA])

Opioids and benzodiazepines (FDA black box warning).

DISCUSSION AND RECOMMENDATIONS

In light of the increase in opioid prescribing since 2012, and the opioid overdose death rates surpassing deaths caused by traffic accidents and illicit drugs, urgent actions are necessary. These actions must be taken by physicians, health plans, the government, and others. Most prescribing physicians feeding the opioid epidemic are well meaning, naïve, or just too busy to recognize the dangers.

Physicians must educate themselves and proactively do the right thing as far as opioid prescribing. Physicians and society must be reeducated that opioid pain medications for noncancer pain should be the rare exception, rather than the rule. Written visit checklists may be useful, especially in group practices where the patient may be seen over time by multiple physicians³¹ but also for physicians in smaller or one-physician offices. Electronic medical record systems are able to assist in many ways, including incorporating best practice alerts.

Practical actions physicians can take include

- Recognize that the opioid crisis is ravaging families and communities
- Avoid opioid pain medications whenever possible; start with safer alternatives
- Follow the CDC opioid prescribing guidelines² (see Sidebar: Centers for Disease Control and Prevention [CDC] 2016 Opioid Prescribing Guidelines Summary) for new patients with pain and for patients with chronic pain when possible
- Ensure that the opioid prescriptions are truly for medically legitimate purposes, with vigilance for red flags (see Sidebar: Red Flags for Drug Abuse, Addiction, or Diversion)
- Carefully follow in substantial compliance the Opioid Prescribing Guidelines described above, and in the Sidebar:
 Checklist for Prescribing Opioids—with the provision of detailed documentation in the medical record

- Follow the US Surgeon General's call to action and consider taking the Surgeon General's pledge at http:// turnthetiderx.org:
 - Educate ourselves to treat pain safely and effectively
 - Screen patients for opioid use disorder and provide or connect them with evidence-based treatment
 - Talk about and treat addiction as a chronic illness, not as a moral failing.

Physicians, among others, played a major part in the current opioid crisis. Committed and caring physicians will also have a great impact in "turning the tide" of the opioid crisis. •

Disclosure Statement

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Centers for Disease Control and Prevention (CDC) 2016 Opioid Prescribing Guidelines Summary¹

Because of increasing risks of overdose and death of users of opioids, the CDC released its "Guideline for Prescribing Opioids for Chronic Pain" in March 2016. The guidelines can be used as a best practice guideline but are not the standard of care at this time.

- Avoid benzodiazepines with opioids (increases risk of overdose and death vs opioid-only use)
- Perform periodic benefit-risk evaluation, including prescription drug monitoring program database review and urine drug screen
- Prescribe nonpharmacologic and nonopioid treatment as first line
- For chronic pain, avoid opioids; risk outweighs benefits for most
- · Discuss risk-benefits with patients and document
- Establish realistic goals before opioid therapy starts
- Start with immediate-release opioids; avoid methadone as first line because of higher risk
- Use additional precautions if dose exceeds morphine equivalent dosing (MED) of 50 mg/d
- Generally, avoid increasing the dosage to MED 90 mg/d
- Prescribe a maximum of only 3 days of opioids for acute pain for most nontraumatic, nonsurgical pain.

Concerns regarding the CDC guidelines are that they may limit access to opioids for some patients for whom opioids may benefit.

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Starting Points

Pain the monitor, and Rest the cure, are starting points for contemplation which should ever be present to the mind of the surgeon in reference to his treatment.

 John Hilton, FRCS, FRS, FZS, 1805-1878, English surgeon and Charter Fellow of the Royal College of Surgeons, professor of anatomy

ORIGINAL RESEARCH & CONTRIBUTIONS

Special Report

The Kaiser Permanente Northern California Enhanced Recovery After Surgery Program: Design, Development, and Implementation

Vincent X Liu, MD, MS; Efren Rosas, MD; Judith C Hwang, MD, MBA; Eric Cain, MD, MBA; Anne Foss-Durant, RN, MSN, FNP, MBA; Molly Clopp, RN, MS, MBA; Mengfei Huang, MSc; Alexander Mustille; Vivian M Reyes, MD; Shirley S Paulson DNP(c), MPA, RN, NEA-BC; Michelle Caughey, MD; Stephen Parodi, MD

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ABSTRACT

Complications are common after surgery, highlighting the need for innovations that reduce postsurgical morbidity and mortality. In this report, we describe the design, development, and implementation of an Enhanced Recovery After Surgery program in the Kaiser Permanente Northern California integrated health care delivery system. This program was implemented and disseminated in 2014, targeting patients who underwent elective colorectal resection and those who underwent emergent hip fracture repair across 20 Medical Centers. The program leveraged multidisciplinary and broad-based leadership, high-quality data and analytic infrastructure, patient-centered education, and regional-local mentorship alignment. This program has already had an impact on more than 17,000 patients in Northern California. It is now in its fourth phase of planning and implementation, expanding Enhanced Recovery pathways to all surgical patients across Kaiser Permanente Northern California.

INTRODUCTION

The publication of *To Err is Human* by the Institute of Medicine in 1999 elevated patient safety to a national priority. Yet, despite substantial investments aimed at reducing adverse events resulting from health care, surgical complications in the US continue to be both common and costly.²⁻⁸ In 2014, Kaiser Permanente Northern California (KPNC) implemented a new approach to surgical care delivery: Enhanced Recovery After Surgery (ERAS; see Sidebar: The Kaiser Permanente Nothern California Team). The first phase of the program targeted two surgical patient populations—elective colorectal resection and emergent hip fracture surgery-in the KPNC integrated health care delivery system. In less than two years, ERAS has fundamentally altered the delivery of surgical care at KPNC.

Since 2014, the process of care redesign has had an impact on more than 4500 patients undergoing colorectal resection or hip fracture surgery. An additional 11,000 patients undergoing total joint replacement have been included in the second phase, with implementation now entering its third phase. This program has resulted in dramatic changes in practice and declines in hospital length of stay and complication rates, along with promising trends toward reduced hospital mortality and decreased discharge rates to nursing facilities. In this article, we describe the design, development, and implementation process of the KPNC ERAS program. In future reports, we will describe how ERAS implementation affected process and outcomes measures among the target populations.

The Landscape of US Surgical Safety

More than 30 million operations are performed in the US each year, together accounting for a substantial fraction of all national health care costs.9 Unfortunately, complications after surgery are also common, with some reports estimating that as many as one-fourth of patients suffer postoperative complications.^{3,9-11} The types of complications may vary, including cardiac, pulmonary, renal, neurologic, and/or infectious sequelae, but all of them contribute to substantial morbidity and, sometimes, mortality. These events dramatically increase health care costs through additional diagnostic or therapeutic procedures as well as corresponding prolonged hospitalizations or rehospitalization.²⁻⁸ The psychological and social impact on patients, their families, and other support systems is also substantial.12 Thus, there is an urgent need to develop, test, implement, and evaluate new approaches to optimizing surgical care delivery.

Surgical Enhanced Recovery Programs

Numerous programs have been developed since the early 1990s that focus on facilitating patient recovery after surgery. Early iterations included "fast track" pathways focused on standardizing postoperative care to promote rapid recovery and shorter hospitalizations. 13,14 More recent approaches incorporate multiple

Vincent X Liu, MD, MS, is a Research Scientist in the Division of Research and Regional Director for Hospital Advanced Analytics in Oakland, CA. E-mail: vincent.x.liu@kp.org. Efren Rosas, MD, is the Assistant Physician in Chief for the San Jose Medical Center in CA. E-mail: efren.rosas@kp.org. Judith C Hwang, MD, MBA, is an Anesthesiologist at the Vallejo Medical Center in CA. E-mail: judith.c.hwang@kp.org. Eric Cain, MD, MBA, is an Orthopedist at the Fremont Medical Center in CA. E-mail: eric.cain@kp.org. Anne Foss-Durant, RN, MSN, FNP, MBA, is the former Director of Adult Services and Caring Science Integration for Kaiser Permanente Northern California in Oakland. E-mail: anne.foss-durant@kp.org. Molly Clopp, RN, MS, MBA, is a Strategic Leader for Kaiser Permanente Northern California Patient Safety in Oakland. E-mail: molly.p.clopp@kp.org. Mengfei Huang, MSc, is the ERAS Regional Director for Quality and Operations Support for The Permanente Medical Group in Oakland, CA. E-mail: exander.mustille@kp.org. Vivian M Reyes, MD, is the Regional Director for Hospital Operations for The Permanente Medical Group in Oakland, CA. E-mail: vivian.m.reyes@kp.org. Shirley S Paulson DNP(c), MPA, RN, NEA-BC, is the Regional Director for Adult Patient Care Services for Kaiser Permanente Medical Group in Oakland. E-mail: michelle.caughey@kp.org. Michelle Caughey, MD, is an Associate Executive Director for The Permanente Medical Group in Oakland, CA. E-mail: stephen.m.parodi@kp.org. Stephen Parodi, MD, is an Associate Executive Director for The Permanente Medical Group in Oakland, CA. E-mail: stephen.m.parodi@kp.org.

care elements together, aiming to reduce the stress of surgery while also facilitating patient recovery. 15-20 These ERAS programs combine preoperative preparation for surgery, perioperative nutrition, improved fluid management, early mobilization of the patient, and opiate-sparing pain management.

Although most of the ERAS literature pertains to the colorectal surgical population, emerging reports focus on gastrointestinal, orthopedic, urologic, gynecologic, obstetric, and thoracic surgical patients. ²¹⁻²⁵ Prior studies of ERAS implementation in colorectal surgery report robust reductions in hospital length

The Kaiser Permanente Nothern California Team

Barbara Crawford, RN, MS, NEA-BC

(executive sponsor)

Derrick Lee, MD (physician lead)

Glenn Tse, MD (physician lead)

Hemant Keny, MD (physician lead)

Christopher Grimsrud, MD (physician lead)

Timothy Brox, MD (physician lead)

David Redlin, MD (physician lead)

Nicholas Riegels, MD (physician lead)

Paul Preston, MD (physician lead)

Vikant Gulati, MD (physician lead)

Shideh Shadan, MD (physician lead)

Cynthia Rahn, MD (physician lead)

Jorge Abaunza, PharmD, MS (pharmacy lead)

William Doyle, PT (physical therapy lead)

Mary Kaye Giudici, MPT (physical therapy)

Christina Solis, RN, BSN, MHA, CPHQ,

CLSSBB (ERAS mentor)

Pearl Paras, RN, MPH (ERAS mentor)

Bri Dinoso, MPH, MBA (ERAS mentor)

Karen Leibovitz, RN (ERAS mentor)

Tracy Trail-Mahan, RN-BC, MS, CPHQ

(ERAS mentor)

Heather Brown, MSPT (business consulting)
Jennifer Chiu, MPH (business consulting)

Julia Herzenberg, MS (business consulting)

Belia Roybal (analytic consulting)

Paul Feng (analytic consulting)

Alamanda Malamana (anal tina

Alexander McKenzie (analytic consulting)

Tammy Peacock, MAPSY, BSN, RN, CPPS,

LSSBB (NSQIP patient safety)

Sandra Brown Robinson, MCSW

(Regional Health Education)

Nancy Richardson (Regional Health Education)
Margaret Mentakis, MD (KP HealthConnect)
Elaine White, RN (KP HealthConnect)
Lucia LaRocca, RN, BSN (KP HealthConnect)
Jeffrey Hoffman (KP HealthConnect)

of stay and in the time needed to restore gastrointestinal function. However, they have yielded mixed results with respect to reducing major complications, hospital readmission, or mortality. 15-20 Clear conclusions about the impact of ERAS programs on outcomes beyond length of stay are limited because many prior

ERAS studies have had modest sample sizes, less robust study designs, or smaller numbers of implementation target populations, clinicians, or sites. Few studies have examined the barriers to program implementation, an important consideration that could have an impact on the real-world effectiveness of ERAS.

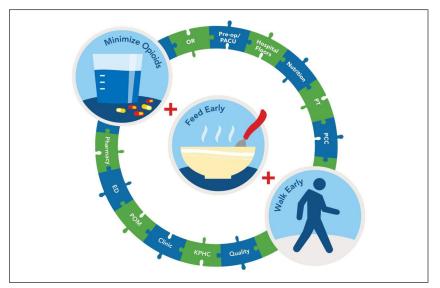


Figure 1. Schematic overview of the main goals of the Kaiser Permanente Northern California (KPNC) Enhanced Recovery After Surgery program and the supporting multidisciplinary teams needed to successfully implement large-scale changes in surgical care.

ED = Emergency Department; KPHC = Kaiser Permanente HealthConnect; OR = operating room; PACU = postanesthesia care unit; PCC = patient care coordinater; pre-op = preoperative; POM = preoperative medicine; PT = physical therapy.

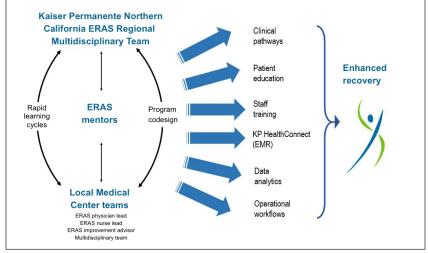


Figure 2. Overview of the Enhanced Recovery After Surgery (ERAS) program design demonstrating the close collaboration between the regional ERAS multidisciplinary team and local Medical Center teams. Program codesign, learning cycles, dissemination, and implementation were facilitated by bidirectional partnerships with ERAS mentors who partnered with multiple Medical Centers.

EMR = electronic medical record; KP = Kaiser Permanente.

STRATEGIC APPROACH TO IMPROVING SURGICAL OUTCOMES

In 2013, KPNC executive leadership, in partnership with surgical and anesthesia clinician leaders, identified the need to improve surgical outcomes. The leadership recognized ERAS as an ideal opportunity to implement, test, and evaluate an innovative and unifying approach to improving surgical care. Patients undergoing elective colorectal resection or emergent hip fracture surgery were selected as the target populations for initial implementation because of their higher baseline rates of complications.

The ERAS program design included the following primary operational elements:

1) preoperative surgical preparation; 2) intraoperative normovolemia; 3) multimodal pain management through the preoperative, perioperative, and postoperative phases of care; 4) early feeding and nutrition after surgery; and 5) postoperative mobilization. The program also sought to empower patients so they could actively participate in their own surgical recovery. One additional goal was to challenge KPNC to implement the ERAS program at all 20 Medical Centers in just 1 year.

Assessing the Challenges to Implementation

Preliminary "on-the-ground" assessment of workflows revealed the major challenges that would accompany the implementation of system-level changes in surgical care practice. First, the preoperative, intraoperative, and postoperative phases involved a large number of clinicians and staff from a broad swath of disciplines and touched each patient (Figure 1); it was not unusual for 30 to 40 unique staff to provide care for a single case. The broad categories included nursing, physician, pharmacy, physical therapy, nutrition, patient care coordination, and health education staff; each discipline also contained many subspecialists (eg, surgeons, anesthesiologists, preoperative medicine staff, emergency medicine staff, and hospitalists). The new program would also challenge existing tenets of surgical care, for example, nothing by mouth after midnight and strong opioids for pain. As a result, successful implementation would require a highly orchestrated, multidisciplinary, and collaborative effort

seamlessly integrating the traditional siloes and processes of surgical care.

Second, implementation would concurrently need to address the substantial differences in the characteristics and care patterns of the target populations. For example, triage and treatment of patients who sustained hip fracture and who presented to the Emergency Department diverged widely from that of patients who were admitted electively for colorectal resection surgery. Not surprisingly, the approach to perioperative nutrition in colorectal surgical patients was very different from that in hip fracture surgical patients; the same was true for postoperative mobility. Consequently, system-level implementation would require a careful balance between the individual needs of specific surgical populations and the overarching principles that would facilitate a unified and restorative approach to surgical care.

Third, system-level implementation would require the contributions of thousands of staff across 20 heterogeneous Medical Centers. The KPNC Medical Centers are diverse with respect to size, presence of subspecialty services, teaching hospital status, patient demographics, and surgical case mix. Therefore, the regional ERAS team relied heavily on local teams to codesign and further strengthen the program to meet the needs of local implementation (Figure 2). Finally, the implementation timeline of 12 months from design and development through pilot site testing and full regional implementation was ambitious. Rapid feedback

Subject Matter Expert Workgroup Members

Orthopedics

Anesthesia

Preoperative Medicine

Hospital-based specialists

Pharmacy

Nursing

Surgical quality team (National Surgical

Quality Improvement Program)

Physical Therapy

Nutrition

Consulting and Analytics

Regional Health Education

Physician Education

Kaiser Permanente HealthConnect

Regional leadership

loops and clear, consistent communication were essential to adopt this new approach to surgery.

Building on Systems-Level Implementation Experience

Experience gleaned from prior population-level quality improvement programs at KPNC provided a critical backdrop against which certain elements of ERAS could be cast. For example, large-scale investments to improve sepsis care, reduce hospital-associated infections, and redesign critical care also resulted in substantial changes in practice that together had an impact on hundreds of clinicians and tens of thousands of patients. 26,27 The ERAS team built on these prior approaches by

Key Elements for Achieving Enhanced Recovery After Surgery

Facilitating multilevel leadership alignment

Regional leadership and program development Building a shared culture of change

Ensuring local-regional alignment

An innovation: Regional mentors

Accelerating high-quality reliable care

Taking on the "sacred cows" of surgical care Engaging stakeholders through transparency

Supporting rapid-cycle feedback and improvement Building robust evaluation into implementation

Leveraging technology and data to improve recovery

Electronic medical record decision support: "Making the right thing easier to do" Efficiently extracting high-quality data to support change

Using a national standards program to assess surgical quality Enabling care improvement through rapid data review

Embedding patient-centeredness in routine care

Enabling patients to participate in the surgical journey

1) facilitating multilevel leadership alignment, 2) accelerating high-quality reliable care, 3) leveraging technology and data, and 4) embedding patient-centeredness in routine care (see Sidebar: Key Elements for Achieving Enhanced Recovery After Surgery). In the sections that follow, we describe how each of these elements influenced the design and deployment of ERAS.

Facilitating Multilevel Leadership Alignment Regional Leadership and Program Development

Successful implementation required a high degree of leadership alignment across two major axes: 1) the differing needs and practices of individual clinical disciplines and subspecialty groups and 2) the combined regional and Medical Center management of operations and clinical practice. A regional multidisciplinary subject matter expert workgroup, composed of a set of highly engaged clinicians and staff representing the diversity of program needs, was convened (see Sidebar: Subject

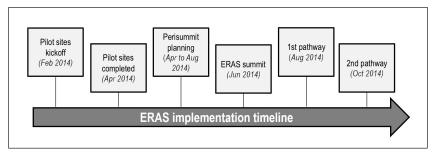


Figure 3. Enhanced Recovery After Surgery (ERAS) implementation timeline.

Apr = April; Aug = August; Feb = February; Jun = June; Oct = October.

Matter Expert Workgroup Members). The workgroup included surgeons, nurses, analytic staff, anesthesiologists, pharmacists, regional health educators, preoperative physicians, quality measurement staff, physician education staff, hospitalists, physical therapists, and electronic medical record (EMR) development staff, among others. This multidisciplinary group brought together many perspectives so that the challenges of future deployment could be addressed.

Table 1. Sample of an enhanced recovery preoperative clinical pathway Item No. Practice Team member Standard preoperative clinical pathway item 1.1 Patient education to help inform of ERAS approaches that Surgery MA/RN may be unfamiliar (eg, reducing narcotics, early feeding and and Preoperative ambulation) Medicine MA/RN 1.2 No prolonged fasting RN in clinic and Clear liquids up to 2 hours before surgery (including Preoperative carbohydrate loading with drink). Acceptable substitutes: juice Medicine or drink. Do not use in patients with bowel obstruction or on nasogastric tube. See amended guidance for diabetics. Solids up to 8 hours before surgery 1.3 Chlorhexidine mouthwash (HAP measure) Surgeon/RN 1.4 Chlorhexidine wipe (SSI bundle) Surgeon/RN 1.5 Standardizing PONV prophylaxis Anesthesia/RN 2 Colorectal patients only 2.1 Preoperative albumin for risk assessment Surgeon Preoperative Medicine/laboratory Multimodal pain management 3 1 Decrease sedative medications, especially in the elderly Anesthesia/RN population (eg, midazolam, 2 mg maximum) 3.2 Acetaminophen (caution in patients with liver disease) Surgeon/RN/ Anesthesia Patient weight ≥ 50 kg, 1 g IV single dose Patient weight < 50 kg, 15 mg/kg IV single dose 3.3 Gabapentin (if already on this medicine, continue usual dose) Surgeon/NR Patients aged 18-59 years: 600 mg oral single dose Patients aged 60-69 years: 300 mg oral single dose

ERAS = Enhanced Recovery After Surgery; HAP = hospital-acquired pneumonia; IV = intravenous; MA = medical assistant; PONV = postoperative nausea and vomiting; RN = registered nurse; SSI = surgical site infection.

The workgroup reviewed existing literature, sought clinician feedback, defined program elements, and established program metrics to track implementation. They also focused on transparent and collaborative decision making and iterative improvements throughout the design and implementation phases. Their work culminated in a set of practices that formed the basis of the ERAS clinical pathways (Table 1). These pathways also served as the surgical timelines around which patient engagement materials (eg, calendars and education discussed later) were designed.

The ERAS workgroup members also served as the clinical champions at their individual Medical Centers, leading pilot-site implementation and testing of the program (see Figure 2). Two alpha pilot sites went live in February 2014, with additional beta pilot sites going live through Spring 2014. These pilots provided critical insights into the implementation process (Figure 3). Iterative program improvements, based on initial results and performance improvement methods, continued through June 2014 when the program elements were formalized in preparation for regional deployment.

Building a Shared Culture of Change

Prior KPNC initiatives successfully leveraged program "summits"—in-person meetings including hundreds of leaders, clinicians, and staff from the Medical Centers—to facilitate dissemination and generate broad-based support for the program. Using this model, a KPNC ERAS Summit was held on June 30, 2014, with more than 400 people in attendance. The summit included focused presentations detailing the program's objectives

and processes (Figure 4). Expert panels reviewed specific guidelines (eg, multimodal pain management) followed by interactive question-and-answer sessions. In addition, standardized tools were disseminated to facilitate local implementation. They included 1) ERAS EMR order sets to facilitate standardized care, 2) performance dashboards and analytic tools to foster rapid program and case review, and 3) patient education and engagement materials. The challenge for full program implementation at all sites by October 2014 was established and set as a clear goal.

Ensuring Local-Regional Alignment

At the summit, Medical Centers were provided with the tools to develop local ERAS teams, which paralleled the composition of the regional multidisciplinary workgroup. These teams were designed to include engaged staff from every surgical care domain; facilitate multidisciplinary communication; and quickly address barriers and resistance to practice change. Each team was led by a Physician Lead, Nursing Lead, and Project Manager or Improvement

Advisor (see Figure 2). Local implementation followed a similar pattern to regional deployment beginning with a Medical Center kickoff meeting and celebrations or recognitions of ongoing success.

A New Innovation: Regional Mentors

The program also employed three fulltime mentors, specializing in performance improvement methods, assigned to assist implementation for a set of Medical Centers (see Figure 2). The mentors provided critical "boots on the ground" expertise to engage and coach local teams. They also formed the backbone of a rapid-response learning system that could identify an innovative best practice developed at one Medical Center and rapidly disseminate it to multiple other centers. Moreover, they built personal relationships across disciplines and functional domains facilitating process improvement, thereby strengthening local capabilities and infrastructure for ERAS. They served as a seamless bidirectional channel for information exchange between the regional and local Medical Center teams. This process allowed them to identify barriers, questions, and concerns, and then provide rapid turnaround and guidance back to each center.

Accelerating Excellent and Reliable Care Taking on the "Sacred Cows" of Surgical Care

Certain elements of perioperative care have remained largely unchanged for decades, including practices related to "nothing by mouth after midnight," pain control primarily using opioids, limited early mobilization, and conservative reintroduction of nutrition. These approaches have persisted in part because of the limited evidence base to motivate change, as well as the desire to not disrupt traditional workflows. In ERAS, KPNC recognized an opportunity to transform surgical care by introducing new care practices that could drive improved surgical outcomes. However, to execute high-quality and reliable care, experts in surgical care needed to define optimal treatment pathways and to incorporate them in practical clinical workflows.



Figure 4. Enhanced Recovery After Surgery (ERAS) summit agenda.

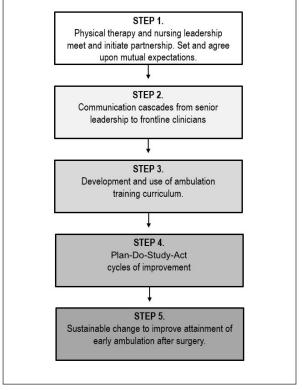


Figure 5. Example of a process for redesigning systems of care to improve early ambulation attainment.

Program elements included the prevention of prolonged fasting through carbohydrate loading before surgery and starting early oral nutrition shortly after surgery, even among patients who underwent colorectal resection. Another key area was reducing the use of opioids by implementing multimodal analgesia through the incorporation of intravenous acetaminophen, nonsteroidal anti-inflammatory drugs, and the use of local anesthetic with peripheral nerve blocks (administered by anesthesiologists and emergency physicians). Patients who were alert, fed, and comfortable were much better prepared to ambulate within 12 hours of surgery, and to maintain frequent ambulation even after hip fracture repair.

Engaging Stakeholders through Transparency

Throughout this process, program leaders worked to ensure the program design remained transparent so practicing clinicians could easily appreciate and contribute to the rationale for the program elements. This need was heightened by the varied quality of the evidence-based literature supporting existing ERAS programs. Because the KPNC ERAS program ultimately included elements described in the literature but also local innovations, it was essential that clinicians were highly engaged partners. As was clear from prior system-level efforts, even seemingly simple interventions would require a thorough reengineering of complex systems of care. In ERAS, organizing early and sustained ambulation, for example, required high degrees of integration between physical therapists, nurses, orthopedic surgeons, pharmacists, anesthesiologists, and workplace safety staff (Figure 5).

This program pursued a highly deliberate and collaborative approach to program development to overcome potential or real barriers. All stakeholders were actively engaged, including those who were not part of the traditional decision-making process, to secure broad-based support for implementation. Regional leadership also modeled the collaborative relationship building required at the local level, by highlighting interdisciplinary collaboration and fostering open conversations about the fears, concerns, and questions relevant to individual groups.

Supporting Rapid-Cycle Feedback and Improvement

Even with the careful and collaborative approach to program design, implementation required iterative improvements as more centers went live and new challenges arose. In addition, the highly focused timeline for implementation meant critical feedback needed to be addressed promptly. The regional mentors facilitated these bidirectional conversations by leading regional collaborative calls and participating in regional and local Medical Center workgroup meetings. They quickly diffused best practices such as the widespread use of unit-based visual board huddles. Visual boards are templates for posters or bulletin boards that allow care teams to collaboratively post and evaluate information during Plan-Do-Study-Act cycles. During the ERAS implementation, hospital units would often hold huddles around their visual boards during each nursing shift to facilitate education and discussions about the program.

Building Robust Evaluation into Implementation

Realizing that a large-scale ERAS program would move KPNC beyond the current evidence base, it was essential to develop a robust measurement strategy to quantify changes in patient outcomes. At program outset, physicians in the Division of Research participated in the operational design so the program's results could be evaluated with robust methods. Throughout the design phase, ERAS leaders and research staff worked closely together to create an analytic approach that served both operational and research needs. They also chose to analyze



Figure 6. Sample of Enhanced Recovery After Surgery (ERAS) order set to help standardize high-reliability care. Intra-op = intraoperative; NPO = nothing by mouth; OR = operating room; Pre Day = before day; pre-op = preoperative.

Enhanc	ed ER	AS Reg	gional Da	shboa	ard: E	lective	e Colo	recta	Surge	ery		MET	RIC DE	FINIT	IONS						
	Imp	lemen	tation				Pre	ocess								Out	comes				
					175	HOLD CO.	Avg		50	1500			- Avg III		38-Day Post Operative						
	Team Established	Education Completed	Implementation Milestones	Last Liquids selfs 2-4Hz	Lest Solids solid 8 - 12 Hes	Multimodal Analgeria Given Zi	Morphine Equivalent Mgs	Benzo Daus Z	Early Feeding win 12 Hz 2	First Ambulation win 12Hrs 22	Sustained Ambulation 22	Total Surgical Cases	Hosp LOS Days	Median Admit to Surgery Hours	Ham Free Surgecy 24	Monality 22	Readmission 22	Pneumonia 24	un z	Transfusion 2	DVIDE
itudy Period		As of 8/15	/14				Apr -	Jun 2014				Jul 2013 - Jun 2014 Q2 2013 - Q1 2014									
arget	•	•	•	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	N/A	NA	N/A	TBD	TBD	TBD	TBD	TBD	TBD	TBD
	•	•	•	13%	19%	0%	TBD	4%	10%	27%	49%	107	5.4	2.0	87%	0.0%	6.5%	0.0%	0.0%	1.6%	0.0%
	•	•	•	18%	18%	0%	TBD	2%	5%	55%	64%	85	5.2	1.9	82%	0.0%	6.7%	1.7%	3.3%	3.3%	1.7%
	•	0	•	21%	32%	0%	TBD	6%	21%	50%	58%	77	5.5	1.8	80%	2.3%	11.4%	2.3%	0.0%	2.3%	2.3%
	•	•	•	26%	11%	11%	TBD	11%	4%	26%	69%	115	5.6	2.0	83%	0.0%	2.9%	2.9%	2.9%	5.7%	0.0%
	•	•	•	44%	26%	35%	TBD	4%	29%	38%	47%	139	5.8	2.2	76%	2.4%	12.2%	2.4%	0.0%	12.2%	0.0%
			0	8%	38%	0%	TBD	0%	0%	38%	72%	59	6.7	2.4	88%	0.0%	3.9%	3.8%	3.8%	3.8%	0.0%

Figure 7. Sample of Enhanced Recovery After Surgery (ERAS) Colorectal Surgery performance dashboard to enable data review.

a contemporaneous set of similar surgical patients to isolate the effects of the ERAS program, rather than other secular changes in surgical practice.

Technology and Data Improve the Program

Technology and data presentation were essential to embedding the major practice changes into the system. These changes included standardizing care through the EMR; efficiently extracting high-quality data to support process change; using a national standards program to assess surgical quality; and enabling care improvement through low-latency data review.

Electronic Medical Record Decision Support: "Making the Right Thing Easier to Do"

In 2006, KPNC began using a comprehensive EMR (Kaiser Permanente HealthConnect) based on Epic (Epic, Verona, WI) at its clinical sites. It has consistently developed new EMR-based tools to improve clinical care, data analysis, performance improvement, and research. As shown in Figure 6, ERAS order sets were built to reflect the clinical practice guidelines and foster standardization of care. All order sets were tagged with an ERAS identifier flag so that once an order was placed, targeted ERAS patients could be clearly identified. In total, 13 new order sets were released to support rapid implementation and became the functional backbone supporting rapid practice change. As new surgery types were added to the ERAS project, more order sets were developed in rapid cycle fashion.

Efficiently Extracting High-Quality Data to Support Process Change

Prior systems-level efforts established the importance of using high-quality data to support and to evaluate process changes. Manual data abstraction of ERAS data could not be expected to adequately support the scale and speed of ERAS implementation (Table 2). More importantly, even if manual abstraction could be accomplished in one implementation phase, it would be unsustainable in subsequent phases. Thus, analytic staff matched ERAS elements with granular and precise electronic algorithms to extract supporting data directly from the EMR. These algorithms were directly aligned with the order sets to ensure consistent approaches to charting and reporting.

A core priority of the ERAS program was to reduce the postoperative use of opioids, while maintaining the same levels of pain control, with the use of multimodal analgesia. To track changes over time in the use of opioids, analytic staff designed an algorithm to extract opioid dosages given to patients as recorded in the medication administration record, generate morphine equivalence dosages for each opioid, and aggregate dosages within specific periods for comparison. They also used patient-reported pain measures to calculate the difference between patients' reported pain score and their self-described acceptable level of pain (delta pain score). This score was necessary to account for patient-level differences in their tolerance and reporting of pain. Once validated, these algorithmic approaches gave clinicians an unprecedented method for evaluating existing pain control practice and postimplementation practice change.

Using a National Standards Program to Assess Surgical Quality

Because manually abstracting all process and outcomes data elements was not feasible, we used a validated approach for evaluating complication rates: the National Surgical Quality Improvement Program (NSQIP).28 A program of the American College of Surgeons, NSQIP is designed to evaluate complication rates compared with risk-adjusted US national norms. In 2014, the KPNC NSQIP data collection process was fully standardized with a centralized regional staff reviewing local Medical Center data. Program participation in the colorectal and hip fracture repair modules was extended to all centers, allowing for a more robust sample size for analysis. This centralized approach increased the timeliness and quality of data collection, improving confidence that ERAS outcomes were evaluated on the basis of a shared and reliable method.

A core priority of the ERAS program was to reduce the postoperative use of opioids, while maintaining the same levels of pain control, with the use of multimodal analgesia.

Enabling Care Improvement through Rapid Data Review

Dashboards for ERAS were released, allowing leaders, clinicians, and staff to assess and to improve their own care through rapid reviews. Columns indicating performance on individual metrics and rows showed Medical Center-level performance for each target population (Figure 7). Dynamic dashboard features allowed users to select specific elements to evaluate trends over time, either at the regional or Medical Center level. Dashboards included data as recent as the prior month for most measures; NSQIP data were reported on a quarterly basis. Trends in performance were displayed visually with statistical process control charts to identify when "breakthrough" performance was achieved. To enable local teams to do rapid cycle improvement, weekly patient-level reports were sent to each Medical Center detailing performance on ERAS elements for individual patients. Local centers were able to do in-depth reviews of their successes and challenges in protocol adherence and to identify the systems of care needing improvement. This approach also fostered a healthy competition among the Medical Center teams.

Table 2. Enhanced recovery key standardized process and outcome measures							
Process measures	Outcome measures						
Last liquids given within 2 to 4 hours	Hospital length of stay						
Multimodal analgesia given	Harm-free surgery rate						
Total opioid use	Hospital mortality						
Benzodiazepine days ^a	Hospital readmission within 30 days						
Early feeding within 12 hours	Pneumonia						
First ambulation within 12 hours	Urinary tract infection						
Sustained ambulation	Blood transfusion						
	Venous thromboembolic disease						

^a Number of days on which a benzodiazepine was given.

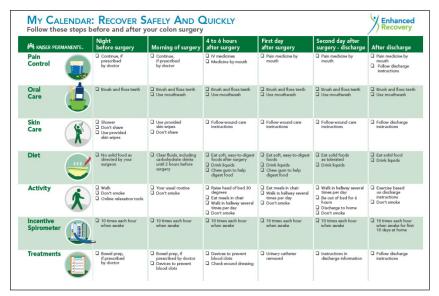


Figure 8. Enhanced Recovery After Surgery (ERAS) calendar sample.

Embedding Patient-Centeredness in Routine Care

The ERAS program was designed to enable large-scale collaboration and culture change so that patients could experience a radical improvement in their surgical recovery. As such, the voice of our patients was critical to the design and implementation process.

Engaging Patients to Participate in the Surgical Journey

Early on, we heard from many patients that they were often challenged with a lack of information and even conflicting information about how to prepare for and what to expect after surgery. We realized that creating a clear roadmap of surgical events would not only increase patient satisfaction but, more importantly, empower patients to be in the driver's seat during their own recovery. We also knew that a number of the ERAS practices might be viewed as "surprising" or even "scary" for patients used to traditional surgical care. Thus, educating patients on the ERAS program principles, as well as reviewing what they should expect throughout their hospital stay, was critical to alleviating anxiety and helping patients understand the importance of their recovery program.

Key members of the regional multidisciplinary workgroup included KPNC Health Education staff. From program outset, they were given the task of designing patient-facing materials. These materials, including calendars (Figure 8), brochures, and videos, were tested and optimized through a series of feedback cycles driven by pilot site teams as well as patients and family members. Calendars facilitated patient engagement in their surgical care; patients were also able to follow along with what they should expect in each period of the surgical process, empowering patients to actively participate with the staff in their recovery. For example, the calendar of events for colorectal surgery led patients through key surgical time points (eg, night before surgery, morning of surgery, after discharge) with checklists of important items in seven domains: pain control, oral care, skin care, diet, activity, incentive spirometer, and treatments.

Hearing how ERAS had made a positive difference in the quality of patients' hospital experience—from including patients in local ERAS team meetings to having them as keynote speakers at the 2014 Regional Summit—has continued to be a major motivator for staff to embrace this initiative.

CONCLUSION

Surgical complications are an all too common occurrence in the US. In KPNC, the ERAS program represents a comprehensive approach to reducing surgical complications and improving patients' surgical experience. To maintain organ

function and to reduce the profound surgical stress response, this program aims to optimize pain control, promote early mobility, maintain adequate nutrition, and engage patients to participate in their care. This program was implemented in 2014 with the use of multidisciplinary and broadbased leadership and Medical Center teams, high-quality data and analytic infrastructure, patient-centered education, and regionallocal mentorship alignment. It has already had an impact on more than 17,000 patients in Northern California and is in its fourth phase of planning and implementation, expanding enhanced recovery pathways to all surgical patients across KPNC. Care has changed dramatically since implementation, with decreases in length of stay and complication rates.²⁹ Engagement among patients and clinicians is excellent, and the ERAS team is working toward realizing the vision of enhanced recovery hospitals where the ERAS paradigm becomes the standard of care for the 190,000 adult inpatients hospitalized in KPNC each year. ❖

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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Care in the Ritual

Every operation in surgery is an experiment in bacteriology. The success of the experiment in respect to the salvation of the patient, the quality of healing in the wound, the amount of local or constitutional reaction, the discomforts during the days following operation, and the nature and severity of any possible sequels, depend not only on the skill but also upon the care exercised by the surgeon in the ritual of the operation.

— Sir Berkeley Moynihan, 1865-1936, 1st Baron Moynihan, CDMB, CB, FRCS, British abdominal surgeon

REVIEW ARTICLE

Supporting Muslim Patients During Advanced Illness

Nathan A Boucher, DrPH, PA-C, MS, MPA, CPHQ; Ejaz A Siddiqui, MIS; Harold G Koenig, MD, MHS

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ABSTRACT

Religion is an important part of many patients' cultural perspectives and value systems that influence them during advanced illness and toward the end of life when they directly face mortality. Worldwide violence perpetrated by people identifying as Muslim has been a growing fear for people living in the US and elsewhere. This fear has further increased by the tense rhetoric heard from the recent US presidential campaign and the new presidential administration. For many, this includes fear of all Muslims, the secondlargest religious group in the world with 1.6 billion adherents and approximately 3.5 million in the US alone. Patient-centered care requires health professionals to look past news headlines and unchecked social media so they can deliver high-quality care to all patients. This article explores areas of importance in the context of advanced illness for practitioners of Islam. These include the conditions needed for prayer, the roles of medical treatment and religious authority, the importance of modesty, the religious concordance of clinicians, the role of family in medical decision making, advance care planning, and pain and symptom management. Initial recommendations to optimize care for Muslim patients and their families, informed by the described tenets of Muslim faith, are provided for clinicians and health systems administrators. These include Islamic cultural awareness training for staff, assessment of patients and families to determine needs, health education and decision-making outreach, and community health partnerships with local Islamic institutions.

INTRODUCTION

Adherents to the Muslim faith are a vulnerable group in health care today, subject to potential discrimination because of the widespread negative public view of Muslims. Clinicians and administrators alike, particularly in the US, can benefit from enhanced knowledge about the Muslim faith. The US has its roots in supporting the freedom of religious practice as stated in the First Amendment of the US Constitution.1 However, worldwide violence perpetrated by people identifying as Muslims has been a growing concern for US citizens. This tension has been further exacerbated by the rhetoric heard during the 2016 US presidential campaign and from the new presidential administration. Since the World Trade Center attacks of 2001, concerns have evolved into a generalized fear of an entire religious group practicing Islam. Clinicians and systems are not insulated from the undercurrent of discrimination against Muslims.

Islam is the world's second-largest religion with 1.6 billion practitioners worldwide and approximately 3.5 million in the US.² Supported by provisions of the 2010 US Affordable Care Act,³ clinicians and hospital systems are evolving to deliver care that is more patient-centered and equitable. Projections indicate a doubling of the US Muslim population by 2030.² A growing and aging Muslim population will have care needs related to chronic and terminal illnesses.

Discrimination in Health Care Settings

Muslims have reported discrimination in health care settings, including denial of services, on the basis of their religion. An *Economist* poll of 1000 adult US citizens found that Muslims face "a great deal" (39%) of discrimination in America. Respondents reportedly perceived discrimination to be higher for Muslims than for Christians (23% reporting "a great deal" and 16% reporting "a fair

amount" of discrimination) or for Jews (33% and 11%, respectively).7 Muslims are also more likely to report depression as a result of discriminatory verbal insults compared with those not subjected to such treatment.8 The Institute of Medicine described racial and ethnic disparities in health care as arising from broader historic and contemporary social inequality, influencing clinician bias and prejudice.9 Patient-centered care requires us to look past news headlines and unchecked social media to deliver high-quality care to patients. In the setting of chronic, serious, or terminal illness, Muslim patients—like any ill patient-require care that meets them where they are, supporting medical as well as psychosocial needs.

Religion is an important part of many patients' cultural perspectives and value systems that come to the forefront during advanced illness and near the end of life when mortality must be addressed. Yet, religious needs are minimally met, if at all, in contemporary US health care. 10,11 Evidence suggests that health care professionals' willingness to explore patients' spiritual needs during advanced illness is low, 12 and this may stem from a lack of spiritual care knowledge and training. 13 Ignorance about Muslim culture in this regard has negative implications for shared decision making,14 psychosocial support,15 and management of disease.¹⁶ One pilot intervention involving a one-hour educational intervention delivered by a Muslin chaplain demonstrated improved knowledge of Islamic teachings regarding end-of-life care among participating palliative care clinicians.¹⁷ Additionally, the available research may reflect presumptions that being Muslim means rejecting biomedical innovation and health education when the opposite may be true.18 Assessing and attending to religious and spiritual needs of patients with

Nathan A Boucher, DrPH, PA-C, MS, MPA, CPHQ, is a Postdoctoral Fellow at the Geriatric Research Education and Clinical Center at the Durham Veterans Administration Medical Center and a Senior Fellow at the Duke University Center for the Study of Aging in NC. E-mail: nathan.boucher@duke.edu. Ejaz A Siddiqui, MIS, is the Muslim Liaison at the Mount Sinai Medical Center in New York, NY. E-mail: ejaz.siddiqui@mountsinai.org. Harold G Koenig, MD, MHS, is a Professor of Psychiatry and Behavioral Sciences and an Associate Professor of Medicine at Duke University Medical Center in Durham, NC, and an Adjunct Professor in the Department of Medicine at King Abdulaziz University in Jeddah, Saudi Arabia. E-mail: harold.koenig@duke.edu.

advanced and terminal illness is supported by the National Consensus Project¹⁹ and the Institute of Medicine²⁰ in the US, and by the World Health Organization.²¹

We address areas of importance in the context of advanced illness for Muslim patients. These areas include prayer, medical treatment values, role of religious authority, modesty, medical decision making, advance care planning, and pain management. Recommendations to optimize care for Muslim patients and their families include Islamic cultural awareness training for health care staff, assessment of patients and families to determine needs, and community health partnerships with local Islamic institutions. This review is provided to familiarize the reader with tensions at the intersection of Islam and Westernized health care in advanced illness contexts. There is, of course, variation between individual Muslim patients and families. Clinicians and administrators can acknowledge and assess this variation by engaging with their patients, and asking them about their religious and spiritual needs.

Considerations for Muslim Patients and Families

The Sidebar: Case Vignette illustrates the case of a female Muslim patient with advanced illness who encounters challenges in adhering to her faith and practice during an acute care hospitalization. Reallife patient concerns and responses listed support a collaborative approach in caring for a Muslim patient.

DISCUSSION

The Sidebar: Recommendations for Culturally Sensitive Care to Muslim Patients with Advanced Illness details seven areas in which clinicians can address Muslim patients' spiritual and religious needs.

Prayer

Prayer and one's preparation for prayer play a central role in Muslim religious practice as one of the five pillars of Islam. The five pillars are profession of faith, prayer while facing toward the holy city of Mecca (in Saudi Arabia), fasting during the holy month of Ramadan, giving of alms (or *zakat*) to the poor, and pilgrimage to Mecca at least once during

one's lifetime.²² Notably, each pillar is strongly connected to prayer and devotion, a source of strength important to recovery from illness.²³ Maintaining personal cleanliness and a clean space to pray in health care settings in the midst of illness are particular challenges. This is an important concern for Muslim patients with advanced illness who spend a good deal of time in hospitals, clinics, and other health care environments.

Muslims will generally wash their hands, face, and feet in preparation for prayer (known as *wudu*).²² *Tayammum*, touching both hands to clean sand and sweeping them over the face and hands, can be done if the person is too ill for the standard wudu ritual washing.²⁴ The availability of certain items, such as prayer rugs, and an acknowledgment and understanding of the importance of prayer, have been identified by some

Case Vignette

A 44-year-old Muslim woman is admitted for management of complications related to lung cancer with metastasis to her spine. She lives an independent life and is considered a financial supporter for her family. In her current state, she is becoming dependent on others, losing independence in simple activities, and is concerned about the well-being of her children. Her husband provides minimal emotional support.

During an initial visit from her Muslim chaplain she is still independent but becoming incontinent. This is affecting her ability to stay clean and pray in the traditional way. She has concerns about her children and their financial situation after her death. After a week, her condition deteriorates. She loses 60% to 70% of her independence and is now mostly confined to her bed.

The patient has increasing pain, and there is potential for palliative surgery, although surgeons are reluctant to operate given the advanced stage of illness. One surgeon agrees to operate and, while in the initial preparation stage, discovers that the woman might have tuberculosis. She is placed in an isolation room waiting for results of confirmatory studies. Her older brother visiting from abroad needs to return to his work, and she has only her husband and two young children for support.

- *Patient's concern:* Inability to offer her daily prayers because of frequent incontinence. *Response:* A Muslim chaplain informs her about using the option of *Tayammum* (dry ablution in place of ritual washing) and offering her prayers as soon as she cleans herself and changes clothes with assistance from hospital staff.
- Patient's concern: Pain control, inability to get halal (prepared per Islamic law specifications) meals, and not getting enough nutritious food to regain strength. Response: With staff input, the imam (an Islamic leader) counsels her on the benefit of pain control to relieve suffering under the circumstances. She is advised by the imam to start consuming all types of fruits and vegetables as well as nutritious drinks and fish from the hospital menu.
- *Patient's concern:* That her surgical case is being delayed because of her faith. *Response:* Hospital staff along with the Muslim chaplain are able to comfort her and explain the factors related to the delay.
- Patient's concern: If paralyzed after surgery, her hygiene will not be properly cared for. Response: The imam reminds her to have faith in Allah and have hope because she is in a competent medical facility. The imam reminds her that by Allah's will all her postsurgical care, including her hygiene requirements, will be taken care of by hospital staff and her family members. The treating clinician and nurse indicate their support. The imam prays with her and comforts her by indicating that special healing prayers will take place during Jummah (Friday noon prayer) by the hospital's Muslim community.
- Patient's concern: Support from her available family member, her husband.
 Response: The imam, with a hospital social worker, helps to link her husband to the Muslim community and social work supports so that he can be more resilient and supportive.

Muslims as ways to assist adherence to religious practice while ill in health care facilities. 25,26 Turning immobile Muslim patients' beds toward Mecca for prayer, making Qur'ans readily available, and replacing wall-hanging crucifixes (in traditionally Catholic hospitals) with crescents (a symbol of Islam for some adherents), if the institution will allow, have also been described as ways to make clinical space more welcoming for prayer and Islamic faith.²⁷

Medical Treatment

Science, medicine, and faith are not separate in Islam. Indeed, a legacy of scientific and medical advancement is owed to the Islamic world.²⁸ Although the Arab Muslim influence on modern medicine is not often highlighted, Muslim faith generally welcomes innovations in health care.5 Muslims are expected to seek treatments for curable disease and to view incurable disease as God's will.6 Some Muslims may not wish to consider the withdrawing of care or organ donation from their loved ones.²⁹ However, withdrawal of futile life support in the context of inevitable death is permissible, provided it is done with informed consent.30 Islamic law allows patients to refuse futile treatment, but it also forbids passively or actively causing death to self or others.³¹ In the setting of incurable disease or terminal illness, Muslims' views may vary depending on religious and social contexts. It is advised to ascertain the views of patients and families/surrogates and to seek out Muslim clerics, imams (a mosque's prayer leader), or chaplains when possible for clarification and help with family communication.³²

Role of Religious Authority

It can be a challenge for religious Muslims to navigate the decidedly secular US health system and the approaches to care that characterize it. Muslims may wish to consult their imam or other knowledgeable Islamic practitioner for guidance in medical decision making.³² Although this person may not have any particular medical knowledge, this practitioner is called on to help with health care decisions, especially in the setting of severe illness.^{32,33} There is evidence that patient and family requests for religious guidance increased after the

9/11 attacks in New York City because of increased stress from discrimination. 5,34 Muslim chaplains, when available, can help patients reconcile faithful practice and health care decisions in advanced illness. 27 Additionally, and importantly, *fatwas*, or authoritative religious rulings by Islamic jurists, provide guidance for Islamic adherents regarding treatment or other health decisions. 5,35 Spiritual assessment plays a critical role in determining patients' and families' needs during advanced illness, 36 but knowledge of Muslim religious authorities' power is also critical to a broader understanding of how decisions are made.

Modesty

Modesty for women in Muslim practice transcends that of members of the opposite sex. Physical modesty for women, usually involving the physical covering of the body, signifies respect for self and devotion to and respect for Allah—one of the five pillars of Islam.²² Modesty in dress applies to men as well, but Muslim women are more iconic for their modest attire.³⁷ Modesty in one's affairs—language and actions—applies to both men and women and shows respect for society, interpersonal

relationships, and Allah.38 This includes refraining from vanity as well as unlawful or hurtful behavior. Although some non-Muslims may view aspects of this requirement to be extreme, such as Muslim women's wearing of the hijab (head/body cover variations), knowledge of its purpose is important in understanding Islam and, ultimately, providing culturally sensitive care. The experience of advanced or terminal illness adds another layer to this culturally and religiously embedded behavior, particularly for women. Losing the ability to be independent and care for others, requiring instead to be cared for in institutional settings, makes control of one's body and its image much more important.³⁹

Gender concordance of clinicians is linked to modesty as well. A Muslim woman or man may require that the treating clinician be the same sex as themselves. ⁴⁰ Honoring such a preference, a preference that may be shared by non-Muslims as well, will allow for optimal patient assessment and relief of suffering in advanced illness. Although a religious context may be discussed here, a patient's requirement or preference for gender concordance may reflect his/her culture, religion, or simply preference.

Recommendations for Culturally Sensitive Care to Muslim Patients with Advanced Illness

- Prayer: Make the clinical space more welcoming for prayer and Islamic faith, such as by turning immobile Muslim patients' beds toward Mecca for prayer, making Qur'ans and prayer rugs readily available, and removing any non-Islamic religious symbols.
- Medical Treatment: Avoid assumptions about Muslim patients' desire for medical treatment. Frankly explore the treatment options with patients and/or surrogate decision makers.
- Role of Religious Authority: Invite patients, if they wish, to consult their trusted religious leaders as they make decisions about their care.
- Modesty: Keep patients draped and provided with gowns or other materials to
 maintain modesty. Ask patients about their preference for same-sex clinicians and
 provide, if able. Otherwise, explore the patient's preference for a trusted chaperone to be present during examination or treatment.
- Advance Care Planning: Ask Muslim patients about their preferences for care should they become unable to make their own decisions and document these preferences in the medical record.
- Pain Management: Assess patients' pain adequately, describe the options available to relieve pain, and discuss the benefits and side effects of available treatments. If pain medication is desired or not, document the patient's choice in the medical record.
- Address Mental Health Needs: Advanced illness is associated with many emotional and mental health issues. Identify these issues and use the patient's religious faith to help address those needs. Resources are available in this regard.
- Koenig HG, Al Shohaib S. Islam and mental health [Internet]. Seattle, WA: Amazon: Create Space; 2017 [cited 2017 Mar 27]. Available from: www.amazon.com/dp/1544730330.

Health Decision Making and Advance Care Planning

The Muslim faith and the cultures in which the Muslim faith is practiced influence the way health care decisions, including advance care planning, are made. For example, Muslim families often share health decisions for individual family members, in effect rejecting the concept of autonomous decision making typically encouraged in US health care. 41,42 An imam may assist decision making as well through counsel and interpretation of Islamic teachings.³² Additionally, patients may prefer or request that a treating clinician is also Muslim and understands the characteristics of their faith.5 Delivering on such a request may not be possible in some settings; however, advance care planning done truly in advance of serious illness may allow time for patients to seek a suitable Muslim clinician. Whereas life, death, and suffering is determined by Allah according to the Qur'an (57.22), the Islamic Medical Association of North America, for example, encourages the use of advance care planning to prepare for future illness. Furthermore, Muslims are permitted to refuse treatment in the context of incurable diseases and to not have undesired treatments given to them.⁴³

Pain Management

First, optimal communication and supportive, empathetic care is essential in assisting pain treatment.44 Building on this necessary foundation, there are certain considerations for Muslim patients. Although a Muslim patient may very well desire pain management and although Islamic teachings view relief of suffering as virtuous,45 some Muslim patients may view suffering as a way to atone for their past sins. Counsel from an imam can assist this process and understanding. Furthermore, drugs that make thinking or decision making more difficult are generally eschewed, but may be accepted if the medical utility is explained to patients and families.²⁴ Obtaining informed consent before the administration of pain medication, although not a standard process in most US hospitals, documents the choice made.⁴⁶

CONCLUSIONS

Some programs may offer formal training on the intersection of health care and

Islam, but access is limited to certain professions such as physician trainees. 47 There is no clear evidence in the literature that a formalized training on Muslim culture is available for delivery to a multidisciplinary health care professional audience. Therefore, it is up to individual organizations to develop such a module with the help of knowledgeable Muslim community leaders. Indeed, it may be more efficient if several systems or societies (eg, American Medical Association and American Nurses Association) undertook a nonproprietary joint development that could then be borrowed by others. Interprofessional training focused on care in advanced illness for older Muslim patients might include a review of the following: The Five Pillars of Islam, Procedures Related to Prayer, Principles of Pain/ Symptom Management, Role of Family and Religious Leaders in Health Decisions, Islamic Definition of Death, Obligation to Preserve Life and the Exceptions, and Procedures Related to Death. 46,48 With the growing focus on interprofessional health professions education and interdisciplinary health care delivery,⁴⁹ it may be beneficial to add a Muslim clinician to the health care team in areas where there are substantial Muslim populations. Similarly, Muslim chaplains should be made available in health care facilities, working collaboratively with local imams and facility staff to respond to patients' needs.50

Actively determining Muslim patients' and families' needs should be a standard practice in health care institutions. Prayer needs, modesty requirements, approaches to decision making, need for a Muslim chaplain or liaison, and dietary requirements (ie, halal [prepared per Islamic law specifications] or vegetarian meals) are among a Muslim's concerns during a hospital stay or care during advanced illness. Directly asking and documenting these needs or obtaining answers via other screenings (eg, during registration, questionnaires on electronic tablets) will help Muslim patients of any age feel more welcome in US health care systems where secularization is usually the norm.

Community partnerships to improve the care of Muslim patients can also be encouraged. Partnering with mosques or Islamic centers or key community leaders, such as imams, can ease the tensions between the Muslim faith and Westernstyle health care delivery.^{32,51} Acknowledgment of the US population's religious diversity can be accomplished without personal or professional compromise, if that is a concern, by putting support and referral processes in place for Muslim patients with advanced illness.⁵² Resources offered by organizations such as the Islamic Medical Association of North America (https://imana.org) may be useful to hospitals or medical practices looking to improve the services delivered to their Muslim patients.

Responding to religious and spiritual diversity acknowledges the role that one's faith can play in coping with illness and making health care decisions and aligns clinician/health system practices with health care standards regarding cultural competence.⁵³ A critical step toward truly patient-centered care is honoring the possibility, and reality, that patients and families are often guided by faith in the context of largely secular health care. ❖

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CLINICAL MEDICINE

Use of a Technetium99m-Sestamibi Scan to Detect Ipsilateral Double Adenoma in a Patient with Primary Hyperparathyroidism: A Case Report

Joseph Gabriel Gabriel, MD; Alejandro Contreras, MD; Andrew Rosenthal, MD

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ABSTRACT

Introduction: Patients with primary hyperparathyroidism generally have a single parathyroid adenoma that causes excessive excretion of parathyroid hormone. For about 2% to 15% of these patients, a double adenoma is present that involves one lesion on each side of the neck.

Case Presentation: We describe a case of double parathyroid adenoma causing asymptomatic hypercalcemia. A presurgical technetium99m (Tc99m) sestamibi scan suggested an ipsilateral double adenoma in the left thyroid lobe. An intraoperative parathyroid hormone assay confirmed its successful removal.

Discussion: Although double adenomas are not yet widely acknowledged, presurgical imaging and nuclear scans can help to localize multiple lesions, and intraoperative parathyroid hormone assays can confirm the diagnosis and cure.

INTRODUCTION

Primary hyperparathyroidism (PHPT) is the most common cause of hypercalcemia in the US.¹ Most cases can be explained by a single parathyroid adenoma, defined as a solitary neoplastic lesion bordered by normal parathyroid tissue, which is followed by 4-gland hyperplasia and, rarely, parathyroid carcinoma.² Small subsets (2%-15%) of PHPT contain 2 solitary adenomas as seen during explorative parathyroidectomy, however. The double adenoma (DA) remains controversial among investigators, some of whom deny its existence. This report looks at a patient with asymptomatic hypercalcemia that was caused by an elusive DA. The DA was discovered with use of a technetium99m (Tc99m) sestamibi scan and successfully removed as seen by a decline in intraoperative parathyroid hormone (IOPTH) levels.

CASE PRESENTATION

A 63-year-old white man was referred to the surgical team for asymptomatic hypercalcemia of 12.9 mg/dL (reference range [rr], 8.4-10.2 mg/dL). His primary care physician first recognized his elevated calcium level 2 years before this referral. During previous visits to his primary care physician, the patient did not have signs and symptoms of hypercalcemia, and, aside from his hypertension, was otherwise healthy. Presurgical ultrasonography imaging studies suggested a normal-appearing thyroid gland with 2 hypoechoic well-defined masses seen posterior to the left lobe, the larger

of which measured 2.5 cm. The patient underwent a standard Tc99m-sestamibi scan that revealed heterogenous delayed persistent tracer localization in the left upper and lower parathyroid regions, which could indicate a multifocal parathyroid adenoma (Figure 1). Of note, the patient's presurgical serum calcium and intact parathyroid hormone (iPTH) levels were 13.3 mg/dL and 354 pg/mL (rr, 8.4-10.2 mg/dL and 15-65 pg/mL), respectively.

During an elective parathyroidectomy, the thyroid gland was found to be grossly normal. An inferior adenoma (0.85 g) in the left lobe was removed for frozen section analysis.

A left-sided superior parathyroid adenoma (2.5 g) was also discovered and sent for confirmation. Frozen sections of both specimens confirmed hypercellular parathyroid tissues. Electrochemiluminescence immunoassay was used to measure IOPTH levels. A drop in iPTH from 397 pg/mL to 169 pg/mL was seen 13 minutes after the second adenoma was removed. A subsequent drop to 118 pg/mL occurred 5 minutes later, representing a 70% decline and appropriate treatment of the disease. The patient was discharged to home the next day. No further evidence of hypercalcemia was noted at 3-month follow-up, and his serum calcium levels remained stable at 9.6 mg/dL. Long-term follow-up included a measured iPTH of 42 pg/mL approximately 1 year later, which remained within defined limits.

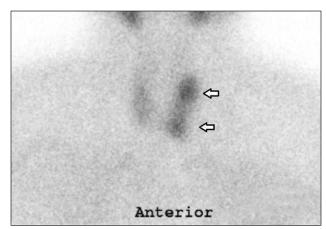


Figure 1. An early 26mCi Tc99m-sestamibi scan showing a left-sided multifocal parathyroid adenoma (arrows).

Joseph Gabriel Gabriel, MD, is a Resident in Internal Medicine at the East Tennessee State University James H Quillen College of Medicine in Johnson City. E-mail: gabriel@etsu.edu. Alejandro Contreras, MD, is a Resident in Surgery at the Baystate Medical Center in Springfield, MA. E-mail: alejandro.cont85@gmail.com.

Andrew Rosenthal, MD, is the Associate Director of Trauma Services at Memorial Regional Hospital in Hollywood, FL. E-mail: rasolomon@mbs.net.

Use of a Technetium99m-Sestamibi Scan to Detect Ipsilateral Double Adenoma in a Patient with Primary Hyperparathyroidism: A Case Report

DISCUSSION

PHPT is the most common cause of hypercalcemia.¹ This is especially relevant when a patient's elevated calcium level is an incidental finding. With the addition of serum calcium level on standard chemistry panels in 1974, there was an increase in documented US PHPT incidence; approximately 22 cases per 100,000 people per year were identified between 1993 and 2001.¹

For 87% to 91% of patients with PHPT, a single adenoma is the culprit.² The remaining cases are caused by 4-gland hyperplasia (10% to 15%) and the controversial DA.¹.² Some researchers continue to doubt the existence of DAs and regard them as uneven multiglandular hyperplasia.² However, studies confirm the presence of DAs in 2% to 15% of patients undergoing parathyroid explorations; often, one is located on each side of the neck.².³ A 2009 retrospective review² described the occurrence of DAs in 47 of 552 patients (8.5%), whereas a 2002 article⁴ described 44 of 401 patients (11%) with DAs who were undergoing consecutive conventional parathyroid explorations.

Of note, the standard surgical approach is to investigate the neck, remove abnormal parathyroid gland tissue, and send the sample for intraoperative frozen section.⁵ This method, however, fails to detect all abnormal tissue in some cases of multiglandular disease, with discrepancies between the frozen section and the definitive histology in up to 10% of cases.^{3,5} As a result, the use of minimally invasive parathyroidectomy is increasing. Presurgical localization of adenomas with ultrasound imaging and Tc99msestamibi scans is used with consideration of IOPTH level to confirm removal of these lesions.3 A decrease of at least 50% in perioperative iPTH suggests likely biochemical cure.² In a 2010 clinical study,3 use of IOPTH level helped physicians identify a DA that was missed by presurgical scans; IOPTH level was associated with 100% sensitivity in detection compared with ultrasound or nuclear imaging alone (15% of DAs are missed).3 Case reports appear to confirm that IOPTH level can serve as an accurate predictor of cure in combination with presurgical scanning to help physicians prevent unsuccessful outcomes, surgical reexploration, and unnecessary patient costs.^{2,3} Despite these advantages, the use of IOPTH level is not yet widely accepted in the management of PHPT.³ Concerns include increases in minimally invasive parathyroidectomy surgery time, cost, and reports of false-negative rates in other studies. Nevertheless, IOPTH level assessment should remain part of the arsenal in PHPT treatment.^{3,6}

CONCLUSION

This report describes a case of PHPT that was caused by a DA and identified with a presurgical Tc99m-sestamibi scan. The result was a 70% decline in IOPTH levels after excision. Although DAs are not universally recognized, physicians should be cognizant about the possibility that DAs can (rarely) cause PHPT. Presurgical testing that includes a Tc99m-sestamibi scan and IOPTH level is necessary to maximize successful outcomes. ❖

Disclosure Statement

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Experience

The art of the practice of medicine is to be learned only by experience, 'tis not an inheritance; it cannot be revealed.

 William Osler, MD, 1849-1919, physician, pathologist, teacher, diagnostician, bibliophile, historian, classicist, essayist, conservationalist, organizer, manager, and author



Plitvice Falls Boardwalk Panorama photograph

David D Clarke, MD

This photograph was taken from a boardwalk in Plitvice Lakes National Park in central Croatia. The almost 300-square kilometer forest reserve features waterfalls, terraced lakes, and trails and walkways. The reserve was designated a UNESCO World Heritage site in 1979.

Dr Clarke is President of the Psychophysiologic Disorders Association and Assistant Director at the Center for Ethics at Oregon Health & Sciences University in Portland. More of his photographs can be seen in this and other issues of The Permanente Journal.

CLINICAL MEDICINE

A Clinical Approach to Animal Bites with an Avulsion Flap: A Case Report

Andrew Williamson, MD; Cyril Thomas, MS, PA-C

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ABSTRACT

Introduction: Animal bites are a common reason for visits to the Emergency Department in the US and worldwide. There are many different approaches to managing these wounds.

Case Presentation: We present a case of a 90-year-old white woman who sustained a large dog bite to her hand, over the dorsal aspect of the first metacarpal. We used the avulsion flap as a biologic dressing and employed a perforating technique to successfully treat the wound and allow for optimal wound healing.

Discussion: Pitfalls to this dog bite management approach include the risk of infection and flap necrosis. Patients must obtain proper follow-up in 24 to 72 hours to reevaluate the wound. To optimize outcomes, comorbidities, location of the bite, complexity of the bite wound, and the risks of infection must be considered when one is choosing the best approach.

INTRODUCTION

Animal bites are a common chief complaint seen in the Emergency Department (ED) and urgent care centers. There are many different approaches and considerations in the management of these wounds. It is always important to consider and identify the best approach to allow for maximal wound healing and to reduce the risk of infection as much as possible. We present one possible approach to treating a patient with a dog bite who had an avulsion flap that was used as a biologic dressing, allowing for optimal wound healing.

CASE PRESENTATION Presenting Concerns

A 90-year-old white woman came to our ED less than 1 hour after sustaining a dog bite to her nondominant hand. There was a $4 \text{ cm} \times 1 \text{ cm}$, gaping wound over the dorsal aspect of the first metacarpal. Of note, there was a large full-thickness avulsion flap attached distally (Figure 1).

Radiographs confirmed that the patient did not have an acute fracture or retained a foreign body.

Therapeutic Intervention and Treatment

The decision was made to reapproximate the skin flap loosely using 4.0 single interrupted nylon sutures. We ultimately elected to use a fenestration technique. With use of an 18-gauge needle, multiple puncture wounds were made in the skin flap. The skin flap was loosely reapproximated, to allow the wound to drain while providing the best biologic dressing, with fenestrations in the skin flap (Figure 2). A pressure dressing was applied using petrolatum and 3% bismuth tribromophenate-infused gauze dressing, a woven gauze bandage, and a splint.

Follow-up and Outcomes

On Day 13, the patient returned for a scheduled wound recheck. The flap continued to be viable without signs of skin necrosis (Figure 3).

On Day 19, the decision was made to remove the woman's sutures despite some concerns for possible epidermolysis of the skin flap (Figure 4). The wound was gently cleaned using hydrogen peroxide. Another pressure dressing and a splint were reapplied.



Figure 1. There was a 4 cm × 1 cm wound over the dorsal aspect of the first metacarpal. There was also a large full-thickness avulsion flap attached distally.



Figure 2. The skin flap was loosely reapproximated to the skin edges, avoiding tension on the flap. Small fenestrations were made with an 18-gauge needle in the skin flap.



Figure 3. The skin flap continued to be viable without signs of skin necrosis on Day 13 after treatment.

Andrew Williamson, MD, is an Emergency Physician at the San Diego Medical Center in CA. E-mail: andrew.t.williamson@kp.org. **Cyril Thomas, MS, PA-C,** is a Physician Assistant in the Emergency Department at the San Diego Medical Center in CA. E-mail: erpa911@gmail.com.



Figure 4. Sutures were removed on Day 19.



Figure 5. The wound was almost completely healed and the skin flap was viable on Day 29.

On Day 29, the wound was almost completely healed and the skin flap was viable (Figure 5). A timeline of the case is shown in Table 1.

DISCUSSION

Complex dog bite wounds are often seen for the first time in the ED. Primary closure of a dog bite wound remains controversial. This case offered several challenges in the decision making of the proper wound care of a dog bite. The first was the advanced age of the patient. Second was the location of the bite on the hand. Last, the wound involved a large skin flap avulsion. Fortunately, despite her advanced age, this patient was very healthy.

There are several comorbidities that one must consider when choosing the ideal method of closure. In a diabetic, immune-compromised, or malnourished elderly patient, our approach would have been different. In these patients, wound healing is often impaired, and therefore keeping the wound open to drain and allowing the wound to heal by secondary intention or delayed closure would most likely be a better alternative. It is important to

avoid primary closure of wounds that are at high risk of infection.¹

The time to presentation to the ED or urgent care center is another important consideration. In this case, the patient presented to our ED within 1 hour of the time of injury. Previous studies have shown that the rate of infection increases from 4.5% to 22.2% if the patient seeks medical attention after 8 hours. Therefore, primary closure should be avoided in patients who have a delayed presentation to the ED.

Other considerations include débridement of the wound. Wounds should be irrigated thoroughly and inspected for necrotic tissue. Débridement of any devitalized tissue should be considered. General surgical consultation should be obtained in patients with deep wounds, signs of abscess, or evidence of deep-tissue infection. These patients may benefit from extensive washout or operative management.³ Furthermore, complex facial bite wounds or complex pediatric wounds often warrant plastic surgery consultation to improve cosmetic outcomes and reduce scarring.⁴

Prophylactic antibiotics should be considered in patients with dog bite wounds. There are several common organisms in the oral flora of dogs. *Pasteurella* species are isolated from 50% of dog bite wounds and 75% of cat bite wounds. Other considerations are gram-negative organisms as well as common skin flora such as staphylococci and streptococci. Amoxicillin-clavulanate is often a good choice for antibiotic coverage in these patients given the common organisms. Furthermore, tetanus prophylaxis should be considered in all patients with open wounds.

CONCLUSION

This case provides one approach to managing dog bites. Some pitfalls to this approach include the risk of infection and flap necrosis. It is important that patients obtain proper follow-up in 24 to 72 hours to reevaluate the wound. There are many factors involved in wound management, as discussed earlier. To optimize outcomes, comorbidities, patient population, location of the bite, complexity of the bite wound, and the risks of infection must be considered when one is choosing the best approach. �

Table 1. Timeline of the case				
Day	Event			
0	Patient presented with dog bite to hand			
13	Patient presented for wound check; flap remained viable without signs of infection			
19	Suture removal			
29	Wound almost completely healed			

Disclosure Statement

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CLINICAL MEDICINE

Splenic Abscess in Immunocompetent Patients Managed Primarily without Splenectomy: A Series of 7 Cases

S Divyashree, MBBS, MD; Nikhil Gupta, MBBS, MD

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ABSTRACT

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Introduction: Splenic abscesses are rare in immunocompetent adults. Despite advances in diagnosis and treatment, these abscesses are still potentially life threatening. Various factors have been reported to predispose otherwise immunocompetent adults to splenic abscesses. Splenectomy was once considered the "gold standard" treatment. However, the trend is shifting to a conservative approach.

Case Description: We describe seven cases of splenic abscess in immunocompetent adults, the cause of which ranged from tuberculosis to salmonella and was as rare as *Plasmodium vivax*. All the patients presented with fever (median duration = one month; range = one week to six years) and abdominal pain, and most also had weight loss. All patients were in their third to fifth decades of life. The patients were successfully treated with appropriate antibiotic therapy, after which they were clinically normal.

Discussion: A microbiological diagnosis of splenic abscess is of utmost importance. In this series, all patients underwent percutaneous aspiration. This was performed under radiologic guidance (either ultrasonography or computed tomography). Only one patient required diagnostic splenectomy. Irrespective of whatever surgical or nonsurgical drainage measures are employed, appropriate antibiotic therapy is the cornerstone of management. The dose and duration of antibiotic therapy depend on the causative organism and its sensitivity pattern.

INTRODUCTION

Splenic abscess is a rare entity, especially in developed countries. 1-6 On autopsy, the incidence of splenic abscess ranges between 0.14% and 0.7%. The causative microorganisms can be very diverse. Splenic abscess is uncommon among immunocompetent adults. Recognized risk factors in such patients include conditions such as infective endocarditis, diabetes mellitus, trauma, intravenous drug abuse, and hemoglobinopathies. Splenectomy was once considered the gold standard treatment. However, the trend is shifting to a conservative approach. Here, we report a series of 7 cases of splenic abscess in immunocompetent hosts. We emphasize the importance of obtaining an accurate microbiological diagnosis and discuss key management issues.

CASE PRESENTATIONS

Case

A 20-year-old man, a resident of Uttar Pradesh, India, was seen in the Medicine Outpatient Department because of complaints of left upper quadrant abdominal pain associated with low-grade fever and weight loss for the last month. The pain was a continuous, dull aching without any aggravating or relieving factor. He had a history of pulmonary tuberculosis 6 years earlier, which was treated with antituberculous therapy (ATT) for 6 months. He had been completely asymptomatic since then. There was no other remarkable medical history. On physical examination, he was febrile with a temperature of 37.8°C (100°F). On abdominal examination, the only abnormal finding was a palpable spleen tip. The remaining examination findings were normal.

His complete blood cell counts and liver function and kidney function test results were normal. The erythrocyte sedimentation rate was elevated to 80 mm in the first minute. An enzyme-linked immunosorbent assay (ELISA) was negative for human immunodeficiency virus (HIV). Markers for viral hepatitis were negative. A blood culture was negative for bacteria and fungus. Stool examination did not reveal any parasite. A Mantoux test using 10 IU of purified protein derivative showed a 15-mm induration at 48 hours. Chest radiography and echocardiography results were normal. Contrast-enhanced computed tomography (CT) scan of the abdomen showed mild splenomegaly with a single 2 cm × 2 cm, hypodense cystic lesion, likely to be a splenic abscess. He underwent a diagnostic CT-guided aspiration. The aspirate was positive for acid-fast bacilli, and cultures yielded *Mycobacterium tuberculosis*.

He was started on a regimen of ATT, after which his symptoms started to improve, and he became asymptomatic after a month of therapy. The patient was given Category 1 ATT (Revised National Tuberculosis Control Program) for 9 months, after which he was completely normal. Ultrasonography was repeated, and the result showed resolution of the abscess.

Case 2

A 30-year-old woman, who was a resident of Delhi, India, presented to our Medical Outpatient Department with high-grade continuous fever with chills and rigors and left upper quadrant abdominal pain of 2-week duration. There was no other unusual history. On physical examination, she was febrile with a temperature of 38.9°C (102°F). Abdominal examination

S Divyashree, MBBS, MD, is a former Assistant Professor of Medicine at the MS Ramaiah Medical College in Banagluru, Karnataka, India. E-mail: doc.divyashree@gmail.com. **Nikhil Gupta, MBBS, MD,** is a Fellow in Clinical Immunology & Rheumatology at the Christian Medical College in Vellore, India. E-mail: drnikhilguptamamc@gmail.com.

found normal results. The rest of the examination findings were also unremarkable.

Her complete blood cell counts and liver and kidney function test results were normal. An ELISA test for HIV was negative. Stool examination had a normal result. Chest radiography and echocardiography also showed normal results. The Widal test and a blood culture were negative. Contrast-enhanced CT of the abdomen showed multiple hypodense, cystic lesions, with the largest measuring $2~{\rm cm}\times 1~{\rm cm}$, likely to be splenic abscesses. The largest of these was aspirated by a CT-guided procedure. Gram staining revealed gram-negative bacilli. Cultures yielded Salmonella typhi.

She was given intravenous antibiotics (ceftriaxone 1 g every 12 hours) and prescribed oral ofloxacin, 400 mg twice daily for 3 weeks. Subsequently, she received oral cefixime, 200 mg, and ofloxacin, 400 mg, both twice daily for 3 more weeks. She responded well to treatment, and symptoms completely resolved over 2 weeks. An ultrasonogram after 6 weeks showed resolution of the splenic abscess.

Case 3

A 32-year-old woman, a resident of Delhi, India, presented to the Medical Emergency Department with high-grade intermittent fever with chills and rigors and left upper quadrant abdominal pain of 1-week duration. There was no other unusual history. On physical examination, she was febrile with a temperature of 40°C (104°F). On abdominal examination, the only abnormal finding was splenomegaly. The rest of the examination findings were unremarkable.

Her complete blood cell counts and liver function and kidney function test results were normal. An ELISA test for HIV was negative. Chest radiography and echocardiography had normal findings. An antigen test for *Plasmodium vivax* malarial parasite was positive. Contrast-enhanced CT examination of the abdomen showed splenomegaly, with single hypodense cystic lesions measuring $2~\rm cm \times 3~cm$, likely to be splenic abscesses. This was aspirated by a CT-guided procedure. The aspiration was negative for gram stain and acid-fast bacillus. A culture was sterile.

The patient was given intravenous artesunate and oral doxycycline, after which she improved completely. After treatment, a repeated ultrasonogram showed resolution of *P vivax* infection.

Case 4

A 44-year-old man from West Bengal, India, presented to our institute with intermittent fever of 3-month duration and abdominal pain of 2-week duration. He also had a documented weight loss of 6 kg during the previous 3 months. His medical history contained nothing abnormal. Physical examination findings revealed splenomegaly with ascites.

Abdominal ultrasonography showed multiple hypoechoic splenic lesions, with the largest measuring $2.3~\rm cm \times 1.7~\rm cm$. These findings were confirmed by CT scan (Figure 1). Three blood cultures were negative for bacteria and fungus. Echocardiography demonstrated normal results. Diagnostic aspiration from the splenic abscess was performed, and cultures yielded pansensitive *Escherichia coli*.

He received ceftriaxone therapy for eight weeks, followed by eight weeks of oral cotrimoxazole treatment. He was clinically better by two weeks from initiation of treatment and made a complete clinical recovery by the end of eight weeks of treatment. Abdominal ultrasonography one month after the start of intravenous antibiotic therapy showed incomplete resolution of the abscess. By the end of four months of therapy, there was complete resolution on the ultrasonogram. Four months after the end of antibiotic treatment, he has not had a recurrence of splenic abscess and remains in good health.

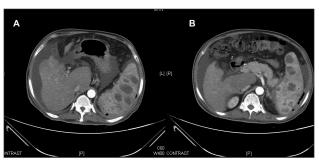


Figure 1. Abdominal computed tomography scans (A, B) showing multiple splenic abscesses. Note markedly irregular liver outline and ascites suggestive of chronic liver disease.

Case 5

A 36-year-old woman from Jharkhand, India, presented to us with a 3-week history of fever, abdominal pain, and unquantified weight loss. She had no unusual findings in her medical history. Examination revealed that she was febrile and had hepatosplenomegaly (palpable 3 cm and 5 cm below the costal margin).

Abdominal ultrasonography showed hypoechoic splenic lesions, predominantly located peripherally. These features suggested a splenic abscess. A CT scan performed for further characterization of these lesions showed multiple, predominantly peripheral irregular lesions, with the largest measuring 51 mm × 59 mm (Figure 2A). Three blood cultures were negative for bacteria and fungus. She was seronegative for HIV. Cultures from the splenic aspirate yielded quinolone-resistant *S typhi*.

She was treated with intravenous ceftriaxone for two weeks along with oral azithromycin for six months. She recovered clinically, with resolution of the abscess on the subsequent ultrasonogram (Figure 2B).

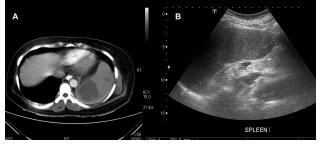


Figure 2. (A) Pretreatment computed tomography scan showing the largest splenic lesion and another lesion superior to it. (B) Ultrasonogram three months after initiation of treatment shows resolution of the lesion.

Case 6

A 36-year-old man from Andhra Pradesh, India, and an agriculturist by occupation came to our hospital with fever, abdominal pain, and weight loss (8 kg) of 3-month duration. He denied any prior illnesses, drug abuse, or extramarital sexual exposures. Clinical examination findings were unremarkable except for hepatosplenomegaly.

An ELISA for HIV was negative. Ultrasonography showed a single 8.9 cm × 6.0 cm splenic abscess with abdominal adenopathy. CT-guided diagnostic aspiration was performed (Figure 3). Cultures from the splenic aspirate did not yield a causative organism. A diagnostic splenectomy was done, cultures from which yielded *Burkholderia pseudomallei*. Postoperatively, a surgical site infection developed, and cultures also yielded the same organism. Sensitivity testing showed resistance to cotrimoxazole and aminoglycosides.

He was treated with 6 weeks of intravenous ceftazidime along with 12 weeks of oral cotrimoxazole and doxycycline. At end of 18 weeks of therapy, he was clinically well without any residual or recurrent collection on ultrasonography.

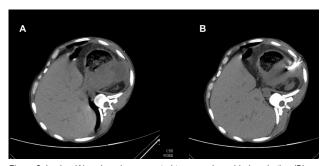


Figure 3. Lesion (A) undergoing computed tomography-guided aspiration (B).

Case 7

A 44-year-old diabetic man from Bangladesh presented to our Medicine Outpatient Department with a 6-year history of fever and abdominal pain and had lost about 18 kg of weight in the same period. He was a long-term smoker but denied alcoholism or other forms of drug abuse. His general physical examination findings were unremarkable except for hepatomegaly of 6 cm. On abdominal examination, the only abnormal finding was a palpable spleen tip.

Ultrasonography showed multiple splenic abscesses, the largest of which measured $1.2 \text{ cm} \times 1.1 \text{ cm}$. Three blood cultures taken on three successive days were negative for aerobic and anerobic bacteria. Cultures from the splenic aspirate yielded *B pseudomallei*. On further evaluation, he was found to have hypocomplementemia (serum complement < 60% of normal).

He received ceftazidime therapy for four weeks, after which he was prescribed oral cotrimoxazole and doxycycline. He was lost to follow-up after completion of four weeks of intravenous antibiotic treatment, at which time he was clinically well.

All cases are summarized in Table 1.

DISCUSSION

Splenic abscess is an uncommon entity among immunocompetent adults. As noted previously, the autopsy incidence of splenic abscess ranges from 0.1% to 0.7%.⁷ Infective endocarditis, diabetes mellitus, trauma, intravenous drug abuse, and hemoglobinopathies are some of the reported predisposing factors in immunocompetent adults.^{9,10} Infective endocarditis seems to be the most common among these.

The spectrum of organisms that can cause splenic abscess is very large and has tended to change over time. An American study conducted nearly 3 decades ago found that anaerobes were more common as causative organisms than the aerobes;

Table 1. Summary of cases of splenic abscesses in immunocompetent adults											
Case no.	Age/ Sex	Fever	Weight loss	Duration of symptoms	Abscess, single or multiple	Blood culture	Diagnostic test performed	Causative organism	Treatment	Clinical recovery	Radiologic resolution documented
1	20/M	Yes	Yes	1 month	Single	Negative	Aspiration	Mycobacterium tuberculosis	ATT	Yes	Yes
2	30/W	Yes	No	2 weeks	Multiple	Negative	Aspiration	Salmonella typhi	Aspiration + antibiotics	Yes	Yes
3	32/W	Yes	No	1 week	Single	Negative	Serology for Plasmodium vivax	P vivax	Antimalarials	Yes	Yes
4	44/M	Yes	Yes	3 months	Multiple	Negative	Aspiration	Escherichia coli	Aspiration + Antibiotics	Yes	Yes
5	36/W	Yes	Yes	3 weeks	Multiple	Negative	Aspiration	S typhi	Aspiration + Antibiotics	Yes	Yes
6	36/M	Yes	Yes	3 months	Single	Negative	Splenectomy	Burkholderia pseudomallei	Splenectomy + Antibiotics	Yes	Not applicable (splenectomy)
7	44/M	Yes	Yes	6 years	Multiple	Negative	Aspiration	B pseudomallei	Aspiration + Antibiotics	Yes	Lost to follow-up

ATT = antituberculous therapy; M = man; W = woman.

among the aerobes, E coli was the most common isolate.8 Other studies published in the past 17 years also noted that gram-negative organisms were the most common causative organisms.^{1,2} However, a more recent study from Pakistan found that gram-positive organisms were more than twice as common as gram-negative organisms. 9 Polymicrobial flora is responsible for at least 10% to 15% of patients with splenic abscess.^{3,11-14} Negative culture from splenic abscess have been reported in up to 30% of cases,11 which may reflect prior antibiotic use or fastidious organisms. Apart from these, cases of splenic abscess caused by Mycobacteria, 15 Brucella, 16 Coxiella burnetti, 17 Bartonella, 18 and other organisms (eg, Candida 19 and Actinomyces²⁰) have also been reported. Similar to other studies, our series also highlights a multitude of causative organisms. Collectively, these data point to the extremely diverse microbiology of splenic abscesses and suggest that establishing a microbiological diagnosis is of paramount importance. The causes of splenic abscesses are listed in Sidebar: Causative Organisms for Splenic Abscesses.

The clinical presentation of our series of patients with splenic abscesses is not different from that of other studies. All our patients were in their third to fifth decades of life. All patients

Causative Organisms for Splenic Abscesses

Aerobic gram-positive bacteria

Streptococci

Staphylococci

Enterococci

Aerobic gram-negative bacteria

Escherichia coli

Klebsiella pneumoniae

Pseudomonas aeruginosa

Proteus mirabilis

Serratia marcescens

Salmonella

Anaerobic bacteria and facultative anaerobes

Peptostreptococci and microaerophilic streptococci

Clostridium

Fusobacterium

Bacteroides

Prevotella

Propionibacterium acnes

Morganella morganii

Other bacterial causes

Burkholderia pseudomallei

Brucella

Coxiella burnetii

Bartonella

Actinomyces

Mycobacteria

Fungi

Candida

Parasites

Plasmodia

had fever and abdominal pain, and most (five) also had weight loss. The median duration of symptoms was one month (range = one week to six years). Several other studies from Asia have reported similar findings. 9,21,22

For establishing the microbiological diagnosis, we used blood cultures and percutaneous diagnostic aspiration for all patients. None of our patients had a positive bacterial blood culture. This is in contrast to some reports suggesting that blood cultures may be positive in about half of the patients with splenic abscess.8 Diagnostic aspiration was performed under radiologic guidance (either ultrasonography or CT). None of our patients had any procedural complications, and the diagnostic yield was high. Only one patient (who had a negative culture of the diagnostic aspirate) needed a diagnostic splenectomy. With the availability of more advanced diagnostic modalities, diagnostic splenectomy is now rarely needed. Other useful methods of diagnosis include serologic analysis,²¹ which may be useful particularly for Coxiella burnetti. 17 There are no data on the acid-fast bacillus positivity in patients with splenic abscess. In our series, serologic analysis for *P vivax* was useful in one patient.

From a therapeutic perspective, splenectomy was previously considered the gold standard.² Some of the recent reports also mention splenectomy as the common initial treatment.¹⁰ However, the need for splenectomy as a primary modality has been questioned by several recent studies showing that conservative management (ie, antibiotics with or without percutaneous drainage) is possible.^{9,21} In these studies, only about 18% to 22% of patients required therapeutic splenectomy. Approximately 80% of the patients were managed conservatively. Whether splenectomy should be done as a primary treatment modality or only in event of failure of antibiotic therapy remains unclear, and both of these approaches have been followed.^{2,9,21} In our series, no patient needed a therapeutic splenectomy.

Far less debatable is the role of antibiotics in these patients. Irrespective of whatever surgical or nonsurgical drainage measures are employed, appropriate antibiotic therapy is the cornerstone of management. The dose and duration of antibiotic therapy depend on the causative organism and its sensitivity pattern, thereby bringing us to stress again the need to establish a clear microbiological diagnosis. There is no guideline to suggest the duration of ATT in patients with tubercular splenic abscess. We propose that all patients with splenic abscess be evaluated for underlying predisposing conditions and multiple blood cultures be obtained. If the blood cultures identify the causative organism and the imaging (ultrasonography or CT) shows features of evolving abscess, an appropriate antibiotic regimen should be started. This subset of patients with evolving splenic abscess and one or more organisms identified by blood culture may not need splenic aspiration. For all other patients (ie, those without an identified organism and those with fully established splenic abscess), splenic aspiration (diagnostic and/ or therapeutic) is necessary, followed by appropriate antibiotic treatment. The duration of antibiotics is often prolonged and depends on the causative organism or organisms, the clinical improvement, and resolution on radiologic images.

CONCLUSION

Splenic abscesses are rare in immunocompetent adults. Most of these so-called immunocompetent adults might have a predisposing factor. The spectrum of causative organisms is very diverse. Diagnostic aspiration is safe and has a high yield in establishing the diagnosis. Appropriate antibiotics with appropriate duration (along with percutaneous drainage as needed) are the mainstay of therapy. Splenectomy is rarely necessary for treatment. If splenic abscess is diagnosed and treated appropriately, the mortality of this potentially catastrophic condition can be reduced. •

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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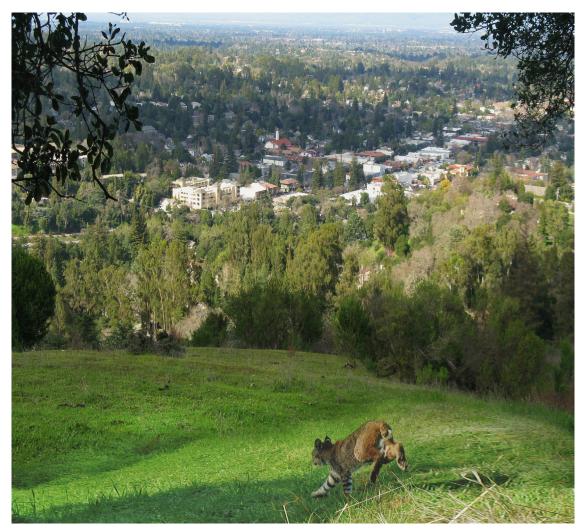
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Of No Use

On attentive Enquiry into the Office of that Organ [the spleen], it evidently appears to me, that it was not formed for the Benefit and Preservation of the Animal, of which it is a Part; and therefore it is of no use at all in respect of the Individual I myself have opened the Side of a Dog, and torn off with my Fingers the Spleen from the Parts to which it grew; yet without so much as tying up the Vessels, the Wound in the Side being sowed up, the Creature soon recovered, and shewed no sign of any Damage.

— Sir Richard Blackmore, 1654-1729, English poet, religious and political writer, and physician



Bobcat, Los Gatos, California photograph

J Richard Gaskill, MD

Los Gatos, CA, was named for the many bobcats and mountain lions that used to roam the area. A few still remain. Here is one romping through the hills overlooking downtown Los Gatos.

Dr Gaskill is a retired Otolaryngologist from the Santa Clara Medical Center in CA.

CLINICAL MEDICINE

Flood Syndrome: Spontaneous Umbilical Hernia Rupture Leaking Ascitic Fluid—A Case Report

Emilie T Nguyen, MD; Leah A Tudtud-Hans, MD

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https://doi.org/10.7812/TPP/16-152

ABSTRACT

E-pub: 06/26/2017

Introduction: We report a rare case of Flood syndrome, which is a spontaneous rupture of an umbilical hernia.

Case Presentation: A 42-year-old man with decompensated hepatitis C and alcoholic cirrhosis complicated by ascites and esophageal varices presented with 1 day of ascitic fluid drainage after rupture of a preexisting umbilical hernia associated with diffuse abdominal pain and tenderness. A pigtail drain was placed in the right upper abdominal quadrant to decrease fluid drainage from the abdominal wall defect, allowing it to heal naturally.

Discussion: The spontaneous rupture of an umbilical hernia in our patient highlights a rare complication with high mortality rates and stresses the challenge of treatment that falls in the area between medical and surgical management.

INTRODUCTION

This case report presents the challenge in management of patients with Flood syndrome, the eponym for spontaneous umbilical hernia rupture, which is a rare yet potentially serious complication of the massive ascites in cirrhotic patients. Medical management of these patients can be difficult because of electrolyte abnormalities and medical comorbidities. Surgical intervention is often precluded by the high mortality risk in patients with decompensated cirrhosis. This poses the question of how to treat these patients and prevent the development of peritonitis through an open defect in the abdominal wall. We present a case of Flood syndrome managed with an interventional radiology procedure of a pigtail drain placed in the right upper abdominal quadrant.

CASE PRESENTATION Presenting Concerns

A 42-year-old Hispanic man with decompensated hepatitis C and alcoholic cirrhosis (Child-Pugh Grade B, Model for End-stage Liver Disease Score = 15) complicated by ascites and esophageal varices presented to the Emergency Department with 1 day of ascitic fluid drainage after rupture of a preexisting umbilical hernia associated with diffuse abdominal pain and tenderness. The patient had previously received weekly paracentesis, during which 10L to 15L of fluid was removed each time. Physical examination revealed a tender, compressible umbilical hernia with ulceration of the overlying skin, draining straw-colored ascitic fluid (Figure 1). He was admitted to the



Figure 1. Photograph of the abdomen showing a tender, compressible umbilical hernia with ulceration of the overlying skin.

Internal Medicine service for medical management. The patient was afebrile during this admission, with mild hypotension and otherwise normal vital signs. After evaluation, a transplant surgeon and a general surgeon deemed the patient unfit for any surgical closure of the abdominal wall defect. In addition, he was not a candidate for a transjugular intrahepatic portosystemic shunt procedure. The patient reported that he was still drinking alcohol, and thus he was not a candidate for a liver transplant.

Therapeutic Intervention and Treatment

Initially, an ostomy bag was placed over the hernia for hygiene and to collect the one to three liters of ascitic fluid drainage each day. Optimal medical management with diuretics for ascitic fluid control was attempted but was precluded by hyperkalemia and hypotension. The patient was subsequently started on midodrine therapy for his hypotension and given a low-sodium, low-potassium diet. Although the ascitic fluid results did not meet the criteria for spontaneous bacterial peritonitis, the patient was treated with cefotaxime because the clinical picture was consistent with peritonitis. His diffuse abdominal pain resolved after he completed the course of antibiotics.

The transplant surgeon recommended placement of a peritoneal pigtail drain, which was subsequently positioned by an interventional radiologist in the right upper abdominal quadrant. On the day of discharge, there was no ascitic fluid draining

Emilie T Nguyen, MD, is a Radiology resident in the Department of Diagnostic Imaging at the Los Angeles Medical Center in CA. E-mail: emilie.t.nguyen@kp.org. Leah A Tudtud-Hans, MD, is an Associate Chair for Continuing Medical Education and an Associate Professor of Medicine at the Loma Linda University School of Medicine in CA. E-mail: ltudtudh@llu.edu.

from the umbilical hernia defect. The pigtail drain continued to drain clear, straw-colored fluid. The plan was to remove the pigtail drain after two weeks in the outpatient setting, once the umbilical hernia ulceration had healed. The patient was discharged with a prescribed regimen of sulfamethoxazole and trimethoprim daily for prophylaxis of spontaneous bacterial peritonitis.

Follow-up and Outcomes

Unfortunately, the patient canceled two subsequent appointments, and six weeks after discharge he presented to the Emergency Department for suspected peritonitis. The pigtail drain was still intact, and his umbilical hernia skin ulceration had healed and no longer drained ascitic fluid. The pigtail drain was removed without any continued leakage of ascitic fluid. The patient was treated with a course of antibiotics, which resolved his symptoms.

DISCUSSION

Flood syndrome, the eponym for spontaneous umbilical hernia rupture, is an unusual yet potentially serious complication of end-stage liver disease with ascites that has a high mortality rate of 30%. ^{1,3} It was first reported in 1961 by Frank B Flood⁴ during his residency. The combination of increased intraabdominal pressure and the inherently weakened abdominal wall at the linea alba in the umbilical region causes the formation of umbilical hernias in approximately 20% of patients with cirrhosis and ascites. ⁵ Paracentesis, typically therapeutic more often than diagnostic with the removal of large volumes of ascites, can increase the risk of developing hernias because of the drastic changes in pressure during the procedure.

With cirrhosis itself being a marker of adverse postoperative outcomes,⁶ surgeons have been reluctant to operate on these patients. Recent studies, however, have shown that emergent surgical repair of these hernias poses a much greater risk of the development of complications in addition to higher rates of morbidity and mortality.⁶⁻⁸ Elective herniorrhaphy is now recommended after the patient is stabilized using optimal medical management,^{2,9,10} with the possibility of a transjugular intrahepatic portosystemic shunt procedure to prevent recurrence of the ascites.^{11,12} In institutions where surgical intervention is not possible, there have been alternative methods studied, including the injection of fibrin glue into the defect to stem drainage^{13,14} or, as in our case, the placement of a pigtail drain to allow the leaking ulceration to heal naturally.

CONCLUSION

This case presents the challenge in management of patients with Flood syndrome. Although there have been case reports and studies performed on the best treatment of Flood syndrome, ^{1,2,5,10,11,13,14} this condition is rarely seen, making development of a standardized treatment protocol difficult. In our case, the pigtail drain worked as a short-term solution for decreasing

the amount of ascitic fluid draining out of the ruptured umbilical hernia. However, it was a source of subsequent infection, in part because of its prolonged use, and it was not a good option for long-term treatment. The spontaneous rupture of an umbilical hernia in our patient with cirrhosis and ascites highlights a rare complication with high mortality rates and stresses the challenge of treatment that falls in the area between medical and surgical management. �

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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CLINICAL MEDICINE

Image Diagnosis: Multivessel Percutaneous Coronary Intervention in Dextrocardia: Success with Usual Techniques in a Case of Mirror-Image Heart

Mohamed Morsy, MD; Pranab Das, MD; Inyong Hwang, MD; Rami N Khouzam, MD, FACC, FACP, FASNC, FASE, FSCAI

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CASE PRESENTATION

A 59-year-old man with an unremarkable medical history except for tobacco abuse presented to our hospital with chest pain, dyspnea, orthopnea, and edema. His physical examination was notable for jugular venous distention, distant heart sounds, and bilateral pitting lower-extremity edema.

An electrocardiogram showed negative P waves in leads I and aVL, reversed R wave progression across the anterior leads, and Q waves in leads II, III, and aVF (Figure 1). A chest radiograph demonstrated dextrocardia with a right-sided stomach bubble, indicating situs inversus (SI) totalis (Figure 2). The patient's troponin I level was elevated to 2 ng/mL (normal value, < 0.04 ng/mL). He was started on optimized medical treatment for acute coronary syndrome, which included anticoagulation in the form of heparin and starting on aspirin and prasugrel, as well as a beta blocker. A transthoracic echocardiogram showed severely depressed left ventricular systolic function with ejection fraction of 10% to 20% and global hypokinesis.

Our patient underwent left heart catheterization through the left common femoral artery approach. A Judkins JL4 catheter (Cordis Corporation, Hialeah, FL) was used to engage the right-sided anatomically located left main coronary artery. Engagement was successful with clockwise rotation of the catheter. This rotation revealed 90% stenosis in the mid left anterior descending artery (Figure 3). The right coronary artery was engaged

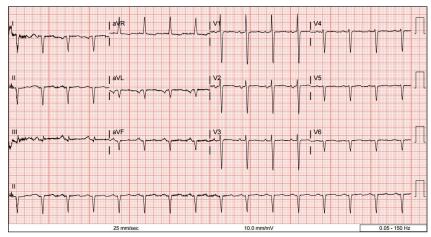


Figure 1. Electrocardiogram showing negative P waves in leads I and aVL, reversed R wave progression across the anterior leads, and Q waves in leads II, III, and aVF.



Figure 2. Chest radiograph demonstrating dextrocardia with a right-sided stomach bubble, indicating situs inversus totalis.

successfully using a Judkins JR4 catheter with counterclockwise rotation. This revealed 95% stenosis in the mid vessel (Figure 4). Using an XB 3.5 catheter guide (Medtronic, Minneapolis, MN) and a balance middleweight guidewire (Abbott

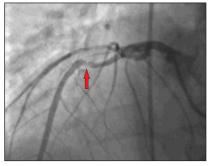


Figure 3. Angiogram revealing stenosis in the mid left anterior descending artery.

Industries, Abbott Park, IL), the left anterior descending lesion was crossed, and a drug-eluting stent was successfully placed. Then, a 6-French JR4 catheter guide (Abbott Industries, Abbott Park, IL) was used for right coronary artery engagement.

Mohamed Morsy, MD, is a Cardiology Fellow at the University of Tennessee Health Science Center in Memphis. E-mail: mohamedsamir7@hotmail.com. Pranab Das, MD, is a Cardiologist at the Methodist University Hospital in Memphis, TN. E-mail: pranabmonisha@gmail.com. Inyong Hwang, MD, is a Cardiology Fellow at the University of Tennessee Health Science Center in Memphis. E-mail: inwang@uthsc.edu. Rami N Khouzam, MD, FACC, FACP, FASNC, FASE, FSCAI, is a Cardiologist and the Program Director of the Interventional Cardiology Fellowship at the University of Tennessee Health Science Center in Memphis. E-mail: rkhouzam@uthsc.edu.



Figure 4. Angiogram revealing stenosis in the mid vessel of the right coronary artery.



Figure 5. Postprocedure angiogram showing no evidence of stenosis.

A balance middleweight guidewire was used to cross the lesion, and a drug-eluting stent was again successfully placed. A final angiogram showed excellent angiographic results (Figure 5).

The patient was discharged after 48 hours on medical management for coronary artery disease that included dual antiplatelet therapy with aspirin and prasugrel. He continued to take beta blockers and statins, which were initiated at presentation.

At 1-month follow-up, our patient was feeling much better, with no symptoms of chest pain or shortness of breath. A repeat echocardiogram 2 months later revealed improvement of left ventricular systolic function, with an ejection fraction of 40% to 45%. He was continued on medical therapy for coronary artery disease and optimized guideline-directed medical therapy for congestive heart failure, which included a beta blocker and an angiotensin-converting enzyme inhibitor.

DISCUSSION

SI is a rare medical condition that presents as a complete reversal of the internal organs, including circulatory and gastro-intestinal systems. It can present with or without Kartagener syndrome. Kartagener syndrome also involves primary ciliary dyskinesia. SI presenting without Kartagener syndrome, as in our case, has a widely accepted prevalence of 1:10,000, as reported by Torgersen in 1947. SI

presenting without Kartagener syndrome does not cause abnormality in health condition, so the majority of patients can go completely undetected until a medical workup is done, such as an electrocardiogram or chest x-ray.²

Percutaneous coronary intervention in patients with dextrocardia can be challenging, because there is no consensus regarding diagnostic and interventional catheters choice, coronary engaging techniques, or choosing best radiologic views and angles.3 After thorough review of the literature, we found only scarce reports describing multivessel percutaneous coronary intervention in dextrocardia patients in the same setting.4,5 We searched the literature via MEDLINE and PubMed, using the terms "dextrocardia," "acute coronary syndrome," and "percutaneous intervention." In our case, we report a successful single-stage multivessel percutaneous coronary intervention in SI dextrocardia using a transfemoral approach in the setting of acute coronary syndrome.

CONCLUSION

Dextrocardia is a very rare condition and is usually an incidental finding in healthy individuals. However, it could be clinically noted in a variety of cardiovascular and noncardiovascular conditions. Patients with dextrocardia can have various clinical presentations, including acute coronary syndrome and congestive heart failure. Successful diagnostic

catheterization and multivessel intervention can be achieved through conventional catheters with appropriate reversed rotation and without need for right/left reversal of radiologic views.³⁻⁵ �

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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CLINICAL MEDICINE

Image Diagnosis: A Gastric Signet-Ring Adenocarcinoma of Type Linitis Plastica Mimicking Splenomegaly in a Patient with Chronic Lymphocytic Leukemia

Leonid L Yavorkovsky, MD, PhD; Shazia Ali, MD

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CASE PRESENTATION

E-pub: 05/19/2017

A 56-year-old Vietnamese man was found to have leukocytosis during a respiratory infection. Review of systems revealed "swollen" neck lymph nodes, but no fever, night sweats, weight loss, bruising, jaundice, or weakness. There were 1.5-cm bilateral cervical and axillary lymph nodes but no hepatosplenomegaly. A blood test showed white blood cell count was 29,100/µL (normal range, 3,500/μL-12,500/μL), hemoglobin was 13.4 g/dL (normal range, 13.0 g/dL-17.0 g/dL), and platelet count was 247 K/ μ L (normal range, 140 K/μL-400 K/μL). Peripheral smear demonstrated 72% lymphocytes and 1+ smudge cells. Blood chemistry and protein electrophoresis were unremarkable. Blood flow cytometry showed phenotypically abnormal B cells positive for CD19, CD20, CD25 (partial), FMC-7 (dim), CD5, CD23, and kappa, but negative for lambda. A computed tomography scan of the neck, chest, abdomen, and pelvis revealed diffuse lymphadenopathy and no splenomegaly. The patient was diagnosed with Rai stage I, B-cell chronic lymphocytic leukemia (CLL). No treatment was recommended.

Almost two years later, the patient presented with weight loss, postprandial abdominal pressure, and a "bump" in his left upper abdomen. On examination, his peripheral lymph nodes had increased in number but not in size. His abdomen exhibited a protruding area in the left upper quadrant (Figure 1) where a firm, nontender mass was palpable extending 14 cm below the left costal margin. White blood cell count was 31,200 μL , hemoglobin was 12.1 g/dL, and platelet count was 200 K/ μL . A computed tomography scan of the abdomen and pelvis demonstrated marked stomach wall thickening, which was concerning for lymphomatous involvement (Figure 2). The spleen appeared normal. An esophagogastroduodenoscopy revealed a poorly distensible stomach with marked wall edema, friability, and ulceration (Figure 3). Biopsy showed diffuse signet-ring cell adenocarcinoma.

Three months after presentation, our patient completed three cycles of FLOT chemotherapy (fluorouracil, leucovorin, oxaliplatin, docetaxel) without improvement. Because of treatment failure, he decided to forgo further therapy and died from progressive cancer five months later.



Figure 1. Photograph of the patient's abdomen. The black arrows indicate a visible area of a protruding mass.

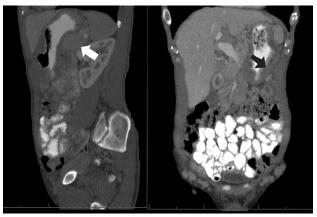


Figure 2. Computed tomography scan of the abdomen and pelvis. The white arrow shows the spleen pressing on the posterior wall of the stomach. The black arrow demonstrates a grossly thickened gastric wall.

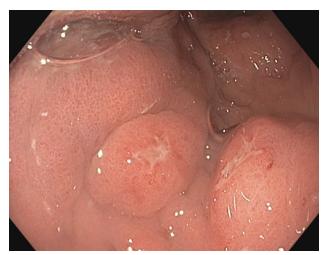


Figure 3. Esophagogastroduodenoscopy demonstrating a circumferential erythematous stenotic gastric mass with associated edema and ulceration.

DISCUSSION

Typically, adenocarcinoma of type linitis plastica (LP), known as Brinton disease or leather bottle stomach, is characterized by diffuse infiltration of neoplastic signet-ring cells with significant desmoplastic response. This imparts a rigid consistency to the stomach wall, with a thickened, fibrotic appearance. In our patient, the firm consistency of his stomach, along with its location, shape, and characteristic downward movements with deep breaths, mimicked the appearance of an enlarged spleen. The computed tomography scan was a definitive test that demonstrated an abnormal stomach but stable spleen size.

Gastric cancer occurs rarely in association with CLL.² To our knowledge, gastric LP, which represents 7% to 10% of gastric adenocarcinomas in its typical "signet-ring" form,³ has not been

reported in conjunction with CLL. Patients with LP of the stomach typically show very poor response to chemotherapy or combination radiation/chemotherapy⁴⁻⁸ and have a dismal prognosis with a 5-year survival of 3% to 12%.^{3,5,7}

In a presentation such as this, one might ordinarily assume spleen enlargement in a patient with known CLL. However, our case of gastric LP stresses the importance of considering other causes for an abdominal mass. �

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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Harmony

The poets did well to conjoin music and medicine in Apollo, because the office of medicine is but to tune this curious harp of man's body and to reduce it to harmony.

— Francis Bacon, 1st Viscount St Alban, PC KC, 1561-1626, English philosopher, statesman, scientist, jurist, orator, and author

CLINICAL MEDICINE

Image Diagnosis: Rapidly Enlarging Scrotal Hematoma: A Complication of Femoral Access?

Raza Askari, MD; Rami N Khouzam, MD, FACC, FACP, FASNC, FASE, FSCAI; Dwight A Dishmon, MD, FACC

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CASE PRESENTATION

A 69-year-old man with known ischemic cardiomyopathy presented to our Emergency Department with chest pain. He underwent cardiac catheterization via right femoral approach with placement of a drug-eluting stent to his mid left anterior descending artery, and dual antiplatelet therapy with aspirin and clopidogrel was started. Postintervention, the arteriotomy site was sealed using a Mynx (Cardinal-Health Inc, Dublin, OH) vascular closure device. No immediate postprocedure complications were noted. Overnight, the patient developed hypotension with penile swelling along with a progressively enlarging scrotal hematoma (Figure 1). No access site swelling or hematoma was evident. A computed tomography scan of the abdomen and pelvis showed soft tissue extending from the pelvis into the scrotum (Figure 2). The patient's baseline hemoglobin level before the procedure was 10.5 g/dL, and hematocrit was 32.2%. At the time the swelling was noted, the patient's hemoglobin had dropped to 7.5 g/dL, and hematocrit was down to 23.3%. He required transfusion of 2 units of packed red blood cells.

The next morning, because of a continued drop in hemoglobin and worsening scrotal swelling, the patient was taken urgently to the catheterization laboratory for right femoral angiography via left femoral approach. The femoral angiogram showed continued spurting of blood from the right common femoral artery access site (Figure 3), probably because of posterior wall puncture during cardiac catheterization. Percutaneous balloon angioplasty was performed using an 8 mm x 40 mm compliant balloon with prolonged inflation (more than 5 minutes) to tamponade



Figure 1. A photograph of the scrotal hematoma taken after cardiac catheterization. The patient is in the right lateral decubitus position.

the site of the posterior ooze. A subsequent angiogram showed no evidence of bleeding from the common femoral artery (Figure 4). An orthogonal-view angiogram was repeated a few minutes later with similar results.

During the next day, the patient's hemodynamic and hematologic parameters stabilized. There was gradual reduction in the scrotal swelling until complete resolution was confirmed at follow-up 2 weeks later.

DISCUSSION

Access site bleeding is an important complication of femoral access during cardiac catheterization. Causes of access site bleeding include multiple sticks, back wall stick, failure of the closure device, or residual bleeding from the initial site.^{1,2} The most dreaded manifestation of femoral access site bleeding is retroperitoneal hemorrhage presenting as hypotension, back/flank pain, and sequelae of acute blood loss anemia without any overt signs

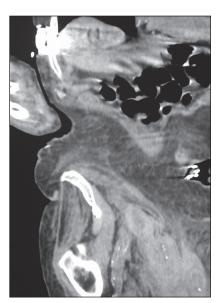


Figure 2. A coronal-view computed tomography scan of the abdomen and pelvis showing soft tissue extending from the pelvis into the scrotum via the inquinal canal.

Raza Askari, MD, is an Assistant Professor and an Interventional Cardiologist in the Department of Cardiology at the University of Tennessee Health Science Center in Memphis. E-mail: raskari@uthsc.edu.

Rami N Khouzam, MD, FACC, FACP, FASNC, FASE, FSCAI, is an Associate Professor and an Interventional Cardiologist in the Department of Cardiology at the University of Tennessee Health Science Center in Memphis. E-mail: rkhouzam@uthsc.edu. Dwight A Dishmon, MD, FACC, is an Assistant Professor and an Interventional Cardiologist in the Department of Cardiology at the University of Tennessee Health Science Center in Memphis. E-mail: ddishmon@uthsc.edu.

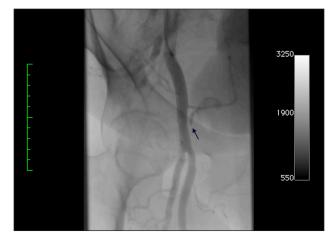


Figure 3. A femoral angiogram showing bleeding from the common femoral artery.



Figure 4. A postangioplasty femoral angiogram with no evidence of continued bleeding.

of bleeding. This manifestation can prolong hospital stay and in rare instances can be fatal. Access site bleeding for femoral access occurs in 0.82% of cases after percutaneous coronary intervention.1 Retroperitoneal bleeding is the most catastrophic manifestation of access site bleeding, occurring in 0.29% of cases.3 A scrotal hematoma occurs when the stick is at or very close to the inguinal ligament, with blood tracking along the spermatic cord into the scrotum. To our knowledge, only a handful of cases of development of scrotal hematoma after femoral artery access have been reported in the literature.^{4,5} The incidence of bleeding complications has not been shown to be different whether a closure device is used or not.3

Diagnosis of retroperitoneal bleeding is made with abdominopelvic computed tomography. Ultrasound or computed tomography can provide the diagnosis for scrotal hematoma. Treatment of scrotal hematoma has ranged from conservative measures, including scrotal elevation and resuscitation with IV crystalloids or blood products, to open surgical options. Ultrasound-guided compression and ultrasound-guided thrombin injection are noninvasive measures that are effective for femoral artery pseudoaneurysms, but these measures are unlikely to be effective for unrestrained obvious bleeding. Endovascular

balloon tamponade is a minimally invasive option that is frequently successful⁹ and offers the option to use covered stents in case of failure.⁶ �

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

How to Cite this Article

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CLINICAL MEDICINE

Image Diagnosis: Iliopsoas Abscess from Crohn Disease

Ashley S Abraham; Michelle Y Liu; David R Vinson, MD

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CASE PRESENTATION

A 42-year-old woman presented to her primary care physician with several years of intermittent right-sided lower abdominal cramps and pain associated with diarrhea, which during the previous 3 weeks had worsened in frequency and severity. Her physician ordered a contrast-enhanced abdominal computed tomography (CT) scan, which revealed terminal ileitis, the differential of which included Crohn disease as well as infectious and neoplastic processes. An inflammatory bowel disease serology panel showed a pattern consistent with Crohn disease. The patient was started on oral mesalamine. Outpatient colonoscopy showed the ileocecal valve to be narrowed with evidence of erythema, friable mucosa, and beefy ileal mucosa. Biopsies revealed ulcerations and granulation tissue.

During the next 2 weeks, the patient's abdominal pain failed to subside, so she was started on a 12-day tapered course of oral prednisone. During the last 4 days of her steroid regimen, she developed new-onset right hip pain and weakness of hip flexion, causing a moderate gait disturbance. She presented to the Emergency Department for evaluation and reported an increase in her mild, long-standing, right lower quadrant abdominal pain. She denied trauma, nausea, vomiting, fever, chills, or bloody stool, and had no history of abdominal surgery or appendicitis.

On physical examination, the patient was afebrile and had minimal right lower quadrant abdominal tenderness without guarding or rebound. She had moderate weakness of right hip flexion with limited range of motion. Her white blood cell count was elevated at 15.1 10°/L. The rest of her complete blood cell count was normal, as were her electrolytes, creatinine, liver function tests, urinalysis, and pregnancy test. The emergency physician sought to exclude bony pathology and so ordered x-rays of the right hip, which were unremarkable. A contrast-enhanced CT scan of the abdomen revealed a 5-cm right iliopsoas abscess containing air. The terminal ileum was thick-walled with pericolonic inflammatory changes. The dilated adjacent bowel was consistent with local ileus (Figure 1).

The patient was started on intravenous piperacillin/tazobactam and admitted to the hospital. Symptoms improved the next day after CT-guided percutaneous abscess drainage, the culture of which was positive for *Klebsiella pneumoniae*. This common gram-negative enteric organism was sensitive to the administered antibiotics. The patient was discharged home on hospital day



Figure 1. Axial view (A) and coronal view (B) contrast-enhanced computed tomography scans of the abdomen showing the terminal ileum (TI) and iliopsoas abscess (IPA).

four with a seven-day course of oral amoxicillin/clavulanate and ciprofloxacin. Her drain was removed one week later.

One month after the initial presentation, the patient returned to the Emergency Department with increasing right lower quadrant abdominal pain. A recurrent abscess was seen on contrastenhanced abdominal CT. She underwent exploratory laparotomy with wash out of the abscess and drain placement. Acute appendicitis was also discovered and removed. The affected bowel was resected. A communication between the bowel and the abscess was not described. The pathology report noted chronic active

Ashley S Abraham is a Research Intern with the CREST (Clinical Research on Emergency Services and Treatment) Network in Sacramento, CA. E-mail: ashley.sa.abraham@gmail.com. Michelle Y Liu is a Research Assistant with the CREST (Clinical Research on Emergency Services and Treatment) Network in Oakland, CA. E-mail: myxliu@berkeley.edu. David R Vinson, MD, is a Senior Emergency Physician at the Sacramento Medical Center and Co-Chair of the CREST (Clinical Research on Emergency Services and Treatment) Network. He is an Adjunct Investigator at the Division of Research in Oakland, CA, and an Assistant Clinical Professor, Volunteer Clinical Faculty, in the Department of Emergency Medicine at the University of California, Davis in Sacramento. E-mail: drvinson@ucdavis.edu.

ileitis with ulceration, granulation tissue, and transmural inflammation. No obvious perforation was identified on the appendix. Cultures from the abscess were negative. During the following 12 months, the patient was stable on mesalamine and experienced only 1 exacerbation requiring brief steroid treatment. She developed no further abscesses.

DISCUSSION

Crohn disease is a common cause of secondary iliopsoas abscesses, occurring in an estimated 0.4% to 4.3% of patients.¹⁻³ Although long-term corticosteroid use with its attendant immunosuppression could increase the risk for abscess formation, a short course is unlikely to have the same effect.⁴⁻⁶ The diagnosis of iliopsoas abscess can be difficult to make, and delays in diagnosis can result in sepsis and organ failure and are known to increase mortality.^{2,3,7} Hip pain with impaired flexion and antalgic gait are characteristic complaints associated with iliopsoas abscesses and can serve as diagnostic clues. The pain, though usually localized to the hip, may radiate up into the flank area or down into the thigh.^{1,2,8-10} Clinicians should keep this diagnosis in mind when evaluating hip complaints in a patient with Crohn disease.

Crohn disease increases the risk for contiguous abscesses because the transmucosal inflammation predisposes patients to bowel wall perforations and fistula formation. ¹¹ Gram-negative bacilli and anaerobes are the most common pathogens identified in intestinal-associated abscesses. ¹⁰ *K pneumoniae*, identified in our patient's iliopsoas abscess, has been associated with more invasive infections. ¹²

Apart from removal of the inflamed bowel, patients with Crohn disease and a treated first abscess are at risk for local abscess recurrence. Treatment of an iliopsoas abscess requires drainage and antibiotic therapy, but recurrent abscesses may necessitate surgical resection of the affected bowel, as in our case. ��

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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The Important Difference

The most important difference between a good and indifferent clinician lies in the amount of attention paid to the story of a patient.

 — Sir Edward Farquhar Buzzard, 1st Baronet, KCVO, FRCP, British physician and Regius Professor of Medicine at the University of Oxford

COMMENTARY

Considerations in the Neuropsychological Evaluation and Treatment of Children with Limited English Proficiency

Alonso Cardenas, MD; Laura Villavicencio, MD, MS; Mani Pavuluri, MD, PhD

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The intention of this article is to raise the awareness of clinicians regarding the appropriate assessment of intellectual competence and neuropsychological function of children and adolescents whose first language is not English. Given the large number of Spanish speakers in the US, we illustrate, with a case example, the need to test students in their native language especially when the second language has not yet been mastered. Accurate assessment of the brain's potential may yield enhanced opportunities and optimize expectations, rather than undervaluing a developing child's elastic brain maturation. Our article intends to raise awareness of the developmental and school psychologists, neuropsychologists, and child psychiatrists who serve a broad base of the immigrant population.

Language is fundamental to virtually all aspects of human experience and represents a core focus of neuropsychological evaluation.¹

Our patient was an 11-year-old, Spanish-speaking patient with disruptive mood dysregulation disorder who was recently ad-

Language dominance and proficiency must be determined² before using a psychometric battery. ... Would the child need to first understand the question in his/her nonnative or second language, then translate it into his/her native language, and then translate back to English in order to respond?

mitted to a behavioral health facility after an altercation in school involving a knife. He was being seen at our pediatric mood disorders clinic. During a recent inpatient admission, he had a neuropsychological evaluation, including neurocognitive testing, which showed moderate mental retardation—currently termed "intellectual disability" in the Diagnostic Statistical Manual of Mental Health Disorders-Fifth Edition (DSM-V). Both the child psychiatry fellow and the medical student who are native Spanish speakers noticed the incongruence between the test results and the patient's clinical presentation. During the interview, it was apparent that

the patient was quite comfortable conversing in English, though his understanding was greater in Spanish.

Neuropsychological testing evaluates a child's cognitive abilities by assessing memory, attention and concentration, problem solving, language, and emotion among other neuropsychological domains. Physicians and other clinicians use the results to

clarify the relationship among an individual's brain, thoughts, behavior, and mood.

In our patient's case, the intelligence test battery (Wechsler scale) compared the child's overall abilities with specific functions to identify a potential cognitive issue possibly exacerbating his emotional frustration and physical aggression. However, because the test was not normed to the patient's native language as would be recommended,² because Spanish was the language of schooling, and because of the patient's short length of stay in the US leading to the administration of the test, the test was not considered a relevant factor, and thus the results of the test were not accurate or valid. Furthermore, the misdiagnosis did not reflect his adaptive functioning as is recommended in the DSM-V.

In light of these common unsuspected problems in evaluation, we suggest the following pragmatic considerations:

- 1. Language dominance and proficiency must be determined before using a psychometric battery. Did the child with limited English proficiency (LEP) learn certain concepts such as multiplication tables in his/her native language? Would the child need to first understand the question in his/her nonnative or second language, then translate it into his/her native language, and then translate back to English in order to respond? These processes take time and mental effort beyond what is needed to solve the underlying test question or problem.
- 2. In the case of a child using two languages, there could be competition or interference between the languages. For example, the child could be asked to say as many words as s/he can think that begin with a certain letter. However, if s/he thinks of a word in one language and the same word does not start with the same letter or fit in the same category in the other language, s/he loses time and may not attain the same level of proficiency as his/her monolingual counterpart. The problems of delay and translational difficulty can be anxiety provoking, which in turn affects concentration and overall outcome.
- 3. With regard to testing in bilinguals, Mindt et al¹ illustrated the well-established connection between frequency of use and lexical accessibility explaining that by virtue of speaking each language only some of the time, bilinguals use each language less frequently than their monolingual counterparts. In addition, cognitive academic language proficiency takes longer to develop compared with conversational proficiency. Thus individuals with LEP also have disadvantages when tested in

Alonso Cardenas, MD, is a Psychiatrist for the Southern California Permanente Medical Group in Pasadena. E-mail: alonso.cardenas@kp.org. Laura Villavicencio, MD, MS, is a Fourth-Year Medical Student at the University of Illinois College of Medicine in Chicago. E-mail: lvilla27@uic.edu. Mani Pavuluri, MD, PhD, is the Berger-Colbeth Chair in Child Psychiatry and the Pediatric Mood Disorders Program at the Institute of Juvenile Research at the University of Illinois College of Medicine in Chicago. E-mail: mpavuluri@psych.uic.edu.

- their first-acquired, dominant language. The child with LEP must be assessed at least partially in his/her native or primary language to avoid misclassifications.¹
- 4. Self-reported ability alone may not always be the most accurate assessment of actual proficiency.³ Researchers and clinicians must provide more accurate assessments by using both subjective and objective measures. Proficiency in each language may differ depending on the skill assessed (eg, conversation, reading, writing, or mathematics), and thus evaluation in both languages is preferred where possible. Subjective measurement includes clinical interview in which the examiner can judge basic interpersonal fluency, questionnaires regarding linguistic preferences in which the client rates her or his own fluency, and measures of acculturation.
- 5. Issues including the degree of acculturation and assimilation, education, socioeconomic status, immigration history and country of origin, housing issues, experience of stress, any racial bias, social support, and access to/use of health care services are important considerations when interpreting the battery results and developing the written assessment.
- 6. Specifically, examiners looking to evaluate a Spanish-speaking child can use any one of the following batteries: See Sidebar: Intelligence Assessments Available in Spanish.

Although being bilingual can confer disadvantages in a timed neuropsychological evaluation, research also suggests there are advantages to bilingualism. Bilingual children exceed monolinguals in executive control tasks because language switching

Intelligence Assessments Available in Spanish

- Batería Woodcock-Muños which tested individuals from Costa Rica, México, Peru, Puerto Rico, Spain, and the US
- Escala de Inteligencia Wechsler Para Niños Revisada or EIWN-R
- WISC-R version normed in México or Escala de Inteligencia Wechsler para Niños-Revisada de Puerto Rico (EIWN-R-PR) which was developed by translating some items from the WISC-R and by adding, as well as adapting, items that are appropriate for the Puerto Rican culture

requires exercising inhibition and attention.⁴ Preliminary data also suggest a protective effect of bilingualism against cognitive decline.4 Thus, balanced bilingualism is to be encouraged, and promoted. However, language-sensitive services should be provided while proficiency is developing.2 Moreover, from a social justice perspective, neglecting language-assistance needs of LEP individuals is not clinically appropriate, and the US Office of Civil Rights mandate in Title VI of the US Civil Rights Act requires that no one be denied services on grounds of national origin.5 With respect to our case, pharmacotherapy for mood regulation and therapeutic school placement involving clear communication with school staff on the absence of intellectual disability led to the student being placed back in a traditional school setting. The reinterpretation of neuropsychological test results as well as knowledge of native language capabilities in the context of recent immigration and comorbid mental illness offered a valuable new beginning to our patient. �

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Language

If you talk to a man in a language he understands, that goes to his head. If you talk to him in his own language, that goes to his heart.

— Nelson Mandela, 1918-2013, South African anti-apartheid revolutionary, politician, philanthropist, and President

COMMENTARY

To Err is Human: Can American Medicine Learn from Past Mistakes?

Jeffrey B Ritterman, MD Perm J 2017;21:16-181

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ABSTRACT

The history of medicine includes many errors. Some persisted for decades and caused great harm. Several are highlighted in this article, including the mythical thymic diseases: thymic asthma and status thymicolymphaticus. Some medical mistakes, such as the diet-heart hypothesis of Ancel Keys, continue to cause harm. To avoid future errors and their associated harm, I suggest a cultural shift encouraging professional humility and greater questioning of medical dogma. Medical education focused on teaching students this history may help with this cultural shift.

INTRODUCTION

During my medical training, we were taught that stress and lifestyle factors caused gastritis and peptic ulcer disease. We accepted without question the idea that bacteria could not live in the highly acidic environment of the stomach. Patients with severe ulcer disease would be offered surgery. We now know, thanks to the pioneering work of Marshall and Warren, that peptic ulcer is caused by a bacterium, *Helicobacter pylori*.

Warren discovered the curved bacteria in the stomachs of patients with peptic ulcer disease and gastritis in 1979.² But it wasn't until his research partner, Marshall, deliberately infected himself with the bacterium and gastritis developed that their findings were taken seriously.

Marshall's ability to take a fresh look at these gastric bacteria as etiologic agents, rather than to uncritically accept the stress theory of ulcer disease, was in part because of his lack of experience. Having started his study of gastroenterology in 1981, Marshall had an easier time than more seasoned researchers in overcoming a "set of well entrenched beliefs that conflicted with the new ideas."³

It took a generation for Marshall and Warren's pioneering work to be recognized and acknowledged. They first published their findings on *H pylori* in 1984. More than a decade later, in 1995, only 5% of American physicians were prescribing antibiotics for treatment of peptic ulcer disease.³ In 2005, Marshall and Warren received the Nobel Prize in Medicine for their discovery, 26 years after Warren discovered *H pylori*.²

This problem of mistaken ideas persisting despite scientific evidence to the contrary has been present since the onset of the scientific method. In 1633, Galileo was sentenced to house arrest for the crime of proclaiming that the sun, not the earth, was the center of our planetary system.⁴

Three hundred years later, Nobel prizewinning physicist Max Planck⁵ stated: "A new scientific truth does not triumph by convincing its opponents and making them see the light, but rather because its opponents eventually die, and a new generation grows up that is familiar with it."

Or more succinctly: "Science advances one funeral at a time."

This problem is of particular concern in medical science, where outmoded ideas translate into excess morbidity and mortality. How can medicine learn from its mistakes and make these timely corrections? Perhaps a few additional examples will help make clear the importance of doing so.

A CAUTIONARY TALE: SUDDEN INFANT DEATH SYNDROME AND THE "ENLARGED" THYMUS GLAND

In the first half of the 19th century, physicians were becoming alarmed by sudden infant death syndrome (SIDS). Healthy

infants would be put to bed and found dead in the morning. In 1830, pathologists noted that SIDS-affected infants had enlarged thymus glands compared with "normal" autopsy specimens. It seemed logical to conclude that these "enlarged" glands were in some way responsible for the deaths.

In 1830, Kopp introduced the term *thymic asthma*, suggesting that the "enlarged" thymus occluded the trachea.⁸ The existence of this fictitious disease became widely and quickly accepted, and persisted for at least a century. The thymic syndrome underwent an additional modification by the Austrian physician, Paltauf, who added the term *status thymicolymphaticus* to the medical lexicon in 1889.⁸ Paltauf believed that a systemic disorder leading to vascular collapse caused the sudden deaths. The enlarged thymus, it was believed, caused this unexplained vascular collapse, often precipitated by minor stress.

Descriptions and case reports of these thymus "diseases" appeared in medical articles and textbooks. 9,10 There was even a list of physical characteristics that accompanied these syndromes, including changes in incisor teeth, heart size, and skin color. The 1924 edition of *Management of the Sick Infant* claimed that the clinical picture of thymic asthma was "so characteristic that once seen, it is unlikely to be mistaken."8

If an enlarged thymus was leading to sudden infant death, removal of the thymus might be of preventive value. Radiology had advanced to the point at which physicians began making the diagnosis of thymic enlargement from x-ray films. After radiographic diagnosis, thymectomy was initially recommended, but the mortality rate was unacceptably

Jeffrey B Ritterman, MD, is the retired Chief of Cardiology of the Kaiser Richmond Medical Center; he is the Clinical Coordinator and Associate Professor in the Joint MSPAS/MPH Program at Touro University in Vallejo, CA. E-mail: jeffritterman@gmail.com.

high. Thymus irradiation became the treatment of choice.8

The first "successful" use of irradiation to shrink the thymus was reported by Friedländer in 1907.¹¹ Thousands of children eventually received radiation to prevent status thymicolymphaticus. Some physicians advocated prophylactic irradiation for all neonates.⁸

There was only one slight problem. It turned out to be deadly. 7

The cadavers used by anatomists to determine the "normal" thymus size were from the poor, most having died of highly stressful chronic illnesses such as tuberculosis, infectious diarrhea, and malnutrition. What was not appreciated at the time was that chronic stress shrinks the thymus gland. The "normal" thymus glands of the poor were abnormally small. Here is where the fatal mistake occurred: because the autopsied thymus glands of the poor were regarded as normal in size, the SIDS-affected infants were erroneously believed to have thymic enlargement.^{7,8}

the mistaken therapy.⁷ Virchow, the man who first explained the pathophysiology of pulmonary embolus, the man who named leukemia, and a founder of social medicine, got it wrong!¹⁷

A CAUTIONARY TALE: FAT

Perhaps there is no better modern medical example of our capacity for serious error than the fact that we have given the wrong dietary advice since shortly after President Eisenhower's heart attack in 1955. Not only has our advice been wrong, it has been dangerously wrong. 18

As in the case of the supposed thymic disorders, once again a mistake has led to great harm.

Ancel Keys, PhD, a physiologist, studied the American and European diets after World War II. He studied the epidemiology of cardiovascular disease (CVD) and noted that American business executives had high rates of CVD,^{19,20} whereas the heart disease rates in postwar Europe had fallen sharply, presumably from reduced

of cholesterol and fatty acid metabolism, work for which they received the Nobel Prize in 1985.25 Working with skin cells from patients with a rare genetic disorder, familial hypercholesterolemia, Brown and Goldstein²⁵ demonstrated the presence of the low-density lipoprotein (LDL) cholesterol receptor. Patients with the disorder lacked the normal number of receptors, had high serum cholesterol levels, and had a risk of heart attack early in life. The new knowledge seemed to fit well with Keys' "dietary fat hypothesis" as the cause of CVD. Because LDL cholesterol correlated with the risk of CVD and dietary fat increased blood LDL cholesterol levels, it seemed logical to conclude that dietary fat was the cause of CVD.

Once again, incomplete knowledge led to the pursuit of a dangerous path. In the dietary guidelines case, epidemiologic research that showed an association was wrongly assumed to prove causality. In addition, the contrary evidence to Keys' diet-heart hypothesis was ignored. There never was any association between dietary fat and all-cause mortality. Certainly, if dietary fat was the cause of CVD, one would expect such an association. In the single randomized controlled trial that compared a 10% saturated fat intake vs a diet with unrestricted saturated fat, the subjects with low-fat intake had a higher death rate due to all causes, including heart disease.²⁶

In 1977, the McGovern Commission, chaired by then Senator George McGovern, issued dietary guidelines in keeping with the diet-heart hypothesis.²⁷ Decades later, we have continued to follow these guidelines.²⁸ Americans have been repeatedly told to consume no more than 30% of total calories from fat and no more than 10% from saturated fat.²⁸

When the food companies responded to the guidelines by removing the fat from food, the taste went with it. The solution: add sugar, and lots of it. This worked well economically, as the invention of high-fructose corn syrup provided an endless supply of cheap sugar. The result of admonishing people to eat less fat was that sugar consumption skyrocketed. ^{24,29,30} This substitution of sugar for fat has been the major driver of the diabetes epidemic ^{31,32,33} and has played a key role in causing coronary heart disease, ³⁴⁻³⁶ strokes, ³⁷ fatty liver

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The thyroid gland, which is highly sensitive to irradiation, sits close to the thymus. The increased risk of thyroid malignancy in the patients who had undergone thymic irradiation was first recognized in 1949. The patients subjected to thymic radiation "therapy" also experienced higher rates of breast cancer. 13-15

The regular practice of thymic irradiation was finally halted in the 1940s, almost four decades after Friedländer irradiated the first patient. In the first edition of his radiology textbook in 1945, ¹⁶ John Caffey, MD, a pioneer in pediatric radiology, proclaimed that "a causal relationship between hyperplasia of the thymus and sudden unexplained death has been completely refuted. ... [I]rradiation of the thymus ... is an irrational procedure at all ages." ¹⁶

More than 10,000 deaths caused by thyroid cancer resulted from this treatment.⁷

Rudolf Virchow, the father of cellular pathology, a man who stood at the top of the academic medical world for 50 years, was one of those who endorsed food supplies. He postulated that the different rates of CVD were owing to markedly different rates of dietary fat consumption. Keys was convinced that dietary fat led to elevated cholesterol levels, which then caused CVD.21 Keys presented his diet-heart hypothesis to the World Health Organization in 1955. His research was epidemiologic and could only prove an association, not causality. But Keys was a convincing salesman at a time when the country was searching for solutions to prevent the sudden deaths resulting from this newly recognized killer. In January 1961, Keys became a cultural hero, his picture gracing the cover of Time Magazine, and the diet-heart hypothesis was accepted.²²

In 1978, Keys published his data in support of dietary fat as the cause of CVD, in the Seven Countries Study.²³ Unfortunately, he excluded data from 15 countries and 4 indigenous tribes that did not fit well with his hypothesis.²⁴

While Keys was proposing dietary fat as the cause of CVD, Brown and Goldstein were advancing our understanding disease,³⁸ obesity,³⁹ hypertension,⁴⁰ and some cancers.⁴¹ In addition, as Americans began avoiding fat, they also increased their intake of simple starches. Like sugar, diets high in refined starches are associated with an increased risk of obesity, CVD, and Type 2 diabetes.⁴²⁻⁴⁴

Now the so-called "French paradox" makes sense. 45,46 People in France consume high rates of fat but do not have correspondingly high rates of CVD. It isn't a paradox. There simply is no connection between CVD and dietary fat.

Many physicians continue to warn their patients to avoid dietary fat despite accumulating evidence showing that unrefined carbohydrates cause metabolic syndrome and its related illnesses. In 2015, the Dietary Guidelines Advisory Committee Report⁴⁷ for the first time started to change course and to exonerate fat and saturated fat. Instead, the report focuses our attention on fructose and other simple carbohydrates as the real culprits of dietrelated illnesses. It took 100 years for the faux thymic conditions to be understood to be a gross medical error. How many more years will it take before we correct our mistaken dietary advice?

Embracing Professional Humility

During a leadership training session that I attended, a National Aeronautics and Space Administration (NASA) scientist explained that the July 1969 Apollo Mission to the moon was on the ideal flight path only 3% of the time. Great achievements depend not on perfection, but on our ability to quickly notice when we are off course and to make adjustments.

As a profession, we have failed miserably to notice that we were terribly off course in both the fictitious thymus diseases tragedy and the dietary guideline mishap. In the first instance, the error persisted for more than 100 years, in the second, many decades. In each case, innumerable people were harmed, and many died.

To prevent similar tragedies in the future, we will need a cultural shift in medicine. Coulehan⁴⁸ has critiqued our present medical culture as "characterized by arrogance and entitlement." Berger⁴⁹ pointed out that the arrogance goes beyond the individual physician and is systemic:

The physician has become a "provider" and the patient a "health consumer." This distancing of the doctor from the patient breeds a kind of "system arrogance," in which the patient is no longer seen as a human being but simply as a job to be done cost-effectively.

The late Franz Ingelfinger,⁵⁰ former editor of the *New England Journal of Medicine*, stated: "Efficient medical practice, I fear, may not be empathic medical practice, and it fosters, if not arrogance, at least the appearance of arrogance."

If the toxin is professional arrogance, the antidote is professional humility.

One area in health care in which we have witnessed a cultural shift is in our understanding of how to provide competent care to patients from different backgrounds. Tervalon and Murray-Garcia⁵¹ have challenged us to go beyond "cultural competency" and to embrace "cultural humility." They explain:

... cultural competence in clinical practice is best defined not by a discrete endpoint but as a commitment and active engagement in a lifelong process that individuals enter into on an ongoing basis with patients, communities, colleagues, and with themselves. ... It is a process that requires humility as individuals continually engage in self-reflection and self-critique as lifelong learners and reflective practitioners.

The underlying principle is that, given the great diversity of cultural practices and beliefs, humility is the appropriate mindset. Practitioners should be humble enough "to say that they do not know when they truly do not know and to search for and access resources"⁵¹ The practitioner is both a teacher and a student.

This model holds for the general practice of medicine as well. Humility is both a personal virtue and a professional necessity. Personal humility is essential for good doctoring. ⁵²⁻⁵⁵ Professional humility promotes the questioning of medical dogma, leading to the scientific testing of hypotheses.

William Osler,⁵⁶ considered by many the father of American Medicine, addressed the question of humility in a 1906 lecture to medical students at the University of Minnesota:

In these days of aggressive self-assertion, when the stress of competition is so keen and

the desire to make the most of oneself so universal, it may seem a little old-fashioned to preach the necessity of this virtue, but I insist for its own sake and for the sake of what it brings, that a due humility should take the place of honour on the list [of virtues] ... since with it comes not only reverence for truth, but also proper estimation of the difficulties encountered in our search for it. ... [T] his grace of humility is a precious gift.

The more humble the medical profession is, the more likely we will avoid costly errors.

To facilitate this cultural shift, we will need to unlearn old behaviors and replace them with new ones. This will require a major re-education effort for those already in practice, and the development of a robust curriculum to reach those in training. To be successful, we will need to have an impact on all layers of the medical hierarchy, including nonphysician health care workers, students, physicians-in-training, and those in positions of authority.

Our aim must be to create a safe learning environment where questions and alternative points of view are encouraged. The curriculum in medical and allied health professional schools should include courses on medical history, highlighting past medical errors, and stressing the importance of questioning current medical practice.⁵⁷ Medical and allied health professional students should be required to research an area of medical care to determine if current practices are consistent with the latest medical science.

Continuing medical education courses should be developed to reach those who have already completed their formal medical education. When it became clear that physicians in practice were not well educated in end-of-life care and in pain management, training in both areas became mandatory for medical license renewal. We can do the same for professional humility.

It will be crucial to this effort for the leaders in American medicine to embrace this cultural shift. Those in authority must be open to new ideas, even if those ideas challenge paradigms associated with their own success. Medical students and physicians-in-training will find it much easier to raise important questions if they feel encouraged to do so.

Would the terrible health outcomes from thymus irradiation have been avoided if a medical student had felt empowered to ask, "Dr Virchow, are we sure that the thymus gland is abnormally enlarged in infants with SIDS?" *

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Much Labour and Time

In medicine (what men are scarcely aware of until they become somewhat severely practical), it requires as much labour and time fairly to lay hold of an error, and uproot it, and have done with it, as to learn and settle a truth, and abide by it.

— Peter Mere Latham, MD, 1789-1875, British physician and medical educator, physician extraordinary to Queen Victoria

COMMENTARY

The Patient-Centered Medical Home as a Community-based Strategy

Berkeley A Franz, PhD; John W Murphy, PhD

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ABSTRACT

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Increasing attention has been devoted to the important role that primary care will play in improving population health. One innovation, the patient-centered medical home (PCMH), aims to unite a variety of professionals with patients in the prevention and treatment of illness. Although patient perspectives are critical to this model, this article questions whether the PCMH in practice is truly community-based. That is, do physicians, planners, and other health care professionals take seriously the value of integrating local knowledge into medical care? The argument presented is that community-based philosophy contains a foundational principle that the perspectives of health care practitioners and community members must be integrated. Although many proponents of the PCMH aim to offer patient-centered and sustainable health care, focusing on this philosophical shift will ensure that services are organized by communities in collaboration with health care professionals.

INTRODUCTION

The American health care system is in trouble on at least two levels. Care is too costly and is unevenly distributed. As a result, many disparities exist. The patient-centered medical home (PCMH) is proposed as a remedy for this situation. According to the National Committee for Quality Assurance, which provides official PCMH recognition for practices through care coordination, "Patient-centered medical homes transform primary care practices into what patients want: health care that focuses on them and their needs." The fundamental premise is that this model will allow care to be accessible and offered in a sensitive and effective manner. Money will thus be saved and care improved.

In this regard, some critics argue that the PCMH represents "enhanced primary health care." In fact, the conference held in Alma-Ata, USSR (now Almaty, Kazakhstan), in 1978, has been identified as the proper context for this movement. The assumption that guided this meeting was that health care had to be improved for the masses. Morally and socially, the health disparities that existed around the world should no longer be tolerated.

The philosophical change that was generally endorsed elevated the role of communities in delivering adequate care. With care tied closely to these groups, relevant services could be provided in a timely manner. Along with community involvement, prevention and education should be emphasized. In this

way, a range of care would be integrated into local settings, so that health promotion was normalized and made a vital part of everyday life.

In many ways, the PCMH represents this sort of coordinated care. The goal is to meet a variety of needs in a holistic manner, within the framework of the family and community.⁴ The emphasis is on care coordination and continuity so that health decisions are made jointly by clinicians, patients, and others deemed to be relevant to treatment. This ongoing process of communication is thought to minimize gaps in care and to promote widespread access to services that are necessary for each patient. This kind of care environment is thought to lead to favorable health outcomes.

The problem is that the PCMH in theory or in practice is not necessarily community-based.^a For example, in Ohio some practices transitioning to PCMHs have attempted to center care around patients by gathering data on patient satisfaction through the use of surveys, focus groups, or patient advisory boards.⁵ These strategies allow patients to weigh in on existing practices but do not instigate a truly collaborative model of care. Although the language of patient-centeredness is at the core of the PCMH, this does not necessarily ensure that authentic practice changes will follow that are community-based in nature.

Perhaps advocates of this model did not appreciate the radical nature of public health care? Nonetheless, many patients are not comfortable with the PCMH, and critics have questioned whether this model is suited to address the social determinants of health and inform health policy.^{6,7} To correct these shortcomings and to integrate patients effectively into care, health care leaders may enhance the PCMH with a dose of community-based philosophy. After all, patients and their communities must be fully engaged if interventions are going to be perceived as valid and if this model is to be truly effective.

Yet, becoming community-based is not as simple as making contact with a few prominent members of a community or locating a clinic in a neighborhood. In fact, identifying a community is difficult. As will be discussed in the section Becoming Patient-Centered, communities are certainly real but are somewhat elusive, and thus gaining entrée to these groups and gaining their trust takes time and a lot of effort. What is needed to achieve this aim, in addition to a proper philosophy, is a long-term vision of health care and a clear understanding of the role a community must play in the process of delivering these services.

BECOMING PATIENT-CENTERED

Many critics today argue that the current health care system is unworkable. 9,10

To the detriment of the public, the promise of PCMH has not been realized, and treatment has drifted away from communities. Primary health care is thus again en vogue, particularly the notion that local persons should play a central role in the design of interventions. For health care leaders to make care relevant and sustainable, and thereby reduce costs, the health system must be revamped from the ground up. Especially important is that attention be directed to the cultural side of medicine.¹¹

Although competing definitions of primary care exist, some common elements are present.¹² Particularly noteworthy is that care is coordinated. An integrated system is created with a single point of entry with uniform, sequential steps of treatment and referral. Perhaps most important is the focus of this system: The community. In this sense, public health care is patient-centered.¹³ The values, beliefs, and commitments of these persons should guide the development, implementation, and evaluation of any social intervention.

The assumption is that communities are not simply places or associated with a collection of demographic traits. Communities constitute worlds—specifically moral worlds, as Kleinman¹⁴ says—that outline a range of norms, including those related to health and illness. These rules, furthermore, reflect the definitions and decisions these persons treat as central to maintaining their community.

Communities are not necessarily identified with objective referents. Persons weave stories about themselves, their relationships, histories, and other facets of their lives. ¹⁵ These narratives, accordingly, provide insight into the multiple perspectives that are present, along with how these outlooks sometimes overlap. Different portrayals may exist, for example, about the boundaries of a community or the most accessible location of a clinic. In this regard, a community constitutes a montage of worlds created by the story lines that members understand and should be the focus of interventions.

Allowing communities to control health projects makes sense only within this framework. Illness is predicated on the experiences and the community story lines that are operative. ¹⁶ Accordingly, the relevance and success of interventions depends on the local stories, and related explanations, about sickness and cure. This change in strategies, however, is not merely a philosophical concern and should not be perceived as a burden to medical practitioners. After all, community engagement is touted to be essential for appropriate interventions. ¹⁷ Furthermore, improved health care should serve to reinforce the effort needed to truly engage individuals and communities.

Gaining entrée to the world of a community is vital to the success of primary care. In some circles, emotional intelligence is considered to be part of this process. ¹⁸ Because of the need to enter the world of a community, emphasis has been placed on developing interpersonal skills, such as empathy and emotional management. The point is that through these activities interpersonal connections can be made that are informative and supportive.

With these skills, health planners can develop the partnerships necessary to engage communities. A community's needs, perceptions, and expectations, along with dignity and respect, can become the focus of attention. Additionally, a corollary of this participation is that communities can become more selfreliant and healthy places to reside. Communities can acquire the skills necessary to monitor themselves, construct interventions, and formulate effective health policies.¹⁹

However, some of these aims have not been realized. Many health projects have made connections with communities, but entering their worlds has been a different issue altogether. For example, many patient or community advisory boards exist to solicit opinions from community members, but there is little room for authentic collaboration.²⁰ In these cases, planners and practitioners have been sensitive and compassionate without necessarily giving a community control of a clinic or project.²¹ Consultations, in this sense, are insufficient to achieve community entrée.

However, without placing a community's world at the center of an intervention, how can these projects be relevant? These assumptions, definitions, and actions are crucial to the correct understanding of health behavior. Real public health care requires a close reading of the historical context and current preferences of a community if interventions are going to be effective.

Becoming patient-centered must extend beyond a concern for the well-being of patients and a sensitivity to their interests or fears. In public health care after the Declaration of Alma-Ata, a larger issue must be addressed:³ How can local knowledge begin to guide health care? The success of this maneuver depends on a philosophical shift that will be raised later in the section A Community-based Additive. At this juncture, however, the important point is that communities are not objects but are actively created by their members. Here again, the issue of a community's world arises.

PATIENT-CENTERED MEDICAL HOME

A relatively new health care model, rooted in primary care, is receiving some attention nowadays.²² This strategy appeared initially in 1967 to provide holistic and dependable care to the chronically ill.²³ The name *patient-centered medical home* has been adopted by this approach to providing health care.

Although facilities are a part of this health project, the PCMH constitutes a model rather than a specific institution. The metaphor of "home," however, is telling. The aim is to offer accessible, comprehensive, continuous, and coordinated care.²⁴ Consistent with the notion of home, patients are supposed to be treated in a sensitive and supportive environment, with emphasis placed on their values and preferences.

At the core of the PCMH is the goal of transforming medicine to meet the needs of individuals and communities. In this regard, a "whole person" orientation is adopted. Rather than a bundle of organs, persons are understood to be socially situated and expressive. Any adequate intervention, accordingly, requires that they be actively engaged and directly involved in the treatment process.

Patients, family members, and caregivers are at the center of every medical decision.²⁵ Therefore, coherent and lasting

partnerships should be fostered with these persons. Decision making should reflect the daily practices of patients, thereby including interpersonal contacts and local health networks. Patients and their communities, in short, are presumed to be interconnected.

Clearly, patients are not passive in this process. Medical information should be shared, in addition to emphasizing the importance of relationships in healing. Transparency and sensitivity are the watchwords of the PCMH. Indeed, these traits are thought to lead to better health outcomes and a higher degree of patient satisfaction.

Yet, the question remains whether the PCMH is really community-based. Focusing on treatment goals and options, monitoring, information dissemination, and support, for example, does not necessarily mean that individuals or communities are in charge of interventions. In this regard, some research has found that the physicians involved with the PCMH are aloof, distant, self-absorbed, and too focused on medical technology, such as their computers. 6

Apparently patients are consulted but often are not quite the centerpiece of this medical model. Although the rhetoric is appealing, the real interpersonal connections that are essential

for the PCMH to succeed are missing. In the absence of patient control, dignity and respect can easily fall by the wayside.

The result is that the PCMH has been characterized by patients as too formulaic and heavy on bureaucratic control. In fact, medical technology is often relied on to provide a seamless network of care, rather than interpersonal dialogue or community entrée. To become community-based and avoid these negative outcomes, a PCMH must address several philosophical issues that have not been emphasized by the PCMH. These themes illustrate the importance of individual and community control in formulating a health intervention.

A COMMUNITY-BASED ADDITIVE

In theory, the PCMH seems to be committed to patients participating in their care, but in practice this activity is often lacking. The participation that does exist is limited to consultations, although partnership is desired.

Consultations may be sufficient to exhibit interest in patients, and perhaps supply some emotional support, but becoming community-based is far more complicated.²⁶ Specifically noteworthy is that this outlook is based on a philosophical maneuver that is not an integral part of the current discussion about the PCMH. However, according to some critics, a health project will not likely become community-based in the absence of this shift in thinking.¹⁹

At the core of this community-based philosophy is an epistemology that leads to authentic participation by individuals and communities. Persons are understood to shape their realities through their actions and communication. ²⁷ Through the use of language, for example, persons and communities weave stories about themselves that give meaning and continuity to their lives.

Social reality is thus not something encountered but constructed.²⁸ Persons define, select, and commit to certain interpretations of behavior and events, thereby giving these phenomena significance. Health and illness also are enmeshed in this process. How these medical considerations are conceptualized, and thus dealt with in practical terms, may differ greatly between communities.

Those who are committed to a community-based philosophy reject the dualism that supports mainstream thinking about

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medicine.²⁹ According to the dualist paradigm, facts are objective, whereas definitions and commitments are subjective and treated as ancillary to these data. A community-based health strategy, on the other hand, does not make this distinction and marginalize the daily experiences of persons and communities. For this reason, personal and collective beliefs and other sentiments are thought to shape how people respond to health and illness, and thus should not be downplayed or overlooked.

Local knowledge, therefore, directs all community-based interventions.²¹ Personal and collective control are paramount to a community-based project. What this term means in this context is that local definitions,

conceptual schemes, history, and related cultural themes are central to adequately identifying illness and all remedies. Local knowledge is not optional in the design, implementation, and evaluation of a project and entertained, if available, but key to a successful intervention.

Community members are invited to participate in the construction of any instruments that may be used to accrue data or make clinical assessments. Community-based projects have used local health workers or health committees that function in this capacity. 30,31 In these examples, local residents are trained to participate fully in research or clinical care. Health committees, which are often composed of both community health workers and other community members, can develop research projects to assess illness in an area and discuss interventions that are compatible with local values. For example, a health committee in the Southeastern US developed research instruments to understand human immunodeficiency virus (HIV) stigma in a community, and through a collaborative research process informed local HIV clinical trials and educated practitioners on the services needed by local residents.³² Most important is that in community-based projects, persons are not merely consulted but play a key role in and basically control any intervention.

In the context of primary care, a recent project on the island of Grenada aimed to engage local residents in developing a local health needs assessment that would be used to inform the development of local services and as a basis for making referrals for specialty care.³³ A health committee was formed of neighborhood residents, and they worked collaboratively to develop an assessment that would screen for health conditions that were relevant in this community and would improve communication between physicians and patients. The outcome of

this process was that residents felt integral to primary health care in this area.

Because persons and communities create worlds through their actions, entrée must be gained to those domains, or we risk never properly understanding illness-related behavior. The aim of a community-based initiative, accordingly, is not simply to amass data about the objective features of an individual or collective, but rather to become correctly attuned to the interpretive and inventive process that creates the meanings treated as factual. Any method used, therefore, should not focus on the collection of data but on how the meanings of health and illness have been socially constructed through personal and interpersonal actions.

The principle that is operative at this juncture of community-based work is dialogue.³⁴ Although this idea is a regular part of discussions of community-based strategies, dialogue is often trivialized by health practitioners. Often dialogue is equated with exchange, awareness, companionship, or helping.^{35,36} In each of these cases, persons or communities may be encountered, but a genuine relationship is not necessarily established.

Dialogue requires that persons confirm one another. The world advanced by a person or community must be grasped, although in a particular way. Specifically, others must be understood in their own terms. Persons enter the experience of others and treat this knowledge as real, even if this realm defies normal expectations. The thrust of dialogue, accordingly, is to overcome preconceptions about normalcy or illness and to understand the perspectives held by others on these or related issues. In this regard, real dialogue involves discovery.³⁷

Clearly, dialogue is related to trust, but in a strange way. Dialogue cannot occur without trust, although trust is supposed to be enhanced by this process. In the end, however, trust is not a matter of contact, decorum, or emotional connection, but related to world entry.³⁸ Individuals must make themselves vulnerable enough to let others into their worlds while becoming more confident in this activity as interaction proceeds. As trust becomes more stable, practitioners and community members can begin to collaborate more fully in designing health services.

Niklas Luhmann, a seminal writer on this issue, made a distinction that is important between trust and familiarity.³⁹ His point was that becoming familiar with persons is not the same as, and does not necessarily lead to, trust. Regarding becoming community-based, the idea is that simply hanging around a community or making intermittent contact is insufficient to establish trust. Trust instead requires that solidarity be established; practitioners and community members must treat one another seriously, and over time the prospect for world entry and, thus, true collaboration improves.

In the absence of dualism, the world of others is not off limits. For this reason, local knowledge is accessible if persons take the time to reflect on their preconceptions and address what others intend. In this way, the PCMH can become community-based and realize the partnerships that are touted as basic to effective health care. A certain philosophical gambit, however, is required to achieve this end.

CONCLUSION

Home is an appropriate term to characterize the care promoted by the PCMH. Connotations such as comfort, connection, and support reveal the aim of this health strategy: To provide pertinent and comprehensive services in an inviting manner. Care should be offered in a commodious realm.

Home is a metaphor rather than a specific institution. Nonetheless, in a community-based project, home does have a location. Home, created by persons and communities, represents the domain or world where their values, definitions, and commitments are normative. When provided in the context of this home, care should be appealing and likely accepted. Sustainability, in fact, depends on this appeal.

For the aims of the PCMH to be realized, one must seriously reflect on the theme of home. The aim of this article is to link this idea to the world created by the interpretive actions undertaken by persons and communities. As a result, the improvements in health care that are associated with the PCMH might come to fruition. The desire to become community-based might be more than an ideal.

Like any home, however, outsiders must be invited to enter. Clinicians, accordingly, do not gain entry by simply showing up, but through dialogue that opens the doors to a person's or community's world. From this vantage point, care is not a service or an exchange, but an invitation to listen, to help, and to mentor. Surely, in this manner, medical treatment can become dignified, respectful, and effective, as proponents of the PCMH desire. •

^a Although an analysis of the criteria for a PCMH is beyond the scope of this article, there is certainly an opening for requiring the implementation of community-based strategies into a practice. For example, local health committees could develop sustainable practice interventions to engage patients, evaluate patient care, and conduct research on health outcomes.

Disclosure Statement

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Personal

The treatment of a disease may be entirely impersonal; the care of a patient must be completely personal.

— Francis Weld Peabody, MD, 1881-1927, American physician and professor at Harvard Medical School

EDITORIAL

Philanthropy and Beyond: Creating Shared Value to Promote Well-Being for Individuals in Their Communities

Thomas E Kottke, MD, MSPH; Nico Pronk, PhD, MA; Andrew R Zinkel, MD, MBA; George J Isham, MD, MS

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ABSTRACT

Health care organizations can magnify the impact of their community service and other philanthropic activities by implementing programs that create shared value. By definition, *shared value* is created when an initiative generates benefit for the sponsoring organization while also generating societal and community benefit. Because the programs generate benefit for the sponsoring organizations, the magnitude of any particular initiative is limited only by the market for the benefit and not the resources that are available for philanthropy.

In this article we use three initiatives in sectors other than health care to illustrate the concept of shared value. We also present examples of five types of shared value programs that are sponsored by health care organizations: telehealth, worksite health promotion, school-based health centers, green and healthy housing, and clean and green health services. On the basis of the innovativeness of health care organizations that have already implemented programs that create shared value, we conclude that the opportunities for all health care organizations to create positive impact for individuals and communities through similar programs is large, and the limits have yet to be defined.

INTRODUCTION

In 2015, when Tyler Norris was Vice President for Total Health Partnerships at Kaiser Permanente, he collaborated with Ted Howard, President of The Democracy Collaborative in Washington, DC, to challenge hospitals to help heal American communities.¹ They argued that health care organizations should be accountable for all their impacts as they deliver health services and that they should leverage all their assets to create benefit.

One of these assets is philanthropy, characterized by Porter and Kramer² as a component of corporate social responsibility. Although it can be used effectively as a tool for benefit, philanthropy is limited by the size of the organization, and it inevitably raises costs and reduces profits. By contrast, initiatives that create shared value are not inherently limited by organizational size because they generate a return on investment for the organization while creating social value and vice versa.

According to Porter and Kramer,² "The concept of shared value can be defined as policies and operating practices that enhance the competitiveness of a company while simultaneously advancing the economic and social conditions in the communities in which it operates." Their 2011 "big idea" paper offers several examples of initiatives that have created shared value. Among these are:

- Vodafone's M-Pesa mobile banking service in Kenya.³ The M-Pesa service creates shared value by decreasing the costs of banking for its customers while generating a profit for Vodafone. In Kenya alone, the service had enrolled 17 million subscribers between March 2007 and December 2011.
- RML (Reuters Market Light) Information Services Pvt Ltd. This service generates income for both Reuters and its customers because, by subscription, it provides weather information, croppricing information, and agricultural

- advice to Indian farmers in their preferred language. AML Information Services Pvt Ltd received a World Business Development Award for this program in 2010.
- General Electric's Ecomagination. General Electric's Ecomagination creates shared value by improving economic outcomes for its own operations (revenue of \$232 billion generated between 2005 and 2015) and its customers while simultaneously reducing emissions and mitigating other negative environmental impacts associated with commerce. Specific shared-value initiatives include increasing energy efficiency, increasing water reuse, and producing energy-neutral wastewater.

OPPORTUNITIES FOR HEALTH CARE ORGANIZATIONS TO CREATE SHARED VALUE

The number of opportunities for US health care organizations to implement programs that create shared value is limited only by imagination. In this section, we present examples of five types of products, each of which shows how health care organizations can reach beyond philanthropy and simultaneously create value for themselves while improving the well-being of the individuals, organizations, and communities they serve.

Telehealth

Telehealth encompasses a broad variety of technologies and tactics to deliver virtual medical, health, and education services. Examples of telehealth services are direct clinical services, home health and chronic disease monitoring and management,

Thomas E Kottke, MD, MSPH, is the Medical Director for Population Health for HealthPartners and a Senior Clinical Investigator for HealthPartners Institute for Education and Research in Minneapolis, MN, and a Professor at the University of Minnesota Medical School in Minneapolis. E-mail: thomas.e.kottke@healthpartners.com. Nico Pronk, PhD, MA, is the Vice President of Health and Care Engagement for HealthPartners in Minneapolis, MN. E-mail: nico.p.pronk@healthpartners.com. Andrew R Zinkel, MD, MBA, is the Associate Medical Director of HealthPartners in Minneapolis, MN. E-mail: andrew.r.zinkel@healthpartners.com. George J Isham, MD, MS, is a Senior Advisor to HealthPartners in Minneapolis, MN. E-mail: george.j.isham@healthpartners.com.

disaster management, and consumer and professional education.⁶

Telehealth services provide consultation through a range of media that include the telephone and Internet so that two or more individuals can consult without travel. The benefits of properly organized and supervised telehealth programs for medical care include lower-cost care; uniform, evidence-based care; care that is more convenient and, in many cases, quicker; travel is eliminated; and the patient neither exposes other individuals nor is exposed by others to infectious conditions. Because overhead is lower and telehealth services offer a new avenue of access for patients, they can generate new revenue for health care organizations.

HealthPartners' virtuwell is one example of a telehealth service that addresses all 3 components of the Institute for Healthcare Improvement's Triple Aim: health, cost, and experience.^{7,8} Starting in Minnesota and now licensed in 12 states, virtuwell offers treatment of more than 50 common conditions, including sinus infections, bladder infections, conjunctivitis, and acne. On the basis of an online questionnaire and an interview, a certified nurse practitioner makes a diagnosis, creates a personalized treatment plan, and sends a prescription directly to a pharmacy, if needed. The patient is charged \$45, and follow-up care is free. There is no charge if the patient's condition is not suitable for treatment through virtuwell. HealthPartners estimates that, on average, the services offered by virtuwell would cost \$560 if provided in an Emergency Department (ED), \$175 if provided in an urgent care center, \$140 if provided in a physician's office, and \$89 if offered in a retail clinic. HealthPartners claims analysis calculated that, by the third quarter of 2016, virtuwell had delivered treatment plans to more than 220,000 patients, with an average savings of \$105 per visit or a total of \$22 million. Nearly all (97%) of the patients agreed that the experience was worth the cost, and 99% agreed that virtuwell is simple to use, saves time, and is safe. Many insurance plans cover the service after the application of copays and deductibles.

Similar to other telemedicine programs, virtuwell creates social value in several ways. Among these are reducing pathogen

transmission by reducing visits to clinics and reducing carbon emissions by reducing the need to travel for care. The service also reduces roadway congestion and increases productivity by reducing time away from work for clinic visits.

Worksite Health Promotion in and by Health Care Organizations

Worksite health promotion programs that assess health risks and provide feedback improve health and well-being when combined with health education programs. 9,10 These programs create social value when they reduce disease burden, increase disposable income by reducing health care costs and increase productivity. Because there are markets for these programs, they also create an opportunity for health care organizations to create shared value. Best practices for worksite health promotion programs have been identified,11-13 and a 2013 publication discusses the benefits and opportunities that emerge when health systems integrate lifestyle behavior interventions into their products and services.¹⁴ Case studies also illustrate the substantial improvement in health-related behaviors and reduction in health risk associated with worksite health promotion programs. 13,15

One example of worksite health promotion is the one implemented, in 1979, by Johnson & Johnson. Associated with the program, average annual growth in total medical spending was 3.7 percentage points lower than for similar large companies between 2002 and 2008.16 Company employees benefited from meaningful reductions in rates of obesity, hypertension, hypercholesterolemia, tobacco use, physical inactivity, and poor nutrition. Average annual savings per employee were \$565 (2009 dollars), producing a return on investment equal to \$1.88 to \$3.92 saved for every \$1 spent on the program.¹⁶ We have calculated that the impact of risk factor changes of this magnitude far outweigh the potential impact that might be achieved by improving access or quality of medical care for acute events caused by heart disease.¹⁷ The benefits of improvements in employee health and productivity can accrue not only to customers of the health care organization but also to the health care organization itself if its own employees can access the program. Worksite health promotion programs have also been associated with improved company financial performance, creating yet another value for the employer.^{12,18}

School-Based Health Centers

School-based health centers (SBHCs), first organized more than 40 years ago and now numbering more than 2300, strive to keep students healthy and ready to learn. They have achieved both health and educational milestones.¹⁹ The Community Preventive Services Task Force recommends the implementation and maintenance of SBHCs in low-income communities to improve educational and health outcomes.²⁰ The positive educational impact includes school performance, grade promotion, and high school completion. Positive health outcomes include delivery of vaccinations and other recommended preventive services, reduced asthma morbidity and ED and hospital admissions, increased contraceptive use among sexually active females, better prenatal care and birth weight, and improved health risk behaviors. Because SBHCs aim to meet the needs of disadvantaged populations, address the health-related obstacles to educational achievement, and address the cultural, financial, and privacy- and transportation-related barriers to clinical, preventive, and health care services, they have the potential to promote social mobility and improve health equity.

A recent analysis reported the economic impact of SBHCs from several perspectives.21 From society's perspective, the annual benefit per SBHC ranged from \$15,028 to \$912,878. From a health care payer's perspective, especially that of Medicaid, SBHCs resulted in net savings of \$30 to \$969 per visit. Two cost-benefit studies21 showed that the societal benefit of an SBHC exceeded the intervention cost, with the benefit-cost ratio ranging from 1.38:1 to 3.05:1, and from the patients' perspective, savings were also positive because of decreased losses in school attendance, decreased travel time, and improved health.

SBHCs offer two business opportunities to health care organizations. They offer the opportunity to capture new revenue from a new care delivery site with the potential to provide services to school employees, too. Because they are associated with a lower rate of ED visits and hospitalizations, SBHCs reduce the use of expensive care and reduce the risk of needing to provide uncompensated care in the ED and hospital.

Green and Healthy Housing

Health care organizations have an opportunity to create shared value by investing in housing in the neighborhoods that surround their facilities. Clean and affordable housing increases the health of the occupants, particularly by reducing the burden of asthma, and it creates value for health care organizations by decreasing burden on Medicaid budgets.

As an example, the Green & Healthy Homes Initiative in Baltimore, MD, describes the case of a woman in Baltimore whose son's intractable asthma disappeared and her energy bills declined by 30% when the Green & Healthy Homes Initiative corrected the health hazards in her home.²² She had been about to lose her job because of the time she needed to spend with her son in the ED. After the Initiative's intervention she received a job promotion and her son joined the honor roll with perfect school attendance. She is now contributing to a 401K and a 529 college savings account. The savings to Medicaid are estimated to be \$48,000.

Another example of healthy housing is the collaboration between HealthPartners and St Paul Ramsey County Health Department in Minnesota to reduce the incidence of lead poisoning in the county. When the county Health Department identifies a building where children are being exposed to lead, it works with the landlord to replace the windows, the main source of lead-containing dust.²³ To increase the impact of the program, HealthPartners notifies the county Health Department of the address of residence when its staff members identify a child with high lead levels. Identification can result from screening or because of manifest illness. Because the costs of the windows are partially subsidized by the program and the alternative for the landlord is to bear the full cost if they do not participate in the program, they usually participate.

Because many hospital workers live close to their place of work, clean and affordable

housing also benefits the sponsoring health care organization when the health and productivity of hospital employees improve. Because young employees today want to live closer to work and are becoming increasingly concerned with a hospital's approach to the community and the

environment, anchoring neighborhoods can also improve employee retention and improve organizational image in the eyes of its neighbors, a need faced by many health care organizations.

In 2013, David Zuckerman²⁴ and his colleagues at The Democracy Collaborative published an extensive analysis of the opportunities that hospitals are taking to anchor neighborhoods while satisfying some of their own

needs. For example, Bon Secours Baltimore Health System in Baltimore, MD, and St Mary's Health System in Lewiston, ME, implemented neighborhood revitalization strategies partially because the physical condition of the surrounding community was negatively affecting employee recruitment efforts. Likewise, Mayo Clinic in Rochester, MN, created a permanent stock of affordable housing in the 1990s because an affordable housing crisis was driving away new employees. Henry Ford Health System and Detroit Medical Center in Detroit, MI, provide financial assistance for potential homeowners and renters seeking to live in Midtown Detroit. Finally, St Joseph's Health System in Syracuse, NY, and Cleveland Clinic and Cleveland University Hospitals in Cleveland, OH, all offer guaranteed mortgage programs to help reduce the costs of home ownership.24

Clean and Green Health Services

The clean and green health care movement creates many opportunities for health care organizations to create shared value by reducing their carbon footprint and reducing the amount of pollution they generate. ^{25,26} All costs, including those generated by energy-inefficient buildings and the byproducts of care, are borne by

patients, and health suffers when community members are exposed to the emissions of coal-fired power plants.²⁵

Although not the only health care organization committed to creating shared value by reducing its environmental impact, Gundersen Lutheran (now Gunder-

> sen Health System) in La Crosse, WI, is an outstanding example of leadership in clean and green health services. Gundersen is an organization with 41 clinic facilities and a 325bed tertiary care hospital; a physician-led integrated delivery system with approximately 700 physicians and 6500 employees; residency and medical education programs; a health plan; and a variety of affiliates, including an ambulance service, rural

ambulance service, rural hospitals, nursing homes, and a hospice service. Not only has Gundersen made a commitment to the health and well-being of its patients and communities through its sustainability program, it has spun off a successful consulting business, GL Envision (now Gundersen Envision).^{27,28}

The Envision Web site lists five reasons why Gundersen developed a sustainability program and why other health care organizations would benefit²⁷:

- 1. Funds once budgeted for energy expenses can be used to improve margins
- 2. Sustainability programs help to reduce costs associated with disposal
- Sustainable practices are becoming more important to customers and potential employees as they make their choices about where to spend their dollars and where to work
- 4. Emissions from fossil fuels and other hazardous waste have a harmful health impact
- Sustainability is better for the environment.

The Envision program contains 4 components: energy management, waste management, recycling, and sustainable design. Because of these programs, Gundersen Health System generated 72 days of energy independence in 2015, experienced an 81-day stretch of cumulative

energy independence (September 11, 2015, to November 30, 2015), and reduced preconsumer food waste by 88% from a 2010 baseline. In 2014, they saved nearly \$500,000 by recycling waste.

HealthPartners, in the Twin Cities metropolitan area of Minnesota, has also had considerable success in reducing landfill waste and its carbon footprint through a multifaceted sustainability program.^{29,30} For example, in 2015, it diverted nearly 100 tons (90 metric tons) of operating room waste from landfills, and it decreased paper use by 7.1 million sheets through the implementation of electronic communications. Solar gardens at 2 locations generate enough energy to power nearly 7 houses.

TAKING ACTION AND SETTING PRIORITIES TO CREATE SHARED VALUE

Unfortunately, the opportunities to create shared value outstrip the available resources; prioritization is required. The organizational resources that are required to develop and to maintain a shared value program, and organizational expertise and naiveté in the area, must be considered when prioritizing initiatives. Although an analytic framework might be seen as easing the prioritization process, we are cautious about adopting one that is more stringent than the criteria defined by Porter and Kramer² (and thus constrains thinking): "policies and operating practices that enhance the competitiveness of a company while simultaneously advancing the economic and social conditions in the communities in which it operates." However, we have identified a few

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issues that must be considered.

The prioritization process is ideally transparent, with the resulting programs addressing community concerns and priorities. Using the local community health needs assessment can help achieve this goal. Both burden and disparity must be considered.³¹ For example, even though

employed individuals tend to be healthier than the average population, ³² worksite health promotion programs can have a major impact because they can reach most American families. On the other hand, although homelessness does not affect nearly as many people, programs that reduce homelessness have a very large impact on each recipient and on the costs borne by health care organizations because the homeless tend to have high needs for health care.

There are additional barriers to the implementation of shared value programs in the health care sector.³³ For example, organizational leaders may need assistance to make the connection between the health of the community and their organization's business interests. They might not immediately grasp how housing or other community interventions promote their organizational mission. Even if convinced of the value of program development, they may not know what to do.

Case studies of successful shared value programs might increase executive confidence and organizational capability.^{1,24} Participating in a collaborative effort can provide additional guidance and experience. In the field of telehealth, the Center for Connected Health Policy is an organizational resource.6 For organizations that are interested in building their worksite health promotion capabilities, Health Enhancement Research Organization is an excellent resource. 18,34 Organizations that wish to improve student outcomes by sponsoring SBHCs might turn to the School-Based Health Alliance.³⁵ Multiple organizations can help health care organizations understand how to create shared value by improving housing stock and access to affordable homes; such organizations include LISC (Local Initiatives Support Corporation) and its partners who are advancing the Healthy Futures Fund, the Corporation for Supportive Housing, and the Build Healthy Places Network. 36-39 Stakeholder Health, an organization of health care organizations that are investing in community development through local purchasing and similar initiatives, can provide insight through shared mission and experience.⁴⁰ In the area of environmental action, Practice Greenhealth and Health Care Without Harm are examples of resource organizations.^{25,26} A 2016 National Academy of Medicine workshop summary also describes a number of ways by which businesses can improve the health of communities.⁴¹

CONCLUSION

In 2011, Porter and Kramer² introduced the concept of creating shared value: adopting "policies and operating practices that enhance the competitiveness of a company while simultaneously advancing the economic and social conditions in the communities in which it operates." In this article, rather than presenting a systematic review of the opportunities to create shared value or potential program impact, we have simply provided examples in five areas where health care organizations might simultaneously advance their own mission and the conditions of the communities they serve: telehealth, worksite health promotion, SBHCs, green and healthy housing, and clean and green health services. Although there are obviously opportunities that we have not described and there are shared value products that are yet to be identified, these examples are evidence of the immense opportunities for health care organizations to create shared value for the communities in which they operate. �

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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The Test

A decent provision for the poor is the true test of civilization.

— Samuel Johnson, 1709-1784, English poet, essayist, moralist, literary critic, biographer, editor, and lexicographer

NARRATIVE MEDICINE

Lessons Learned in War

Alberto Hayek, MD Perm J 2017;21:16-176

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Conscription—the draft—in the US ended in 1973, making Vietnam the last war in which civilian physicians were drafted for war service in the military. The changes from civilian to military life were not easy and, for foreign physicians coming with a green card for medical training to the US, the transition went from troublesome to traumatic. Most single physicians at the peak of the war were drafted, and with exception of the group of "yellow berets," physicians who spent the war in places such as the National Institutes of Health, most were exposed to war.

Every day I see human reminders of the tragedies of war in our homeless soldiers begging on the streets of San Diego, CA. They are mostly men, bald or white-haired veterans of the Vietnam War and the younger ones from the Iraq and Afghanistan Wars who always look much older than their age.

I was drafted into the US Army in my mid-20s, soon after immigrating to the US for postgraduate medical training. Being the 1960s, this made me an ideal candidate for the draft as a young, single, and newly minted MD. Promptly after basic training I was sent to Vietnam to serve as a flight surgeon for an Army helicopter battalion. Even now after more than 40 years, when I see those poor and homeless veterans, I witness the enduring side effects that war leaves on all its participants. In my case, I still harbor not the physical but the emotional scars that I now know account for mild posttraumatic stress disorder (PTSD). Fortunately, my PTSD is easily manageable, save for the sporadic nightmares that take me back to unwanted war memories and the exaggerated motor responses to sudden loud noises-always a surprise to those who witness those responses and an embarrassment to me.

I certainly can't forget the soldiers suffering or the Vietnamese civilians of all ages, wounded for no reason, who were simply in the wrong place at the wrong time. During the 30-plus years of medical practice after my war experiences, in a life dedicated to caring for children and their families, I have many times relived an episode that touched me deeply and contributed to my professional behavior as a pediatrician.

Being the only MD for an Army flight battalion stationed in the heart of the Mekong Delta put me in very close contact with all the pilots. My medical crew was first to take care of those wounded during battle, mainly stabilizing vital signs before evacuating them to facilities for more definitive treatment. Part of my responsibilities included listening to the pilots' private concerns because in their eyes, short of a minister, I had the capacity to understand and provide counseling. The rest of my time was dedicated to caring for the many Vietnamese civilians constantly hurt during combat operations, where they rarely knew who the aggressor was. While treating civilians, I saw horrible wounds like the burns inflicted by napalm bombs on women and their children during military operations. Wounds, almost impossible to describe, inflicted on every organ and extremity of the body, including the severe head trauma that, for Vietnamese civilians, almost always carried a fatal prognosis. Although a daily occurrence, I could not avoid sharing the emotional burden with patients confronting the face of death with a dignity and resignation that I profoundly respected but never understood.

I learned much from the suffering of so many; my bearing witness and participating in those moments profoundly imprinted on me forever. An especially painful episode involved a senior helicopter pilot in his mid-40s with the rank of captain. Nick was at the age where he would not advance in rank any further. From the few words we exchanged during routine encounters in the evenings at the barracks, I learned that he came from a small town in the South and had risen through the ranks to become an officer through training at the Officers Candidate School.

Once back in the barracks, a building retrofitted into lodging in the only 5-story building in Can Tho, a city 60 miles south of Saigon, now Ho Chi Minh City, it was usual for the pilots to get together after each "workday" as battles are called in the daily parlance of war. The officers gathered on the top floor, which contained a bar that opened onto a balcony. From there one could see the multitudes of flares that were dropped to identify potential infiltrators into the surrounding plains. The talk was always war related, in efforts I suppose to relieve the stress of the day and the reality that the next day would bring another occasion to do or to experience harm.

One particular evening, Nick was, as usual, on his own just listening to his buddies talk when he approached me, asking to move a bit further away from the group of pilots. On the other side of the bar, we quietly sat in a corner protected by a wall and the privacy of a cloudy night. We sat there silently for a few minutes until Nick began to tell me about the search and destroy operation of the day, looking for Vietcong soldiers or sympathizers along the river traversing the Mekong Delta. A pilot in a helicopter flying near one of the hamlets reported incoming ammunition—that was all the provocation needed to call for a coordinated attack on the four or five huts comprising the hamlet. Three or four helicopters discharged their rockets into the village until only fire and

smoke remained. To end the operation, Nick was ordered to fly in a final circle around the hellish scene left from the decimated, burning huts. Suddenly he saw what looked like a small child crawling out of the burning huts and into a clearing near the thick surrounding jungle. Coolly, Nick felt instantly that the child wouldn't survive on its own and that a terrible death awaited the infant left alone in the jungle. Automatically, he pushed a button that fired his last rocket and, as the missile exploded, he flew away feeling that he had done something that would never leave his mind. When he finished telling me this experience, in a voice fractured by emotion, I looked at his tearing eyes and instinctively I knew that the pain of this tragedy would involve me forever. No words came from my mouth. I just put a hand on his shoulder while I also cried. By the next day he was again flying another mission, carrying the hidden ghosts of his actions.

Nick and I both came out alive from the war knowing we would always be marked by the atrocities we had caused or witnessed. I don't know what happened to Nick after his discharge from the Army, I just know that my silent listening had allowed him to forever share the horror he had caused. In civilian life one does not encounter these kinds of experiences, but the pain of a family with an ill child confronting a fatal prognosis is akin to a missile sent from an unknown source. As a physician, these painful experiences haunt me when all I can do is to be a silent participant while sharing the pain of unavoidable death. ❖

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World War IV

I know not with what weapons World War III will be fought, but World War IV will be fought with sticks and stones.

— Albert Einstein, 1879-1955, German-born theoretical physicist

NARRATIVE MEDICINE

Deer in the Headlights

Tom Paluch, MD Perm J 2017;21:17-014

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"But I'm only thirty-three years old," she says plaintively, as if some promise had been broken, some warranty had yet to reach its term. I have no easy response. Not quite speechless, I'm left with words that are of no value: words that can't possibly weaken the blow of the single, brutal word I'd just spoken. My first inclination is to duck behind the statistics that roll from my lips with practiced ease: they've served me well enough thus far. Easy to manipulate, the *numbers* lend a certain comfort or impose a certain gravitas depending on how I present them, on what I choose to emphasize.

"... Ninety percent survive ..." usually brings a brief halt to the tears, despite the fact that those very words mean that one-in-ten dies. I rarely mention the minority: it serves little purpose on a day like this, a day on which I've brought to someone's world a sentence that I haven't imposed, but merely transmitted.

The numbers matter not to her right now. She's only 33 years old. Only 33 and she has cancer. Her eyes are filled with tears and terror. She looks at me with those eyes I've seen a thousand times, searching mine for a hint, a clue, some subtle suggestion that it, that she, will be okay. I look at her as she sits in an openback gown, its silly blue and white pattern a garish contrast to the simple, but elegant, pinstriped suit she'd chosen to wear this morning. She'd probably chosen that suit as she had chosen her clothes each day: with an eye toward the effect they'd have on her appearance and on those who would see her. The effect was meant to be handsome and professional; the navy blue a stunning and contrasting complement to her flawless white skin and shoulderlength blonde hair. Now, as she sits on my examination table, her hands clutching the end of the cheap vinyl cushion in a grip that turns her knuckles white, her choice, her suit, is irrelevant. Her appearance is that of an innocent and vulnerable girl-child ripped from the predictability and security of her known world and thrown into mine, a world of frightening caprice, coarsened by nearly unintelligible jargon and terribly expensive technology. She doesn't know it now, but she'll never wear that suit again.

"Nobody in my family has breast cancer," she argues, as if that fact can somehow make benign the malignant cells that my biopsy needle removed from the lump in her right breast. I'll come to learn that she's an attorney, a bright and promising one at that; an attorney whose incisive intellect, diligence, and poise point to a future envied by her contemporaries. None would envy her at this moment.

"How sure are you that it IS cancerous?"

"Most breast cancers are sporadic," I respond quickly; then immediately, "Very sure," snuffing out any hope, desperate as it might be, that this was all a terrible mistake, and we all could

go on as if nothing had happened. I begin my spiel, my canned speech explaining how "hopeful" breast cancer really is, using those damned statistics to show her how happy she should be that she has breast cancer, a cancer that claims only one-in-ten of its victims' lives over ten years, and not pancreatic cancer, which takes nearly every life it touches in less than three. I tell her of patients past, who are alive and well, leaving out the stories of those who were not fortunate enough to fall under the *survivor* curve in the graphs. She listens carefully, intently, hearing nothing.

She nods her head at the appropriate phrases, interrupting my practiced stoicism now and then to wipe a traitorous tear from her cheek. She barely flinches when I speak of operations yet to come, of the small but real chance that she may lose her breast, of the chemotherapy that will sicken her, steal her hair, and make her more fatigued than she can possibly imagine.

I look at her as I speak, and I hope my eyes won't betray me that the calm, even-tempered demeanor, the act I've cultivated for so many years, during so many of these conversations, will hold sway over my sadness: the deep, abiding grief that I feel at moments like this.

I hide in the safety of my lab coat, my hands shoved deep into its pockets. Its stiff white fabric offers armor-like security and authority. Yet somehow, it remains at once cold and stifling, like the corner of a deep cellar in the face of an oncoming storm. And like the family hiding from the tornado, I am at this moment impotent—little more than a spectator, doing what I know must be done but wondering just what good, if any, it will do.

She returns my gaze, eyes puddled with tears. I can smell the quiet terror beneath those tears. She's more concerned about the impact of this moment on her life than about her life itself. Immortality, that trait we quietly, insidiously learn as children, test as adolescents, accept as self-evident as young adults, then find so deceptively, patently false as we age, won't allow her to even consider the possibility of her death. She imagines the impact of this disease on her career and on her body, never giving thought to what it might do to the little girl that lives beneath the fine veneer of the woman she's become. I cannot and will not be the one who will frighten that little girl with the healthy dose of reality that has become my *clinical experience*.

For now, I'm the kindly doctor: reassuring, patriarchal, authoritative. In her eyes, I see the need for her to believe that I can do something—no, everything—to stand between her and her cancer. I don't have the heart to tell her that I'm just a man, a man with a special gift. It is a gift that lets me touch people's bodies in times of need. In that touch, on occasion, is a gift that's even greater: a chance to cure. Yet, as a condition of that gift, that

unique and precious gift, comes a curse: a curse so oppressive and heartlessly savage that at times I wish to return the gift, to rescind the offer, to run away from this job, this profession, and never look back. The curse is simply that it is not up to me, that I can never, ever, choose whom it is who gets the cure.

And so I look at her, she with her frightened eyes and brave demeanor and wonder as I always wonder, "Will she be one of the lucky ones?"

"So what do you think my chances are?" she asks, eerily echoing my thoughts.

I stammer, then pause, the statistics poised on my tongue, ready to leap to the rescue: my rescue, not hers. Honesty prevails.

"I just don't know," I respond flatly. The profundity of those four words is not lost on her. Her eyes widen like those of a deer in the headlights on a lonely country road late at night, frozen by the oncoming, unknown terror, unable to run, waiting to see if this thing, this rushing menace will stop or sweep it away.

And then, forsaking technology, clinical acumen, surgical experience and expertise, abandoning science and logic, I practice the best medicine I know: I pull my hands from my pockets, place

my arms around her shoulders, and hold her. Her sobs come now in huge heaves. Thankfully, there are no words.

At that moment, in the deepest recess of my soul, in that place where words don't dwell, but images live and flourish, I see that deer, the deer in the headlights, the one I saw moments ago. In this moment, this once, I imagine turning the wheel of that rushing machine, that determined, most certain engine of doom, and watching those soft, silent black eyes turn away knowingly, gratefully, and leap in a graceful, most vital leap, vanishing into the woods, finding its way to safety and survival.

I hold her until she somehow senses that image, until she, like that deer, chooses to fly to life. ❖

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Delicious Ambiguity

I wanted a perfect ending. Now I've learned, the hard way, that some poems don't rhyme, and some stories don't have a clear beginning, middle, and end. Life is about not knowing, having to change, taking the moment and making the best of it, without knowing what's going to happen next.

- Gilda Radner, 1946-1989, American comedian and actress

NARRATIVE MEDICINE

Abdominal Distension—An Unexpected Gift

Ching Soong Khoo, MD, MRCP (UK)
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ABDOMINAL DISTENSION

"Doctor, there's a lady with abdominal distension."

"Certainly, please ask her to see me," I replied.

It was a scorching day at a district clinic in Phnom Penh. The sun blazed down on us with stifling heat. I was one of a group of 20 volunteers from various strata of Malaysian society, including medical and dental students, laboratory technicians, clinicians, and administrative staff. We were volunteering in a health-screening program to deliver care in one of the marginalized communities in Phnom Penh.

As the patient entered the room, I smiled and tried to build rapport with her, using my limited Cambodian vocabulary. She was a Cambodian woman in her late 20s. Apart from looking malnourished with a vague mass at the umbilical level, her physical examination was grossly unremarkable. Because of her presenting concern of the abdominal mass, I recommended an abdominal ultrasound. Although initially apprehensive, she agreed to the scan once the translator (a local student) persuaded her.

"That is a baby!" I swiftly showed her the fetal heartbeats on the scan. Her eyes immediately welled up with tears of joy-relieved that the swelling in her tummy wasn't something more sinister. Furthermore, she had hoped for a baby since her marriage 6 months earlier. Being underprivileged with limited access to health care services, she had felt helpless and frightened by her abdominal distension. The news of her pregnancy was an unexpected gift of joy to her. I reviewed her vital signs and discovered that her blood sugar level was low at 3.3mmol/L. While I was working out a plan for her antenatal follow-up and low blood sugar, the local student translator reassured me, "Doctor, it is common to see people with low blood sugar in our community."

True indeed, I had seen a few adults earlier at this clinic with low blood sugar and unknown past medical history.

CAMBODIAN HISTORY AND THE RESULTS OF GENOCIDE

The day before I began my medical volunteering program, I visited the Tuol Sleng Genocide Museum in Phnom Penh, which chronicles the terror of the Khmer Rouge and Cambodian genocide. The Nobel Laureate Pearl S Buck is often quoted as saying, "If you want to understand today, you have to search yesterday." I was profoundly affected by the history of Cambodia I learned during my visit to the museum. Cambodia had been wobbling with political turmoil not long after independence was gained in the year 1953. From 1975 to 1979, the Khmer Rouge regime devastated Cambodia completely:

paralyzing the economy, decimating the cultures and traditions, destroying the health care system, increasing poverty and famine levels, and killing and torturing hundreds of thousands. More than a million (21% of the population) were estimated to have perished in this Cambodian genocide. Cambodia was placed under a state of international embargo for almost a de-

cade after the fall of the Khmer Rouge. In the 1990s, financial support for extensive reconstruction of Cambodia was granted from international and nongovernmental organizations.

Today, Cambodia is classified by the World Bank Group as a lower middle-income country.² With sustained efforts between the government and the international organizations to rebuild and

reform health care services, Cambodia has made significant progress in health status. However, there are still major ongoing challenges. Inequities in access to and utilization of health care remain profound owing to wide gaps in socioeconomic status and geographic distribution. There is a diversified health system in Cambodia in terms of service providers, ranging from local qualified physicians, physicians from nongovernmental organizations, and private care providers to traditional healers. Though poorly regulated, patients turn to private care providers for curative care, whereas the public sector is primarily responsible for preventive care. Use of the public health care services is low because of the poor infrastructure, low staff numbers, inaccessibility in some rural regions, and lack of staff motivation. Reform in health care financing re-

> mains a challenge because expenditures on health services are accounted for by household out-ofpocket payments, which are paid overwhelmingly to the private sector.

> Women's health is one of the most exigent issues in Cambodia. Women suffer greatly from the effects of poverty: poor access to education, physical abuse and violence, sexual exploitation, inaccessibili-

ty to health care, malnutrition, communicable diseases, unwanted pregnancies, and high maternal morbidity and mortality. Despite a dramatic decline, Cambodia's maternal mortality ratio remained high at 250 deaths per 100,000 live births in 2010.3 Women from remote communities have little access to antenatal care. The major challenges in those areas include poor sanitation, inadequate supply of safe

Cultural beliefs, which emphasize the use of traditional practices and dissuade pregnant women from seeking antenatal care and support from qualified birth personnel during delivery, are dominant in the rural areas.

Ching Soong Khoo, MD, MRCP (UK), is an Internist at Pusat Perubatan Universiti Kebangsaan Malaysia in Kuala Lumpur. E-mail: chingsoongkhoo@gmail.com.

drinking water, lack of skilled midwives and obstetricians. Lack of transportation and financial assistance is a barrier to seeking antenatal care. Cultural beliefs, which emphasize the use of traditional practices and dissuade pregnant women from seeking antenatal care and support from qualified birth personnel during delivery, are dominant in the rural areas. Many women must turn to abortions and to deliveries in unsafe conditions. Unmet demand for family planning and birth spacing remains high because there is poor availability of and access to contraceptive options.

AN UNEXPECTED GIFT

Those above-mentioned issues explained precisely how a pregnancy would go undetected in Cambodia. My patient's situation was just the tip of the iceberg.

My patient stood up from the couch and thanked me. I attempted my very best to provide her with antenatal education via the translator. Feeling reassured, she left the consultation room with an appointment card. I prayed for her. I hoped that she would deliver a healthy baby in the future without complications.

"Next patient, please." After regaining my composure, I continued to see patients, many of whom had been enduring long waits.

"Doctor, another lady with abdominal distension," the triage student/assistant said, passing me the case note.

"Sure, my pleasure," I replied smilingly. ❖

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Handsomest Things

A Ship under sail and a big-bellied Woman, Are the handsomest two things that can be seen common.

— *Poor Richard's Almanac;* Benjamin Franklin, 1706-1790, polymath, author, printer, political theorist, politician, freemason, postmaster, and Founding Father of the United States

BOOK REVIEW

Prenatal Development and Parents' Lived Experiences: How Early Events Shape Our Psychophysiology and Relationships by Ann Diamond Weinstein

Review by Anna Luise Kirkengen, MD, PhD

Perm J 2017;21:16-186

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Why is this book, with its complex title linking life events to the fetus, the human psyche, physiology, and relationships—an important book for us physicians? The answer is straightforward, yet both demanding and advanced. This book provides a special body of new knowledge related to good medical care for pregnant women and babiesto-be. No other phase in the human life cycle offers us professionals a more fruitful realm for preventive measures with regard to future sickness in both parents and children. Here is the true arena for the best in family practice and the most cost-effective care. Dedicated physicians, especially primary care physicians, will see their opportunities in medical practice guided by this synthesis of multidisciplinary knowledge.

What makes this knowledge special is its relevance to the becoming of a human being, a child, as it is embedded in the long history of the evolution of life and humankind, condensed in the specific history called phylogenesis, influenced by sociopolitical contexts and cultural practices, and informed by the personal lifetime experiences of its parents. The most recent contribution to this knowledge is provided by epigenetics, a discipline exploring how life experiences affect genetic functionality. This implies the recognition that personal experiences can affect whether a particular gene will express its genetic information or not. In simple words, genetic function can be either activated or blocked, depending on a particular person's life experiences. What seems to activate potentially pathogenic genes most efficiently may be a person's long-standing feeling of being powerless as a result of lifetime adversity.

Here we enter the everyday clinical scene: Our encounters with persons experiencing hardship, which is frequently more or less hidden because of secrecy, shame, or cultural conventions. In the clinical situation of encountering and counseling pregnant women and their partners, epigenetics literally may be the key in terms of health risks for both the mother and the unborn child. The prevention of these risks is a significant medical task and challenge. To be in charge of the future health of a child-to-be demands more of a responsible physician than giving advice as to smoking, drinking, eating, and the like. The physician is called to familiarize him/herself with the life of this particular pregnant woman, and whether her life is affected by burdens that may affect her unborn child on the epigenetic level—and with potentially lifelong impact on health and functioning. Knowing this is crucial.

This is the core of the present book, which provides a threelayered complex of understanding. First, knowledge of the scientific facts about the phylogenetic process, the becoming of a human being, the literal unfolding of the evolutionary script of making human bodies adapted to the physical world. Next, the pregnant woman's embodied, experienced knowing about her world, her sociocultural context and conditions, her familiarity with and confidence in her lifeworld, and her sense of safety and agency in terms of self-confidence and trust toward other people. Finally, the developing not-yet-born child's knowingby means of streams of information-about the "outer" world, predominantly provided by its mother's psychophysiology.

The term psychophysiology denotes the translation of emotions into bodily, material

Prenatal Development
and Parents' Lived
Experiences

How Early Events Shape Our Psychophysiology
and Relationships

Ann Diamond Weinstein

New York, NY: WW Norton and Co; 2016 ISBN-10: 0393711064

ISBN-10: 0393711064 ISBN-13: 978-0393711066 Hardcover: 496 pages; \$47.50

processes involving the hormonal, cellular, and neural aspects of bodily being. We need to acknowledge that there are no body-less thoughts, perceptions, emotions, or sentiments. There are no "pure" psychic experiences. All experiences—all learning, and thereby knowing—are grounded in as well as expressed bodily. Current research in the rapidly evolving field of epigenetics is helping us recognize that the unborn "knows" not only about the physical world for which it is designed by evolution, but also the social world it is informed about in utero by its mother's physiology. This kind of knowing is not cognitive in nature but hormonal, preparing the child for being born into sociality and relatedness. It is a major advance in our professional understanding of the earliest phenomena affecting human development, and ultimately health and social function. In short, this book is about new insights into the very earliest determinants of sickness we later see in the office, and how we, as medical professionals, might support a healthy development by early application of this new understanding. �

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Anna Luise Kirkengen, MD, PhD, is a Professor in Family Medicine at the Universities of Tromsø and Trondheim, and a former Family Practice Physician in Oslo, Norway. She now lectures on the topic of how abused children become sick adults. E-mail: anlui-k@online.no.

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rticle 1. (page 4) Body Mass Index and Mortality in a Very Large Cohort:	Article 3 (page 46) Physician Guide to Appropriate Opioid Prescribing for Noncancer Pain			
test Really Healthier to Be Overweight? hese data show that overweight (body mass index [BMI] 25-29 kg/m²) or obese (BMI ≥ 30 kg/m²) ersons are at increased risk of death vs persons with BMI < 25 kg/m². Which one of the bllowing statements about this increased risk is false? a. the data prove that weight loss reduces risk b. it was present for men and women c. it was more pronounced for younger than for older persons d. it was more pronounced for Asian Americans than for Whites or African Americans e. it was more pronounced for cardiovascular causes than for noncardiovascular causes here was increased mortality of underweight (< 18.5 kg/m²) persons in these data. //hich one of the following statements is true? a. this was an unexpected finding b. increased risk was concentrated in the later years of follow-up c. the increased risk was greater risk for cardiovascular causes than for noncardiovascular causes d. the finding could be an early indicator of a lethal disease process	A 32-year-old man comes in for a first visit, stating his prior physician was Dr Fiel Goode. The patient reports taking oxycodone 30 mg twice daily and hydrocodone 10 mg-acetaminophen 325 mg four times daily for chronic low back pain. The morphine equivalent dosing of this current regimen is: a. 70 mg/d b. 100 mg/d c. 130 mg/d d. 160 mg/d All of the following are red flags for potential prescribing misuse and/or diversion except: a. asking for an early refill, stating medications were stolen b. urine drug testing results that are consistent with prescriptions being received c. marijuana use while being in the possession of a marijuana card d. a patient driving 90 miles to see you for care and opioid prescriptions since "you are the only doctor who understands me"			
e. this is called the "obesity paradox"	Article 4 (page 62) Supporting Muslim Patients During Advanced Illness			
rticle 2. (page 17) Nasopharyngeal Carcinoma Diagnostic Challenge in a Nonendemic etting: Our Experience with 101 Patients /hich of the following is false?	When caring for a Muslim patient, all the following are appropriate except: a. assess pain, adequately describing treatment options and their benefits and side effects b. if pain medication is desired or not, document the patient's choice in the medical record c. do not involve a patient's religious leader d. turn an immobile patient's bed toward Mecca, if possible When treating a Muslim patient for depression or anxiety, what is the most appropriate action that the treating clinician should take? a. prescribe an antidepressant or antianxiety medication b. ask about what drugs have been helpful in the past c. encourage the patient to perform the five daily prayers and recite the Qur'an d. share with the patient the clinician's own religious beliefs and how they have been helpful			
a. the two most common presenting symptoms of nasopharyngeal cancer are neck mass and ear-related b. approximately one-third of nasopharyngeal cancers are difficult to visualize on nasal endoscopy and on radiographic imaging c. nasopharyngeal cancer can present with a wide variety of head and neck symptoms, and therefore diagnosis is often delayed, even by otolaryngologists d. the most common presenting symptom of nasopharyngeal cancer is throat pain				
our patient is a 45-year-old man who immigrated from Vietnam 10 years ago. He reports 3 tonths of muffled hearing in his left ear. On examination, the tympanic membrane appears dull ith a serous effusion, without erythema, and there is a 2-cm lymph node in his left upper neck. If the syour next step in management? a. ofloxacin ear drops b. otolaryngology referral c. amoxicillin d. computed tomography scan of the neck	e. take a brief spiritual history to determine if spiritual needs are present			
ction B.	Section C.			
ction 6. ferring to the CME articles, how likely is it that you will implement this learning to improve your practice				

Key 5 = highly likely 4 = likely 3 = unsure 2 = unlikely 1 = highly unlikely 0 = I already did this

Objective 1 Integrate learned knowledge and increase competence/ confidence to support improvement and change in specific practices, behaviors.

and performance.

Objective 2

Lead in further developing "Patient-Centered Care" activities by acquiring new skills and methods to overcome barriers, improve physician/patient relationships, better identify diagnosis and treatment of clinical conditions, as well as, efficiently stratify health needs of varying patient populations.

Objective 3

Implement changes and apply updates in services and practice/policy guidelines, incorporate systems and quality improvements, and effectively utilize evidencebased medicine to produce better patient outcomes.

Article 1	5 4 3 2 1 0	5 4 3 2 1 0	5 4 3 2 1 0
Article 2	5 4 3 2 1 0	5 4 3 2 1 0	5 4 3 2 1 0
Article 3	5 4 3 2 1 0	5 4 3 2 1 0	5 4 3 2 1 0
Article 4	5 4 3 2 1 0	5 4 3 2 1 0	5 4 3 2 1 0

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Section C.					
What other changes, if any, do you plan to make in your practice as a result of reading these articles?					
Section D. (F	. ,				
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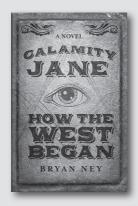
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