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The Permanente Journal

Spring 2012 Volume 16 No. 2

A peer-reviewed journal of medical science, social science in medicine, and medical humanities

Original Research & Contributions

4 Influence of Vascular Access Type on Sex and Ethnicity-Related Mortality in Hemodialysis-Dependent Patients

10 Financial Implications of Increasing Medical School Class Size: Does Tuition Cover Cost?

15 Out-of-Plan Pharmacy Use by Members of a Managed Care Organization

23 Association of Child and Adolescent Psychiatric Disorders with Somatic or Biomedical Diagnoses: Do Population-Based Utilization Study Results Support the Adverse Childhood Experiences Study?

28 Long-term Outcomes of Shamanic Treatment for Temporomandibular Joint Disorders

36 The Kaiser Permanente Implant Registries: Effect on Patient Safety, Quality Improvement, Cost Effectiveness, and Research Opportunities

Review Article

45 Transanal Endoscopic Microsurgery for Rectal Tumors: A Review

Case Studies

51 False Estimates of Elevated Creatinine

54 Management of the Athlete with Concussion

Commentaries

60 The Familiar Foundation and the Fuller Sense: Ethics Consultation and Narrative

67 The Health Care Professional as a Modern Abolitionist

Editorial

73 Medical Education—the Challenge of Distinguishing Actual Costs versus Charges (Tuition)

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Spring 2012/ Volume 16 No. 2

The Permanente Journal

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Circulation: 25,000 print readers per quarter, and 1 million hits in 2011 from 150 countries.

ON THE COVER
"Ancient Magnolid"
a photograph by Latifat Apatira, MD, was taken in San Francisco, CA. Magnolias are primeval, having evolved before bees; their flowers are tough and waxy to withstand the damage caused by their pollinators: beetles. The appearance of these brilliant flowers on naked trees welcomes spring to the city of San Francisco.

Dr Apatira is a second-year Resident in Internal Medicine and Preventive Medicine at the Kaiser Permanente San Francisco Medical Center. Her research interest includes examining the human health impacts of large-scale anthropogenic environmental change. In her spare time, she enjoys roaming the San Francisco Botanical Garden with her camera. This photograph is taken with a simple "point-and-shoot" Sony DSC-W90.

75 LETTERS TO THE EDITOR
78 BOOK REVIEWS
80 CME EVALUATION FORM

The Permanente Journal
500 NE Multnomah St, Suite 100
Portland, Oregon 97232
www.thepermanentejournal.org

ISSN 1552-5767

ORIGINAL RESEARCH & CONTRIBUTIONS

CME

4 **Influence of Vascular Access Type on Sex and Ethnicity-Related Mortality in Hemodialysis-Dependent Patients.**
Karen Woo, MD; Janis Yao, MS; David Selevan, BS; Robert J Hye, MD

In an analysis of a database containing 6052 chronic hemodialysis patients between 2000 and 2008, age, male sex, prosthetic graft, tunneled catheter and diabetes are independent predictors of mortality. After controlling for these variables, when compared to Caucasians, African-American, Asian, Hispanic, and Pacific Islander ethnicity all demonstrate significantly decreased risk of mortality. Type of dialysis access is not responsible for gender and ethnicity-related mortality differences in this population.

10 **Financial Implications of Increasing Medical School Class Size: Does Tuition Cover Cost?**
Danny A Schieffler, Jr, PhD; Benjamin M Azevedo; Richard A Culbertson, PhD; Marc J Kahn, MD, MBA

To determine the financial consequences of increasing medical student enrollment, adjusted secondary revenue data are analyzed using linear regression to determine average fixed costs and variable costs per student. The best point estimate of the annual variable cost of educating a medical student is $62,877. Tuition and fees revenue from increasing enrollment will not increase overall revenue to medical schools.

15 **Out-of-Plan Pharmacy Use by Members of a Managed Care Organization.**
Thomas Delate, PhD, MS; Gale Albrecht, MS, PharmD Candidate; Kari L Olson, PharmD, BCPS, FCCP

This retrospective health services investigation examined characteristics of patients in a managed care organization (MCO) who did and did not have a prescription written to an out-of-plan pharmacy (OOPP) from October 1, 2006 through September 30, 2010. A total of 10,353,283 prescriptions were included. Prescriptions written to an OOPP were more likely to be for chronic disease states. Patient age and MCO termination were associated with having a prescription written to an OOPP.

CME

23 **Association of Child and Adolescent Psychiatric Disorders with Somatic or Biomedical Diagnoses: Do Population-Based Utilization Study Results Support the Adverse Childhood Experiences Study?**
T C R Wilkes, MB, ChB, M Phil, DCH FRCP(Edin), MRCPsych, FRCPC, FAPA; Lindsay Guyn; Bing Li, MA; Mingshan Lu, PhD; David Cawthorpe, PhD

From a randomly selected sample of 205,281 patients under age 18 years, on their index visit, this study examined the effect on somatic or biomedical diagnosis costs during a 16-year period. All physician billing records (8,724,714) from the study period were grouped on the basis of presence or absence of any International Classification of Disease diagnosis of psychiatric disorder. The somatic disorder billing costs (nonpsychiatric costs) were 1.8 times greater for those with psychiatric disorders. Somatic costs peaked before the age of 6 years and remained higher than the same-age groupings without psychiatric disorders in each age group.

28 **Long-term Outcomes of Shamanic Treatment for Temporomandibular Joint Disorders.**
Nancy H Vuckovic, PhD; Louise A Williams, PhD; Jennifer Schneider, MPH; Michelle Ramirez, PhD, MPH; Christina M Gullion, PhD

Temporomandibular joint disorders (TMDs) are chronic pain conditions often refractory to treatment. Twenty-three women, ages 25 to 55 years, with a diagnosis of TMD were contacted at 1, 3, 6, and 9 months after treatment to record self-reported pain and disability outcomes and qualitative feedback. The improvements in usual and worst pain, and functional impairment at end of treatment persisted without change to 9 months.

SPECIAL REPORT

CME

36 **The Kaiser Permanente Implant Registries: Effect on Patient Safety, Quality Improvement, Cost Effectiveness, and Research Opportunities.**
Elizabeth W Paxton, MA; Maria CS Inacio, MS; Mary-Lou Kiley, MBA

The purpose of this article is to describe the Kaiser Permanente implant registries, which leverage the integrated health care system's administrative databases and electronic health records system. Data collection, quality control and validation, and statistical analysis for the registries are described. Areas discussed include: patient safety enhancement successes such as assistance during major recalls, identification of risk factors, risk calculator development, infection and adverse event surveillance, and research studies conducted using registry data.

CME

CME credits are available online at www.thepermanentejournal.org. The mail-in CME form can be found on page 80.

REVIEW ARTICLE

45 Transanal Endoscopic Microsurgery for Rectal Tumors: A Review.
Hiroko Kunitake, MD; Maher A Abbas, MD, FACS, FASCRS

Since its introduction in 1983, Transanal Endoscopic Microsurgery has emerged as a safe and effective method to treat rectal lesions including benign tumors, early rectal cancer, and rectal fistulas and strictures. This minimally invasive technique offers the advantages of superior visualization of the lesion and greater access to proximal lesions with lower margin positivity and specimen fragmentation and lower long-term recurrence rates over traditional transanal excisions, with less morbidity, faster recovery, and greater potential cost savings.

CASE STUDIES

Corridor Consult

51 False Estimates of Elevated Creatinine.
Manpreet Samra, MD; Antoine C Abcar, MD

One of the most common reasons for a nephrology consult is an elevated creatinine. An elevation in the serum creatinine concentration usually reflects a reduction in the glomerular filtration rate (GFR). At times the elevation of the creatinine is not representative of a true reduction in GFR. Various causes of factitious elevation of creatinine include increased production of creatinine, interference with the assay and decreased tubular secretion of creatinine.

Corridor Consult

54 Management of the Athlete with Concussion. John K Su, MD, MPH; Joel F Ramirez, MD

The approach to and management of the athlete with concussion can be a challenging endeavor to physicians that care for athletes who have suffered a head injury—this group includes family physicians, pediatricians, internists, emergency medicine physicians, primary sports medicine physicians, orthopedic surgeons, neurologists, and neurosurgeons. Sometimes questions regarding the need for neurologic, psychologic, or radiographic imaging can make the decision for return to play unclear. New legislation will undoubtedly increase physician visits for these athletes to return to play.

CLINICAL MEDICINE

57 ECG Diagnosis: Hypokalemia.
Joel T Levis, MD, PhD, FACEP, FAAEM

The earliest electrocardiogram change is a decrease in the T-wave amplitude. As potassium levels decline further, ST-segment depression and T-wave inversions are seen. The U wave is described as a positive deflection after the T wave, often best seen in the mid-precordial leads (eg, V2 and V3). When the U wave exceeds the T-wave amplitude, the serum potassium level is < 3 mEq/L.

58 Image Diagnosis: Abdominal Wall Hematoma. Jasmine K Dhaliwal, MD; Gus M Garmel, MD, FACEP, FAAEM

Abdominal wall hematoma is uncommon, but may be a life-threatening condition. Risk factors include older age, female sex, systemic anticoagulation, abdominal wall trauma, pregnancy, and impaired renal function. Clinical manifestations include abdominal pain, abdominal wall ecchymosis, drop in hematocrit, and a positive Carnett's sign indicating the abdominal wall and not the abdominal cavity as the source of pain.

COMMENTARY

60 The Familiar Foundation and the Fuller Sense: Ethics Consultation and Narrative. Craig Nelson, PhD, CLS

The intention of this essay is to examine "ethical expertise" and the idea of clinical ethics "consulting." The author's position champions the use of two tools: "familiar foundation" and "fuller sense." The "familiar foundation" represents a body of knowledge. Through a deep analysis of patient narrative found in the "fuller sense," the ethicist sharpens focus and achieves a richer understanding of the patient's situation in life. In using both tools, patients and families are better served.

65 A Retirement and A Reservation: A Retrospective Autobiography.
Sok K Lee, MD, MA

For 37 years, the author was a healing professional, a breadwinner, and a working spouse. After retirement, he felt like a jobless loner, an inactive pensioner, and a homebound spouse. In this retrospective autobiography, he suggests professional, financial, social, and familial points to help younger colleagues better their upcoming retirement. To overcome Erikson's identity crisis, he volunteered to be a (wounded) healer at Warm Springs Indian Reservation.

67 The Health Care Professional as a Modern Abolitionist.
Michael G O'Callaghan, DDS

Health care professionals are in a unique position to identify and to assist victims of human trafficking, which today occurs both domestically and globally. It manifests in many forms, including adult and child forced labor, involuntary domestic servitude, adult and child sexual slavery, involuntary servitude, debt bondage, and child soldiers. This article offers insight into modern human trafficking and ways health care professionals can be activists.

70 Can Kawasaki Disease Be Managed?
Alberto Coustasse, DrPH, MD, MBA, MPH; Julius Larry, DDS, JD, MPH; Doohee Lee, PhD

Kawasaki Disease (KD) is the leading cause of acquired cardiovascular disease among children, most commonly among Asians and Pacific Islanders. In 2006, over 5500 KD cases were reported in the US. Because the etiology remains unknown, and there is no specific laboratory test, timely and accurate diagnosis remains difficult. Developing a specific registry or a surveillance system may be necessary for increasing awareness and decreasing complications related to misdiagnosis.

EDITORIAL

73 Medical Education—the Challenge of Distinguishing Actual Costs versus Charges (Tuition). William L Toffler, MD

The author of this editorial writes that Scheiffler et al (page 10) use a creative "back door" approach to assess whether or not tuition covers medical school costs. It may provide insight into the true cost, if, and only if, two basic underlying assumptions are correct: 1) the funding coming from these sources does correlate with true costs, and 2) the estimated percentage actually allocated to education is correct. In conclusion, like all good research, the authors' published work raises more questions than have been answered.

SOUL OF THE HEALER

Original Visual Art

22 "Birney Creek"
Stephen Jacobs

27 "Hearing Loss"
Mohamed Osman, MD

53 "Focus on the Physical"
Marilyn Mitchell

64 "Genetic Engineering"
Mohamed Osman, MD

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medical lit-art e-journal

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a thin triangular flap of a heart valve
a small book usually having a paper cover
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The Permanente Press, in conjunction with *The Permanente Journal,* present the medical literary and arts e-journal, *leaflet,* available at http://xnet.kp.org/permanentejournal/leaflet. We developed *leaflet* to open greater opportunity to share the creative visual and written works of physicians, practitioners, and nurses. The table of contents of the latest issue is below.

Submissions are open to anyone; preference will be given to works that address the themes of health, illness, healing, and the life and soul of the healer. Poems, short fiction, personal essays, and visual arts: photography, painting, sculpture, etc, will be considered. Submissions may be made through the electronic submission site of *The Permanente Journal* (www.thepermanentejournal.org/authors/artwork.html), please indicate in the cover letter that the submission is for *leaflet* consideration.

Questions may be directed to: Ms Max McMillen, ELS, Editor *leaflet,* e-mail: max.l.mcmillen@kp.org.

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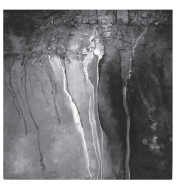
Cheetah
Stuart Hahn, MD

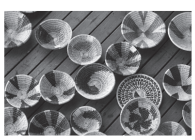
Abundance
Kamran Nikravan, MD

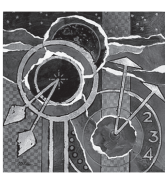

Breakwater
Carol Nelson

Health Care Reform
Christina M Holmes

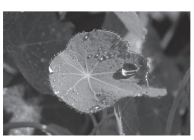
Jaguar
Stuart Hahn, MD

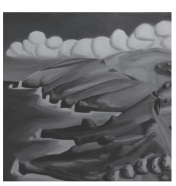
Curiosity
Mohamed Buwe Osman, MD


Baskets
David Clarke, MD


Mountain Time Zone
Carol Nelson

Emerald Lakes, New Zealand
by Michael Krall, MD


Morning Garden Light
Robert W Hogan, MD


Kalwi Coast
Douglas Davenport, MD

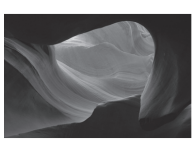
Loneliness
Mohamed Buwe Osman, MD

Tuscan Twilight
Philip R Brunner, MD, FAAP

Tranquility
Tri V Tran, MD

Opiate Addiction
Mohamed Buwe Osman, MD

Water Color Pond
Caroline Magruder, MD


Rolling Waves, Lower Antelope Slot Canyon Near Page, AZ
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CME credits available for this article — see page 80.

ORIGINAL RESEARCH & CONTRIBUTIONS

Influence of Vascular Access Type on Sex and Ethnicity-Related Mortality in Hemodialysis-Dependent Patients

Karen Woo, MD; Janis Yao, MS; David Selevan; Robert J Hye, MD

Perm J 2012 Spring;16(2):4-9

Abstract

Objectives: To determine whether sex- and ethnicity-based mortality differences in patients dependent on hemodialysis (hemodialysis patients) are because of prevalence of vascular access type.

Methods: Southern California Permanente Medical Group Renal Database, which contained 5821 chronic hemodialysis patients between 2000 and 2008, was studied.

Results: Mean age of the patients was 62 years, and 59% were male. Of the population, 33% were white; 32%, Hispanic; 23%, African American; 9%, Asian/Pacific Islander; and 3%, other race or ethnicity. Predominant access type over the course of the study was arteriovenous fistula (AVF) in 73%, arteriovenous graft (AVG) in 12%, and tunneled catheter in 14%. There was a higher percentage of AVF in whites (71%) than in African Americans (63%). Risk of death was independently increased by age (hazard ratio [HR], 1.04; 95% confidence interval [CI], 1.04-1.05), male sex (HR, 1.33; 95% CI, 1.22-1.45), diabetes (HR, 1.22; 95% CI, 1.12-1.33), use of an AVG (HR, 1.51; 95% CI, 1.34-1.71) or a tunneled catheter (HR, 6.45; 95% CI, 5.78-7.20). Compared with whites, African-American race decreased the risk of death (HR, 0.63; 95% CI, 0.56-0.70), as did Asian/Pacific Islander (HR, 0.58; 95% CI, 0.49-0.69), Hispanic (HR, 0.58; 95% CI, 0.51-0.65), and other race (HR, 0.67; 95% CI, 0.52-0.86).

Conclusion: Age, sex, race or ethnicity, access type, and diabetes are independent risk factors for mortality in hemodialysis patients. After controlling for potential confounders, when compared with whites, minorities all demonstrate significantly decreased risk of mortality. African Americans had reduced mortality risk despite a lower prevalence of arteriovenous fistula compared with whites. Male sex increased mortality. Differences in mortality between sexes and ethnicities in this population cannot be accounted for by differences in type of dialysis access.

Table 1. Patient demographics and clinical characteristics (N = 5821)

Characteristic	No. of patients (%)[a]
Sex	
Female	2407 (41.4)
Male	3414 (58.6)
Race/ethnicity	
African American	1320 (22.7)
Asian/Pacific Islander	511 (8.8)
Hispanic	1884 (32.3)
White	1938 (33.3)
Other	168 (2.9)
Vascular access type most used during follow-up	
Fistula	4274 (73.4)
Graft	718 (12.3)
Catheter	829 (14.3)
Diabetes	
No	2288 (39.3)
Yes	3533 (60.7)
Age, years	
Mean (SD)	62.2 (14.3)
Median	64.0
Range	15-95
Percentage with household income ≥ $50,000	
Mean (SD)	53.7 (20.0)
Median	54.5
Range	0-100
Percentage with education < 12 years	
Mean (SD)	29.7 (19.5)
Median	25.6
Range	0-100

[a] Unless indicated otherwise.

Introduction

The number of patients dependent on hemodialysis (hemodialysis patients) in the US continues to increase, with more than 360,000 individuals receiving this therapy in 2009.[1] There are 3 options for hemodialysis access: arteriovenous fistula (AVF), arteriovenous graft (AVG), and tunneled hemodialysis catheter. An AVF is created by surgically connecting a vein to an artery, usually in the upper extremity, and consists of all native tissue. An AVG uses a prosthetic tube graft as the conduit between an artery and a vein, usually in the upper extremity. A tunneled catheter has exposed ports for connecting to the hemodialysis machine and is usually tunneled subcutaneously into the subclavian vein or internal jugular vein. As patient volumes have increased and additional experience has been acquired in the management of these patients, a number of factors have been identified that influence outcomes and survival in particular.

Long-term all-cause mortality in the hemodialysis population has been found to vary on the basis of sex, ethnicity, medical comorbidities, and age.[2-7] Male sex, the presence of diabetes, and advanced age have all been associated with decreased survival in hemodialysis patients.[7,8] Ethnic differences have also been observed, with African-American, Asian, and Hispanic

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hemodialysis patients all being shown to have a survival advantage over non-Hispanic white hemodialysis patients.[2,3,5-7] The cause of these differences in mortality is unclear.

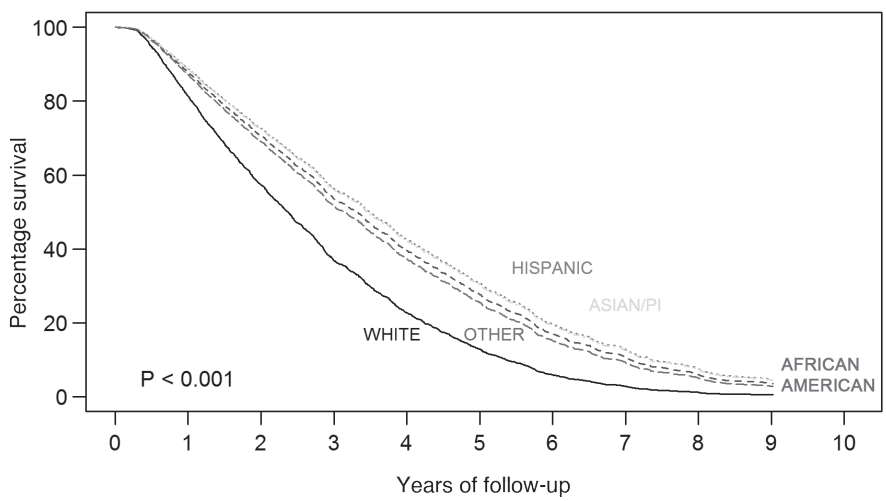
Since the early 2000s, there has also been increasing awareness of the impact of the type of dialysis access on morbidity and survival in the dialysis population. Variability in access patency, infection rates, and mortality among types of hemodialysis accesses is well established, with AVF being superior to AVG in all three of these outcome measures and tunneled catheter being the most inferior.[9-13] The National Kidney Foundation Kidney Disease Outcome Quality Initiative guidelines and the Fistula First Breakthrough Initiative are a result of these observations.[14-16] Although data are limited in this area, it seems unlikely that variability in outcomes of type of access explains the mortality differences seen between different ethnic groups because African-American hemodialysis patients have been found to have a lower prevalence of AVF than do non-Hispanic white hemodialysis patients.[17,18] Whether this difference in prevalence is related to biologic, socioeconomic, or other factors is not known.

Outcomes of various procedures in other areas of vascular surgery, including endovascular abdominal aortic aneurysm repair and lower extremity revascularization, have been shown to vary on the basis of ethnicity and sex.[19-22] These associations are not well defined in the area of dialysis access surgery. Thus, the purpose of this study was to examine the relationships between mortality, vascular access type, sex, and ethnicity in a large health maintenance organization's dialysis population. The Kaiser Permanente (KP) Southern California (KPSC) patient population is ideally suited for this analysis because of its large size, heterogeneous patient population, relatively standard practice patterns, and low patient turnover. Additionally, the Kidney Disease Outcome Quality Initiative guidelines were adopted early by Kaiser Permanente, and there is a very high prevalence of AVF throughout our hemodialysis patient population. Thus, the impact on mortality in a population where autogenous fistula prevalence exceeds the goal of the Fistula First Initiative can be fully assessed.

Methods

A retrospective review of the prospectively recorded Southern California Permanente Medical Group Renal Database was performed from January 2000 through July 2009. All new hemodialysis patients, with no prior dialysis history, who were enrolled in the Renal Program from January 2000 through December 2008 were included. All causes of renal failure were included. Patients were excluded who changed from hemodialysis to peritoneal dialysis, underwent transplantation before January 2000, no longer required dialysis during the study period, and/or had missing data points.

The primary outcome measure was mortality. Follow-up began on the date of first hemodialysis and ended with any mortality or a censoring event (renal transplant during the study period, expiration of Health Plan membership, relocation out of the Southern California area, or end of study period, whichever occurred first). Variables obtained from the database included age, sex, race, most frequently used access type during the follow-up period, and diabetes. Primary hemodialysis access type for each patient was defined as the hemodialysis access type that the patient used for most of the follow-up time. Geospatial Entity Object Coding (Geocoding) was used to link members' address data to census geographic areas (block, block group, and tract). The percentage with household income $50,000 or greater and the percentage with education below 12 years was obtained through this method.



Race/ Ethnicity	Number at Risk									
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
White	1938	1515	1001	656	386	218	108	44	16	6
African American	1320	1091	810	565	397	259	147	77	34	6
Hispanic	1884	1581	1186	841	612	415	252	116	47	15
Asian/PI	511	413	306	222	152	97	60	38	17	5
Other	168	140	101	79	48	33	18	9	2	1

Survival curves were adjusted by age, gender, race/ethnicity, diabetes, percentage of years of education less than 12 years.
PI = Pacific Islander.

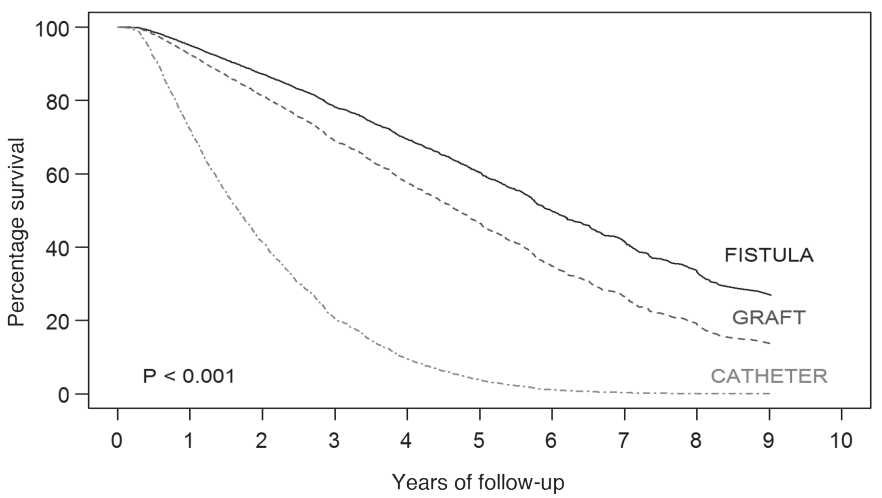
Figure 1. Adjusted survival by ethnicity.

Table 2. Race and sex by vascular access type

Access type	Race, no. (%)					Sex, no. (%)	
	White (n = 1938)	African American (n = 1320)	Asian/PI (n = 511)	Hispanic (n = 1884)	Other (n = 168)	M (n = 3414)	F (n = 2407)
AVF	1373[a] (70.8)	837[a] (63.4)	398 (77.9)	1539 (81.7)	127 (75.6)	2720 (79.6)	1554 (64.5)
AVG	223 (11.5)	272 (20.6)	56 (11.0)	145 (7.7)	22 (13.1)	286 (8.4)	432 (18.0)
TC	342 (17.7)	211 (16)	57 (11.1)	200 (10.6)	19 (11.3)	408 (12.0)	421 (17.5)

[a] $p < 0.001$.
AVF = arteriovenous fistula; AVG = arteriovenous graft; PI = Pacific Islander; TC = tunneled catheter.

Statistical analyses were performed using SAS Enterprise Guide 4.3, (SAS Institute Inc, Cary, NC). Summary results were presented as mean (standard deviation), median, and range for continuous variables and as frequency (percentage) for categorical variables. Univariate analysis was performed using the χ^2 test and the Cox proportional hazard model. Multivariate Cox proportional hazard model was applied to assess the factors independently associated with survival. The multivariate model included age, sex, race or ethnicity, vascular access type, diabetes, household income, and education. Interactions were examined between access type and all other variables in the model as well as race and all other variables in the model. Both crude and adjusted hazard ratios (HRs) were reported with 95% confidence intervals (CI). The survival curves were constructed using Kaplan-Meier estimators, and the log-rank test was performed to assess for differences. The number at risk for the survival curves is the number of patients still alive who have not been censored.



Access type	Number at Risk									
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Fistula	4274	3811	2837	2022	1383	892	520	255	97	7
Graft	718	609	433	281	187	119	56	28	17	4
Catheter	829	321	133	58	24	10	7	1	0	0

Survival curves were adjusted by age, gender, race/ethnicity, diabetes, percentage of years of education less than 12 years.

Figure 2. Adjusted survival by access type.

Results

During the study period, 8621 patients were in the renal database. Of these, 989 had started hemodialysis before January 2000 and were excluded. Another 918 patients were using peritoneal dialysis or were predialysis. Sixty-six were pediatric patients or in the expansion area that is no longer covered by KP. Additionally, 475 patients recovered renal function and no longer required dialysis, moved out of the Southern California area before January 2000, or had their KP Health Plan membership expire before January 2000. Finally, 352 patients had missing data on sex, race, income, and/or education. After all these patients were excluded, 5821 patients remained.

The mean age of the patients was 62. Of the 5821 patients, 59% were male and 61% were diabetic. Thirty-three percent were non-Hispanic white; 32%, Hispanic; 23%, African American; 9%, Asian/Pacific Islander; and 3%, other race.

The predominant vascular access over the course of the study was AVF in 73%, AVG in 12%, and a tunneled catheter in 15% (Table 1). The distribution of access type varied by ethnicity and sex (Table 2). Patients with an AVF used an AVF for 86% of the total follow-up time. Patients with an AVG used an AVG for 84% of the total follow-up time. Patients with a tunneled catheter used a catheter for 96% of the total follow-up time. The hemodialysis access procedures were performed at 12 KPSC Medical Centers. All access procedures were performed by vascular surgeons.

Survival for whites was significantly lower than that of the other ethnicities

($p < 0.001$; Figure 1). On the basis of vascular access type, the survival for patients who had a tunneled catheter was significantly lower than that of patients who had an AVF or an AVG ($p < 0.001$; Figure 2). On univariate analysis, the risk of death was increased by age (HR, 1.05; 95% CI, 1.05-1.05), use of an AVG vs AVF (HR, 1.60; 95% CI, 1.42-1.80), or use of a tunneled catheter vs AVF (HR, 6.89; 95% CI, 6.20-7.66). Diabetes and household income did not have any influence on survival using univariate analysis. Education had a very small statistically significant, but not clinically significant, effect on survival. Compared with non-Hispanic whites, African-American race decreased the risk of death (HR, 0.56; 95% CI, 0.50-0.62), as did Asian/Pacific Islander race (HR, 0.49; 95% CI, 0.42-0.58), Hispanic ethnicity (HR, 0.45; 95% CI, 0.40-0.50), and other race (HR, 0.56; 95% CI, 0.42-0.72), as shown in Table 3.

By multivariate analysis, the risk of death was independently increased by age (HR, 1.04; 95% CI, 1.04-1.05), male sex (HR, 1.33; 95% CI, 1.22-1.45), diabetes (HR, 1.22; 95% CI, 1.12-1.33), use of an AVG vs AVF (HR, 1.51; 95% CI, 1.34-1.71), or use of a tunneled catheter vs AVF (HR, 6.45; 95% CI, 5.78-7.20). The annual household income did not have any influence on survival using multivariate analysis. Education less than 12 years had a small statistically significant, but not clinically significant, effect on survival (Table 3). Compared with non-Hispanic whites, African-American race decreased the risk of death (HR, 0.63; 95% CI, 0.56-0.70), as did Asian/Pacific Islander race (HR, 0.58; 95% CI, 0.49-0.69), Hispanic ethnicity (HR, 0.58; 95% CI, 0.51-0.65), and other race (HR, 0.67; 95% CI, 0.52-0.86). None of the interactions examined were statistically significant.

Discussion

The effect of race and ethnicity on outcomes of hemodialysis access types has been poorly studied. Despite the clearly demonstrated survival benefit of minority ethnicity in hemodialysis patients, the reasons for this finding remain unknown. The present study confirms the earlier findings that minority ethnicity in hemodialysis patients confers significantly improved survival over that seen in white hemodialysis patients.[7,8,22,23] Previous reports have also noted that, in particular, Hispanic hemodialysis patients have a survival advantage over non-Hispanic hemodialysis patients.[24,25] Similarly, Asian hemodialysis patients have improved outcomes compared with non-Asian hemodialysis patients.[26]

Despite the clearly demonstrated survival benefit of minority ethnicity in hemodialysis patients, the reasons for this finding remain unknown.

A small amount of data exists with regard to the cause of these survival discrepancies. One study showed that the lower mortality in minority groups could not be explained by differences in demographic characteristics, comorbidities, or nutritional parameters such as body mass index and serum albumin.[27] Although our study did not include body mass index or serum albumin, we did

Table 3. Association between clinical characteristics and mortality: unadjusted and adjusted hazard ratios and 95% confidence intervals (CI)

Factor	Crude hazard ratio (95% CI)	p value[a]	Adjusted hazard ratio (95% CI)	p value[a]
Age	1.051 (1.047-1.054)	<0.0001	1.044 (1.041-1.048)	<0.0001
Sex				
Female	1	Reference	1	Reference
Male	1.057 (0.973-1.149)	0.1895	1.333 (1.223-1.453)	<0.0001
Race/ethnicity				
White	1	Reference	1	Reference
African American	0.559 (0.501-0.623)	<0.0001	0.625 (0.557-0.702)	<0.0001
Asian/Pacific Islander	0.489 (0.415-0.577)	<0.0001	0.583 (0.494-0.689)	<0.0001
Hispanic	0.447 (0.404-0.496)	<0.0001	0.576 (0.514-0.646)	<0.0001
Other	0.557 (0.431-0.721)	<0.0001	0.666 (0.515-0.862)	<0.002
Access type most used during follow-up				
AVF	1	Reference	1	Reference
AVG	1.601 (1.421-1.803)	<0.0001	1.514 (1.340-1.711)	<0.0001
TC	6.889 (6.196-7.658)	<0.0001	6.448 (5.778-7.196)	<0.0001
Diabetes	1.046 (0.962-1.137)	0.2965	1.22 (1.12-1.33)	<0.0001
Percentage with household income ≥$50,000	1.001 (0.999-1.004)	0.1662	1.000 (0.997-1.002)	0.7664
Percentage with education <12 years	0.995 (0.993-0.997)	<0.0001	1.004 (1.001-1.007)	0.0181

[a]The p values were obtained from Cox proprotional hazard model.
AVF = arteriovenous fistula; AVG = arteriovenous graft; TC = tunneled catheter.

find that minority race or ethnicity was an independent predictor of improved survival compared with non-Hispanic whites when controlling for age, sex, access type, diabetes, household income of ≥$50,000, and education below 12 years. This represents a paradox because other authors have demonstrated that mortality caused by cardiovascular disease is highest in African Americans.[28] One explanation that has been proposed for this phenomenon is that African Americans have a higher risk of death in the early stages of chronic kidney disease, such that those who survive long enough to reach dialysis dependence are the healthiest of the group and thus have a survival advantage.[29]

Annual income and education less than 12 years did not have any influence on survival in our univariate and multivariate analyses. Other authors have also investigated socioeconomic factors as a cause for the difference in mortality among ethnic or racial groups and found that there were no mortality differences among income level groups.[30]

Abundant data exist that AVF is the most reliable and durable dialysis access method.[9,31] Similarly, tunneled catheter has repeatedly been shown to result in the worst patient outcomes.[12,32,33] Both AVG and tunneled catheter are associated with an increased risk of death in hemodialysis patients, compared with AVF.[11] This study clearly confirms those earlier reports but is the first to examine the impact of dialysis access type on the observed mortality differences seen on the basis of sex and ethnicity. The results in this large database show that patients who were dialyzed by AVG had a nearly 50% increased risk of mortality over those dialyzed by AVF and that patients dialyzed by tunneled catheter had a 6.5-fold increased risk of mortality over AVF. Despite the significantly lower prevalence of AVF in African Americans, African Americans still had a 40% reduced risk of mortality compared with whites in the multivariate analysis. This suggests that type of dialysis access is not responsible for ethnicity-related mortality differences in this population. The lower prevalence of AVF in the African-American population in our study is not explainable because of the limitations of our database but is worthy of further investigation.

Our results also showed that male hemodialysis patients have a 32% increased risk of mortality compared with female hemodialysis patients. This is consistent with previously published results.[8] Similarly, diabetes increased the risk of mortality by 20%, which has also been demonstrated by other authors.[4,34]

The major weakness of this study is that it is limited by the data points available from the database. There are multiple other patient factors that would be useful to include in the multivariate analysis, such as coronary artery disease, peripheral vascular disease, and smoking history, but were not included in the database. Furthermore, a host of other patient factors that would be very difficult to measure, including dietary influences and social-family support, may have an effect on survival. Ultimately, we cannot conclusively determine cause and effect from this type of study. We have demonstrated associations of certain exposures with risk of mortality; however, further study is required to determine whether the identified exposures are a direct cause of mortality or merely markers for other risk factors.

Conclusion

Age, male sex, AVG, tunneled catheter access, and diabetes were independent predictors of mortality in hemodialysis patients. After we controlled for these variables, when compared with non-Hispanic whites, African Americans, Asian/Pacific Islanders, and Hispanics all demonstrated significantly decreased risk of mortality. African Americans had a reduced mortality risk despite a significantly lower prevalence of AVF compared with non-Hispanic whites. This would suggest that type of dialysis access is not responsible for sex- and race- or ethnicity-related mortality differences in this population. Further investigation is needed to determine the cause of these variations in mortality risk. ❖

Disclosure Statement

Robert J Hye, MD, receives research support from WI Gore, BTG International, and Proteon Therapeutics. None of these products or services is discussed in this manuscript, nor were they part of this study. The author(s) have no other conflicts of interest to disclose.

Acknowledgment

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

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Phenomena Termed Uremic

A large proportion of the phenomena termed uremic are, as Volhardt and Foster pointed out almost 40 years ago, vascular in origin, consequences of hypertension, arterial disease, and heart failure. Others are results, not of retention of waste products, but of failure of the conservative functions of the kidneys. If their true nature were more frequently analyzed in detail and corrective measures instituted for each, therapy would be greatly advanced. The term uremia has a defeatist ring that fosters complacency or routine procedures rather than thoughtful action.

— John Punnett Peters, 1887-1955, physician and professor of medicine

Financial Implications of Increasing Medical School Class Size: Does Tuition Cover Cost?

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Perm J 2012 Spring;16(2):10-14

Abstract

Introduction: In 2006, the Association of American Medical Colleges (AAMC) issued a recommendation that medical schools increase the supply of physicians by 30% to meet the patient needs of the new millennium.

Objective: To provide financial analysis of the cost of increasing class size.

Methods: To determine the financial consequences of increasing medical student enrollment and in the absence of nationally published cost data for medical schools, adjusted secondary revenue data was analyzed using AAMC and Liaison Committee on Medical Education (LCME) financial data from 2009. Linear regression analysis was used to determine average fixed costs and variable cost per student in USD.

Results: In USD, $62,877 represents the best point estimate of the annual variable cost of educating a medical student.

Conclusion: Comparing this cost to current tuitions and fees of LCME-accredited medical schools suggests that revenues other than tuition are needed to cover increases in class size. Tuition and fees revenue from increasing enrollment will not increase overall revenue to medical schools.

Introduction

The 1910 Flexner report established basic requirements for admission to medical schools, set the length of general medical education, and recommended university affiliation as a means of providing better academic oversight among other sweeping reforms.[1] Flexner further set priority to the theoretical triadic framework of education, research, and clinical care that would become the objective of the majority of medical schools today. Little attention was paid at the time to the monetary burdens of this framework. Understanding the finances associated with modern academic medicine has become mired in layers of administrative funding sources and ancillary revenue streams that vary across schools. One difficulty in appreciating the economic structure of academic medicine lies in distinguishing the measurement of the cost of education apart from the other functions of an academic medical center.[2] Explicitly, what does it cost to educate one medical student for one year and would an increase in the number of medical students necessarily increase revenue to the school for its overall mission? If it does not, by how much must those payments be adjusted such that more students creates more revenue to the school given the general costs associated with education related expansion?

Studies addressing this issue have only skimmed the surface of the number of variables that such questions encompass. The Association of American Medical Colleges (AAMC) issued a recommendation that graduates of "LCME [Liaison Committee on Medical Education]-accredited medical schools should be increased by 30%" through both increases in existing class sizes and through the development of new medical schools.[3] This equates to raising the number of graduates in allopathic medical schools to 21,434 on the basis of 2002 matriculate numbers. This increase is needed in large part because of the growing age of the general population and the relative flat matriculation rates of US medical students.[4] Although these recommendations include suggestions for studies on the impact of market forces, little attention has been paid to the financial ramifications of student increases on the fiscal health of the parent school.

In follow-up, the AAMC presented the results of a 2006 survey addressing expansion planning in medical schools. Of the reporting schools, 58.6% had planned to increase enrollment at the time with a majority reporting a strategic increase of 5 or more students in the 2011-2012 academic year.[5] This is in accordance with the additional recommendation that schools slowly add to class enrollment and not overwhelm the educational balance. Some schools were reporting much larger increases. However, only 63 of the 121 schools responding to the survey acknowledged conducting "financial analysis" on this topic. Some schools, however, reported increasing faculty numbers and reconfiguring and constructing new teaching space in anticipation of class expansion without mentioning fiscal expectations or analysis.[5] Although cost was considered a "major" expansion barrier for some schools, few indicated that expansion would not take place at some future date hence the need for further research into cost allocation.[5]

Paradoxically, in the 2009 Enrollment Survey, 12 schools had developed plans to reduce enrollment as a result of the slump in the US economy.[6] This decline in enrollment pushed the projection of a 30% increase in medical school

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graduates to 2018. Despite this, 83% of 125 medical schools have increased their enrollment. The largest increases have been, and are anticipated to occur, in publicly funded medical schools as opposed to privately funded schools. Funding of public medical schools is often more fluid than that of private schools, which must rely on somewhat limited resources in the absence of state funding.[7,8] Yet, only 28% of all schools in that survey believed that the economic recession would affect their ability to increase class sizes in the future albeit in the absence of any national cost analysis. Given these results, it would appear that few schools have noticed or have been unable to absorb the financial impact of increased enrollment. One assumption might be that funds outside of tuition and fees are used to support the educational mission or that the larger enrollment numbers are being absorbed using existing staffing and facilities. Or, another possibility is that the increased tuition gained is indeed enough to cover those new costs. However, without some analysis of those numbers, it is difficult to determine.

Additionally, much has been written about the impact of medical student debt on future career choice and community involvement.[9-11] Medical schools should evaluate the impact of increasing tuition as both a financial and social burden. Schools considering tuition increases to offset enrollment costs face the challenge of justifying those increases in light of a number of factors that recommend against it such as access to financial aid, competing funding requests from allied health sciences, and general student ability to repay.[12-14] Yet, the impact that tuition revenue can have on institutions has not been widely examined because of the difficulty of isolating direct revenue streams to education as a function of that tuition versus other funding sources across the entire spectrum of US medical schools.[15-17]

However, isolating the financial impact on institutions from tuition revenues can be done, but few studies have attempted to address that influence beyond any individual schools. This is further impeded as schools are not required to report cost inputs in relation to education to any national organization thus making comparisons between institutions difficult. One study examined the cost of education and other expenses in contrast to the consumer price index and its medical component of two teaching hospitals. The authors concluded that the impact of medical education does indeed affect the overall financial balance of academic health centers. That is, they determined that loss of medical education revenues (both undergraduate and graduate medical education) would have a negative effect on the financial viability of these hospital-based institutions. However, we drew no conclusions on the impact of tuition revenue as a function of class size specifically to schools.[18]

Other work isolated the actual cost of educating medical students with greater specificity.[19] Virginia Commonwealth University used a compound method of average scheduled instruction workload, salary rates of faculty, and faculty-to-student ratios to determine that $69,992 was necessary to educate 1 medical student per year.[19] On a larger scale, studies conducted at the University of Wisconsin took a much broader approach to calculating cost by simplifying the methods of assigning budget dollars to the various aspects of medical education.[20] They concluded that 60% of budgeted education revenues to departments went to medical education within their system with the remaining funds used for research, for faculty support, and for development.

Most recently, a global independent commission examined financing of medical education on an international scale.[21] Using a combination of micro and macro approaches, the North American estimated expenditure per graduate is $497,000 based on 2008 data with an average, global cost per medical graduate of $122,000.[21] Western Europe at $400,000 is the only territory measured in this work that approaches the North American estimate. This has direct implications for this current work given its relation to other physician-producing countries and the further acknowledgment that more research is needed to determine financial considerations of medical education in the US.

Of those schools not covering costs, 91% were public and 9% private.

Methods

Given the absence of nationally published cost data by institution directly related to education, raw data for our study came from the 2009 LCME Part-1-A Annual Financial Questionnaire (AFQ), taken from the AAMC's Medical School Profile System (MSPS) Database. This database provides 7 categories of revenues for each of the 131 LCME accredited medical schools except for the newly established Virginia Tech Carillion. On the basis of the assumption that these funds were most reasonably allocated to the cost of educating medical students, we chose 3 revenue streams for our analysis.[8] Total Tuition and Fees Revenues, Total Government and Parent Support, and Total Revenues from Gifts and Endowment Funds were the 3 categories used from this database as reported at the time of the study. Tuition and fees are obviously attributable to the cost of educating a medical student. Government and parental support revenues are particularly important for state-funded public institutions that receive this revenue on an annual basis and are likely to use these funds in educating their students.[2] As such, the average public school revenue in this category was almost 8 times the average amount received by private schools. Finally, Total Revenues from Gifts and Endowment Funds were included in our computations because many institutions pay for scholarships for students or professorship chair positions both of which contribute to costs in student education.[7]

The other 4 categories (Total Federal Research Grants and Contracts, Other Grants and Contracts, Total Expenditures and Transfers from Hospital Funds, and Other Revenues) were not included in our analysis as these revenues are not clearly identified with medical student education. The University of Central Florida, Commonwealth Medical College, and Uniformed Services University of the Health Sciences were not included in our analysis because these schools indicated no charges for tuition, bringing the total number of schools in our analysis to 127.

Table 1. Sensitivity analysis varying percentages of education revenues to calculate cost of education[1]

	Analysis 1	Analysis 2	Analysis 3
Percentage of revenue allocated	40% of revenue	50% of revenue	60% of revenue
Fixed cost	$13,379,828	$16,724,785	$20,069,742
Variable cost per student (95% confidence interval)	$41,918 ($25,485-$58,351)	$52,397 ($31,856-$72,939)	$62,877 ($38,227-$87,527)
Number of schools covering cost with tuition and fees	28[a]	0	0

[a] All 28 are private schools.

[1] Ridley GT, Skochelak SE, Farrell PM. Mission aligned management and allocation: a successfully implemented model of mission-based budgeting. Acad Med 2002 Feb;77(2):124-9.

After adding the 3 revenue categories together for each school, we proportioned 60% of that total as being our best estimate of the total school cost for medical education based on published criteria of allocation of revenue.[20] Using linear regression (Microsoft EXCEL, version 2007; Redmond, WA) total education costs were regressed with student enrollment numbers using the 2010-2011 matriculation numbers for each of the 127 schools according to the LCME Part II Annual Medical School Questionnaire in the MSPS database. Linear regression was chosen so that it could be determined how the created continuous variable measured against a single predictor. That is, the y-intercept of the resultant line represents the total fixed cost of education whereas the slope represents the annual variable cost of educating a medical student. Sensitivity analysis was performed in Table 1 by varying the revenue/cost percentage at 40% and 50%. Tuition values for each school were obtained from the AAMC Tuition and Student Fees Survey as published by the AAMC.[22] Sensitivity at higher percentages would be meaningless. To simplify the calculations, we speculated that only state residents attended a given public school and therefore used in-state tuition and in-state fees. Similarly, we used out-of-state tuition and out-of-state fees for all private schools except for Mercer University in Georgia that admits only Georgia residents despite being a private institution.[23]

Results

On the basis of our regression analysis, the best point estimate of the variable cost of educating a medical student in the US is $62,877 (95% confidence interval (CI): $38,227-$87,527; $p < 0.00001$). The best point estimate of fixed cost is $20,069,742 for each school ($p = 0.01$). That is, to educate medical students, a school would have to allocate an average fixed cost of approximately $20 million plus $62,877 for every student in any of the 4 years of medical school. From another perspective, assuming an average school size of 578 and an average tuition of $30,886 (as derived from the AAMC

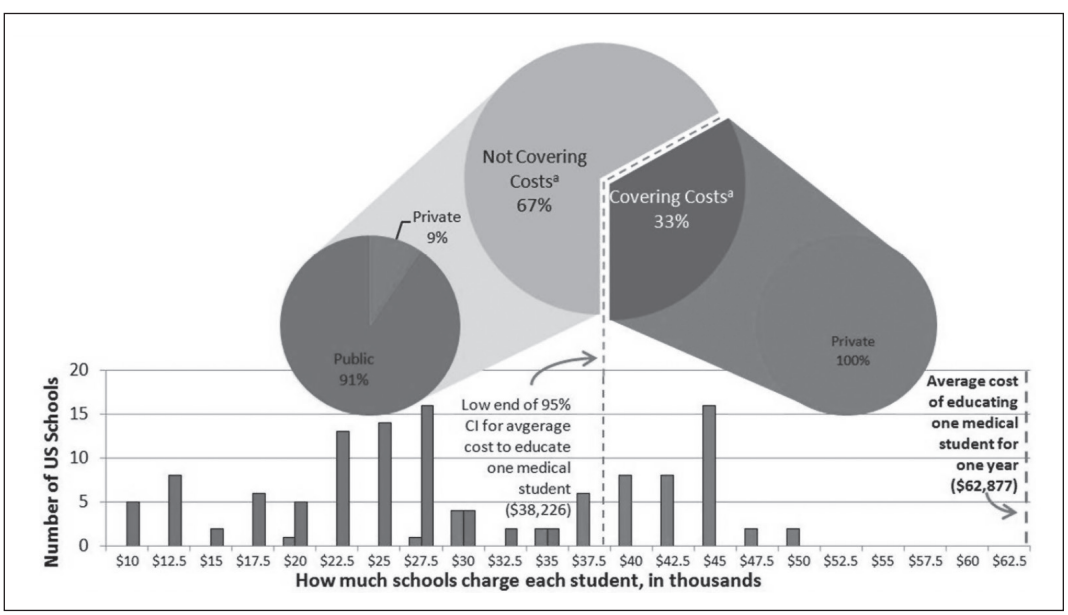

Figure 1. The percentage of US schools are covering the costs of medical education at $38,226 (lower 95% confidence interval [CI]).[1]

[1] Center for Workforce Studies. Results of the 2009 Medical School Enrollment Survey—report to the Council of Deans. Washington, DC: Association of American Medical Colleges; 2010 Apr.

database), the average medical school would have to identify $5,549,588 to increase their class size by 30%. Table 1 shows our sensitivity analysis varying the assumed percentage of total revenue attributable to the cost of educating a medical student at both 40% and 50%.

Discussion

Given that no school has current tuition at $62,877 per year, increasing class size will not result in increased revenue for medical schools as the variable cost of educating a medical student is not covered by the additional tuition revenue or absorbed by existing structures. This amount is lower, in fact, than the amount determined by individual analysis at Virginia Commonwealth in 1997.[19] As $62,877 is based on national data, this could imply that the amount is indeed approaching the actual amount. Figure 1 shows that using the lower end of the 95% CI from our analysis, $38,226, only 33% of medical schools examined could cover variable costs with tuition and fees.[6] Of those schools whose tuition was more than the lower 95% CI for the cost of educating a student, not surprisingly, all were privately funded schools. Of those schools not covering costs, 91% were public and 9% private. Consequently, any planning on the part of a medical school to increase enrollment must identify revenue sources that go beyond tuition and fees to afford expansion. Because schools in the US are not facing bankruptcy, it would appear that other revenue streams or currently funded structures not reported are being used to cover both the fixed and variable costs of increasing class size.

A limitation of this study is the assumption that only three of the identified revenue categories are directed toward medical education: tuition and fees, government and parent institution support, and gifts. Of the other categories collected by the AAMC, allocated grant funds would not likely contribute to medical education directly, although indirect use of the laboratory and research equipment and teaching time by research may be contributions to student education that are not included in our analysis. Time spent by research faculty independent of work supported by grant funding is often difficult to calculate, yet may be a part of the costs associated with medical education.[19] Similarly, the revenue category of affiliated institutional support, primarily used to support graduate medical education, might also contribute to medical student education in a small way. Although not directly related to student instruction, the funds provided for graduate medical education allow for resident and faculty instruction that may not be available if those individuals were engaged in more direct revenue-generating activities and not education.[16,17]

Our assumption that 60% of total educational revenue is used for educating medical students is based on the allocation of revenue percentages reported by the University of Wisconsin Medical School in their Mission Aligned Management & Allocation model of 1999.[20] This percentage is the anticipated direct educational proportion of the total allocated budget given to each department. This figure has been chosen because it does not include other types of revenue streams such as practice plan contributions and general university funds.[20] This figure does, however, assume expansion allocations such as additional staffing or facility needs if necessary. Notwithstanding, sensitivity analysis at the 50% level showed that no school was able to cover the cost of medical education on the basis of the slope variable and that school's tuition charge (Table 1). Only at the 40% level were some schools able to cover the cost of the slope variable with their tuition dollars (Table 1). Our analysis assumes a linear relationship of cost to enrollment. The relationship may be curvilinear with larger student numbers at some institutions.[24] However, our data suggests reasonable linearity within the normal range of student numbers.

Conclusions

If no school is able to currently shield the variable costs of educating a medical student solely with tuition and fees revenues, increasing class size is not a revenue-generating endeavor. Given the precarious financial positions of many academic medical centers in the current economic environment, and considering length of time students spend in medical education compared with other professional degrees, increasing class size, given our data, is counterintuitive from a cost–revenue perspective.[10] This seems ironic given the public policy position advocated by the AAMC to increase school class size by 30%.[3] Additionally, this direction is certainly not discouraged by the stipulation in the 2010 Patient Protection & Affordable Care Act for a comprehensive work force review to examine the adequacy of physician supply and distribution.[25]

Yet, it is hard to imagine attainment of what is an overarching policy goal of producing more practitioners if achievement comes at the expense of medical schools' financial balance. Public universities are clearly experiencing financial pressure as a direct consequence of compromised public support resulting from declining tax revenues in the recent economic downturn.[26] If public policy goals of physician workforce expansion and replenishment are to be achieved, enhanced revenue sources are required for both public and private medical schools in this challenging fiscal environment. ❖

Disclosure Statement

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

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The Mighty Instruments

Let us not forget that a university or a medical college may have large endowments, palatial buildings, modern laboratories, and still the breath of life may not be in it. The vitalizing principle is in the men—both teachers and students—who work within its walls. Without this element of life, this bond between teacher and taught, these things are but outward pomp and show. But let these greater opportunities receive the breath of life from the inspiration of great teachers and they then become the mighty instruments of higher education and scientific progress.

— William H Welch, 1850-1934, physician, pathologist, medical school administrator, cofounding professor at Johns Hopkins University

Out-of-Plan Pharmacy Use by Members of a Managed Care Organization

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Perm J 2012 Spring;16(2):15-21

Abstract

Background: Bargain generic programs have proliferated rapidly since 2006. Little is known about the use of these programs. The purpose of this study was to assess the rate and characteristics of prescriptions written in a managed care organization (MCO) to an out-of-plan pharmacy (OOPP).

Methods: This retrospective health services investigation examined characteristics of patients in an MCO who did and did not have a prescription written to an OOPP from October 1, 2006 through September 30, 2010, and patients who had a prescription transferred to an OOPP in September 2008 (only month with data available). Descriptions of the longitudinal rate of OOPP use, OOPP patient and medication characteristics, and OOPPs where prescriptions were transferred are reported. Patient characteristics independently associated with an OOPP prescription were analyzed with logistic regression modeling.

Results: A total of 10,353,283 prescriptions were included. The monthly rate of OOPP usage during the study period increased from 1.5% to 5.2% and then stabilized at around 5%. Prescriptions written to an OOPP were more likely to be for chronic disease states. Patient age and MCO termination were associated with having a prescription written to an OOPP; whereas increasing medication purchases, a drug benefit, and a health maintenance organization plan type were associated with not having a prescription written to an OOPP. More than 80% of transferred prescriptions went to an OOPP with a bargain generic program.

Conclusion: The rate of OOPP prescriptions increased rapidly over the study period. Prescriptions written to an OOPP were predominantly for chronic diseases. Further research is warranted to assess if OOPP use results in reduced quality of health care system oversight or compromises patient health.

Introduction

To receive subsidized prescription medications, members of managed care organizations (MCOs) are often required to purchase such medications at in-plan pharmacies, whether MCO-owned or within a specific network of community pharmacies. In September 2006, the Wal-Mart corporation launched a program that offered several generic prescription medications at a reduced price of $4 per 30-day supply.[1] Since then, numerous other pharmacies have introduced similar bargain generic prescription programs (BGP). These programs often undercut MCO drug benefit copayments (eg, a typical generic copayment is $5 to $10, yet a BGP may offer the generic for $4 per 30-day supply). Thus, MCO members may opt to use out-of-plan pharmacies (OOPP) that have a BGP to obtain prescriptions at a lower cost. This conjecture is supported by a report that a $1 increase in copayment is associated with a 12% increased likelihood of having a prescription medication purchased from an OOPP.[2]

These BGPs are not without risks; use of an OOPP may result in adverse clinical outcomes for the patient. A pharmacist supplying medication at an OOPP may not be able to screen thoroughly for drug-drug interactions because the electronic medical records (EMRs) of all current medications and medical conditions will not be available at the OOPP. Additionally, OOPP use has the potential to result in negative financial consequences for patients: Patients who have a high-deductible drug benefit or who are Medicare Part D beneficiaries may not have their medication out-of-pocket expenditures count toward their deductible minimum and maximum limits.[1] Little evidence exists describing the prevalence and characteristics of OOPP use.[1,3,4] The Kaiser Permanente (KP) Colorado (KPCO) MCO offers a naturalistic setting in which OOPP use can be studied. Members of KPCO use in-plan pharmacies to obtain subsidized prescription medications; however, members can have new prescriptions written from the EMR (Epic Clarity; Madison, WI) to be taken to an OOPP and current prescriptions can be transferred to an OOPP. These two approaches for acquiring medications from an OOPP offer rich data sources. The aim of this study was to describe OOPP use among MCO members with an in-plan pharmacy benefit. This information will provide a basis for future studies to understand the risks associated with OOPP use.

Methods

Study Design and Setting

This was a retrospective health services research investigation. The primary objective was to calculate the rates at which prescriptions are written to OOPPs. A longitudinal panel study design was used to examine the rates from October 2006 through September 2010. Secondary objectives (as described in the Outcomes section) were approached with a cross-sectional study design.[5] Characteristics of patients who had at least one prescription written to

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an OOPP in September 2010 (the most recent data available) were contrasted with characteristics of patients who had no prescriptions written to an OOPP in the same month. Additionally, to characterize the OOPPs members were likely to use (the KPCO EMR does not readily capture this information), the records of prescriptions transferred to an OOPP from KPCO were examined. The records of these transfers were only available from September 2008.

The study was conducted at KPCO, a not-for-profit MCO with approximately 500,000 members in the Denver/Boulder metropolitan area. KP uses an EMR system at all medical offices that incorporates e-prescribing capabilities, allowing for the assessment of whether a prescription was written for an in-plan or for an OOPP. At KPCO, pharmacies work collaboratively with physicians, nurses, and other health care professionals and their patients to provide prescription transfers to OOPPs. This study used data from queries of integrated, electronic, and administrative databases and was reviewed and approved by the KPCO institutional review board before data collection.

Study Population

The target sample was KPCO patients who had at least one prescription written for an OOPP from October 1, 2006 through September 30, 2010. A prescription was included in the panel analysis if the patient 1) was a Denver/Boulder KPCO member, 2) received the prescription from a KPCO clinician, and 3) had continuous KPCO eligibility in the 180 days before the prescription was written or transferred.

Outcomes

The primary outcome was the rates at which prescriptions were written to an in-plan or out-of-plan pharmacy, from October 1, 2006 through September 30, 2010. The secondary study outcomes were 1) a description and comparison of characteristics of patients who had at least one prescription written to an OOPP (observation group) versus those who had all their prescriptions written for an in-plan pharmacy (control group); 2) a description and comparison of characteristics of prescriptions written to an in-plan pharmacy versus those written to an OOPP; 3) identification of patient factors independently related to OOPP use; and 4) a characterization of the OOPPs where prescriptions were transferred.

Data Collection

The number of prescriptions written was determined from the electronic data repository of the EMR (Epic Clarity, Madison, WI). Information extracted included patient MCO membership number, prescription date, prescribed medication National Drug Code, and whether the prescription was written to an in-plan pharmacy or to an OOPP. Characteristics were identified using the membership numbers of patients who had a prescription written in September 2010 to query electronic administrative pharmacy, medical, membership, and census databases. Information obtained at the time prescriptions were written includes patient age, sex, health plan type (eg, health maintenance organization [HMO], high deductible, preferred provider), prescription drug benefit (ie, Medicare status and prescription drug plan), socioeconomic status (ie, median household income and percentage of households with at least some college education), total unique medications prescribed in the 90 days before September 1, 2010, membership termination or death from August through November 2010, and formulary status and medication drug class of prescribed medication. Information on OOPPs where prescriptions were transferred was obtained from the KPCO Pharmacy Information Management System electronic database. A chronic disease score, a validated measure ranging from 0 to 35, with a higher score representing an increased burden of chronic disease,[6] was calculated from medication purchases during the 180 days before September 1, 2010.

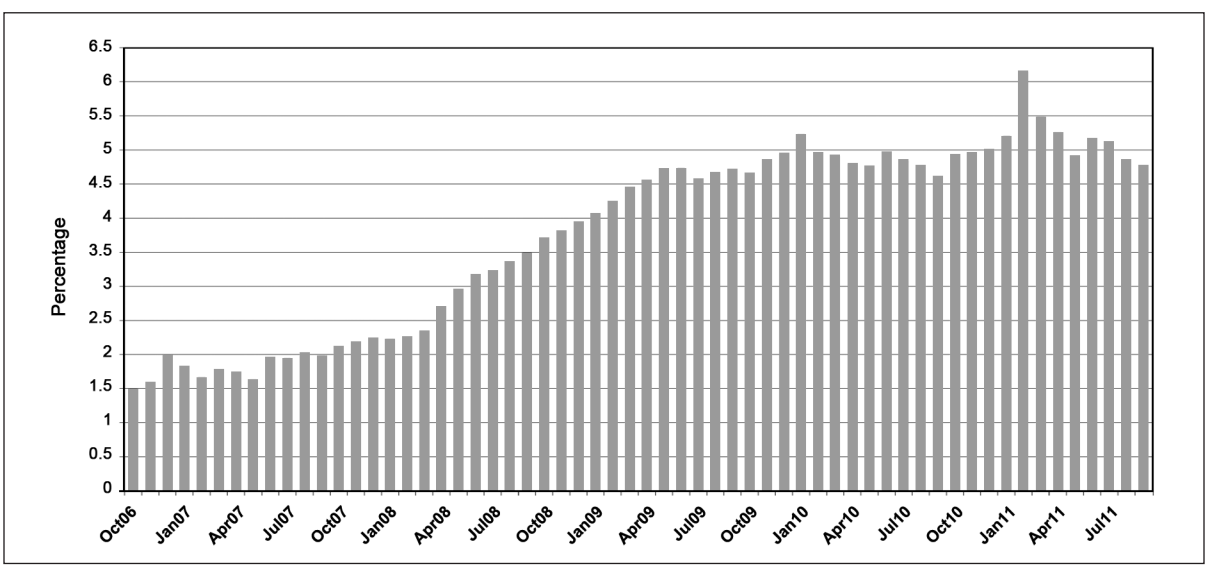

Figure 1. Percentage of Kaiser Permanente Colorado prescriptions written to out-of-plan pharmacies, from October 2006 through September 2010.

Data Analysis

No *a priori* power sample size calculation was performed because the counts of patients and prescriptions were very large; thus, only very small differences between groups or months would not be statistically significantly different. The rate of OOPP was determined by dividing the count of prescriptions written for OOPPs by the total count of all prescriptions written. Monthly percentages of prescriptions written for OOPPs were plotted. Medicare status was categorized as Medicare beneficiary with a coverage gap, Medicare beneficiary without a coverage gap, or commercial non-Medicare. Health plan type was categorized as high deductible health plan, traditional HMO, or other (eg, preferred provider option). Medications were classified into therapeutic drug classes based on the National Drug Code. OOPPs were categorized as 1) big-box (eg, Wal-Mart, Kmart); 2) discounter (eg, Sam's Club, Costco); 3) other KP Region (technically not an OOPP, but requires an OOPP prescription to be written); 4) chain (eg, CVS, Walgreens); 5) supermarket (eg, Krogers, Safeway); or 6) other (eg, independent pharmacy, Veterans Affairs).

Interval-level characteristics (eg, age, chronic disease score) are reported as means and medians with standard deviations, while categorical characteristics (eg, sex and Medicare status) are reported as percentages. Interval-level patient characteristics were assessed for normality and compared between groups using appropriate parametric and nonparametric analyses. Categorical characteristics were compared using the χ^2 test of association. Logistic regression analysis was performed to identify patient characteristics independently associated with having a prescription written to an OOPP. All variables with a p value < 0.2 in the bivariate analyses were entered into the model. The Medicare status variable was further categorized as Medicare beneficiary Yes/No for modeling. Adjustment was made for the intracorrelations of observations from the same patient having more than one prescription in September 2010. The α level was set to 0.05. All analyses were performed using SAS v 9.1.3 (SAS, Cary, NC).

… patients with a prescription written to an OOPP were more likely to … be ≥ 65 years of age.

Results

From October 1, 2006 through September 30, 2010, a total of 10,353,283 prescriptions were written. In October 2006, the rate of prescriptions written for an OOPP was 1.5% (Figure 1). This rate grew slowly until March 2008 (approximately 2.3%) and then increased rapidly. The rate peaked in February 2010 (approximately 5.25%) then decreased and

Table 1. Characteristics of patients who did and did not have a prescription written to an out-of-plan pharmacy

Patient characteristic	Out-of-plan patients[a] (n = 4569)	In-plan only patients (n = 81,894)	P value
Age in years,[b] n (%)			
< 30	766 (16.8)	14,798 (19.3)	<0.001
30-49	133 (29.1)	20,565 (25.1)	<0.001
50-64	1567 (34.3)	22,880 (27.9)	<0.001
≥ 65	9051 (9.8)	22,741 (27.7)	<0.001
Chronic disease score, mean (± SD, median)	2.0 (2.8, 0)	2.6 (3.1, 2)	<0.001
No. prescriptions purchased,[c] mean (± SD, median)	75 (11.6, 3)	11.1 (12.7, 7)	<0.001
Women, %	60.3	60.9	0.410
Medicare status,[b]			
With coverage gap, %	13.0	18.9	<0.001
Without coverage gap, %	8.0	11.5	<0.001
Comercial non-Medicare, %	78.0	69.6	<0.001
Median household income in dollars, mean (± SD, median)	58,928 (24,211, 55,853)	59,120 (23,216, 55,871)	0.225
Households with at least some college education, % (± SD, median)	66.1 (17.6, 69)	65.7 (18.0, 69)	0.265
Prescription drug benefit[b] (% Yes)	87.0	97.8	<0.001
Plan type,[b] %			
Deductible	15.4	9.0	<0.001
HMO	82.1	89.5	<0.001
Other	2.5	1.4	<0.001
Membership terminated,[d] %	6.5	2.3	<0.001
Death,[d] %	0.5	0.4	0.048

[a] Out-of-plan patients had at least one prescription written to an external pharmacy.
[b] As of first written prescription in September 2010.
[c] In June, July, and August 2010.
[d] Any time after first written prescription in September 2010 and November 30, 2010.
HMO = health maintenance organization; SD = standard deviation.

Table 2. Characteristics of prescriptions that were and were not written to an out-of-plan pharmacy

Prescription characteristic	Prescriptions written for out-of-plan pharmacies (n = 7212)	Prescriptions written for in-plan pharmacies (n = 199,942)	P value
Formulary type, %			
Nonformulary	17.0	6.1	<0.001
Medical class, %			
Antihypertensive	16.7	10.2	<0.001
Central nervous system	14.1	11.2	<0.001
Hormone	9.5	4.4	<0.001
Antilipidemic	5.2	3.8	<0.001
Antidiabetic	4.1	2.1	<0.001
Erectile dysfunction	2.7	0.3	<0.001
Analgesic/anti-inflammatory	13.6	18.4	<0.001
Anti-infective	10.1	12.8	<0.001
Other	7.7	5.2	<0.001
Respiratory	5.8	7.2	<0.001
Gastrointestinal	4.0	6.9	<0.001
Biologic	<0.01	<0.01	0.124

stabilized in the 4.6% to 5% range.

In September 2010, 207,154 prescriptions were written for 86,463 patients (Table 1). There were 4569 (5.3%) patients who had at least one prescription written to an OOPP. Compared with patients with prescriptions written only to in-plan pharmacies, patients with a prescription written to an OOPP were more likely to have had MCO membership terminated, a lower burden of chronic disease, purchased fewer prescriptions in the previous 90 days, carried commercial non-Medicare insurance plans, and also a deductible plan type, but they were less likely to have had a prescription drug benefit and be ≥ 65 years of age (all $p < 0.001$).

Of the 207,154 prescriptions written in September 2010, 7212 (3.5%) were written for an OOPP (Table 2). A greater percentage of OOPP prescriptions were not on the KPCO formulary compared with prescriptions written to in-plan pharmacies ($p < 0.001$). Medication classes that were more likely to be written to an OOPP included antihypertensives, central nervous system medications, hormone therapy, antilipidemics, antidiabetics, and medications for erectile dysfunction (all $p < 0.001$). Medication classes that were more likely to be written to an in-plan pharmacy included analgesic/anti-inflammatories; anti-infectives; respiratory, gastrointestinal, topical, neuromuscular, and hematologic medications; and supplies (all $p < 0.001$).

Patient characteristics independently associated with having had at least one prescription written to an OOPP in September 2010 were increasing age (age categories 30 to 49 years, 50 to 64 years, and ≥65 years had a higher odds of having a prescription written to an OOPP than those patients age <30 years) and MCO membership termination during August through November 2010 (odds ratio [OR] = 2.88; both $p < 0.05$; Table 3). Purchasing a greater number of prescriptions in the previous 90 days (OR = 0.97), being a Medicare beneficiary (OR = 0.66), having a prescription drug benefit (OR = 0.18), and being in an MCO health care plan (OR = 0.70) were independently associated with not having at least one prescription written to an OOPP (all $p < 0.05$).

In September 2008, 2404 prescriptions were transferred from KPCO to an OOPP (Figure 2). Of these prescriptions, the majority of transfers went to OOPPs at supermarkets (37%, n = 897), followed by big-box stores (28%, n = 678), and chain stores (22%, n = 519). Eighty-four percent (n = 753) of the supermarket transfers went to Kroger, 80% (n = 542)

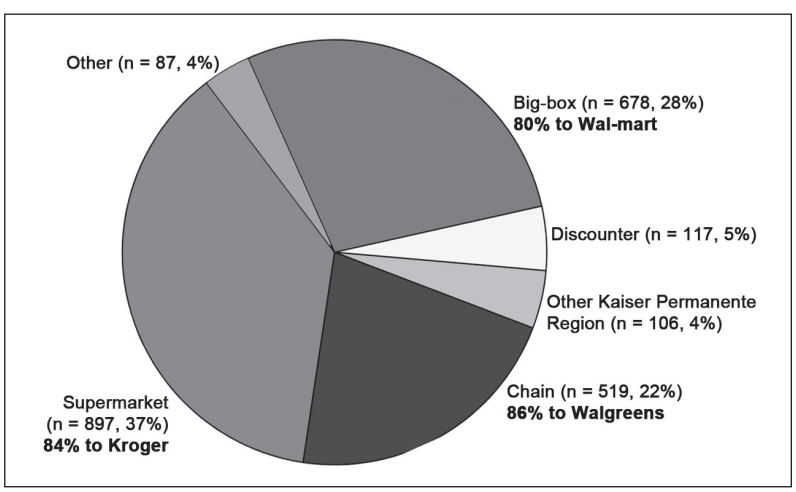

Figure 2: Out-of-plan pharmacy type where prescriptions were transferred (n = 24).

of the big-box transfers went to Wal-Mart, and 86% (n = 446) of the chain transfers went to Walgreens. More than 80% of transfers went to a pharmacy with a BGP.

Discussion

In September 2006, Wal-Mart initiated a BGP program. During the next 2 years, many additional pharmacy chains also initiated BGPs.[3] In our retrospective health services research study of more than 10 million prescriptions written from October 2006 through September 2010, we found that the rate of prescriptions written to OOPPs has more than tripled (from 1.5% to approximately 5.0%) since the inception of BGPs. Convenience and perception of prescription medications as being inexpensive are among the factors that predict satisfaction with pharmacy services among MCO patients.[7,8] Thus, the realization that prescription medications are available at lower prices could increasingly drive health care consumers to obtain bargain generics. Nevertheless, our data indicate that OOPP use by MCO patients has recently leveled off. This suggests that the negative consequences of OOPP use or the opportunity cost of using an OOPP may be more widely understood by our patient population, especially because our MCO has not matched all available BGP prices.

Limited data have been reported on the rate of prescriptions written from MCOs to OOPPs. The reported rates of OOPP use range from 1% to 31%;[4,9] however, these data are either outdated or from very small patient samples. Although the destination of an OOPP prescription is not explicitly tracked in our electronic prescribing system, we attempted to identify the pharmacies where OOPP prescriptions were to be dispensed by examining the pharmacies where prescriptions were transferred from our MCO as recorded in our Pharmacy Information Management System. Our analysis of transferred prescription data revealed that the vast majority of transferred prescriptions were sent to an OOPP that had a BGP. Implications of OOPP use are important from both the patient and MCO standpoints.

A potentially problematic issue with the use of OOPPs is that most of the medications on BGP lists are used in the treatment of chronic disease states.[1] The medication classes that we identified as most likely to be written to an OOPP included antihypertensives, antilipidemics, antidiabetics, and central nervous system medications (including anticonvulsants). All of these medications are for chronic diseases that should be monitored. Use of BGPs may compromise drug allergy screening and monitoring for drug-drug interactions and drug-disease interactions at the time medication is dispensed.[1]

In an MCO, electronic tracking of patient medical and pharmaceutical histories allows for screening programs to optimize patient medication safety. In addition, MCOs use pharmacy purchase data for disease management programs. When patients use OOPPs, clinicians working in disease management programs lose important data (eg, adherence/persistence information) that affect clinical decisions. Patel and colleagues[3] have noted that pharmacies that promote BGPs do not have the ability to manage patient disease states and patient care at the same level as MCOs.

Another issue of importance from the MCO's perspective is that use of OOPPs may negatively affect Healthcare Effectiveness Data and Information Set (HEDIS) health care performance scores. Performance scores for HEDIS that require reporting medication use (eg, beta-blocker persistence following myocardial infarction) suffer when medication purchase data are unavailable.[10]

Additionally OOPP use limits the ability to track medication-related expenses. Patients who have a high-deductible drug benefit or who are Medicare Part D beneficiaries most likely will not have

Table 3. Patient characteristics[a] independently associated with having at least one prescription written to an out-of-plan pharmacy

Characteristic	Odds ratio	95% confidence interval
Age, years		
<30	Referent	—
30 to 49	1.56	1.42-1.72
50 to 64	1.95	1.77-2.14
≥65	1.23	1.01-1.52
Chronic disease score	1.00	0.99-1.02
Sex		
Men	1.03	0.96-1.09
Women	Referent	—
Prescriptions purchased	0.97	0.96-0.98
Membership terminated		
Yes	2.88	2.51-3.30
No	Referent	—
Deceased in September, October, or November 2010		
Yes	1.11	0.71-1.72
No	Referent	—
Medicare beneficiary		
Yes	0.66	0.60-0.73
No	Referent	—
Pharmacy benefit		
Yes	0.18	0.16-0.20
No	Referent	—
HMO health plan		
Yes	0.70	0.64-0.76
No	Referent	—

[a] Only includes variables with $p < 0.2$ in bivariate analysis and sex; C-statistic = 0.662.
HMO = health maintenance organization.

their out-of-pocket expenditures for OOPP prescriptions accrue toward their deductible minimum and maximum limits, because OOPPs are not incentivized to process these purchases as claims to the patients' insurers.[1]

Although BGPs may increase access to necessary medications, clinicians and health care systems may find that the effective promotion of higher quality care is challenged by these programs. Short of matching BGPs' reduced medication prices to disincentivize members from obtaining their medications from a BGP, one strategy clinicians and health systems could employ to increase the quality of care would be to have OOPP pharmacists submit to pharmacy benefit managers all claims for patients, including those that paid in cash.[1] However, this is unlikely to occur without governmental regulation or clinicians/health system financial compensation to the OOPP.

We identified several patient characteristics independently associated with OOPP use and nonuse. Patients age 30 to 64 years had a higher prevalence of having had a prescription written to an OOPP. Because older patients have a higher disease burden and would be more likely to receive centralized health care, one might expect a more linear relationship, with OOPP use consistently diminishing with age. However, Gatwood and colleagues[4] noted a similar phenomenon in which the oldest and youngest patients had lower prevalences of a prescription written to an OOPP in their small study, but the association did not hold up in adjusted analysis.

We found an inverse relationship: the higher the number of prescriptions purchased in the previous 90 days, the lower the likelihood of having a prescription written to an OOPP. Our findings run counter to those of Gatwood and colleagues,[4] who identified patients with more prescriptions as being more likely to use an OOPP. Whereas our findings may seem counterintuitive (patients with more prescriptions might be expected to seek out BGPs to offset prescription copayments), health services research suggests that patients with a high burden of disease are more likely to continue with their health plan and its requirements.[11]

We found that patients who were Medicare beneficiaries were less likely to have a prescription written to an OOPP. Although Medicare beneficiaries might be expected to use BGPs to reduce their prescription medication contribution,[12-14] Part D programs at KPCO require patients to purchase their medications at a KPCO pharmacy for those purchases to count toward their out-of-pocket minimum and maximum. A survey of MCO members revealed that members have limited knowledge with respect to financial implications of OOPP use.[15] However, this survey was conducted around the time Medicare Part D was initiated, and Medicare beneficiaries now may be more attuned to the financial consequences of out-of-plan use.

We found that patients with a pharmacy benefit and those in an HMO health plan were less likely to have had a prescription written to an OOPP. These findings are not surprising, as both the pharmacy benefit and the HMO health plan are suggestive of patients who can purchase subsidized prescriptions at a pharmacy in the medical office where they receive care. At KPCO, approximately 2% of the overall membership did not have a pharmacy benefit throughout the study period. Approximately 1% of overall KPCO members are members who work for an employer who supplies their pharmacy benefit (eg, grocery store workers). These members could have had a prescription written to their employer's pharmacy during the study period, thus, these would be counted as a prescription written to an OOPP in this analysis. Conversely, these members could have chosen to have their prescription written to a KPCO pharmacy as some could do for convenience. The proportion of the other 1% of members without a KPCO pharmacy benefit who required a prescription to be written to an OOPP by a KPCO prescriber is not known. However, not all of the members who required a prescription to be written would necessarily have been seen by a KPCO prescriber because a fair proportion of the 1% encompasses members with a medical benefit (eg, preferred provider plans) that allows them to be seen by non-KPCO clinicians.

We found that patients who terminated MCO membership were highly likely to have had a prescription written to an OOPP. This is not surprising, either. Patients transitioning out of the MCO would, perhaps, transfer their prescriptions to their new insurer's network pharmacy; if losing health care coverage entirely, they would use different means to purchase essential medications.

This study is not without limitations. We were unable to identify where prescriptions written to an OOPP were actually dispensed. However, we used data on where prescriptions were transferred as a surrogate for this information and found that the vast majority was transferred to an OOPP with a BGP program. Because this study was retrospective, we were unable to query patients as to their rationale for having a prescription written to an OOPP. We attempted to understand patient behaviors by using administratively available information about patient characteristics. Approximately 2% of KPCO membership did not have a pharmacy benefit and, thus, could have required a prescription to be written to an OOPP. However, this likely only contributes insignificantly to the increase in the rate of prescriptions written to an OOPP as this percentage was consistent throughout the study period. Further research opportunities exist, including analysis of long-term medical outcomes for patients using OOPPs compared with patients who use only in-plan pharmacies.

Conclusion

The rate of prescriptions written to OOPPs rapidly increased after the introduction of BGP programs but then stabilized at approximately 5%. The majority of prescriptions written to OOPPs appear to be in the medication therapy classes offered by BGP programs. Because OOPP prescriptions were written predominantly for chronic diseases, further research should be conducted to investigate whether such programs reduce the quality of health care system oversight or compromise patient health. ❖

Disclosures

This study was funded by Kaiser Permanente Colorado. The authors have no conflicts of interest to disclose.

Acknowledgment

Leslie E Parker, ELS, provided editorial assistance.

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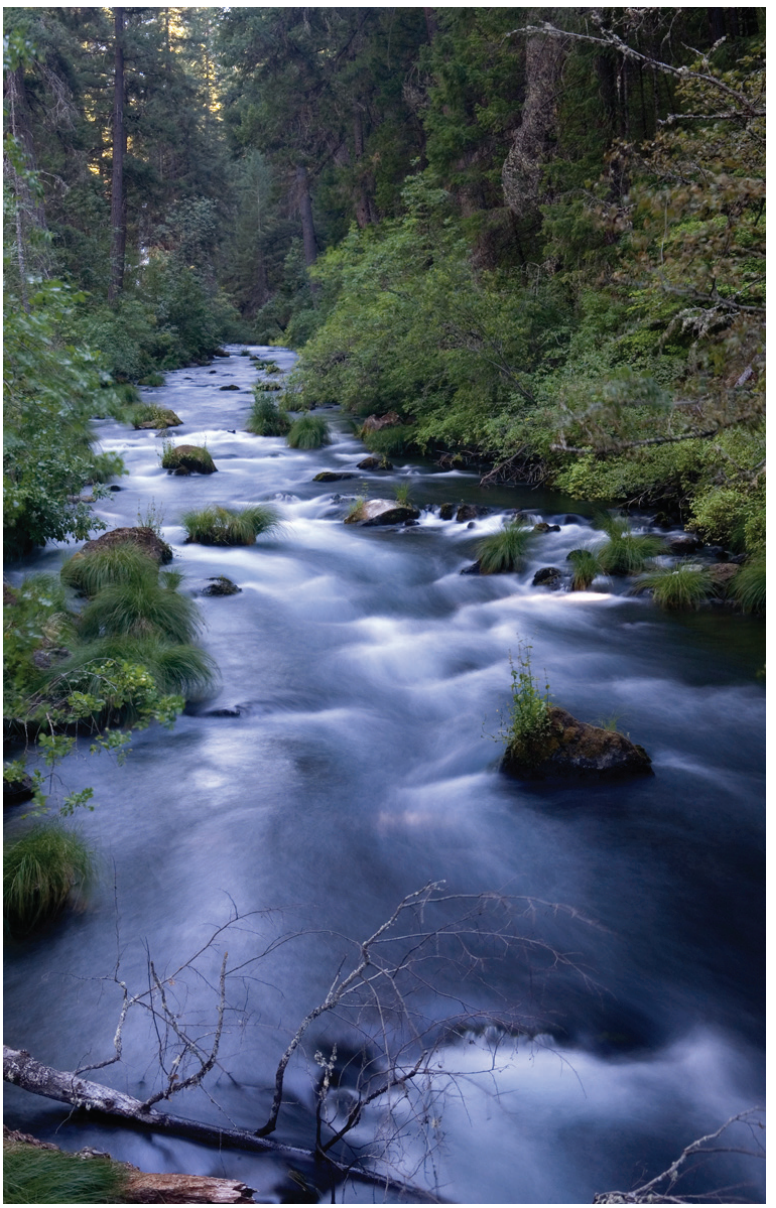
The Essential Factors

The physician, the patient, the medicine, and the attendants (nurses) are the four essential factors of a course of medical treatment. Even a dangerous disease is easily cured, or it may be expected to run a speedy course in the event of the preceding four factors being respectively found to be qualified, self-controlled, genuine and intelligently watchful.

— *Sushruta Samhitá,* Sushruta, circa 600 BCE, Indian surgeon, known as the "Father of Surgery"



"Birney Creek"
photograph

Stephen Jacobs, MD

This is a photograph of Birney Creek just above Birney Falls in Northern California. The falls were behind Dr Jacobs as he took the photograph of what appears to be a gentle mountain stream. Within a few hundred yards the water cascades over 100 feet to the basin below.

Dr Jacobs is a Pediatrician at the Modesto Medical Center in California.

CME credits available for this article — see page 80.

ORIGINAL RESEARCH & CONTRIBUTIONS

Association of Child and Adolescent Psychiatric Disorders with Somatic or Biomedical Diagnoses: Do Population-Based Utilization Study Results Support the Adverse Childhood Experiences Study?

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Perm J 2012 Spring;16(2):23-26

Abstract

Context: Few population-based studies have examined the relationship between psychiatric and somatic or biomedical disorders.

Objective: We examined the effect of the presence or absence of any psychiatric disorder on somatic or biomedical diagnosis disorder costs. Guided by the Kaiser Permanente and Centers for Disease Control and Prevention Adverse Childhood Experiences (ACE) Study, we examined our administrative data to test if psychiatric disorder is associated with a higher level of somatic disorder.

Design: A dataset containing registration data for 205,281 patients younger than age 18 years was randomly selected from administrative data based on these patients never having received any specialized, publicly funded ambulatory, emergency or inpatient admission for treatment of a psychiatric disorder. All physician billing records (8,724,714) from the 16 fiscal years April 1993 to March 2009 were collected and grouped on the basis of presence or absence of any International Classification of Diseases (ICD) psychiatric disorder.

Main Outcome Measures: We compared 2 groups (with or without any psychiatric disorder: dependent variable) on the cumulative 16-year mean cost for somatic (biomedical, nonpsychiatric) ICD diagnoses (independent variable).

Results: Billing costs related to somatic and biomedical disorders (nonpsychiatric costs) were 1.8 times greater for those with psychiatric disorders than for those without psychiatric disorders. Somatic costs peaked before the age of 6 years and remained higher than the groupings without psychiatric disorders in each age range.

Conclusion: In support of the ACE study, ICD psychiatric disorders (as an index of developmental adversity) are associated with substantially greater ICD somatic disorders. The findings have implications for health care practice.

Introduction

The association between general health care costs and mental problems is emerging as an important topic in policy development related to reducing the burden of mental illness on society. Seligman[1] proposed in 1989 that an epidemic of depression was on the horizon. A published study in our catchment indicates that psychiatric disorder is indeed epidemic.[2] Furthermore, the health care cost reductions associated with health improvement are better for those with somatic or biomedical problems (eg, asthma) than in those with mental problems.[3,4]

As individuals develop, those with early adversity (eg, abuse and neglect) have a greater likelihood in adulthood of using health services more frequently—an effect modulated by psychiatric status.[5] Childhood psychiatric conditions such as depression and substance abuse have a long-term economic cost and are estimated to reduce subsequent lifetime family income by $300,000 US, at a national cost of $1.2 trillion US.[6] Felitti et al[7] have studied extensively the association between childhood adversity and adult health status, with the finding that adversity-affected adults are at considerably higher risk of having serious health concerns. Here, we present population-based results that support the findings of Felitti et al's Adverse Childhood Experiences (ACE) study.

Materials and Methods

Health care in Canada is primarily universal. Medically necessary health services in each province include family physician visits and access to specialized ambulatory, emergency, and inpatient health treatment, including mental health, and are covered under public provincial health plans. In addition, family physicians serve as gatekeepers for specialty care. Most people who require mental health care are first served by their family physicians. For each patient visit, physicians bill the provincial health plan directly to receive payment for the services they deliver. Each billing includes at minimum a unique patient identifier, an International Classification of Diseases (ICD) diagnosis, and an associated visit cost.

The April 1993 through March 2009 data used in this study consisted of physician billings (Calgary Research Ethics Board ID 21695) for patients from the Calgary Zone in Alberta who were younger than age 18 years on their index visit. Physician billing data represented the records of all health services rendered to all individuals from the catchment sample who sought health care on a specified date for a specified problem and were assigned an ICD diagnosis.

The group under study consisted of those who had physician health care billings and did not have a personal health number associated with treatment by specialized, publicly funded ambu-

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latory, emergency, or inpatient mental health services. The randomly selected files of physician billing data consisted of 205,281 unique individuals having 8,724,714 billing records submitted by regional physicians. These records included billing data related to somatic or biomedical and psychiatric diagnoses assigned by physicians. All diagnoses were based on ICD-9 or ICD-10 mental health diagnostic codes. The data formed two natural groups of individuals: those with a psychiatric diagnosis and those without any physician-assigned psychiatric diagnoses (no psychiatric diagnosis). Each of these groups had physical biomedical or somatic disorders that formed the basis for comparison.

Diagnosis-related costs were recorded in the dataset as the total amount paid by the provincial health plan to the physician for each visit. Physical (somatic and/or biomedical) diagnosis costs were summed across each group and did not include visit costs related to any psychiatric disorder billings. Psychiatric diagnosis costs were totaled separately.

Data Analysis

Groupings based on the presence or absence or any psychiatric disorder represented the dependent or outcome variable. Costs and visits for somatic or biomedical diagnoses represented the main independent variables. Age and sex represented covariates of analysis. Descriptive statistics were calculated as the mean per patient for visits and costs related to somatic or biomedical diagnoses (eg, subtracting billing costs for psychiatric diagnoses) by patient age and sex for each outcome group (those with or without psychiatric diagnoses). In the data shown in the results section, costs related to a somatic diagnosis were calculated independently of psychiatric diagnosis costs.

Results

Age ranged from younger than age 1 year to age 17 years. The sample consisted of 150,380 individuals with no psychiatric diagnosis and 54,901 with any psychiatric diagnosis. Approximately half of the sample was female (49%). There were no differences in the distribution of age or sex between the two groups.

Thirty-seven percent of the sample had a psychiatric disorder over the 16-year study period. The mean number of visits related to somatic or biomedical diagnoses for unique individuals in each grouping was as follows: no psychiatric diagnosis, 28; psychiatric diagnosis, 47. Those with a psychiatric disorder had between 1.7 times more visits for somatic disorders on average than those without a psychiatric disorder. Individual patients had an average of 5 visits during the study period related to treatment of psychiatric disorders, at an average cost of $380 per patient.

Figure 1 represents the mean cost of physician billing for somatic or biomedical diagnoses per unique individual for the 2 study groups. For those with any psychiatric disorder, the somatic or biomedical diagnosis costs were 1.8 times higher than those without psychiatric disorders.

There was, however, an age effect (Figure 2). Even though the relative ratios of cost in each age category were approximately the same, overall costs decreased as age increased and were greatest for preschool children. The decrease occurred because the sample was truncated when any patient reached the age of 18 years, thereby representing only pediatric physician visits.

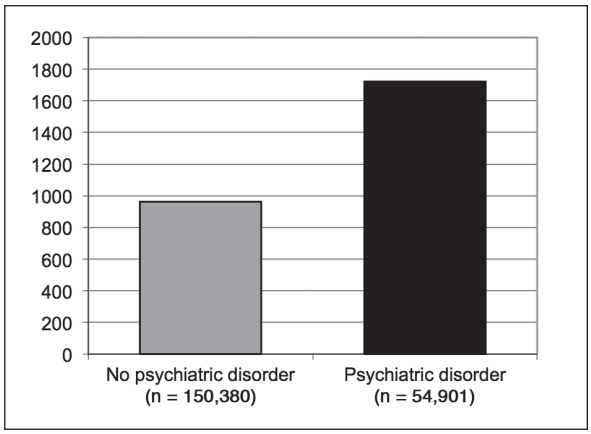

Figure 1. Mean physician billing cost related to a somatic or biomedical disorder.

Discussion

The ACE Study (www.acestudy.org) has described the relationship between health status in adulthood and reported adverse childhood experiences.[8-10] The ACE Study has provided a great deal of information related to the reporting of adversity, present health status, and health economy. We are currently seeking how to implement the ACE survey in our publicly funded health system because of substantial health expenditure savings reported with the use of this survey. For example, at Kaiser Permanente in a sample of 125,000 adult patients in one department using such a questionnaire, routinely gathering this information was associated with a 35% reduction in doctor office visits in the subsequent year (Vincent Felitti, MD, personal communication; 2012 Apr 1).[a]

Furthermore, a recent study has identified the effect of psychiatric morbidity on mortality, noting that the burden of psychiatric illness goes on largely unattended and unnoticed.[10] To our knowledge, no population-based studies to date have provided information about the relationship between psychiatric disorder and health status over time. However, in terms of developmental psychopathology, childhood adversity has long been considered a harbinger of psychiatric disturbance and disorder.

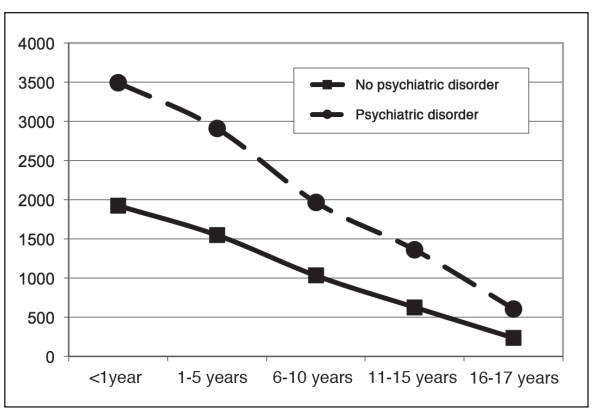

Figure 2. Mean somatic/biomedical disorder billing cost (Canadian dollars) per unique patient by age group for groups with and without any psychiatric diagnosis over the 16-year period.

Of the randomly selected study group, 37% had a physician billing for a psychiatric disorder. Prior analysis of a 9-year and 16-year dataset, including adult and geriatric data, indicated that 46% of the randomly selected comparison group had a physician billing for a psychiatric disorder.[2] Somatic and biomedical disorder costs among those in the psychiatric disorder group were higher than in the group with no psychiatric disorder.[2] Furthermore, the psychiatric disorder rate was higher overall (46%) in the sample that included all ages,[2] indicating that the somatic morbidity associated with psychiatric disorder increased with age. In our study, we observed that across childhood and adolescence the rate of contact with regional physicians decreased up to the age of 18 years (Figure 2). The psychiatric disorder group had a consistently higher proportion of biomedical and somatic disorder-related costs at each age. The age-related decrement represents the result of truncating all visit dates when any patient reached age 18 years. Hence, a patient who was age 17 years at the index visit would have accumulated fewer visits before his/her 18th birthday than a patient who was 1 year old at the index visit in the first year of the study (1994). Data inclusion was truncated for all patients when they turned 18 years old because this directly reflects the organization of our health care system, especially in psychiatry.

The results of the present large population-based study demonstrated the physical (somatic or biomedical) liability of having a psychiatric disorder in childhood and adolescence. The cost related to somatic or biomedical disorders, given any psychiatric diagnosis, were 1.8 times as high compared with the group with no psychiatric disorder. Similarly, the burden of a somatic or biomedical disorder given the presence of a psychiatric diagnosis also increased in proportion with age to 3.3 times higher in the previously reported sample that included all ages.[2]

The burden of somatic or biomedical disorders in the psychiatric disorder group emerged early in life (Figure 2) and much earlier than the investment we make in psychiatric care. Considering that the sample size in this study was approximately two thirds of the total base population of those younger than age 18 years in the catchment, the somatic or biomedical diagnosis-related cost burden having any psychiatric disorder becomes paramount, especially given the early-life onset of physical (somatic or biomedical) disorders. Our current dataset holds the potential to examine patterns of emergence and co-occurrence of somatic and psychiatric disorders over time. For example, preliminary results (unpublished data, 2010) indicate that neurotic and anxiety disorders are much more prevalent in the sample and, therefore, have the highest direct (psychiatric) and indirect (physical) physician billing costs in total, even though their per capita cost is comparatively less than other psychiatric diagnoses, such as organic brain syndromes and mental retardation.

There were several limitations of the study. Any physician billing could include costs associated with up to three diagnoses. If any one of these diagnoses was a psychiatric diagnosis, the total cost of that visit was assigned to the total mental health costs for that unique individual. As a result, the total health costs for each unique individual were marginally underestimated if there were additional somatic or biomedical diagnoses associated with a psychiatric diagnosis for a given visit. Multiple diagnoses, however, were associated with a minority of the physician billings. A second limitation was associated with the reliability and validity of the assignment of psychiatric diagnoses by the billing physicians. Compared with specialists, family physicians have limited psychiatric training (given the large number of unspecified psychiatric diagnoses). However, the same threats to validity and reliability were present in the assignment of all psychiatric diagnoses in each of the study groups. We acknowledge that diagnostic precision may be an issue in some instances. Finally, by excluding in the sampling process patients known to have received publicly funded, specialized ambulatory, inpatient, or emergency psychiatric services, the possible differences between the psychiatric and nonpsychiatric groups in this study have been minimized. We were not able to account for additional privately funded health care in either group, however, where available, privately funded health care is not the norm in Canada.

Conclusion

The association between general somatic and biomedical health costs and the health care costs of psychiatric disorder is emerging as an important topic in policy development related to understanding and reducing the burden of mental illness on society.[11] However, there have been few systematic population-based health care utilization studies. We examined the health costs in a pediatric population over a 16-year period. The main finding was that health costs of individuals with a psychiatric diagnosis were about twice as high on average per unique patient given any psychiatric diagnosis compared with those without a psychiatric diagnosis. Psychiatric billing costs independently added on to the costs of somatic or biomedical diagnoses. The physical (somatic and biomedical) disorders were directly comparable between the study groups with and without psychiatric disorders, and the ratio of the average costs per individual between these 2 groups over the 16-year period was the main finding of this study. This ratio (2:1) was lower than the ratio observed in the previous study of the 9-year period for a sample of all ages,[2] including child, adult, and geriatric populations, suggesting that the physical burden of psychiatric disorder increases with age.

Psychiatric assessment and treatment, if required, should always include assessment and treatment of physical conditions.

The type of physical problems and the relationship between patterns of biomedical or somatic disorders and specific types of psychiatric disorder remain to be examined. Whereas a specific pattern of association is beyond the scope of the present report, what has been established is the fundamental relationship between the biologic substratum and psychiatric disorder in a form that may be examined exhaustively in a population. The implications for policy and practice are self evident. Psychiatric assessment and treatment, if required, should always include assessment and treatment of physical conditions. Segregated systems of care may, in fact, be detrimental in terms of long-term outcome and more costly in managed health care.

The present dataset holds the potential to reveal the relationships among specific diagnostic groupings that develop and are observed over time. The order of costs by psychiatric diagnoses provides a logical point of entry to examine the patterns of

psychiatric and concurrent or prodromal somatic burden that develop over time. Profiles and patterns may emerge from the combinations and permutations in these data, which permit the identification of standard clinical pathways together with their associated costs. Such analysis represents a classic roadmap problem, and given the large numbers of permutations and combinations, it would take many researchers many years to unravel. Hence, we are developing a standardized algorithm to make the time-dependent results from these data accessible to investigators. This information is beginning to form the empirical basis on which to study and measure future innovation related to optimization of clinical pathways.

The main policy implication of the study's results points to the universal integration of psychiatric and health care structures and processes. Our findings bring to the fore the call to action embodied in the 1977 observation by Engles,[12] the father of biopsychosocial theory:

> *The dominant model of disease today is biomedical, and it leaves no room within this framework for the social, psychological, and behavioral dimensions of illness. A biopsychosocial model is proposed that provides a blueprint for research, a framework for teaching, and a design for action in the real world of health care.*

Although Engle's theory has been refined and advanced over the years, it is our hope that the present study will facilitate detailed examination of the relationships among the "biopsycho" spheres of a representative population. ❖

[a] Co-Principal Investigator, The Adverse Childhood Experiences (ACE) Study; San Diego, CA

Disclosure Statement

This study was funded, in part, by the Norlien Foundation. The author(s) have no other conflicts of interest to disclose.

Acknowledgment

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

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The Right to Be Protected

Children have the right to be protected from all forms of maltreatment by any adult, including a parent. This includes but is not limited to: physical abuse, including torture, violence, hitting and slapping; harmful drugs, including alcohol and tobacco; mental abuse; and sexual abuse.

— *The Children's Bill of Rights,* 1968, Billy F Andrews, MD, pediatrician and lecturer

"Hearing Loss"
acrylic on canvas
24 x 30

Mohamed Osman, MD

Dr Osman is formerly a physician from Group Health Permanente and continues to practice as a Board-certified Physician and Geriatrician, who owns an innovative medical practice that is also an art gallery in St Pauls, NC, which may be viewed at: www.primarycareofstpauls.com. He is a self-taught artist and credits his early life in Somalia, his medical education in Russia, and his medical experience in Kenya and Somalia as major influences on his art. Dr Osman has been published many times in *The Permanente Journal* and *leaflet.* More of Dr Osman's artwork can be seen on page 64 and on his Web site: www.osmanart.net.

Long-term Outcomes of Shamanic Treatment for Temporomandibular Joint Disorders

Nancy H Vuckovic, PhD; Louise A Williams, PhD; Jennifer Schneider, MPH; Michelle Ramirez, PhD, MPH; Christina M Gullion, PhD

Perm J 2012 Spring;16(2):28-35

Abstract

Background: Temporomandibular joint disorders (TMDs) are chronic, often refractory, pain conditions affecting the jaw and face. Patients least likely to respond to allopathic treatment have the most marked biologic responsiveness to external stressors and concomitant psychosocial and emotional difficulties. From a shamanic healing perspective, this describes individuals who are thought to be "dispirited" and may benefit from this ancient form of spiritual healing.

Objective: To report on the long-term quantitative and qualitative outcomes relative to end-of-treatment status of a phase I study that evaluated the feasibility and efficacy of shamanic healing for people with TMDs.

Methods/Design: Participants were contacted by telephone at one, three, six, and nine months after treatment and asked to report pain and disability outcomes and qualitative feedback.

Setting: Portland, OR.

Participants: Twenty-three women aged 25 to 55 years diagnosed with TMD.

Primary Outcome Measures: Participants rated their TMD-related pain and disability (on the TMD Research Diagnostic Criteria Axis II Pain Related Disability and Psychological Status Scale) at each follow-up call and were asked to describe their condition qualitatively.

Results: Improvements in usual pain, worst pain, and functional impairment reported at end of treatment did not change during the 9 months after treatment ended ($p > 0.18$).

Conclusion: Shamanic healing had lasting effects on TMDs in this small cohort of women.

Introduction

Temporomandibular joint disorders (TMDs) are chronic, recurrent, nonprogressive pain conditions affecting the temporomandibular joint and surrounding tissues.[1-4] TMDs are primarily found in young and middle-aged adults and are nearly twice as prevalent in women.[5,6] Individuals with TMD may experience a range of symptoms, including facial pain, jaw-joint pain, headaches, earaches, dizziness, limited ability to open the mouth, and clicking or popping in the jaw joint. In addition to the physical pathology associated with TMDs, many patients with TMD exhibit a range of physical comorbidities such as gastrointestinal symptoms, frequent infections, and fibromyalgia, as well as psychological comorbidities such as stress, depression, and anxiety.[5,7-9]

Clinical evidence indicates that psychosocial stressors play a role in the clinical course of TMD[7] and can predict the outcome of symptomatic treatment.[8,10] Twenty percent to 30% of patients nonresponsive to standard allopathic treatment appear to have more complex psychosocial problems, including severe depression.[8,11-15] Several studies that combine symptomatic treatment (splint therapy and pain medication) with biobehavioral treatments suggest that therapies that attend to both mind and body may be essential to providing symptomatic relief for individuals with chronic TMDs.[16,17] Complementary and alternative medicine (CAM) treatments, including shamanic healing, may be appropriate for people with chronic illnesses, such as TMDs, that elude conventional treatment.

Shamanic healing is an ancient and widespread form of spiritual healing that focuses on illness (ie, the patient's experience of their disorder), which can be influenced by both biology and the sociocultural context of the disorder.[18] In the shamanic worldview, illnesses may be due to both spiritual and nonspiritual factors.[18-23] Shamans worldwide believe all living beings have a soul—the vital essence required for life.[19,21,23,24] The soul is the spiritual, nonphysical part of us that is the center of our emotions, feelings, and spirit. Part of this vital essence can "split away" when there is trauma (eg, an accident or loss of a loved one). A person suffering from soul loss may feel dead inside, suffer memory gaps, experience out-of-body or listless feelings, or have frequent physical illnesses. For a shamanic practitioner (SP), it is important to find those essences that have split away, help them to heal, and bring them back into the person to help make him/her whole again.[19] Although the client may express their experience of shamanic healing to the SP, the SP encourages the client to experience the changes quietly; clients need not describe their experience to the SP. In contrast, contemporary psychology recognizes the phenomenon of dissociation, when people split off from their body at times of stress. In this context, the client is helped to regain and sometimes describe the lost experience and can be healed.[25]

Shamans recognize two realities reflecting an individual's state of consciousness. People in the ordinary state of consciousness perceive ordinary reality; those in the shamanic

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state of consciousness enter into and perceive nonordinary reality. SPs in contemporary Western practice enter the shamanic state of consciousness through the use of sonic driving (drumming or rattling).[26-30] Entrance into nonordinary reality and experiences while in this state comprise a shamanic journey. Shamans, by definition, are individuals who journey with discipline in nonordinary reality with the specific intent of helping others.[19,21,24,31]

The primary task of the SP is to help restore wholeness to the individual or community. SPs use their connection with helping spirits to clear out blocking, or negative, intrusive energy (extraction), bring back soul essences lost during trauma or illness (soul retrieval), and engage in spiritual healing (guided visualizations, ritual, etc).[19,32] The shaman's preverbal imagery for treating health problems may permit the client's imagination to act directly upon the physical substrate of tissues, organs, and cells through a system of biologic communication that evolved before language.[23,33-35] This healing information and energy is transmitted to the participant through verbal and nonverbal communication.

Shamanic healing is interactive, enabling individuals to regain their power and participate in their own healing. An individual need not be an SP to learn to journey, although simply learning to journey does not qualify one to be an SP.

In a previous study[36] examining the effect of various CAM treatments on TMDs, the authors (NV, JS) found that, in addition to having physical symptoms of TMDs, study participants shared other characteristics. They had a great deal of stress and often indicated a sense of being dispirited—commonly described as not feeling "present in my body"—or expressed that something was missing. These symptoms are consistent with soul loss, a condition treatable within the paradigm of shamanic healing.[19,32]

Anthropologists have traditionally focused their studies of shamanism on the shamans' belief systems, healing practices, and role in their communities.[19,21,24,37-39] Other studies have focused on physiologic changes that accompany the shamanic journey and use of sonic drumming.[26-30,40] Although there are a few retrospective, descriptive studies in which people described their experience of shamanic healing, before our study, no clinical trial of shamanic healing had ever been recorded.[19,41,42]

Drawing on these observations, the study authors designed a phase I clinical trial to assess the feasibility of treating TMDs with shamanic healing. The short-term clinical outcomes (from baseline to final treatment) have been reported elsewhere.[43] In brief, at the final treatment visit, we found significant decreases from baseline in three primary outcome measures: usual pain ratings declined from 4.96 to 2.70, $p < 0.0001$; worst pain from 7.48 to 3.60, $p < 0.0001$; and functional impact of TMD from 3.74 to 1.15, $p < 0.0052$. The results of qualitative interviews, in which participants described a process of transformation that included changes in self-awareness, capacity for coping, and improvement in relationships as a result of shamanic treatment, are described elsewhere.[44] This article describes the long-term clinical outcomes, from the end of treatment to 9 months after the shamanic treatment intervention ended.

Methods

Overview

In the intervention phase of the study,[43] 20 women with diagnosed TMDs were randomly assigned to an SP and completed 5 visits with that practitioner. During the 5 visits, the SP brought back healing information and used shamanic treatments, such as soul retrieval, extraction, and guided meditation, to facilitate healing in the

The primary task of the SP is to help restore wholeness to the individual or community.

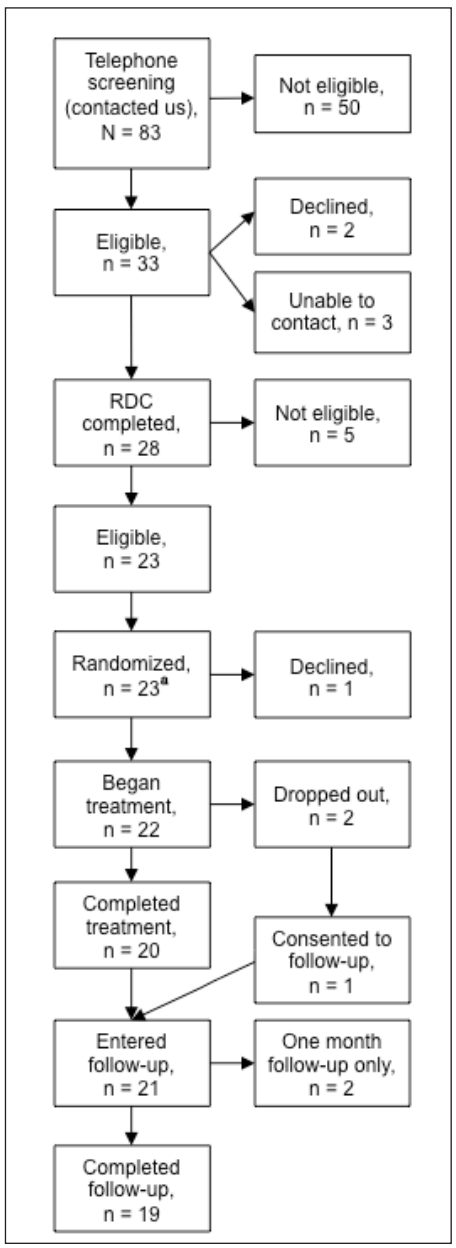

Figure 1. Consort Diagram.

[a] One participant was randomized in error and excluded when error was discovered.

participant. At each visit the participant completed a pain questionnaire. Because shamanic healing had never before been evaluated in a clinical trial, we designed this phase I project as a feasibility study and therefore did not include a control group.

Participants were interviewed by telephone at one, three, six, and nine months after the five visits. We attempted to follow up all eligible and enrolled participants, regardless of whether treatment was completed. The participants were informed at the beginning of the study that they would be contacted up to nine months after the visits to the SP. This study was approved by the institutional review board of Kaiser Permanente Northwest, the institutional home of The Center for Health Research-Northwest.

Participants

Participants were recruited from the general population of Portland, OR, by means of newspaper advertisements and flyers. Twenty-three participants were enrolled in the intervention phase of the study (Figure 1). All were women aged 25 to 55 years (mean, 38.3; standard deviation 8.3) who were identified as having a diagnosis of TMD (based on the Research Diagnostic Criteria exam)[45] and a usual pain level of 3 or greater on the 10-point Research Diagnostic Criteria pain scale. Because we sought to identify participants with complicated TMDs, an additional eligibility criterion was 2 or more of the following self-reported chronic conditions in the past 2 years: fibromyalgia; chronic fatigue syndrome; depression; stomach or intestinal problems (eg, ulcers, irritable bowel, and Crohn's disease); reproductive problems (eg, endometriosis, fibroids, and menstrual problems); upper respiratory problems (eg, asthma and chronic bronchitis); or chronic headaches or migraines. Complicated, chronic TMDs are characterized by the presence of one or more of these comorbidities.[1,45] None of the participants had received previous shamanic treatment.

Providers

The SPs were all women who had an active contemporary Western shamanic healing practice for at least two years in the Portland, OR metropolitan area. The authors purposely chose SPs trained in a Western form of shamanic practice to increase the cultural acceptability[46] of the shamanic intervention for women participants drawn from a North American, urban setting. The authors required that the SPs were trained in the core elements of shamanism at Michael Harner's Foundation for Shamanic Studies, and in soul retrieval by Sandra Ingerman,[19] under Foundation sponsorship. In addition, the SPs had trained on their own with other SPs and indigenous shamanic teachers. None of the SPs had previously participated as providers in a clinical trial.

Materials/Methods

After completing five visits with an SP, the participants were contacted by telephone four times, at one, three, six, and nine months after treatment, to rate their TMD-related pain and disability and to report qualitative changes (Table 1).

One trained clinical interviewer carried out all of the telephone interviews to establish a rapport with the participants and to maintain consistency in data collection. During these interviews, each participant rated facial pain on a standardized scale. The 2 pain measures are 11-point scales, where the lowest value (0) represents "no pain" and the highest value (10) represents "pain as bad as it could be." The 11-point functional impairment scale asks how much the TMD-related pain interferes with daily activities, with ratings

Table 1. Follow-up questionnaire for telephone interviews at 1, 3, 6, and 9 months after treatment[1]

1	In the *last week,* how intense was your **worst** TMD-related pain, rated on a 0 to 10 scale, where 0 is "no pain" and 10 is "pain as bad as could be"?
2	In the *last week, on average,* how intense was your TMD-related pain, rated on a 0 to 10 scale, where 0 is "no pain" and 10 is "pain as bad as it could be"?
3	In the *last week,* how *improved* was your TMD-related pain, rated on a 0 to 10 scale, where 0 is "much worse," 10 is "much improved," and 5 is "no change"?
4	In the *last week,* how much has TMD-related pain *interfered* with your daily activities, rated on a 0 to 10 scale, where 0 is "no interference" and 10 is "unable to carry out activities"?
5	In the *last week, on average,* how intense was other pain, rated on a 0 to 10 scale, where 0 is "no pain" and 10 is "pain as bad as it could be"?
6	Did you take any medications for your pain last week?
7	What changes have you noticed [at 1 month] since you ended treatment in the study? [At 3, 6, 9 months] Since the last time we talked to you?
8	[At 1 month] Since completing treatment in the study, have you had any additional shamanic treatment? [At 3, 6, 9 months] Since the last time we talked, have you had any additional shamanic treatment?
9	[At 1 month] Since completing treatment in the study, have you learned to journey? [At 3, 6, 9 months] Since the last time we talked, have you learned to journey?
10	Has anything else in your life changed as a result of the treatment (ie, sleep, exercise, energy, other conditions, feel more at ease/balanced, feel differently about things, etc)?

[1] Dworkin SF, LeResche L. Research diagnostic criteria for temporomandibular disorders: review, criteria, examinations and specifications, critique. J Craniomandib Disord 1992 Fall;6(4):301-55.

TMD = temporomandibular joint disorders.

from "no interference" (0) to "unable to carry out activities" (10). Self-report is the gold standard for assessment of pain syndromes[47] (Table 1).

Each participant was asked to describe any changes that had occurred since the last study contact using standard qualitative assessment probes. Each participant was also asked whether she had received any additional shamanic treatment or had learned to journey (Table 1).

Outcome Measures

The measures of long-term treatment effects were patient ratings of usual pain, worst pain, and functional impact of TMDs on subscales of the Research Diagnostic Criteria Axis II Pain-Related Disability and Psychological Status Scale.[45] These outcome measures were collected during each telephone interview and each treatment visit.

Statistical Analysis

Data were reviewed for missing and out-of-range data and corrected as needed. We checked to see if the distributional assumptions of the planned analyses were met, and if they were not, we transformed the data as needed to meet those assumptions.

Efficacy was evaluated on the basis of changes in self-reported symptoms relevant to TMDs from end of treatment to end of follow-up (a maximum of 5 repeated measures per participant). We hypothesized that outcomes would show a worsening trend toward pretreatment (baseline) levels, as often occurs with chronic pain interventions. The primary test of change was on the slope of ratings from end of treatment to month 9. We estimated this change using a repeated measures multilevel mixed model (SAS Proc Mixed 8.2 SAS Institute, Cary, NC), with a spatial power covariance structure to adjust for dependency between measures for each subject. The restricted maximum likelihood algorithm in PROC MIXED uses all available subjects, despite gaps in follow-up. Because this was a pilot study, we set α at 0.05 and did not adjust for multiple comparisons.

Finally, we evaluated whether participant outcomes might depend on which SP provided treatment. This analysis was also a repeated measures mixed model, with SP added as an experimental factor and baseline score on the corresponding outcome measure as a covariate. If the SP effect was significant, we tested differences between pairs of SPs on the participant-within-SP means in the same mixed model.

Table 2. Participant demographics

Variable	Randomized (n = 23)	Entered follow-up[a] (n = 21)
Mean age (SD), years	38.3 (8.3)	39.5 (8.3)
Education, %		
Less than college degree	39.1	33.3
College graduate or higher	60.9	66.7
Income, %		
$0–$14,999	39.4	42.9
$15,000–$49,999	34.8	28.6
$50,000 or more	26.1	28.6
Marital status, %[b]		
Single	45.4	55.0
CAM therapy, n (SD)		
For TMD	4.3 (2.8)	4.1 (2.8)
For other conditions	8.7 (4.1)	8.6 (4.2)
Allopathic treatments, n (%)		
For TMD	1.8 (1.3)	1.8 (1.3)
Overall health, %		
Excellent/very good	17.4	19.1
Good/fair	82.6	80.9

[a] One person who dropped out of treatment agreed to follow-up.
[b] One missing.
CAM = complementary and alternative medicine; SD = standard deviation; TMD = temporomandibular joint disorders.

Qualitative Analysis

Participants' responses to questions 7 to 10 (Table 1) were reviewed by 2 of the authors (JS, MR) trained in qualitative analysis methods. Using an iterative process of coding, discussion, and review,[48-51] participant responses were grouped into 2 main themes of interest: 1) change in TMD symptoms; and 2) reported changes in psychosocial well-being. Applying a matrix coding process[49,52,53] to these 2 main themes yielded 5 categories of participant experience.

Results

Data Completeness

Of the 23 participants who entered treatment, 20 completed the full course of 5 treatment visits. In addition, 1 participant who dropped out of treatment agreed to long-term follow-up and was included in the follow-up analyses. However, 2 participants dropped out after the first telephone

Table 3. Outcomes of shamanic treatment at baseline (n = 23), end of treatment (n = 20), and 9 months after treatment (n = 19)

Outcome[a]	Baseline, mean (SD)	End of Treatment, mean (SD)	End of follow-up, mean (SD)
Usual pain score	4.96 (1.33)	2.70 (2.20)	2.00 (2.00)
Worst pain score	7.48 (1.41)	3.60 (2.52)	3.42 (2.50)
Functional impact of TMD	3.74 (3.15)	1.15 (2.25)	1.11 (1.88)

[a] Measured on the TMD Research Diagnostic Criteria Axis II Pain Related Disability and Psychological Status Scale.[45]
SD = standard deviation; TMDs = temporomandibular joint disorders.

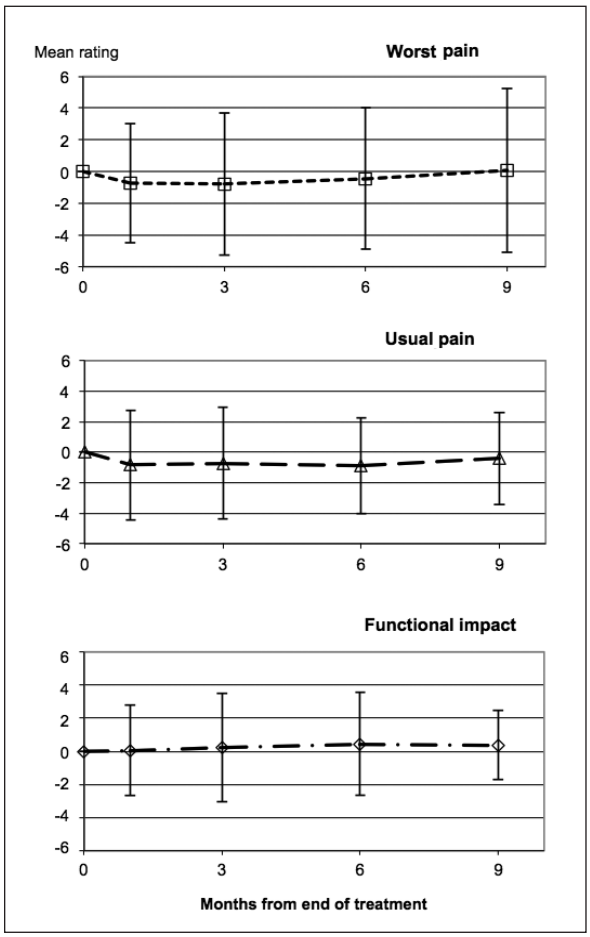

Figure 2. Means of participants' pain ratings from end of treatment through 9-month follow-up (bars, 95% confidence interval).

interview (at 1 month), leaving 19 who participated in the final interview (at 9 months). Table 2 compares characteristics of the participants who entered the trial with characteristics of those who entered follow-up.

Treatment Effects over Time

As reported previously, levels of pain and functional impact of disease decline significantly from baseline to end of treatment.[43] Pain measures continued to show nonsignificant declines from end of treatment to nine months after treatment ended. Table 3 presents mean outcome measures at baseline, at the end of treatment, and at the end of follow-up. The raw means and standard deviations from end of treatment through the four follow-up interviews show no detectable change (Figure 2). Table 4 presents the results of the mixed-model analysis of outcomes for usual pain, worst pain, and functional impact. In every case, the slope over follow-up visits does not differ from zero. This analysis suggests that improvements experienced during treatment persisted for at least nine months following treatment.

Shamanic Practitioner Effect

We found a significant difference between SPs in the mean posttreatment self-ratings of their assigned participants, after adjusting for the corresponding baseline mean ($p < 0.0001$). Our comparisons between SPs revealed that one SP differed significantly from the other 3 in posttreatment mean. However, the overall slopes over time did not differ between SPs. This indicates that the magnitude of the differences between the SPs did not change during the follow-up period. Also, the null effect found for slope over time in the primary model was observed after adjusting for SP differences. We found the same pattern of results for all 3 outcome measures.

Changes Reported in Qualitative Data

At all 4 assessments, 19 of the participants provided responses to additional exploratory questions about their shamanic treatment experience and any changes in TMD status or other areas of well-being (Table 1). Our qualitative data revealed that the majority of participants consistently reported some positive ongoing benefit to their TMD symptoms, psychosocial state, or both that they perceived to be a result of shamanic healing. On the basis of these responses and our qualitative analysis approach described above, 5 categories of participants were defined.

No TMD symptoms and consistent positive changes in psychosocial well-being: Three women reported that their TMD symptoms were "nil" or "not on their mind." They also reported positive changes in their overall well-being, such as feeling "more balanced" and "more calm" and "at peace."

TMD symptoms still perceptible but improved, and con-

Table 4. Estimated rate of change (slope) in primary outcomes, from end of treatment through nine months follow-up

Dependent variable[a]	Slope estimate	Standard error	Degrees of freedom	*t*	Probability
Usual pain	0.046	0.054	18	0.85	0.4071
Worst pain	0.106	0.077	18	1.38	0.1851
Functional impact of TMD	0.038	0.049	18	0.79	0.4381

[a] Measured on the TMD Research Diagnostic Criteria Axis II Pain Related Disability and Psychological Status Scale.[45]
TMD = temporomandibular joint disorder.

sistent, positive changes in psychosocial well-being: Eleven women reported improvement in their TMD symptoms across follow-up interviews. Although they still had some symptoms, many attributed their pain to stressful life events or to dental work. These women reported that their experience of pain had been transformed by shamanic healing because they felt less hopeless about the pain; they perceived that the SP had given them ways to cope with their pain, or both. Women in this category also reported feeling more at ease, balanced, and in control of their lives.

Reduced TMD pain, but inconsistent or missing reports on psychosocial changes: Two women were in this category. One reported improved TMD pain at all four follow-up interviews; however she reported only positive changes, such as feeling "calm and centered," at the first two follow-up assessments. The other woman reported less pain but did not discuss other aspects of her psychosocial well-being.

TMD very painful since ending treatment, but consistent positive changes in psychosocial well-being: The one woman in this category reported considerable life stressors, including moving through various homeless shelters. Nevertheless, she consistently reported positive psychosocial changes in her life and believed that she had benefited a great deal from shamanic healing.

Increasing TMD pain and minimal positive changes in psychosocial well-being: Two women reported minimal or short-term treatment effects during follow-up. One woman reported that shamanic treatment had been valuable but felt that the effects "wore off" shortly after treatment ended. The other participant reported that during treatment she felt it was powerful; however, so much had happened in her life that she had difficulty determining if anything else had changed as a result of treatment.

Additional Shamanic Treatment

All participants were asked if they had initiated shamanic treatment after completion of the five visits and if they had learned to journey. Seven participants sought additional treatment from an SP. Five of these indicated they had learned to journey in those sessions. Another seven participants learned to journey on their own.

The statistical analysis compared the group who had received shamanic treatment (n = 7) to the group who had learned to journey on their own (n = 7), plus those who did nothing (n = 5).There were no statistically significant differences in the means of pain scores between those who received additional healing and those who had learned to journey on their own or did nothing.

Discussion

This research supports other studies suggesting that treatments that attend to the psychosocial needs of individuals with TMDs may have lasting effects.[10,16] For most of the participants in this study, the positive effects of treatment appear to have lasted for at least 9 months after treatment ended. Moreover, the continued participation of those who entered treatment (19/23, or 83%) suggests that shamanic healing is feasible and acceptable to women with TMDs. This study differs from previous studies involving psychological or spiritual healing in that participants did not receive adjuvant physical treatment. The mechanism by which healing occurs without physical intervention has yet to be examined. It may involve reframing the patient's perception of the symptoms as a dysfunction so that they are viewed as a cue to physical and mental states that are within the individual's control.[23] This seems to be supported by comments in the interview data by participants who had a better quality of life despite some continued symptoms.

The mechanism by which healing occurs without physical intervention … may involve reframing the patient's perception of the symptoms as a dysfunction so that they are viewed as a cue to physical and mental states that are within the individual's control.

The results of this study should be considered in light of some limitations. First, we had no control group. Rather, since shamanic healing had never been evaluated in a clinical trial, we conducted a feasibility trial and integrated qualitative interviews into the study design to determine how participants define and assess healing. Reports and systematic reviews in the literature provide comparative information on outcomes of usual care, behavioral and CAM treatments, although these studies vary in terms of measures and protocols used.[54,55] Findings from the randomized control trial that provided the basis for this research offer a clearer look at outcomes of a usual-care care control group, though assessments ended at three months after treatment. Subjects in that study reported decreases in usual pain, worst pain, and functional impact, but these improvements did not approach the level of those obtained from shamanic treatment.[56]

Reviews of other mind-body interventions, such as CAM treatments, mindfulness meditation, and yoga, provide some suggestion of how shamanic healing would compare to these treatments. Outcomes of Traditional Chinese Medicine and Naturopathic Medicine reported by Ritenbaugh et al indicate that these therapies may also be efficacious in treating TMD, as do systematic reviews of CAM treatments.[54,55,56] Individual studies of mindfulness meditation[57] characterize it as a promising intervention for chronic pain, although a recent systematic review found insufficient evidence to determine the magnitude of effects or to distinguish between specific and nonspecific effects.[58]

A second limitation of our study is the small sample size, which permitted only limited examination of provider effects and precluded multivariate analyses. Third, all of our participants were women and Caucasian. However, these characteristics are consistent with TMD prevalence data,[5,6] and thus we do not believe this limits the applicability of these results to the affected population.

Conclusion

This study of shamanic healing for women with TMDs is, to our knowledge, the first clinical trial of shamanic healing for TMDs. Despite the discussed limitations, the sustainability of substantial improvements, from end of treatment through nine months of follow-up, suggests that further research into this form of healing as treatment for TMD is warranted. ❖

Disclosure Statement

Funding for this study was provided by the National Center for Complementary and Alternative Medicine, grant R21 AT000951. The author(s) have no conflicts of interest to disclose.

Acknowledgments

The authors express their appreciation to the shamanic practitioners who consulted with us and provided care in this study. We could not have completed this study without their dedication and willingness to engage in clinical research. We also acknowledge Victoria Gojio and Kelley Reis for their valuable assistance and Jeanne Reinhardt for administrative support. We are also grateful to our participants for their time and commitment.

Leslie E Parker, ELS, provided editorial assistance.

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The Path

The only question is: Does this path have a heart?
If it does, then it is a good path. If it doesn't, then it is of no use.

— Carlos Castañeda, 1925-1998, American anthropologist and author

CME credits available for this article — see page 80.

SPECIAL REPORT

The Kaiser Permanente Implant Registries: Effect on Patient Safety, Quality Improvement, Cost Effectiveness, and Research Opportunities

Elizabeth W Paxton, MA; Maria CS Inacio, MS; Mary-Lou Kiley, MBA

Perm J 2012 Spring;16(2):36-44

Abstract

Introduction: Considering the high cost, volume, and patient safety issues associated with medical devices, monitoring of medical device performance is critical to ensure patient safety and quality of care. The purpose of this article is to describe the Kaiser Permanente (KP) implant registries and to highlight the benefits of these implant registries on patient safety, quality, cost effectiveness, and research.

Methods: Eight KP implant registries leverage the integrated health care system's administrative databases and electronic health records system. Registry data collected undergo quality control and validation as well as statistical analysis.

Results: Patient safety has been enhanced through identification of affected patients during major recalls, identification of risk factors associated with outcomes of interest, development of risk calculators, and surveillance programs for infections and adverse events. Effective quality improvement activities included medical center- and surgeon-specific profiles for use in benchmarking reports, and changes in practice related to registry information output. Among the cost-effectiveness strategies employed were collaborations with sourcing and contracting groups, and assistance in adherence to formulary device guidelines. Research studies using registry data included postoperative complications, resource utilization, infection risk factors, thromboembolic prophylaxis, effects of surgical delay on concurrent injuries, and sports injury patterns.

Conclusions: The unique KP implant registries provide important information and affect several areas of our organization, including patient safety, quality improvement, cost-effectiveness, and research.

Introduction

Each year approximately 773,000 total joint replacements, 358,000 operations to implant pacemakers and pacemaker leads, and more than 310,000 intervertebral disk excision or destruction procedures are performed in the US.[1] The use of these devices and procedures has increased greatly. For example, in the last 2 decades use of cervical spine fusion increased by 90% in the non-Medicare population and by 206% in the Medicare population.[2,3] Similarly, pacemaker implantation has increased by 19% between 1997 and 2004, and implantable cardioverter-defibrillator (ICD) use has increased by 60% during the same period.[4] Projections indicate additional increases in total joint replacement procedures, with a 174% increase in total hip replacements and 673% increase in knee replacements expected between 2005 and 2030.[5]

These high-volume procedures involve ever more technologically advanced, innovative, and costly devices. In 2009, the US Food and Drug Administration Center for Devices and Radiologic Health approved 740 new devices, a 52% increase from 2001.[6] The cost of some of the latest introduced devices can include, according to conservative estimates, an increase of $1000 in knee replacements, $800 in hip replacements,[7] or more dramatically $15,000 in spine surgery.[8] Often, these new and more costly devices are introduced into the market with little to no evidence of enhanced clinical effectiveness.

In addition, new technology sometimes fails, requiring recalls of medical devices. In 2011 a total of 41 Class 1 recalls happened in the US.[9] Recalls of medical devices can put patients at major risk of complications and mortality. Although some recalls require only patient consultations, others can require close monitoring of patients, and in some more serious cases a high-risk reoperation. Early identification of device failures is therefore necessary to prevent implantation of defective devices and harm to patients.

Considering the high cost, volume, and patient safety issues associated with medical devices, monitoring of medical device performance is critical to ensure patient safety and quality of care. One method for tracking these devices is the use of patient registries. A patient registry is defined as "an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes."[10] Patient registries provide a unique opportunity to enhance patient safety, quality of care, cost effectiveness, and research. As such, Kaiser Permanente (KP) developed and implemented several orthopedic (total knee and hip replacement, hip fracture, shoulder arthroplasty) and cardiac registries (ICD, pacemaker, heart valve) to monitor these high-risk implantable devices within our health care system. The registries were specifically developed for the following reasons: 1) to identify

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procedure incidence and implantable device utilization; 2) to evaluate patient and device outcomes; 3) to identify patients at risk of poor clinical outcomes; 4) to identify and monitor devices in a recall/advisory situation; 5) to evaluate comparative effectiveness of devices; and 6) to serve as a foundation for quality improvement and research studies.

The purpose of this article is to describe the KP implant registries and to highlight the benefits of these implant registries on patient safety, quality, cost effectiveness, and research.

Methods

The KP device registries leverage our integrated health care system's administrative databases and electronic health records (EHR) system. Some of the registries include data collection at the point of care (eg, Total Joint Replacement Registry), and others are virtual registries with data collected completely behind the scenes (eg, Hip Fracture Registry and Spine Registry).

Data Collection

The registries were initially designed to capture data at the point of care through standardized paper-based forms at preoperative, intraoperative, and postoperative encounters. These forms not

Table 1. Registry volumes, time periods, 2010 voluntary participation rate, contributing surgeons, KP Regions, and targeted population of each registry (as of December 31, 2010)

Registry name	Start of data collection	Volume	Participation rate (%)	Surgeons	KP Regions	Targeted population	Outcomes[a]
Orthopedic registries							
Total Joint Replacement							
Knee	2001	76,853	95	>400	7	Total, unicompartmental, and bicompartmental knee replacement	Standard only
Hip	2001	43,031	90	>400	7	Total hip replacement, hip resurfacing	Standard only
Total Shoulder Arthroplasty	2006	6000/ 290[b]	100/53[b]	54	2	Total shoulder replacement, hemi replacement, humeral head resurfacing, reverse total shoulder replacement	Standard only
ACL Reconstruction	2005	13,008	93	218	5	Graft type, fixation technique, concurrent procedures	Reoperation
Hip Fracture	2009	11,242	100[c]	648	6	Fracture category by orthopedic trauma proximal femur classification	Reoperation, dislocation, myocardial infarction, pneumonia
Spine	2009	9247	100[c]	>100	4	Pedicle screws, total disc replacement, anterior cervical plates, bone morphogenic protein	Reoperation
Cardiac registries							
Cardiac device							
ICD	2000	7702[d]	100[c]	>200	7	Single, dual, and biventricular pulse generators Explants: revision, replacement, upgrade	Mechanical failure, hematoma, pneumothorax tamponade, battery longevity
Pacemakers	2000	12,002[d]	100[c]	>200	7		
Leads	2000	85,579	100[c]	>200	7	Implanted with device or lead only procedure	Dislodgement, perforation, insulation failure, conductor fracture
Heart valve	1999	58,765[e]	100[c]	N/A	4	Mitral, aortic, pulmonic, tricuspid	Tissue vs mechanical mitral valve survival
Endovascular stent graft	2008	1733	100[c]	132	5	AAA	Graft tear/fracture, limb occlusion/kinking, AAA rupture, endoleak, stenosis, myocardial infarction, hematoma

[a] In addition to the outcomes collected by all registries: revisions, death, surgical site infection, and thromboembolic events.
[b] 6000/100% is the number of cases captured electronically and retrospectively (from 2006 onwards). 290/53% is the number of cases with both paper and electronic information available (from 04/2010 onwards).
[c] All cases are captured electronically.
[d] Other data sources include device manufacturers, the National Cardiovascular Data Registry and other proprietary data repositories.
[e] Data extraction from comprehensive and mandatory Society for Thoracic Surgeons database.
AAA = abdominal aortic aneurysm; ACL = Anterior Cruciate Ligament; ICD = implantable cardioverter defibrillators; KP = Kaiser Permanente.

only standardized chart documentation but also allowed registry data collection of patient characteristics, device information, surgical procedures, and outcomes. In addition to the standardized registry forms, administrative and claims databases were used to supplement the registry database. These standardized forms are now electronically captured in our EHR system. With the full implementation of our EHR system in 2009, it provided an opportunity to capture data completely from our EHR for several registries. Integration of EHRs and database development has been described elsewhere.[11] A brief summary follows. Data from all data sources are extracted and sent to the registries' centralized office, where they are assembled and managed, and quality control routines are applied to them. Outcomes are identified using electronic screening algorithms and then adjudicated by clinical content experts.[11,12]

… multivariable analytical approaches, such as regression and survival analyses, are performed to identify and to assess risk factors, to determine populations at risk, and to assess device performance.

All KP Regions are eligible to participate in the registries. Most Regions participate in the registries, and the ultimate goal of each registry is to include cases from all Regions. Because of the implementation schedule of features of our EHR, some Regions may not have the electronic forms available at this time, but the development is under way in all participating Regions.

Quality Control and Validation

For all registries, there are rigorous quality control and data validation processes. Continuous quality control is carried out by automated computer algorithms that flag data anomalies, which are then reviewed by data quality personnel. These routines are supplemented by quarterly logical and cross-validation checks. The denominators of the registries are based on an International Classification of Diseases, Ninth Revision, Clinical Modification procedure code algorithm to identify cases (see Registry denominator identification algorithms online at: www.thepermanentejournal.org/issues/2012/spring/4554-implant-registries.html#add). Validation of case capture centers on the forms received and manual chart review. For postoperative complications, electronic algorithms have been developed internally (ie, infection,[12] reoperation, and revision) or with support of external algorithms, such as the Agency for Healthcare Research and Quality's inpatient quality indicator algorithm for pulmonary embolism and deep venous thrombosis.[13] After possible cases are flagged using the electronic algorithms, patient charts are manually reviewed and confirmed by specially trained content experts.

Analyses

Several analytical strategies are used to analyze the registries' data. Each registry produces an annual report with frequencies and proportions of the cases registered, basic demographics, surgical techniques, and implant utilization. In this same report, multivariable analytical approaches, such as regression and survival analyses, are performed to identify and to assess risk factors, to determine populations at risk, and to assess device performance. Complex analytical projects have required data imputation, propensity scores analysis, and sensitivity analysis, among other sophisticated techniques employed by the analytical staff.

Results

Registry Overview

KP currently has eight implant registries. The first of the KP implant registries developed, the Total Joint Replacement Registry, is now the largest total joint replacement registry in the US. Established in 2001, it was designed as a postmarket surveillance system for elective total hip and knee replacement. This model was replicated to create other registries for orthopedic implants, including the Anterior Cruciate Ligament (ACL) Reconstruction Registry, Spine Registry, Hip Fracture Registry, and Shoulder Arthroplasty Registry. We expanded our scope into cardiac and vascular surgery to create ICD and pacemaker, heart valve replacement, and endovascular stent graft registries.

Table 1 describes how long each registry has been implemented, its current volume, participation rate, targeted population, and outcomes of interest. Common data elements included in all registries are patient demographics (age, sex, body mass index, race), diagnosis, devices used, and membership enrollment history. Surgical outcomes tracked for all registries include revision procedures, surgical site infection (deep or superficial), thromboembolic events (deep venous thrombosis and pulmonary embolism), and death. All suspected surgical complications are validated through KP's EHR by clinical content experts to determine if they meet preestablished criteria.

The KP implant registries have been instrumental in enhancing patient safety, quality, cost-effectiveness, and research. The contribution of the registries in each of these areas is highlighted below.

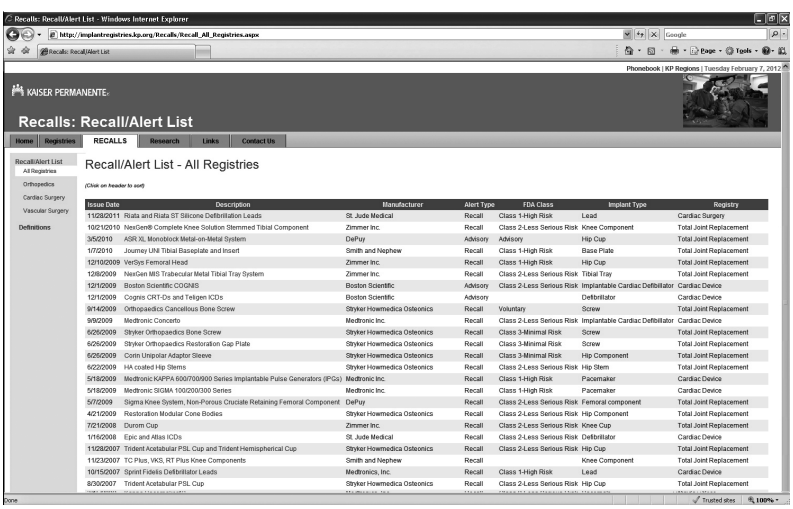

Figure 1. Recall/alert list from implant registries Web site.

Table 2. Crude incidence of revision and complication of primary orthopedic surgeries for all KP Regions (percentage)

Complication	Total knee replacement (04/2001-12/2009)	Total hip replacement (04/2001-12/2009)	ACL reconstruction (02/2005-06/2010)	Total shoulder replacement (01/2005-12/2009)
Revision surgery	2.0	2.0	1.6	2.9
Deep surgical site infection	0.7	0.5	0.2	0.4
Superficial surgical site infection	0.3	0.3	0.3	0.1
Deep vein thrombosis	0.4	0.7	0.1	0.4
Pulmonary embolism	0.5	0.5	<0.1	0.4

ACL = anterior cruciate ligament reconstruction; KP = Kaiser Permanente.

Enhancing Patient Safety

Recalls and Advisories: The registries are uniquely designed to efficiently identify cases. Therefore, when recalls and advisories occur, quick identification of patients with the device or biologic is possible, along with any patient-specific adverse events and the status (whether the implant was revised or not). In addition, a recent enhancement to monitoring implant performance is the development of real-time, proactive tracking of adverse trends. As a result of this surveillance, the Cardiac Device Registry detected an adverse trend in the performance of a particular defibrillator lead and alerted our physicians in advance of a recall of that lead by the US Food and Drug Administration. Although the registries do not handle the recall management, they work in sync with the KP National Product Recall Department to identify patients, identify their postoperative outcomes, and develop case management tools for patient surveillance if necessary. Information on all the recalls assisted by the registries can be found at an internal KP Web site.[14]

Since the first components started to be tracked, at least 40 recalls occurred, and since 2008 (when most registries were ongoing), the registries assisted in 19 recalls and advisories (Figure 1). These recalls included 2 advisories (Warsaw, Indiana–based DePuy Orthopaedics' ASR XL Monoblock Metal-on-Metal System for hip replacement and Natick, Massachusetts–headquartered Boston Scientific's Cognis CRT-Ds [Cardiac Resynchronization Therapy Defibrillators] and Teligen ICDs for cardiac procedures). Among the recalls were 4 Class 1 recalls, the most serious type of recall, for which a serious possibility exists of the device or biologic causing adverse health consequences to the patient.[15] These Class 1 recalls included London, UK–headquartered Smith & Nephew's Journey Unicompartmental Baseplate and Insert and Warsaw, Indiana–based Zimmer's Versys Femoral Head in the Total Joint Replacement Registry, and Medtronic's (Minneapolis, Minnesota) Kappa 600/700/900 Series and Sigma 100/200/300 Series Implantable Pulse Generators in the Cardiac Device Registry.

Risk Factors: Identification of variables that are associated with increased or decreased risk of failures, adverse events, and other outcomes are of special interest to the registries, and extensive work has been done on this topic. Annual reports of the registries and specific projects have investigated risk factors.[16-19] For example, in the 2010 Total Joint Replacement Registry annual report, risk factors identified for aseptic total knee replacement revision included younger age, diabetic status, black race, unresurfaced patella, and certain types of mobile bearing implants. Bilateral procedures were found to be at a lower risk of revision. Similar multivariable analysis was conducted for the identification of risk factors associated with revision procedures in ACL reconstructions, and age, race, and graft type were found to be associated with risk of revision. Analyses are under way in the registries to identify risk factors for all-cause revisions and specific types of revisions, as well as for infection and thromboembolic events.

Risk Calculators: Using the detailed multivariable analyses that are carried out for the identification of individual risk factors for adverse events, the registries have developed prognostic tools that can be used by surgeons and patients for decision making at the point of care. These

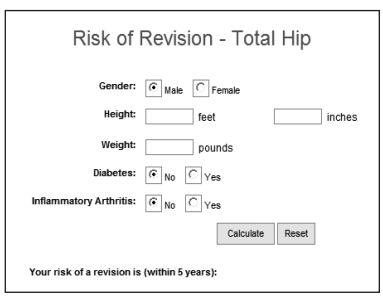

Figure 2. Risk calculator for risk of revision after total hip replacement.

Table 3. Crude incidence of complications for cardiac devices for all KP Regions, 2007-2010 (percentage)

	Implantable cardiac defibrillators	Pacemakers
Deep surgical site infection	0.7	0.6
Superficial surgical site infection	<0.1	<0.1
Tamponade	0.3	0.2
Hematoma	0.3	0.2
Pneumothorax	0.2	0.5
Mechanical failures	1.2	0.3
Lead failures	2.6	1.8

KP = Kaiser Permanente.

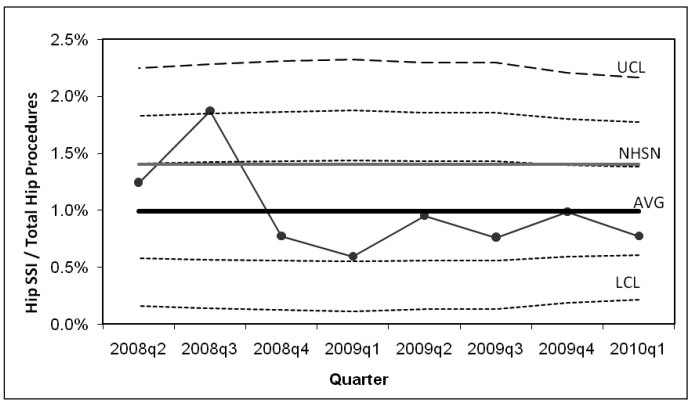

Figure 3. Southern California regionwide total hip replacement surgical site infection rates (2008 quarter 2 to 2010 quarter 1).

AVG = average; LCL = lower confidence limit; NHSN = National Healthcare Safety Network; q = quarter; SSI = surgical site infection; UCL = upper confidence limit.

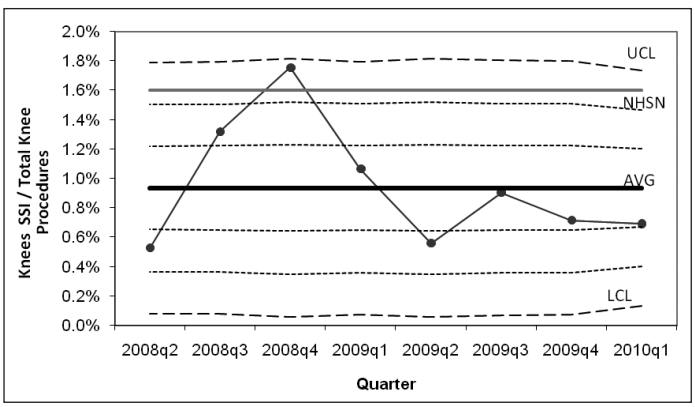

Figure 4. Southern California Regionwide total knee replacement surgical site infection rates (2008 quarter 2 to 2010 quarter 1).

AVG = average; LCL = lower confidence limit; NHSN = National Healthcare Safety Network; q = quarter; SSI = surgical site infection; UCL = upper confidence limit.

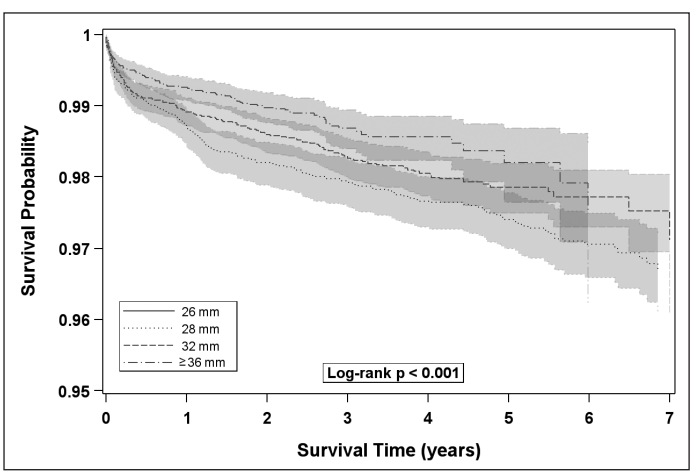

Figure 5. Kaplan-Meier Survival curves with 95% confidence intervals for patients undergoing primary total hip replacement, by femoral head size (April 2001 to March 2009).

prognostic tools work much like the more commonly known cardiovascular event risk calculators developed by the Framingham Heart Study.[20] Surgeons have access to these tools via the internal KP Web site. During any consultation, physicians can give patients the probability of an event given certain patient characteristics that have been found to be associated with the risk of that event happening. Currently a risk calculator for joint replacement revision (Figure 2) is deployed, and a risk calculator for deep surgical site infection is being implemented.

Infection and Adverse Event Surveillance: The registries contribute to patient safety through ongoing surveillance, validation, and reporting of complications, revisions, and reoperations. These outcomes are monitored and reported to the locations on a quarterly basis. Tables 2 and 3 describe the main outcomes reported by the registries. Infection surveillance reports are now provided with detailed case level information to the participating centers as well as through tools such as statistical process control charts (Figures 3 and 4). These charts can be used to monitor the variation in events over time, allow for the detection of variation that should be addressed, and assist with the elimination of unwanted variation.

Quality Improvement

Communications and Report: Registry findings about clinical best practices or quality improvement opportunities are communicated to widespread audiences of surgeons, administrators, and clinical staff through chiefs of service and administrator meetings, the internal Web site, individualized physician practice profiles, site visits, newsletters, e-mails, and presentations at regional or national conferences. This dynamic feedback within KP's collaborative culture is an integral part of surgical quality improvement initiatives and yields measurable objective improvements in care.

Medical Center-Specific Results and Surgeon Profiles: One of the main tools used to communicate with specific stakeholders is the medical center- and surgeon-specific reports that the registries provide. The medical center-specific reports from the Total Joint Replacement and ACL Reconstruction registries are

available via an internal KP Web site. All other registries can provide this information via e-mail on request and are expected to be available in the internal Web site shortly. Surgeon-specific reports can be obtained as well by secure communication if requested by the surgeons themselves. These targeted reports can be used to compare information among locations, Regions, and even nationally, creating an opportunity for benchmarking and learning.

Changes in Practice: We present four examples of changes in KP practice associated with registry findings and other published studies. First, the number of uncemented total knee replacement and unicompartmental knee replacement surgeries was reduced because of higher failure rates. Second, the use of small femoral head sizes for total hip replacement decreased after superior performance was demonstrated with larger head sizes (Figures 5 and 6). Third, KP had decreased use of DePuy LCS mobile bearing knee replacements after lower survival of this prosthesis type was observed (Figures 7 and 8). Fourth, use of the conventional polyethylene hip insert was essentially terminated after its performance was shown to be inferior to that of other hip insert materials (Figures 9 and 10).

A more large-scale observation has been the overall decrease in the burden of total hip replacement revision since the implementation of the KP Total Joint Replacement Registry in 2001 (Figure 11).

We expect to see changes in practice and similar contributions following the dissemination of findings from the other registries as they mature. The registries also verify adherence to national practice guidelines, such as indications for ICD implantation as established by the American Academy of Cardiology.

Cost-Effectiveness

In addition to the registries' contributions to improvements in quality and patient safety, there is demonstrated cost effectiveness. The registries provide device performance evaluations comparing similar implants and patient and surgical characteristics. These analyses are critical in new technology adoption or for cost-benefit analysis of similar implants, or both.

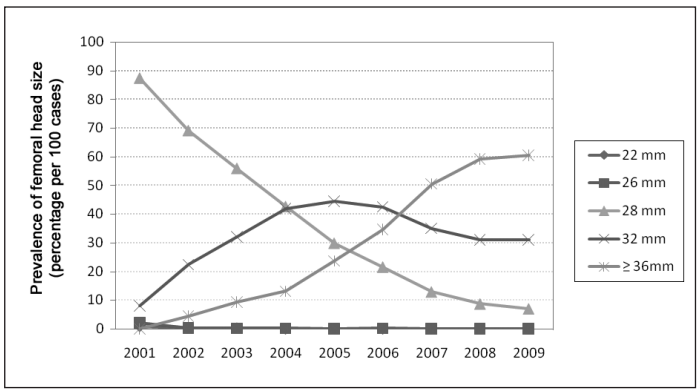

Figure 6. Prevalence of primary total hip replacement femoral head size use (per 100 cases, April 2001 to April 2009).

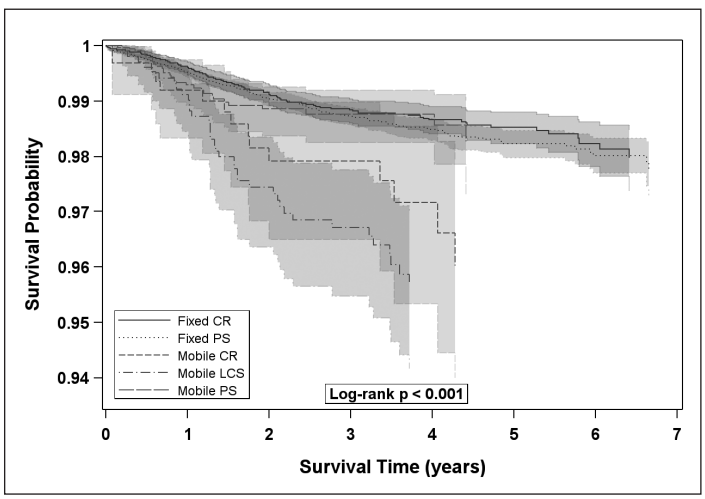

Figure 7. Kaplan-Meier Survival curves with 95% confidence intervals for patients undergoing primary total knee replacement, by implant mobility and stability characteristics (April 2001 to March 2009).

CR = cruciate retaining; LCS = low contact stress; PS = posterior stabilized.
All cases of revision due to infection were excluded from analysis.

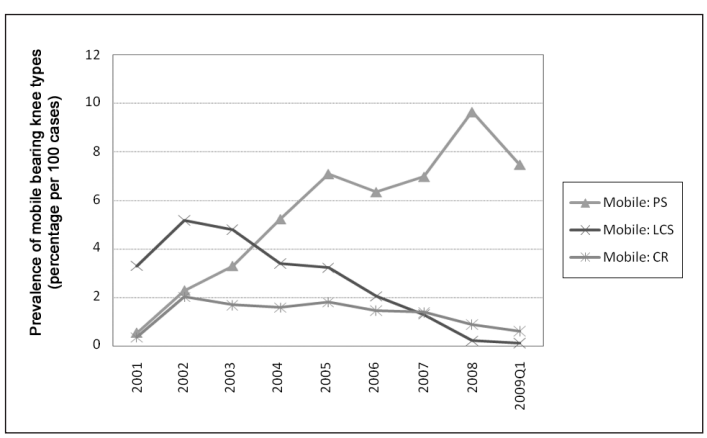

Figure 8. Prevalence of mobile bearing use for primary total knee replacement (per 100 cases, April 2001 to December 2009).

CR = cruciate retaining; LCS = low contact stress; PS = posterior stabilized; Q = quarter.

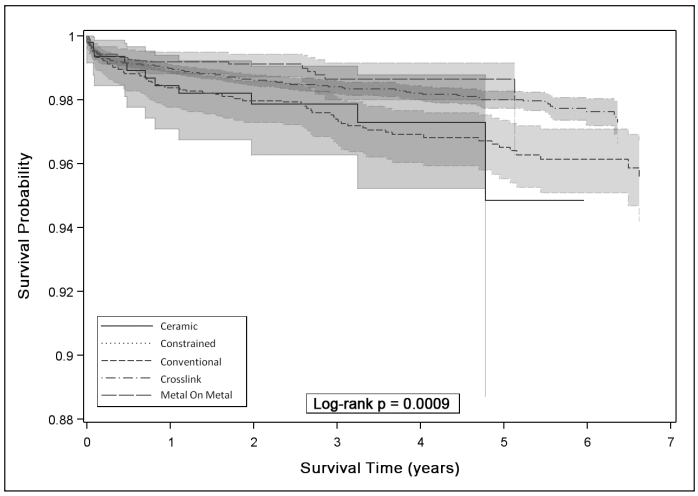

Figure 9. Kaplan-Meier Survival curves with 95% confidence intervals for patients undergoing primary total hip replacement, by insert material (April 2001 to March 2009).[a]

[a] Cases with infection were excluded from analysis.

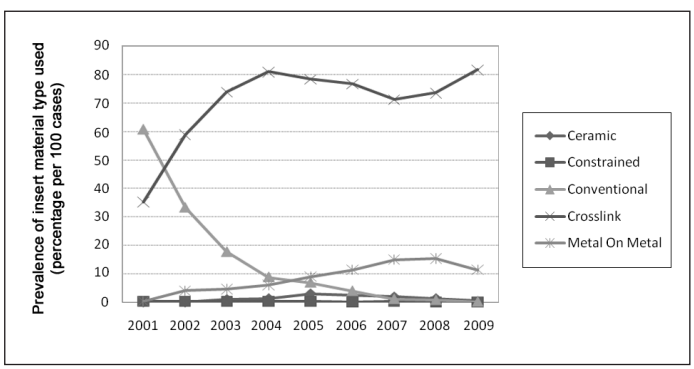

Figure 10. Prevalence of insert material type used for primary total hip replacement (per 100 cases, April 2001 to December 2009).

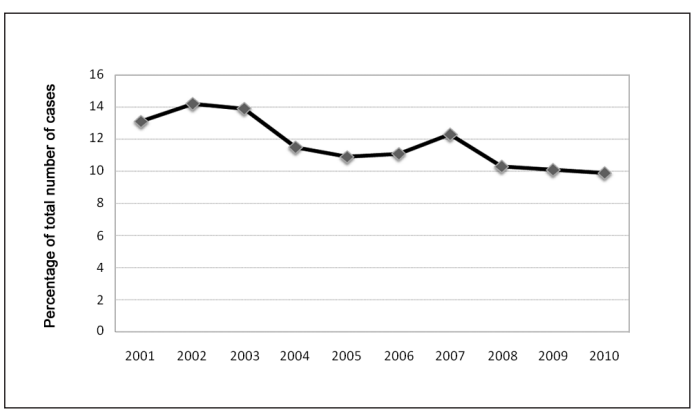

Figure 11. Total hip replacement revision burden (April 2001 to December 2010).[a]

[a] Cases with infection were excluded from analysis.

Each registry monitors trends in implant performance. These comparative evaluations directly influence contract and purchasing decisions. Registry representatives are integral partners with the content experts and procurement staff of the national Sourcing and Standards Teams. In turn, these national teams provide consultation to the KP National Product Council for the development of national purchasing contracts. The ability of KP to negotiate favorable device contracts with suppliers benefits from its economies of scale and evidenced-based implant performance and longevity studies.

Another cost-effectiveness strategy directly resulting from registry data use was the development of formularies for total joint replacement and cardiac devices. Physician leaders within orthopedics and cardiology created formularies on the basis of best practices. The purpose of the formularies is to maximize treatment benefits and value of devices by educating physicians, standardizing device selection and ensuring contract compliance. In collaboration with KP's Procurement and Supply Team, the registries produce timely device utilization reports that verify adherence to formulary guidelines and purchasing agreements and support monitoring of any unique contract features such as warranties, rebates, or volume discounts.

Research

Registry data provide the basis for myriad research studies, including comparative effectiveness studies, something the registries are naturally set up to perform. These external contributions are driven by our commitment to the dissemination of quality research and information, and to the promotion and enhancement of national evidence-based practice guidelines.

Most of the registries have contributed to different studies in some capacity. All the studies have shown how these community-based samples are of much interest to the external community and can help address important questions. The Total Joint Replacement Registry has made contributions in the areas

of short-term complications[16,18,19] and resource utilization,[21] risk factors associated with infections,[17] thromboembolic prophylaxis,[22,23] and registry structure and methods.[11,12,24] Staff with the Total Joint Replacement Registry are working on publications regarding the topics of mobile knee bearings, hip bearings, risk factors for deep surgical site infection after hip and knee arthroplasty, and risk factors for unicompartmental knee revision surgery. The ACL Reconstruction Registry has helped study the epidemiology of ACL reconstruction in the organization,[25] as well as looked into the effect of surgical delay on concurrent injuries,[26] variables that are associated with graph selection.[27] The ACL Reconstruction Registry staff are working on publications about the risk factors associated with aseptic revision, comparing the current population with the Norwegian Ligament Registry population,[28] and sports-specific injury patterns. The other registries, despite being younger, are also starting to contribute to research and have provided data presented at major national meetings and congresses.

Discussion

KP's integrated health care system, administrative databases, and comprehensive EHR provide a unique opportunity for implant registries to enhance patient safety, quality, cost-effectiveness, and research. The implant registries have been critical for early identification of device failures. Similarly, the registries provide an important function during implant recalls and advisories allowing us to immediately identify and notify patients with specific implants and monitor patient follow-up to ensure that our patients receive the best possible care. Patient safety is also enhanced through the use of risk calculators that allow patients and surgeons to make clinical decisions at the point of care. The registries also are important for quality improvement, providing tools for practicing evidenced-based medicine through identification and dissemination of clinical best practices to our physicians. Quarterly quality reports provide yet another method for monitoring infection and other complications at the medical center level. In addition to enhancing patient quality and safety, the implant registries have provided clinical outcomes to our contracting teams to allow for identification of the best implants for our patients. Finally, registries provide an opportunity for conducting research that has been translated into clinical practice in implant selection and techniques.

Registries have limitations that should be recognized. Data from registries are observational in nature, and analyses deriving from such data cannot control for all confounding factors. Multivariate analyses can attempt to control for known confounding factors; however, other factors may exist. In addition, registry data are not experimental and therefore cannot be used to establish causal relationships. Despite this limitation, registries are important in investigating associations of exposures and outcome in real-world settings and provide important feedback regarding implant performance. Registries are also limited to the number of variables and detail of procedures that can be captured. The number of data points captured by registries is limited to the most important factors associated with procedures, which can restrict potential analyses. This minimal dataset is advisable in order to minimize the burden of data collection, management, and validation and to guarantee maximum participation and data quality.

Finally, registries can be limited because of attrition of their covered population, which, if not properly accounted for, can bias results and information from the registry. Bias introduced with the loss to follow-up is accounted for in our system through active surveillance of our covered cohorts and by conducting sensitivity analysis with best- and worst-case scenarios.

The implant registries provide an important function in monitoring and tracking the large number of devices implanted in our population of more than nine million members. To continue to provide high-quality information and maintain the success described in this article, KP is exploring new ways to achieve the overall goals of the registries. These include creating interactive registry components, where patients and surgeons can communicate and use information from the registry on a real-time basis. We also hope to expand patient-reported outcomes. Participation of patients in the care and assessment of their procedures is deemed very important in our organization, and the registries are implementing this self-reported type of assessment to the measurements of success of our procedures. Another area we are aggressively pursuing is the development of automated postmarket surveillance. Two methods of ascertaining device failure or early warning signs are being explored using registry data, and we hope they will be implemented internally by the end of 2012. Finally, with the success of the revision risk calculator for joint replacement surgery and the large body of research we have on other outcomes tracked by the registries, we are now investing in developing other prognostic calculators for our surgeons and patients. ❖

Acknowledgments

The authors would like to thank all Kaiser Permanente orthopedic and cardiac device surgeons and the staff of the Department of Surgical Outcomes and Analysis who have contributed to the success of the national implant registries. We also wish to thank Alan L Schepps, MS, for his assistance creating the figures used in this manuscript and Faith Anthony, MA; Kim Phan; Jessica Harris, MS, RD; and Mary F Burke, MPH, for assistance with assembling the tables and content for the manuscript.

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

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Pieces of the Puzzle

The operation of a health service depends upon a complex interaction between the patient, the environment in which care is provided and the people, equipment and facilities that deliver the care.

— *Medical Mishaps: Pieces of the Puzzle,* Sir Liam Donaldson, b 1949, Chief Medical Officer of England

CME credits available for this article — see page 80.

REVIEW ARTICLE

Transanal Endoscopic Microsurgery for Rectal Tumors: A Review

Hiroko Kunitake, MD; Maher A Abbas, MD, FACS, FASCRS

Perm J 2012 Spring;16(2):45-50

Abstract

Since its introduction in 1983, transanal endoscopic microsurgery (TEM) has emerged as a safe and effective method to treat rectal lesions including benign tumors, early rectal cancer, and rectal fistulas and strictures. This minimally invasive technique offers the advantages of superior visualization of the lesion and greater access to proximal lesions with lower margin positivity and specimen fragmentation and lower long-term recurrence rates over traditional transanal excision. In addition, over two decades of scientific data support the use of TEM as a viable alternative to radical excision of the rectum with less morbidity, faster recovery, and greater potential cost savings when performed at specialized centers.

Introduction

Cancer of the rectum is the fifth most common form of cancer in adults worldwide. In 2012, an estimated 40,300 new rectal cancers will be diagnosed in the US with a median age 69 years.[1] Five-year survival rates for rectal cancer are high for early stage disease (90% for Stage I disease)[2] but drop significantly with worsening stage (7% for metastatic Stage IV disease). Recently, advances in neoadjuvant and adjuvant therapy have decreased the rate of local recurrence and improved long-term survival for some patients. Although the treatment for rectal cancer has become increasingly multimodal, surgical excision of the primary tumor remains essential for eradication of disease.[3]

For a long time there has been a debate about the best surgical approach to early stage rectal cancer, whether treatment should involve radical excision (excision of the rectum) or local excision (tumor alone). Proponents of radical surgery argue that excision of the rectum with its surrounding lymphatic drainage offers the best chance for cure. On the other hand, advocates of local excision feel that a less-aggressive approach can avoid the potential ramifications of major pelvic surgery such as sepsis, poor anorectal function, sexual dysfunction, and difficulty with urination and can eliminate the potential need for a permanent stoma. Although the debate has gone back and forth on the adequacy of local excision, there is a growing body of scientific data that suggests that local excision can be sufficient in patients with early rectal cancer of the mid and distal rectum with good histologic features and preoperative imaging (computed tomography, magnetic resonance imaging, and endorectal ultrasound) that shows no evidence of lymph node involvement. Traditionally, transanal excision has been performed with the conventional technique using traditional equipment. Although this conventional technique can give surgeons operative access to most distal rectal lesions, it can be difficult to conduct on mid-rectal tumors or in large patients with a deep buttock cleft. The technical difficulties experienced under such circumstances can lead to poor visualization, inadequate margins, or specimen fragmentation.

In response to the technical limitations of conventional transanal excision, in the 1980s Professor Gehard Buess from Tubingen, Germany, began to develop the technique of transanal endoscopic microsurgery (TEM). In collaboration with the Richard Wolf Company in Germany, Dr Buess developed the specialized instruments necessary to perform endoscopic surgery transanally.[4,5] TEM was introduced into

Figure 1. Transanal endoscopic microsurgery equipment: operating instruments and endosurgical unit.

(With permission from Richard Wolf Medical Instruments Corporation, Illinois, USA)

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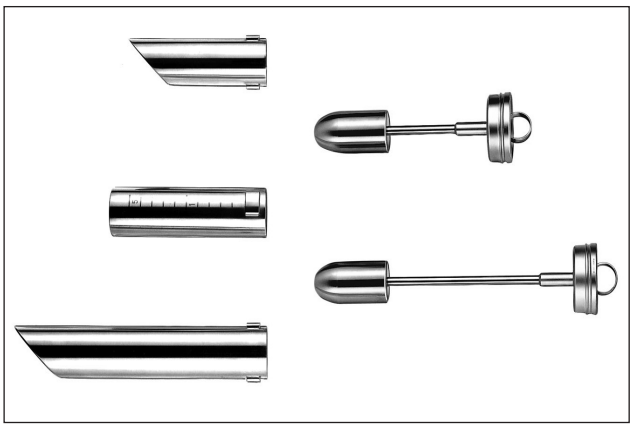

Figure 2. Operating rectoscope.

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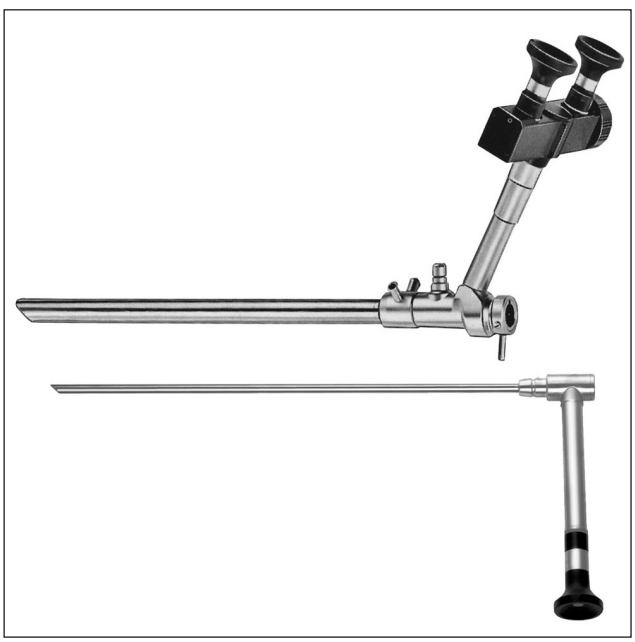

Figure 3. Optical stereoscope.

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clinical practice in 1983, and was gradually implemented in several European countries and eventually introduced in North America and Asia. The last decade has witnessed international growth in the application of TEM yielding a significant amount of scientific data to support its clinical merits and advantages and also shedding some light on its limitations.

Indications for TEM

TEM was initially used exclusively for benign lesions and for invasive lesions in patients who were considered to be too high risk for radical surgery. However, as experience with TEM has grown, TEM has become recognized as an effective and safe option for rectal tumors such as adenomas, carcinoid, and gastrointestinal stromal tumors (GIST).[6] TEM has been selectively used in the treatment of fistulous disease such as high anorectal fistulas (suprasphincteric or extrasphincteric), rectourethral, and rectovaginal fistulas.[7] Limited application of TEM has also been reported in the treatment of anastomotic strictures (stricturoplasty) or the correction of rectal prolapse (fixation of the posterior wall of the rectum to the presacral tissue).[8,9]

Current indications for TEM have expanded to include the treatment of early stage rectal cancer in addition to palliation in cases of advanced rectal cancer in patients who refuse radical excision or in those who are poor surgical candidates.[10,11] Patients with incidental carcinoma following polypectomy are suitable candidates for TEM especially in the setting of a sessile polyp or when there is concern about margin positivity. For potentially curative resection of malignant lesions, preoperative staging is of the utmost importance so that only those lesions with the lowest likelihood of nodal metastases are selected for TEM. Both endorectal ultrasound or MRI can be used to determine the lesion depth of penetration and to evaluate the mesorectum for metastatic disease.[12,13]

TEM Equipment

TEM equipment can be divided into 2 major components: 1) operating instruments and 2) the endosurgical unit (Figure 1). The operating instruments, which are handled by the surgeon during the procedure, include: the operating rectoscope (Figure 2), the stereoscope (Figure 3), and the long-handled instruments for dissection, excision, and suturing (Figure 4). The endosurgical unit provides carbon dioxide (CO_2) insufflation, suction, irrigation, and continuous monitoring of intrarectal pressure. The operating rectoscope is approximately 4 cm in diameter and either 12 cm or 20 cm in length with a beveled or straight-faced end. The surgeon's end has an airtight faceplate with 4 ports sealed by capped rubber sleeves through which the optical stereoscope, suction, and 2 long-shafted operating instruments are inserted (Figure 5). The surgeon visualizes the field through the binocular stereoscopic eyepiece, which provides a precise 3-dimensional view of the operative area with up to 6-fold magnification of the operative field. The stereoscopic eyepiece itself includes dual lenses, an insufflation channel, and lens irrigator operated by foot pedal. An accessory monocular scope is connected to a video screen to allow the surgical team to view the procedure. All operating instruments are 5 mm in diameter and include graspers, scissors, a high-frequency knife, needle driver and clip applier. Most instruments angle downward at the tip. Graspers are made both with a right or left curve. The rectoscope and its attachments are secured to the operating room table using a multijointed clamp, the Martin's Arm.

The endosurgical unit provides the light source, irrigation, and suction, and is equipped with a pressure-controlled insufflator that measures pressure constantly via a separate channel so that interruption of the gas insufflation for pressure

measurement is not necessary. Simultaneously, an integrated roller pump provides constant suction at the same rate as the gas insufflation to allow for stable gas pressure in order to maintain visualization of the distended rectum without insufflation of the more proximal colon.

Operative Technique

Rectal cleansing is critical for adequate visualization of the rectal lumen and lesion. It can be achieved with either a mechanical bowel preparation or, alternatively, 2 rectal enemas depending on the patient's regular bowel habits. Intravenous antibiotics are used selectively. TEM procedures are usually performed under general anesthesia and a Foley catheter is used to decompress the bladder. Preoperative localization of the tumor is performed with rigid sigmoidoscopy in the clinic setting to determine the quadrant location of the lesion and to plan for operative positioning of the patient to allow the lesion of interest to sit at the 6-o'clock position. Patients with an anterior-based lesion are positioned in the prone jackknife position (legs spread apart and secured to arm boards) while those with a posterior lesion are positioned in lithotomy. Laterally located lesions are best approached with patients in the appropriate lateral decubitus position.

The operation starts with gentle dilation of the anus with two fingers and insertion of the rectoscope, inspection of the rectum under manual air insufflation and positioning of the rectoscope for optimal visualization of the lesion. The rectoscope is then attached to the operating table using the Martin's arm. During the resection, frequent repositioning of the scope is often necessary to keep the operative field in optimal view. Optics and operative instruments are introduced and the endosurgical unit is activated providing insufflation, suction, irrigation and pressure monitoring. Using cautery, the surgeon first makes the desired margin of clearance. This margin should be 5 mm from the macroscopic tumor edge for benign lesions and 10 mm in cases of invasive carcinoma. For adenomas located within the intraperitoneal portion of the rectum, a careful mucosectomy is performed to prevent entry into the peritoneum with the ensuing loss of rectal distention. For extraperitoneally located adenomas and for all invasive carcinomas, full thickness resection is standard. Circumferential adenomas in the lower and middle rectum can be resected as complete full thickness segments followed by an end-to-end anastomosis. Invasive carcinoma in the posterior or lateral position may be resected with some perirectal fat, which can often yield 1 or 2 adjacent lymph nodes, which can be examined for metastatic spread.

The resection bed for lesions below the peritoneal reflection may be left open or closed using a running suture with 3-0 polydioxanone suture (PDS) on a small-half (SH) needle. Knot tying using TEM equipment is very difficult and is instead achieved using silver clips, which are secured onto the suture. Closure of all intraperitoneal defects is mandatory and should be performed in 2 layers with separate closure of the peritoneum if entered.

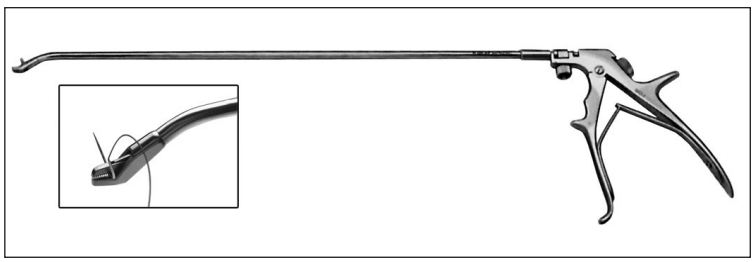

Figure 4. (above) Long-handled transanal endoscopic microsurgery instrument.

(With permission from Richard Wolf Medical Instruments Corporation, Illinois, USA)

Figure 5. (left) Operating rectoscope faceplate with four ports.

(With permission from Richard Wolf Medical Instruments Corporation, Illinois, USA)

Outcomes

Complications

The overall complication rate for TEM for benign and for malignant lesions has been reported to range from 6% to 31%.[14-25] Perioperative complications include hemorrhage and peritoneal entry, which may require conversion to laparotomy. The intraperitoneal perforation rate varies from 0% to 9%.[14,18,21,26,27] However, perforation into the peritoneal cavity does not always necessitate conversion to open laparotomy. In a series of 144 patients by Ganai and colleagues, 9 patients (6%) had peritoneal entry but all were managed by primary closure of the defect avoiding conversion to open anterior resection.[27] Moreover, in a retrospective review of 34 patients, Gavagan and colleagues reported no increase in major or minor complications and no significant increase in the hospital length of stay for those with peritoneal perforation compared with those without.[28]

Postoperative hemorrhage has been reported in 1% to 13% of patients.[11,14,17,22,28-31] Most resolve spontaneously or are managed conservatively with blood transfusion. Very few patients require surgical intervention. Suture line dehiscence, perirectal abscess, and rectal stenoses have also been described. In most instances, suture line dehiscence is managed nonoperatively and treated with local therapy and antibiotics.[25]

Early and late complications in TEM patients were similar or lower than for patients undergoing open resection in several randomized trials comparing TEM with radical excision.[31-33] Lezoche and colleagues found no significant difference in complication rates between patients randomized to either TEM (n = 35) or laparoscopic total mesorectal excision (n = 35) for T2N0 rectal cancer following neoadjuvant treatment. Winde and col-

leagues randomized 50 patients with T1 rectal cancer to TEM (n = 24) and anterior resection (AR) (n = 26). Patients were not statistically different in age or tumor location. However, early morbidity was 21% in the TEM group compared with 35% in AR group. TEM patients also had significantly shorter average operating times (103 min vs 149 min, $p < 0.05$), lower blood loss ($p < 0.001$), shorter length of stay (5.7 days [standard deviation {SD}] 1.8 days vs 15.4 days [SD 1.5 days], $p < 0.0001$) and a lower postoperative analgesia requirement.[31]

Recurrence

The adenoma recurrence rate following TEM ranges from 0% to 16%.[14,18,26,29,34,35] McCloud and colleagues reviewed their experience with 75 patients who underwent TEM for rectal adenomas to determine predictors of early recurrence. Although recurrence at 6 months was not found to be significantly associated with age, gender, type, or position of the adenoma, distance from the anal verge or degree of dysplasia, there was a significant association between incomplete adenoma excision and risk of recurrence. Recurrence rates at 6 months were 0% for completely excised adenomas and 21% for those incompletely excised as determined by histologic evaluation.[36] Comparison of TEM with conventional transanal excision for adenoma resection has also shown lower margin positivity, less specimen fragmentation, and a lower recurrence rate with TEM than conventional excision (3% vs 32%, $p = 0.003$).[37]

TEM as the definitive and sole curative treatment should be limited to early stage T1N0 cancer (submucosal invasion with negative nodes, preoperative imaging stage). The recurrence rate following TEM for T1 lesions ranges from 0% to 11%.[16,21-23,31,38] Several studies comparing TEM and radical surgery for T1 cancers demonstrated no statistically significant difference in recurrence rate or survival for TEM compared with radical surgery.[30,31] If unfavorable histologic characteristics are found following TEM excision or if the lesion penetrates into the muscularis propria (pT2) or if there is lymphovascular invasion or involved margins, most surgeons advise immediate radical surgery. Borschitz and colleagues studied 105 patients with T1 rectal carcinoma resected by TEM and stratified them into low- and high-recurrence risk by histologic characteristics including tumor differentiation and lymphatic or venous invasion. The local recurrence rate for low-risk carcinomas was 6% and for high-risk tumors was 39% after TEM resection. However immediate reoperation of the high-risk tumors resulted in a reduction of the recurrence rate to 6%, the same rate as for low-risk tumors.[39]

Early and late complications in TEM patients were similar or lower than for patients undergoing open resection in several randomized trials comparing TEM with radical excision.

With recent advances in chemoradiation, local excision can be used selectively for T2 lesions when augmented by neoadjuvant or adjuvant therapy. Overall recurrence rates following TEM excision of T2 lesions (including patients who did and did not have chemoradiation) range from 6% to 18%.[15,21-23,40] However, the use of neoadjuvant or adjuvant therapy has been demonstrated to significantly reduce local recurrence rates. Duek and colleagues reviewed their experience of 21 patients with T2 tumors and demonstrated a 0% local recurrence rate in patients who underwent radiotherapy following TEM compared to a 50% recurrence rate in patients who refused adjuvant radiotherapy following TEM.[41] Lezoche and colleagues compared TEM and laparoscopic total mesorectal excision in a prospective randomized study of 70 patients with T2 lesions (35 TEM and 35 laparoscopic excision) all of whom had neoadjuvant chemoradiation therapy and found no significant difference in local recurrence or disease-free survival during a minimum 5-year follow-up.[33] However, Lee and colleagues demonstrated a significantly higher 5-year local recurrence rate following TEM compared with radical excision for T2 lesions (19.5% vs 9.4%, $p = 0.035$) but similar disease-free survival (80.5% vs 83.3%, $p = 0.12$) in patients who did not receive adjuvant chemoradiation.[30]

Patients with T3 lesions are not suitable candidates for TEM alone because of the high risk of local recurrence and lymph node metastases and limited data is available on the oncologic outcome of such patients. Guerrieri and colleagues reported on 23 patients with T3 rectal cancer treated with TEM following preoperative radiotherapy. Local failure occurred in 2 cases (9%) and disease-free survival was 59% at a mean follow-up of 46 months.[38] Similarly, Lezoche and colleagues showed a local recurrence rate of 4% with an 85% rectal cancer specific survival rate at 90 months in T3 patients following radiotherapy.[25]

Functional Outcomes

The physiologic effect of TEM on postoperative anal sphincter function has been investigated and demonstrates diminished anorectal manometric resting pressures following TEM.[42-44] Kennedy and colleagues performed anorectal physiologic studies preoperatively and at 6 weeks postoperatively in 18 consecutive patients undergoing TEM. A significant decrease in maximum anal resting pressure was noted which correlated with duration of the procedure. However, no significant change in continence level was noted and pudendal nerve terminal motor latency, mucosal electrosensitivity and rectal compliance were not significantly changed.[42] Impairment in continence was seen in 37% of patients following TEM in a study conducted by Dafnis and colleagues and was again correlated with prolonged operative time but not associated with patient age or gender.[26]

Cataldo and colleagues assessed baseline and postoperative anorectal function in 37 patients undergoing TEM using validated functional assessment tools (Fecal Incontinence Severity Index [FISI] and Fecal Incontinence Quality of Life [FIQL]) and found no significant difference between baseline and postoperative FISI and FIQL scores.[45] Similarly, a study comparing quality of life between patients undergoing TEM and patients undergoing total mesorectal excision (TME) found that general quality of life was similar between the 2 groups postoperatively but TEM patients had fewer problems with defecation than the TME patients.[46]

Cost

TEM benefits include decreased morbidity, shorter hospital length of stay, and faster recovery. However the initial cost of the specialized TEM equipment is perceived by some surgeons as a limiting factor in the widespread adoption of this technique. Nevertheless, TEM can be cost effective if offered at high-volume centers. In a case-controlled study, Maslekar and colleagues compared 52 patients undergoing TEM with 52 patients undergoing open procedures at a single institution between 1997 to 2003.[46] TEM costs were $3500 to $5800 lower per patient compared with patients who had an anterior resection when taking into consideration the hospital stay, equipment and instruments, and stoma closure when applicable.[47] An even larger cost saving was seen in the retrospective review by Cocilovo and colleagues who reported an average cost for TEM of $7775 compared with $34,018 for a low-anterior resection at their institution.[48]

Conclusion

Since 1983, TEM has been used effectively to treat benign rectal lesions and early rectal cancer. TEM allows the surgeon to tackle lesions too difficult to approach with conventional transanal excision with improved immediate endpoints (margin positivity and specimen fragmentation) and lower long-term recurrence rates. Over two decades of scientific data support the use of TEM as a viable alternative to radical excision of the rectum with less morbidity, faster recovery, and potential cost savings when performed at specialized centers. Functional disturbance of continence occurs in a minority of patients.

The role of TEM in patients with T2N0 and T3N0 is still being debated and warrants further investigation. Currently TEM should be limited in these cases to patients who refuse or are too high risk for transabdominal radical excision. Under such circumstances serious consideration should be given to adjuvant or neoadjuvant chemoradiation to reduce the risk of local recurrence. ❖

Disclosure Statement

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

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Life!

Surgeons must be very careful
When they take the knife!
Underneath their fine incisions
Stirs the Culprit - Life!

— Emily Dickinson, 1830-1886, American poet

CASE STUDY

Corridor Consult

False Estimates of Elevated Creatinine

Manpreet Samra, MD; Antoine C Abcar, MD

Perm J 2012 Spring;16(2):51-52

Abstract

One of the most common reasons for a nephrology consult is an elevated creatinine. An elevation in the serum creatinine concentration usually reflects a reduction in the glomerular filtration rate (GFR). Given the association of elevated creatinine and risk of cardiovascular mortality, it is important to keep in mind that at times the elevation of the creatinine is not representative of a true reduction in GFR. There are various causes of factitious elevation of creatinine. They can be broadly grouped into increased production of creatinine, interference with the assay and decreased tubular secretion of creatinine.

Introduction

A colleague asks about a patient: a woman, age 48 years, diagnosed with hypertension for 2 years and with hyperlipidemia for 10 months who has had a steadily increasing creatinine level, from 0.7 to 1.8 over the last 8 months. Her medications include hydrochlorothiazide per os 12.5 mg/day and fenofibrate per os 200 mg/day.

One of the most common reasons for nephrology consult is elevated creatinine, which usually reflects a reduction in glomerular filtration rate (GFR). Given the association of elevated creatinine with cardiovascular mortality, it is important to keep in mind that elevated creatinine is not always representative of a reduction in GFR. Here, we will discuss the various causes of false estimates of elevated creatinine.

Patients have few signs and symptoms during early renal disease. Early detection of abnormal kidney function is important, because early treatment usually slows disease progression.

Because it is not possible to directly measure kidney function or the GFR, a surrogate is needed. The endogenous marker most commonly used to measure kidney function is creatinine.[1] Creatinine is generated in muscle and is proportionate to muscle mass and remains relatively constant. Eighty-five percent to 90% of creatinine is excreted by the kidney; the rest undergoes tubular secretion. It is most commonly measured by a colorimetric assay called the Jaffe reaction. In the Jaffe reaction, creatinine combines with picric acid to form a colored complex that is measured to quantify the creatinine.

With this in mind, we can discern multiple factors that may artificially increase the estimated creatinine level. These can be grouped into three categories: increased production of creatinine, interference with the assay, and decreased tubular secretion of creatinine.

Increased Creatinine Production

Creatinine is produced in muscle by the nonenzymatic conversion of creatine and phosphocreatinine. The creatinine generated is proportional to muscle mass and is relatively constant. The liver has an important role in the formation of creatinine through methylation of guanidine aminoacetic acid. The serum creatinine can vary by 0.5 to 1.0 mg/dL according to diurnal and menstrual variations, race, and diet (and method of meat preparation).

An increase in serum creatinine can result from increased ingestion of cooked meat (which contains creatinine converted from creatine by the heat from cooking) or increased intake of protein and creatine supplements, in excess of the recommended dosage. Creatine is present in the organs, muscles, and body fluids of animals. Creatine supplements promote protein synthesis and are a quickly available source of energy for muscle contraction, hence they are used to enhance athletic performance. Furthermore, intense exercise can increase creatinine by increasing muscle breakdown.[2,3]

Interference With the Assay

As stated earlier, the Jaffe reaction is a colorimetric assay. It can be influenced by other endogenous chromogens such as acetone and acetoacetate (such as in diabetic ketoacidosis), fasting, lipemia, and hemolysis, resulting in an overestimate of the serum creatinine. Drugs that can interfere with the assay include antibiotics such as cephalosporins, specifically cefoxitin and cefazolin; barbiturates; N-acetylcyteine; and chemotherapeutic agents such as flucytosine (although by a different assay: the Kodak Ektachem method).[4,5] Another material known to interfere with the Jaffe reaction is nitromethane, a common component of radio-controlled-vehicle fuels.

The Kodak Ektachem method uses an ammonia reaction to quantify creatinine. Creatinine is converted to N-methylhydantoin and ammonia. Flucytosine is the only agent known to cause a false elevated creatinine result when this method is used.[6] This artificial result is attributed to the 4-amino group of flucytosine, which is converted to free ammonia by creatine iminohydrolase.

More specific creatinine assays not subject to such interference are being investigated. One such assay, the VITROS CREA, employs an oxidation reaction to measure endogenous creatinine levels and will soon be available at laboratories within Kaiser Permanente. The VITROS CREA assay will quantify creatinine with greater precision.

Decreased Secretion

Approximately 15% of creatinine is secreted in the tubules. It is secreted by the organic cation secretory pump that

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Table 1. Common causes of false estimates of elevated creatinine

	Mechanism		
	Decreased secretion of creatinine	**Interference with the serum assay**	**Increased creatinine production**
Causes	Trimethoprim	Cefoxitin	Increased intake of cooked meat
	Cimetidine	Flucytosine	Fenofibrates
	Ranitidine	Acetoacetate (in DKA)	Rhabdomyolysis

DKA = Diabetic ketoacidosis.

can be inhibited by other organic cations. Trimethoprim, cimetidine, and other H2-blockers medications can inhibit this process and cause an increase in the measured serum creatinine[7,8] (Table 1).

Case in Question

In the above-mentioned patient we stopped the fenofibrate, and we saw her creatinine trend toward normal in a few months. It is postulated that fibrates (particularly fenofibrate) impair the generation of vasodilatory prostaglandins and could alter intrarenal hemodynamics, possibly altering GFR, but the definitive mechanism by which this occurs is still to be elucidated.[9]

Case studies of renal transplant patients have shown evidence of tubular toxicity caused by fenofibrates and increased creatinine production.[10] The magnitude of changes in creatininemia ranged from 8% to 18% for fenofibrate. The change in creatinine, though, has been shown to be reversible after fibrate withdrawal.

In conclusion, when elevated serum creatinine is detected, it is important to evaluate the patient as a whole to rule out possible causes. ❖

Disclosure Statement

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

Acknowledgment

Leslie E Parker, ELS, provided editorial assistance.

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The Source of Important Discoveries

The urine of man is one of the animal matters that have been the most examined by chemists, and of which the examination has at the same time furnished the most singular discoveries to chemistry, and the most useful application to physiology, as well as the art of healing. This liquid, which commonly inspires men only with contempt and disgust, which is generally ranked amongst vile and repulsive matters, has become, in the hands of the chemists, a source of important discoveries.

— Antoine François, Comte de Fourcroy, 1755-1809,
French chemist and collaborator on *Méthode de Nomenclature Chimique*

"Focus on the Physical"
oil paint and India ink on Yupo paper
26"x13"

Marilyn Mitchell

This piece is based on an image of a stroke from a medical journal and an *ArtForum* cover that featured the work of Brice Marden. The lively energy and the sinuous lines are common denominators between the stroke image and the art piece.

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CASE STUDY

Corridor Consult

Management of the Athlete with Concussion

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Perm J 2012 Spring;16(2):54-56

Abstract

The approach to and management of the athlete with concussion can be a challenging endeavor to physicians who care for athletes who have suffered a head injury—this group includes family physicians, pediatricians, internists, emergency medicine physicians, primary sports medicine physicians, orthopedic surgeons, neurologists, and neurosurgeons. Sometimes questions regarding the need for neurologic, psychological, or radiographic imaging can make the decision for return to play unclear. New legislation will undoubtedly increase physician visits for these athletes to return to play. Thus, the goal of this article is to review the latest guidelines regarding concussion management to help all physicians who care for athletes do so appropriately.

Introduction

Up to 250,000 concussions occur each year in high schools alone.[1] The approach to and management of the athlete with concussion can be a challenging endeavor to physicians who care for athletes who have suffered a head injury—this group includes family physicians, pediatricians, internists, emergency medicine physicians, primary sports medicine physicians, orthopedic surgeons, neurologists, and neurosurgeons. Sometimes questions regarding the need for neurologic, psychological, or radiographic imaging can make the decision for return to play unclear. New legislation will undoubtedly increase physician visits for these athletes to return to play. Thus, the goal of this article is to review the latest guidelines regarding concussion management to help all physicians who care for athletes do so appropriately. The following case illustrates a presentation of concussion in a young athlete in the primary care setting.

Case Report

A 17-year-old male football player presented to our primary care clinic on a Wednesday at the recommendation of his athletic trainer. His father accompanied him. The patient reported that he was involved in an on-field collision in the 4th quarter of the previous Friday night's football game. He did not recall much about the episode, but his father said that he was in the air attempting to catch a pass when an opposing player leapt headfirst into him, causing a helmet-to-helmet collision. He remained on the ground for about 5 to 10 seconds but then was able to stand on his own and make his way over to the sideline. The patient reported that he did not feel dizzy or have a headache, but he felt a little "fuzzy" and slow. He was not allowed to complete the game. Since then, he has not practiced with his team but has been doing light jogging and running pass routes without any difficulty or complaint of any symptoms.

On physical examination, he appeared alert and oriented. His neurologic findings showed no deficits, and results of cardiovascular, pulmonary, and musculoskeletal examinations also were normal. The patient had normal results of a mental status examination. He requested clearance to return to play.

A concussion was diagnosed on the basis of the mechanism of injury and the patient's symptoms immediately after the injury. Because he did not have any "red flags," such as focal neurologic deficits, at the sideline or at the office visit, imaging was not warranted. Five days after injury, he had already been doing light jogging and running pass routes—essentially noncontact drills—without any symptoms. The next step would be to allow him to attempt full contact play in practice. If he were to experience any concussion symptoms, he was advised to stop playing and return for a follow-up visit. If he remained symptom-free, he could engage in full contact game play in the next Friday night's game.

Time was spent to educate the patient and his father about concussion and about the importance of this stepwise approach to ensure the safety of the athlete.

Discussion

This discussion reviews the latest guidelines regarding concussion management, with the goal of helping physicians who care for athletes after concussion do so appropriately.

According to the latest Consensus Statement from the 3rd International Conference on Concussion in Sport, held in Zurich, Switzerland, in 2008, concussion is defined "as a complex pathophysiological process affecting the brain induced by traumatic biomechanical forces."[2] A more colloquial expression among athletic trainers and coaches is having one's "bell rung." Although helmets help to reduce skull fractures and severe brain injury, they have not been shown to protect against concussion.[3] Concussions often are underreported or unreported among athletes and coaching staff[4] because of lack of knowledge regarding concussion as well as not wanting the athlete pulled from play.

If the athlete has a second concussion before recovering from the first one, a potentially fatal condition known as second-impact syndrome can result. For this reason, the California Interscholastic Federation passed a bylaw in 2010 allowing for

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game referees to remove players from games when concussion is suspected[5] and requiring medical clearance from a physician before returning to play.

The general approach to concussion in a game setting is to begin with the evaluation of the athlete in the same manner as for any patient who has undergone trauma: the ABCs of airway, breathing, and cervical spine precautions. Once an athlete's ABCs are confirmed clear, s/he should be moved to the sideline for further evaluation. Athletes may complain of headache, dizziness, nausea, a "foggy" or "slow" feeling, visual or balance disturbances, amnesia, or irritability. There may be loss of consciousness, convulsion, or even seizure. These concussion symptoms typically spontaneously improve within minutes of impact and resolve by about five to seven days, although in some cases they may persist for weeks.

Once the patient is on the sideline or later in the examination room, useful tools such as the Standardized Assessment of Concussion (SAC)[6] (available from: www.csmisolutions.com/PDFS/SAC%20Informational%20Kit.pdf) or the Sport Concussion Assessment Tool (SCAT2),[7] which is part of the Zurich guidelines,[2] should be used. The SCAT2 can be downloaded as a PDF (www.csmfoundation.org/SCAT_Card.pdf) in full form for the clinic,[8] printed in pocket form for the sideline, or downloaded as a smart phone application: Pocket SCAT2 (Inovapp, Inc; La Mesa, CA; available from: http://itunes.apple.com/au/app/pocket-scat2/id453095629?mt=8&ign-mpt=uo%3D4). The SCAT2 provides a standardized scoring system that takes into account symptoms, physical examination findings, cognitive function, balance, and coordination, as well as Glasgow Coma Scale scores. During sideline evaluation, alarming "red flags" of a head trauma include focal neurologic deficits, a deteriorating level of consciousness, prolonged confusion lasting greater than 30 minutes, or a loss of consciousness lasting greater than 5 minutes. These athletes do not have symptoms typical of concussion and should be brought to an emergency room urgently for immediate imaging. Although loss of consciousness was previously considered a marker of a more severe concussion, evidence does not support this conclusion; rather, amnesia has been shown to be most predictive of neurocognitive deficits.[2]

The diagnosis of concussion is largely based on the clinical examination, yet certain imaging studies can be considered, such as computed tomography or magnetic resonance imaging, if an intracranial bleed is suspected. Functional magnetic resonance images and positron emission tomographic scans have been used in concussion research but serve no role in the clinical management of concussion.[9,10]

Commercial neuropsychologic testing programs (eg, ImPACT, ImPACT Applications Inc, Pittsburgh, PA; Axon Sports Computerized Cognitive Assessment Tool [CCAT, formerly CogSport], Axon Sports LLC, Wassau, WI; Automated Neuropsychological Assessment Metrics [ANAM], Vista LifeSciences, Parker, CO) have been advocated by some groups and schools as an aid in the return-to-play decision. These tests can help only when baseline testing is done and used for comparison to monitor improved test scores as an athlete recovers. However, no large well-designed studies have shown these commercial tests to improve health outcomes over good clinical follow-up in concussed athletes.[11-14]

The athlete found to have concussion on the sideline should be removed from play immediately and not allowed to return that day under any circumstances. It is recommended to perform serial examinations to monitor for worsening neurologic decline. These examinations should include testing of the cranial nerves, coordination, strength, and sensation. Any signs of deterioration should be presumed to indicate intracranial bleeding until proved otherwise. After completion of the game, the athlete and family should be advised of the diagnosis and given warning signs of which to be attentive.

… Although loss of consciousness was previously considered a marker of a more severe concussion, evidence does not support this conclusion; rather, amnesia has been shown to be most predictive of neurocognitive deficits.

The decision for return to play should take place in a stepwise fashion.[15,16] The typical progression from rest to resumption of full activity lasts approximately six days (Table 1). This is based on the studies that show, despite denying symptoms, athletes often have balance or coordination issues lasting five to seven days in adults or up to ten days in children and adolescents.[17] On day one, the athlete should have complete physical and cognitive rest. In this age of Internet use, social media, and gaming, the athlete and family should be advised of the importance of avoiding these neurologically stimulating activities as well as delaying schoolwork during this period. If the athlete remains asymptomatic after day one, s/he may attempt aerobic exercise on day two. If there are no symptoms, the athlete may attempt sports-specific exercises on day three. On day four, the athlete may perform noncontact training drills. Full contact training may be attempted on day five after medical clearance has been granted. If at any point during the progression, the athlete has any symptoms of concussion return, s/he must return to day one (rest) and restart the day-by-day progression. If the athlete remains asymptomatic through the five days of stepwise increasing activity, the athlete may be allowed to participate in competitive game play on day six. The patient and family should be educated about the importance of adhering to these steps.

Besides second-impact syndrome, postconcussive syndrome is another complication that can occur after a concussion, when neurologic deficits persist beyond two weeks. For athletes

Table 1. Stepwise return to activity[1]

Day	Activity allowed
1	No physical or cognitive activity until asymptomatic (rest)
2	Light aerobic exercise (eg, stationary bike)
3	Sport-specific exercise (eg, shooting free-throws, throwing football)
4	Noncontact drills (eg, running for passes, dribbling ball down court)
5	Full contact practice (after medical clearance)
6	Game play

[1] McCrory P, Meeuwisse W, Johnston K, et al. Consensus Statement on Concussion in Sport, 3rd International Conference on Concussion in Sport held in Zurich, November 2008. Clin J Sport Med 2009 May;19(3):185-200.

who have a history of persistent or worsening concussion symptoms for greater than two weeks or a history of multiple concussions, or for those who have persistent abnormal results of neuropsychological tests, a referral to a neurologist should be considered.[18]

The medical care of athletes can be an enjoyable experience. With a better understanding of concussion and the latest consensus recommendations for its management, physicians who care for athletes can be better equipped to keep them safe and healthy. ❖

Disclosure Statement

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

Acknowledgment

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

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Weakness to the Animal Faculty

Sometimes a great wound or concussion of the head,
especially which happens by falling headlong from a high place,
brings a prejudice and weakness to the animal faculty, dulling the understanding.

— Thomas Willis, 1621-1675, English physician and founding member of the Royal Society

ECG Diagnosis: Hypokalemia

Joel T Levis, MD, PhD, FACEP, FAAEM

Perm J 2012 Spring;16(2):57

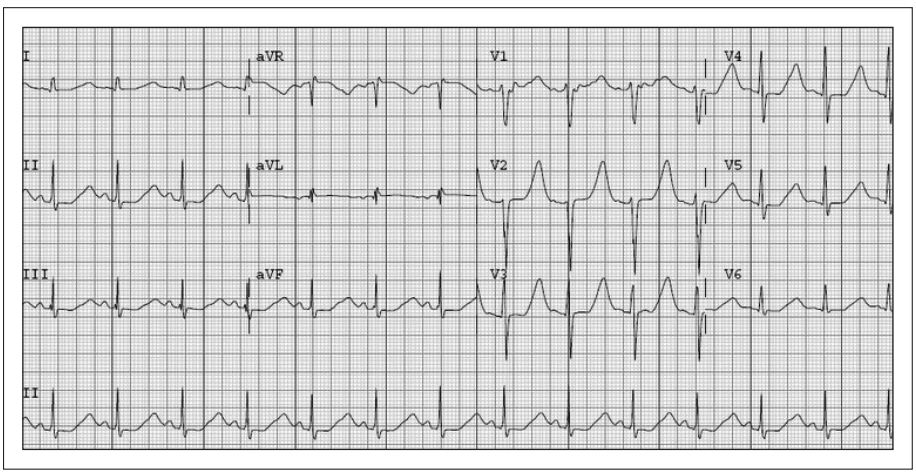

Figure 1. 12-lead ECG from a 21-year-old man with syncope, generalized weakness, and severe hypokalemia (serum potassium 1.6 mEq/L).

Demonstrates prolonged QT interval (649 ms), ST-segment depression, prominent U waves and slurring of the T waves into the U waves (most prominent in lead II).

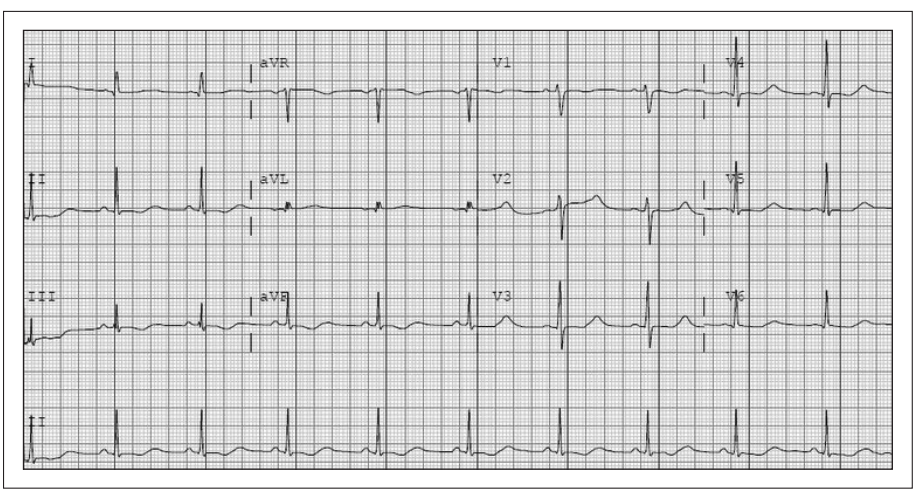

Figure 2. 12-lead ECG from same patient following oral and intravenous potassium replacement (serum potassium 2.5 mEq/L).

Demonstrates improvement in ST-segment depression, less prominent U waves and decreased QT prolongation (590 ms).

The earliest electrocardiogram (ECG) change associated with hypokalemia is a decrease in the T-wave amplitude.[1] As potassium levels decline further, ST-segment depression and T-wave inversions are seen, while the PR interval can be prolonged along with an increase in the amplitude of the P wave.[1] The U wave is described as a positive deflection after the T wave, often best seen in the mid-precordial leads (eg, V_2 and V_3). When the U wave exceeds the T-wave amplitude, the serum potassium level is < 3 mEq/L.[2] In severe hypokalemia, T- and U-wave fusion with giant U waves masking the smaller preceding T waves becomes apparent on the ECG.[1,2] A pseudo-prolonged QT interval may be seen, which is actually the QU interval with an absent T wave.[1] Severe hypokalemia can also cause a variety of tachyarrhythmias, including ventricular tachycardia/fibrillation and rarely atrioventricular block.[3] Treatment of hypokalemia involves parenteral and oral potassium supplementation, as well as identification and treatment of the underlying cause.[1] ❖

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Image Diagnosis: Abdominal Wall Hematoma

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Perm J 2012 Spring;16(2):58-59

A spontaneous abdominal wall hematoma developed in a 70-year-old woman with interstitial lung and mixed connective tissue disease during hospitalization for dyspnea. Diagnosed with a recurrent deep venous thrombosis of her left common femoral vein, enoxaparin by abdominal subcutaneous route and warfarin were administered. Within 48 hours, the patient developed pain, tenderness, and a large area of bruising in the left lower quadrant.

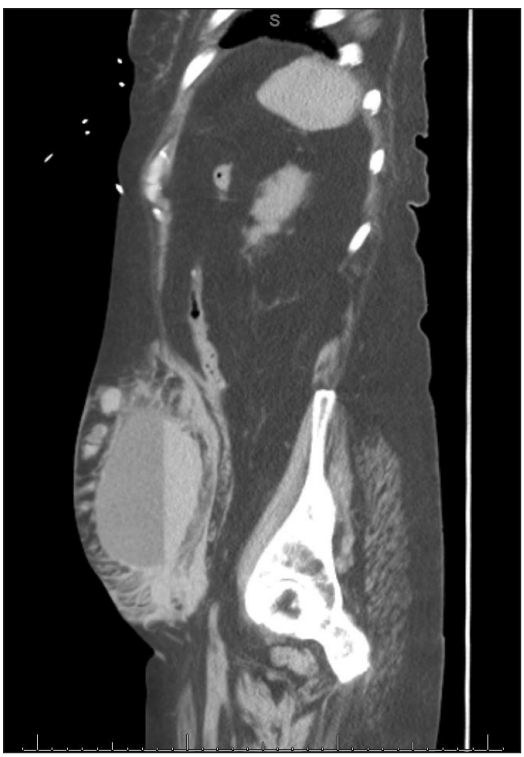

Figure 1. Computed tomography (CT) scan sagittal section demonstrating a 12.8 x 5.3 x 11.4 cm abdominal wall hematoma in left lower quadrant with a fluid-fluid level, representing layering blood products.

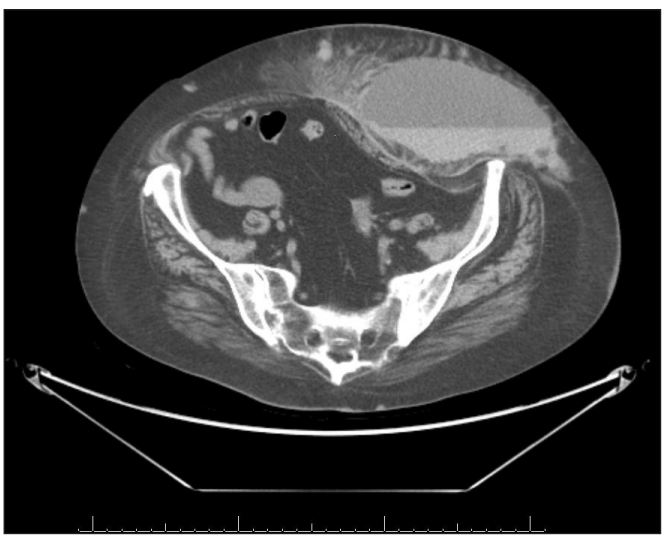

Figure 2. Cross-section CT image through the abdominal wall hematoma.

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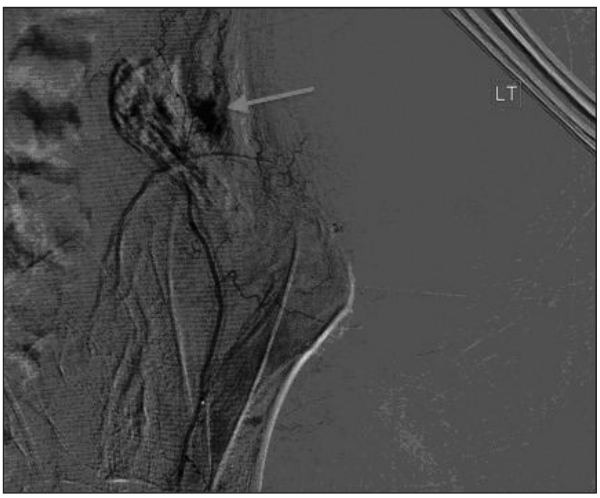

Figure 3. After cannulation of right femoral artery, angiography of inferior epigastric and lateral circumflex arteries was obtained. Several blushes representing active bleeding from lateral circumflex artery were identified (see arrow).

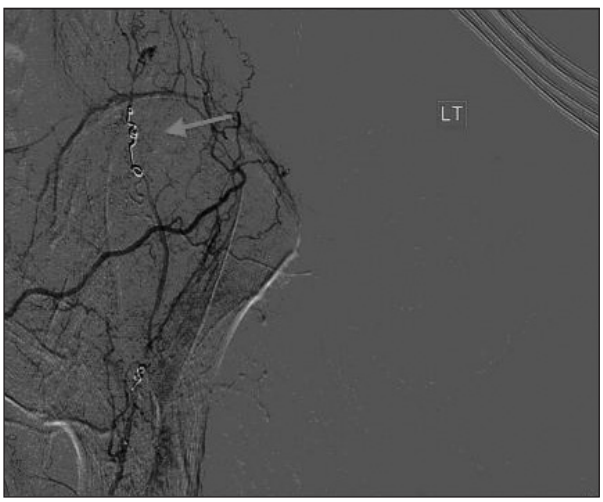

Figure 4. Successful coil embolization of the lateral circumflex artery is demonstrated (see arrow).

Abdominal wall hematoma is uncommon, but may be a life-threatening condition. Risk factors include older age, female sex, systemic anticoagulation, abdominal wall trauma, pregnancy, and impaired renal function.[1] Clinical manifestations include abdominal pain, abdominal wall ecchymosis, drop in hematocrit, and a positive Carnett's sign (increase in abdominal pain when a supine patient tenses his or her abdominal wall by lifting their head and shoulders off the exam table, indicating the abdominal wall and not the abdominal cavity as the source of pain).[2] In severe cases, signs of hemodynamic compromise can occur, as developed in our patient. Treatment in cases of hemodynamic compromise includes resuscitation with intravenous fluids and blood products, and normalization of coagulation status with the fresh frozen plasma and vitamin K. Surgical management (which is extremely challenging) or embolization by angiographic specialists is necessary in patients who fail conservative measures. ❖

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COMMENTARY

The Familiar Foundation and the Fuller Sense: Ethics Consultation and Narrative

Craig Nelson, PhD, CLS

Perm J 2012 Spring;16(2):60-63

Abstract

As clinical ethicists and ethics committee members, we strive to create the ideal situation for moral conversation and ethical reflection. Using both the familiar foundation and the fuller sense, the ethicist and ethics committee are aided in participating more fruitfully in a process of resolution. The familiar foundation represents a body of knowledge that ethics consultants and ethics committees should thoroughly understand. In addition, there is a depth of analysis found in the fuller sense, through narrative, that sharpens ethical focus and enables richer understanding of the patient's situation in life.

In using both tools, patients and families are better served than they would be relying on either tool by itself. Stakeholders and their relationships become more clearly assessed and individuals more effectively discover their own legitimate position. This can mean a more thorough representation of moral problems, a deeper understanding of all parties involved, and a greater opportunity to help parties better understand themselves and each other.

This commentary examines ethical expertise and the idea of clinical ethics consulting. The *familiar foundation* and the *fuller sense* are two important tools used in clinical ethics consulting. I will champion the use of both tools for the ethical enterprise and will emphasize that the fuller sense supplements the familiar foundation. In using both tools, patients and families are better served than they would be relying on either tool by itself. The familiar foundation represents a body of knowledge that ethics consultants and ethics committees should thoroughly understand. In addition, there is a depth of analysis found in the fuller sense, through narrative, that sharpens ethical focus and enables richer understanding of the patient's situation in life.

Familiar Foundation

It is of no surprise that the ethical expertise needed for the work of clinical ethicists has been both principle centered and context centered.[1] The knowledge found in the familiar foundation of principle-centered ethical conversation has been instrumental in defining ethical expertise.[2p657,3p2] This foundation is familiar because it consists of a well-known and well-used core of ethical understanding that depends heavily on theories and principles. The core of this familiar foundation reads like a chapter out of William Frankena's *Ethics*.[4p12-61] Act-and-rule utilitarianism, act-and-rule deontology, theories of justice, principles such as autonomy and beneficence, and the use of casuistry all give shape to this familiar foundation. Expert ethical opinion has often been conflated with how well one knows and understands the knowledge that flows from this familiar foundation. An excellent in-depth discussion of ethics expertise can be found in Rasmussen's "An Ethics Expertise for Clinical Ethics Consultation."[2]

Fuller Sense

In addition to the principle-centered familiar foundation in clinical ethics, there is a knowing that flows from a context-centered fuller sense. The term fuller sense or *sensus plenior* was popularized by biblical scholar Raymond Brown.[5p92] Brown defines *sensus plenior* or the fuller sense as "that additional, deeper meaning, intended by God but not clearly intended by the human author, which is seen to exist in the words of a biblical text (or group of texts, to even a whole book) when they are studied in light of further revelation or development in the understanding of revelation." In the use of the term fuller sense, one is not to understand the term as a divine communication or a holy path to a singular moral truth that applies to everyone, but as a way to supplement critical questioning and a way of sharpening focus so that ethical conversation and deliberation may be more meaningful. The fuller sense produces a richer understanding about the patient because one has better understood the context of a patient's story by moving deeper into the details of the patient's lived experience and social network. The fuller sense of a patient's story allows the hearer to have a greater understanding of the patient's situation in life.

This deeper sense of the patient's story relies on conceptual coherence, existential meaningfulness, and common human experience.[6p407-8] The hearer of story draws on personal analogy using this triad and finds in the patient's story *similarities-in-difference.* By analogy, a concept is formed, something is pictured in the hearer's mind, and common roots are mentally acknowledged. There is, in a sense, similarity discovered in variety.

In addition to this similarity in variety, the fuller sense helps the hearer understand how the patient's story can be seen as a metaphor for a particular vision of reality. The hearer passes over from the standpoint of his or her life to the standpoint of the storyteller, finding enrichment and deeper understanding in the process.[7p243ff]

The context-centered fuller sense of clinical ethics does not need to jettison the familiar foundation. The fuller sense augments the familiar foundation and adds a depth dimension to practicing clinical ethics. The use of both the familiar founda-

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tion and the fuller sense emphasizes that the clinical ethicist and the ethics committee do not simply form a repository of institutional morality or become the hospital's conscience. The clinical ethicist and ethics committee gather together as an ethical community to use the knowledge of the familiar foundation and to implement the wisdom of the fuller sense drawn from the patient's narrative. This enables the gathered community of concern,[8p26-7] including ethicist and ethics committee, to keep open, accessible, and active ethical reflective space where sound and shared processes of deliberation can occur.

The process of deliberation also involves identifying moral understanding that comes from personal narrative. The community of ethicist and ethics committee receives from the narrative the patient's story and patterns of moral thinking. The story forms the tapestry within which morally relevant information can be organized. This calls the listener to polish his/her skills of attention and appreciation. As stories are heard, perceptions are discovered that flow from valuable character traits of the agents found in the story. The wisdom of rich and inclusive life experience of patient story, or narrative, form the concrete reality that give the abstract principles of ethics shape and substance because abstract principles do not decide the cases. The context shapes the vision of the ethical community, the community of concern, to make an ethical recommendation.[9] Ethical action then flows from a lived social medium that cultivates perceptions to assist the moral agent within the narrative to move toward resolution and produce clarified responsibility along the way. The act, the intent, and the circumstances form the elements of this lived contextual story of the patient narrative, and give texture to the principles of the familiar foundation.

Stories of identity and relationship viewed through this fuller sense shed light upon the ethical consideration and the possible resolution of specific cases. This can show the cost of ethical participation for the parties involved. As Mary Elizabeth Moore stresses, "Narrative can expand the range of our imagination and our courage to act in new directions toward new possibilities."[10p157]

Narrative can be seen as a helpful tool by showing that certain kinds of things are better or worse for patients from their own perspective. Narrative can also help uncover real-life values and obligations that must be reckoned with. Embedded within narrative lies the answer for how values and obligations can guide patients facing complex problems. Perspectives that form a vehicle for honoring all agents of value in the narrative become expanded. One goes beyond knowing definitions of theories, principles, and concepts to arriving at knowing what they are used for and under what conditions they can help.

The content of a specific patient narrative helps determine ethical responsibilities in the concrete here and now and acts as a tutor for understanding how to use both the familiar foundation and the fuller sense. Consider the case study of the young woman patient presented here.[11p227-38]

Case Study

A woman, age 34 years, with a long-standing history of alcoholism and alcoholic liver disease was admitted to a local hospital. The patient admits to typically drinking $1^1/_2$ quarts of alcohol per day, though for the last few days her father, who often drinks with her, has limited her intake to 2 to 3 glasses of wine per day. One year earlier, she was hospitalized for delirium tremors, alcoholic hepatitis, hemorrhagic gastritis, hemorrhagic duodenitis, and esophageal varices. The patient is divorced and lives with her parents. Her 10-year-old daughter lives with her ex-husband.

The patient was brought to the emergency room by ambulance complaining of vomiting blood. She has had tarry stools for two weeks. The patient's physician of record, when contacted by the emergency medicine physician, states that the patient had been discharged from his practice because of persistent drinking. The patient was admitted to the Intensive Care Unit for transfusion therapy and to control her delirium tremors.

The patient continued to bleed despite transfusion therapy, which itself was complicated because of the patient's rare blood type. The patient was evaluated by a surgeon for possible surgical intervention but it was felt that because of her coagulopathy and poor overall prognosis, the patient would not survive a total gastrectomy.

Initially, when consulted, the patient's mother stated that the patient had expressed the desire not to be mechanically supported, but would consent to surgery if it was a realistic possibility. Wondering, "What if she got better?" the mother resisted a no-code order. Intensive support was therefore continued.

As the patient's bleeding slowed somewhat, the physician followed the family's wishes to have the no-intubation order changed to a full-code order, which would include intubation and mechanical support if necessary. Over a two-day period, the patient became unresponsive and had rapid breathing. Her extremities became bluish. The patient's mother was apprised of her daughter's grim prognosis and told that she was slowly dying. The mother expressed that she still wanted her daughter kept on life support.

Narrative can be seen as a helpful tool by showing that certain kinds of things are better or worse for patients from their own perspective. Narrative can also help uncover real-life values and obligations that must be reckoned with. Embedded within narrative lies the answer for how values and obligations can guide patients facing complex problems.

The patient stabilized and was transferred to the medical-surgical unit. Her level of alertness improved. She required a paracentesis whereby one liter of fluid was removed. Although she had no further exsanguination, she continued to slowly bleed. Her hepatic function continued to deteriorate. Both parents were again approached and agreed that the patient's status be changed to "no code."

The case was initially brought to the hospital ethics committee by a participating physician who sought guidance with respect to discontinuing treatment. In his view, further treatment, specifically transfusions, would be nonbeneficial. In the course of discussion it became evident that the patient herself had not been consulted because of her perceived questionable mental capacity. After the committee meeting, a psychiatric consultation was obtained and the patient was found to have the mental capacity to make medical treatment decisions on her own behalf. Later that day, the patient stated to her physician and primary nurse that she wanted to

start all over again, that life was worth living, and that she was "kicking the habit." After that discussion, the physician rescinded the no-code order. Four days later, the patient began to deteriorate. She had become obtunded and remained unresponsive. An extensive family conference without the patient's participation was held with the pulmonologist resulting in a unanimous decision to provide only supportive care and comfort measures; no further therapy, including blood transfusions or hyperalimentation would be provided; the patient's status would be made a no code. The patient's primary nurse, disturbed by the change in therapeutic plan, brought the case back to the hospital ethics committee.

Two Ethical Approaches

Two ethical processes are reviewed: one from the familiar foundation and one from both the familiar foundation and the fuller sense. In review number one, the clinical ethicist poses the ethical question for the ethics committee and the committee relies heavily upon the familiar foundation for their analysis without any practical commitment to use the fuller sense. The ethical question of review number one takes this form: Does the duty to patient autonomy outweigh a duty to honor the conscientious refusal of the attending physician to provide invasive and intensive measures that may only prolong the dying process?[12]

In answering this question, the bioethics committee felt obligated to honor the patient's autonomous wishes and believed honoring autonomy was a benefit in itself. This position is grounded in the deep respect for an individual's right to self-determination and insists that we must honor a patient's autonomous choice.[2p657] Although there were burdens associated with this approach (ie, the poor quality of life, therapeutic struggle, and conflict with physician autonomy), the committee remained motivated to offer the following recommendation: temporize and take a wait-and-see approach; attempt care short of offering a liver transplant including a therapeutic trial to include transfusion and hyperalimentation. If the patient makes a remarkable recovery in this trial period, the transplant option could be further discussed.

In review number two, the clinical ethicist relies on the combined insight of both the familiar foundation and the fuller sense in posing the ethical question and assisting the bioethics committee to form a recommendation. The ethical question for this case might be: In alignment with the patient's previously known wishes and lived values, and to attain the optimum balance of ethical obligation to offer benefit, to prevent harm, and to represent patient autonomy, what is the appropriate treatment plan for his patient in her current clinical context?

In our current situation what ultimately helps in determining what is right or wrong is not solely the patient's autonomous choice. We must describe how the combination of this case's situational perspective, combination of grounds for moral judgment, and patient hopes emphasize the way we should form the summation or recommendation for this case. What has been happening in the revealed past for this patient has been the continual offering of second chances while strongly denying the severity of her alcoholic condition. The demands of the present situation indicate that the patient has experienced a severe combination of medical trauma that may place her beyond hope of ever recovering healthy hepatic function, of eliminating severe gastrointestinal complications and of reversing her severe hemorrhagic problems (eg, esophageal varices).

Although some medical and ethical authorities would not discount the possibility of this patient receiving a liver transplant, her present condition would deem a transplant extremely extraordinary, likely to fail in prolonging life and to tend toward the "experimental" rather than a treatment of choice. Certainly this would shade toward being less ethically acceptable because of the nature of the circumstances surrounding the patient.

In this case, it is important to discuss how best to honor the dignity of the patient, not completely losing hope for her in her condition while also not subjecting her to extreme measures that would only prolong the dying process without ever coming close to realizing a desirable outcome (ie, some quality of life beyond the hospital doors that would allow her to attempt to overcome her addiction and to "start over" as she commented to her nurse).

As we examine ultimate questions about nature, purpose, and destiny for this patient we must recognize that she never mentioned anything concerning her lived values beyond the comment that life is worth living and that she wanted to "kick the habit." These ultimate questions could be probed by an appropriate member of the community of concern (eg, chaplain or member of family's religious affiliation) to help us get in better touch with where the patient sees herself in relation to those questions.

An interesting sphere of justice to examine for this patient would be what an inappropriate "full course of treatment" would look like, with these complications and this case history.

The recommendation presented by ethicist number two and the ethics committee using the fuller sense was similar to the recommendation offered by the ethicist number one and his ethics committee. The temporize, wait-and-see approach with a therapeutic trial to include transfusion and hyperalimentation was offered to the treatment team in hopes of giving the patient some chance to rally without committing to an overzealous treatment plan that might place the patient in a position to suffer beyond the reasonable hope of treatment success. This sensitivity gives honor to the physician's conscientious refusal to employ nonbeneficial treatment in treating this very ill patient. The option of temporizing with the intention of giving some treatment also gives the community of concern time to separate issues of no-code, intensive care, comfort measure, and moderate invasive treatment.

The final outcome of this case ended in the patient expiring after one week of following the temporize plan that the medical team and family agreed was the wisest and yet most prudent way of dealing with the patient's situation with dignity and a modicum of hope. As the patient slipped more deeply into a coma the family requested that no heroic measures would be attempted to revive her and she passed away gently in her sleep.[a]

The ideal situation for moral conversation and a key way to nurture a culture of ethical reflection in clinical medicine is to combine both the familiar foundation and the fuller sense of

the ethical enterprise. With both the familiar foundation and the fuller sense, the ethicist and ethics committee are aided in participating more fruitfully in a process of resolution. Stakeholders and their relationships can become more clearly assessed and individuals become keener in discovering their own legitimate position. This can mean a more thorough representation of moral problems, a deeper understanding of all parties involved, an opportunity to help parties better understand themselves and each other, and a chance to better understand the moral options and the forces that shape them. Using both the familiar foundation and the fuller sense of the ethical enterprise allows us to become those architects of ethical space who empower our patients and clinicians to build enduring consensus. ❖

[a] As such a complicated case should include a discussion concerning injustice and a call for responsibility, it should be noted that the committee's deliberation touched these issues. In the patient's final grave medical state and with no known history of psychological counseling or intervention, the best the committee could offer was temporizing with the intention of giving some treatment as the patient's prognosis improved. Dealing with these two issues (injustice and responsibility) was recognized as important but also as a future recommended course of discussion when the patient could possibly benefit from the ramifications of both what would be just for her future and what responsibility was needed for her further total treatment and recovery.

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One Rule

Only one rule in medical ethics need concern you—
that action on your part which best conserves the interests of your patient.

— Martin H Fischer, 1879-1962, German-born American physician and author

"Genetic Engineering"
Acrylic on canvas
30" x 40"

Mohamed Osman, MD

Dr Osman is formerly a physician from Group Health Permanente and continues to practice as a Board-certified Physician and Geriatrician, who owns an innovative medical practice that is also an art gallery in St Pauls, NC, which may be viewed at: www.primarycareofstpauls.com. He is a self-taught artist and credits his early life in Somalia, his medical education in Russia, and his medical experience in Kenya and Somalia as major influences on his art. Dr Osman has been published many times in *The Permanente Journal* and *leaflet*. More of Dr Osman's artwork can be seen on page 27 and on his Web site: www.osmanart.net.

COMMENTARY

A Retirement and A Reservation: A Retrospective Autobiography

Sok K Lee, MD, MA

Perm J 2012 Spring;16(2):65-66

Abstract

A retirement is a rite of passage that requires careful planning, because it forces a retiree to make a shift in the paradigm in life.

For 37 years, I was a healing professional, a breadwinner, and a working spouse. I am now a jobless loner, an inactive pensioner, and a homebound spouse. In this retrospective autobiography, I suggest a few points to help my younger colleagues to better their upcoming retirement: professional, financial, social, and familial. To overcome Erikson's identity crisis, I volunteered to be a wounded healer at Warm Springs Indian Reservation.

My volunteer medical service at Warm Springs Indian Reservation was a good antidote to creatively overcome my postretirement blues.

At age 32, as a young allergist and pediatrician, I began my practice at the South Bay Medical Center (then Harbor City) with great hope and enthusiasm. Born and educated in Seoul, Korea during post-Korean War poverty, I outcompeted and thrived in my education to accomplish a medical degree at the College of Medicine, the prestigious Seoul National University in 1970. After 33 years of medical practice and after seeing all 3 children married out, I began a retirement life in 2011. Retirement, I found, is not the same as what we typically consider a rite of passage, such as graduation, marriage, immigration, parenthood, and even grandparenthood, because a retirement is not a progression, but a retreat. I am not sure what my eventual last breath will be like, but death is what every one of us will experience once. To be truthful, I might have been in postretirement blues, if I am allowed a self-diagnosis. I would like to write on my experience of the retirement as a retrospective autobiography, so that my fellow partners may live better than I have. To describe my journey, I must share with you my 10-week-long medical service at Warm Springs Indian Reservation in Oregon, as a volunteer pediatrician in Spring 2011. A joy in heart blooms like a flower when it is shared with others. I write this reflection to share my joy of the reservation service and as a chance to debrief my adventure, as once implied by Dostoevsky's *Notes from the Underground*.[1]

A Retirement, Reflective And Autobiographical

As a partner physician at the Permanente Medical Group, I have worked for 9 hours a day or more at the Medical Center. After 33 years of healing work, I figure that I've spent more than a quarter of the whole waking hours of my life at work. Therefore, it was no wonder that my retirement was a big psychological shock when I met the last day of my job in December 2010. Although I had read *The Physician* by John P Callan[2] to prepare myself to be a retired physician of comfort and freedom, and although my wife and I attended the 2-day seminar on retirement with one additional visit to the Walnut Center to understand our financial situation, my retirement felt like a locomotive screeching to a sudden halt after long years of steady steamy work. To show the predicament of my retirement life, let me categorize them into the 4 aspects: professional, financial, social, and familial.

Professional

On the day after my retirement, there were no patients waiting in need of my service. I faced no duty to serve and no responsibilities to care for my asthma patients who needed ongoing adjustment of daily medications! In a few short hours, I had been transformed from needed, caring professional to stay-at-home retiree. Although I might have found relief from these duties, I realized that I had been thriving on the ongoing professional demands and responsibilities. Before retirement, occasional vacations out of my arduous healer's work were a respite to reinvigorate my daily service, avoiding what is commonly referred to as doc's burnout syndrome. But this retirement, this having-nothing-to-do was boring and meaningless. In retrospect, I should have kept my professional licenses and memberships active, instead of downgrading them to retired status. Once my retirement was official and I was disconnected from the electronic medical record system, I lost all connection to my colleagues and partner friends. Fortunately, I had kept a few e-mail addresses of close friends and dear patients.

Financial

I found myself downgraded from bread winner to pensioner. Moving from regular paychecks to a fixed income has been a challenge, mostly from losing the satisfaction of receiving a regular paycheck. I feel insecure about potential needs for long-term medical care in the coming years. And my retirement cost me an additional $30,000 in taxes. I probably should have saved and invested more. I certainly should have taken full advantage of the company-sponsored 401K and Keogh plans; they are a great benefit for Kaiser Permanente physicians.

Social

I was a partner friend and now I feel I am a deserted loner. To keep in touch with old colleagues, I joined the Kaiser Permanente Retirement Society. Now, I attend some lunch meetings and I play flute weekly as a hospital music player. I have returned to the after-hour clinic as a part-time pediatrician.

Family

I was transformed from working spouse to homebound husband. The stereotype is true and although I expected that

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Dr Lee playing the American Indian Native flute.

family dynamics would change when I was home all the time, I was challenged to find I needed to readjust. I was fortunate that my wife joined me during the ten weeks I volunteered at Warm Springs Indian Reservation.

Happily, I discovered that my adventure to Warm Springs Indian Reservation turned out to be a cure for my postretirement blues.

The Warm Springs Reservation

The Warm Springs Reservation was established in 1855 when the US Government signed a treaty with the Confederated Tribes of Warm Springs: the Wasco, the Warm Springs, and the Paiute. In exchange for losing 95% of their tribal lands, the 3 tribes were provided with provision to establish a farming town, new buildings on the reservation, and a health service.

In the 1970s, Indian Health Services was established to enhance the quality of medical care on reservations. The reservation tribal government of Warm Springs built a lumber industry, hydroelectric power plants along the Deschutes River, and a resort-casino, Kah-Nee-Ta. There is a Native museum and a second casino in progress next to the museum. After decades of attempted assimilation and loss of culture, the tribal government is trying to revive and revitalize the Native culture by promoting Native language classes, the seven drum Waashat long houses, the Indian Shaker church, and Native arts programs. The medical care for the Warm Springs Natives, at the "Health and Wellness Center" is provided by Indian Health Service, staffed by 5 physicians of family practice and other ancillary services. They care for a population of about 4000 with a referral hospital nearby. I was able to see 250 children at the clinic for 10 weeks and made a healer's visit to child protective service and the Early Child Education Center. I became a member of the museum, my wife and I hiked almost all of the local trails around the reservation, and I have learned to play my *Warm Springs Song* with the American Indian Native Flute, made by Little Leaf, a Native flute maker.

To heal the wounded heart, the Warm Springs Native People are trying to forgive past oppression by doing forgiveness rituals. A few years ago, the Warm Springs People walked the path of oppression as a symbolic way to remember and to forgive. They are trying to revive their traditions by returning to the ancient fishing spot, Sheras Fall, and building Long House Churches.

Several months after my volunteer service at Warm Springs, I realized that Americans need to harmonize our western culture with the Native one to better understand their ways of life and their past history of oppression. Anger and fear will not build better communities. Rather, heartfelt repentance and forgiveness, leading to a friendly embrace and mutual trust, will beget a peaceful land of America. My way of doing this at Warm Springs was to serve the Native children and to learn the Native flute, languages, and religions. I look forward to continuing my retirement service in 2012 by volunteering for 3 months at an Apache Reservation in Dulce, New Mexico.

A Retiree, Humiliated? No! Reinvigorated

Being retired and aged should not mean being brushed off as being inefficient, feeble, and slow; rather my senescence offers new opportunities. Although I may need to compensate for memory loss by keeping notes, and I may not be as agile as I once was or able to pass a Romberg test, I am, perhaps, more patient, thoughtful, and careful in making decisions and am wiser from my abundant experiences. I realize that I am closer to my own death, and see that this is a time for reconciliation for peace in personal relationship. To my surprise, I read that Carl Rogers, an American psychologist, announced at the age of 75, that he had accomplished more after turning 65 than he did before.[3] I was encouraged when I discovered Dr Rogers' reflection of his retirement. Furthermore, retirement life is a wonderful time to rejoice in the freedom from planning for the rest of life and a time to serve the less fortunate. Finally, it is a time of self-transformation and a time for contemplation to try to reconcile one's own end of life with grace and peace rather than with despair. Despair or integration? It is the choice we are obliged to make as admonished by Erik Erikson.[4] For me, the Warm Springs medical mission was the time for a spiritual creative transformation in the first year of my retirement.

To end, I share a poem born in my heart on the hiking trail of Warm Springs: *A Poetic Letter from the High Desert Wilderness.*

Sagebrush leaf smells pungent
Wild birds warning of my presence
A lone hiker finds his own footsteps
on the way back.

Solitary man feels not lonely with
wind and clouds
Talking to the Other in his heart,
I am learning to be a butterfly in
contemplation. ❖

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COMMENTARY

The Health Care Professional as a Modern Abolitionist

Michael G O'Callaghan, DDS

Perm J 2012 Spring;16(2):67-69

Abstract

Health care professionals are in a unique position to identify and to assist victims of human trafficking. Human trafficking today occurs both domestically and globally. It manifests in many forms, including adult and child forced labor, involuntary domestic servitude, adult and child sexual slavery, involuntary servitude, debt bondage, and child soldiers. This article offers insight into modern human trafficking and ways health care professionals can be activists.

Background

The past several years have seen a proliferation of information regarding human trafficking. Television news reports and articles in print media appear with increasing frequency. A recent Google search had more than 12 million matches to the term "human trafficking." Many universities now offer courses on "human trafficking and contemporary slavery."

This is remarkable considering that in the early 1980s comparatively little attention was given to the subject of human slavery. In 2000, the United Nations adopted the *Protocol to Prevent, Suppress and Punish Trafficking in Persons especially Women and Children, supplementing the United National Convention against Transnational Organized Crime*[1] (commonly referred to as *The Palermo Protocol*). That same year, the US passed the Trafficking Victims Protection Act.[2]

Various efforts to confront the scourge of modern human slavery now span the globe. They are necessarily multifaceted requiring involvement of those in law enforcement, national security, human rights, public policy, social work, community education, victim protection, and rehabilitation. There is a scarcity of professional medical literature on the topic of human trafficking. A February 2012 PubMed search of the term "human trafficking" yielded just three references. There are additional references in the professional, nonmedical literature and many more resources in the lay literature, yet misinformation and ignorance on this important topic is still widespread.

According to the US State Department's *Trafficking in Persons Report 2011:* "trafficking in persons" or "human trafficking" have been used as umbrella terms for activities involved when one person obtains or holds another person in compelled service.[3] People may be trafficking victims regardless of whether they were born into a state of servitude or were transported to the exploitative situation, whether they once consented to work for a trafficker or whether they participated in a crime as a direct result of being trafficked. At the heart of this phenomenon are the myriad forms of enslavement—not the activities involved in international transportation.[3] The same document reports the major forms of human trafficking as forced labor, sex trafficking, bonded labor, debt bondage among migrant laborers, involuntary domestic servitude, forced child labor, child soldiers, and child sex trafficking.

Although the increased awareness is encouraging, there is still a great deal of work to be done. For example, as of 2010, of the 117 nations that signed The Palermo Protocol, 62 nations have yet to convict a single trafficker, though there are an estimated 12 million[4] to 27 million[5] slaves today. In absolute numbers, that is more than at any other time in human history. It has been reported that adjusted for inflation, slaves are cheaper today than they have ever been. The enslaved fieldworker who costs the equivalent of $40,000 in 1850 costs less than $100 today.[6] The estimated 27 million slaves in the world now equal more than twice the number taken from Africa during the entire 350 years of the Atlantic slave trade.[7]

In addressing human trafficking, national governments invariably prioritize state security issues over human rights and health issues. One reason why health care concerns have taken a back burner is that "the health consequences (of human trafficking) are commonly severe and long lasting, indicating that intervention strategies will be resource intensive. Most destination countries do not want to accommodate and pay for new residents or citizens with significant health and social support needs. Most countries of origin have limited health resources even for the average needs of their citizens."[8]

Common signs and symptoms of human trafficking[1]

A patient who:

- is younger than age 18 years and is a commercial sex worker
- is accompanied by someone who seems to be controlling and may act as a translator
- does not have appropriate identification or documentation, or who is not allowed to handle the identification or documentation
- lacks knowledge of his/her whereabouts
- shows signs of neglect or abuse
- has a discrepancy between history provided and clinical findings
- is unusually fearful or submissive
- has recently entered the US from Asia, Eastern Europe, or Latin America

[1] Spear DL. Human trafficking: health care perspective. AWHONN Lifelines 2004 Aug-Sep;8(4):314-21.

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It is an error to think that human trafficking is a problem largely confined to distant lands. Human trafficking occurs all too commonly, even openly, in many other parts of the world. Yet the US is a well-documented "source, transit and destination country for men, women and children subjected to forced labor, debt bondage, document servitude and sex trafficking. Trafficking (in the US) occurs for commercial sexual exploitation in street prostitution, massage parlors, and brothels, and for labor in domestic service, agriculture, manufacturing, janitorial services, hotel services, hospitality industries, construction, health and elder care and strip club dancing." [3]

… health care professionals should be leaders in the fight against this modern form of human slavery.

The 2011 Trafficking in Persons report also stated that "US citizen victims, both adults and children, are predominantly found in sex trafficking; US citizen child victims are often runaways, troubled and homeless youth. Foreign victims are more often found in labor trafficking than sex trafficking. In 2010, the number of female foreign victims of labor trafficking served through victim services programs increased compared with 2009. The top countries of origin for foreign victims in FY 2010 were Thailand, India, Mexico, Philippines, Haiti, Honduras, El Salvador and the Dominican Republic." [3]

The Role of the Health Care Professional

It has been suggested that "the health care community must become more engaged in increasing the recognition of trafficked women and girls in health care settings, in provision of appropriate services and in helping shape public policy to address what is one of the most disturbing health issues of our time."[9] Yet amid the struggle to understand and to confront contemporary slavery, a critical question arises: how can individual health care professionals effectively engage in this battle?

We have increasing awareness of the horror of human slavery in its myriad forms. We see images and read narratives of those whose most basic human freedom has been stolen from them. Yet we also have several hundred thousand compassionate, educated, and articulate health care professionals across the globe not yet engaged in this struggle. Some choose to be self-absorbed or uninterested; others are too busy to address one more injustice on the world's stage; many others have heard about human trafficking and are profoundly disturbed, but, for the most part, that concern has not yet been translated into an effective force for change.

My contention is that health care professionals should be leaders in the fight against this modern form of human slavery. As health care professionals, we have dedicated our lives to the betterment of our fellow man. We have the training and expertise required to assist the victims of slavery in the arduous road to recovery. Trafficking victims report a myriad of health concerns, such as psychological problems including posttraumatic stress disorder, infectious diseases including HIV, reproductive health problems, substance abuse, headaches, fatigue, dizziness, back pain, dental problems and the effects of physical trauma.[10,11]

Besides caring for the victims of trafficking, health care professionals can combat the scourge of human trafficking by becoming modern abolitionists. which would manifest differently in personal and professional lives. The term "abolitionist" brings many different images to mind; some of which may seem inappropriate for a health care professional. Yet in reality, health care professionals can engage in the battle against human trafficking in many different ways, perhaps as many as there are people willing to make that commitment. Some possible means of involvement in the abolition of human slavery today are:

Become better informed: Acknowledging the Latin maxim *scientia potentia est* (knowledge is power), it is certainly true in the arena of human trafficking. There are many resources one can employ to gain more knowledge on this topic.

Share your growing knowledge and passion with others: Be part of a growing grassroots abolitionist movement. Affect the world through your sphere of influence to help those trapped in bondage.[12] Heath care professionals can share with friends, family, and colleagues in various venues such as staff meetings, continuing education courses, places of worship or even during lunch. Strive to eliminate the "'culture of tolerance' that supports flourishing sex trafficking markets."[13]

Support organizations that combat human trafficking: This includes local and international organizations that are on the ground rescuing and rehabilitating victims, as well as development agencies that are attacking the root causes of human slavery (such as poverty or corruption). These organizations often seek volunteers, especially those who are willing to make a long-term commitment to assist with financial needs and/or in leadership roles.

Be a wise consumer: Encourage vendors and suppliers to strive to eliminate slave-made products from their supply chain.[14]

Practice medicine vigilantly: According to a study by the Family Violence Prevention Fund, 28% of trafficking victims came in contact with health care providers during their captivity, yet every one of these opportunities for intervention was missed.[15] In the same way that health care professionals train to respond to an emergency in their clinical setting, one can prepare to respond in a timely and appropriate manner to a suspected victim of human trafficking presenting for care (see Sidebars Common signs and symptoms of human trafficking and

Suggested questions to pose to a patient suspected of being a victim of human trafficking[1]

- Where do you live?
  Be suspicious if the patient lacks knowledge of his/her whereabouts and/or is unable to state where s/he is staying.
- Where do you work? What hours do you work? When you are not working can you come and go as you please?
- Are you free to quit your job and get a different job?
- Have you or family members been threatened or mistreated by your employer?
- Have you ever been forced to do work that you did not want to do?
- Have you ever been forced to have sex?
- Has anyone lied to you about the type of work you were to do?

[1] Barrows J, Finger R. Human trafficking and the healthcare professional. South Med J 2008 May;101(5):521-4.

Suggested questions to pose to a patient suspected of being a victim of human trafficking[10]). To seek assistance for a victim of human trafficking, call the National Human Trafficking Resource Center (NHTRC) at 1-888-373-7888.[16]

Provide volunteer health care services for the victims of human trafficking: This can be done locally or internationally. There may be a local organization that cares for victims of trafficking or refugees that would appreciate pro bono health care assistance. Clinicians can serve internationally by volunteering either on a long-term basis or on a short-term medical mission to assist the victims of trafficking.[17] Being able to use professional skills to treat victims of human trafficking is a rewarding life experience. The restoration of hope, dignity, and wellness is a long-term process. The victims of slavery need loving, competent, and patient professional assistance on that journey.

Disseminate and educate through research and publishing: Health care professionals can advance the abolitionist cause by obtaining and publishing credible data on this subject. There is a dearth of academic research in the field.[18]

Human trafficking is a great injustice. As health care professionals, we can make a difference in the battle against this violation of the most basic of human rights. ❖

The only thing necessary for the triumph
of evil is for good men to do nothing.
— Author unknown

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The Responsibility We Bear

The more freedom we enjoy,
the greater the responsibility we bear,
toward others as well as ourselves.

— Óscar Arias Sánchez, b 1940, President of Costa Rica from 2006 to 2010,
1987 Nobel Peace Prize Laureate, and recipient of the Albert Schweitzer Prize for Humanitarianism

COMMENTARY

Can Kawasaki Disease Be Managed?

Alberto Coustasse, DrPH, MD, MBA, MPH; Julius Larry, DDS, JD, MPH; Doohee Lee, PhD

Perm J 2012 Spring;16(2):70-72

Abstract

Kawasaki Disease (KD) is the leading cause of acquired cardiovascular disease among children, but management of KD has received relatively little attention. In the US alone, about 5500 cases were estimated in 2009. KD is most common among Asian and Pacific Islander children but can affect all ethnicities and races. Timely and accurate diagnosis remains critical, but difficult: the etiology of KD is unknown, and no accurate diagnostic laboratory test has been developed. Continuing medical education can help physicians, clinicians, and nurse practitioners accurately diagnose and treat KD. A registry specific to KD or a surveillance system may be necessary to increase awareness among health care professionals and to decrease complications related to misdiagnosis.

What is Kawasaki Disease?

Kawasaki Disease (KD) is an acute febrile illness that can potentially affect the heart and its larger arteries. It often affects children younger than five years.[1] KD is also called mucocutaneous lymph node syndrome, because it involves lymph nodes, skin, and mucous membranes inside the mouth, nose, and throat.[1,2] According to the American Heart Association[3] and the Centers for Disease Control and Prevention,[1] KD diagnostic criteria include high fever lasting four or five days, along with four or more of the following seven symptoms: 1) rash, 2) red eyes, 3) red, swollen, and cracked lips, 4) "strawberry" tongue, 5) swollen hands and feet, 6) swollen lymph nodes, and 7) redness of the palms and soles of the feet.

Statistics and Recent Trends

In the US alone, about 5500 cases of KD were estimated in 2009.[1] In Japan, a 2008 nationwide study conducted by Nakamura et al[4] found that 19,138 patients were suffering from KD during the 2-year period 2003–2004, revealing the continuation of an upward trend that started in Japan in the mid-1990s. A survey in 2009 suggested that the incidence is also rising in India.[5] This may be explained by greater awareness or by rapid industrialization.[6]

The latest incidence statistics available for the US are from a 2010 retrospective national study by Holman et al[7]: the rate of hospitalization related to KD in 2006 was 20.8 per 100,000 children younger than age 5 years. It is more frequent in children older than 1 year and toddlers ages 1 to 4 years. KD affects all ethnicities and races, but it is most common among children of Asian and Pacific Islander descent, with 30.3 cases per 100,000 hospitalizations. The incidence for non-Hispanic Blacks, non-Hispanic Whites, and Hispanics is 17.5, 12, and 15.7 cases per 100,000 hospitalizations, respectively.[7]

KD is the leading cause of acquired cardiovascular disease in children in the US.[8] The etiology of KD remains unknown after 40 years of intense research,[9] and no laboratory test can accurately diagnose KD and atypical cases that are approximate KD but do not meet all diagnostic criteria for KD.[1] Delayed diagnosis and treatment remain prevalent and unavoidable.[10] Diagnosis is further complicated in that KD shares symptoms and signs with other illnesses.[2] Therefore, the real number of undertreated and misdiagnosed cases is unknown.[11]

Diagnosis and Etiology

Virtually all deaths in patients who have experienced KD result from cardiac sequelae, or secondary cardiac conditions such as arrhythmia, chest pain, myocardial infarction (MI), and sudden death.[12,13] Mortality peaks 15 to 45 days after the initial onset of fever. However, sudden death from MI may occur many years later in individuals who had coronary artery aneurysms (CAA) and stenoses as children. The potential for death years later because of KD complications suggests that it is important to follow KD patients throughout childhood. Many cases of fatal and nonfatal MIs in young adults have been attributed to "missed" KD in childhood.[12]

A recent study by Coustasse and associates[10] revealed that fewer than half of the patients in their Texas sample (n = 303) were correctly diagnosed with KD upon hospital admission. The majority of KD cases were misdiagnosed. In their cross-sectional analysis, there were 41 admitting diagnoses other than KD. Although misdiagnosis appears to be common, the overwhelming majority (> 96%) of children with KD are hospitalized.[14,15] The remaining 4% are treated on an outpatient basis.

Untreated, KD can lead to serious complications that involve the heart and cardiovascular system.[2] Because CAA occurs more frequently in untreated patients,[16] effective interventions are required to enhance clinicians' ability to accurately identify KD in children younger than age 5 years presenting with high fever and rash.[17] Treatment within 10 days after onset of fever is essential to decrease the risk of heart problems. With appropriate detection and treatment, the prevalence of CAA is reduced to as few as 1% and no more than 5% of cases.[18]

The Lloyd et al study[19] investigated clinical and epidemiologic features of KD and emphasized the likelihood of an infectious cause. Consequently, several microbial agents have been studied in connection with KD: *Rickettsiae, Propioni-*

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bacterium acnes, Klebsiella pneumoniae, Ehrlichia, parainfluenza virus types 2 and 3, Epstein-Barr virus, and rotavirus, among others.[20,21] Additional possible causes for the disease are prior respiratory disease; exposure to carpet cleaning chemicals; use of humidifiers; and living in close proximity to lakes, rivers, bays, or oceans.[8,22] Although multiple infectious agents and toxins have been implicated, none have been conclusively identified as a causative or contributing agent.[15]

Treatment

First-line treatment consists of intravenous immunoglobulin for 8 hours to 12 hours within 10 days of the first onset of fever. High doses of aspirin must be administered until the fever subsides. Aspirin should be continued and gradually tapered for at least 2 months to reduce the risk of spontaneous coronary thrombosis.[2,18] A substantial number of patients have an incomplete response to intravenous immunoglobulin and require additional treatment. Unresponsive patients are at high risk of coronary abnormalities and adverse events resulting from multiple therapies.[23] In 13% to 30% of KD patients, fever persists or recurs. Fever may recur several days after hospital discharge. Doctors must bear the responsibility of warning parents to return to the hospital if fever or other signs of KD recur; inadequate discharge instructions put patients at risk for developing coronary artery abnormalities.[24] Untreated recurrences can lead to aneurism of the coronary arteries, myocarditis,[25] toxic shock,[26] and sudden death.[27] Sudden death from MI can occur many years later in individuals who developed CAA and stenoses in childhood.[28]

Ongoing Surveillance

Developing and maintaining a KD-specific national registry or a KD surveillance system may help reduce the nationwide incidence of KD. National and state incidence is difficult to estimate, because reporting of KD cases to the Centers for Disease Control and Prevention remains sporadic,[9] and all tracking and reporting is left to state agencies to enforce.[29] As with any large passive surveillance system, only a fraction of cases is reported.[22] Researchers are forced to rely on hospital discharge data.[15] The central public health policy problems related to KD are the need to educate clinicians, and the need for a government policy ensuring the timely acquisition of accurate data for all suspected KD cases for purposes of early diagnosis, patient tracking, and determining the cause of the disease.[10]

Continuing Medical Education

Although KD is now the leading cause of acquired heart disease among children in developed countries,[30] its etiology remains unknown. To diagnose KD early and accurately, clinicians must be educated to recognize the signs and symptoms of KD and make differential diagnoses. This training should begin in medical schools and continue through continuing medical education courses. Pediatricians, emergency medicine physicians, and primary care physicians must stay abreast of the latest developments in pediatric medicine and infectious diseases. Continuing medical education has become increasingly important to the management of KD because of the serious and sometimes fatal consequences of delayed treatment caused by erroneous diagnoses. If professional associations and state licensure boards were to require KD-specific education, perhaps the national rate of misdiagnosis could be significantly reduced.

Conclusion

Because KD is the leading cause of acquired heart disease among children in the US, and considering the sudden deaths that result from coronary aneurysm and thrombosis, effective management of KD would substantially benefit public health.[8] It is imperative to educate physicians and other clinicians, including nurses, to recognize the signs and symptoms of KD, because delayed or erroneous diagnoses delay treatment and sometimes lead to death. This also hinders cost containment efforts at the national level. Active surveillance could potentially yield long-term benefits for clinicians, patients, and society as a whole by facilitating the identification, prevention, and treatment of KD. The financial costs and benefits of accurate diagnosis and treatment may be further quantifiable when more accurate data are available. ❖

Disclosure Statement

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

Acknowledgments

Leslie Parker, ELS, provided editorial assistance.

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The Principle of Life

Since all living things are warm, all dying things cold,
there must be a … seat and fountain,
a kind of home and hearth, where the cherisher of nature,
the original of the native fire, is stored and preserved;
from which heat and life are dispensed to all parts as from a fountain head;
from which sustenance may be derived; and upon which concoction and nutrition,
and all vegetative energy may depend. Now that the heart is this place,
that the heart is the principle of life … I trust no one will deny.

— *On Circulation of the Blood,* William Harvey, 1578 – 1657, English physician and first person to describe completely and in detail the systemic circulation and properties of blood being pumped through the body by the heart

EDITORIAL

Medical Education—the Challenge of Distinguishing Actual Costs versus Charges (Tuition)

William L Toffler, MD

Perm J 2012 Spring;16(2):73-74

How much does it cost to educate a medical student? At face value such a straightforward question seems trivial. Yet the complexity of income sources and lack of transparency of medical university budgeting makes the answer elusive.

In the article "Financial Implications of Increasing Medical School Class Size: Does Tuition Cover Cost?" (see page 10), Scheiffler et al take on the challenge. Having an accurate answer is of increasing importance as most medical schools are expanding or making plans to expand in the near future.

Their methodology involves the use of published (albeit self-reported) data of available funding for medical education for American medical schools[1] and an estimate from the University of Wisconsin, as to what percentage of this funding is dedicated to actually paying for medical student education.[2] This creative "back door" approach might indeed provide insight into the true cost, if, and only if, two basic underlying assumptions are correct—that: 1) the funding coming from these sources does correlate with true costs, and 2) the estimated percentage actually allocated to education is correct.

In reality, there is no way to know with certainty that either assumption is correct. As such, this approach may be inherently flawed. Consider the following:

The first assumption that income stream directly correlates with cost may indeed be true as it is with some common commercial products—for example, food items like eggs and milk. On the other hand, the income stream with other less competitive and more exclusive products may have little connection with cost—for example, high-end perfumes or designer dresses. With these, the cost of making the product may have little bearing on the charge set by the seller.

The accuracy of the second assumption—the estimated percentage of a given income stream directly relates to the actual cost—is also uncertain. Decisions by medical university Presidents and Deans aren't made public. Income streams may well be partially, or even fully, fungible (excepting dedicated scholarships, endowments, and fees). Tuition dollars, then, could be shifted to support a building program, a dowry for a new department chair, research programs, or, even a different program entirely disconnected from any medical student educational costs. In short, the percentage estimate could be entirely wrong.

Furthermore, despite perennial complaints from medical school leaders as to the lack of state and federal funding,[3] Scheiffler et al are correct in pointing out that no medical school is currently filing for bankruptcy. How then have schools achieved so much with so little? Many medical schools not only survive, they appear to thrive—expanding despite seemingly "inadequate" tuition? Have the Deans discovered how to replicate the miracle of the "loaves and fishes"?[4-7] It is unlikely.

On the other hand, I believe the following factors, among others (not meant to be an exhaustive list) favorably affect the fiscal health of medical schools:

- Although increasing class size can increase some costs (eg, the need for more microscopes and number of small-group facilitators), other costs per student actually remain the same—for example, there is no additional cost to provide a lecture to 200 students than to 100. Further, at some schools, real cadavers and microscopes have been replaced with their virtual equivalents.[8,9] Teaching materials increasingly are in digital format—eg, syllabi and handouts now incur little or no printing and collating costs.
- Often, unpaid, volunteer faculty from the community (or even senior students or graduate students) facilitate small-group learning.
- Almost half of medical school learning occurs in hospital settings where students are taught and evaluated by physicians and residents who receive most or all of their compensation from other sources apart from tuition dollars. In addition, students now spend time in outpatient settings with urban, suburban, and rural practices. Often, the physicians in these practices volunteer to teach—with little or no pay from the university. Although teaching students in the office has been shown to take additional time, there may be minimal impact to the physician's income.[10]
- Increasingly with distance learning and related online technology, lectures and class time all have been reduced as students become active learners online. In fact, at some medical schools, attendance in class is now optional.[11]
- Testing and grading is increasingly automated; even objective structured clinical exams can be done without the need for on-site, physician reviewers.

Instead of asking "Where will additional tuition dollars be found?," the question instead should become, "Where are current tuition dollars going?"

Furthermore, if medical school education is as expensive as the authors conclude, it becomes difficult to explain the rapid expansion of osteopathic schools where student enrollment increased by 30% between 2000 and 2008.[12] Admittedly, such schools depend on a higher percentage of volunteerism by faculty.[13] At the same time, they generally do not enjoy the same degree of state, research,

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or endowments available to most allopathic institutions.

On the other hand, if medical schools (whether allopathic or osteopathic) currently receive adequate (or even excess tuition dollars), the question then shifts. Instead of asking "Where will additional tuition dollars be found?," the question instead should become, "Where are current tuition dollars going?" Is there justification that the average cost of medical education has risen far faster than the cost of living?[14] Are students really getting what they pay for?

Such questions certainly challenge the status quo. Answers aren't likely to be easily forthcoming. Yet, at least some medical schools, like the Mayo Medical School, have been able to eliminate tuition as a barrier to admission?[15] All students are on scholarships and any qualified student, regardless of financial institution, can gain entrance.

Clearly, the development of a more affordable and equitable tuition can positively affect the quality and diversity of the applicant pool. This, in turn, directly relates to the quality and ultimately impacts the overall health of everyone.

In conclusion, like all good research, the authors' published work raises more questions than have been answered. At the same time, their work should call all of us to persistently and patiently press the leadership of our medical schools to provide clearer answers. ❖

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The Path We Must Pursue

There is no short cut, nor "royal road," to the attainment of medical knowledge.
The path which we have to pursue is long, difficult, and unsafe.
In our progress, we must frequently take up our abode with death and corruption;
we must adopt loathsome diseases for our familiar associates,
or we shall never be thoroughly acquainted with their nature and dispositions;
we must risk, nay even injure, our own health in order to be able
to preserve or restore that of others.

— John Abernethy, 1764-1831, Fellow of the Royal Society and English surgeon

Physician-Assisted Suicide and Euthanasia

Dear Editors:

Re: Boudreau JD. Physician-assisted suicide and euthanasia: can you even imagine teaching medical students how to end their patients' lives? Perm J 2011 Fall;15(4):79-84.

Considering that physician-assisted suicide and euthanasia is a sensitive and controversial topic, the reductionism and the lack of objectivity of the question asked and of its discussion are intriguing. It is clear that the author and advisers wished no answer but their own. It is not usual for scholars to be reluctant to confront their views with others.

Surprising it is, that of those with the most experience in the field, none were consulted, namely from the Netherlands, Belgium, and the State of Oregon. Their comments would have broadened the horizon for the readership and rectified some lexical vagaries. It is generally understood that kill and murder are acts perpetrated on nonconsenting victims. Thus, the *absolute moral value* of "not to kill" does not apply to requested euthanasia, and "self-murder" is an oxymoron.

The experts from overseas would have insisted that euthanasia cannot be reduced to the "teaching of an act intended to hasten death"; and that what can very well be role-modeled is a humanism paving the way toward the "presence and accompaniment," hailed by Dr Boudreau, which is the essence of the Belgian Integral Palliative Care: high-quality palliative care, open to the "act" of advancing death, when suffering cannot be relieved and proves intolerable to the desolate dying patient, who requests it.[1] From the Netherlands likewise, one would appreciate how the "euthanasia talk," over weeks and months, can be taught, along with excellent palliation and end-of-life care. In this humanistic, reassuring process, nine out of ten formal requests sublimate into a natural death.[2] Only one in ten will want the request honored, as recommended by Eric Cassell, MD: "Assisting a patient in dying is not an easy way out. When terminally ill patients request assistance in dying because of their suffering, and their request meets commonly endorsed safeguards, their request should be honored."[3]

In that perspective, bright and sensitive medical students, learn to develop a rich "autonomie-en-lien" (bonds in autonomy), an *obbligato* tandem between patient and physician, wherein both remain free, yet tied by the bonds of humanity (Marc Desmets, MD; personal communication; 2012).[a] The morality of an act resting on its justification and its benevolence—as per philosopher Tom Beauchamp, MD[4]—is in the realm of the physician; benevolence, as the answer to suffering, affirmed solely by the patient. "Only the patients know how awful their own suffering is," wrote Cassell.[3]

In the above context, to entertain nightmares of "Modules of euthanasia," taught by certified "euthanatricians" teaching evidence-based medicine, which may well be irrelevant when "The One and Only Mrs Jones" will face death,[5] all belong to fiction.

Curricula, textbooks, research, hence journals, on end-of-life and palliative care abound and have been on the rise, more so where regulated physician-assisted dying has been enacted. Palliative care, including medically assisted dying are already taught in the Netherlands and in Belgium by qualified medical educators. "Palliative care education fits very well with the aims and agenda of general medical education, helping to correct the imbalance between knowledge, skills and attitudes."[6] In 2007, the Flemish Palliative Care Federation stated: "No dual track in end-of-life care by which palliative care practice and teaching on the one hand and euthanasia on the other would develop in separation" … "Each patient's choice must be respected."[1]

What is needed then is a continued expansion of those activities by mentors respectful of patients' autonomy and for whom the faculty's agenda is aligned with, and subordinated to, the patient's own. Paternalism is no longer a virtue but an oppressive tyranny (*vide infra*). "The first duty of the physician is no longer to save life at all costs, but to respect his patient's choices," affirmed the Hon Baudouin.[7] Dr Cicely Saunders reminded all that: "Whatever our own beliefs, we should never impose them on another person, least of all on any individual who is dependent upon us."[8]

Should a ludicrous specialty of "euthanatrists" ever be considered necessary, one for "terminalists" or "sedationists" is then urgently needed to administer terminal sedation, for both euthanasia and terminal sedation end in death. The insinuated inadequacies regarding "death talk," diagnosing depression, and pain management are still being raised. To be noted, even in reputed palliative care units, terminal sedation can last more than 10 days (in 10% of cases) and even more than 20 days (in 3.4% of cases).[9] The longer it lasts, the more knowledge, skills and humanism are necessary to cope with the wide spectrum of physical, psychosocial and spiritual problems that develop,

(Continued on next page.)

Response to Dr Boisvert:

By qualifying it as "fiction" it seems to have escaped Dr Boisvert that my commentary was rhetorical—intended to persuade the reader towards a particular perspective. Although the word rhetoric has acquired a pejorative connotation it arises out of an honored tradition. The question, "Can you even imagine teaching medical students how to end their patient's lives" is rhetorical affirmation. "Can you even imagine" is meant to be received as, "No, of course not—one should not contemplate such a scenario." With this goal in mind it would have been inappropriate to consult pro-euthanasia lobbyists.

The emotional tone evoked in Dr Boisvert's letter is surprising to me. We are urged to conceive of end-of-life talk and actions as a sublime, stylized, mutually enriching, and obligatory pas-de-deux between suffering patient and benevolent physician, choreographed under bonds of autonomy. This is problematic on several levels. First, I believe that autonomy is inadequate as an ethical framework to understand the fiduciary duties of physicians. The ethicist Alfred Tauber has outlined the limitations of our rights-based politicojudicial and commercial culture where an atomistic interpretation of autonomy obfuscates the moral identity of the physician. His essay entitled "Sick Autonomy" is critical to the euthanasia debate.[1] Second, the notion of a *linked* autonomy may very well be internally flawed and indefensible. If I, in my role as physician, am to enjoy inviolate personal autonomy and exercise interdependent autonomous acts along with my patient how could I be obliged to act against my convictions? This notion merits judicious reflection. Third, although the term *obbligato tandem* is a lovely one and it may capture the ideal relationship between physician and patient, in the context of end-of-life care I fear that it borders on unwarranted Panglossism. It is at odds with my own clinical practice and that of most physicians called to the bedside of dying patients. I am convinced that Dr Boisvert would be in agreement with the depiction of death as invariably painful and alienating. It is often experienced, at least initially, as a disorienting catastrophe. It is uncommonly wished for, rarely unfolds at convenient times and is endowed with few redeeming features. As such, I have reservations with the dance metaphor; this does not negate the desirability of a tight interpersonal bond implied with the eloquent phrase *obbligato tandem*.

Dr Boisvert reports that physicians in the Netherlands are highly trustworthy and opines that this status may be tied to their willingness to look favorably upon requests to be euthanized. The article by Kmietovicz, cited to support his claim, is hardly compelling. The authors themselves offer this disclaimer: "Our straw poll would never receive awards for being scientifically robust … ." There is no

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for both staff and families. Not rarely, experienced palliativists at times do poorly in such situations, as heard personally in workshops on "prolonged terminal sedations."

Humanism and Values

Such "deep-seated personal convictions about one's obligation to others—especially those in need" (humanism as defined in the commentary) has made the physicians in the Netherlands the most trustworthy physicians in the seven countries in the *British Medical Journal* inquiry, which included the United Kingdom (UK) and the US,[10] whereas Belgium is second only to the UK for its palliative care activities. And contrary to unsubstantiated fears, there is no evidence of a slippery slope,[7,11] no evidence that "vulnerable" persons have suffered any abuses[12] and that requests for death are not less numerous from patients followed in palliative care rather than receiving standard care.[13]

Dr Boudreau is right, this question is not "exclusively axiologic," nor is it exclusively humanistic, yet, it is nearly so for both these terms. The Hon Baudouin also declared: "One's opinion (about euthanasia) and personal sentiments, depend, *above all,* on one's own moral and religious convictions,"[7] (emphasis added; translation by author). That represents a cunning slope towards paternalism, "a tyranny sincerely exercised for the good of its victims may be the most oppressive …" wrote CS Lewis: "… those who torment us for our own good will torment us without end for they do so with the approval of their conscience.[14]

As well, humanism is unevenly displayed by physicians. It has also been displaced by science and technology, premedical marks gaining in importance at admission time. Obvious to all, knowledge and skills are so much more easily taught than are personal values influenced or attitudes changed. Students soon learn to appreciate—and rate—the great and the less great humanists, all doing their best. Some cases will overwhelm the very best end-of-life care. Humility is not humiliating. In the end, students will learn that euthanasia is not a choice between life and death but a personal choice about a personal death, which should be honored.

William Osler would wonder what "Whole Person Medicine" is all about. Did the faculty ever have any other goal? Likewise, euthanasia modules and euthanatricians can only result from a misguided hypercompartmentalization, which might have suited Descartes but surely not Spinoza.[15]

Profoundly humanist mentors CAN teach compassion and respect, from birth till, and including, death. ❖

Respectfully,

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(Continued from previous page.)

empirical evidence to support the claim that physicians endorsing physician-assisted suicide are more meritorious than those who are opposed.

Dr Boisvert rejects the slippery slope argument stating that "there is no evidence that 'vulnerable' persons have suffered any abuse." His belief that the acceptance of physician-assisted suicide has not harmed vulnerable members of society is ill informed. The slippery slope is an important, sophisticated, and multifaceted construct. There is evidence for it in numerous crosscultural and historical contexts.[2] The trajectory from top (morally desirable) to bottom (pernicious) situation has many slopes.[3,4] One of these is the potential impact on those unable to give informed consent, ie, the transition from voluntary to "involuntary" euthanasia. The latter should be referred to as culpable homicide. The (2005) Dutch Euthanasia Report concludes that a significant number of physician-assisted deaths occurred without explicit requests or consent.[5] Recent studies from Belgium reveal similar findings.[6,7] The softening of limits or constraints (eg, euthanasia of those with unbearable suffering to those with lesser degrees of existentialist angst) represents yet another slope.[8] I wish to shine the light on a third slope: pedagogy.

The Netherlands recently approved the launching of mobile euthanasia clinics.[9] A stated reason was that patients' goals in self-determination were being thwarted by physician resistance. It establishes, yet again, that not all physicians, including many Dutch colleagues, are on-side with having euthanasia become a medical act. The mobile clinics reveal the pedagogical slippery slope; it is one greased with a generous dollop of absurdity and impudence. This unfortunate development buttresses the arguments contained in my commentary. The Royal Dutch Medical Association has expressed reservation with respect to roving professional teams available to deliver death-on-demand; it has suggested that end-of-life decisions should ideally occur in the context of close relationships between patient and caregiver: "We have serious doubts whether this [physician-assisted suicide] can be done by a doctor who is *only focused* on performing euthanasia."[9] (my emphasis) Although the neologisms "euthanasist" or "euthanologist" were not used by the association's spokesperson they could well have been as they describe the practitioner of an emergent discipline—one with an eye to euthanizing. The consequences I envisioned were not so ludicrous after all.

The suffering of dying patients must not be ignored. No arguments there. I believe, however, that options available to the profession (and society) to respond need be constrained by moral limits. It must be acknowledged that supporters and opponents of euthanasia have different understandings of autonomy (atomistic versus relationship-based

(Continued on next page.)

How Do Adolescents Access Health Information?

Dear Editors:

Re: Ettel G III, Nathanson I, Ettel D, Wilson C, Meola P. How do adolescents access health information? And do they ask their physicians? Perm J 2012 Winter;16(1):35-8.

As a Pediatric and Adolescent Gynecologist I have struggled with the fact that the electronic medical record (EMR) cannot be accessed by adolescents. I worked at the Kaiser Permanente Los Angeles Medical Center for 14 years and am now at Group Health in Washington State using the Epic EMR. I am quite frustrated by the fact that my teenage patients cannot exchange e-mails with me regarding their care.

I assume that federal law prohibits teenagers ages 12 to 18 (and their parents) from accessing their results and using the e-mail function of the EMR because it applies in both California and Washington. I am sure this was a well-intentioned idea to protect adolescents and help keep their parents in the loop, but restricting electronic access to physicians only adds a barrier to access of high-quality medical care and advice. I have to resort to playing phone tag via cell phone with all of my teenage patients—or worse, texting—this is inefficient and inadequate.

I agree that teenagers should speak with their parents first and keep them in the loop regarding health matters, but the reality is that some teenagers are not comfortable doing this. Then where do they turn? I think most parents, myself included, would prefer that their teenage sons and daughters get advice from a responsible adult who can be trusted to protect their best interests, ie, their physician, rather than seeking advice from the Internet, their friends, or on the "street."

It is my hope that the laws regarding adolescent access to their own physician via EMR e-mail will be reevaluated and changed so that this important and vulnerable group of patients can communicate in a manner we know they are comfortable using with a responsible adult who can be trusted to give appropriate advice and care in health-related matters: their physician. ❖

Respectfully,

Diana Currie, MD
Pediatric and Adolescent Gynecology; Department of Obstetrics and Gynecology; Group Health Cooperative, Olympia Washington;
E-mail: currie.d@ghc.org.

Erratum

Newberry JA, Garmel GM. Image diagnosis: perilunate and lunate dislocations. Perm J 2012 Winter;16(1):70-1.

In the article listed above, an error occurred in the order of the figures in the "Lunate Dislocation" section. Figure 4 should have been labeled Figure 6; Figure 5 should have been labeled Figure 4; and Figure 6 should have been labeled Figure 5. The corrected article may be viewed at: www.thepermanentejournal.org/issues/2012/winter/4261-image-diagnosis-perilunate-and-lunate-dislocations.html.

We regret this error.

(Continued from previous page.)

autonomy), rely on different scripts of logic for slippery slope arguments, hold different conceptions as to the scope of a life worth living and subscribe to differing priorities with regards to personal responsibilities. The clash of values is undeniable. But, the argument advanced by Dr Boisvert that ministering to patients with authentic compassion, within a mutually trusting relationship, is an example of medical arrogance must be repudiated. It is offensive to conclude that the refusal of a physician to assist in a patient's suicide is tantamount to oppression and paternalism.

Dr Boisvert invokes William Osler as a role model for contemporary physicians. Although this is totally conjectural, I consider it highly unlikely that Osler would have allied himself with the pro-euthanasia lobby or would have signed up for duty on the mobile euthanasia clinics. He practiced whole person care (even though he did not use that phrase) and enjoined the profession to spirituality. In an article entitled "The faith that heals," he stated, "The angel of Bethesda is at the pool—it behooves us [the profession] to jump in."[10] A wissenschaft of this nature seems incongruent with a physician placing a lethal dose of medication in someone's mouth, vein, or … hand.

It was pointed out in a recent report by the British House of Lords that the greater the experience with end-of-life care, the less sure professionals are about the prospect of a change in the law in favor of euthanasia.[11] Dame Cicely Saunders, founder of the modern hospice movement, was opposed to euthanasia. Balfour Mount, who coined the term palliative care and founded the McGill Programs in Whole Person Care, is opposed to euthanasia. Opposition by physicians to euthanasia is generally strongest amongst palliative care experts.[12] Notwithstanding the recent endorsement by the College of Physicians of Quebec for Belgian-style euthanasia there are other developments, such as the recent vote taken by the Massachusetts Medical Society, confirming that we have not all gone soft on our values.[13] We should not accept anything that might dampen the reflex to comfort at all times and for all times. Vigilance is called for. "Euthanatrics" can beguile even the most well-intentioned and sensitive "palliativist." ❖

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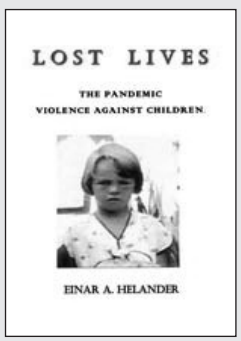
BOOK REVIEW

Lost Lives. The Pandemic Violence Against Children

By Einar A Helander

Review by Anna Luise Kirkengen, MD, PhD

Perm J 2012 Spring;16(2):78



Lund, Sweden: Academic Press, 2011
ISBN 978-91-979208-0-3
298 pages; $25.00

Lost Lives is a book of great passion and meticulous documentation. It discusses the range and amount, locally, nationally, and globally, of childhood violation. It makes evident how violated children's health is impaired and plays out in subsequent everyday medical encounters. The book combines individual and global perspectives and integrates medical, psychological, and relational facts and data in a reflection about the origins and impacts of a global phenomenon: the violation of children, rightly defined as a pandemic.

The author, a cosmopolitical Swedish physician, has dedicated most of his professional life to collecting, exploring, and condensing a particular type of documentation: *how and why the cutting of roses releases tornados*. Einar A Helander, MD, former Chief Medical Officer for the World Health Organization (WHO) Disability Prevention and Rehabilitation Programme, uses this metaphor to make clear that if a rose is cut (a child is violated), an irreversible disruption takes place that represents a disturbance, the extent of which nobody can predict. Such "tornados" shake and destroy lives, they cause misery and transgenerational suffering and disease, and they fuel aggression, brutality, addiction, war, and crime. By means of figures, numbers, and reports from 185 of the 195 countries represented in the United Nations, Dr Helander makes obvious how far from real civilization the global society still stands.

Dr Helander also presents a calculation of the sociopolitical costs generated by the world's violated, abandoned, and abused children, and he documents that "in no less than 153 countries there were—in 2009—reports of non-war-related human rights abuses of children." Thereby he places the responsibility for an extended "legitimacy" of illegitimate crime against children at the highest sociopolitical level: childhood sexual abuse, child labor, child trafficking, and female sexual mutilation, although documented beyond doubt, are not responded to by means of adequate actions from the side of the rulers, some of whom have, according to Dr Helander, "been involved in this abuse."

The author's term *lost lives* refers to children who meet a premature death because of violation, who suffer from the long-term impact of having been traumatized, who live without a family, and who are exploited. In other words, he counts lives as lost not only in case of factual death, but also in the sense of present and future health being seriously impaired and their potentials for flourishing and unfolding decisively hampered or disrupted by abuse, deprivation, and neglect.

Child abuse occurs not only in a comfortable distance from affluent societies, in countries of the third world, among immigrant populations to developed countries, and in strata of populations that physicians in Western countries seldom encounter. Violated and abused children enter—either as molested children, troubled adolescents, or diseased adults—every clinical office, including Kaiser Permanente. This fact can be deduced from studies on population[1] and individual levels.[2] All physicians are confronted with the impact of the patients' violation experiences, whether they recognize or fail to understand the true origin of the health problems presented.

The book, introduced by a former Prime Minister of India, a former Director-General of WHO, and a clinical professor in pediatrics, ought to have a warning sign on its cover, a kind of BEWARE!, telling potential readers that the content is as far from comfortable reading as it can get. This is no book for physicians who *don't want* to know what children are exposed to, and how that plays out later in life in their offices.

People who not only want to appraise the theories of human rights' declarations in general, but who want to know how these are practiced in their own society in particular, to delineate how they themselves might contribute to improvements, will find a wealth of useful facts in the book's tables, boxes, and lists. They will also find carefully selected photographs, none of which are speculative. It befits the message of this book to illustrate cultures of violence by an insight into an American gun shop or the pompous glory of a dictator along with a few photos of molested children. The guns and the glory are the other side of the coin of childhood misery worldwide. Dr Helander offers us knowledge that is highly relevant to successful clinical practice. Do we want to know? ❖

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BOOK REVIEW

Scared Sick. The Role of Childhood Trauma in Adult Disease

By Robin Karr-Morse, assisted by Meredith S Wiley

Review by Anna Luise Kirkengen, MD, PhD

Perm J 2012 Spring;16(2):79

A Book I Would Have Liked to Have Written

Family therapist Robin Karr-Morse, assisted by Meredith S Wiley, presents a condensate of knowledge from a wide, new, and multidisciplinary field in medicine comprising a multitude of translational research and documentations. The *field* is "multihyphened," so to say, as it has gradually emerged during the last two decades by linking psychology—neurology—endocrinology—immunology, in short psychoneuroimmunology, and the neurosciences including neuroradiology, genetics and, quite recently, epigenetics.

Its *essence* is the interplay between human biology and personal biography, in other words the impact of personal experience on this person's physiology, the *lived body.* This phenomenological term accounts for the fact that human bodies are not purely biological organisms or entities void of history and experience, but rather informed by embodied life and lived experience, in other words inscribed bodies.[1]

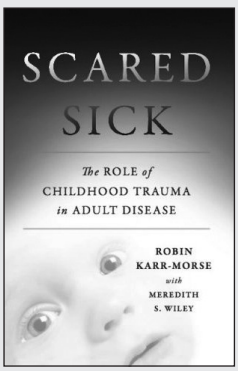
Karr-Morse and Wiley refer to a steadily growing body of knowledge and international literature and report from dialogues with some of the most experienced, leading, and—quite often—pioneering scholars in this field, as for example Bessel van der Kolk, Bruce Sperry, Allan Schore, Daniel Siegel, Bruce McEwen, Robert Anda, Vincent Felitti, and Robert Scaer. These scholars do not only represent a variety of disciplines but also combinations of experimental and epidemiologic research and clinical practice. Despite their different points of departure, these scientists have come to contribute to a converging and ever more solidly documented message: childhood trauma affects health. Having been deathly frightened early in life means, highly probably, falling sick later, if no appropriate "buffers" or protective measures are available.

Deathly scared children, when left to themselves (which means left by relevant others), are not only existentially shaken but also epistemologically disturbed. This means: their very framework, the ground from where to interpret and understand the world, is that of shattered trust and of permanent fear, alarm, alertness or—utmost problematic—chronic powerlessness.

To be in the world as permanently alerted or profoundly powerless is not a thought or an emotion. It is a *fear-full, pain-full,* violated being. Such states of being are toxic because they tax the body's adaptability, straining the flexible interplay in and between the central nervous, hormonal, and immune systems.[2] Here is the entrance to complex, chronic sickness and premature death.[3]

This is what Karr-Morse and Wiley write about, and they do so in a language and style that renders the really demanding, scientific "stuff" they deal with comprehensible for every reader. This is indeed impressive.

Are there no drawbacks? Almost none, although two objections can be made. First, the authors have omitted the fascinating documentation that the telomeres, the tips of our chromosomes, are also affected by overwhelming adversities, implying an experiential effect on genetic level. Next, the authors refer to currently available therapies for, or therapeutic approaches to, the long-term impact of childhood trauma. But all approaches mentioned are, by necessity, inappropriate for the matter at hand since the most crucial consequence of the converging knowledge implies that the very foundation of biomedicine, the theory of bodily matter as different and separate from the mind, has been invalidated and must be revised.



New York: Basic Books, 2012.
ISBN-10: 0465013546
ISBN-13: 978-0465013548
Hardcover: 320 pages
$26.99

This theory, constituting the divide between somatic and psychiatric medicine and rendering the human body a separate entity, has been overruled by now and needs to be transcended. The knowledge offered in the present book indicates, literally, that *mind matters*. Consequently, a new theory is urgently called for, namely a theory appraising that human bodies are embodied in time-space, and that human beings are relational and social. This implies that every person, from conception to death, is embedded in relationships and systems of socioculturally constituted values and meaning, informing every level of being, from the metaphysical to the genetic with a transgenerational impact. This is an important and practical book for physicians. ❖

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Section A.

Atricle 1. (page 4) Influence of Vascular Access Type on Sex and Ethnicity-Related Mortality in Hemodialysis-Dependent Patients

In this study, the factor that resulted in the greatest increase in the risk of mortality in hemodialysis-dependent patients was:
- ☐ a. use of an arteriovenous graft for hemodialysis access
- ☐ b. diabetes
- ☐ c. education
- ☐ d. use of a tunneled catheter for hemodialysis access
- ☐ e. African-American race

Which of the following hemodialysis patients has the lowest risk of mortality?
- ☐ a. non-Hispanic Caucasian male with diabetes using a tunneled catheter
- ☐ b. Hispanic female with diabetes using an arteriovenous fistula
- ☐ c. Hispanic female with diabetes using an arteriovenous graft
- ☐ d. non-Hispanic Caucasian male, nondiabetic using an arteriovenous fistula
- ☐ e. Hispanic male with diabetes using an arteriovenous fistula

Article 2. (page 23) Association of Child and Adolescent Psychiatric Disorders with Somatic or Biomedical Diagnoses: Do Population-Based Utilization Study Results Support the Adverse Childhood Experiences Study?

In this randomly selected 1994-2009 study of physician billing data in Canada comparing groups of children (<18 years) those with and those without psychiatric disorders, the biomedical and somatic disorders were more frequent in the psychiatric group. Which of the following is correct in describing how much more frequent this was for children with any psychiatric disorder:
- ☐ a. 2 1/2 times
- ☐ b. 2 times
- ☐ c. 4 times
- ☐ d. 1.7 times

The cumulative presence of psychiatric disorders in our study sample was which of the following:
- ☐ a. 20%
- ☐ b. 14%
- ☐ c. 25%
- ☐ d. 30%

Article 3. (page 36) The Kaiser Permanente Implant Registries: Effect on Patient Safety, Quality Improvement, Cost Effectiveness, and Research Opportunities

Which statement is inaccurate? For detection and validation of postoperative complications such as infections, pulmonary embolism, and deep vein thrombosis, the registries rely on:
- ☐ a. electronic algorithms based on quality indicators and standard definitions
- ☐ b. physicians contacting the registries to report complications
- ☐ c. confirmation by clinical content experts through electronic health record review
- ☐ d. responses from a questionnaire sent to every patient in the registries to inquire about postoperative complications

Annual reports and specific projects based on registry data investigated risk factors for adverse events or implant failures. On the basis of the 2010 Total Joint Replacement Registry annual report, one risk factor identified for aseptic total knee replacement revision was:
- ☐ a. older age
- ☐ b. diabetic status
- ☐ c. Caucasian race
- ☐ d. resurfaced patella

Article 4. (page 45) Transanal Endoscopic Microsurgery for Rectal Tumors: A Review

All of the following lesions can undergo a curative resection by the Transanal Endoscopic Microsurgery (TEM) technique, except:
- ☐ a. adenomas
- ☐ b. small carcinoid
- ☐ c. early rectal cancer
- ☐ d. anal cancer

All of the following complications can occur following TEM, except:
- ☐ a. impotence
- ☐ b. bleeding
- ☐ c. pelvic sepsis
- ☐ d. perforation

Please return completed form by September 28, 2012

Objectives
1. to inculcate the use of evidence-based medicine as part of the science of medicine
2. to stress the art of medicine via enhanced patient-physician communication, improved care experience for patients, and more satisfying caregiving experience for physicians and staff through better teamwork
3. to review appropriate updates on the diagnosis and treatment of clinical conditions
4. to describe infrastructure and systems improvements that lead to improvements in outcomes and patient care experiences

Section B. Referring to the CME articles and the stated objectives, please choose your level of agreement next to each statement as appropriate.

	Article 1	Article 2	Article 3	Article 4
	strongly agree / strongly disagree	strongly agree / strongly disagree	strongly agree / strongly disagree	strongly agree / strongly disagree
The article covered the stated objectives.	☐☐☐☐☐	☐☐☐☐☐	☐☐☐☐☐	☐☐☐☐☐
I learned something new that was important.	☐☐☐☐☐	☐☐☐☐☐	☐☐☐☐☐	☐☐☐☐☐
I plan to use this information as appropriate.	☐☐☐☐☐	☐☐☐☐☐	☐☐☐☐☐	☐☐☐☐☐
I plan to seek more information on this topic.	☐☐☐☐☐	☐☐☐☐☐	☐☐☐☐☐	☐☐☐☐☐
I understood what the author was trying to say.	☐☐☐☐☐	☐☐☐☐☐	☐☐☐☐☐	☐☐☐☐☐

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Section C. What change(s) (if any) do you plan to make in your practice as a result of reading these articles?

_____

_____

_____

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